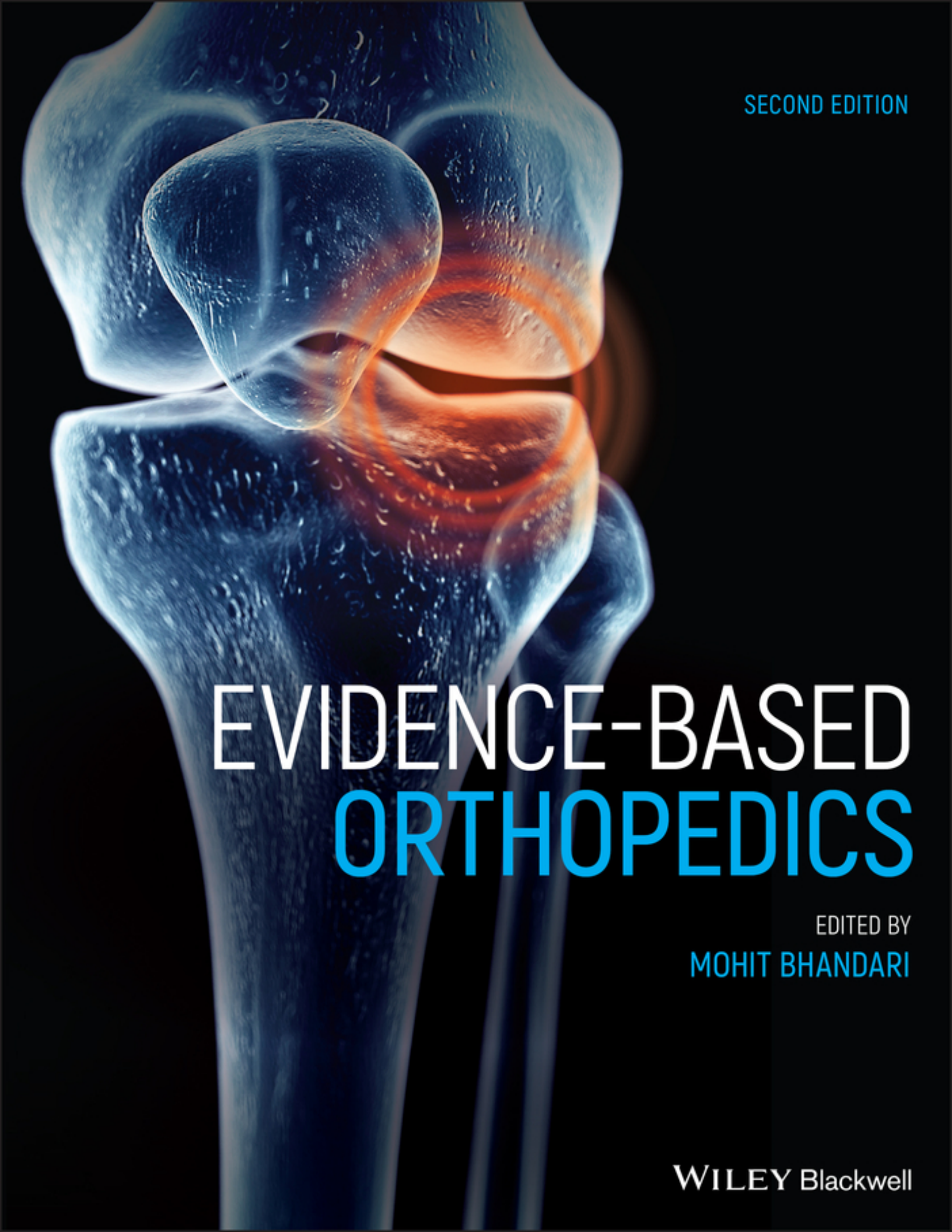

SECOND EDITION

EVIDENCE-BASED ORTHOPEDICS

EDITED BY

MOHIT BHANDARI

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Second Edition

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To all those whose pursuit of knowledge is not predicated on the
destination, but the mere joy of the journey itself.

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Foreword

Evidence-based medicine (EBM) – or evidence-based surgery, or evidence-based orthopedics (EBO) – is about solving clinical problems. In particular, EBO provides tools for using the medical and surgical literature to determine the benefits and risks of alternative patient management strategies, and to weigh those benefits and risks in the context of an individual patient's experiences, values, and preferences.

The term *evidence-based medicine* first appeared in the medical literature in 1991; it rapidly became something of a mantra. EBM is sometimes perceived as a blinkered adherence to randomized trials, or a healthcare manager's tool for controlling and constraining recalcitrant physicians. In fact, EBM and EBO involve informed and effective use of all types of evidence, but particularly evidence from the medical literature, in patient care.

EBM's evolution has included outward expansion – we now realize that optimal healthcare delivery must include evidence-based nursing, physiotherapy, occupational therapy, and podiatry – and specialization. We need evidence-based obstetrics, gynecology, internal medicine and surgery, and, indeed, urology and neurosurgery. And, of course, we need evidence-based orthopedics.

Applying EBO to management decisions in individual patients involves use of a hierarchy of study design, with high-quality randomized trials showing definitive results directly applicable to an individual patient at the apex, to relying on physiological rationale or previous experience with a small number of similar patients near the bottom rung. Ideally, systematic reviews and meta-analyses

summarize the highest-quality available evidence. The hallmark of evidence-based practitioners is that, for particular clinical decisions, they know the quality of the evidence, and therefore the degree of uncertainty.

What is required to practice EBO? Practitioners must know how to frame a clinical quandary to facilitate use of the literature in its resolution. Evidence-based orthopedic surgeons must know how to search the literature efficiently to obtain the best available evidence bearing on their question, to evaluate the strength of the methods of the studies they find, extract the clinical message, apply it back to the patient, and store it for retrieval when faced with similar patients in the future.

Traditionally, neither medical schools nor postgraduate programs have taught these skills. Although this situation has changed dramatically in the last decade, the biggest influence on how trainees will practice is their clinical role models, few of whom are currently accomplished EBO practitioners. The situation is even more challenging for those looking to acquire the requisite skills after completing their clinical training.

This text primarily addresses the needs of both trainees and, of this last group, practicing orthopedic surgeons. Appearing 20 years after the term *EBM* was coined, the first edition of this text represented a landmark in a number of ways. It was the first comprehensive EBO text. As with the first edition, this edition represents a successful effort to comprehensively address the EBO-related learning needs of the orthopedic community, and summarize the key areas of orthopedic practice.

To achieve its goals of facilitating evidence-based orthopedic practice, the text begins with chapters that introduce the tools for evaluating the original orthopedic literature. Those interested in delving deeper into issues of

how to evaluate the literature, and apply it to patient care, can consult a definitive text: *Users' Guides to the Medical Literature*.

The bulk of the current text, however, provides evidence summaries to guide each of the key common problems of orthopedic practice. Thorough and up to date at the time of writing, they provide a definitive guide to evidence- based orthopedic practice today. That evidence will, of course, change – and in some areas change quickly. Clinicians must therefore use *Evidence-Based Orthopedics* not only as a text for the present but also as a guide for updating their knowledge in the future. That future will hopefully hold the advent of an evidence-based secondary journal similar to those that have been developed in other areas, including *Evidence-Based Mental Health*, *Evidence-Based Nursing*, and the *ACP Journal Club*, which does the job for internal medicine. These survey a large number of journals relevant to their area and choose individual studies and systematic reviews that meet both relevance and validity screening criteria. These journals present the results of these studies in structured abstracts that provide clinicians with the key information they need to judge their applicability to their own practices. Fame and fortune await the enterprising group that applies this methodology to produce *Evidence-Based Orthopedics*.

Whatever the future holds for the increasing efficiency of evidence-based practice, the current text provides an introduction to a system of clinical problem-solving that is becoming a prerequisite for modern orthopedic practice.

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Preface

History has demonstrated that “evidence does not cease to exist, just because it is ignored.” The World Health Organization's declaration of a global pandemic on 11 March 2020 was preceded by what quickly became coined as an *infodemic*. Misinformation is the unfortunate consequence of 24-hour news cycles, social media, and expert opinions. Infodemics also present challenges in the propagation of scientific literature. During the first 12-week period of the 2020 novel coronavirus pandemic, we saw an unprecedented 1700 new, virus-related, peer-reviewed publications in over 400 different journals. The peer-reviewed literature was further contributing to the misinformation epidemic. In a period of uncertainty, high-quality data become invaluable. Evidence becomes the signal to guide healthcare decisions during a crisis.

The second edition of *Evidence-Based Orthopedics* is grounded in evidence, and fueled by a global collaborative of authors with wide-ranging expertise in orthopedic surgery worldwide. The uniqueness of *Evidence-Based Orthopedics* has as much to do with our global family of expert contributors as our innovative, standardized format. With over 430 contributors, this book was an enormous undertaking of commitment and purpose. I personally thank each and every individual, from associate editors to section editors to chapter contributors for aligning their chapters into the most comprehensive summary of orthopedics in our field. This second edition has updated content, a streamlined chapter design, and clear evidence-based recommendations. All chapters contain a summary of the highest level evidence studies we identified and our appraisal of this evidence. A trusted resource for best

evidence, readers can quickly review the recommendations sections in each chapter to gain the evidence-based summary of the topic.

On a personal note, this textbook comes at a time in our history where our decisions will be tested, and the evidence we used to make them scrutinized. With unparalleled focus on the value and outcomes associated with orthopedic surgical care, this book is the *signal* in a noisy information ecosystem. With access to surgery challenged, we are now re-envisioning orthopedic surgery priorities, not based on opinion – but evidence. To those before us who have spent countless hours conducting research to produce evidence to guide insights summarized in this textbook, I thank you.

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Abbreviations

1RM
one repetition maximum

30MWT
30-meter walk test

3DGA
three-dimensional gait analysis

4CA
four-corner arthrodesis

AAEM
American Association of Electrodiagnostic Medicine

AAOS
American Academy of Orthopaedic Surgeons

AC
acromioclavicular

ACB
adductor canal block

ACCP
American College of Chest Physicians

ACDF
anterior cervical discectomy and fusion

ACI/MACI
autologous chondrocyte implantation/matrix-induced autologous chondrocyte implantation

ACL
anterior cruciate ligament

ACL+MCL
combined anterior cruciate ligament and medial collateral ligament

ACLR
anterior cruciate ligament reconstruction

ADLs
activities of daily living

ADP
adenosine diphosphate

AE
all-epiphyseal

AE
angioembolization

AFF
atypical femoral fractures

AFOs
ankle foot orthoses

AHO
acute hematogenous osteomyelitis

AI
acetabular index

AIBG
autogenous iliac bone graft

AICBG
anterior iliac crest bone grafting

AIMN
antegrade intramedullary nailing

AIS
adult idiopathic scoliosis

AJCC
American Joint Committee on Cancer

AKA
above knee amputation

AKPS
Anterior Knee Pain Scale

ALB
anterolateral bundle

ALBC
antibiotic-loaded bone cement

ALIF
anterior lumbar interbody fusion

ALR
anatomic ligament repair

ALT
atypical lipomatous tumor

AMF
anteromedial facet

AMRI
anteromedial rotatory instability

AOFAS
American Orthopaedic Foot and Ankle Society

AORI
Anderson Orthopaedic Research Institute

AP
all-polyethylene

AP
anterior-to-posterior

AP
anteroposterior

APC
allograft-prosthetic composite

ARDS
Adult Respiratory Distress Syndrome

ARMD
adverse reaction to metal debris

AROM
active range of motion

ARR
absolute risk reduction

AS
affected side

ASA
acetylsalicylic acid

ASA
American Society of Anesthesiologists

ASAD
arthroscopic subacromial decompression

ASBMR
American Society for Bone and Mineral Research

ASES
American Shoulder and Elbow Surgeons

ASIA
American Spinal Injury Association

ASK
Activities Scale for Kids

AT
Achilles tendinopathy

ATFL
anterior talofibular ligament

ATP
adenosine triphosphate

AVN
avascular necrosis

BESTT
BMP-2 Evaluation in Surgery for Tibial Trauma trial

BFR
blood flow restriction

BMD
bone mineral density

BMI
body mass index

BMP
bone-morphogenetic protein

BOM
bacterial osteomyelitis

BP
blade plate

BPI
bactericidal/permeability-increasing protein

BPI
Brief Pain Inventory

BPTB
bone patellar tendon bone

BrAIST
Bracing in Adolescent Idiopathic Scoliosis Trial

BSM
bone substitute material

BTB
bone tendon bone

BTMs
bone turnover markers

CA
coracoacromial

CAM
controlled ankle motion

CaO
calcium oxide

CAROC
Canadian Association of Radiologists and Osteoporosis Canada

CAT

computerized adaptive testing

CBT
cognitive behavioral therapy

CCH
controlled continuous heparinization

CDVC
care delivery value chain

CFL
calcaneofibular ligament

CFR
canal-filling ratio

CG
conventional group

CHQ
Child Health Questionnaire

CI
confidence interval

CMC OA
carpometacarpal osteoarthritis

CMN
cephalomedullary nail

CMT
Charcot-Marie-Tooth

CN
calcaneonavicular

CNBs
core needle biopsies

CNO
chronic nonbacterial osteomyelitis

CoC
ceramic-on-ceramic

COTS
Canadian Orthopaedic Trauma Society

CPCHILD
Caregiver Priorities and Child Health Index of Life with Disabilities

CPM
continuous passive motion

CR
cruciate-retaining

CRIF
closed reduction with internal fixation

CRMO
chronic recurrent multifocal osteomyelitis

CRP
C-reactive protein

CRPS
complex regional pain syndrome

CS
compartment syndrome

CSRS
Cervical Spine Research Society

CT
complete transphyseal

CT
computed tomography

CTA
cuff-tear arthropathy

CTEV
congenital talipes equinovarus

CTR
carpal tunnel release

CTS

carpal tunnel syndrome

CWHTO
closed-wedge high tibial osteotomy

DAA
direct anterior approach

DAIR
debridement, antibiotics, and implant retention

DASH
Disabilities of the Arm, Shoulder, and Hand

DCM
degenerative cervical myelopathy

DCO
damage control orthopedics

DCS
dynamic condylar screw

DDH
developmental dysplasia of the hip

DESI
desorption electrospray ionization

DFR
distal femoral replacement

DIP
distal interphalangeal

DISI
dorsal intercalated segment instability

DMAA
distal metaphyseal articular angle

DNA
deoxyribonucleic acid

DOM
difference of medians

DORs
diagnostic odds ratios

DRUJ
distal radioulnar joint

DS
delayed surgery

DVT
deep vein thrombosis

DXA
dual energy x-ray absorptiometry

EAC
early appropriate care

EAM
early active motion

EBL
estimated blood loss

ECCO
European Cancer Organization

ECG
electrocardiogram

ECTR
endoscopic carpal tunnel release

ECTS
European Calcified Tissue Society

ECU
extensor carpi ulnaris

EDC
extensor digitorum communis

EDI
extensor digitorum indices

EDM
extensor digiti minimi

EI
extensor indices

EIN
elastic intramedullary nailing

ELA-2
elastase 2

ELISA
enzyme-linked immunosorbent assay

EMAS
European Menopause and Andropause Society

EORTC
European Organization for Research and Treatment of Cancer

EOS
early onset scoliosis

EPM
early protective motion

EQ5D
EuroQol five-dimensional questionnaire

ES
early surgery

ES
effect size

ESI
epidural steroid injections

ESIN
elastic stable intramedullary nailing

ESR
erythrocyte sedimentation rate

ESWT
extracorporeal shock wave therapy

ETC

early total care

ETO
extended trochanteric osteotomy

EVGS
Edinburgh Visual Gait Score

FABER
flexion, abduction, and external rotation

FADIR
flexed, adducted, and internally rotated

FAI
femoroacetabular impingement

FAITH
Fixation using Alternative Implants for the Treatment of Hip Fractures

FAO
foot abduction orthosis

FAOS
Foot and Ankle Outcome Score

FAQ
Functional Assessment Questionnaire

FCR
flexor carpi radialis

FDG
F-18 fluorodeoxyglucose

FDP
flexor digitorum profundus

FDS
flexor digitorum superficialis

FE
fat embolism

FEV_1

forced expiratory volume in one second

FFD
fixed flexion deformity

FGF
beta, fibroblast growth factor

FIT
Fracture Intervention Trial

FMS
Functional Mobility Scale

FNA
fine needle aspiration

FNB
femoral nerve block

FRAX®
Fracture Risk Assessment Tool

FREEDOM
Fracture Reduction Evaluation of Denosumab in Osteoporosis Every 6 Months

FT
fast-track

FTR
femoral/tibial ratio

FV
femoral varus

FVC
forced vital capacity

GA
general anesthesia

GB
gap balancing

GCTB
giant cell tumor of bone

GDI
Gait Deviation Index

GGI
Gillette Gait (Normalcy) Index

GI
gastrointestinal

GIRD
glenohumeral internal rotation deficit

GJ
torsional rigidity

GMFCS
Gross Motor Function Classification System

GMFM-66
Gross Motor Function Measure

GOAL
Gait Outcomes Assessment List

GPA
glenopolar angle

GPS
Gait Profile Score

GRADE
Grades of Recommendation, Assessment, Development, and Evaluation

GVS
Gait Variable Scores

HA
hemiarthroplasty

HA
hydroxyapatite

HBG
heterologous bone graft

HCLPE

highly crosslinked polyethylene

HHS
Harris Hip Score

HIP
Hip Intervention Program Trial

HKA
hip–knee–ankle angle

HNP
herniated nucleus pulposus

HOOS
Hip Disability and Osteoarthritis Outcome Score

HORIZON
Health Outcomes and Reduced Incidence with Zoledronic Acid Once Yearly

HOS
Hip Outcome Scores

HR
hip resurfacing

HRQoL
health-related quality of life

HSS
Hospital for Special Surgery

HT
hamstring tendon

HTO
high tibial osteotomy

HUI
Health Utilities Index

HV
hallux valgus

HVA
hallux valgus angle

I and D
irrigation and debridement

IBH
intermittent bolus heparinization

IBs
incisional biopsies

ICAM
immediate controlled active motion

ICBG
iliac crest bone graft

ICF
International Classification of Functioning, Disability and Health

ICM
International Consensus Meeting

ICP
intracompartmental pressure

ICRS
International Cartilage Repair Society

ICU
intensive care unit

IG
isokinetic group

IKDC
International Knee Documentation Committee

IL-6
interleukin 6

IM
immobilization

IM
intramedullary

IMA

intermetatarsal angle

IMN
intramedullary nailing

IPACK
infiltration between the popliteal artery and the capsule of knee

IPD
intra-prosthetic dislocation

IPs
interphalangeals

IPV
intimate partner violence

IRAM
immediate relative active motion

IRB
institutional review board

IRT
item response theory

ISS
Injury Severity Score

ITB
iliotibial band

IU
international units

IV
intravenous

IVC
inferior vena cava

IVDU
intravenous drug use

KA
kinematic alignment

KABB
knowledge, attitudes, beliefs, and self-reported behaviors

KAFO
knee–ankle–foot orthosis

KOOS
Knee injury and Osteoarthritis Outcome Score

KSFS
Knee Society Function Score

KSS
Knee Society Score

K-wires
Kirschner wires

LAS
lateral ankle sprains

LB
liposomal bupivacaine

LBOS survey
Low Back Outcome Score

LC
long chevron

LC-DCP
low-contact dynamic compression plate

LCEA
lateral center-edge angle

LCL
lateral collateral ligament

lCU/HDU
intensive care unit/high dependency unit

LDUH
low-dose unfractionated heparin

LE

leukocyte esterase

LEAP study
Lower Extremity Assessment Program

LET
lateral extra-articular tenodesis

LF
limited fasciectomy

LFCN
lateral femoral cutaneous nerve

LHB
long head of the biceps

LIA
local infiltration analgesia

LIPUS
low-intensity pulsed ultrasound

LISS
Less Invasive Stabilization System

LIV
lower instrumented vertebra

LLD
leg length discrepancy

LMWH
low-molecular-weight heparin

LOS
length of hospital stay

L-P FRS
Laaveg-Ponseti Function Rating System

LR
ligament reconstruction

LRs
likelihood ratios

LRTI
ligament reconstruction and tendon interposition

LSS
lumbar spinal stenosis

LT
lunotriquetral

LTIL
lunotriquetral interosseous ligament

LTT
lymphocyte transformation test

LV
limb varus

LVST
laxity valgus stress test

M/L
mediolateral

MA method
mechanical alignment

MABC-2
Motor Assessment Battery for Children

MAID
mesna, doxorubicin, ifosfamide, and dacarbazine

MALDI-TOF MS
matrix-assisted laser desorption ionization time-of-flight mass spectrometry

MAP
Movement Analysis Profile

MARS-MRI
metal artifact reduction sequence magnetic resonance imaging

MB
metal-backed

MC
metacarpal

MCGRs
magnetically controlled growing rods

MCID
minimal clinically important difference

MCL
medial collateral ligament

MCP
metacarpophalangeal

MCS
mental component score

MD
mean difference

MDA
metaphyseal diaphyseal angle

MDASI
MD Anderson Symptom Inventory

MDCT
multidetector computed tomography

MEPS
Mayo Elbow Performance Score

MEPs
motor-evoked potentials

MeSH
medical subject headings

METRC
Major Extremity Research Consortium

MF
microfracture

MFC
medial femoral condyle

MFH
malignant fibrous histiocytoma

MFS
myxofibrosarcoma

MgO
magnesium oxide

mHHS
modified Harris Hip Score

MHQ
Michigan Hand Outcomes Questionnaire

MINORS
Methodological Index for Non-randomized Studies

MIPO
minimally invasive plate osteosynthesis

mIRAM
modified immediate relative active motion

MIS techniques
minimally invasive surgical

mJOA
modified Japanese Orthopaedic Association

MLS
multilevel orthopedic surgery

MLST
multilocus sequence typing

MMWS
Modified Mayo Wrist Score

MN
multinational

MFIQ
Modified Functional Index Questionnaire

MOF
multiple-organ failure

MoM
metal-on-metal

MoM-THA
metal-on-metal total hip arthroplasty

MoP
metal-on-polyethylene

MORE
Multiple Outcomes of Raloxifene Evaluation

MoXLPE
metal-on-cross-linked polyethylene

MP
migration percentage

MPA
medial parapatellar approach

MR
measured resection

MRA
magnetic resonance arthrogram

MRI
magnetic resonance imaging

mRMS
modified relative motion splint

MSC
mesenchymal stem cell

MSIS
Musculoskeletal Infection Society

MSTS
Musculoskeletal Tumor Society

MTM
manual thrust manipulation

MTP
metatarsophalangeal

MUA
manipulation under anesthesia

NA
North America

NAHS
Non-Arthritic Hip Scores

NAS
nonaffected side

NCS
nerve conduction studies

NDI
Neck Disability Index

NESMS
New England Spinal Metastasis Score

NGAL
neutrophil gelatinase-associated lipocalin

NHA
nonhydroxyapatite

NHSN
National Healthcare Safety Network

NMAs
network meta-analyses

NMES
neuromuscular electrical stimulation

NNH
number needed to harm

NNT
number needed to treat

NOACs
new oral anticoagulants

NoC
no therapy

NOF
National Osteoporosis Foundation

NOGG
National Osteoporosis Guideline Group

NPV
negative predictive value

NR
no reported

NRT
nicotine replacement therapy

NS
not statistically significant

NSAIDs
nonsteroidal anti-inflammatory drugs

NSQIP
National Surgical Quality Improvement Program

NT
neuromuscular training

NVBGs
nonvascularized bone grafts

NW
intercondylar notch width

NWI
notch width index

OA
osteoarthritis

OAI
osteoarticular infections

OAR
Ottawa Ankle Rules

OATs
osteochondral autologous transplantation

OC
open chevron

OCD
osteochondritis dissecans

OCTR
open carpal tunnel release

ODI
Oswestry Disability Index

OGA
observational gait analysis

OHS
Oxford Hip Score

OKS
Oxford Knee Score

ONJ
osteonecrosis of the jaw

OPLL
ossification of the posterior longitudinal ligament

ORIF
open reduction and internal fixation

OSS
Oxford Shoulder Score

OWHTO
open-wedge high tibial osteotomy

OxAFQ-C
Oxford Ankle Foot Questionnaire for Children

PA
posterior-to-anterior

PAO
periacetabular osteotomy

PB
pelvic binder

PB
peroneus brevis

PBM
patient blood management

PCA
patient-controlled analgesia

PCL
posterior cruciate ligament

PCLR
posterior cruciate ligament reconstruction

PCORI
Patient-Centered Outcomes Research Institute

PCR
polymerase chain reaction

PCS
physical component score

PCT
pantaloon cast test

PDGF
platelet derived growth factor

PE
pulmonary embolism

PECA
percutaneous modified chevron-akin

PedsQL
Pediatric Quality of Life Inventory

PEMF
pulsed electromagnetic field

PET
positron emission tomography

PFF
periprosthetic femoral fracture

PFJ
patellofemoral joint

PFL
popliteofibular ligament

PICC
peripherally inserted central catheter

PI-LL
pelvic incidence minus lumbar lordosis

PIP
proximal interphalangeal

PJI
periprosthetic joint infection

PJK
proximal junctional kyphosis

PL
peroneus longus

PLC
posterolateral corner

PLT
popliteus tendon

PMB
posteromedial bundle

PMCs
posteromedial corners

PMMA
polymethylmethacrylate

PMR
posteromedial release

PNF
percutaneous needle fasciotomy

POD
postoperative day

PODCI
Pediatric Outcomes Data Collection Instrument

PONV
postoperative nausea vomiting

ppb
parts per billion

PPP
pre-peritoneal pelvic packing

PPS
passive muscle stretch

PPV
positive predictive value

PRAISE
PRevalence of Abuse and Intimate Partner Violence Surgical Evaluation

PRC
proximal row carpectomy

PREMIS
Physician Readiness to Manage IPV Survey

PRISMA
Preferred Reporting Items for Systematic Reviews and Meta-analyses

PROM
passive range of motion

PROMIS
patient-reported outcome measure information system

PROMs
patient-reported outcome measures

PROOF
Prevent Recurrence of Osteoporotic Fractures Study

PROs
patient-reported outcomes

PROSPERO
International Prospective Register of Systematic Reviews

PRP
platelet-rich plasma

PRWE
Patient-Rated Wrist Evaluation

PS
posterior stabilized

PSTA
primary subtalar arthrodesis

pt
patient

PT
pelvic tilt

PTFL
posterior talofibular ligament

PTH
parathyroid hormone

PTOA
post-traumatic osteoarthritis

PVNS
pigmented villonodular synovitis

PVO
percutaneous V-shaped osteotomy

PVST
pain valgus stress test

QALYs
quality-adjusted life years

QMA
quality of movement analysis

QOL

quality of life

QP
quadricepsplasty

qPCR
quantitative polymerase chain reaction

QR
interquartile range

QS
quadriceps snip

QuickDASH
Quick Disabilities of the Arm, Shoulder and Hand

QUOROM
Quality of Reports of Meta-analysis

RA
rheumatoid arthritis

RASL
reduction and association of the scapholunate ligament

RCT
randomized controlled trial

RD
risk difference

rhBMP
recombinant human bone morphogenetic proteins

RICE
rest ice compression elevation

RIHM
running-interlocking horizontal mattress

RIMN
retrograde intramedullary nailing

RLL
radiolucent lines

RM
repetition max

ROC
receiver operating characteristic

ROH
removal of hardware

ROM
range of motion

RR
relative risk

RRR
relative risk reduction

RSA
radiostereometric analysis

RSA
reverse shoulder arthroplasty

RT
reverse transcription

rTKA
revision total knee arthroplasty

RTP
return to play

RTPP
return to their prior performance

rTSA
reverse total shoulder arthroplasty

RTW
return to work

SA
septic arthritis

SC
scarf

SCA
scarf-akin

SCFE
slipped capital femoral epiphysis

SCM
sternocleidomastoid

SD
standard deviation

SF-12
Short Form 12

SF-36
36-item Short Form Health Survey

SF6D
six-dimensional health state short form

SHS
sliding hip screw

SINS
Spinal Instability Neoplastic Score

SIP
Sickness Impact Profile

SL
scapholunate

SLAC
scapholunate advanced collapse

SLAP
superior labral tear anterior to posterior

SLIC
scapholunate intercarpal

SLIL
scapholunate interosseous ligament

SMAC
Sarcoma Meta-analysis Collaboration

SMD
standardized mean difference

SMFA
short musculoskeletal functional assessment

SMPA
silicone metacarpophalangeal joint arthroplasty

SNAC
scaphoid nonunion advanced collapse

SNB
sciatic nerve block

SOB
shortness of breath

SOOB
sit-out-of-bed

SOSG
Spine Oncology Study Group

SPECT/CT
single-photon emission computed tomography/computed tomography

SPORT
Spine Patient Outcomes Research Trial

SPR
secondary patellar resurfacing

SRM
standardized response means

SRS
Scoliosis Research Society

SRS-22r
Scoliosis Research Society 22-item

SSEPs
prolonged somatosensory-evoked potentials

SSIs

superficial surgical site infections

SSL
sagittal spine length

SSRIs
selective serotonin reuptake inhibitors

SSV
Simple Shoulder Value

ST
strength training

STBSG
Soft Tissue and Bone Sarcoma Group

STS
soft tissue sarcoma

STT
scaphotrapeziotrapezoidal

SVA
sagittal vertical axis

TAM
total active motion

TARVA
total ankle replacement versus arthrodesis

TBW
tension-band wiring

TC
talocalcaneal

TDABC
time-driven activity-based costing

TEA
total elbow arthroplasty

TEN
titanium elastic nails

TENS
transcutaneous electrical nerve stimulation

TESS
Toronto Extremity Salvage Score

TFCC
triangular fibrocartilage complex

TGF
transforming growth factor

TGRs
traditional growing rods

THA
total hip arthroplasty

TI
tendon interposition

TJA
total joint arthroplasty

TKA
total knee arthroplasty

TLR
triangular ligament reconstruction

TM
trapeziometacarpal

TMA
Trapeziometacarpal arthrodesis

TMDA
tibial metaphyseal diaphyseal angle

TNM
tumor–node–metastasis

TOP
Treatment of Osteoporosis Study

TPA
T1 pelvic angle

TRALI
transfusion-related acute lung injury

TRAP
triceps-reflecting anconeus pedicle

TRICC
Transfusion Requirements in Critical Care

TROM
total range of motion

TROPOS
Treatment of Peripheral Osteoporosis Study

TSA
total shoulder arthroplasty

TSN
Trauma Survivors Network

TT
terrible triad

TTE
transthoracic echocardiography

TV
tibial varus

TWF
total wrist fusion

TXA
tranexamic acid

UBC
unicameral bone cyst

UCL
ulnar collateral ligament

UCLA
University of California Los Angeles

UCLR
ulnar collateral ligament reconstruction

UFH
unfractionated heparin

UH
unfractionated heparin

UHMWPE
ultra-high-molecular-weight polyethylene

UIV
upper instrumented vertebra

UKA
unicompartmental knee arthroplasty

UMC
usual medical care

UMD
unadjusted mean difference

UPS
undifferentiated pleomorphic sarcoma

US
ultrasound

VAS
Visual Analog Scale

VAS-U
Visual Analog Scale, usual pain

VAS-W
Visual Analog Scale, worst pain

VBGs
vascularized bone grafts

VC
vital capacity

VCS
Vancouver Classification System

VERT
Vertebral Efficacy with Risedronate Therapy

VISA-A
Victorian Institute of Sports Assessment-Achilles

VKAs
vitamin K antagonists

VMO
vastus medialis oblique

VTE
venous thromboembolism

WALA
wide awake, local anesthesia

WALANT
wide awake, local anesthesia, no tourniquet

WBC
white blood cell

WDLS
well-differentiated liposarcoma

WHO
World Health Organization

WOMAC
Western Ontario and McMaster Universities Osteoarthritis Index

WOOS
Western Ontario Osteoarthritis of the Shoulder

WORC Index
Western Ontario Rotator Cuff

XLIF
extreme lateral interbody fusions

XLPE
cross-linked polyethylene

XRT
radiation therapy

ZDS

Zung Depression Scale

I Methodology of Evidence-Based Orthopedics

1 Principles of Evidence-Based Orthopedics

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Introduction

The traditional approach to clinical problem solving places a great emphasis on professional authority. Decision making is based primarily on the intuition, experience, and rationale of the clinician, and it is heavily influenced by their opinion.[1] Since it is unlikely that the opinion of every physician is identical, it is reasonable to suggest that not all opinions can be correct.[2] Evidence-based orthopedics does not accept this approach. Although it acknowledges the importance of clinical judgment, it emphasizes that this alone is not enough to make optimal clinical decisions, especially with the large amount of evidence that is available. Evidence-based orthopedics combines the judgment of the clinician and values of the patient with the best available clinical evidence (Figure 1.1). The goal is to use the best available evidence to guide the management of individual patients based on their preferences.

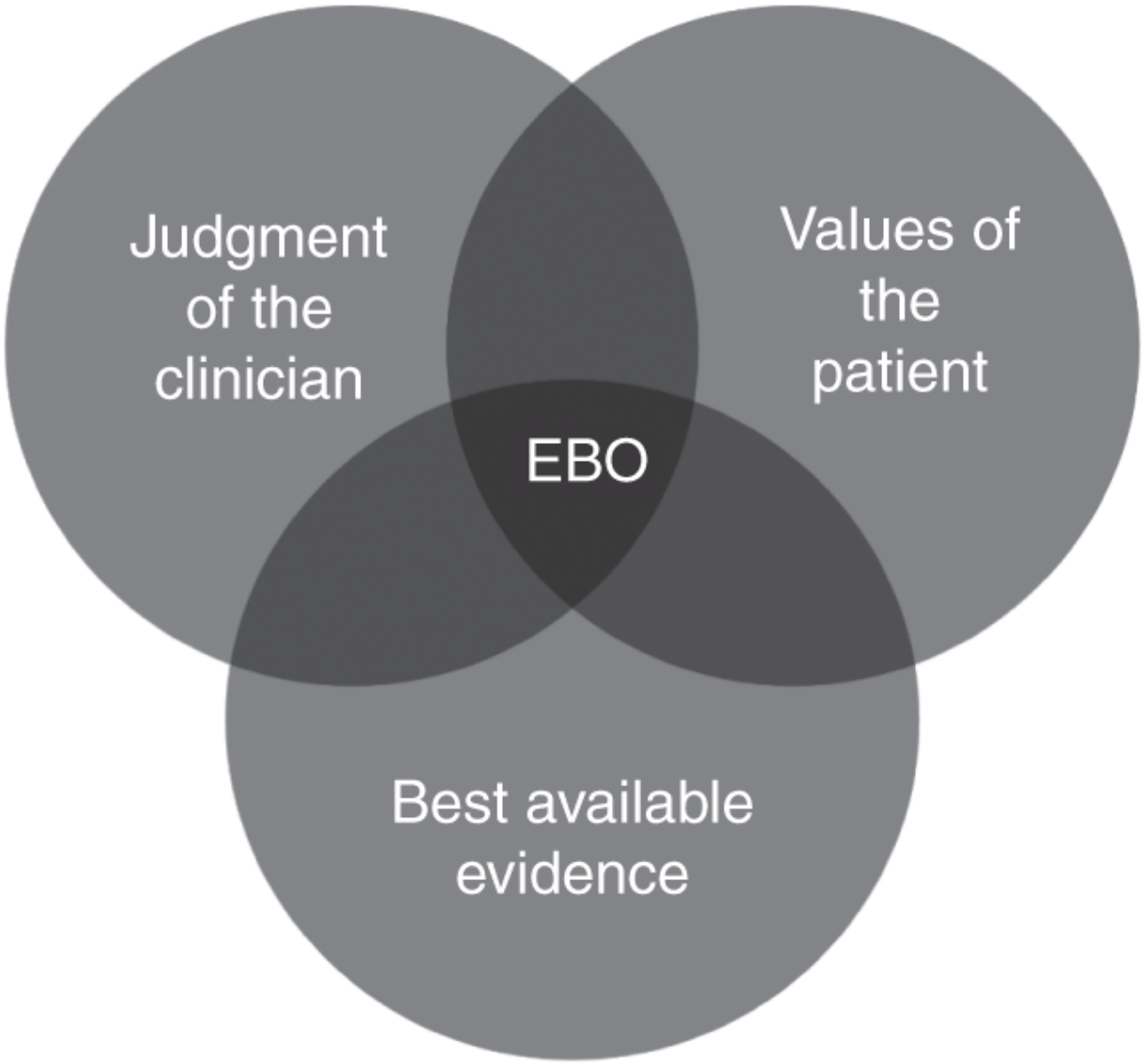

Figure 1.1 Visualization of the different aspects of evidence-based orthopedics (EBO).

Evidence-based orthopedics is a part of a larger movement called *evidence-based medicine*. This term was first used by Gordon Guyatt in the 1990s in the curriculum of the residency program at McMaster University.[3] The term was more formally defined in 1996 by Sackett et al. as "the conscientious and judicious use of current best evidence from clinical care research in the management of individual patients."[4] Evidence-based medicine is more than just a

positive alternative in patient care, it is on the *British Medical Journal*'s list of the top-15 most important medical milestones along with vaccines, the discovery of DNA structure, and the discovery of antibiotics.[5]

Importance of evidence-based orthopedics

Understanding the importance of evidence-based orthopedics is necessary to fully appreciate its principles. The goal of the clinician is to provide individual patients with the best clinical care.[2] Clinical research can help the clinician achieve this goal. The proper evaluation of clinical trials helps to define the risks and benefits of different treatment options, aiding the clinician and patient in making an optimal treatment decision.[6]

In 1992, Antman et al. compared the data from clinical research with expert opinions on the treatment of myocardial infarction.[7] This article showed that there was a difference in opinion between clinical experts and that it took experts 10 years for their opinions to catch up with the clinical evidence. While systematic reviews and meta-analyses may make information found in individual trials more accessible, there is still a lag between the publication of high-level evidence and its acceptance.[8]

Top four questions

1. What are the most important principles of evidence-based orthopedics?
2. How do you apply evidence-based orthopedics?
3. What is an example of applying evidence-based orthopedics?

4. What are the misconceptions of evidence-based orthopedics?

Question 1: What are the most important principles of evidence-based orthopedics?

Evidence is needed for optimal clinical care

Clinicians must acknowledge the importance of evidence and recognize that they need evidence in their daily practice. In evidence-based orthopedics, clinicians actively search for the best available evidence to supplement their judgment. There is a large body of evidence available to assist clinicians in many areas, from assessing the efficacy of treatment modalities to lifestyle recommendations to prevent disease.[6]

Keeping up to date with the growing volume of primary literature can be daunting, but it is incumbent upon all clinicians to do so. Systematic reviews can help the clinician to keep up to date, but these reviews are only one interpretation of the literature and clinicians should be aggressive about reading the original sentinel works. There are several resources to help the clinician find the best current evidence, such as the Cochrane Database of Systematic Reviews or the Clinical Queries feature in PubMed.[9]

Not all evidence is equally useful

There is a vast amount of evidence available and it is important to understand how the quality of the work contributes to its value in answering a clinical question. For example, a case report is much more vulnerable to bias than a randomized controlled trial (RCT). Randomized

treatment allocation balances the known and the unknown prognostic factors, making it less vulnerable to bias.[10] Table 1.1 shows the hierarchy of evidence from the least-biased study designs on the top of the hierarchy to the most-biased on the bottom.

Furthermore, there is a difference in the quality of evidence between studies, even those on the same level. For example, not every RCT is equally applicable to a particular clinical question. The inclusion and exclusion criteria must match the patient whom the clinician is treating. Outcomes of trials must be clinically important to the patient. Trials may report statistically different outcomes without a real clinical difference in patient outcomes. Finally, RCTs may have serious flaws, making them vulnerable to bias, such as a large percentage of patients who are lost to follow-up. This type of problem may threaten study validity.[11] A randomized trial with serious design flaws can no longer qualify as high-quality evidence.

Table 1.1 The hierarchy of evidence. Source: Modified from Schunemann.[1]

Least bias	Meta-analyses of RCTs
	RCTs
	Controlled trials
	Case control studies and cohort studies
	Cross-sectional studies
Most bias	Case reports, case series, and expert opinion

Evidence alone is not enough

In making a clinical decision, published evidence alone is never enough. The best treatment option is influenced by the patient's lifestyle, specific needs, and preferences as well as the judgment of the clinician. A deep understanding

of the patient, their medical history, and the pathophysiology of their disease is necessary. Most important, evidence-based orthopedics supports an active role of the patient in decision making, acknowledging the importance of the values and preferences of the patient. The most common example of this is in cases where multiple reasonable options exist. Patients should be free to choose their treatment based on their own set of goals and their personal assessment of the risk/benefit profile of the treatment options.

Question 2: How do you apply evidence-based orthopedics?

There is a five-step cycle called the *evidence cycle* that can help in applying the evidence-based orthopedics in daily practice.

Assess

A thorough understanding of the clinical situation is essential to develop a treatment plan. This includes a full understanding of the pathophysiology of the patient's complaints, symptoms, and physical findings in addition to the patient's medical history. From this, a differential diagnosis is created and whatever further testing is required to confirm a clear diagnosis is performed. Only with a correct diagnosis can the clinician form a clear question to research.

Ask

A well-formed research question is necessary to filter out irrelevant evidence without excluding valuable evidence. The PICO format can be used to compose a research question. In essence, every clinical research question

contains four components: a Patient or Population, description of the patient group; the Intervention, the treatment being considered; the Comparison, the alternative treatment(s) that is (are) to be compared; and the Outcome: the eventual goal of treatment or method of assessing treatment.

Acquire

With a well-formed research question, the clinician can start searching for evidence using any of the available search engines, such as PubMed. MeSH (Medical Subject Headings) terms are vocabulary produced by the National Library of Medicine. MeSH terms are used for indexing, cataloging, and searching of biomedical and health-related information. Using the correct MeSH terms and subheadings as well as filters helps to limit the dataset to the most relevant trials or reviews. If needed, a librarian can be of help in finding the right information. Or visit https://www.nlm.nih.gov/mesh/meshhome.html.

Appraise

Clinicians must also take it upon themselves to assess the literature for bias and quality. There are several tools available to assess primary literature, such as the Cochrane Collaboration's risk of bias assessment tool.[12]

Apply

Finally, the clinician must view all of the available evidence through the prism of a particular patient's needs. They must determine how the evidence applies to the clinical problem seen in their patient. The clinician must determine if differences exist between their patient and the evidence and judge what effect this might have on the outcome. For example, a trial comparing treatments for fractures in a

rheumatoid arthritis population may not apply to a young athlete.

Question 3: What is an example of applying evidence-based orthopedics?

A 48-year-old female arrives at the Emergency Department with pain and deformity of the clavicle after a fall on her shoulder. The patient smokes and there are no other injuries. The X-ray shows a 100% displaced midshaft clavicular fracture without an obvious shoulder droop. She reports a high degree of pain. The primary goal is to return her to her prior level of activity and have as normal shoulder function as possible. This type of fracture may be managed operatively or nonoperatively.[13–20]

The midshaft clavicular fracture is the most common fracture of the clavicle and numerous studies have been published on its treatment.[14–20] A recent meta-analysis of RCTs shows a significant reduction in nonunion rate after plate fixation of midshaft clavicular fractures compared with conservative treatment even though no clinically relevant increase of function was demonstrated.[21] Secondary operations were common in both groups. Meta-analyses of RCTs offer high-quality evidence and are the least susceptible to bias; however, they can focus only on the outcomes in each and every trial included.[1]

The authors of this meta-analysis found that there is insufficient evidence for routine plate fixation of displaced midshaft clavicular fractures, but it is a good option for patients who have risk factors for nonunion, such as smoking, highly displaced and/or comminuted fractures, and for patients who demand a faster recovery and optimal

arm function.[21] Additionally, the patient should be made to understand that if they heal their fracture then their outcome would be as good without surgery and that if it went on to nonunion and were then repaired, they could also expect a good result.[14],[17],[20_22]

This example shows that evidence can help in making a clinical decision while not replacing the judgment of the clinician and the values of the patient.

Question 4: What are the misconceptions of evidence-based orthopedics?

Evidence-based orthopedics replaces the judgment of the clinician

The judgment of the clinician is necessary in evidence-based orthopedics, the core principle being that evidence alone is not enough. The clinician and the patient are not bound to a certain course of action. While the reported evidence gives important information, the clinical decision remains in the hands of the clinician and the patient.

Only randomized controlled trials are acceptable evidence

RCTs are considered the highest level of evidence, but other types of studies have value also. Not every clinical question can be answered using a RCT. For example, it would be unethical to determine the negative effects of smoking on bone healing in a RCT. Although not all study designs can produce a definitive clinical answer, they can help to develop a relevant hypothesis.

One needs to be a statistician to practice evidence-based orthopedics

A basic understanding of statistics is attainable by all surgeons. Simply understanding the concepts of power, sample size, minimal clinically important difference, confidence intervals, and p values is all that is needed. This basic understanding can help the clinician independently determine the implications of trials.

Summary of answers

- Evidence-based orthopedics emphasizes that high-quality clinical research is necessary for optimal care.
- There is a large amount of evidence available and not all clinical research is equally useful.
- Critically appraising evidence is essential for evidence-based orthopedics.
- The clinician must determine how the evidence applies to their patient and combine this with the patient's values to find the best treatment together.

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2 Hierarchy of Evidence and Common Study Designs

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Introduction

The number of clinical studies in the field of orthopedics is overwhelmingly large and continually growing. It stands to reason that some of this research is of higher quality than others. How do we know which studies we can trust? Proponents of evidence-based medicine have developed a hierarchy of evidence which divides studies into groups according to study design to highlight the foundational role that appropriate study design plays in study quality. It should be noted that study design is not the only factor involved in study quality, but it does form the basis for making a decision about the trustworthiness or credibility of the evidence. It is important to have a thorough understanding of the theoretical underpinnings of each major study design and how these designs and methodological decisions affect study quality and credibility of the evidence. This principle of a hierarchy of evidence became prominent in the early 1990s as evidence-based medicine was formalized and physicians started to

appraise and apply evidence to their practice,[1,2] and this developed into a pyramid structure, with the best evidence placed at the top of the pyramid and called *level I evidence*, and the lowest-quality evidence at the bottom, called *level V evidence* (Figure 2.1).

Top five questions

1. What is the hierarchy of evidence for therapy studies?
2. What are randomized controlled trials (RCTs)?
3. What are observational studies?
4. What are case series and case reports?
5. What are systematic reviews and where do they fit in the hierarchy of evidence?

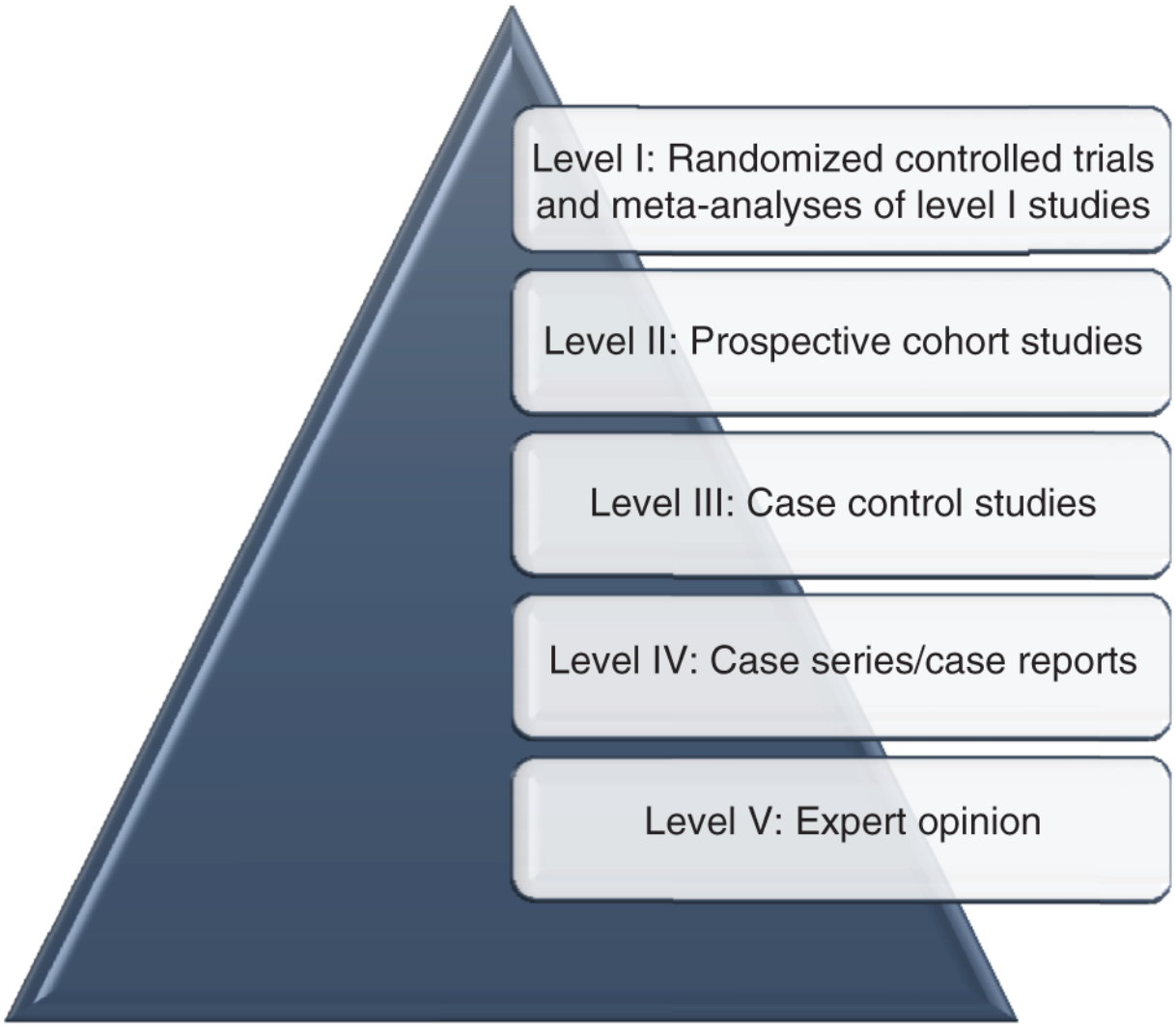

Figure 2.1 Levels of evidence pyramid for therapy studies.

Question 1: What is the hierarchy of evidence for therapy studies?

There are several major types of research questions that researchers can answer. These are typically classified into therapy, prognosis, harm, diagnosis, and economic questions.[3] In this chapter we will focus on those studies addressing therapy, as this is generally the most common type of study in the orthopedic surgical literature. In the case of therapeutic trials, RCTs and meta-analyses of RCTs

are considered the “best evidence.” This is because randomization allows investigators to control for both known and unknown prognostic factors, which cannot be done with other study designs. High-quality observational studies can control very well for known prognostic factors, but only well-done randomization with allocation concealment can control for all prognostic variables. Allocation concealment ensures that the investigators and the participants cannot manipulate the treatment group that they are randomly assigned to.

The second level of evidence is prospective cohort studies. This study design involves two (or more) groups of participants who are exposed to a factor of interest, for example direct anterior versus lateral surgical approach in total hip arthroplasty. The difference between a prospective cohort study and an RCT is that the participants are not randomized to groups: they are assigned by choosing who is in each group or by some other nonrandom means. Modern statistical methods are excellent at controlling for prognostic variables in large high-quality prospective cohort studies, but we can never be sure that all unknown prognostic variables are accounted for, as with RCTs. This is why this design is on the second level of the hierarchy of evidence. It should be noted that some groups put retrospective cohort studies on the second level of evidence, but some put them on the third level due to their retrospective nature. For example, the Oxford Centre for Evidence-Based Medicine's well-used 2009 hierarchy of evidence table puts all cohort studies on level II regardless of whether they are retrospective or prospective.[3] However, the *Journal of Bone and Joint Surgery* puts retrospective cohort studies in level III with other retrospective studies.[4]

The third level of evidence is case-control studies. This study design is unique in that it starts with an outcome and looks backward to determine if there was a particular exposure of interest. Case-control studies are useful for rare outcomes or cases where there are long latency periods between an exposure and an outcome. However, they are vulnerable to recall bias and are not randomized.

The fourth level on the hierarchy is case reports and case series. These studies are often retrospective in nature (but can be prospective) and they are characterized by having no comparison group. This means that we cannot compare the treated/exposed group to untreated/unexposed controls, and it is therefore very difficult to determine whether the participants would have improved (or not) had they not received the treatment/exposure.

Finally, the lowest level on the hierarchy is expert opinion. Experts have worked hard to develop their expertise usually over a period of many years. However, there are myriad biases that an expert can encounter that can color their opinions. Systematic research, such as the levels of evidence and study designs noted above, are theoretically more sound than expert opinion alone.

It should be noted that the study design is not the only consideration when assigning a level of evidence to a study. Studies can be downgraded for poor quality. For example, if an RCT has a major methodological flaw that leads to bias, it can be downgraded to level II evidence.

Question 2: What are randomized controlled trials (RCTs)?

RCTs, if conducted rigorously, are the gold standard for ascertaining the effectiveness and safety of a treatment.[2,3] RCTs can demonstrate the superiority of a new treatment

over an existing standard treatment or a placebo, or they can demonstrate that a new treatment is noninferior to an established treatment. In some cases, RCTs are required by government regulatory bodies as the basis for approval decisions for new medicines and medical devices.

The strengths of RCTs primarily include excellent internal validity, which is based largely on randomization. Randomization itself serves to ensure that the only difference between two (or more) treatment arms is their exposure to the treatment of interest. In other words, well-designed RCTs can provide good measures of the effect of treatments administered under ideal conditions. A criticism of RCTs is that they can be limited in terms of external validity (i.e. generalizability). In particular, patients, providers, and concurrent care in the general population are different from those in clinical trials and, as a result, the generalizability of RCTs may be limited.[2] However, RCTs can be designed such that they are more pragmatic (i.e. how care would be done in normal practice). A pragmatic approach often sacrifices some internal validity in favor of improved generalizability and giving better "real-world" data.

Since randomization is the key factor that distinguishes level I evidence from other levels of evidence, we will describe some of the major randomization methodologies. The simplest method of randomization is aptly named *simple randomization*. A common example of this approach includes flipping a coin. For example, in the case of treatment groups (control vs novel treatment), the side of the coin (e.g. heads being control and tails being treatment) determines the assignment of each participant. This randomization approach is easy to implement in a clinical setting. In large clinical studies, simple randomization is likely to generate similar numbers of participants among groups. However, simple randomization

could be problematic for smaller studies, resulting in an unequal number of participants among groups by chance.[5] The block randomization method randomizes participants into groups that result in equal sample sizes. Blocks are small and balanced with predetermined group assignments, which ensures the number of participants in each group is very close.[5] Stratified randomization is primarily used to balance the influence of important baseline factors that can affect outcomes. For example, if sex is an important factor, investigators may choose to stratify by sex. Males are randomized into treatment groups separately from females to ensure there is a balance of males and females in each group. For stratified randomization to work, baseline characteristics of all participants must be known before randomization occurs.[5]

There are other important factors to consider in RCT design as well, such as blinding participants and the research team, appropriate selection of participants, minimizing attrition, and allocation concealment.

Question 3: What are observational studies?

Observational studies inform clinicians about disease etiology, natural history, prognostic factors, and sometimes treatment effectiveness. The most common observational study designs include cohort and case-control studies.[6]

In a cohort study, participants are divided into two or more groups called *cohorts*. Cohorts are defined by whether they are exposed to a particular treatment, genetic factor, environmental factor, etc. The groups are then followed prospectively and are observed for an outcome of interest. It should be noted that cohort studies are not always prospective. They can be conducted on an existing

database, which is often called a *retrospective cohort study*. A key factor of cohort studies is temporality, or the ability to assess causality by establishing a temporal link (i.e. the exposure came before the outcome).[6] Cohort studies are particularly useful for examining rare exposures or exposures where it is impractical, impossible, or unethical to randomly assign participants to a particular exposure.[6] A common example is that it is unethical to randomize participants to smoke tobacco. A common criticism of cohort studies is that they exposure is not randomized so we cannot be sure that the exposure is the only factor that led to the outcome (i.e. confounding).[6] There are sophisticated statistical methods for accounting for confounding, but it is argued that these are not as effective as randomization at limiting bias.[7],[8]

Case-control studies are characterized by starting with an outcome of interest and looking backward (retrospectively) to see if the participant was exposed to a factor of interest. Participants who have experienced an outcome are called *cases* and they are often matched with participants who have not experienced an outcome, called *controls*. Case-control studies effectively investigate rare outcomes or outcomes with a long latency period because subjects are selected from based on their outcome status.[6] In comparison to cohort studies, case-control studies are quick, relatively inexpensive to implement, require fewer subjects, and allow for multiple exposures or risk factors to be assessed for one outcome. However, they are at greater risk of bias because there can be errors with recalling whether someone was exposed or not, particularly if the exposure occurred many years ago, and again participants are not randomized to an exposure so there may be confounding factors.

Observational studies dominate the surgical literature in orthopedic surgery. The primary reason for this is that many questions in surgical subspecialties cannot be ethically or feasibly answered with RCTs. A candidate for surgery may not wish to be randomized to operative or nonoperative treatment and a surgeon cannot feasibly be blinded to surgery. However, well-designed observational studies can provide useful data on treatment effectiveness and harms that are close to real-world usage, or they can be a stepping-stone to generate hypotheses for future studies.

Question 4: What are case series and case reports?

Case reports and case series are descriptive studies to present patients in their natural clinical setting. Case reports generally consist of three or fewer patients,[9] and are used to illustrate very rare diseases or very new treatments done in only a few patients. In addition to their teaching value for highlighting rare instances, case reports help create a foundation for further research investigation. Case series involve more than three patients. They are characterized by having only one group (i.e. lacking a control group). Usually, one surgeon or several surgeons review all patients that they have treated in a certain manner and describe what their outcomes are. Patients can either be followed prospectively or surgeons can look back at a database that they have collected over a period of time, which is called a *retrospective case series*.

The strengths of case reports and case series include the fact they can give foundational evidence or proof-of-concept that a treatment is doable and provide preliminary evidence of safety and effectiveness. Additionally, they can

be easy, quick, and inexpensive to conduct, particularly if the data are already collected.[9] They can also identify rare manifestations of a disease or drug.[9] The limitations of case reports and case series include the fact that they lack a control, which means that comparisons between treated and nontreated groups are not possible. The cases that are included may not be generalizable and are prone to selection bias.

Question 5: What are systematic reviews and where do they fit in the hierarchy of evidence?

Systematic reviews are well named because they aim to systematically review all the available literature on a topic and synthesize the information into a usable form. They are characterized by a detailed and comprehensive search strategy, critical appraisal of included studies, and either a qualitative or quantitative synthesis of the results. Systematic reviews may include a meta-analysis, which is a statistical method for quantitatively pooling results from two or more similar studies to get a summary effect size for a particular outcome. The advantage of meta-analyses is that they are able to increase the number of included patients and events for a research question of interest to provide a more precise estimate of the effect of a treatment.[10]

Systematic reviews and meta-analyses require multiple steps to conduct correctly. Firstly, the review question must be defined and hypotheses should be formulated. These studies also require defining inclusion and exclusion criteria. For examples, authors must decide on their population age range, conditions, outcomes, type(s) of interventions, and control groups. It is also important to

define what types of studies will be included (e.g. RCTs, observational studies, case series). When developing the search strategy, it is important to come up with a comprehensive list of key terms to be able to identify all relevant studies on the topic. Searches generally include several relevant electronic databases but can also include checking article reference lists, hand-searching key journals, etc. Once a comprehensive list of study titles and abstracts has been retrieved and reviewed, any studies appearing to meet inclusion criteria would then be obtained and reviewed in full.[8] Relevant data are extracted and summarized for each included study, often by two independent reviewers to prevent errors. Then the data are synthesized and, if possible, pooled using meta-analysis techniques.

It is a common misconception that systematic reviews are always the highest level of evidence. However, systematic reviews are subject to the same biases that the included studies are subject to, and more. If a systematic review included all level I evidence studies, then the systematic review is level I evidence. If the review is of observational studies, then it would be level II or III evidence, depending on the quality and design of included studies. Systematic reviews of case series are level IV evidence. The general rule is that a high-quality systematic review is more credible than an individual study from the same level of evidence. For example, a well-conducted systematic review of RCTs is preferable to a single RCT. Systematic reviews and meta-analyses are discussed in further detail in Chapter 3.

Summary

This chapter summarizes the different types of study designs and their associated levels in the hierarchy of

evidence. The hierarchy of evidence is a core principle of evidence-based medicine and addresses the question of "What is the best available evidence?"[9] It takes a top-down approach in locating the best available evidence whereby one would first search for a recent systematic review on the topic of interest, and if these studies are not available for this topic, then one would move down to the next level of evidence. The higher up the hierarchy the study design is positioned, the more rigorous the methodology and hence the more likely it is that the study design can minimize the effect of bias on the results of the study. In most evidence hierarchies, well-designed systematic reviews and meta-analyses of level I evidence are at the top of the pyramid, and expert opinion and anecdotal experience are at the bottom.

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3 Systematic Reviews and Meta-Analyses

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Introduction

Published medical research enhances our understanding of disease and helps us critically evaluate the efficacy of our treatments. As the volume of published research grows, it becomes unrealistic to attempt to read primary source literature on a clinical question (Figure 3.1). The purpose of a review is to summarize updates from recent research, outline the scope of a topic, or pool data from multiple studies to draw insights not obtainable with a single study. A hierarchy of reviews exists regarding methodology, objectivity, and clinical utility. The purpose of this chapter is to equip the reader with an understanding of the appropriate role of each type of review, as well as the tools to create each.

Top four questions

1. What are the types of literature reviews?
2. How is a systematic review performed?
3. How is a meta-analysis performed?

4. How does one critically appraise a systematic review and meta-analysis?

Question 1: What are the types of literature reviews?

Narrative reviews, scoping reviews, and *systematic reviews* are descriptive, or nonquantitative. *Meta-analysis* involves additional statistical comparisons of treatment effects using data pooled from multiple studies. *Network meta-analysis* indirectly compares more than two treatments by linked analyses of common treatments across multiple studies.

Narrative review

A *narrative review* is a selected summary of primary literature, often for a concise synopsis of recent advances or reference guide for readers new to a topic. A narrative review is not the most objective source of evidence for it is vulnerable to multiple types of bias. Selection bias arises from article inclusion or exclusion without specific criteria. Inattentive data abstraction produces measurement bias. Reporting bias stems from disingenuous descriptions of methods or data. Narrative reviews may include expert interpretations based on authors' experience. Confirmation bias may occur if the authors report only findings that support their personal beliefs. Time lag bias may occur if authors may omit new reports of efficacious treatment or advocate a therapy that has since been proven harmful or ineffective.[1]

Systematic review

A *systematic review* is a scientific investigation of published literature that objectively summarizes available evidence. Cook et al. defined it as, “the application of

scientific strategies that limit bias to the systematic assembly, critical appraisal, and synthesis of all relevant studies addressing a specific healthcare question."[2] The scope is narrow, often a single question on a specific topic. The review process is an algorithmic assembly and assessment of original studies as "subjects" from multiple sources following a prospectively defined protocol.[3] The protocol, which makes a systematic review a reproducible investigation, specifies the sources and search strategy for identifying potentially relevant articles, inclusion and exclusion criteria for article selection, and methods for data abstraction and analysis. When included studies are sufficiently similar to statistically pool effects, meta-analysis may be performed, as discussed below. The level of evidence of the review is dictated by included studies: level I–II evidence from randomized controlled trials (RCTs) will produce a level I–II systematic review, while level III and IV evidence may have meaningful roles in the study of rare events or justifying need for additional research on a sparsely studied topic.[4]

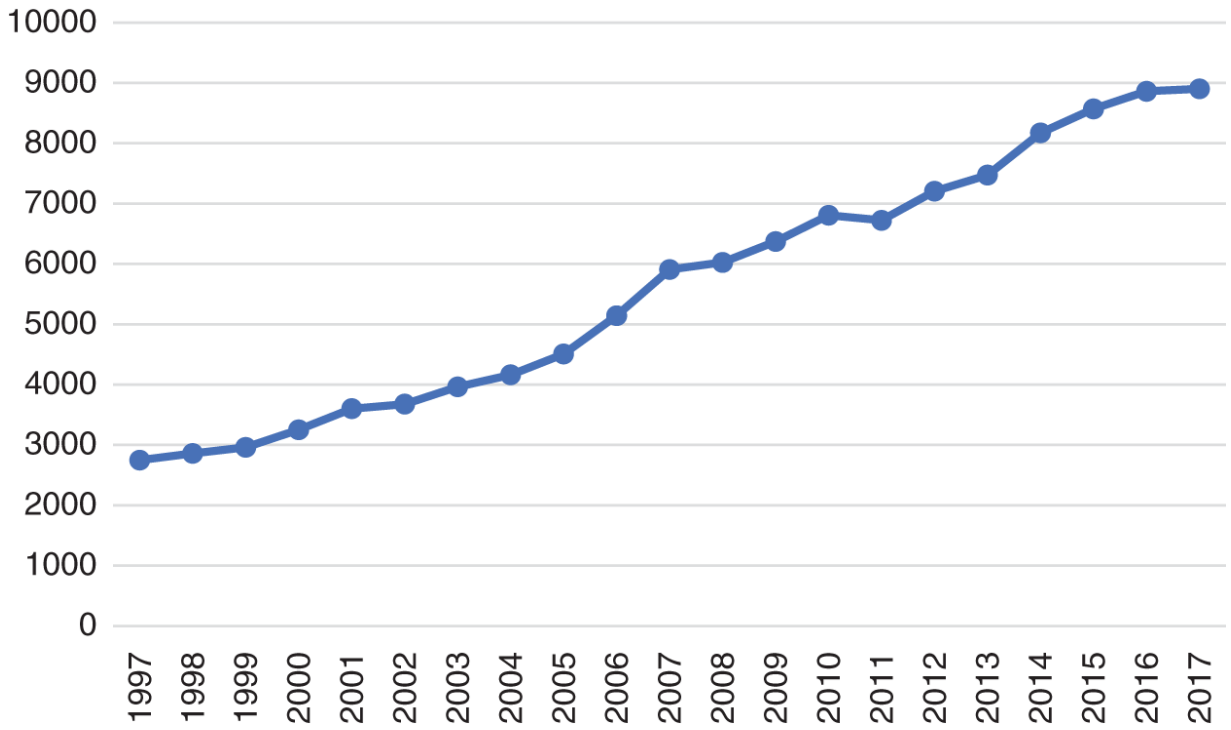

Figure 3.1 Published articles per year in the top 25 highest-impact factor orthopedic surgery and sports medicine journals 1997–2017.

Scoping review

A *scoping review* is a truncated systematic review that maps the existing literature on a subject in terms of the volume, nature, and characteristics of the primary research.[5] This review is useful when the topic has not yet been extensively reviewed, is complex, or appears heterogeneous.[6] As a rigorous and transparent method for mapping areas of research, a scoping review can be a standalone project to synthesize findings and identify gaps in the existing literature, or a preliminary step to a systematic review that defines the potential breadth and cost of undertaking a full systematic review.[5,7]

The major limitation of a scoping or systematic review is sensitivity to publication bias. Treatment effects may be overestimated: published trials are more likely to describe

positive treatment effects,[8] negative results are less likely to be published,[9] and unpublished negative results are difficult to locate.

Guidelines for systematic reviews have evolved with innovations in review design and analytic methods. The Quality of Reports of Meta-analysis (QUOROM) guidelines morphed into the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) statement.[10] The Cochrane Collaboration produces systematic reviews to inform health decision-making using an even more stringent quality standard.[11] Adherence to reporting guidelines is associated with greater citation rate and scholarly impact.[12] Prospectively and publicly registering a protocol on a registry, such as the International Prospective Register of Systematic Reviews, better known as PROSPERO, can prevent unwitting duplication by others and uncover reporting bias if a completed review does not match what was planned.[13]

Meta-analysis

Meta-analysis is the quantitative investigation of data aggregated through a systematic review of data reports.[14] Meta-analysis can be performed from published results without original or patient-level data. When individual patient data can be acquired, more nuanced analyses of predictors and effect modifiers may be conducted through *patient-level meta-analysis*. In meta-analysis, studies must be sufficiently *homogeneous* for valid comparison: studies must evaluate the same the test, exposure, or treatment and assess similar outcomes. The outcomes of multiple studies are *pooled*: the number of patients and events in each treatment or exposure group are summed across studies. Association between the exposure/treatment and the outcome is tested with the pooled data, often weighted

by the sample size of each study. Pooling studies improves the power of the statistical analysis, increasing the likelihood that any association is statistically significant. However, pooling studies does not eliminate bias or improve the quality of the studies. We describe the tools to rigorously perform and evaluate conventional meta-analysis in this chapter.

Network meta-analysis

The transitive property: if A = B and B = C, then A = C. Two distinct, direct comparisons support an indirect, inferred comparison. *Network meta-analysis* – also called *multiple treatments meta-analysis*, or *mixed-treatment comparisons* – expands on this concept to assess the relative effect sizes of more than two interventions have on one outcome.[8] Several trials each comparing two or more interventions on one common outcome each provide *direct evidence*. *Indirect* comparisons can be made between interventions not directly compared in an actual trial by organizing the studies into closed- and open-loop networks.[9,15] *Transitivity* describes similarity in patients, interventions, and outcomes across the studies in the network. If patients from all arms of the various trials do not meet the inclusion/exclusion criteria of a single intervention arm, then the principle of transitivity has been violated and the network meta-analysis is not credible.[9] *Incoherence* is disagreement between direct and indirect estimates; this may arise from bias in the indirect comparisons due to intransitivity or bias in the published direct comparisons. Numeric or visual estimates of relative treatment effect estimates may underrepresent uncertainty and do not convey bias, incoherence, or transitivity.[16] Conclusions about treatment superiority from network meta-analysis should be made with caution.

Question 2: How is a systematic review performed?

The following sections guide the reader through a workflow for performing a high-quality systematic review and conventional meta-analysis that conforms to the PRISMA statement and Cochrane Collaboration definitions.[10] For further details, we recommend the Cochrane Handbook[17] as well as texts by Petitti[18] and Egger et al.[19]

- *Define the specific review question*. Develop a research question by specifying the target population, intervention, control (or comparators), and outcomes of interest (PICO format). See Chapter 1 for guidance on formulating a research question.
- *Query PROSPERO for a similar active or published review*. A review may take months to complete. Other investigators may have recently published or may be actively conducting a systematic review that overlaps with the research question. The planned review could become redundant, and possibly unpublishable, between starting and publication.
- *Perform a preliminary search for key citations*. Identify investigations and reviews that address the research question. Review the discussions and citations for "must-include" primary papers. The titles and abstracts of these papers may contain synonyms, related concepts, alternate spellings of key words, and medical subject headings (MeSH) worth including in the *search strategy*. The National Library of Medicine curates MeSH as a restricted vocabulary of terms for indexing and cataloguing biomedical information on PubMed/MEDLINE.[20]

- *Develop the review protocol*. The protocol specifies how to perform and how others could reproduce the review. The protocol specifies the title, personnel, funding, conflicts of interest, research question, eligibility criteria, literature sources and search strategy, article selection and adjudication methods, data extraction, bias assessment, data synthesis, planned analysis, and plan for dissemination of results. A useful template is the PROSPERO standardized protocol format.[13]
- *Eligibility criteria* for a systematic review are not unlike those of human subject research: specify which studies (patients) are eligible to participate (Table 3.1). Inclusion criteria select for similar methods and participants across all studies. This will define the population to whom inferences can be made from the summarized findings.

Table 3.1 Criteria for study inclusion in a systematic review of a treatment.

Date of publication	Studies of a medication published after the date of regulatory (e.g. Food and Drug Administration) approval of the medication may reduce vulnerability of the review to reporting bias by excluding trials sponsored by the manufacturer during the regulatory approval process
Language	Including and searching as many languages as feasible for the review team minimizes selection bias Full text translation may be necessary
Study design	Type and methods of studies by ICMJE Levels of Evidence[4]
Target population	The demographics of the patients and specific conditions of interest
Intervention	The exposure or treatment of interest
Comparator	The control group, i.e. placebo or no treatment
Primary outcome	Be specific Heterogeneity in the methods of outcome assessment between studies will negatively affect the validity of pooled analyses For example, for a primary outcome of rate of deep vein thrombosis, the modalities of assessing that outcome (venography, Doppler ultrasound, or telephone survey) have different sensitivity, specificity, and accuracy
Secondary outcomes	Studies may report secondary outcomes relevant to the condition studied Assess the feasibility of a pooled analysis of these secondary outcomes

- *Literature sources*. No single electronic database includes all published, potentially relevant literature. Systematic reviews therefore combine searches of multiple sources. Table 3.2 provides a brief but not comprehensive list of English-language citation databases.

Table 3.2 Literature sources.

Electronic citation databases	• MEDLINE/PubMed (United States National Library of Medicine): electronic database of biomedical journal citations and abstracts published since 1946 • Embase is a subscription-based (Elsevier) electronic database of full text drug, disease, and medical device data published since 1947 as well as journals unique to the publisher. There is considerable but incomplete overlap with MEDLINE for orthopedic topics, such that searches may cover both databases[21] • Web of Science (Clarivate Analytics) is a subscription-based citation indexing service covering records from 1900 to present • Scopus (Elsevier) is a subscription-based electronic database of peer-reviewed scientific journals, books, and conference proceedings since 2004 • Google Scholar (Alphabet) is a free index of over 160 million of journals, books, conference papers and abstracts, theses and dissertations, technical reports, court opinions, and patents covering 80–90% of the English-language scientific literature[22]
Clinical trial registries	May identify studies that are unpublished at the time a review begins but which may become published and eligible for inclusion during the review period

	• The Cochrane Central Register of Controlled Trials (CENTRAL): PubMed, Embase, and unpublished data[23] • ClinicalTrials.gov (United States National Library of Medicine, National Institutes of Health)[24] • EU Clinical Trials Register: European Union and Economic Area member nations[25] • International Clinical Trials Registry Platform (World Health Organization)[26]
Data published outside of indexed medical journals	Not subject to the level of peer review required for journal publication. The latest data and most complete census of potentially relevant literature may come at a cost of quality without peer view • Conference abstracts. Search of conference proceedings may require manual review of final conference programs. Authors may need to be contacted for unpublished complete methods, data, and results • Preprint servers appeared in the biomedical sciences as a vehicle for sharing data prior to journal acceptance, i.e. without peer review. By consensus, orthopedic material made available via a preprint server is generally not accepted for subsequent publication on the basis of redundant publication[27]

- *Search terms* are the exact text queries entered in a search engine. Developing the search terms is an

iterative optimization of phrases coded in the engine's language. Terms should capture the maximum number of citations relevant to the research question (sensitivity) and capture the key citations identified in the preliminary search (specificity). Some authors develop separate sensitive searches for each of the PICO components of the research question.[28] We prefer to develop our search strategy in MEDLINE by identifying search terms from MeSH subject headings that apply to the research question, then add clinically related phrases, synonyms, alternate spellings, and other nosologic permutations using Boolean operators and bracket logic. Search terms published as a supplement for transparency may offer insight into formatting.[29]

- *Citation management software* (EndNote, Mendeley, Zotero, RefWorks, etc.) is helpful for organizing studies during each phase of the review. Software packages designed specifically for systematic review are also available (e.g. Covidence, DistillerSR, EPPI-Reviewer, Rayyan, RevMan, Systematic Review Data Repository, SUMARI).
- The *systematic review process* is an iteratively more detailed appraisal of the citations identified by the systematic search for eligibility per the review protocol. Multiple reviewers consider each study at each stage of the review; any disagreement regarding eligibility of an article is discussed and agreement reached by consensus. The review begins with title and abstract review, which reduces the number of full text reviews.
- *Data extraction* from each included full text article is done with a standardized data collection form. The data extracted relate to assessment by the reviewers of study design, quality, validity, and bias, as well as

sample and outcomes. Typical fields include: journal; authors; year of publication; country; study design; method of randomization; baseline population demographics including proportion of men or women, race, age, socioeconomic characterizations; sample size; allocation concealment and blinding; intervention and control arms; duration of treatment or follow-up; outcome assessment method or modality; outcome assessors; and event rates or risk estimates.

- *Assess the risk of bias* by evaluating the methodology of included studies. Factors commonly associated with bias in randomized trials include lack of concealment of randomization, lack of blinding, and failure to report reasons for excluding patients.[30] Tools designed to assess bias are available including the Newcastle–Ottawa Quality Assessment Scale for prospective and retrospective cohort and case-control studies; the Cochrane Collaboration's risk of bias tool or Jadad scale for reporting RCTs; and the Methodological Index for Non-randomized Studies (MINORS) score for nonrandomized studies.[31] Quality scoring is not required to conduct a systematic review and may impose certain biases on the review in the process; therefore, weighting studies by a quality score is discouraged in meta-analysis.[32],[33] Assessing quality based on specific characteristics is a preferred way of stratifying included studies.[32],[34],[35]

- *Reporting* should adhere to the PRISMA checklist and illustrate study inclusion using the PRISMA flow diagram.[10]

Question 3: How is a meta-analysis performed?

- *Pool the outcomes*. The pooled incidence for a binary outcome is the count of events divided by the number of patients in each groups across all studies. The risk for a binary outcome may be represented as an odds ratio, risk ratio, risk difference, or incident rate for time-dependent outcomes. The inverse of the risk difference yields the number of patients that would need to be treated (number needed to treat; NNT) to prevent one outcome. Continuous outcomes can be summarized by the raw mean difference between the treatment and comparator groups when the same scale is used. When different scales are used, a number of methods, such as the standardized mean difference (effect size), can be used. Correlation coefficients can be used to compare two continuous variables. Censoring due to loss to follow-up should be considered, especially if study durations vary. Standard methods should be applied to the management of missing data.
- *Assess heterogeneity*. Studies usually report different estimates of treatment effect. While sampling error may account for some variation, so may clinical, methodological, and statistical differences between the studies. *Heterogeneity* describes the statistical, methodological, and clinical diversity of the treatment effect reported among different sets of data, and attempts to quantify the portion of that variance attributable to sources other than random error.[36] Pooling data is appropriate only if the differences in treatment effect are mostly due to chance; otherwise, estimates of the true treatment effect from meta-analysis will be biased or may result in wide confidence intervals with limited clinical utility.

Heterogeneity should be identified and explained. The I^2 statistic is a popular test, of many available, which represents the proportion (0–100%) of total variation in the estimates of treatment effect that is due to heterogeneity between studies versus random error, independent of the number of studies and the metric for treatment.[36] The I^2 statistic is an improvement over the Cochran's χ^2 test (Q-test), which is underpowered to detect between-study variability when the number of studies is small (and the number of studies is often small).[37] For χ^2, $p < 0.10$ is an accepted cutoff to suggest heterogeneity, while I^2 values of 25, 50, and 75% have been interpreted as representing small, moderate, and high levels of heterogeneity, respectively.[38] Once heterogeneity is identified, subgroup analysis or regression of the summarized effect on individual study characteristics or methodologic features (*meta-regression*) can be used to investigate differences between study findings further.[39]

- *Assess for publication bias*. Time-lag bias can occur if a study is published more rapidly than other studies subsequently published with differing results. Small studies, nonrandomized studies, non-English-language work, and studies with negative results are less likely to be published or published in a timely manner. In the presence of publication bias, a plot of sample size or variance against effect size is usually skewed or otherwise asymmetric (Figure 3.2).[36] The inverted funnel plot, or Egger test, is commonly used to assess publication bias. A scatter plot of the standard error of each effect estimate against the effect estimate for each study is created. A random sample of unbiased studies should report effects normally distributed about

the pooled effect or summary estimate, illustrated as a vertical line along the x-axis. The “cone” of the plot typically represents a 95% confidence interval for the standard error expected for a given effect size. Asymmetry, or nonrandom deviation from the summary estimate, evidences publication bias: typically, studies reporting no significant effect or a “negative effect” have not been published and the summary effect size is falsely overestimated (Figure 3.2).[40]

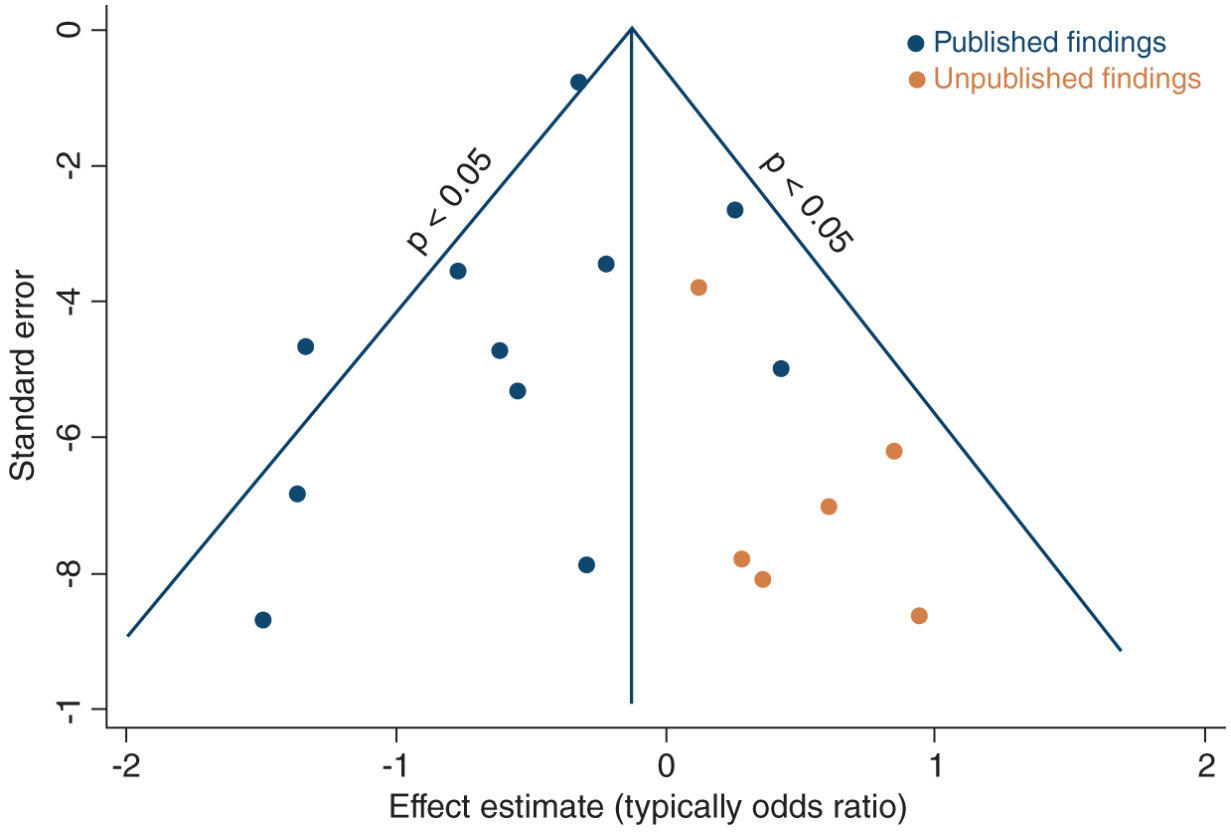

Figure 3.2 Inverted funnel plot demonstrating publication bias overestimating summary effect size. Source: Modified from Sterne and Egger.[40]

- *Select an effects model*. A *fixed effects* model assumes the only difference between studies is their power to detect the true outcome: that all were conducted under similar conditions with similar subjects without random

sampling. Fixed effects modeling may be appropriate when I^2 is low. A *random effects* model considers between-study variance in sampling the treatment effect. Consequently, more data are required for random effects models to achieve the same statistical power as fixed effects model; estimates may be unstable for sparse data.[41]

- *Perform meta-analysis* by estimating the pooled effect size using an inverse-variance-weighted mean. More advanced meta-analysis techniques such as meta-regression and network meta-analysis are beyond the scope of this chapter. Packages available for statistical software such as R, SAS, SPSS, STATA, etc., will generate a forest plot showing the confidence intervals for estimate treatment effect from each study as well as pooled estimate, represented as a diamond (Figure 3.3).[42]

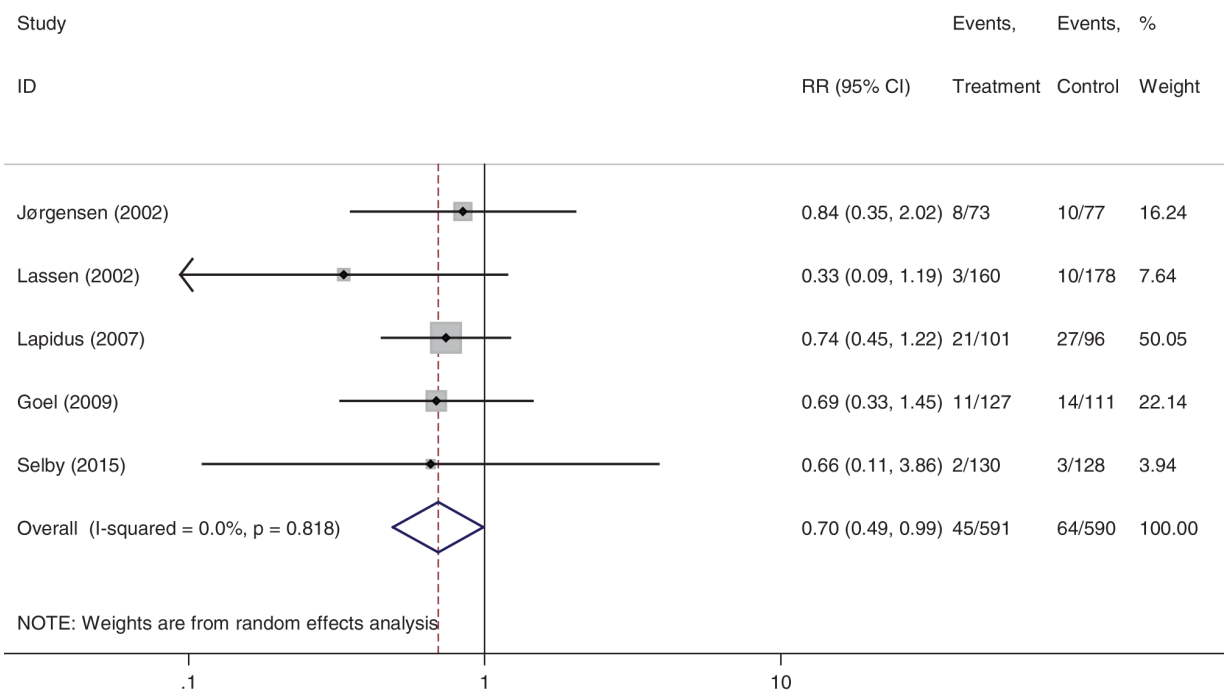

Figure 3.3 Weighted meta-analysis of pooled trials demonstrates significant relative risk reduction for postoperative deep venous thrombosis randomized after prophylaxis with low molecular weight heparin versus placebo or no treatment. Source: Reproduced with permission from Patterson and Morshed.[29]

Report findings as per PRISMA guidelines.[10]

Question 4: How does one critically appraise a systematic review and meta-analysis?

Systematic reviews vary in quality. Limitations may arise from how studies were selected, the quality of the included studies, the clinical utility of the outcomes assessed, and the methodologic rigor of pooling and analysis. Included studies should be assessed as above for potential within-study bias due to methodologic shortcomings. Then consider between-study variability: is the reported

heterogeneity statistic appropriate for the studies, and is the value so great that it hinders interpretation of the results? Half of 509 meta-analyses in the Cochrane database had I^2 statistics >0 indicating some level of inconsistency between studies.[43] Determine whether sensitivity analyses were performed and that the exclusion of any given study does not substantially alter the results or conclusions.

Oxman and Guyatt published a subjective 10-item index for systematically grading the quality of a systematic review (Table 3.3).[43] Using this instrument, Dijkman et al. found that 18 and 30% of meta-analyses in orthopedic surgery published in 2005 and 2008, respectively, had major to extensive flaws in their methodology.[8]

Table 3.3 Oxman and Guyatt criteria for assessing scientific quality of research overviews. Source: Modified from Higgins, et al.[43]

1. Were the search methods reported?	Yes, partially/can't tell, no
2. Was the search comprehensive?	Yes, partially/can't tell, no
3. Were the inclusion criteria reported?	Yes, partially/can't tell, no
4. Was selection bias avoided?	Yes, partially/can't tell, no
5. Were the validity criteria reported?	Yes, partially/can't tell, no
6. Was validity assessed appropriately?	Yes, partially/can't tell, no
7. Were the methods used to combine studies reported?	Yes, partially/can't tell, no
8. Were the findings combined appropriately?	Yes, partially/can't tell, no
9. Were the conclusions supported by the reported data?	Yes, partially/can't tell, no
10. What was the overall scientific quality of the overview?	1. Extensively flawed

	3. Major flaws 5. Minor flaws 7. Minimally flawed

The purpose of a systematic review is to inform clinical practice with evidence. When appraising a review, consider the clinical question addressed. Is it relevant to my practice? How well could the design of the review objectively answer that question? Were the target populations of the included studies inclusive of patients with problems similar to mine? Was heterogeneity reported and, if so, were sources adequately investigated? Were there clinically relevant differences reported? Were other sources of bias considered?

Summary of answers

- Narrative reviews provide background information across a broad scope relating to a topic.
- Systematic reviews are a preferred, scientifically rigorous method for mapping the types of literature pertaining to a field of inquiry (scoping reviews) or specific clinical question.
- Meta-analyses and network meta-analyses quantitatively synthesize evidence to answer a specific clinical question and require a high-quality systematic review as a prerequisite.
- When performing a review: register systematic reviews before starting and follow guidelines; assess bias, appreciate the statistical basis of analysis, and perform quantitative synthesis only when appropriate.

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4 Healthcare Recommendations: Grades of Recommendation, Assessment, Development, and Evaluation (GRADE) Approach

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Case scenario

You have been asked to join a guideline panel working group that is tasked with developing a clinical practice recommendation for the use of hemiarthroplasty (HA) versus total hip arthroplasty (THA) for the management of displaced femoral neck fracture in patients over the age of 60. The team has decided that the important outcomes to evaluate within their recommendation are revision rates, one-year mortality, and dislocation rates. Interested in understanding the best method in developing this recommendation, you have decided to investigate the Grades of Recommendation, Assessment, Development, and Evaluation (GRADE) approach to guideline recommendation development.

Top three questions

1. What is GRADE?
2. What are the components of a GRADE quality of evidence assessment, and how do you evaluate them for a body of evidence?
3. How do you use your GRADE quality of evidence assessment to develop a clinical recommendation?

Question 1: What is GRADE?

GRADE is a tool that has been developed to provide a transparent and thorough guide for rating the quality of evidence and strength of recommendations made within healthcare research.[1] A GRADE assessment is conducted on a body of literature that was collated through a systematic review. The first step of recommendation development, after the guideline panel and clinical question to be answered have been defined, is to conduct a comprehensive systematic review that captures all evidence pertaining to the research question of interest.[1] For this scenario, we are assuming that this systematic review of available literature on displaced femoral neck management using HA or THA has already been conducted, and all relevant research evidence has been collected for the outcomes of interest.

It is important to note that GRADE is used to assess the quality of evidence for each individual outcome that will be considered within the clinical recommendation.[1] This means that the GRADE approach would be repeated three times for the current scenario: assessing the quality of evidence for revision rates, one-year mortality, and dislocation rates separately. This is done because the body of evidence for each outcome may not be the same. For example, there may be different ratings of the quality of evidence due to a large number of studies reporting revision rates, while fewer of them provide information on dislocation. The GRADE framework then provides guidance on how the working group should proceed to develop a clinical recommendation on HA or THA use for displaced femoral neck fractures.

After collecting all relevant evidence and assessing the quality of that evidence for each individual outcome, the GRADE approach provides a transparent framework to create clinical recommendations based on the strength and quality of the evidence. This includes decisions by the working group regarding the balance between desirable and undesirable consequences of using the treatment options.[2] It also requires the working group to provide a strength to their recommendation, based on the available evidence.

Recommendations may be considered either “strong” or “weak,” depending on the certainty that the working group has regarding the quality and magnitude of the evidence that has been evaluated.[2]

Question 2: What are the components of a GRADE quality of evidence assessment, and how do you evaluate them for a body of evidence?

Quality of evidence assessment

The GRADE approach to assessing quality of evidence takes the following concepts into consideration: the study design of the available evidence, risk of bias, imprecision, inconsistency, indirectness, and publication bias.[3] Additionally, assessment of all plausible confounders, magnitude of effect, and the presence of a dose-response gradient are additional factors that are assessed within GRADE when evaluating observational data in order to potentially increase the quality of evidence rating.[3] These considerations are each taken into account to provide a categorical quality rating of either very low, low, moderate, or high for each of the outcomes of interest.[4] Evidence from randomized trials is initially regarded as high quality, but the evaluation of each of the considerations can influence the final rating given to the body of evidence (Table 4.1).

Table 4.1 GRADE approach to rating quality of evidence. Source: Modified from Balshem, et al.[3]

Study design	**Quality of initial body of evidence**	**Decrease the quality rating if**	**Increase the quality rating if**	**Final quality rating**
Randomized controlled trials Observational studies	High (initial score of 4) Low (initial score of 2)	Risk of bias −1 Serious −2 Very serious Inconsistency −1 Serious −2 Very serious Indirectness −1 Serious −2 Very serious Imprecision −1 Serious −2 Very serious Publication bias −1 Likely −2 Very likely	For observational studies: Large effect +1 Large +2 Very large Dose response gradient +1 Present Plausible residual effect +1 Would reduce the demonstrated effect +2 Confident that all plausible confounders are accounted for	**High** (score of 4 or higher) **Moderate** (score of 3) **Low** (score of 2) **Very low** (score of 1 or lower)

A rating of high-quality evidence by the guideline panel signifies that “[the panel] is very confident that the true effect lies close to that of the estimate of the effect”; while a rating of very low evidence is described as “[the panel] has very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect.”[3] In order to determine an appropriate rating for the quality of evidence, each of the

aforementioned considerations need to be evaluated in detail for each of the included outcomes.

Assessing risk of bias

Assessors evaluating risk of bias can reduce the quality of evidence by one category if it is deemed to be a serious risk, or by two categories if it is deemed to be very serious. For example, a body of randomized trial evidence would initially be categorized as high-quality evidence. If there was considered to be a serious risk of bias within the evidence, the rating would then be categorized as “moderate quality.” A rating that states a very serious risk of bias within the evidence would change the rating from high quality to low quality.[5] In order to comprehensively evaluate the risks of bias for GRADE, there are a number of key study limitations that should be assessed in order to decide the risk of bias rating for a body of study of randomized trials:[5]

1. Inappropriate/absent allocation concealment.
2. Inadequate blinding.
3. Incomplete follow-up or failure to conduct intention-to-treat analysis.
4. Selective outcome reporting.
5. Trials that were stopped early for benefit.
6. The use of inappropriate/unvalidated outcome measures.
7. Inappropriate carryover effects (in cross-over studies).
8. Recruitment bias (in cluster randomized trials.)

There are specific limitations for bodies of evidence containing observational studies as well, which are described in detail within the GRADE publication series.[5]

Assessing inconsistency

The quality of evidence rating can be rated down by either one or two categories depending on the assessment of inconsistency

by the guideline panel.[4] *Inconsistency* refers to the similarity (or lack thereof) of effects seen within each individual study within the body of evidence.[6] This is evaluated by assessing the similarity in point estimates from included trials, the extent of overlap between individual trial confidence intervals, and statistics of heterogeneity for the included studies.[6] It is important for studies to explore plausible hypotheses regarding any heterogeneity seen, and the guideline panel should consider rating down the quality of evidence if there is a large amount of unexplained inconsistency. This should be particularly considered if some included studies demonstrate a large benefit, while other included studies demonstrate no effect or harm.[6] The use of forest plots is valuable in aiding with the visualization of inconsistency, as forest plots provide the point estimates, confidence intervals, and heterogeneity statistics. All of these components are important for the guideline panel to review in order to decide whether the quality of evidence should be rated down due to inconsistency.

Assessing indirectness

Indirectness refers to the extent to which the research questions of the included studies applies to the research question that is being answered by the guideline panel.[7] In order to assess indirectness, an assessment must be done of the similarities or differences between the study patient populations, interventions, and outcomes assessed.[7] If there is not a sufficient body of evidence evaluating the outcomes for the appropriate interventions within the patient population of interest, indirect evidence may be used to make inferences about the guideline panel research question. Indirectness could be a result of a lack of evidence for a specific patient age group, so evidence from a different age group is used to infer the effects of the interventions on the population of interest. If this is done, the quality of evidence should be rated down for indirectness.[7]

Another possible reason for downgrading the quality of evidence for indirectness is the use of comparison between two

treatments that have not directly been compared to one another within primary investigations.[7] From the example scenario of this chapter, this could be conceptualized if we were to imagine that there is currently no evidence directly comparing HA and THA. Instead, there is only evidence of these treatments being compared to internal fixation. If this were true, the guideline panel could assess the effects of both treatments against internal fixation, and statistically infer the relative difference in effect of between HA and THA. If this were to be done, the quality of the evidence would be rated down for indirectness.[7]

Assessing imprecision

Imprecision is a term used to characterize the confidence that individuals in the guideline panel have regarding the estimates of effect for each of the outcomes. This is primarily done by evaluating the confidence intervals (CIs) surrounding the pooled effect estimate for each outcome.[8] The criterion that should be considered by the guideline panel when assessing imprecision is the clinical decision that would be made if the true effect laid at either extreme end of the CI. If the panel believes that a different clinical decision would be made if the true effect resembled a value at the high end of the 95% CI versus a value at the low end of the 95% CI,[8] then the panel would consider rating down the quality of evidence for imprecision. This scenario would typically occur in situations with wide CIs that may range from substantial clinical benefit to minimal/no effect.[8] For example, if the relative risk of revision surgery between HA and THA yielded a CI that extended from potential superiority of one treatment at the high end of the CI to no difference in revision rates at the low end of the CI, the body of evidence for revision rates may be rated down for imprecision.

Assessing publication bias

The last criterion that can be used to rate the quality of evidence lower is *publication bias*. The risk of publication bias is typically considered if the body of evidence for the outcome consists of a small number of studies, especially when those

studies are primarily funded by industry.[9] This often leads to an overestimate of the true effects of a treatment. Publication bias may be common, particularly in newer treatments that do not have a substantial body of studies with large sample sizes. Funnel plots are a typical tool used to visualize publication bias; however, there are no concrete criteria for the decision to rate down for publication bias.[9] Without concrete criteria for determining publication bias, the guideline panel should be careful when dealing with small bodies of evidence for newer treatment options.

Criteria for increasing quality of evidence ratings

Although many guideline panels seek evidence from randomized trials in order to develop clinical practice recommendations, there may not always be randomized investigations available for the research question of interest. For example, it can be imagined that there are no available randomized trials assessing one-year mortality after HA versus THA for displaced femoral neck fractures in patients over 60. The guideline panel must thus utilize evidence from a number of cohort studies in order to gain insights into the quality of evidence for this outcome. After assessing each of the criteria to rate down the quality of evidence for one-year mortality, there are now three criteria that the guideline panel needs to assess in order to possibly increase the quality of evidence rating.

The first criterion for increasing the quality of evidence rating for observational studies is the presence of a large magnitude of effect. The GRADE group suggests that a twofold increase in risk would constitute a substantial magnitude of effect.[10] This would warrant increasing the quality of evidence by one category. The quality of evidence rating may be increased by two categories if there is a fivefold difference in risk between the interventions with regard to our example outcome of one-year mortality.[10]

The second possible reason for the guideline panel to increase the quality of evidence for observational studies is the presence of a dose-response gradient. This criterion does not apply to the

example scenario due to the comparison being between two surgical interventions; however, it may be more relevant to guideline questions that evaluate therapies that could be provided at a variety of dosages. If there is a strong relationship between an increased dose and a corresponding increase in treatment effect, there may be greater confidence that the treatment effects seen are a direct result of the treatment.[10] This warrants an increase of one quality of evidence category for the assessed outcome.

The final criterion that can be used to increase the quality of evidence rating for observational evidence is the presence of a comprehensive evaluation of all plausible confounders that could have an impact on the treatment effects observed.[10] Well-done observational studies will include adjusted analyses that incorporate all important factors that may be confounders. When the guideline panel is confident that the included observational data have taken these confounders into account in their analyses, the quality of evidence rating may be increased by one category.[10]

Question 3: How do you use your GRADE quality of evidence assessment to develop a clinical recommendation?

It takes significant consideration and deliberation regarding the available evidence in order to move from rating the quality of evidence to developing a guideline recommendation. When determining the direction and strength of a guideline recommendation, there are four key factors that must be considered:[11]

- Balance of desirable and undesirable outcomes of interest.
- Confidence in the effect estimates observed for each outcome.
- Considerations of values and preferences for all relevant stakeholders.

- Resource use related to the treatment options evaluated.

When deciding on the balance of desirable and undesirable effects by the guideline panel, there are a number of suggested considerations. A strong recommendation would typically be warranted if there are large differences in the magnitude of benefits and harms.[11] For example, if the evidence suggested a large clinical improvement with very little associated harms, a strong recommendation may be warranted. When considering the confidence that the guideline panel has in the effect estimates, they should consider the quality of evidence that they had determined using the criteria from the previous section of this chapter. When the quality of evidence is high, guideline panel members should be inclined to have greater confidence in the effects.[11] Values and preferences of relevant stakeholders are also an important consideration.[12] The strength of a guideline recommendation may be reduced if there are strong preferences from relevant stakeholders that would be pertinent to the clinical decision-making process.[11] Finally, the strength of the guideline recommendation should take resource use into consideration. If there is a large difference in cost between the two treatments evaluated, the guideline panel should consider this when developing their recommendation.[11]

Summary of answers

- GRADE is a tool that provides a comprehensive and transparent method of developing clinical practice recommendations.
- GRADE requires the guideline group to evaluate the quality of evidence based on the following factors:

    Risk of bias.

    Inconsistency.

    Indirectness.

    Imprecision.

Publication bias.

Magnitude of effect (observational studies).

Dose-response gradient (observational studies).

Assessment of all plausible confounders (observational studies).

- Quality of evidence assessments are used to generate an overall rating of high, moderate, low, or very low quality for the evidence of each outcome.
- After determining the quality of evidence, guideline panel members must take the evidence and formulate clear clinical recommendations. These recommendations need to account for:

  The balance between desirable and undesirable outcomes of interest.

  Confidence in the effect estimates observed for each outcome, through assessment of the quality of evidence.

  Considerations of values and preferences for all relevant stakeholders.

  Resource use related to the treatment options evaluated.
- The GRADE approach results in a transparent clinical recommendation with a corresponding strength associated with the certainty of the guideline panel.

Additional resources

There is a complete series of GRADE publications that comprehensively discusses each of the concepts summarized within this chapter. This GRADE series is published online by the *Journal of Clinical Epidemiology*. Software is available that provides a comprehensive method to using and organizing the GRADE approach (GRADEpro GDT).

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5 Outcomes and Their Interpretations

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Introduction

The World Health Organization defines an outcome measure as a “change in the health of an individual, group of people, or population that is attributable to an intervention or a series of interventions.”[1] Outcome measurement is becoming increasingly important in an effort to document the value of interventions to both patients and society. Harvard Business School professor and healthcare policy expert Michael Porter has proposed a framework that defines *value* as health outcomes achieved relative to the costs incurred.[2] Outcome measures are critical to both clinical research and public health, because this is the primary driver influencing one's ability to answer important questions in a reliable manner. Outcome measures serve as the target that both researchers and healthcare organizations or governments monitor or attempt to modulate in an effort to improve the quality and/or cost of care. The past 30 years have seen a rise in interest in the measurement of the outcomes of medical care, to the extent that an “outcomes movement” has been described and been labelled “the third revolution in healthcare.”[3] Types of outcome measures can be seen, broadly, as biophysical measures, like morbidity and mortality, or patient-based measures that incorporate a patient's subjective experience of illness.

Top three questions

1. What is an outcome measure?
2. What properties of outcome measures do I have to know?
3. How should I choose an outcome measure?

Question 1: What is an outcome measure?

An outcome measure is a measure of the health of an individual, group of people, or population. There are several broad categories of outcome measure:

1. Biophysical outcome measures: these are objective health measures. Some common examples include morbidity, mortality, complication rate, and quality of reduction.
2. Patient-based measures: these outcome measures incorporate a patient's subjective experience of illness. These may be generic or disease/joint-specific.
    a. Generic outcome measures are not specific to any one disease or anatomic location. They can be used to compare across or within specific pathologic conditions. These have the potential advantage of being more able to measure downstream consequences of a treatment or condition that permits comparison to other unrelated conditions. They also may measure the side effects of complications of a treatment or condition that occur in a different anatomic location. Two common examples of a generic patient-reported outcome measure are the Short Form 36 (SF-36) and the

Patient-Reported Outcomes Measurement Information System (PROMIS) Physical Function. Preference-weighted outcome measures are a subset of generic outcome measures. These outcome measures weight items or dimensions differently to account for how people value a health state, rather than assigning equal weight to each dimension or item included in the outcome measure. Measuring preference-weighted generic outcome measures is becoming increasingly important in an effort to optimally distribute resources in a resource-constrained environment. The most commonly used preference-weighted generic outcome measures are the EuroQol five-dimensional questionnaire (EQ5D) and the six-dimensional health state short form (SF6D).

b. Disease- or joint-specific outcome measures may be more sensitive measures of the specific disease or joint being assessed. For example, joint-specific outcome measures have been shown to be more sensitive to arthroplasty procedures compared to generic outcome measures.[4–7] Common joint-specific outcome measures in orthopedic surgery include the Western Ontario and McMaster Universities Arthritis (WOMAC) Index, Harris Hip Score (HHS) and the Hip Disability and Osteoarthritis Outcome Score (HOOS) Knee Injury and Osteoarthritis Outcome Score (KOOS).

Question 2: What properties of outcome measures do I have to know?

There are several properties and attributes that have to be considered when choosing appropriate outcome measures.

1. Reliability: the degree to which a score or other measure remains unchanged upon test and retest, across different interviewers or assessors, or across items on the same test.
    a. Forms of reliability include:
        i. Internal consistency: measures whether several items or questions that propose to measure the same general construct produce similar scores.
        ii. Test–retest reliability: measures whether the same person receives the same score on the same test at different time points.
        iii. Intra-rater reliability: the degree of agreement among repeated administrations of an outcome measure assessed by a single rater.
        iv. Inter-rater reliability: the degree of agreement between different administrations of the same outcome measure.
    b. Measured by statistics:
        i. Kappa: a statistic which measures inter-rater agreement for categorical items.
        ii. Intra-class correlation coefficient: descriptive statistic which describes how strongly units in the same group resemble each other.
2. Validity: the degree to which a measure or tool actually measures what it is intended to measure.
3. Variability: distribution of values associated with an outcome measure in the population of interest.
    a. Broader range of values shows more variability.

i. *Ceiling and floor effects* are a measurement limitation that occurs when the highest and lowest possible scores on an outcome instrument does not reflect the true range of the domain being tested. This can lead to a mismatch between the distribution of responses and the true distribution of the concept of interest in the population. For example, if a patient reported outcome (PRO) instrument only assesses physical activities that are easy to perform, and the majority of the population scores perfect, then the instrument will not reflect the true distribution of physical abilities.

4. Responsiveness: ability to detect change in the underlying construct, even if changes are small.
    a. Minimally important difference (MID).[8,9]
        i. Smallest change in an outcome that a patient would identify as important or meaningful.
        ii. This is an important property because, given a large enough sample size, statistical significance between groups may occur with very small differences that are clinically meaningless.[9]
        iii. When determining how many patients to enroll in a study, the calculation usually reflects the intention to reliably find a clinically important effect of a treatment as well as a statistically significant difference.

Question 3: How should I choose an outcome measure?

When choosing an outcome measure, there are issues that are critical to consider:

- Does the outcome measure answer the question that you are asking?
- Reliability, validity, variability, and responsiveness.
- Ease/cost of data collection.
- Latency from intervention to occurrence of outcome event.

The choice of outcome measures may be the most critical component in study development. These decisions drive important protocol and funding decisions including the data source, the frequency and length of follow-up, as well as sample size (which is influenced by the expected frequency of outcome and magnitude of treatment effects).

Intermediate outcome measures are measures that serve as a proxy for the true outcome of interest. The underlying assumption is that the intermediate outcome measure correlates perfectly with the true outcome of interest. They are most frequently chosen to improve ease and feasibility of data collection given study-specific constraints. This is often related to constraints associated with cost and/or follow-up (such as length of follow-up, time needed to collect the outcome measure, or follow-up frequency). They are more often utilized in association with pilot studies or in situations when the outcome of interest is extremely difficult to measure or extremely rare. For example, ultrasound-detected deep vein thrombosis can serve as an intermediate outcome measure for death from pulmonary embolus.[10] The increased incidence of deep vein thrombosis detected via screening lower extremity ultrasounds helps improve study feasibility with regards to sample size. However, it is critical to keep in mind the

outcome measure that you are truly interested in. For example, hospital readmission rate is frequently used as a proxy for a patient's health state. However, in reality, readmission can occur for many reasons other than the health state of the patient. A high readmission rate may indicate that the patient's health has deteriorated, or it could indicate another issue, such as lack of caregivers in the home or a misjudgment about the discharge destination at time of discharge. A high rate of readmission could reflect poor care during the first admission or superior care leading to rescue and a sicker population on average at discharge. When designing a study utilizing intermediate outcome measures, investigators must always consider the degree to which the intermediate end point is reflective of the main outcome, as well as the degree to which effects of the intervention may be mediated through the intermediate endpoint. Investigators must always consider other factors that may influence the relationship between the process of care and the outcome.

The usefulness of a study as a contribution to clinical knowledge hinges on the adequacy of the chosen outcome measure. The best design and most rigorously executed procedures cannot make up for a poorly chosen measure. Important knowledge about the impact of the intervention may be lost because the selected measure was unable to capture it or, even worse, distorted the true results.

Biophysical/clinical outcome measures

These are objective health-related outcomes. They tend to be dichotomous outcomes that are relatively easy to interpret with good face validity. Some examples include

mortality, complications (operative or nonoperative), hospital readmission rate, new institutionalization, direct costs of care, return to work, range of motion, and radiographic alignment. There are several advantages of biophysical or clinical outcome measures:

- Obvious face validity, leading to easy buy-in from clinicians and public health officials.
- Generally easy to understand both analytic plan and clinical relevance.
- Hawthorne effect: measurement alone may improve outcomes. For example, surgical morbidity and mortality rates in Veterans Affairs hospitals have fallen dramatically since the implementation of the National Surgical Quality Improvement Program (NSQIP) in 1991.[11] This may be an advantage for patients as it has been shown that studying these outcomes improves them. However, it is important to consider the implications of this effect in analyzing and interpreting studies.
- Disadvantages of utilizing biophysical or clinical outcome measures include:
- Sample size: adverse events may be relatively uncommon, resulting in a need for huge numbers of patients to show meaningful, procedure-specific differences.
- These outcome measures do not detect the effect or weight of these variables on patients' lives.

Patient-reported outcome measures (PROMs)

Patient-reported outcome measures (PROMs) refer to patient perceptions and ratings on symptoms, functioning, health status, health-related quality of life, and/or satisfaction. They can focus on generic health-related outcomes (e.g. SF-36), disease/diagnosis-specific outcomes (e.g. WOMAC), or regionally/anatomically specific outcomes (e.g. Disabilities of the Arm, Shoulder, and Hand (DASH). Data are provided by patients or their proxies.

While biophysical/clinical outcomes tend to have the highest impact, they measure extremes. Most patients, particularly in elective orthopedic practices, elect to undergo orthopedic surgery to relieve pain and improve physical function (and not to avoid complications or revisions). Some have argued that, in order to demonstrate value, orthopedic surgeons must assess the results of their surgical interventions by measuring the degree of pain relief and improved physical function the patient experiences after surgery. Thus PROMs are becoming increasingly important as focus shifts to patient-centered care.

Generic outcomes measure general health status inclusive of physical symptoms, function and emotional dimensions of health. These are designed to be used across different subgroups of individuals and contain common domains that are relevant to almost all populations. They can be used to compare one population to another or to compare scores in a specific population to normative scores. Furthermore, they can focus on a comprehensive set of domains or on a narrow range of domains. Some examples include physical function (e.g. PROMIS physical function), pain (e.g. Brief Pain Inventory), return to activities (e.g. Paffenbarger Physical Activity Scale), or general health/quality of life (e.g. SF-36). Some advantages of generic outcome measures include the ability to compare a patient population of interest to normative populations and that

they are easily generalizable. Some disadvantages include that they may not always provide a sufficient level of detail or responsiveness for measuring change in a single patient over time. Furthermore, they tend to be less responsive when capturing particular changes at the targeted region due to the multiple components, such as mental, social, and physical constructs, all of which are related to overall health.

Health-related quality of life (HRQoL) is a multidimensional concept that includes domains related to physical, mental, emotional, and social functioning, specifically focusing on the impact that health status has on quality of life. These constructs comprise outcomes from the patient perspective and reflect the relative importance of the domain on their life. These outcome measures weight items or dimensions differently to account for how people value a health state, rather than assigning equal weight to each dimension or item included in the outcome measure. HRQoL measures can be translated into quality-adjusted life years (QALYs) which can be used for economic or cost-effectiveness analyses. Utility (preference) scores are reported on a generic scale where dead equals 0 and perfect health equals 1. This is becoming increasingly important in an effort to optimally distribute resources in a resource-constrained environment. The most common generic measures of HRQoL are the EQ5D, the SF-6D, and the Health Utilities Index (HUI).

Anatomic-specific or condition-specific measures are outcome measures that are specific to anatomic areas, for example DASH, or to specific diseases, for example Western Ontario Rotator Cuff (WORC) Index. These may be more sensitive to symptoms that are experienced by a particular group of patients and are, thus, thought to detect smaller or subtler differences and changes in scores when they occur in response to interventions. Anatomic- or

condition-specific measures may be able to detect small changes that generic measures may not be sensitive to. This may be important in trials comparing interventions but may not as useful for population-based analyses.

There have been several new developments in measurement of PROMs. Item response theory (IRT) is a process used to develop tests that differentiate respondents along the continuum of a specific trait, such as degrees of pain or levels of physical function.[12] IRT focuses on the measurement parameters of each item or question, allowing test designers to verify that each item or question actually measures what they expect it to measure. This allows IRT-based surveys to be more valid estimations of the trait of interest than those provided by classical test theory. IRT-based scores can be directly compared with scores from different surveys, as long as both surveys were calibrated to measure the same underlying trait (e.g. physical function). The benefits of IRT are derived from defining the measurement parameters of each individual item or question (as opposed to the entire questionnaire). Each item or question is, essentially, a test for a portion of the trait scale, with each response to an item positioning the respondent along the continuum.

Computerized adaptive testing (CAT) is another innovative development in PROMs, based upon IRT. CAT achieves the goal of minimizing burden by only delivering the items needed to measure the respondent's condition. After starting at a predefined point on the trait scale, CAT software chooses each subsequent item based on answers to previous items. The software refines its estimate of the person's trait level with targeted questions, narrowing in on the patient's true condition until a predetermined precision has been achieved.

Objective physical function outcome measures

Objective physical function outcome measures can be used to objectively measure physical performance. These may be less influenced by culture, language, or education level than by self-reported or proxy-reported measures. However, more resources are required to collect these data, such as time and adequately trained personnel. It is important to consider the patient population in choosing the most appropriate measures. The physical function outcome measure most appropriate for a geriatric patient will be very different than that appropriate for a young active patient. Objective physical function outcome measures can be stratified by domain (agility, strength/power, speed, postural stability) or by the demand of test (less demanding/more demanding).

Summary of answers

- Choice of outcome measure is a critical component to optimize data collection in research and quality improvement.
- Understanding the definitions and nuances of each type of outcome measure is essential to optimize choice of the most appropriate outcome measure(s).
- An understanding of the strengths and limitations of each type of outcome measure is essential in appropriately interpreting and applying the results of the data collected.
- Please see Chapter 173 for an in-depth look at pediatric orthopedic outcome instruments

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6 Value-Based Orthopedics

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Introduction

Healthcare expenditures account for roughly 10–20% of the gross domestic product in most high-income countries.[1] Despite rising healthcare costs in many of these countries, most countries have observed limited improvement in basic health outcomes, such as life expectancy.[2] Currently, models of healthcare are often volume based and compensate providers using a fee-for-service system. While the volume-based reimbursement model rewards activity, it has limited influence in ensuring improved patient outcomes. To reduce the disconnect between health treatments and patient outcomes, Robert Kaplan and Michael Porter, professors at the Harvard Business School, have proposed a new model deemed *value-based healthcare*.[3]

Top four questions

1. What is value-based healthcare?
2. How can value be improved?
3. How can value-based healthcare be applied to orthopedics?

4. What are the practical challenges with value-based orthopedics?

Question 1: What is value-based healthcare?

In value-based healthcare, *value* is generally defined as the benefits (health outcomes, patient satisfaction, prevention of illness) over the costs, both direct and indirect.[4] As in other fields, value should be from the consumer's perspective, or in healthcare – the patient's perspective. The delivery of healthcare services involves numerous organizational units, ranging from hospitals to a physician's clinic and laboratories to imaging facilities. However, the proper unit for measuring value should encompass all of the services or activities that, in combination, will determine if a patient meets their desired outcomes for a given medical condition.

Value for the patient is created through the combined efforts of healthcare providers over the full cycle of care for a given medical condition. The benefits of any one intervention may be contingent on the effectiveness of other interventions throughout the care cycle. For primary and preventative care, value should be measured for a defined patient population with similar healthcare needs, such as healthy children, healthy adults, or frail elderly people.

Defining specific outcome dimensions and measures

For patients with multiple medical conditions, value should be measured for each condition, with the presence of the other conditions used for risk adjustment. This approach allows for relevant comparisons among the patient's

results, including comparisons of providers' ability to care for patients with complex conditions.

Determining the group of relevant outcomes to measure for any medical condition should follow several principles. Outcomes should include the health circumstances most relevant to patients and include both short-term and long-term health. Long-term health should be a time period long enough to encompass the ultimate results of care. Risk factors or initial conditions should be incorporated into the outcome measurement to allow for accurate risk adjustment. For any medical condition or patient population, multiple outcomes measures will collectively define success. The complexity of medical care means that competing outcomes (e.g. short-term safety versus long-term function) must often be weighed against one another.

Hierarchy of outcomes

The outcomes for any medical condition can be arrayed in a three-tiered hierarchy. The top tier is generally the most critical, and the lower-tier outcomes involve a progression of results contingent on higher-tier outcomes. Each tier of the framework contains two levels, involving one or more distinct outcome dimensions. For each dimension, success is measured with one or more specific metrics.

Tier 1 is the health status that is achieved or, for patients with some degenerative conditions, retained. The first level, survival, is of overriding importance to most patients and can be measured over various periods appropriate to a given medical condition. However, maximizing the duration of survival may not be the most important outcome to all patients. The second level in Tier 1 is the degree of health or recovery achieved or retained. Examples may include freedom from disease and relevant functional status. For

some patients, the second level in Tier 1 may, in fact, be more important than survival.

Tier 2 outcomes are related to the recovery process. The first level is the time required to achieve recovery and return to the patient's normal or best attainable function. Recovery can be further divided into the time needed to complete various phases of the care cycle. Cycle time is a critical outcome for the patient – not a secondary process measure. Delays in diagnosis or formulation of treatment plans can cause unnecessary anxiety. Furthermore, reducing the cycle time can improve functionality and reduce complications. The second level in Tier 2 is the disutility of the care or treatment process in terms of discomfort, short-term complications, adverse events.

Tier 3 is the sustainability of health. The first level of Tier 3 outcomes is the recurrences of the original disease or longer-term complications. The second level captures new health problems created as a consequence of treatment. When recurrence or new illnesses occur, all outcomes must be remeasured.

Measurement efforts should begin with at least one outcome dimension at each tier, and ideally one at each level. Improving one outcome dimension can benefit others. Mapping these trade-offs, and seeking ways to reduce them, is an essential part of value-based healthcare.

Relating outcomes to processes

To identify the set of outcome dimensions, the cycle of care for the medical condition can be charted using a care delivery value chain (CDVC). A CDVC maps the full set of activities or processes involved in patient care and highlights the associated entities or units within the full care cycle. This chart allows a systematic identification of all relevant outcome dimensions as well as when and where

measurement should occur. The CDVC also enables particular outcome dimensions to be linked to the specific processes of care from which they arise. Using the CDVC and outcomes in tandem can guide outcome improvement.

Selecting particular measures

The specific measure selected for an outcome dimension should be based on several criteria. First, measures should optimally reflect the perspective of the patient. For some outcomes, a general health utility metric such as the EuroQol five-dimensional questionnaire (EQ5D) may be appropriate. For other medical conditions, a more specific index such as the Western Ontario *and* McMaster Universities *Arthritis (*WOMAC*)* Index may be more suitable. One should also strive to use validated measures that will enable reliable comparison across providers as this reduces bias and interpersonal errors. Many outcomes may require multiple measurements at various times in the cycle of care depending on the medical condition.

Practical considerations, such as the availability of data and the cost of data acquisition, will also factor into the measures selected. Measures that require patients to self-report are vulnerable to respondent bias. Immediate complications are much easier to track than longer-term outcomes that require patient follow-up. Advances in electronic medical records are continually reducing the costs associated with measuring outcomes.

Adjusting for risk

Achievable outcomes for a given patient will depend, to some degree, on a patient's initial condition or risk factors. Measuring and adjusting for risk factors is crucial to accurately interpret, compare, and improve outcomes. Patient compliance may also be interpreted as a risk factor.

Accurate risk adjustment is challenging but may be achieved through a variety of strategies including stratification or regression. Inadequacy or an inability to adjust for risk will limit the validity of any value-based outcome measure and reduce the acceptance of these data by the medical community. Robust risk adjustment mitigates the risk that providers will discriminate against unhealthy patients to improve their outcomes. Inadequate risk adjustment limits the understanding of actual costs and often leads to underpayment of providers for complex care.

Determining costs

Few clinicians are aware of what each component of care costs, and fewer understand how costs relate to the outcomes achieved. In a field with rising costs, the absence of accurate cost information in healthcare is an astounding systematic barrier to improving value. In the United States, cost allocations are often based on charges, not the actual costs, creating further error in cost estimates.

Costs, like outcomes, should be measured around the full cycle of care for a patient's medical condition. Many healthcare costs for a patient involve shared resources, such as physicians, administrative staff, investigations, facilities, and equipment. However, to measure true costs, shared resources costs must be attributed to an individual patient based on actual resource use for the care. The substantial cost variation among medical conditions presents a tremendous opportunity for cost reduction.

The optimal method to measure costs is time-driven activity-based costing (TDABC).[5] TDABC attempts to simplify accounting by using only two parameters. First, determine the cost of each of the resources used in the

cycle of care. Second, determine the quantity of time the patient spends with each health resource.

Question 2: How can value be improved?

Value depends on results, not inputs, and therefore value in healthcare must be measured based on the outcomes achieved, not the volume of services delivered. Shifting the focus from volume to value is a systematic challenge. As value is based on outcomes relative to costs, efficiency is paramount. Cost reductions without regard for the outcomes achieved are dangerous and self-defeating, and lead to false saving and potentially less effective care. Outcomes in healthcare, the numerator in the value equation, are inherently condition-specific and multidimensional. No single outcome encapsulates the results of care. *Cost*, the value equation's denominator, refers to the total costs of the full cycle of care for the patient's medical condition, not the cost of individual services. To reduce overall costs, the best approach may be to spend more on some services to reduce the need for other expenses.

Innovation in care delivery comes not only from focusing on individual outcome dimension but also from harnessing efficiencies from complementary aspects of care. A value-based system should aim to eliminate unnecessary process variation and processes that fail to add value. Improving value is an iterative process. As survival rates improve for a certain medical condition, providers may shift focus to increase the speed and reduce the discomfort associated with a treatment.

Measuring the full hierarchy of outcomes not only ensures multidimensional quality improvement but also expands the

areas in which providers can differentiate themselves. As providers achieve parity on specific dimensions, providers can look to other dimensions in the hierarchy that may be more heavily weighted by certain segments of a given patient population. Furthermore, certain health services and treatments may be performed by lower-cost healthcare professionals without adversely affecting patient outcomes. Such process changes would avail physicians and nurse to focus on their highest-value roles in the cycle of care.

Innovation outcomes must be measured continually and prospectively with constant reporting to providers. Feedback to providers that includes both outcomes and costs is fundamental to improving efficiency.

Hierarchy of outcomes and cost reduction

Historically, there has been tremendous focus on improving Tier 1 outcomes, particularly survival for a given medical condition. Marginal improvements in survival are often associated with substantial costs and may lead to lesser second level Tier 1 outcomes, such as functional status. A broader focus on the hierarchy of outcomes should lead to a re-evaluation of the cycle of care. Lower-tier outcomes are almost invariably associated with lower costs. Faster cycle times, fewer complications, and fewer failed therapies have considerable cost efficiencies. Improvements to Tier 2 and Tier 3 outcomes can also reduce the cost of improving Tier 1 outcomes due to many complementary forms of care. Advances in early diagnostics of medical conditions have enabled early, typically less costly, treatments that may improve the overall value for a given medical condition.

New reimbursement structures

Improving value is often confused with cost reduction. Efforts toward cost containment and strategies to ration

healthcare services can often lead to the increased demand for downstream, much costlier, interventions. Innovation to the healthcare reimbursement system is critical to driving the change to value-based health systems that will allow patients to achieve excellent outcomes through a more efficient and sustainable health system. Bundle reimbursement payment models are a practical approach to compensate for value-based care, where a fixed reimbursement amount is shared among all providers for a defined cycle of care that meets specific quality standards. Such an approach requires hospitals and health providers to work collaboratively to manage costs and processes across the cycle of care. Models, such as bundled payments, are intended to shift financial incentives away from service volume and toward more coordinated, patient-centered care with more predictable results.

The TDABC approach identifies how much of each resource's capacity is actually used to perform health services and to treat patients versus how much capacity is unused. Resource utilization data also uncover where increasing the supply of certain resources will ease a bottlenecked process, enabling more timely care and serve more patients with minimal cost increases.

Question 3: How can value-based healthcare be applied to orthopedics?

Orthopedics, as a specialty, is well suited to applying the principles of value-based care. There is a high prevalence of musculoskeletal disease and injury, implants and procedural costs are high, and there is a significant impact on patient quality of life associated with good treatment outcomes. For many orthopedic conditions, the cycle of care will include acute care, related complications, rehabilitation, and reoccurrences. Shifting focus to the full

cycle of care is essential to improving value. If a surgical procedure is performed flawlessly, but a patient's subsequent rehabilitation fails, the outcome will likely be poor.

Orthopedics, as a specialty, has many disease-specific, patient-reported outcome measures available, such as the WOMAC, the Knee Injury and Osteoarthritis Outcome Score (KOOS), and Disabilities of the Arm, Shoulder, and Hand (DASH). These instruments can be used to measure disease states both pre- and postintervention to assess patient improvement. However, as many of these measures report numeric scores, determining a minimum clinically important difference for the outcome can present another challenge to calculating value. There are different techniques available to define a minimum clinically important difference for a disease-specific, patient-reported outcome, such as distribution-based and anchor-based techniques. Incorporating minimum clinically important differences into the value measurement ensures patient-important improvements are appropriately valued.

Question 4: What are the practical challenges with value-based orthopedics?

The current organizational structure, information, and accounting systems in most healthcare systems make it challenging to measure and deliver value-based care. Providers tend only to measure what they directly control in a particular intervention and what is easily measurable, rather than what matters for patient outcomes. For example, a measure may only cover a single department (too narrow to be relevant to patients) or outcomes, such as infection rates, calculated for a whole hospital (too broad to

be meaningful for the patient). Often providers only measure what is billed, even though most reimbursement practices are misaligned with value. Implementation of value-based orthopedics will require standardized outcome measures for orthopedic conditions and new cost accounting systems.

Delivering health services requires multidisciplinary teams. It is difficult to determine which specific aspects or interactions in a cycle of care are improving patient value, primary due to the delays from treatment to a realized benefit for the patient. A patient will often interact with several different units of care or health systems during their cycle of care. Reimbursing multiple units based on the outcomes achieved by a shared patient presents a challenge and may require substantial reorganization in patient-care processes. Finally, health providers dictate which treatments will be provided to a patient. Successful implementation of value-based care requires clinicians to be engaged in the process and believe the measures are valid and important for patient care.

The application of value-based orthopedics should not be restricted to high-income countries. The principles of a value-based model can have a substantial impact on underserved and resource-poor health systems. Using easy-to-administer tools to measure a hierarchy of outcomes for common orthopedic conditions and injuries, in combination with a simple TDABC system, can enable the identification and evaluation of value within care cycles. Viewing orthopedic conditions and injuries through the value-based perspective, rather than an intervention perspective, has several implications. This model assists in the prudent use of limited health resources. A value-based model rewards shared delivery infrastructures, including facilities, information systems, and personnel. Finally, the value-based model can be used to identify opportunities for

improved reach and access for patients, as identified in the CDVC.

Summary of answers

- Healthcare systems can be incredibly complex. A single surgeon may provide treatment for a variety of different medical conditions. However, the process of measuring and prioritizing value in healthcare will spawn systematic innovation in both the delivery of care and reimbursement for health services.
- Value-based healthcare rewards providers for efficiency in achieving good outcomes while creating accountability for substandard care.

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II Orthopedic Medicine

7 Critical Issues in Osteoporosis Management

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Clinical scenario

- Seventy-year-old ambulatory postmenopausal Caucasian female who lives independently slips and falls in the bathtub.
- She is unable to bear weight with her right leg and has significant pain in the right groin.
- Radiographs in the Emergency Department reveal a femoral neck fracture and she is sent in for surgical repair of the fracture.
- Following discharge, she is sent for bone mineral density (BMD) testing by dual energy x-ray absorptiometry (DXA) and has blood tests to rule out secondary causes of osteoporosis (negative).
- The DXA scan reveals that the patient has a T score of −2.0 at the lumbar spine (L1–L4), a T score of −3.9 at the left femoral neck and a T score of −4.1 at the left total hip.

- The patient discloses that she has had a prior wrist fracture at age 55 and that her mother had a hip fracture.
- A complete dietary history reveals that the patient consumes 1 glass of milk (350 mg dietary calcium), 1000 mg of elemental calcium in the form of supplements, and 1000 IU of vitamin D per day.
- The patient has since been started on calcium, vitamin D, and denosumab. Although upset about her recent fracture she is optimistic and eager to learn and has many questions.

Importance of the problem

Over 200 million people worldwide suffer from osteoporosis.[1] Fragility fractures, the consequence of osteoporosis, are responsible for increased morbidity, mortality, chronic pain, and increased healthcare utilization.[2] These fractures account for 0.83% of the global burden of noncommunicable disease.[3] In postmenopausal women, fragility fractures are more common than stroke, myocardial infarction, and breast cancer combined.[4]

In the year 2000, there were an estimated 9 million fragility fractures worldwide, of which, 1.6 million were hip fractures, 1.7 million were forearm fractures and 1.4 million were vertebral fractures.[3] It is projected that there will be an increase to 2.6 million hip fractures by 2020, and 4.5 million vertebral fractures by 2050.[5] The lifetime risk of any fragility fracture is 40–50% in women and 13–22% in men.[6]

Hip fractures are the most severe type of fragility fracture as they require hospital admission and are associated with significant morbidity and mortality.[6] At one year post hip

fracture, mortality (in part due to other co-morbidities) ranges from 12–20%,[6] with the majority of deaths occurring within the first few months after fracture. An excess risk of death may persist for at least 5 years afterwards.[7] Globally, there are approximately 740 000 deaths per year due to hip fracture and resulting complications.[8]

The long-term costs associated with hip fractures are devastating. Available data on the economic burden of osteoporosis shows that currently, the cost of osteoporosis is 37 billion EUR per year in the European Union, 19 billion USD per year in the United States and $2.3–$3.9 billion per year in Canada.[9–11] Due to the significant burden fragility fractures put on patients, their families, and the economy it is important to find the optimal pharmacotherapy to improve bone mass and prevent further traumatic injuries.

Top three questions

1. In postmenopausal women aged >50 who have sustained fragility fractures, how does the diagnosis of osteoporosis determine the risk for future fracture?
2. In postmenopausal women with low BMD or prior fragility fractures, which pharmacological therapies, compared to no medications, best reduce the risk for future fractures?
3. In patients with low BMD or who have sustained a fragility fracture, what is the appropriate duration of pharmacotherapy to avoid adverse side effects?

Question 1: In postmenopausal women aged >50 who have sustained fragility fractures, how does the diagnosis of osteoporosis determine the risk for future fracture?

Rationale

The presence of a fragility fracture is a major risk factor for osteoporosis and is an important indicator for osteoporosis diagnosis and treatment.[12]

Orthopedic surgeons are in an ideal position either individually or collaboratively with colleagues to initiate and provide osteoporosis care for patients with fragility fractures, as they are the first physicians to make contact with the patient following fracture. It is estimated that the annual number of hip fractures worldwide will increase to 4.5–6.3 million by 2050.[3,13,14] Therefore, identifying those who are at risk for future fractures is an important step in the management and prevention of osteoporosis.

Clinical comment

The diagnosis of osteoporosis is determined by measuring a patient's BMD – the average concentration of bone mineral (g) per unit of bone area (cm^2). Bone mineral density is measured using DXA, the gold standard method of measurement.[2] A T-score is the number of standard deviations (SD) above or below the mean value of BMD for young adults (20–30 years old). The World Health Organization (WHO) defines *osteoporosis* as a T-score of −2.5 or less at the hip or lumbar spine.[15]

Findings

A systematic review of 35 studies that evaluated practice patterns related to osteoporosis management after fragility fracture found that recognition and treatment of osteoporosis in these patients remained inadequate,[16] confirming the persistence of an earlier identified global osteoporosis care gap.[17] In this review, a clinical diagnosis of osteoporosis was reported in less than 30% of patients in the majority of studies. Further, DXA scans were performed in less than 15% of patients in studies that reported on BMD testing.

Until recently, decisions about osteoporosis therapy were made based on the presence or absence of fractures and on T-score values ≤ −2.5 SD from DXA measurements of BMD. While low BMD is a strong and independent risk factor for fracture,[18,19] it is not the only risk factor for fracture. Indeed, most fractures occur in women with osteopenia (T-score between −1.0 and −2.5 SD) and not osteoporosis.[15] A reason for this observation is that BMD measures bone quantity and does not take into account bone quality. Bone quality represents characteristics of bone tissue other than BMD that contribute to the strength of a bone, such as geometry, microarchitecture, remodeling, mineralization, and damage accumulation.[20] For this reason, recent treatment guidelines have focused on evaluating a patient's absolute fracture risk, which considers BMD as well as other clinical risk factors for fracture.

The Fracture Risk Assessment Tool (FRAX®), can be used to compute the 10-year probability of fractures in men and women based on clinical risk factors for fracture, with or without the measurement of femoral neck BMD.[21] The performance characteristics of the clinical risk factors have been validated in independent, population-based, prospectively studied cohorts with over a million person years of observation.[22] The FRAX® tool calculates the 10-

year probability of a major fragility fracture (clinical spine, hip, forearm, or proximal humerus) and hip fracture calibrated to the fracture and death hazard of several countries.[23]

Moreover, there is the Osteoporosis Canada 10-year Fracture Risk Assessment Tool which was developed by Osteoporosis Canada using the Canadian 2010 Osteoporosis Guidelines[2] and the Canadian Association of Radiologists and Osteoporosis Canada (CAROC) system (http://www.osteoporosis.ca/health-care-professionals/clinical-tools-and-resources/fracture-risk-tool/). The Canadian Association of Radiologists and Osteoporosis Canada tool was calibrated using the same fracture data as the FRAX Canada calculator.[24–26] The CAROC tool can be used on men and women over the age of 50, and stratifies them into three groups for risk of major fragility fracture within the next 10 years, low (<10%), moderate (10–20%), and high (>20%). The CAROC tool integrates age, sex, T-score at the femoral neck, prior fragility fractures, and recent prolonged systemic glucocorticoid use.[2]

Resolution of clinical scenario

In patients aged 50 years or older who have sustained a hip or other fragility fracture, evidence suggests that:

- Many patients are not receiving appropriate evaluation and treatment for osteoporosis post fracture.
- The FRAX and CAROC tools can and should be used to calculate the 10-year probability of a major fragility fracture (clinical spine, hip, forearm, or proximal humerus) and hip fracture.

Question 2: In postmenopausal women with low BMD or prior fragility fractures, which pharmacological therapies, compared to no medications, best reduce the risk for future fractures?

Rationale

A number of different pharmacologic agents are available for the treatment of osteoporosis.[27] Opinion among orthopedic surgeons is divergent on which pharmacologic agents are best to reduce the relative risk of hip fractures in postmenopausal women who present with low BMD or a fragility fracture.

In a systematic review of 35 studies evaluating osteoporosis management after fragility fracture, more than half of the studies reported that no more than 30% of fracture patients were taking calcium and vitamin D and less than 15% of patients were receiving bisphosphonate therapy.[17] As the majority of pivotal clinical trials were in postmenopausal women, data in men are limited and will not be reviewed.

Clinical comment

Recommended daily calcium and vitamin D intakes for populations vary between countries. The US National Osteoporosis Foundation (NOF) recommends an intake of 1200–1500 mg of calcium and 800–1000 IU of vitamin D per day for men and women aged 50 years and older.[28]

Available literature and quality of the evidence

Current opinion suggests that orthopedic surgeons prescribe one of the recommended anti-osteoporotic drugs for the treatment of fragility fractures in addition to calcium, vitamin D, and exercise. The majority of pharmacological agents available for the treatment of osteoporosis are antiresorptive agents which include: bisphosphonates (oral or intravenous [IV]), hormone replacement therapy, raloxifene, denosumab, and to a lesser extent strontium ranelate. Other available anabolic agents are parathyroid hormone (PTH 1-84), teriparatide (rh-PTH 1-34), and abaloparatide (PTHrP). A summary of the efficacy of pharmacologic agents on the relative risk reduction of hip fractures is presented in Table 7.1. As the majority of pivotal clinical trials were in postmenopausal women, data in men are limited. Several studies have examined the use of alendronate and risedronate for the treatment of osteoporosis in men.[29–31] These medications have been shown to improve BMD and reduce the risk of vertebral fracture. However, given the limited number of studies, clinicians should refer men with osteoporotic fractures to a bone specialist for further recommendations and management.

Table 7.1 Efficacy of pharmacologic agents on the relative risk reduction of hip fractures in postmenopausal women.

Drug	Description of Clinical Trial	% Relative Risk Reduction for Hip Fracture
Oral bisphosphonates		
Alendronate[32–34]	FIT-1; n = 2027; postmenopausal women with low femoral neck BMD and ≥ vertebral fracture; alendronate 5 mg/d (then increased to 10 mg/d at 24 months) or placebo; 3 yr	51%
	FIT-2; n = 4432; postmenopausal women with low femoral neck BMD but no vertebral fracture; alendronate 5 mg/d (then increased to 10 mg/d at 24 mo) or placebo; 4 yr	NS
	FLEX; n = 1099; postmenopausal women from FIT-1 and FIT-2 trials; alendronate 5 mg/d or alendronate 10 mg/d or placebo; 5 yr	NR

Drug	Description of Clinical Trial	% Relative Risk Reduction for Hip Fracture
Risedronate[35–38]	VERT-NA; n = 2458; postmenopausal women with ≥2 vertebral fractures or 1 vertebral fracture and low lumbar spine BMD; risedronate 2.5 mg/d (discontinued partway through trial) or risedronate 5 mg/d or placebo; 3 yr	NR
	VERT-MN; n = 1226; postmenopausal women with ≥2 vertebral fractures; risedronate 2.5 mg/d (discontinued partway through trial) or risedronate 5 mg/d or placebo; 3 yr	NR
	VERT-MN Extension; n = 265; risedronate 5 mg/d or placebo; 2 yr	NR
	HIP; n = 9331; postmenopausal women with osteoporosis at femoral neck and/or with ≥1 non-skeletal risk factor for hip fracture; risedronate 2 mg/d or risedronate 5 mg/d or placebo; 3 yr	30%

Drug	Description of Clinical Trial	% Relative Risk Reduction for Hip Fracture
	BONE; n = 2946; postmenopausal women with 1 to 4 vertebral fractures and osteoporosis in ≥1 vertebra; ibandronate 2.5 mg/d or ibandronate 20 mg every other day for 12 doses every 3 mo or placebo; 3 yr	NR
Intravenous bisphosphonates		
Ibandronate[39,40]	DIVA; n = 1395; postmenopausal women with osteoporosis; 2 mg ibandronate injections every 2 mo plus oral placebo or 3 mg ibandronate injections every 3 mo plus oral placebo or 1 of 2 groups receiving oral ibandronate 2.5 mg/d plus placebo injections every 2 or every 3 mo; 1 yr	NR

Drug	Description of Clinical Trial	% Relative Risk Reduction for Hip Fracture
Zoledronic acid[41,42]	HORIZON – Pivotal Fracture Trial; n = 7765; postmenopausal women with osteoporosis at femoral neck with or without vertebral fracture or osteopenia with radiologic evidence of ≥2 mild vertebral fractures or 1 moderate vertebral fracture; single 5 mg infusion of zoledronic acid every 12 mo or placebo; 3 yr	41%
	HORIZON – Recurrent Fracture Trial; n = 2127 men and women ≥50 yr who had undergone recent surgical repair of a low trauma hip fracture; single 5 mg infusion of zoledronic acid every year; 2 yr	30%
Other		
Raloxifene[43]	MORE; n = 7705; postmenopausal women with osteoporosis; raloxifene 60 mg/d or raloxifene 120 mg/d or placebo; 3 yr	NS

Drug	Description of Clinical Trial	% Relative Risk Reduction for Hip Fracture
Denosumab[44]	FREEDOM; n = 7868; postmenopausal women with osteoporosis; denosumab 60 mg subcutaneously every 6 mo or placebo, 3 yr	40%
Calcitonin[45]	PROOF; n = 1255; postmenopausal women with osteoporosis; calcitonin 100 IU/d or calcitonin 200 IU/d or calcitonin 400 IU/d or placebo; 5 yr	NS
Anabolic agents		
Teriparatide (rh-PTH 1-34)[46]	n = 1637; postmenopausal women with prior vertebral fractures; PTH (1-34) 20 µg/d or PTH (1-34) 40 µg/d of or placebo; 1.8 yr	NR
Parathyroid hormone [PTH (1-84)][47]	TOP; n = 2679; postmenopausal women with low BMD at hip or spine; recombinant human PTH (1-84) 100 µg/d or placebo; 1.5 yr	
Antiresorptive/Anabolic agents		

Drug	Description of Clinical Trial	% Relative Risk Reduction for Hip Fracture
Strontium ranelate[48]	TROPOS; n = 5091; postmenopausal women with osteoporosis; strontium ranelate 2 g/d or placebo; 3 y	NS

BMD, bone mineral density; BONE, Oral Ibandronate Osteoporosis Vertebral Fracture Trial in North America and Europe; DIVA, Dosing Intravenous Administration Trial; FIT, Fracture Intervention Trial; FLEX, Fracture Intervention Trial Long-Term Extension; FREEDOM, Fracture Reduction Evaluation of Denosumab in Osteoporosis Every 6 Months; HIP, Hip Intervention Program Trial; HORIZON, Health Outcomes and Reduced Incidence with Zoledronic Acid Once Yearly; IU, international units; MN, multinational; MORE, Multiple Outcomes of Raloxifene Evaluation; n, total number of participants randomized; NA, North America; NR (separate hip data) no reported; NS, not statistically significant; PROOF, Prevent Recurrence of Osteoporotic Fractures Study; PTH, parathyroid hormone; TOP, Treatment of Osteoporosis Study; TROPOS, Treatment of Peripheral Osteoporosis Study; VERT, Vertebral Efficacy with Risedronate Therapy.

d, day; mo, month; yr, year.

Findings

Calcium and vitamin D

There is no clear evidence that calcium in combination with vitamin D reduces the risk of fragility fractures,[49] but we do know that vitamin D on its own has no fracture risk benefit.[50–53] That being said, there is strong evidence that calcium and vitamin D together are beneficial in patients with osteoporosis, especially postmenopausal women.[51,52] The most severe adverse effect from taking calcium is the potential increased risk of cardiovascular events. At this time, there is no clear evidence to suggest that taking

calcium with or without vitamin D increases one's risk of cardiovascular events.[54,55]

Exercise

The mean BMD at the lumbar spine (1.77% [1.26–2.28%]) significantly increased after 18 months in the exercise group ($p < 0.001$). There was also significant differences in BMD at both locations between the exercise and control groups ($p < 0.001$).[56] Tai chi has been investigated as well and has shown less BMD loss at the hip compared to controls ($p < 0.05$) but did not show an overall increase in BMD.[57] The most inclusive meta-analysis of randomized control trials on the effect of resistance training 2–4 days/week for 15–90 minutes in postmenopausal women demonstrated a weighted mean difference in BMD of 0.012 g/cm^2 (95% CI 0.002–0.022) at the lumbar spine and 0.014 g/cm^2 (95% CI 0.003–0.025) at the femoral neck ($p < 0.001$).[58]

Bisphosphonates

A recent review article summarized the efficacy results from pivotal clinical trials of four commonly prescribed bisphosphonates – alendronate, risedronate, ibandronate, and zoledronic acid – for the treatment of postmenopausal osteoporosis.[59] In the review, a total of 11 randomized placebo-controlled trials were identified (three for alendronate, [32–34] four for risedronate,[35–38] two for ibandronate,[39,40] and two for zoledronic acid[41,42]). Compared with placebo controls, alendronate, risedronate, and zoledronic acid but not ibandronate (no available hip data) were found to reduce the relative risk of hip fractures in postmenopausal women by 20–51%, vertebral fractures by 41–70%, and nonvertebral fractures by 12–40% in

postmenopausal women with low BMD and/or prior vertebral fracture.

The most common side effects from oral bisphosphonates are nausea, epigastric pain, esophagitis, and gastric ulcers.[60] The most common adverse effects when taking zoledronic acid include pyrexia, myalgia, flu-like symptoms, bone pain, and chills, which can be classified as acute phase response.[61] This usually occurs after the first infusion, resolves in 3–4 days, and is less common with subsequent infusions.[62] Acute anterior uveitis is associated with zoledronic acid therapy, usually occurs within three days of infusion, resolves with topical cyclopentolate, and has no lasting sequelae.[63] The more severe adverse events include osteonecrosis of the jaw (ONJ) and atypical femoral fractures (AFF). The American Society for Bone and Mineral Research (ASBMR) has recently published a revised case definition for AFF as a fracture located along the femoral diaphysis from just distal to the lesser trochanter to just proximal to the supracondylar flare. Further criteria are provided in the ASBMR Task Force 2013 Revised Case Definition of AFFs.[64] A systematic review and meta-analysis of 11 studies, including five case controls and six cohorts, showed bisphosphonate use was associated with increased risk of subtrochanteric femoral shaft fractures (adjusted risk ratio [RR] = 1.70; 95% CI 1.22–2.37).[65] The report concluded that, while the relative risk of patients with AFFs taking bisphosphonates is high, the absolute risk of AFFs in patients on bisphosphonates is low, ranging from 3.2 to 50 cases per 100 000 person years. However, long-term use may be associated with higher risk (~100 per 100 000 person years).[64] They also published recommendations for orthopedic and medical management of AFFs (Table 7.2).[64,66]

Table 7.2 ASBMR Task Force on Atypical Femoral Fracture recommendations for orthopedic and medical management of atypical femoral fractures. Source: Modified from Shane, et al.[64]

Issue	Recommendations
Surgical management	
History of thigh or groin pain in a patient on bisphosphonate therapy	Rule out femoral fracture. AP and lateral plain radiographs of the hip, including the full diaphysis of the femur should be performed. If the radiograph is negative and the level of clinical suspicion is high, a technetium bone scan or MRI of the femur should be performed to detect a periosteal stress reaction

Issue	Recommendations
Complete subtrochanteric/diaphyseal femoral fracture	Orthopedic management includes stabilizing the fracture and addressing the medical management (below). Endochondral fracture repair is the preferred method of treatment since bisphosphonates inhibit osteoclast remodeling. Intramedullary reconstruction full-length nails accomplish this goal and protect the femur. Locking plates preclude endochondral repair, have a high failure rate, and are not recommended as the method of fixation. The medullary canal should be overreamed to compensate for the narrow intramedullary diameter, facilitate insertion of the reconstruction nail, and prevent fracture of the remaining shaft. The proximal fragment may require additional reaming to permit passage of the nail and avoid malalignment. The contralateral femur must be evaluated radiographically whether or not symptoms are present

Issue	Recommendations
Incomplete subtrochanteric/femoral shaft fractures	Prophylactic reconstruction nail fixation is recommended if pain is present. If there is minimal pain, a trial of conservative therapy in which weight bearing is limited through the use of crutches or a walker may be considered. However, if there is no symptomatic and radiographic improvement after 2– 3 months of conservative therapy, prophylactic nail fixation should be strongly considered because of the possibility of complete fracture. For patients with no pain, weight bearing may be continued but should be limited and vigorous activity avoided. Reduced activity should be continued until there is no bone edema on MRI
Medical management	

Issue	Recommendations
Prevention	Decisions to initiate pharmacologic treatment including bisphosphonates to manage patients with osteoporosis should be made based on an assessment of benefits and risks. Patients who are deemed to be a low risk of osteoporosis-related fractures should not be started on bisphosphonates. Physicians need to be wary of thigh or groin pain in patients on bisphosphonates. Complaints of thigh or groin pain in a patient on bisphosphonates require urgent radiographic evaluation of both femurs even if pain is unilateral

Issue	Recommendations
Treatment	For patients with a stress reaction, stress fracture, or incomplete or complete subtrochanteric femoral shaft fracture, potent antiresorptive agents should be discontinued. Dietary calcium and vitamin D status should be assessed and adequate supplementation should be prescribed. Teriparatide should be considered in patients who suffer these fractures, particularly if there is little evidence of healing by 4–6 weeks after surgical intervention

The patients who are most at risk of ONJ are those with other risk factors, including glucocorticoid therapy, chemotherapy, antiangiogenic agents, and radiotherapy. The incidence of ONJ in cancer patients is estimated to be 1–15% and is associated with the dose and duration of bisphosphonate therapy.[67]

Denosumab

The fracture clinical trial of denosumab (FREEDOM) reported a relative risk reduction of hip fracture with denosumab of 40% and vertebral of 68% (Table 7.1).[44] A post hoc analysis of the FREEDOM trial data stratified by level of kidney function showed that denosumab was effective in reducing fracture risk among patients with impaired kidney function and was not associated with any increase in adverse events.[68] The DIRECT clinical trial

conducted on male and female Japanese patients with osteoporosis showed that denosumab reduced the risk of new or worsening vertebral fracture by 65.7%.[69] In a systematic review, serious side effects were seen in 24.9% compared to 23.8% of controls.[70] The FREEDOM study showed no significant difference in side effects between groups.[44] There were a total of two AFF in the FREEDOM trial where 7868 postmenopausal women with osteoporosis were enrolled.[44] In the first three years of the FREEDOM there were no reported cases of ONJ; in the extended study that went up to 10 years there were 13 cases.[44,71] Postmarketing exposure to denosumab is estimated to be 1 960 405 patient years in 2 427 475 patients as of May 2014 and a total of 47 cases of ONJ have been confirmed. In these patients they have all had other risk factors.[72]

Teriparatide (rh-PTH 1-34) and parathyroid hormone (PTH [1-84])

Two pivotal trials have examined the effects of recombinant human parathyroid hormone ([rh-PTH[1-34]) and parathyroid hormone analogues (PTH [1-84]) on fracture risk reduction in postmenopausal women.[46,73–79] rh-PTH(1-34) was shown to reduce the relative risk of nonvertebral fractures.[46] However, the number of women with hip fractures was too small to estimate the incidence of hip fracture, and thus the specific relative risk reduction at the hip site. Similarly, the PTH(1-84) trial[47] did not report on the specific relative risk reduction of hip fractures, but the difference in the number of reported nonvertebral fractures was not statistically significant between treated and untreated groups. The most common adverse effects associate with teriparatide are nausea, headache, dizziness, and leg cramps.[46] There are data that suggest a link between osteosarcoma and teriparatide in rats.[80] In the US

postmarketing surveillance study there was no association between teriparatide exposure and osteosarcoma.[81]

Resolution of clinical scenario

- Calcium and vitamin D are essential components of all osteoporosis treatment plans and mandatory components in drug trials testing the fracture risk reduction of other medications.[82]
- Exercise has always been part of osteoporosis treatment as it is thought to strengthen bones through stress.
- High-intensity exercise programs that focus on balance, stretching, isometric strength training, and weight-bearing exercises have proven to increase BMD and decrease the fall rate in postmenopausal women.
- Alendronate, risedronate, and zoledronic acid are all effective pharmacologic agents for reducing the relative risk of hip fracture.
- There is no clear association between bisphosphonate use and the rate of serious or nonserious atrial fibrillation, regardless of dose or duration of bisphosphonate therapy.
- The risk of developing bisphosphonate-associated ONJ with routine oral therapy for osteoporosis is very low.
- Atypical femur fractures are associated with long-term bisphosphonate therapy. The risk of this is small, while the benefits of treatment are great in reducing fractures.
- Denosumab is an effective pharmacologic agent for reducing the relative risk of both hip and vertebral fractures and for patients who either cannot tolerate

oral or IV bisphosphonates or have impaired renal function.

- The risk of developing denosumab-associated AFF and ONJ with routine subcutaneous therapy for osteoporosis is very low.
- Parathyroid hormone/parathyroid hormone-related protein analogs should be considered in patients with severe osteoporosis at high risk of fracture and in patients who have failed other anti-osteoporosis medications.

Question 3: In patients with low BMD or who have sustained a fragility fracture, what is the appropriate duration of pharmacotherapy to avoid adverse side effects?

Rationale

The optimal duration of pharmacological treatment for osteoporosis is up for debate. The area of concern is centered on the long-term side effects and the benefit-to-risk relationship. The beneficial effects of bisphosphonates persists for months to years after discontinuation because of their high affinity for hydroxyapatite, meaning they can be stopped and still have an effect on BMD.[33] The retention of bisphosphonates in the bone also raises the concern for increased potential side effects such as AFF and ONJ. In contrast, drugs that are not retained in the skeleton – such as denosumab, teriparatide, and raloxifene – may require a longer or indefinite duration of treatment. If therapy is stopped, then alternative therapies should be considered or commenced.

Clinical comment

First-line therapies include bisphosphonates and denosumab. Duration of therapy remains controversial with some recommending therapy limited to five years of bisphosphonate use given the potential for side effects.[83] Others recommend indefinite treatment for those at high risk for fracture as the benefits of therapy in preventing fractures are felt to outweigh the potential risk for rare side effects.[84,85] If denosumab is discontinued, alternative therapy must be commenced to prevent bone loss and fractures.[86]

Current opinion

While one might consider a drug holiday for those on bisphosphonates in those at low to moderate risk of fracture, for those on denosumab or PTH, discontinuation of treatment results in bone loss and an increase in fracture risk if some other treatment is not instituted. Studies have focused on the discontinuation of bisphosphonates and denosumab.

Bisphosphonates

The FLEX study on alendronate concluded that stopping alendronate resulted in significant decline in lumbar, total hip, and femoral neck BMD compared with treatment extension for five years.[33] The HORIZON extension study which looked at patients who received zoledronic acid annually found that 55% of the participants had a low three-year risk of fracture (average 3.2% risk of morphometric vertebral fracture and 5.8% risk of nonvertebral fracture) if treatment was discontinued.[87] The ASBMR Task Force has provided its recommendations for bisphosphonate therapy based on evidence from these studies. They recommend after three years of treatment

with IV zoledronic acid or five years with oral bisphosphonates, a treatment break often referred to as *drug holiday* should be considered, unless there are characteristics indicative of high fracture risk (e.g. older age, low hip T-score, or high fracture risk score, previous major fragility fractures, or fractures on therapy).[83] Additionally, the UK National Osteoporosis Guideline Group (NOGG) (Figure 7.1)[88] and the European Menopause and Andropause Society (EMAS) have issued similar recommendations.[85]

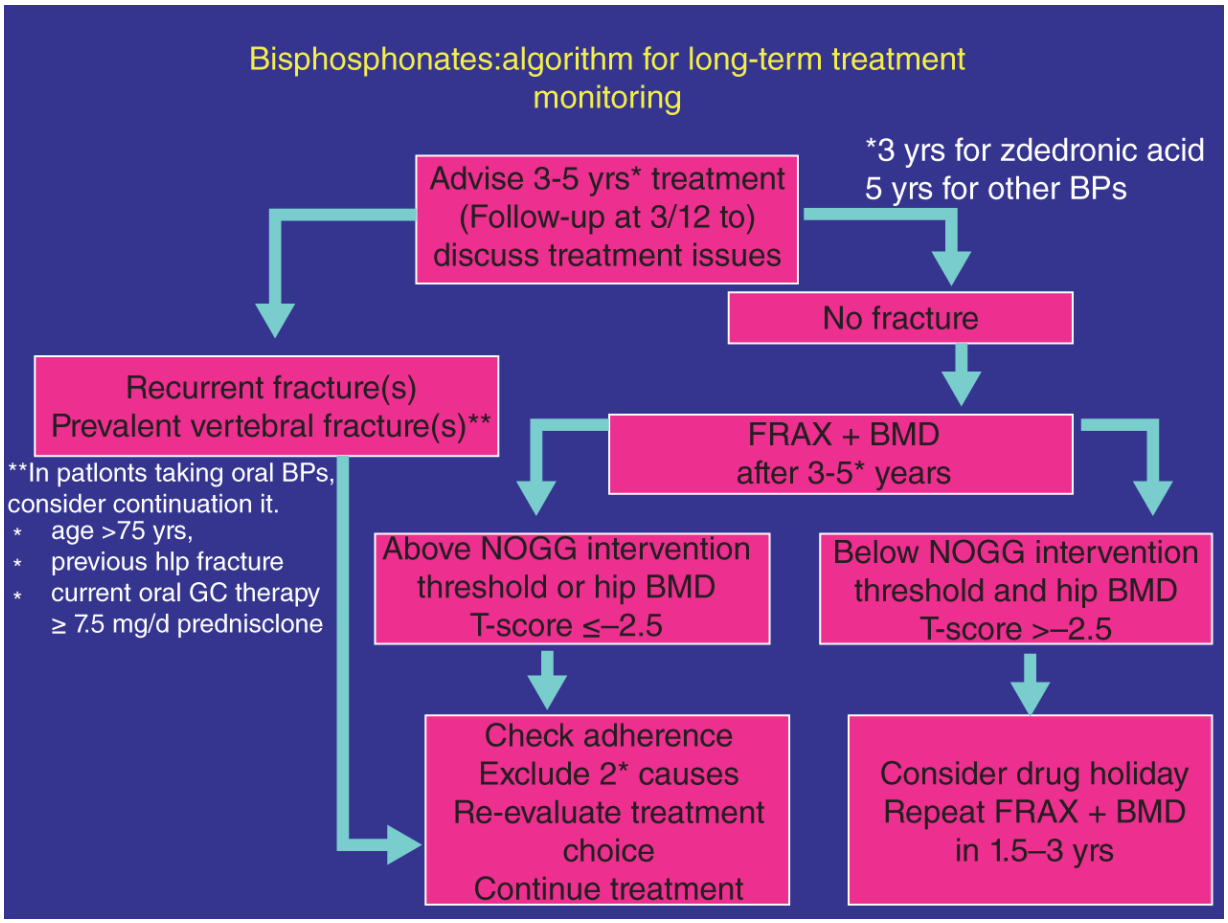

Figure 7.1 NOGG recommendations for long-term bisphosphonate use. Source: Reproduced from Compston J, et al.[88]

There are few data estimating the risk of AFF after discontinuing bisphosphonates. Schilcher et al. reported the odds of AFF increased with the duration of treatment. They further found age-adjusted relative risk of atypical fracture associated with bisphosphonate use. The RR after four years or more of use reached 126 (CI: 55–288), with a corresponding absolute risk of 11 (CI: 7–14) fractures per 10 000 person years of use. After stopping therapy, the risk of AFF decreased by 70% per year since last use.[89]

Denosumab

The FREEDOM extension trial on denosumab, which extended the original three years of denosumab therapy for up to 10 years, showed continued increase in BMD, a sustained reduction in bone turnover markers (BTMs) and low fracture incidence.[90] Multiple studies have shown a rapid decrease in BMD that was gained during treatment upon discontinuation.[91–93] In a post hoc analysis of the FREEDOM trial and its extension, fractures were examined after treatment discontinuation. Of all the patients who sustained new vertebral fractures off treatment, 60.7% of those that discontinued denosumab and 38.7% who discontinued placebo sustained multiple vertebral fractures.[94] However, in the DATA follow-up study they found the large increases in BMD by denosumab were maintained by those who received prompt treatment with bisphosphonates, but not those who were left untreated.[95] As a result of these studies, the European Calcified Tissue Society (ECTS) has proposed the following recommendations:

- In patients who are low risk for fracture after five years there are two options:

    discontinue denosumab and promptly initiate a bisphosphonate to prevent rebound bone turnover;

or

continue denosumab for a total of 10 years and wait for further publications to guide treatment strategies.

- In patients who are high risk for fracture after five years, continue denosumab for up to 10 years and consolidate with a single infusion of zoledronic acid, or one or more years of an oral bisphosphonate.[86]

Withdrawing treatment of other osteoporosis medications (excluding bisphosphonates) results in rapid loss of their effects on BMD and BTMs. The gains in BMD that are achieved with selective estrogen receptor modulators (SERMs), estrogens, teriparatide, and denosumab are lost over the first 1–2 years.[86] With regards to ONJ, the American Dental Association reported that there is insufficient evidence to recommend a drug holiday from antiresorptive medications before performing dental treatment for prevention of ONJ.[96]

Resolution of clinical scenario

In patients aged 50 years or older who use long-term antiresorptive therapy for osteoporosis, evidence suggests that:

- It is important to re-evaluate patients after initiating pharmacotherapy as there are severe potential side effects, such as AFF, ONJ, venous thromboembolism (VTE), and stroke.
- After three years of treatment with IV zoledronic acid or five years with oral bisphosphonates a treatment break often referred to as *drug holiday* should be considered, unless there are characteristics indicative of high fracture risk.

- Patients taking denosumab should be re-evaluated after five years of treatment. Patients at high risk for fracture should continue denosumab, whereas patients at low risk should either continue denosumab or switch to a bisphosphonate.

Summary of answers

Many patients are not receiving appropriate evaluation and treatment for osteoporosis post fracture.

The FRAX and CAROC tools can and should be used to calculate the 10-year probability of a major fragility fracture (clinical spine, hip, forearm, or proximal humerus) and hip fracture.

Alternative methods are also available to determine absolute fracture risk.

Alendronate, risedronate, zoledronic acid, and denosumab are all effective pharmacologic agents for reducing the relative risk of hip fracture.

The risk of developing bisphosphonate-associated ONJ with routine oral therapy for osteoporosis is very low.

Atypical fractures are associated with anti-resorptive therapy. The exact mechanism by which they occur has yet to be determined.

- It is important to re-evaluate patients after initiating pharmacotherapy as there are severe potential side-effects such as AFF, ONJ, VTE, and stroke.
- After three years of treatment with IV zoledronic acid or five years with oral bisphosphonates, a treatment break often referred to as *drug holiday* should be considered, unless there are characteristics indicative of high fracture risk.

- Patients taking denosumab should be re-evaluated after five years of treatment. Patients at high risk for fracture should continue denosumab, whereas patients at low risk should either continue denosumab or switch to a bisphosphonate.

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8 Venous Thromboembolic Events

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Clinical scenario

- An 81-year-old lady was admitted after a ground-level fall.
- She has a history of diabetes mellitus and hypertension and was premorbidly ambulant.
- She suffered a femoral neck fracture and had a cemented hemiarthroplasty within 24 hours.
- On the third postoperative day, she developed a fever and shortness of breath.
- Examination revealed swelling of the right lower leg.
- Deep venous thrombosis (DVT) extending above the knee was demonstrated on ultrasonography, and CT angiography showed a large saddle pulmonary embolism (PE) within the pulmonary trunk.
- The patient required ventilator and inotropic support, and eventually succumbed to secondary pneumonia after a prolonged stay in intensive care.

Top three questions

1. In patients undergoing major orthopedic surgery, does one modality, compared to others, most effectively reduce thromboembolic event rates?
2. In patients undergoing major orthopedic surgery, does preoperative initiation of thromboprophylaxis, compared to peri- or postoperative initiation, reduce thromboembolic event rates?
3. In patients with isolated lower-limb injuries who require immobilization, does thromboprophylaxis, compared to no prophylaxis, reduce thromboembolic event rates?

Question 1: In patients undergoing major orthopedic surgery, does one modality, compared to others, most effectively reduce thromboembolic event rates?

Rationale

Major orthopedic procedures including hip and knee arthroplasty and hip fracture surgery confer the highest risk for venous thromboembolic events and remain a challenge globally.[1]

Mechanical compression methods – including graduated compression stockings, intermittent pneumatic compression, and foot-pumps – are widely available, variable in expense, and have very few contraindications. These measures can be employed as monotherapy in patients with contraindications to anticoagulant therapy, or in conjunction with anticoagulants in higher-risk patients. The 2012 American College of Chest Physicians (ACCP) guidelines recommend the use of several anticoagulants for

orthopedic surgery.[2] These include low-dose unfractionated heparin (LDUH), low-molecular-weight heparin (LMWH), more recent novel oral anticoagulants, aspirin, and vitamin K antagonists (VKAs), exemplified by warfarin.

New oral anticoagulants (NOACs) are broadly divided into direct thrombin inhibitors (dabigatran) or direct factor Xa inhibitors (fondaparinux, rivaroxaban, and apixaban).

Clinical comment

Evidence has been contradictory regarding the effectiveness of mechanical thromboprophylaxis.

LDUH has largely been surpassed by the LMWHs. NOACs may have even greater thrombo-prophylactic efficacy and ease of administration, but this is balanced by a higher rate of bleeding events. The ideal anticoagulant should have high efficacy, safety, low levels of bleeding, rapid onset of action, fixed dosing, and no requirement for therapeutic monitoring.

Available literature and quality of the evidence

- Systematic reviews/meta-analyses: 2 (level I).
- Systematic reviews/meta-analyses with methodological limitations: 1 (level II).
- Case series: 2 (level IV).

Findings

Pooled data from low-quality randomized controlled trials (RCTs) comparing mechanical compression to no thromboprophylaxis show a relative risk reduction of >50% for both DVT and PE in arthroplasty and hip fracture surgery (pulmonary embolism [PE] risk ratio [RR] = 0.4,

95% confidence interval [CI]: 0.17–0.92; DVT RR = 0.46; 95% CI: 0.35–0.61).[2]

A meta-synthesis identified six good-quality systematic reviews that compared anticoagulants with LMWH.[3] The risk for symptomatic DVT was reduced with factor Xa inhibitors compared to LMWH (four fewer events per 1000 patients), albeit with an increase in major bleeding events (two per 1000 patients). Dabigatran had similar outcomes to LMWH. Conclusions about differences between NOACs could not be ascertained. In a meta-analysis of six RCTs on arthroplasty patients, the combination of pharmacologic and mechanical prophylaxis conferred a lower risk for DVT (relative risk 0.48, 95% CI 0.32–0.72) compared to pharmacologic prophylaxis alone.[4]

Asian patients undergoing hip and knee arthroplasty have been shown to have a noticeable low prevalence of DVT and PE. A recent large case series highlighted the prevalence of DVT at 6.6%, and proximal DVT of 0.4%, with no PE in patients undergoing total knee arthroplasty with only mechanical prophylaxis.[5] Another case series in Asian patients undergoing total hip arthroplasty with only mechanical prophylaxis revealed a DVT prevalence rate of 4.8%, 1.6% with proximal DVT, 0.7% with asymptomatic PE, and no symptomatic PE.[6] The authors recommend mechanical compression devices only in Asian patients.

Resolution of clinical scenario

There is no ideal modality for thromboprophylaxis. Upon recognition of this patient's high risk for venous thromboembolism, she should have received mechanical prophylaxis via foot-pumps, or intermittent pneumatic calf compression on admission. An LMWH should be started 12–24 hours after acute fracture surgery.

Question 2: In patients undergoing major orthopedic surgery, does preoperative initiation of thromboprophylaxis, compared to peri- or postoperative initiation, reduce thromboembolic event rates?

Rationale

The belief that venous thrombi are formed perioperatively has directed the practice of providing antithrombotic prophylaxis preoperatively to maximize antithrombotic effectiveness. On the other hand, postoperative initiation of anticoagulation allows hemostasis of the wound and reduces the risk of bleeding complications.[7] Thromboprophylaxis is commonly administered for the duration of the hospital stay, which can range from 4 to 14 days. However, patients are still at risk of developing symptomatic thromboembolism after discharge from hospital. New guidelines now recommend the use of extended, out-of-hospital prophylaxis, but this has to be balanced against the cost effectiveness and risk–benefit ratio of such regimens.

Clinical comment

Current opinion suggests that there is no significant difference in venous thromboembolism (VTE) incidence if thrombo-prophylaxis is initiated pre- or postoperatively. The optimal duration of prophylaxis after major acute or elective orthopedic surgery is still controversial.

Available literature and quality of the evidence

- Systematic reviews/meta-analyses: 2 (level I).

Findings

A meta-analysis compared three regimens for elective hip surgery: preoperative (at least 12 hours, or the evening before surgery), postoperative (12–24 hours after surgery), and perioperative (2 hours before to ≤ 4 hours after) initiation of LMWH.[8] DVT rates were 19.2, 12.4, and 14.4%, respectively, suggesting that postoperative regimes were just as effective as pre- or perioperative prophylaxis. However, the rate of major bleeding was highest in the perioperative group at 6.3%, compared to 1.4% in the preoperative, and 2.5% in the postoperative groups.

In a meta-analysis of eight RCTs,[9] extended-duration prophylaxis for ≥21 days reduced the rate of pulmonary embolism (odds ratio [OR] = 0.14; 95% CI: 0.04–0.47; absolute risk reduction [ARR] 0.8%) and symptomatic DVT (OR = 0.35; 95% CI: 0.15–0.81; ARR 1.5%) when compared with standard duration therapy (7–10 days). However, this was associated with a higher rate of minor bleeding events (OR = 2.44; 95% CI: 1.41–4.20; ARR 6.3%). There are insufficient data relevant to knee arthroplasty or hip fracture surgery.

Resolution of clinical scenario

In the absence of any contraindications or bleeding risk, the patient should receive chemical prophylaxis in the form of LMWH, 12–24 hours following acute fracture surgery. Anticoagulation should be extended for at least 21 days into her postoperative rehabilitation period to reduce the risk of out-of-hospital embolism. If available, NOACs may be used

for extended thromboprophylaxis, as they are easily administered and do not require monitoring.

Question 3: In patients with isolated lower-limb injuries who require immobilization, does thromboprophylaxis, compared to no prophylaxis, reduce thromboembolic event rates?

Rationale

Injuries at or below the knee are associated with a low-to-intermediate VTE risk, and rarely does asymptomatic DVT propagate or progress to become clinically important VTE.[10–14] In contrast, rates of DVT for injuries involving the femoral shaft have been reported up to 40%,[10,15] with proposed mechanisms, including direct endothelial injury in these higher energy fractures, hypercoagulable states following significant blood loss, as well as immobilization in the perioperative period.

Clinical comment

Routine anticoagulation for isolated lower-limb injuries requiring immobilization, is still controversial, and is not based on strong evidence or guidelines.

Available literature and quality of the evidence

- Systematic reviews/meta-analyses: 1 (level I).
- RCT: 1 (level I).

Findings

In patients who had received surgical treatment for fractures of the tibia, ankle, or foot, chemoprophylaxis with an LMWH compared with placebo did not significantly reduce the risk of clinically important VTE (RR = 0.865; 95% CI [pooled RR = 0.112–3.963], p = 0.790; homogeneity P = 0.718, I^2 = 0%).[16] For patients with lower leg casts, the POST-CAST Trial showed that chemoprophylaxis with LMWH during the full period of immobilization did not significantly reduce the risk of clinically important VTE compared to no treatment (RR: 0.8; 95% CI: 0.3–1.7).[17]

Resolution of clinical scenario

There is no evidence base for the use of prophylaxis in injuries at or below the knee. If the injury involves the femur shaft or is associated with a polytraumatic scenario or failure to mobilize, then prophylaxis with an LMWH is recommended for up to 35 days from the day of surgery[2].

Summary of answers

- Low-molecular-weight heparins remain the best anticoagulation agent currently available for thromboprophylaxis in elective orthopedic or orthopedic trauma patients. They are effective, safe, and relatively inexpensive.
- New oral anticoagulants are feasible alternatives in elective arthroplasty patients, but they should be used judiciously in patients with increased bleeding risk.
- Mechanical prophylaxis in combination with pharmacological prophylaxis should be considered in patients undergoing major orthopedic surgery. In patients with high bleeding risk or Asian patients undergoing arthroplasty, it can be provided as monotherapy.

- Thromboprophylaxis started 12 hours before surgery has not been shown to be more effective than prophylaxis initiated 12–24 hours after surgery.
- Close-proximity perioperative regimens are not recommended due to the higher risk for bleeding complications.
- Extended duration of prophylaxis is an effective and safe means to reduce the rate of symptomatic out-of-hospital venous thromboembolic events in elective hip arthroplasty patients and hip and femur trauma patients.
- For isolated lower-limb injuries below the knee requiring immobilization, routine pharmacologic thromboprophylaxis is not required.

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9 Blood Transfusion

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Clinical scenario

- An 84-year-old woman is admitted to hospital with an intertrochanteric hip fracture and undergoes surgery for a cephalomedullary nail.
- Medical history is significant for coronary artery disease, hypertension, and chronic renal failure.
- On the second postoperative day, the patient is having difficulty ambulating due to fatigue. Vital signs are stable; electrocardiogram (ECG) is unchanged. Bloodwork reveals a hemoglobin concentration of 82 g/L.

Top three questions

1. Amongst patients undergoing orthopedic surgery, how common are perioperative blood transfusions compared to patients undergoing other types of surgery?
2. In patients undergoing orthopedic surgery, are perioperative blood management strategies effective at reducing transfusion rates compared to usual care?

3. In postoperative orthopedic surgery patients, what transfusion threshold results in optimal outcomes compared to usual care?

Question 1: Amongst patients undergoing orthopedic surgery, how common are perioperative blood transfusions compared to patients undergoing other types of surgery?

Rationale

Anemia is common in perioperative patients. It is important to understand how orthopedic patients compare, and if these trends are changing over time.

Clinical comment

Approximately one-third of patients are found to be anemic at their preoperative assessment.[1] In addition, perioperative anemia is an independent risk factor for increased length of stay in hospital, increased time in intensive care, perioperative complications, and mortality.[2] Patient blood management (PBM) is an evidence-based approach to reducing the need for transfusions, and, when necessary, making transfusions safer and more effective.[3] In order to implement PBM principles effectively, it is important to know how frequent the need for transfusion is among orthopedic surgery patients.

Available literature and quality of evidence

Mazzeffi et al. performed a retrospective review of the National Surgical Quality Improvement Program (NSQIP) over a five-year period comparing various surgical

specialties, including orthopedic surgery (2018, level III).[4] Slover et al. performed a database study (2017, level III) looking at 59 038 patients undergoing total joint arthroplasty and analyzed transfusion rates among this population.[5] Sherrod et al. analyzed the NSQIP Pediatric database for 1184 patients undergoing surgery for hip dysplasia to examine transfusion rates (2018, level III).[6] Soleimanha et al. performed a prospective study (2016, level II) to analyze transfusion rates among 872 patients at a trauma centre.[7]

Findings

In their retrospective review of NSQIP data, Mazzeffi et al. identified an interesting trend in transfusion rates across five different surgical specialties (orthopedics, vascular, gynecology, neurosurgery, and thoracic surgery). In the first year of the study (2011), orthopedic surgery had the highest rate of transfusions among the various specialties (22.4%). By the final year of the study (2015), this rate was down to 6.3%, and was lower than vascular and gynecological surgery (2018, level III).[4] In their large database study of nearly 60 000 patients, Slover et al. found that 18% of patients undergoing total joint arthroplasty required transfusion (2017, level III).[5] In their NSQIP pediatric database study, Sherrod et al. found 22.4% of patients undergoing surgery for hip dysplasia required transfusions (2018, level III).[6] Finally, in their study of orthopedic trauma patients, Soleimanha et al. found that 36.5% of patients required a transfusion in the perioperative period (2016, level II).[7]

Resolution of clinical scenario

- Based on large database studies, transfusion rates in orthopedic surgery range from between 20 and 35%,

compared to 5–15% in other surgical specialties.

- Based on a longitudinal study, transfusion rates in orthopedic surgery have been on the decline more recently and are now comparable to other surgical specialties.

Question 2: In patients undergoing orthopedic surgery, are perioperative blood management strategies effective at reducing transfusion rates compared to usual care?

Rationale

Transfusion of blood products is both expensive and has numerous associated risks. Thus, it is important to identify evidence-based perioperative strategies that can reduce transfusion rates.

Clinical comment

Over one hundred million units of blood are collected worldwide annually.[8] Transfusion is one of the only therapeutic interventions available to increase oxygen delivery to tissues; however, transfusion is expensive and not without risk. The total cost of a single unit of allogenic blood – including acquisition, storage, and personnel – is close to CAD$700.[9] Blood transfusion safety is continuously improving, but adverse events including transfusion-related acute lung injury (TRALI), cardiac overload, hemolysis, and infection do continue to occur.[10] A number of well-studied PBM strategies have been described, including (i) iron therapy, (ii) erythropoietin (EPO) administration, (iii) cell salvage, and (iv) antifibrinolytic therapy.

Available literature and quality of the evidence

Four separate randomized controlled trials (RCTs) (all level I) have analyzed the effectiveness of intravenous (IV) iron therapy in orthopedic surgery patients. The four studies, conducted between 2006 and 2016, randomized between 31 and 306 patients to IV iron, control, and in some cases IV iron plus EPO groups.[11–14] A meta-analysis of 32 RCTs (2019, level I, n = 4750) has evaluated the efficacy and safety of perioperative EPO administration in multiple surgical specialties, including seven orthopedic surgery trials.[15] Similarly, a meta-analysis of 25 RCTs by Li et al. (2018, level I, n = 4159) analyzed the use of EPO in total hip and knee arthroplasty.[16] A meta-analysis of RCTs (2016, level I) assessed the use of cell salvage in multiple surgical specialties, including 15 orthopedic RCTs (n = 1207).[17] Perhaps one of the most-studied PBM strategies in orthopedic surgery is the use of tranexamic acid (TXA). Comprehensive network meta-analyses have analyzed the use of TXA in total hip (2018, level I, n = 2227) and knee (2018, level I) arthroplasty.[18,19] In addition, a meta-analysis by Sun et al. (2019, level I), analyzed the use of IV, topical, or combined TXA regimens in hip and knee arthroplasty.[20]

Findings

Iron therapy

Four RCTs analyzing the efficacy of IV iron therapy in orthopedic surgery included a total of 616 patients (all level I). None of the studies found a statistically significant benefit for IV iron therapy in terms of transfusion rate, units per patient, length of stay, infection rate, or mortality.[11–14]

EPO administration

A meta-analysis of 25 RCTs (n = 4159) looking at the use of EPO in total hip and knee arthroplasty found that the use of EPO, whether compared to controls or preoperative autologous blood donation, provided significantly reduced rates of blood transfusion, with an odds ratio of 0.42 ($p < 0.0001$).[16]

Cell salvage

Meybohm et al. performed a meta-analysis which included 15 orthopedic surgery RCTs (level I, n = 1207). They found that the use of cell salvage significantly reduced the need for allogenic blood transfusion (risk ratio [RR] = 0.43; $p < 0.001$) and resulted in an average saving of 0.80 units per patient. Cell salvage did not result in a difference in infection or mortality rates.[17]

Tranexamic acid

In their network meta-analysis of 25 RCTs looking at total hip arthroplasty (level I), Yoon et al. found that IV, topical, or combined TXA were all effective at reducing transfusion rates, with no significant increase in thromboembolic events. In addition, they found that combined IV and topical TXA was superior to single route regimens.[18] Fillingham et al. conducted a similar network meta-analysis in total knee arthroplasty, including 67 RCTs and over 9000 patients (level I). They found that, while IV, topical, or combined TXA were all superior to placebo, none of the administration regimens was clearly superior to the others.[19] Finally, a meta-analysis of 26 RCTs looking specifically at the question of which administration regimen was superior was performed by Sun et al. (level I). They found that combined regimens (i.e. IV and oral administration) had significantly less blood loss (−198 mL; $p < 0.05$), significantly lower transfusion rates (RR = 2.51; p

<0.05), and no difference in thromboembolic events (p = 0.32).[20]

Resolution of clinical scenario

- Level I evidence suggests that IV iron therapy does not result in significantly reduced transfusion rates after orthopedic surgery.
- Level I evidence suggests that cell salvage and EPO administration does significantly reduce the need for transfusion in orthopedic surgery patients.
- Strong level I evidence demonstrates that TXA administration does consistently reduce the need for transfusions after total joint arthroplasty, and that combined IV and topical is as safe, and possibly more effective, than single route administration.

Question 3: In postoperative orthopedic surgery patients, what transfusion threshold results in optimal outcomes compared to usual care?

Rationale

Based on the emergence of high quality evidence, traditionally liberal transfusion thresholds have been re-evaluated and restrictive thresholds are advocated for most patients, particularly in the intensive care setting. Given the importance of early mobilization and compliance with rigorous physiotherapy routines, it is important to understand whether these same thresholds can be applied to orthopedic surgery patients.

Clinical comment

The Transfusion Requirements in Critical Care (TRICC) trial (level I) is a landmark study which randomized over 800 intensive care unit (ICU) patients to a either a restrictive (70 g/L) or liberal (100 g/L) transfusion threshold. The number of units transfused was lower in the restrictive group (2.6 vs 5.6 units; $p < 0.01$), and overall 30-day mortality did not differ between the two groups. There was, however, lower mortality in the restrictive group for patients under 55 years of age ($p < 0.02$) and less ill patients ($p < 0.02$). The only group that may have benefited from a liberal transfusion threshold were patients with acute myocardial infarction and unstable angina.[21] Since the publication of the results from the TRICC trial, the transfusion threshold of 70 g/L has become popular across a wide range of inpatient settings. Given that the TRICC trial was limited to ICU patients, it is important to understand how these findings compare in orthopedic surgery patients specifically.

Available literature and quality of evidence

Two overlapping meta-analyses of RCTs (level I) have considered the question of transfusion thresholds in orthopedic surgery patients. The two meta-analyses by Mitchell et al. (2017, level I) and Gu et al. (2018, level I) include the same nine RCTs, while Gu includes an additional RCT.[22,23] The 10 RCTs involved 3968 participants, and were conducted between 1998 and 2015. Sample sizes ranged from 66 to 2016 patients, and all trials were focused on hip and knee surgery, specifically arthroplasty and hip fracture surgery. The focus of all of these trials was on older patients, with the mean participant age ranging from 68.7 to 86.9 years old. The most common thresholds were 80 g/L for the restrictive

group and 100 g/L for the liberal group. None of the trials was found to be at high risk of bias.

Findings

In their meta-analysis of RCTs, Gu et al. (level I) analyzed cardiovascular events as their primary outcome. They found that, based on eight of the included RCTs (n = 3618), restrictive transfusion thresholds were associated with a significantly higher risk of cardiovascular events (RR = 1.51; p = 0.003), which remained the case regardless of preexisting cardiovascular disease. Subgroup analyses revealed that the increased risk of cardiovascular events was observed in patients undergoing hip fracture surgery, but not in those undergoing elective arthroplasty. In terms of secondary outcomes, based on moderate quality evidence, no difference between the two thresholds in terms of infection, 30-day mortality, or cerebrovascular accidents was found.[22]

Interestingly, in their overlapping meta-analysis, Mitchell et al. (level I) found that restrictive transfusion thresholds resulted in significantly lower infection rates compared to liberal thresholds (RR = 0.60; p = 0.004). Subgroup analysis revealed that this difference was true for the arthroplasty population, but not for the fracture patients. There was no significant difference between the two thresholds in terms of total adverse events.[23]

Resolution of clinical scenario

- Based on moderate-strength level I evidence, a restrictive transfusion threshold does reduce infection rates, particularly in those undergoing hip and knee arthroplasty surgery.

- Based on moderate-strength level I evidence, a restrictive transfusion threshold is associated with a significantly higher risk of cardiovascular events, particularly in those undergoing hip fracture surgery.

Summary of answers

- Orthopedic surgery patients are at a relatively higher risk (20–35%) of receiving a transfusion compared to other surgical specialties, though this rate may have been trending down in recent years.
- Cell salvage and erythropoietin administration are effective interventions in reducing the need for transfusions in orthopedic surgery patients.
- Tranexamic acid (TXA) is supported by extensive level I evidence as an effective and safe intervention in orthopedic surgery patients, and combined intravenous and topical TXA may the most effective regimen.
- It remains unclear whether liberal or restrictive transfusion thresholds are best for orthopedic surgery patients, with different thresholds likely indicated based on patient comorbidities and type of surgery.

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10 Wound Infections

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Clinical scenario

- A 30-year-old male sustained a lateral split-depression tibial plateau fracture after a fall from a ladder.
- He underwent open reduction and internal fixation, and at his two-week follow-up appointment there was wound drainage with surrounding erythema.

Top three questions

1. In patients undergoing orthopedic surgery, does routine antibiotic prophylaxis, compared to antibiotic administration, prevent surgical site infections?
2. In patients with a suspected surgical site infection, what is the optimal workup leading to accurate diagnosis and treatment?
3. In patients with a surgical site infection and infected hardware, does hardware retention, compared to removal of hardware, result in improved outcomes?

Question 1: In patients undergoing orthopedic surgery, does routine antibiotic prophylaxis, compared to antibiotic administration, prevent surgical site infections?

Rationale

Optimal prophylactic antibiotic management in orthopedic surgery has not been fully answered and is an area of ongoing research.

Clinical comment

Despite established guidelines for surgical site infection (SSI) prevention, studies show that antibiotic prophylaxis is not always correctly administered.[1,2] Antibiotics should be administered within 30 minutes prior to incision, and inappropriate utilization of antibiotics contributes to antibiotic resistance and increased health care costs.[3–6]

Available literature and quality of the evidence

- Level I: 16 studies
- Level II: 8 studies
- Level III: 14 studies
- Level IV: 6 studies
- Level V: 9 studies.

Findings

Prophylactic antibiotic effectiveness was first demonstrated in 1961 in a *Staphylococcus aureus* infection model in guinea pigs; antibiotics given within one hour of bacterial

inoculation showed no inflammatory response.[7] Guinea pigs that received antibiotics >3 hours after inoculation received no more benefit than those not receiving antibiotics. Lidwell et al. demonstrated a threefold decrease in total knee and hip arthroplasty infections with usage of antibiotic prophylaxis.[8] A prospective, randomized double-blind study of general orthopedic procedures showed that a group receiving cefamandole compared to placebo had a significantly reduced rate of infection.[9] The Dutch Trauma Trial assigned 2195 patients with closed fractures to a single 2 g preoperative dose of ceftriaxone versus placebo, with a placebo group infection rate of 8.3% versus ceftriaxone rate of 3.6%.[10]

The optimal duration of antibiotics is not known with poor evidence.[11,12] Current American Academy of Orthopaedic Surgeons (AAOS) guidelines recommend antibiotic duration <24 hours, even with drains or catheters present.[12] In trauma and elective surgery populations, single-dose antibiotic prophylaxis appears to be noninferior to multiple doses.[13–15] In a meta-analysis by Morrison et al., 921 patients pooled between two studies analyzing single versus multiple postoperative antibiotic doses demonstrated no significant differences. Multiple doses of postoperative antibiotics had a slightly lower deep SSI rate (risk ratio [RR] = 0.13; 95% confidence interval [CI]: 0.02–0.99).[16] Antibiotics should be re-dosed for operations >3 hours, >2 half-lives of the antibiotic, or with blood loss >1500 mL.[17] Antibiotic dosing should be weight based to ensure adequate tissue concentrations.[1,18]

Resolution of clinical scenario

- Antibiotics should be administered within 30 minutes prior to incision.

- Perioperative antibiotic course should not exceed 24 hours.
- Antibiotics should be re-dosed when the duration of the procedure exceeds two-times the antibiotic half-life, with significant intraoperative blood loss, and dosed by weight.

Question 2: In patients with a suspected surgical site infection, what is the optimal workup leading to accurate diagnosis and treatment?

Rationale

Accurate and timely diagnosis of SSIs is important for guiding treatment.

Clinical comment

The evaluation of a suspected wound infection is clinically based. C-reactive protein (CRP) and erythrocyte sedimentation rate (ESR) are useful for diagnosis and following treatment response.

Available literature and quality of the evidence

- Level II: 7 studies
- Level III: 4 studies
- Level IV: 1 studies
- Level V: 7 studies.

Findings

The Centers for Disease Control and Prevention categorizes SSIs as *Superficial Incisional SSI* (<30 days involving skin/subcutaneous tissues), *Deep Incisional SSI* (involves deep soft tissues <30 days without implant, <1 year with implant), or *Organ/Space SSI* (involves any part of the anatomy other than incision which was opened/manipulated, <30 days without implant, <1 year with implant).[19] Infection course is subject to many variables, including organism virulence, wound condition, host factors, and presence of nonbiologic substances such as metallic implants.[6,20,21] Failure of eradication leads to colonization and further bacterial adaptation including biofilm and glycocalyx formation.[22]

Drainage, erythema, fever, and pain may signify SSI. Laboratory workup should include blood cultures, white blood cell (WBC) count, ESR, and CRP. Erythrocyte sedimentation rate peaks five days postsurgery followed by a slow and irregular decrease, often remaining elevated at 42 days after uncomplicated spine surgery.[23,24] CRP is a more effective marker for diagnosis of infection due to established postoperative kinetics, as demonstrated in spine literature, with a half-life of 2.6 days and first-order elimination kinetics.[24] Most diagnostic data are drawn from the arthroplasty literature, so caution must be taken when interpreting for trauma populations. In fracture patients, studies show persistent elevation of CRP beyond postoperative day (POD) 4 is associated with an SSI; one study demonstrated 92% sensitivity and 93% specificity for deep infection, with elevation of CRP >96 mg/L beyond POD 4 associated with infection.[25,26] When used together, ESR and CRP demonstrated a 98% sensitivity in a study of 265 children with osteoarticular infections.[27] Elevated ESR, CRP, and WBC demonstrated 100% positive predictive value of infection in 30 patients with infected nonunions.[28] For concerns of periprosthetic joint infection

(PJI) following arthroplasty for fracture, additional tests are utilized. Leukocyte esterase (LE) is an enzyme produced by activated neutrophils. Synovial fluid testing of LE showed pooled sensitivity of 81% and specificity of 97% for PJI.[29] The role of this test in infection associated with nonarthroplasty fracture treatment has not yet been investigated. Interleukin-6 (IL-6) is supported by the arthroplasty literature, but is prone to nonspecific elevation in trauma patients and less specific than CRP.[30,31] Next-generation sequencing is a molecular technology that can characterize all microbial DNA present within a sample. Further clinical testing is needed.[32] The 2018 Definition of Periprosthetic Hip and Knee Infection incorporates variables including CRP, ESR, synovial fluid WBC count or LE, synovial alpha-defensin, and synovial polymorphonuclear WBC percentage broken down into major and minor criteria. It demonstrated a 97.7% sensitivity and 99.5% specificity.[33]

An optimal diagnostic approach necessitates proper diagnosis of the infectious organism. Deep intraoperative cultures are the gold standard for diagnosis and necessary to guide treatment. Polymerase chain reaction (PCR) testing has an evolving role in diagnosing slower-growing organisms, albeit with a sensitivity of 9–85%.[34]

Radiographic imaging is normal initially; 30–50% of bone density loss is necessary to be visible on plain xrays.[35,36] Magnetic resonance imaging (MRI) is the test of choice for soft tissue evaluation; however, infection is hard to diagnose with metallic implants present.[36] Standard bone scintigraphy has high sensitivity, but lacks specificity, while technetium tc-99m-labeled leukocyte scans demonstrate excellent accuracy and sensitivity, but they are limited by cost and extensive preparation.[37] F-18 fluorodeoxyglucose (FDG) positron emission tomography (PET) demonstrates increased sensitivity and specificity as compared to prior

modes of bone scintigraphy, showing results of 100, 93, and 97% for sensitivity, specificity, and accuracy of metallic implant-associated infections and osteomyelitis, respectively.[38]

Resolution of clinical scenario

- Wound drainage, erythema, fever, and pain may suggest an SSI and should prompt workup.
- CRP and ESR in conjunction with appropriate imaging should be used to diagnose and follow a wound infection.
- MRI is the test of choice for evaluation of soft tissue infection. PET scan is an adjunct method for evaluation in the setting of metallic implants.

Question 3: In patients with a surgical site infection and infected hardware, does hardware retention, compared to removal of hardware, result in improved outcomes?

Rationale

Hardware-related infections are a challenging problem. As implants and techniques continue to improve, there is an increasing number of operatively treated fractures with subsequent associated infections.

Clinical comment

Infected hardware can affect fracture healing and cause significant morbidity with prolonged recovery.

Available literature and quality of the evidence

- Level II: 2 studies
- Level III: 3 studies
- Level IV: 3 studies
- Level V: 3 studies.

Findings

The need for continued fracture stabilization versus implant removal is a debated topic in managing infections in operatively treated fractures. Fracture stabilization and union helps both prevent and clear infections.[39] Rightmire et al. demonstrated that 32% of patients with acute infection who received irrigation and debridement, antibiotics, and hardware retention needed hardware removal before fracture healing.[40] Only 49% of original study group achieved healing and were infection-free at six months. Berkes et al. demonstrated a 71% fracture union following operative debridement, hardware retention, and culture-specific antibiotic treatment.[41] Open fractures and presence of an intramedullary nail, smoking, and *Pseudomonas* were associated with failure. It is reasonable to conclude that, in most patients, hardware should remain in place in the acute period followed by debridement and culture-specific antibiotics. Antibiotic cement-coated plates, antibiotic impregnated polymethylmethacrylate, and antibiotic cement-fashioned intramedullary nails are treatment options being used in hardware removal cases for infection eradication.[42]

Resolution of clinical scenario

- Prompt debridement and hardware retention is recommended for most acute deep infections.

- After fracture union, the hardware should be removed to reduce risk of recurrent infection.

Summary of answers

- Prophylactic antibiotics should be administered prior within 30 minutes to incision and be continued for no more than 24 hours. Antibiotics should be dosed according to patient weight, re-dosed for excessive blood loss and prolonged operative time.
- ESR, CRP, and appropriate imaging modalities should be used together as part of workup for wound infection.
- Infected hardware may prevent full eradication of infection, but must be weighed with need for fracture union. In most cases, it is recommended to retain hardware in the acute period and remove after fracture healing.

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11 Smoking Cessation

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Clinical scenario

- A 27-year-old female with a history of depression and tobacco abuse presents to the Emergency Department after falling off a ladder at home.
- Physical and radiographic examinations demonstrated an open tibial plafond fracture.
- She was urgently debrided and temporized with external fixation.
- She follows up in clinic one week later to schedule her definitive fixation.
- She asks what she can do to improve her chances of walking again and whether she should stop smoking.

Introduction

Despite national public health campaigns, smoking in the United States remains a common and preventable cause of morbidity and mortality. In 2015, 15.1% of all adults (36.5 million people) were current everyday cigarette smokers.[1] Smoking is linked to 480 000 deaths per year in the United States (1 in 5 deaths) and 8 million deaths worldwide and has been clearly linked to multiple types of cancer,

cardiovascular and respiratory disease, reproductive complications, and multiple other effects. Patients that smoke die on average 10 years earlier than patients that do not smoke.[2] Fortunately, this may be reversible. Five to 15 years of smoking abstinence makes the risk of coronary heart disease, stroke, and all-cause mortality drop to the level of nonsmokers.[3]

Despite widespread knowledge regarding the general ill effects of smoking on personal health, less is known about smoking with regards to the musculoskeletal system.[4] This is concerning, as orthopedic trauma is associated with a much higher rate of smoking than the general public, with some studies quoting as high as 50–60% smokers.[5] Smoking carries significant risks for the musculoskeletal system. Tobacco smoke contains approximately 4000 potentially toxic substances. Nicotine is the most frequently cited culprit, although evidence supporting this is contradictory. Basic science research has shown that nicotine has sympathomimetic action, stimulating epinephrine and norepinephrine release, causing vasoconstriction and stimulating platelet adhesion causing micro clot formation and limiting tissue perfusion.[6,7] Nicotine also reduces red blood cell, macrophage, and fibroblast proliferation and has been linked to decreased vascular endothelial growth factor, various bone morphogenic proteins, and collagen expression. It has been suggested, based on experimental animal studies, that these combined molecular influences cause nicotine to impair bone healing by inhibiting neovascularization and osteoblast differentiation.[8–11] However, other studies have shown that nicotine at lower doses may, in fact, increase osteoblast activity *in vitro*.[12,13] Thus, the negative musculoskeletal effect of nicotine may be dose dependent.

Top three questions

1. In patients undergoing orthopedic procedures, do smokers, compared to nonsmokers, have worse outcomes?
2. In patients undergoing orthopedic procedures, does smoking cessation, compared to persistent smoking, decrease the likelihood of a poor outcome?
3. In orthopedic patients, are certain modalities, compared to others, more effective at initiating smoking cessation in orthopedic patients?

Question 1: In patients undergoing orthopedic procedures, do smokers, compared to nonsmokers, have worse outcomes?

Rationale

To improve patient outcomes in orthopedics, it is critical to understand which reversible factors may predispose to poor outcome. Similarly, in orthopedics, it has been conclusively shown that smoking is associated with worse outcomes.

Clinical comment

Patients that smoke tend to be younger and have lower comorbidity profiles than nonsmokers.[14] However, despite being on average younger and healthier, orthopedic patients that smoke have been found to have longer surgical and anesthesia times, spend more time in the hospital, and have higher average hospital charges compared to nonsmokers. The reason for this discrepancy

is difficult to decipher. Patients that smoke may be more likely to have other associated underlying diagnoses that make their care more complex and smoking is more likely in patients with underlying psychiatric illnesses including depression, schizophrenia, and bipolar disorder, which have been linked to poor outcomes.[15] Regardless, smoking is now recognized as a moderator for poor outcome. Smoking increases the risk of postoperative complications of any kind as well as deep wound infections.[16] Procedures reliant on bony healing or osseointegration may be particularly susceptible. Smokers have increased time to union and nearly twice the risk for nonunion after fracture, spinal fusion, osteotomy, arthrodesis, or nonunion treatment.[17]

Findings

In the arthroplasty literature, smoking has been linked to increased risk of prosthesis-related complications. A meta-analysis of 8181 smokers undergoing total hip arthroplasty (THA) found a significantly increased risk of aseptic loosening (risk ratio [RR] = 3.015; 95% confidence interval [CI]: 1.42–6.58), deep infection (RR = 3.71; 95% CI: 1.86–7.41), and all-cause revision (RR = 2.58; 95% CI: 0.77–2.10).[18] A large retrospective cohort study of THA and total knee arthroplasty (TKA) performed at a single institution found significantly higher risk for factors associated with poor outcome including deep infection (hazard ratio [HR] = 2.37; 95% CI: 1.19–4.27) and all-cause revision (HR = 1.78; 95% CI: 1.01–3.13) in smokers.[19] A meta-analysis reviewed 528 abstracts on foot and ankle surgeries for the effect of tobacco use on an array of foot and ankle procedures. All procedures dependent on bone healing – including joint arthrodesis, fracture fixation, and deformity correction at all levels – were adversely impacted by smoking.[20] Smoking negatively impacts both the

objective and subjective outcomes of lumbar and cervical spine surgery. Patients that currently smoke at the time of spinal procedure are more likely to experience pseudarthrosis and postoperative infection and report lower subjective outcome scores.[21] In the patient who smokes and has a long-bone fracture there is an increased risk for nonunion (odds ratio [OR] = 2.32; 95% CI: 1.76–3.01; p <0.001) or delayed healing (30.2 weeks [95% CI: 22.7–37.7] for smokers, 24.1 weeks [95% CI: 17.3–30.9] for nonsmokers).[22] The Lower Extremity Assessment Project (LEAP) study looked at the impact of current and former smoking on limb-threatening open tibia fractures. Current smokers were more than twice as likely to develop infection (OR = 2.22; 95% CI: 1.01–4.91; p = 0.05) and almost four times as likely to develop osteomyelitis (OR = 3.72; 95% CI: 1.25–11.1; p = 0.01). Former smokers' risk for osteomyelitis was lower (OR = 2.80; 95% CI: 0.89–8.83; p = 0.07) than their actively smoking counterparts.[23]

Resolution of clinical scenario

Smoking has been associated with increased risk for postoperative wound complication and infection across all surgical subspecialties. However, patients that smoke are particularly susceptible to procedures reliant on osseous healing for a good outcome. This includes the osseointegration of the bone–implant interface in arthroplasty and osseous healing necessary in successful joint arthrodesis, osteotomy or deformity correction, and fracture care. Smoking is associated with increased rates of nonunion.

Question 2: In patients undergoing orthopedic procedures, does smoking cessation, compared to persistent smoking, decrease the likelihood of a poor outcome?

Rationale

In the clinical scenario presented, we described a healthy young patient that smokes at the time of a limb-threatening open fracture. If she were to stop smoking before her definitive procedure, would that change her expected outcome? The evidence is mixed.

Clinical comment

Across all surgical specialties there are good data to support that having longer periods of smoking cessation at least four weeks prior to a procedure decreases the incidence of total complications, including postoperative wound healing and pulmonary complications.[15]

Findings

A meta-analysis of randomized trials evaluated the effect of smoking cessation on postoperative complications across a range of surgical subspecialties. Trials with >4 weeks of preoperative smoking cessation showed significantly larger risk reduction than trials <4 weeks (relative risk reduction = 20%, RR = 0.80; 95% CI: 3.0–33.0; p = 0.02). Patients that quit 2–4 weeks before procedure had a similar risk profile to those that continued smoking.[24] Another meta-analysis reviewed all cohort and randomized controlled trials (RCTs) that reported postoperative complications in patients that quit smoking within six

months prior to undergoing general surgical procedures. Using a random effects model, ex-smokers were compared with current smokers.[25] Patients that quit smoking >4 weeks prior to surgery significantly lowered their risk for respiratory and wound healing complications. A multicenter, single-blinded, controlled trial randomized 105 daily smokers with acute fractures requiring acute intervention into control and intervention groups. The intervention group was given a standardized smoking cessation program for six weeks. Patients not included in the intervention arm had a significantly increased risk for postoperative complications, such as wound infection, pulmonary complication, skin breakdown, and urinary tract infection (OR = 2.51; 95% CI: 0.96–6.9).[26] Based on these reviews, it seems safe to conclude that discontinuing smoking >4 weeks before an elective surgical procedure brings wound healing and pulmonary complication rates closer to those of individuals without a smoking history and discontinuing smoking at the time of acute injury can minimize complications.

The temporal relationship between smoking cessation and surgery is still more uncertain with regards to bone healing. Animal studies have examined the chronology of smoking cessation and found a dose-dependent response between the earlier cessation of nicotine exposure after surgery and increasing spinal fusion rates.[27] A meta-analysis of human subjects undergoing spinal fusion showed smoking cessation four weeks prior to surgery could lower the rate of pseudarthrosis to a level closer to that of nonsmokers.[28] The LEAP study looked at patients who were never smokers, former smokers, and current smokers at the time of a unilateral open tibia fracture and their time to fracture healing.[23] Former smokers were defined as those that had smoked >100 lifetime cigarettes but were not currently smoking. Even when adjusted for

covariates, at two-year follow-up current smokers were 37% less likely to be united than nonsmokers (p = 0.01) and previous smokers were 32% less likely to be healed than nonsmokers (p = 0.02). While the exact chronology of smoking cessation was not examined, the authors concluded even former smokers were subject to the lingering effects of past smoking on bone healing.

Resolution of clinical scenario

Current smokers are at increased risk for wound and pulmonary complications at the time of surgery. Smoking cessation interventions at least four weeks prior to elective procedures or at the time of acute injury decrease the risk for complications. While studies on the effect of timing of smoking cessation on bone healing are limited, there may be some benefit in overall risk reduction, including fracture healing, even if the detrimental effects on bone healing may linger over a longer period.

Question 3: In orthopedic patients, are certain modalities, compared to others, more effective at initiating smoking cessation in orthopedic patients?

Rationale

Unfortunately, despite the well-recognized negative impact of smoking on orthopedic patients, there is surprisingly little evidence supporting modalities affecting smoking cessation. In general, options include counseling and with nicotine replacement therapy (NRT) or other pharmacologic options, such as varenicline.

Clinical comment

Compared to the general population, patients that smoke are more likely to be less knowledgeable of its negative health effects.[4] There are promising data to support perioperative smoking cessation counseling.

Findings

An RCT of smokers who received cessation counseling while hospitalized for acute fracture found that a brief educational intervention temporarily changed attitudes toward smoking.[29] In a study of smokers scheduled to undergo arthroplasty, a preoperative counseling intervention maintained a quit rate of 22% at one year following surgery versus 3% in a control group.[30] A separate study of smokers scheduled to undergo hip and knee arthroplasty randomized them into a control or smoking intervention group. Patients with intervention that successfully quit smoking 6–8 weeks prior to surgery showed a reduction in complication rate compared to those in the control group.[31] Elective surgery may offer sufficient motivation to reduce smoking rates, and preoperative interventions have shown benefit by reducing complication rates. However, what about the fracture patient in the clinical vignette at the beginning of this chapter? The urgent nature of her care does not allow for preoperative intervention. A single-center cross-sectional cohort study of 112 fracture patients that smoked found 48% expressed an interest in smoking cessation and 11% increased their interest in quitting smoking at the time of their injury.[4] The addition of cessation counseling may increase these rates. Of 41 smokers being treated with a circular frame external fixation for acute lower extremity injury, 56% were smokers at the time of injury and were educated on the negative impacts of smoking. Eighty-seven percent of patients were unaware of the negative effects of

smoking at the time of intervention. After counseling, 74% felt it increased their likelihood of smoking cessation and 48% successfully quit by the end of the study period.[32] The period immediately following acute injury appears to be a critical period for counseling and education regarding smoking to decrease its health burden.

Adjunctive support measures for those trying to quit or decrease smoking currently include NRT and pharmacologic support. Nicotine replacement substances may have benefit in those with strong physiologic addiction.[33] There is strong evidence that NRT enhances the efficacy of tobacco use interventions.[34] Preclinical studies support no increased risk for healing or cardiopulmonary related complications secondary to NRT, and clinical studies show a reduction in postoperative complications when NRT leads to successful smoking cessation. Other pharmacologic options supporting smoking cessation include pharmacologic behavior modifiers such as antidepressants. The most commonly prescribed is varenicline, a partial agonist of nicotinic acetylcholine receptors. In a randomized, placebo-controlled, double-blind trial of smokers willing to reduce tobacco consumption, a group of 760 patients prescribed varenicline had a smoking abstinence rate by one year of 27.0% versus 9.9% for the 750-patient placebo group; relative risk (RR = 2.7; 95% CI: 2.1–3.5).[35] Based on available studies, the most effective way to help patients cease smoking is a combination of active, guided counseling combined with NRT.

While it may be difficult or time consuming in the clinic or inpatient setting for the orthopedic surgeon to formally provide counseling for the patient without any training, there are free options available to patients that the surgeon can refer the patient to easily. The US National Tobacco Quitline (1-800-QUIT-NOW) is a publicly available,

federally funded, state executed tobacco control program. Awareness and use of this program remain low, with many physicians unaware of available services.[36] While brief, physician-guided education and support has some utility, a proactive telephone counseling service offers many superior benefits including accessibility and reduced time constraints. Many of the state-based quitlines offer free NRT in addition to the provided counseling. Physicians and providers may refer patients to the quitline via either facsimile, email or directly through the electronic medical record. This will initiate a series of phone calls from the quitline to the patient at various times to initiate the service. There is also evidence supporting a dose-dependent response to quit rates with increased number of calls to the 1-800-QUIT-NOW hotline increasing chances of quitting compared to standard self-help materials or brief advice.[37]

Resolution of clinical scenario

Orthopedic surgeons can play an important role in smoking cessation by offering education, support, and encouragement. Elective procedures and acute injuries offer important timepoints to discuss smoking cessation with patients. Patients awaiting elective procedures should be counseled to discontinue smoking at least four weeks before their scheduled procedure. Although there is no time to allow cessation prior to surgery in acute orthopedic trauma, patients with acute injury have a critical window when they may be more receptive to smoking cessation counseling. Additional evidence-supported resources are available, including NRT, behavioral modifying pharmacologic, and the 1-800-QUIT-NOW national hotline. A multimodal approach yields the highest chance of smoking cessation.

Summary of answers

- Smokers are at increased risk for wound and pulmonary complications at the time of surgery.
- Tobacco exposure negatively affects bone healing, increases nonunion and delayed union rates, and can be expected to decrease subjective outcome scores in any procedure reliant on bone healing.
- Smoking discontinuation >4 weeks before an elective procedure reliably decreases pulmonary and wound complication rates to levels approaching those of nonsmokers.
- More research is needed to support the timing of smoking cessation in regard to its effect on bone healing.
- There is strong evidence to support the merits of smoking cessation counseling, especially when planning for elective procedures or in the immediate aftermath of an acute injury.
- Physicians and health professionals can aid patients actively trying to quit smoking by offering advice and support. Nicotine replacement, pharmacologic support, and utilization of available resources, including the National Tobacco Quitline, in combination with physician-guided counseling offers the highest chance of successful smoking cessation.

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12 Perioperative Medical Management

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Top three questions

1. In patients presenting with a fragility hip fracture, does routine preoperative echocardiography, compared to no echocardiography, improve survival?
2. In fragility fracture patients, does orthopedic and medical co-management, compared to usual care, improve outcomes such as length of stay, mortality, and readmission?
3. In fragility fracture patients undergoing surgery, does early surgery, when compared to delayed surgery, have an effect on mortality risk?

Question 1: In patients presenting with a fragility hip fracture, does routine preoperative echocardiography, compared to no echocardiography, improve survival?

Rationale

Wide practice variations exist with regard to obtaining preoperative echocardiograms for the purposes of cardiac risk stratification. It is necessary to establish whether patients undergoing fragility hip fracture surgery benefit from this test as part of a standard preoperative evaluation.

Clinical comment

Preoperative testing, if appropriately utilized, has the potential to improve patient outcomes. However, in some contexts, echocardiography and other tests can cause iatrogenic harm. In cases when surgical intervention is considered urgent, testing can lead to surgical delay. Additionally, many fragility fracture patients are medically complicated by chronic cardiovascular conditions, and abnormal test results may trigger intensive perioperative monitoring (raising risk of delirium, limiting mobility) and medication prescribing that can be harmful in the acute fracture setting.

Available literature and quality of the evidence

There are three retrospective cohorts deemed relevant and of acceptable quality to answer this question (level III).

Findings

A retrospective review of patients treated surgically for hip fracture found transthoracic echocardiography (TTE) prior to hip fracture was not associated with improvements in hospital mortality (3.8% vs 1.8%, p = 0.18), 30-day mortality (6.9% vs 6.6%, p = 0.90), or one-year mortality (20.6% vs 20.1%, p = 0.89).[1] Similarly, another retrospective review of fragility fracture patients (>65 years old) found that inpatient mortality was not statistically different between patients who did or did not undergo TTE prior to surgical repair (2.4% vs 3%, p =

0.493).[2] A third retrospective trial found that one-year mortality was not significantly affected by perioperative TTE (p = 0.137) in older adults with similar cardiac risk profiles undergoing hip fracture repair.[3] Notably, all these trials also measured surgical timing, and echocardiography was associatxed with delay to surgical intervention.

Resolution of clinical scenario

- Echocardiogram prior to hip fracture surgery rarely changes management but often will result in delay of surgery.
- Short- and long-term mortality are not improved by routine echocardiography prior to hip fracture surgery.

Question 2: In fragility fracture patients, does orthopedic and medical co-management, compared to usual care, improve outcomes such as length of stay, mortality, and readmission?

Rationale

In an effort to improve clinical outcomes for patients who experience a fragility hip fracture, there is a growing trend for geriatricians or hospitalists to co-manage the patient alongside orthopedic surgeons. This unique model of care has yielded promising results in several centers.

Clinical comment

Patients with fragility fractures often have multiple medical comorbidities that warrant careful management by care

teams well versed in perioperative geriatric medicine. The expertise of the medical doctor (usually a hospitalist or geriatrician) and their relationship with the orthopedic surgeon has the potential to positively impact clinical outcomes in this frail patient population. Co-management is a distinct relationship between two physicians in which there is shared responsibility for patient care and outcomes. Both teams perform daily rounds, contribute to the plan of care, document, and write orders. Frequent, respectful communication between teams is expected. Most co-management programs include close collaboration and aligning of practice patterns with emergency medicine and anesthesia physicians in addition to the disciplines of nursing, social work, occupational therapists, and physical therapists. Additional features of many high-performing co-management programs include proactive hospital discharge planning, standardized order sets, and ongoing quality improvement.

Available literature and quality of the evidence

Eight studies, all prospective (level II) and retrospective (level III) cohort studies, were deemed to be the highest-quality evidence on this topic.

Findings

A sentinel study in 2008 found that, compared to usual care, co-management of fragility fractures by geriatricians and orthopedists significantly improved length of stay (4.6 vs 8.3 days, $p < 0.001$), rates of postoperative infection (2.3% vs 19.8%, $p < 0.01$), complications (30.6% vs 46.3%, $p = 0.005$) and use of restraints (0% vs 14.1%, $p < 0.001$).[4,5] In-hospital mortality and 30-day readmission rates were also improved (1.6% vs 2.5%, $p = 0.68$, and 9.8% vs 13.2%, $p = 0.35$, respectively), though neither was statistically significant.

Several medical centers have subsequently instituted comprehensive co-management programs for fragility hip fractures and compared outcomes before and after program implementation (i.e. utilizing prospective observation with retrospective, historical controls). Results from five programs are outlined below:

1. A significant reduction in hospital length of stay (6.4–5.5 days, $p = 0.0004$) with stable 30-day readmission rate and time to surgery. Increase in number of patients receiving osteoporosis evaluation and receiving outpatient follow-up in the metabolic bone clinic ($p < 0.001$) and orthopedics clinic ($p = 0.005$).[6]
2. A significant reduction in inpatient length of stay after program implementation (delta = 1.6 days, $p = 0.01$). A nonsignificant improvement in the percentage of patients operated upon within 48 hours (86% vs 96%, $p = 0.15$).[7]
3. A significant increase in the number of hip fracture patients obtaining surgical fixation within 48 hours ($p = 0.013$) and a reduction in the average length of hospitalization (19.3 vs 15.1 days, $p = 0.013$).[8]
4. Significant reductions in length of hospital stay (27.5 vs 21 days, $p < 0.001$), time to surgery (41.8 vs 27.2 hours, $p < 0.001$) and in 30-day mortality (13.2% vs 10.3%, $p = 0.04$).[9]
5. Reduction in hospital length of stay (18.2 vs 11.9 days, $p < 0.001$), decrease in cost per case by $4953 ($p < 0.001$), decrease in time to surgery (45.8 vs 29.7 hours, $p < 0.001$). No significant difference but trend in reduced mortality rate (5.0% vs 2.1%, $p = 0.06$) and readmission rate (4.6% vs 6.0%, $p = 0.56$).[10]

A prospective trial of 400 home-dwelling patients with hip fractures aged 70 and above, randomly assigned the subjects to either a comprehensive geriatric care team or a standard orthopedic ward within the same medical center. Patients in the comprehensive geriatric care arm received structured, interdisciplinary comprehensive geriatric assessment, early discharge planning, early mobilization, and initiation of rehabilitation. This was compared with standard care in an orthopedic ward. The primary outcome was mobility (as measured by the Short Physical Performance Battery) four months after surgery for the fracture. Mean scores on the Short Physical Performance Battery for the comprehensive geriatric care group were significantly higher than those of the orthopedic care group ($p = 0.01$).[11]

A population based cohort study utilizing the Danish Multidisciplinary Hip Fracture Registry studied >11 000 patients aged 65 and above with hip fracture. The subjects were grouped by admission to an integrated orthogeriatric unit versus traditional orthopedics unit. Thirty-day mortality was found to be reduced for patients in the orthogeriatric unit (adjusted odds ratio [OR] 0.69; 95% CI: 0.54–0.88). Length of stay and time to surgery were not significantly different between groups in this study.[12]

Resolution of clinical scenario

Co-management between medical doctors and orthopedic surgeons has multiple benefits for patients with fragility hip fractures, most commonly a reduction in hospital length of stay and reduction in time to surgery. Decreased readmission rates and mortality have also been found with high-performing co-management centers. Variability in patient outcomes is likely reflected in how a co-management program is operationalized.

Question 3: In fragility fracture patients undergoing surgery, does early surgery, when compared to delayed surgery, have an effect on mortality risk?

Rationale

Early surgical repair for hip fracture has become standard in many centers, yet debate remains about the optimal timing of surgical repair, and what constitutes an unacceptable delay, especially in instances when expedited surgery places demands for finite hospital resources such as operating room time.

Clinical comment

Most patients undergoing hip fracture repair are at inherently high risk of perioperative complications and mortality due to frailty, multimorbidity, and advanced age. Delay in time to surgery can add additional avoidable risk, such as increased blood loss at the fracture site leading to hemodynamic instability and anemia, prolonged bedrest leading to skin breakdown and pneumonia, and prolonged periods of severe pain at the fracture site causing delirium and poor sleep. Common reasons for delay in surgical fixation include time spent medically optimizing the patient and lack of operating room availability.

Finding the evidence

Four studies were determined to be the highest-quality evidence (level II) and are reviewed here.

Findings

A 2010 systematic review (level II evidence) included 16 studies totaling 14 171 patients aged 60 and older.[13] In five studies that adjusted for medical complexity, age, and sex, early surgery (defined variably as either <24 hours, <48 hours, or <72 hours) was associated with a significant reduction in all-cause mortality by 19% (risk ratio [RR]: 0.81, 95% confidence interval [CI]: 0.68–0.96). All 16 studies provided unadjusted estimates of mortality, and collectively found that early surgery was associated with a 45% risk reduction of one-year mortality (RR 0.55; 95% CI: 0.40–0.75; p <0.001). Four studies within the systematic review discussed postoperative complications with respect to surgical timing. Early surgery (<24 or <48 hours) was found to result in a 41% risk reduction of postoperative pneumonia compared with delayed surgery (RR 0.59; 95% CI: 0.37–0.93; p = 0.02). Early surgery was associated with a 52% reduction in the incidence of postoperative pressure ulcers (RR 0.48; 95% CI: 0.34–0.69; p <0.001). Surgical timing did not significantly affect rates of thromboembolic events.

No significant mortality benefit to early surgery was found in a 2016 multicenter retrospective cohort study of 243 patients who had sustained fragility fracture of a native hip with median time to surgery of two days.[14] On Kaplan–Meier plotting, no relationship was found between timing of surgery (either <24 hours, 24–48 hours, or >48 hours), and mortality at 3 or 12 months. A higher American Society of Anesthesiologists (ASA) grade, however, was associated with a shorter survival time in this study.

A large, multicenter retrospective cohort study in Italy evaluated mortality risk at one year of 405 037 patients aged 65 and over who had undergone surgery for hip fracture.[15] Those who had surgery within two days of admission were found to have a significantly lower one-year

mortality than those who waited >2 days (HR: 0.83; 95% CI: 0.82–0.85).

Time from fracture to surgery (<12 hours, >12 hours; <36 hours and >36 hours) failed to have a significant effect upon one-year mortality in a prospective observational study of 2916 patients with hip fracture ($p = 0.40$).[16] More patients with high medical complexity as measured by ASA classification (groups IV and V) were in the late surgery group compared with the early surgery groups. Nonsignificant trends for adverse medical complications were found in those who had longer wait times for surgery (i.e. pressure sores, urinary tract infections, thrombosis, and pneumonia).

Resolution of clinical scenario

- Prompt surgical fixation for fragility hip fracture is indicated for patients who are medically optimized. There is a benefit of early surgery upon mortality risk as well as lower risk of common postoperative complications such as pressure ulcers, pneumonia, and delirium.
- To minimize mortality risk, timing of surgical intervention should be within 48 hours of fracture.[17] Some data have failed to show a significant improvement in mortality within the 72-hour window from fracture to OR,[14,16] suggesting that perhaps there is a plateau in the benefit of expedited surgery within this time period. Notably, early surgery was not associated with an increased risk of mortality in these study populations.

Summary of answers

- Routine echocardiogram does not improve outcomes for patients with hip fracture and may lead to unnecessary delays in care. Echocardiogram should be reserved for patients with evidence of new or unstable cardiac conditions that would benefit from cardiac intervention prior to surgery.
- Co-management between medical providers and orthopedic surgeons has the potential to decrease time to surgery, length of stay, mortality, and hospital readmission.
- Prompt surgical fixation of fragility hip fractures (<48 hours from fracture) is indicated for patients who are medically optimized in order to reduce risk of mortality and postoperative complications.

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13 Orthobiologics

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Clinical scenario 1

- A 64-year-old male with insulin-dependent diabetes and a 40 pack-year smoking history presents after a motor vehicle accident with an open tibial shaft fracture. The patient undergoes irrigation and debridement and placement of a reamed intramedullary nail.
- One year after presentation, the patient presents with continued pain at the fracture site. On plain radiographs, there is a continued gap at the fracture site with no evidence of cortical bridging.

Clinical scenario 2

- A 55-year-old obese female with chronic debilitating low back and right leg pain is found to have a degenerative spondylolisthesis of L5–S1 with significant stenosis.
- The patient has failed conservative therapy and is indicated for L5–S1 decompression and transforaminal lumbar interbody fusion.

Top three questions

1. In patients with open tibial shaft fractures, does the addition of bone-morphogenetic protein (BMP) at the fracture site during intramedullary nailing reduce the risk of nonunion compared to intramedullary nailing alone?
2. In patients with long-bone nonunions, does the use of BMP during revision surgery improve the rate of union compared to revision surgery alone?
3. In patients undergoing primary spinal fusion, does the use of BMP improve the rate of union compared to the use of iliac crest bone graft?

Question 1: In patients with open tibial shaft fractures, does the addition of bone-morphogenetic protein (BMP) at the fracture site during intramedullary nailing reduce the risk of nonunion compared to intramedullary nailing alone?

Rationale

Delayed fracture healing and nonunion can present a challenging clinical scenario for the treating physician. Recombinant human bone morphogenetic protein-2 ([rh]BMP-2) is the most studied orthobiologic used to enhance fracture healing.

Clinical comment

While the majority of fractures heal uneventfully, it has been reported that 5–10% of fractures either fail to unite or demonstrate a delay in healing, and this risk varies

depending on the bone involved (e.g. higher risk of delayed or nonunion in fractures of the tibia and proximal fifth metatarsal).[1] The concept of *healing* itself is also variably defined, as it can refer to radiographic healing (e.g. complete bridging at all cortices), clinical healing (e.g. no pain, return to activity), or a combination of the two. Therefore, alternative strategies designed to enhance fracture healing and to improve the treatment of delayed unions and nonunions are required. Growth factors, by virtue of their ability to regulate cell behavior, have been studied as a potential therapeutic to enhance fracture healing. The growth factors known to be expressed during fracture healing include BMPs, transforming growth factor (TGF) beta, fibroblast growth factor (FGF), and platelet derived growth factor (PDGF).[2–9] Bone morphogenetic proteins are members of the TGF-β superfamily, and have been most extensively studied in the context of fracture healing.[10] Bone morphogenetic proteins mediate their effect by binding to osteoprogenitor cells, thereby increasing the transcription of osteoinductive genes such as RUNX2 to enhance osteoblast differentiation.[11]

Two different recombinant BMPs have been approved by the Food and Drug Administration (FDA) for clinical use in specific populations: (1) rhBMP-2 (INFUSE® Bone Graft, Medtronic), which may be used for acute open tibial shaft fractures in addition to standard fixation with intramedullary nail, or as an adjunct treatment to single-level anterior interbody lumbar-spinal fusion (L2–S1) in patients with degenerative disc disease, and (2) rhBMP-7 (OP-1 Putty, Stryker) which has received a humanitarian device exemption approval in tibial nonunion when an autograft is not allowed or has failed.[12] While both of these BMPs have been approved for clinical use, their testing and regulation have been different.

Available literature and quality of evidence

There are a number of high-quality studies demonstrating the efficacy of rhBMP-2 in enhancing fracture healing in animal models.[13–15] To date, there are three level I studies evaluating the efficacy of rhBMP-2 in enhancing fracture healing in the setting of open tibial shaft fractures.

Findings

The first randomized controlled trial (RCT) to test the safety and efficacy of rhBMP-2 was the BESTT (BMP-2 Evaluation in Surgery for Tibial Trauma) trial.[16] In this trial, Govender et al. randomized 450 patients with an open tibial shaft fracture to receive either standard of care (intramedullary nail and soft tissue management, n = 150) or the standard of care plus an implant containing rhBMP-2/absorbable collagen sponge (0.75 mg/mL, n = 151 or 1.5 mg/mL, n = 149). The high-dose rhBMP-2 group (1.5 mg/mL) had significantly faster healing rates, lower infection rates (among Gustilo-Anderson type IIIA and IIIB fractures), and a significant reduction in secondary interventions.[16] At 12 months after surgery, 58% of the BMP-2 group were “healed,” compared to 38% of the group treated with intramedullary nail alone (p = 0.001). The study defined *healing* as a combination of radiographic healing and meeting clinical criteria for healing. There were no significant differences in complications or adverse events between treatment groups. Based on the results of this study, the FDA granted premarket approval for rhBMP-2 for the treatment of acute (within 14 days), open tibial shaft fractures. Following the publication of this study, other investigators noted the high proportion of patients in the control group that underwent unreamed intramedullary nailing compared to the study group.[17] Reamed intramedullary nailing has been shown to have a possible

benefit in the treatment of tibial shaft fractures, and was therefore likely a strong confounding variable in the BESTT trial results.[18]

Since the FDA approval of BMP-2 for clinical use, several trials using BMP-2 have had less-promising results. In 2006, Swiontkowski et al. combined the data from the original BESTT trial with a second prospective RCT using the same methodology.[19] The authors evaluated the use of rhBMP-2 in open tibial shaft fractures in two separate subgroups: (1) 131 patients with Gustilo-Anderson type 3A or 3B fractures and (2) 113 patients treated with reamed intramedullary nail.[19] Within each subgroup, a comparison was made between those receiving rhBMP-2 and controls who did not receive rhBMP-2. In the first subgroup, the authors found that there was a significant improvement in the rhBMP-2 groups, including fewer bone-grafting procedures ($p = 0.0005$), fewer patients requiring secondary interventions ($p = 0.0065$), and a lower rate of infection ($p = 0.0234$) compared to the control group.[19] In the second subgroup, there was no difference between those that received rhBMP-2 and those that did not. The authors concluded that rhBMP-2 significantly reduces the frequency of bone grafting in Gustilo-Anderson type 3 fractures, but that this study was not originally designed for subgroup analysis, and therefore the data should be viewed with caution. In addition, the authors stated that, although rhBMP-2 did not have any significant difference in patients that underwent reamed intramedullary nailing, there was a trend toward improvement in the rhBMP-2 group, and therefore larger RCTs should be performed to answer this question.

In 2011, Aro et al. evaluated the efficacy of rhBMP-2 in an RCT of 277 patients with open tibial shaft fractures treated with reamed intramedullary nailing.[17] The authors found no

significant difference in the rate of fracture healing or need for secondary procedures between treatment groups. Of note, there was a trend toward a higher rate of infection in the rhBMP-2 group compared to the control group (19% vs 11%, p = 0.0645; difference in infection risk = 0.09; 95% confidence interva: 0.0 to 0.17). The authors concluded that the healing of open tibial shaft fractures treated with reamed intramedullary nailing was not significantly accelerated by the addition of rhBMP-2. The trend toward an increased rate of infection differed from previous studies which demonstrated a possible decrease in infection rate with use of rhBMP-2, and requires further study.

Another consideration with regards to the use of rhBMP-2 is cost. The use of rhBMP-2 may add anywhere from $5000 to $15 000 to the cost of treatment, depending on the amount of protein needed.[20] Proponents argue that these costs are offset by savings related to decreased operative time, lack of a bone grafting procedure, quicker hospital discharge, and faster return to work. There is limited evidence to support these claims, and a high risk of bias as the authors received financial support from the BMP manufacturing company.[21,22] A 2007 systematic review of RCTs did find that BMPs were associated with a reduced operating room time, improvement in clinical outcomes, and a shorter hospital stay as compared to autograft.[23] This study evaluated both rhBMP-2 and rhBMP-7, and included acute tibial fractures, nonunions, and spinal procedures. The true cost efficacy of BMP is probably not known at this time. There is a need for more rigorous cost-effectiveness analysis related to the use of BMP.

Resolution of clinical scenario

- rhBMP-2 may assist with the healing of open tibial fractures treated with unreamed nails, but it has shown no effect when reamed intramedullary nailing is performed.
- There is conflicting evidence that BMP improves infection rates.
- The high cost and safety concerns for the use of rhBMP-2 currently limit its utility as a therapeutic in the treatment of open tibial shaft fractures.
- Further research aimed at increasing the clinical efficacy of rhBMP-2, while decreasing the risk of side effects and reducing overall cost, may improve the therapeutic potential of this growth factor.

Question 2: In patients with long-bone nonunions, does the use of BMP during revision surgery improve the rate of union compared to revision surgery alone?

Rationale

Delayed fracture healing and nonunion is commonly treated with autologous bone grafting, which has been shown to enhance fracture healing. Given the increased risk of complications and donor site morbidity with harvesting autograft bone, several studies have evaluated the efficacy of using BMP in treating nonunions.

Clinical comment

Fracture nonunion is a challenging clinical scenario, and the cause of delayed healing is frequently multifactorial. To

enhance fracture healing, autologous bone grafting has traditionally been used, as it not only provides structural support but also contains osteoinductive and osteogenic factors to assist with healing. The major drawback of autologous bone grafting is the donor site morbidity.[24,25] Therefore, several investigators have evaluated the efficacy of BMP in enhancing fracture healing for long-bone nonunions.

Bone morphogenetic protein-7, also known as osteogenic protein-1 (OP-1), is a member of the TFG-β superfamily that has been shown to be involved in fracture healing in experimental models. This molecule demonstrates an increased expression during endochondral ossification, and has been shown to strongly induce osteoblastic differentiation.[6,26] The strong association between fracture healing and BMP-7 expression led to human clinical studies to rescue nonunions, potentially through the stimulation of local osteoprogenitor cells.

Available literature and quality of evidence

Overall, there are few high-quality studies on the use of BMP-7 in treatment of long-bone nonunions. A 2010 Cochrane systematic review identified eight RCTs of the use of rhBMP-7 in fracture healing, however, these studies varied substantially in their methodology and setting.[27] Overall, the quality of the studies was graded “poor,” as most studies were small, did not report methods of randomization or allocation, or were industry sponsored.[27]

Findings

The first clinical trial of BMP-7 was a prospective RCT of 122 patients with 124 tibial nonunions, half of whom had previously been treated with intramedullary nailing.[28] The primary inclusion criterion was a tibial nonunion of at least

nine months' duration, with no evidence of healing in the three months prior to surgery. All patients received standard of care treatment with insertion of an intramedullary rod, and were randomized to receive either rhBMP-7 in a type I collagen carrier (treatment group, n = 63) or autologous bone graft (control group, n = 61).[28] At nine months after surgery, 81% of those treated with rhBMP-7 and 85% of those treated with autogenous bone graft were judged to have been treated successfully (p = 0.524).[28] Using the same time point, 75% of those in the rhBMP-7 group and 84% in the bone graft group had “healed” fractures, as determined by radiographic criteria (p = 0.218). The authors concluded that rhBMP-7 is a safe and effective alternative to bone graft for the treatment of tibial nonunion, without the added donor site morbidity from obtaining autologous bone graft.[28] While the data showed that BMP-7 was safe and effective, they showed no improvement compared with autologous bone grafting. As a result, the FDA did not provide premarket approval for this treatment. Instead, the FDA issued a *humanitarian device exemption*, allowing a limited distribution to 4000 patients per year only at institutions where an institutional review board (IRB) was present to monitor the use of this treatment.

There are a number of other complications associated with BMPs that are related to either the initial inflammatory response induced by the protein (seroma, neuritis, neck swelling) or their osteoinductive properties (heterotopic ossification, transient osteopenia).[29–31]

As a result of these concerns, rhBMP-2 is not approved for use in children, pregnant women, and cancer patients. rhBMP-2 is also contraindicated for use in the cervical spine as a result of severe complications including infection and dysphagia.[32,33] Similar to BMP-2, concerns regarding

patient safety and high cost surround the use of BMP-7. While there are fewer studies on the use of BMP-7 in the treatment of fracture and nonunion compared to BMP-2, similar side effects may occur, such as seroma, significant edema near the application site, and heterotopic ossification.[30,34] Similar to BMP-2, BMP-7 is expensive and the cost-effectiveness of this treatment modality is not known.

Resolution of clinical scenario

- In early studies, rhBMP-7 was shown to be equally effective as autologous bone grafting in the treatment of tibial nonunion in the context of intramedullary (IM) nail fixation as a secondary intervention.
- A variety of studies have demonstrated promising results for the use of rhBMP-7 in other long-bone nonunions, but the true cost and potential complications associated with this growth factor treatment are not known.
- Further high-quality evidence is needed to elucidate the future role of rhBMP-7 in the treatment of long-bone nonunions.

Question 3: In patients undergoing primary spinal fusion, does the use of BMP improve the rate of union compared to the use of iliac crest bone graft?

Rationale

Lumbar spinal fusion has been shown to significantly relieve pain and improve function in patients with degenerative lumbar spondylolisthesis. The risk of pseudarthrosis in patients undergoing spine fusion with iliac crest bone graft (ICBG) is estimated to be as high as 12%, with advancing age being a risk factor for this complication.[35] The use of BMP to enhance spinal fusion has been studied extensively.

Clinical comment

Pain and disability from degenerative spine disease, particularly low back pain, is a tremendous burden on both patients and society. Treatment of this disorder is typically conservative, although fusion of the spine is an option for patients who have failed conservative management. This can be accomplished from an anterior, posterior, or combined approach, and stability and fusion can be accomplished with or without the use of instrumentation. The gold standard to enhance fusion is autograft in the form of ICBG (ICBG), although there is significant morbidity associated with harvesting it.[36] Additional drawbacks of ICBG include increased operative time, blood loss, and postoperative pain.[36] In an effort to decrease the need of autologous graft, orthobiologics including BMP-2, have been used with increasing frequency.

Available literature and quality of evidence

Animal studies have demonstrated the efficacy of rhBMP-2 in spinal fusion.[37–42] There are a number of high-quality RCTs comparing the use of BMP-2 with ICBG in patient's undergoing lumbar spinal fusion.[43–49]

Findings

In 2002, Boden et al. first evaluated the efficacy of rhBMP-2 in enhancing posterolateral spinal fusion.[49] In this study, 25 patients were randomized in a 1 : 2 : 2 ratio to instrumented posterior fusion supplemented with autograft, instrumented posterior fusion with the addition of BMP-2, or BMP-2 alone without instrumentation.[49] The patients treated with BMP-2 (with or without instrumentation) achieved 100% rate of fusion at one-year follow-up, compared to only 40% of those patients treated with instrumentation and autograft ($p = 0.004$). The promising results of this pilot study led to a larger randomized study comparing rhBMP-2 in an absorbable collagen sponge carrier versus ICBG in combination with a structural allograft dowel in 131 patients undergoing anterior lumbar interbody fusion (ALIF).[48] At two-year follow-up, the rate of fusion (defined as radiographic healing based on four criteria as assessed by blinded radiologists) was significantly greater in the rhBMP-2 treated patients (98.5% vs 76.1%, $p < 0.001$).[48] The rate of revision surgery was also significantly higher in the control group, with eight patients returning to the operating room as compared to only two patients in the rhBMP-2 group (15% vs 3%, $p < 0.05$).

As the early results of BMP-2 use were promising in enhancing lumbar spinal fusion, novel carrier methods were developed. A modification of the BMP-2 carrier was developed which included a matrix that contained 15% hydroxyapatite and 85% β-tricalcium phosphate particles, and demonstrated improved properties with respect to bone remodeling.[50] Dimar et al. studied the use of this novel carrier in 463 patients who underwent posterolateral instrumented fusion randomized to receive either autogenous ICBG or BMP-2.[45] The authors found that patients in the ICBG group had longer operative times and greater blood loss, although the length of hospital stay was

comparable with the BMP-treated group. The rates of fusion were higher for rhBMP-2 at all time points, with 96% achieving fusion by radiographic parameters compared to 89% at two years ($p = 0.014$). Several other high-quality RCTs have supported the efficacy of BMP-2 in enhancing lumbar spinal fusion compared to ICBG,[44,47] while others have shown that there is no difference in fusion rates between BMP-2 and ICBG.[43]

A cost analysis of BMP-2 use was performed in conjunction with an RCT of patients over 60 years of age who underwent posterolateral lumbar fusion.[51] The investigators found that, compared to patients treated with BMP-2, the final costs at two years were over $2000 higher per patient for those treated with autogenous ICBG. The authors suggested that the increased expenses in the ICBG group may have been related to the nonsignificant increased rate of nonunion and subsequent revision operations.[51]

Resolution of clinical scenario

- High-quality RCTs indicate that rhBMP-2 is effective in achieving fusion and this rate of fusion is superior, or at least equivalent, to that achieved with ICBG.
- rhBMP-2 does not appear to be associated with significantly increased cost or rate of complications compared to ICBG in achieving lumbar spine fusion.

Summary of answers

- rhBMP-2 may enhance fracture healing in open tibial shaft fractures, but has shown no beneficial effect when reamed intramedullary nailing is performed.

- The high cost and safety concerns for the use of rhBMP-2 currently limits its utility as a therapeutic in the treatment of open tibial shaft fractures.
- In early studies, rhBMP-7 has shown to be equally effective as autologous bone grafting in the treatment of tibial nonunion.
- High-quality RCTs indicate that rhBMP-2 is effective in achieving lumbar spine fusion and this rate of fusion is superior, or at least equivalent, to that achieved with ICBG.

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14 Intimate Partner Violence

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Clinical scenario

- A 32-year-old woman presents to your fracture clinic with a displaced clavicle fracture.
- Your physical examination reveals multiple bruises across her chest, back, and arms which are in various stages of healing.
- Radiographs reveal a previous clavicle fracture and a partially united ulna fracture.

- The woman presents with her husband, who appears agitated and will not let her answer medical questions for herself.

Top three questions

1. In adult women with orthopedic injuries who present to fracture clinics, what is the prevalence of intimate partner violence (IPV), and how does this compare to the general population?
2. Do specific educational programs, compared to traditional education, for healthcare professionals improve universal IPV identification and referral to assistance programs?
3. In adult women who present to fracture clinics, are universal IPV identification and assistance interventions, compared to standard practice, effective at improving health outcomes for women?

Question 1: In adult women with orthopedic injuries who present to fracture clinics, what is the prevalence of intimate partner violence (IPV), and how does this compare to the general population?

Rationale

To determine the relevance of IPV (also known as *domestic violence*) to orthopedic practice, it is important to understand how frequently it affects individuals with orthopedic injuries.

Clinical comment

While healthcare professionals (HPCs) have a duty of care to protect all vulnerable patients, the prevalence of IPV amongst orthopedic injury patients is an important factor in determining the amount of resources that fracture clinics should invest to implement IPV identification and assistance programs.

Available literature and quality of the evidence

PRAISE (PRevalence of Abuse and Intimate Partner Violence Surgical Evaluation), a large, multinational, cross-sectional study, is the only study to have been conducted that assesses the prevalence of IPV within women attending fracture clinics.[1] To determine prevalence, women (n = 2945) attending fracture clinics (n = 12) located across Canada, the United States of America, the Netherlands, Denmark, and India were asked to complete an anonymous questionnaire. Additionally, multiple studies have been conducted to assess prevalence in other healthcare settings,[2] as well as the general population.[3] The best available evidence is a systematic review by Sprague et al. which examined IPV prevalence rates across medical and surgical healthcare settings and provided pooled prevalence estimates.[2] This review included 37 studies with a primary aim of determining IPV prevalence rates in adult women presenting to physicians regardless of medical specialty. Studies were conducted in family medicine (n = 15), emergency medicine (n = 12), obstetrics and gynecology (n = 3), internal medicine (n = 3), or multiple specialties (n = 4). Lastly, a large-scale systematic review conducted by the World Health Organization (WHO) examined IPV prevalence in the general population.[3] This review included all representative, population-based studies that examined prevalence of IPV. The study

included data from 185 studies from 86 countries. Because prevalence studies do not address therapeutic research questions, the level of evidence schema is not applicable and is therefore not provided here.[4]

Findings

IPV prevalence in orthopedic populations

The PRAISE study asked women to report experiences with IPV in their lifetime, within the last 12 months, and acutely.[1] For the purpose of this study, IPV was defined as physical, emotional, sexual, psychological, or financial abuse between intimate partners. Results showed that one in three participants experienced IPV at some point in their lifetime (34.6%; 95% confidence interval [CI]: 32.8–36.5%) and one in six experienced IPV within the past year (16.0%; 95% CI: 14.7–17.4%) (Figure 14.1). Additionally, one out of every 50 participants (2.7%; 95% CI: 1.3–2.2%) were attending fracture clinics to receive treatment for an injury sustained as a direct result of IPV (acute prevalence).

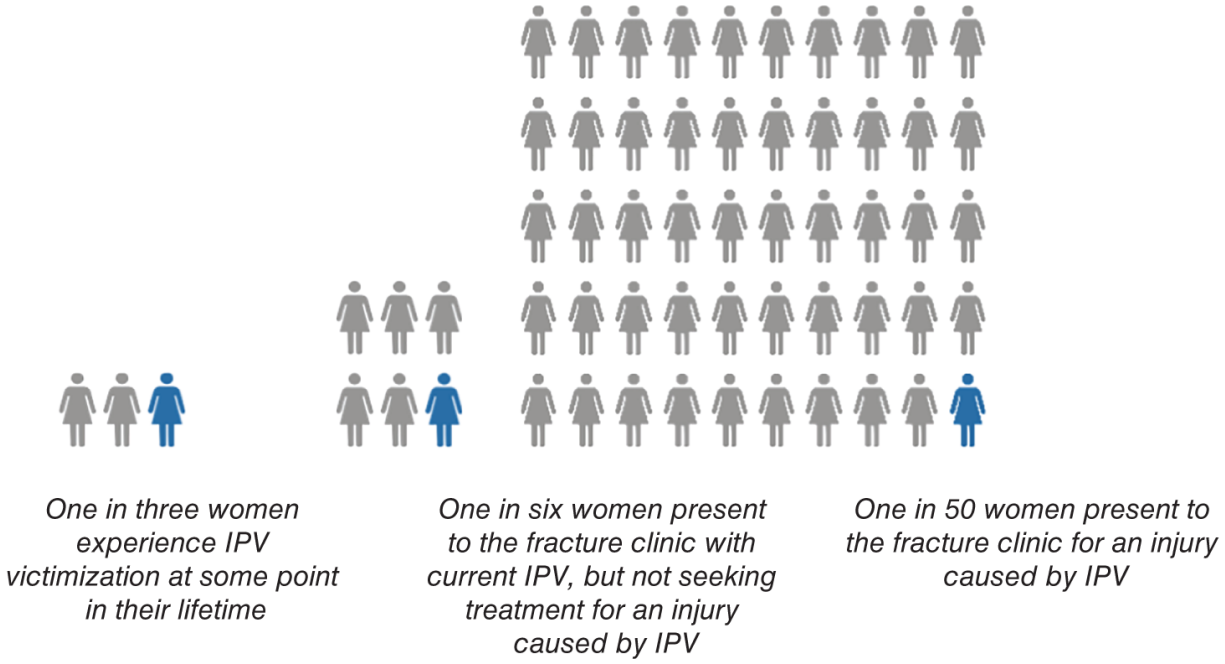

Figure 14.1 Prevalence of IPV in orthopedic populations.

IPV prevalence in other patient populations

The systematic review by Sprague et al. pooled the results of 10 studies conducted in emergency medicine which estimated a lifetime IPV prevalence rate of 38%.[2] Similar results were found in family medicine (40%, n = 12) and slightly higher in other subspecialties including obstetrics and gynecology (59%, n = 4). Pooled 12-month IPV prevalence rates were 20% in both family medicine (n = 8) and emergency medicine (n = 7). Additionally, between 2 and 4% of female patients presenting to emergency medicine settings were found to have injuries that were caused by IPV. There was heterogeneity in how studies defined IPV; however, this did not prevent pooling.

IPV prevalence in the general population

The systematic review by the WHO (2013) pooled the results of 155 population-based studies from 81 countries.[3] The estimated global lifetime prevalence for physical and sexual IPV among women who have been in relationships

was 30% (95% CI: 27.8–32.2%). Regional pooled estimates of prevalence ranged from 16.3% (95% CI: 8.9–23.7%) in East Asia to 65.6% (95% CI: 53.6–77.7%) in Central Sub-Saharan Africa. The pooled estimate for North America was 21.3% (95% CI: 16.2–26.4%) and ranged from 19.3% (95% CI: 15.9–22.7%) to 27.8% (95% CI: 22.7–33.0%) in Europe, depending on location.

Resolution of clinical scenario

- The lifetime prevalence of IPV among orthopedic patients is similar to the global prevalence, but higher than the North American general population prevalence.
- Orthopedic surgeons should be aware of the potential for IPV to be directly affecting the lives of their patients.
- Orthopedic surgeons should consider IPV as a possible cause of injury, or coexisting life circumstance.
- Concerning features in this clinical scenario include recurrent fractures, fractures, and bruises at various stages of healing, and the accompaniment of an agitated and controlling partner.
- The absence of these signs does not indicate the absence of IPV.

Question 2: Do specific educational programs, compared to traditional education, for healthcare professionals improve universal IPV identification and referral to assistance programs?

Rationale

Though orthopedic surgeons and allied HCPs are uniquely positioned to identify and provide critical assistance to women experiencing IPV, they often report barriers to doing so. Previous research has found that education is one key barrier. It is therefore important to understand whether an educational program for HCPs is an appropriate method for improving IPV identification and assistance programs.

Clinical comment

Continuing education that helps HCPs safeguard vulnerable populations is an important part of orthopedic practice. Educational programs that supply HCPs with knowledge about IPV, strategies for improving care, and information on local resources may be helpful for improving existing IPV identification and assistance programs.

Available literature and quality of the evidence

A single pretest–posttest study, EDUCATE (Education on Domestic Violence: Understanding Clinicians' and Traumatologists' Experiences), is available that evaluated the impact of an educational program on 140 orthopedic fracture clinic staff (level III evidence).[5,6] The program focused on teaching HCPs how to identify cases of IPV and provide assistance with an emphasis on practical training and referral to locally available resources. It included specific phrases to use when asking about IPV as well as videos of HCPs demonstrating how to ask about IPV and providing assistance upon disclosure. The study assessed changes in HCPs' knowledge, attitudes, beliefs, and self-reported behaviors (KABB) using the Physician Readiness to Manage IPV Survey (PREMIS) both immediately and

three months after completing the educational program. The PREMIS is a self-administered questionnaire and consists of 10 validated subscales which are scored individually and include: (i) perceived preparation to manage IPV, (ii) perceived knowledge of important IPV issues, (iii) actual knowledge, (iv) preparation, (v) legal requirements, (vi) workplace issues, (vii) self-efficacy, (viii) alcohol/drugs, (ix) victim understanding, and (x) practice issues. Additionally, there are two systematic reviews available on this topic; however, neither review presents a meta-analysis. The first is a systematic review by Waalen et al. which included any study that investigated barriers to provider IPV identification programs or that tested an intervention designed to change provider behaviors around IPV identification.[7] This study included 24 articles, 12 on barriers and 12 on educational interventions. The second is a systematic review by Zaher et al. which included randomized controlled trials (RCTs) of educational interventions among physicians.[8] This review included nine RCTs that described different educational approaches with various outcome measures. Both systematic reviews are considered level II evidence.

Findings

Effect of educational programs for HCPs on IPV identification and assistance

The pretest–posttest study evaluating the EDUCATE program found HCPs had significantly improved scores for KABB on all 10 PREMIS subscales immediately after training (p values ranged from <0.0001 to 0.0056) and on 8 out of the 10 subscales three months after training (all p <0.0001). This suggests that HCPs were better prepared to identify and assist with IPV after completing the educational program. Contrastingly, the systematic review

by Waalen et al. found, based on the 12 studies evaluating educational interventions, that education of HCPs alone had no effect on IPV identification rates.[7] However, when paired with other strategies (i.e. providing specific questions to ask), educational programs were found to have a significant increase on identification rates (no point estimate provided). Other strategies included introducing a protocol for IPV identification and referral or having a designated IPV advocate staff member. Similar results were found in the systematic review by Zaher et al.[8] Of the nine RCTs included in the study, three examined the effects of educational interventions and found an increase in IPV knowledge, but no change in behavior regarding identification of IPV. The other six studies investigated the effects of multifaceted educational interventions and were found to benefit victims of IPV and increase referrals to IPV resources.

Clinical pearls from the EDUCATE study

The EDUCATE program advocates for fracture clinics to take an active role in identifying and providing assistance to women experiencing IPV (Figure 14.2). Table 14.1 includes tips from the EDUCATE program on what to consider when asking patients about IPV. For more information about the EDUCATE program, and IPV in orthopedic patients, please go to www.IPVeducate.com, or the Canadian Orthopaedic Association (COA) or American Academy of Orthopaedic Surgeons (AAOS) IPV position statements.[9,10]

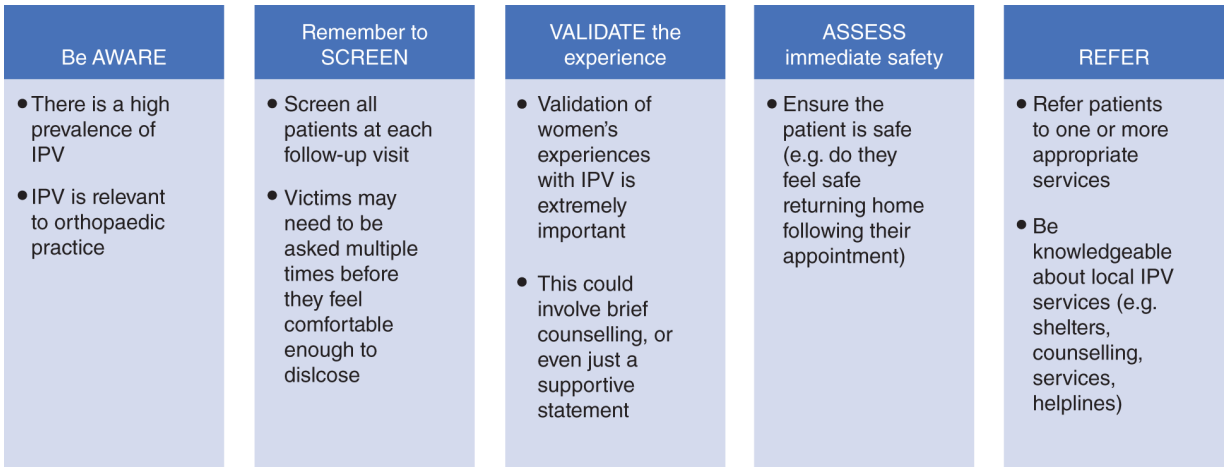

Figure 14.2 Role of the orthopedic surgeon.

Table 14.1 Tips for healthcare providers on asking about IPV from the EDUCATE program.

	Tips for healthcare providers
WHO	• Being a woman is the strongest single predictor for becoming a victim of IPV • IPV affects women of all races/ethnicities, socioeconomic status, age, and relationship status • Some signs of IPV include: frequent injuries, injuries at different stages of recovery, strangulation injury, explanation for mechanisms of injury that do not match the injury pattern, chronic unexplained pain, substance abuse, depression, anxiety • However, not all victims show these signs – the best way to consistently identify IPV is to **ask all female patients**
WHEN	• Ask about IPV at any time during a fracture clinic appointment; mid-appointment may be most appropriate (once rapport has been established) • Develop a routine and conversation starter that is comfortable for you and fits with your practice • Important to ask about IPV at each appointment – women may need to be asked multiple times before they feel comfortable enough to disclose IPV

	Tips for healthcare providers
WHERE	• Ensure environment is safe to ask (i.e. no others present, including partners) • If partners won't leave, you can make a statement that reflects routine practice (even if it's not something you specifically need to have done) i.e. “Mr. Smith at this point in time we need to take Mrs. Smith in for an x-ray. Could you please wait in the waiting room until we call you?”

	Tips for healthcare providers
HOW	• Don't use the words *abused* or *battered* – women may not identify with these labels or recognize their partner's behaviors as abusive • When there are injuries that are suggestive of IPV you could try saying something like: “The injuries you have suggest to me that someone hit you. Is that possible?” “In my experience, often women get these kinds of injuries from someone who has hit them. Has this happened to you?” • When there are injuries not suggestive of IPV, you could try saying something like: “From my experience, I know that being hurt physically or emotionally at home is a problem for many women. Is it a problem for you in any way?” “We know violence in the home affects many women and directly affects health. Have you ever experienced being hurt physically or emotionally at home?” “Violence can be a problem in many women's lives, so I now ask every female patient I see about their safety in their relationships. Do you feel safe in your relationship?”

As the treating physician your role is not to be an expert in delivering IPV interventions. Instead it is important to be aware of IPV, make the effort to identify patients

experiencing IPV, validate their experience, assess safety and refer appropriately.

Resolution of clinical scenario

- Orthopedic surgeons looking for education on IPV should look for programs, such as EDUCATE, that include practical guidance or are combined with IPV identification and assistance programs.
- Education programs consistently improve HCP knowledge regarding IPV.
- There is mixed evidence as to whether these programs also change behavior in terms of referrals to services.

Question 3: In adult women who present to fracture clinics, are universal IPV identification and assistance interventions, compared to standard practice, effective at improving health outcomes for women?

Rationale

To determine whether fracture clinics should routinely ask patients about IPV, it is important to understand if asking about IPV is effective at eliciting a greater number of disclosures. Furthermore, since IPV identification programs should be implemented in conjunction with IPV assistance programs, it is also important to understand if IPV assistance programs are beneficial to patients.

Clinical comment

The high prevalence rate of IPV amongst female orthopedic patients suggests that fracture clinics may be an appropriate setting to identify and help IPV victims. When asking about IPV, it is important for HCPs to be knowledgeable and comfortable with responding appropriately to disclosures and offering appropriate assistance. While fracture clinics may deliver some brief interventions (e.g. referral, brief counselling, immediate safety assessment), other more intensive interventions (e.g. long-term advocacy and counselling, safety planning) may be delivered in a community setting and initiated through a referral from the fracture clinic.

Available literature and quality of the evidence

There have not been specific studies that evaluate IPV identification programs in orthopedic settings; however, one Cochrane systematic review and meta-analysis (level I evidence) by O'Doherty et al. has evaluated the effectiveness of IPV identification programs conducted within healthcare settings.[11] This review included all RCTs and quasi-RCTs published before February 2015 that evaluated the effectiveness of IPV screening by an HPC compared to usual care (or no screening). *Usual care* could refer to a control group which did not receive screening, or a comparator group that received screening by a non-HCP. Eleven eligible trials were identified (n = 13 027) and the overall quality of these studies was low to moderate. One Cochrane systematic review and meta-analysis (level I evidence) has also been published that investigates the effectiveness of IPV assistance programs, though it is not specific to healthcare settings.[12] This review included RCTs that evaluated advocacy-based IPV interventions. *Advocacy interventions* in this context referred to individual or group-based programs if safety planning was included or if they facilitated access to community resources. Comparisons

between brief (<12 hours) and intensive interventions (>12 hours) were made; however, all studies included were very heterogeneous in study methodology, setting, intensity, and abuse severity. Furthermore, the quality of evidence was considered low to moderate for brief advocacy interventions and very low for intensive advocacy interventions.

Findings

Effectiveness of IPV identification programs

O'Doherty et al. included six studies in a meta-analysis which showed that IPV identification programs are effective at increasing the rates of IPV disclosure (relative risk [RR] 2.33; 95% CI 1.39–3.89).[11] Debate also exists as to whether IPV identification programs are effective at increasing referrals to IPV services. O'Doherty et al. reported that based on three studies (n = 1400) there was no evidence that IPV identification programs increase referrals (RR 2.67; 95% CI: 0.99–7.20). Similarly, debate exists as to whether IPV identification programs help to improve health outcomes for women, including recurrent IPV post-identification. Only two studies reported rates of re-victimization and found that there was no reduction in IPV after screening. MacMillan et al. was the only included study in the O'Doherty systematic review that examined the impact of IPV screening on physical health and psychological health (including quality of life, post-traumatic stress disorder, depression, and substance abuse) and found there to be no associated significance.[13] Investigators of the study noted, however, that the results are complicated by a high loss to follow-up rate (43%). Based on these results O'Doherty et al. concluded that there was insufficient evidence to recommend routine screening for IPV. It is important to note that most of the

studies included in the Cochrane review did not include an IPV assistance component, and identification programs alone are unlikely to reduce violence or improve quality of life.[14,15] Furthermore, IPV identification programs have been endorsed by both international and national associations such as the WHO, the COA, and the AAOS.[9,10,16]

IPV identification programs and the potential for harm

Many critics of IPV identification programs argue that although these programs increase rates of IPV disclosures, there is a lack of proven effectiveness in increasing referral rates or health outcomes which may make IPV identification a potentially harmful intervention. Very few studies, however, have investigated harm as an outcome, as pointed out by O'Doherty et al.[11] MacMillan et al.'s study was the only one included in the O'Doherty et al. systematic review that investigated the potential for IPV screening to cause harm to victims.[13] Based on their results, not only did screened women report no harms of screening, but a subscale analysis comparing women exposed to IPV and not exposed to IPV showed no difference between groups and their reports of potential harm of screening.

Effectiveness of IPV assistance programs

One of the primary outcomes of most IPV assistance interventions is the rate of re-victimization. The most rigorous study that has investigated the effectiveness of IPV assistance programs at reducing rates of re-victimization is the systematic review by Rivas et al.[12] Three studies were pooled and found that there was no effect on physical abuse for brief advocacy interventions in 12 months of follow-up (standardized mean difference = 0.00; 95% CI: −0.17–0.16). Pooled results from two

intensive advocacy trials, though, showed a reduction in physical abuse at 24 months (OR 0.39; 95% CI: 0.20–0.77), but not at 12 or 36 months. In addition to evaluating the effectiveness of IPV assistance programs at decreasing rates of re-victimization, many studies have examined the effects of IPV assistance programs on other health outcomes for women. Evaluations of quality of life from the meta-analysis by Rivas et al. suggests that intensive advocacy programs (two studies) may improve the quality of life of women (n = 265) recruited from shelters (mean difference 0.23; 95% CI: 0.00–0.46). Contrastingly, analysis of two brief interventions (n = 149) showed that fewer women developed depression (OR 0.31; 95% CI: 0.15–0.65) with brief advocacy, but that there was no evidence that intensive advocacy is effective at reducing severity of depression at <12 months or two years. In interpreting these results, it is important to consider the appropriateness of the outcomes and follow-up periods used to measure effectiveness. Most outcomes for IPV assistance programs are relatively short (12–24 months). Considering the barriers to leaving abusive relationships (including, but not limited to, safety, custody of children, financial burden, and housing stability), it may take a much longer follow-up to see a decrease in IPV re-victimization or an increase in quality of life.

Resolution of clinical scenario

HPCs should consider asking patients about IPV experiences, and if disclosed they should:

- Respond supportively and offer brief interventions when comfortable.
- Be aware of more intensive interventions available to patients in the community.

- Refer patients to available services.

HPCs should be comfortable using methods to ensure a private and safe environment for asking about IPV and should ask about IPV on multiple occasions, if following a patient serially.

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15 Pain Management in Orthopedic Surgery

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Clinical scenario 1

- A 72-year-old male patient has been managed nonoperatively for years for his right knee osteoarthritis, and is now having worsening pain.
- He undergoes an uneventful total knee arthroplasty (TKA).
- He is treated with multimodal analgesics perioperatively, including patient-controlled analgesia (PCA) followed by short- and long-acting opioids orally.
- Upon discharge postoperative day two, he is given a prescription for anticoagulation orally and oral opioids for pain management.

Clinical scenario 2

At six months after his TKA, the patient continues to have pain that interferes with his daily activities.

He uses slow-release morphine twice a day along with acetaminophen four times daily.

He sometimes uses a cane when the pain is severe.

Due to persisting pain, the patient feels his sleep and quality of life are affected.

Top three questions

1. In adult patients undergoing surgery, which acute perioperative pain management strategies, compared to others, are most effective at managing perioperative pain?
2. In adult patients undergoing surgery, which opioid-sparing strategies, compared to standard care, are most effective?
3. In adult patients undergoing surgery, what is the burden of persistent postoperative pain, and are there any interventions which, compared to usual care, can prevent persistent postsurgical pain?

Question 1: In adult patients undergoing surgery, which acute perioperative pain management strategies, compared to others, are most effective at managing perioperative pain?

Rationale

Total knee arthroplasty (TKA) is associated with significant pain postoperatively.[1] Poorly controlled pain following TKA can not only lead to impaired mobilization and rehabilitation but also increase the likelihood of complications.[2] Severity of acute pain is also known to be

an independent predictor of chronic postsurgical pain after TKA.[3] Ideal perioperative analgesic technique should provide excellent analgesia, limit opioid consumption, and facilitate early mobilization and rehabilitation.

Clinical comment

Broadly, the analgesic options following TKA include pharmacological and nonpharmacological techniques. In clinical practice, these options tend to be used either alone or in combination.

- *Systemic options include*: (1) opioid-based intravenous PCA and (2) multimodal oral analgesia, including acetaminophen, nonsteroidal anti-inflammatory drugs (NSAIDs) +/− opioid analgesics.
- *Regional options include*: (1) local anesthetic infiltration techniques, including periarticular infiltration, intra-articular infiltration, and infiltration between the popliteal artery and the capsule of knee (IPACK); (2) peripheral nerve blocks (+/− continuous catheter techniques), including femoral nerve block (FNB) or adductor canal block (ACB) +/− sciatic nerve block (SNB); and (3) neuraxial techniques, including continuous epidural analgesia and intrathecal morphine.
- *Nonpharmacological options include*: continuous passive motion (CPM), preoperative exercise, cryotherapy, electrotherapy, including transcutaneous electrical nerve stimulation (TENS), and acupuncture.

Available literature and quality of the evidence

As we included systematic reviews and meta-analyses of randomized controlled trials (RCTs) for all interventions except the use of cannabis were level I. Only three studies

were found with regards to cannabis, all of which were level III or IV.

Findings

Intraoperative anesthetic techniques

TKA is commonly performed either under general anesthesia (GA) or neuraxial anesthesia (spinal or epidural). A systematic review involving knee and hip arthroplasty observed that neuraxial anesthesia was associated with shorter hospital length of stay compared to GA, without any other differences.[4] Another systematic review and meta-analysis demonstrated decreased surgical site infections after hip and knee arthroplasty with neuraxial anesthesia compared to GA.[5]

Systemic analgesia

NSAIDS

COX-2 inhibitors are preferred over nonselective NSAIDS because of the lower risk of perioperative bleeding. A meta-analysis of eight small RCTs showed that the perioperative administration of selective COX-2 inhibitors reduces postoperative pain, opioid consumption, and postoperative nausea vomiting (PONV) after TKA without increasing the risk of perioperative bleeding.[6] Furthermore, perioperative use of selective COX-2 may improve postoperative knee function.[6]

Acetaminophen

Two recent systematic reviews show that intravenous acetaminophen added to multimodal analgesia leads to reduced pain and opioid consumption after total joint arthroplasty with few adverse effects.[7],[8] Further, no

difference has been observed between oral and intravenous acetaminophen.[9]

Gabapentinoids (gabapentin and pregabalin)

Although one review with meta-analysis did not find clinically important effect with gabapentin for the management of acute pain following TKA,[10] another review with meta-analysis observed that it decreases opioid requirements at 24 and 48 hours.[11] Small (probably clinically insignificant) analgesic efficacy, antiemetic and opioid-sparing effects of gabapentinoids need to be balanced against a significant increase in the risk of sedation.

Ketamine

There is limited evidence on the use of ketamine for TKA. Three small RCTs showed that adding intraoperative small-dose intravenous ketamine infusion to multimodal analgesic regimen decreased morphine consumption and improved early rehabilitation without increasing the incidence of side effects.[12–14]

Cannabis

As there has been renewed interest in looking at the effect of cannabis on pain and other outcomes in TKA patients, we performed a specific search to identify any such literature. In general, substance abuse increased the risk of complications including infection and prolonged discharge.[15,16] Another retrospective study using the Medicare database suggests that the risk of revision surgery is significantly increased among cannabis users.[17]

Steroids

At least six different groups have reviewed the evidence on use of systemic steroids for TKA.[18–23] The included studies had marked heterogeneity regarding the type and dose of steroid used. The reviews either show an analgesic benefit of steroid use or no difference in pain compared to control patients. In particular, steroid use was associated with reduced pain at rest and activity and lower opioid use during the first 24 hours after operation. Additionally, patients given perioperative steroids had a lower incidence of nausea and vomiting.[19] Generally, no significant adverse effects were observed in the outcomes, such as superficial or deep infections. However, perioperative steroid use was associated with clinically nonsignificant increase in blood glucose for the first six hours. The analgesic benefits of systemic steroids were more apparent in patients undergoing TKA compared to total hip arthroplasty.[18]

Regional analgesia

Femoral nerve block (FNB)

A Cochrane review observed that FNB provided more effective analgesia than PCA opioid alone with less nausea and vomiting, and it was as effective as epidural analgesia.[24] Although continuous FNB can provide superior pain relief and fewer side effects, local infiltration analgesia (LIA) can potentially provide similar outcomes of analgesia with earlier mobilization.[25] More recently, another review with meta-analysis showed that ACB provides equally effective analgesia with early ambulation.[26]

Intrathecal morphine

A meta-analysis showed that FNB provides equal postoperative pain control with similar morphine

consumption compared with intrathecal morphine following TKA, although there were fewer side effects in the FNB groups.[27] Particularly, the incidence of itching in the intrathecal morphine group was higher than in the FNB group.[28] Postoperative urinary retention is also a potential concern.[29]

FNB + SNB

Five different systematic reviews support the analgesic benefits of adding SNB to FNB following TKA. SNB added to FNB reduces postoperative opioid consumption and reduces pain scores after TKA.[30–33] However, SNB is not routinely used in clinical practice, as it interferes with the postoperative assessment of potential nerve injury and impedes early mobilization.[34]

Periarticular local infiltration analgesia (LIA)

There is significant heterogeneity in the mixture and technique of LIA used across the studies which makes the comparisons with other modalities difficult.[35] When compared to placebo, LIA appears to reduce pain scores and opioid consumption in the first 24 hours (but not 48 hours) postoperatively. Another systematic review suggested that intraoperative periarticular but not intra-articular injection may be helpful in pain control up to 24 hours after TKA.[36] Overall, LIA reduces short-term pain compared to placebo and provides improved early postoperative pain relief compared to FNB.[37] Multiple reviews comparing LIA with FNB found that LIA was as effective as FNB in terms of 24- to 48-hour pain scores, total morphine consumption, and range of motion.[25,38–40] However, two systematic reviews found that single-injection FNB was associated with reduced pain upon movement compared with single-injection LIA.[41,42]

Intra-articular local anesthetics

Compared with the placebo group, the single local anesthetic group had a significantly lower pain score at rest, less opioid consumption, and greater range of motion at 24, 48, and 72 hours postoperatively. There were no significant differences in side effects or length of hospital stay.[43] Considering other effective treatment modalities that are available, intra-articular LA is not a popular option.

Adductor canal block (ACB)

- *ACB vs. FNB:* most studies have found no significant differences in pain scores at rest or mobilization at 24 and 48 hours between ACB group and FNB group. While Dong et al. found no significant differences in the strength of quadriceps and adductors between ACB and FNB groups,[44] multiple different systematic reviews have shown early sparing of quadriceps strength and enhanced ambulation ability with ACB.[45–52]
- *ACB vs. LIA*: evidence suggests that LIA is more effective than ACB regarding pain control and opioid use following TKA. However, no clear difference has been observed regarding short-term functional outcomes when the two modalities are compared.[53]
- *ACB + LIA:* evidence suggests that adding ACB to LIA is more effective than single therapy within the first 48 hours following TKA.[54,55] Combining the two modalities was associated with statistically significant lower pain scores, opioid consumption, and more distance walked on postoperative day 1. These differences were not significant on postoperative day 2.[56]

Epidural analgesia

As peripheral nerve blocks[57] and LIA[58] are as effective as epidural analgesia for postoperative pain management in TKA, the role of continuous epidural analgesia is limited considering the higher risk of complications associated with epidural and the common use of anticoagulants for thromboprophylaxis after TKA.

Liposomal bupivacaine (LB)

LB is intended to prolong the action of bupivacaine employed for regional analgesia. It has been shown that LIA with LB is better than placebo for analgesia;[59] it provides similar pain relief as FNB with decreased opioid requirements,[60] and with shorter length of hospital stay than FNB.[61] However, considering that other meta-analyses have shown equivalent analgesia between LIA and FNB (without any LB), its superiority is uncertain.

IPACK

IPACK refers to infiltration between popliteal artery and the capsule of the knee. It is typically performed under ultrasound guidance to achieve pain relief to the posterior aspect of the knee by blocking branches of the tibial, common peroneal, and obturator nerves in the popliteal region. The only RCT comparing LIA group versus IPACK + ACB and modified LIA reported significantly lower pain scores on ambulation than the control group on postoperative days 0, 1, and 2.[62] Patients in the IPACK group were more satisfied and had lower intravenous PCA usage.

Nonpharmacological options

Continuous passive motion (CPM)

A Cochrane review found no benefits of CPM on function, pain, or quality of life after primary TKA.[63] In contrast, CPM is expensive, time consuming, and associated with an increased length of stay.

Preoperative exercise

The evidence suggests that preoperative exercise may slightly improve early postoperative pain and function for patients undergoing joint replacement. However, these effects may not be clinically important considering small effect size and short duration.[64]

Cryotherapy

A Cochrane review concluded that the potential benefits of cryotherapy on blood loss, postoperative pain, and range of motion may be too small to justify its use. Again, the potential inconveniences and expense do not justify its routine use after routine TKA.[65]

Electrotherapy including transcutaneous electrical nerve stimulation (TENS)

A recent meta-analysis suggests that electrotherapy is probably the most effective nonpharmacological intervention. Electrotherapy not only reduces early pain but also changes the long-term trajectory of recovery from pain after TKA.[66] However, its effect on long-term pain is not known.

Acupuncture

Meta-analysis of three studies (230 patients) suggested a significant short-term improvement in pain scores and opioid use with acupuncture use.[66]

Question 2: In adult patients undergoing surgery, which opioid-sparing strategies, compared to standard care, are most effective?

Rationale

Given the current opioid crisis globally and especially in North America, any strategies which can help to minimize perioperative opioid use are important to identify.

Clinical comment

Pain is a common presenting complaint for orthopedic surgery patients; in addition, major orthopedic surgery such as TKA is undoubtedly painful in and of itself given the large incision, extensive dissection, and significant bony work. Thus, opioid-sparing strategies are an important and topical issue in orthopedic surgery.

Available literature and quality of the evidence

Two recent network meta-analyses (NMAs) compare all commonly used analgesic modalities for TKA (level I).

Findings

Comparison of analgesic techniques for TKA

The NMA by Terkawi et al. looked at 170 studies with 17 different options and concluded that the combination of FNB + SNB was the best overall modality regarding analgesia, opioid consumption and rehabilitation profile.[67] However, heterogeneity in measuring rehabilitation precluded them from combining rehabilitation outcomes other than for range of motion and degree of flexion. Thus, it is very likely that the combination of femoral and SNB,

though it provides the best analgesia, may not provide the best condition for active rehabilitation. Dong et al. assessed the outcomes of pain scores, opioid consumption, and length of hospital stay in their NMA of 58 studies.[68] They concluded that continuous FNB is superior to other treatments in decreasing pain scores and opioid requirement. Based on the comparison of individual treatment effectiveness, periarticular infiltration combined with intra-articular infiltration was the best analgesic strategy during the first 6–8 hours after TKA. Periarticular infiltration combined with FNB or epidural was the best during the first postoperative day. The potential to impede rehabilitation and risk of fall is less with intra- and periarticular infiltration and ACB.

Effect of regional analgesia on long-term functional outcome after TKA

There is a lack of evidence on the effect of regional anesthesia on long-term outcomes after TKA. A review of evidence pointed out that more studies are needed to establish the effects of regional analgesia on long-term function and adverse events such as the risk of falls after joint replacement surgery.[69]

Findings

All modalities using LA have the potential for an opioid-sparing effect. However, the choice of a particular modality must be weighed against its risks and should be considered along with nonopioid analgesics as components of multimodal analgesia. FNB, ACB, and LIA provide good analgesia with decreased opioid requirements and are currently preferred at most centers over FNB + SNB. However, ACB and LIA have less potential to impede rehabilitation and hence may facilitate earlier discharge.

Question 3: In adult patients undergoing surgery, what is the burden of persistent postoperative pain, and are there any interventions which, compared to usual care, can prevent persistent postsurgical pain?

Rationale

Despite a technically well-performed surgery, a substantial proportion of patients suffer from persistent postoperative pain and decreased quality of life after TKA. As the number of patients undergoing TKA increases, it is important to address the problem of persistent pain to decrease patient suffering and chances of long-term opioid medication, and to decrease continued healthcare expenses.

Clinical comment

TKA remains the definitive therapy for osteoarthritic knee pain. There is an expectation by most patients to overcome the problem of chronic knee pain with their surgery. Although it is an effective modality of therapy for the majority of patients, 10–34% of patients report persisting pain and functional limitation.[70],[71] Surgical and anesthetic interventions performed during the perioperative period may have a bearing on the incidence and severity of persistent pain.

Relevant background

Epidemiological studies have observed that higher preoperative pain, pre-existing psychological comorbidity in the form of anxiety or depression, pain catastrophizing, and the presence of other musculoskeletal pain conditions

(such as low back pain) increase the chances of persistent pain, apart from the duration and severity of acute postoperative pain.[72] [73]

Available literature and quality of the evidence

As we had two systematic reviews of RCTs (Cochrane) and six individual RCTs (MEDLINE), we rate the evidence as level I.

Findings

There is insufficient evidence to promote the use of regional analgesia for the improvement of long-term functional outcome or pain after elective TKA.[74] One study reported decreased incidence of neuropathic pain six months after TKA with the use of perioperative oral pregabalin; 0% (0 of 113) in the pregabalin group and 5.2% (6 of 115) in the placebo group.[75] However, similar results have not been shown by other studies using pregabalin.[76]

Summary of answers

A variety of systemic, regional, and nonpharmacological pain management modalities exist with differing levels of efficacy and evidence.

For perioperative pain management for elective uncomplicated primary TKA (opioid naive patient), we recommend:

- Spinal anesthesia.
- Aggressive multimodal analgesia with acetaminophen, COX-2 inhibitor, and perioperative systemic steroids.
- ACB +/− catheter.
- LIA +/− IPACK.

For perioperative pain management for elective opioid tolerant primary TKA, we recommend:

- Spinal anesthesia.
- Continue routine opioids (possibly increase dose short term).
- Aggressive multimodal analgesia with acetaminophen, COX-2 inhibitor, and perioperative systemic steroids.
- Continuous FNB or continuous ACB.
- Consider gabapentinoids in the perioperative to postdischarge period.
- Consider ketamine infusion in the perioperative period.
- SNB may be used as a rescue analgesia for uncontrolled pain after TKA.

No analgesics or psychological interventions, used perioperatively, have been shown to influence the incidence or severity of persistent pain after TKA.

Based on the knowledge of potential risk factors, appropriate patient selection, improving pre-existing pain, and psychological comorbidities should be considered to improve long-term pain and functional outcomes.

Observational studies and a clinically reasonable rationale support the potential for decreased chances of persistent pain with better management of acute postoperative pain.

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16 Post-Traumatic Stress Disorder and Depression

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Clinical scenario

- A 32-year-old Latin American presents to the office three months after an open bicondylar tibial plateau fracture via a motor vehicle accident.
- He has been reliving the accident and is anxious and depressed.
- He has been having difficulty sleeping.

Top three questions

1. What are post-traumatic stress disorder (PTSD) and depression, and does their presence, in orthopedic patients, have an impact on postoperative outcomes?
2. How prevalent is PTSD and depression after acute trauma in the orthopedic trauma population?
3. In orthopedic trauma patients with PTSD and/or depression, are there resources that, compared to usual care, improve outcomes?

Question 1: What are post-traumatic stress disorder and depression, and does their presence, in orthopedic patients, have an impact on postoperative outcomes?

Rationale

Identifying the difference between these two psychological disorders is very important for the orthopedic surgeon to comprehensively treat patients.

Clinical comment

PTSD and depression have distinguishing characteristics and potentially affect outcome.

Findings

Orthopedic injuries have a significant impact on society. In 2000, productivity losses from lower extremity injuries alone was $17.5 billion which is 75% more than the losses from nonfatal traumatic brain injuries, 50% more than the losses from nonfatal upper extremity injuries, and 600% more than losses from nonfatal spinal cord injuries.[1]

Treatment of orthopedic trauma injuries is multifaceted. What is often overlooked is the psychological component of recovery. Certain psychological factors such as depression, anxiety, and PTSD can affect outcomes. Zatzick et al. reviewed 101 trauma patients evaluated at admission and again at one year. In this study, PTSD had the strongest association with outcome. Patients with PTSD demonstrated worse outcomes in seven of eight domains of the 36-Item Short-Form Health Survey compared to patients without PTSD.[2]

The first step in management of these patients is to understand these disorders. Depression is a psychiatric disorder characterized by persistent sadness, decreased ability to experience pleasure, and decreased interest in usual activities.[3] Depression can affect outcomes by reducing patient motivation to fully engage in rehabilitation activities.[4] PTSD is a disorder secondary to a traumatic experience or a long-term exposure to a traumatic stress which is characterized by re-experiencing the incident, avoidance, and hypervigilance. The current diagnostic criteria for PTSD is defined by the *Diagnostic and Statistical Manual of Mental Disorders* (DSM-5), and includes symptoms from the following categories: intrusion, avoidance, negative alterations in cognition and mood, alteration in arousal, and reactivity.[5]

Half of patients with PTSD go on to develop chronic progression and take approximately three years to remit. A third of the patients will suffer from PTSD-related symptoms for more than 10 years.[6] Clinical presentation and timing of onset is variable. deRoon-Cassini et al. found that patients can present with PTSD symptoms as early as the initial hospital stay. At one to six months postdischarge, some patients developed worsening symptoms, others' symptoms improved, and some had the same severity throughout.[7] When identifying the stressor causing PTSD, patients reported a lack of control over the situation leading up to the traumatic event and/or death of a family member at the scene.[8]

Risk factors, signs, and symptoms

Young age, female sex, poor education, lower socioeconomic class, alcohol abuse, drug abuse, and physical pain have been identified as risk factors for the development of PTSD.[9],[10] A study by Norman et al. on 115

patients evaluated by using the Visual Analog Scale (VAS) at a level one trauma center identified pain as a risk factor for the development of PTSD. An increase of half a standard deviation on the VAS was found to have a fivefold increase at four months and seven-fold increase at eight months postdischarge of developing PTSD.[11] Castillo et al. identified a recurring relationship between pain and associated psychological distress. It was determined that pain and psychological stress could be exacerbated by each other during the chronic stage of trauma. More specifically, it was discovered that pain influenced psychological distress early in the recovery process. At the one-year mark, anxiety in turn affected the level of pain.[12]

Another variable in the development of PTSD is resilience. Clinically, resilience is healthy recovery from extreme stress and trauma.[13],[14] Patients have varying degrees of resilience with several factors involved with its development. Wilson et al. identified seven factors associated with resilience.[13] These included: (i) locus of control (i.e. a sense of efficacy and determination), (ii) self-disclosure of the trauma experience to significant others, (iii) a sense of group identity and sense of self as a positive survivor, (iv) the perception of personal and social resources to aid in coping in the post-traumatic recovery environment, (v) altruistic or prosocial behaviors, (vi) the capacity to find meaning in the traumatic experience and life afterward, and (vii) connection, bonding, and social interaction within a significant community of friends and fellow survivors. King et al., studying Vietnam veterans and PTSD, found that hardy veterans coped better with life than less hardy veterans due to the hardy veterans seeking out and utilizing social support in their local environment to overcome stress.[15]

Question 2: How prevalent is PTSD and depression after acute trauma in the orthopedic trauma population?

Rationale

PTSD and depression are very common in the orthopedic trauma population and have been shown to affect outcome.

Clinical comment

PTSD and depression affect postoperative outcomes. By understanding the prevalence of these psychological disorders in the orthopedic trauma population, surgeons will be more aware of their presence and potentially more likely to screen patients.

Findings

Psychological stress is common in the orthopedic population. In the Lower Extremity Assessment Project (LEAP) study, patients reported elevated levels of psychological distress compared to age- and sex-matched cohorts. One-fifth to one-sixth of the patients reported severe levels of depression, phobia, and anxiety.[16] The National Study on the Costs and Outcomes of Trauma, a multicenter prospective cohort study performed at 69 hospitals in 12 states on 2707 patients, had 20.7% of patients report symptoms of PTSD. Starr et al. used a Revised Civilian Mississippi Scale for Post-traumatic Stress Disorder to measure PTSD symptoms in 580 persons at two level-one trauma centers. Fifty-one percent of these patients met the criteria for PTSD including 57% of those involved in motor vehicle accidents and 65% of the pedestrians struck by a motor vehicle.[17] A prospective cohort on 200 patients with musculoskeletal injuries were

studied to identify the correlation of injury and the development of psychopathology. Patients were evaluated by the General Health Questionnaire and on functional outcomes (measured by Short Form 36 [SF-36], Sickness Impact Profile, and Musculoskeletal Function Assessment). Pre-existing psychological disturbance was seen in 11% of patients but increased to 46% at two months; this later decreased to 22% at six months.[18]

Depression, anxiety, and PTSD are some of the predictors of poor long-term quality of life and reliance of pain medication.[19],[20] The National Study on the Costs and Outcomes of Trauma measured the extent to which patients with PTSD developed functional impairment at 12 months, and the severity of this impairment, through the use of the SF-36 work questionnaire. Patients with PTSD had significantly increased impairments in all functional domains, associated with elevated odds of one or more activities of daily living impairments, a threefold increase of PTSD and five- to sixfold increase of PTSD plus depression.[21]

Lower extremity injuries have a high incidence of PTSD. Crichlow et al. assessed 161 patients 3–12 months postdischarge. A subset of 99 patients with lower extremity injuries reported that 57% of patients had a minimal level of depression, 26% had a moderate level of depression, and 6% had severe levels of depression.[22] A Korean study on 148 men who had one or more long bone fractures found that 27% met the criteria for the diagnosis of PTSD. Lower extremity fracture, multiple extremity fracture, and higher pain VAS were significantly related to the occurrence of PTSD.[23] A Norwegian cohort of patients recovering from orthopedic injuries were one standard deviation below the healthy population with almost one-third of these patients having a diagnosis of PTSD.[24] When looking specifically at

amputations, the number of patients with PTSD is drastically higher. Copuroglu et al. reported that, during the early post-traumatic period, 36.3% of patients were being treated for PTSD; by year five, the percentage drastically rose to 77.2%.[25] PTSD is often seen after motor vehicle accidents and has been shown to persist long after the physical injuries have healed. Studies found that more than 25% of survivors experienced PTSD with even more meeting the subthreshold criteria.[26,27] More than half of the motor vehicle crash survivors with PTSD at one year still had the diagnosis two years later.[28]

Depression has been found in 45% of orthopedic trauma patients with a strong correlation of global disability.[22] Crichlow et al.'s study on 116 patients found a relationship between injury severity and level of depression. In this study, 55% of patients reported minimal depression, 28% experienced moderate depression, and 13% experienced severe depression. Patients with open fractures were 4.6 times more likely to experience depression than patients with closed fractures.[22] Patients with severe lower extremity injury had a 56.6% rate of depression two years after injury.[16]

Williams et al. performed a study looking to estimate the prevalence of PTSD and depression in hand injured patients, and found that 30.2% (32/106) met diagnostic criteria for PTSD, 17.9% (19/106) for depression, and 15.1% (16/106) qualified for both PTSD and depression. This study also found that the association between PTSD and depression was significant ($p < 0.01$). Patients with PTSD had significantly lower scores than those who did not endorse items consistent with PTSD or depression on the SF-36 subscales. In addition, those with both PTSD and depression had significantly lower scores than patients who had neither PTSD nor depression.[29]

Question 3: In orthopedic trauma patients with PTSD and/or depression, are there resources that, compared to usual care, improve outcomes?

Rationale

It is imperative that the treating health provider understand the different resources available to patients. A thorough understanding of how these programs work will assist healthcare providers in directing patients to the appropriate mental health provider.

Clinical comment

Understanding the resources available to patients will help guide them to the appropriate treatment.

Treatment

Cognitive behavioral therapy (CBT) is the mainstay of nonpharmacologic management for PTSD with the focus on changing perception after trauma along with exposure to provocative stimuli in a controlled manner. CBT is also the mainstay of nonpharmacologic treatment for depression.[30] Immediate one-time CBT has not shown to be effective in treating PTSD, though longer-term therapy has shown efficacy. An RCT of 152 patients who underwent four sessions of CBT 5–10 weeks after injury found significantly lower total impact of event scores compared to those not receiving any intervention.[31`] Although CBT has been shown to positively affect outcomes, medication is often used as a supplement. Pharmacologic management for PTSD and depression consists of antidepressants with

selective serotonin reuptake inhibitors (SSRIs) as the most commonly used. Sertraline and fluoxetine are the most commonly used SSRIs. Tricyclic antidepressants, monoamine oxidase inhibitors, and anticonvulsants are also used.[32] It is important to note that the use of benzodiazepines for PTSD has fallen out of favor due to the vulnerability of this patient population to developing addiction.[33]

Trauma collaborative programs – for example the Trauma Collaborative Care (TCC) program – focus on the relationship between a patient and their physician. These programs coordinate resources to patients to address the psychosocial sequelae following trauma. These models focus on the need to empower patients and have them assume more responsibility for their recovery and the need to be proactive. This is implemented by the creation of proactive practice teams which can be molded by training providers to facilitate patient engagement.[34]

The Trauma Survivors Network (TSN) was developed by the American Trauma Society in conjunction with Johns Hopkins University.[35] The TSN is a standardized program which has been used in multiple trauma centers throughout the United States (www.traumasurvivorsnetwork.org). This highly integrative program has been shown to be effective in improving functional outcomes and quality of life. The TSN consists of (i) timely access to information for patients and families via the TSN website, and receipt of the *Trauma Patient and Family Handbook*, which provides information regarding their injury and what to expect during their hospitalization; (ii) peer support provided by visitation of experienced trauma survivors, regular support groups, and an online social networking website; (iii) family education classes; and (iv) a self-management class (NextSteps, offered both online and in person). The goal of

these components is to increase the patient's self-efficacy, support network, and capacity to actively engage in the recovery process.[35]

During the postoperative period, the orthopedic surgeon will often be the only physician that the patient sees on a consistent basis. In order to be able to effectively treat orthopedic trauma patients, the orthopedic surgeon needs to be able to identify PTSD and depression early in the postoperative process. This will not only allow patients to heal from the physical trauma but also help them recover psychologically.

Summary of answers

- Depression and PTSD are common among orthopedic trauma patients.
- The presence of depression and/or PTSD has a negative impact on postoperative/postinjury outcomes.
- Many resources exist for patients who have been through a traumatic experience.
- Orthopedic surgeons should be proactive in assessing for, recognizing, and referring the occurrence of depression and PTSD in their patients.

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17 Nutrition and Supplements in Orthopedic Care

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Clinical scenario

Over the weekend, you operatively treat two patients with femoral neck fractures. During rounds on Monday morning, you follow up with the patients with a new surgical resident. You both walk into the first wardroom and differences in body mass index (BMI) and nutrition status between the two patients do not pass unnoticed. One patient is obese and the other shows signs of undernutrition. Your resident then starts asking questions...

Top three questions

1. In orthopedic surgery patients, do vitamin D and calcium supplementation, compared to no supplementation, confer a benefit in terms of fracture risk, fracture healing, or bone mineral density?
2. Among patients undergoing orthopedic surgery, do those with a high BMI have a higher risk of complications compared to those with a normal BMI?

3. Among patients undergoing orthopedic surgery, do those with undernutrition or malnutrition have poorer outcomes compared to those with adequate nutrition?

Question 1: In orthopedic surgery patients, do vitamin D and calcium supplementation, compared to no supplementation, confer a benefit in terms of fracture risk, fracture healing, or bone mineral density?

Rationale

Vitamin D and calcium are well known to be necessary for building and maintaining bone strength and preserving skeletal health across all ages.[1,2] Individuals obtain vitamin D from exposure to sunlight or by consuming foods that contain vitamin D, while calcium is primarily retrieved from dairy products.[1,3] It can be difficult to obtain adequate vitamin D and calcium from these sources alone, especially since sun exposure levels vary depending of the latitude, season, time of day, skin pigmentation, cloud cover, smog, and sunscreen use, so individuals often also derive vitamin D and calcium from supplements.[1,3,4] Although Health Canada recommends that adults take a daily vitamin D supplement of between 600–800 IUs, vitamin D deficiency and insufficiency are prevalent and recognized as worldwide health problems.[1,5] The role of calcium in the pathogenesis of osteoporosis has received increasing attention and the recommended amounts for calcium intake have risen steadily in the past 35 years.[6] This is mainly because calcium deficiency activates bone destruction through bone resorption mechanisms. The use of

prevention therapies, such as vitamin D and calcium supplementation, aims to maintain and improve bone quality and minimize fractures.

Clinical comment

Osteoporosis and osteopenia are highly prevalent among fracture patients.[7] As well, there is uncertainty and a lack of consensus in the use and dosing of vitamin D and calcium supplementation.

Available literature and quality of the evidence

Although the US Institute of Medicine and Health Canada have released dietary reference intakes for vitamin D and calcium. To the best of our knowledge, there are no widely accepted clinical guidelines on supplementation in an orthopedic fracture care practice.[1],[2] Pre-appraised research information was obtained using the OrthoEvidence database of randomized trials. Further, meta-analyses consisting of level I evidence randomized controlled trials (RCTs), level II and III evidence prospective and retrospective comparative studies, as well as level IV evidence case series, and cross-sectional studies, have been published that address our question.[8],[9]

Findings

Vitamin D deficiency in orthopedic patients

Vitamin D deficiency is endemic worldwide in all subsets of orthopedic patients, and osteoporosis is commonly found in those patients with fractures. Although most experts define vitamin D deficiency as levels <20 ng/mL and insufficiency as 21–29 ng/mL, there is no universal agreement for these cutoffs.[10] Based on these definitions, approximately 75% of the general population have serum 25-hydroxyvitamin D

(25[OH]D) levels below 30 ng/mL.[11] One study on orthopedic trauma patients with acute fractures reports overall prevalence rates for combined vitamin D deficiency or insufficiency of 77% and a 39% prevalence rate for vitamin D deficiency alone.[12] It has also been suggested that the prevalence of vitamin D inadequacy, defined by the authors as serum 25(OH)D levels <32 ng/mL, in athletes is prominent.[11]

Vitamin D and calcium supplementation for osteopenia and osteoporosis

Weaver et al. have conducted an updated meta-analysis of vitamin D and calcium supplementation which suggests that the combination of vitamin D and calcium supplementation is statistically significantly associated with reduced fracture risk.[9] Further results from this meta-analysis suggest that supplementation could decrease the relative risk of fractures by 14% (relative risk [RR] = 0.85; 95% confidence interval [CI] 0.73–0.98).[9] However, a meta-analysis by Zhao et al. showed no significant association of calcium or vitamin D (alone or combined) with reduced risk of hip, vertebral, or other fractures in community-dwelling older adults.[13] Also, calcium supplementation alone has not been demonstrated to reduce the rate of fractures in elderly women.[14]

Vitamin D supplementation and fracture healing

Data on the effects of vitamin D and calcium supplementation on fracture healing are limited. Briefly, research suggests that vitamin D supplementation safely increases 25(OH)D serum levels and improves bone mineral density.[8] To date, there has only been one preliminary study, presented as an abstract at a meeting, which reported a trend toward lower nonunion rates in

acute fracture patients receiving vitamin D supplements.[15] Additionally, there is emerging, but inconclusive, evidence that vitamin D levels decrease following a fracture[16–20] and it has been hypothesized that postfracture vitamin D supplementation alone, and possibly in combination with oral calcium supplementation, may improve fracture healing.[21–23] However, although limited, there is some evidence suggesting that dietary calcium intake is associated with cardiovascular risk. Any benefit of calcium supplements on preventing fractures may be outweighed by increased cardiovascular events, more specifically myocardial infarction and stroke.[24] As evidence regarding the use of these therapies has shown inconsistent results, there is a need for more high-quality research to be conducted in this area.

Risks of vitamin D and calcium supplementation

Vitamin D supplementation typically leads to increased levels of serum 25(OH)D. The most well-known risk of increased 25(OH)D is hypercalcemia, which occurs secondary to increased calcium intestinal absorption and bone resorption.[25] However, evidence that excess vitamin D can cause hypercalcemia in generally healthy adults comes from daily intakes of vitamin D >100 000 IU or having levels of serum 25(OH)D exceeding 240 nmol/L (96.15 ng/mL), which is far higher than that necessary to achieve the benefits.[26]

The side effects reported after receiving calcium therapy have been an important drawback for its use. Constipation, excessive abdominal cramping, bloating, upper gastrointestinal (GI) events, GI disease, GI symptoms, and severe diarrhea or abdominal pain were described in a meta-analysis by Lewis et al.[27] More importantly, hospital admissions for GI complaints were higher in calcium-

treated patients (6.8%) compared to those who obtained a placebo (3.6%) (RR = 1.92; 95% CI: 1.21–3.05; p = 0.006).

It has also been reported that the use of calcium supplementation may be associated with increases in urine calcium excretion.[28] In the Women's Health Initiative Calcium/Vitamin D Supplementation Study, there was found to be an increased risk of renal calculi following calcium supplementation.[29]

Regarding cardiovascular events, an RCT of calcium supplementation compared to placebo in healthy postmenopausal women showed a statistically significant increase in the number of women who had a myocardial infarction in the calcium treatment group (RR = 2.24; 95% CI: 1.20–4.17; p = 0.0099).[25] These effects could outweigh benefits that calcium supplements may have on bone health.

Resolution of clinical scenario

- Vitamin D and calcium supplementation is important in the prevention and management of osteoporosis.
- Vitamin D deficiency is common in orthopedic patients.
- It remains unknown whether vitamin D improves fracture healing.

Question 2: Among patients undergoing orthopedic surgery, do those with a high BMI have a higher risk of complications compared to those with a normal BMI?

Rationale

The prevalence of obesity, defined as a BMI of ≥30 kg/m^2, has tripled since 1975, with 650 million adults being reported as obese globally in 2016.[30] Obesity is leading to an increased use of the healthcare system.[31] Obese individuals often have multiple co-morbidities and are therefore at a higher risk for perioperative complications.[32] Co-morbidities associated with obesity include type 2 diabetes mellitus, hypertension, dyslipidemia, cardiovascular disease, stroke, sleep apnea, hyperuricemia, gallbladder disease, gout, osteoarthritis, and certain cancers.[33] Orthopedic patients who are obese may be at a higher risk of both general medical and fracture-related complications. Specific intraoperative and perioperative challenges and complications have also been associated with obesity, including the requirement of special surgical equipment, longer operating times, potentially significant anesthetic issues, as well as a longer postoperative length of stay.[34] From a biomechanical point of view, postoperative rehabilitation may prove difficult as well, as there may be an increase in stress on orthopedic implants with subsequent possible failure of fixation or mechanical failure of the implant itself.[35–38]

Clinical comment

Despite the increase in obesity globally, there are no clinical guidelines for managing overall orthopedic surgical care in obese patients. Therefore, as with any patient undergoing surgical management, it is important to evaluate potential risk factors for both mortality and morbidity while having an understanding of the potential co-morbidities associated with obesity.

Available literature and quality of the evidence

To the best of our knowledge, there are no existing clinical guidelines on this topic. No pre-appraised research information is currently available. Level II–III evidence, consisting of cohort studies, has been used to address this question.

Findings

A study including a general surgical population reported obesity rates of up to 30%.[32] In a large longitudinal study of older US men, 68% of all incident clinical fractures and 62% of incident hip fractures occurred in those who were overweight or obese, while 19% of all clinical fractures and 13% of hip fractures occurred in obese men.[39] In the Million Women Study in the UK, almost one-half of all postmenopausal hip fractures occurred in women who were overweight (40%; BMI 25–29.9 kg/m^2) or obese (9%; BMI $\geq 30\ kg/m^2$).[40]

Regarding orthopedic patients, an analysis of the demographic information reported in recent studies, such as the Fixation using Alternative Implants for the Treatment of Hip Fractures (FAITH) trial, indicates that up to 40% of patients undergoing surgical procedures for femoral neck fractures were overweight or obese.[41] A recently completed substudy of the FAITH trial found that for every five-point increase in BMI, participants experienced an average increased risk of 19% for revision surgery (HR = 1.19; 95% CI: 1.02–1.39; p = 0.027) during the 24-month follow-up period.[42]

In patients with multiple system trauma and surgically treated fractures, complications occurred more often in obese patients (38.0% vs 28.4%; p = 0.03). Significantly more infections (11.4% vs 5.50%; p = 0.04) and renal failures occurred in this patient group (5.70% vs 1.38%; p= 0.02), as well, more deep vein thrombosis events were

identified.[43] In another study, reoperation for implant failure, nonunion, or infection was 4.68 (95% CI: 2.03–10.76) times more likely to occur in patients with BMI >30 kg/m^2.[44]

Another study comparing thresholds for obesity in trauma patients states that the greatest rise in morbidity and mortality was seen among patients with a BMI >35.[45] The mortality of patients with a BMI >35 (obese patients) was 10.7% vs 4.1% for patients with a BMI <35 (lean patients; p = 0.003). Highest mortality rates were seen among patients with a BMI of ≥35. This study also indicates that patients with BMIs between 30 and 35 have similar outcomes to leaner patients (BMI <30).

Although the BMI scale is a convenient method for quantifying the amount of tissue mass in an individual, it does not take into account muscle mass, bone density, overall body composition, racial and sex differences, or changes that occur with age. These confounding variables, which also include socioeconomic status, comorbidities, and geographic region may potentially affect BMI and outcomes in studies resulting in important bias, deeming it an imperfect tool for outcome predictions in patients with obesity.[46] Similarly, these confounding variables may have the ability to distort the association between BMI and outcomes of interest when examining the trauma, surgical, and orthopedic population.

Resolution of clinical scenario

- Overweight and obese patients are a notable and growing group of patients undergoing surgical orthopedic trauma procedures.
- Patients with a higher BMI have typically reported a greater number of complications for important

outcomes, including serious adverse events and revision surgery.

- Ensuring that the perioperative risks and short- and long-term complications for these patients are considered preoperatively is important to minimize increased healthcare costs attributable to complications.

Question 3: Among patients undergoing orthopedic surgery, do those with undernutrition or malnutrition have poorer outcomes compared to those with adequate nutrition?

Rationale

According to the World Health Organization, undernutrition is defined by poor anthropometric status, and is mainly a consequence of inadequate diet and frequent infection, leading to deficiencies in calories, protein, vitamins, and minerals.[47] *Malnutrition* refers to deficiencies, excesses, or imbalances in a person's intake of energy and/or nutrients.[48]

It is estimated that at least 23–33% of patients undergoing orthopedic surgery are malnourished or at risk for malnutrition upon admission.[49] Often, these patients continue to be at risk of undernutrition and malnutrition following their surgical procedures. Previous research suggests that being undernourished may lead to an increase in the development of postoperative medical complications and slower recovery.[50]

Clinical comment

Malnutrition status could be a marker for other comorbidities which are more important in determining outcomes. Making links between nutritional status and recovery is complicated by the fact that markers of dietary protein depletion measured in blood – such as albumin, prealbumin, and transferrin – are partly affected by fluid shifts and responses to injury and infection.[51] Other more direct markers of nutritional status include mid-upper-arm circumference, triceps skinfold, and weight in relation to height (BMI).

Available literature and quality of the evidence

Level II evidence RCT, quasi-RCTs, and prospective cohort studies of nutritional interventions are available to address this question.

Findings

Prevalence

At least one-third of orthopedic trauma patients of all ages that are admitted to a hospital are malnourished, and if left untreated, many of these patients will continue to decline nutritionally, which may adversely impact their recovery and increase their risk of complications and readmission.[52] Furthermore, nutrient deficiencies are highly prevalent in obese patients. In particular, the prevalence of vitamin D insufficiency in obese individuals ranges from 80 to 90%.[53] These patients should ideally undergo a nutritional consultation before elective surgery procedures in order to determine how their nutritional status may impact their recovery process.

Clinical management

Effective management of malnutrition requires collaboration among multiple clinical disciplines including physicians, nurses, dietitians, and pharmacists.[54]

Incidence of complications

A prospective cohort study including 1055 traumatology and orthopedic patients admitted to a level I trauma center aimed to evaluate the relationship between malnutrition and clinical outcomes.[55] Although this study did not focus strictly on orthopedic patients, the overall findings suggested that patients at risk of malnutrition had suboptimal clinical outcomes. Patients at risk of malnutrition showed statistically significant prolonged hospital stay (18.2 ± 11.7 vs 13.7 ± 11.1 days; Spearman's rank correlation, $R = 0.273$; $p < 0.05$), and delayed postoperative mobilization (4.0 ± 4.9 vs 2.2 ± 2.9 days; Spearman's rank correlation, $R = 0.281$; $p < 0.05$). In patients being at risk for malnutrition, the incidence of adverse events was statistically significantly higher compared to that of patients with normal nutritional status (37.2 vs 21.1%; $p < 0.001$). Adverse events were defined as death, infections, wound healing disorders, further operations, thrombosis, and other adverse events (postoperative anemia, postoperative electrolyte imbalance with therapeutic necessity, or treatment specific complications).

Several studies have also evaluated the impact of malnutrition on fracture healing. In spite of fractures eventually healing in the malnourished patient, there is evidence to suggest that both the quality and strength of the healed bone are reduced.[56] Findings have also proposed that perioperative malnutrition may be related to increased rates of pneumonia, urinary tract infections, wound infections, and sepsis.[57] Not only do these complications lead to overwhelming situations for both

patients and their families, but hospitals and insurance companies may incur additional financial burdens from these events.[57] To minimize the negative outcomes associated with undernourishment, prompt identification of malnourished or underweight orthopedic patients, as well as early initiation of specialized nutrition intervention, may help.[57]

Resolution of clinical scenario

- High prevalence of undernutrition in orthopedic surgery patients.
- Risk of undernutrition following orthopedic surgery.
- Malnutrition is associated with higher complication rates in traumatology and orthopedic patients.

Summary of answers

- Although available data suggest that the combination of vitamin D and calcium supplementation is associated with a reduced risk of fractures in females between the ages of 58 and 88, there is emerging evidence to suggest that oral calcium supplements alone may be associated with an increased risk of cardiovascular events.
- Higher BMI ratios seem to be associated with increased risks of short- and long-term operative complications.
- In patients being at risk for malnutrition, the incidence of adverse events was statistically significantly higher compared to that of patients with normal nutritional status.

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III Joint Reconstruction

18 Outpatient Total Joint Arthroplasty

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Clinical scenario

- A patient without significant co-morbidities undergoing a primary total joint arthroplasty (TJA).
- The patient has sufficient caregiver support at home.
- The patient lives close to the operating hospital in case of emergency.

Top three questions

1. In eligible patients undergoing TJA, does performing the procedure and discharging the patient on the same day of the operation result in an additional risk of serious adverse events or readmissions compared to the same procedures performed on an inpatient basis?
2. In eligible patients undergoing TJA, does performing the procedure on an outpatient basis result in cost savings compared to the same procedures performed on an inpatient basis?
3. In patients undergoing an outpatient TJA, what factors are necessary to ensure a successful procedure compared to the general population undergoing TJA?

Question 1: In eligible patients undergoing TJA, does performing the procedure and discharging the patient on the same day of the operation result in an additional risk of serious adverse events or readmissions compared to the same procedures performed on an inpatient basis?

Rationale

The primary concern with performing outpatient TJA is patient safety. As readmission rates are increasingly used as a performance indicator, there is concern that outpatient surgery may increase these rates. If TJA are going to be performed on an outpatient basis, it is imperative to ensure there are no additional risks of serious adverse events compared to the same procedures performed on an inpatient basis.

Clinical comment

The major deterrent for outpatient TJA is patient safety. Proponents against outpatient joint replacements advocate that the majority of complications following surgery occur within the time-frame of the typical hospital stay.[1] There is a fear that outpatient TJA will lead to additional adverse events and an increase in hospital readmissions. However, the majority of literature illustrates that outpatient joint replacements can be safely performed with comparable complication rates to similar inpatient procedures.

Available literature and quality of the evidence

- Level IV: 1 systematic review.[2]
- Level I: 2 randomized controlled trials (RCTs).[3],[4]
- Level III: 2 large observational studies.[5],[6]

Findings

To assess the safety of performing outpatient total joint arthroplasty recent literature has quantified the rate of adverse events following outpatient arthroplasty as either acute (intraoperative or immediately perioperative) or postdischarge. A systematic review of outpatient total hip arthroplasty (THA), total knee arthroplasty (TKA), and unicompartmental knee arthroplasty (UKA) reported that the rate of acute adverse events ranged from 0 to 25%, whereas the rate of postdischarge adverse events ranged from 0 to 7%.[2] More importantly, this review reported that outpatient procedures did not lead to a higher complication rate compared to inpatient procedures.[2]

Two RCTs allocated study participants undergoing a THA to be either discharged on the day of surgery (outpatient) or admitted to the hospital overnight following surgery (inpatient).[3],[4] In both RCTs, there were no significant differences in rates of adverse events between study arms.[3],[4] Similarly, two large retrospective reviews concluded that outpatient THA can be safely performed in appropriately selected patients.[5],[6] Courtney et al. conducted a retrospective review of the National Surgical Quality Improvement Program (NSQIP) records between 2011 and 2014 pertaining to outpatient TJA.[5] They found that of the 169 406 patients who underwent a primary TKA or THA 1220 were performed on an outpatient basis (0.7%). Outpatient TJA alone did not increase the risk of

readmission (odds ratio [OR] = 0.652; 95% confidence interval [CI]: 0.243–1.746; p = 0.395) or reoperation (OR 1.168; 95% CI: 0.374–3.651; p = 0.789). Furthermore, they found that outpatient TJA was a negative independent risk factor for complications (OR: 0.459; 95% CI: 0.371–0.567; p <0.001).[5] Nelson et al. conducted a similar study retrospectively reviewing 63 844 THAs between 2004 and 2015 tracked by NSQIP.[6] Of these patients, 420 (0.66%) were performed as an outpatient. These authors reported that outpatients had no difference in any of the adverse events evaluated other than blood transfusion, which was less for the outpatient group compared to the inpatient group (3.69% vs 9.06%; p <0.001).[6] This evidence supports the notion that outpatient TJA can be performed safely in appropriately selected patients. Li et al. remark that the essential components of a successful outpatient TJA program include proper patient selection, preoperative patient/family education, perioperative multidisciplinary coordination and opioid-sparing analgesia, and early and effective postdischarge planning.[7]

Resolution of clinical scenario

- The available literature illustrates comparable complication rates between outpatient arthroplasty and similar inpatient procedures.
- In selected patients, outpatient arthroplasty can be performed safely and effectively.

Question 2: In eligible patients undergoing TJA, does performing the procedure on an outpatient basis result in cost savings compared to the same procedures performed on an inpatient basis?

Rationale

A significant portion of the cost associated with TJA is attributed to overnight admission. With the constraint on healthcare resources, developing a successful outpatient joint replacement pathway opens up the potential for substantial cost savings from the perspective of the Ministry of Health, the institution, and society.

Clinical comment

Outpatient discharge protocols remove most of the associated inpatient costs of the procedures leading to an overall reduced cost. Reducing the cost of healthcare improves access to services for both patients and healthcare centers.

Available literature and quality of the evidence

- Level I: 1 RCT.[3]
- Level III: 1 systematic review[8] and 4 economic analyses.[9–12]

Findings

One of the benefits of the movement toward outpatient arthroplasty is the potential for considerable cost savings. Pollock et al. conducted a cost-minimization analysis in

London, Canada and compared outpatient THAs with inpatient (next-day discharge) THAs.[3] The authors showed that the outpatient group was significantly less expensive than even an enhanced recovery pathway from the perspectives of the hospital (CAD$5170 vs CAD$4403) and the Ministry of Health (CAD$6752 vs CAD $5890), primarily because of a shorter length of stay, less time in the postanesthetic recovery unit, and less time following discharge from the recovery unit.

A systematic review of outpatient orthopedic surgeries performed by Crawford et al. found seven studies addressing cost with an overall savings between 17.6 and 57.6% for outpatient procedures relative to standard discharge protocols.[8] Of the seven studies included in the review, three investigated hip or knee arthroplasty. In 2014, Aynardi et al. conducted an economic analysis in Pennsylvania and illustrated that the overall cost in an outpatient setting (US$24,529) was significantly lower than the same procedures performed in an inpatient setting (US$31,327) ($p = 0.0001$).[9] In 2005, Bertin conducted an economic analysis in Maryland and found that the total average cost for an outpatient THA, including preoperative, intraoperative, and postoperative charges, was approximately US$2500 less than for the inpatients.[10] Finally, Lovald et al. retrospectively reviewed the Medicare 5% Limited Data Set to identify patients with TKAs between 1997 and 2009 and found a mean savings of US$8527 in outpatient TKAs compared to the reference group, which stayed in the hospital for an average of three to four days postoperatively.[11] More recently, Huang et al. conducted a cost-minimization analysis in Ottawa, Canada between 2012 and 2013 and looked at costs between same-day discharge TKA and standard inpatient TKA.[12] They found same-day discharge to be less costly in every case-control

match and found a median savings of 30% for those undergoing same-day discharge.[12]

Resolution of clinical scenario

- Overall, there is a consensus in the literature that outpatient discharge protocols provide significant cost savings for TJA.

Question 3: In patients undergoing an outpatient TJA, what factors are necessary to ensure a successful procedure compared to the general population undergoing TJA?

Rationale

It is important to understand that outpatient joint replacements are not appropriate for all patients and all care centers. Rather, there are a combination of factors that are required to ensure successful procedures. Before outpatient total joint replacements can be more widely adopted, it is imperative to illustrate these factors.

Clinical comment

To successfully achieve outpatient joint replacements, a combination of factors are necessary, including careful patient selection, a multidisciplinary team-based approach, appropriate preoperative education, and perioperative pain management. Furthermore, optimal surgical techniques are essential to facilitate same-day discharge.

Available literature and quality of the evidence

- Level IV: 2 systematic review.[2],[13]
- Level II: 1 prospective study.[14]

Findings

Appropriate patient characteristics are essential to ensure safe and successful arthroplasty in an outpatient setting. Current literature advises that outpatient TJA protocols place restrictions on age, body mass index (BMI), and severity of comorbidities.[2] Kort et al. performed a review of the literature to determine the patient selection criteria for outpatient TJA and found that there was no general consensus.[13] However, the authors reported that ideal patients for these outpatient procedures are those willing to go home the same day of surgery, with a low American Society of Anesthesiologists (ASA) classification (<III), age <75, and sufficient support at home.[13] Furthermore, extensive pre-existing comorbidities are a contraindication for outpatient procedures. In Denmark, Gromov et al. conducted a prospective two-center study investigating the feasibility of outpatient arthroplasty in unselected patients to identify the proportion of patients suitable for these procedures. They found that social network support, safe mobilization, and improved blood saving strategies are crucial to optimize the number of patients eligible for same day discharge.[14] Outpatient TJA is not possible without the proper education and motivation from the patient and their caregiver.

Beyond optimal patient selection, a multifactorial approach is crucial for outpatient TJA to be safely performed. This includes improved analgesia, early physiotherapy, and advanced surgical techniques.[2] These improved surgical techniques limit muscle damage and blood loss, which leads to less pain, quicker recovery, and rapid mobilization following surgery.[2] Pollock et al. reported that surgical

techniques varied across the outpatient total joint replacement literature, which is encouraging so that surgeons can be reassured that there are numerous techniques that can be safely and effectively performed without having to change their practice drastically.[2] Furthermore, the literature illustrates that there needs to be optimal coordination between surgeons, physiotherapists, occupational therapists, nurses, and anesthesiologists to ensure everyone involved is working together to provide the best and most efficient care possible.[2]

Resolution of clinical scenario

- For successful outpatient THA surgery, a number of studies conclude that careful patient selection is necessary (e.g. restrictions on age, BMI, and severity of comorbidities).
- Successful accelerated clinical pathways feature a multidisciplinary approach involving a range of healthcare professionals.
- Patients and their caregivers must be motivated for outpatient pathways to be effective.

Summary of answers

- In selected patients, outpatient joint replacements can be performed safely and effectively.
- In appropriate patients, orthopedic surgeons can perform outpatient total joint replacements at a signification reduction in final cost compared to inpatient procedures in similar patients.
- For successful outpatient surgery, careful patient selection is necessary (e.g. restrictions on age, BMI,

and severity of comorbidities).

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19 Hip Preservation

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Introduction

There has been a resurgence of interest in the preservation of the native hip joint. The development of new techniques in pelvic osteotomies[1,2] for hip dysplasia and subsequently the introduction of the concept of femoroacetabular impingement (FAI)[3–5] have led to an increase in both open and arthroscopic procedures used in the management of hip pathology in young adults. In this chapter, we aim to review the available evidence for certain hip-preserving procedures in the orthopedic literature. Table 19.1 lists the common causes of hip pain in young adult patients.

Clinical scenario

- A 22-year-old female patient is reporting progressive pain in her right hip over the last six months.
- She also has occasional catching sensation in her right hip and she feels that her hip clicks as well. She does not have any medical co-morbidities.

Top three questions

1. In patients with femoroacetabular impingement, does hip preservation surgery, compared to nonoperative treatment, result in better functional outcomes?
2. In young adults with acetabular dysplasia, does periacetabular osteotomy, compared to conservative care, result in better functional outcomes?
3. Among patients with mild or borderline acetabular dysplasia, does hip arthroscopy, compared to conservative care, produce better functional outcomes?

Question 1: In patients with femoroacetabular impingement, does hip preservation surgery, compared to nonoperative treatment, result in better functional outcomes?

Rationale

The concept of FAI was introduced by Ganz and associates in 2003 as a cause for osteoarthritis of the hip.[3] The classic types of FAI include cam deformity, and pincer and mixed impingement.[3] The treatment of FAI includes nonsurgical (personalized hip therapy) and surgical methods. Personalized hip therapy provides muscle control, strength around the hip, and movement patterns, which can lead to the avoidance of hip impingement.[6] The surgical management has been described through both open[7–9] and arthroscopic procedures,[10–12] which allows resection of the bony impingement, treatment of the labral tears, and management of articular chondral lesions. Hip arthroscopy has equal or better outcomes compared to open surgical techniques and is associated with a lower incidence of major complications.[13] In a systematic review comparing

the results of open surgical dislocation, mini-open technique, and hip arthroscopy, the authors found a higher incidence of complications with open surgical dislocation primarily because of trochanteric osteotomy related issues. The mini-open procedure had a significantly higher incidence of iatrogenic injury of the lateral femoral cutaneous nerve.[13]

Table 19.1 Common causes of hip pain in young adult patients.

A. Intra-articular
Capsulolabral 1. Labral tears 2. Capsular laxity 3. Adhesive capsulitis
Ligamentous Ligamentum teres tear
Articular cartilage 1. Arthritis (osteoarthritis, inflammatory arthritis, post-traumatic, septic arthritis) 2. Articular cartilage injury
Synovium 1. Synovial chondromatosis 2. Pigmented villonodular synovitis (PVNS)
Osseous 1. Acetabular under-coverage (dysplasia) 2. Acetabular over-coverage (pincer impingement) 3. Femoroacetabular impingement 4. Osteonecrosis 5. Perthes disease 6. Slipped capital femoral epiphysis

7. Osteoid osteoma and other neoplastic causes 8. Stress fracture 9. Transient osteoporosis
B. Extra-articular
Muscular 1. Adductor muscle strain 2. Abductor tear 3. Iliopsoas tendinitis 4. Piriformis syndrome 5. Proximal hamstrings avulsion/tear
Impingement Ischiofemoral impingement
Osseous 1. Avulsion fracture (e.g. anterior superior iliac spine) 2. Sacroiliac injuries 3. Neoplastic
Athletic pubalgia
C. Referred pain
Lumbar spine
Genito-urinary system
Pathology of abdominal organ or abdominal wall (e.g. inguinal hernia)

Clinical comment

Both hip arthroscopy and personalized hip therapy are successful methods in the management of FAI; however, hip arthroscopy can result in greater improvements of patients' symptoms in the short term.

Available literature and quality of the evidence

- Level I: 1 study (hip arthroscopy versus physical therapy).
- Level IV: 1 meta-analysis of level III and IV evidence.

Findings

Griffin et al. compared the clinical effectiveness of hip arthroscopy versus the best conservative care for patients with FAI in a multicenter trial (UK FASHIoN study) conducted in 23 hospitals in the UK.[6] The study was an assessor-blinded randomized controlled trial (RCT) that included 348 patients with symptomatic FAI with no radiographic evidence of osteoarthritis. Patients were allocated to receive either hip arthroscopy or personalized hip therapy (an individualized, supervised, and progressive physiotherapist-led program of conservative care). Their primary outcome was the patient-reported International Hip Outcome Tool (IHOT-33) 12 months after randomization. Both groups showed an improvement of the average IHOT-33; however, the mean difference in IHOT-33 scores was 6.8 (95% confidence interval [CI]: 1.7–12.0) in favor of hip arthroscopy ($p = 0.0093$). The UK FASHIoN study is the first RCT that shows that hip arthroscopy is effective in the treatment of FAI. This study published in 2018 reported only 12 months clinical outcome after randomization and longer-term follow-up is still needed. In a recent meta-analysis of 1981 hips assessing the outcome of hip arthroscopy for FAI (level IV), the reported risk of reoperation was 5.5%, while the risk of clinical

complications was 1.7%. These complications included heterotopic ossification, transient neuropraxia, adhesions, stiffness, wound infection, skin necrosis, and nondisplaced femoral head-neck fracture.[14]

Resolution of clinical scenario

- Patients with FAI can be managed operatively or nonoperatively. Hip arthroscopy has better outcomes at short-term follow up (level I).
- Both hip arthroscopy and open surgical procedures are effective methods in the management of FAI; however, open procedures are associated with a higher incidence of complications (level III, IV).
- Hip arthroscopy for FAI has a reoperation rate of 5.5% and a complication rate of 1.7% (level IV).

Question 2: In young adults with acetabular dysplasia, does periacetabular osteotomy, compared to conservative care, result in better functional outcomes?

Rationale

Acetabular hip dysplasia covers a spectrum of deformities and is considered present when the lateral center-edge angle (LCEA) is <25° and/or the acetabular index (AI) is >10°.[15,16] Symptomatic hip dysplasia is associated with hip pain and functional limitations.[16,17] Moreover, acetabular under-coverage can lead to early secondary osteoarthritis of the hip. The Bernese periacetabular osteotomy (PAO) was proposed as a method of treatment for symptomatic

acetabular dysplasia by Ganz and his colleagues in 1988.[1] This osteotomy has potential advantages of maintaining the posterior column integrity, preserving the acetabular blood supply and enabling multiplanar acetabular reorientation.[18_20]

Clinical comment

Periacetabular osteotomy can be used for the treatment of residual acetabular dysplasia in young adults with closed triradiate cartilage. Periacetabular osteotomies can improve patients' symptoms and function. The hip survivorship after PAO was reported as 86, 60, and 29% over 10-, 20-, and 30-year periods, respectively.[21],[22] This is despite the fact that the original cohort has a significant number of less-than-ideal hips for preservation with osteotomy.

Available literature and quality of the evidence

Multiple level III and IV studies seek to answer this question.

Findings

The longest follow up after PAO for dysplastic hip patients was reported by the Bernese group in 2016.[21] They published a 30-year follow-up report on their first 63 patients (75 hips) who underwent PAO for hip dysplasia between 1984 and 1987. About 24% of this cohort showed preoperative radiographic evidence of osteoarthritis. Their results have shown cumulative survivorship was 29% at 30 years with 71% of the hips converted to total hip arthroplasty, showed progression of osteoarthritis, or patients had a low Merle d'Aubigné-Postel score (<15). Among the factors they have identified to be associated with failure of PAO, they found that patients with

preoperative radiographic evidence of osteoarthritis were 40 years or older, had preoperative low hip scores, and that patients with preoperative signs of impingement are prone to have poor clinical outcome. They also concluded that PAO should be avoided in patients with preoperative advanced degenerative hip changes.

In a large prospective multicenter study, The ANCHOR group reported a good improvement of pain, function, quality of life, overall health, and activity level of patients who underwent PAO for hip dysplasia.[23] Their cohort included 391 patients who had a mean age of 25 years with a minimum two years' follow-up. They found that patients with moderate to severe dysplasia had more improvement compared to those with mild dysplasia.

Resolution of clinical scenario

- There is moderate evidence that PAO can be successful in improving the symptoms of patients with acetabular hip dysplasia (level III).
- Less than one third of dysplastic hips survived after PAO at 30 years follow up (level III).
- Patients older than 40 years, with preoperative signs of osteoarthritis or impingement, can have poor results after PAO (level III).

Question 3: Among patients with mild or borderline acetabular dysplasia, does hip arthroscopy, compared to conservative care, produce better functional outcomes?

Rationale

Mild and borderline acetabular dysplasia is considered in patients with LCEA between 18 and 25°.[24] Although, hip arthroscopy is associated with high failure rates in the setting of moderate and severe dysplasia,[25] the surgical management of symptomatic patients with mild/borderline hip dysplasia is still controversial. Some studies have reported less improvement of patients with mild dysplasia after PAO compared to those with moderate to severe dysplasia.[23] Common hip arthroscopic procedures do not address the primary pathology in hip dysplasia which is the deficient acetabulum; however, they can address the sequalae of the dysplasia such as labral tears, chondral injuries, and capsular laxity.[25–28] Moreover, arthroscopic femoral osteochondroplasty can be done to manage cam impingement which can be associated with hip dysplasia.[25,29]

Clinical comment

The results of the use of hip arthroscopy in the setting of mild hip dysplasia are inconsistent in the orthopedic literature. However, studies have shown symptomatic relief in short- and medium-term follow-up, especially with labral repair and capsular repair/plication in selected patients. Inadequate patient selection, labral debridement, absence of capsular repair/plication, presence of degenerative changes, and severe grades of dysplasia are associated with poor outcome.

Available literature and quality of the evidence

Multiple level III and IV studies are available on this topic.

Findings

Previous studies reported a high failure rate with hip arthroscopy in patients with acetabular dysplasia; however, their cases were associated with debridement of the labrum which is an important stabilizer in dysplastic hips.[30],[31] Grammatopoulos et al. have reported the outcomes of hip arthroscopy in a historical cohort of patients with hip dysplasia and found a higher failure rate (conversion to total hip arthroplasty) with moderate and severe dysplasia; however, they reported approximately 90% survivorship of hips with mild dysplasia over seven years.[25] They have also found a significant clinical improvement in the postoperative patient-reported outcomes for patients with preserved hips after hip arthroscopy. In a retrospective study, Hevesi et al. investigated the midterm results of arthroscopic labral repair in hip dysplasia. They matched a group of dysplastic patients to nondysplastic controls.[32] They did not find differences in the rate of failure or the clinical outcome between both groups at five years' follow-up.

More recently, Maldonado et al. analyzed the risk factors associated with arthroscopic capsular plication in patients with labral tears and borderline hip dysplasia.[33] They found that patients who were older than 35 years had relative risk of 2.25 of failure (95% CI: 1.10–4.60; p = 0.0266) at a minimum of two years postoperatively.

Resolution of clinical scenario

- There is moderate to poor evidence that hip arthroscopy can improve symptoms of patients with mild acetabular dysplasia (level III, IV).
- Labral debridement and large capsulotomies should be avoided when performing hip arthroscopy in patients with mild dysplasia (level III, IV).

Summary of answers

- Over the last decade, more evidence has become available for hip preservation surgery.
- Although there are multiple level III and IV evidence reports that support the use of these procedures, there is still paucity of RCTs in the orthopedic literature.
- In 2018, the first RCT was published on the use of hip arthroscopy in FAI and we believe that more level I evidence will be available soon.

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20 The Direct Anterior Approach

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Clinical scenario

- A 65-year-old female presents to your clinic after reading about the direct anterior approach (DAA) to total hip arthroplasty (THA).
- She wants to know what the pros and cons are to this approach.

Top three questions

1. In patients requiring THA for arthritis, does a DAA provide early and late functional benefit compared to posterior and lateral approaches?
2. In patients requiring THA for arthritis, does a DAA provide acceptable radiographic alignment compared to other approaches?
3. In patients who undergo THA, does a DAA have a higher complication rate compared to lateral or posterior approaches?

Question 1: In patients requiring THA for arthritis, does a DAA provide early and late functional benefit compared to posterior and lateral approaches?

Rationale

A minimally invasive internervous approach such as an anterior approach to the hip has been thought to result in less muscle damage and earlier recovery. However, controversy exists about the advantages of the anterior approach as many of the early outcome differences are shortlived.[1–3] Thus, it is important to understand the early and late functional outcomes when using a DAA for THA.

Clinical comment

The results of THA performed through a DAA are largely comparable to posterior and lateral approaches and are not considered superior.[1–5] Outcomes are dependent on the volume and experience of the surgeon.[6–9]

Available literature and quality of the evidence

Seven level I prospective randomized controlled trials (RCTs) assessed early functional differences when using the DAA for THA.[210–15]

Findings

Barrett et al. showed early benefit to pain scores, walking distance, and stair climbing but no differences at six months and a year between anterior and posterior approaches.[10] In a study comparing anterior to posterior approaches, time to ambulation without ambulatory aids and voluntary quitting of ambulatory aids was better in the

anterior group; however, no other clinical or radiographic differences were seen.[14] Zhao et al. showed that using an anterior approach resulted in shorter hospital stays, lower self-reported pain and lower muscle damage markers.[13] Functional outcomes based on the Harris Hip Score (HHS), University of California Los Angeles activity score and gait analysis was better at three months for the anterior group but was not different at six months.[13] Similarly, Christensen et al. showed the anterior approach resulted in shorter hospital stays, greater change in pain scores, and discontinuation of assisted devices at an earlier time.[15] There were no functional differences seen at six weeks.[15] Finally, Cheng et al. showed no differences between anterior and posterior approach besides subgroup analysis, which showed the anterior group having shorter hospital stays, less opiate requirements, and smaller wounds.[2]

Two RCTs compared the direct anterior and lateral approaches.[11],[12] Restrepo et al. in a study of 100 patients showed at one year that the anterior approach had significantly better improvement in Short Form 36 (SF-36) and Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) scores, but at two years were the same.[11] De Anta-Diaz et al. showed that inflammatory biomarkers (IL-6, IL-8, CK) were significantly higher and magnetic resonance imaging (MRI) results at six months showed significantly more fibrosis and atrophy of the abductors in the lateral group.[12] Functional scores at three months and one year were similar in both groups[12] concluding that this early muscle damage in the lateral approach may not be clinically relevant.[12]

Currently, there are limited long-term data evaluating outcomes following a THA through the DAA. In an RCT, Brismar et al. showed no differences in hip function or pain at one or five years following THA from a DAA or lateral

approach.[16] Reichert et al. showed in a level III retrospective study of 171 hips with follow-up between 3.7 and 5.4 years, similar HHS, SF-36, and activity questionnaires comparing anterior and lateral approaches.[1] In an analysis 21 860 THAs in the Norwegian registry, there were no significant differences in revision for any cause and survival between anterior, lateral, and posterior approaches at two and five years.[17] In an analysis of the Dutch registry, 12 274 patients were evaluated including anterior, direct lateral, anterolateral, and posterolateral approaches. Minimal clinical differences were seen between approaches after three months.[18]

Resolution of clinical scenario

- The use of the DAA for THA may enhance early functional performance compared to other approaches.
- There are no long-term differences between the DAA and other approaches for THA.

Question 2: In patients requiring THA for arthritis, does a DAA provide acceptable radiographic alignment compared to other approaches?

Rationale

The importance of component alignment relates to its influence on longevity of the implant as well as functionality.[19]

Clinical comment

It has been hypothesized that component positioning may be more challenging with the DAA.[8] It is therefore important to assess radiographic alignment following THA using a DAA.

Available literature and quality of the evidence

Four level I studies, two level II studies, and one level III study attempt to answer this question.

Findings

Zhao et al. 2017 showed in a level I RCT of 120 patients that an anterior approach had significantly lower variance in anteversion and inclination compared to a posterior approach.[13] Furthermore, Taunton et al. in a level I study of 54 patients showed no difference between limb length and abduction angle when comparing anterior and posterior approaches.[14] Similarly, Barrett et al. in a level I study showed on the six-week postoperative radiographic that more direct anterior cups were within the Lewinnek safe zone; however, this wasn't significant when comparing to the posterior group.[10] Furthermore, the direct anterior group were significantly more likely to have the femoral stem placed in neutral varus/valgus position.[10] There was no evidence of migration and all components achieved osseointegration in both groups.[10] Finally, Cheng et al. in a level I study of 72 patients showed there was no significant radiological positioning differences between DAA and posterior groups.[2] There was more stem subsidence in the anterior group; however, this was not significantly different from the posterior group and these patients stabilized without symptoms or revision.[2]

In a recent systematic review (level II), Lanting et al. showed that surgical approach was not an important variable for implant position, suggesting all approaches are

adequate for exposure.[20] Similarly, Higgins et al. in a level II systematic review showed a greater percentage of acetabular cups placed within the safe zone when using the DAA; however, this was not significant when comparing to the posterior approach.[4]

Moreover, level III studies suggest the DAA with fluoroscopy is more accurate in regards to cup positioning; however, these studies compare to a posterior approach without fluoroscopy.[21–23] One possible explanation is that in the supine position this recreates the functional pelvic orientation facilitating more optimal acetabular positioning.[13,23]

Resolution of clinical scenario

- There are no differences between radiographic outcomes following a THA using a DAA.
- The use of fluoroscopy may play a role in cup positioning.

Question 3: In patients who undergo THA, does a DAA have a higher complication rate compared to lateral or posterior approaches?

Rationale

It is important to understand what unique complications a surgeon faces when using the DAA and compare these to other hip approaches.

Clinical comment

There appears to be a higher rate of early complications when a surgeon starts to use a DAA.[8,9,24–27] Furthermore, it has been shown that surgeons who had performed fewer than 100 cases were twice more likely to have complications in their patients, thus a low-volume surgeon may find this approach to have unacceptable complications.[6,24]

Available literature and quality of the evidence

Nine level I studies and nine level III studies exist that help to answer this question.

Findings

In a level I RCT, the number of adverse events was higher in the DAA group (11%); however, this was not statistically significant compared to the posterior group (5%).[2] This was similar to Barrett et al. 2013 in a level I study, which showed no difference in intraoperative and postoperative complications between anterior and posterior approaches.[10]

Injury to the lateral femoral cutaneous nerve (LFCN) is one of the more common complications when using a DAA for THA.[2] The incidence is highly varied in the literature likely related to how thorough postoperative physical examinations are, ranging from 0 to 80%.[1,2,6,11,28] In two RCTs, the rate of LFCN palsy was 0 and 83%, respectively.[2,11]

A perioperative fracture is potentially a devastating complication often requiring further fixation and or surgical procedures. Possible explanations for perioperative femur fractures when using a DAA include limited exposure for broaching, excessive retraction required to anteriorize the femur, as well as stress on the

greater trochanter from tense posterior soft tissue structures.[26,29] The rate is fairly low, ranging from 0 to 7% in level I and level III studies.[2,11,13,14,30–32] Four RCTs reported on fractures with a total of 172 patients with fractures occurring in five patients (3%), which included two calcar, one nondisplaced greater trochanter, one femoral perforation, and one greater trochanter tip avulsion fracture.[2,11,13,14] Matta et al. in a level III retrospective study reported seven proximal femoral fractures (three calcar, four greater trochanter), two femoral shaft fractures, and three traction-related ankle fractures in 494 patients, with an overall rate of 1.8%.[33] Treatment for this complication depends on location and implant stability but can include restricted weightbearing, cerclage wiring for greater trochanter fractures, and longer stem revisions for perforation or implant instability.[6,33]

Many surgeons have switched approaches due to the fear of dislocation and hip instability.[34] Registry data from two different level III studies of 22 237 and 21 860 patients respectively showed that the anterior and anterior lateral approaches had a lower dislocation rate compared to posterior.[16,35]

Due to the anterior location of the skin incision, this poses unique wound healing considerations as it is under increased shear stress.[26] Skin maceration and abrasion from broaching is not uncommon (around 5%) potentially increasing risk of wound breakdown, infection and reoperation.[15,25,26] Multiple level III studies suggest the rate of deep infection is between 0.5 and 2%.[6,26,32,33,36,37] The increasing number of assistants, operating personnel including a fluoroscopy technician, the movement and positioning of the C-arm above the incision, and the proximity to the groin all make contamination more likely.[25,38,39] In a level I RCT of 77 patients, Barrett et al.

had one patient in the DAA group who had a small dehiscence of the proximal aspect of the wound.[10] In a retrospective cohort study of 4651 patients, Purcell et al. showed no differences in deep infection rates between direct anterior and posterior approaches in patients with greater than or less than BMI of 35.[40]

Resolution of clinical scenario

- Overall complication rates are similar among hip approaches.
- When counselling a patient about a total hip through a DAA, one must discuss LFCN palsy, wound breakdown, and fracture as possible complications.

Summary of answers

- The use of the DAA for THA may enhance early functional performance compared to other approaches.
- There are no long-term differences between the anterior approach and other approaches for THA.
- There are no differences between radiographic outcomes following a THA using a DAA.
- The use of fluoroscopy may play a role in cup positioning.
- Overall, complication rates are similar among hip approaches.
- When counselling a patient about a THA through a DAA, one must discuss LFCN palsy, wound breakdown, and fracture as possible complications.

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21 Computer Navigation in Total Hip Arthroplasty

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Clinical scenario

- An 80-year-old man with back and left hip pain from severe combined osteoarthritis needs total hip arthroplasty (THA).
- He had right THA and suffered an episode of dislocation one year earlier, and is concerned about this happening again.
- Based on pre-operative imaging, the patient is found to have a stiff kyphotic spine with 10° of functional pelvic range of motion from sacral slope 15° standing to a low sacral tilt angle of 5° sitting.
- Computer assisted THA has been recommended for precise implant positioning aiming for a low combined anteversion to reduce risk of anterior dislocation.

Top three questions

1. For patients with combined hip-spine pathologies who require total hip arthroplasty, which evidence-based clinical investigations, compared to others, correctly evaluate their disease?

2. In patients undergoing total hip arthroplasty, which surgical techniques, compared to other techniques, result in optimal implant positioning and biomechanical hip reconstruction to reduce impingement and dislocation?
3. In patients undergoing total hip arthroplasty, does computer navigated surgery, compared to manual techniques, demonstrate superior implant positioning?

Rationale

Despite improved surgical techniques and implant designs, dislocation is still a leading cause for revision total hip surgery, inducing as many as one in five total hip arthroplasty (THA) revisions.[1,2] This is a major concern for the patient and hip surgeon alike. Total hip arthroplasty patients experiencing dislocation require significant healthcare resources to evaluate and manage this complication.[3,4] Ensuring that evidence-based techniques are employed for THA reconstruction will translate into appropriate use of these limited resources.

Clinical comment

Dislocation through implant malposition is a dynamic problem. Many studies have demonstrated that the classic static target numbers as referenced to anatomical landmarks for implant positioning are insufficient to ensure stability, and functional studies of implant positioning are required.[5–13] There is still no consensus towards the ideal target implant position, but data confirms the importance of incorporating pelvic functional tilt with combined femoral and acetabular version and femur first preparation to maximize range of motion (ROM) and minimize the risk of implant impingement and dislocation .[14–19] Patients with combined pelvic-spine deformities are at high risk for bone

on bone impingement despite avoiding implant impingement and require additional workup.

Understanding an algorithm with evidence-based investigations for common causes of impingement and pain in THA ensures that correctable problems are addressed.[5,10,11,20,21]

Available literature and quality of evidence

The quality of literature addressing appropriate investigations for functional implant positioning is highly variable with the vast majority being Grade II-IV evidence, mainly case series or consecutive cohort studies. Dorr et al. analyzed the influence of pelvic mobility to cup position through conventional radiography and recommended standing and sitting anteroposterior (AP) and lateral pelvic radiographs for patients identified as high risk.[8] Lazennec and Sariali used the EOS® radiographic technique which takes simultaneous capture of two full body orthogonal AP and lateral images and provides two- and three-dimensional models using its Stereos® software.[7,22] This allows superior functional analysis of hip-spine deformities and implant position.[23–25]

Findings

Kanawade et al. confirmed the normal range of pelvic motion from sitting to standing is 20–35° with increase in anteinclination upon sitting being 25° inclination and 14° anteversion. Their studies of pelvic tilt confirmed that 20% of patients present with a stiff (≤20°) or hypermobile (≥35°) hip-pelvic motion making them at risk for impingement and dislocation, respectively.[8,26] The particular preoperative mobility of the pelvis predicts the necessary modifications in strategy of implant position to minimize this risk. The fact that nearly 80% of THA are

implanted near their functional position makes THA tolerant to minor errors in positioning and explains the excellent long-term results that it has enjoyed.[27]

Dropout dislocation occurs upon sitting in patients with 1) hypermobility – posterior pelvic tilt upon sitting (as their functional inclination can be near 80–90°) or 2) hips that are shortened upon reconstruction. Intraoperatively, stability against dropout is tested by pushing the hip to its maximal flexion to the chest and observing that it does not dislocate. These patients (mainly females) need the cup at 35–40° inclination and 25° anteversion so that combined anteversion (CAV) is about 40–45° as they are at risk for posterior dislocation. Stiff pelvis (mainly males) with little posterior tilt and low functional anteinclination needs a cup position around 40–45° inclination as they bend forward more (trunk flexion) from sitting to standing and 15° anteversion so that CAV is about 25–30° to minimize risk for anterior dislocation in extension upon standing.[7,8,28,29] Additional measures such as trochanteric transfer may be required to minimize bone on bone impingement.[12,13]

The EOS® system was confirmed to achieve less radiation with accurate and reliable information for measuring spine acetabular, femoral and pelvic variables; it especially improves measurement of femoral offset and anteversion which standard 2D radiographs under-value from external rotation contracture.[22,23,30]

Resolution of clinical scenario

- Level II–IV evidence shows that 20% of patients present with pathologic pelvic-spine mobility at risk for dislocation.
- Level III evidence confirms utility of preoperative functional radiographs or EOS imaging to work up at-

risk patients.

- Level II evidence confirms surgical strategies and modification of implant position are required for at-risk patients.

Question 2: In patients undergoing total hip arthroplasty, which surgical techniques, compared to other techniques, result in optimal implant positioning and biomechanical hip reconstruction to reduce impingement and dislocation?

Rationale

The range and type of pelvic tilt influences functional cup position.[6–8,10] Thus, it is important to understand which surgical techniques allow for the most accurate functional implant positioning.

Clinical comment

Dislocation is the most alarming complication after THA, but pain, accelerated wear or loosening are also related to impingement and are probably clinically underestimated. In cementless THA, femoral anatomy dictates postoperative implant position, with about 20% of femurs in retroversion ≤0° (cam deformity), or ≥20° anteversion (dysplasia) and puts the patient at risk for impingement dislocation.[20,31,32] This was the basis for femur first preparation and the concept of CAV.

At present it is still difficult to quantify the implications of implant malposition on gait and stance,[33,34] but greater

knowledge in this field has opened new research opportunities.

Available literature and quality of the evidence

To analyze anatomy, surgeon perception, impingement and dislocation Dorr et al. studied a series of cohorts of over 200 patients with navigation and postop CT-scans.[20,31,35,36] With cementless femoral implants femur-first was used and cup anteversion was adjusted towards a combined anteversion of 25–45° while incorporating navigated pelvic tilt to try and achieve impingement free range-of-motion between stem and cup (level III and IV studies).[31,35] As discrepancies in definitions of target acetabular positioning in literature was found, laboratory models were developed to try and obtain consensus for reporting implant position, especially acetabular anteversion (level IV).[16,37] Zhu and Maratt et al. in a consecutive series of patients analyzed the influence of pelvic tilt on cup functional position.[14,38]

Renkawitz et al. in an RCT compared navigated femur-first technique with conventional THA to assess clinical functional outcomes (level II).[39] Weber in a prospective study of 135 patients evaluated 6 current definitions of combined anteversion for impingement free range of motion (level II).[40]

Findings

Total hip arthroplasty using the combined anteversion technique with navigation found no dislocations and achieved the targeted combined anteversion in 96% of cases. Dorr et al. confirmed that even experienced hip arthroplasty surgeons with mechanical guides had outliers over 5° in 31% of cases for acetabular inclination, 39% for anteversion and 46% for the femur version.[8,20,31,35–37] Similar results were found from other studies of

postoperative implant position with outliers of up to 50%.[41–43] Implant positioning depending on human experience alone is imprecise and inaccurate.[36,39,44–52]

Weber et al. concluded that standard rules of combined anteversion improved prosthetic range of motion in 90% of cases but failed to prevent combined osseous and prosthetic impingement in up to 40% of cases because of anatomic variants which occur in individuals.[33] Renkawitz also concluded that despite potentially improved implant positioning and hip flexion there were no significant differences with respect to any gait, functional or clinical outcomes at six months and one year of follow-up between the two treatment groups.[39,53]

Through a laboratory model, we found a correlation of 0.8° change in anteversion for every degree of pelvic tilt change, with the greatest change in anteversion in patients with over 10° of tilt.[14] A 10° magnitude of tilt can thus create an absolute error of 8° in judging the cup relative to the coronal position.[14,16,36,37] In our studies, 77 of 477 (16%) hips had an excess of 10° anterior or posterior tilt.[14] Maratt et al. similarly found 17% of patients with tilt ≥10°.[38] Our clinical studies of pelvic tilt later confirmed that about 20% of patients present with a stiff (≤20°) or hypermobile (≥35°) hip-pelvic motion and require adjusted cup positions.[8,54]

The CAV technique for cementless stems can eliminate stem-on-cup impingement but reduction of bone-implant and bone-bone impingement requires correct cementless cup coverage and correct leg-length (LL) and offset restoration.[33,53,55] In normal hips this requires cup center of rotation (COR) to be reamed on average 5 mm medially and 3 mm superiorly for non-cemented cups. In a clinical study of 82 navigated THAs, we confirmed that

reconstruction within 6 mm of anatomic position was achieved in 95% of cases (78/82 hips) for offset and 99% (81/82) of cases for LL.[55] Honl et al. confirmed that mean error in depth of manual reaming is 6.4 mm from anatomic COR.[56] Hips with dysplasia are difficult to maintain in their anatomic position and often require non anatomic cup positions and offset stems. When added stability is required for high risk patients, dual mobility or constrained cups may be indicated.

Resolution of clinical scenario

- Level II–IV evidence shows cementless femoral implant position as potentially at-risk for dislocation in about 20% of cases due to abnormal version.
- Level II evidence has confirmed that femur first preparation and combined anteversion potentially reduce the risk for prosthetic impingement in 90% of cases but do not improve clinical or functional results at one year.
- Level II–IV evidence of bone on bone impingement from anatomic variants occurs in up to 40% of cases and may require use of dual mobility or constrained implants.

Question 3: In patients undergoing total hip arthroplasty, does computer navigated surgery, compared to manual techniques, demonstrate superior implant positioning?

Rationale

The hip surgeon's most common error is malposition of the acetabular component which is independent of expertise or approach.[20],[57],[58] Non-cemented femoral implant position is not consistent and induces errors when standard acetabular position is targeted.[32],[42]

Clinical comment

Standard surgery cannot evaluate pelvic tilt and functional hip position which is greater than expected in about 20% of cases.[8]

Available literature and quality of the evidence

Dorr et al., in a consecutive prospective cohort series of over 200 patients validated their navigation system for precision and bias with postoperative computed tomography (CT) scans (Grade III-IV). Multiple studies on navigation even by pioneers like DiGioia et al. were on limited number of patients or on laboratory models (Grade III–V).[15],[45],[59] There are only 7 prospective randomized trials comparing 255 patients with navigation and 259 patients with freehand cup placement with (level II).

Findings

Dorr et al. confirm that, for all variables analyzed, computer assisted THA (CAS-THA) is more precise (reproducible) with less bias (error) in comparison to experienced surgeons (ES).[8],[20],[31],[35–37] With computer navigated (NAV) cup inclination, bias was 0.03° and precision 4.4°; for anteversion bias was 0.73° and precision 4.1°. Experienced surgeons present a bias of 1.0° and a precision of 11.5° for cup inclination, and a bias of 2.1° and a precision of 12.3° for anteversion.[36] For femoral position the NAV bias was 0.2° with precision of 4.8°, and for ES the bias was 0.3° and precision 16.8°.[31] For combined

anteversion determined by NAV, the bias was 0.2° and precision 4.8°, while for ES estimates the bias was 3.7° and precision 18°.[37] As mentioned earlier, ES have outliers over 5° in 31% of cases for acetabular inclination, 39% for anteversion and 46% for femur version.[8,20,31,35–37]

Multiple groups working with CAS-THA surgery have consistently confirmed these results. A meta-analysis by Gandhi et al. confirmed more precise cup positioning with NAV-THA without increase in complications, except longer operating times.[60] The meta-analysis by Xu et al. confirmed superior cup positioning and leg length reconstruction with NAV but longer operating times.[61] No differences were found in dislocation rates, deep vein thrombosis or functional outcomes at different time points.[61] Snijders conducted a systematic review and meta-analysis to assess the precision and accuracy from all available high-quality RCTs to date.[62] Six out of seven studies concluded a statistically significant difference in precision in anteversion between the NAV group and the freehand group.[46,48,49,52,63–65] Five out of seven studies concluded a statistically significant difference in precision in inclination. There is a significantly better accuracy for the CNAV-THA group than for the freehand group for anteversion ($p = 0.002$) and for inclination ($p = 0.01$). Parrate confirmed at 10-year follow-up that NAV-THA for cup placement did not confer any substantial advantage in function, wear rate, or survivorship.[64]

Resolution of clinical scenario

- Level II–IV studies have confirmed that computer-navigated implant positioning is more precise with less bias than experienced surgeons.

- Level IV evidence studies confirm that navigation provides more functional implant positions by incorporating pelvic tilt.
- Level II evidence at 10-year follow-up shows that navigation for cup placement does not confer any substantial advantage in function, wear rate, or survivorship.

Summary of answers

- About 20% of patients with pathologic spinopelvic mobility and abnormal femoral version are at risk for dislocation.
- Preoperative functional studies are required to identify this subset of patients who require modifications in surgical strategy and implant positioning.
- Femur first and combined anteversion reduce prosthetic impingement between implants but have not been shown to improve clinical or functional results.
- Computer navigation is superior to experienced surgeons in precise and functional implant positioning but has not been demonstrated to confer any substantial advantage in function, wear, or survivorship to date.

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22 Highly Crosslinked Polyethylene in Total Hip Arthroplasty

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Clinical scenario

- A 55-year-old active female presents to an orthopedic surgeon with advanced osteoarthritis in her right hip.
- Her quality of life is significantly affected by the pain and lack of motion in her right hip.
- Conservative treatment options have been exhausted and she is scheduled for a total hip arthroplasty (THA) with the use of ultra-high-molecular-weight polyethylene (UHMWPE).

Top three questions

1. In patients receiving a THA, does highly crosslinked polyethylene (HCLPE) result in a reduction in the wear rate compared to standard UHMWPE?
2. In patients receiving a THA, does HCLPE result in a reduction in osteolysis compared to UHMWPE?
3. In patients with a THA, does the use of HCLPE result in the potential for mechanical failure compared to standard UHMWPE?

Question 1: In patients receiving a THA, does highly crosslinked polyethylene (HCLPE) result in a reduction in the wear rate compared to standard UHMWPE?

Rationale

The purpose of HCLPE is to improve the longevity of THA by decreasing the wear rate of the bearing used during THA. The use of THA in younger and presumably more active patients has led surgeons to be concerned about the wear rate of polyethylene and to seek out expensive alternate bearings such as HCLPE, ceramic on ceramic, or metal on metal. Clearly any change made to polyethylene has the potential for decreasing wear rates but also increasing adverse events.

Clinical comment

The clinical importance of decreasing polyethylene wear rates is significant to THA recipients. The main theory of late failure of THA is that the wear of the bearing generates particulate debris that leads to loosening, mechanical failure, and/or instability of the THA.

Available literature and quality of the evidence

Ten high-quality randomized controlled trials (RCTs), level I, are available to answer this question.

Findings

A considerable amount of research on the topic of THA wear rates has been published. Many of the studies are RCTs to demonstrate the improvement in wear rates with

HCLPE as compared to regular polyethylene. What complicates the interpretation of the literature is that various different types of HCLPE, which use different techniques to achieve crosslinking and eliminating free radicals, have been used in the clinical studies. In order to interpret the substantial amount of reported data on HCLPE, a basic knowledge of the different methods to measure in vivo wear of polyethylene is necessary. There are manual techniques that rely on manual edge detection to calculate the migration of the femoral head.[1] To improve accuracy and reproducibility, computer-aided techniques have been developed.[2,3] The most accurate method of measuring wear is radiostereometric analysis (RSA).[4,5] Studies looking at wear rates require follow up of at least two years, in order to get a true estimate of steady state wear rate because of the effect of plastic deformation, otherwise known as *bedding in* or *creep*.[6–8]

There have been eight papers that have performed RCTs using cobalt chrome femoral heads on HCLPE and have used some form of computer-assisted technique to measure the polyethylene wear.[9–16] Many of the major manufactures of HCLPE are represented in these articles. Marathon (5 Gy), Durasul (9.5 Gy), Longevity (10 Gy), and Crossfire (7.5 Gy) have all demonstrated significant reductions in steady state wear rates compared to UHMWPE. The reduction in wear varies from 55 to 95% and this often is a function of the wear properties of the control group. Importantly, the follow-up was 2 to 10 years confirming the improved wear of HCLPE.

There have been 12 RSA studies, eight of which are level I studies, reported in the literature.[6,17–25] Arcom, E1 Vitamin E poly, Reflection, Durasul, Longevity, and Crossfire HCLPE have all been demonstrated to have significantly

decreased wear rates compared to UHMWPE. The length of follow-up varied from 2 to 13 years.

Resolution of clinical scenario

- HCLPE results in a significant reduction in polyethylene wear in vivo compared with regularly UHMWPE.
- This reduction in wear remains present at follow-up of 13 years.

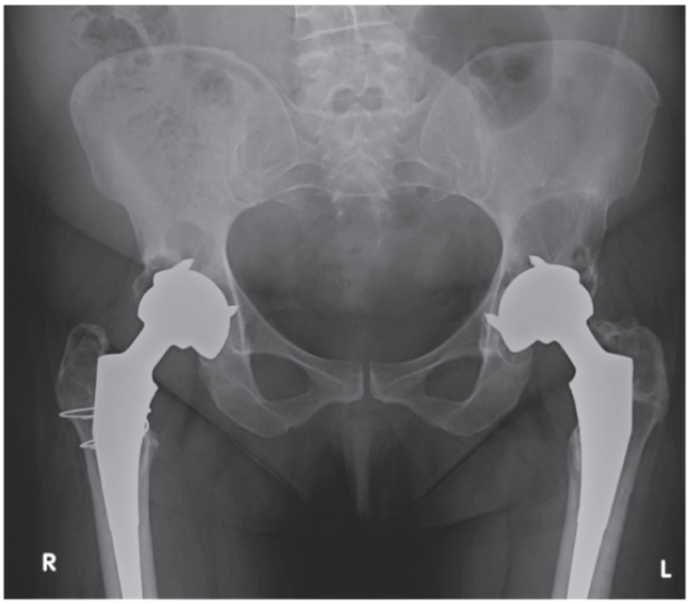
Question 2: In patients receiving a THA, does HCLPE result in a reduction in osteolysis compared to UHMWPE?

Rationale

There has been concern that the smaller wear particles of THA will lead to an increased risk of osteolysis compared to UHMWPE.[26,27]

Clinical comment

One of the major reasons for revision of THA is the presence of progressive osteolysis (Figure 22.1).[28] Thus, it is important to understand if HCLPE results in reduced osteolysis.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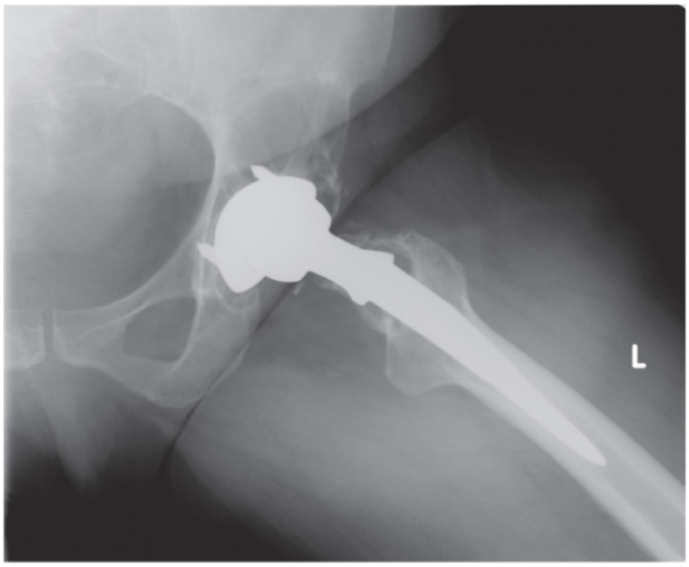
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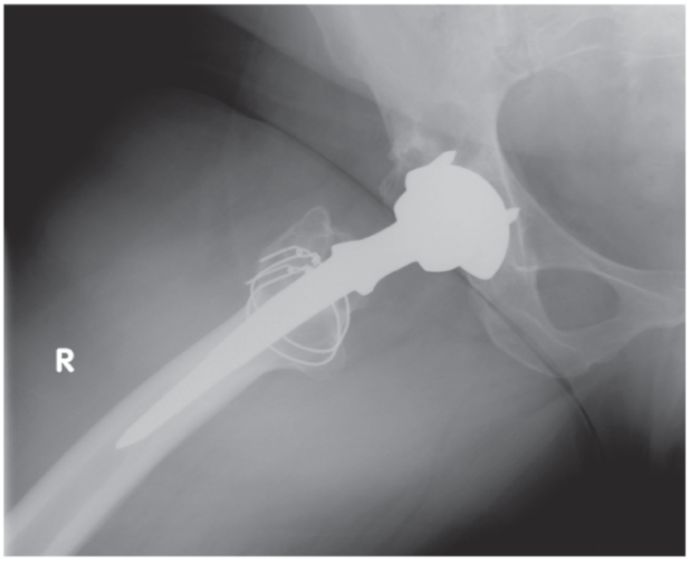
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Figure 22.1 AP and lateral views of bilateral hip replacements with UHMWPE demonstrating advanced polyethylene wear and associated osteolysis six years postoperatively in a modestly active female.

Source: Glen Richardson, Michael J. Dunbar.

Available literature and quality of the evidence

There are six level I RCTs and three level III systematic reviews of case-controlled and retrospective studies that aim to answer this question.

Findings

There have been a number of studies that have looked at wear and reported on the incidence of osteolysis as part of an RCT.[9,16,19,29–31] All studies noted a statistically significant decrease in the presence of osteolytic lesions at up to 13 years' follow-up. The method used to evaluate the osteolytic lesions is important, with two studies using the more sensitive technique of CT (computed tomography) scans.[29,31] Both studies noted a significant reduction in the incidence of osteolysis. Ultimately, this is an expected result with yearly wear rates for HCLPE well below the suggested 0.1 mm per year threshold for the formation of osteolytic defects.[32]

Resolution of clinical scenario

- Use of HCLPE demonstrated a significant reduction in the presence of osteolytic lesions.
- Decreased osteolysis is consistent with the low wear rates measured with the use of HCLPE.

Question 3: In patients with a THA, does the use of HCLPE result in the potential for mechanical failure compared to standard UHMWPE?

Rationale

In processing HCLPE the steps taken to increase the cross-linking weaken its mechanical properties and this could result in mechanical failures of the insert.

Clinical comment

The creation of HCLPE results in unfavorable changes with ultimate tensile strength, ductility, modulus, toughness, and crack propagation resistance.[33],[34] There are cases of liner failures reported in the literature, but some of the failures likely were related to implant design.[35]

Available literature and quality of the evidence

Four level IV studies (case series) and three level V (case reports and expert opinion) exist on this question.

Findings

The case reports in the literature only represent small series up to four cases and one report from a voluntary report to the United States Food and Drug Administration of 74 cases.[35–41] The key finding in these analyses is that most failures of HCLPE liners are due to impingement at the areas of the liner that are unsupported and thin, such as elevated rims or locking grooves. It is clear that, with the large number of HCLPE being used, mechanical failure of HCLPE is a rare occurrence.

Resolution of the clinical scenario

- The process of creating HCLPE weakens its mechanical properties.
- There are case reports of HCLPE fractures, almost exclusively at the rim of the liner.
- Avoiding impingement and cup malposition is key to limit this mode of failure.

Summary of answers

- The use of HCLPE consistently demonstrates a reduction in wear rates compared with UHMWPE.
- This reduction in wear is also associated with significantly fewer osteolytic lesions at long-term follow-up.
- Mechanical failure of HCLPE is unusual but there are case reports.
- The fracture of the liner occurs at the rim, where the HCLPE is unsupported and thin due to elevated rims or locking mechanisms.

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23 Hip Resurfacing

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Clinical scenario

- A 48-year-old healthy male presents with right groin pain that has progressively limited his work and leisure activities over the last two years.
- Clinical examination of the affected hip reveals restricted motion and antalgia while radiographs demonstrate advanced degenerative joint disease.
- The patient is a manual laborer and avid hockey player who is seeking a surgical intervention to restore his function with durable results.

Top three questions

1. In young, active patients with advanced degenerative hip disease, does hip resurfacing result in superior patient-reported outcome measures compared to total hip arthroplasty (THA)?
2. In patients with advanced hip osteoarthritis, does hip resurfacing result in higher revision rates compared to THA?
3. Does more surgeon experience or technique, compared to less surgeon experience or other techniques, impact

the clinical outcome of patients undergoing hip resurfacing?

Question 1: In young, active patients with advanced degenerative hip disease, does hip resurfacing result in superior patient-reported outcome measures compared to total hip arthroplasty (THA)?

Rationale

While THA has consistently demonstrated excellent long-term clinical outcomes in patients suffering from end-stage degenerative joint disease,[1] hip resurfacing has emerged as an alternative option with several potential advantages. By only resurfacing the articulation, a relatively larger head is employed which may improve stability.[2] Furthermore, hip resurfacing maintains more femoral bone stock,[3] thereby facilitating future revision surgery and theoretically preserves each patient's native anatomy and biomechanics, which may result in improved motion and function. This is especially pertinent to young and active patients wishing to return to physically demanding activities. A comparison of patient-reported outcome measures between hip arthroplasty and resurfacing is therefore of paramount interest.

Clinical comment

The theoretical advantages of hip resurfacing must be demonstrated clinically through improved patient-reported outcomes over THA (the current gold standard treatment) before widespread adoption is advocated.

Available literature and quality of the evidence

The majority of studies comparing patient reported outcomes between hip resurfacing and replacement surgery are case-controls (level III) and report mixed results.[4–11] Nonetheless, there are four randomized controlled trials (RCTs) (level I) that compare clinical outcomes between hip resurfacing and replacement in relatively young and active patients. Two of these studies compare resurfacing with contemporary nonmetal-on-metal total hips,[12,13] while the other two studies compare hip resurfacing with metal-on-metal THA.[14,15]

Findings

Focusing our discussion on the available level I evidence, there are two studies that compare hip resurfacing to THA with nonmetal-on-metal articulations. Costa et al. randomized 126 patients to receive either hip arthroplasty or resurfacing and reported similar Oxford Hip Scores (mean 38.2, 95% confidence interval [CI]: 35.3–41.0 vs 40.4, 95% CI: 37.9–42.9, respectively) and Harris Hip Scores (HHS; 82.3, 95% CI: 77.2–87.5 vs 88.4, 95% CI: 84.4–92.4, respectively) at 12-month follow-up.[13] Strengths of this study include: adherence to a standardized preoperative assessment and perioperative care pathway for both groups, blinded measurement and assessment of outcomes, low cross-over rates, excellent follow-up (95%), and the fact that each patient had the allocated surgery according to the preferred technique of the operating surgeon. While clinical outcomes were similar between the two groups, they were limited to a one-year follow-up and may not reflect long-term results between these two interventions. More recently, Haddad and colleagues reported on the long-term results of their randomized trial involving 80 patients treated with either cementless THA or

a Birmingham hip resurfacing.[12] Similar to Costa's study, there was no difference in mean Oxford Hip Scores (37.9 ± 0.6 for replacement vs 40.1 ± 0.4 for resurfacing) nor HHS (96 ± 4.2 for replacement vs 97.1 ± 5.1 for resurfacing) at mean follow-up of 12 years. Nonetheless, the authors report that a higher proportion of patients with a hip resurfacing were running and involved in sport and heavy manual labor after 10 years. The authors suggest an advantageous return to high-level activity in resurfaced patients, perhaps below the sensitivity threshold of the Oxford and HHS. It must be noted, however, that there was a large amount of crossover in this study where only 24 of the 80 patients actually underwent the treatment to which they were randomized.

There are two RCTs comparing hip resurfacing to metal-on-metal THA. Vendittoli et al. randomized 209 hips to undergo resurfacing or replacement with a metal-on-metal bearing using a 28 mm head.[14] They demonstrated a marginally better Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) score in the resurfacing group (5.7 ± 8.6 for resurfacing vs 9 ± 11.0 for THA) at two-year follow-up. Garbuz et al. randomized 107 patients to either hip resurfacing or a large head metal-on-metal hip arthroplasty.[15] Exceedingly high metal ion levels discovered in the hip arthroplasty group raised concern for trunnionosis and eventually led to the premature termination of the trial. Similar early failures of large head metal-on-metal total hips have been identified from multiple studies and registries leading to the widespread abandonment of these implants.[16]

Resolution of clinical scenario

- Current level I evidence does not support a clear clinical benefit in patient-reported outcome measures

following hip resurfacing in comparison to THA.

- Nonetheless, hip resurfacing as compared to THA may offer advantageous long-term function with respect to specific high-demand actives such as participation in running sports and manual labor.

Question 2: In patients with advanced hip osteoarthritis, does hip resurfacing result in higher revision rates compared to THA?

Rationale

Higher-than-expected revision rates for resurfaced hips have been reported for numerous reasons including femoral neck fractures,[17,18] implant position,[19] and size,[20,21] adverse reactions to metal ions,[22,23] and certain implant designs.[24,25] Given the generally young age and high activity level of this patient population, revision is a major concern – albeit revising a hip resurfacing may be easier than a THA due to preserved femoral bone stock. A critical evaluation of survivorship is therefore necessary to guide surgical indications and appropriate patient selection for successful hip resurfacing.

Clinical comment

Notwithstanding potential clinical benefits of hip resurfacing, the survivorship of these implants in comparison to conventional THA remains a critical concern in the young and active patient.

Available literature and quality of the evidence

Numerous case series, cohort studies, and small single-center RCTs have compared the revision rates between hip resurfacing and replacement as summarized in the systematic review by Marshall et al.[2] and meta-analysis performed by Smith et al.[26] The former reported an average time to revision was 3.0 years for metal-on-metal hip resurfacing (95% CI: 2.95–3.1) versus 7.8 years for THA (95% CI: 7.2–8.3). Similarly, Smith et al. demonstrated a risk ratio for revision of 1.72 (95%CI: 1.20–2.45) with hip resurfacing compared to replacement; however, both Marshall and Smith caution the lack of high-quality data included in these analyses. Few studies reported medium- or long-term follow-up or adequate matching of controls, and included a variety of hip resurfacing implants – some of which have been shown to be far more successful than others. Consequently, we believe the data from national joint registries, which collect detailed information on patients undergoing joint replacement, are the best available data on survivorship and will be used in this section to compare revision rates of hip resurfacing and replacement implants.

Findings

The 2016 annual report of the Australian National Joint Replacement Registry analyzes 498 660 primary and revision hip arthroplasty procedures with up to 15-year follow-up.[27] While the number of hip resurfacing procedures has dropped considerably over the last few years (accounting for only 0.8% of hip arthroplasty procedures in 2016), a total of 16 521 hip resurfacing procedures have been captured and are tracked in the registry. The cumulative percent revision of primary hip resurfacing for patients with osteoarthritis (which accounts for >95% of the hip resurfacing procedures in the registry) is 9.5% (95% CI: 9.0–10.0) at 10 years and 12.9% (95% CI:

11.8–14.0) at 15 years. This is considerably higher in comparison to primary THA, which has a cumulative percent revision of 5.1% (95% CI: 5.0–5.2) at 10 years and 8.0% (95% CI: 7.7–8.3) at 15 years. However, when comparing only male patients younger than 55 years old (the typical candidate for resurfacing[28]) and excluding implants with poor performance, the 10-year revision rates are lower with resurfacing 3.7% (95% CI: 3.1–4.4) compared to replacement 5.4% (95% CI: 5.2–5.6). Prior case series have associated component malpositioning[19] and a small head size[20,21] with increased risk of failure. The registry reiterates the latter, reporting 10-year cumulative percent revision rates of 23.0% (95% CI: 20.6–25.6) and 5.1% (95% CI: 3.8–6.8) for head sizes of ≤44 and >55, respectively (hazard ratio of 3.2; 95% CI: 2.3–4.5). The registry also reports markedly higher failure rates in females (10-year cumulative percent revision of 18.3%; 95% CI: 16.9–19.7 for females vs 6.6%; 95% CI: 6.1–7.1 for males), likely reflecting smaller component sizes in these patients. Finally, the wide range of clinical success of specific resurfacing implants is highlighted in the registry; reporting overall 10-year percent revision from as low as 6.9% (95% CI: 6.4–7.5) for the Birmingham Hip Resurfacing System to as high as 30.1% (95% CI: 27.4–33.1) for the Articular Surface Replacement (which was recalled in 2010). The strengths of these data include the large number of patients included, long-term follow-up, and the fact the majority of the resurfacing implants used were the Birmingham Hip Resurfacing System which has an excellent track record and therefore represents a best-case scenario. The biggest limitation of the Australian data, alike other registries, is that they do not capture detailed level II data (e.g. body mass index, comorbidities, activity-level, surgeon volume) and therefore makes for a potentially biased comparison to patients undergoing THA.

Other national registries such as the Swedish Hip Arthroplasty Register[29] and National Joint Registries (UK)[30] demonstrate similar findings to those described above. The latter reports 10-year revision rates of 8.4% (95% CI: 7.9–8.9) for the Birmingham Hip Resurfacing System, where the leading causes for revision were pain and adverse soft tissue reactions. Interestingly, the registry also reports revision rates following first revision (re-revision), which are 11.5% (95% CI: 10.3–12.9) for hip resurfacing and 13.0% (95% CI: 12.1–13.8) for uncemented hip arthroplasty.

Resolution of clinical scenario

- According to national joint registry data, the long-term revision rates of hip resurfacing are higher than THA except in males younger than 55 years of age where resurfacing has advantageous survivorship.
- Younger age, female sex, small head size, and certain implant designs are all strongly associated with a higher cumulative percent revision following hip resurfacing.
- Following first revision, the risk of subsequent revision is similar between a THA and resurfacing.

Question 3: Does more surgeon experience or technique, compared to less surgeon experience or other techniques, impact the clinical outcome of patients undergoing hip resurfacing?

Rationale

While the concept of hip resurfacing was established as early as the 1940s,[31] technological advances in metal-on-metal bearings[32] enabled an all-metal acetabular component and spawned renewed interest in resurfacing over the last two decades.[28] The adoption of new implants and techniques for resurfacing therefore introduced a new learning curve to surgeons. Subsequently, the clinical outcomes have improved through refinement of implant design, surgical technique, and patient selection, all of which are essential to successful hip resurfacing.

Clinical comment

An understanding of the lessons learned from early experiences with metal-on-metal hip resurfacing and appreciation of the learning curve are critical for surgeons who wish to perform this procedure.

Available literature and quality of the evidence

The clinical success of various hip resurfacing implants is well followed in national joint registries (see above). With regard to surgeon experience, technique, or patient selection, the literature is sparse. The effect of these parameters is limited to several large case series (level IV) as discussed below.[33–37]

Findings

Berend and Lombardi, two experienced high-volume joint surgeons, described their initial experience with hip resurfacing.[33] Following surgeon-to-surgeon training and practice sessions on cadavers, they reported on their first 73 patients who underwent hip resurfacing. There was an 8% prevalence of early failure requiring revision (at mean

follow-up of 25 months). While a high number of patients were lost to follow-up, of the 77% evaluated at a minimum of one year (average, 33 months), only 79% were reported to have a good or excellent result and only 65% were free from pain. Della Valle et al. reported on the first 537 cases performed in the United States using the Birmingham Hip Resurfacing System with 14 component revisions (7.4%) within the first year, including 10 for femoral neck fracture, two for dislocations, and two for acetabular component loosening.[34] These failure rates contrast starkly to those reported by surgeons with a long experience using the same implant such as the series reported by Treacy et al. with a five-year revision rate of only 2%.[37] These series clearly warn of a learning curve associated with the surgeon new to hip resurfacing.

Beyond the initial learning curve of the procedure, refinement of technique has led to improved outcomes in several studies. Mont et al. reported on a series of 1016 hip resurfacings by a group of surgeons who convened after the first 292 cases for an *investigator meeting* where they reviewed their results. The following risk factors for failure were identified:[35]

- Preoperative assessment

  Large or multiple cysts situated near the femoral head-neck junction.

  Poor bone quality.

- Operative/technical factors

  Leaving reamed bone uncovered by femoral component.

  Minimizing the size of the femoral component to conserve acetabular bone.

Leaving the femoral component proud on the femoral head.

Malpositioning of the acetabular shell.

- Postoperative factors

  Noncompliance with postoperative restrictions.

  Weightbearing and traumatic events.

  Malpositioning: acetabular shell <30°, >60°, or femoral component <135°.

The group made a concerted effort to address the above listed risk factors thereafter. Comparing outcomes before and after the meeting, overall complication rates were significantly reduced, notably in the rates of revision for femoral neck fracture (7.2 to 0.8%) and aseptic loosening of the acetabular component (3.4 to 1.9%) with mean follow-up of 33 months. Amstutz et al. elaborated on a series of 1000 patients undergoing resurfacing with the Conserve Plus and demonstrated that improvements of their femoral fixation technique (termed *first*, *second*, and *third generation*) correlate with significant improvements in medium-term implant survivorship: with a hazard ratio of 0.37 (95% CI: 0.17–0.83).[38] Siebel et al. reported similar improvements in revision rates as the number of cases performed increased, dropping from 5% in the first hundred cases to 1% in the third hundred cases.[36] Despite reducing failure rates with experience and refinement of technique in all of the above studies, patient-reported outcomes were similar over time.

Resolution of clinical scenario

- Surgeons who are inexperienced in hip resurfacing should be aware of a potential learning curve and increased risk of implant failures (particularly femoral

neck fracture and aseptic loosening of the acetabular component) during this period of adaptation.

- Experience and a concerted effort to obviate potential sources of failure have led to improved survivorship following hip resurfacing. However, an improvement in patient-reported outcomes has not been found.

Summary of answers

- Experience with contemporary hip resurfacing over the last two decades has tremendously enhanced our knowledge on the indications for surgery, implant design, and operative technique. Today, hip resurfacing remains an option for the younger, active, male patient to provide durable survivorship and a favorable condition for future revisions.
- Although hip resurfacing as compared to THA may offer advantageous long-term function with respect to specific high-demand actives, current level I evidence does not support a clear benefit in patient-reported outcome measures.
- According to national joint registry data, the long-term revision rates of hip resurfacing are higher than THA except in males younger than 55 years of age where resurfacing has advantageous survivorship.
- Younger age, female sex, small head size, and certain implant designs are all strongly associated with a higher cumulative percent revision following hip resurfacing.
- Surgeons who are inexperienced in hip resurfacing should be aware of a potential learning curve and increased risk of implant failures (particularly femoral

neck fracture and aseptic loosening of the acetabular component) during this period of adaptation.

- Experience and a concerted effort to obviate potential sources of failure have led to improved survivorship following hip resurfacing.

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24 Metal-on-Metal Hip Arthroplasty

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Clinical scenario

- A 40-year-old semiprofessional athlete comes to your clinic with recalcitrant groin pain after failed conservative treatment.
- Radiographs show advanced degenerative changes.
- The patient enquires about a metal-on-metal (MoM) hip resurfacing (HR) because he has many friends with the same type of implant who continue to play sports routinely.

Top three questions

1. In young, active patients undergoing MoM HR, is the revision rate higher than those undergoing metal-on-metal total hip arthroplasty (MoM-THA)?
2. In patients who have undergone MoM HR, does monitoring metal ion levels, compared to no active monitoring, affect outcomes or revision rates?

3. In patients with suspected pseudotumor and systemic toxicity, which diagnostic tests, compared to other tests, are most accurate?

Question 1: In young, active patients undergoing MoM-HR, is the revision rate higher than those undergoing metal-on-metal total hip arthroplasty (MoM-THA)?

Rationale

The indications for MoM-THA are currently limited due to a loss of confidence in certain devices. In analyzing survival rate of MoM hip implants, it is important to differentiate between HR and THA. While some MoM devices associated with recalls have caused concern, other MoM-THA devices continue to have an acceptable rate of success.

Clinical comment

In young patients, MoM-HR is believed to provide slightly better functional outcomes but slightly worse survival rate in the long-term compared with ceramic-on-ceramic (CoC).

Available literature and quality of the evidence

- Level I: 1 meta-analysis.[1]
- Level II: 4 systematic reviews.[2–5]
- Level III: 5 case control retrospective studies.[3_7]
- Level IV: 5 case series.[8_12]

Findings

Two studies that have analyzed 28 mm femoral head MoM-THA found better outcomes compared to 36 mm heads, with a survivorship greater than 90% survivorship at 15.[11,12] National database registries report failure rates with MoM-THA to be two- to threefold higher than THA with non-MoM bearings. In a meta-analysis, MoM was found to have an all-cause revision rate that was higher than CoC.[1] Similarly, in a cohort of 6215 MoM-THA patients versus 7360 CoC THA patients, the revision rate in MoM was higher than CoC bearing cohort. A recent systematic review which included 40 randomized controlled trials (RCTs) confirmed the same conclusion of a lower survival rate of MoM-THA.[3] Higuchi et al. compared MoM and CoC hip arthroplasties and concluded that the incidence of osteolysis was lower in CoC, but that the survival rate was similar in both groups.[3] Another long-term study revealed that patients younger than 50 years of age with MoM HR maintained substantial improvements in health and function beyond 10 years after the surgery.[10]

The Nordic Arthroplasty Register Association analyzed 32 678 cementless stemmed THA. At six-year follow-up, the revision rate was significantly higher for MoM compared to metal-on-polyethylene (MoP) stemmed THA. In contrast, the prevalence of revision due to dislocation was lower for MoM-THA.[4] The Australian Joint Registry demonstrated 5- and 10-year revision rates of 3.3 and 7.4%[5] with stemmed MoM-THA. Seppanen et al. reported an 86% 10-year survival rate of MoM-HR from the Finish registry when all type of centers were analyzed.[7] However, excellent survival rates were reported from certain single centers as high as 97% at 10 years.[8] In patients younger than 45 years of age, survival rate was similar between HR and conventional THA, and HR patients were able to return to a moderate or high activity level.[9] Furthermore, recent systematic review

has suggested some clinical potential advantages of HR against THA[1] but slightly higher revision with lower complications rates.[2]

At the 6th Advanced Hip Resurfacing Course, 67% of surgeons suggested completely abandoning stemmed MoM-THA with large diameter heads.[6] Younger women in combination with larger head size were associated with increased revisions. Moreover, it was described that reoperations were more frequent and occurred earlier for MoM in this high-risk group.[2] However, they recommended that MoM-HR should not be abandoned and should be viewed separately from stemmed MoM-THA with a large diameter head.[6]

Resolution of clinical scenario

- Stemmed MoM-THA, particularly with large femoral heads, should no longer be used.
- There is still a role for MoM-HR in low-risk patients by experienced surgeons.

Question 2: In patients who have undergone MoM-HR, does monitoring metal ion levels, compared to no active monitoring, affect outcomes or revision rates?

Rationale

Metal ion levels of chromium (Cr) and cobalt (Co) in patients with MoM-THA could be increased during follow-up and this issue could be related with THA malfunction and potential complications.

Clinical comment

The authors have in their experience seen asymptomatic young patients with an MoM-THA and minimal radiological changes during routine follow-up visits who have incidentally been noted to have elevated metal ion levels. Optimal monitoring of metal ion levels is unclear.

Available literature and quality of the evidence

- Level II: 3 systematic reviews.[13–15]
- Level III: 12 cohort studies.[16–27]
- Level IV: 5 case series.[628–31]
- Level V: 2 studies.[32,33]

Findings

Metal ions levels and adverse tissue reaction

After MoM hip arthroplasty, patients with blood metal ions levels below international thresholds have a lower risk of adverse reactions to metallic debris.[16] However, some authors have reported that blood metal ions levels are not correlated with intraoperative tissue damage, presence of pseudotumor, or pseudotumor size.[28,29] Another study reported that the synovial fluid metal ions levels were also not correlated with histological severity in MoM hip arthroplasty revisions.[17] Moreover, it's known that the interpretation of the blood metal ions levels can be difficult in patients with systemic renal disease, other metallic implants, or bilateral MoM implants. Thus, the analysis of the blood metal ion levels should be used as complementary information but not as an isolated parameter to establish the need for revision surgery.[18]

Metal ion levels and imaging findings

MacNair et al. found poor correlation between blood metal ion levels and the occurrence of adverse reaction to metal debris (ARMD) on magnetic resonance imaging (MRI) and recommended that the decision to revise implant should be based on imaging and not on blood metal ion levels.[23] Malek et al. demonstrated positive MRI findings combined with high metal ions levels increased detection of a malfunctioning MoM-THA implant.[24] Langton et al. recommended measuring ion values even in asymptomatic patients due to silent osteolysis when Co blood concentration greater than 20 μg/L was present.[25]

Metal ion levels and component malpositioning

Ohtsuru et al. recently reported a positive correlation in cup inclination and metal ion levels.[19] However, another study concluded that the acetabular inclination angle was not a meaningful determinant of higher metal ion levels.[20] Furthermore, RCT data have reported no correlation between acetabular inclination and metal ion levels.[13] Another study analyzed malfunctioning MoM-THA with a mean cup inclination of 45.6° and concluded that there is no relationship between cup inclination and metal ion levels.[34] The 6th Advanced Hip Resurfacing Course established 40° of inclination (±10°) and 15° of anteversion (±10°) as acceptable limits for acetabular positioning.[6] De Haan et al. proposed that metal ion levels increased when cup inclination was >55° compared with <55°. Indeed, functional arc of cover and component design were mentioned as important risk factors.[31] In contrast, a prospective study with unilateral MoM HR concluded that metal ion levels positively correlated with the three-dimensional orientation of the acetabular component and

gender but not body mass index (BMI), femoral head size, or hip type.[14]

Metal ion level threshold

Threshold of seven parts per billion (ppb) had 89% specificity, but only 52% sensitivity for detecting a failed MoM hip prosthesis. At a threshold of 4.97 µg/L sensitivity was 63%, and specificity was 86%.[14] Van Der Straeten et al. reported that the acceptable upper levels for well-functioning devices were: Cr 4.6 µg/L and Co 4.0 µg/L for unilateral implants, and Cr 7.4 µg/L, Co 5.0 µg/L for bilateral MoM-THA.[21] The American Academy of Orthopedic Surgeons (AAOS) defined a cut-off <3 µg/L for the low-risk group, 3–10 µg/L for the medium-risk group, and >10 µg/L for the high-risk group. The European Commission specifies a threshold of 2–7 µg/L for further imaging investigations. The European Federation of National Associations of Orthopedics and Traumatology (EFORT) and the European Hip Society (EHS) have proposed as levels of *without clinical concern* when Cr and Co are <2 µg/L and a level for *clinical concern* within the range of 2–7 µg/L. In 2011, the Dutch Orthopedic Association (NOV) established as normal values <2 µg/L, slightly elevated 2–4 µg/L, elevated above 4 µg/L, and extremely elevated at >20 µg/L.

Metal ion levels and international protocols

The United States Food and Drug Administration (FDA) recommends follow-up every six months, with possible imaging and assessment of metal ions in the blood, but does not recommend a specific metal ion level as a trigger for revision or other medical intervention.

The United Kingdom Medicine and Healthcare products Regulatory Agency (MHRA) recommends routine blood

metal ion testing and cross-sectional imaging. However, a prospective study of 256 asymptomatic patients with unilateral MoM-THA described a significant increase in blood ion values in the first two years. After seven years, there was no significant change in Co values, and there was a decline in Cr value after nine years. The authors concluded that annual metal ions may be unnecessary in asymptomatic patients.[22]

The Agence Francaise de Securité Sanitaire des Produits de Santé does not propose specific ion levels but emphasizes clinical and radiological follow-up.[26],[32],[33] A recent systematic review about the best protocol to detect MoM-THA and MoM-HR failures recommended clinical and imaging follow-up of asymptomatic HR but recommended blood metal ion levels in MoM THA patients.[15]

Resolution of clinical scenario

- There is no consensus in the current literature on threshold levels for metal ions (Cr and Co).
- Metal ion levels should be repeated periodically and their development over time considered.
- Rather than being a single diagnostic tool, metal ions should be assessed in the entire context of the clinical and radiological findings.

Question 3: In patients with suspected pseudotumor and systemic toxicity, which diagnostic tests, compared to other tests, are most accurate?

Rationale

MoM-THA is considered a potential contributor to the local release of metal ions with tissue reaction and the formation of local *pseudotumor*. High blood levels of metal ions could also be related to clinical symptoms and systemic toxicity.

Clinical comment

During routine medium- or long-term follow-up, patients with MoM-THA could present with pain, fatigue, weakness, hypothyroidism, and mild peripheral neurological symptoms. Presence of pseudotumor or systemic toxicity related to increased blood metal ions levels should be considered as a possibility in these cases.

Available literature and quality of the evidence

- Level II: 7 systematic reviews and RCTs.[35–41]
- Level III: 5 cohort studies.[42–46]
- Level IV: Five case series.[947–50]

Findings

Pseudotumors

Many factors are associated with local tissue reaction and pseudotumor formation after MoM-THA. Risk factors include large femoral head size, acetabular malpositioning, female sex, dysplasia, metal hypersensitivity, low BMI, and higher level of activity.[35] Van der Veen et al. reported a pseudotumor incidence of 54% with MoM-THA compared to 22% with MoP-THA. In this cohort, blood Co levels did not exceed acceptable clinical values and no difference was detected between the two groups at the final follow-up.[36]

Local effects of metal ions were local discoloration, tissue necrosis, and pseudotumor formation.[37,47]

Systemic toxicity

Systemic metal toxicity, including cobaltism, was considered a potential complication of MoM arthroplasty that could lead to organ failure.[43] Patients with systemic effects of metal ions commonly present with fatigue, weakness, hypothyroidism, polycythemia, cognitive dysfunction, neuropathy, and encephalopathy.[38,47,48] Patients may also complain about black tongue discoloration and a metallic gustation.[49] Thus, the inspection of the oral mucosa is recommended when blood metal ions levels are elevated. Though a relationship between MoM-THA and cardiac disease had previously been proposed in the literature,[50] a recent well-conducted study of over 50 000 patients demonstrated that MoM-THA was not associated with any cardiac complications.[41]

In a recent systematic review, symptoms associated with cobaltism appeared at a mean of 41 months and involved the cardiovascular system (60%); the audio-vestibular system (52%); the peripheral motor-sensory system (48%); the thyroid (48%); psychological functioning (32%); the visual system (32%); and the hematological, oncological, or immune systems (20%). Blood Co levels (mean 324 µg/L), but not Cr levels, were highly associated with a quantitative measure of overall symptom severity (Pearson's r, 0.81; $p < 0.001$). Surprisingly, revision of failed CoC-THA was the main cause of this cobaltism disease.[38]

Indications for revision of MoM-THA

It is accepted that the presence of a symptomatic MoM-THA, along with elevated metal ions levels, and the

presence of a pseudotumor on an imaging study are an indication for revision surgery.[39] Cup loosening remains the main cause of failed MoM hip arthroplasty.[9] Revision surgery should include a meticulous debridement in order to remove the necrotic tissues associated with pseudotumor.[40] However, pseudotumor recurrence was reported in 9–18% according to some studies.[44],[45] Revision of failed MoM-THA requires conversion to a metal-on-polyethylene or ceramic-on-polyethylene bearing.[46]

Resolution of clinical scenario

- Patients with MoM-THA who present with fatigue, weakness, cognitive dysfunction, or neuropathy should be examined to rule out systemic metal toxicity.
- Blood metal ion levels and imaging studies should be done to investigate pseudotumor presence.
- Patients with symptoms, elevated metal ions levels, and the presence of a pseudotumor on an imaging study may require revision surgery.

Summary of answers

- MoM bearing surfaces for hip arthroplasty and resurfacing have gained a negative reputation due to recalls and concerns with high revision rates.
- MoM-THA with large head size should be avoided altogether.
- MoM bearings should be avoided in females and those with known metal hypersensitivity.
- MoM-HR, particularly in carefully selected patients, does represent an attractive option for younger and more active male patients.

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25 Ceramic in Total Hip Arthroplasty

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Clinical scenario

- A 57-year-old active woman has progressively developed severe pain in her right hip.
- She has exhausted conservative treatments and is keen to remain active with hobbies including golf and badminton.
- At present she has mild rest pain, frequent sleep disturbance, and walking is limited to half a mile.
- She is unable to perform any sporting activities. She is otherwise fit and well.
- She has done some research and is curious about ceramic versus other bearing surfaces and if ceramic has any unique complications or considerations.

Top three questions

1. In patients undergoing total hip arthroplasty (THA), do ceramic bearing surfaces, compared to metal or polyethylene, result in better outcomes?
2. In patients undergoing THA, are ceramic bearing surfaces, compared to metal or polyethylene,

associated with a unique set of complications?

3. In patients who have undergone THA with ceramic bearing surfaces, compared to metal or polyethylene, are revisions more likely and/or more difficult to perform?

Question 1: In patients undergoing total hip arthroplasty (THA), do ceramic bearing surfaces, compared to metal or polyethylene, result in better outcomes?

Rationale

With over 4.5 million ceramic THAs implanted worldwide before the turn of the last century,[1] and more recently and in its most modern form, over eight million delta ceramic components sold,[2] it is important to understand its place in today's THA landscape.

Clinical comment

THA surgery is one of the most common procedures performed in orthopedic surgery. It is considered one of the most effective orthopedic procedures with excellent long-term survival in the elderly.[3] Metal-on-polyethylene (MoP) replacements are still the traditionally implanted bearings, used initially by Charnley in the 1960s, and still recommended by many today. Long-term survival of this bearing combination is limited by polyethylene wear and related osteolysis.[4] In the younger patient, with longer life expectancy and increased activity, there is an up to tenfold increase in the demands of any replacement bearing.[5] Regarding this, there is an oft-quoted, long-term study of

patients under the age of 51 which demonstrated a failure rate requiring revision arthroplasty of over 25% at 20 years and almost 50% at 27 years.[6] Revision procedures are challenging, a risk to the patient, and of considerable cost to health service providers.[7–10] Alternative bearings and joint replacements have therefore been developed and include ceramic bearings, metal-on-metal (MoM) resurfacings, and highly cross-linked polyethylene, all aiming to prolong the survival of the prosthesis, and prevention of osteolysis and its consequences.

Available literature and quality of the evidence

Randomized controlled trials (RCTs) and meta-analyses are available to answer this question.

Findings

A randomized controlled trial (RCT) comparing 31 ceramic-on-ceramic (CoC) THAs with 30 cobalt chrome on highly cross-linked polyethylene (MoP) revealed no difference in outcome scores between the two groups looking at Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) and Short Form 36 (SF-36) scores at a follow-up of between 2 and 24 months.[11] Another compared 30 CoC replacements with 26 ceramic-on-plastic (CoP) replacements and reported no significant difference in joint specific outcome scores at a mean follow-up of eight years.[12] A further RCT with a mean follow-up of 35.2 months compared 346 CoC with 168 MoP replacements, and reported equivalent Harris Hip Scores (HHSs) and patient satisfaction.[13] A five-year RCT published in 2005 comparing 213 CoC with 101 MoP hips concluded that CoC articulations were at least equivalent in performance to the MoP design.[14] HHSs were 96.6 in the ceramic and 97 for MoP. An extension of this series, assessing a titanium-

coated ceramic bearing, again identified no difference in HHS with a mean of 96.6 at 4.2 years' follow-up.[15] A subsequent review of the same cohorts at a mean follow-up of eight years again identified no difference in outcome scores.[16] Finally, a minimum two-year follow-up RCT compared 250 CoC articulations with 250 CoP hips showed no difference in clinical outcome.[17]

Three meta-analyses[18–20] all published in 2015 included in excess of 5000 patients and failed to show a significant clinical difference, be this CoC, CoP, or MoP.[20] The authors concluded that other factors, including cost, be considered rather than clinical outcomes. Furthermore, 10 RCTs, all published from 2005 to 2013, showed no statistical difference in survival or patient outcomes.[12,17,21–28] However, some of these trials did confirm radiographic changes with slight increased wear in the CoP compared to the CoC. A Canadian study identified this wear to be three times that of CoC,[21] and one further study identified significant wear but no clinical sequelae in the CoP prosthesis at 10 years.[12]

Despite so much data suggesting no clinical difference but some radiographic deterioration, several papers deserve specific mention of practical significance to our patient. Petsatodis et al. undertook a study of 100 young patients (mean age 46) who had undergone a CoC THA and showed that at 10 and subsequently 20 years a very satisfactory result with only six requiring revision, these due to loose ceramic chips.[29] Another studied 100 patients (mean age 45), each of whom underwent CoC and CoP in bilateral replacements.[24] Patients were reviewed after 12.4 years (mean) with, in effect, each patient acting as their own control. There was no difference in clinical outcomes at their latest follow-up. These data appear to support the view that there may be some deterioration on scientific

review but no difference in patient satisfaction or clinical outcome.

Ceramics have continually improved over the years. First-generation alumina ceramics (1974–1988) were characterized by low density, high porosity, and large grain size, and did not perform well with early series reporting high failure rates, but not directly due to the alumina itself. The main failures were aseptic loosening of the femoral stem[30],[31] or of the monoblock acetabular system[32] with reported fracture rates of 3–13%.[33]

Second- and third-generation alumina ceramics (1988–1994 and 1994–present, respectively) are characterized by a reduced grain size with increased alumina purity with the addition of calcium oxide (CaO) or magnesium oxide (MgO) materials.[34] With third-generation ceramics there has been further improvements with hot isostatic pressing, laser etching (avoiding surface stress risers), and proof testing.[33] Prior to proof testing, ceramic components were subject to a finished product audit in which only a sample from each batch was subject to testing.

Despite these improvements there continues a search for a ceramic material to satisfy increasingly more challenging patient demands. These changes include smaller components, additional sizes, along with even greater reliability and longevity. Known as a *fourth-generation ceramic*, BIOLOX delta (CeramTec AG, Plochingen, Germany) is a combination of both the major subsets of ceramic, an alumina matrix with zirconia particles homogeneously dispersed and encapsulated increasing the fracture toughness.[33]

Ceramics may be used as an alternative to a metal head in a conventional hard-on-soft bearing against polyethylene. With a lower Ra (the mathematical average of all deviations

from the mean line of the surface profile) and improved wettability, this combination has the potential to provide a low wear alternative to either stainless steel or cobalt chrome. Ceramic may also be used as a more modern hard-on-hard bearing against either a ceramic liner or, as a more recently introduced, ceramic-on-metal (CoM) bearing surface.[35–37] Advantages with hard-on-hard bearings is the potential for fluid film lubrication, an exceptionally low wear rate, and avoiding osteolytic polyethylene debris. Using hard-on-hard bearings also allows the use of large heads, which if used with a conventional polyethylene option would create excessive volumetric wear. CoC options also avoid the production of metal ions, which are released and may complicate MoM and CoM alternatives.[35–38]

Using a MoP articulation also offers the surgeon access to multiple head sizes and modular neck lengths spanning 20 mm. On the acetabular side, in addition to multiple inner diameter options, there is also the availability of lateralized liners, elevated rims, and anteverted, eccentric, and constrained liners. In contrast most CoC systems have only one head size per cup diameter, with three or four head lengths spanning 10 mm or less. These alternatives for equalizing leg lengths and maximizing stability are two crucial goals of THA.[8] Numerous liners and head options assist in achieving these goals. Any loss of these options may currently be the most substantial disadvantage of CoC THA.

Resolution of clinical scenario

- Overall, there is some evidence to suggest lower wear rates with ceramic-bearing surfaces.
- There is little evidence to demonstrate clinical benefit in most patients, and cost is a major consideration.

- There is evidence to demonstrate excellent results with ceramic surfaces in young patients.

Question 2: In patients undergoing THA, are ceramic bearing surfaces, compared to metal or polyethylene, associated with a unique set of complications?

Rationale

Being the second hardest material, after diamond, wear-resistant benefits must be weighed against the unique disadvantage risks of fracture and squeaking.

Clinical comment

Some issues unique to ceramic bearings include stripe wear, osteolysis, fracture, and squeaking.

Available literature and quality of the evidence

RCTs, as well as retrospective cohort studies and case series, are available to answer this question.

Findings

Stripe wear

Stripe wear is the term given to a localized crescent-shaped area of surface alteration of a ceramic femoral head.[32] Its cause is not fully understood. The resultant damage to the surface takes the form of grain fracture or pullout with resultant loose bodies and a roughened surface. This roughened area may then be the precursor of more extensive wear.[8]

Osteolysis

A short-term RCT comparing CoC and metal on cross-linked polyethylene reported no osteolysis at 24 months in either group,[11] not unexpected as even with conventional polyethylene hips wear-related osteolysis is not a short- or even medium-term complication. In a longer-term study, with mean follow-up of eight years, cortical erosions were reported in 4 of 287 (1.4%) alumina ceramic hips and 25 of 82 (30.5%) control MoP hips.[16] Within this latter group, one patient required revision of cup and liner for osteolysis at 10.5 years and another had a liner exchange at 52 months for polyethylene wear and osteolysis at eight years.[16] This report followed an earlier five-year follow-up of the cohorts with osteolysis recorded in 1.4% of 213 alumina hips and 14% of the 101 control MoP hips.[14]

One important retrospective review of 103 THAs deserves mention where ceramic implants reported a rate of osteolysis far higher than that found in other RCTs. At a mean follow-up of 92 months femoral osteolysis was reported in 23 hips (22%) with 10 requiring revision for loosening.[39] Tissue retrieved at revision confirmed abundant wear particles with the authors concluding ceramic particles can stimulate foreign body response and periprosthetic osteolysis. This was the first published series of patients with a CoC articulation demonstrating such a high level of osteolysis. However, the prosthesis used in this study was subsequently withdrawn from the USA due to high failure rates.[40]

Numerous medium- and long-term retrospective studies and reviews have shown limited or no evidence of osteolysis in modern well-functioning ceramic articulations.[41–45]

Fracture

Fracture is a catastrophic complication of a ceramic articulation requiring immediate revision. Benefits of low wear articulations need to outweigh specific risks associated with the bearing.

Early in the production of ceramics, fracture rate was as high as 13.4% for those manufactured before 1990, with catastrophic consequences.[46] The same paper reported the fracture rate of ceramic BIOLOX femoral heads as 0.026% for first generation, 0.014% for second, and 0.004% for femoral heads manufactured after 1994 based on data collected from over two million femoral heads. Sedel's review of the 30-year history of alumina suggests the risk of fracture is 1 in 2000 for a 10-year period.[42] A further historical review reports 80% of ceramic head fractures occur within the first two years and 90% within the first three years.[17]

Reviewing level I evidence, an RCT comparing MoP with a number of full ceramic options confirmed two fractures at 9.0 and at 6.5 years, in a total cohort of 380 ceramic hips[16] with an overall mean follow-up of eight years. There were also four ceramic chips on insertion of the liner, which were immediately changed to a new liner and shell, none of these required revision.[16]

In order to address the issue of fracture on insertion, a titanium-cased alumina ceramic component was introduced as a fourth group. In a separate publication, this group showed no chips, fractures, or failures at a mean follow-up of 4.2 years in 209 hips.[15] An RCT by Bierbaum et al. involving 514 hips in 458 patients comparing MoP articulations with CoC revealed no fractures in the 346 in the ceramic group with a mean follow-up of 35 months.[13] There was, however, an insertional chip rate of 2.6% (9/346 hips), each identified and replaced at the time of surgery with as yet no sequela. Another large medium-term

study involving 500 hips comparing an equal number of CoC articulations with CoP, at a minimum follow-up of two years, reported no ceramic fractures; one liner chipped on insertion requiring exchange (0.4%).[17] A review of 56 hips at a mean follow-up of eight years reported no ceramic fracture or liner chips in 30 CoC articulations and 26 CoP hips.[12]

Lastly, no fractures were reported at a mean of 50.4 months in 103 hips in 97 patients in a retrospective review.[43] A number of case reports of fracture have been published, one of which from 1995 reviewed the available data from 10 previous published fracture reports. They concluded that, including their own case, common characteristics for fracture included young age at surgery, heavy and active patients, and 8 of the 10 were male.[47],[48]

Squeaking

Squeaking from the site of THA is a phenomenon unique to hard-on-hard bearings, whether MoM or CoC.[49]–[53] The cause is not fully understood and a number of possible etiologies have been postulated including component mismatch, insufficient lubrication, stripe wear, and third body metal debris.[49]

In our review of ceramic meta-analyses, two confirmed squeaking as an occurrence[18],[19] but Wyles et al.[20] failed to report it as an outcome measure. As for RCTs (of which there were 10), squeaking was rarely mentioned and Hamilton in 2009 in 263 patients specifically found squeaking not to have occurred.[22]

Question 3: In patients who have undergone THA with ceramic bearing surfaces, compared to metal or polyethylene, are revisions more likely and/or more difficult to perform?

Rationale

It is important to know if revision rates are different among patients with ceramic bearing surfaces as this is perhaps the single most impactful outcome both from the patient perspective and from a systems perspective.

Clinical comment

As a surgeon, it is important to know if revision surgery is different depending on the bearing surfaces. This is particularly important given that patients may end up seeing a different surgeon for their revision surgery than the one who performed the primary procedure. Thus, even surgeons who do not routinely use ceramic bearings need to be aware of their implications for revision surgery.

Available literature and quality of the evidence

Level I evidence reviewing THA revision is difficult to obtain. Observational and retrospective evidence is available. Five trials (1511 patients total) report postoperative revision rates in comparative randomized studies involving CoC articulations.[11–13,16,17] Three further trials were excluded from analysis as they were previous publications from the same cohort.[14,15,54] The results of pooled statistics are shown in Table 25.1.

Table 25.1 Revision surgery. CoC: ceramic on ceramic, CoP: ceramic on polyethylene, MP: metal on polyethylene, RR: relative risk of revision with ceramic on ceramic compared to alternatives (values <1 favors CoC, >1 favors control).

		Events			
	N	**CoC**	**Control**	**RR**	**95% CI**
CoC vs CoP	475	2/226	7/249	0.309	0.063–1.502
CoC vs MP	1036	14/744	16/292	0.331	0.159–0.687
CoC vs all	1511	16/970	23/541	0.378	0.198–0.721

Findings

Two studies compared CoC articulations with CoP and concluded a reduced risk of revision in the CoC group (risk ratio [RR] = 0.309; 95% confidence interval [CI]: 0.063–1.502).[12,17] Follow-up in these studies varied from a minimum of two years (n = 460) to a median of eight years (n = 55). Two hips required revision in the ceramic group due to recurrent dislocations, while in the control group seven revisions were performed, one for pain of unknown etiology, one loose acetabulum, and five for recurrent dislocation. Within the remaining three studies comparison was made between CoC articulations and MoP in 1036 hips.[11,13,14] Again, a reduced overall risk of revision was observed in the ceramic group (RR = 0.331; 95% CI: 0.159–0.687). Follow-up in these studies ranged from two to eight years (sample size ranged from 61 to 500). Taking all CoC articulations and comparing these with controls revealed a relative risk of revision of 0.378 (n = 1511; 95% CI: 0.198–0.721) for the CoC option.

Revision of any hip replacement is a complex undertaking. Theoretically, the use of ceramic articulations during primary surgery should reduce the frequency of revision

hip replacement. However, when one is required, the absence of osteolysis facilitates revision surgery[45] avoiding the need for bone grafting.[44] Worse, if revision is required following fracture, there will be extensive third body debris within the effective joint space damaging exposed femoral trunnions and acetabular shells. Any delay causes further damage and soft tissue contamination and therefore revision is urgently required. The revision also requires exchange of all components to prevent subsequent bearing exposure to macro- and microscopic ceramic particles.

Allain published a case report and a study on a large series of head fractures.[55],[56] The case report was of a 54-year-old who sustained a traumatic fracture of their femoral head five years after implantation.[55] This was revised to a stainless-steel-on-polyethylene liner. Subsequently, at 11 months the patient developed pain and at 18 months the patient required a second revision. Intraoperatively, the stainless-steel femoral head was deformed and severe metallosis was noted. Histologically, fragments of both stainless steel and alumina ceramic were noted in the soft tissues.

A multicenter review by the same author reviewed 105 revisions for ceramic head fractures.[56] Thirty-one percent went on to require at least one repeat revision with an overall five-year survival rate of only 63%. This rate was worse than most revision series and, in all likelihood, due to retained ceramic particles.[8] Allain's review is the most extensive review available in the literature and makes a number of recommendations.[56] Factors influencing results included whether the cup was changed (57% required re-revision without, 21% with exchange), extent of synovectomy (re-revision in 67% with partial synovectomy, 19% with complete synovectomy), and patient age (54 years in those requiring revision and 63 in those who did

not; p = 0.02). Although definitive conclusions could not be made, this paper does imply that any revision following ceramic fracture should include cup exchange, total synovectomy, and a cobalt chrome or ceramic head.

Lastly, one paper deserves specific mention. Sharma et al. in 2010 published a long-term follow-up of an admittedly small number of THAs for ceramic head fractures.[9] The authors emphasized that ceramic fractures, although increasingly rare with newer ceramics, are associated with ceramic particles penetrating the surrounding tissues. Thus, they undertook and described a radical synovectomy and metal on polyethylene articulation. There were no revisions at 10 years and a yearly wear rate comparable with a matched controlled group of primary metal on polyethylene THAs.

Resolution of clinical scenario

- A revision following ceramic bearing THA is not a simple undertaking.
- The best approach is likely extensive revision, including radical synovectomy and use of an MoP bearing.[8,9]

Summary of answers

- The use of modern ceramic bearings has become significantly safer than when it was first introduced.
- Using the most modern ceramic and testing techniques, a patient receiving a ceramic THA can expect a very low wear articulation, clinical outcome scores at least equivalent to conventional hip replacements, and a low risk of long-term osteolysis.
- Fracture, particularly during insertion remains a risk, as does squeaking which may be an underreported

issue.

- Revision procedures following failed ceramic hip replacements are challenging.
- Retained exceptionally hard fracture debris often necessitates complete component revision with its potential to compromise the long-term survival of the revised hip.

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26 Cement in Total Hip Arthroplasty

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Clinical scenario

- A 60-year-old female, without medical history of interest, presents with left groin pain.
- She is an active person who works and plays nonprofessional sports, but now she has a left hip pain that interferes with her activities of daily living.
- Her x-rays reveal advanced osteoarthritis of her left hip.

Top three questions

1. In patients undergoing primary total hip arthroplasty (THA), does a cemented femoral stem, compared to an uncemented femoral stem, provide better function and patient outcomes?
2. In patients undergoing primary THA, does a cemented femoral stem, compared to an uncemented femoral stem, provide longer-term survival?
3. In patients undergoing cemented primary THA, does antibiotic cement, compared to plain cement, effectively prevent infection?

Question 1: In patients undergoing primary total hip arthroplasty (THA), does a cemented femoral stem, compared to an uncemented femoral stem, provide better function and patient outcomes?

Rationale

THA is one of the most common procedures performed in orthopedic surgery. Over the last decade, there has been a trend toward an increasing number of uncemented THA with a subsequent decline in the overall use of cemented implants for primary THA.[1] Hence, this question sought to analyze if patient-reported outcome measures differ depending on the type of fixation. This can be concerning for the patient and surgeon alike because the method of fixation itself may affect patient outcomes.

Clinical comment

The choice of optimal implant fixation in THA – fixation with or without cement – has been the subject of much debate[2] as the method of fixation itself may influence outcomes.[1–3] In cemented joint replacement polymethylmethacrylate (PMMA) is used to fix the prostheses to the bone. In cementless or uncemented joint replacement, hydroxyapatite (HA), porous coatings, or trabecular metal avoid the need for cement as bony in or on-growth occurs. The primary fixation is anatomic/press-fit technique, with secondary biological bone ingrowth producing long-term stable fixation. In hybrid fixation, one component is cemented and the other is uncemented.

Available literature and quality of the evidence

The quality of literature addressing appropriate investigations for cemented versus uncemented in primary THA is highly variable with level I–IV evidence. There are some randomized trials; however, the majority of the outcome studies are multicenter cohort studies or single-center cohort studies.

Findings

Clinical outcomes

The patient's experience in the short-term is important. Multiple studies have demonstrated better pain relief and short-term clinical outcomes, including earlier weight bearing, with cemented THA. Abdulkarim et al., in a meta-analysis of randomized controlled trials (RCTs; mean age 60.5 years, postoperative follow-up mean 4.3 years) comparing cemented and uncemented hips found a significantly improved pain score with cemented fixation compared to uncemented fixation ($p = 0.04$).[3] In contrast, in a study of the Swedish Hip Arthroplasty Register, 3118 patients with uncemented THA due to primary osteoarthritis with complete one-year follow-up were matched with a control group of patients with cemented THA ($n = 3118$). The authors reported that uncemented fixation is associated with better patient-reported outcomes including the EQ-5D, a Visual Analog Scale (VAS) on hip pain, as well as a VAS addressing satisfaction with the outcome of the procedure.[4] Meding et al, found that the 5-, 10-, and 20-year Harris Hip Score (HHS) was not significantly different between cemented and uncemented groups and the 15-year HHS only differed (on average) by four points ($p = 0.0054$). The pain scores were not different at 5, 10, or 15 years, but the 20-year average pain score

were significantly lower (more pain) in the uncemented group ($p < 0.0001$).[5]

Morbidity and mortality

The early postoperative mortality after THA is low and has been decreasing.[1,3] However, cemented fixation is associated with potential perioperative morbidity in the form of bone cement implantation syndrome and even death of the patient. The Finland National Hip Arthroplasty Register analyzed 73 915 patients they found that adjusted perioperative and short-term mortality was similar between patients treated with cemented THA and patients treated with uncemented (odds ratio [OR] = 0.5; 95% confidence interval [CI]: 0.3–1.1) or hybrid (OR = 0.6; 95% CI: 0.3–1.6) THA. The mean age of the patients in that register was 68.3 years old.[6] The Swedish Hip Arthroplasty Register found that, after adjustment for age, gender, co-morbidities, and socioeconomic background, there was a small but statistically significant increased relative risk of death in patients who underwent cemented, but not cementless, THA, up to 14 days after surgery (OR = 1.3; 95% CI :1.11–1.44). Between days 15 and 29, this increased risk of mortality in those with a cemented THA was reverted, and from day 30 after the operation all patients, irrespective of the mode of fixation, had a lower risk of mortality than their controls.[7]

Aseptic loosening

Aseptic loosening is the most common reason for revision, accounting for nearly half of all cases, followed by pain and instability.[8] A known disadvantage of cemented prostheses, however, is the risk of aseptic loosening. Cemented THAs have a significantly higher rate of aseptic loosening when compared to uncemented prostheses.[9] The Health East Joint Registry of USA (6498 THA) found that uncemented

stems were associated with fewer revisions for aseptic loosening in patients <70 years old, but when all-cause revision was considered, neither group demonstrated superior survival (mean follow-up of 6.5 years).[9]

Periprosthetic fracture

Evidence suggests that the increasing usage of uncemented stems may be associated with a higher rate of periprosthetic femoral fracture (PFF) when compared to cemented stems.[10] In a prospective multicenter study found that uncemented femoral components were associated with an increased risk of early PFFs (<90 days; risk ratio [RR] = 4.1; 95% CI: 2.3–7.2), especially in elderly (RR = 1.4 per 10 years; CI: 1.2–1.6), female (RR = 1.6; CI: 1.1–2.2), and osteoporotic patients (RR = 2.8; CI: 1.6–4.8).[10] Also Thien et al. studied the incidence of periprosthetic fracture around the femoral component in cemented and uncemented hips in the two years following implantation. They found a rate of 0.07% for cemented stems and 0.47% for uncemented stems (RR = 8.72; 95% CI: 7.37–10.32; p <0.0005).[11] The National Joint Registry for England, Wales, Northern Ireland and the Isle of Man, using univariate and multivariate Cox models, found an unadjusted hazard ratio (HR) for PFF for cementless compared to cemented stems of 1.43 (95% CI: 1.29–1.58). After adjustment for age, gender, and American Society of Anesthesiologists (ASA) grade, the HR was 1.68 (95% CI: 1.51–1.87). Also, comparing the rate of PFF revision within and beyond the first three months following primary THA in cementless versus cemented stems, the covariate-adjusted HRs were 8.82 (95% CI: 6.89–11.30) and 0.84 (95% CI: 0.49–1.41), respectively.[9]

Resolution of clinical scenario

- Better pain relief and short-term clinical outcomes, including earlier weightbearing have been reported with cemented THA; however, more studies need to focus on this point.
- Perioperative and short-term mortality was similar between patients treated with cemented and uncemented THA.
- There is a higher rate of periprosthetic fracture rates when using uncemented femoral stems; however, cemented THAs have higher rates of aseptic loosening when compared to uncemented THA.

Question 2: In patients undergoing primary THA, does a cemented femoral stem, compared to an uncemented femoral stem, provide longer-term survival?

Rationale

Literature suggests there are differences in survival for cemented as compared to uncemented femoral stems. The survival of uncemented and hybrid implants continues to dramatically improve. For this reason, it is important to evaluate the literature on this topic.

Clinical comment

A number of cementless femoral stems are associated with excellent long-term survivorship. Cementless designs differ from one another in terms of geometry and the means of obtaining initial fixation. Strict classification of stem designs is important in order to compare results among

series.[12] Uncemented designs can be classified based on the following factors:[13]

- *Surfaces and coatings:* for example, porous coated titanium stem, grit blasted implant surface, and HA coating.
- *Size of the stem:* standard length uncemented stems or short uncemented stems.
- *Modularity:* modular stems have another modular interface at the neck/stem junction of the implant. This allows intraoperative flexibility to adjust anteversion/offset and limb lengths.

Available literature and quality of the evidence

The quality of literature addressing appropriate investigations for cemented versus uncemented stems in primary THA is highly variable with levels I–V evidence. The majority of the outcome papers are observational multicenter cohort studies or single-center cohort studies.

Findings

Survivorship between cemented and uncemented stems

The published evidence suggests that cemented fixation still has superior survival among large subgroups of populations studied; however, the survival of uncemented and hybrid implants continues to improve.[2] The National Joint Registry for England, Wales, Northern Ireland and the Isle of Man (992 090 THAs) found an estimated Kaplan–Meier cumulative percentage probability of revision 14 years following a primary THA of 4.88 (4.67–5.10) for cemented hips, compared to 8.94 (8.55–9.35) for uncemented hips, and 5.38 (4.97–5.83) for hybrid fixation.[8] The Swedish (170 413 THAs) and the Irish (1697 THAs)

Hip Arthroplasty Registers also demonstrate superior survivorship of cemented over uncemented THAs with revision free component survival at 10 years of 94% versus 85% ($p < 0.001$) and 98.8% versus 96.8% ($p < 0.001$), respectively. No age or diagnosis group was found to benefit from the use of uncemented THA.[14],[15]

The New Zealand Joint Registry (42 665 THAs) reports that the overall all-cause revision rate is lower in cemented than uncemented THA, although, in contrast to the larger registries above, they found uncemented acetabular components performed better in the medium term (nine years) across all age groups.[16] The combined Nordic Arthroplasty Register Association database (347 899 THAs) found that in patients aged 65–74 and 75 or older the 10-year survival of cemented implants was higher than that of uncemented, hybrid, and reverse-hybrid implants, but in patients aged 55–64, survivorship of cemented and uncemented implants was found to be similar.[17] In a meta-analysis of RCTs, the cemented THA had a higher but statistically non-significant revision rate ($p = 0.14$).[3] Finally, Meding et al., in a review of 1017 primary THAs using the same porous-coated, titanium-alloy, femoral component, found that cemented and uncemented stem survivorship at 20 years was 98.1 and 99.6%, respectively. There was no difference in cemented or uncemented stem survivorship at any time period.[5]

Survivorship between uncemented stems

The Australian Joint Registry has one of the most robust datasets on uncemented implants (200 398 implants) which demonstrates cumulative revision rates at 10 years of 5% (4.9–51), and revision rates at 17 years of 7.5% (7.0, 8.0). They also found that the 10-year cumulative percent revision for total conventional hip replacement using a mini

stem (3706 implants) is 5.9% compared to 5.1% for other femoral stems. There are no differences in the overall rate of revision when a short stem is used; however, the cumulative incidence of loosening for procedures using a short stem is over twice that of other femoral stems at 10 years (2.5 compared to 1.2%).[18]

Comparison of implants that had the same design but were made of different alloys showed no significant difference in the outcomes or rates of thigh pain.[12] Hailer et al. in an analysis of 116 069 THAs in the Nordic Arthroplasty Register Association database found that uncemented HA-coated stems had similar results to those of uncemented stems with porous coating or rough sand-blasted stems. In the unadjusted 10-year survival with the endpoint revision of any component for any reason was 92% (CI: 91.7–92.4) for the group of THAs without HA-coated stems (number at risk after 10 years: 6676) and it was 92.1% (CI: 91.7–92.5) for those with HA-coated stems (number at risk after 10 years: 6464) ($p = 0.3$). They also found that the use of HA coating on stems available both with and without this surface treatment had no clinically relevant effect on their outcome.[19] About the size, Kim et al. reported in their RCT of 200 patients at mean follow-up of 12 years that ultrashort stems showed no differences from conventional cementless stems in terms of validated outcomes scores (mean HHS; $p = 0.189$; mean WOMAC scores; $p = 0.191$; and mean UCLA activity scores; $p = 0.381$) or fixation (revision one hip, 0.5%, in the short-stem group vs one hip, 0.5%, in the conventional group; $p = 1.881$).[19] Future studies of cementless implants should consistently address patient age, activity level, bone type, and deformities so that more definitive conclusions can be drawn about when to use each design.

Resolution of clinical scenario

- Moderate evidence supports that cemented stems still have superior survival among large subgroups of populations studied; however, the survival of uncemented and hybrid implants continues to improve.
- There is no difference between implants that had the same design but were made of different alloys. Uncemented HA-coated stems had similar results to those of uncemented stems with porous coating or rough sand-blasted stems.
- Evidence reveals a moderate difference in the overall rate of revision between short stem and standard length uncemented stems. Long-term survival is still unknown for most of these components.

Question 3: In patients undergoing cemented primary THA, does antibiotic cement, compared to plain cement, effectively prevent infection?

Rationale

Periprosthetic joint infection (PJI) is a major complication of joint replacement. One year after primary THA, around 1% of patients have been revised due to deep infection; superficial surgical site infections (SSIs) are more common and occur in around 3% of cases. The type of fixation (i.e. the use of antibiotic cement) may reduce the risk of PJI and is important to evaluate if differences exist as compared to cementless fixation for femoral stems.

Clinical comment

Perioperative wound contamination during implantation of primary THAs occurs in more than 30% of all operations in

standard and in ultraclean operating theaters. Many THAs are considered to fail due to the presence of clinically unrecognized low-grade infection.[20] Moreover, the outcomes of hip replacement surgery and the survival of implants have improved during the last decades. However, an increase in the risk of revision due to infection after THA has also been reported in recent years.[1],[21],[22]

Available literature and quality of the evidence

The quality of literature addressing the incidence of PJI for cemented versus uncemented femoral stems in primary THA is highly variable with level I–IV evidence. Several RCTs have compared the surgical outcomes of cemented and uncemented THA. However, most of the studies were unable to reach a conclusion on the risk of PJI based on the type of fixation due to the infrequent occurrence of SSI/PJI and low number of subjects in the cohort. Among the RCTs comparing cemented and uncemented THA, no difference has been observed in the rates of PJI.[21]

Findings

Current moderate evidence supports the routine use of antibiotic-laden bone cement (ALBC) in cemented primary THA to reduce the risk of deep PJI especially in patients with immunosuppressive co-morbidities.[22],[23] However, data from the Swedish Hip Arthroplasty Registry between 1992 and 2007 demonstrated that uncemented THA did not present a higher risk of revision due to infection compared to antibiotic-laden cemented THA.[14] In contrast, a higher risk of PJI in THA using bone cement without antibiotics was reported by the Norwegian Arthroplasty Register.[24] This study directly compared the revision rates due to infection in primary uncemented THA with cemented THA with ALBC as well as cemented THA without ALBC. The

results showed that the risk of revision due to infection was the same for uncemented and cemented arthroplasties with ALBC, but higher for cemented arthroplasty without ALBC.[24]

A recent meta-analysis including eight clinical studies (two RCTs and six observational studies) revealed that the incidence of PJI was 0.5% (310/67 531) in the cemented group and 0.3% (47/16 669) in the uncemented group ($p < 0.008$). The use of cement in THA was associated with an increased risk of PJI (OR 1.53; 95% CI: 1.12–2.10; $p < 0.008$).[21] However, the authors could not tell the influence of the type of cement used on the risk of PJI because five of the eight studies included did not specify if they used cement loaded with antibiotics or not. Registry data from large population-based studies (432 168 THAs) appear to show that the risk of revision due to PJI is roughly equal comparing uncemented with cemented fixation. However, using a multivariable Cox analysis, the use of cement without antibiotics and hybrid configurations was found to be risk factors for infection.[25]

Resolution of clinical scenario

- Current weak to moderate evidence supports the use of ALBC in cemented primary THA to reduce the risk of deep PJI, especially in high-risk populations.
- The risk of revision due to infection, in general, was the same for uncemented and cemented arthroplasties with ALBC, but higher for cemented arthroplasties without ALBC.

Summary of answers

- There may be some early benefits to cemented fixation, such as less pain and earlier weightbearing.
- Cemented fixation has unique complications, such as cement embolus, which need to be considered.
- Cemented stems have better long-term survival, though uncemented and hybrid designs are continuing to improve.
- There is no difference in the overall risk of infection between cemented and uncemented THA.
- If deciding to use cement, there is some evidence to suggest a higher risk of infection with plain cement compared to ALBC.

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27 Head Size in Total Hip Arthroplasty

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Clinical scenario

- A 68-year-old male presents with his second total hip arthroplasty (THA) dislocation seven months postoperatively.
- Risk factors for hip dislocation were evaluated and the patient was revised, changing the size and position of the cup, as well as exchanging the femoral head for a larger one.
- The patient was satisfied but 12 years postoperatively the x-rays evidence moderate polyethylene wear.

Top three questions

1. In patients undergoing THA, does larger femoral head size, compared to smaller head size, result in improved stability?
2. In patients undergoing THA, do certain bearing couples, compared to others, result in better outcomes depending on femoral head size?
3. In patients undergoing THA, do larger femoral head sizes, compared to smaller sizes, result in greater levels of trunnion corrosion?

Question 1: In patients undergoing THA, does larger femoral head size, compared to smaller head size, result in improved stability?

Rationale

Unstable THA should not be treated with any special device before knowing the etiology of instability. Larger femoral head size improves stability by increasing the jump distance. Routine use of large-diameter femoral heads have become more popular because of the associated improvement in stability.[1]

Clinical comment

Femoral head size has increased over time, from 22 mm heads in the 1960s to 36 mm heads in the last decade. According to the majority of the registries, the most common femoral head diameters are 32 and 36 mm.[2] Femoral head size has also been shown to improve range of motion and function.[3]

Available literature and quality of the evidence

The quality of literature addressing the effect of the bearing surface and the head size is highly variable with level I–IV evidence. There are some randomized trials; however, the majority of the outcome papers are multicenter cohort studies or single-center cohort studies and in vitro studies.

Findings

Larger heads increase impingement-free range of movement between components and have the ability to

offer longer neck options improving the possibility to obtain adequate soft tissues tension.[4] Cinotti et al. reported the effect of head size on impingement in both optimally and nonoptimally positioned acetabular components, and found limited benefits to increasing head size beyond 32 mm.[5]

Howie et al. in a randomized controlled trial (RCT) demonstrated a significantly lower dislocation rate at one year for the 36 mm head group (0.8%) compared to a 28 mm head (4.4%) in primary THA.[6] Another RCT which included 32, 36, and 40 mm heads concluded at five years after surgery that a larger femoral head group had a significantly lower risk for dislocation.[7] Kostensalo et al., with data obtained from the Finnish Arthroplasty Register analyzed 4379 primary THA procedures concluded that 32 mm, 36 mm, and >36 mm were associated with a lower risk of revision due to dislocation compared with 28 mm heads.[8] The Dutch Arthroplasty Register reported a 58% higher risk of revision due to dislocation for THA performed with 22–28 mm head compared with 32 mm.[9] In the setting of the Nordic Arthroplasty Register Association database, Tsikandylakis et al. analyzed 186 231 metal-on-polyethylene THA (head size 28 mm, 32 mm, or 36 mm). They found in an adjusted Cox regression mode that patients with 28 mm heads had a higher risk of revision for dislocation (hazard ratio [HR] = 1.67; 95% confidence interval [CI]: 1.38–1.98) compared with 32 mm, whereas there was no difference between patients with 36 mm (HR = 0.85; 95% CI: 0.70–1.02) and 32 mm heads.[10]

Resolution of clinical scenario

- The use of femoral heads larger than 28 mm may improve THA stability and range of motion in primary THA.

- This improvement has not been shown to increase with femoral heads greater than 36 mm.

Question 2: In patients undergoing THA, do certain bearing couples, compared to others, result in better outcomes depending on femoral head size?

Rationale

Over the last years, the use of large-diameter replacement femoral heads in THA has increased.[2],[11] Large femoral heads provide a wider impingement-free range of motion and also increase the jump distance, improving stability and reducing the risk of dislocation.[12] However, one of the main concerns when it comes to larger femoral heads is the longevity of the bearing surface.

Clinical comment

Bearing wear and head size cannot be examined irrespective of the bearing surface as different materials have different bearing friction properties. The conventional polyethylene has a greater risk of wear, but the relatively recent development of hard-on-hard bearings and the introduction of cross-linked polyethylene has led to the revision of this concept.

Available literature and quality of the evidence

The quality of the literature addressing bearing wear is variable with level I–IV evidence. Most are cohort studies, national hip arthroplasty registries, and in vitro studies.

Findings

Polyethylene bearing

The success of THA has been limited by periprosthetic osteolysis related to particulate polyethylene wear debris, but highly cross-linked polyethylene (XLPE) was developed to decrease polyethylene wear and decrease osteolysis. Engh et al. conducted a prospective, randomized study of 236 patients (XLPE group: 116 patients/non-XLPE group: 114 patients) and concluded that the XLPE liners have a95% wear rate reduction compared with the mean wear rate of the non-XLPE, and the incidence of osteolysis was lower in the XLPE group.[13]

Assuming the outer diameter of the acetabular shell is kept the same, larger diameter bearings require accordingly thinner polyethylene liners. Johnson et al. considered that the minimum thickness could be reduced to 3.9 mm with XLPE,[14] but in another study, by Girard et al., it was concluded that given the current data on wear and fatigue resistance surgeons should comply with the traditional 6 mm thickness, even with XLPE liners.[15] *Wear*, in relation to larger femoral heads, could be linear and volumetric. It has been shown that linear wear rates of less than 0.1 mm per year have been associated with a low incidence of osteolysis, and in long-term clinical studies no differences have been demonstrated in linear wear rates between 26, 28, 32, 36 and 40 mm heads when metal-on-cross-linked polyethylene (MoXLPE) are used.[16],[17] However, surgeons and manufacturers should focus on decreasing volumetric wear. Currently, there is no agreed-on threshold with respect to volumetric wear rates and osteolysis. Cross et al. proposed that a volumetric wear of 40 mm^3/yr could eliminate osteolysis and up to 80 mm^3/yr could be tolerated.[18]

Lachiewicz et al. in 2009 found no association between femoral head size and the linear wear rate, but observed an association between larger (36 and 40 mm) head size and increased volumetric wear rate and total volumetric wear.[19] Authors re-evaluated the previous reported cohort at a mean follow-up of 11 years (range 10–14 years) and they found again that 36–40 mm femoral heads had a higher volumetric wear (median 26.1; 95% CI: 11.3–47.1) than did 26 mm heads (median 3,1; 95% CI: 0.7–12.3), 28 mm heads (median 12.3; 95% CI: 3.0–19.3), and 32 mm heads (median 12.9; 95% CI: 6.6–16.8; p = 0.02).[20] A 13-year report on THA survival from the 2017 Australian Registry report shows that THA with both bigger and smaller than 32 mm MoXLPE bearings have a greater risk of revision compared with 32 mm. Heads smaller than 32 mm were revised due to dislocation more frequently, while heads larger than 32 mm were revised in the majority of cases due to aseptic loosening or fracture, complications that can be associated with wear.[21] Heckmann et al. examined the THA bearing surface trends in the United States from 2007 to 2014. Over this period ceramic-on-polyethylene (CoP) bearing surfaces steadily increased in popularity to become the most popular bearing surface type. Although concerns about fracturing of the femoral head and increased costs had decreased usage of ceramic heads in the 1980s and 1990s, the advent of the delta ceramic with improved material composition, low fracture rates, and low wear rates has again increased the use of CoP bearings.[22] While this has been well established in wear-simulator studies,[23] recent clinical studies have begun to demonstrate clinical differences.[24]

Resolution of clinical scenario

- Bearings >32 mm have increased volumetric wear compared with 32 mm or smaller in MoXLPE THA, but not in ceramic-on-XLPE.
- THA survival is better for 32 mm MoXLPE bearings compared with both bigger and smaller ones.
- The use of the 32 mm head size is recommended when an MoXLPE is used. If bigger head sizes are desired then ceramic heads up to 36–38 mm on XLPE should be considered.

Question 3: In patients undergoing THA, do larger femoral head sizes, compared to smaller sizes, result in greater levels of trunnion corrosion?

Rationale

Trunnionosis is defined as the wear of the femoral head–neck interface and has been acknowledged as a source of THA failure.[25] Several reports indicate a rising awareness of the trunnionosis-related implant failure in the last 10 years.[26] It is estimated that up to 2% of all THA patients can be affected and reports have demonstrated an incidence ranging from 0.7 to 3% of all THA revisions.[21],[27],[28] Hence, this question sought to analyze if the chosen femoral head size can affect trunnion corrosion in THA. This can be concerning for the patient and surgeon alike, because this may affect survival of the THA and patient outcomes. A more complete discussion of trunnionosis can be found in Chapter 29.

Clinical comment

Trunnionosis is a phenomenon that has gained prevalence with newer THA implant designs, particularly when modularity is used.[28] Modularity allows for a better intraoperative restoration of leg length and control of hip offset, but while this enables a more customized fit for the patient, it may have untoward effects. The modularity at times may play a role in increased wear and mechanical insufficiency at the trunnion, ultimately leading to revision.[28,29]

Available literature and quality of the evidence

The quality of literature addressing appropriate investigations for the effect of the wear of the femoral head–neck interface is highly variable with level III–IV evidence. The majority of the outcome papers are multicenter cohort studies or single-center cohort studies.

Findings

Due to galvanic corrosion with mixed metal combinations at the head–neck junction, cobalt-chrome/cobalt-chrome couples are less susceptible to corrosion than cobalt-chrome/titanium or stainless steel couples; this has been evaluated in both in vitro and in vivo settings.[30,31] In a multicenter retrieval analysis of 231 modular hip implants, corrosion was observed in 28% of similar metal couples, compared with 42% in mixed couples.[31] Notably, ceramic femoral heads appear to be much less susceptible to the process of corrosion than those composed of cobalt-chromium (CoCr) alloy.[32–34]

Currently, the evidence is conflicting for the association of head size with trunnion corrosion.[29] Finite element analysis of head–neck junctions demonstrated increased maximum stress on the trunnion as head diameter increased from 28 to 40 mm.[35–37] Bolland et al. in a wear analysis of a series

of 5/17 retrieved large diameter (>40 mm) MoM THAs revealed increased wear at the head–neck junction, but normal wear at the articulating surface suggesting an association between large heads and trunnionosis.[38] Del Balso et al. performed a retrieval analysis of 23 femoral heads of 32 mm diameter matched with 28 mm heads based on time in vivo and head length (−3 to +8 mm). They found that 32 mm femoral heads exhibited greater total fretting scores than 28 mm heads ($p < 0.01$).[35] An analysis of the National Joint Registry for England, *Wales*, *Northern Ireland* and the *Isle* of *Man* data showed a relative risk of adverse reaction to metal debris (ARMD) 2.8 times (95% CI: 1.74–4.36) higher in 36 mm MoP bearings compared with 28 and 32 mm ($p < 0.001$).[27]

However, other studies have refuted an association between trunnionosis and head size. Triantafyllopoulos et al., in 154 MoP THAs retrieved as part of 3282 revision surgeries, found that the fretting and corrosion of the tapers and the trunnions were not affected by head size ($p = 0.247$, $p = 0.471$, $p = 0.837$, and $p = 0.868$, respectively).[39] Cartner et al, in an analysis of 210 femoral heads, found that an increased head size and increased time in vivo did not correlate to higher corrosion scores.[40]

Resolution of clinical scenario

- Based on current evidence, the results suggest that cobalt-chrome/cobalt-chrome couples are less susceptible to corrosion than cobalt-chrome/titanium or stainless steel couples. Also using a ceramic femoral head appears to be much less susceptible to corrosion than those composed of CoCr.
- Currently, evidence is conflicting for the association of head size with trunnion corrosion. Finite element

analysis of head–neck junctions has demonstrated an increased maximum stress on the trunnion as head diameter increased from 28–40 mm. However, recent study has refuted this association.

Summary of answers

- Larger femoral head size (>28 mm) is associated with a lower risk of dislocation.
- Size increases beyond 36 mm do not seem to further reduce dislocation risk.
- Larger head sizes are susceptible to greater volumetric wear rates.
- Femoral head size should be selected carefully in consideration with coupling choice, as different materials have different volumetric wear rates.
- Ceramic is least susceptible to corrosion, followed by CoCr/CoCr, and lastly by CoCr/titanium or steel couplings.
- There is conflicting evidence regarding the impact of head size on trunnion corrosion.

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28 Dual Mobility in Total Hip Arthroplasty

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Clinical scenario

- A 66-year-old woman presents with a painful left hip since about two years ago, without history of a traumatic event, that is poorly controlled with oral medication and strongly affects her daily activities.
- She had a history of posterior spinopelvic fusion (T12-S1-iliac arthrodesis) one year ago.
- Physical exam shows a walking sagittal spinopelvic imbalance due to bilateral hip flexion and a rigid spinopelvic fusion (Figure 28.1).

Top three questions

1. In patients undergoing primary total hip arthroplasty (THA), do some patient characteristics, compared to others, predict dislocation?
2. In patients undergoing THA, do dual mobility (DM) implants, compared to standard implants, result in a different type of dislocation?
3. In patients undergoing THA, do DM implants, compared to standard implants, have better long-term survival?

Question 1: In patients undergoing primary total hip arthroplasty (THA), do some patient characteristics, compared to others, predict dislocation?

Rationale

Postoperative dislocation is still a common, troublesome complication after THA, being the second most frequent complication[1] and the predominant indication for revision THA in the United States, representing 17–22% of all revision THAs in that country.[2,3] This complication faced by the orthopedic surgeon has a high morbidity, as well as a high economic cost.[4] Identifying patients at risk for dislocation is important, as it can help with preoperative patient education, postoperative prevention measures, and the approach in the management of primary THA instability when planning revision surgery.[5,6]

Clinical comment

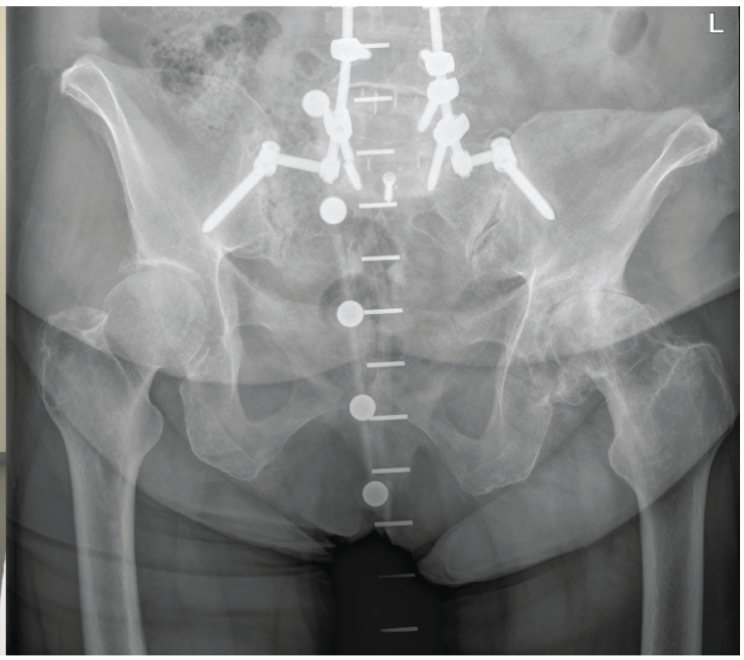
The outcome following a first episode of THA dislocation is threefold: first, the patient will have a suboptimal clinical result; second, it will increase the risk of further episodes of instability; and finally, there will be an increased requirement for revision surgery.[7] Therefore, the ideal solution to instability is prevention achieved through optimal surgery.[5] Recognizing adequately the potential causative factors for instability in a patient who is going to undergo a primary THA surgery is crucial.[8]

Available literature and quality of the evidence

Quality of literature addressing appropriate investigations evaluating risk factors for instability after THA is variable with level II–III evidence. There are no randomized trials.

Findings

Due to the multifactorial etiology of hip instability, a detailed assessment of the patient and surgical plan is essential.[6] Patient-specific risk factors for THA instability include female gender, older age, history of previous dislocation, abductor deficiency,[9] American Society of Anesthesiologists (ASA) score of 3 or more, hip fracture, mega or tumor prosthesis,[10] multiple previous surgeries, revision THA,[11] altered neurologic or proprioception around the hip from neurologic or spinal disease, and, importantly, after a recent lumbar fusion surgery. There is a great deal of evidence that spinal fusion alone is a significant risk factor for instability[12],[13] and the most important independent predictor of dislocation within the first six months after surgery.[14],[15] Specific surgical precautions should be taken in this population regarding implant design and orientation, and considering DM implants and surgical approach to reduce the risk of dislocation.[16],[17]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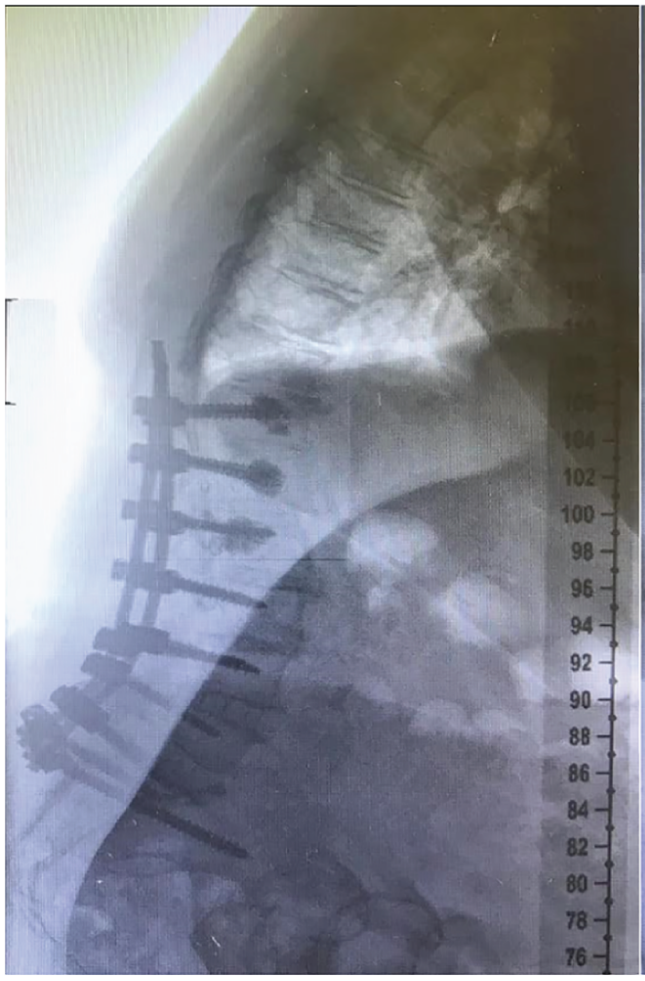
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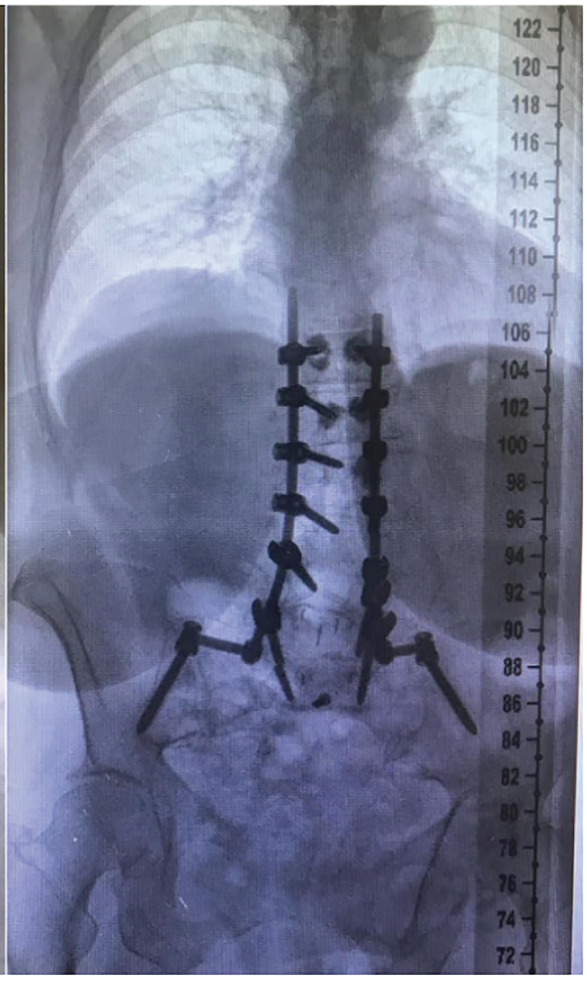
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Figure 28.1 Photographs and radiographs of a patient with previous spinopelvic fusion.

Source: Iñaki Mimendia, Maria Jurado, Ernesto Guerra–Farfán, Vicoria Barro.

There is increasing concern over spinal imbalance, acetabular component position, and its relation to dislocation after THA.[13] Restricted pelvic movement due to degenerative disc disease as well as lumbar surgery does not allow the acetabulum to open during flexion of the hip with sitting, needing high inclination and anteversion, and remaining at risk for impingement at the extremes of movement. Advances in positional preoperative imaging (such as standing, sitting, and squatting) help identify high-risk situations and alterations consequently. Stefl et al. suggested that in patients with spinopelvic imbalance the use of DM articulation should be considered.[16]

The soft tissue envelope of the hip joint provides the major secondary stabilizer of the THA. Deficiency of the soft tissue envelope, especially the hip abductors, is also a well-studied risk factor. In this manner, when utilizing the posterior approach, preservation and reattachment of the capsule and external rotators greatly reduces the risk of dislocation.[18],[19]

The surgeon's role in THA stability includes patient selection, choice of surgical approach and implant, technical execution, and experience. Clearly, therefore, the surgeon should understand the design implications of the diverse modular components that constitute the hip prosthesis as a whole.

Resolution of clinical scenario

- A thorough anamnesis on the characteristics of the patient is mandatory to identify the presence of

possible risk factors. This should include gender, age, previous hip surgery, neuromuscular disorders, cerebral dysfunction, poor patient cognition or compliance, lumbar spine disease, and previous lumbar surgery.

- Patients in general should be counseled regarding the risk of THA dislocation, and patients at higher risk should be educated regarding the presence of risk factors that make them particularly high risk for this complication.
- The surgeon performing the surgery must identify patients at high risk and consider all options to minimize the risk of this complication.
- Patients with pathological spinal imbalance and a biological or surgical hip fusion that are at high risk for impingement and THA dislocation may be good candidates for increased constraint such as a DM implant.

Question 2: In patients undergoing THA, do dual mobility (DM) implants, compared to standard implants, result in a different type of dislocation?

Rationale

DM cups consist of a fixed head coupled to a mobile intermediate polyethylene (PE) liner, which articulates with a smooth metal shell. Thus, there is an inner, small diameter articulation, with a capture mechanism between the head and the liner, and a larger, unconstrained, outer articulation.[20] Because there is an additional bearing

interface compared with fixed bearing in THA, DM hips can suffer a unique failure mechanism known as an *intra-prosthetic dislocation* (IPD), in which the inner prosthetic femoral head decouples from the outer PE bearing.[20] IPD is irreducible by closed means and always requires surgical management and DM bearing component revision.

Clinical comment

The most accepted indication of DM is revision surgery; however, with the development of new designs and some promising results, the use of DM in primary hip arthroplasty is increasing, especially in patients with a high risk of dislocation. With poor clinical studies regarding the results of DM in long-term follow-up, IPD is one of the major concerns when using a DM cup in THA.[21] IPD may occur any time after the index procedure. However, the European experience suggests that IPD was predominantly a late complication particularly with conventional PE in the first generation DM designs. Philippot et al. classified three types of IPD, using radiographic and perioperative features: type I, IPD secondary to wear of the PE retentive rim with no evidence of arthrofibrosis or cup loosening; type II, IPD secondary to an extrinsic phenomenon (arthrofibrosis or heterotopic ossifications) as cause for the blockage of the larger articulation, and thus accelerated wear of the PE retentive rim; type III, IPD secondary to cup loosening as cause of wear of the PE retentive rim.[22] Some studies suggest that a high body mass index (BMI), some femoral stem designs, and a large diameter of DM can be predictive factors of IPD.[23]

Available literature and quality of the evidence

Current available literature regarding IPD are from studies with low-quality evidence, mainly case series (level IV).

There are no randomized trials.

Findings

Historically, one of the most common and specific complications in relation to DM implants has been IPD.

Mitchell and colleagues presented in 2017 a historic literature review of IPD in United States.[24] In 2004, Lecuire and colleagues reported seven cases of IPD occurring a mean of 10 years after implantation during the period 1989–1997.[25] In 2013, Philippot and colleagues reported that 81 of 1960 primary THAs performed between 1985 and 1998, developed IPD a mean of nine years after implantation.[22] These IPD cases were attributed to PE wear or outer articulation blockage caused by arthrofibrosis or heterotopic ossification. In 2011, Stigbrand and Ullmark reported three cases in which the DM prosthesis dislocated within one year after implantation. It was suggested that the inner metal head dissociated from the larger PE component after attempted closed reduction for dislocation.[26]

Darrith et al. reviewed 24 studies of DM primary THAs including 10 783 THAs with a mean follow-up of 8.5 years (2–16.5).[21] The second most common complication was IPD, with an incidence of 1.1% (122 hips); however, no cases of IPD were reported for DM primary THAs undertaken after 2007 or for any of those using 28 mm heads. There was a significantly greater incidence of IPD, 3.3% (95% confidence interval [CI]: 2.7–3.9%) in the older series of primary THAs using an inner head size of 22 mm, the causes of which are likely to have been multifactorial. Not only has the quality of the PE liners improved but also the size of the femoral head typically used has increased in diameter.

Resolution of clinical scenario

- IPD is a specific complication of DM and must be considered.
- The latest reviews seem to show a marked decrease of the incidence with the new generations of implants.
- IPD could be in relation to 22 mm heads and PE wear in long-term implanted cases, and inappropriate implantation of DM system in acute cases.

Question 3: In patients undergoing THA, do DM implants, compared to standard implants, have better long-term survival?

Rationale

Dislocation is the most common cause of revision during the first two years after a THA,[27,28] and the most frequent reason for dislocation is implant impingement. For this reason, DM use has been popularized in the last few years in patients with high risk of instability, both in THAs and in revision surgery.[29]

Clinical comment

Surgeons in France began experimenting with the DM concept in the 1970s and 1980s with good results, but IPD and wear were not infrequent problems.[30–33] However, the new designs of DM have been changed in relation to surface coatings, materials, and shape in order to improve these issues. Around the world, interest in DM has been growing since its introduction to the market nearly a decade ago. There are no high-quality prospective studies

in the American or European literature. Although many authors have documented advantages of the DM components in preventing and treating instability,[30–33] there are concerns about the quality of this evidence, the length of follow-up, and the potential for complications unique to these components, such as IPD and accelerated PE wear.[34]

Available literature and quality of the evidence

The current best available evidence in relation of DM in THA consists in a case control study (level III) and case series and prospective and retrospective cohorts (level IV).

In revision surgery of THA the best available evidence consists in one study of level III, retrospective cohort by Jauregui et al., and a systematic review by Darrith et al. (level III).[35] There are no level I studies.

Findings

In terms of DM in primary THA, the most evidence is about first designs of Bousquet DM. Although there is some study about the DM new generation, more evidence is needed.

Vielpeau et al. reported a large series of 668 cases of primary THA.[35] A subgroup of 437 cases with original Bousquet tripolar cups (Novae-1®, Serf, France) with a mean follow-up of 16.5 years was compared with a subset of 231 cases with second-generation cups (Novae E®, Serf, France) with a follow-up of 5.2 years. Revision-free survival was 95.6 and 84.4 % at 5 and 15 years, respectively, for the original Bousquet cups. The second-generation Novae cups showed a five-year survival rate of 99.6 %.

Puch et al. reported a prospective and consecutive series of 119 THAs with a cementless DMC of second-generation (GIROS) were performed in patients aged less than 55

years and 444 in patients aged more than 55 years.[36] The mean follow-up was 11 years (8–15 years). Survivorships (failure of both components or cup loosening) were not different between patients aged less than 55 years and patients aged more than 55 years.

The second-generation DM has increased use in revision surgery, due to the high risk of instability in these patients, and its good results in this term, but there are no level I–II studies at long-term.

Jauregui et al. compared revision THA with DM articulations (n = 60) matched (1 : 2) to patients who had conventional single articulation prostheses, in terms of age, gender, BMI, and Paprosky acetabular defect (n = 120).[36] The DM group had lower dislocation – 1.7% (1 out of 60) vs 5.8% (7 out of 120) – and aseptic loosening rates – 1.7% (1 out of 60) vs 4.2% (5 out of 120) – compared to the control group. There were no significant differences in functional outcomes, activity level, or overall physical and mental health status between the two cohorts.

In a systematic review Darrith et al. analyzed 25 studies of DM revision THAs, including 3008 THAs with a mean follow-up of 5.4 years (2–8 years). A total of 103 (3.4%) had been further revised.[21] The incidence of dislocation was 2.2% (67 THAs), making extra-articular dislocation the most common complication. The rate of aseptic loosening in this group was 1.4% (29 hips) and the rate of IPD was 0.3%.

The new DM generation seems to improve the results of the first original Bousquet system, in terms of survivorship, IPD, and wear. However, we do not have any studies of level I–II or long-term outcomes, so more evidence is needed to extend its use beyond high-risk patients.

Resolution of clinical scenario

- The DM implant is an alternative to keep in mind in cases at high risk for dislocation.
- A few long-term outcome studies of second-generation DM show a higher survivorships, and lower rates of IPD and wear, than first-generation models.
- High-quality, prospective, comparative studies are necessary to broaden the DM use beyond high-risk patients.

Summary of answers

- Patients in general should be counseled regarding the risk of THA dislocation, and patients at higher risk should be educated regarding the presence of risk factors that make them particularly high risk for this complication.
- Intra-prosthetic dislocation is a specific complication of DM and must be considered.
- The DM implant is an alternative to keep in mind in cases at high risk for dislocation.
- A few long-term outcome studies of second-generation DM show a higher survivorships, and lower rates of IPD and wear, than first-generation models.
- High-quality, prospective, comparative studies are necessary to broaden the DM use beyond high-risk patients.

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29 Trunnionosis

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Clinical scenario

- A 64-year-old female presents with worsening pain in the right groin, abductor weakness, and associated Trendelenburg gait; the patient underwent an uncemented right total hip arthroplasty (THA) with a cobalt-chromium (CoCr) femoral head on highly cross-linked polyethylene three years ago.
- The patient did well following right THA with no issues until six months ago; erythrocyte sedimentation rate (ESR) and C-reactive protein (CRP) are within normal limits.
- X-rays reveal subtle lucency about the proximal aspect of the femoral stem; a metal artifact reduction sequence magnetic resonance imaging (MARS-MRI) reveals a large peri-articular encapsulated soft tissue mass; serum metal ion levels are >1 ppb (parts per billion) with increased cobalt (Co) relative to – (Cr).

Top three questions

1. In patients with metal-on-polyethylene (MoP) THA who develop an adverse local tissue reaction (ALTR), does the mechanism by which this occurs differ from that observed in metal-on-metal (MoM) THA?

2. In patients undergoing THA, are there factors which increase the risk of trunnionosis and potential subsequent development of an ALTR in MoP THA when compared to ceramic-on-polyethylene (CoP)?
3. In patients with MoP THA and radiological evidence of an ALTR secondary to trunnionosis, does management differ compared to that of patients with ALTRs from MoM THA?

Question 1: In patients with metal-on-polyethylene (MoP) THA who develop an adverse local tissue reaction (ALTR), does the mechanism by which this occurs differ from that observed in metal-on-metal (MoM) THA?

Rationale

Although ALTRs initially were described to occur in association with MoM articulations, they also have been shown to occur in association with other articulations.[1–4] These include the modular head–neck taper junction as well as modular neck–body taper junctions in MoP THA. In MoM articulations, metal debris is undoubtedly produced at bearing surfaces. However, such debris is also produced at the head–neck taper interface, as demonstrated in studies comparing MoM THA with hip resurfacing.[5,6]

Clinical importance

ALTRs are not simply the result of metal debris produced at the bearing surfaces of MoM THA. Metal debris can be produced at modular head–neck and neck–body taper

junctions. This is a clinical entity referred to as *trunnionosis,* and can occur in MoP THA.

Available literature and quality of the evidence

- Level I: 1 RCT.
- Level III: 1 retrospective cohort study.
- Level IV: 1 case series.

Findings

When comparing large-head MoM THA with MoM hip resurfacing, Garbuz et al. noted increased serum Co and Cr ion levels from baseline in both groups.[6] Excessively high serum Co and Cr levels (at two years) in the large-head MoM THA were shown to not be solely from the bearing surface since the two groups had the same bearing surface. The only plausible explanation for the markedly elevated serum Co and Cr levels relates to the two areas of modularity for the attachment of the femoral head to the stem. In the large-head MoM THA group in this study, the two modular junctions and mismatch of metals between the titanium stem and the Co-Cr alloy adaptor could account for the elevated metal ion levels seen.

In clinical studies of MoP THA designs, metal ion release and ALTRs due to trunnionosis have been reported. A retrospective cohort study by Cooper et al. showed ALTRs can occur in patients with a MoP bearing secondary to corrosion at the modular femoral head–neck taper, and their presentation is similar to the ALTRs seen in patients with a MoM bearing.[1] Elevated serum metal ion levels, particularly a differential elevation of serum Co levels with respect to Cr was shown. Safe levels of serum Co are <1 ppb.[7],[8]

Trunnionosis following MoP THA has been demonstrated in retrieval studies.[3] However, the factors that potentiate trunnionosis are controversial. Both biomechanical and bio-electrochemical factors have been described. The concept of mechanically assisted crevice corrosion (MACC) has also been supported.[9],[10] As described by Goldberg et al., trunnionosis may be enabled by the disruption of the protective oxidative layer on the metal by fretting, potentiating the corrosion of the exposed metal beneath the oxidative layer through an active combination of biochemical and electrochemical methods.[10]

Resolution of clinical scenario

- ALTRs can occur in MoP THA in addition to MoM THA.
- While the bearing surface may be the principle source of metal debris in MoM THA, the taper junction(s) are the source in MoP THA, causing ALTRs and elevated serum metal ion levels (Co > Cr).
- The mechanism by which trunnionosis occurs is MACC.

Question 2: In patients undergoing THA, are there factors which increase the risk of trunnionosis and potential subsequent development of an ALTR in MoP THA when compared to ceramic-on-polyethylene (CoP)?

Rationale

If the factors contributing to the development of trunnionosis are elucidated than the possibility of ALTRs as a result of MACC at metal head–neck and neck–body taper

junctions can be minimized. Alternatively, if trunnionosis occurs solely at metal taper junctions, CoP THA represents a means to avoid the problem altogether.

Clinical importance

In recent years, arthroplasty surgeons have increasingly been utilizing CoP as bearing surfaces to avoid the metal head–neck taper junction implicated in trunnionosis. To date, there has been only a single case report of ALTR secondary to trunnionosis in CoP THA.[11]

Available literature and quality of the evidence

- Level IV: 2 case series.
- Level IV: 2 retrieval studies.

Findings

As ALTRs and trunnionosis are rare entities, the ability to prospectively examine the causative factors is limited. Attempts to date to elucidate these factors are largely based on retrieval studies, case series, and retrospective case cohort studies. Time in vivo consistently has been shown to be a risk factor for trunnionosis.[10,12–14] The biomechanical argument has been supported by studies examining how increased head length, diameter, and offset affect trunnionosis. Increased head length has been shown, in retrieval studies, to increase the severity of corrosion and fretting.[13] Head diameter was also found to be a substantial risk factor for the development of trunnionosis.[14,15] This has been refuted in a report which indicated that head diameter does not contribute to the development of trunnionosis.[12] The role of head diameter is, therefore, unclear.

Both the design and flexural rigidity of the trunnion are purported to play an important role in the development of trunnionosis. A flexible trunnion may allow fretting as well as point loading at the head–neck junction,[16] and stems that have decreased mechanical rigidity have been associated with higher rates of trunnionosis.[10] The relatively shorter mating surface of modern trunnions means the stem trunnion mating surface ends within the head, which leads to edge loading.[17] Edge loading is known to make tribocorrosion more likely to occur. Reports in the literature have indicated that specific trunnion designs have higher rates of fretting and corrosion.[18] The specific feature or combination of features of these trunnions that play a role in the development of trunnionosis is as yet unclear. Increased corrosion is observed with dissimilar head–stem metal combinations.[9,12] In vitro studies do not support this, and therefore the clinical significance is unclear.

There have been issues with implant design, with catastrophic failure having been reported in one particular design.[19,20] Urish et al. reported implant failure in 4.7% of 636 implants at eight years.[19] Catastrophic failure occurred in 18 cases with head–neck taper corrosion in 12 cases. In all failures, MARS-MRI demonstrated large cystic fluid collections typical of ALTR, and pseudotumor was observed in all cases at the time of revision.

The use of ceramic femoral heads as an alternative to CoCr as a means to reduce fretting corrosion is supported in the literature.[21–23] Ceramic does not corrode because it is electrochemically inert. The metal femoral stem mated with a ceramic head remains susceptible to corrosion; however, adverse reactions to metallic debris with CoP THA is exceedingly rare.[11] In a retrieval study, Kurtz et al. demonstrated that taper corrosion was mitigated, although

not completely eliminated, with the use of ceramic heads as compared with Co-Cr heads.[21]

Resolution of clinical scenario

- Factors purported to increase the risk of trunnionosis in MoP THA include increased head length, diameter, offset, stem design, flexural rigidity, and dissimilar head–stem metal combinations.
- Evidence for each of these factors remains limited, and the clinical significance is unclear.
- There are implant designs which have been associated with catastrophic failure and pseudotumor formation.
- Use of ceramic femoral heads in CoP THA can mitigate, although not completely eliminate, taper corrosion.

Question 3: In patients with MoP THA and radiological evidence of an ALTR secondary to trunnionosis, does management differ compared to that of patients with ALTRs from MoM THA?

Rationale

Over the past two to three decades a MoP articulation with a modular head–neck taper has been by far the most common form of total hip replacement implanted worldwide. While believed to be a relatively rare clinical entity, appropriate management for patients with ALTRs secondary to trunnionosis remains unclear.

Clinical importance

Guidelines for the revision of MoP THA in the setting of ALTRs secondary to trunnionosis may assist arthroplasty surgeons in achieving the best possible outcomes for affected patients.

Available literature and quality of evidence

- Level IV: 1 case series, 2 therapeutic studies.

Findings

What surveillance is required for head–neck taper junctions in the setting of MoP THA is unclear. Algorithms for the adequate follow-up and investigation of ALTRs related to MoM THA, including the role of both metal ion analysis and advanced imaging, have been proposed.[24] Trunnionosis arising from MoP THA represents a relatively rare clinical problem. Therefore, routine follow-up, without the need for advanced imaging and/or metal ion analysis, is all that is required for an asymptomatic patient with a well-functioning hip and no radiographic abnormalities. When a patient has hip pain of unknown origin, it might be appropriate to investigate with advanced cross-sectional imaging (i.e. MARS-MRI) and/or metal ion analysis.[1,25] In a retrospective observational study of 3340 revisions for adverse reactions to metal debris and ALTRs, Matharu et al. reported that 7.5% were observed in non-MoM THAs.[26] The authors cautioned that, although revision surgery in non-MoM THAs appears low, this risk is increasing and significantly higher in ceramic-on-ceramic THA and 36 mm MoP THA. Therefore, ALTRs may represent a more significant clinical problem in non-MoM THAs than currently appreciated.

Although there are guidelines for clinically important serum ion levels in patients with MoM THA, guidelines for suspected trunnionosis do not exist. However, Cr levels

may be relatively lower than Co levels in cases of trunnionosis compared with cases of failed MoM total hip replacements.[27]

Treatment algorithms to deal with head–neck trunnionosis and the associated ALTRs are derived from relatively small case series. Engh et al. highlighted the fact that the current treatment protocols for taper corrosion originated from 8 case reports and a single level IV study.[28] Therefore, there is no high-quality (level I or II) evidence to support the proposed algorithms for the treatment of trunnionosis. Most of the regimens designed for the treatment of ALTRs associated with head–neck trunnionosis have originated from the literature on MoM total hip replacement.[6],[29] Soft tissue reactions to metallic debris have been far more common after MoM total hip replacement, and the importance of a thorough debridement of the pseudotumor material, often requiring a subtotal capsulectomy, has been recommended.[6],[29]

In patients with ALTRs in MoP THA secondary to trunnionosis, whether to revise a well-fixed stem in order to remove the potentially damaged male taper junction is of interest. A retrospective review by Goyal et al. demonstrated that there was no difference in survivorship between total hip replacements that were revised to a new metal femoral head in the presence of either high-grade or low-grade head taper corrosion, thus providing strong support for leaving the corroded stem taper in place.[30] Implantation of a new femoral head, in combination with a new acetabular bearing surface, should be performed. The most common bearing replacement combination is a ceramic head, with a titanium adapter sleeve articulating with a highly cross-linked polyethylene insert decreasing the potential for ongoing corrosion and fretting because of

the chemically inert properties of the ceramic material.[1,28,31]

Resolution of clinical scenario

- As trunnionosis in MoP THA is a relatively rare clinical problem, routine follow-up without advanced imaging or metal ion analysis is all that is required for asymptomatic patients.
- In patients with ALTRs secondary to trunnionosis, as with patients with ALTRs from MoM THA, debridement of the pseudotumor with subtotal capsulectomy, femoral stem retention, and implantation of a new ceramic head on highly cross-linked polyethylene insert should be performed.

Summary of answers

- ALTRs can occur in MoP THA in addition to MoM THA.
- While the bearing surface may be the principal source of metal debris in MoM THA, the taper junction(s) are the source in MoP THA, causing ALTRs and elevated serum metal ion levels (Co > Cr).
- The mechanism by which trunnionosis occurs is MACC.
- Factors purported to increase the risk of trunnionosis in MoP THA include increased head length, diameter, offset, stem design, flexural rigidity, and dissimilar head–stem metal combinations.
- Evidence for each of these factors remains limited, and the clinical significance is unclear.
- Use of ceramic femoral heads in CoP THA can mitigate, although not completely eliminate, taper corrosion.

- As trunnionosis in MoP THA is a relatively small clinical problem, routine follow-up without advanced imaging or metal ion analysis is all that is required for asymptomatic patients.
- In patients with ALTRs secondary to trunnionosis, as with patients with ALTRs from MoM THA, debridement of the pseudotumor with subtotal capsulectomy, femoral stem retention, and implantation of a new ceramic head on highly cross-linked polyethylene insert should be performed.

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30 Periprosthetic Hip Fractures

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Clinical scenario

- An 81-year-old woman with a previous uncemented total hip arthroplasty (THA) presents with severe thigh pain and inability to weight bear after a fall.
- Examination reveals external rotation deformity of the leg, bony crepitus, and tenderness around the proximal and midthigh.
- Radiographs demonstrate a displaced periprosthetic femur fracture.
- Her daughter tells you she has a diagnosis of rheumatoid arthritis and osteoporosis and asks if this predisposes her to this complication.

Top three questions

1. In patients who sustain a periprosthetic femur facture, are there factors that may be predictive of this complication after primary THA?
2. In patients with periprosthetic fractures of the femur, is there a validated classification system that has satisfactory intraobserver and interobserver reliability and validity that aids in therapeutic planning?
3. In patients with Vancouver type B periprosthetic femur fractures, does operative management, compared to

nonoperative management, result in a better clinical outcome?

Question 1: In patients who sustain a periprosthetic femur facture, are there factors that may be predictive of this complication after primary THA?

Rationale

The question of risk factors in periprosthetic fractures is debated extensively in the literature and as such, a review of the current evidence is helpful to identifying these risks as they pertain to this common complication.

Clinical comment

Periprosthetic femur fractures after THA can be a difficult complication to manage. Recognition of features associated with periprosthetic fractures could allow for prophylactic measures to prevent a fracture in the at-risk patient.

Available literature and quality of the evidence

One level II prospective registry study was identified,[1] while the remainder were generally level III,[2–9] including several large database and registry studies.[10–14]

Findings

Gender

A summary of cohort and case-control studies classified as level III evidence noted a tendency of periprosthetic fracture patients to be female gender.[2–5,10–12] A meta-

analysis concluded an odds ratio (OR) of 1.534 (95% confidence interval [CI]: 1.345–1.749, p <0.001), while a Swedish registry study showed a relative risk of 1.6 (95% CI: 1.1–2.3).[6,13] A prospective registry study as well as a retrospective cohort did not conclude gender to be a risk factor.[1,7] Abdel et al. in their retrospective review of 32 644 primary THAs found female gender to be a risk factor of intraoperative (CI: 1.2–1.7; p <0.001) but not postoperative fractures.[14]

Patient age

Several retrospective studies have shown age to be a risk factor for fracture.[7,8,10,12,13] One meta-analysis concluded that age greater than 80 is a risk factor (OR = 4.203; 95% CI: 2.859–6.181; p <0.001)[6] while another prospective cohort study concluded that age is a risk factor with a relative risk of 1.4 for each decade of increasing age (95% CI: 1.2–1.6; p <0.001). In contrast, Lindahl et al. found a significantly higher fracture rate in younger patients (p <0.001),[1] while a large-scale retrospective cohort study did not find age to be a risk factor.[14]

Rheumatoid arthritis

In the prospective Swedish National Registry study, only 6% overall were patients with rheumatoid arthritis. They had an increased prevalence in the periprosthetic fracture group, with an incidence of 11 and 10% in the primary and revision populations, respectively (p <0.001).[1] Zhu et al. in their meta-analysis showed that rheumatoid arthritis is a statistically significant risk factor for periprosthetic fracture (p <0.001).[6]

Osteoporosis and prior fragility fracture

A large-scale prospective cohort study reported osteoporosis to increase fracture risk by 2.8 times (95% CI: 1.6–4.8; p <0.001).[12] Wu et al. found that preoperative osteoporosis was a significant predictor for fracture.[8] In a small case control study, Sarvilinna reported a risk ratio of 4.4 (95% CI: 1.4–14) for periprosthetic fracture if the primary diagnosis for arthroplasty was fracture.[9]

Timing to fracture and implantation method

A large-scale 40-year follow-up retrospective cohort documented the incidence of fracture to be 0.4% at 1 year, 0.8% at 5 years, 1.6% at 10 years, and 3.5% at 20 years.[14] Lindahl et al. reported an average of 7.4 years post primary THA (688 fractures), and 3.9 years post revision hip arthroplasty (361 fractures).[1] The timing of periprosthetic fractures from the index procedure, however, seems to relate in part to the type of prosthesis used. A large prospective cohort study reported that 77% of all prostheses used were uncemented and the incidence of fracture was 2.4% for uncemented and 0.9% for cemented (p <0.001) hips.[12] The Nordic registry reported that fracture risk for uncemented stems was highest in the first six months, while fractures with cemented stems tended to occur later.[13] Abdel et al. found that, overall, uncemented stems had a higher prevalence of fracture at all time points up to 20 years (p <0.001).[14] The reason for early postoperative fractures in uncemented components appears to be related to technical intraoperative errors that lead to fractures in the period of latency before osteointegration.[13],[15] Late postoperative fractures have been associated with loosening and osteolysis.[15],[16] For instance, in the Swedish Hip Arthroplasty Register 70% of implants were noted to be loose prior to periprosthetic fracture.[1]

Resolution of clinical scenario

- Patients who have a history of rheumatoid arthritis, osteoporosis, or previous fragility fracture are at increased risk of periprosthetic hip fracture, whereas those with female gender or increased age are more debated.
- Uncemented stems have a higher risk of fracture in the early postoperative period.
- Femoral component loosening is a risk factor for late periprosthetic fracture.

Question 2: In patients with periprosthetic fractures of the femur, is there a validated classification system that has satisfactory intraobserver and interobserver reliability and validity that aids in therapeutic planning?

Rationale

The Vancouver Classification is the most widely used periprosthetic fracture classification and the evidence behind its use is important to review in the context of this complication.

Clinical comment

The variability of pathology seen in periprosthetic fractures of the femur necessitates an effective classification system to aid in the communication of diagnoses among surgical colleagues and to develop a management plan. The ability

to classify these fractures properly will assist in their management.

Available literature and quality of the evidence

The two studies available to address this question are validation studies.[17],[18]

Findings

A useful classification system incorporates clinical and radiographic information to guide management, allowing for appropriate treatment and comparison of similar fractures.

In 1995, Duncan and Masri published the Vancouver Classification System (VCS), which emphasized the quality of the prosthetic–bone interface (stability) as well the host bone stock in the therapeutic decision-making process.[19],[20] This system divides the femur into three regions regarding the stem: the trochanteric (A), around or just below the stem (B), and distal to that (C). It further subdivides the B type into those with a well-fixed stem (B1), a loose stem (B2), and a loose stem with poor bone stock (B3). The VCS has now been expanded so as to include three fracture types not originally included (D, E, and F), as well as to apply its well-accepted principles to other bones and joints[21],[22] For the purpose of this review, which deals with the femur alone, we will use the VCS.

The VCS has been subjected to reliability and validity testing in both North America and Europe,[17],[18] and is accepted universally. Brady et al. demonstrated reliability of the system when evaluated by experts and nonexperts alike, with intraobserver agreement ranging from 0.73 to 0.83, and interobserver agreement of 0.61 to 0.64 by kappa analysis indicating substantial agreement between observers. Validity was also evaluated revealing substantial

agreement (kappa value of 0.78).[17] It has, however, been subject to criticism, mainly with the reliance of the system on subjective surgeon judgment of implant stability. Failure to differentiate between a type B1 and B2 is associated with higher reoperation rates from implant failure,[23] and therefore distinguishing between B1 and B2 fractures preoperatively, and if this is difficult then checking intraoperative stability of the stem is of great importance.

Resolution of clinical scenario

The VCS for postoperative periprosthetic fractures of the femur is reliable and valid for both experts and nonexperts.

Question 3: In patients with Vancouver type B periprosthetic femur fractures, does operative management, compared to nonoperative management, result in a better clinical outcome?

Rationale

Periprosthetic femur fractures are a recognized complication of arthroplasty with a variety of types and treatment methods. An evidence-based approach to management of these fractures is the main topic of this chapter.

Clinical comment

Periprosthetic fractures are a well-known complication of THA and their management has evolved as implants and techniques have improved. An evidence-based approach to their management is important to improve outcomes.

Available literature and quality of the evidence

One level II prospective study was included,[24] while the remainder of the included evidence is made up of level III or IV studies,[25–31] as well as several systematic reviews and meta-analyses.[32–34]

Findings

Type B1 fractures are located around or adjacent to a stable femoral implant, whereby the fracture has not rendered the implant loose by either debonding a cemented composite beam stem or by involving the primary fixation surface of a cementless stem. It is generally accepted that these fractures should be treated with internal fixation; however, there is debate in the literature as to the more superior fixation method or to the value of adding strut allografts. Moore et al., in their systematic review, showed union with (n = 208) and without (n = 503) an allograft strut was 91.5 and 90.7%, respectively. The time to union was on average 2.5 months longer (95% CI; $p < 0.001$) with the use of an allograft.[32] Furthermore, union with a locking versus nonlocking plate was 91.7 and 92.4% with no difference in the time to union. In contrast, however, another systematic review showed that fractures treated with locking plates (n = 20) compared to nonlocking plates (n = 152) had a statistically significant increased risk to nonunion at 9 versus 3%, respectively ($p = 0.02$).[33] These systematic review results are limited, however, as they only involved level IV studies. However, as internal fixation techniques for periprosthetic fractures have continued to evolve, we cannot simply compare locking versus nonlocking plates as modern devices allow the use of locking screws, nonlocking screws, and cerclage cables using the same plate. The surgeon needs to understand the basic principles of the use of these plates: to allow healing

with callus as opposed to attempting primary bone healing, the bone stock and the presence of an implant make primary bone healing with compression almost impossible.

Revision arthroplasty with a long tapered fluted stem is generally the most accepted treatment for B2/B3 fractures and is associated with good outcomes.[25],[26],[34] The largest retrospective study to date showed a 98% healing rate with the use of a long tapered fluted stem for B2 and B3 fractures with an average Harris Hip Score of 80.[27] In another systematic review,[34] of 343 B2 fractures around both cemented and noncemented stems, 86.8% were treated with revision arthroplasty with or without open reduction and internal fixation (ORIF) while 12.6% were treated with ORIF alone. The re-operation rate for the revision arthroplasty and ORIF alone was 12.8 and 13.1%, respectively. The authors felt the incidence of B2 revisions managed with ORIF was likely underrepresented as the scope of their study did not include misclassified B1 fractures. They concluded that the re-operation rate for B2 fractures managed with ORIF is likely closer to the prospective Swedish registry, which reports a 32% overall re-operation rate for B2 fractures including a 10% re-operation rate of those managed with revision arthroplasty alone and a 23% re-operation rate of those managed with ORIF alone.[24],[34]

With the increasing use of polished tapered cemented stems (also known as *slip taper stems*), it has become apparent that these stems behave differently when subjected to a periprosthetic fracture in comparison to composite beam cemented stems. The polished tapered stems do not have any fixation into the cement mantle, but the cement mantle needs to be fixed to the bone, as the stems are designed to subside into the cement mantle. The composite beam stems, in contrast, are designed to fix to

the cement mantle, which is also required to fix to the host bone. A fracture around a polished tapered stem that does not compromise the fixation at the cement–bone junction, and thus does not lead to stem loosening as long as the bone is reduced and fixed in an anatomic manner so that the cement mantle is restored anatomically. For this reason, these fractures can be classified as B1 fractures. Goudie et al. found that ORIF using a dynamic compression nonlocking plate around polished tapered cemented stems for these fractures resulted in 91% union with nonanatomic reduction predicting failure, emphasizing the above-noted principles.[28] Anatomic restoration of an intact bone–cement mantle allows for controlled subsidence of a polished tapered cemented stem and a revision surgery may be avoided in elderly patients of low demand and significant medical comorbidities.[29],[35] As long as bone stock is reasonable, the fracture is reduced perfectly, and the cement mantle is intact except for the fracture line then these fractures do not require revision of the stem.

Khan et al. in their systematic review of 22 studies showed that 95.8% of Vancouver B3 fractures were treated with revision arthroplasty with or without internal fixation, with the majority being uncemented.[34] The re-operation rate for revision arthroplasty with or without ORIF and ORIF alone were 14.4 and 28.6%, respectively (RR = 1.38; p = 0.63). The revision rates for B2 and B3 fractures treated with uncemented tapered stems was 12.3 and 15.5%, respectively, which is in keeping with the Swedish registry results of 18.5 and 15.5%, respectively.[24] Common reasons for revision include subsidence, re-fracture, and infection.[24],[34] Caution should be used in interpreting these results due to the lower levels of evidence of these studies and due to case heterogeneity.

Using another successful technique, Maury reported on his outcomes of 25 Vancouver B3 fractures treated with allograft prosthetic composites, with the mean postoperative Harris Hip Score at two years of 70.8.[30] Most of their patients were ambulatory (23/24) and pain-free (21/24) at the time of last follow-up. Four of the 25 hips required repeat revision for subsidence and failure. Babis et al., in their long-term study, showed survivorship at 69% with the severity of preoperative bone loss, number of prior revisions >2 and length of the allograft as statistically significant risks for revision.[31] With the current use of either modular or nonmodular tapered stems, the indications for allograft prosthetic composites have been extremely limited in recent years, and the senior authors have not performed this operation for the past 15 years, and it should be considered of historical interest only.

Proximal femoral replacement prostheses, with a reported survivorship of 64% at 12 years, is an option for elderly patients with a limited life expectancy and low functional demands due to a reduced rehabilitation time and immediate weight bearing capacity that these implants allow.[36]

Resolution of clinical scenario

- Vancouver B1 fractures should be treated with open reduction and internal fixation; however, the method of fixation and use of strut allograft remains controversial based on the available literature. The authors recommend the use of a long dedicated periprosthetic fracture plate that allows the use of locking screws, nonlocking screws, and cables in a minimally invasive approach and using indirect reduction technique. Lag screws at the fracture site should be avoided and cables should be used in order to allow healing with

callus. Stable fixation of the proximal and distal fragments needs to be achieved using a combination of locking and nonlocking screws as well as cables with the equivalent of eight cortices in each fragment. The screws should be spaced as far away from the fracture to allow some flexibility at the fracture site to allow for healing with callus. Filling every screw hole with a screw is not recommended as this makes the construct very stiff, and can lead to nonunion. Because the bone is generally osteopenic in these patients, a long plate should be used to protect the entire bone. In general, struts are not recommended, with the exception of transverse fractures at the tip of the stem where rotational control with a plate alone is not possible, and because of the high stress concentration at the tip of the stem.

- Vancouver B2/B3 fractures are ideally managed by long stem revision arthroplasty with or without osteosynthesis. Certain cases involving fractures with a cemented polished tapered implant with a largely intact cement–bone interface and potential for anatomic reduction may be amenable to osteosynthesis alone.
- Other options for Vancouver B3 fractures include allograft composite constructions and proximal femoral replacement. Proximal femoral replacement should be considered in more elderly and low demand patients.

Summary of answers

- Risk factors for periprosthetic fracture include: rheumatoid arthritis, osteoporosis, previous fragility fracture, or the use of uncemented stems.
- The Vancouver Classification System is reliable and valid for periprosthetic hip fractures.

- Treatment depends on Vancouver fracture types, and is dictated by the stability of the implant and the degree of bone loss.

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31 The Infected Total Hip Arthroplasty

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Clinical scenario

- A 59-year-old female is one year out from revision of a left total hip arthroplasty (THA) due to recurrent dislocation.
- She is now nonambulatory due to pain and presents with a draining sinus on her hip.
- Radiographs reveal loosening of the acetabular cup.
- Further diagnostic workup showed an elevated C-reactive protein (CRP: 159 mg/L), erythrocyte sedimentation rate (ESR: 96 mm/h) and a positive aspiration fluid culture for *Enterococcus faecalis* (Figure 31.1).

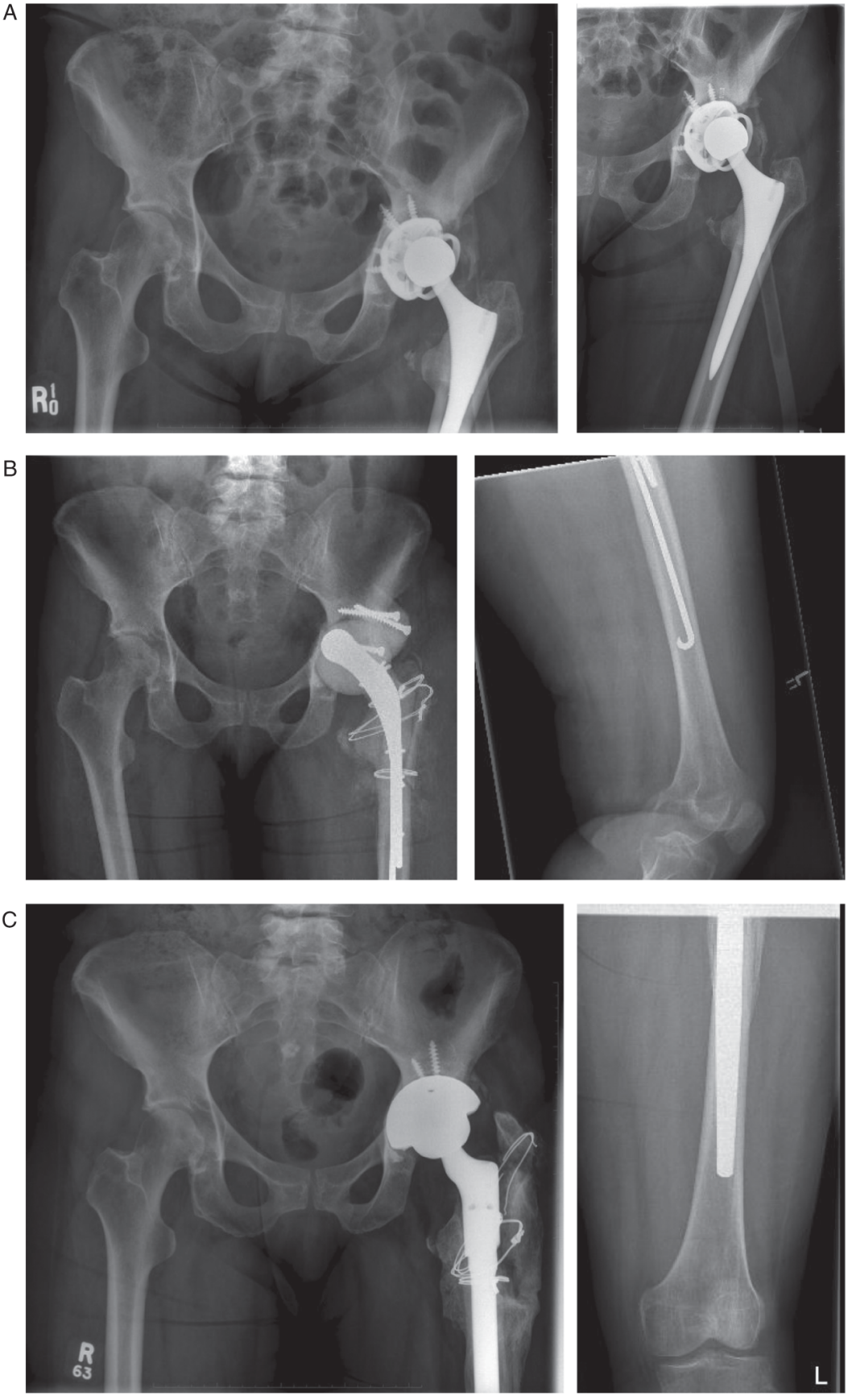
A
B
C
R
L

Figure 31.1 Radiographs: (A) preoperative; (B) first-stage; (c) second-stage.

Source: Sebastián, Xin Y. Mei, Paul R. Kuzyk.

Top three questions

1. In patients with suspected periprosthetic joint infection (PJI), are novel biomarkers such as alpha-defensin and leukocyte-esterase better screening tests for than ESR, CRP, and synovial fluid polymorphonuclear cells (PMNs)?
2. In patients with late PJI, do two-stage revisions have better rates of infection eradication than one-stage revisions?
3. In patients who have undergone two-stage revision, does an additional course of prophylactic oral antibiotics reduce the rates of reinfection compared to no additional antibiotics?

Question 1: In patients with suspected PJI, are novel biomarkers such as alpha-defensin and leukocyte-esterase better screening tests for than ESR, CRP, and synovial fluid PMNs?

Rationale

Current guidelines recommend a combination of blood tests (ESR, CRP) and synovial fluid analysis for workup of suspected PJI. Recent studies have shown promising results using synovial fluid biomarkers in the diagnosis of PJI.

Clinical comment

PJI affects 1–2% of patients after primary THA,[1],[2] and is responsible for 12.8% of revision THAs.[3] Current guidelines from the Musculoskeletal Infection Society (MSIS) and the International Consensus Group recommend obtaining serum ESR and CRP levels in the workup of all patients with suspected PJI.[4],[5] Despite their universally accepted use, neither test is completely reliable in diagnosing PJI. To improve the accuracy of this diagnosis, several synovial fluid biomarkers have been investigated and shown to outperform traditional tests in diagnosing PJI.[4],[6] Of these, alpha-defensin and leukocyte esterase (LE) have shown promising results.

Alpha-defensin is an antimicrobial peptide released by activated neutrophils that has the ability to adhere to and destroy the bacterial cellular membrane.[7] It is unique to neutrophils found in infected joints, and is not released by neutrophils in aseptic joint inflammations such as gout.[8] There are currently two commercially available methods for measuring alpha-defensin in synovial fluid. The enzyme-linked immunosorbent assay (ELISA)-based alpha-defensin immunoassay measures the fluorescent signal released by tagged antibodies binding to alpha-defensin antigen, and provides a quantitative readout within 24 hours. By contrast, the alpha-defensin lateral flow test is a paper-based platform that detects the presence or absence of alpha-defensin in three drops of a diluted aspirate placed on a test device, and provides a binary readout within 20 minutes.[9] Although these tests are easy to perform, they are much more costly than conventional tests.

LE is an enzyme secreted by activated neutrophils and is currently part of the minor diagnostic criteria of PJI according to MSIS and International Consensus Meeting

guidelines.[10],[11] Its presence in synovial fluid can be detected using colorimetric strip tests.[12] Blood-contaminated synovial fluid samples can interfere with interpretation of the colorimetric strip; however, the use of a centrifuge to separate synovial fluid from contaminant blood can help yield accurate results.[13] Advantages of the LE test include it being quick and easy to perform, as well as the low cost of the colorimetric strip.

Available literature and quality of the evidence

- Level II: 2 systematic review/meta-analyses of prospective cohort studies.[14],[15]
- Level III: 1 systematic review/meta-analysis of level II and III diagnostic studies.[9]
- 3 retrospective cohort studies.[16]–[18]

Findings

A recent systematic review and meta-analysis by Wyatt et al. evaluated the diagnostic accuracy of alpha-defensin (six studies) and LE (five studies) for PJI.[15] The pooled sensitivity and specificity of alpha-defensin were 1.00 (95% confidence interval [CI]: 0.82–1.00) and 0.96 (95% CI: 0.89–0.99), respectively. The pooled sensitivity and specificity of LE were 0.81 (95% CI: 0.49–0.95) and 0.97 (95% CI: 0.82–0.99), respectively. Diagnostic accuracy, as defined by the area under the receiver operating characteristic curve, was 0.99 (95% CI: 0.98–1.00) for alpha-defensin and 0.97 (95% CI: 0.95–0.98) for LE.

Emerging evidence suggests that the alpha-defensin lateral flow test may have lower diagnostic accuracy than its ELISA-based immunoassay counterpart. A 2018 systematic

review comprising 601 patients across seven studies showed the ELISA-based immunoassay to have superior overall diagnostic value compared with the lateral flow test (AUC, 0.98 vs 0.75) with higher sensitivity (96%, 95% CI: 90–98% vs 71%; 95% CI: 55–83%; p <0.001) but no difference in specificity (96%, 95% CI: 93–97% vs 90%; 95% CI: 81–5%; p = 0.060).[9]

A meta-analysis by Berbari et al. evaluated the diagnostic accuracy of serum biomarkers for PJI.[14] Data were pooled from 30 eligible studies. The pooled sensitivity and specificity of ESR were 75% (95% CI: 72–77%) and 70% (95% CI: 68–72%), respectively. The pooled sensitivity and specificity of CRP were 88% (95% CI: 86–90%) and 74% (95% CI: 71–76%), respectively. The diagnostic odds ratio was 7.2 (95%: CI 4.7–10.9; 25 studies) for ESR and 13.1 (95% CI: 7.9–21.7; 23 studies) for CRP.

Shahi et al. evaluated the diagnostic odds ratios (DORs) of five routine laboratory markers for PJI in 4662 revision THAs.[17] The DORs for PJI, from highest to lowest, were LE: 30.06 (95% CI: 17.8–50.7), synovial fluid white blood cell count: 29.4 (95% CI: 20.2–42.8), CRP: 25.6 (95% CI: 19.5–33.7), synovial fluid PMN percentage: 25.5 (95% CI: 17.5–37.0), and ESR: 14.6 (95% CI: 11.5–18.6). The authors concluded that among the minor diagnostic criteria, LE has the best performance.

Tarabichi et al. reviewed the records of 319 patients who had ESR and CRP screening prior to LE testing for diagnosis of PJI.[18] The authors reported that when LE is concordant with ESR and CRP levels it can effectively rule out or diagnose PJI with >95% certainty. When discordant, only stricter LE thresholds (2+ or negative) are adequate to suggest a change in clinical decision-making. In this context, intermediate LE values require further diagnostic testing.

Shahi et al. reported that prior antibiotic administration is associated with lower ESR and CRP values in comparison with no antibiotics, with difference of medians (DOM) of 15 mm/h ($p = 0.018$) and 58 mg/L ($p = 0.038$), respectively, which may lead to increased risk of false negative tests.[16] The same group later reported that alpha defensin levels did not vary significantly with antibiotic administration (DOM 0.68; 95% CI: −0.98–1.26; $p = 0.451$).[19] Alpha defensin was also found to have higher sensitivity (100%; 95% CI: 88.4–100.0%) in diagnosing PJI than ESR (69.0%; 95% CI: 49.17–84.72%; $p = 0.001$) and CRP (79.3%; 95% CI: 60.3–92.0%; $p = 0.009$).

Resolution of clinical scenario

Preliminary studies have shown alpha defensin to be highly sensitive and specific in diagnosing PJI, with superior performance compared to ESR and CRP. Results also appear to remain unaffected by prior antibiotic administration. However, the high cost of the test remains a barrier to its routine use.

The LE strip test is inexpensive and has also shown superior performance in comparison to routine serum biomarkers such as ESR and CRP. Results are most promising when used in conjunction with ESR and CRP.

The 2018 International Consensus Meeting on Musculoskeletal Infection supported the use of the alpha-defensin lateral flow test and the LE test strip in the diagnosis of PJI.[20]

Question 2: In patients with late PJI, do two-stage revisions have better rates of infection eradication than one-stage revisions?

Rationale

Two-stage revision is widely accepted as the standard of care in North America for treating late chronic PJI, while one-stage revision remains a frequent option among European surgeons.

Clinical comment

The goal of any revision for PJI is eradication of infection. This is accomplished through extensive irrigation, debridement, and removal of all implants, cement, and any foreign material present at the time of revision. Reimplantation of a new permanent prosthesis can either be delayed after a course of systemic antibiotics (two-stage) or performed during the same irrigation and debridement procedure (one-stage).

The two-stage approach has long been accepted as the standard of care for management of chronic PJI, and it is considered the only safe method for treating chronic infection when the organism and/or its sensitivities are unknown. Between the first and second stage, the patient requires an extended period of systemic antibiotic therapy in addition to the locally eluted antibiotics from the antibiotic-loaded cement spacer.[21] It has been associated with high morbidity and mortality, pain and disability in the interim period, and sometimes, persistent functional deficit after the final reimplantation procedure.[22–25]

There is increasing interest in the one-stage revision as it may be associated with better functional outcomes and lower overall healthcare costs.[25–27] Cemented components are generally preferred to ensure high levels of local antibiotic elution,[28,29] though reports using a noncemented technique exist.[30,31] Identification of the infecting organism and its antibiotic sensitivity through synovial fluid culture is mandatory in order to establish a targeted antibiotic regimen.[32]

Available literature and quality of the evidence

- Level III: 1 systematic review of retrospective cohort studies.[33]
- Level IV: 2 systematic review/meta-analyses of case series and retrospective cohort studies.[34,35]

Findings

In a systematic review of nine retrospective cohort studies, Leonard et al. did not find a statistically significant difference in infection-free survival between single- and two-stage revisions.[33] Although overall rates of reinfection had a higher trend for one-stage (16.8%) than two-stage (10.6%) revisions, there was also a trend toward better functional outcome in one-stage revision.[36]

In a meta-analysis of 38 one-stage (2536 patients) and 60 two-stage (3288 patients) studies, Kunutsor et al. found similar reinfection rates for the two approaches: 8.2% (95% CI: 6.0–10.8) and 7.9% (95% CI: 6.2–9.7), respectively.[34] Lange et al., in a meta-analysis of 36 noncomparative studies, also found similar reinfection rates between one- and two-stage revisions: 13.1% (95% CI: 10.0–17.1%) and 10.4% (95% CI: 8.5–12.7%), respectively.[35]

Resolution of clinical scenario

The current available evidence fails to demonstrate a significant difference in reinfection rates between the two-stage revision arthroplasty and one-stage exchange arthroplasty for PJI.

The 2018 International Consensus Meeting on Musculoskeletal Infection suggested that one-stage exchange arthroplasty remained a viable option for the management of chronic PJIs. One-stage exchange arthroplasty is contraindicated in patients with signs of systemic sepsis, extensive comorbidities, infection with resistant organisms, culture-negative infections, and poor soft tissue coverage.[37]

Question 3: In patients who have undergone two-stage revision, does an additional course of prophylactic oral antibiotics reduce the rates of reinfection compared to no additional antibiotics?

Rationale

There is a lack of consensus regarding the use of additional prophylactic oral antibiotic therapy following two-stage revision in preventing reinfection.

Clinical comment

Reinfection after two-stage revision for PJI is a devastating complication with reported incidences ranging from 3.2–13%.[38],[39] Treatment of reinfection poses large physical, economic, and emotional burdens on the patient, and is

frequently associated with significant morbidity and poor functional outcomes.

Second-stage reimplantation takes place when the treating medical team feels that the infection is under control. There is currently no consensus regarding the optimal timing for reimplantation. Some authors have suggested reimplantation if the incision has healed and ESR/CRP levels continue to decline following a two-week antibiotic holiday.[21] Intraoperative frozen sections are useful to confirm the eradication of infection,[40] but are not routinely performed at all centers. Despite this, reinfection may occur due to residual bacteria or seeding of the joint at the time of reimplantation. In addition, multiple prior operations on the joint may render patients more susceptible to an early new infection. Administration of oral antibiotics tailored to the original infecting organism(s) after second-stage reimplantation has been proposed as a potential strategy to decrease the rate of reinfection.

Available literature and quality of the evidence

- Level I: 1 randomized controlled trial.[41]
- Level III: 2 retrospective cohort studies.[38],[42]

Findings

At a minimum follow-up of 12 months, Zywiel et al. reported one (4%) reinfection in 28 TKA re-implantations receiving a minimum 28-day course of prophylactic oral antibiotics compared to six (16%) reinfections in 38 patients who did not receive postoperative oral antibiotics.[42] This difference was not statistically significant. On a similar note, Johnson et al. reported no reinfections in 23 THA re-implantations receiving a minimum 14-day course of prophylactic oral antibiotics

compared to six (13.6%; p = 0.087) reinfections in 44 patients who did not receive postoperative oral antibiotics.[38]

Frank et al. reported interim analysis of an ongoing multicenter randomized trial comparing reinfection rates in 59 second-stage hip or knee arthroplasties randomized to receive three months of oral antibiotics post reimplantation versus 48 randomized to receive only routine perioperative antibiotics.[41] At a mean follow-up of 14 months in the antibiotic group and 10 months in the control group, the authors reported a significantly lower reinfection rate in the antibiotic group (3/59; 5% vs 9/49; 19%; hazard ratio, 4.37; 95% CI: 1.297–19.748; p = 0.016).

Resolution of clinical scenario

Preliminary studies with short-term follow-up suggest that prophylactic oral antibiotic therapy after second-stage reimplantation may improve infection-free survival. Further studies with longer-term follow-up are required.

Summary of answers

- Alpha-defensin is a highly sensitive and specific test for diagnosing PJI, with superior performance compared to ESR and CRP. It may be particularly useful in patients with suspected PJI who have been receiving antibiotics prior to workup. Evidence suggests that the lateral flow test has a lower diagnostic accuracy than the ELISA-based immunoassay.
- The LE strip test is inexpensive and has also shown superior performance in comparison to routine serum biomarkers such as ESR and CRP. Results are most promising when used in conjunction with ESR and CRP.

- Although the available evidence fails to demonstrate a significant difference in reinfection rate between two-stage and one-stage revision for PJI, this finding should be treated with caution, as there's a lack of high-quality evidence.
- At short-term follow-up, prophylactic oral antibiotic therapy after second-stage reimplantation may improve infection-free survival.

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32 The Painful Total Hip Arthroplasty

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Clinical scenario

- A 70-year-old patient with a total hip arthroplasty (THA) performed eight years ago presents with pain in his hip for the last four months.
- He had unremarkable postoperative recovery and was asymptomatic for the last eight years. He has no significant medical comorbidities.

Table 32.1 Causes of painful THA.

Intrinsic	Extrinsic
Intracapsular Infection Aseptic loosening Osteolysis Instability Impingement Polyethylene debris Trunnionosis/ALTR Metal hypersensitivity Crystalline arthropathy	**Local** Hernia – inguinal, abdominal Hernia – vastus lateralis Hernia – fascia lata Tumor Genito-urinary tract
Extracapsular Iliopsoas tendonitis Trochanteric bursitis Heterotopic ossification Periprosthetic fracture Complex regional pain syndrome	**Remote** Spinal pathology Neuropathy Nerve entrapment Vascular claudication Complex regional pain syndrome

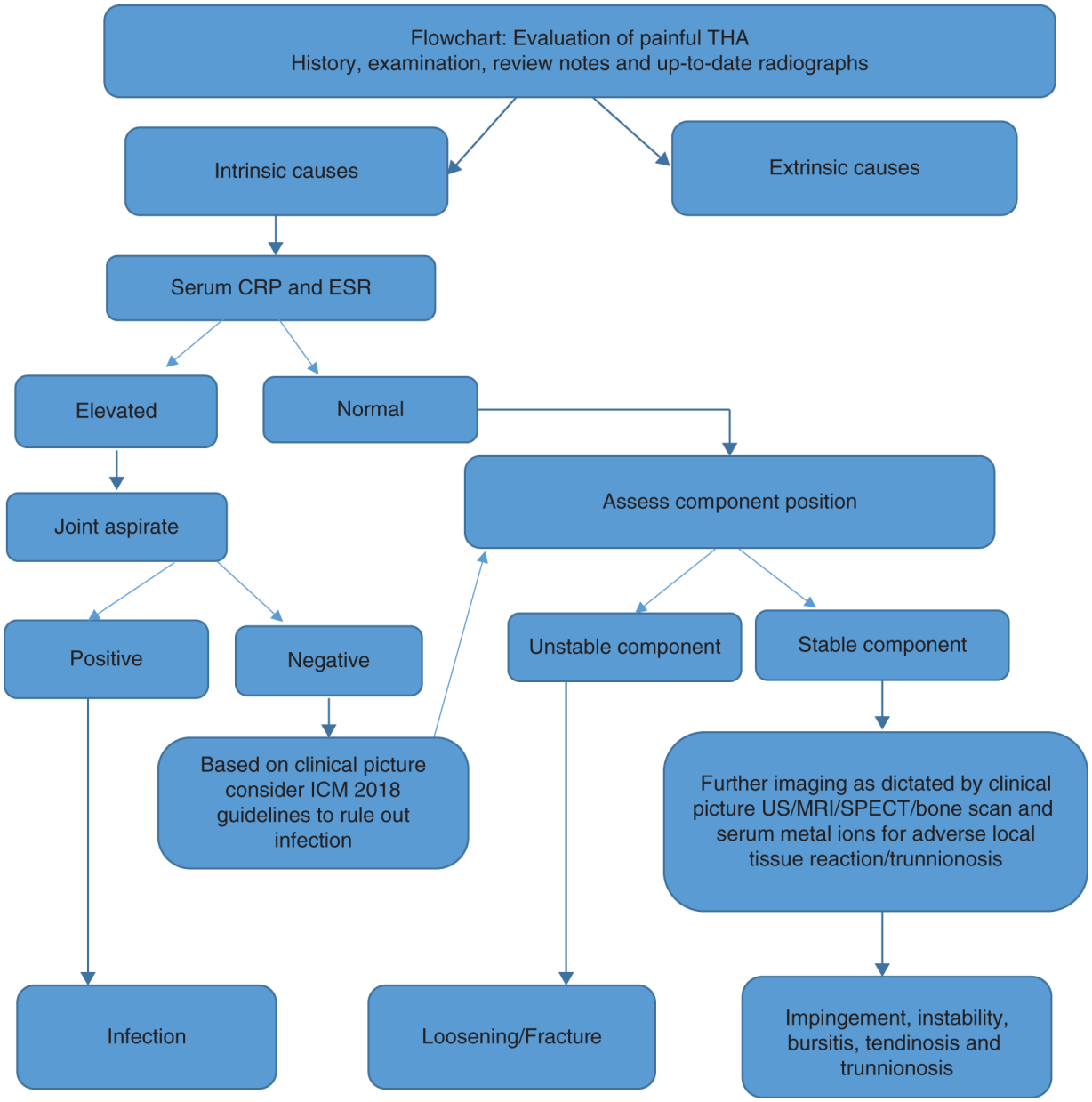

Figure 32.1 Approach to painful THA.

Introduction

Although majority of the patients with THA have a high satisfaction rate, between 7 and 23% of the patients report some dissatisfaction following THA.[1] The aim of this chapter is to provide a systematic evidence-based approach to the evaluation of a painful THA.

Top three questions

1. In patients presenting with a painful THA, what are the key features on history, clinical examination, and investigation, compared to others, that are pertinent to formulating the diagnosis?
2. In patients presenting with a painful THA, which diagnostic tools, compared to others, are most evidence-based to diagnose periprosthetic joint infection (PJI)?
3. In patients presenting with a painful metal-on-polyethylene (MoP) THA, what is the role of metal ion levels, compared to other diagnostic tools, in diagnosing trunnionosis?

Question 1: In patients presenting with a painful THA, what are the key features on history, clinical examination, and investigation, compared to others, that are pertinent to formulating the diagnosis?

Pain following THA is multifactorial. The causes of a painful THA are listed in Table 32.1.[2,3] It is critical to establish the accurate diagnosis with history, clinical examination, and relevant investigations to provide most appropriate nonoperative or operative management.

History

Identifying the precise location of pain is paramount. Groin pain may indicate acetabular pathology and thigh pain

exacerbated by activity may suggest loosening of implant. Buttock pain can be from hip or spinal pathology. Start-up pain may suggest loosening. Local findings such as swelling around the hip may indicate infection or may be due to a pseudotumor. Rest pain warrants investigations for infection or malignancy. It is imperative to question the patient about duration of pain and postoperative recovery after the arthroplasty particularly wound complications and infections.[3]

Clinical examination

Clinical examination should include gait analysis, Trendelenburg sign secondary to abductor muscle weakness; limb length discrepancy; and hip, knee, and spine examination. Progressive shortening of the limb suggests subsidence of femoral component. Active and passive range of movement of the hip with signs of apprehension in extreme positions must be assessed as this may suggest instability. Pain in resisted hip flexion suggests iliopsoas pathology. The hip should be examined for anterior and posterior impingement. This is particularly important in hip resurfacing patients due to a decreased head : neck ratio. Finally, neurovascular examination of the lower limb should be performed and compared with the opposite side.

ALTR: adverse local tissue reaction

Imaging

Plain radiographs play the primary role in the initial evaluation of painful THA and provide baseline imaging for subsequent surveillance. Due to its lower rates of sensitivity and specificity, higher modalities of imaging are often needed to confirm the diagnosis.[4] Hargunani et al. in 2016 have published the role of various imaging modalities

with the pros and cons of each in the evaluation of painful THA.[4] The clinician is often in a position to formulate provisional diagnosis and choose further investigations after clinical assessment and appropriate imaging, plain radiographs being essential. Figure 32.1 demonstrates a systematic and evidence-based method of approaching the most accurate diagnosis during evaluation of painful THA.

US: ultrasound; MRI: magnetic resonance imaging; SPECT CT: single-photon emission computerized tomography?

Question 2: In patients presenting with a painful THA, which diagnostic tools, compared to others, are most evidence-based to diagnose periprosthetic joint infection (PJI)?

Rationale

The Musculoskeletal Infection Society (MSIS) criteria were introduced in 2011 for the diagnosis of PJI of THA and total knee arthroplasty (TKA).[5] This was a revolutionary step in diagnosis and management of PJI with confidence and standardization. These criteria were further modified at the International Consensus Meeting (ICM) in 2013.[6] Since then, further new tests and evidence have evolved, hence the need to update the diagnostic criteria for PJI.

Clinical comment

There is no single test to diagnose PJI with accuracy. This is done by a combination of clinical findings, laboratory results both from peripheral blood and synovial fluid, identification of microorganism, histological evaluation of local tissue, and intraoperative findings.[7]

Available literature and quality of the evidence

- Level II (1 study) and level IV (multiple studies).

Saleh et al. in 2018 have reviewed the evidence looking at serum biomarkers for the diagnosis of PJI.[8] They found that currently C-reactive protein (CRP) and erythrocyte sedimentation rate (ESR) remain the most commonly used biomarkers as other tests have not shown superior sensitivity as first line screening tests for PJI. They have acknowledged increasing interest in the development of newer biomarkers from both serum and synovial fluid and the potential of using genomic and proteomics through messenger RNA in future for diagnosis of PJI.

The MSIS has published characteristics of 43 synovial fluid biomarkers for diagnosis of PJI in a level II study.[9] Out of these 43 they evaluated 16 synovial biomarkers which demonstrated the most consistent results. They reported that out of these 16 synovial biomarkers, five markers – namely human alpha defensin (a-defensin), elastase 2 (ELA-2), bactericidal/permeability-increasing protein (BPI), neutrophil gelatinase-associated lipocalin (NGAL), and lactoferrin – had sensitivity of 100% confidence interval (CI) (88–100%) and a specificity of 100% with 95% CI (94–100%).

Lee et al. published a systematic review and meta-analysis on synovial fluid biomarkers for the diagnosis of PJI.[10] They evaluated 13 synovial biomarkers with high sensitivity to diagnose PJI and reported the superiority of a-defensin over other biomarkers.

- Level: II diagnostic study.

Based on most recent literature and new tests, ICM 2018 proposed and validated new criteria for diagnosis of PJI, as

shown in Table 32.2.[11]

Findings

These criteria to diagnose PJI of the hip and knee were developed after retrospective review of medical records of all the patients undergoing revision THA and TKA at three academic centers between 2001 and 2016. Patients who did not have serum CRP, serum ESR, and/or joint aspiration were excluded. Patients were considered to have PJI if they met the major diagnostic criteria of MSIS and previous ICM.[5,6] Patients who developed PJI within three months from index arthroplasty procedure were defined as acute PJI and were excluded. These criteria were based on current guidelines from the American Academy of Orthopaedic Surgeons (AAOS) and were validated by an external body to avoid the bias.

As per these new criteria listed in the Table 32.2, PJI is diagnosed if at least one of the two major criteria were positive. Major criteria include either two positive cultures of the same organism or sinus tract communicating to the joint or visualization of the prosthesis. In the absence of major criteria, minor criteria based on preoperative diagnosis were evaluated. Minor criteria include elevated levels of serum CRP, D-dimer, ESR, and elevated levels of synovial white blood cells (WBCs), leukocyte esterase (LE), polymorphonuclear (PMN) percentage, CRP, and positive a-defensin. A score of more than six is considered to be positive for PJI. Cases in which the pre-operative score was between two and five were further evaluated for intraoperative variables which include positive histology, positive purulence, and single positive culture with incorporation of pre-operative score. Intraoperative score of more than six was considered positive for PJI.

Table 32.2 Showing new scoring-based criteria from ICM 2018 for diagnosis of PJI.

Major criteria (at least one of the following)			**Decision**
Two positive culture of the same organism			Infected
Sinus tract with evidence of communication to the joint or visualization of the prosthesis			
Preoperative diagnosis			
	Minor criteria	**Score**	**Decision**
Serum	Elevated CRP or D-Dimer	2	≥6 Infected 2–5 possibly infected[a] 0–1 not infected
	Elevated ESR	1	
Synovial	Elevated WBC count or LE	3	
	Positive a-defensin	3	
	Elevated synovial PMN	2	
	Elevated synovial CRP	1	
Intraoperative diagnosis			
Inconclusive preop score or dry tap	**Score**		**Decision**
Preoperative score	—		≥6 Infected 4–5 Inconclusive[b] ≤3 not infected
Positive histology	3		

Positive purulence	3	
Single positive culture	2	

[a] For patients with inconclusive minor criteria, operative criteria can also be used to fulfill definition for PJI.

[b] Consider further molecular diagnostics.

They have advocated to proceed with caution in ALTR, crystal deposition disease, and slow-growing organisms.

The sensitivity for diagnosis of PJI as per the MSIS criteria was reported to be 79.3% with 95% CI (73.–84.4%). This further improved with ICM 2013 criteria as they reported sensitivity of 86.9% with 95% CI (81.8–91.1%). The sensitivity and specificity for the diagnosis of PJI with 2018 criteria was 97.7% with CI 95% (94.7–99.3%) and 99.5% with 95% CI (97.3–99.99%), respectively. This is the first validated evidence-based scoring system for the diagnosis of PJI and has higher level of sensitivity compared to previous scores.[7] The proposed threshold for both serum and synovial markers is shown in Table 32.3.

Table 32.3 Proposed threshold for serum and synovial markers.

Marker	Chronic (>90 days)	Acute (<90 days)
Serum CRP (mg/dL)	1.0	10
Serum D-dimer (ng/mL)	860	860[a]
Serum ESR (mm/h)	30	—
Synovial WBC count (cells/μL)	3000	10 000
Synovial PMN (%)	80	90
Synovial CRP (mg/L)	6.9[a]	6.9
Synovial a-defensin (signal-to-cutoff ratio)	1.0	1.0

[a] Further studies are needed to validate a specific threshold.

Resolution of clinical scenario

- Patient presented with painful THA. History, clinical examination, and plain radiographs did not show any signs of mechanical failure or aseptic loosening.
- The next step was to carry out workup for infection. Accurate diagnosis of PJI is challenging. The patient was investigated as per the new criteria by ICM 2018.
- Patient's score was more than six and the diagnosis of PJI was confirmed.
- This enabled the clinician to undertake appropriate revision arthroplasty.

Question 3: In patients presenting with a painful metal-on-polyethylene (MoP) THA, what is the role of metal ion levels, compared to other diagnostic tools, in diagnosing trunnionosis?

Rationale

Trunnionosis, also known as *taper corrosion*, is one of the complications of modular femoral stems. This term has been widely used in the arthroplasty literature to describe corrosion reaction at the Morse taper of various bearing surfaces. Serum ion levels for trunnionosis in metal-on-metal (MoM) articulation has been investigated extensively in the past. Literature in recent years has shown rising awareness about trunnionosis and role of blood ion levels in MoP articulation due to increasing incidence of trunnionosis-related implant failure.[12] Taper corrosion disrupts the protective oxide layer on the taper. This process is also known as *mechanically assisted crevice corrosion* (MACC). MACC can potentially produce metal ions which can migrate locally causing ALTR or systemically causing systemic metal ion toxicity features.[13] It is estimated that up to 2% of all THA patients might be affected by trunnionosis.[12]

Clinical comments

There are no specific clinical signs to diagnose trunnionosis. This has been reported to present as early as nine months from index procedure.[14] The signs of osteolysis on plain radiographs can be very subtle and variable.

Available literature and quality of the evidence

- Level: III (1 study) and level IV (multiple studies).

Findings

Hussey et al. have published a level III study on MACC in 1352 consecutive patients with MoP THA from a single manufacturer.[15] The inclusion criteria were unexplained pain or osteolysis of >1 cm. They diagnosed trunnionosis based on three criteria:

- Two or more serum metal ion levels showing cobalt (Co) values more than 1.0 parts per billion (ppb) or single test showing Co >1.6 ppb in patients with no other co-exposure.
- Single serum metal ion level showing Co >1.0 ppb in conjunction with metal artifact reduction sequence (MARS) magnetic resonance imaging (MRI) positive for complex fluid collection, pseudotumor, or tissue necrosis.
- Intraoperative findings of ALTR and corrosion at head–neck junction.

They reported 3.2% prevalence of MACC in their study. They also observed that the Zimmer M/L taper stem had higher prevalence 4.9% compared to other stems from the same manufacturer.

Sultan et al. published a systematic review on trunnionosis in MoP THA.[12] They identified following risk factors for trunnionosis.

- Large metal femoral head (36 mm and above).
- More common with metal (Co-Cr) heads compared to ceramic heads.

- Short taper with smaller diameter.
- Stems with stiffer alloys (Co-Cr compared to titanium).
- High body mass index (BMI) and higher functional level of activity.

They have reviewed studies looking at serum metal ion levels in painful MoP THA and have emphasized the disproportionate elevation of serum Co ions versus serum Cr ions. Cooper et al. in 2013 have reported 10 times higher levels of Co vs Cr,[16] while Plummer et al. in 2016 reported five times higher levels of Co vs Cr during their work up for trunnionosis in patients with MoP hips.[17] In the same study Plummer et al. also demonstrated that Co levels of more than 1 ppb was associated with ALTR.

It can be difficult to differentiate between corrosion and PJI as both can have equivocal presentation. In case of nonspecific rise in inflammatory markers, joint aspiration should be carried out. It is reported that automated machines can have false elevation of WBCs in trunnionosis, hence it is recommended to perform manual cell count on the aspirate to avoid false positive results.

Resolution of clinical scenario

- Patient presented with a new onset of unexplained hip pain with a previously well-performing MoP THA.
- History, clinical examination, plain radiographs, serum ESR, CRP, and joint aspiration were inconclusive.
- Patient had serum Co and Cr ions tested which showed disproportionate elevation of Co over Cr. MARS MRI confirmed ALTR and patient had revision arthroplasty.

Summary of answers

- Evaluation of painful THA is challenging. It needs a evidence based systematic approach which helps to narrow down the differential diagnosis and choose appropriate investigations.
- Criteria to diagnose PJI have been evolving with time. ICM 2018 presented the most recent criteria with excellent sensitivity and specificity. These should be considered in clinical practice to evaluate PJI.
- Incidence of trunnionosis is rising. Recent literature has pointed out risk factors for MACC. Unexplained painful MoP THA where infection, aseptic loosening, and iliopsoas tendonitis have been ruled out, warrants trunnionosis work up with serum metal ions.

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33 Revision of the Femoral Component

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Clinical scenario

- A 55-year-old man with a history of a total hip arthroplasty (THA) 15 years ago presents with a 12-month history of left groin pain and progressively declining function.
- Imaging shows extensive bone loss of his proximal femur with subsidence of his femoral stem.

Top three questions

1. In patients undergoing revision arthroplasty with impaction grafting and segmental replacement, what are the technical aspects of impaction, compared to routine technique, that improve clinical outcome?
2. In patients who are undergoing revision THA, how does impaction allografting for femoral revision, compared to no impaction allografting, perform in terms of outcomes?
3. In patients who are undergoing revision THA, how does proximal femoral segmental allografting, compared to other treatments, perform in terms of clinical outcomes?

Question 1: In patients undergoing revision arthroplasty with impaction grafting and segmental replacement, what are the technical aspects of impaction, compared to routine technique, that improve clinical outcome?

Rationale

Impaction and proximal segmental femoral allografting are options for revision arthroplasty in the setting of significant bone loss, thus understanding the technical aspects of these procedures is critical to optimize functional outcome.

Available literature and quality of the evidence

The majority of the available evidence is level IV[1–5] with two level III studies.[6,7] Expert opinion (level V) was also frequently found.

Clinical comment

Impaction and proximal segmental femoral allografting are both technically challenging procedures that should be performed by experienced surgeons. It is critical that the surgeon understand both the technical and the potential intraoperative pitfalls such that the outcome can be maximized while complications and patient morbidity are minimized.

Findings

Impaction allografting

The principle of impaction grafting is to restore cavitary meta-diaphyseal bone loss with morselized allograft to support a cemented stem (Figures 33.1 and 33.2). Poor-quality cement mantle (≤2 mm) appears to influence migration of the femoral stem.[6] The greatest migration, typically into varus and retroversion, occurs in the first three months and is attributed to further graft compaction and a poor cement mantle,[6,8] which is often due to poor instrumentation.[2,3,6] Furthermore, cement mantle defects may cause progressive migration during creeping substitution.[2] Masterson et al. in their study of multiple stem techniques documented concerns with the quality of the cement mantle due to inadequate instrumentation.[9] The Exeter system lead to absence of cement in 50% of Gruen zones, which was attributed to the trial impactors being shorter and more sharply tapered, which created an inadequate cavity. The CPT and Harris Precoat systems led to an absence of 21 and 18%, respectively. In a later study, design improvements in a commercially available system utilized with Exeter stems allowed an improvement of 23.4% of Gruen zones absent of cement.[10]

Vigorous pressurization of the cement can lead to its contact with the endosteal bone, which improves overall stability of the construct, but also potentially impacts revascularization and remodeling.[11] Adequate size of the graft particles to achieve interfragmentary stability[12] and quality of graft impaction are also important to prevent subsidence and poor outcome.[4,6] Ultimately, a combination of construct stability and graft incorporation and remodeling must be obtained. When an extended trochanteric osteotomy (ETO) is performed, the ETO is closed first prior to impaction. With older designs, a cortical only strut allograft was used to reinforce the

osteotomy. However, with the advent of long stems for impaction allografting this is no longer necessary.[7]

Tight allograft packing is critical, which may lead to intraoperative fractures. Adequate exposure, prophylactic cerclage wire or cable fixation, and avoidance of bending stresses and torque within the femur at the time of impaction are important.[7] In addition, bone defects can be reinforced with specialized wire mesh or with cortical only allograft struts (Figure 33.1). A variety of instrument systems have been introduced to help standardize the impaction technique and assess stability.[13] Longer stems with or without additional fixation may be required for added stability and should bypass weakened regions by two cortical diameters.[7]

Figure 33.1 Intraoperative photographing showing a revision THA with impaction allografting along with a cortical strut graft and mesh for a proximal femoral defect.

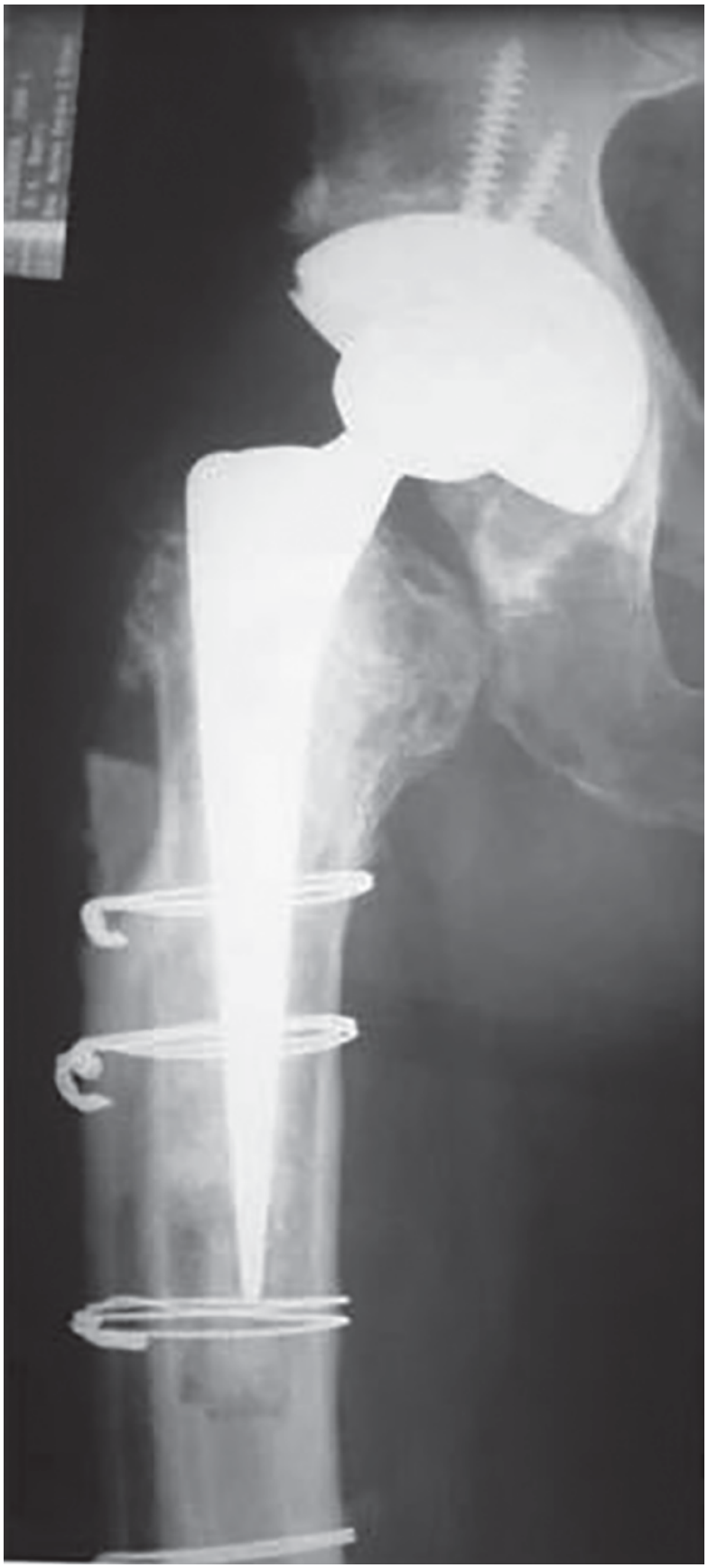

Figure 33.2 Postoperative AP radiograph of the proximal femur showing the revision of a failed THA with impaction allografting and a cortical strut graft for a proximal femoral defect.

Proximal femoral allografting

The surgical technique for proximal segmental femoral allografts is demanding and is typically reserved for selected cases of Paprosky type IIIB and IV defects. Possible surgical approaches that may be used include either a trochanteric slide,[14] which may reduce trochanteric migration, or a trochanteric splitting osteotomy.[15] The length of the allograft required depends on the degree of bone loss, stability, and leg length assessment which is determined from preoperative templating and intraoperative assessment. Soft tissue should be preserved as much as possible and every effort should be made to preserve the greater trochanter.

Allograft bone is biologically inactive and cannot grow into cementless implants; therefore, the prosthesis should be cemented into the allograft.[5,16] The distal aspect of the stem can be cemented or uncemented; however, care should be taken to ensure that no cement remains at the host bone/allograft junction. Additionally, autogenous reamings from the acetabulum, or from the resected proximal femoral bone, can be utilized along the allograft–host junction to facilitate union. The canal of the allograft should not be over-reamed so as to preserve its strength. If the host canal is larger, as is often the case, a telescoping method can be used,[17] during which the smaller allograft segment is *telescoped* into the large and vacuous distal host femur. The addition of a step cut or oblique cut with cable reinforcement, plate fixation, strut allografts, and distal press fit stems aim to improve the stability of the

construct to promote union.[16] However, if plate fixation is chosen, the portion lying on the allograft should not be fixed with screws, but instead by cables, so as to avoid fatigue fractures. Proximal femur remnants, with their intact soft tissue attachments can then be wrapped around the construct to provide improved soft tissue attachments (Figure 33.3), and to provide a vascularized graft around the allograft–host junction.

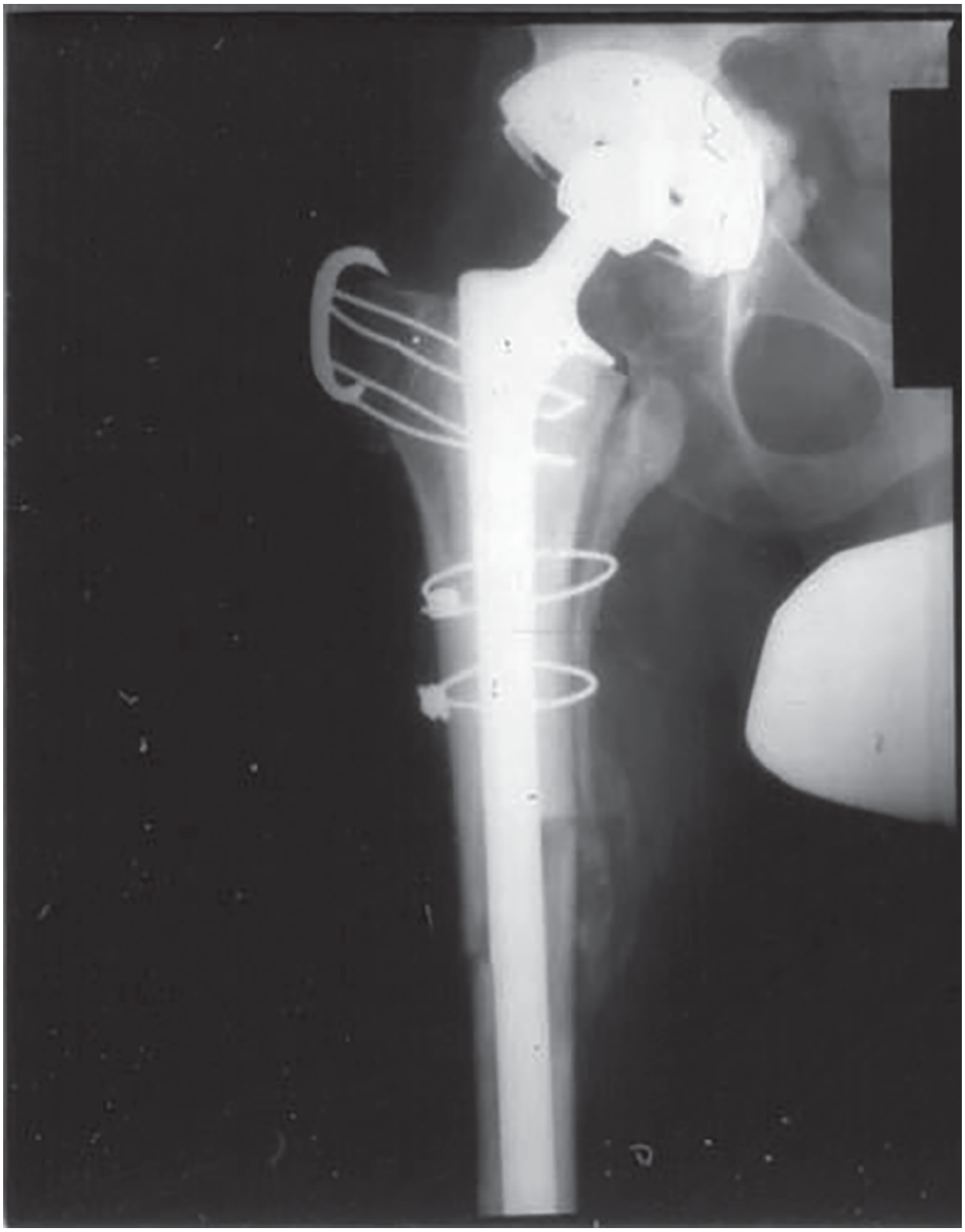

Figure 33.3 Postoperative AP radiograph of the proximal femur showing a long-stemmed implant cemented into a proximal femoral allograft. Note the step-cut junction to enhance junction stability.

Resolution of clinical scenario

- Impaction and proximal femoral bulk allografting are technically demanding techniques that should only be performed by experienced surgeons in experienced centers.
- Preoperative planning for both techniques is important.
- Proper allograft impaction and cement technique are critical for success in impaction allografting.
- All cement should be removed at the host–implant interface in proximal femoral allografting.
- Preservation of the soft tissues and stability of the construct for both techniques are important for long-term success.

Question 2: In patients who are undergoing revision THA, how does impaction allografting for femoral revision, compared to no impaction allografting, perform in terms of outcomes?

Rationale

Impaction allografting is a viable option in revision THA. Knowledge of the clinical outcomes of this technique is

important in deciding whether it is a suitable option for femoral revision.

Clinical comment

Impaction allografting is a technically demanding procedure that can be associated with several complications that may influence outcomes. As such, an evidence-based review of outcomes is important for patient-centered care.

Available literature and quality of the evidence

There are several level II[18–20] studies, while the majority is classified as level III/IV.[4,21–37]

Findings

The results of impaction allografting for femoral revision are generally encouraging. Gie et al. revised 58 hips with minimal bone loss and found that the average clinical scores for pain function, and mobility had improved at the final follow-up.[21] Patients reporting minimal to no pain in some studies is reported as >80%.[4,22,23] Other studies have used the Harris Hip Score and have reported an average value of 78 to 90 depending on the study.[4,23–26] Overall survivorship is reported between 77.4 and 100% up to 19 years,[1,18,19,25–30,37] while survivorship for aseptic loosening is reported as 98–99% up to 19 years.[1,28,30,37]

Subsidence and fracture are the two most commonly reported complications. Most studies show <5 mm subsidence in the majority of revisions; however, subsidence of >5 mm has been reported in as high as 38% in some studies.[4,23,31–34] It has been shown that greater preoperative bone loss corresponds with higher subsidence,[33,34] as does poor cementation and impaction.

Masterson compared noncemented versus cemented stems and found migration to be 4.4 and 1.85 mm, respectively, after the first year.[35] The current evidence, however, has failed to show the clinical significant of implant finish and subsidence.[1] Collared stem use has been described;[19],[25] however, it is suggested that highly polished, collarless double-tapered stems are the most appropriate implants to use given their propensity for controlled subsidence and physiological loading of the allograft envelope and surrounding host bone.[38] Reconstitution of the medial calcar with bone graft, mesh, or augmentation with cortical allograft appears to be important in reducing subsidence.[27],[30]

The prevalence of periprosthetic fractures ranges from 5 to 24% depending on the study source.[220_22],[25],[27],[29],[30],[36],[37] Intraoperative fractures tend to occur during impaction of the allograft which can be partially avoided by adequate exposure, prophylactic cerclage fixation and augmentation of the femoral shaft with cortical strut grafts.[22],[36] Removal of cement is also a risk for cortical perforation and is reported to occur in 10% of cases.[20] Furthermore, Ornstein et al. in their registry study reported that 6% of their patients sustained a postoperative diaphyseal fracture,[20] which is thought to be due to unrecognized intraoperative fractures or weakened areas of osteolysis. Infection rate was recorded as 2.7% in a prospective registry study,[20] while a large retrospective cohort study documented 3.9%.[37] Ornstein et al. in the largest retrospective cohort study documented a combined infection and periprosthetic fracture rate of 47% but did not report infection separately.[1]

Resolution of clinical scenario

- Outcomes for femoral impaction grafting are varying but satisfactory when the proper technique is utilized.
- Subsidence and periprosthetic fracture are common complications which negatively affect outcomes.
- Implant stability is important and adjuncts may be required.

Question 3: In patients who are undergoing revision THA, how does proximal femoral segmental allografting, compared to other treatments, perform in terms of clinical outcomes?

Rationale

Proximal femoral bulk allografting is also an option in revision THA with extensive meta-diaphyseal bone loss. Understanding the clinical outcomes is important to understanding its role in revision arthroplasty.

Clinical comment

Proximal femoral allografting is a viable option in cases of extensive bone loss, with an incompetent and nonsupporting diaphysis. It is technically demanding and associated with several complications of which surgeon should be aware. Decision-making for this technique using evidence-based outcomes is important for patient-centered care.

Available literature and quality of the evidence

The available literature consists of level III/IV[16,39–46] studies as well as a meta-analysis.[47]

Findings

Generally, the reports of success with proximal femoral replacement is considered satisfactory. Haddad et al. reported a Harris Hip Score of 79 and report a high level of satisfaction.[39,40] Rogers et al. in their meta-analysis of 16 studies and 498 patients quoted an overall success rate of 66–95% (average 80%) with no significant heterogeneity for the fixed and random effects model. Ilyas et al. reported on the use of freeze-dried allografts and reported the five-year survival at 87%.[41] Roos et al. reported 90% success in 20 patients in 4–20 years' follow-up.[42] Furthermore, Blackley et al. reported survivorship as 90% at five years and 86% at 10 years.[43] Survivorship is significantly affected by the degree of preoperative bone loss and length of graft used.[48]

The technique is not without its complications which commonly include infection, nonunion, dislocation, and fracture. As per Rogers et al., the pooled infection rate with the fixed and random effects model was 8% (95% confidence interval [CI]: 0.06–0.11).[47] Infection is thought to be a result of the length of procedure, soft tissue dissection, and contamination of the graft.[44,49,50] Failures due to fracture or aseptic loosening were pooled at 15%. However, there was some associated heterogeneity. They were not able to perform a meta-analysis of the nonunion rate due to a significant heterogeneity of data but provided a range of 1–25%.[47] Cementation into the distal portion has been suggested as a cause for nonunion.[51] Four of the studies included in the meta-analysis contained two of the highest nonunion values (18 and 25%) while one was not reported. Dislocation was reported as 12.8% (range 0–54%)

and again had significant data heterogeneity. Trochanteric nonunion or migration is reported as 7–77% with a mean of 25.25%. The lack of a strict definition of nonunion precluded a detailed analysis. Furthermore, the clinical implication of trochanteric nonunion is largely unknown.[45]

Graft resorption has also been a documented concern with incidences ranging from 3 to 58% in the reported literature.[43,46,49,51–54] The significance of this, however, is unclear. Several large-scale studies reported significant allograft resorption of 20 to 33%; however, none required revision.[39,40,43]

Resolution of clinical scenario

- Complications are common and generally include infection, nonunion, dislocation, and fracture.
- Length of graft and preoperative bone loss are predictive of outcome.
- The stem should be cemented into the allograft and construct stability at the allograft–host junction must be achieved to promote union.

Summary of answers

- Impaction grafting and allograft composite grafting are technically demanding procedures that should only be done by experienced surgeons. Proper preoperative planning is required.
- Due to the success of modular and nonmodular titanium diaphyseal fit stems, they are performed less frequently but still have a role in revisions with extensive bone loss that will not support a diaphyseal stem.

- Impaction grafting and proximal allograft grafting have encouraging results when done properly; however, they are subject to a wide variety of complications that can significantly affect outcome. Patient selection is important to optimize outcome.
- These techniques are now rarely used, and they are of historical interest. Nevertheless, on rare occasions, they may be useful and should remain as options for the rare case that cannot be addressed using modern fluted tapered stems.

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34 Revision of the Acetabular Component

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Clinical scenario

- A 41-year-old male presented with a two-year history of progressive left groin pain on weight bearing.
- He had a total hip arthroplasty (THA) performed 15 years ago for osteoarthritis of his left hip secondary to a displaced fracture of the acetabular dome.
- Clinical examination of the left hip showed restricted motion and antalgia, but good abductor muscle function.

An anteroposterior view of both hips of our patient (Figure 34.1) and a lateral view of the left hip (Figure 34.2) are shown after a first-stage revision THA performed elsewhere for infection. A second-stage procedure was planned after a period of appropriate antibiotic therapy and normalization of inflammatory markers.

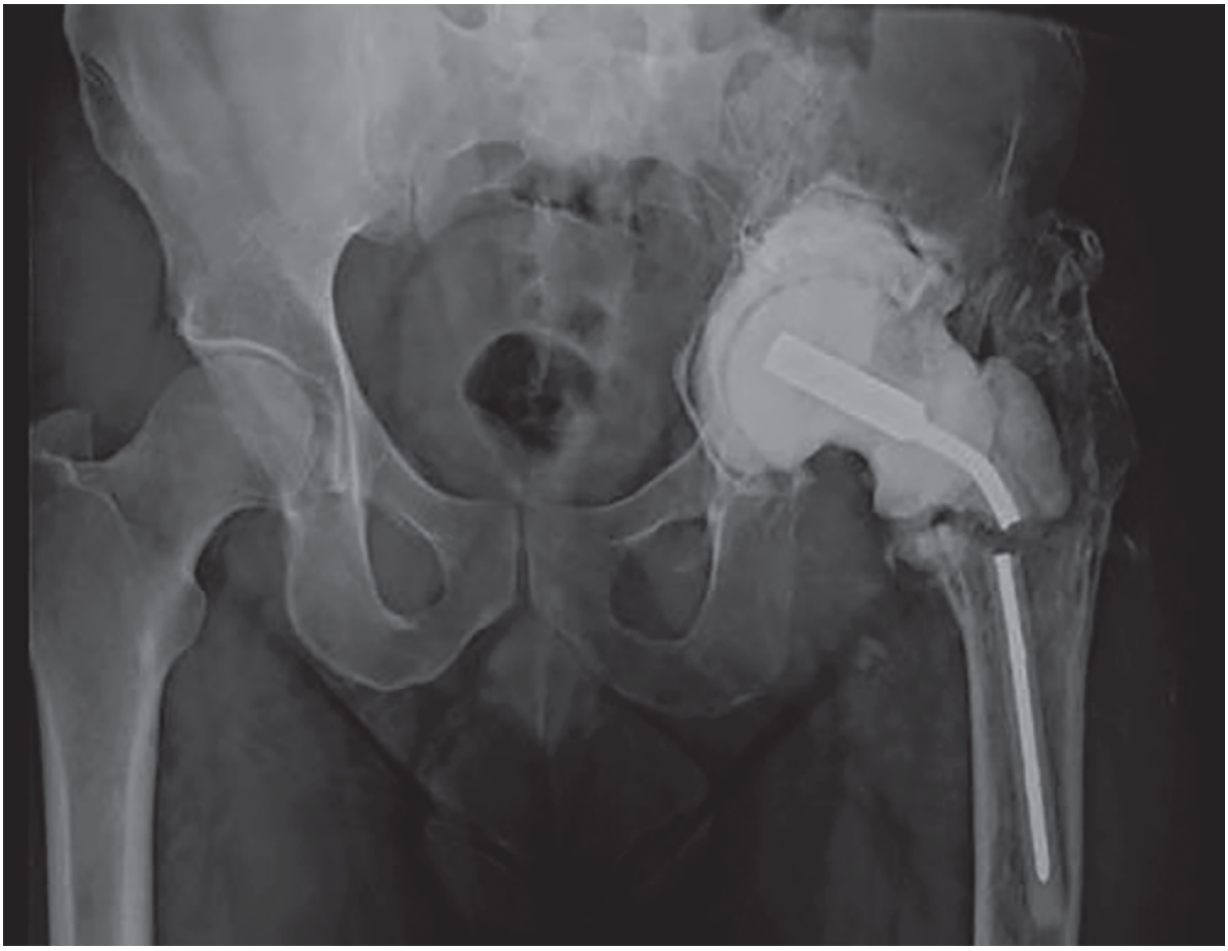

Figure 34.1 Anteroposterior radiograph of both hips of the clinical case showing a fractured cement spacer in situ after a first stage revision left total hip arthroplasty.

Top three questions

1. In patients with acetabular bone loss, which classification system, compared to others, is most useful?
2. In patients undergoing revision THA, which acetabular bone loss management techniques, compared to others, perform best in terms of outcomes?
3. In patients undergoing revision THA, does the use of porous tantalum, compared to other alternatives, result

in better outcomes?

Question 1: In patients with acetabular bone loss, which classification system, compared to others, is most useful?

Rationale

The goal of revising a loose acetabular component of a THA is to provide a stable construct that alleviates pain and restores lost function. Loosening of a primary acetabular component can be associated with significant periacetabular bone loss. Prior to revision, hip surgery it is of utmost importance to quantify the acetabular bone stock. Any deficiency needs to be addressed. Bone graft, reconstructive hardware, or a combination of both may be required. As such, a classification system for acetabular bone loss would facilitate preoperative planning.

Clinical comment

There is not a single accepted, standardized way to classify acetabular bone loss. The three classification systems most commonly used are: D'Antonio,[1] recommended by the American Academy of Orthopaedic Surgeons (AAOS), Paprosky et al.,[2] and Gross et al.[3]

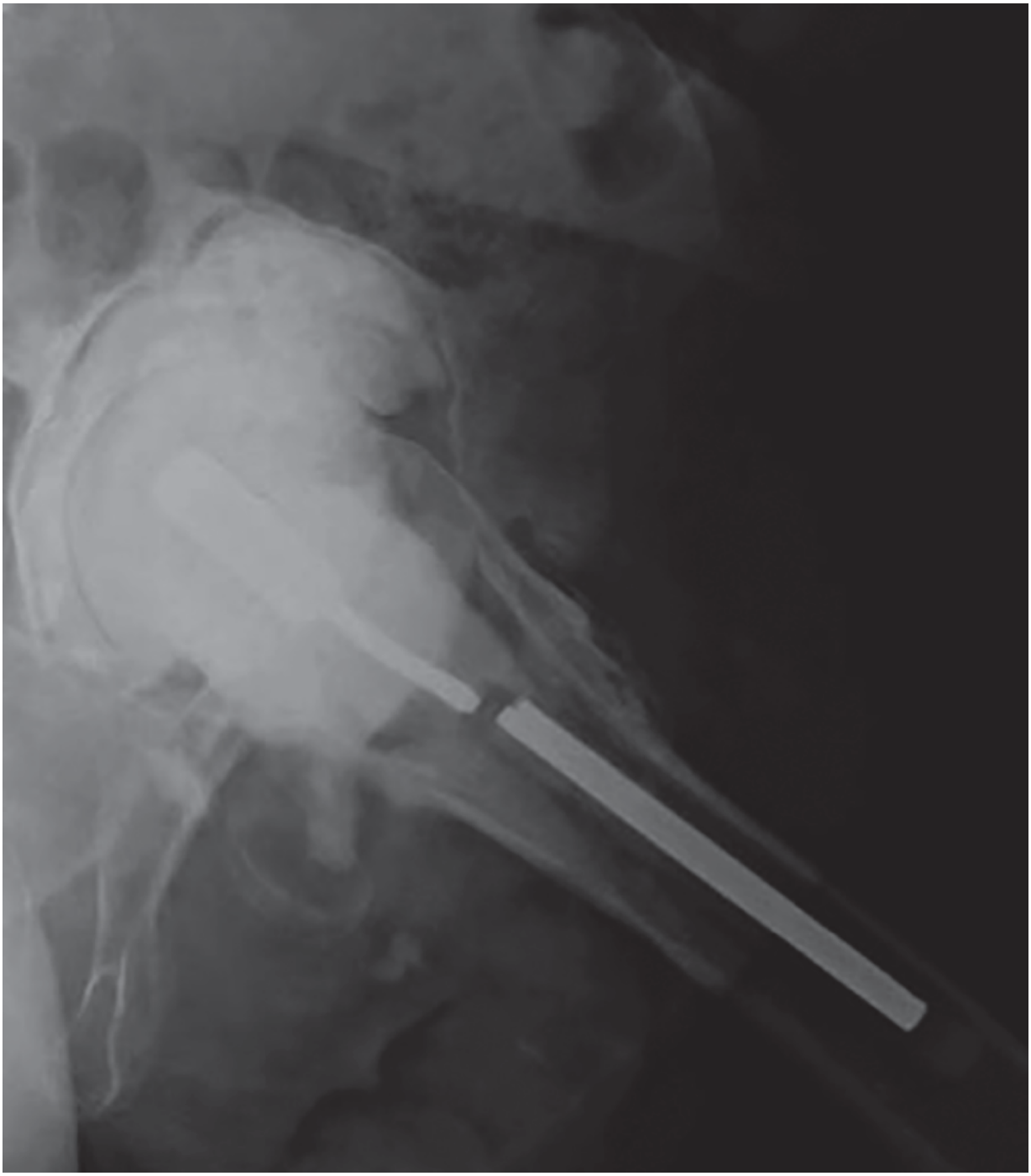

Figure 34.2 Lateral radiograph of the left hip of the clinical case showing a fractured cement spacer in situ after a first stage revision left total hip arthroplasty.

Available literature and quality of the evidence

The overall quality in the literature is low. We identified one level II and three level V studies.

Findings

The AAOS classification (Table 34.1) of D'Antonio is a descriptive classification.[1]

Table 34.1 AAOS classification.

Type	Description of Deficiency
IA	Segmental (Peripheral)
IB	Segmental (Central)
II	Cavitary
III	Combined
IV	Pelvic Discontinuity
V	Arthrodesis

The Paprosky classification[2] uses anatomical landmarks to classify the extent of bony deficiency (Table 34.2) and guides reconstruction based on available techniques. Defects can be graded as completely (type 1), partially (type 2), or non- (type 3) supportive.

Table 34.2 Paprosky classification.

Type of Defect	Superior Migration of Hip Center*	Medial Migration of Hip Center**	Osteolysis of Teardrop***	Osteolysis of Ischium****
I	Minimum	None	None	None
2A	Minimum	Grade I	Mild	Mild
2B	Minimum to Marked	Grade II	Mild	Mild
2C	Minimum	Grade III	Moderate or Severe	Mild
3A	Marked	Grade II+ or III	Moderate	Moderate
3B	Marked	Grade III+	Severe	Severe

* Minimum is ≤3 cm proximal to the superior transverse obturator line, and marked is >3 cm proximal to the superior transverse obturator line.

** Grade I = lateral to Kohler's ilioischial line, grade II = to Kohler's line, grade II+ = medial expansion of Kohler's line into the pelvis, grade III = violation of Kohler's line with some migration into the pelvis, and grade III+ = marked migration into the pelvis.

*** Mild = minimum loss of the lateral border, moderate = complete loss of the lateral border, severe = loss of the lateral and medial borders.

**** Mild = 0–7 mm distal to the superior transverse obturator line, moderate = 8–14 mm distal to the obturator line and severe ≥15 mm distal to the obturator line.

Gross et al. devised a classification based on the type of bone graft required for revision (Table 34.3).[3] Campbell et al. critically evaluated the reliability of these three classification systems showing inconsistency in both interobserver and intraobserver reliability among all three.[4]

Table 34.3 Gross classification.

Type	Description of Deficiency
I	Contained defect with intact rim and columns
IIA	Noncontained defect – minor column (>50% of host acetabulum in contact with cup
IIB	Noncontained defect – major column (<50% of host acetabulum in contact with cup

Resolution of clinical scenario

These classifications show limited reliability and should be considered a general guide to discern between simple and complex reconstructive scenarios. There is no clear best option.

Question 2: In patients undergoing revision THA, which acetabular bone loss management techniques, compared to others, perform best in terms of outcomes?

Rationale

There is no consensus regarding the optimal method of reconstruction in cases of revision hip arthroplasty with severe bone loss. The major decisions regarding surgical technique for complex acetabular revision concerns the use of bone graft, cages, and cemented versus cementless components. The plethora of potential combinations of grafts and metallic devices has led to a huge diversity of reconstructive options in revision acetabular arthroplasty. This creates significant difficulty for systematic analysis of clinical literature incorporating a very heterogeneous mix of surgical techniques.

Clinical comment

Acetabular bone loss can be compensated by placing a high hip center or by using asymmetrical or bilobed acetabular components. Cementless hemispherical cups provide durable survivorship in the revision setting if initial stability and contact with sufficient host bone is possible. Cemented fixation of a polyethylene cup or liner into a supporting cage has often been the construct of choice where allograft is required to support more than 50% of the new acetabular component. Supplementary acetabular fixation may be necessary to stabilize pelvic discontinuity and protect or support bone graft and/or cups. Trabecular metal shells can be used for severe acetabular defects where bone grafting has traditionally performed poorly.

Available literature and quality of the evidence

The overall quality in the literature is low. Most of the evidence was level III–V with level IV being the most frequent.

Findings

Basically, smaller defects (contained or cavitary) can be treated with impacted morselized cancellous allograft bone chips. Satisfactory outcomes have been reported using cementless porous hemispherical acetabular components for these defects.[5–7]

Noncontained, segmental defects are subdivided into those where host bone support for the implant is >50% (Paprosky 3A, Gross 2A) or <50% (Paprosky 3B, Gross 2B). Radiologically, these defects produce significant superolateral and superomedial cup migration respectively. Sporer et al. achieved 78% 10-year survival with cementless acetabular components supported by distal femoral structural bulk allograft buttress for 3A defects.[8] Paprosky

et al. published a series in 2016 with a 21 year follow-up concluding that the use of distal femoral allograft can be considered in young patients with type IIIA acetabular defects that could benefit from restoration of bone stock.[9] Others have shown either good medium term survival with bulk grafts[10–12] or frequent loosening with graft resorption.[13,14]

Options for 3B defects include placing the component high on the remaining host bone, implanting a large cementless acetabular component, using structural bone graft, or replacing lost bone with massive partial or total acetabular allograft, protected with an antiprotrusio cage, containing a cemented liner. Reconstructing the acetabulum with a high hip center has been associated with early loosening,[15] although 94% survival at 10.4 years has been reported.[16] Treatment of type 3B defects with cemented polyethylene cups and large allografts alone has produced poor results.[17,18] The use of reconstruction cages improves their survival despite implantation difficulties and low potential for biological bone ingrowth.[19]

Use of porous tantalum acetabular shells, cups, and augments can address these difficulties.[20–35] Brubaker et al.[35] proposed specific interventions for different grades of acetabular defect based on a modification of the classification of Gross et al.,[3] validated by Saleh et al.[36] They calculated a prognosis for each intervention based on the available literature (Table 34.4). Kosashvili et al. reported good short-term outcomes with the “component-cage technique”, combining ilioischial cages with trabecular metal shells for pelvic discontinuity.[30] Sculco et al. reported the evolution of the cup-cage technique for major acetabular defects.[37] Hourscht et al. discussed the reconstruction of AAOS type III and IV defects with the Ganz reinforcement ring.[38] Abolghasemian et al. reported the reconstruction of

massive uncontained acetabular defects using allograft with cage or ring reinforcement.[39] Garcia-Rey et al. published THA revision series using impaction allografting with mesh.[40] Finally, Maruyama et al. published a new reconstruction method using a medial-reduced cemented socket and additional bulk bone in conjunction with impaction morselized bone grafting fixed by cement.[41] Conventional porous-coated acetabular implants have proven effective in revision THA where bone stock is sufficient for stability and ingrowth, and success with these implants occurs when contact with host bone is greater than 50%.[5–7] Antiprotrusio cages are recommended for host support of less than 50%, but implantation is problematic and biological bone ingrowth is not possible.[19,42]

Table 34.4 Modified gross classification.

Defect Type	Bone Loss	Treatment	Survival (Min 5 years)
I	None	Primary component	As for primary THA
II	Contained	Morselized allograft ± roof ring	84–95%
III	Segmental <50%	Minor column structural allograft + cage, or bilobed cup, or tantalum component	76–94%
IV	Segmental >50%	Major column or acetabular structural allograft with cage, or custom implant	77–100%
V	Discontinuity	As for type IV + fixation of discontinuity	As for type IV

Porous tantalum acetabular cups may provide a solution.[20–34] The porosity of materials commonly used to manufacture acetabular shells approximates 30–50% of their volume. Porous tantalum exhibits almost double this porosity (80%) for bone-metal interdigitation.[43] Porous tantalum implants display high surface frictional characteristics and good osseointegration properties.[43–45] Trabecular metal revision shells are made completely of porous tantalum and have perforations for screw fixation. These shells can be positioned for maximal bone contact using a polyethylene liner locked within or cemented at the required orientation.[22,33,46] When less than 50% host bone is available to support the shell, tantalum augments are used to help fill the defect. A thin layer of cement between the shell and each augment minimizes metal fretting.[46] For pelvic discontinuity, tantalum cup and reconstruction cage constructs can be used. The cage is positioned over the cup, bridging the acetabular defect, and a polyethylene liner is cemented into the cage.[20,46,47]

An alternative approach to pelvic discontinuity was first published by Paprosky et al. in 2014 describing the technique of pelvic distraction using porous tantalum.[48]

Resolution of clinical scenario

There are no trials in the clinical literature to differentiate between treatment modalities for each grade of acetabular bone loss in revision hip arthroplasty. Evidence for different surgical techniques is limited to comparison of case series and expert reviews. The up-to-date studies treating acetabular bone loss are presented in table format with their respective survivorships (Table 34.5).

Table 34.5 Sample summary of studies dealing with acetabular bone loss (in bold the ones using porous tantalum).

Year	Author	Number of cases	Mean follow-up (years)	Survival (%)
2004	**Nehme[49]**	**16**	**2.7**	**87.5**
2005	**Unger[22]**	**59**	**3.5**	**88**
2006	**Sporer[8]**	**13**	**2.6**	**100**
2006	**Boscainos[41]**	**14**	**2.5**	**100**
2007	**Weeden[7]**	**43**	**2.8**	**100**
2008	**Flecher[27]**	**23**	**2.9**	**100**
2008	**Kim[21]**	**46**	**3.3**	**98**
2009	**Fernandez-Fairen[33]**	**263**	**6.1**	**100**
2009	**Kosashvilli[29]**	**26**	**3.7**	**88.5**
2009	**Lakstein[32]**	**53**	**3.8**	**96**
2009	**Malkani[26]**	**22**	**3.3**	**100**
2009	**Siegmeth[28]**	**34**	**2.8**	**94**
2009	**Van Kleunen[31]**	**97**	**3.8**	**100**
2010	**Lachiewicz[50]**	**39**	**3.3**	**97 (component fixation)**
2011	**Davies JH[51]**	**46**	**4.1**	**Not reported**
2011	**Pierannunzii L[52]**	**21**	**1.8**	**100**

Year	Author	Number of cases	Mean follow-up (years)	Survival (%)
2012	**Del Gaizo DJ**[53]	**37**	**2.2**	**95**
2014	Moličnik **A**[54]	**25**	**1.8**	**100**
2014	**Batuyong ED**[55]	**24**	**3**	**92 (osseointegration)**
2014	Abolghasemian M[56]	50	5 and 10	75 at 5 yr and 56 at 10
2015	Garcia-Rey E[40]	226	10	83
2015	**Meneghini RM**[57]	**8**	**16.5**	**100**
2016	**Konan S**[58]	**46**	**11**	**96**
2017	Sculco PK[37]	57	4.6	89
2017	Hourscht C[38]	46	6.2	86 for type III and 57 for type IV
2017	Maruyama M[41]	102	10	99
2017	**Flecher X**[59]	**51**	**6.8**	**92.3**
2017	**Jenkins DR**[60]	**85**	**5**	**97**

Question 3: In patients undergoing revision THA, does the use of porous tantalum, compared to other alternatives, result in better outcomes?

Rationale

The advent[61] and validation[62] of porous tantalum trabecular metal shells signaled a new era in the management of severe acetabular defects. Tantalum is more porous, less stiff, and creates more friction with bone than conventional porous-coated acetabular implants with better potential for biologic osteointegration. Since the trabecular metal has such biologically attractive properties, the expectation has been better survivorship of the implants and improved patient clinical outcomes such as Harris Hips Scores and overall survivorship. Yet, when compared with other cementless designs, porous tantalum does not reduce the risk of re-revision after revision THA in a study involving two national registries.[63]

Clinical comment

Despite its promising short- to medium term results and its sound biologic milieu, porous tantalum does not provide all the answers to the problem of acetabular bone loss when present in the face of revision THA. Custom triflange cups represent such a new direction with early success that complements the promising work of porous tantalum.[64]

Available literature and quality of the evidence

The overall quality in the literature is low. The evidence was level III for both the porous tantalum and the triflange cup studies.

Findings

A total of 2442 first-time THA revisions with porous tantalum cups and 4401 first-time revisions with other uncemented cups were included in this collaborative study between the Australian and Swedish national joint registries. The mean age of the patients was 69 years (range 19–97 years), 3754 (55%) of the patients were women, and the mean follow-up for the porous tantalum and uncemented

control groups was 3.0 years (standard deviation [SD]: ±2.1 years) and 3.4 years (SD: ±2.3 years), respectively. Concomitant stem revision was more common in the porous tantalum group (43% vs 36%). Kaplan–Meier survivorship with re-revision for any reason up to seven years was comparable between the porous tantalum cup group and the uncemented cup control group (86%; 95% confidence interval [CI]: 85–89%, and 87%; 95% CI: 85–89%, respectively; p = 0.85) and the overall survivorship up to seven years with a second revision for periprosthetic joint infection (PJI) as the endpoint (97%; 95% CI: 95–98%; and 97%; 95% CI: 96–98%, respectively; p = 0.64). Excluding procedures where augments had been used or studying primary osteoarthritis and first revision owing to aseptic loosening subgroups did not change this result. Implant survival for a porous tantalum cup in first-time THA revision was similar to the survival of the uncemented cup control group. With the numbers available, no benefit in survival with re-revision for infection as the endpoint could be ascribed to the porous tantalum cup group, as has been suggested by earlier work.[63]

The custom triflange is a patient-specific implant for the treatment of severe bone loss in revision THA. Through a process of three-dimensional modeling and prototyping, a hydroxyapatite-coated component is created for acetabular reconstruction. In their paper, the authors present a table/review of the case series with of custom triflanges. The most common complications include dislocation and infection, although the rates of implant removal are low. Clinical results are promising given the challenging problem.[64]

Resolution of clinical scenario

Porous tantalum trabecular metal shells have good survival statistics for reconstruction of severe acetabular defects in

case series with short- to medium term review. Yet, these promising results have not yet translated into long-term benefits as per the findings of the Swedish and Australian registries. The custom triflange cup is an alternative solution gaining popularity due to its affordability, relatively uncomplicated surgical technique and patient specific design.[64]

Summary of answers

- There is no single, standardized, readily reproducible classification system with prognostic ability regarding the treatment of acetabular defects in revision hip surgery.
- The main management options for the surgeon include bone graft, acetabular cups, rings or cages, and combinations of the above. The techniques have unique pros and cons, but the goals are to obtain stable and durable acetabular component fixation and a healed pelvis while minimizing complications leading to the highest possible functional patient outcome.
- Structural bulk allografts may be used to provide a mechanical environment that supports host bone ingrowth into an acetabular component. Alternatively, they may allow restoration of joint mechanics in situations where host bone loss precluded biologic fixation.
- Porous tantalum has provided a much-needed solution for large defects with good short- to medium term results. Indeed, the use of tantalum appears to answer many of the questions faced in these difficult cases.
- The custom triflange cup seems to complement the porous tantalum success well for larger defects

(Paprosky IIB) and offers a comparable alternative in terms of results and pricing.

- Revision hip surgery and in particular acetabular surgery addressing bone loss is complex. Its principles reflect a variety of choices with no direct comparisons of the surgical approaches and hardware options. Each patient's treatment is individualized based on their underlying disease process and previous surgical history. So, direct comparison with other techniques of revision THA can be misleading unless the studies are stratified for variables such as: type of study, sample size, the acetabular defect type, mean follow-up, indication for revision, patient outcomes, and study endpoints, patient's American Society of Anesthesiologists (ASA) class, and of course the surgeon's training and experience.

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35 Antibiotic Cement in Total Knee Arthroplasty

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Clinical scenario

- A 65-year-old male with tricompartmental arthritis undergoes a primary total knee arthroplasty (TKA).
- His past medical history is remarkable for rheumatoid arthritis, type 2 diabetes mellitus, chronic diabetic nephropathy, and peripheral vascular disease.

Top three questions

1. For patients undergoing primary TKA, does the routine use of antibiotic-loaded bone cement (ALBC) reduce the rate of periprosthetic joint infection (PJI) compared to cement without antibiotics?
2. In patients undergoing TKA, does the routine use of ALBC lead to higher aseptic mechanical failure rates compared to cement without antibiotics?
3. In patients undergoing TKA, is the routine use of antibiotic-impregnated cement cost-effective compared to antibiotics without cement?

Question 1: For patients undergoing primary TKA, does the routine use of antibiotic-loaded bone cement (ALBC) reduce the rate of periprosthetic joint infection (PJI) compared to cement without antibiotics?

Rationale

By 2030, it is predicted that 3.48 million primary TKAs will be performed each year in the United States.[1] As the number of procedures performed continues to rise, the burden of PJI following TKA will rise concomitantly.

Clinical comment

PJIs are associated with patient morbidity and mortality, poor patient-reported outcomes, and tremendous costs to the healthcare system.[2–4] Any intervention that mitigates the risk of PJI following TKA would be worthwhile.

Available literature and quality of the evidence

The best available evidence includes three randomized, controlled trials.[5–7] One of these trials is a level I (therapeutic) trial. The other two trials are graded as level II (therapeutic) despite their randomized study design because of lack of blinding and poor randomization technique. Impactful data are also available from large registry-derived studies, graded as level IV (therapeutic) based on their retrospective design.[8,9] Finally, there is a meta-analysis of randomized controlled trials (RCTs; level I) that also seeks to answer this question.

Findings

There are three randomized trials examining the clinical effectiveness of ALBC on PJI following TKA. Chiu et al. randomized 78 patients undergoing TKA to receive cement with or without 2 g of cefuroxime added to each 40 g batch of cement.[5] The primary diagnosis was osteoarthritis in all cases, and every patient had been diagnosed with diabetes mellitus. At mean follow-up of 50 months, there was a significant reduction in deep PJI for patients with ALBC (relative risk [RR] = 0.865; 95% confidence interval [CI]: 0.77–0.97; p = 0.021). However, this study had methodological and practical limitations, including lack of blinding, small sample size, and hybrid fixation technique (cementless femur and cemented tibia). Chiu et al. later published a series of 340 primary TKAs randomized to receive ALBC (178 knees) and cement without antibiotics (162 knees).[6] The PJI rate was significantly lower in the group with ALBC (0% vs 3.1%, p = 0.024). Similarly, this study was limited by the lack of blinding, as well as generalizability, as the procedures were performed in an environment that was not optimized for sterility. In the largest trial to date on the topic, Hinarejos et al. randomized 3000 TKA patients to ALBC (n = 1483) versus plain cement (n = 1465).[7] They found no significant difference in the deep infection rate between the two groups (1.4% in both, p = 0.96). In their meta-analysis of RCTs, which included all of the above trials, Zhou et al. found no significant difference in deep or superficial infection rate.[10]

A large series from the Finnish Arthroplasty Register retrospectively examined 40 135 primary TKAs using a Cox regression analysis to determine risk factors for PJI.[8] The risk of PJI was higher for cases without ALBC (hazard ratio [HR] = 1.35; 95% CI: 1.01–1.18), as well as for cases with intravenous (IV) antibiotics alone compared to IV antibiotics with ALBC (HR = 1.42; 95% CI: 1.08–1.88).

Patients with secondary osteoarthritis (HR = 1.86; 95% CI: 1.12–3.11) and rheumatoid arthritis (HR = 1.86; 95% CI: 1.31–2.63) were identified as having a higher risk of PJI after primary TKA. A more recent registry review performed in Spain examined the effect of ALBC on infection rates in 1250 TKAs (555 with and 695 without ALBC).[9] They found a significant reduction in PJI rates (RR = 0.37; 95% CI: 0.16–0.87; p = 0.019) after the introduction of ALBC. Interestingly, two other registry studies, one from New Zealand (n = 64 566 joints) and another from the United States (n = 56 216 knees) both found increased infection rate in those undergoing surgery with ALBC.

Registry data should be interpreted cautiously, as the diagnosis of PJI cannot be confirmed, and the data output is limited by the initial accuracy of diagnostic coding at the time of treatment. In addition, registry data are naturally prone to selection bias.

Resolution of clinical scenario

- There is conflicting evidence as to whether ALBC reduces the rate of PJI following primary TKA.
- The risk of PJI after TKA is higher in certain patient populations, such as diabetes mellitus and inflammatory arthropathy, and ALBC should be used to reduce the risk of infection following TKA in these patients.
- A large level I, RCT would add to the literature, as current recommendations are based on studies with methodological shortcomings.

Question 2: In patients undergoing TKA, does the routine use of ALBC lead to higher aseptic mechanical failure rates compared to cement without antibiotics?

Rationale

One of the most commonly reported modes of failure requiring revision after TKA is aseptic loosening.[11],[12] Identifying a modifiable, surgeon-controlled risk factor that could reduce the rate of aseptic mechanical failure would improve long-term patient outcomes and reduce the burden of revision surgery.

Clinical comment

Basic science research suggests that the addition of antibiotics to polymethylmethacrylate may compromise the structural integrity of the cement in a dose-dependent fashion.[13] There is clinical concern that the addition of antibiotics to bone cement may lead to earlier mechanical loosening of TKA implants.

Available literature and quality of the evidence

The available literature on aseptic loosening rates and the use of ALBC is based on limited data where implant loosening is a secondary reported outcome after infection rates. There are two RCTs (level II, therapeutic) reporting aseptic loosening rates using ALBC following TKA. In addition, a large database study assessed the issue in total hip arthroplasty (THA).

Findings

The aforementioned study by Chiu et al. examined 340 primary TKAs randomized to either cement with or without antibiotics with a mean follow-up of 49 months.[6] There was one (0.6%) reported femoral component loosening at two years in the ALBC cohort and none in the plain cement cohort. Additionally, a randomized study using radiostereometric analysis (RSA) compared two different bone cements impregnated with gentamicin to determine differences in tibial component migration. At two-year follow-up, there were no differences identified, suggesting that early implant migration as a surrogate for loosening did not differ depending on the brand of ALBC selected.[14] Although there are no studies examining implant migration using RSA comparing plain cement and ALBC following TKA, Bohm et al. used similar RSA techniques to demonstrate that implant subsidence was no different using ALBC versus plain cement following cemented THA.[15] Finally, in a study of over 20 000 Norwegian THA patients, Engesaeter et al. found a significantly higher infection rate in the systemic-only antibiotic group compared to the combined systemic and bone cement group (odds ratio = 1.4; p = 0.001).[16]

Resolution of clinical scenario

- Based on limited data, it appears that using ALBC does not increase the risk of aseptic loosening following TKA.
- Further research is needed through either a prospective, comparative study or large-scale retrospective study to discern the long-term risk of ALBC on aseptic loosening rates following TKA.

Question 3: In patients undergoing TKA, is the routine use of antibiotic-impregnated cement cost-effective compared to antibiotics without cement?

Rationale

The addition of antibiotics to bone cement is costlier than cement prepared without antibiotics. The cost of antibiotics added to commercially available bone cement (typically 1 g of antibiotic per 40 g of cement) ranges from $210 to $500 per batch of cement.[17,18]

Clinical comment

The treatment of PJI following TKA ranges from $25 000 to over $100 000 depending on surgical technique, duration of parenteral antibiotic therapy, and complexity of reimplantation surgery.[3,19,20] If antibiotics added to cement could reduce the burden of PJI following TKA, it may be a cost-effective intervention in the long term.

Available literature and quality of the evidence

There are no cost-effectiveness studies modeling the economic impact of ALBC usage during TKA utilizing the landmark methodology outlined by Chang et al.[21] Two retrospective studies (level IV, economic and decision analysis) have examined the costs of ALBC in TKA; however, neither study performed a true cost-effectiveness analysis.

Findings

A retrospective study by Gutowski et al. modeled the cost-effectiveness of various preparations of antibiotic cement on PJI rates after TKA.[18] They determined that, depending on the preparation used (hand-mixed versus pre-mixed), a cost of $2112 to over $100 000 was necessary before one case of PJI was prevented. The hand-mixed preparations (1 g of either vancomycin or tobramycin added to each batch of cement) were less costly and as effective as the premixed varieties for PJI prophylaxis. Although hand-mixing antibiotics into the cement is off-label usage, the authors recommend that its usage should be considered in a cost-conscious environment.

A registry review by Sanz-Ruiz et al. also compared the cost savings of using ALBC routinely compared to plain cement in primary TKA.[9] It should be noted that the cost of ALBC was less expensive (€60) compared to the cost of commercially available cement in North America. The incidence of PJI dropped by 61% after the introduction of ALBC in this series, which amounted to $1295 cost savings per case based on the number of infections prevented with ALBC and the mean added cost to treat PJI in Spain (approximately $45 000).

Resolution of clinical scenario

- The routine use of ALBC should result in cost savings through a reduction in PJIs.
- Consideration should be given to hand-mixed antibiotic preparations, as these are far less costly than premixed variations, and seemingly as effective.
- A more robust cost-effectiveness analysis examining ALBC in TKA is required, as the current cost data are piggy-backed onto retrospective studies examining different outcomes.

Summary of answers

- ALBC reduces the rate of periprosthetic joint infection in RCTs and large registry database studies.
- The rate of aseptic loosening following TKA with the use ALBC does not differ compared to using plain bone cement.
- Although the use of ALBC may reduce costs by reducing the burden of periprosthetic joint infection, formal cost-effectiveness analysis studies are needed to affirm findings from limited existing literature.

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36 Unicompartmental Knee Arthroplasty and Patellofemoral Resurfacing Arthroplasty

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Clinical scenario 1

- An active 58-year-old female has lateral knee pain that is disabling.
- She had lateral meniscectomy as a teenager.
- Her flexion is to 130° and there is no contracture, and ligaments are otherwise stable.

Clinical scenario 2

- A 46-year-old woman with a medical history of multiple patella dislocations with previous lateral release.
- Progressive worsening of anterior knee pain, aggravated by climbing and descending stairs and rising from sitting position. Injections and physical therapy ineffective.
- Left knee range of motion is from 0–20° flexion. Lateral patella tracking and stable knee ligaments. Her radiographs show a severe lateral patellofemoral osteoarthritis (PF OA).

Top three questions

1. Does unicompartmental knee arthroplasty (UKA) provide better patient-reported outcomes despite worse survivorship than total knee arthroplasty (TKA) in patients under age 60 with isolated medial compartment OA?
2. Is lateral UKA a better alternative to TKA for patients under age 60 with respect to functional outcome?
3. What are the patient-reported outcomes for patellofemoral arthroplasty (PFA) versus TKA for patients under age 55 with isolated PF OA ?

Question 1: Does unicompartmental knee arthroplasty (UKA) provide better patient-reported outcomes despite worse survivorship than total knee arthroplasty (TKA) in patients under age 60 with isolated medial compartment OA?

Rationale

UKA has been an accepted alternative to TKA since the 1970s. It is attractive because of its ligament and bone preserving surgery, shorter and simpler rehabilitation, and some findings suggesting improved function and satisfaction when compared to TKA. However, registry data have consistently shown nearly double the revision rate to that of TKA across all age categories, especially in those under the age of 60, fueling the debate as to the role for UKA in this age group.

Clinical comment

Many patients under the age of 60 with isolated medial compartment OA which has failed conservative management have the surgical option of either medial UKA or TKA. Although of limited strength, recent literature supports the notion that UKA produces as good and sometimes more favorable reported patient-reported outcome measures (PROMs) compared with TKA and yet reported survivorship is typically only half as good.

Available literature and quality of the evidence

The available literature to answer this question is limited to level III retrospective observational studies, level IV case series, and systematic reviews of the former.

Findings

Multiple level III and IV studies have been completed to ascertain the survivorship of UKA in young patients, and there are mixed results in the literature. The evidence is mixed between the designer center series, cohort groups, and national registries. In 2011, Pandit et al. published a retrospective review of their first 1000 phase three Oxford medial UKAs implanted at the designer center and subdivided the patients into those younger (245 patients) and older than 60 (755 patients) at age of implantation. They found no difference in 10-year survivorship between the two groups, 97.3% (91.3–100%) and 95.1% (90.8–99.3%), respectively, with functional scores equal or better in the under 60 years of age group.[1] Several other case series have been published with similar outcomes and survivorship beyond 10 years.[2–5] A 2018 systematic review by Kleeblad et al. aimed to compare outcomes and revision rates between UKA and TKA in patients under the age of 65.[6] To calculate revision rates, the authors identified 21 cohort studies reporting data on 2224 UKAs and 33 cohort

studies reporting data on 4737 TKAs. The overall UKA revision rate was 8.2% at a mean follow-up of 9.8 years and an annual revision rate (ARR) of 1.00 (95% confidence interval [CI]: 0.77–1.30). Alternatively, the overall TKA revision rate was 6.95% at a mean follow-up of 8.4 years and an ARR of 0.53 (95% CI: 0.36–0.78). Few studies have specifically assessed survivorship of UKA in very young patients. Parratte et al. performed a retrospective review of 25 patients under the age of 50 who underwent medial UKA, and although they found that the mean KSS score improved from 54 to 89 preoperatively, their 12-year survival rate was 80.6%.[7] The 2018 annual report of the Australian Orthopaedic Association National Joint Replacement Registry looking at 52 000 primary UKAs reported the cumulative percent revision of primary UKAs and found that patients aged between 55–64 had a 15.9% (range 15.3–16.6%) revision rate at 10 years and 30.4% (range 28.0–33.0%) at 17 years. Further, patients with UKA under the age of 55 had a cumulative percent revision of 22.8% (21.7–23.9%) at 10 years and 39.4% (36.6–41.4%) at 17 years.[8] Conversely, TKA patients between the ages of 55 and 64 had an 11.8% (11.1–12.5%) revision rate and patients less than 55 had a 17.8% (16.4–19.3%) revision rate at 17 years.

Regarding functional outcomes, in the Kleeblad et al. systematic review, significantly higher overall ROM (125° vs 114, $p = 0.004$) as well as higher Knee Society Scores at long-term follow-up were found in the UKA group compared to the TKA group (88.1 and 85.8, respectively, $p = 0.04$).[6] A retrospective case series by Walker et al. of 118 consecutive Oxford medial UKAs in patients aged 60 or younger found that 93% of patients returned to activity postoperatively at minimum two-year follow-up and 62% of patients were defined as “very active” based on the UCLA score of ≥7.[9] Von Keudell et al. performed a retrospective

age matched cohort analysis of 485 knee surgeries with a minimum three-year follow-up and found that in patients between the ages of 55 and 64 higher satisfaction was found in the UKA group with 93% of patients having excellent/good patient satisfaction compared to 89% in the TKA group.[10] In those under the age of 55, 96% of patients with UKA had excellent/good patient satisfaction compared to 81% in the TKA group. Goh et al. published a retrospective matched cohort analysis of 160 patients under the age of 55 who underwent TKA and found that at both six months and two years patients in the UKA group had significantly greater ROM than those who underwent a TKA (128° ± 11° vs 117° ± 15°, respectively, at two years, $p < 0.001$). They did not, however, identify any difference in functional outcomes or patient satisfaction scores.[11]

At this time, UKA in patients under the age of 60 requires careful patient selection, meticulous surgical technique, and adequate surgical experience and also benefits from a shared decision-making process between the patient and surgeon. To this end, several authors have developed surgical decision tools to provide support and information to patients deciding between undergoing TKA and UKA.[12–14] Prospective randomized studies, some of which are ongoing, are required to better answer this question.[15]

Question 2: Is lateral UKA a better alternative to TKA for this patient under age 60 with respect to functional outcome?

Rationale

Despite the potential benefits of UKA as a bone preservation technique with faster recovery and lower

morbidity, lateral UKA accounts for less than 1% of all knee replacement procedures.

Clinical comment

It is critical to appreciate whether the benefits to patients outweigh the concerns of technical complexity and survivorship.

Available literature and quality of the evidence

Multiple retrospective case series provide the only real evidence from which to answer the question.

Consistently good early results were obtained by Berend with contemporary metal backed tibia designs.[16] They reported on 93 patients who had 100 lateral UKA and average age 68 years done through a lateral parapatellar approach. Knee Society Scores averaged 46 for pain, 94 for clinical, and 89 for function, and ROM averaged 124° with only two related reoperations – one for open reduction and internal fixation for fracture and one revision for pain. Furthermore, implant survivorship studies have showed very encouraging results with a range of 95–99% survivorship at 10-year follow up.[17–19] Indications for lateral UKA have been extended to include young patients with higher levels of activity. More importantly, Walker et al. showed that 98% of their cohort returned to sports and recreational activities after a lateral UKA. Two-thirds of them achieved high activity levels as measured by the Short Form 36 Health Survey.[19] As in medial UKA, most of the outcome studies involve fixed-bearing constructs, but interest remains as to whether the low wear characteristics of a mobile-bearing insert may have long-term benefits. Early studies of mobile-bearing lateral UKA were plagued with high dislocation rates.[20] Design modifications were required to account for the laxity and increased femoral

roll-back unique to lateral joint kinematics, and improvements in technique and design have led to a dramatic reduction in dislocation rate from 10% to 1.7% in the designer series.[21] Independent studies have reported good early- and medium-term outcomes, though some did have a high dislocation rate of 6%.[22] Though bearing dislocation and revisions are a concern, other potential issues also exist with either technique, such as overcorrection into varus, which must be avoided to prevent early failures. A recent systematic review confirmed that progression of OA and aseptic loosening are the major overall failure modes in lateral UKA. Bearing dislocation was the main failure mode in early years and in mobile-bearing implants, whereas OA progression caused most failures in late years and in fixed-bearing implants.[23]

Resolution of clinical scenario

- Lateral UKA can provide clinical functional results as good as medial with a high level of activity permitted.
- Mobile-bearing lateral UKA can theoretically allow slightly more flexion than fixed-bearing design at risk of insert dislocation.
- Care must be taken not to overcorrect into varus position and best results are maintained with slight valgus postoperative alignment.

Question 3: What are the patient-reported outcomes for PF arthroplasty (PFA) versus TKA for patients under age 55 with isolated PF OA?

Rationale

PF malalignment resulting in lateral facet overload is a common precursor to articular wear.[24] PF OA affects approximately 10% of patients aged over 40 years, with a female preponderance.[25]

Clinical comment

Currently, conservative treatment of PF OA includes quadricep strengthening, bracing or taping, oral and topical NSAIDs, hyaluronic acid and/or corticosteroid injections, and activity modification. Critical evaluation of the location and extent of PF cartilage lesions is required to properly stratify patients for procedures after patients have completed a thorough rehabilitation regimen.

Findings

Nonarthroplasty options

There is little evidence to use a simple procedure such as lateral release. Shea et al. recommended lateral release be reserved for patients with anterior knee pain who had computed-tomography-proven patellar tilt with minimal facet changes and minimal or no subluxation and cautioned that it should not be offered in cases of normally aligned patella.[26] Patellectomy is no longer considered a mainstream option for PF OA as quadricep weakness will result and only half of patients can expect good to excellent results.[27]

The most commonly performed osteotomies are for isolated lateral facet disease with severe narrowing where a simple debridement and lateral release are ineffective. The anteromedialization tibial tubercle osteotomy popularized by Fulkerson is conceptually most appealing with reliable outcomes and is specifically suited for cases where

articular lesions are concentrated in the lateral and distal facet of the patella given that medialization and anteriorization will address each of these individually.[28] It is important to taper the osteotomy distally to avoid a stress riser as fractures have been reported, leading to a recommendation of six weeks of non-weight-bearing postoperatively.[29]

Patellofemoral arthroplasty (PFA)

Patients in their 40s and 50s who fail repeated surgical intervention need a practical alternative to TKA for the medium-term improvement that can be achieved with PFA. Results with contemporary PFA designs have a reduced incidence of the problems related to patellar maltracking that typically plagued earlier generation designs. Patients must be advised that progression of tibiofemoral OA will likely be the main reason for revision emphasizing good patient selection and preoperative discussion. As per the 2018 Australian registry annual report, the cumulative percent revision for primary PFA undertaken for OA was 14.3% at five years and 45.9% at 15 years.[8] Younger patients can be reassured that failed PFA can be readily and successfully converted to TKA, as Lonner et al. have shown.[30] Prosthetic design (be it onlay or inlay), the need of realignment procedures, and the etiology of PF arthritis (post-traumatic, dysplastic, or idiopathic) are important factors to consider when planning the surgery and prognosticating patient results.[31]

Total knee arthroplasty (TKA)

TKA can provide significant improvement in younger patients with isolated PF arthritis. Lonner et al. have shown 91% excellent objective outcome in 32 knees in patients 40 years or younger with a 7.9-year mean follow-up.[30] However, only 50% of patients had good to excellent

functional outcomes on the Knee Society Score. Additionally, limitations in functional activities (i.e. moving laterally, turning, carrying loads, playing tennis) have been reported in 52% of TKA patients, compared with 22% in age-matched patients without reported knee complaints.[32]

Few studies to date have compared the functional outcomes of TKA with those of PFA using modern implants in a younger patient cohort. Meding and colleagues compared the outcome of TKA versus PFA in younger patients.[33] The study consisted of a retrospective cohort of 27 patients (33 TKAs) with average follow-up of 6.2 years. The patients ranged in age from 38 to 60 years of age with a mean of 52 years. The investigators used comparative historical data on PFA outcomes in 10 studies. The investigators concluded that TKA was a superior procedure. However, of the 10 PFA papers reviewed six involved first-generation PF designs that have largely been abandoned or redesigned. On the other hand, Dahm et al. retrospectively compared the clinical and functional outcomes of patients from their institution who underwent either PFA or TKA for the treatment of isolated PF OA.[34] Twenty-three PFA and 22 TKA patients were included with a mean follow-up of 2.5 years. Mean age was 60 years and 69 years, respectively. Patients treated with PFA demonstrated similar results with respect to pain relief but showed improved function and return to activity when compared to TKA patients. PFA patients also experienced less intra-operative blood loss, fewer complications, and shorter hospital stays following surgery. These results allowed them to conclude that PFA is a less invasive treatment option for patients with isolated PF OA, with outcomes comparable with TKA.

Summary of answers

- At this time, UKA in patients under the age of 60 requires careful patient selection, meticulous surgical technique, and adequate surgical experience, and also benefits from a shared decision-making process between the patient and surgeon.
- Lateral UKA can provide clinical functional results as good as medial with a high level of activity permitted.
- Mobile-bearing lateral UKA can theoretically allow slightly more flexion than fixed-bearing design at risk of insert dislocation.
- Care must be taken not to overcorrect into varus position and best results are maintained with slight valgus postoperative alignment.
- PFA is a reasonable choice to extend function and reduce pain while avoiding a more complex TKA.
- Like UKA, it remains an intermediate solution for some patients and an important option.

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37 Cemented versus Uncemented Fixation in Total Knee Arthroplasty

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Clinical scenario

- A 57-year-old female office worker with two years of severe bilateral knee pain (body mass index [BMI]: 34).
- Walking tolerance is about one block, unable to participate in recreational activities, sleep is regularly disrupted by pain.
- Has failed nonoperative management, correctable varus deformity, range of motion (ROM) 10–120°, advanced radiographic osteoarthritis medially with lateral compartment changes.

Top three questions

1. In total knee arthroplasty (TKA) in younger patients, is the survival of the implant improved with uncemented components as compared to cemented fixation?
2. In patients undergoing TKA, are the clinical outcomes improved with cementless fixation versus those fixed with cement?
3. In patients undergoing TKA, is the bone quality adjacent to the TKA improved following uncemented TKA as opposed to cemented TKA with intended benefit for future TKA revision?

Question 1: In total knee arthroplasty (TKA) in younger patients, is the survival of the implant improved with uncemented components as compared to cemented fixation?

Rationale

The durability or survival of TKA is a key feature to consider, especially in younger patients undergoing TKA.

Clinical comment

There are numerous impacts when considering TKA surgery. For the patient, there is the pain and effort of rehabilitation associated with the initial procedure. The patient is also exposed to the risks of surgery, which in rare cases can be as severe as death.[1] There is lost income from work in addition to missed family and social opportunities.[2] To governments and payors, there is the financial cost of the implant and the procedure. If revision TKA is required, all of the above impacts tend to be greater than in the primary procedure.[3],[4] By maximizing the survival of the TKA implant and procedure, the risk of subsequent revision is reduced, thereby minimizing the impact to the patient's personal, financial, and social wellbeing and to the healthcare system.

Available literature and quality of the evidence

While there have been multiple randomized controlled trials (RCTs) assessing the survival of uncemented versus cemented TKA, most are too small to determine implant survival between groups. To address the limitations of these smaller studies, five meta-analyses have been

performed including a Cochrane review that provide some clarity, but each has limitations to answer the question of survival. Multiple national joint registries provide the clearest information on real-world use of cemented and uncemented TKA, but these are limited based on the granularity of the data within the registries.

Findings

When performed well and with consistent subject matter, meta-analyses can provide strong recommendations. The Cochrane review by Nakama et al. (level I) focused principally on the fixation and stability of cemented and uncemented tibial components as assessed by radiostereometric analysis (RSA) in three RCTs at two years.[5] RSA is a high-resolution radiographic technique that compares the position of radio-dense implants to small marker beads embedded in the bone to assess relative motion between implant and bone. Early continuous migration of the mean total point motion of the implant relative to bone of >0.2 mm at two years has been associated with a high risk of early loosening and implant failure.[6] The review found the overall movement of cemented tibial implants was less than uncemented, but that uncemented implants were at lower risk of future aseptic loosening with a risk ratio (RR) of implant instability to bone versus cement fixation (RR = 0.47; 95% confidence interval [CI]: 0.24–0.92; p = 0.03).[5] They found that the uncemented implants tended to move a small amount early and then stabilize. Most cemented tibial components were stable, but those that were not stable never stabilized and continued to migrate. In reviewing clinical outcomes, Gandhi et al. reviewed 15 studies that were a mix of RCTs and cohort studies (level II).[7] They found that the combined odds ratio (OR) for failure due to aseptic loosening for the uncemented group was 4.2 (95%

CI: 2.7–6.5; p <0.001). However, when they only assessed the five RCTs in the review, there was no statistical difference (level I) between fixation types. They concluded that there was improved survival of the cemented compared to uncemented implants. Mont et al. (level II) described a similar phenomenon in their 37 study review with uncemented implants with an OR 1.8 (95% CI: 1.1–3.1) of failure with all study types assessed, but with no survival difference found when only the five RCTS (level I) were assessed.[8] Wang et al. reviewed nine studies (level II) which were a mix of RCT and case series and reported ORs of 3.41 (95% CI: 1.83–6.35) at five years and 4.73 (95% CI: 2.07–10.79) in favor of cemented fixation over uncemented.[9] Voigt et al. reviewed 14 RCTs (level I) and used both survival and implant instability by RSA as a marker or failure and found no difference between fixation methods at either 5 or 8–10 years.[10] Survival with cement TKA fixation appears better, but despite the rigors of meta-analysis methods the results are not entirely conclusive.

National joint registry data are a powerful tool that can attest to real-world use of implants. While causality can be difficult to prove with registries, their massive scale can lead to strong conclusions. Unlike the meta-analyses, the registries have been consistent in their overall finding that uncemented TKAs have reduced survival as compared to cemented TKAs with relative risks ranging from 1.1 to 1.9.[11–15] All of the registries recognize that younger patients undergoing TKA have higher revision rates and that the trend in the use of uncemented TKA is in younger patients. As a result, age is a confounder in the assessment of uncemented TKA survival and is controlled for in the analysis by the different registries. While the overall survival is reduced, sub-analysis within the registries demonstrates some interesting findings. The New Zealand registry reported on only three uncemented knee designs

with one design accounting for 78% of the uncemented volume (level II).[13] While the survival of the predominant design was worse than the mean survival of cemented designs, the remaining two uncemented designs did not differ suggesting that the single poorly performing design skewed the results for the uncemented group as a whole. The Swedish Registry (level II) found that, after controlling for confounders, that the relative risk of failure for of a TKA with an uncemented tibial component was 1.6 (95% CI: 1.3–1.9) times higher than for cemented tibial components.[15] That said, it reported no difference for knees implanted within the last 10 years and indicated that the driving force for their finding was uncemented knees performed between 1985 and 1994. This raises the possibility that more modern implant designs and surgical techniques may have improved the survival of uncemented TKA to that of cemented TKA. The British National Joint Registry (level II) found that uncemented and hybrid fixation (typically cemented tibial fixation and uncemented femoral fixation) performed more poorly with posteriorly stabilized designs versus minimally constrained TKA.[12] The Australian Registry (level II) reported that hybrid fixation with posterior stabilized designs had increased failure rates (HR = 1.29 [1.18, 1.40]) with uncemented versus cement fixation, but no difference in minimally constrained designs.[11] Completely uncemented designs fared worse in both design styles (HR = 1.12 [1.00, 1.26] and HR = 1.25 [1.20, 1.31], respectively). The general conclusion of the registry data suggests that survival is not improved with uncemented fixation and is, in fact, worse than cemented fixation but that there may be design issues that cause some variation in the results.

Resolution of clinical scenario

- Survival of uncemented implants may be design-dependent.
- There is no substantial evidence that uncemented TKA improves the implant survival versus cemented TKA in any patient group, and survival appears to actually be greater with cemented fixation.

Question 2: In patients undergoing TKA, are the clinical outcomes improved with cementless fixation versus those fixed with cement?

Rationale

The underlying purpose of TKA is to relieve pain and restore function. Regardless of fixation type, knee replacements must be effective to be of value to both the patients and the healthcare system.

Clinical comment

The patient is undergoing surgery due to the pain that she is experiencing and the significant limitations on her activities and reduced quality of life. Regardless of implant survival, the success in pain relief and restoration of function will be her biggest immediate concern. She will not want to sacrifice her clinical outcome quality to potentially improve a subsequent surgical procedure.

Available literature and quality of the evidence

There have been a number of RCTs assessing the outcome of TKA using the two fixation types. The challenge is that most are inadequately powered to assess for clinical outcome metrics. Meta-analysis is ideal for merging these

types of data to help address this shortcoming; however, the variety of outcome metrics make pooling data from multiple studies challenging.

Findings

The power to pool clinical data using meta-analysis has been performed by a few studies. The Cochrane review by Nakama et al. (level I) found no difference in patient-reported outcome measures (PROMs) of the three RCTs reviewed.[5] The review of RCTs and cohort studies by Gandhi et al. (level II), assessed nine studies using the Knee Society Score (KSS) and also found no difference between groups, but found the results to vary from study to study.[6] One RCT of 81 subjects found that pain scores neared statistical and clinical significance with uncemented knee patients reporting more pain at six months from surgery, but that the finding dissipated by one year (level I).[16] Demey et al. (level I) assessed the KSS in an RCT powered to detect a difference of 15 points at a minimum of 24 months' follow-up and found no difference between fixation types.[17] The minimal clinically important difference (MCID) of the KSS has been identified as six points.[18] Fernandez et al. published their findings (level I) on 145 subjects in a blinded RCT and found that subjects with a porous tantalum uncemented tibial base plate had statistically improved KSS and Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) scores at five years versus cemented tibial base plates (mean difference of 3.9 and 4.0 points [$p = 0.02$], respectively).[19] Given the MCID for the KSS is approximately six points and for the WOMAC has been reported as high as 15, these results do not appear to be clinically important.[18],[20] Powered to find a five-point difference in KSS at two years, Fricka et al. (level I) found

no difference between fixation types in their RCT.[21] Similarly, in an RCT powered to detect a three-point difference in KSS in patients younger than 55, Kim et al. (level I) found no difference between groups at a mean follow-up of 16.6 years.[22] There has been no clinically important difference demonstrated between uncemented and cemented fixation in TKA.

Significant complications can lead to negative impacts on quality of life. In reviewing their outcomes through their meta-analysis of 953 patients, Wang et al. (level II) found no difference in infection rates between the two fixation methods (OR = 0.96; 95% CI: 0.37–2.48).[9] Similarly, Voight et al. (level I) found no difference between the groups (RR = 1.20; 95% CI: 0.63–2.28) in the rate of *adverse events*.[7]

Resolution of clinical scenario

- There is no evidence of differences in clinical outcomes for patients undergoing either cemented or uncemented fixation of their TKA.
- Complication rates appear to be similar between fixation types.

Question 3: In patients undergoing TKA, is the bone quality adjacent to the TKA improved following uncemented TKA as opposed to cemented TKA with intended benefit for future TKA revision?

Rationale

Given her age, the patient wonders if using an uncemented TKA will help in the face of a future surgery by preserving bone for future use.

Clinical comment

For younger patients, the risk of future revision of their TKA is real.[11–15] A common argument for the use of uncemented TKA is to preserve bone for use in future revision surgery by avoiding the stress shielding and bone mineral density loss associated with cemented fixation.[23]

Available literature and quality of the evidence

The available literature assessing bone mineral density difference between uncemented and cemented fixation is of limited quality. There is a single, small RCT with no power calculations to justify the sample size. There are three cohort studies with only one providing a sample size justification.

Findings

While several cohort studies have reviewed specific implant designs, to date only one RCT has assessed the issue of bone mineral density comparing fixation types. In their small (38 knee) study (level II), they were unable to detect a difference in bone mineral density between fixation groups.[24] A cohort trial of the same size (38 knees) was powered to detect a bone density difference of approximately 28%.[25] They, too, found no difference between fixation types, but were unable to control for preoperative bone density due to the nonprospective design of the study (level III). Small et al. reviewed bone density based on radiographic assessment in matched cohorts of 67 knees.[26] They found no difference between fixation types more than 10 years from surgery (level III). A second

matched cohort study with prospective data collection included preoperative bone densitometry testing (level II). In their cohorts (28 knees in each), they found the bone mineral density declined by 37% (±24%) in the lateral tibia with cemented fixation versus only 7% (±23%) in the uncemented porous tantalum fixation group at two years from surgery ($p = 0.001$).[27] No difference was identified in the medial tibial bone density between groups.

Resolution of clinical scenario

- There is no consistent benefit in maintenance of bone mineral density of the tibia following uncemented TKA fixation.
- There is potential for different implant designs to have differing impacts on long-term bone mineral density of the tibia.
- No clear benefit has been shown to the preservation of bone density based on uncemented versus cemented fixation of TKA.

Summary of answers

- There is no consistent evidence that uncemented TKA improves the implant survival versus cemented TKA in any patient group.
- There is no evidence of differences in clinical outcomes for patients undergoing either cemented or uncemented fixation of their total knee replacement.
- There is no consistent benefit in maintenance of bone mineral density of the tibia following uncemented TKA fixation.

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38 Cruciate Retaining versus Posterior Stabilized Total Knee Arthroplasty

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Clinical scenario

- A 63-year-old woman who is otherwise independent presents with progressive, symptomatic end-stage tricompartmental osteoarthritis of the knee.
- She has exhausted nonoperative modalities and wishes to proceed with total knee arthroplasty (TKA).

Relevant background

Contemporary TKA designs vary in the degree to which the tibial and femoral articular surfaces are constrained to one another by patient soft tissues versus elements of the prosthesis itself. It is generally accepted that lower-constraint designs are preferable in the context of modest deformity and competent knee ligaments, allowing forces across the knee joint to be maximally absorbed by patients' own soft tissues. In contrast, greater amounts of implant constraint typically require more bone resection may constrain joint motion and result in greater forces on implant components as well as the bone–implant interface, increasing the risk of earlier failure.

The large majority of primary TKA procedures involve the implantation of lower-constraint implants that rely entirely on the medial and lateral collateral ligaments for varus/valgus stability, while sacrificing the anterior cruciate.

However, primary TKA implant designs differ in terms of treatment of the posterior cruciate ligament (PCL). Generally speaking these can be divided into two groups: those that retain the PCL (cruciate-retaining, or CR) and those that sacrifice it (PCL-sacrificing or posterior stabilized, or PS). CR designs have limited conformity between the tibial and femoral articulations, conceptually relying on the retained PCL to limit posterior tibial translation and facilitate femoral rollback in flexion. In contrast, PS designs rely on the tibiofemoral articulations for femoral rollback. Traditionally, this has been achieved through the use of a cam-and-post mechanism, whereby a post on the tibial polyethylene engages with the femoral component as the knee is flexed.

Advocates of CR implants have suggested advantages to their use, including less femoral bone resection, lower risk of iatrogenic fracture, more physiologic knee kinematics, superior function owing to retention of proprioceptive receptors within the PCL, and lower rates of polyethylene liner failure particularly as compared to the cam-and-post design. In contrast, advocates of PS implants suggest benefits, such as greater range of motion (ROM), more predictable outcomes, and lower risk of late instability attributable to PCL rupture.

Importance of the problem

TKA is among the most common contemporary surgical procedures. In 2012, 700 100 knee arthroplasty procedures were performed in the United States, making it the most

common operating room procedure with a population rate of over wo surgeries per 1000 people.[1] In addition to being common, surgical treatment of knee osteoarthritis represents a considerable healthcare cost burden. In 2013, osteoarthritis was the second-most-expensive condition billed to Medicare, and the most expensive condition billed to private insurance in the United States.[2] Although TKA has shown good results in decreasing pain and improving function in patients with symptomatic degenerative disease, up to 20% of patients remain dissatisfied with the results of their surgery.[3] Considering the marked health economic burden of TKA, and the notable patient dissatisfaction rate with this procedure, it is critical that evidence-based decisions be made around implant selection so as to maximize healthcare value.

Top three questions

1. In older active patients with osteoarthritis of the knee, is the use of CR TKA implants associated with differences in patient-reported clinical outcomes as compared to PS designs?
2. In older active patients with osteoarthritis of the knee, is the use of CR TKA implants associated with differences in implant survival as compared to PS designs?
3. In older active patients with osteoarthritis of the knee, is the use of CR TKA implants associated with differences in ROM as compared to PS designs?

Question 1: In older active patients with osteoarthritis of the knee, is the use of CR TKA implants associated with differences in patient-reported clinical outcomes as compared to PS designs?

Rationale and clinical comment

TKA is an elective procedure, with the primary therapeutic goals of improving patients' function and quality of life. Consequently, assessment of the outcomes of this procedure should be made from the patient's perspective. Thus, it is important to consider whether the choice of CR versus PS implants results in any difference in outcomes of the surgery from the patient perspective, as measured using validated patient-reported outcome measures.

Available literature and quality of the evidence

Multiple randomized controlled trials (RCTs) are available assessing this question. Four of these were summarized in a Cochrane review published in 2013.[4–8] A literature search of Embase and Medline databases identified an additional seven subsequently reported RCTs.[9–15] Thus, a total of 11 randomized trials were used to address this question, all with a level of evidence of I. Given this available evidence, no lower-quality studies were used to address this question.

Findings

A Cochrane review that included studies published up to December 2012 found no significant difference in patient-reported outcome scores between CR and PS TKA across

four studies that used the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC).[13–16] One more recent study was identified that reported WOMAC scores, which found a mean difference in WOMAC scores of 3.8 points (significant difference [SD] 2.8 points; p <0.001) favoring an ultra-congruent PS liner over a CR implant in 210 knees. Pooled results from these studies encompassing 641 knees at follow-up times from 24 to 87 months found an absolute difference in scores of 2.11 points in favor of PS knees (95% confidence interval [CI]: −0.11–4.33 points),[12] which narrowly missed statistical significance and is unlikely to reach the threshold of a minimal clinically important difference (MCID). The overall quality of evidence was low, with a frequently unclear or high risk of bias.

Four studies were identified that reported Visual Analog Scale scores for knee pain,[13,14,17,18] with no significant differences identified. Pooled results encompassing 315 knees at follow-up times ranging from one to six years found no significant difference in outcomes (1.44 mm on a 100 mm scale in favor of PS; 95% CI: −1.8–4.68 mm).

Of the remaining four studies, three reported individual WOMAC domain scores only,[9,10,15] while one reported individual domain Knee Osteoarthritis Outcome Scores (KOOS) only.[11] Of these, one study identified worse WOMAC pain subdomain scores in those patients who received a PS design (mean 4.2 points vs 2.5 points; p = 0.043), but no difference in other domains.[15] The remaining studies did not identify any significant differences in any PROMs.

Overall, the presently available evidence is limited somewhat by relatively small individual studies and variability in both outcome measures and follow-up intervals. Nevertheless, it is possible to say with moderate

certainty that there is no clinically relevant difference in patient-reported outcomes of TKA associated with the use of CR as compared to PS designs.

Resolution of clinical scenario

In terms of patient-reported outcomes of TKA, the best available evidence suggests no difference in outcomes associated with the use of CR versus PS designs. In the absence of other factors, and assuming the surgeon is comfortable with both designs, either would be an excellent choice for this patient.

Question 2: In older active patients with osteoarthritis of the knee, is the use of CR TKA implants associated with differences in implant survival as compared to PS designs?

Rationale and clinical comment

Mean life expectancies in the developed world are continuing to increase, and are currently approaching or exceeding 80 years of age. In contrast, the prevalence of total knee replacement in younger patients, including those under 50 years of age, is rising. While total knee replacement in younger patients has been shown to be effective at improving quality of life, it is also associated with higher risks of revision.[19],[20] Given the considerable patient and health resource burden associated with revision surgery, as well as the more modest outcomes achieved as compared to primary surgery, both patients and surgeons should seek strategies to maximize the survival of a well-functioning primary TKA.

Available literature and quality of the evidence

Multiple RCTs are available to assess this question, although in all cases data were reported as incidental comments within the manuscript and were not included among the primary or secondary outcome measures. Seven of these studies were summarized in a Cochrane review published in 2013. A literature search of Embase and Medline databases identified an additional three subsequently reported RCTs that included survivorship data.[10],[12],[16] One of these is an update of the report from Chaudhary et al. included in the Cochrane review.[10] Thus, a total of nine randomized trials were used to address this question, all with level I evidence.

Given that none of the identified studies included implant survival among the reported primary or secondary outcome measures, an additional search was performed of the English-language reports of available national joint replacement registries. This search identified two joint registries that reported data relevant to the question.[20],[21] These reports could be considered level III evidence, although there is some debate regarding the appropriateness of applying the traditional hierarchy of clinical evidence to registry data.[22]

Findings

No single available study included implant survival as an outcome measure, and the Cochrane review did not report any pooled results across studies. Both aggregated data from the nine identified studies, as well as results of joint replacement registries, suggest a possible small survival advantage for CR knees, albeit with a high degree of uncertainty.

When aggregated, the nine identified studies included a total of 741 CR knees and 735 PS implants with follow-up times ranging from 2 to 10 years. Among these, six CR implants were reported to have been revised, as were eight PS implants. This represents revision rates of 0.8 and 1.1% for CR and PS knees, respectively. However, it must be recognized that the quality of this evidence is low, given that survival was not tracked as an outcome measure in any study, as well as heterogeneity in follow-up times and lack of available statistical analysis of pooled results.

Data from the United Kingdom and Australian joint replacement registries support a small survival advantage for CR knees at follow-up times over 10 years. The Australian Joint Replacement Registry reports significantly lower revision rates for CR knees at 10-year follow-up (5.0% [95% CI: 4.9–5.2%] vs 6.1% [95% CI: 5.9–6.3%]), a trend that persists at 15 years but narrowly misses significance (7.1% [95% CI: 6.8–7.3] vs 8.2% [95% CI: 7.2–9.2]). A similar survival advantage for CR knees is reported by the United Kingdom's registry at 13-year follow-up, with absolute difference in revision rates of 0.87% (3.82% [95% CI: 3.66–3.96] vs 4.69% [95% CI: 4.43–4.96]). Although the number of knee replacements tracked by each of these registries is in the hundreds of thousands, the quality of the evidence remains low as a result of the high risks of bias and confounding, and other weaknesses inherent in observational cohorts.

Resolution of clinical scenario

Although there may be a small survival advantage for CR implants, the absolute magnitude of this difference is small and the quality of evidence low. In the absence of other factors, the use of a CR design can be considered in this patient. However, this should only be done if the surgeon is comfortable using these implant designs.

Question 3: In older active patients with osteoarthritis of the knee, is the use of CR TKA implants associated with differences in ROM as compared to PS designs?

Rationale and Clinical Comment

As total knee replacement has become more reliable in providing relief from arthritis pain, there has been increasing emphasis on restoring patient function. Advanced knee arthritis is frequently characterized by restricted ROM, and both patients and surgeons may expect to see improvements in the arc of motion following arthroplasty surgery. Some authors have suggested that a minimum of 110° of flexion is required to successfully complete a range of activities of daily living,[23] with increasing motion being associated with improved postoperative function up to an optimal arc of approximately 130°.[24–26] In some patient populations and cultures, even greater postoperative flexion may be desirable to allow participation in social and religious activities that require kneeling.[27] Given this, any differences in postoperative ROM associated with CR versus PS designs may be relevant to both surgeons and patients in decision-making around knee replacement surgery.

Available literature and quality of the evidence

Multiple RCTs are available assessing this question. Eleven of these were summarized in a Cochrane review published in 2013.[4,5,7,17,18,28–34] A literature search of Embase and Medline databases identified an additional six subsequently

reported RCTs.[9,12–16] Thus, a total of 17 randomized trials were used to address this question, all with level I evidence. Given this available evidence, no lower-quality studies were used to address this question.

Findings

Pooled data from 11 studies as reported in the Cochrane review from 2013 demonstrated a statistically significant, albeit likely clinically insignificant, advantage for PS knees in terms of total ROM.[4,5,7,17,18,28–34] A small difference in flexion favoring PS knees narrowly failed to reach significance. Over a total of 1440 knees, PS implants demonstrated a mean of 2.4° greater ROM (95% CI: 0.13–4.61°) and 1.5° greater flexion (95% CI: −0.24–3.15°). In contrast, there was no significant observed difference in extension, with mean difference of 0.36° (95% CI: −0.63–1.36°). The authors of the review reported overall low quality of evidence, citing multiple studies with high of frequently unclear risk of bias.

The results of the six more recent trials are consistent with these findings, with five of these studies finding significant advantages in terms of ROM and/or flexion for PS knees,[12–16] and the sixth finding no difference between groups.[9] Rajgopal et al. evaluated total arc of motion, finding a mean difference of 4.6° (95% CI: 3.7–5.4°).[12] Of the five studies that evaluated flexion, four reported sufficient data for pooling.[13–16] Overall, the quality of evidence from these more recent studies is moderate, with some uncertainty around randomization methodology and follow-up intervals in isolated studies.

When pooled across all 12 available studies encompassing 1650 patients, the use of PS implants was associated with a 2.98° (95% CI: 2.03–3.92) greater arc of motion. Similarly, when pooled across all 13 studies encompassing 1165

patients, the use of PS implants was associated with a 3.59° (95% CI: 1.44–5.75) greater maximum flexion angle.

Overall, the available evidence consistently demonstrates an advantage in terms of both flexion and total ROM for PS TKA, with moderate certainty. However, in the absence of accepted MCIDs for these outcomes, the clinical relevance of these differences remains debatable.

Resolution of clinical scenario

Although PS implants appear to be associated with greater ROM and flexion, the clinical relevance of this difference remains uncertain, and this does not appear to consistently translate into improved patient-reported outcomes. Thus, in the general population, either a CR or PS implant remains and excellent choice. In patients whose specific postoperative activity goals include the need for deeper flexion (e.g. frequent kneeling), surgeons and patients may consider preferentially using a PS implant. However, any associated incremental ROM may not be clinically significant, and must be weighed against the surgeon's technical comfort and the potential for decreased survivorship.

Summary of answers

- The use of CR TKA implants is not associated with any differences in patient-reported clinical outcomes as compared to PS designs.
- The use of CR TKA implants may be associated with a small improvement in implant survival as compared to PS designs, although the quality of evidence supporting this is low.

- The use of CR TKA implants is associated with a lesser arc of motion (between 2–4°) and flexion (between 1 and 6°) as compared to PS designs as supported by moderate quality evidence, although the clinical significance of these differences remains unclear.

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39 Patellar Resurfacing in Total Knee Arthroplasty

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Clinical scenario

- A 67-year-old woman with end-stage tricompartmental osteoarthritis of the knee, and who is otherwise independent, undergoes elective total knee replacement.
- She asks her surgeon whether she will have the underside of her patella resurfaced as part of the procedure.

Introduction

Since the introduction of the total condylar knee prosthesis in the 1970s, virtually all total knee arthroplasty (TKA) surgery is characterized by complete resection of the distal femoral and proximal tibial articular surfaces, and replacement with synthetic materials. Consequently, all abnormal cartilage and subchondral bone associated with osteoarthritis is removed from the primary weight bearing surfaces of the knee joint. Although there is little controversy about the routine resection of the femoral and tibial articular surfaces in the setting of multicompartmental osteoarthritis of the knee, optimal management of the patellar articular surface is less clear. Some knee surgeons advocate leaving the native patellar surface intact, others recommend routine resurfacing with

a polyethylene component, while yet others recommend selective resurfacing based on one or more patient factors and/or intraoperative findings.[1]

Top four questions

1. In older active patients with osteoarthritis of the knee, is patellar resurfacing associated with differences in patient-reported clinical outcomes as compared to nonresurfacing?
2. In older active patients with osteoarthritis of the knee, is patellar resurfacing associated with differences in objective functional outcomes as compared to nonresurfacing?
3. In older active patients with osteoarthritis of the knee, is patellar resurfacing associated with differences in complications (anterior knee pain, and complications other than anterior knee pain) as compared to nonresurfacing?
4. In older active patients with osteoarthritis of the knee, is patellar resurfacing associated with differences in reoperation rates as compared to nonresurfacing?

Available literature and quality of the evidence

A considerable body of higher-quality evidence was identified to answer these questions. A search of Medline and EMBASE databases identified 11 English-language meta-analyses of randomized and/or quasi-randomized controlled trials that address one or more of these questions,[2–12] with publication dates spanning from 2005 until 2018. These meta-analyses aggregate data from between 8 and 28 individual level I and II studies published

between 1982 and 2015, with a total of 53 studies appearing in one or more meta-analyses.

Question 1: In older active patients with osteoarthritis of the knee, is patellar resurfacing associated with differences in patient-reported clinical outcomes as compared to nonresurfacing?

Rationale and clinical comment

The primary goals of total knee replacement surgery are to improve patients' quality of life on an elective basis, specifically in terms of reducing pain and functional limitations associated with degenerative disease of the *Knee* Consequently, any assessment of the relative outcomes of knee replacement surgery with or without patellar resurfacing should be made from the patients' perspective, using validated patient-reported outcome measures (PROMs). Patient-reported outcome measures reflect the results of surgery that matter most to patients. They have a high importance when determining the effectiveness of TKA in treating patient symptoms, as well as when comparing different surgery performed using different techniques or implants. Although TKA can affect general health, joint/disease-specific patient-reported outcomes are more sensitive in detecting differences in outcomes of this procedure.

Available literature and quality of the evidence

Of the 11 meta-analyses identified, four specifically assessed for differences in patient-reported outcomes

following TKA with or without patellar resurfacing.[2,7,9,12] These four meta-analyses synthesized data from between 5 and 9 individual controlled trials, encompassing between 456 and 1102 individual TKA procedures. Three of these meta-analyses assessed patient satisfaction,[7,9,12] while the fourth assessed patient-reported general knee pain using a Visual Analog Scale (VAS).[2]

None of the meta-analyses assessed outcomes in terms of validated joint-specific outcome measures. Consequently, Medline, Embase, and the reference lists of all 11 meta-analyses were searched to identify individual studies that assessed outcomes using joint-specific PROMs, with three level I studies identified.[13–15] Given this available evidence, no lower-quality studies were used to address this question.

Findings

Three meta-analyses synthesized data from between five and nine studies to assess in the impact of patellar resurfacing on patient satisfaction with surgery,[7,9,12] with all three finding no significant difference between groups. Two meta-analyses pooled data from five and nine trials respectively to determine aggregate satisfaction rates,[9,12] with both finding near-identical proportions of satisfied patients in both groups, ranging from 90.0 to 92.1% among patients who underwent patellar resurfacing, and between 89.1 and 89.3% in patients who did not. The relative risk for dissatisfaction after TKA failed to reach significance in all three meta-analyses, with a 95% confidence interval (CI) spanning one in all cases.

One network meta-analysis with inclusion criteria limited to level I trials compared 10-point VAS pain scores between three groups of patients across nine studies who underwent TKA: those with patellar resurfacing (n = 154), those with patellar denervation but no resurfacing (n = 135), and

those with no denervation or resurfacing (n = 167).[2] Analysis of pooled results failed to identify any significant unadjusted mean difference (UMD) in pain scores associated with patellar resurfacing, irrespective of whether unresurfaced patellae were (UMD 0.11 points [−0.21 to 0.43]) or were not (UMD 0.11 [−0.21 to 0.44]) denervated.

Three individual trials were identified that reported joint-specific patient reported outcomes, none of which identified any significant differences associated with patellar resurfacing.[13–15] Two trials reported components of the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) at follow-up times between 1 and 10 years,[14,15] while one reported the Knee Osteoarthritis Outcome Score (KOOS) at three months to six years.[13] All three studies were limited by small sample sizes (ranging from 16 to 54 per group) and notable loss to follow-up. Differences in reporting (absolute vs change scores, time intervals) precluded pooling of WOMAC scores across the two studies. While a number of meta-analyses reported outcomes measured using surgeon-reported outcome measures such as the Knee Society Score (KSS) or Hospital for Special Surgery (HSS) knee score, nonpooled PROM data.

Overall, while a number of studies have reported differences in patient satisfaction associated with patellar resurfacing in TKA, the presently available evidence is limited by infrequent reporting of validated joint-specific PROMs and variability in reporting. It is possible to say with moderate-to-high certainty that there is no clinically relevant difference in patient-reported satisfaction with TKA associated with patellar resurfacing versus nonresurfacing. While the available evidence suggests no difference in joint-specific PROMs associated with patellar

resurfacing, certainty in this finding is low owing to marked limitations with the available evidence.

Resolution of clinical scenario

In terms of patient-reported outcomes of TKA, the best available evidence suggests no difference in patient satisfaction with surgery irrespective of whether or not the patellar is resurfaced. However, insufficient evidence is available to guide decision-making around patellar resurfacing based on potential differences in joint-specific PROMs

Question 2: In older active patients with osteoarthritis of the knee, is patellar resurfacing associated with differences in objective functional outcomes as compared to nonresurfacing?

Rationale and clinical comment

Many patients with symptomatic osteoarthritis are otherwise healthy and independent in their community. However, many also complain of significant functional limitations secondary to the pain and stiffness of knee osteoarthritis, such as limited walking tolerance, difficulty with climbing and descending stairs, and need for a walking aid. Patients frequently cite these functional limitations as reasons to pursue knee replacement surgery, with an implicit or explicit desire to return to pre-disease function. Given these common expectations of TKA surgery, surgeons and patients may wish to know whether this

outcome might be affected by the decision of whether to resurface the patella at the time of surgery.

Available literature and quality of the evidence

Of the 11 meta-analyses identified, eight specifically assessed for differences in objective function scores following TKA.[2,3,5–9,11] However, one study did not pool results citing excessive heterogeneity.[11] As a result, seven meta-analyses reported sufficient data to address this question, pooling data from between 3 and 14 individual trials, encompassing between 507 and 2194 knees. All seven meta-analyses evaluated objective functional outcomes using the Knee Society Function Score (KSFS). Given this available evidence, no lower-quality studies were used to address this question.

Findings

All seven meta-analyses consistently found no significant difference in mean KSFS – a clinician-reported outcome score evaluating walking tolerance, stair climbing ability, and reliance on a walking aid – irrespective of whether the patella is resurfaced at the time of TKA.[16] Pooled results revealed mean differences in scores of between 0.16 and 2.58 points on a 100-point scale, with 95% CIs crossing 0 in all cases. One study performed subgroup analyses, finding no difference in functional outcomes even when pooled analysis was limited to follow-up intervals of more than five years; mean difference of 1.82 (−1.44 to 5.08) points.[3] No other measures of objective function were reported in the identified studies.

Resolution of clinical scenario

Based on the available evidence, it is possible to say with high certainty that patients and clinicians can expect to

achieve similar objective function following TKA in terms of walking tolerance, stair climbing ability, and need for a walking aid, irrespective of whether the patella is resurfaced. Consequently, the decision of whether to resurface should not be made based on expected differences in objective function following recovery.

Question 3: In older active patients with osteoarthritis of the knee, is patellar resurfacing associated with differences in complications (anterior knee pain, and complications other than anterior knee pain) as compared to nonresurfacing?

Rationale and clinical comment

With survival rates exceeding 90% at 15 years, total knee replacement is among the more successful modern surgical interventions. Nevertheless, studies have suggested that around 20% of patients may be dissatisfied with the results of TKA, with persistent pain among the more common reasons.[17] With around 700 000 primary TKA procedures performed annually in the United States alone,[18] significant numbers of otherwise well patients may be left dissatisfied with the results of their surgery.

Some authors have suggested that a failure to resurface the patella during TKA may result in higher rates of persistent pain, particularly in the anterior aspect of the knee.[1] However, others argue that the link between retention of the native patellar articular surface and persistent pain are unclear, and that resurfacing may in fact increase the risk of other patellar complications.[1]

Given the large number of TKAs performed in the developed world, the potential impact of patellar resurfacing on anterior knee pain and patellofemoral complications may be of interest to both surgeons and patients as part of surgical decision-making.

Available literature and quality of the evidence

Of the 11 meta-analyses identified, 10 specifically assessed for differences in anterior knee pain and/or other related complications associated with patellar resurfacing.[2,3,5–12] One study did not pool data as a result of excessive heterogeneity.[11] All of the remaining nine meta-analyses evaluated differences in knee pain, while three additionally evaluated the risk of other related complications including patella fracture, pain with climbing stairs, or a composite measure of patellofemoral complications.[2,9,12] The nine studies that reported sufficient data to address this question pooled data from between 7 and 13 individual trials, encompassing between 634 and 2453 knees. Given this available evidence, no lower-quality studies were used to address this question.

Findings

The nine studies evaluating the relationships between patellar resurfacing and postoperative anterior knee pain consistently identified considerably lower rates of anterior knee pain in patients who had undergone patellar resurfacing, but confidence in these findings was low as a result of high heterogeneity between studies.

Five studies reported aggregate rates of persistent anterior knee pain summed across individual trials, and all five found that rates were approximately twice as high in patients with unresurfaced patellae.[6–9,12] Pooled rates of anterior knee pain ranged from 7.6 to 16.2% in knees with

resurfaced patellae, compared to between 15.9 and 26.2% in unresurfaced knees. However, the results of meta-analyses were less consistent. Only three studies identified significant differences in anterior knee pain favoring patellar resurfacing: two found risk ratios of 0.39 (0.20–0.75) and 0.40 (0.19–0.85),[9,10] and one reporting an odds ratio of 0.58 (0.45–0.75).[8] The remaining six studies all reported risk ratios favoring patellar resurfacing between 0.63 and 0.97, but with CIs spanning one.[2,3,5–7,12] Three studies reported absolute risk reduction associated with resurfacing ranging from 13.8 to 0%,[3,5,10] with only one of the three observed differences reaching statistical significance.[10]

Meta-analyses of other patellar complications similarly appear to, on balance, favor resurfacing. One study that pooled data from 254 knees in two trials found significantly lower rates of stair climbing pain associated with patellar resurfacing (12.7% vs 26.4%; RR = 0.43 [0.22–0.83]),[9] while a second that pooled data from 3220 knees in 14 trials found significantly lower rates of any patellofemoral complications following resurfacing (5.9% vs 12.6%; RR = 0.55 [0.34–0.90]).[12] While some authors have suggested that patellar resurfacing may be associated with an increased risk of patellar fracture,[19,20] a recent meta-analysis that pooled data from 2791 knees in 11 trials found no differences in patellar fracture rates irrespective of whether or not resurfacing was performed (RR = 1.12 [0.49–2.52]).[2,14,21–30]

Resolution of clinical scenario

On balance, it appears that patellar resurfacing is associated with considerably lower rates of postoperative anterior knee pain, as well as with lower rates of pain associated with stair climbing and overall patellofemoral

complication rates. These differences may very well be clinically significant, with absolute risk differences potentially exceeding 10%. However, certainty in these findings, particularly the magnitude of difference, is hampered by considerable heterogeneity between studies. Nevertheless, patients and clinicians can have moderate certainty that routinely resurfacing the patella at the time of TKA will result in clinically meaningful reduction in anterior knee pain and overall patella-related complications following surgery.

Question 4: In older active patients with osteoarthritis of the knee, is patellar resurfacing associated with differences in reoperation rates as compared to nonresurfacing?

Rationale and clinical comment

The need to undergo reoperation following primary knee replacement surgery is an undesirable outcome for all involved. It is necessarily associated with additional costs for the healthcare payor, and frequently places incremental financial and psychosocial burden on the patient. It also exposes the patient to additional perioperative risks that can have devastating consequences. While patients and surgeons are rarely keen to pursue additional surgery, both may be more willing to consider this when the outcome of index surgery is unsatisfactory. Some authors have suggested that patients with unresurfaced patellae may be more likely to undergo a second operation in an attempt to address persistent postoperative knee pain or otherwise attempt to improve on an unsatisfactory outcome.[1] However, some surgeons may worry that patellar

resurfacing may increase the risk of patellar fracture or other challenging complications that would require reoperation.[1] Given these competing interests, surgeons and patients are likely to want to know whether patellar resurfacing may influence subsequent reoperation rates.

Available literature and quality of the evidence

Ten of the 11 meta-analyses assessed for differences in reoperation rates associated with patellar resurfacing, pooling data from between 10 and 22 individual trials, encompassing between 1003 and 3335 knees.[2,3,5–12] Given this available evidence, no lower-quality studies were used to address this question.

Findings

All 10 meta-analyses found significantly lower reoperation rates in patients who had undergone patellar resurfacing at the time of index TKA. These findings were consistent irrespective of whether the indications were specifically limited to patellofemoral problems (n = 6 studies).[2,5,6,8,9,12] While four studies did not explicitly state any inclusion/exclusion criteria based on reason for reoperation,[3,7,10,11] it is also not clear that all reoperations for any reason were included.

Five studies aggregated reoperation rates across the included trials, consistently finding an absolute difference in reoperation rates of between 3 and 4%.[6–9,12] The reported aggregated reoperation rates with resurfacing ranged from 1 to 4.95%, while those without resurfacing ranged from 4 to 7.8%. Two meta-analyses that assessed absolute risk reduction both reported rates of 4%.[3,5]

Of the nine meta-analyses that reported relative risk, findings ranged from 0.46 to 0.68 in favor of patellar

resurfacing, with 95% CIs remaining below one in all nine.[2,3,5–7,9–12]

Resolution of clinical scenario

The available evidence suggests with high confidence that routine patellar resurfacing is associated with statistically significant and clinically meaningful reductions in reoperation rates for patellofemoral problems following TKA. However, it is less certain from the available evidence whether this holds true for reoperations for any reason. Regardless, surgeons might consider routinely resurfacing the patella at the time of index TKA to decrease the likelihood of subsequent reoperation for patellofemoral pain.

Summary of answers

- Patellar resurfacing in TKA does not appear to be associated with differences in patient-reported outcomes, albeit based on very limited available evidence.
- Patellar resurfacing is not associated with any difference in objective functional outcomes in terms of walking distance, stair climbing ability, and use of a walking aid.
- Patellar resurfacing is associated with meaningfully lower rates of anterior knee pain as supported by moderate quality evidence, and appears to also be associated with lower overall rates of patella-related complications.
- Patellar resurfacing is associated with lower reoperation rates following TKA, particularly for patella-related indications.

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40 Mechanical versus Kinematic Alignment in Total Knee Arthroplasty

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Clinical scenario

- A 65-year-old man with end-stage degenerative knee disease scheduled for total knee arthroplasty (TKA).
- He has slightly bowed lower limbs (varus) and is asking if this will be modified by the surgery.
- He is wondering if there is a TKA technique that could restore his knee anatomy and function.

Top three questions

1. In patients undergoing TKA, does kinematic alignment provide better functional outcomes than mechanical alignment?
2. In patients undergoing TKA, does kinematic alignment (KA) result in different complications compared to mechanical alignment (MA)?

3. In patients with knee degeneration, is KA TKA suitable for all patients' anatomies treated with MA TKA?

Question 1: In patients undergoing TKA, does kinematic alignment provide better functional outcomes than mechanical alignment?

Rationale

A stable knee with a neutral mechanically aligned lower limb MA has been one of the primary surgical aims of TKA,[1] as it provides good long-term implant survivorship.[2] Despite the many improvements in implant design and in the precision of surgery (computer navigation, patient-specific instrumentation and robotics), MA TKA functional outcomes are disappointing (high rates of dissatisfaction and residual symptoms).[3],[4]

Clinical comment

Interest in alternative, more anatomical, surgical techniques like the kinematic alignment (KA) TKA has recently re-emerged,[5] with the hope they would provide better knee kinematics and functional outcomes than MA TKA.

Available literature and quality of the evidence

- Level I: 2 meta-analyses and 4 randomized trials.
- Level II: 1 randomized trial with methodologic limitations.
- Level III: 3 case-control studies.

Findings

At one or two years' follow-up, three randomized controlled trials (RCTs)[6–8] found better clinical scores (Knee Society Score [KSS] and Western Ontario and McMaster Universities Osteoarthritis Index [WOMAC]) with KA TKA, while two others found no significant difference.[9,10] The KA technique demonstrated quicker recovery (measured by the KSS and WOMAC scores), higher rates of forgotten knee, and lower rates of residual pain.[6–8] Five meta-analyses including the above RCTs have also demonstrated improved functional outcomes according to WOMAC, Oxford Knee Score (OKS), and KSS scales, and increased knee flexion with KA compared to MA.[11–15] Another meta-analysis limiting the analysis to studies including patient-specific instruments did not find a difference.[16] None have found improved outcomes for MA.

Mechanical alignment is known to modify knee kinematics and gait.[17] A case-control study demonstrated that MA TKAs displayed several significant knee kinematic differences to a healthy group: less sagittal plane range of motion, decreased maximum flexion, increased adduction angle, and increased external tibial rotation. Conversely, there was no significant knee kinematic differences between KA and healthy knees. The postoperative Knee injury and Osteoarthritis Outcome Score (KOOS) was significantly higher in the KA group compared to the MA group. Similarly, Niki et al. in a matched study of KA and MA TKAs found an increased knee adduction moment in the MA group.[18] Another gait study by McNair et al., however, found little difference between KA and MA.[19]

Resolution of clinical scenario

- With the studies available, KA demonstrates improved clinical outcomes scores at 1–2 years postoperatively compared to MA.
- MA does not replicate normal knee kinematics and gait.
- There is level III evidence that found KA to better replicate healthy knee kinematics.

Question 2: In patients undergoing TKA, does kinematic alignment (KA) result in different complications compared to mechanical alignment (MA)

Rationale

One of the concerns about performing KA TKA is that it might be associated with an increased risk of early failure and other complications. It is therefore important to assess the evidence regarding complications in KA versus MA TKA.

Clinical comment

When considering a new technique for surgery, it is important to compare its clinical performance with the current standard of practice.

Available literature and quality of the evidence

- Level I: 2 meta-analyses and 5 randomized trials.
- Level II: 1 randomized trial with methodologic limitations.
- Level III: 2 case control studies.

Findings

A meta-analysis of an aggregated 877 kinematic TKAs reported a cumulative survivorship of 97.4% at a weighted mean follow-up of 37.9 months.[12] The most common reasons for revision were patellofemoral problems in eight patients (1.2%). There was no difference reported in the complication rate between 229 KA and 229 MA TKA patients (3.9% vs 4.4%, p = 0.83). A second meta-analysis had the same findings.[11]

There were no significant differences in the complications rates seen between the MA and KA groups in all five RCTs at a follow-up of 1–2 years, although all these trials were underpowered to assess the early complication rate.[6–10]

To estimate tibial component long-term survivorship with KA TKA, Laende et al. used radiostereometric analysis in an RCT comparing tibial component migration of TKAs implanted with patient-specific instrumentation targeting kinematic alignment (n = 24) versus components placed using computer-assisted surgery targeting neutral mechanical alignment (n = 23).[20] They found no difference over two years in longitudinal migration of the tibial component between the two groups (reaching median maximum total point motion migration at two years of 0.40 mm for the KA group and 0.37 mm for the MA group, p = 0.82; p = 0.68 adjusted for age, sex, and body mass index [BMI] for all follow-ups). Both groups had mean migrations below acceptable thresholds. There was no difference in inducible displacement (p = 0.34) or patient-reported outcome measures (PROMS) (p = 0.61 for the OKS). Their findings support that KA is a viable option with no evidence that it compromises fixation.

A retrospective review of a single surgeon's database of 2725 TKAs with a minimum follow-up of two years

contained eight patients (0.3%) that presented with tibial component failure.[21] These patients were compared to 24 matched cohort patients to determine the cause of failure. Patients with tibial component failure had a significantly greater BMI (6 kg/m^2; p = 0.034) and greater posterior slope of the tibia component than controls (11° ± 3.1 vs 6° ± 2.7, p = 0.002). There was an increase in the varus position of the tibial base plate in the group with component failure, but this was not statistically significant (4° ± 2.7 vs 2° ± 2.3, p = 0.07).

Resolution of clinical scenario

- Although all RCTs are underpowered to assess with confidence the early complication rate, no obvious increase is seen with KA TKA.
- No RCT has long enough follow-up to evaluate implant survivorship.
- Further long-term follow-up studies are required.

Question 3: In patients with knee degeneration, is KA TKA suitable for all patients' anatomies treated with MA TKA?

Rationale

There are concerns that KA alignment techniques may not be appropriate for extreme patient anatomies. In particular, whether restoring severe constitutional limb valgus or varus, femorotibial joint line obliquity or varus obliquity of the tibial plateau might affect clinical outcomes and/or implant survivorship.

Clinical comment

It is important to know if KA is safe to use for all patients and define those, if any, for which the technique should be modified or avoided.

Available literature and quality of the evidence

- Level I: 4 randomized trials.
- Level II: 2 randomized trial with methodologic limitations.
- Level IV: 5 case series.

Findings

There is currently little clinical evidence about which particular knee anatomies might not be suitable for KA technique. The fundamental premise of KA TKA is to restore the pre-arthritic knee alignment and kinematics. Patients in which disease has modified the knee or lower limb anatomy to such an extent that it cannot be restored by TKA would therefore not be appropriate candidates for KA TKA. Authors have suggested extra-articular deformity, post-traumatic joint modifications, collateral ligament insufficiency, patellar instability, and severe fixed contracture may be contraindications to KA TKA.[22–24] We found no evidence that severe constitutional limb valgus or varus, femorotibial joint line obliquity, or varus obliquity of the tibial plateau might affect clinical outcomes (functional score and implants survivorship) in KA TKA.

Howell et al. looked at 222 KA TKAs at 10 years post-surgery.[25] Implant survivorship was 97.4% for any reason and 98.4% for revisions exclusively for aseptic failure at 10 years. They found no correlation of survival with postoperative limb alignment classified as varus outlier,

valgus outlier, or in-range. There were also no clinical differences seen with tibial components placed in varus alignment.

In their RCT, Calliess et al. found no correlation between preoperative deformities and postoperative outcomes; however, the authors only included mild to moderate deformities (<10° frontal limb deformity and <4° tibial implant obliquity relative to the tibial mechanical axis).[7]

Young et al. reported that 31% of tibias were in >5° varus alignment compared with 4% in the MA group, yet they detected no increase in complications at two-year follow-up.[9] They, however, excluded patients with >15° of varus or valgus deformity preoperatively. Waterson et al. similarly excluded patients with a varus or valgus deformity >10° in their trial.[10] In the RCT by Dossett et al. the range of deformities was only from 11.4° valgus to 9.3° varus.[6] Therefore, most of the trials assessing kinematic alignment do not include extreme anatomies. Almaawi et al. analyzed preoperative CT scans of 4884 patients undergoing TKA and demonstrated the hip–knee–ankle angle (HKA) was >5° in 19% and >10° in 3% of them.[23] It is in these 3% of patients with extreme anatomy that strict kinematic alignment may not be appropriate.

A number of recent case series looking at outcomes from MA TKA have reported no significant difference in long-term survivorship when the postoperative HKA is within ±3° of neutral compared to malaligned knees.[26–28]

Restricted KA protocols have been suggested for patients with extreme anatomies.[20] There is currently little evidence to support their use.

Resolution of clinical scenario

- RCTs of KA to date have not displayed correlation between preoperative deformities and postoperative outcomes at short-term follow-up.
- Many of the trials, however, excluded patients with extreme anatomies.

Summary of answers

- The KA technique generally results in higher functional scores in comparison to the MA technique.
- Early complication rates are comparable to the MA technique.
- There is minimal evidence to support KA use in all patient anatomies.
- Longer follow-up is needed to assess survivorship and define the correct indications for KA techniques in TKA.

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41 Ligament Balancing in Total Knee Arthroplasty

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Top three questions

1. In subjects without knee pathology, what are the normal collateral ligaments' tensions/laxities during range of motion?
2. In patients with knee degeneration treated with a total knee arthroplasty (TKA), do those with greater ligament stability, compared to those with laxer ligaments, have better clinical results?
3. In patients with knee degeneration treated with a TKA, do some surgical techniques, compared to others, achieve better ligament balance and knee stability?

Question 1: In subjects without knee pathology, what are the normal collateral ligaments' tensions/laxities during range of motion?

Rationale

Understanding the laxity of the collateral ligaments of the native knee, in extension and flexion, may help surgeons to avoid undesirable outcomes following TKA. It may allow for the improvement of implant designs and for the modification of surgical techniques to better restore or preserve the tension of native ligaments.

Clinical comment

With the traditional use of nonanatomical alignment methods and implants in TKA, it is unknown whether the ligament laxities following TKA should replicate the values observed in native knees in order to provide improved knee function, patient satisfaction, and implant survivorship.

Available literature and quality of the evidence

Nine studies that evaluated laxities of the collateral ligaments in the arc of motion of normal knees were identified. These studies are descriptive in nature, using a limited number of living subjects, cadaveric specimens, or reconstructed three-dimensional (3D) models. Quality of evidence: level IV. Moreover, protocols and methods to assess the ligaments' behavior were very different from one study to the next.

Findings

Both collateral ligaments were found to be tighter in extension than in flexion. Comparing both collaterals in extension, a looser lateral collateral ligament (LCL) was reported. This difference in side-to-side LCL laxity increased with greater flexion.[1–9] During knee flexion, a tighter medial collateral ligament (MCL) with a laxer LCL results in posterior translation of the lateral condyle over the lateral tibial plateau, creating internal rotation of the tibia with a medial pivot center of rotation.[4,7,10–12] This internal tibial rotation allows higher postoperative knee flexion[13] and reduces pressure on the patella.[14,15] In papers comparing males and females, females tend to have laxer ligaments than males.[1–8,10,16]

Many authors evaluating collateral ligament laxities identify that MCL tightness plays a major role in native knee function and stability.[4,7,10–12] In addition to its function as the major valgus stabilizer, the deep MCL has a significant role in knee rotational stability, especially with a ruptured or sacrificed anterior cruciate ligament (ACL).[14,16–18] The knee's collateral ligaments laxities are rarely modified in knees with less than 15° of deformity.[19] The biomechanics of a knee that has undergone TKA are different from those of a normal knee. It is therefore unknown if ligament tension values aimed for during TKA should be the same values that are measured in normal knees. Some authors suggest that medial soft tissue releases or femoral component external rotation may loosen the MCL and affect TKA outcomes.[9,14]

Resolution of clinical scenario

- In normal knees, both collateral ligaments are tighter in extension than in flexion, with the LCL laxer than the MCL with increased flexion.

- The MCL plays a major role in valgus and rotational knee stability, especially in the presence of a deficient or sacrificed ACL.
- Medial soft tissue releases when performing a TKA, which leads to increased MCL laxity, which may have a significant impact on postoperative knee function.

Question 2: In patients with knee degeneration treated with a total knee arthroplasty (TKA), do those with greater ligament stability, compared to those with laxer ligaments, have better clinical results?

Rationale

TKA with mechanical alignment (MA) may not replicate collateral ligament laxity/tensions observed in the native knee. Often, surgeons must perform collateral ligament release to adjust the mediolateral (M/L) and flexion/extension balance. Is there clinical evidence that a certain level of collateral ligament laxity and M/L or flexion/extension imbalance would impact patients' function and satisfaction?

Clinical comment

Understanding the postoperative correlation between ligament balance and clinical results may help surgeons to improve their surgical technique, thereby improving their patients' results.

Available literature and quality of the evidence

- 1 level III and 4 level IV studies that evaluated the correlation between ligamentous laxity and clinical and functional outcome were identified in the literature.
- 2 level IV studies that evaluated the extent of acceptable ligamentous laxity were also identified.

Findings

Knee instability after TKA is considered the second most common cause of revision surgeries, with rates varying from 21 to 35%.[20,21] An unbalanced knee is defined as failure to balance the soft tissue envelope to obtain a rectangular flexion and extension gap. Residual imbalance was associated with loosening, polyethylene wear, and failure.[22,23]

Looking at the relation between patient outcomes measured by clinical scores and ligament balance, an M/L gap difference of <3 mm, using an intraoperative tensor and navigation, provided better Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) scores than larger gaps (84.9 ± 18 vs 74.8 ± 20.8, p = 0.017) in 108 TKA patients.[24] Using a knee balancer in 526 TKAs and defining the unbalanced knee with an M/L difference of more than 3°, a significant difference was found between balanced and unbalanced knees regarding the change in the clinical rating knee score for the extension and flexion balance (t-test, p = 0.046; and ANOVA, p = 0.001, respectively). On the other hand, the authors did not find a significant difference in the change in the Oxford Knee Score.[25]

In a multicenter study involving 176 TKAs, the use of intraoperative pressure sensors helped distinguish balanced from unbalanced knees. Balanced knees were defined as having M/L intercompartmental loading difference ≤15 lb through a range of motion. At six months

postoperatively, balanced patients showed significantly better WOMAC (14.5 vs 23.8, p = 0.0001) and Knee Society Score (KSS) scores (172.4 vs 145.3, p = 0.0001) compared to unbalanced knees.[20] Conversely, a study comparing medial/lateral compartmental force ratio and total contact force found no correlation with functional scores at one year in a cohort of 101 TKAs.[26]

Regarding range of motion and ligament laxity, in a study of 63 TKAs, 78% of slightly loose knees reached more than 100° of flexion compared to 62.5% of tighter knees.[27] Evaluating bilateral TKA patients with different postoperative contralateral laxities (evaluated with stress radiographs, >3° opening was considered loose), 10/11 patients preferred the loose side compared with 11/22 who preferred the other side ($p < 0.05$).[28] Evaluating anteroposterior laxity at 75° of flexion in 93 TKAs, patients with knee laxity >10 mm had significantly inferior KSS (77.0 vs 55.3, p = 0.05) and knee flexion (99° vs 112°, p = 0.01).[29]

Computer navigation may be predictive of the need for ligament release and may reduce systematic over-release.[30] On the other hand, surgeons' appreciation of ligament balance by feeling was shown to be very limited. Without special instruments, the surgeon's perception of balance depends on surgical training, operative experience, and overall skill, but it may be influenced by different patient factors, such as body mass index, gender, and comorbidities.[31],[32]

Resolution of clinical scenario

- It is still not clear what maximal M/L gap difference is acceptable/desirable.

- An unstable TKA is linked with increased complication and revision rates.
- Better M/L balanced TKAs seem to provide higher clinical scores.
- A looser well-balanced TKA seems to be better tolerated by patients than a tighter TKA.

Question 3: In patients with knee degeneration treated with a TKA, do some surgical techniques, compared to others, achieve better ligament balance and knee stability?

Rationale

Numerous TKA surgical techniques have been described to adjust implant position and help balance collateral ligaments in flexion and extension. Determining if one technique is more efficient and/or provides better clinical results would help surgeons performing TKA to obtain better outcomes for their patients.

Clinical comment

Normal knees do not have symmetric M/L collateral ligament balance. Most techniques have been developed for the MA method and aim at creating rectangular extension and flexion gaps.

Available literature and quality of the evidence

- 3 level I and 1 level IV articles compared the difference between measured resection (MR) and gap balancing (GB) techniques.

- 1 level III article on pressure sensors.
- 1 level II article on navigation.
- 4 level I randomized controlled trials (RCTs) and 1 level II RCT with methodologic limitations were found comparing the kinematic alignment (KA) technique and MA method.

Findings

With MA, two main techniques have been used: GB and MR.[33] GB relies on soft tissue release followed by appropriate femoral bone cuts to obtain balanced rectangular gaps in flexion and extension, whilst MR uses anatomical landmarks (the anteroposterior axis, the transepicondylar axis, and the posterior femoral condylar surfaces) to guide bone resection, followed by soft tissue releases to balance the flexion/extension spaces.[29,32]

Comparing implant position and orientation between the two techniques, a meta-analysis found that GB gives significantly better femoral axial ($p < 0.0001$) and rotational alignments ($p = 0.007$) but was associated with more the joint line elevation ($p < 0.00001$).[34] Evaluating ligament balance obtained with GB or MR, a meta-analysis found similar results for both techniques, except for the mean extension gap M/L difference, which was greater in patients undergoing MR technique (0.58 mm; $p = 0.008$). With GB technique, the femoral component was more externally rotated by less than 1° and the joint line was higher by 1 mm. Authors concluded that both methods were equally efficient to balance collateral ligaments.[35] Precise estimation of the ligament balance is difficult to perform during surgery.[31] Different tools, such as balancers, computer navigation, or pressure sensors, have been tested to improve the accuracy of GB and MR techniques. Using

computer navigation on 225 knees, Fickert et al. obtained rectangular gaps with ±3 mm M/L difference in 98% of the cases for the extension gap and 93% of the cases for the flexion gap.[36] Using intraoperative pressure sensors during TKA, M/L pressures within 15 lb of intercompartmental force were obtained in 15% (n = 29); 57% (n = 107) were balanced between 15–75 lb, and 28% (n = 53) with >75 lb of force difference. In this study, greater improvement in the University of California Los Angeles activity level was associated with a M/L force difference <60 lb (p = 0.006), but no correlation was found with KSS objective, function, and satisfaction scores. With a specific knee gap balancer, TKAs were balanced within a M/L difference of 3° or less in 175/218 (80%) knees for the flexion space and 214/218 (98%) knees for the extension space.[25]

Comparing patient outcomes between the MR and GB techniques, a randomized study of 24 single radius posterior-stabilized TKAs found no differences for the WOMAC (p = 0.15) or KSS (p = 0.06), and no difference regarding the frequency of liftoff, were observed.[37] A meta-analysis found that GB gives statistically significant higher KSS (p = 0.04) and KSS Function Score (p <0.0001).[34] A systematic review and meta-analysis of 2259 TKAs concluded that total outliers were lower with GB (risk ratio = 1.72; p = 0.0004) but the two techniques were comparable in range of motion, WOMAC, complications, and revision rate.[38]

Evaluating 1000 lower limb CT scans of patients scheduled for TKA, Blakeney et al. found MA bone resections created significant gap imbalances.[39] Extension space imbalances (≥3 mm) occurred in 25% of varus and 54% of valgus knees and severe imbalances (≥5 mm) were present in up to 8% of varus and 19% of valgus knees. Only 49% of varus and 18% of valgus knees had <3 mm of imbalance throughout

the extension and flexion spaces and medial and lateral compartments. MA techniques such as MR or GB, aimed at rectangular and equal extension and flexion gaps, do not consider the natural higher laxity of the LCL and the increased laxity of the collaterals in flexion.[3,40] Only KA technique aims to maintain/restore the native ligament laxities and joint orientation.[41] Three RCTs found better clinical scores (KSS and WOMAC) with KA,[42–44] while two others found no significant difference.[45,46] Three meta-analyses demonstrated better WOMAC and KSS scores, and increased knee flexion with KA compared to MA,[47–49] while one which limited their analysis to RCTs using patient-specific instruments did not find a difference.[50]

Resolution of clinical scenario

- It is still not clear from the literature what the ideal collateral ligament laxities and joint spaces should be during TKA, especially with current TKA implant designs and MA.
- M/L ligament balance is difficult to estimate during surgery; different tools like knee balancers, computer navigation, or pressure sensors can be used to improve accuracy of GB and MR techniques.
- Comparing GB and MR efficacy to balance joint spaces, no conclusion can be drawn regarding the superiority of one technique over the other.
- KA aims at preserving/restoring native knee collateral ligament laxities and was found to improve clinical scores in comparison to MA.

Summary of answers

- The collateral ligaments play a significant role in knee balance post TKA and should be carefully considered intraoperatively.
- No conclusions can be drawn about gap balancing versus measured resection for achieving mediolateral balance.
- Mediolateral balance is important, but it is unclear what the optimal parameters are.

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42 Robotics in Total Knee Arthroplasty

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Clinical scenario

- You see a 59-year-old female patient in your office who has advanced knee osteoarthritis, primarily in the medial compartment. Her symptoms are limited to the medial compartment and no longer respond to conservative treatment. Her quality of life is also compromised as a result of her symptoms.
- She is interested in her surgical options, and has heard about “robotic surgery” in the news. She asks you about arthroplasty options, including replacing “just the arthritic compartment.”
- As the chief executive officer (CEO) of a different hospital, she is also curious about the impacts of robotic-assisted surgery at a hospital level.

Top three questions

1. In patients undergoing knee arthroplasty, does robotic-assisted surgery result in more accurate component positioning compared to conventional knee arthroplasty?
2. In patients undergoing knee arthroplasty, does robotic-assisted surgery result in improved patient-centered

outcomes compared to conventional knee arthroplasty?

3. In patients undergoing knee arthroplasty, is robotic-assisted surgery cost-effective compared to conventional knee arthroplasty?

Question 1: In patients undergoing knee arthroplasty, does robotic-assisted surgery result in more accurate component positioning compared to conventional knee arthroplasty?

Rationale

One of the most promising aspects of robotic-assisted knee arthroplasty is the achievement of more accurate component positioning by eliminating human error and variability. Thus, it is important to understand if, and by how much, robotic-assisted surgery improves accuracy.

Clinical comment

Despite improvements in technology and technique,[1] about one in five patients undergoing total knee arthroplasty (TKA) are unsatisfied, usually due to persistent postsurgical pain and stiffness.[2] The knee is a complex joint, with simultaneous rotation, pivot, and translation in multiple planes throughout its range of motion.[3] As well, proprioception in the knee is an important aspect of balance, gait, and overall lower limb function.[4] The ability to precisely determine patient-specific bone cuts and implant positioning, while preserving native anatomy may help to create a knee that feels and behaves more like the patient's native knee, thereby resulting in improved

satisfaction. Robotic-assisted surgery has the potential to achieve this level of accuracy.

Available literature and quality of the evidence

Multiple randomized controlled trials (RCTs) have investigated the impact of robotic-assisted surgery on the accuracy of final component position. In 2007, Park et al. reported the results of the one of the earliest studies on robotic knee arthroplasty (level I).[5] They randomized 72 patients to robotic or conventional TKA. They found no difference in the overall mechanical axis alignment between the two groups, but did find that components placed using the robotic-assisted technique were significantly more accurate in terms of component axis and alignment. Similarly, Song et al. (level I) randomized 100 patients to robotic-assisted versus conventional TKA.[6] They found no significant difference between the two groups in terms of overall mechanical axis alignment or tibial component positioning between the two groups. Femoral prosthesis alignment in the coronal plane was significantly more accurate in the robotic-assisted group compared to the conventional group. In addition, there were significantly fewer outliers in terms of mechanical axis alignment in the robotic-assisted group compared to the conventional group (0% vs 24%, $p < 0.001$).[6] Liow et al. randomized 60 patients to robotic or conventional TKA (level I).[7] Once again, they reported no significant difference in terms of mechanical axis alignment, but did find significantly higher rates of coronal plane outliers and femoral notching in the conventional group. In addition, the robotic-assisted group had significantly more accurate restoration of the joint line compared to the conventional group (3.2% shift vs 20.6% shift, $p = 0.001$).[7]

The same appears to be true for unicompartmental knee arthroplasty (UKA). Bell et al. (level I) randomized 139 patients to conventional or robotic UKA. They found that there were significantly fewer errors in component positioning for all components and in all planes.[8]

Findings

Overall, level I evidence suggests that robotic-assisted knee arthroplasty is significantly more accurate than conventional surgery in terms of component positioning, but it does not affect overall mechanical axis alignment.[5–8] There are limitations in postoperative alignment assessment using only plain radiographs, as these measurements are affected by lower limb loading, rotation, and flexion angles. Importantly, most studies report significantly fewer outliers in terms of component positioning with robotic surgery compared to conventional surgery.[6,7] Further, most clinicians' assessments of TKA alignment are based primarily on the coronal plane with less attention given to sagittal plain alignment. Robotic-assisted surgery may be particularly important in patients with significant deformity or bone loss. While conventional surgery may still allow the achievement of an acceptable mechanical axis, accurate component positioning is significantly more difficult in these patients due to the loss of normal anatomical landmarks.

Resolution of clinical scenario

- Level I evidence suggests that robotic-assisted knee arthroplasty *does* result in significantly more accurate component positioning, joint line restoration, and fewer outliers; this is true for both UKA and TKA.
- Level I evidence suggests that robotic-assisted TKA *does not* result in significantly different mechanical axis

alignment.

Question 2: In patients undergoing knee arthroplasty, does robotic-assisted surgery result in improved patient-centered outcomes compared to conventional knee arthroplasty?

Rationale

With robotic-assisted surgery, there is the potential for less invasive, more tissue-friendly, and more patient-specific surgical techniques. Do these technical improvements then translate into the potential for patients to experience faster postoperative recovery and better functional outcomes? It is important to understand if this potential is borne out in clinical practice.

Clinical comment

As with any new healthcare intervention, it is crucial to understand the impact on patient outcomes. Robotic-assisted prostatectomy is one of the first widely used robotic surgical procedures, and has shown promise for improving patient-important outcomes. A recent meta-analysis found that robotic-assisted prostatectomy was associated with better outcomes in terms of blood loss, nerve injury, urinary incontinence, and erectile dysfunction compared to open or laparoscopic surgery.[9] As well, studies of minimally invasive surgery across different surgical specialties have consistently demonstrated lower levels of postoperative pain and faster recovery with less invasive techniques.[10–12] It is important to understand which, if any, of these potential benefits can be expected with current robotic-assisted knee arthroplasty technology.

Available literature and quality of the evidence

A prospective cohort study (level II) by Kayani et al. compared 20 patients undergoing robotic-assisted TKA with 20 patients undergoing conventional TKA.[13] They reported that patients undergoing robotic surgery had significantly lower pain scores and opioid requirements on each of the first three days after surgery. As well, patients in the conventional group had a significantly greater drop in postoperative hemoglobin values compared to the robotic-assisted group. In addition, patients in the robotic-assisted group were discharged over a full day earlier on average compared to the conventional group (delta 28 hours, $p < 0.001$). Finally, at time of discharge, patients in the robotic-assisted group had significantly faster attainment of physiotherapy targets, specifically straight leg raise and maximal knee flexion ($p < 0.001$).

Multiple RCTs have assessed the impact of robotic-assisted TKA on patient-reported outcomes during outpatient follow-up. In their RCT of 72 patients (level I), Park et al. followed patients for approximately four years after surgery. They found no difference between robotic-assisted TKA patients and conventional TKA patients in terms of Knee Society Score (KSS) or range of motion at final follow-up.[5] Song et al. randomized 100 patients to robotic versus conventional TKA (level I), and found that at a final follow-up of 3.5 years, there were no significant differences between the two groups in terms of Hospital for Special Surgery Knee score, Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) score, or range of motion.[6] Similarly, in their RCT of 60 patients (level I), Liow et al. found no significant differences between robotic-assisted and conventional group patients in terms of KSS, Oxford Knee Score (OKS), or overall patient satisfaction. Interestingly, they did find significantly higher scores on

the SF-36 vitality and role emotional subscales for patients in the robotic-assisted group.[14]

Evidence from an RCT has reported similar findings for robotic-assisted UKA. Gilmour et al., in their RCT of 139 patients (level I), found no significant differences in KSS or OKS scores at two-year follow-up.[15] Data from the same RCT, however, found that patients in the robotic-assisted group had significantly lower pain scores in the first eight postoperative weeks compared to patients in the conventional group ($p = 0.04$).[16] Evidence from a recent RCT of 120 patients (level I) found that patients undergoing robotic-assisted UKA had greater knee excursion between foot-strike and mid-stance (18.0° vs 15.7°, $p = 0.04$) compared to conventional UKA. There were no significant differences in terms of total knee excursion, or excursion from midstance to terminal stance.[17] It is unclear if this small magnitude change in one specific phase of the gait cycle has any patient-important benefits.

Findings

Overall, weak level II evidence, based on a study with a small sample size demonstrates that in the acute and subacute postoperative period, patients undergoing robotic-assisted TKA experience a smaller drop in hemoglobin, lower pain scores and analgesic needs, faster functional recovery, and are discharged earlier compared to those undergoing conventional TKA surgery.[13] Similarly, a single level I study with fewer than 100 patients per arm, suggests that patients undergoing robotic-assisted UKA surgery had significantly lower pain scores in the subacute postoperative period compared to patients undergoing conventional UKA surgery.[16] These conclusions should be

viewed with much caution given the limited sample sizes and quantity of studies.

In contrast, multiple level I studies demonstrate that at two to five years after surgery, there are no significant differences in patient-reported outcomes for those undergoing conventional TKA or UKA compared to those undergoing robotic-assisted surgery, with the exception of some subscales of the SF-36.[5,6,14,18]

Resolution of clinical scenario

- A single, small, level II evidence study suggests that robotic-assisted TKA *may* result in less pain, faster functional recovery, and shorter inpatient stay compared to conventional TKA surgery.
- Based on a single level I evidence study, patients undergoing robotic-assisted UKA *may* have lower pain scores in the subacute postoperative period compared to conventional UKA.
- Multiple level I studies suggest that robotic-assisted TKA *does not* result in significantly different patient-reported outcomes at two to five years postoperatively.

Question 3: In patients undergoing knee arthroplasty, is robotic-assisted surgery cost-effective compared to conventional knee arthroplasty?

Rationale

As with any new healthcare technology, there are concerns regarding the impact of incorporating robotic-assisted surgery, particularly with regards to the cost of new

devices and additional preoperative investigations. It is important to understand the short- and long-term cost implications of any proposed healthcare technology.

Clinical comment

In order to deliver healthcare effectively, it is important to consider the impact of any new intervention at both the patient level and the systems level. In an era of rising healthcare costs,[19] the micro- and macrolevels of healthcare are more intimately linked than ever. In addition to understanding the discrete cost of incorporating a new technology, it is important to consider complications, learning curves, and impact on operative resources in an effort to gauge the overall cost-effectiveness of the intervention.

Available literature and quality of the evidence

Evidence from RCTs has produced mixed results in terms of differences in operative time for robotic versus conventional TKA. Liow et al. found no difference in operative time between the two groups in their RCT of 60 patients (level I).[14] In contrast, Song et al. (level I) found significantly longer operative times by 25 minutes in the robotic-assisted group compared to the conventional group ($p < 0.001$).[6]

Evidence from a case series (level IV) demonstrates that the learning curve required for robotic-assisted TKA is about 20–40 cases for each surgeon, after which time there are no significant differences in operative time between robotic-assisted and conventional surgery. The authors suggested that early in the learning curve there was likely to be increased cost due to longer operative times and less expertise, though this was not assessed empirically.[20] For UKA, level II evidence demonstrates a learning curve of

only six cases to reach the same operative time as conventional surgery.[13]

Based on a Markov decision analysis (level II), robotic-assisted UKA was determined to be cost-effective in high-volume UKA centers (>94 cases/year), but not in lower volume centres.[21] No peer-reviewed, evidence-based economic analysis is available for robotic-assisted TKA. There is, however, a registered prospective cohort study that is underway with the specific goal of answering this question.[22]

Evidence from RCTs (level I) has demonstrated no difference in complication rates between robotic-assisted versus conventional knee arthroplasty; this is true for both TKA[6],[7] and UKA.[18] Finally, as mentioned above, level II evidence has found that patients undergoing robotic-assisted surgery are discharged over a full day earlier than those undergoing conventional surgery.

Findings

Overall, there is a lack of direct, evidence-based economic analysis to help determine whether robotic-assisted TKA is cost-effective. There is, however, level I–IV evidence that, when considered together, suggests that cost-effective robotic-assisted TKA is an attainable goal. Specifically, limited level I and II evidence has thus far shown a short learning curve for robotic UKA,[13] and has found that robotic UKA may have the potential to be cost-effective in high-volume centres.[21] Furthermore, complication rates and operative times are not significantly different between robotic and conventional knee arthroplasty, particularly once the learning curve has passed.[6],[7],[14],[18] Finally, robotic-assisted surgery may lead to shorter inpatient stays following knee arthroplasty. Taking into consideration this body of evidence, it is hypothesized that robotic-assisted

TKA can be cost-effective in high-volume TKA centers, though empirical economic analysis is needed to confirm this.

Resolution of clinical scenario

- A single study (level II evidence) demonstrated that robotic-assisted UKA *may* be cost-effective in high-volume centers (>94 cases/year).
- Level I evidence demonstrated *no difference* in complication rates for robotic versus conventional TKA or UKA.
- Level I evidence demonstrated *mixed evidence* regarding operative times for robotic versus conventional TKA, with some studies reporting longer times for robotic surgery, while others report no significant difference between the two.

Summary of answers

- Robotic-assisted knee arthroplasty results in more accurate component placement compared to conventional surgery, but it does not impact overall mechanical axis alignment.
- Based on very few, small studies, patients undergoing robotic-assisted knee arthroplasty may experience faster functional recovery, shorter inpatient stays, and lower pain levels in the acute and subacute postoperative periods, though larger studies are needed to truly assess this issue.
- There is no significant difference on the majority of patient-reported outcome measures at medium-term follow-up.

- Complication rates and operative times are similar between robotic-assisted and conventional knee arthroplasty after a brief learning curve.
- Based on a recent economic analysis, robotic-assisted UKA is cost-effective in large-volume UKA centers.

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43 Patient-Specific Instrumentation in Total Knee Arthroplasty

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Clinical scenario

- You see a 65-year-old male patient in your office with tricompartmental knee osteoarthritis. He is quite symptomatic and is no longer responsive to nonoperative management.
- He is interested in total knee arthroplasty (TKA), and has heard about “personalized” implants on social media. He would like to know if such implants are better than standard implants.
- When you ask your company representative about patient-specific instrumentation (PSI) options, she tells you that some systems use computed tomography (CT), while others use magnetic resonance imaging (MRI). You wonder if there is a difference between the two.

Top three questions

1. In patients undergoing TKA, does PSI result in better radiographic outcomes compared to standard instrumentation?
2. In patients undergoing TKA, does PSI result in better functional outcomes compared to standard instrumentation?

3. In patients undergoing TKA with PSI, are CT-based PSI systems more accurate than MRI- based PSI systems?

Rationale

PSI has increased in popularity in recent years as orthopedic surgery responds to the growing trend of *personalized medicine*. This technology utilizes the patient's own anatomy, as visualized on advanced imaging, to create anatomically matched instruments, such as cutting jigs, to be used in that patient's operation. The hypothesized advantages of PSI are preoperative planning to minimize bony resection thus resulting and more accurate component positioning compared to standard instrumentation.[1]

Clinical comment

Overall, TKA is quite successful. A recent systematic review of 208 studies found that the majority of studies reported a patient satisfaction rate of 81–90% as measured by a response of “satisfied” or “very satisfied” on a five-point Likert scale. The median rate of satisfied patients was 88.9%.[2] Nonetheless, this leaves 10–20% of patients who undergo a major elective operation that are not satisfied with their outcome. It has been hypothesized that this may be due, at least in part, to component malpositioning, which occurs in up to 40% of cases.[3] PSI has the theoretical benefit of making accurate alignment technically easier, but it is important to understand whether this benefit is supported by evidence.

Available literature and quality of the evidence

Multiple randomized controlled trials (RCTs) have compared PSI to standard instrumentation in terms of radiographic outcomes. A recent meta-analysis of RCTs

(level I) analyzed 23 RCTs published before March 2018, involving a total of 2058 knees, with all patients randomized to either PSI or standard instrumentation.[1] A number of radiographic measures were used to judge component position accuracy, and most commonly included: hip–knee–ankle axis (HKA), coronal, sagittal, and axial alignment of the femoral component, and coronal and sagittal alignment of the tibial component. No new RCTs have been published since the aforementioned meta-analysis was performed and this publication was produced.

Findings

Based on the pooled estimate from trials assessing HKA as an outcome, there was no significant difference between PSI and standard instrumentation in terms of >3° deviation from target alignment (180°) or number of outliers. In fact, only 1 out of 14 trials found a significant difference in number of HKA outliers, favoring PSI.[1]

Coronal alignment of the femoral component was assessed in 13 RCTs. Meta-analysis revealed no significant difference between PSI and standard instrumentation patients with regards to absolute deviation from target alignment (90°) or number of outliers. Similarly, the sagittal alignment of the femoral component, from eight RCTs, was not found to be significantly different between the two groups in terms of absolute deviation or outliers. When assessing axial alignment of the femoral component, there was no significant difference between the two groups in terms of number of outliers. There was, however, a significant difference in terms of absolute deviation from target alignment (mean difference: −0.46, $p = 0.0004$, $I^2 = 48\%$). In the context of moderate heterogeneity ($I^2 = 48\%$, $p = 0.05$), this finding should be interpreted with caution.[1]

Tibial component alignment was also assessed in the sagittal (nine RCTs) and coronal (14 RCTs) planes. There was no significant difference either in terms of absolute deviation from the desired target (90°) or in terms of outliers.[1]

Overall, there are a large number of RCTs which have assessed whether PSI improves component positioning accuracy. Though each RCT in isolation must be interpreted with caution (no study randomized 100 or more patients per arm), a recent meta-analysis of these RCTs (level I) provides fairly robust data overall. There are clearly limitations in the postoperative measurement of component alignment. This produces a static image which does not account for changes during weightbearing or range of motion. Nonetheless, the best available evidence suggests that the use of PSI does not result in significantly more accurate tibial component positioning. For the femoral component, PSI may have a small effect (~0.5°) on axial alignment, but not sagittal or coronal alignment.

Interestingly, computer-assisted navigation and robotic-assisted total joint replacement surgery do appear to result in more accurate component positioning. Refer to the following chapters in this book for further details: “The Role of Computer Navigation in Total Hip Arthroplasty” (Chapter 21), “Mechanical versus Kinematic Alignment in Total Knee Arthroplasty” (Chapter 40), and “Robotics in Total Knee Arthroplasty” (Chapter 42).

Resolution of clinical scenario

- Level I evidence suggests that PSI *does not* result in significantly more accurate component positioning compared to standard instrumentation for most parameters.

- The only radiographic benefit of PSI *may* be in terms of the axial alignment of the femoral component, though the effect size is small and associated with moderate heterogeneity.

Question 2: In patients undergoing TKA, does PSI result in better functional outcomes compared to standard instrumentation?

Rationale

Underpinning all efforts to improve TKA is the ultimate goal of improving patient outcomes and satisfaction rates. Though there is a theoretical reason to believe that more accurate component positioning is possible with PSI, further evidence is required to assert that PSI improves outcomes. Thus, it is critical to understand whether PSI confers any clinical benefit in terms of patient-important outcomes.

Clinical comment

Evaluating and understanding the clinical benefits (if any) of any new intervention or technology is important in understanding its utility and communicating this information to patients. A number of potential explanations for patient dissatisfaction following TKA surgery have been proposed; these include stiffness, component malpositioning or malrotation, midflexion instability, subclinical infection, extensor mechanism deficiency, and neuropathic pain.[4] Patient-specific instrumentation has a theoretical potential to alleviate at least some of these concerns, such as component position, unnecessary bony resection, and soft tissue dissection.

Available literature and quality of the evidence

Woon et al. performed a meta-analysis of RCTs (level I) in 2018 (search date May 2016) to assess patient-reported outcomes following PSI TKA versus standard TKA. The study included four RCTs with a total of 458 patients.[5] Due to quite restrictive inclusion criteria, they included significantly fewer RCTs than another meta-analysis of RCTs (level I) published in 2016 by Huijbregts (search date May 2015). Huijbregts et al. included 21 RCTs, involving 1587 patients having undergone TKA.[6]

Findings

In their meta-analysis of four RCTs (level I), Woon et al. assessed four different patient-reported outcome measures. All four outcome measures were reported in all four included RCTs, which were the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), and the Knee Society Score (KSS) pain, function scores, and combined scores. Follow-up was between one and two years in all studies and only included cruciate-retaining knees. The meta-analysis found no significant difference between PSI and standard instrumentation on any of the clinical outcomes except for the KSS pain score, which showed an effect size of 3.6 in favor of PSI (95% confidence interval [CI]: 0.18–0.71; $I^2 = 0$).[5]

Huijbregts et al. also looked only at RCTs, but included 21 studies with over 1500 patients. Once again, no individual study randomized 100 or more patients per arm. Patient-reported outcome measures that were analyzed included the KSS, the Short Form 12 (SF-12), Oxford Knee Score (OKS), the Knee injury and Osteoarthritis Outcome Score (KOOS), and the Knee and Function Score. Pooled analysis revealed no significant difference for KSS, KOOS, Oxford or SF-12 scores three months postoperatively.[6] A single study with outcomes at one year found no difference in SF-12

scores, but did find a difference of two points in median OKS in favor of PSI at one year (p = 0.49).

Resolution of clinical scenario

- Level I evidence suggests that PSI *does not* result in improved patient outcomes at up to two years' follow-up.
- There is very little evidence to assess outcomes beyond the short to medium term.

Question 3: In patients undergoing TKA with PSI, are CT-based PSI systems more accurate than MRI-based PSI systems?

Rationale

PSI is available in one of two main ways: (i) through the company providing the TKA implants or (ii) through the hospital, in the form of three-dimensional (3D) planning and printing of instruments, followed by on-site sterilization and packaging.[7] The imaging modalities used to assess patient anatomy and create this instrumentation are also variable, and can be accomplished using CT or MRI.

Clinical comment

New technologies often have ancillary costs that must be considered when assessing their feasibility for introduction into a healthcare system or hospital. The vast majority of PSI systems require either CT or MRI to accurately determine patient anatomy prior to designing and producing the instrumentation. Intuitively, CT scan would be expected to provide a better view of bony anatomy,

whereas MRI is more useful for assessing soft tissue. From a cost perspective, CT is generally cheaper and more available than MRI in most centers. On the other hand, MRI has a more favorable safety profile compared to CT, given that no exposure to radiation is required.

Available literature and quality of the evidence

A meta-analysis of prospective comparative studies (level II) was published in 2017 by Wu et al.[8] Their search was inclusive up to and including June 2016, and their final analysis included six studies and a total of 336 patients. They assessed the proportion of outliers for the following alignment parameters: coronal overall limb alignment, and coronal and sagittal alignment of each component. More recently, Thijs et al. (level I) randomized 124 patients to either CT or MRI for PSI planning and reported implant survival and patient-reported outcomes at two years postoperatively.[9]

Findings

In their meta-analysis of prospective comparative studies, (three RCTs, one nonrandomized study, level II), with a total of 282 patients, Wu et al. found no significant difference between MRI and CT with regards to outliers for femoral or tibial component positioning in sagittal or coronal planes.[8] There was a significant difference in favor of MRI when assessing outliers for overall coronal limb alignment (risk ratio = 1.67; p = 0.04; 95% CI: 1.03, 2.72; I^2 = 0%).

Thijs et al. performed a RCT (level I) and at one-year follow-up had found no difference in hip–knee–ankle axis when using CT or MRI-based cutting guides; however, there were significantly more outliers for posterior tibial slope when using CT guides compared to MRI guides.[10]

Interestingly, at two years' follow-up, there was no difference between the two groups in terms of implant survival or revision surgery. Furthermore, there were no significant differences between the two groups with regards to any of the following patient-reported outcome measures: OKS, WOMAC, Visual Anal Scale (VAS) pain score, EQ-5D (a health-related quality of life measure).

Resolution of clinical scenario

- Level I and II evidence suggests that there *is no* significant difference in accuracy between CT and MRI on most radiographic parameters. There may be some isolated and small advantages in favor of MRI, though further, well-powered studies would be needed to confirm this.
- Level I evidence suggests that there *is not* a significant difference in implant survival or patient-reported outcomes with PSI regardless of the imaging modality used for planning.

Summary of answers

- Based on meta-analysis of many RCTs, patient-specific instrumentation does not result in more accurate component positioning, except perhaps in the case of axial alignment of the femoral component.
- Patient-specific instrumentation does not result in improved outcomes compared to standard instrumentation in TKA.
- There does not appear to be a major difference between CT and MRI for the planning and production of PSI. Thus, if PSI is employed, issues of cost and

safety can be considered on a case-by-case basis without concern regarding accuracy.

- Overall, based on a sizeable body of RCT evidence, there is little justification to recommend PSI in routine primary TKA.

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44 Metal Allergy in Total Knee Arthroplasty

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Clinical scenario

- A 65-year-old female, otherwise healthy, with end-stage osteoarthritis of her knee, undergoes an uncomplicated total knee arthroplasty (TKA) with a cobalt-chrome (Co-Cr) cemented prosthesis. The patella is resurfaced as well. The patient is discharged home after two days and within a few days postoperatively her range of motion (ROM) is 0–130°. At the six-week follow-up, ROM is the same with no effusions; the scar has healed properly and the patient is satisfied with the results. However, at the six-month follow-up, she presents with a painful knee, reduced ROM, mild effusion, and localized erythema.
- X-rays show no obvious loosening. Computed tomography (CT) reveals correct alignment of the components and infectious workup is negative including erythrocyte sedimentation rate (ESR), C-reactive protein (CRP), white blood cell (WBC) count, and cultures. Arthroscopic arthrolysis is performed, revealing adhesions and synovitis. At the end of the operation the ROM is restored. All samples are negative for infection. Passive and active physiotherapy is initiated and pain is controlled.
- The patient's overall condition improves, but at the 12-month follow-up (six months post arthroscopy) she

returns with a similar picture: effusion, localized erythema, reduced ROM, and pain. Once more infection is ruled out, and no evidence of implant loosening is detected.

Introduction

The number of TKAs is increasing annually worldwide as a consequence of aging and higher rates of secondary osteoarthritis in the younger population.[1] Despite the technological advancement, as well as the expertise of the surgeons, some reports state that almost 20% of patients with well-fixed, properly aligned knee implants are not satisfied for various reasons.[2] Additionally, some experience pain and stiffness for which no readily available explanation exists.[3]

Type IV hypersensitivity reaction, on the other hand, is mediated by T-cell lymphocytes, taking days to occur in patients previously sensitized to the allergen. This is the classic contact dermatitis that appears in 10–48% of the general population. Metal particles cross-link with proteins and act as antigens initiating an immune response.[4]

Reports of unexplained persistent pain and loosening after joint replacement caused by hypersensitivity to metal implants were initially published in the mid-1970s and concerned mostly metal-on-metal hip prostheses.[5–8]

As in our clinical scenario, if all other common reasons of postoperative complications are excluded, metal hypersensitivity may be a possible predisposing factor that leads to this unexplained clinical picture and possibly to implant failure.

Top three questions

1. Among patients awaiting TKA, does routine allergy screening, compared to no screening, affect management and/or outcomes?
2. Among patients with suspected hypersensitivity reaction, does any diagnostic method perform better than others?
3. Among patients with a confirmed hypersensitivity reaction, which treatment options, compared to others, result in the best outcomes?

Question 1: Among patients awaiting TKA, does routine allergy screening, compared to no screening, affect management and/or outcomes?

Rationale/clinical comment

If routine screening for metal allergy of TKA candidates can identify those at higher risk of developing such hypersensitivity reactions then unwanted reactions leading to socioeconomic burden (prolonged hospitalization, revision surgeries, reduced quality of life, etc.), for an otherwise highly successful intervention, may be prevented.

Findings

The only published randomized controlled trial involved 120 patients that were randomized to receive either a seven layer-coated or noncoated total knee implant and had their plasma ion levels and patch test (PT) assessed preoperatively and at 12 months. This showed that sensitization (positive PT postoperatively) was rare (only 3/120 pts). There was a functional improvement and better

quality of life in both groups for all patients. However, those with known metal allergies were excluded from the study since according to local guidelines they could not be randomized.[9]

Some studies give emphasis to the preoperative history-taking which, in addition to laboratory testing, can potentially identify patients at risk of metal sensitivity.[10–13]

Niki et al., in their prospective study, suggested that routine prescreening is clinically useful, especially related to Cr sensitivity. In a total of 92 patients, 26% (24 patients) tested positive with lymphocyte transformation test (LTT) preoperatively. An additional five patients developed metal-related eczema that was relieved fully only in those who had subsequent revision surgery with nonchromium-containing implants.[14]

Granchi et al., in two publications, supported that medical history or symptoms of metal allergy prior to implantation seem to be a risk factor for failure. TKA failure was four times more likely in such patients and this was reaffirmed after the systematic review of literature.[15,16] Given that many patients with a documented metal allergy on history actually have negative allergy testing, the relationship between the two is somewhat unclear.

Additionally, authors in recently published articles recorded that patient reported allergies (metal and/or environmental exposure, foods, medications, etc.) are associated with significantly decreased functional outcomes and mental health scores after TKA and total hip arthroplasties (THAs) with a follow-up from one to five years.[17–19]

Conversely, Zeng et al. found no relationship between pain and metal allergy in TKAs or THAs in their study of 87

patients that were pre- and postoperatively tested for metal allergy.[20]

The counterargument is supported by a cohort study of 127 patients, 56 of whom tested positive for metal allergy with the skin PT. This cohort was matched to 161 control TKAs without history or positive laboratory findings. A follow-up at five years showed no difference in complications, reoperation, or pain.[21]

Münch et al. from Denmark reported that metal allergy diagnosed preoperatively did not increase the revision surgery in TKAs, after they matched their national knee arthroplasty registry and the national allergy database.[22] Additionally, recent reviews have not supported routine testing, and diagnosis should be made when all other possibilities are excluded.[4],[23]

Resolution of clinical scenario

Routine preoperative screening or testing is not clearly supported and opinions vary regarding the appropriate patients to test prior to surgery.

Question 2: Among patients with suspected hypersensitivity reaction, does any diagnostic method perform better than others?

Rationale/clinical importance

As in our previous question, if screening methods can identify potential metal hypersensitive patients awaiting TKA, this will aid toward the best possible and long lasting outcome. On the other hand, postoperative screening may

help in the differential diagnosis and provide information valuable toward the next intervention.

Findings

Skin PT is an in vivo method that is most frequently used for detecting type IV hypersensitivity reactions. Other options include the in vitro LTT and its modifications: biopsies, cytokine production analysis, and confocal microscopy.

Patch testing is widely available and easy to apply, while also providing results within a few days. However, questions have arisen to the sensitivity of the PT with differences reported in the number of antigen presenting cells in the skin and those in the periprosthetic tissues. This questions whether PT is the most appropriate test.[24,25]

Of the total of 25 studies reviewed, 22 use the PT alone or in conjunction with other tests to detect metal hypersensitivity reactions in pre- or postoperative screening.

The concept of postoperative sensitization is supported by some authors given the fact that in their studies some patients who were patch tested negative before surgery were patch tested positive at last follow-up. None of these patients required revision surgery, although some received hypoallergenic implants.[9–11,15]

Conversely, Thyssen et al. found that the prevalence of patients testing positive to metal allergy PT after operation was lower (6%) than in those who had tested positively before surgery (16%).[26] In addition, two studies recommend against patch testing since it was of no clinical value in predicting clinical outcome and the probability of revision surgery.[21,22]

The LTT is a laboratory measure of the level of lymphocyte proliferation in response to an allergen. The availability of LTT is limited, the number of allergens to be tested is small, and, once taken, blood samples need to be transported to the lab rapidly to avoid T-cell decay.[25]

The LTT is reported in 10 studies and three case reports. Specificity and sensitivity of such tests has not been defined yet with many false positives and negatives.[13,23] The number of LTTs performed was too low and provided only additional support in some reports.[10,12,24]

In one study, lymphocytic infiltration was found in 81% of PT-positive patients, although the number of cases was small.[24] A systematic review supports the concomitant use of both tests despite the fact that they could not differentiate between stable and unstable implants.[16]

The LTT was used as a single method of diagnosis in two studies and in three case reports.[14,27–30] Niki et al. reported a significant relationship between Cr sensitivity, the development of eczema in TKA patients, and testing positive to LTT. After revision surgery, symptoms resolved and the LTT turned negative.[14] Hallab et al. indicated elevated metal-specific lymphocyte reactivity in THA patients, especially in those with moderate radiographic osteolysis.[27]

Other laboratory methods have been described. Three reports concluded that the LTT, combined with PT, histopathology, and cytokine detection could be useful tools for the prevention and monitoring of possible metal sensitization.[24,31,32] Knee arthroscopy is recommended to obtain tissue for microbiological and histopathological examination, before revision surgery, by one author.[12]

Resolution of clinical scenario

Patch testing is the most readily available test to detect metal sensitivity, although its validity has to be verified. Lymphocyte transformation testing may be more useful; however, it is not widely available and must be standardized. False-negative results are common with both tests. Combining those tests may provide better diagnosis and monitoring of suspicious cases. Other interventions are rarely described and therefore further research is required.

Question 3: Among patients with a confirmed hypersensitivity reaction, which treatment options, compared to others, result in the best outcomes?

Rationale/clinical importance

Our patient is still in pain and distress; all common possible causes have been excluded and our data suggest that the patient may have developed sensitization to the implant. What would be our treatment plan?

Findings

Only anecdotal information exists regarding the mode of treatment in such cases. Complete resolution of symptoms, after revision surgery with a nonallergic prosthesis, has been described in several case reports.[28–30,33–36]

Contradictory to those reports, Verma et al. reported that 15 patients with dermatologic manifestations over the knee resolved with local corticosteroid treatment.[37]

In one case a large intra-articular pseudotumor was resected 13 years post TKA; no signs of implant loosening were observed and the prosthesis was not revised.

However, the patient did not fully recover. Her contralateral knee was also replaced with a press-fit implant and no complications. History was positive for sensitivity to cement but not on metals.[38]

In another prospective study, 5 out of 92 patients presented with eczematous manifestations. One showed spontaneous resolution, two underwent revision (one ceramic, one standard) with complete recovery in both, and two followed clinical observation with mild, but persistent, features.[14]

Innocenti used a hypoallergic implant in 25 metal-sensitive patients with no adverse effects at six-year follow-up.[13]

Similarly, in three studies, patients characterized as metal sensitive (PT and/or LTT) received hypoallergenic implants at revision and reported symptoms relief.[12],[24],[32]

Resolution of clinical scenario

After exclusion of all other causes of failure, patients with persistent symptoms of dermatitis and/or persistent pain, reduced ROM, and pain of unknown origin, the patient could be offered a revision surgery to a nonallergic prosthesis if conservative methods fail to improve symptoms. Several types of such prostheses exist, some of them providing the same designs and surgical techniques as standard ones, making them easy to use.[39] Caution should be used if the nonallergic prosthetic system is not one that the surgeon is familiar with, as this may in and of itself result in suboptimal outcomes.

Summary of answers

- Routine preoperative screening or testing is not clearly supported and opinions vary regarding the appropriate

patients to test prior to surgery.

- Patch testing is the most readily available test to detect metal sensitivity, although its validity has to be verified. Lymphocyte transformation testing may be more useful; however, it is not widely available and must be standardized.
- Several types of hypoallergenic prostheses exist, and if revision is indicated, these may be considered.

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45 Perioperative Management in Total Knee Arthroplasty

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Clinical scenario

- A 63-year-old patient is awaiting his total knee arthroplasty (TKA), which is scheduled for the next day. As you search his medical records you find that the patient has had a surgical site infection (SSI) after being treated with open reduction internal plate fixation for a broken clavicle in the past. Therefore, you are thinking about taking additional prevention measures.
- Your patient is an active person in good physical condition with no significant co-morbidities. Since he wants to exercise with his new joint like he did prior to surgery, he asks you if there are any perioperative therapy plans that could improve the surgical result regarding knee function and shorten the hospitalization time.
- The patient is concerned about postoperative pain. He wants to take as few pain pills as necessary and knows the pain reduction potential of cryotherapy from his sports activities. He therefore asks you if cryotherapy could help to reduce the required pain medication, and if a postoperative outcome improvement can be expected.

Top three questions

1. In patients scheduled for primary TKA, does preoperative bathing/showering or wiping with antiseptics result in fewer SSIs compared to nonantiseptic preparations?
2. In patients after primary TKA, does a fast-track (FT) early-mobilization schedule lead to an improved outcome in functional scores and hospitalization time compared to a regular joint care protocol?
3. In patients after primary TKA, does local cryotherapy have a positive effect on early postoperative parameters compared to protocols without cryotherapy application?

Question 1: In patients scheduled for primary TKA, does preoperative bathing/showering or wiping with antiseptics result in fewer SSIs compared to nonantiseptic preparations?

Rationale

Prosthetic joint infection (PJI) after TKA is among the most frequent indications for revision TKA.[1–4] A huge economic burden is associated with the increasing number of (septic) revision TKA.[5]

Clinical comment

One of the most frequent causes for wound contamination is skin microflora. With the incision made during surgery,

micro-organisms may be able to infect tissue, joint, and/or implant. It is a widely accepted fact that the use of an antiseptic skin wash product can reduce skin microflora. However, there is no consensus whether this leads to a reduced incidence of SSI/PJI.[6,7] Knowing the history of the patient, you want to know if bathing/showering with antiseptic skin wash products prior to surgery can help prevent an SSI/PJI.

Available literature and quality of the evidence

- Level III: our literature search showed 1 meta-analysis (including 4 retrospective comparative studies with 8787 patients) investigating exclusively TKA patients.[8]
- Level III: 1 retrospective comparative study including 2055 TKA patients.[9]
- Level I: 1 Cochrane systematic review (including 7 randomized controlled trials [RCTs] with 10 157 patients) investigating SSI of all localizations.[10]

Findings

The level III meta-analysis results (total study population) indicate a reduced incidence of SSI when chlorhexidine (the active substance in all investigations) was used in preoperative washing/wiping (risk ratio [RR] = 0.22; 95% confidence interval [CI]: 0.12–0.40; p = 0.000). Furthermore, a reduction of SSI rates in moderate and high risk patients according to the National Healthcare Safety Network (NHSN) risk classification is shown (RR = 0.18; 95% CI: 0.05–0.63; p = 0.007 and RR = 0.13; 95% CI: 0.03–0.67; p = 0.014.[8,11]

In contrast, the level I systematic review as well as the retrospective comparative study found no benefits in the chlorhexidine groups regarding SSI incidences. A

discrimination by risk classification has not been performed in these studies. Insignificant differences in SSI rates are reported in the chlorhexidine and in the placebo groups (RR = 0.60; 95% CI: 0.22–1.60; p = 0.330.[8–10]

Resolution of clinical scenario

- Routine use of preoperative chlorhexidine baths/showers or wipes is not recommended for daily clinical practice as it shows no SSI rate reduction in TKA.[9,10]
- The SSI risk should be calculated if deemed necessary.[11]
- In TKA patients with moderate to high SSI risk profiles chlorhexidine baths/showers or wipes should be considered, especially regarding the low cost and the very rare unwanted side effects. However, the available data do not support a final recommendation.[8]

Question 2: In patients after primary TKA, does a fast-track (FT) early-mobilization schedule lead to an improved outcome in functional scores and hospitalization time compared to a regular joint care protocol?

Rationale

Multidisciplinary perioperative treatment protocols for TKA have been presented and further advanced in recent years, aiming to provide standardized treatment leading to a

reduced length of stay, improved clinical outcome, and patient satisfaction.[12–14] To achieve this, physicians, anesthesiologists, physiotherapists, and nurses must closely work together and adhere to evidence-based protocols, known as *fast track* (or *FT*).

Clinical comment

Perioperative management plays a very important role regarding the outcome of a surgical procedure and overall patient satisfaction. FT protocols take an evidence-based approach to optimizing the clinical and organizational aspects aiming to reduce morbidity and mortality and speed up functional convalescence with a subsequently shortened length of hospitalization. You want to know if these protocols can help you and your patient to achieve a short hospital stay and a better functional outcome.

Available literature and quality of the evidence

- Level I: the literature search showed 2 meta-analysis including 16 studies on this topic.[15,16] In addition, there is 1 RCT focusing on early outcome in FT TKA.[17]

Findings

Both the meta-analysis and the RCT showed significantly reduced length of stay times in acute healthcare facilities when comparing the FT mobilization group to the control group. Guerra et al. found a reduction by 1.8 days (95% CI: 1.1–2.6; 6.9 vs 5.1 days). All studies report this without an increase in adverse events.[15–17]

Advantages regarding early functional outcomes (first 1–2 weeks) after surgery were reported by the analyzed studies, showing improved Knee Society and Western Ontario and McMaster Universities Osteoarthritis Index

(WOMAC) scores, and earlier sit-out-of-bed (SOOB) and walking. However, no differences could be shown regarding medium- and long-term functional outcomes when comparing FT protocols to standard mobilization schedules.[15–17]

Resolution of clinical scenario

- FT protocols significantly reduce the length of stay times in acute healthcare facilities without an increase in adverse events.[15–17]
- FT protocols show advantages regarding early functional outcomes; however, improved medium- and long-term outcomes are not apparent.[15–17]

Question 3: In patients after primary TKA, does local cryotherapy have a positive effect on early postoperative parameters compared to protocols without cryotherapy application?

Rationale

Basic cryotherapy via cool packs or ice is a relatively safe and cost-effective intervention. More sophisticated cryotherapy techniques include computer-assisted continuous cold flow devices which should provide a more even distribution of cooling fluid or gas but are substantially more expensive. While cryotherapy is the standard care in some countries, differing results in literature and few available level I studies might be the reason for its rare use in other countries.[18,19]

Clinical comment

Cryotherapy, the application of low temperatures to the skin surrounding a wound, works via reduction of inflammation enzyme activity, slowing of nerve signal conduction and a subsequent decrease of local swelling and perceived pain.[20–22] The further induced vasoconstriction should theoretically reduce blood loss following a surgical procedure or injury.[23]

Available literature and quality of the evidence

- Level I: the literature search showed one meta-analysis and 1 Cochrane review including a total of 14 different RCTs on this topic.[24,25]
- Level I: 5 RCTs were identified examining outcomes of continuous cold flow devices including 381 patients.[26–30]

Findings

Minor improvements of low quality regarding standard cryotherapy were reported by the meta-analysis, with a reduction in opioid consumption (mean difference, −0.13; 95% CI: −0.26 to −0.01 morphine equivalents in milligrams per kilogram per 48 hours; p = 0.03) and in pain improvement (mean difference, −0.51; 95% CI: −1.00 to −0.02 on the Visual Analog Scale [VAS]; p <0.05).[25]

The Cochrane review found very low-grade evidence favoring cryotherapy regarding blood loss (mean 225 mL, 95% CI: 39–410 mL less blood loss), pain at the second postoperative day (1.3 VAS, 95% CI: 2.37–0.27 VAS points lower), and range of motion (ROM) at discharge (11.39 [18%] more degrees of flexion, 95% CI: 4.13–18.66).[24]

The results of five RCTs investigating cryotherapy via continuous cold flow devices versus standard cryotherapy techniques showed an improved ROM (86 vs 80° of flexion,

p = 0.021). Further, one study found pain reduction on the second postoperative day similar to the Cochrane review.[30] No further improvements were found in these investigations.[26–30]

Resolution of clinical scenario

- No postoperative outcome improvement has been reported[25–29] except a minor improvement of ROM at time of discharge.[24,30]
- The evidence shows a minor improvement in opioid consumption and pain on the second postoperative day.[24,25,30]
- It seems that cryotherapy has minor benefits, but the routine use of standard and/or continuous flow cryotherapy cannot be recommended based on the present data.

Summary of answers

- The preoperative use of chlorhexidine baths/showers or wipes in primary TKA is not recommended for daily clinical practice.
- Although a final recommendation cannot be given with the present data, it should be considered to use chlorhexidine baths/showers or wipes in TKA patients with moderate to high SSI/PJI risk profiles.
- FT protocols can reduce the length of stay in acute healthcare facilities and lead to improved early functional outcomes.
- FT protocols do not lead to improved medium- and long-term outcomes.

- Due to minor benefits, the routine use of standard and/or continuous flow cryotherapy cannot be recommended based on the present data.

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46 Arthrofibrosis following Total Knee Arthroplasty

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Top three questions

1. In patients undergoing total knee arthroplasty (TKA), does continuous passive motion (CPM), compared to standard postoperative care, help prevent arthrofibrosis?
2. In patients undergoing manipulation under anesthesia (MUA) for stiffness after TKA, is early manipulation better than late manipulation at restoring range of motion (ROM)?
3. In patients with arthrofibrosis following TKA, does open arthrolysis provide superior outcomes compared to arthroscopic arthrolysis?

Question 1: In patients undergoing total knee arthroplasty (TKA), does continuous passive motion (CPM), compared to standard postoperative care, help prevent arthrofibrosis?

Clinical scenario

A 65-year-old male has just undergone primary TKA under your care, and is now back on the ward. He is keen to start mobilizing as soon as possible and would like to have CPM as he has heard that this may reduce his risk of developing stiffness in the joint.

Rationale

CPM forms part of many postoperative protocols for the treatment of arthrofibrosis once it has occurred. Its value in preventing arthrofibrosis after primary TKA is unclear.

Clinical comment

A stiff knee following arthroplasty is one of the most dreaded complications and its treatment a challenge for surgeons. Arthrofibrosis is one of the most common causes of this stiffness.[1] It is a condition characterized by deposition of fibrous scar tissue within and around a joint, in response to an inflammatory process.

Available literature and quality of the evidence

- Level I: 1 meta-analysis of randomized trials.
- Level III: 3 case-control studies.

Findings

A meta-analysis by Brosseau et al. (level I) included 14 studies (952 patients), after excluding many other studies on the topic which lacked sufficient quality of evidence.[2] The included studies used CPM from 5 to 20 hours per day, for a duration of 18 hours to 2 weeks postoperatively after primary TKA. They performed a pooled analysis comparing patients receiving postoperative physiotherapy combined with CPM, against those receiving physiotherapy only (nine studies included). Eight of the studies initiated CPM on the first postoperative day, and the other study started it on the second day.

Active knee flexion at two weeks following surgery (pooled results from four studies, 286 patients) was compared, and showed that CPM was associated with a weighted mean difference (increase) of 4.30° (95% confidence interval [CI]: 1.96–6.63). They also reported a clinically important benefit in association with CPM, with a relative difference in active knee flexion of 22–25% over the period from 3 to 14 days postoperatively. One of the included studies reported postoperative time to achieve 90° of knee flexion, and found that the CPM group achieved this an average of 4.7 days earlier than the control group (9.1 days vs 13.8 days).[3] Active knee extension was also compared, but no statistically significant difference was found. Similarly, no significant differences were found between the groups for passive flexion or extension at follow-up to six months. The requirement for MUA was used as a marker for knee stiffness, and this was also compared in this study (pooled results from three studies, all began CPM within 24 hours). CPM was associated with a significant reduction in MUA (risk ratio [RR] = 0.12; 95% CI: 0.03–0.53); however, they questioned the clinical importance (5–18% relative difference).[2]

Another case-control study by Trzeciak et al. (level III) evaluated 101 TKAs in 93 patients, and assigned them into two groups.[4] The study group received CPM and active exercises, whereas the control group had only conventional physiotherapy. CPM was started on day one postoperatively, for two hours per day, with an initial ROM of 0–40°. ROM was increased as tolerated, by a mean of 10° per day, until discharge. On day 10 postoperatively, the patients were assessed, demonstrating no significant difference in mean ROM between the two groups: CPM group: 83° ±14°; control group: 77° ±21°. They reported that there may be some subjective improvement in pain level, joint stiffness, and function associated with CPM, but were not able to demonstrate any statistically significant differences. This study focused on the early postoperative outcomes, as it only showed follow-up at 10 days postoperatively, which may be too early to make a diagnosis of arthrofibrosis. Nonetheless, early progression in ROM and function is important in its prevention, and therefore these early outcomes may be related to arthrofibrosis risk.

There is debate about when CPM should be initiated to provide most benefit. A level III study by Daluga et al. evaluated the outcome of requirement for MUA after TKA over a three-year period, with a change in the CPM protocol halfway through.[5] The requirement for MUA was based on failure to meet flexion goals (70° before discharge – early MUA, failure to surpass 65–75° at early follow-up – intermediate MUA, failure to achieve 80–85° at three-month follow-up – late MUA). During the first half, CPM was commenced on day 3 postoperatively, and during the second half of the study, CPM was commenced on day one, and continued until discharge (length of stay not reported). The MUA rate remained constant at 12% throughout the

period despite the change in CPM protocol, suggesting no difference between starting CPM at day one or day three.

Additionally, there is no consensus about duration and method of CPM, and most studies do not evaluate this. The aforementioned meta-analysis stated that a comparison was made between short and long duration of CPM, and also between small and large range CPM, but that no statistically significant differences were found in relation to any outcome measures and the results were not shown.[2]

Many other studies included CPM as part of their postoperative rehabilitation protocol for all patients. At the time of writing, there are no other available studies that compare CPM against a control group, reporting arthrofibrosis as an outcome. Further work is needed to reinforce the evidence of the benefit of CPM in prevention of arthrofibrosis, but the limited evidence currently available suggests that CPM may lead to early improvements in ROM, and therefore may have a preventative effect.[2]

Resolution of clinical scenario

This patient should be assessed by the physiotherapists and early movement encouraged. CPM may be included as part of this protocol if appropriate.

Question 2: In patients undergoing manipulation under anesthesia (MUA) for stiffness after TKA, is early manipulation better than late manipulation at restoring range of motion (ROM)?

Clinical scenario

The gentleman returns to clinic two months after TKA with marked pain and stiffness in his knee. His knee flexion is limited to 60°.

Rationale

There are a range of treatment modalities available for arthrofibrosis following TKA. There are conservative options such as analgesia and physiotherapy, and more invasive interventions ranging from MUA to arthroscopic arthrolysis, open arthrolysis, and revision surgery. A key question that has been raised on this topic is that of the optimal timing for the procedure. If done too early (a level V narrative review by Schiavone Panni et al. suggested three weeks), this can cause wound breakdown.[6] However, if done too late, fibrous bands may have solidified and will not be amenable to breakdown via this method, and there may be a higher rate of complications, such as femoral fracture.

Clinical comment

This is a common scenario, which has been subject to various opinions on methods and timings of treatment. In reality, it may be reasonable to adopt a stepwise approach with many of these options. The first treatment modalities to be considered in the early stages should be conservative measures such as improved analgesia, physiotherapy, and exercises aimed at gradually improving ROM. Once these have been exhausted, some surgeons consider MUA as the next step. This section will explore the existing evidence for MUA as a treatment for arthrofibrosis.

Available literature and quality of the evidence

- Level III: 2 case-control studies.
- Level IV: 3 case series.

Findings

Manipulation under anesthesia (MUA)

A retrospective case-control series (level III) by Daluga et al. reviewed 94 TKAs that required MUA postoperatively, separating these into early (0–21 days), intermediate (22–90 days), and late (after 90 days), and compared them against a control group of 41 TKAs during the same period that had not required MUA.[5] The indications for MUA were flexion <70° or insufficient progress for the early group, flexion <65–75° at discharge or insufficient progress for the intermediate group, and flexion <80–85° at three months for the late group. They reported that MUA provided an overall mean increase in flexion ROM of 42°, and there was a significantly better result for the early group when compared with the late group in terms of mean flexion achieved (104° vs 97°). Unfortunately, there was no further analysis involving the intermediate group, which is the group representing the time period in which the majority of MUA procedures are undertaken. However, they did report that there was no significant difference in final flexion between the early and intermediate groups. No complications as a result of MUA were reported in any of the groups.

Similarly, in a retrospective case series (level IV) by Yercan et al., a series of 1188 TKAs over an 18-year period were reviewed, with 46 patients requiring MUA.[7] This study considered two different indications for MUA, which were flexion less than 75° after 10 days (early MUA), or flexion less than 95° within three months (late MUA). They showed a significant improvement in mean ROM for patients

undergoing MUA from 67° to 117°, with a mean increase in ROM of 47° at 31 months ($p < 0.015$), and that this benefit was largely maintained at final follow-up (mean ROM 114°). They also showed that there was greater long-term benefit for those having early MUA (10 days to 3 weeks), compared with those having late MUA (three weeks to three months), with final follow-up mean ROMs of 121° and 112°, respectively ($p = 0.021$). There were no complications following MUA for any of their patients.

A retrospective case series (level IV) by Bawa et al. reported 3244 TKAs over an eight-year period, of which 140 (4.3%) underwent MUA for stiffness, as indicated by failure to reach 90° of flexion by six weeks.[8] They demonstrated a mean increase in ROM of 34° after MUA ($p < 0.001$). Comparing MUAs done before and after 75 days, they showed a significant benefit in the group having early MUA (final ROM 103° vs 92°, $p = 0.001$). Additionally, they showed a negative correlation between time from TKA to MUA, and final ROM ($r = -0.20$, $p = 0.04$).

In a retrospective case-control study (level III), Keating et al. evaluated a series of 6297 TKAs over a 14-year period, and found that 113 (1.8%) of these developed early stiffness requiring MUA.[9] They defined their indication for MUA as flexion restriction to 90° or less after 2–3 months, after a supervised physiotherapy program had failed. In this cohort, MUA significantly improved ROM, with a mean flexion range of 70° before manipulation, increasing to 94.0° at six months, and 105° at five years ($p < 0.0001$). In response to previous work discussing a cut-off of 12 weeks for MUA, they compared their results of those undergoing MUA before and after 12 weeks, and found no significant difference ($p = 0.3597$).

A retrospective series (level IV) by Ipach et al. evaluated 858 TKAs over a five-year period, and showed that 39 of

them required MUA for stiffness, indicated by flexion <90° after two weeks.[10] The mean flexion ROM improved following MUA by 26.5°, but no statistical analysis was undertaken. They separated the MUAs by early (before 30 days) and late (after 30 days), and reported that there was no statistical significance between the absolute flexion ($p = 0.655$) or the gain in flexion ($p = 0.328$) between these groups.

Summary

Whilst there is contradictory evidence, most sources seem to suggest that MUA is best carried out in the early postoperative period. The evidence presented here suggests that while early MUA is indeed preferable low-level evidence suggests that benefits are still possible after three months.

Resolution of clinical scenario

As the patient is two months following surgery, it would be reasonable to offer an MUA in the first instance.

Question 3: In patients with arthrofibrosis following TKA, does open arthrolysis provide superior outcomes compared to arthroscopic arthrolysis?

Clinical scenario

A colleague refers you a 70-year-old gentleman who had a TKA nine months previously. He now has marked pain and stiffness in his knee, despite previous attempts at MUA.

Rationale

If symptoms of arthrofibrosis remain troublesome after several months, and more conservative measures have failed, the next consideration is arthrolysis. This section will focus on a comparison between the two different methods of arthrolysis (arthroscopic vs open).

Clinical comment

Arthroscopic procedures are generally less invasive, and involve smaller wounds and less disruption to surrounding tissues. It is important to understand if satisfactory results can be achieved arthroscopically.

Available literature and quality of the evidence

- Level III: 2 systematic reviews including level III evidence.
- Level III: 1 cohort study.
- Level V: 1 narrative review.

Findings

A systematic review by Ghani et al. (level III) included data from 25 studies (level III–IV) to evaluate the efficacy of different treatment modalities for arthrofibrosis including arthroscopic arthrolysis and open arthrolysis.[1] The increase in ROM was pooled and compared, showing reported ROM increases of 36.2° for arthroscopic arthrolysis and 43.4° for open arthrolysis, suggesting better results for open arthrolysis.

A systematic review (level III) by Fitzsimmons et al. included 20 articles in total (level II–IV), and evaluated MUA, arthroscopic arthrolysis and open arthrolysis, in the context of motion restriction after TKA, although not all

treatment modalities were represented in each study.[11] Arthroscopic arthrolysis resulted in a mean increase in ROM of 18.5–60° (12 studies), and in nine of these studies the arthroscopic procedure was combined with MUA. Open arthrolysis gave a mean increase in ROM of 19–31° (three studies). These findings suggest that greater ROM benefits can be achieved with arthroscopic arthrolysis combined with MUA, in contrast to the previously mentioned study. However, simply comparing ROM outcomes for each approach may be an oversimplification, as they have different roles and indications.

The aforementioned paper by Schiavone Panni et al. suggested that arthroscopic arthrolysis should only be performed in stiff painless knees, and much like MUA its role is predominantly in relieving flexion deficits as these are associated with fibrosis of the anterior structures.[6] The arthroscopic approach allows good access to the suprapatellar pouch, the intercondylar notch, and the medial and lateral gutters. Posterior capsule adhesions are difficult to address with this approach, but the posterior cruciate ligament can be accessed if necessary.[12]

Open arthrolysis may be considered in severe arthrofibrosis, at a later stage once conservative management has failed, and if the components are correctly placed. This procedure can be combined with exchange of polyethylene inserts or patellar components, and with additional procedures such as patellar tendon lengthening or tibial tuberosity transfer.[6]

A retrospective cohort study (level III) by Keeney et al. evaluated a series of 23 stiff TKAs, and drew comparison between revision TKA (n = 11) and a limited approach open arthrolysis procedure with exchange of the polyethylene insert component only (n = 12).[13] Both groups demonstrated significant improvements, with the limited

approach group producing a mean increase in ROM of 25.7° (70.6° to 96.3°, p <0.0001), and a reduction in mean extension deficit of 6.63° (7.45° to 0.82°, p = 0.002). In the limited approach group, there were also significant improvements in mean patient-reported measures of Knee Society Score – Knee (KSS; 36.9–74.7, p <0.0001), KSS – Function (41.7–62.5, p = 0.03), and pain score (7.9–1.5, p = 0.002).

Summary

Direct comparison between arthroscopic and open arthrolysis procedures may not always possible, as their indications and timings are different, but studies directly comparing them directly report equivocal findings.[1,11] In reality, the main advantage of performing open arthrolysis is that it can be combined with other procedures that are not possible arthroscopically. Given the evidence available, it seems reasonable to preferentially perform arthrolysis via an arthroscopic approach, unless there is felt to be a need for an additional procedure at the same time (e.g. downsizing of polyethylene insert).

Resolution of clinical scenario

Given that there is no evidence of any mechanical issues, and the implants appear to be well sized, the patient may be offered arthroscopic arthrolysis

Summary of answers

- CPM is often incorporated into early rehabilitation protocols after TKA. The limited evidence available suggests that it can improve early gains in ROM and may lead to a reduction in the risk of developing arthrofibrosis.

- MUA should be performed if arthrofibrosis is present within three months postoperatively, and the earlier the better once the diagnosis is made.
- After more than three months, arthroscopic arthrolysis (usually combined with MUA) can be considered, as this may prevent the need for more extensive revision procedures, and could be effective as late as two years postoperatively. For persistently stiff knees with late arthrofibrosis and severe restriction, open arthrolysis or revision procedures may be considered.

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47 High-Flexion Implants in Total Knee Arthroplasty

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Clinical scenario

- A 55-year-old Muslim woman presents with end-stage degenerative joint disease of her knee. She has marked varus angular deformity with limited knee flexion to 100°.
- Radiographic evaluation demonstrates severe varus osteoarthritis. She explains how it is very important for her to properly position herself into prayer position.
- She has read about high-flexion (HF) total knee replacement prostheses and insists it is the only route for her.

Top three questions

1. In a patient who is considering a total knee arthroplasty (TKA), what design rationale can be provided for HF implants and are patients more satisfied with such designs compared to a conventional knee prosthesis?
2. Are functional outcomes superior in a patient who has undergone a TKA with a HF prosthesis compared to a

conventional total knee prosthesis?

3. In a patient who has undergone TKA with a HF TKA, what unique complications are encountered as compared to a conventional TKA?

Question 1: In a patient who is considering a total knee arthroplasty (TKA), what design rationale can be provided for HR implants and are patients more satisfied with such designs compared to a conventional knee prosthesis?

Rationale

HF TKA implants were designed and marketed for patients who desire to continue leisure and sporting activities or to return to cultural norms such as prayer. Moreover, these design changes were undertaken to see if patient satisfaction and overall function could be improved.

Findings

An easily measured shortfall of contemporary TKA is the range of motion (ROM) routinely obtained after surgical intervention and its comparison to the amounts required to perform routine activities of daily living (ADLs). This is supported by postoperative outcome studies that reveal stiffness as a cause of dissatisfaction amongst some patients.[1,2] HF total knee systems were designed to imitate the natural function of the knee more closely allowing for greater contact area and knee flexion.[3] Modifications in the HF design include the femoral condylar component

geometry and offset, curvature of radius, geometry and cutouts of the polyethylene insert, and height and position of the cam/post engagement.[4,5] The changes to the femoral component aim to make the most posterior lip of the posterior femoral condyles more rounded in order to increase the weight bearing area of this edge while the prosthesis is in deep flexion. These changes are also necessary to avoid impingement or edge loading of the component into the polyethylene insert, thus preventing fractures and/or delamination of the insert. These design changes require resection of extra host bone, which is replaced by the more rounded edge of the implant. Changes to the polyethylene insert have consisted of decreasing the congruency of the posterior portion to avoid impingement on the femur[6,7] and creating a recess in the polyethylene anteriorly to accept the patellar tendon as it "leans back" in deep flexion. Additionally, increasing the height of the posterior cam[6,7] has been addressed in some posterior stabilized designs to decrease the chance of "jumping the post" with increased flexion. These design changes would theoretically allow for greater ROM and better patient satisfaction.

In a level I meta-analysis of randomized controlled trials (RCTs), Li et al. evaluated 18 studies with 2069 knees. There was no difference in patient satisfaction scores with those who received HF total knees as compared to conventional knees.[4] There were no differences in Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) or Short Form 36 (SF-36) scores.[4] Fu et al. evaluated 10 studies and 1230 knees in a level I meta-analysis of RCTs.[8] Similarly, they found no differences in WOMAC and SF-36 scores (weighted mean difference [WMD] = −0.03; 95% confidence interval [CI]: −4.11 to 4.06; p = 0.99; I^2 = 62%).[8] Both studies concluded that HF

prostheses did not appear to confer any superiority over standard prostheses.

Several RCTs have evaluated patient satisfaction following HF TKAs as compared to standard TKAs. Van der Ven et al. in an RCT of 56 patients comparing press-fit condylar (PFC) sigma fixed bearing cruciate retaining knee to PFC sigma rotating platform HF posterior stabilized knee showed no differences in patient reported outcome measures (WOMAC and Visual Analog Scale [VAS]).[9] Springorum et al. in a prospective RCT of 69 consecutive knees compared a PFC cruciate-retaining (CR) HF knee to a standard PFC total knee and found no differences in WOMAC scores.[10] McCalden et al. showed in an RCT of 100 patients comparing Genesis II standard posterior-stabilized (PS) inserts to HF inserts with no differences in WOMAC or SF-12 scores.[5] Finally, Lutzner et al. in an RCT of 122 patients compared Scorpio NRG HF implants to a standard Scorpio prosthesis and showed no differences in SF-36 scores.[11]

Similarly, in a prospective study comparing 100 patients who underwent bilateral total knees, one with a NexGen Legacy PS knee and the other with a NexGen PS-Flex knee, Kim et al. 2012 showed that 87% of patients had no preference as to which knee was better or were more satisfied with.[12] Lastly, in a large prospective level III study of 960 patients with a mean of 13.2 year follow-up, Kim et al. showed no differences in patient satisfaction at final follow-up when comparing NexGen Legacy PS total knee to the NexGen PS HF total knee.[13]

Resolution of clinical scenario

- HF total knee implants have different design modifications in posterior femoral condylar offset and

geometry, in polyethylene insert geometry including anterior cutouts and cam/post height and position to allow for more optimal contact area and knee flexion.

- There are no differences in patient satisfaction when comparing HF total knee implants to conventional implants.

Question 2: Are functional outcomes superior in a patient who has undergone a TKA with a HF prosthesis compared to a conventional total knee prosthesis?

Rationale

Although the theoretical advantage of HF TKAs is to obtain greater flexion and improve clinical outcomes, controversy exists whether such designs truly change functional outcomes. It is therefore important to critically examine outcomes when using HF designs and compare them to conventional total knee replacements.

Findings

In a level I meta-analysis of RCTs, Li et al. evaluated 18 studies with 2069 knees. When comparing postoperative ROM there was no difference between HF and standard knees (WMD = 0.78; 95% CI: −0.19 to 1.74; WMD = 0.41; 95% CI: −2.01 to 2.83).[4] There was also no difference found in Knee Society Score (KSS) and Harris Hip Score (HSS).[4] Furthermore, in a level I meta-analysis of RCTs, Jiang et al. evaluated 17 studies with 1778 patients.[4] Subgroup analysis showed there was no difference between PS flexion and PS knees (mean difference [MD] = 0.96;

95% CI: −0.23 to 2.15; p = 0.11) as well as CR flexion and CR knees (MD = 1.18; 95% CI: −0.55 to 2.91; p = 0.18) in terms of ROM. There was no difference in these subgroups in terms of KSS (MD = −0.67; 95% CI: −3.05 to 1.71; p = 0.16); (MD = 1.87; 95% CI: −1.49 to 5.23; p = 0.45) or HSS (MD = −0.13; 95%: CI −1.15 to 0.90; p = 0.81); (MD = 2.10; 95% CI: −0.39 to 4.59; p = 0.10).[14] Finally, Fu et al. evaluated 10 studies and 1230 knees in a level I meta-analysis of RCTs. There were no differences between HF and conventional components in terms of range of flexion (WMD = 1.14°; 95% CI: −0.11–2.39°; p = 0.07; I^2 = 39%).[8] There were also no differences observed in KSS (WMD = −0.03; 95% CI: −4.11 to 4.06; p = 0.99; I^2 = 62%).[8]

In the last decade several RCTs have been identified evaluating functional outcomes following HF TKAs. Guild and Labib evaluated the NexGen LPS standard and NexGen HF total knees in 278 knees. At two-yar follow -up there were no differences in ROM, clinical outcome, or radiographic evaluation.[3] At two-year follow-up the standard prosthesis group had a mean flexion of 121° and the HF group had a mean flexion of 120°.[3] Van der Ven et al. in an RCT evaluated 56 patients comparing PFC sigma fixed bearing cruciate retaining knee to the PFC sigma rotating platform HF posterior stabilized knee. Maximum knee flexion during kneeling was higher for the HF group although there were no differences seen in KSS.[9] Furthermore, in a prospective randomized study of 69 consecutive patients, Springorum et al. compared a PFC CR HF knee to a standard PFC knee. Knee flexion was 112.6° in the standard group and 117.3° in the HF group (p >0.05; 95 % CI: −11.5–1.9°).[10] There were no differences between groups at any time point in terms of KSS.[10] Lutzner et al. in an RCT of 122 patients compared Scorpio NRG HF implants to a standard Scorpio prosthesis and

showed no differences in postoperative ROM and KSS.[11] McCalden et al. in an RCT of 100 patients comparing Genesis II standard PS inserts to HF inserts showed no differences in knee flexion at two years ($p = 0.811$).[5] There were no differences in Knee Society clinical rating scores.[5] Finally, Hamilton et al. in a prospective RCT studied 142 patients comparing a HF and standard rotating platform knee showing no differences at one year in terms of clinical outcomes ($p = 0.949$), as well as radiographic flexion between groups ($p = 0.985$).[15]

Similarly, in a large prospective level III study of 960 patients, Kim et al. showed no differences in ROM ($p = 0.305$) or KSS scores ($p = 0.921$) when comparing NexGen Legacy PS knee and NexGen PS HF total knees.[13]

Resolution of clinical scenario

- There are no differences in ROM or functional scores when comparing HF total knees to conventional total knees.

Question 3: In a patient who has undergone TKA with a HF TKA, what unique complications are encountered as compared to a conventional TKA?

Rationale

It is important to investigate whether there are any potential complications with HF implants that need to be disclosed to patients prior to surgery. In particular, any TKA that undergoes deep flexion is subject to high shear

forces between the tibia and femur, which may result in early loosening.

Findings

In a level I meta-analysis of RCTs, Li et al. evaluated seven studies comparing complications with HF total knees compared to conventional knees. Overall, the odds ratio (OR) was 1.50 (95% CI: 0.95–2.39), suggesting that the risk of complications between HF and conventional knees is not different.[4] Another level I meta-analysis of RCTs by Jiang et al. showed no difference in revision rates between HF and conventional total knees (OR = 2.95; 95% CI: 0.70–12.45; p = 0.18).[14] There was no difference seen in component loosening rate (OR = 2.37; 95% CI: 0.35–16.26; p = 0.38), deep infection (OR = 1.93; 95% CI: 0.54–6.94; p = 0.31), anterior knee pain (OR 1.17; 95% CI: 0.52–2.61; p = 0.71), fracture (OR = 0.24; 95% CI: 0.47–19.35; p = 0.24), or patellar clunk (OR = 1.42; 95% CI: 0.05–40.47; p = 0.84).[14] Finally, Fu et al. did not show any differences in number of complications between HF and conventional implants when evaluating seven RCTs in a level I meta-analysis.[8]

Several RCTs have evaluated differences in complication rate when using HF total knee implants as compared to conventional implants. Guild and Labib showed in an RCT of 278 knees similar complication rate in NexGen LPS standard and NexGen HF knees.[3] Five knees in the NexGen HF group required manipulation under anesthesia for stiffness in addition to one case of patella fracture and superficial infection.[3] There were no cases of aseptic loosening, infection, or osteolysis.[3] Springorum et al. in an RCT compared a PFC CR HF knee to a standard PFC knee and showed no differences in complications (aseptic loosening, infection, reoperation).[10] Furthermore, Hamilton et al. in a prospective RCT studied 142 patients comparing

a HF and standard rotating platform knee. There were no differences in requirement for manipulation under anesthesia.[15] However, there was a significant increase in patellar crepitus in the HF group ($p = 0.017$). Finally, McCalden et al. in an RCT of 100 patients comparing Genesis II standard PS inserts to HF inserts showed no differences in anterior knee pain, reoperation, and infection at two years.[5] There were two cases requiring manipulation under anesthesia both of which were in the standard PS group.[5] Similarly, in a prospective study comparing 960 patients with mean follow-up of 13.2 years who underwent total knees with either a NexGen Legacy PS knee or a NexGen PS-Flex knee, Kim et al. showed no differences in implant survivorship at 14 years which was 99.8% in both groups (95% CI: 95–100).[3] There were no differences in complications and aseptic loosening was 0.2% in both groups.[13]

Lastly, in a retrieval study, Schnaser et al. compared 20 HF inserts to 20 PS standard inserts across three manufacturers in 120 patients. Ranges of motion between matched patients were not different.[6] There were no differences between mean overall damage scores, post damage, or posterior articular surface damage between groups ($p = 0.25$, $p = 0.11$, $p = 0.6$). This is in contrast to the award-winning paper from Paterson et al. which matched 20 retrieved HF inserts to 20 retrieved PS inserts from the same implant system. These authors found greater backside and post damage in the HF group but no difference in the articular surface or overall damage scores. These authors concluded that HF inserts are more susceptible to post damage, possibly as a result of higher contact stresses from greater flexion.

Resolution of clinical scenario

- There are no differences in complication profiles when comparing HF TKAs to conventional TKAs, with the exception of one retrieval study identifying greater post damage in HF polyethylene inserts.

Summary of answers

- HF total knee implants have alterations in posterior femoral condylar offset and geometry, polyethylene insert geometry including anterior cutouts, and cam/post height and position to optimize contact area and knee flexion.
- There are no differences in patient satisfaction when comparing HF total knees to conventional total knees.
- There are no differences in ROM or functional scores when comparing HF implants to conventional total knee implants.
- In clinical studies, there are no differences in complication rates when comparing HF total knees to conventional total knees.
- Retrieval studies suggest that HF inserts may be more susceptible to post damage.
- The introduction of a highly cross-linked HF inserts will require close clinical follow-up.

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48 Venous Thromboembolism in Total Knee Arthroplasty

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Clinical scenario

- A 70-year-old gentleman presents to your clinic for a preoperative appointment. He is scheduled to undergo a total knee arthroplasty (TKA) for debilitating multicompartmental osteoarthritis.
- He presents to you concerned about “blood clots” after surgery, as his wife suffered from a pulmonary embolism (PE) after her recent total knee replacement surgery.
- Specifically, he would like to know your regimen for screening and preventing venous thromboembolism after surgery.

Top three questions

1. In patients undergoing TKA, are newer-generation anticoagulants superior to older agents for venous thromboembolism prophylaxis?
2. In patients undergoing TKA, is routine postoperative screening, compared to no screening, for venous

thromboembolic disease effective in preventing morbidity and mortality?

3. In patients undergoing TKA, is extended duration venous thromboembolism prophylaxis more effective than short duration prophylaxis?

Question 1: In patients undergoing TKA, are newer generation anticoagulants superior to older agents for venous thromboembolism prophylaxis?

Rationale

Thromboembolic disease – specifically PE and deep vein thrombosis (DVT) – was once a common and morbid complication following TKA. The combination of iatrogenic surgical trauma, immobilization, and venous stasis (the so-called Virchow's triad) result in the formation of clots in the deep veins of the lower extremity, some of which migrate to the pulmonary circulation, potentially leading to fatal pulmonary disease. The introduction of prophylactic anticoagulation following TKA substantially reduced the incidence of thromboembolic disease in the lower extremities.[1] However, PE remains a dreaded, albeit infrequent, postoperative complication. Ongoing research has endeavored to determine the optimal prophylactic regimen to prevent thromboembolism following TKA.

Clinical comment

There are several available options for the prophylaxis of thromboembolic disease following TKA. Mechanical prophylaxis includes the use of lower extremity pneumatic

compression devices or continuous passive motion (CPM) to prevent venous stasis and the subsequent development of DVT. Chemoprophylaxis has traditionally involved the use of warfarin (i.e. a vitamin K antagonist), acetylsalicylic acid (ASA), heparin, or low-molecular-weight heparin (LMWH). Newer pharmacologic agents, referred to as *direct oral anticoagulants* or *DOACs*, are gaining widespread acceptance due to their perceived efficacy and convenience (i.e. oral administration, no requirement for weekly monitoring, etc.). DOACs include agents which directly inhibit thrombin or clotting factors (e.g. factor Xa inhibitors). The optimal choice has remained elusive.

Two competing issues have led to substantial controversy over the years. The need to prevent thromboembolism, including *asymptomatic* DVT, figured prominently in the first set of clinical guidelines on thromboembolism prophylaxis developed by the American College of Chest Physicians (ACCP).[2] On the contrary, concerns regarding clinically important bleeding complications (e.g. hematoma, wound healing complications, etc.) in addition to the prevention of PE (but not necessarily asymptomatic DVT) were important considerations in the initial guidelines developed by the American Academy of Orthopaedic Surgeons (AAOS).[2] Owing to these differences, some of the recommendations issued by each association, particularly pertaining to the use of ASA and other pharmacologic prophylactic agents, were in direct conflict with one another.[3] The most recent guidelines, however, are more concordant and have resolved major conflicts.[4,5]

Available literature and quality of the evidence

There are multiple randomized controlled trials (RCTs) addressing the topic of older (or traditional) prophylactic options (i.e. mechanical prophylaxis, warfarin, heparin, and

LMWHs), as well as several methodologically robust systematic reviews and meta-analyses.[6,7] Similar quality evidence exists comparing newer-generation anticoagulants to other newer-generation anticoagulants.[8,9] The most thorough quantitative summary of the latter is provided by a network meta-analysis comparing venous thromboembolism and major bleeding amongst six common prophylactic anticoagulants: fondaparinux, dabigatran, rivaroxaban, apixaban, edoxaban, and enoxaparin.[8]

The use of ASA for thromboembolism prophylaxis instead of anticoagulants has been the subject of controversy,[10] but it has also been the explored in several RCTs and a meta-analysis.[11] The meta-analysis evaluated eight RCTs comparing ASA versus anticoagulants in 1408 patients undergoing surgery for hip fracture, hip arthroplasty, or knee arthroplasty along with subgroup analyses conducted in each subcategory.

Collectively, the available literature on these comparisons represents level I evidence.

Findings

Mechanical prophylaxis

The use of a mechanical prophylaxis devices alone (i.e. intermitted pneumatic leg compression) does not prevent the risk of DVT as effectively as if an anticoagulant is added to this regimen (risk ratio [RR] = 0.52; 95% confidence interval [CI]: 0.33–0.82).[6] The risk of PE, or major or minor bleeding, is no different between regimens. The use of CPM devices after TKA has also been investigated in terms of preventing venous thromboembolism. A Cochrane review found that there was no advantage to the use of CPM in preventing venous thromboembolism after TKA (RR = 1.22; 95% CI: 0.85–1.79).[7]

DOACs

In a network meta-analysis, LMWH was compared to DOACs (and various DOACs were compared to one another).[8] The following DOACs were found to decrease the odds of venous thromboembolism as compared to enoxaparin (i.e. LMWH): apixaban (odds ratio [OR] = 0.59; 95% CI: 0.42–0.84), fondaparinux (OR = 0.47; 95% CI: 0.33–0.65), rivaroxaban (OR = 0.41; 95% CI: 0.30–0.58), and edoxaban (OR = 0.45; 95% CI: 0.24–0.84). Fondaparinux and rivaroxaban were found to increase the odds of major bleeding in comparison to LMWH (OR = 1.46; 95% CI: 1.05–2.03 and OR = 1.28; 95% CI: 1.04–1.57, respectively), whereas apixaban appeared to decrease the odds of major bleeding (OR = 0.82; 95% CI: 0.69–0.98). Importantly, the authors noted that all trials informing these conclusions were vulnerable to unclear or high risk of bias, and all were industry-sponsored trials.[8] In a separate meta-analysis, most newer-generation anticoagulants (with the exception of apixaban) were also found to increase bleeding risk compared to a LMWH.[9]

Acetylsalicylic acid (ASA)

Based on a meta-analysis of current level I evidence, ASA does not differ from anticoagulants in terms of incidence of proximal DVT in patients undergoing elective hip or knee arthroplasty (RR = 1.00; 95% CI: 0.49–2.05).[11] Rates of PE were too low to make meaningful comparative estimates. The risk of bleeding complications was also no different between groups following elective arthroplasty (RR = 0.63; 95% CI: 0.33–1.21). Of note, the anticoagulants used in the trials included in this estimate were all traditional anticoagulants (i.e. heparins or warfarin). An RCT comparison to between ASA and existing DOACs was not found. Further, in the hip fracture subgroup within the meta-analysis, it was noted that risk of bleeding was lower

with the use of ASA as compared to anticoagulants (RR = 0.32; 95% CI: 0.13–0.77).

Resolution of clinical scenario

There is currently no single gold standard regimen for thromboembolism prophylaxis. Guidelines remain broad, and more recent evidence has failed to resolve the issue. Some form of chemoprophylaxis is recommended, with or without the use of supplemental mechanical prophylaxis. Acceptable pharmacologic agents include ASA, warfarin, and newer-generation anticoagulants. There is a theoretical advantage of DOACs over ASA in terms of preventing thromboembolism; however, these agents have been associated with a higher risk of clinically important bleeding.

In this context, DOACs may represent the optimal choice in patients at high risk of thromboembolism, such as those requiring prolonged immobilization or with a previous history of DVT or PE. ASA may be the more appropriate option in patients at higher risk of bleeding or wound complications. These relative advantages have not been proven in high-quality RCTs of lower-extremity joint arthroplasty patients and therefore clinical equipoise remains.

Question 2: In patients undergoing TKA, is routine postoperative screening, compared to no screening, for venous thromboembolic disease effective in preventing morbidity and mortality?

Rationale

The use of investigations to routinely screen patients for asymptomatic DVTs is not currently the standard of care following TKA. Such screening may be advisable if it leads to a reduction in morbidity and mortality associated with thromboembolic disease.

Clinical comment

Color doppler-compression ultrasound has emerged as the most sensitive and specific diagnostic modality to detect DVT, particularly after orthopedic surgery.[12] A further advantage of this diagnostic test over traditional venography is that it is fast, convenient, and noninvasive. As such, it has excellent potential as a routine DVT screening tool as well. However, given the number of TKAs that are performed each year (i.e. over 600 000 annually in the United States alone), the use of a screening investigation for asymptomatic patients would add millions of dollars to costs every year.[13] These costs may be considered justifiable if such screening could help identify patients at risk for PE. Whether routine screening and detection of clinically asymptomatic DVTs (many of which will never become clinically important DVTs or PEs) leads to a clinical reduction in morbidity and mortality is debatable, however, and has been the subject of investigation.

Available literature and quality of the evidence

There are two high-quality RCTs, representing level I evidence, assessing the effectiveness of routine ultrasonographic screening following hip or knee arthroplasty in detecting clinically important venous thromboembolic events (i.e. PE or symptomatic DVT).[14],[15] Robinson and colleagues randomized 1024 patients

undergoing hip or knee arthroplasty to either bilateral lower extremity ultrasound screening or a sham screening procedure.[14] For both groups, pharmacologic prophylaxis was discontinued after hospital discharge in patients who did not have any evidence of thromboembolism. Schmidt and colleagues randomized 346 elective lower-extremity arthroplasty patients stratified by type of arthroplasty (i.e. hip or knee) to either prolonged prophylaxis (i.e. five weeks of LMWH) or both short duration prophylaxis (i.e. 10 days maximum of LMWH) and postoperative ultrasound screening.[15] In the latter group, anticoagulation was only continued beyond the tenth day if there was evidence of venous thromboembolism.

Findings

Robinson and colleagues found no benefit in preventing symptomatic PE or symptomatic proximal DVT between the two groups within the 90-day follow-up window (0% difference; 95% CI: −1.2% to 1.2%).[14] Schmidt and colleagues also found no differences in a composite endpoint of venous thromboembolism and mortality (8.7% with screening vs 4.3%, p = 0.12) or venous thromboembolism alone (1.2% with screening vs 0.6%, p = 0.34) at 35-day follow-up.[15] This study also evaluated for asymptomatic DVT – the clinical importance of which is less clear – and found no difference between groups at day 35.

Resolution of clinical scenario

The routine use of ultrasonographic DVT screening for patients following TKA is not recommended, as it does not lead to a reduction in clinically important venous thromboembolic events.

Question 3: In patients undergoing TKA, is extended duration venous thromboembolism prophylaxis more effective than short duration prophylaxis?

Rationale

The duration of required prophylaxis is a common inquiry posed by both patients and orthopedic surgeons. There are risks to lengthier regimens of thromboembolism prophylaxis, and identifying the optimal duration is therefore important.

Clinical comment

The delicate balance between avoidance of bleeding complications and prevention of venous thromboembolism and PE is a recurrent theme in decision-making around venous thromboembolism prophylaxis in arthroplasty surgery.[3,10] In terms of length of prophylaxis, there are two schools of thoughts. One school believes that thromboembolism prophylaxis should occur for a period of 1–2 weeks (or occasionally only until discharge from hospital), while the other argues for a more prolonged regimen of 5–7 weeks.

It is in the immediate postoperative period that patients are most pro-inflammatory and most immobile, and therefore likely at highest risk for developing venous thromboembolism. Once discharged, ongoing mobilization and physiotherapy is encouraged, theoretically decreasing the risk of thromboembolism. This would favor limiting the length that patients are exposed to anticoagulants to limit bleeding complications. On the contrary, once the

immediate postoperative inflammation settles and the wound heals, the bleeding risk of prophylactic anticoagulation is arguably lower as well. Indeed, there are certainly physiologic reasons for and against extended duration prophylaxis. Ideally, clinical outcomes – and more specifically, evidence of clinical benefit associated with acceptable rates of adverse bleeding events – would guide this decision.

Available literature and quality of the evidence

There is a high-quality level I systematic review and meta-analysis of RCTs available to answer this question published by the Cochrane group.[16] The most recent iteration of this review was published in 2016. This review evaluated trials which compared anticoagulants including LMWH, UFH (unfractionated heparin), vitamin K antagonists, and/or DOACs administered for an extended duration (5–7 weeks) with similar anticoagulants administered for only 1–2 weeks. Importantly, trials of ASA were not included in this review.

Findings

Sixteen RCTs comprising a total of 24930 patients were included in this systematic review.[16] Only three of the 16 trials included TKA, with the remaining focused on total hip arthroplasty. The comparisons were further subdivided for meta-analysis based on the pharmacologic agents included in the RCTs. A total of six different pharmacologic treatment combinations were identified. The only positive finding was a reduction in all symptomatic venous thromboembolic events (OR = 0.20; 95% CI: 0.06–0.68; moderate confidence) and symptomatic DVT alone (OR = 0.18; 95% CI: 0.04–0.81) with an extended duration of DOAC prophylaxis in patients following total hip arthroplasty. A difference in PE alone was not detected,

although this outcome suffered from low numbers and therefore low confidence. Other anticoagulants (i.e. heparins and vitamin K antagonists) failed to demonstrate a difference between short and extended duration prophylactic regimens.

Resolution of clinical scenario

In the setting of TKA, the evidence to guide decision-making is lacking. Although more extensive evidence is available for total hip arthroplasty, even these data do not conclusively support one regimen over the other. Evidence from two RCTs demonstrates that an extended duration DOAC regimen reduces symptomatic DVT (with high GRADE confidence), but not necessarily PE, without increasing bleeding complications (with moderate GRADE confidence). These findings, however, were not consistent across all types of anticoagulants. Further, whether these findings can be reproduced in TKA remains to be demonstrated.

Summary of answers

- There is no single gold standard pharmacologic agent for venous thromboembolism prophylaxis after TKA. The evidence is not conclusive, and orthopedic surgeons must weigh the need for potent prophylaxis and the need to prevent bleeding.
- Newer-generation anticoagulants (i.e. DOACs) may represent the optimal thromboembolism prophylaxis choice in patients at high risk of thromboembolism, whereas ASA may be the more appropriate choice in patients at higher risk of bleeding or wound complications. These relative advantages have not been proven in high-quality RCTs of lower-extremity joint

arthroplasty patients and therefore clinical equipoise remains.

- Routine postoperative ultrasonographic DVT screening (e.g. to guide the need for prolonged prophylaxis or thromboembolism treatment) does not reduce the incidence of symptomatic DVT or PE, and is not recommended after TKA.
- The ideal length of time for venous thromboembolism prophylaxis after TKA has not been determined. Specifically, there is no definitive difference in venous thromboembolism and bleeding between short duration and extended duration chemoprophylactic regimens following TKA. However, high-quality evidence to guide this decision is lacking.

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49 Highly Cross-Linked Polyethylene in Total Knee Arthroplasty

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Top three questions

1. For patients with total knee arthroplasty (TKA), is highly cross-linked polyethylene (XLPE) more resistant to wear than conventional polyethylene (non-XLPE)?
2. For patients with TKA, does XLPE provide better clinical outcomes and a lower revision rate than conventional polyethylene (non-XLPE)?
3. For patients with TKA, does the addition of antioxidants to XLPE, compared to no antioxidants, make it more resistant to wear?

Question 1: For patients with total knee arthroplasty (TKA), is highly cross-linked polyethylene (XLPE) more resistant to wear than conventional polyethylene (non-XLPE)?

Rationale

The main purported benefit of XLPE is increased resistance to wear.

Clinical comment

Loosening and lysis related to wear are the most common reasons for TKA revision.

Available literature and quality of the evidence

- Level I: 1 meta-analysis, 3 randomized trials.
- Level II: 2 prospective cohort trial.
- Level III: 2 case-control studies.
- Nonclinical: multiple laboratory trials (Table 49.1).

Table 49.1 Clinical trials of TKAs using XLPE.

Author	Year	Trial design	Knees (n)	Follow-up (yr)	Implant and polyethylene	Radiolucency (%)	Osteolysis (%)	Aseptic loosening (%)
Hodrick et al.[10]	2008	CCT	100	6.3 (5.8–6.8)	Natural Knee II, CR (Zimmer); Durasul	2 (2.4)	0§	0§
Minoda et al.[9]	2009	CCT	89	2	NexGen, CR (Zimmer); Prolong	5 (5.6)	0*	0*
Kim and Park[11]	2014	RCT	308	5.9 (5–6.8)	NexGen LPS-Flex, PS (Zimmer); Prolong	—	0*	0*
Kindsfater et al.[13]	2015	RCT	179	5	PFC Sigma, CR/PS (DePuy); XLK	13 (7.3)	2 (1.1)‡	1 (0.6)‡
Meneghini et al.[18]	2016	PCT	114	5 (4.3–7.4)	Triathlon PS (Stryker); X3	8 (8.1)	0*	0*
Lachiewicz and Soileau[12]	2016	RCT	94	4.5 (2–8)	NexGen LPS-Flex, PS (Zimmer); Prolong	15 (16)	0†	0

§ Four patients had osteolysis in the conventional polyethylene group and four had aseptic loosening (p = ns).

* No patients in the conventional polyethylene group had osteolysis or aseptic loosening either.

‡ There were zero patients in the conventional polyethylene with osteolysis and three patients with aseptic loosening (p = ns).

† Two patients in the conventional polyethylene group had osteolysis and none had aseptic loosening (p = ns).

CCT: controlled clinical trial; RCT: randomized controlled trial; PCT: placebo controlled trial.

Findings

Knee simulator studies on the wear behavior of tibial knee inserts have looked at the effects of long-term testing, artificial aging, presence of third body particles, implant design, and malpositioning of implants. The studies uniformly showed improved adhesive/abrasive wear with XLPE compared to non-XLPE in both cruciate retaining and posterior stabilized designs.[1–8]

Two case-control trials reported an increase in radiolucent lines in patients with non-XLPE compared with XLPE. However, there was no evidence of loosening or osteolysis and no failures in either group.[9,10] Three randomized controlled trials (RCTs) and a prospective cohort study demonstrated no differences in radiographic outcomes between TKAs with XLPE and non-XLPE.[11–13] A meta-analysis that included all the above trials found no difference in incidence of radiolucent lines, osteolysis or prosthesis loosening between XLPE and non-XLPE.[14]

Analysis of synovial fluid aspirates of patients at one-year post TKA have shown significantly fewer polyethylene wear particles in knees with XLPE versus non-XLPE.[15–17] The particles produced from the XLPE are also smaller than those produced by non-XLPE.[15–17] The biological implications of these smaller particles, however, remain unknown.

Resolution of clinical scenario

- Knee simulator studies exhibit decreased wear.
- Postoperative knee synovial fluid aspirates have less polyethylene particles in TKAs with XLPE compared with non-XLPE.
- Clinical trials have not demonstrated any difference in radiographic outcomes.

Question 2: For patients with TKA, does XLPE provide better clinical outcomes and a lower revision rate than conventional polyethylene (non-XLPE)?

Rationale

For XLPE to be considered superior to non-XLPE, it needs to demonstrate a lower revision rate and/or provide better clinical outcomes.

Clinical comment

The key factors of importance to a patient undergoing TKA are clinical outcomes and prosthesis survivorship.

Available literature and quality of the evidence

- Level I: 1 meta-analysis, 3 randomized trials.
- Level II: 1 prospective cohort trial, 2 joint registries.
- Level III: 2 case-control studies.

Findings

At short-term follow-up (4–6 years), three RCTs did not detect a difference between XLPE and non-XLPE.[11,13] An RCT by Kindsfater et al. found no significant difference in survivorship or clinical outcomes, between patients randomized to either XLPE (n = 179) or non-XLPE (n = 189) at five-year follow-up.[13] Similarly, in another RCT, Lachiewicz and Soileau found no significant difference in survivorship or clinical outcomes between patients with XLPE and non-XLPE in 236 TKAs at a mean follow-up of 4.5 years.[12] Kim and Park randomized 308 patients undergoing bilateral TKA to receive XLPE in one knee and non-XLPE in the other knee.[11] Again, they found no significant difference in survivorship or clinical outcomes at a mean follow-up of 5.9 years.

A prospective cohort study of 114 consecutive TKAs with XLPE (64) or non-XLPE (50) reported no difference in survivorship at a mean of five-year follow-up.[19] There was an increased Knee Society Score (12 points, $p = 0.01$) and Short Form 36 (SF-36) physical function score (14 points, $p = 0.005$) in the XLPE group, but a selection bias toward younger patients in the XLPE group (by a mean of 3.5 years) compared to the non-XLPE group may explain the difference. A second study that contained the same cohort, as well as patients from other institutions for a total of 224 knees, had no wear-related failures at five-year follow-up.[18]

A meta-analysis that included all the above trials found no difference in clinical outcomes or survivorship comparing XLPE and non-XLPE.[14] It should be noted, however, that all these studies only present results from relatively short follow-up (2–6 years), and that samples sizes were small.

Data from the Australian Orthopaedic Association National Joint Replacement Registry 2017 which included 534 029 primary TKAs demonstrated that using XLPE had a revision rate of 3.7% at 10 years, compared to 5.7% for non-XLPE.[20] The main reason for this difference is a reduced incidence of loosening (0.7% at 10 years for XLPE compared to 1.5% for non-XLPE). The difference in revision is even greater in younger patients (in patients <65 years, XLPE 5.2% compared to non-XLPE 8.4%, p <0.001). However, these results may be confounded by differences in prostheses that use XLPE versus those that do not. To eliminate this potential bias, an analysis was performed comparing revision rates for 16 individual prostheses that have used both XLPE and non-XLPE bearings in at least 500 procedures. The revision rate was lower when XLPE was used in three of the prostheses and there was no difference for the others. A study looking at data from 77 084 primary TKAs the Kaiser Permanente Total Joint Replacement Registry between 2001 and 2011 found no difference in revision rate between XLPE and non-XLPE at five-year follow-up.[21]

Resolution of clinical scenario

- At short-term follow-up, in randomized clinical studies, XLPE demonstrates no clinical differences to non-XLPE.
- At medium-term follow-up, registry data show a reduced rate of revision for XLPE, but only in some prostheses.
- Longer follow-up clinical data are required to determine the real value of XLPE in TKA.

Question 3: For patients with TKA, does the addition of antioxidants to XLPE, compared to no antioxidants, make it more resistant to wear?

Rationale

The rationale behind the development of XLPE with antioxidants was that the residual free radicals from the radiation cross-linking could be stabilized by the antioxidant, eliminating the need for postirradiation melting for oxidative resistance. This should result in the retention of crystallinity and fatigue resistance.

Clinical comment

Oxidized polyethylene is linked to higher incidence of wear and damage in TKAs. Loosening and lysis related to wear are the most common reasons for TKA revision.

Available literature and quality of the evidence

- Level II: 1 joint registry.
- Level III: 1 retrospective study.
- Nonclinical: multiple laboratory trials.

Findings

In vitro biomechanical studies of antioxidant XLPE have reported decreased wear, greater fatigue resistance compared to postirradiation melted XLPE, and high resistance to oxidation.[22–25] Importantly, antioxidant XLPE performed superiorly in studies of accelerated aging.[22,23,26,27] In addition to these mechanical properties, wear particles of

antioxidant XLPE have been reported to produce fewer inflammatory cytokines than conventional polyethylene when exposed to mononuclear cells in a laboratory study.[28]

An in vivo literature review found minimal clinical evidence for the use of antioxidant XLPE in TKAs. A retrospective review of a practice registry included 163 knees at a mean follow-up of 3.2 years (range 6 weeks to 6.4 years).[29] They found no incidence of aseptic loosening at this early stage. The Australian Orthopaedic Association National Joint Replacement Registry 2017 report compared the revision rate of XLPE with antioxidants to XLPE without antioxidants.[20] There was a statistically significant decrease in revision rate for antioxidant XLPE (hazard ratio [HR] = 0.80; 95% confidence interval [CI]: 0.65–0.99; p = 0.044). However, it should be noted that the maximum follow-up was only five years, overall numbers using antioxidant XLPE were small and over 80% of the procedures used a single prosthesis (Attune, Depuy). If the Attune prosthesis were excluded, there would be no significant difference.

Resolution of clinical scenario

Minimal clinical evidence for the use of antioxidant XLPE in TKAs at this early stage of its adoption. Long-term follow-up studies are required.

Summary of answers

- In short- to medium-term clinical trials, XLPE demonstrates no clinical or radiographic differences to non-XLPE.
- Registry data show a reduced rate of revision for XLPE, but only in some prostheses.
- Laboratory trials have demonstrated benefits to XLPE and antioxidant XLPE over non-XLPE.

More long-term clinical data are required.

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50 Exposure and Implant Options in Revision Total Knee Arthroplasty

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Clinical scenario

- A 72-year-old, active woman with a right total knee arthroplasty (TKA) performed 12 years ago complains of pain and locking in her right knee.
- She is having difficulty ascending and descending stairs for a year now, and requires a walking aid, even when walking a few hundred meters.
- On examination, the right knee is unstable in varus-valgus, and on X-ray, there is a valgus collapse of the tibia indicating the possibility of loosening.
- After ruling out infection a revision TKA is indicated.

Top three questions

1. In patients undergoing revision TKA, does one surgical approach, compared to others, result in optimal outcomes?
2. In patients undergoing revision TKA, does a tibial tubercle osteotomy (TTO), compared to quadriceps snip (QS), result in improved functional outcomes and fewer complications?
3. In patients undergoing revision TKA and requiring augmentation due to bone defects, do metaphyseal

cones, compared to sleeves, result in better outcomes ?

Question 1: In patients undergoing revision TKA, does one surgical approach, compared to others, result in optimal outcomes?

Rationale

Controversy exists when regarding the best surgical approach for revision total knee arthroplasty (rTKA). Such an approach should ideally have delicate management of the soft tissue envelope and reduce the risk of extensor mechanism complications.

Clinical comment

Obtaining an adequate surgical exposure is among the first and most important steps in performing an rTKA. Objectives include protecting the extensor mechanism, safely removing the implanted components, and obtaining adequate visualization to prepare the bony surfaces for the revision components.[1] Challenges to these goals include prior skin incisions, dense scarring, and the presence of patella baja.

Available literature and quality of the evidence

- Level I: 1 randomized controlled study.[2]
- Level II: 1 retrospective cohort study.[3]
- Level IV: 5 retrospective case series.[4–8]
- Level V: 1 cadaveric study.[9]

Findings

During the exposure there are three important decisions to be made while dissecting toward the prosthetic components.[10]

Skin incision

Blood supply to the anterior aspect of the knee is predominantly derived from the medial side, and it travels from deep to superficial layers. Hence, if there are many previous incisions, the most lateral one should be utilized, and full thickness skin flaps should be developed, as well as excision of the scar tissue. Transverse scars should be transected at a perpendicular angle to prevent skin necrosis. Patients with multiple scars and densely adherent skin may require a preoperative consultation with a plastic surgeon.

Capsular approach

The workhorse approach to the knee is the medial parapatellar capsular incision. When performed associated with an accurate anterior and posterior intra-articular synovectomy, it provides an adequate exposure for most revision TKAs.[8]

Using extensor mechanism tenolysis and scar removal technique, eversion of the patella and removal of components is readily accomplished for the vast majority of patients.[7] After that, the patella inversion method affords adequate exposure in most patients without violating the extensor mechanism.[4]

Mobilization of the extensor mechanism

If at this point in the procedure the exposure is inadequate, an extensive exposure of the knee is required to increase patellar excursion while maintaining the function of the extensor mechanism. It is a critical step, and it should aim

to minimize the risk of patellar tendon disruption, quadriceps tendon rupture, patellar crepitus, and soft tissue impingement, periprosthetic patella fracture, patellofemoral instability, and osteonecrosis of the patella. The decision to extend the incision proximally, distally, or in combination should be determined on an individual basis.

Proximally, relaxation of the quadriceps tendon can be achieved by a QS.[5],[11] Technically easier, it does not require an alteration in the postoperative physical therapy and it shows similar clinical outcomes as those achieved using an isolated medial parapatellar approach (MPA). However, some studies have demonstrated an increased risk of implant malalignment in primary TKA.[12] An extensive MPA increases the mobility and excursion of the patella to the same extent as the QS technique, and it is theoretically safer in terms of preservation of quadriceps tendon integrity.[9]

The V-Y modified quadricepsplasty (QP) is rarely indicated given the risk of postoperative extensor lag. Notwithstanding the possible extension lag, Zhamilov et al. conclude that QP is as effective as QS when extensile exposure is required and may be used safely, although weightbearing is delayed postoperatively.[3] In general, however, it is considered only when a TTO is contraindicated and there is severe stiffness. Distally, the exposure can be improved by a TTO, which gives the greatest degree of exposure and it is useful in patients with stiff or ankylosed knees, in cases of patella baja or when a well-fixed cemented tibial stem should be removed. TTO should be considered the gold standard in extensile exposure, but it is a technically demanding procedure and also associated with some complications if it is done without a strict technique.

Resolution of clinical scenario

- The appropriate surgical exposure for any revision procedure should be determined by careful preoperative planning based on the assessment of the previous exposures used, of the type of implant to be removed, and the extent of bone deficiencies to be reconstructed.
- A medial capsular approach with a thorough intra-articular release and extensor mechanism tenolysis provides adequate exposure for the majority of revision cases. If additional exposure is needed, a QS through tendon or an extensive MPA is often helpful, and does not alter the postoperative rehabilitation protocol.
- Surgeons performing difficult rTKA cases should be familiar with a range of approaches and must be aware of proximal and distal extension procedures.
- Further studies, preferably in a prospective randomized fashion, are required to define the differences between the more extensile approaches.

Question 2: In patients undergoing revision TKA, does a tibial tubercle osteotomy (TTO), compared to quadriceps snip (QS), result in improved functional outcomes and fewer complications?

Rationale

A MPA with a thorough intra-articular release provides adequate exposure for most revision cases. However, when

it is suboptimal and an extensive approach is needed, the next maneuver is typically a QS or a TTO.

Clinical comment

Common problems associated with multiple revisions are loss of bone stock, progressive scarring, deficits of the extensor mechanism, and stiffness. Therefore, technique modifications that focus on preservation of bone stock, maintenance of the extensor mechanism, and enhanced early mobilization bear importance. The extensile approach should ideally reduce the risk of complications while also considering the higher reinfection rate in cases of septic revisions.

Available literature and quality of the evidence

The quantity and quality of literature comparing QS and TTO is limited. Only one study prospectively compares, after randomization, both approaches.[7] A grade III study, retrospectively addressees the same question.[8] Most articles are case reports or case series that lack standardization of protocols and outcomes.

Findings

Regardless of the need for an rTKA, a safe surgical exposure and exquisite management of the soft tissue envelope is necessary. Various surgical approaches can be used at revision surgery including an MPA with synovectomy, a QS, TTO, and a V-Y quadricepsplasty, each associated with advantages and potential complications.

A medial capsular approach with a thorough intra-articular release provides adequate exposure for over 90% of revision TKA cases.[9],[11] When suboptimal, typically an extensive approach is indispensable. Most surgeons will typically opt for a QS or a TTO. The first releases the

proximal tension, while the latter allows for distal release of the extensor mechanism.

The advantages of the QS approach include its technical ease and the fact that the postoperative rehabilitation protocol does not need to be modified. Despite plausible clinical advantages in developing the plane between vastus medialis and rectus femoris, as opposed to cutting across the quadriceps tendon,[5] studies comparing QS to MPA found it to be a relatively safe approach with equivalent outcomes.[12–15]

Since TTO was first described by Dolin et al. in the 1980s,[14] it has become one of the exposures of choice for revision surgery; because of its low complications rate, it is useful in explanation and implantation, protects the extensor mechanism, lowers tourniquet time, and does not interfere with postoperative mobilization and weight bearing.[5,16,17]

Two studies have directly compared both approaches finding equivalent functional outcomes while complications rates appeared higher on QS than on TTO.[2,6]

Sun et al. enrolled 48 patients undergoing a two-stage RTKA for infected TKA using one of these two surgical approaches, 27 in the QS group and 21 on the TTO.[6] There was a significant improvement in the Knee Society Score (KSS), Hospital for Special Surgery (HSS) score, Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) scores, and maximum flexion compared to the preoperative status in both groups, while there were no statistically significant differences between the two groups. Moreover, the femorotibial alignment and patellar height also showed no differences between the two groups. Regarding complications, they found patellar tendon partial avulsion was more commonly observed in the QS group than in the TTO group (five vs two cases). No cases of

complication related directly to the osteotomy were seen in the TTO group.

Bruni et al. prospectively followed 81 patients with chronic prosthetic knee infections who were randomized to receive a TTO or QS for exposure at the time of reimplantation.[2] Patients in the TTO group had a higher mean KSS and maximum knee flexion with a lower incidence of extension lag than the QS group. There were no differences in the reinfection rate between the two groups at last follow-up and no patient had rupture of the extensor mechanism.

Due to the risk of postoperative extensor lag, a V-Y quadricepsplasty is rarely indicated.[16–18]

Resolution of clinical scenario

- A medial capsular approach with a thorough intra-articular release provides adequate exposure for the majority of revision cases.
- Both TTO and QS in revision TKA are considered reasonable options regarding clinical results, healing potential, and complication rates.
- The TTO appears to be slightly superior to QS, both functionally and in procedure-related complications. Presenting a lower risk of patellar tendon partial avulsion, a superior KSS score, and not impairing the extensor mechanism function or increasing the reinfection rate.
- A V-Y quadricepsplasty is rarely indicated.

Question 3: In patients undergoing revision TKA and requiring augmentation due to bone defects, do metaphyseal cones, compared to sleeves, result in better outcomes?

Rationale

Managing metaphyseal bone loss in rTKA is a difficult task at the best of times. The use of metaphyseal sleeves and cones over modular augments appear to be on the rise. Sleeves are linked and implant specific, whereas cones are nonlinked and can be used with different implants. Knowing which fixation technique provides us with better outcomes with the least possible complications is important.

Clinical comment

When managing metaphyseal bone defects in rTKA, it is important to enter the operating room with all potentially required components available or on call. With metaphyseal sleeves and cones, most Anderson Orthopaedic Research Institute (AORI) type 2 and 3 defects can be addressed.

Available literature and quality of the evidence

The literature comparing the two techniques, sleeves versus cones, is scarce. Most of the papers are level IV evidence, with a few case-control (level III evidence). No randomized controlled trials are available.

Findings

The metaphyseal sleeves and metaphyseal cones are both good techniques to address metaphyseal defects, including

AORI type 2 and 3. Both clinical and radiological results are comparable between both techniques, providing good functional and radiological results. They can control rotational and axial stability immediately due to press-fit configuration, and long term, thanks to the bone ingrowth. None of the currently available, low-quality literature points to a difference in radiographic or functional outcomes between cones and sleeves.[19_31]

Resolution of clinical scenario

- The use of either sleeves or cones for rTKA with metaphyseal defects provide both similar and good outcomes.
- Clinical and radiological results are similar comparing both techniques.
- Further studies, with a higher level of evidence are needed in order to determine which technique has better outcomes.
- The current recommendation is to use the technique that the surgeon manages better.

Summary of answers

- There is no single best approach for revision TKA surgery, and the approach and augmenting techniques should be selected based on the previous surgery and the defects that need to be addressed .
- TTO is superior to QS both functionally and in terms of complications.
- Metaphyseal sleeves and cones provide similar and reliable outcomes for large tibial defects.

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The Painful Total Knee Arthroplasty

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Clinical scenario

- A 57 year-old female presents with a painful total knee arthroplasty (TKA) 18 months postoperatively.
- She had pain relief for a few months postoperatively but she now has pain that interferes with her activities of daily living.
- The patient is dissatisfied with her functional outcome and the TKA.

Top three questions

1. For patients with painful TKA, what are the best evidence-based clinical investigations to assess for intra- and extra-articular etiologies in the initial work-up?
2. Are SPECT scans superior to nuclear medicine imaging or plain computed tomography (CT) scans in the evaluation of the painful TKA?

3. Are synovial biomarkers (i.e. alpha-defensin) superior to aspiration for microbiology and serum laboratory investigations in the evaluation of the painful TKA?

Question 1: For patients with painful TKA, what are the best evidence-based clinical investigations to assess for intra- and extra-articular etiologies in the initial work-up?

Rationale

As many as one in five primary TKA patients are not satisfied with the outcome of their TKA surgery.[1] This can be concerning for the patient and surgeon alike. TKA patients experiencing pain require significant healthcare resources to evaluate and manage. Ensuring that evidence-based investigations are employed will translate into appropriate use of these limited resources.

Clinical comment

Investigating the painful TKA requires a systematic approach that ensures both intra- and extra-articular etiologies are assessed.[2] Potential intra-articular etiologies include: infection, instability in flexion, mid-flexion, or extension, component malalignment, crepitation and patellar clunk syndrome, patellofemoral symptoms, such as maltracking, or avascular necrosis, aseptic loosening, hypersensitivity to metal or cement, complex regional pain syndrome, or pseudoaneurysm.[3,4]

Extra-articular causes of pain after TKA should be considered when infection and other intra-articular pathologies have been ruled out. Potential causes include

referred or secondary pain from spine, hip, foot, or ankle disease that has not yet been diagnosed, as well as vascular pathology, tendinitis, bursitis, iliotibial band syndrome, or medical comorbidities, such as metabolic bone disease or psychological illness.[5]

Understanding an algorithm with evidence-based investigations for common causes of painful TKA ensures that correctable problems are addressed. Intervening with revision TKA when the etiology is unclear generally leads to poor results.[6]>–[8]

Available literature and quality of the evidence

The quality of literature addressing appropriate investigations for a painful TKA is highly variable with level II–IV evidence. The majority of the outcome papers are case series or cohort studies. There are no randomized trials.

Findings

History/old records

A thorough pain history can assist with the diagnosis. This should include an assessment of the character, location, onset, radiation, intensity, and duration of the pain as well as provoking and palliating factors. A history of prior infection is a critical finding.[9] *Start-up* or *initiation* pain is consistent with aseptic loosening, whereas pain that is constant and does not abate should raise suspicion for periprosthetic joint infection (PJI).[7]

Details of the TKA surgery and postoperative course including odds ratio (OR) records and perioperative notes can provide information on surgical complications such as prolonged postoperative wound drainage, delayed wound healing, return trips to the operating room, and treatment with antibiotics following surgery.[7] The patient's medical

history, medications, allergies including metal sensitivities, and expectations for the surgical outcome of the TKA should also be assessed.

Physical examination

Physical examination should include a general exam with vital signs, height, weight, body mass index (BMI), general appearance, and gait. Detailed inspection of the skin can reveal the previous surgical scars, skin lesions, erythema, swelling/effusion, vascular changes, and draining sinus tracts. Gait should be specifically assessed for antalgia, varus/valgus thrust, and a Trendelenburg's sign.[7]

A focused examination of the knee should include measurement of active and passive range of motion, assessment for extensor lag, evaluation of stability to varus and valgus stressing in full extension, mid-flexion (30–60°), and 90° of flexion, and palpation for areas of focal tenderness or swelling. Patellar tracking should be examined throughout the range of motion.

A neurovascular examination should be performed assessing peripheral pulses, motor function, and sensation in the lower extremity.

Examination of joints above (hip, lumbar spine) and below (foot and ankle) the affected knee should be performed to rule out extra-articular sources of pain such as lumbar radiculopathy, vascular claudication, or referred pain from hip arthritis.[7]

Plain radiographs/three-foot standing images

Obtaining serial radiographs can assist with the evaluation of implant stability over time.[4,7] Lucent lines at the bone–implant or bone–cement interface that are complete or

greater than 2 mm may indicate loosening.[10] Implant position changes are pathognomonic for implant loosening.

Three-foot standing, anteroposterior, and lateral and patellofemoral radiographs of the affected TKA are useful for assessing the mechanical and anatomic axes of the lower extremity, as well as component positioning.

Computed tomography (CT) scans

CT assists with the evaluation of component rotation and areas of osteolysis, which are often underestimated on plain radiographs.[11]

Malrotation of the femoral component, typically internal rotation, can lead to pain following TKA through early failure due to instability.[12] Malalignment of the TKA can lead to failure due to implant wear and aseptic loosening.[13] CT can assist with diagnosis of both of these conditions.

Laboratory tests (CBC, ESR, C-reactive protein)

Complete blood count (CBC)/white blood cell count (WBC) Complete blood count or serum white cell count and differential testing is not useful in the evaluation of pain following TKA.[14] The sensitivity of the WBC count was 55% and specificity was 66% in the diagnosis of TKA infection in a recent study by Toossi.[15] However, a CBC may be helpful in the diagnosis of cases of acute hematogenous infection in the setting of a previously well-functioning arthroplasty.

Erythrocyte sedimentation rate (ESR) ESR remains elevated for up to three months post TKA. It is a sensitive but nonspecific test for the evaluation of PJI. Levitsky et al. reported that the ESR was statistically significantly higher in TKA patients with definitive infection. Also, they

reported that an elevated ESR (>30 mm/h) had a sensitivity of 60% and a specificity of 65% for PJI.[16]

Spangehl et al. identified a sensitivity of 0.82 and a specificity of 0.85 for the ESR in 202 revision arthroplasty patients.[17]

C-reactive protein (CRP) CRP can remain elevated for up to three weeks post TKA. Spangehl et al. identified a sensitivity of 0.96 and a specificity of 0.92 for CRP testing in patients with PJI.[17]

Hardcastle identified that a preoperative abnormality of either CRP or ESR significantly increased the risk of re-operation for all reasons (OR = 3.2; p = 0.0028), infection (OR 4.0; p = 0.034), and revision for aseptic loosening (OR = 3.69; p = 0.044).[18]

Alternatively, a normal ESR and CRP are reliable for predicting the absence of infection.[17]

Knee aspiration

If the ESR and/or CRP are elevated in a patient with a painful TKA, aspiration of the knee is necessary to rule out PJI.[19,20] Synovial fluid should be sent for cell count and differential, aerobic, and anaerobic culture and sensitivity, TB and fungal culture (depending on patient comorbidities, immunosuppression, and tuberculous infection prevalence).

A synovial fluid WBC count between 1100 and 3000 cells/mm^3 is strongly suggestive of a deep PJI.[19,21] These values are substantially lower than the 50 000 cells/mm^3 threshold for diagnosis of septic arthritis in a native knee. If the percentage of neutrophils is between 60 and 80%, infection is likely. As well, when the WBC count is below 1100 cells/mm^3 and the neutrophil percentage is less than 64%, the negative predictive value of knee aspiration is

98.2%; when both values are above these thresholds, the positive predictive value is 98.6%.[8]

It is important to note that these values are only accurate more than six weeks following TKA surgery due to postoperative inflammation that can impact cell count and differential aspiration results prior to that time period.

Preoperative aspiration had a sensitivity of 67% and a specificity of 96% and, therefore, has been identified as the most useful single test in the workup of the painful TKA.[16]

Resolution of clinical scenario as it relates to investigations

- A thorough history and physical examination can assist with appropriate use of ancillary tests including bloodwork, aspiration, and diagnostic imaging when evaluating a patient with a painful TKA.
- A CBC has a limited role in evaluating the painful TKA; however, normal ESR and CRP values are reliable for predicting the absence of infection.
- Aspiration of the knee is one of the most useful tests in the systematic workup of the painful TKA.
- Obtaining serial plain radiographs to assess for progressive lucencies at the bone–implant interface can be diagnostic for implant loosening.

Question 2: Are SPECT scans superior to nuclear medicine imaging or plain computed tomography (CT) scans in the evaluation of the painful TKA?

Rationale

A significant percentage of TKA patients have some complaint of pain related to the arthroplasty.[22] Often history and clinical exam can distinguish between pain generators that are self-limited or related to incomplete soft tissue rehabilitation versus those that are more sinister and can lead to revision arthroplasty. A diagnostic test that assesses alignment of a TKA but also correlates it to biologic activity or inflammation at the bone–prosthetic interface would be very helpful. single-photon emission computed tomography/computed tomography (SPECT/CT) imaging can potentially accomplish this.

Clinical comment

There has been rapid progress in diagnostic imaging of painful TKA.[23] CT scans have proven to be reliable for determining implant position within the skeleton, especially rotational alignment that cannot be appreciated easily on plain radiographs.[24] Typically, the rotation of the femoral and tibial component can be determined and correlated to the clinical picture. Radiolucent lines can be seen on plain x-rays and CT but do not necessarily mean that there is a problem with the arthroplasty. Three-phase, planar bone scintigraphy (bone scan) has been used to determine evidence of accelerated bone turnover at the implant–bone interface but is limited by lack of spatial resolution.[23] SPECT was developed to improve resolution but has been supplanted by SPECT/CT, which combines the maximum benefit of both bone scintigraphy and high-resolution CT. Information on both the mechanical and biologic aspects of TKA can potentially help to accurately diagnose the cause of pain status post TKA.

Available literature and quality of the evidence

Unfortunately, the literature on this subject is lacking as few studies directly compare SPECT/CT to three-phase planar bone scintigraphy or CT alone.

Arican et al. compared SPECT/CT to planar bone scan/SPECT in painful THA and TKA patients.[25] This was a retrospective study of patients that were taken for revision surgery. No patients were treated nonoperatively. Thirty TKAs were evaluated. SPECT/CT was shown to be more sensitive than three-phase planar bone scan (94% vs 77%) for diagnosing aseptic and septic loosening in hip and knee arthroplasty. When considering the femur and tibia components of TKA separately, SPECT/CT was more sensitive than planar bone scan, 87 versus 80% for femur and 93 and 86% for tibia. They also showed that both planar bone scan and SPECT/CT were more sensitive for making these diagnoses in knees compared to hips.

Most of the work on SPECT/CT as it relates to TKA has been done by a single research unit in Switzerland.[2226]>–[30] This group has performed a number of prospective and retrospective diagnostic studies, most with low numbers. The largest study by this group was a prospective diagnostic study of 100 painful TKAs excluding septic loosening.[27] SPECT/CT changed the diagnosis in 85% of painful TKs. Intraoperative findings confirmed the SPECT/CT diagnosis in 32/33 cases (97%). Femoral and tibial loosening and progression of patellofemoral osteoarthritis (PF OA) was correctly diagnosed on SPECT/CT in 100%. They concluded that “SPECT/CT should be part of the routine diagnostic algorithm for patients with pain after TKA.”

Al-Nabhani et al. conducted a retrospective case series of 69 patients with pain following TKA who underwent SPECT/CT.[31] They report an ability to detect loosening with a sensitivity of 100% and specificity of 95%. For

infection, the study was highly sensitive but only 88.1% specific and they noticed a more diffuse uptake pattern at the bone–prosthesis interface for infection compared to loosening which shows a more discrete uptake pattern typically around the tibial component. SPECT/CT was very helpful to determine progression of arthritis in unresurfaced compartments of the knee. SPECT/CT was inconclusive in 10 of 69 studies (14.5%) and was clinically useful in 85.5%. Only 24 cases ended up in revision and SPECT/CT diagnoses matched the revision diagnosis in 21/24 cases. The SPECT/CT report was inconclusive in three of the revised cases and turned out to be progression of OA after revision. To improve the specificity for infection, WBC scan was added bringing specificity to 100%. Specificity of SPECT/CT is affected when it is done within the first 12 months post operation.

Abele et al. and Chew et al. reported on the use of radionuclide arthrography SPECT/CT (RNA SPECT/CT) in joint arthroplasty.[32,33] The mode of radionuclide delivery is different in these studies, intra-articular instead of intravenous, in an effort to diagnose prosthetic loosening. Both of these studies are retrospective diagnostic studies with low patient numbers. Both studies looked at both THA and TKA. Abele et al. showed sensitivity of 100% and specificity of 96% for loose components. Chew et al. retrospectively compared their SPECT/CT results to planar radionuclide imaging and found higher sensitivity in diagnosing loose components, but specificity was not excellent. The sparse literature on this technique, with the potential to introduce infection into a prosthetic joint, does not show it to be a significant advance over intravenous administered radionuclide SPECT/CT. Perhaps the value in this technique would be to determine loosening in the first 12 months after TKA when there is still increased uptake

around the prosthesis with intravenous administered radionuclide.

Resolution of clinical scenario as it relates to SPECT/CT

- SPECT/CT is an advance over three-phase planar bone scintigraphy as spatial resolution is improved and it comes with the added advantage of a high-resolution three-dimensional (3D) CT scan which can accurately determine implant position in relation to mechanical and anatomic axes as well as bone and soft tissue changes around the arthroplasty.
- The sensitivity of a SPECT/CT is very high. A negative study in our particular case would be very reassuring that the pain being experienced is either referred pain or related to inadequate soft tissue rehabilitation and does not require revision surgery.
- The diagnostic dilemma is really between aseptic or septic loosening. At 1–2 years post TKA, there can still be nonpathologic radiotracer uptake around the arthroplasty, but the intensity of that uptake should be low. Aseptic loosening on SPECT/CT will be indicated as a more discrete area of increased radiotracer uptake, usually around the tibial stem versus a more generalized increased uptake around the entire TKA implant in the case of infection.
- If persistent ambiguity exists, an Indium-111 WBC scan (or even a leukocyte-labelled SPECT/CT) can be performed to increase the chances of an accurate diagnosis.

Question 3: Are synovial biomarkers (i.e. alpha-defensin) superior to aspiration for microbiology and serum laboratory investigations in the evaluation of the painful TKA?

Rationale

In the evaluation of the painful TKA, it is critical to differentiate between septic and aseptic causes. The efficacy in diagnosing PJIs utilizing synovial biomarkers is becoming increasingly evident.

Clinical comment

The diagnosis of a PJI in the assessment of a painful TKA can be challenging. The current use of serum inflammatory markers (CRP and ESR) as well as joint aspiration for leukocyte count and differential is not uniformly reliable. Therefore, there is a need to improve the efficiency and reliability in diagnosing a PJI as it relates to a painful TKA. Synovial fluid biomarkers have become of interest to improve the diagnostic accuracy of PJIs.[34,35]

Available literature and quality of the evidence

The current best available evidence consists of one level I diagnostic study[36] and several level II diagnostic studies[35,37>-41] that assess the use of synovial fluid biomarkers to diagnose PJIs. This includes one level II systematic review and meta-analysis.[41]

Findings

Bonanzinga et al. performed a prospective study to determine the sensitivity, specificity, as well as the positive

and negative predictive values of the synovial fluid alpha-defensin test to diagnose PJIs.[36] They also sought to determine factors that may lead to false-positive and false-negative results. Their study included 156 patients, 65 of whom had TKAs.

They found that the alpha-defensin immunoassay had a sensitivity, specificity, positive predictive value, and negative predictive value of 97, 97, 88, and 99%, respectively. Of the four false-positive patients, two had metallosis and one had polyethylene wear. Only one patient had a false-negative result who also had a draining sinus, and the intraoperative cultures were also negative.

Deirmengian et al. have performed several studies to evaluate the role of synovial fluid biomarkers in diagnosing PJIs. In 2014, they published two level II studies that examined alpha-defensin.[35,38] In one study, they found that alpha-defensin had a 100% sensitivity and specificity for the diagnosis of PJI.[35] They also found that alpha-defensin in combination with synovial fluid CRP also had a high sensitivity and specificity.[38] In 2015, this same group demonstrated that synovial fluid alpha-defensin had a higher sensitivity (100%) compared to the leukocyte esterase test strip.[37]

Koh et al. performed a prospective, multicenter study to determine the diagnostic efficacy of the leukocyte esterase strip test and to identify its correlation with serum inflammatory markers as well as a synovial WBC count and polymorphonuclear percentage.[39] They enrolled 60 patients scheduled for revision TKA for either PJI or aseptic failure. The sensitivity, specificity, positive predictive value and negative predictive value were 84, 100, 100, and 79%, respectively. This test was strongly correlated with a synovial WBC count and a polymorphonuclear leukocyte count. It was moderately correlated with CRP and ESR.

Tischler et al. prospectively evaluated the presence of leukocyte esterase in synovial fluid aspirates from hip and knee joint replacements.[40] Their cohort consisted of 189 patients, 154 of which were TKAs. They found a sensitivity, specificity, positive predictive value, and negative predictive value to be 66.0, 97.1, 89.7, and 88, respectively. They concluded that the leukocyte esterase strip test provides a high specificity, positive predictive value, negative predictive value, and a moderate sensitivity.

Wyatt et al. performed a systematic review and meta-analysis to evaluate the accuracy of alpha-defensin or leukocyte esterase in the diagnosis of PJIs.[41] They found 11 eligible studies. The pooled sensitivity and specificity for alpha-defensin were 1.00 (95% confidence interval [CI]: 0.82–1.00) and 0.96 (95% CI: 0.89–0.99), respectively. The pooled sensitivity and specificity for leukocyte esterase was 0.81 (95% CI: 0.49–0.95) and 0.97 (95% CI: 0.82–0.99), respectively. The area under the curve for alpha-defensin and PJI was 0.99 (95% CI: 0.98–1.00). The area under the curve for leukocyte esterase and PJI was 0.97 (95% CI: 0.95–0.98). They also found a lot of heterogeneity among studies.

Resolution of clinical scenario as it relates to synovial biomarkers/lab tests

- The differentiation between septic and aseptic causes of pain following TKA surgery is critical, especially prior to revision surgery.
- The use of synovial biomarkers can be helpful to diagnose a PJI.
- The leukocyte esterase colorimetric strip test is now part of the minor criteria from the International Consensus Group on PJI.[42]

- The alpha-defensin immunoassay demonstrates superior sensitivity and equal to superior specificity to the leukocyte esterase colorimetric strip test.

Summary of answers

- Serial plain radiographs, ESR, and CRP are useful for evaluating a painful TKA.
- SPECT/CT may help to distinguish between aseptic and septic loosening more accurately than three-phase planar bone scintigraphy.
- It is important to differentiate between septic and aseptic pain prior to revision surgery.

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Diagnosing the Infected Total Knee Arthroplasty

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Clinical scenario

- A 54-year-old male presents to clinic six months after right primary TKA. He reports a three-week history of progressive right knee erythema. He started using crutches in the last week due to worsening pain with activity.
- He was assessed in the Emergency Department earlier that week and prescribed oral cephalexin for suspected cellulitis of the right extremity. Bloodwork from that visit shows elevated erythrocyte sedimentation rate (ESR), elevated C-reactive protein (CRP), and normal serum white blood cell (WBC) count. An aspirate was not done.
- The patient denies any recent travel, illness, or dental visits.

Top three questions

1. In patients with signs and symptoms of infection, what is the sensitivity and specificity of synovial fluid cytology, compared to preoperative serologic investigations, for diagnosis of TKA infection?

2. In patients with signs and symptoms of TKA infection, what intraoperative measures can be used for identification of joint infection?
3. For patients with failed two-stage prosthetic exchange secondary to infection, how do patient outcomes compare for repeat attempts at implant exchange, compared to arthrodesis or amputation?

Question 1: In patients with signs and symptoms of infection, what is the sensitivity and specificity of synovial fluid cytology, compared to preoperative serologic investigations, for diagnosis of TKA infection?

Rationale

Identification of the microbial pathogen(s) is critical to the diagnosis of TKA infection. However, traditional aspiration and tissue cultures may not be sufficient to identify a pathogen for two main reasons: (i) it may be difficult to culture biofilm-associated organisms in the laboratory and (ii) the preoperative and postoperative use of antibiotics can make culture results negative.[1] For patients with this type of presentation, alternative, nonmicrobiological testing methods are critical for diagnosis of TKA infection.

Clinical comment

Identification of the microbial pathogen(s) is essential for diagnosis of TKA infection and for selection of appropriate pathogen-specific antimicrobial therapy. There has been growing interest in using nonculture-based methods to diagnose TKA infection.

Available literature and quality of the evidence

Level I and II evidence exists to answer this question.

Findings

The initial history and physical exam are crucial to the diagnosis of periprosthetic joint infection (PJI). Patient risk factors and perioperative risk factors should be identified.[2] Blood tests, including serum ESR and CRP have high sensitivity, good negative predictive value, and are cost-effective screening tools.[3] ESR sensitivity and specificity are 75% (95% confidence interval [CI]: 72–77%) and 70% (95% CI: 68–72%), respectively.[4] CRP sensitivity and specificity are 88% (95% CI: 86–90%) and 74% (95% CI: 71–76%), respectively.[4] These blood tests can be used as adjuncts to synovial fluid cytology with WBC differential and synovial fluid culture, which have sensitivities of 90% (95% CI: 78–96%) and 62% (95% CI: 50–74%) and specificities of 91% (95% CI: 80–96%) and 94% (95% CI: 91–96%), respectively, for diagnosis of TKA infection.[5,6] Since inflammatory markers such as ESR and CRP may remain elevated for up to several months following primary TKA, they may be less useful for identifying early postoperative infection.[7] Thresholds for chronic PJI have been identified.[8]

With sensitivity and specificity of 45% (95% CI: 41–49%) and 87% (95% CI: 85–89%), respectively, serum WBC count is not as useful as serum ESR or CRP for diagnosis of TKA infection.[2,4] Serum interleukin 6 (IL-6) may be a more specific marker of acute infection, but it is not be available in all laboratories.[2] Estimated sensitivity and specificity for IL-6 are 97% (95% CI: 93–99%) and 91% (95% CI: 87–94%), respectively.[4] Overall, the diagnostic accuracy for PJI is best for IL-6, followed by CRP, ESR, and WBC count.[4]

A novel approach to PJI diagnosis involves synovial fluid inflammatory biomarkers, such as alpha-defensin. The alpha-defensin assay offers another test with excellent sensitivity and specificity (100% CI: 79–100% and 95% CI: 83–99%, respectively) for diagnosis of PJI, and it is now available for clinical use.[2,9,10] Though preliminary data suggest that alpha-defensin 1 is at least equivalent to other diagnostic modalities, larger studies are required to confirm this finding.[10]

Clinical resolution

- ESR and CRP have excellent diagnostic test performance for chronic TKA infection and should be used as initial screening tools and adjuncts to synovial fluid cytology and culture (level I).
- The diagnostic accuracy of preoperative serologic investigations for PJI is best for IL-6, followed by CRP, ESR, and WBC count (level II).
- Emerging investigations, such as serum IL-6 and synovial alpha-defensin testing, demonstrate improved sensitivity and specificity for detecting TKA infection (level II).

Question 2: In patients with signs and symptoms of TKA infection, what intraoperative measures can be used for identification of joint infection?

Rationale

Infection is the leading indication for revision surgery after TKA, and yet there is no gold standard for diagnosis. For patients with an indeterminate presentation, adjunct

intraoperative investigations are required to confirm diagnosis of TKA infection.

Clinical comment

On some occasions, patients have poor function of their TKA without any abnormal preoperative investigations. In these situations, surgeons are faced with important challenges: (i) do we take the patient to the operating room despite clear documentation of infection and (ii) are there any intraoperative investigations that can help identify TKA infection?

Available literature and quality of the evidence

Level I evidence is available to answer this question.

Findings

The use of polymerase chain reaction (PCR) technologies to diagnose PJIs by detecting bacterial deoxyribonucleic acid (DNA) has received much attention in recent years. The theoretical advantages of PCR compared to intraoperative tissue cultures include higher sensitivity, faster turnaround time, and lack of dependence on prior antibiotic treatment.[11] Tissue, synovial fluid, and sonicated prostheses fluid samples can be used for PCR analysis.[11] Tissue samples have the highest sensitivity at 95% (95% CI: 91–99%), while sonicated prosthesis fluids have this highest specificity at 96% (95% CI: 92–100%).[11] However, this technology is expensive, may not be readily available, and unlike intraoperative tissue culture it does not offer the opportunity to test antibiotic susceptibility. Furthermore, though the use of traditional PCR to detect bacterial DNA has high sensitivity, results may be limited by potential false-positive results.[12] Since bacterial DNA persist after cell death, even an antibiotic-cleared infection could have a

positive result in an otherwise sterile sample. Alternatively, reverse transcription (RT) PCR targeting ribosomal ribonucleic acid (RNA), which degrade after bacterial cell death, has been shown to be a more sensitive and specific method of diagnosing PJI than serum ESR, serum CRP, and synovial fluid analysis.[13] Furthermore, early studies suggest that sequence analysis of the ribosomal RNA may be able to identify the bacterial species in monomicrobial infections.[13]

Sonication involves the use of low-intensity ultrasound to disintegrate the biofilm on removed prosthetic implants. The sonication fluid can then be cultured or subjected to PCR, as described above, to assist with diagnosis of joint infection.[14–17] Sonication of fluid cultures has a sensitivity of 90% (95% CI: 74–84%) and specificity of 95% (95% CI: 90–98%).[18] PCR of sonication fluid, either alone or in addition to culture, is being explored and may be a promising investigation for diagnosis of joint infection in patients treated with antibiotics or those with low-virulence pathogens.[15,16]

A systematic review compared seven categories of diagnostic tests, including blood tests, nuclear diagnostics, synovial fluid cytology, bacteriology, tissue histopathology, PCR, and sonication.[19] The diagnostic test with the highest likelihood of confirming PJI was implant sonication, while the diagnostic tests which were best for ruling out PJI included: serum IL-6, serum CRP, and synovial fluid cytology. This study highlights which tests are best for confirming or ruling out infection.

Still, sonication is expensive and requires an invasive procedure. Presently, if technologies are available, implant sonication may be a useful adjust to rule in joint infection in patients undergoing presumed aseptic revision procedures.[17,19,20]

The utility of intraoperative frozen section is under investigation, and the numerical threshold needed for diagnosis remains unknown.[2,21] New technologies, such as the use of direct analysis of tissue by mass spectrometry-based techniques, including the *iknife* and desorption electrospray ionization (DESI) offer a window into the future of diagnosing PJIs.[22]

Clinical resolution

- Application of various PCR technologies for diagnosis of PJI are still in development but offer advantages over traditional serologic and synovial fluid analysis, including higher sensitivity and specificity, as well as the ability to identify microbial species (level I).
- Assessment of sonication fluid may be used as an adjunct for diagnosis of joint infection in patients undergoing presumed aseptic revision procedures or in patients with suspected PJI who have been treated with antibiotics prior to culture (level I).

Question 3: For patients with failed two-stage prosthetic exchange secondary to infection, how do patient outcomes compare for repeat attempts at implant exchange, compared to arthrodesis or amputation?

Rationale

Two-stage reimplantation is an accepted procedure for management of first-time TKA infections. There is more

uncertainty on treatment of subsequent reinfections.

Clinical comment

TKA infection can be a devastating complication and is associated with significant morbidity to patients and tremendous costs to the healthcare system. The current standard of care for most chronic TKA infections is two-stage exchange arthroplasty, which involves removal of primary implants and placement of antibiotic spacer, treatment with organism-specific antibiotics, and reimplantation following completion of a course of antibiotics and a successful antibiotic holiday.[23] A two-stage reimplantation process requires that patients sacrifice both time and function in an attempt to eradicate the infection. We are faced with a significant challenge when a two-stage reimplantation for TKA fails and the patient has persistent signs and/or symptoms of infection. What is the next best step for the patient?

Available literature and quality of the evidence

Level I–IV literature exists to answer this question.

Findings

A retrospective, population-based study showed that one year after removal of primary implants, 62% underwent reimplantation, while 4.5% underwent arthrodesis, 3.1% underwent amputation, 14.5% underwent repeat debridement without reimplantation, 12.5% did not undergo any procedure, and 3.7% died in a hospital setting.[23] Even with negative cultures at the time of the second-stage reimplantation, nearly 20% of patients have failure of treatment secondary to infection at approximately one year; a three-month course of oral antibiotics following reimplantation surgery may decrease this risk.[24]

A simulated study used a decision tree analysis with previously published values to determine what treatment offered the highest quality of life for patients following a failed two-stage reimplantation TKA. Chronic suppression with antibiotics, arthrodesis, amputation, and repeat two-stage reimplantation were compared. They showed that knee arthrodesis had the highest quality of life after a failed two-stage revision; if there is sufficient residual bone stock, arthrodesis is most likely to provide infection control while maximizing patient function.[25] Utility values for health states were taken from published literature and serve as a proxy for clinical outcomes. Though the value and comparability of utilities may be challenged, this study offers an interesting perspective on procedures that maximize patient quality of life.

However, success with knee arthrodesis is not guaranteed. Bony fusion following primary arthrodesis in the setting of failed TKA is 75%, and 46.5% of patients had at least one complication.[26] Rate of fusion was highest with the intramedullary technique, compared to other fusion techniques.[26] In addition, use of an intramedullary nail was associated with higher functional status, compared to use of an external fixator.[27] Patients undergoing fusion have better function and ambulatory status than those undergoing above-knee amputation (AKA).[28] Seventy percent of patients who had undergone fusion would have repeated this procedure, rather than AKA, if they were presented with both options.[28]

On the other hand, it is argued that AKA can provide greater ability to recreate a functioning joint with an external prosthesis.[29] Consideration of ambulation status and patient factors that influence ability to use a prosthesis are important when deciding between fusion and AKA for failed two-stage revision surgery. The majority of patients

with AKA following TKA wished that they had undergone this procedure sooner.[30]

Clinical resolution

- A three-month course of oral antibiotics following second-stage reimplantation may decrease the risk of revision failure secondary to infection (level I).
- Knee arthrodesis is a treatment option for a failed two-stage revision TKA in the context of infection. Though initial complication rates may be high, knee arthrodesis may maximize patient function (level III).
- AKA should be considered for nonambulatory patients or for patients who are good candidates for an external prosthesis (level IV).

Summary of answers

- ESR and CRP remain mainstays of PJI diagnosis, while emerging investigations, such as IL-6 and synovial alpha defensin, are likely to help improve the accuracy and precision with which PJI can be detected going forward.
- PCR technologies offer some advantages over traditional synovial fluid analysis and have higher specificity and sensitivity.
- A course of oral antibiotics following second-stage reimplantation may decrease the risk of revision failure.
- Knee arthrodesis and AKA are salvage procedures in multiply failed revision TKA patients.

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Management of the Infected Total Knee Arthroplasty

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Clinical scenario

- A 78-year-old female presents herself at the Emergency Department of your hospital. Patient's history mentions a primary total knee arthroplasty (TKA) of the right knee 12 months earlier and type two diabetes treated with oral antidiabetics.
- The patient mentions initial unremarkable recovery, with discharge out of the hospital on the third postoperative day. In the past months, the knee has been alternatingly swollen and painful after long walks. During the last two days, the patient has developed a fever and the knee has become swollen, painful, and warm.
- Physical examination reveals a body temperature of 38.8 °C. You see a diffuse red erythema surrounding the scar on the right knee. There is no wound effusion. Flexion of the knee is painful and limited to 80°. A plain radiograph of the right knee shows an uncomplicated situation after TKA, without signs of loosening.

Top three questions

1. What is the role of debridement, antibiotics, and implant retention in patients with early/acute hematogenous versus chronic prosthetic joint infection?
2. Which type of revision surgery strategy provides the better outcome in chronically infected TKA: one-stage or two-stage revision?
3. Which type of spacer leads to superior outcome after two-stage revision TKA: a static or a dynamic knee spacer?

Question 1: What is the role of debridement, antibiotics, and implant retention in patients with early/acute hematogenous versus chronic prosthetic joint infection?

Rationale

Laboratory findings show an elevated C-reactive protein (CRP; 137 mg/L) and normal erythrocyte sedimentation rate (ESR; 18 mm/h). Sterile aspiration of synovial fluid reveals the aspect of a purulent hematoma, the fluid is sent for culture. You have now confirmed your suspicion of a periprosthetic joint infection (PJI).

Clinical comment

If untreated, the patient will become increasingly ill. Systemic antibiotics will treat the infection but will not eradicate it, as antibiotic penetration into synovial fluid is low. The patient's complaints have changed recently, matching a suspicion for hematogenously spread infection to the TKA of the right knee, even though some complaints have already been present during the past year. You want

to know if duration of infection influences chance of success of a DAIR (debridement, antibiotics, and implant retention) procedure.

Available literature and quality of the evidence

- The literature search showed two systematic reviews (including 31 case series) and four more case series on this topic.[1–6] In addition, there is one publication on irrigation and debridement from the International Consensus Meeting on PJI.[7]
- The quality of the evidence is scored as level IV.

Findings

The reported success rates of DAIR range between 16 and 100%.[6] Because of heterogeneity of and significant methodological inconsistencies between studies, it is not possible to find more precise numbers for early, acute hematogenous and chronic infection, respectively. However, the duration between onset of symptoms and treatment seems to be important; for each additional day that treatment is delayed the odds of success decrease by 7.5%.[1] Another study showed that if the infection were treated more than eight weeks after implantation, the RR for success decreased to 0.6 (95% confidence interval [CI]: 0.3–0.95).[8]

The consensus statement advocates a DAIR procedure as the first treatment option in case of early or acute hematogenous PJI.[7] Multiple (at least three, preferably six) intraoperative tissue samples should be taken for culture.[7] All mobile parts of the prosthesis (the insert) should be replaced during the DAIR procedure.[2,9] In patients with acute hematogenous infection, the same treatment algorithm can be chosen as for early infection.[9,10]

In chronic PJI, there is no role for DAIR procedures, as the chance of success diminishes with longer duration of infection.[1,3,8,9]

Resolution of clinical scenario

- We advise a DAIR procedure with exchange of modular parts in case of an early or acute hematogenous TKA infection.
- Multiple intra-articular tissue samples should be taken for culture to determine the exact causative micro-organism and its antibiotic susceptibility.[9]
- Antibiotics should be continued for three months.[9,11] If the causative bacteria are susceptible to rifampin, it should be administered as co-therapy.[12,13]
- In case of a chronic infection there is no role for a DAIR procedure and one should proceed to an implant revision.[3,7,8]

Question 2: Which type of revision surgery strategy provides the better outcome in chronically infected TKA: one-stage or two-stage revision?

Rationale

The patient is treated with a DAIR procedure and antibiotics for three months. Sixteen months after cessation of antibiotics the patient visits you at the outpatient clinic, complaining of knee pain while walking and intermittent swelling of the knee. Laboratory results show a CRP of 25 mg/L and ESR of 31 mm/h. A plain radiograph of the knee shows a radiolucent line under the medial side of the tibial

component. Culture of sterile aspirate shows growth of the same bacteria the knee was originally infected with.

Clinical comment

In case of persisting or chronic infection of a knee prosthesis, eradication of infection without revising the prosthesis is not possible.[9,11,14] In patients who do not wish further surgery, or cannot safely be operated on, suppressive antibiotics can be considered.[9,11] In healthy patients, revision of the prosthesis is indicated, in either one or two stages.

You want to know which of the options provides her with the better outcome, considering infection eradication as well as functional recovery.

Available literature and quality of the evidence

- The literature search showed three systematic reviews (including 118 case series) and two retrospective comparative studies on this topic.[15–19] In addition, there is one publication on one- versus two-stage revision from the International Consensus Meeting on PJI.[20]
- The quality of the evidence is scored as level III–IV.

Findings

Two-stage revision with the use of an antibiotic-loaded spacer is still the gold standard in case of a chronically infected TKA.[20] The spacer is used to deliver a high local dose of antibiotic, while at the same time keeping soft tissues around the knee at length to facilitate the reimplantation of a revision prosthesis.[11,21,22] In selected patients one-stage revision of infected TKA can be considered, when the patient's immune status and soft

tissues are not compromised and the cultures show a micro-organism susceptible to effective antibiotic therapy.[14,16,18,19]

Successful eradication of infection can be achieved in 89.8% of patients after two-stage revision arthroplasty (range 69.2–100%) and in 81.9% of patients after one-stage revision arthroplasty (range 73.1–100%).[23] When pooling the number of reinfections to calculate an overall odds ratio (OR), the comparative studies produced an OR of −0.06 (95% CI: −0.13 to 0.01), suggesting no significant difference in risk of reinfection between one- and two-stage procedures.[18]

Data on functional outcome after one-stage and two-stage are limited but seem to be in favor of one-stage revision, with the mean Knee Society Score increasing 56 points for one-stage revision and 45 points for two-stage revision ($p < 0.02$), which is a clinically important difference.[15]

Resolution of clinical scenario

- Two-stage revision and one-stage revision in selected patients provide comparable infection eradication rates.[15–19] Patient selection is of key importance when performing one-stage revision.
- Functional outcome after one-stage revision appears to be better, although evidence is limited.[15]

Question 3: Which type of spacer leads to superior outcome after two-stage revision TKA: a static or a dynamic knee spacer?

Rationale

After discussing the treatment options, you agree with your patient to perform a two-stage revision of the knee arthroplasty with the use of an antibiotic-loaded interval spacer. The patient wants to know if the range of motion of her knee will be limited afterward and if certain types of spacers provide superior functional outcome.

Clinical comment

The types of spacers available to be used in a two-stage revision arthroplasty of the knee can be divided into two groups: static and dynamic spacers. A static spacer usually is a nonarticulating block of antibiotic-loaded bone cement filling the joint space. A dynamic spacer is articulating and matches the shape of the femoral and tibial component and can be either from (pre)molded bone cement or a temporary new implant. Dynamic spacers have the advantage that patients are able to perform (non-weight-bearing) flexion-extension exercises during the spacer period.

Available literature and quality of the evidence

- The literature search showed four systematic reviews (including 52 case series)[23–26] and four retrospective case series on this topic.[27–30] In addition, there is one publication on spacers from the International Consensus Meeting on PJI.[22]
- The quality of the evidence is scored as level IV.

Findings

No clear differences exist between the two types of spacers comparing infection eradication rates.[22–26] The eradication rate in the dynamic group was 89.7% (range 63–100%;

standard deviation [SD] = 9.1) and in the static group 84.8 % (range 67–92.4 %; SD 7.8; p = 0.32).[26]

Dynamic spacers seem to provide a slightly better functional outcome after two-stage revision arthroplasty.[23,25] The final mean Knee Society Score was 82 points (range 76–89 points) for patients treated with a static spacer and 83 points (range 64–91 points) for patients treated with an articulating spacer (p = 0.64).[25] The final mean range of motion was 92° (range 78–105°) in patients treated with a static spacer and 100° (range 63–120°) in patients treated with an articulating spacer (p = 0.001).[25]

Resolution of clinical scenario

Dynamic spacers seem to provide slightly better functional outcome compared to static spacers without compromising infection eradication rate.[23–26]

Summary of answers

- DAIR procedures have a good success rate in early or acute hematogenous PJI after TKA.
- DAIR should not be performed in chronic PJI.
- Two-stage revision arthroplasty with the use of an antibiotic-loaded interval spacer is still the gold standard in chronic PJI after TKA.
- One-stage revision arthroplasty can be considered in selected patients with chronic PJI. Results on infection eradication appear comparable to two-stage and functional recovery possibly better.
- Dynamic spacers provide comparable infection eradication rate compared to static spacers, but may

lead to superior functional outcome.

- It is advised to treat PJI after TKA using a standardized protocol and a multidisciplinary team, including a microbiologist and an infection specialist.
- There is a lack of high-quality evidence on the treatment of PJI after TKA. Recommendations are therefore based on the consensus statement and (reviews of) case series. High-level evidence is needed.

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54
Management of the Unstable Total Knee Arthroplasty

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Top three questions

1. In patients who have undergone total knee arthroplasty (TKA), which risk factors, compared to others, predict instability?
2. Among patients with instability who undergo revision TKA, how do functional outcomes compare to primary TKA?
3. In patients undergoing revision TKA for instability, which surgical techniques, compared to others, produce optimal outcomes?

Question 1: In patients who have undergone total knee arthroplasty (TKA), which risk factors, compared to others, predict instability?

Rationale

Identifying the causes of instability prior to revision surgery is imperative for the treating surgeon so that the subsequent revision can be appropriately directed to the

underlying cause. Failure to do this could contribute to ongoing instability following revision TKA.

Clinical comment

Instability following TKA is not uncommon, the etiology of which may be multifactorial. Elucidating the causes of instability after TKA may help prevent their incidence, as well as allow the treating surgeon to specifically look for these underlying causes and correct them through subsequent revision surgery.

Available literature and quality of the evidence

- Level IV.

Findings

The unstable TKA may result from a variety of distinct etiologies,[1] and the identification and treatment of these etiologies at the time of revision is crucial in order to restore stability. The causes of instability that have been described include, flexion/extension gap mismatch, component malposition, isolated ligament insufficiency, extensor mechanism insufficiency, component loosening, and global instability.[1] Calliess et al. in a survey of 1449 TK revisions remarks the evolving etiology of TKA failure.[2] Low-grade infection and instability are two major causes that have increased over the years. To our knowledge, this study represents the largest published series evaluating the specific failure mechanisms in revision TKA.

Surgical treatment for instability may encompass a variety of procedures, especially when the instability results from more than one etiological factor. Technical errors such as flexion/extension gap mismatch and component malpositioning tend to present early. Other causes tend to

present late and result in attenuation of the soft tissue around the knee.[1] Isolated ligament insufficiency may be persistent or iatrogenic. Extensor mechanism insufficiency causing TKA instability may be categorized into patellar component problems, tendinous and patellar bone integrity problems, and soft tissue imbalance or instability of the patellofemoral joint.[3] Component loosening is often identified preoperatively and confirmed at the time of revision surgery. Knees with component loosening may progress to multidirectional instability.[4] Global instability has been subcategorized into soft tissue attenuation (due to chronic synovitis, recurrent hemarthrosis, or undersizing of the polyethylene [PE] insert), direct negative effects of the PE insert (post fracture or wear) and knee dislocation.[1] Knee dislocation after TKA has been attributed to severe flexion/extension gap mismatch and extensor mechanism insufficiency.[1]

Resolution of clinical scenario

- The unstable TKA may arise from one or more etiologies and identification of these etiologies is integral to the restoration of stability.
- Instability is a major cause of the need for revision. Often, increased constraint is needed to supplement or perform the function of incompetent ligament and soft tissue structures.[5]
- Revision TKA for instability should specifically address the causes of the instability.

Question 2: Among patients with instability who undergo revision TKA, how do functional outcomes compare to primary TKA?

Rationale

As the number of primary TKAs performed continues to increase annually, it is reasonable to expect an increase in revision TKAs performed. Outcome data on revision TKA for instability will presumably support it as a reliable pursuit and have the potential to identify predictors of success and failure.

Clinical comment

The efficacy in revision TKA for instability is upheld by its rate of success in restoring stability and by its survivorship.

Available literature and quality of the evidence

- Level III
- Level IV.

Findings

The reason for revision TKA may affect clinical outcome following surgery. Patients having revision surgery for aseptic loosening demonstrate better improvements in Visual Analog Scale (VAS) scores for satisfaction and pain and KSS (Knee Society Score) clinical scores, as well as lower complication rates, compared to those having revision surgery for malposition, instability from ligamentous laxity/insufficiency, septic loosening, and stiffness.[6] It is plausible that with aseptic loosening, symptoms are directly caused by component loosening,

which can be completely resolved with addressing the loosening with revision. Nonetheless, revision for instability ranging from subtle to gross ligamentous laxity results in significant improvements in functional status (as measured by Knee Society and SF-36 scores) and range of motion (ROM).[7,8] The largest improvements in clinical outcomes following revision surgery, irrespective of reason for revision, tend to occur during the first three months after revision with smaller improvements demonstrated in the subsequent 12–24 months.[6]

The rate of success in restoring stability and alleviating symptoms following revision TKA for instability has been shown to be as high as 78% at an average follow-up of three years.[7] Survival rates of revision TKA (re-revision as endpoint) for aseptic causes (i.e. instability) range from 82 to 85% at five years.[9,10] Based on the Norwegian Registry, the cumulative survival rate of revision TKA for aseptic causes was 78% at 10 years and 71% at 15 years. Deep infection, instability, loose tibial component, and pain alone were the most frequently observed causes of re-revision following aseptic revision.[9] Patients with septic revision have a higher risk of revision failure than those who have an aseptic indication for revision.[10]

Resolution of clinical scenario

- Revision surgery for instability from aseptic loosening results in better postoperative clinical outcomes as well as lower complication rates compared to other causes of instability.
- The greatest improvements in clinical outcome following revision TKA occur within three months after surgery.

- Revision TKA for instability has a high rate of success with regards to restoring stability which parallels a high survival rate.

Question 3: In patients undergoing revision TKA for instability, which surgical techniques, compared to others, produce optimal outcomes?

Rationale

The surgical technique for TKA instability may predict surgical outcomes, particularly restoration of stability. It is important to identify those techniques which restore stability in order to decrease re-revision rates.

Clinical comment

An understanding of the surgical techniques that predispose to stability following revision TKA for instability will increase the survivorship of the revision.

Available literature and quality of the evidence

- Level III
- Level IV.

Findings

The type of revision for instability may affect surgical outcomes. Factors that significantly predict the attainment of a stable knee following revision, evidenced by surgeon assessments of knee stability at follow-up, are revising both the femoral and tibial components and the use of femoral augments TKA.[7] Elevation of the joint line correlates

significantly with failure to achieve a stable TKA.[7] Proper restoration of the joint line after revision arthroplasty correlates with better functional outcome.[11] Revision of both the femoral and tibial components is also a predictor of improvement in knee function.[7] Revising both the femoral and tibial components allows the possibility for implanting a more constrained construct, which has been associated with improved stability.[7] Based on survivorship data from the Norwegian Registry, revisions done with exchange of only the femoral component or the tibial component had a 1.7 times higher risk of re-revision (95% confidence interval [CI]: 1.1–2.6) than complete revisions.[9]

Isolated exchange of PE insert has a high incidence of failure in treating instability.[7,12,13] The rate of failure (i.e. persistent instability) following isolated PE insert exchange is as high as 60%.[7] Based on survivorship data from the Norwegian Registry, isolated PE insert exchange tended to have a higher risk of re-revision than complete revision (risk ratio [RR] = 1.5; 95% CI: 0.9–2.3).[9] However, isolated PE insert exchange may be useful in select cases with posterior cruciate ligament insufficiency and concomitant anteroposterior instability, especially when exchange is to a PE insert with more anteroposterior constraint.[1,11] Also, excellent results have been reported for isolated PE insert exchange when coronal instability is the direct result of PE bearing wear.[14]

Resolution of clinical scenario

- In revision surgery for TKA instability, revision of both components and the use of femoral augments offers the most predictable outcome.
- Improvement in component positioning, restoration of the joint line, and better balance of the flexion and

extension gaps can all be facilitated by revision of all components, as well as by the use of metal augments.

- Isolated exchange of PE inserts usually results in poor and unpredictable outcomes; however, it may be successful in select cases of isolated anteroposterior instability or isolated PE bearing wear.

Summary of answers

- Unstable TKA can be due to myriad causes, and is a major cause for revision. Increased constraint is often necessary in a revision setting.
- Revision TKA for instability has a high rate of success with regards to restoring stability.
- In the context of revision surgery for instability, revision of both components and the use of femoral augments is the most reliable option.

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Stem Choices in Revision Total Knee Arthroplasty

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Introduction

The use of stemmed components in revision total knee arthroplasty (TKA) has been well established. Stems can aid in diaphyseal referencing which is thought to improve mechanical alignment intraoperatively in addition to offloading stress upon damaged or absent metaphyseal bone.[1–9] The optimal fixation method of these stemmed components is still not established. Hybrid fixation with cemented articular components and a press-fit uncemented stem has gained popularity along with the use of metaphyseal cones. This chapter will review the available literature regarding revision TKA with a focus upon the use of cemented, hybrid, and uncemented stemmed components in addition to the use of metaphyseal cones.

Clinical scenario

- An 82-year-old male presents with a painful and unstable cemented primary TKA performed 17 years ago for osteoarthritis.

- Radiographs show tibial component loosening with significant loss of medial tibial bone stock and osteolysis (Figure 55.1A and B).

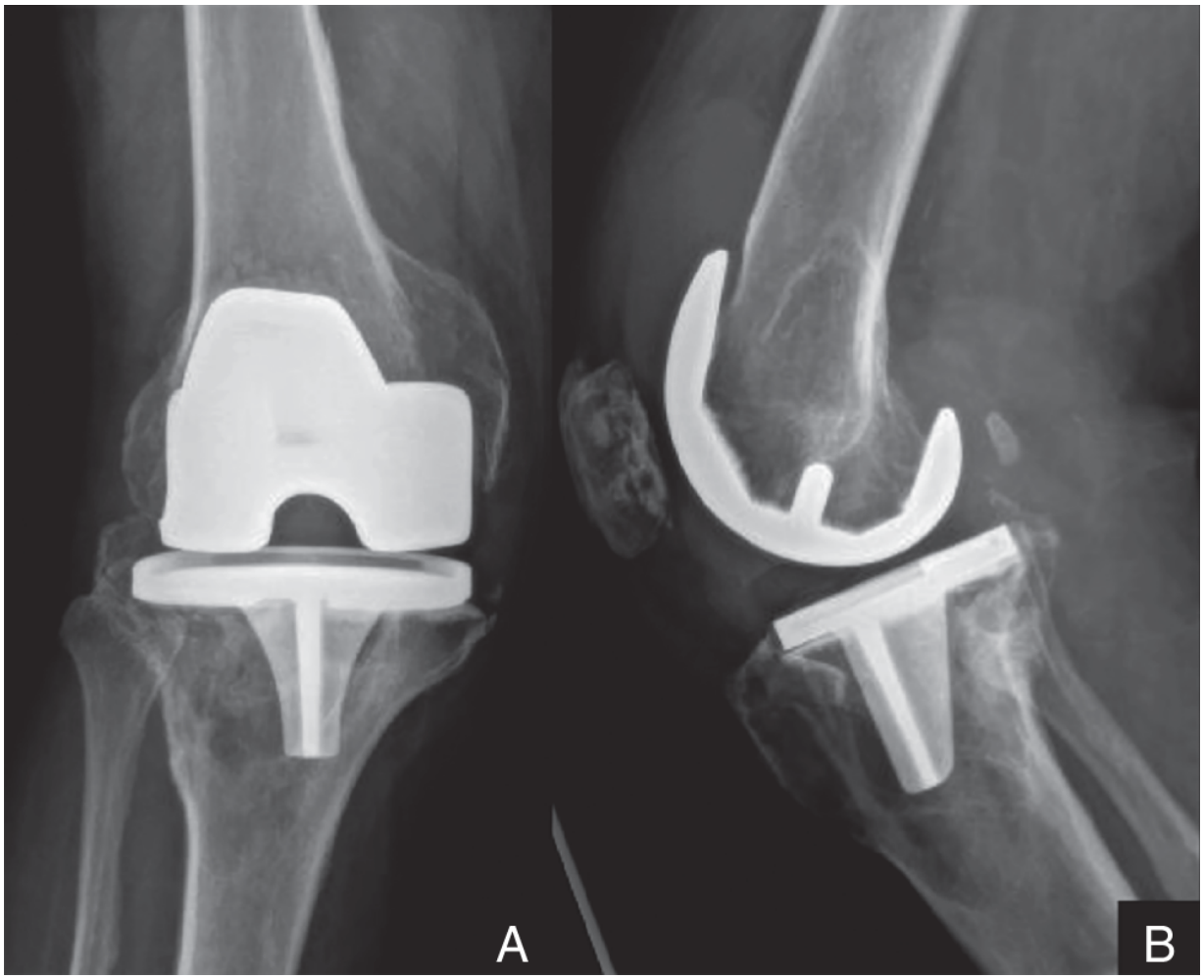

Figure 55.1 Preoperative radiographs demonstrating a loose primary TKA with significant loss of tibial bone stock.

Top three questions

1. In patients undergoing revision TKA, how do uncemented components, compared to cemented components, perform in terms of outcomes?
2. In patients undergoing revision TKA, how do hybrid components, compared to fully cemented or

uncemented components, perform in terms of outcomes?

3. In patients undergoing revision TKA, how do cemented components, compared to uncemented components, perform in terms of outcomes?

Question 1: In patients undergoing revision TKA, how do uncemented components, compared to cemented components, perform in terms of outcomes?

Rationale

A press-fit stem has the theoretical advantage of reduced bone loss with component insertion and ease of extraction if this becomes necessary. Concerns with uncemented stems include a lack of bone ingrowth, increased incidence of malalignment, and an increased incidence of stem tip pain.[10,11]

Clinical comment

An uncemented total knee revision technique offers several advantages, including endosteal referencing and subsequent stabilization of the construct without the difficulty of future extraction compared to cemented fixation.[10] Cementless revision TKA was originally described by Whiteside using a mixture of loosely packed cancellous allogeneic and autogenic morselized bone with a component that had fluted press-fit titanium long stems and a sintered-bead porous tibial under-surface.[12]

Available literature and quality of the evidence

Five studies (levels II–III) are available to answer this question.

Findings

In his prospective series of 110 cases, Whiteside evaluated the results of cementless fixation and morselized allografting of metaphyseal defects at 60 to 127 months of follow-up.[12] He described an apparent increase in radiodensity in the profile views of 31 tibias and 28 femora at postoperative intervals greater than 1 year, suggestive of bone remodeling. Only 1 tibial component was revised for loosening.[12] Hanna et al. reviewed 56 cases of revision TKA using Whiteside's technique (cementless long-stemmed components in combination with morselized bone graft) at a mean of 7.3 years (range 4–10 years), obtaining a 98% survival at 10 years. They reported a 9% reoperation rate including all-cause revision.[13]

Further interest in uncemented components has increased in recent years with the advent of foam metal technology. These metals are made of elemental tantalum or titanium and are highly porous to allow for significant bio-interlock. Foam metal has a modulus of elasticity similar to that of cancellous bone, allowing for a more physiological transfer of force from the implant to the bone interface. In 2015, Kamath et al. showed excellent medium-term (minimum five years) results of a porous tantalum cone used in 15 cases with severe metaphyseal bone stock deficit.[14] Although the authors have described the surgical technique with cementation of the tibial implant after the cone was impacted, it has also been used with allografts, bio-composite scaffolding, or in a fully cementless fashion in more rare situations. These cones may increase bone loss during bone preparation, lead to stable long-term fixation,

and have predictable bony ingrowth with a reduction in proximal stress shielding.[14]

Stem tip pain remains a disadvantage of uncemented fixation. This issue can also occur with cemented stems but at a lower incidence.[5] At a minimum follow-up of two years, Barrack reported localized pain at the end of the stem in 11% of uncemented femurs and 14% of uncemented tibias.[6] Methods to reduce stem stiffness with fluting or slots have been undertaken by some manufacturers to minimize stem tip pain. There is, however, limited evidence comparing fluted and nonfluted stems.[15,16]

Concerns about proximal stress shielding with cementless fixation remain, especially if the stem is well fixed distally.[17–19] There is also no definitive answer on optimal stem size relative to the endosteal canal. Canal filling stems would seem to provide better initial stability and alignment compared to thinner dangling stems, but long-term concerns regarding proximal stress shielding also remain with canal filling stems.[20–22]

Theoretical concern exists with uncemented implants due to greater access areas for polyethylene wear debris to enter the metaphyseal bone compared to a cemented implant.[23] It is thought that cement offers an immediate barrier to third-body debris that is absent with an uncemented prosthesis, especially in cases with increased levels of constraint. The presence of radiolucent lines and its potential association with loosening also remains a concern with uncemented prostheses.[13] It has been demonstrated that when trying to encourage biological interlock, establishing secure initial stability is crucial.[24] Minimal tolerances to micro-motion must exist if true osseointegration is to occur. Porous metals may have

advantages over fiber metal coatings in this regard due to their rougher surfaces.[24]

Finally, a long uncemented stem will not be useful in cases with severe deformities, marked osteopenia, or excessive femoral bowing. There is also an increased risk of periprosthetic fracture on stem insertion.[25] The basis of press-fit stability is also reliant upon complete canal fill when significant proximal bone stock is absent.[26]

Resolution of clinical scenario

- In the setting of severe bone loss, cement augmentation may be less than ideal. Uncemented revision TKA, alone or in combination with allografting, is an attractive option in these situations. Due to a lack of randomized controlled trials (RCTs) there is no ideal method and treatment should be individualized for each patient (level II–III).[27–29]
- Application of foam metal technology to revision TKA has been applied with successful medium-term outcomes (level III).[12,27]
- It has yet to be characterized if an uncemented prosthesis is more or less susceptible to third-body-induced osteolysis in the long term (level III).[19]
- Uncemented stems may not be useful in cases of severe femoral or tibial shaft deformities or in cases of marked osteopenia. Increased risk of periprosthetic fracture has been reported in these types of cases (level III).[27,28]

Question 2: In patients undergoing revision TKA, how do hybrid components, compared to fully cemented or uncemented components, perform in terms of outcomes?

Early work by Bertin et al. introduced the concept of smooth uncemented intramedullary stems with surface cemented tibial components.[7] The polymethylmethacrylate bone cement replaced small surface defects and afforded immediate stable fixation.[7] Parsley et al. showed that tibial anteroposterior alignment was more predictable with long cementless stems that achieved a canal-filling ratio (CFR) greater than 0.85.[1] Intramedullary canal fill and not stem length or diameter was the strongest predictor of failure with hybrid stems at a five-year follow-up period, with the risk reduced by 41.2% for each additional 10% canal fill.[29]

Stem length and diameter should be tailored according to each patient's anatomy. It has been shown that axial load can be reduced by 23 to 39% when stem length reaches 70 mm; however, with a length of at least 150 mm, secondary stress shielding of the proximal tibial cortex and a doubling of strain at the stem tip can occur.[30,31] A long stem can also lead to suboptimal position of the articular components. Gobba et al. showed that a 120 mm tibial stem forced the tibial tray into valgus alignment, and a 200 mm tibial stem deviated the tray position medially and posteriorly.[32] In this scenario, using a hybrid technique with a porous metal cone in the metaphysis and an uncemented stem can allow for the use of shorter stems to avoid articular malpositioning.[15]

Gofton et al. published a review of 89 revision TKAs completed with a hybrid fixation technique at a mean of six years; only five cases had a re-revision surgery, with a Kaplan–Meier survivorship of 93.5% at 8.6 years.[4] Wood et al. reported long-term results of 135 revision TKAs using a press-fit hybrid technique; Kaplan–Meier survivorship analysis calculated a 13% revision rate at 12 years.[3] Although the use of antibiotic impregnated cement is a known advantage to the fully cemented stem technique, in Wood's paper there was no increase in the rate of septic loosening with uncemented stems.[3] Only Shannon et al. reported on a relatively high failure rate (19%) of hybrid fixation components, with additional nonprogressive radiolucencies being found in over 90% of the surviving prosthesis with no effect on clinical outcome.[28]

Concerns have been raised regarding the ability to gain appropriate fixation in the face of poor bone quality. Loss of cortical contact through the tibial tray can increase strain across the proximal tibia. Bottner et al. recommended using fully cemented stems in scenarios of severe bone loss that lead to increased strain at the periarticular region.[11] In an RCT with radiostereometric analysis, Kosse et al. reported on the outcome of 23 (12 cemented, 11 hybrid) revision TKAs with mild to moderate bone loss at a mean of 6.5 years. There were no differences in median micromotion and clinical outcome between either technique.[30]

Gililland et al. performed a multicenter retrospective review of 82 revision TKAs performed for aseptic failure. Re-revision and radiographic failure rates were similar between the cemented and hybrid groups at an average of 76 and 121 months, respectively.[31] In a retrospective study, Gómez-Vallejo et al. found no significant difference in the clinical and radiographic outcomes of 29 cemented and 38

hybrid revision TKAs at a mean of seven years.[33] Although the outcomes were similar between the two groups, hybrid fixation tended to produce better results than cemented fixation and they therefore recommended this approach over fully cemented fixation.[33] In another retrospective study of two-stage revisions for infected TKA, hybrid diaphyseal-engaging stems had a lower rate of radiographic failure than did cemented stems at a mean follow-up of 45 months.[34]

The hybrid fixation technique is able to achieve stable fixation in the properly selected patient (i.e. one with adequate diaphyseal bone stock and minimal diaphyseal deformity) in the medium to long term.[27]

Resolution of clinical scenario

- A cemented articular prosthesis with an uncemented stem (hybrid technique) is able to achieve immediate and stable fixation. Small bony surface defects are easily dealt with by a cemented articular prosthesis (level III).[7,25]
- Lengthy stems can lead to a suboptimal position of articular components. Adding porous metal cones to reconstruct the metaphysis can allow the use of shorter stems (level III).[15,25,27,28]
- Selection criteria for full cementation include low-demand patients, large canals, and diaphyseal deformity (level III).[3,6,11]
- The hybrid technique has successful outcomes when compared to a fully cemented technique at medium and long term, but evidence is lacking (level III).[2531–33]

Question 3: In patients undergoing revision TKA, how do cemented components, compared to uncemented components, perform in terms of outcomes?

Rationale

Fully cemented stems have good long-term results, but potential difficulty with future extraction is a major downside to their use.[9,13,19]

Clinical comment

Proponents of fully cemented fixation are supported by the successful published long-term results of cemented tibial components in primary knee arthroplasty.[35] The use of cement offers immediate fixation with the benefit of intramedullary elution of antibiotics (if utilized) and the reduction of end-of-stem pain.[27] Additionally, cemented fixation is able to distribute load evenly across the prosthesis, preventing point stress shielding. However, difficulty in future extraction and malalignment due to decreased diaphyseal reference remain concerns.[35]

Available literature and quality of the evidence

Five studies (level III) are available to answer this question.

Findings

In a retrospective review of 70 fully cemented revision TKAs, Mabry et al. showed a 10-year survivorship of 92%.[36] Fehring et al. presented a retrospective review of 475 revision TKAs, including 107 fully cemented and 95 press-fit stems.[37] The diaphyseal-engaging stems had a re-

revision rate for aseptic loosening of 4%, while the cemented group had no such cases.[37] However, a recent meta-analysis was unable to find superiority of either type of fixation, as no difference in failure rates was found between the two groups.[38]

Biomechanical data have also shown similar outcomes between both techniques.[39] Despite noting no significant decrease in proximal tibial strain with the use of either cemented or cementless stems, Jazrawi et al. reported that cemented metaphyseal engaging stems had significantly less tray motion than a cementless construct of the same length.[40] Similar to the hybrid technique, the fully cemented one has also proven successful at medium-term follow-up in combination with porous tantalum cones in severe bone defects, with 100 mm being the most common stem length.[40] Therefore shorter stems may be used if a cemented metaphyseal-engaging technique is used and porous tantalum cones help to reduce the incidence of radiolucent lines even further.[40]

The literature supports the use of fully cemented stemmed components as a stable and durable construct. Nevertheless, the lack of randomized trials comparing these two fixation methods (hybrid vs cemented) poses a challenge when selecting the ideal technique.

Resolution of clinical scenario

- Cemented stems have shown excellent long-term outcomes, providing an easy technique and avoiding limb deformity. The major concern with fully cemented stems is the difficulty with later extraction (level III).[10,33]
- When compared to the hybrid technique, no categorical clinical differences were found between the two

techniques (level III).[38]

- Biomechanical data support the stability of fully cemented stemmed components, being noninferior to that of hybrid components. However, metaphyseal-engaged cemented components may enable the use of shorter components, performing better in combination with porous metal cones (level III).[39,40]

Clinical scenario continued

The patient was diagnosed with aseptic loosening and underwent revision TKA. Due to significant loss of tibial and femoral bone stock, a varus-valgus constrained system with a hybrid technique (uncemented stems and cemented metaphyseal components) along with a porous metal cone on the tibial side was implanted. Bone loss was classified as Anderson Orthopaedic Research Institute (AORI) type 3 on the tibial side and as AORI type 2B on the femoral side Figure 55.2a and b. At two-year follow-up of revision surgery, the patient remains asymptomatic with radiographs demonstrating solid fixation of the reconstruction technique (Figure 55.3a and b).

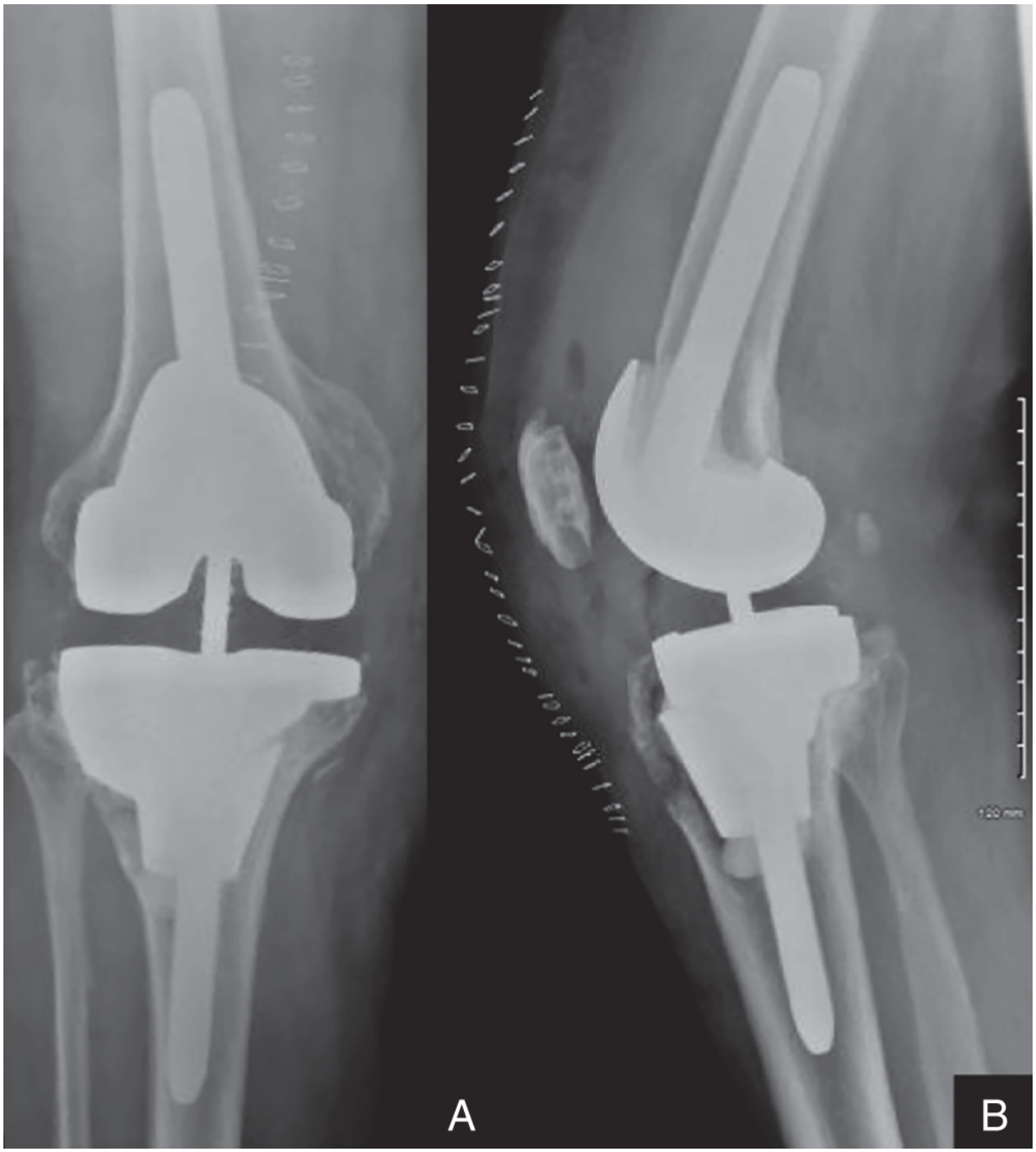

Figure 55.2 Postoperative radiographs showing a revision TKA utilizing a porous cone and hybrid cemented stem technique on both the tibial and femoral sides.

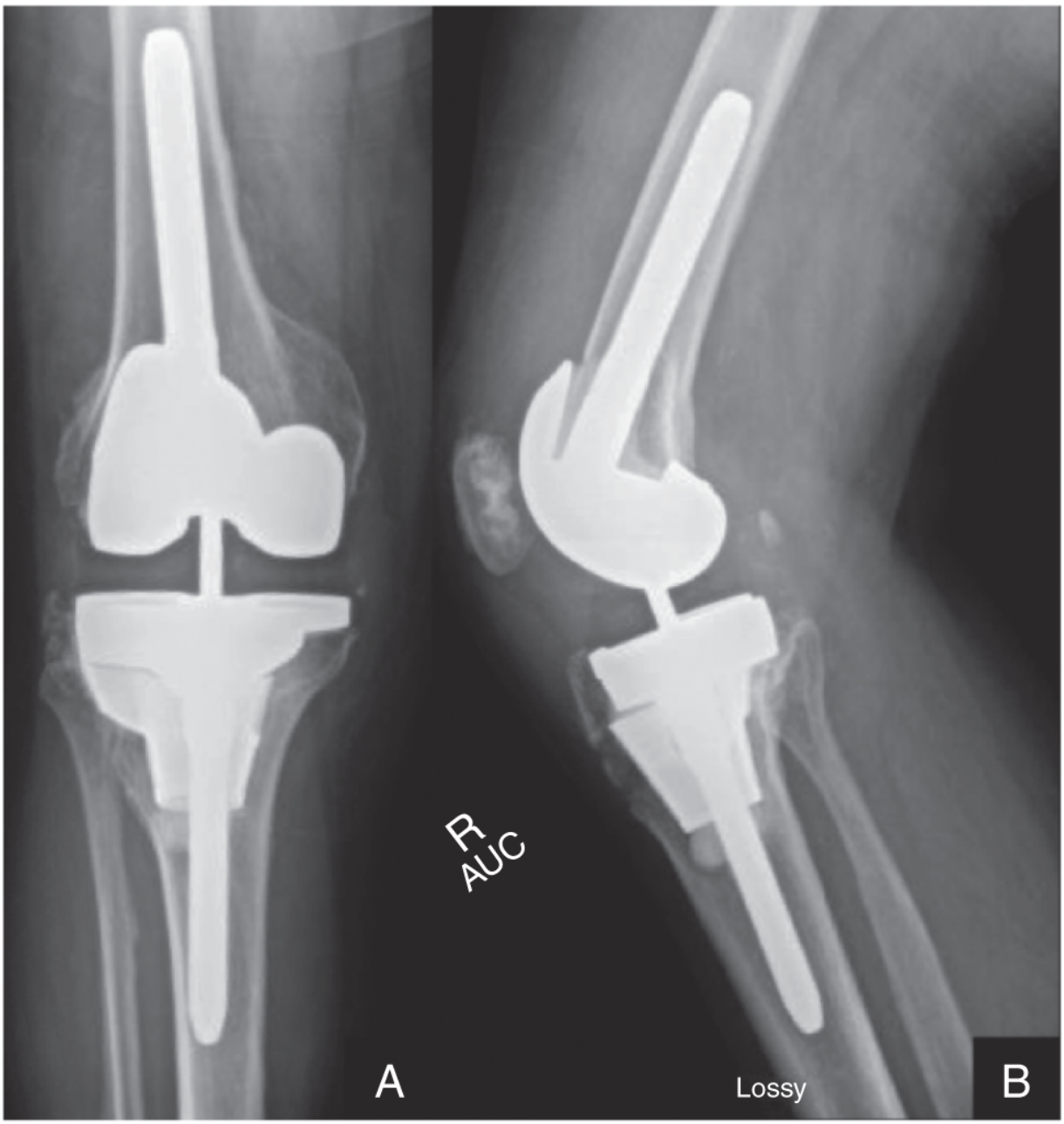

Figure 55.3 Radiographs at two-year follow-up.

Summary of answers

- From the available data, we recommend the use of a hybrid cement technique in the optimal patient where diaphyseal press-fit stemmed components are appropriate.

- Using a stem of the shortest stem length is helpful when considering future revision surgery.
- In cases of severe loss of bone stock, mostly AORI class 2B or 3, the combination of porous metal cones with only metaphyseal cementation can aid in employing a shorter stem with adequate canal filling.
- Patients with large intramedullary canals or diaphyseal deformity would be better served with a cemented component.
- Use of a cement restrictor and having an adequate cement mantle around the stem are recommended technical points when utilizing this technique.

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56
Periprosthetic Fractures: Knee

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Clinical scenario

- A 78-year-old female patient with a previously well-functioning right total knee arthroplasty (TKA) presents to the Emergency Department after suffering a fall from standing height. She is complaining of pain in her right thigh and has an obvious deformity.
- Radiographs demonstrate a distal femur periprosthetic fracture originating at the proximal aspect of a stable femoral component and no evidence of loosening or osteolysis around the tibial components (Figure 56.1).

Top three questions

1. In elderly patients with displaced periprosthetic distal femur fractures, are outcomes improved with open reduction and internal fixation (ORIF) compared to revision TKA?
2. In elderly patients with displaced periprosthetic distal femur fractures, are outcomes improved with retrograde intramedullary nailing (RIMN) compared to periarticular locked plating?

3. In elderly patients with displaced periprosthetic distal femur fractures, what is the minimal remaining bone stock required to successfully perform ORIF?

Question 1: In elderly patients with displaced periprosthetic distal femur fractures, are outcomes improved with open reduction and internal fixation (ORIF) compared to revision TKA?

Rationale

The management of periprosthetic distal femur fractures can be challenging and is often complicated by poor bone quality or bone stock. The ideal management strategy to achieve the best short-term (morbidity, rehabilitation) and long-term (knee function, implant survivorship, union rates, complications) outcomes remains unclear.

Clinical comment

Most patients with distal femur periprosthetic fractures are low-demand, medically complex patients. Careful assessment should be performed preoperatively to assess the quality and amount of bone stock, stability of components, and integrity of the collateral ligaments. Stable components with adequate bone stock are often treated with ORIF with either an RIMN or periarticular locked plating. In patients with unstable components or inadequate bone stock or quality, a revision TKA with either revision components or a distal femoral replacement (DFR) may be indicated.

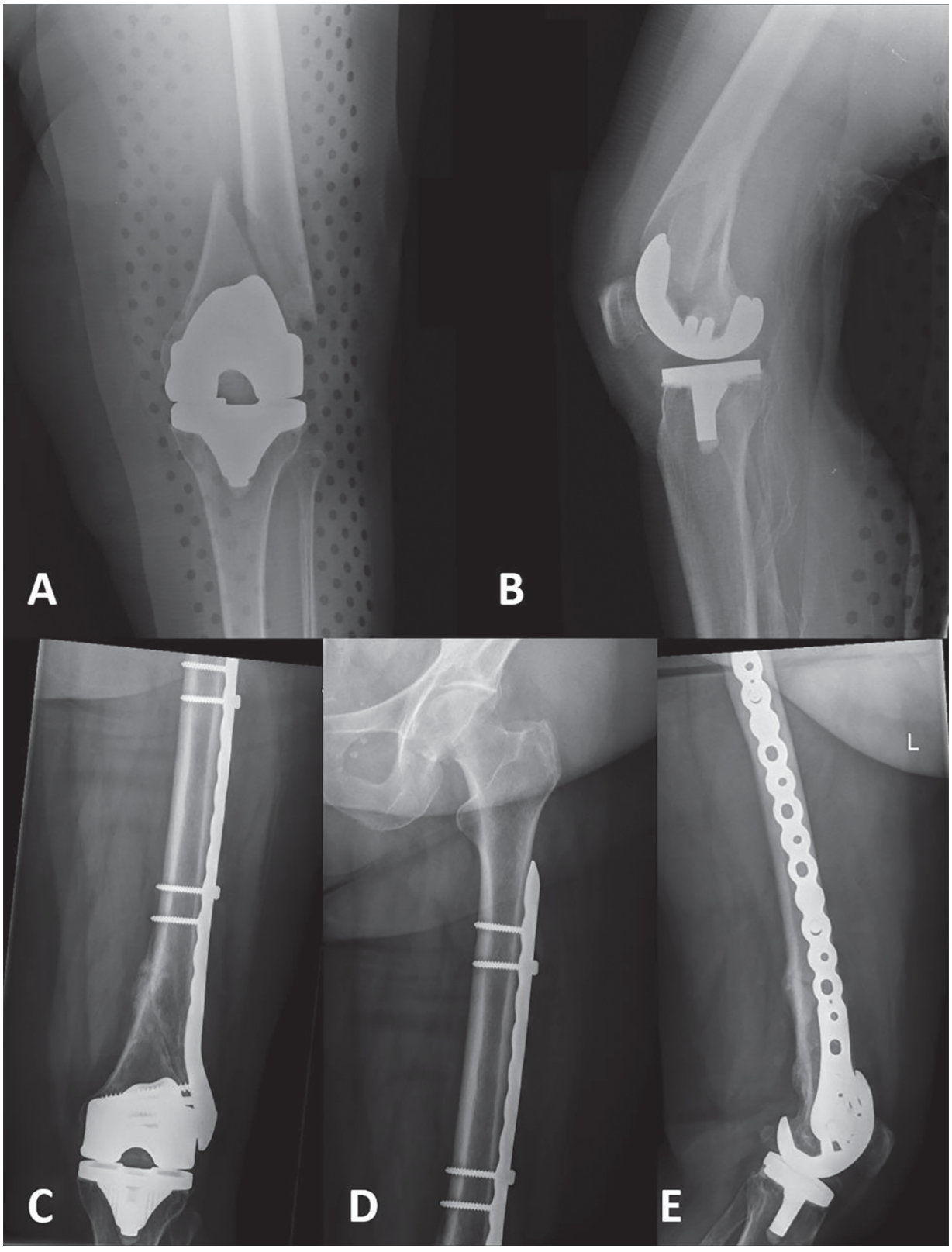
A
B
C
D
E
L

Figure 56.1 Preoperative radiographs of a 78-year-old female patient demonstrating a distal femur periprosthetic fracture above a previously well-functioning TKA (A and B). Nine-month postoperative radiographs demonstrating healing following treatment with locked plating (C–E).

Available literature and quality of the evidence

PubMed, Ovid MEDLINE, and Cochrane databases were searched with the following terms: *periprosthetic femur fracture*, *distal femoral replacement*, *periarticular plate*, *locked plate*, *open reduction internal fixation*, *intramedullary nail*, and *reamed intramedullary nail*. The quality of evidence available to answer the question is limited to four retrospective studies of level III evidence.

Findings

While there are many studies investigating the outcomes of ORIF of distal femur periprosthetic fractures,[1,2] there is a lack of studies investigating revision to a DFR for these fracture types.[3,4] There were only four level III studies that directly compared the outcomes of ORIF and DFR.[5–8]

Thirty-nine patients treated with ORIF using either a conventional or locked plating were retrospectively compared to 29 patients treated by revision to a DFR.[5] Treatment selection with regard to ORIF versus DFR was selected at the discretion of the surgeon based on the fracture pattern. All non- or minimally displaced fractures were treated with ORIF and all fractures with femoral component loosening were treated with DFR. Displaced fractures with a stable femoral component were treated with both techniques (33 with ORIF and 12 with DFR). There was no statistically significant difference between ORIF and DFR regarding clinical outcome ($p = 0.3$), survivorship (0.729, hazard ratio [HR] = 1.19; 95%

confidence interval [CI]: (046–3.09)), and infection (1.000). The only significant difference found was the occurrence of nonunion (15.4% with ORIF group vs 0% with DFR, p = 0.03). Five of the six cases of nonunion eventually underwent conversion to DFR. Three patients (10.3%) in the DFR group required repeat surgery for patellar maltracking.

Ruder et al. performed a retrospective review to assess the functional outcomes of 23 patients treated with DFR and 35 patients treated with ORIF for a distal femur periprosthetic fracture (PPF).[6] The only significant difference found preoperatively was in patient age, with older patients being more likely to receive a DFR (78 in ORIF vs 83 in DFR, p = 0.008). There was no difference in total complications (p = 0.46), hospital length of stay (p = 0.51), ambulatory status (p = 0.08), or mortality. The authors suggested that age is the predominant factor predicting ambulatory status and functional outcomes following distal femur PPF, irrespective of treatment modality.

A recent retrospective study by Hoellwarth et al. reviewed 87 patients treated with locked plating and 53 treated with DFR.[8] There was no significant difference between locked plating and DFR for 90-day mortality (9% vs 4%, p = 1.0), one-year mortality (22% vs 10%, p = 0.41), revision surgery at one year (9% vs 3%, p = 0.36), and maintaining ambulation (77% vs 81%, p = 0.30).

The final study was a retrospective review of 35 patients (36 knees) who underwent primary DFR for periprosthetic fractures and 13 patients with failed ORIF who were converted to a DFR.[7] Thirteen of 141 patients (9.2%) had failed primary ORIF for distal femur periprosthetic fracture, requiring conversion to DFR. The most common causes for failure include nonunion, infection, and refracture. There was a trend toward greater postoperative

complications for patients who failed ORIF and were converted to DFR compared with primary DFR (38.5% vs 16.7%, p = 0.09).

Resolution of clinical scenario

- Primary DFR may be associated with lower rates of complications and revision surgery compared with ORIF for periprosthetic distal femur fractures. However high-level evidence confirming this is lacking.
- DFR allows immediate weight bearing but does not have a clear benefit regarding long-term functional outcomes.

Question 2: In elderly patients with displaced periprosthetic distal femur fractures, are outcomes improved with retrograde intramedullary nailing (RIMN) compared to periarticular locked plating?

Rationale

The optimal choice of implant for ORIF of periprosthetic distal femur fractures with stable components remains unclear.

Clinical comment

Modern implants, including RIMN and locked plating, have been used to treat periprosthetic distal femur fractures. The stability of the femoral component, presence and size of an open femoral box, and location of the fracture must be taken into consideration when choosing the fixation

construct. It is unclear which construct is superior with regards to clinical outcomes, rate and time to union, complications, and need for revision surgery.

Available literature and quality of the evidence

PubMed, Ovid MEDLINE, and Cochrane databases were searched with the following terms: *periprosthetic femur fracture*, *periarticular plate*, *locked plate*, *open reduction internal fixation*, and *intramedullary nail*. The quality of evidence available to answer the question is poor and was limited to four studies with level III evidence and seven studies with level IV evidence. Only studies which directly compared locked plating and intramedullary nailing were included in the review.

Findings

Two biomechanical studies have investigated the ideal construct for periprosthetic distal femur fractures. The first compared a nonlocked plate, polyaxial locked plate, intramedullary fibular strut allograft with polyaxial locked plate, and RIMN and found that the addition of a fibular strut allograft did not improve the strength of the polyaxial locking plate.[9] RIMN had lower stiffness under cyclic torsional loading than the other constructs ($p = 0.046$) but the highest axial stiffness ($p = 0.036$). In contrast, a second biomechanical study found that RIMN with two locking bolts and two oblique distal locking screws had the best combined (torsional and axial) biomechanical stability in osteoporotic distal femur fractures when compared to locked plating, RIMN with two uniplanar locking screws, and RIMN with one screw and one spiral blade.[10]

Most studies comparing locked plating to RIMN have failed to demonstrate a difference in outcomes or complications between the two.[11–17] Bezwada et al. found no difference in

the rates of union, malunion, complications, and ROM between RIMN and ORIF, although it was unclear if they used modern periarticular locked plates or conventional nonlocked plates in the ORIF group.[11] The RIMN group had shorter operative times (45 minutes vs 74 minutes) and less intraoperative blood loss (100 cc vs 450 cc, $p < 0.05$) compared to ORIF. Hou et al. retrospectively compared 34 patients treated with minimally invasive locked plating and 18 patients treated with RIMN.[12] They showed no significant differences in time to union (4.0 ± 0.27 months vs 3.4 ± 0.30 months, $p = 0.95$), intraoperative blood loss (177.5 ± 23.4 mL vs 182 ± 31.6 mL, $p = 0.91$), operative time (87.4 ± 6.4 minutes vs 91.6 ± 6.8 minutes, $p = 0.46$), and complications between the two groups. A retrospective case series comparing seven patients treated with RIMN and nine patients treated with locked plating demonstrated no difference in mean time to union (3.9 months in locked plating group vs 3.8 months in RIMN group, $p = 0.149$), Knee Society Score (KSS), or malalignment in the sagittal or coronal planes.[13] Meneghini et al. compared 22 periprosthetic distal femur fractures treated with a modern RIMN with fixed angle distal locking screws to 63 cases treated with locked plating.[14] A mean of 5.0 distal screws was used in locked plating versus 3.8 distal screws in RIMNs ($p = 0.001$).The two groups had similar rates of nonunion (9% vs 19%, $p = 0.34$), time to union ($p = 0.64$), and malunion, although the RIMN group had a quicker mean time to resume full weight bearing (9.1 weeks vs 11.7 weeks, $p = 0.001$). Gondalia et al. found no difference between 24 patients treated with locked plating and 18 patients treated with RIMN with respect to time to union (49.8 ± 42.5 weeks vs 38.3 ± 25.5 weeks, $p = 0.649$), KSS (77.2 ± 12.7 vs 81.8 ± 8.7, $p = 0.379$), KSS functional score (76.5 ± 14.5 vs 80.6 ± 10.9, $p = 0.310$), change in ROM (11.1° ± 14.5° vs 7.2° ± 14.7°, $p = 0.364$), operative time

(135.0 minutes ± 31.9 vs 125.0 minutes ± 38.5, p = 0.223), and complications (29.2% vs 27.8% p = 0.900).[15] Park et al. performed a retrospective comparison of 20 patients treated with RIMN and 21 patients treated with locked plating using minimally invasive plate osteosynthesis (MIPO) technique.[16] There was no statistical difference between the RIMN and the locked plating groups in range of motion arc at one year (p = 0.642), one-year postoperative Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) score (p = 0.135), time to union (p = 0.081), or malalignment (p = 0.343). Most recently, Matlovich et al. compared 38 cases treated with locked plating and 19 cases treated with RIMN.[17] This study reported no statistical difference between the mean time to full weight bearing (p = 0.94), including a comparison within groups of fractures above and below the TKA flange (p = 0.11 for locked plating and p = 0.72 for RIMN). There was no difference in postoperative extension and flexion between locked plating and RIMN (p = 0.18 and p = 0.81, respectively), time to union (p = 0.64), and sagittal or coronal alignment (p = 0.76 and p = 0.84, respectively). The authors did find a higher reoperation rate (26.3% vs 2.7%) and incidence of subjective instability (17.6% vs 0%, p = 0.04) in the RIMN group, but no difference in requirement of gait aids (p = 0.81) or chronic postoperative pain (22.7% vs 22.2%, p = 0.94). There were two nonunions in the RIMN group in patients who suffered fractures below the TKA flange.

A single level IV study was the only paper to report a difference in rates of nonunion between RIMN and locked plating.[18] The retrospective review of 63 patients with displaced periprosthetic distal femur fractures pooled from three academic institutions found that the rate of nonunion was significantly higher in the RIMN group compared with the locked plating group, at 36 weeks postoperatively

(10/35 in the RIMN vs 2/28 in the locked plating group, p = 0.05). Despite this difference in union rate, the times to full weight bearing for both groups were not significantly different, with an average of 12.4 weeks for the RIMN group and 11.5 weeks for the locked plating group (p = 0.54, 95% CI: 22.02–3.80). The RIMN group had lower transfusion rates (22.9% vs 53.6%, p = 0.02) and mean operative time (113 minutes vs 155.3 minutes, p <0.01), but higher rates of revision surgery (40% vs 14.3%, p = 0.05), mostly to address nonunion.

Ristevski et al. performed a systematic review comparing nonoperative and various operative treatments for periprosthetic distal femur fractures.[1] They showed that locked plating and RIMN had several advantages when compared with nonoperative management and conventional (nonlocked) plating. Locked plating and RIMN demonstrated no significant differences in nonunion rates (odds ratio [OR] = 0.39; 95% CI: 0.13–1.15, p = 0.09) or rate of repeat surgery (OR = 0.65; 95% CI: 0.31–1.35, p = 0.25). However, RIMN had a significantly higher malunion rate when compared to locked plating (OR = 2.37; 95% CI: 1.17–4.81, p = 0.02).

Resolution of clinical scenario

- Biomechanical studies are inconclusive as to the optimal construct for torsional and axial stability in the treatment of periprosthetic distal femur fractures.
- Limited evidence suggests that there is no difference in the nonunion rate, time to union, need for revision surgery, and complications when comparing RIMN and locked plating for the treatment of periprosthetic distal femur fractures. Implant selection can be made based on surgeon discretion and fracture pattern.

- Surgeons should check the manufacturer's information before selecting RIMN for treatment to determine whether the femoral component is compatible with retrograde nailing (i.e. has an open box of adequate size to accommodate a RIMN).[19]

Question 3: In elderly patients with displaced periprosthetic distal femur fractures, what is the minimal remaining bone stock required to successfully perform ORIF?

Rationale

A major concern with ORIF of periprosthetic distal femur fractures is the ability to achieve stable fixation in a short, osteoporotic fragment of distal bone.

Clinical comment

Periprosthetic distal femur fractures with stable femoral components are typically treated with ORIF. Stable fixation can be difficult to achieve because of poor bone stock and quality. Modern intramedullary nails and periarticular locking plates allow for increased fixation in far distal fragments to increase the strength of the overall construct. The exact size of the distal fragment and number of screws required for adequate fixation remains uncertain.

Available literature and quality of the evidence

PubMed, Ovid MEDLINE, and Cochrane databases were searched with the following terms: *periprosthetic femur fracture*, *periarticular plate*, *locked plate*, *open reduction internal fixation*, and *intramedullary nail*. The quality of

evidence available to answer the question is limited to three retrospective studies of level III and IV evidence.

Findings

The three studies did not specify an exact measurement that was used to identify an extreme periprosthetic distal femur fracture, rather they used the Su or Rorabeck classifications.[20] Streubel et al. performed a retrospective review of 61 patients with unilateral periprosthetic distal femur fractures treated at three level I trauma centers with locked plating.[21] Thirty-three of these fractures extended distally from the anterior flange of the femoral component (considered by the authors to be “extreme distal”), with an average follow-up of nine months. The authors found that extreme distal periprosthetic femur fractures can be managed with ORIF with results similar to more proximal fractures. The two groups had similar rates of delayed healing (6% for distal fractures vs 18% for proximal fractures, $p = 0.23$) and nonunion (15% vs 11%, $p = 0.72$).

A second retrospective study followed 32 patients at an average follow-up of 25.3 months.[22] Eighteen patients were treated with a single MIPO locking plate and 14 with double plating. The authors' technique included dual plating in 14 of 21 patients with Su type III fractures (fractures extending distal to the anterior flange of the femoral component), specifically those with medial comminution or severe osteoporosis. There was no difference in nonunion (1/11 vs 1/21, $p = 1.0$) and mean time to union (3.8 vs 3.6 months, $p = 0.914$) between Su type I/II and Su type III fractures. The authors suggested using a second medial plate as an adjuvant for Su type III fractures.

The final study was a retrospective review of 26 patients with displaced periprosthetic distal femur fractures treated

with an RIMN with an average 81 months of follow-up. The number of distal locking screws (1 or 2 vs 3 screws) correlated with both nonunion ($p < 0.1$) and the need for revision surgery ($p < 0.1$), suggesting better outcomes if more fixation could be achieved in the distal fragment.

Resolution of clinical scenario

- Extreme distal periprosthetic femur fractures (those which extend distal to the anterior flange of the femoral component) can be adequately managed with ORIF in the setting of a stable femoral component.
- More points of fixation in the distal fragment are associated with lower rates of nonunion and revision surgery, regardless of construct (locked plating or RIMN).

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Femoral Bone Defects in Revision Total Knee Arthroplasty

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Clinical scenario

- Active 69-year-old male with a history of remote right total knee arthroplasty.
- Presents with increasing right knee pain and instability.
- Examination reveals instability to varus and valgus forces with good range of motion and normal neurovascular exam.

Introduction

One challenge of revision total knee arthroplasty (RTKA) is assessment and restoration of bony defects. Bone loss is often classified according to the Anderson Orthopaedic Research Institute (AORI) Bone Defect Classification.[1]

Defects may be characterized as contained or uncontained. Contained defects may be cavitary, representing loss of cancellous bone with intact cortical rim. By contrast, uncontained defects represent cancellous bone loss in addition to significant loss of surrounding supportive cortical bone. Uncontained defects may be segmental

involving the medial or lateral side of the femur or circumferential, involving the entire bone.[2]

In 2008, Lawrence et al. estimated that clinical osteoarthritis affects up to 27 million adults in the US, with 18 million affected by knee osteoarthritis.[3] For patients with end-stage knee arthritis, TKA is a common and successful procedure with over 95% survivorship at 10 years[4–6] and 90% survivorship at more than 15 years follow-up.[7–10] In spite of the relative success of this procedure, increasing TKA utilization has carried with it increasing rates of RTKA. Increased RTKA costs are driven by longer operating times, costlier implants, additional materials, longer hospital stays, and longer periods of convalescence.[11] Therefore, any treatment modality which can reconstruct bone defects in an efficient manner, while allowing for immediate weight bearing and mobilization, is preferable in the opinion of the authors.

Unfortunately, outcomes and success rates of RTKA are not comparable with primary TKA.[12,13] Structural bone defects commonly contribute to the complexity of RTKA.[14,15] The major etiologies of bone loss include implant wear and osteolysis, aseptic loosening, infection, and stress shielding.[16,17]

Top three questions

1. In patients with periprosthetic distal femoral bone defects, does computed tomography (CT) scan more accurately estimate defect size when compared to x-ray?
2. In large contained distal femoral defects with metaphyseal compromise, does metallic reconstruction

(cones/sleeves) yield improved survivorship compared to structural allograft reconstruction?

3. In patients with large, uncontained structural distal femoral defects (type 3), does distal femoral replacement revision knee arthroplasty yield superior clinical results compared to reconstruction with segmental allograft or allograft-prosthetic composite?

Question 1: In patients with periprosthetic distal femoral bone defects, does computed tomography (CT) scan more accurately estimate defect size when compared to x-ray?

Rationale

A detailed understanding of the location and extent of osteolysis/bone loss, and the quality/quantity of remaining distal femoral bone, is essential for proper planning and management. This is particularly important for surgeons operating in a facility which does not have the equipment and implants necessary to all modalities of reconstruction readily available.

Clinical comment

A thorough clinical assessment is essential prior to knee revision surgery to evaluate the patient's health status with possible consultation from internal medicine and anesthesia. The operative site is assessed for previous incisions and potential wound complications and workup for infection is performed using blood tests, imaging, and possibly joint aspirate for culture.

The reason(s) for TKA failure should be established and a management plan formulated. Component position, stability, and degree and location of bone loss should be assessed with x-rays and CT. Adequate assessment of these aspects of the clinical scenario will allow the surgeon to plan the reconstructive technique and ensure availability of all necessary equipment.

Available literature and quality of the evidence

Multiple studies help address this question, including one prospective study,[18] two retrospective studies,[19–21] and one cadaveric study.[22] Overall quality of evidence is moderate.

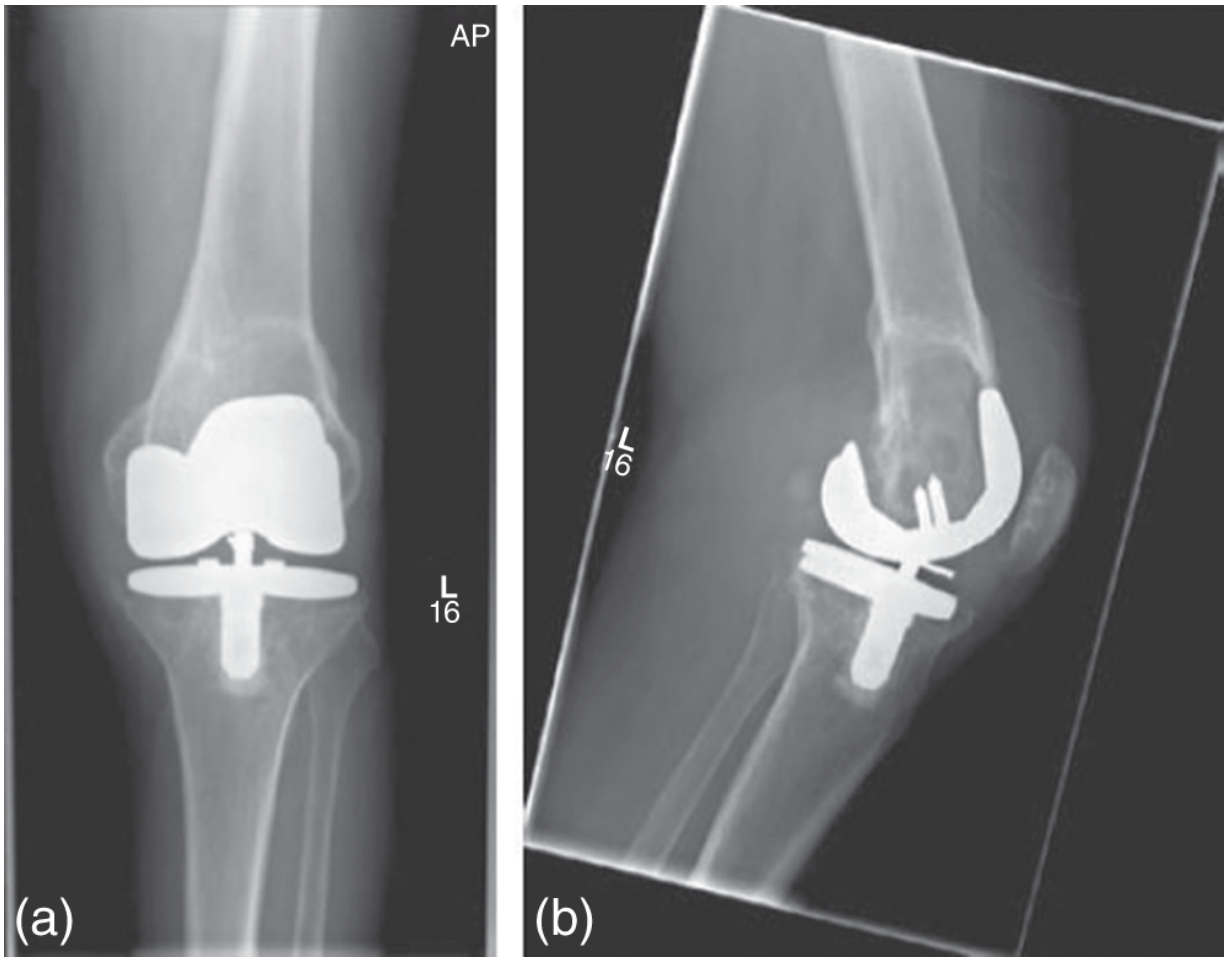

Figure 57.1 Representative radiographs of 69-year-old man with osteolysis around TKA implants. (a) Anteroposterior and (b) lateral radiographs of TKA with femoral bone loss secondary to osteolysis.

Findings

Assessment of bone loss using routine x-rays has been shown to lead to underestimation, and further imaging should be obtained including oblique views or CT scan to achieve reasonable prediction of defect size (Figure 57.1 and 57.2).[18–20,22] Agreement between plain x-ray and intraoperative assessment of bone loss has been shown to be fair based on the AORI classification.[22] Also, analysis of 31 patients who had osteolytic lesions confirmed by

multidetector CT, plain radiography detected only 17% of lesions.[21]

Resolution of clinical scenario

- A CT scan should be performed in cases of suspected bone loss for more accurate delineation of defect size and location.

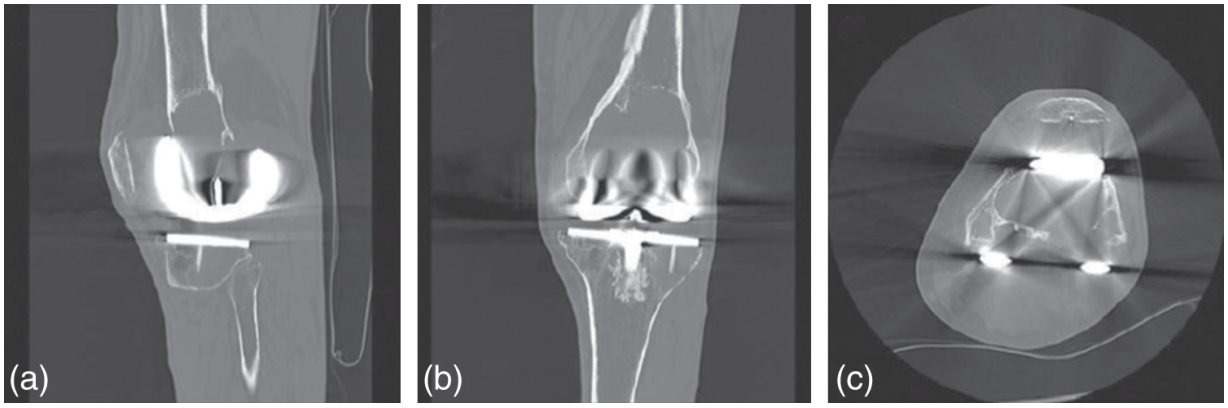

Figure 57.2 CT scan showing femoral bone loss due to osteolysis on cross-sectional imaging in the same 69-year-old patient. Representative (a) sagittal, (b) coronal, and (c) axial images showing degree of bone loss.

Question 2: In large contained distal femoral defects with metaphyseal compromise, does metallic reconstruction (cones/sleeves) yield improved survivorship compared to structural allograft reconstruction?

Rationale

While smaller contained defects are simpler to manage, larger structural defects often require the use of advanced

reconstructive strategies. Multiple reconstructive techniques have been proposed to manage these defects, with the goal of optimizing patient outcomes following this technically demanding procedure.

Clinical comment

Small, contained defects can be filled with cement[23,24] or with impacted morselized bone graft. Cement has been shown to provide inferior load transfer with poor fatigue properties,[25–27] and bone grafting may be preferred due to its biological advantage.[28,29] Smaller uncontained defects may be treated successfully with metallic block augments.[30,31]

Large defects with metaphyseal bone loss must be reconstructed to achieve implant stability, and may require augmentation with allograft or synthetic materials. Traditionally, these defects have been managed with structural and/or morselized allograft in the setting of RTKA. Similar to smaller defects, allograft reconstruction of large bone defects has the advantage of restoring bone stock. Advances in material science and the development of highly porous metal reconstructive augments (titanium sleeves, tantalum cones) has created new strategies for managing femoral defects, which avoid some of the pitfalls of allograft implantation (disease transmission, graft resorption, poor availability).

Both metallic options represent somewhat different philosophies. Tantalum cones are nonlinked to the prosthesis. The preparation of the bone bed for cones is more demanding as precise bone contouring is required while sleeves utilize a simple broaching technique. Sleeves are directly linked to the prosthesis in order to form a single unit, while cones require cement for connection to the TKA prosthesis.

Available literature and quality of the evidence

No studies were identified which directly compare the results of these reconstructive approaches. Four retrospective case series[32–35] (level IV evidence) report outcomes following reconstruction with tantalum cones, while a further two prospective[36,37] and three retrospective studies[38–40] report outcomes using porous titanium sleeves. Outcomes of structural allograft reconstruction are reported in one prospective cohort,[41] two cross-sectional studies,[42,43] and five retrospective case series.[2,44–47] Overall quality of evidence is moderate due to heterogeneity of patient population, reconstructive techniques, and outcome measures reported.

Findings

A single comparative study was identified comparing reconstruction with and without structural allograft;[43] however, the population is heterogeneous, as are the techniques utilized in the nonstructural allograft group. As a result, conclusions which address this question are difficult to draw. The Knee Society knee and functional scores (KSS) are the most commonly reported patient-reported outcome measures (PROMs)[2,32,36,37,40,41,44,45] and scores appear to be highest in titanium sleeve reconstruction (81.0, 78.8) than with tantalum cones (66.0, 61.1) or structural allograft (79.3, 60.0); however, the clinical and statistical significance of this difference is unknown.

When reported,[32–35,37,38,40,42,45,47] range of motion was also slightly greater following metallic metaphyseal reconstruction (108° vs 98°). In the short to medium term (2–5 years), metallic metaphyseal reconstruction was found to have surgical complication and reoperation rates

ranging from 6 to 19%.[32–34,37–39] When infection was excluded, however, all studies reported over 95% aseptic survivorship of metaphyseal sleeves and cones.[32–37]

By contrast, the literature indicates that the results of structural allograft may be less consistent. In addition to the rare but notable risk of disease transmission, structural allografts may be time consuming to sculpt, and resorption has been documented. Mow and Wiedel reported a reoperation rate of 20% in their cohort of 16 RTKA with structural allografts at a mean of four years;[42] however, there were no cases where the femoral component or femoral allograft were revised (100% survivorship). Additionally, several studies have reported graft healing and femoral implant survivorship rates between 77% and 90%.[2,44–47] The study by de Waal et al. stands in contrast to these findings, as only 37.5% of grafts could be confirmed to be healed at three-year follow-up.[41] For the remainder, it was reportedly unclear whether the graft had healed, or there was clear resorption.

Resolution of clinical scenario

- Porous titanium sleeves, tantalum cones, and structural allograft bone may all be considered for reconstruction of large metaphyseal defects.
- Metallic reconstruction options confer more reliable construct healing and survivorship, as well as marginally improved clinical results, while avoiding some challenges associated with the use of allograft bone.

Question 3: In patients with large, uncontained structural distal femoral defects (type 3), does distal femoral replacement revision knee arthroplasty yield superior clinical results compared to reconstruction with segmental allograft or allograft-prosthetic composite?

Rationale

These defects present unique management challenges, as reconstructive strategies must address potential compromise of implant stability, joint stability, and significant bone stock deficiency.

Clinical comment

AORI type 3 defects feature “extensive structural bone loss, involving a major portion of one or both femoral condyles.”[48] Multiple challenges arise in managing these defects: the total volume of bone loss is generally greater than in other lesion types; a segment of structural cortical bone may be absent, leading to difficulties containing and stabilizing cancellous bone or reconstructive implants; and the attachments of the collateral ligaments may be compromised, leading to knee joint instability and failure of conventional primary or revision TKA implants. Reconstruction of type 3 defects must address each of these challenges. Traditionally, these lesions have been most commonly managed with the use of segmental structural allograft. These allografts may be fixed in multiple ways. A sized allograft may be fixed to the residual native bone to restore the architecture of the distal femur,

with a stemmed RTKA implant subsequently impacted to bypass the newly placed graft. Alternatively, the RTKA implant may be cemented onto the sized and prepared allograft to create a single construct comprising the implant and structural allograft, termed an *allograft-prosthetic composite* (APC). This construct is then stabilized to the native bone by the RTKA stem. In both cases, the collateral ligaments (generally with epicondyles attached) must be stabilized to the allograft construct to restore their function. These strategies also help to restore bone stock via the addition of allograft bone. Newer hinged and distal femoral replacing implants may also be used in this circumstance. These implants can accommodate both the degree of bone loss as well as the compromised knee stability. They fail to restore bone stock, and in fact may require further bone removal to accommodate the implant. However, they restore immediate stability of the knee joint and do not rely on allograft incorporation.

Available literature and quality of the evidence

One prospective[49] and four retrospective[50–53] series reported on the results of segmental allografts and APCs, while one prospective[54] and six retrospective[55–60] reported results of hinged or distal femoral replacing implants in this setting. Overall, quality of evidence is moderate due to lack of comparative studies and inconsistency in outcomes reported.

Findings

The literature does not reveal significant differences in clinical outcomes between these two strategies. Three studies report range of motion following allograft/APC reconstruction, with an overall mean of 95.6° among 115 knees at four- to eight-year follow-up.[49,52,53] Only Jones et

al. reported specifically on range of motion following hinged TKA for bone loss, with a mean of 105° among 19 knees at four years postoperatively.[55] Marczak et al. also reported nine out of nine knees with over 90° range of motion at five years; however, exact range of motion was not reported.[56]

Once again the most commonly reported PROM was the KSS. Cumulative mean KSS across three studies (mean two- to eight-year follow-up)[50,52,53] was 86.8 following allograft reconstruction. This appeared to be slightly better than the cumulative mean KSS of 80 seen across three studies of distal femoral replacing TKA at a similar time point.[56,57,60] Statistical comparison could not be performed due to a lack of primary or statistical data reported. Reported failure rates of allograft reconstruction at up to five-year follow-up, including revisions, reoperation, fracture, and patient dissatisfaction, range between 11 and 25%.[49–51] Backstein et al. reported on one of the largest cohorts (68 grafts), reporting a 21% failure rate at a mean of 5.4 years.[51] By contrast, Engh et al. report 100% construct survivorship at a minimum two-year follow-up (mean 50 months), despite only 67% confirmed graft healing.[52] Bauman et al. published the longest term study identified, with five-year survivorship of 80% (95% confidence interval [CI]: 71.7–90.8) and 10-year survivorship of 76% (95% CI: 65.6–87.8).[53] Similar to the results of metallic reconstruction of metaphyseal defects, complication and reoperation rates were shown to be quite high following endoprosthetic reconstruction. Pour et al. reported a 20% one-year failure rate and 32% five-year failure rate following hinged TKA for massive bone loss.[54] Similarly, Marczak et al. reported a 22% failure rate at a mean five years following reconstruction with a distal femoral replacement megaprosthesis.[56] Concerningly,

Kostuj et al. reported up to 30% infection rate within 3.5 years following megaprosthetic RTKA with massive bone loss.[59] With infections excluded, most studies reported very good aseptic survivorship in the medium term (Höll[57] 87%, Kostuj[59] 91%, Marczak[56] and Jones[55] 100%).

Resolution of clinical scenario

- Available evidence is unable to definitively indicate superiority of either endoprosthetic or allograft reconstruction for type 3 femoral bone loss; however, endoprostheses have some inherent advantages.
- Both strategies necessitate technically demanding operative intervention with high complication rates.
- The patient's age, medical status, functional demands, life expectancy, and risk for future revision surgery must be considered when selecting a reconstructive strategy.

Summary of answers

- Determination of the extent of femoral defects:
  - CT scan should be performed in cases of suspected bone loss for more accurate delineation of defect size and location.
- Treatment of large contained metaphyseal defects:
  - Porous titanium sleeves, tantalum cones and structural allograft bone may all be considered for reconstruction of large metaphyseal defects
  - Metallic reconstruction options confer more reliable construct healing and survivorship, as well as marginally improved clinical results, while avoiding

some challenges associated with the use of allograft bone.

- Treatment of large segmental (type 3) defects:
  - Available evidence is unable to definitively indicate superiority of either endoprosthetic or allograft reconstruction for type 3 femoral bone loss; however, endoprostheses have some inherent advantages.
  - Both strategies necessitate technically demanding operative intervention with high complication rates.
  - The patient's age, medical status, functional demands, life expectancy, and risk for future revision surgery must be considered when selecting a reconstructive strategy.

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58
Management of Structural Defects in Revision Knee Arthroplasty: Tibial Side

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Clinical scenario

- A 59-year-old male who is eight years out from a right total knee arthroplasty (TKA) presents with a three-month history of pain dating back to a ground level fall; no infectious symptoms.
- Radiographs reveal tibial loosening with periprosthetic fracture and significant tibial bone loss (Figure 58.1 and 58.2).

Top three questions

1. In patients with moderate tibial bone loss at revision TKA, are porous metal block augments a better option for implant survival compared to cement filling?
2. In patients with moderate to severe tibial bone loss at revision TKA, is impaction bone grafting (IBG),

compared to other options, a viable technique in terms of survival – specifically aseptic loosening?

3. In patients with severe tibial bone loss at revision TKA, do metaphyseal trabecular metal (TM) sleeves and cone augments improve implant survival compared to structural allografts?

Question 1: In patients with moderate tibial bone loss at revision TKA, are porous metal block augments a better option for implant survival compared to cement filling?

Rationale

Current recommendations are that cement-filling techniques be limited to defects <5 mm in depth, and that larger defects be treated with structural augmentation. However, recent evidence suggests that cement may be appropriate in larger defects.[1]

Clinical comment

In planning for any revision TKA, one must estimate the amount of bone loss. Defects are identified and classified using radiographs and computed tomography (CT). The Anderson Orthopaedic Research Institute (AORI) classification is most commonly use.[2] Type 1 defects are minor, contained, with intact cortical bone, and the component sits above the level of the fibular head. Type 2 defects represent considerable loss of cancellous bone and the component sits at or below the proximal fibular head. Type 3 defects have a deficient metaphyseal segment, with possible compromise of ligament or tendon insertions.

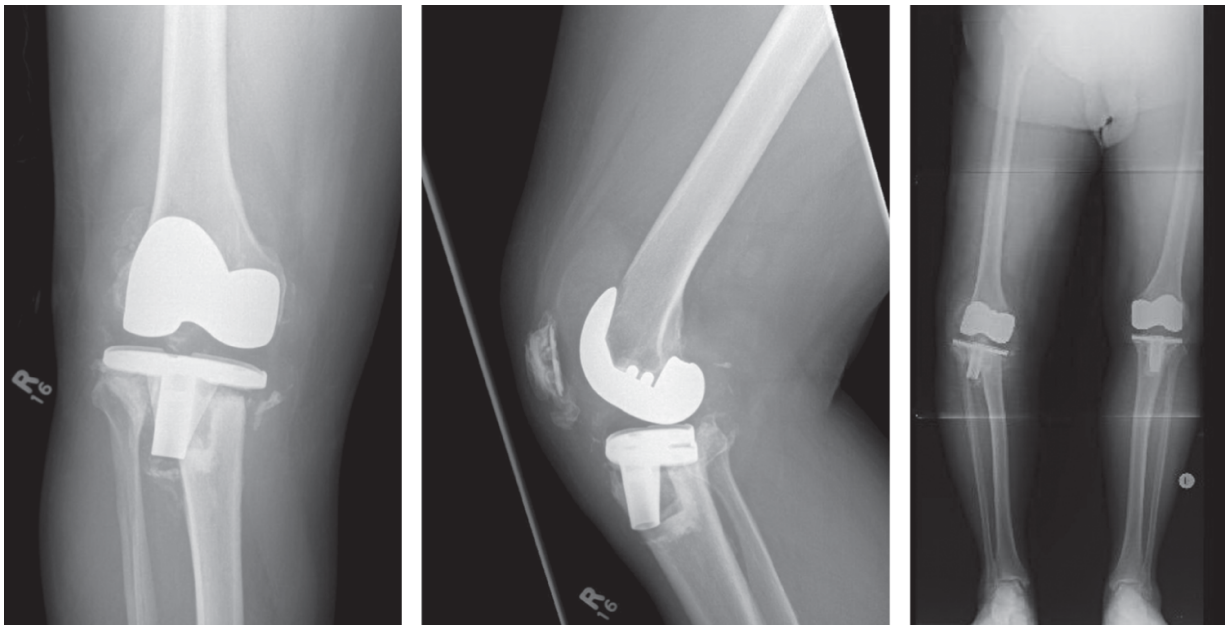

Figure 58.1 Preoperative radiographs.

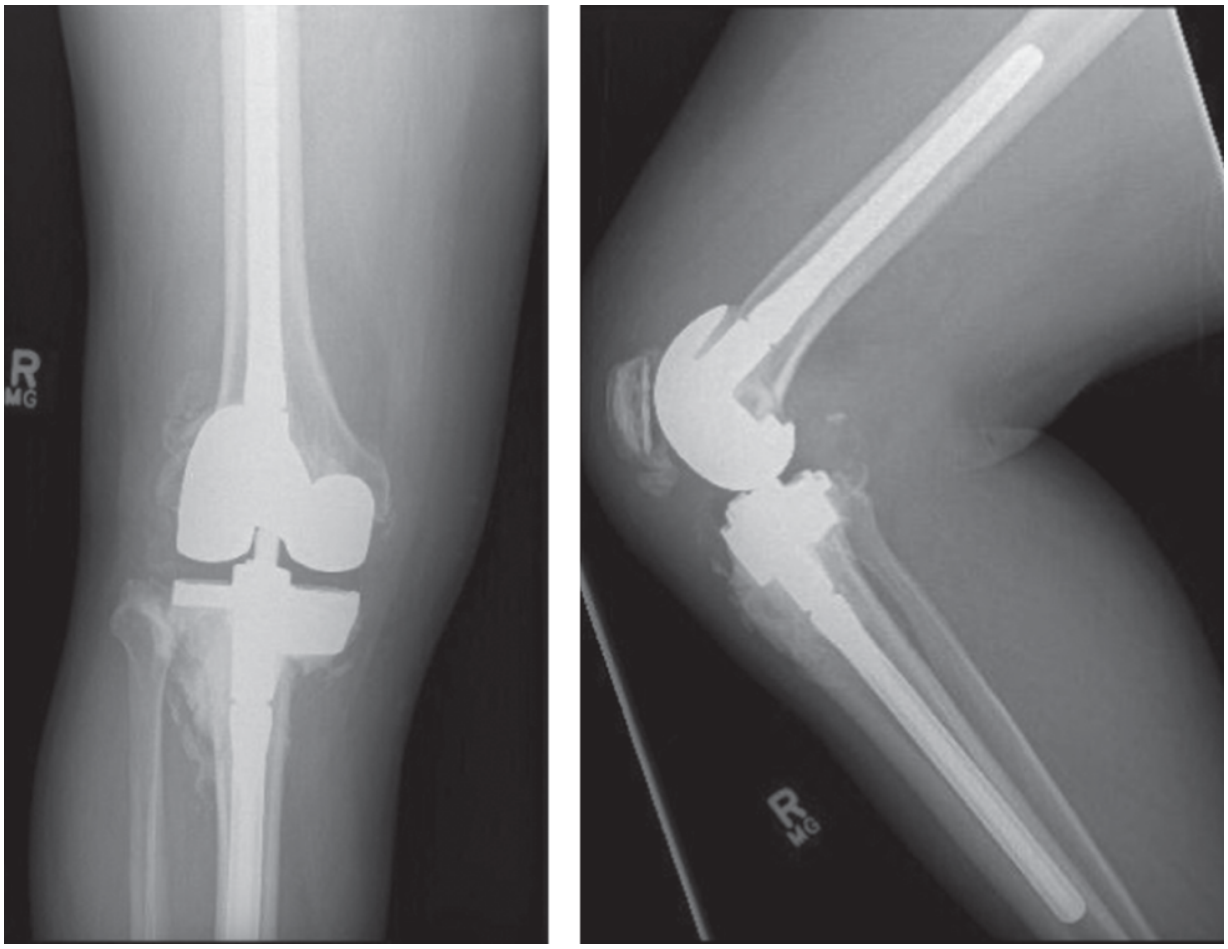

Figure 58.2 Postoperative radiographs.

AORI-1 defects <5 mm in depth have classically been treated using cement or morselized allograft. More recently, AORI-2A defects <20 mm in depth and involving <50% of either plateau have been treated by cement-fill alone.[1] Biomechanical studies comparing cement with metal augments show superiority of metal augments in wedge-shaped defects.[3] However, when converted to a step-cut pattern, cement is comparable to metal augments in resisting axial load.[4] Several studies have reported good results using cement in uncontained defects.[1,5–7] This is an economical way to manage select bone defects.

Alternatively, modular augmentation allows the surgeon to create a “custom” implant and re-establish the normal joint

line. Blocks range in size from 5 to 25 mm, and are fixed to the tibial tray. These are often indicated in AORI-2 defects of >25% of cortical bone, or if >40% of the base plate is unsupported by host bone.[8] Uncontained defects of 20–45 mm can be managed with metal augmentation and a thick polyethylene liner. Larger defects are unsuitable for block augmentation alone, as this places the base plate too distally.[9] In these scenarios, additional diaphyseal fixation using stemmed tibial components is typically needed to offload the metaphyseal augmentation and protect the cement–implant interface from failure.[10]

Cement fixation is inexpensive, readily available, and versatile due to its ability to readily fit and fill the size and shape of the bone defect. Bone cement should be vacuum-mixed to reduce its porosity. The tibia should be cleaned using pulsatile lavage and dried with clean sponges to reduce cement lamination secondary to blood and tissue debris. Some authors have recommended using 3.5 mm drill holes in patients with sclerotic bone to enhance cement penetration and increase surface contact.[11] The routine use of antibiotic-laden bone cement in revision total joint arthroplasty is well supported by the literature.[12]

Available literature and quality of the evidence

- Level IV evidence: 6 case series.[13–18]

Findings

Berend et al. investigated the use of screws and cement for large tibial bone defects in primary TKA.[13] Screws should be sunk into the cement enough to avoid contact between their heads and the implant. The authors report a 20-year survival probability of 98.97 and 93.39% with screws and cement versus cement alone, respectively. Defects treated

with screws were significantly worse than those without ($p < 0.0001$), ranging from 5 to 30 mm in depth. Berend et al. also reported on 609 revision procedures at 17 years' follow-up.[14] Of these, 264 had tibial defects >5 mm. Survival was 98.59 and 98.48%, when a defect was managed using cement with screws and without, respectively. Screws were, again, used in more severe defects ($p < 0.0001$). When primary prostheses were used, there was a trend toward a higher revision rate, though statistical significance was not reached (4.2% vs 1.2%, $p > 0.05$).

Patel et al. prospectively looked at 79 knees with AORI-2 defects treated with metal augments and stemmed prostheses.[18] Mean follow-up was seven years. They found nonprogressive radiolucent lines around 14% of augments, but no correlation with implant survival. They reported 92% survival at 11 years. Hass et al. reported 83% survival of tibial wedges at eight years.[15]

Panni et al. reported on 38 revision TKA with AORI-2 and -3 defects treated with modular augments (blocks: 46 femoral, 38 tibial blocks; wedges: 2 tibial; TM cones: 5 tibial, 4 femoral).[17] Three patients (7.9%) required reoperation, none due to loosening (2 infections, 1 instability). They noted two cases of nonprogressive radiolucent lines around the medial tibia, without platform subsidence.

Hockman et al. reported on 54 revision TKA, using non-modular trays with porous metal wedges.[16] Interestingly, 17 knees failed and 59% of these had only moderate defects. These were revised with metal augmentation alone.

Resolution of clinical scenario

- Defects <30 mm in depth can be managed by augmentation with metal blocks or cement with screws, with comparable results. Porous metal wedges demonstrate inferior results.

Question 2: In patients with moderate to severe tibial bone loss at revision TKA, is impaction bone grafting (IBG), compared to other options, a viable technique in terms of survival – specifically aseptic loosening?

Rationale

IBG has been shown to be a viable option in treating bone loss in revision THA. Its use in revision TKA remains controversial.

Clinical comment

IBG was first described by Hastings and Parker,[19] and later standardized by Sloof et al. for the treatment of large acetabular defects in THA.[20] Its successful use in the hip led to its use in knee revision, [21–23] as first described by Ullmark and Hovelius.[24]

IBG restores bone stock, filling irregular defects without need for further bone removal.[25] Morselized grafts have a higher rate of incorporation, with near-complete substitution by host bone, whereas bulk allografts only incorporate peripherally.[26–29] Several studies have established the mechanical stability of IBG,[30–32] including its use in tibial defects with stemmed implants. Toms et al. demonstrated superior initial stability of long-stemmed

tibial trays, and that migration was inversely proportional to the density of impacted bone.[33]

Bone chips used should be as large as practical (approximately 3–5 mm in diameter) to ensure early stability. Adequate impaction force makes morselized bone grafts strong enough to carry physiologic load, while excessive impaction force reduces host bone ingrowth.[34] Bone grafts are usually preferred in younger patients in whom future revisions are anticipated and potential bone stock restoration is desirable.[35] Incorporating autograft with morselized allograft bone may add osteoinductive properties to the construct.[36]

Available literature and quality of the evidence

- Level IV evidence: 4 case series.[25][37–40]

Findings

Lotke et al. studied the medium-term results of 48 revision TKA treated with IBG.[25] At 3.8 years (mean follow-up) they reported no mechanical failures and 100% radiographic graft incorporation. IBG has become their preferred technique for management of substantial bone loss. Similarly, Lonner et al. reported no re-revision in 14 patients with revision TKA using IBG at a mean follow-up of 16 months.[38] They noted nonprogressive tibial radiolucencies in three patients. Rudert et al. evaluated 28 revision TKA with IBG and found 93.1% (95% confidence interval [CI]: 74.5–98.4%) survival at 27.7 months.[39]

Conversely, Steens et al. reviewed 34 revision TKA using IBG for management of severe bone loss.[40] With 2–9 years' follow-up, five knees failed due to aseptic loosening. Five-year survival was 76% (95% CI: 56–96). In their follow-up

study, they noted 50% at 10 years.[37] This is the longest follow-up published to date.

Resolution of clinical scenario

- Medium-term outcomes for the use of IBG in large tibial defects are conflicting. There may be a role for its use with long-stemmed prostheses, or with adequate containment. Long-term and comparative studies are lacking. Bone grafts are usually preferred in younger patients in whom further revisions are predictable.

Question 3: In patients with severe tibial bone loss at revision TKA, do metaphyseal trabecular metal (TM) sleeves and cone augments improve implant survival compared to structural allografts?

Rationale

In major tibial defects, implant survival depends largely upon achieving stability of the tibial tray and union at the host–implant interface.

Clinical comment

The most frequently used techniques in treating severe bone loss are impaction grafting, structural allograft, and TM metaphyseal cones and sleeves. The latter two are most commonly used in uncontained defects.

Structural allografts were the gold standard in treating uncontained defects until TM implants were introduced. Several studies have reported structural allograft

survivorship between 67 and 92% at five years[41–43] and 72–91% at 10 years.[42,44] High rates of complication (20%) and failure (22.8%) were noted.[42] However, the potential for bone stock restoration is an advantage to consider, particularly in young patients who may require multiple revisions.

The development of TM has revolutionized the treatment of structural defects; with low stiffness and a high coefficient of friction,[45] it is designed to promote bony ingrowth. TM obviates the concern for disease transmission, graft fracture or resorption, and provides early stability.[46] Drawbacks include the inability to restore bone stock, need for further resection to accommodate the augment, and difficulty in implant removal.[8]

Available literature and quality of the evidence

- Level III evidence: 1 retrospective cohort.[47]
- Level IV evidence: 1 systematic review and meta-analysis of level IV studies.[48]

Findings

Sandiford et al. reviewed 450 TKA revisions, of which 45 required augmentation using either structural allografts (75%) or TM cones (25%).[47] With a mean follow-up of nine years, they compared functional outcomes, radiographic loosening, revision, and complication rates. Five-year survival was 93% in the allograft group and 91% in the TM group, demonstrating no significant difference between the two ($p = 0.699$).

Beckmann et al. systematically reviewed studies evaluating failure rates of TM cones and structural allografts.[48] They found 10 studies on TM cones (254 cones in 223 revisions)

and 17 studies on structural allografts (551 bulk allografts in 476 revisions) that met inclusion criteria. They reported an odds ratio (OR) for graft-related aseptic loosening of the prostheses of 0.263 (95% CI: 0.085–0.816, p = 0.021) in favor of TM cones. No differences in infection or overall revision rates were found, though a trend toward lower revision was seen in the TM cones. Interestingly, the two cases of aseptic loosening in TM cones were both on the femoral side. During reoperation, all tibial TM cones were well fixed.

Resolution of clinical scenario

- Defects with major metaphyseal bone loss can be treated with either structural allograft or TM cones, as the best available evidence reports no difference.
- TM cones appear to have excellent integration by host bone, and may have a lower rate of aseptic loosening (level IV).
- Structural allograft may be beneficial in young patients in whom restoration of bone stock is a priority, but no studies have specifically examined this benefit.

Summary of answers

- AORI-2 defects up to 30 mm in depth can be managed by augmentation with porous metal blocks or by cement with screws, with comparable results.
- Results for the use of IBG in large tibial defects are conflicting. There may be a role for its use with long-stemmed prostheses, or with adequate containment. Long-term and comparative studies are lacking.
- Defects with severe metaphyseal bone loss can be treated with either structural allograft or TM cones, as

the best available evidence reports no difference.

- TM cones appear to have excellent rate of integration by host bone, and level IV evidence suggests they may have a lower rate of aseptic loosening.
- Structural allograft may be more beneficial in young patients in whom restoration of bone stock is a priority, but no studies have specifically examined this benefit.

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59
Patellar Options in Revision Total Knee Arthroplasty

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Clinical scenario

- A 65-year-old woman with rheumatoid arthritis presents with a painful right total knee arthroplasty (TKA) five years after index surgery.
- She notes anterior knee pain, difficulty ascending and descending stairs, and pain when standing up from a seated position.
- X-rays, bone scan, and inflammatory markers suggest aseptic loosening of her cemented, metal-backed patellar component.

Top three questions

1. In patients with deficient patellar bone stock, does the use of bone grafting or trabecular metal-backed components improve outcomes compared to patellectomy?
2. In patients with anterior knee pain following TKA with an unresurfaced patella, does secondary resurfacing

reduce anterior knee pain compared to conservative management?

3. When revising a femoral component for aseptic loosening, does retaining a well-fixed patellar component improve outcome compared to revision to compatible patellar and femoral components?

Question 1: In patients with deficient patellar bone stock, does the use of bone grafting or trabecular metal-backed components improve outcomes compared to patellectomy?

Rationale

Patellofemoral complications are the most common cause of re-operation after a TKA. Poor patellar bone stock presents a challenging technical problem during revision TKA, as there is a high risk of fracture, osteonecrosis, and difficulty achieving stable fixation.

Clinical comment

Poor patellar bone stock may be encountered at the time of revision TKA. Historically, patellectomy has been associated with unfavorable outcomes due to poor quadriceps strength and abnormal knee function, and is considered a last resort for compromised patellar bone stock. Patellar resection arthroplasty (patelloplasty) may result in improvements in function when no options are available for resurfacing the deficient patella. More recently, options such as gull-wing osteotomy, bone graft augmentation, cemented all-polyethylene biconvex prostheses, and trabecular metal prostheses have been

introduced to address poor patellar bone stock at the time of revision TKA.

Available literature and quality of the evidence

We found one study with level III evidence, 20 studies with level IV evidence, and one study with level V evidence. Most evidence is drawn from small case series from single institutions with short- to medium-term follow-up.

Findings

The lowest morbidity at the time of revision TKA involves retaining a well-fixed patellar component, but the surgeon must ensure there are no signs of loosening, wear, patellofemoral maltracking, or incompatibility between the femoral and patellar components.[1,2] Most authors advocate revising a well-fixed metal-backed component due to high rates of failure,[3–8] although some small case series have shown high rates of complications and secondary surgery.[5,9] Several options have been proposed to address deficient patellar bone stock at the time of revision TKA.[10] Patellectomy should be avoided because of poor outcomes, including persistent pain, quadriceps weakness, and extensor lag.[1,11,12] Patellar resection arthroplasty is a reasonable option and is preferred to patellectomy,[13] although one-third of patients have persistent anterior knee pain and there is a 15% complication rate.[14] Barrack et al. found a higher level of satisfaction in patients with a retained patellar component compared to patellar resection arthroplasty (98% vs 79%, $p < 0.01$).[15] Of those studied, 47% of patients with a patellar resection arthroplasty had difficulty using stairs compared to 24% with a patellar component in place ($p < 0.05$), and there was a higher rate of dissatisfaction, difficulty with stair climbing, and difficulty with squatting and kneeling. For cases with

central bone loss with only 5–10 mm thickness remaining, an all-polyethylene, biconvex, inlay-type prosthesis can be used.[1] Biconvex patellar components for revision TKA with bone stock as thin as 5 mm have low complication rates at up to seven-year follow-up.[16,17]

Hanssen described packing cancellous bone graft into a tissue flap to restore patellar bone stock, with significant improvements in Knee Society function and pain scores at a mean follow-up of 36.7 months.[18] Another group experimented with adding an Achilles tendon allograft to augment the Hanssen bone graft technique in three patients to allow early mobilization and protect against patellar fracture.[19] These techniques are technically demanding and described by only a few authors. A sagittal *gull-wing* osteotomy has been used with promising results in two studies.[20,21] A sagittal osteotomy is made through the articular surface followed by anterior displacement of the medial and lateral borders of the patella to create a *gull-wing* or *V* pattern that articulates with the concave trochlear groove. Thirty knees in 28 patients with deficient patella during revision TKA (less than 8 mm thickness and cortical rim not intact) were treated with a novel technique involving an onlay prosthesis, cement, and transcortical wiring. At a mean follow-up of 36.6 months, the Knee Society Score (KSS) improved significantly with only one complication (patellar fracture one week after surgery).[22] Fisher described a rebar technique with threaded Kirschner wires (k-wires) to create a buttress to prevent displacement of the pegs in 15 patients with deficient patellar bone stock.[23] Porous tantalum patellar components have demonstrated excellent survivorship. One study found 83% survivorship (19 of 23 patients) at a mean follow-up of 7.7 years. Risk factors for failure were thin or avascular patellar bone and components that were secured directly to

soft tissue.[24] Nasser and Poggie found no evidence of failure, excellent patient satisfaction, and improvements in function scores at 32-month follow-up for patients treated with a porous tantalum implant.[25]

Resolution of clinical scenario

- Patellar components should be retained during revision TKA unless they are metal-backed or show evidence of loosening or maltracking.
- Patellectomy and patelloplasty have poor outcomes in revision TKA and should be avoided in lieu of novel options for managing the deficient patella.
- Bone grafting, osteotomy, biconvex cemented patella, and porous metal components offer good short- and medium-term results for deficient patellae in revision TKA.

Question 2: In patients with anterior knee pain following TKA with an unresurfaced patella, does secondary resurfacing reduce anterior knee pain compared to conservative management?

Rationale

Surgeons must understand the current evidence before offering a secondary resurfacing to patients with anterior knee pain and an unresurfaced patella.

Clinical comment

Persistent anterior knee pain following TKA can be a source of frustration for both patients and surgeons, particularly in the setting of an unresurfaced patella. Current opinion suggests that if a patient has persistent anterior knee pain in the presence of an unresurfaced patella then an isolated secondary resurfacing is a reasonable option for patients, but it is not without its shortcomings.

Available literature and quality of the evidence

We identified eight studies with level IV evidence.

Findings

In a meta-analysis of TKA with or without resurfacing of the patella, Parvizi et al. found that 8.7% of knees with nonresurfaced patellae required secondary resurfacing. However, they did not specifically comment on the outcomes of those patients treated with secondary resurfacing.[26] Barrack et al. reported on seven patients who underwent a secondary resurfacing of the patella: four of the seven patients continued to experience anterior knee pain at an average follow-up of 36.8 months.[27] Daniilidis et al. observed a significant improvement in mean KSS (60.1 ± 8.3 to 77.0 ± 6.3, $p = 0.0063$) and function scores (42.7 ± 2.3 to 60.2 ± 3.9, $p = 0.001$), although a subgroup of six patients (27.3%) remained dissatisfied after secondary resurfacing.[28] Garcia et al. studied seventeen patients with symptomatic anterior knee pain after primary TKA without resurfacing who underwent secondary resurfacing.[29] Fifteen patients with minimum two-year follow-up (average 47.1 months) had significant improvements in their mean Knee Society knee (53 points to 82 points, $p < 0.001$) and function scores (43 points to 69 points, $p < 0.001$). While 40% were completely asymptomatic at the time of most recent follow-up, 47% had persistent anterior knee pain.

Karnezis et al. reported significant improvements with delayed secondary resurfacing of the patella (mean patella score improved from 13.5 (standard deviation [SD] = 5.9) preoperatively to 19.3 (SD = 5.5) at final follow-up, p = 0.01; 95% confidence intervals for the mean difference, 1.6–10.0), although these results were inferior to primary resurfacing.[30] The authors noted that longer delays between primary TKA and secondary resurfacing correlated with worse outcome and concluded that secondary resurfacing should be considered early. Muoneke et al. reported on 20 patients who underwent a revision procedure to resurface only the patella for anterior knee pain and found that 44.4% reported some improvement in pain, with the remainder reporting no change or deterioration.[31] Other authors have had similar results with improvements in mean knee scores but a significant subset of patients remaining unsatisfied after secondary resurfacing.[32,33] Toro-Ibaguen and colleagues in a retrospective study of 46 patients reported there was an improvement of the Knee Society Score scale (from 54 ± 11 to 64 ± 16 points; $p < 0.05$) in patients undergoing secondary patellar resurfacing (SPR).[34] However, in 59% of the cases there was no pain improvement, and 65% of patients were not satisfied. Four patients developed complications (8.7%) and in two cases re-operation was necessary. We did not find any preoperative predictive factor for a favorable outcome after SPR.

Resolution of clinical scenario

- Secondary resurfacing of an unresurfaced patella can result in an improvement in pain and function scores, although a large group of patients may remain unsatisfied due to persistent anterior knee pain.

- Earlier intervention with secondary resurfacing may optimize the outcomes in patients with persistent anterior knee pain following TKA with an unresurfaced patella.

Question 3: When revising a femoral component for aseptic loosening, does retaining a well-fixed patellar component improve outcome compared to revision to compatible patellar and femoral components?

Rationale

Most modern patellar components are symmetrical domes and compatible with the trochlea of most femoral components. We endeavored to identify literature to support the common practice of retaining a well-fixed patellar component regardless of geometric mismatch with the femoral component.

Clinical comment

Revision of the patellar component is associated with several complications, including fracture, avascular necrosis, and aseptic loosening. However, retaining a well-fixed patellar component may not be ideal in the presence of significant wear or a geometric mismatch between the patellar and femoral component. The decision to revise a well-fixed patellar component has significant implications on the outcomes following revision TKA.

Available literature and quality of the evidence

We found one study with level III evidence and five studies with level IV evidence.

Findings

Several studies have shown isolated revision of malrotated femoral or tibial components results in improved outcomes and does not require revision of a well-fixed patellar component unless there are signs of significant wear, damage, or geometric mismatch.[35,36] Barrack et al. retrospectively compared the results of retention versus revision of patellar components in 73 knees with a mean follow-up of 36 months (minimum 24 months).[37] In 34 cases, a well-fixed and well-positioned patellar component with minimal to no surface damage was retained; 12 of these knees had metal-backed components. The remaining 39 cases involved patellar component revision for reasons such as loosening, wear, osteolysis, and malpositioning. Both groups were assessed clinically and radiographically and the authors found no difference in clinical results or patient satisfaction between the two groups. Masri and colleagues retrospectively reviewed 111 patients undergoing a revision TKA.[38] A subgroup of 24 patients undergoing knee revisions already had a well-fixed patellar component present and were left in situ. The authors found no difference in WOMAC, Oxford-12, Short Form 12, and patient satisfaction scores between patients with a patellar component left in situ and those who had the patella removed, leaving only a bony shell. Lonner et al. reviewed a series of 202 revision TKAs that retained a well-positioned and well-fixed all-polyethylene patella.[39] They reported that 10% of patients had anterior knee pain at an average follow-up of 7.3 years and concluded that retaining a well-positioned, stable all-polyethylene patellar component at the time of revision TKA can be successful, provided that the polyethylene has not oxidized. Manufacturing mismatch

is acceptable with most contemporary designs if the patellar component articulates appropriately with the femoral implant. They noted a higher rate of patellar component failure if the component was gamma irradiated in air compared to those sterilized with another method ($p = 0.0008$).

Resolution of clinical scenario

- If the patella is a well-fixed, all-polyethylene component and articulates well with the revision femoral component, it should be left in situ despite manufacturer mismatch.
- If the patella is a metal-backed component and there is good bone stock, it should be revised at the time of revision TKA even if it is well-fixed.

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Implant Design Options in the Treatment of Shoulder Osteoarthritis

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Clinical scenario

- A 70-year-old active, healthy male with left shoulder pain and stiffness. He has been diagnosed with glenohumeral osteoarthritis.
- He is no longer responsive to injection therapy and wishes to discuss operative options.

Top three questions

1. In this patient with end-stage shoulder osteoarthritis, what is the ideal surgical treatment?
2. If an anatomic total shoulder arthroplasty (TSA) is elected, what is the ideal glenoid component design?
3. If an anatomic TSA is chosen, what is the ideal humeral component design?

Question 1: In this patient with end-stage shoulder osteoarthritis, what is the ideal surgical treatment?

Rationale

Several options are currently available for shoulder reconstruction, each with unique indications, benefits, risks, and functional outcomes that must be considered.

Clinical comment

Personal training biases, local trends, and isolated reviews of the literature can be persuasive in clinical decision-making. When deciding on the ideal reconstructive option, it is important to have an unbiased and complete view of the literature.

Available literature and quality of the evidence

This question is best answered with a systematic review of level III and IV studies.

Findings

This is a 70-year-old active individual with end-stage osteoarthritis and a Walch type A1 glenoid. Walch type A glenoids are centered, with or without central deformity. Walch type B glenoids are posteriorly eroded with or without deformity, and Walch type C glenoids are considered dysplastic.[1] The later varieties are more likely to undergo progressive deformity, subluxation, and pose biomechanical challenges that are potentially time sensitive.[2,3] Since this glenoid is concentrically worn, there is less concern for progression and continued injection treatment can be considered (Figure 60.1 and 60.2).

If conservative treatment fails, hemiarthroplasty or anatomic TSA are common reconstructive options. Both of these options require an intact rotator cuff for ideal function, to avoid anterosuperior escape and early glenoid failure from eccentric loading.[4] Fortunately, full thickness rotator cuff tears are only present in 7.6% of patients presenting with primary osteoarthritis, and partial thickness tears have not been shown to influence outcome.[5] This patient has a centered head without radiographic signs of cuff tear arthropathy,[6] but advanced three-dimensional imaging may be obtained when there is clinical concern. A full thickness irreparable supraspinatus tear, or any infraspinatus or subscapularis tear, would be a contraindication to primary TSA.

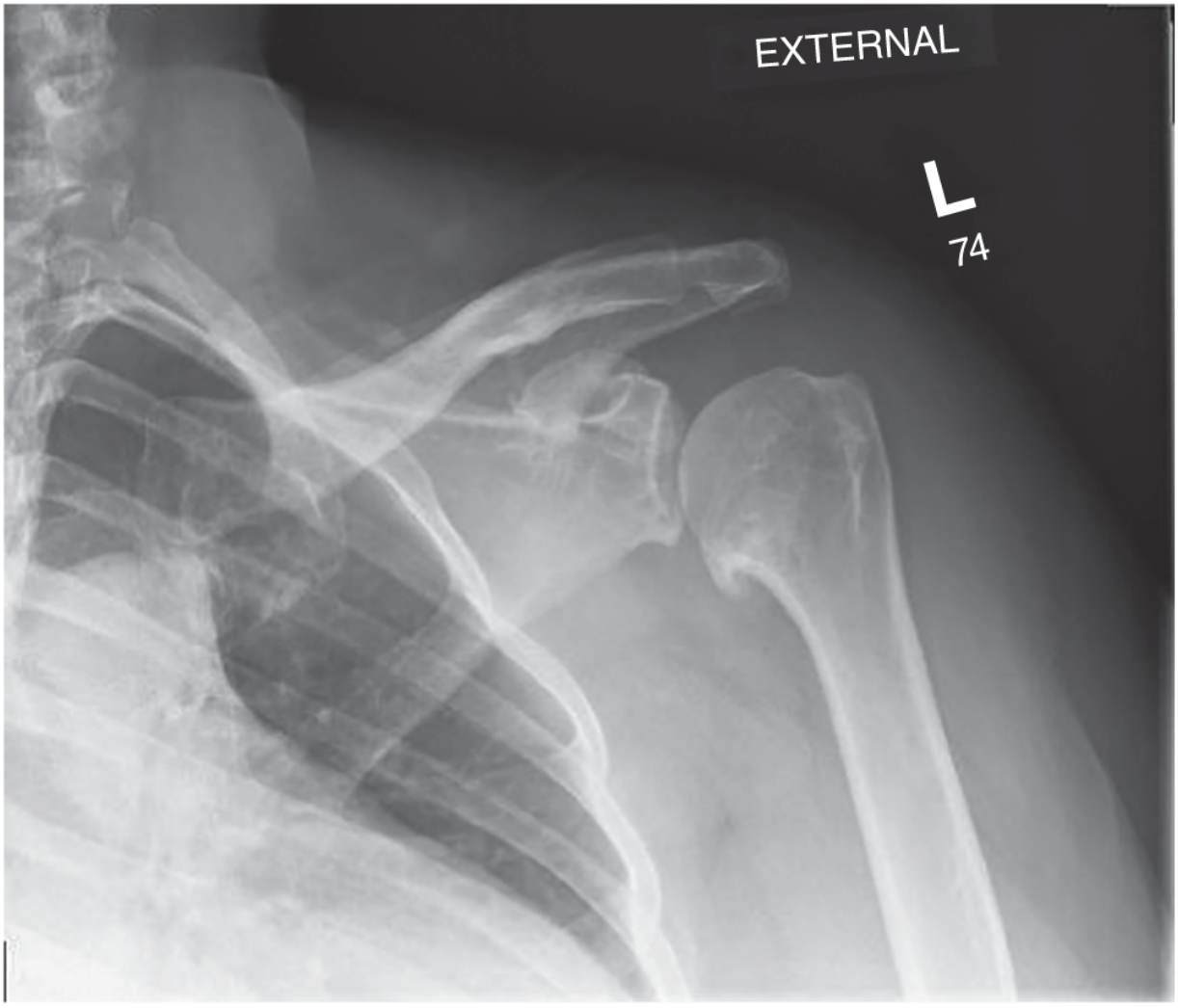

Figure 60.1 True AP radiograph of the left shoulder shows joint space collapse, subchondral sclerosis, inferior humeral osteophytes and medialization of the humerus without signs of rotator cuff insufficiency. Source: Chad Myeroff, Michael Knudsen, Michael D. McKee.

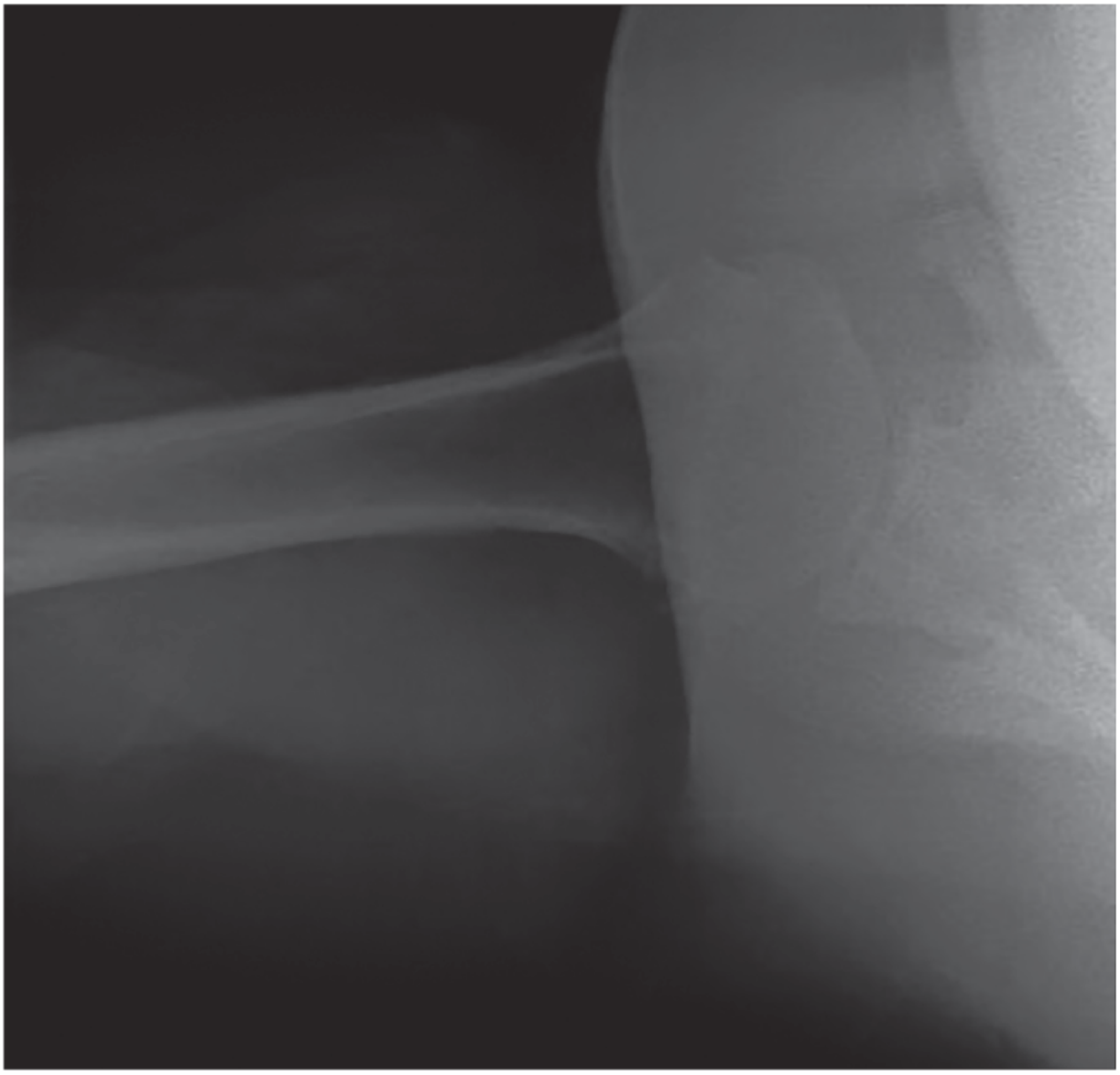

Figure 60.2 Axillary radiograph of the left shoulder showing concentric glenohumeral joint space loss without subluxation of the humeral head or any eccentric ware. Source: Chad Myeroff, Michael Knudsen, Michael D. McKee.

Hemiarthroplasty offers the benefits of preserving glenoid bone stock, less operative time, and less blood loss, and eliminates the risk of glenoid implant failure when compared with TSA. However, hemiarthroplasty carries the inherent risk of progressive glenoid arthritis and pain.

While the results have been variable, some authors report success, especially in young active laborers with intractable pain, especially those with a high degree of posterior wear and subluxation where glenoid components would have a higher risk of failure.[7–9] In TSA, resurfacing of the glenoid theoretically decreases long-term pain and restores physiological tension on the rotator cuff, with the traded risk of glenoid implant failure necessitating later revision surgery.

A randomized controlled trial (RCT) of 42 arthritic shoulders comparing hemiarthroplasty to TSA showed a trend toward improved disease specific quality of life for TSA as measured by the previously validated Western Ontario Osteoarthritis of the Shoulder (WOOS) score,[10] (WOOS 90.6 for TSA vs 81.5 for hemiarthroplasty; $p = 0.18$) but was underpowered to show a difference.[11] Radnay et al. published a systematic review of 23 studies (1952 patients) with an average level of evidence of 3.72 with a mean 43.4 months' follow-up.[12] TSA provided significantly greater pain relief (86 vs 78; $p < 0.0001$), forward elevation ($p < 0.0001$), external rotation ($p = 0.0002$), patient satisfaction (97% vs 80%; $p < 0.0001$), and lower revision rate (10.7% hemiarthroplasty vs 1.7% for TSA with all polyethylene cemented glenoids; $p < 0.025$). Of the included hemiarthroplasties, 10.2% required revisions, 79.4% of which (8.1% of all hemiarthroplasties) were converted to TSA for pain.[12] Economically, TSA is more cost-effective. Mather et al. created a Markov decision model using available literature to compare cost utility and reported that a TSA is $1970 cheaper per patient than hemiarthroplasty and provides more quality-adjusted life years (QALYs).[13] Hemiarthroplasty would not be preferred unless the TSA annual revision rate reached 8.52% or $50 000 in initial cost.[13] In 2011, the American Academy of Orthopaedic Surgeons (AAOS) concluded there was

moderate evidence to recommend TSA over hemiarthroplasty in the surgical management of glenohumeral osteoarthritis.

Resolution of clinical scenario

- TSA is preferred over hemiarthroplasty for advanced glenohumeral osteoarthritis, offering improved outcomes for motion, pain relief, patient satisfaction, lower revision rate, and lower overall cost.

Question 2: If an anatomic total shoulder arthroplasty (TSA) is elected, what is the ideal glenoid component design?

Rationale

Metal-backed (MB) glenoid components were introduced to theoretically offer a better mechanical interface, allow surgical correction of complex glenoid deformity, and allow modularity between TSA and reverse total shoulder arthroplasty (RTSA). All-polyethylene (AP) glenoids have two traditional fixation options: in-line pegged components are relatively bone preserving, while keeled implants may be technically easier in difficult exposures and lower the risk of vault perforation in smaller glenoids.

Clinical comment

The glenoid component is the most technically demanding aspect of TSA and is the most likely reason for mechanical failure postoperatively, necessitating meticulous technique and thoughtful implant choice.

Available literature and quality of the evidence

The vast majority of technical principles have come from level III and IV studies. There are several RCTs comparing glenoid resurfacing options, supported prevalently with level III and IV retrospective studies and biomechanical research.

Findings

Glenoid reconstruction remains the weak link in TSA with a 0.8% risk of glenoid revision per year and is the most common underlying reason for humeral sided revision as well.[14–16] It has been shown that restoring close to normal version (to <10–15° retroversion) lowers radiographic osteolysis and cement mantle shear forces.[17,18] Conservative reaming should maintain the subchondral plate to minimize failure.[19] It is recommended that glenoid surface and humeral head have a 4° radius of curvature mismatch to avoid edge loading and best restore anatomic translation and motion.[20]

Although anatomic glenoid reconstruction has an overall 95% 10-year survivorship on the aggregate, there is variability in implants. Clinical results for MB glenoid components have shown increased failure and revision rates. In Radnay et al.'s systematic review of 1952 patients, they found a higher risk for revision for MB implants (6.8% MB vs 1.7% AP).[12] Cil et al. showed higher humeral sided 10-year revision-free survival with AP glenoids in a systematic review of 1584 implants (96.5% vs 86.8%).[15] Fox et al. reviewed 1542 TSAs and found that revision-free survival was superior for AP glenoids ($p < 0.01$).[21] Clitherow et al. performed a registry study of 1056 AP glenoid implants versus 540 MB glenoid implants placed in

New Zealand. They found a 4.4-fold higher risk for revision in MB (1.92% vs 0.44%; p <0.001).[22]

Boileau et al. published an RCT on 39 patients comparing AP pegged glenoid design to MB glenoid design with 36 months' follow-op and found higher radiolucent lines for AP component (85% vs 25%; p <0.01);[23] however, the majority of AP radiolucencies were nonprogressive and there was no correlation with functional outcome (p = 0.3). Radiolucent lines are rare with MB implants but progressive and sinister when present (clinical loosening/failure: 20% MB vs 0% AP; p <0.001). Additionally, these authors found that MB glenoid implants correlated significantly with decreased functional results and increased pain (p <0.05).[23] The same authors published long-term outcomes of 165 MB glenoids and reported only 46% revision free survival at 12 years.[24] They have subsequently returned to an AP component in their clinical practice. The early failure of MB components initiated interest in hybrid options. Bony ingrowth with hybrid monoblock glenoids was nearly universal, but metal debris and mechanical failure plagued early designs.[25,26] Newer designs offered early peripheral cement fixation followed by central peg ingrowth with more optimistic early- to medium-term clinical results. Nelson et al. reported five-year outcomes on a hybrid option with a central porous titanium peg and peripheral cemented polyethylene pegs showing 64% (29/45) asymptomatic radiographic osteolysis and 2.2% (1/45) mechanical failure at the metal peg-polyethylene junction.[27] Most recently, Friedman et al. reported a large cohort study comparing 316 patients with hybrid cage design to 316 historical controls with a traditional cemented polyethylene pegged component with an average of 50 (24–79) months' follow-up.[28] They found significantly lower glenoid radiolucent lines (9% vs 37.5%; p <0.0001), humeral radiolucent lines (3% vs 9.1%; p = 0.0088), and revision rate (2.5% vs 6.9%;

p = 0.0088) in the hybrid group.[28] While the frontier is promising, cemented AP components remain the gold standard of clinical success.

The surgeon has a choice between pegged and keeled AP components. Two radiostereometric clinical studies to evaluate glenoid component motion reported conflicting results. Rahme et al. found no difference in micromotion,[29] while Nuttall et al. reported increased migration in keeled components.[30] Edwards et al. published results of an RCT of 53 patients randomized to pegged or keeled AP cemented glenoid implants.[31] There was no statistical difference in radiolucent lines immediately (0% peg vs 15% keel; p = 0.128) but at 26 months postoperatively, keeled components had higher radiographic lucency (46% vs 15%; p = 0.003).[31] Two systematic reviews were published in 2013 on the topic. Papadonikolakis et al. found no difference in clinical outcomes.[14] Vavken et al. looked at eight studies (1460 patients) and found a lower pooled risk of revision for pegged implants (0.27; 95% confidence interval [CI]: 0.08–0.28), but they noted the benefit is small and may only be clinically relevant in high volume centers.[32] The AAOS Clinical Practice Guidelines reported weak evidence and support a surgeon's preference between pegged and keeled AP glenoid implants. Radiographic and clinical studies report conflicting conclusion, but overall there was a slight preference toward pegged implants.

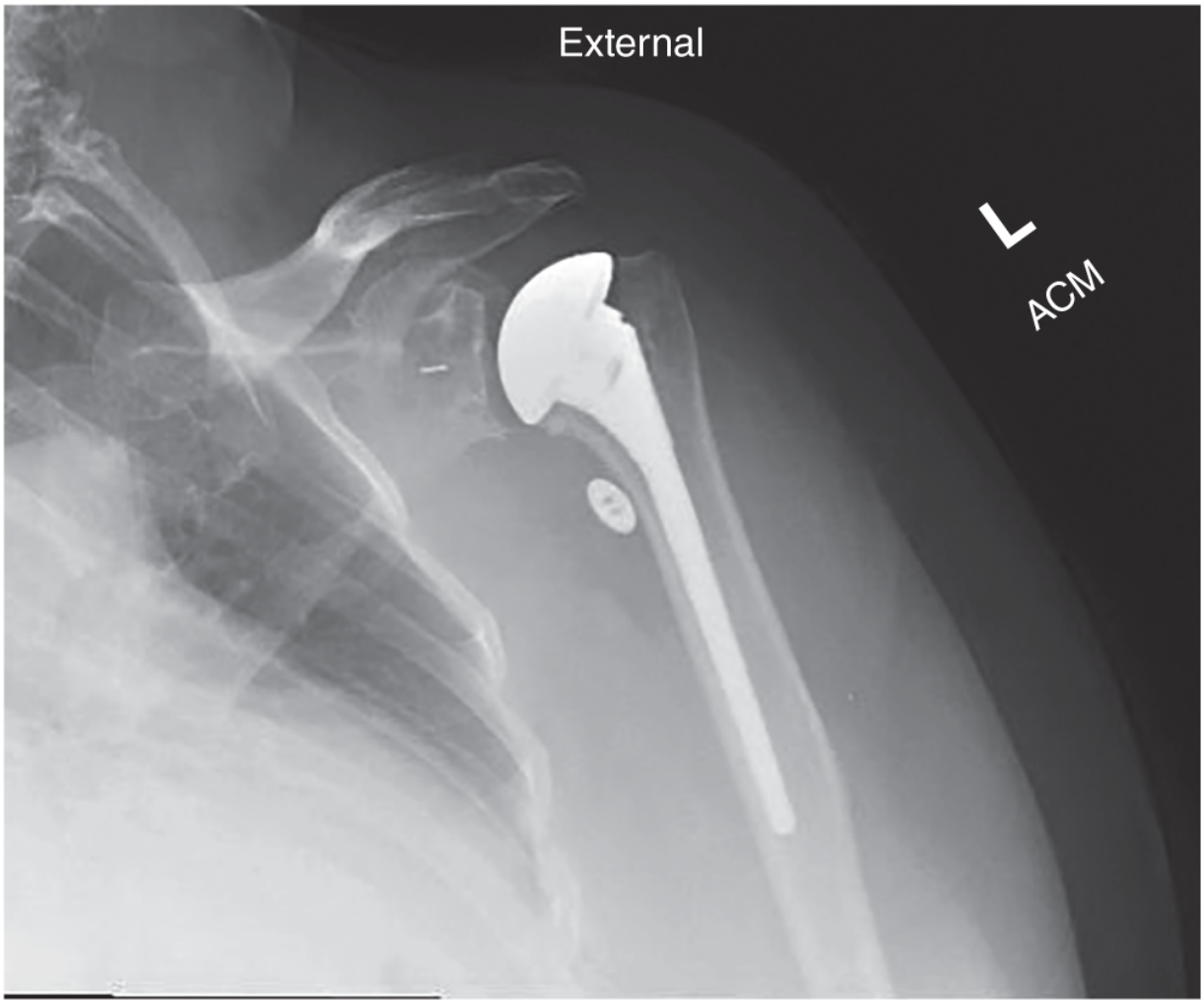

Figure 60.3 Postoperative true AP radiograph of the left shoulder showing anatomic TSA with a cemented, pegged, all-polyethylene glenoid and a press-fit humeral stem. Source: Chad Myeroff, Michael Knudsen, Michael D. McKee.

Resolution of clinical scenario

- Cemented AP glenoids are the gold standard for clinical success in TSA (Figure 60.3).
- The choice between pegged and keeled AP implants are at the surgeon's discretion.

- Pegged implants have lower rates of radiographic lucency and conflicting evidence leaning toward a slightly lower clinical failure rate.

Question 3: If an anatomic TSA is chosen, what is the ideal humeral component design?

Rationale

Aseptic loosening of the humeral component in TSA is rare. Despite this success, the industry continues to develop a variety of different designs, including short-stem and stemless components. Regardless of stem size, proper humeral component size and position are paramount for a balanced, functional, and durable shoulder arthroplasty.

Clinical comment

The treating shoulder surgeon should understand the difference between theoretical advantages and technical imperatives for a well-fixed, well-positioned humeral component.

Available literature and level of the evidence

Most of the data on humeral implants in TSA come from level III and IV studies. There is one RCT comparing cemented and uncemented humeral stems in TSA and one small RCT comparing stemmed and stemless humeral fixation.

Findings

The humeral components of positioning and sizing are critically linked to success.[33] The goal is to recreate the articular anatomy, replicating the anatomic center of

rotation, height, retroversion, and neck shaft angle to minimize impingement and optimize motion with a stable implant that allows for long-term stability.[34] Third-generation stemmed humeral components provide modularity in head size, thickness, and eccentricity to recreate the native articular anatomy. Preoperative templating and intraoperative findings can be used.[35] However, implant design features cannot make up for technical errors in this regard.

Humeral component loosening is rarely a clinical problem. Cil reviewed humeral component survivorship in 1584 arthroplasties and showed an 82.8% 20-year survival.[15] Of the humeral revisions, more than half were due to underlying glenoid failure. Associations with failure were age <65 (1.5×), male gender (2.3×), post-traumatic arthritis (2×), and uncemented (2.7×).[15] Although cementation may marginally decrease loosening,[36] it profoundly complicates revision surgeries[37] and continued trends have led to an increased enthusiasm for uncemented designs, considered by most experts the current gold standard in primary arthroplasty.

Interestingly, only a single double-blind RCT has closely examined the question of cemented versus uncemented humeral stem fixation in TSA. This multicenter trial compared 80 cemented and 81 uncemented TSAs, and found that cemented stem fixation was associated with significantly better WOOS scores at 12, 18, and 24 months postoperatively (cemented 87.9 vs uncemented 79.3 at final follow-up; $p = 0.03$). However, there were no statistically significant differences in Short Form 12 scores, ASES scores, MACTAR scores, motion, complication rates, loosening rates, or revision rates.[38] Additionally, there were no differences in outcome scores in women. It remains unknown if a difference of 8.6 in WOOS score is

significant enough to warrant advocacy for cementing all stems in TSA, as the minimal clinically important difference (MCID) has not been studied for this patient reported outcome score. In 2014, a retrospective comparative series of 395 anatomic TSAs (103 uncemented metaphyseal stems vs 292 cemented stems) demonstrated similar clinical results at a mean follow-up of eight years.[39]

Traditional stems have an approximate 1% complication rate.[40,41] As such, the majority of these stems are well fixed, which can pose significant challenges for revision surgery. Fourth-generation stems include short stems and stemless designs with metaphyseal fixation termed *canal sparing* or *stemless*. The driving force for these designs is the goal of bone preservation, avoidance of stress shielding and diaphyseal stress risers, anatomic reconstruction, shorter operative time, and less morbid revision procedures.[42]

Convertible platform modular stems offer the attractive advantage of allowing humeral stem retention in revision surgery, as they allow for exchange of a TSA/hemiarthroplasty humeral head implant for a RTSA implant, and early reports from the literature are promising. Crosby et al. published results on a multicenter retrospective study of 102 consecutive shoulders that underwent revision of an anatomic shoulder arthroplasty to a reverse shoulder arthroplasty.[43] During that time period, 73 of the shoulders required humeral stem revision and 29 convertible platform stems allowed for stem retention. Stem retention allowed for shorter operative times (130 vs 195 minutes; $p < 0.001$), lower estimated blood loss (292 vs 492 mL; $p = 0.034$), fewer intraoperative complications (0% vs 15%; $p = 0.027$), better postoperative external rotation (26° vs 11°; $p = 0.006$), and better active forward elevation (112° vs 96°; $p = 0.055$). The authors concluded that well-

fixed and positioned convertible platform humeral stems offer numerous advantages over traditional stems if and when the need for revision arises.[43] Previous studies have found similar encouraging medium-term clinical and radiological results in favor of convertible platform technology.[44,45]

Stemless anatomic TSA designs first became available in Europe in 2004. Most recently, stemless designs have gained significant excitement and popularity in the United States. Hawi et al. published their findings of a systematic review that identified 11 studies published between 2010 and 2016 on stemless, or *canal-sparing*, anatomic shoulder arthroplasty implants. They identified 929 cases with a mean follow-up of 26 months.[46] The rate of humeral complications ranged between 0 and 7.9%. Only one case of radiological loosening was identified in this review. Most recently in 2017, Uschok et al. reported on their prospective randomized trial of 40 patients undergoing TSA.[47] They randomized 20 patients to receive a standard stemmed humeral implant and 20 patients to receive a stemless humeral implant. There were no significant differences in Constant Score, active range of motion, or humeral loosening. Excitement for stemless or canal sparring technology in TSA should be tempered as the clinical benefits of stemless fixation is debated, and long-term studies are not yet available.

Resolution of clinical scenario

- Aseptic loosening of the stemmed humeral components in TSA is rare.
- Limited evidence exists to provide strong recommendations regarding humeral stem implant choices; however, revision of well-fixed long stems and cemented stems is well documented to have significant

complication rates and difficulty at the time of revision procedures. Early results of convertible platform stems are promising.

- Innovations such as short-stemmed and stemless designs in TSA are still under investigation, and medium-long term data are lacking.

Summary of answers

- TSA is preferred over hemiarthroplasty for surgical treatment of glenohumeral osteoarthritis.
- Cemented, pegged, AP glenoid components are the gold standard for clinical success in TSA.
- Aseptic loosening of stemmed humeral components is rare.

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Cement in Shoulder Arthroplasty

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Clinical scenario

- A 55-year-old right-hand-dominant man, semiretired accountant with progressively increasing left shoulder pain and decreasing range of motion.
- He complains of pain with use of the affected extremity, difficulty golfing and playing with his grandchildren, and sleeping on his left side due to shoulder pain.
- On physical exam, active and passive range of motion is forward elevation to 100°, abduction to 60°, and external rotation to neutral, with notable grinding and catching during range of motion. He has good strength of his rotator cuff. He is neurovascularly intact.
- Radiographs of shoulder show end-stage osteoarthritis, with no proximal migration of the humeral head.

Top three questions

1. In patients with advanced shoulder osteoarthritis, does cemented fixation of the humeral component result in improved functional outcomes compared to uncemented fixation?

2. In patients undergoing anatomic total shoulder arthroplasty (TSA), is there a difference in implant survival with a cemented versus uncemented technique?
3. In patients undergoing anatomic TSA with a cemented glenoid and/or humeral component, is there a difference in infection rates with the use of antibiotic-impregnated cement compared to plain cement?

Question 1: In patients with advanced shoulder osteoarthritis, does cemented fixation of the humeral component result in improved functional outcomes compared to uncemented fixation?

Rationale

Both cemented and uncemented humeral stems can be utilized in TSA. Cemented fixation may provide better stability in osteoporotic bone; however, bone ingrowth into the proximal porous coating of an uncemented humeral stem may provide improved survivorship and functional outcome.[1] An uncemented implant has a shorted operative time, and potentially simpler revision surgery compared to a cemented stem (in case of revision surgery for infection or loosening).[2,3] These theoretical benefits have not been empirically validated and it is important to consider risks/benefits of TSA with a cemented humeral component as compared to an uncemented stem.

Clinical comment

Current opinion suggests that most surgeons prefer to use an uncemented humeral component in North America, and implant manufacturers have therefore developed and marketed uncemented implants over recent years.[4] However, there is limited evidence comparing functional outcomes of cemented versus uncemented humeral components in TSA.

Available literature and quality of the evidence

- Level I: 1 prospective randomized study.
- Level III: 2 retrospective cohort studies.

Findings

In a prospective randomized study, Litchfield et al. compared cemented (n = 80 patients) with uncemented (n = 81) humeral components (Bigliani/Flatow Total Shoulder Solution, Zimmer, Warsaw, IN, USA) for TSA. They showed a significant difference in Western Ontario Osteoarthritis of the Shoulder (WOOS) score at postoperative intervals of 12, 18, and 24 months ($p = 0.009$, 0.001, 0.028, respectively) in favor of the cemented humeral component. The authors reported no difference in motion or strength improvement between the two groups, compared to preoperative values. Operative time was significantly less for the uncemented group: 1.7 hours versus 2.3 hours ($p = 0.03$). The authors concluded that a cemented humeral component provides better quality of life than an uncemented humeral component. It is important to note that in this study there was a significantly higher number of men in the cemented group compared to the uncemented group, and the differences between the two groups may be due to improvement in male participants. Additionally, the prosthesis used in this study was not specifically designed for bony ingrowth, which could significantly alter outcomes

for the uncemented group.[5] Therefore, it may be difficult to extrapolate the results of this study to other implants.

Though there are no other studies directly comparing outcomes in anatomic TSA between cemented and uncemented humeral components, there are two retrospective cohort studies comparing outcomes with cemented and uncemented humeral stems in reverse total shoulder arthroplasty (rTSA). In a review of 100 operations (51 with cemented and 32 with uncemented humeral stems) performed using the Exactech Equinoxe® System, King et al. showed significant improvement in the 12-item Simple Shoulder Test, 12-item Short Form, Shoulder Pain and Disability Index 130 (SPADI-130), American Society of Shoulder and Elbow Surgeons (ASES) score, and normalized Constant scores for both groups, with no significant differences between the two at two-year follow-up. Additionally, there was no significant difference in complication rate between the two groups.[1]

In a second retrospective cohort study comparing outcomes between cemented and uncemented humeral components in rTSA, Wiater et al. compared 64 cases of cementless rTSA with 37 cases of cemented rTSA. Outcome measures included Constant–Murley scores, American Shoulder and Elbow Surgeons scores, Visual Analog Scale (VAS) pain scores, range of motion, patient satisfaction, and radiographic evidence of complication. Findings included significant improvements in all functional scores, forward flexion, and internal rotation with no significant difference between these values in cemented versus uncemented rTSA. Similarly, there were no differences in radiographic evaluation or complication rate between the two cohorts.[6]

Resolution of clinical scenario

- At the current time, there is only one study comparing outcomes with cemented versus uncemented humeral stem fixation in anatomic TSA. While this is a level I study, a limitation of this study is that results can be applied to the use of the Zimmer BF implant, and not necessarily generalizable to all uncemented humeral components. Additionally, while the differences in functional outcome scores were significantly different, improvements in strength and range of motion were similar when compared to baseline measurements. Finally, this study only reports on the short-term outcomes, and the results may not be extrapolated to long-term follow-up.
- Two level III retrospective cohort studies examine differences between cemented and uncemented humeral stem fixation in rTSA. Both studies suggest that there is no significant difference in functional outcomes, radiographic outcomes, or complications between the two cohorts. It is important to note that the applicability of these studies to anatomic TSA is limited.
- At this time, there is not indisputable evidence demonstrating improved functional outcomes with cemented or uncemented humeral stem fixation in anatomic TSA. The authors recommend discussing factors including ease of revision, implant survivorship, and complications with the patient. Patient factors such as age, expectations, functional level, and proximal humeral bone quality must also be considered. The final decision should be individualized on the basis of these parameters.

Question 2: In patients undergoing anatomic total shoulder arthroplasty (TSA), is there a difference in implant survival with a cemented versus uncemented technique?

Rationale

In the setting of a TSA, loosening of the humeral component increases the need for revision surgery. The use of cement in joint arthroplasty has the potential to decrease stem loosening, especially in patients with poor bone health, or large humeral canals with implant size mismatch.[7] There is concern that press-fitted, uncemented implants will have higher rates of loosening.[8] There is no consensus evidence-based opinion to justify the use of cemented or uncemented implants (either press-fit or ingrowth) for humeral component fixation. However, each option has advantages and disadvantages.

Clinical comment

Component loosening is a significant complication, resulting in significant morbidity and increased risk of secondary surgery.

Available literature and quality of the evidence

- Level I: 1 prospective randomized study.
- Level III: 3 retrospective cohort studies.

Findings

In a small prospective randomized study of 26 patients with rheumatoid arthritis undergoing TSA with a two-year

follow-up, Rahme et al. reported on loosening and micromotion in cemented and uncemented groups. There was no significant difference between the two groups after radiographic analysis with respect to rotation or translation around the x-, y-, or z-axis. The authors conclude that for patients with rheumatoid arthritis a well-fitted press-fit component is equivalent to a cemented component. However, it should be noted that the size of this study sample was likely too small to detect significant differences between the two groups.[9]

A review of 4636 patients undergoing shoulder arthroplasty was conducted, including 1167 patients receiving a cemented humeral component and 3469 receiving an uncemented humeral component. Propensity score-match analysis was performed to match for nine different covariates, and 551 pairs of well-matched patients were identified. At 20 years postoperatively, implant survival without humeral loosening was significantly higher in the cemented group: 98.7% (95% confidence interval [CI]: 97.5–100) versus 91.0% (95% CI: 86.3–95.9; p <0.01). The authors concluded that both implants have excellent long-term survivorship and that while cemented components have lower rates of loosening this should be weighed against the risks of proximal humeral bone loss at the time of revision of a cemented component.[10]

In a review of 2588 shoulder arthroplasties, Singh et al. reported no significant difference in need for all-cause revision between cemented and uncemented fixation (hazard ratio [HR] = 0.62; 95% CI: 0.38–1.02; p = 0.06). While initial univariate analysis suggested decreased revision rates for cemented implants, this difference was not present after multivariate analysis was done to adjust for confounding variables such as gender, age, method of fixation, and diagnosis. In a multivariable analysis, only male gender (HR = 1.72, 95% CI: 1.28–2.31; p <0.001) and

diagnosis of rotator cuff disease (HR = 3.99; 95% CI: 1.91–8.36; p <0.001) and tumor/avascular necrosis (HR = 2.65; 95% CI: 1.40–5.02; p = 0.003) were associated with significantly higher risk of revision surgery.[11]

In a review of 1584 shoulder arthroplasties, Cil et al. reported no significant difference in survivorship (HR = 0.79; 95% CI: 0.22–2.83; p = 0.72) between uncemented and cemented Neer II implants (3M, St. Paul, MN, USA; Kirschner Medical Corporation, Fairlawn, NJ; Biomet, Warsaw, IN, USA). For the Cofield 1 humeral component (Smith & Nephew, Memphis, TN, USA), survivorship was significantly increased for cement fixation relative to fixation without cement (HR = 0.33; 95% CI: 0.13–0.81; p = 0.02). Overall, there was an increased survivorship across all implants for cement fixation compared to a component without cement fixation (HR = 0.31; 95% CI: 0.18–0.76; p = 0.007).[12]

Resolution of clinical scenario

- There is currently insufficient evidence to recommend the routine use of a single method of fixation. The choice between the use of a cemented or uncemented humeral component should be individualized based on patient and diagnostic factors.[9]
- Factors to consider include the patient's age, sex, diagnosis, expectations, functional level, and proximal humeral bone quality.

Question 3: In patients undergoing anatomic TSA with a cemented glenoid and/or humeral component, is there a difference in infection rates with the use of antibiotic-impregnated cement compared to plain cement?

Rationale

The use of antibiotics in cement has the potential to decrease the risk of periprosthetic infections. However, the addition of antibiotics to cement can potentially affect the mechanical properties of the cement and negatively impact fixation strength. In addition, the routine use of antibiotics in this setting may increase the risk of developing antibiotic-resistant bacteria.

Clinical comment

Periprosthetic infection in the setting of a TSA is a devastating complication, with significant morbidity and unsatisfactory patient outcomes after challenging revision procedures.[13-15] It is important to consider interventions that can reduce the incidence of infection and understand their potential risks and benefits.

Available literature and quality of the evidence

- Level III: 1 retrospective cohort study.

Findings

A retrospective review of 501 patients treated with rTSA and mean follow-up of 37 months was performed. The study

demonstrated that in patients receiving cement without antibiotics, rate of periprosthetic infection was 8 of 265 (3%), while none of the 236 patients treated with antibiotic-impregnated cement had a perioperative joint infection ($p < 0.001$). There was no significant difference between the two groups with regards to demographic factors, and the use of antibiotic cement was based upon surgeon preference, rather than patient characteristics. Of the patients with infection, one had a superficial infection while eight had a deep infection diagnosed by positive joint aspiration culture. These infections required additional treatments including suppressive antibiotics, irrigation and debridement, resection arthroplasty, and two-stage exchange arthroplasty.[16]

Resolution of clinical scenario

- To the best of our knowledge, there are no studies that evaluate the use of antibiotic-impregnated cement in anatomic TSA.
- One study reported on the use of antibiotic-impregnated cement in the setting of rTSA humeral stems, which can be extrapolated to our case scenario. This study reported a reduced rate of perioperative deep infection with use of antibiotic-impregnated cement, at short and medium-term follow-up.
- While long-term studies are lacking, there is some evidence that the use of antibiotic impregnated cement may lower the risk of infection when used for humeral stem fixation. Further research in this area is warranted.

Summary of answers

- When comparing cemented and uncemented fixation in TSA, there is limited evidence regarding which method leads to better functional outcomes. While there is one high-quality randomized controlled trial reporting improved functional outcomes with cemented fixation of a specific implant (Bigliani/Flatow Total Shoulder Solution, Zimmer), this may not be applicable to other uncemented implants. We recommend tailoring one's method based on individual patient factors (age, expectations, functional level, and proximal humeral bone quality).
- A number of large retrospective studies have shown conflicting evidence as to whether there is a difference in implant survival with the use of cemented or uncemented humeral implants. Therefore, there is no consensus on whether the use of a cemented versus an uncemented technique affects longevity of the implant.
- There is a single retrospective level III case-control study demonstrating reduced rates of infection in rTSA with antibiotic-impregnated cement, which may be extrapolated to our case scenario. While long-term studies are lacking, there is some evidence that the use of antibiotic-impregnated cement may lower the risk of infection when used for humeral stem fixation. Regarding this question, at the 2018 International Consensus Meeting on Musculoskeletal Infection, the authors concluded that there is insufficient evidence to determine whether antibiotic-impregnated cement should be used during primary or revision shoulder arthroplasty.

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Management of Glenoid Bone Loss

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Clinical scenario

- A 50-year-old patient presents with chronic shoulder pain; severe osteoarthrosis is evident on plain radiographs.
- Pain and limited range of motion interfere with activities of daily living.
- The patient enquires about arthroplasty options.

Top three questions

1. In patients with glenoid bone loss, does computed tomography (CT), compared to other imaging modalities, perform better diagnostically?
2. In patients with glenohumeral bone loss, does reverse total shoulder arthroplasty (rTSA), compared to other treatment options, result in better outcomes?
3. In patients undergoing rTSA, do any bone graft options, compared to others, result in the best outcomes?

Question 1: In patients with glenoid bone loss, does computed tomography (CT), compared to other imaging modalities, perform better diagnostically?

Rationale

Shoulder arthroplasty is a widely used procedure. In the United States, the frequency of both primaries and revisions are continually increasing.[1,2] As with most orthopedic interventions, preoperative planning is essential to achieving favorable results in shoulder arthroplasty.[3]

Clinical comment

In arthroplasty, restoration of correct alignment is the primary objective. When correction of the glenoid version is not achieved, the risk of posterior humeral head displacement increases, causing asymmetric wear of the polyethylene (PE)[4] and consequent risk of prosthetic loosening.[5–10]

Abnormal glenoid morphologies have been well described. In most cases, glenoid bone loss is multiplanar, requiring correction in more than one plane. However, to simplify surgical pre-planning, it is useful to classify these morphologies by the characteristics of the predominant glenoid loss. Four basic patient profiles, with four corresponding deficit patterns, have been described.[11] The first of these profiles is the osteoarthritic patient with a horizontal defect, as described and classified by Walch et al.[12] The second is the patient with inflammatory arthritis, with a central defect and secondary joint-line medialization, as described by Lévigne and Franceschi.[13] The third is the

patient with cuff-tear arthropathy (CTA) with a vertical-plane defect, as described and classified by Lévigne et al.[14] The fourth profile is the patient who requires revision surgery, with a combined and irregular defect pattern, as described and classified by Williams and Iannotti.[15]

In cases of glenoid bone loss with secondary retroversion or inclination, it can be difficult to achieve correct orientation, increasing the risk of premature loosening.[16] For this reason, careful evaluation of bone stock, glenoid version, and inclination is imperative for achieving proper glenoid component implantation.

Available literature and quality of evidence

Literature addressing investigations into shoulder arthroplasty preoperative planning is widely varied, offering only level III–V evidence. Most papers describe case series or cohort studies. No randomized trials have been reported.

Findings

Plain radiography

Despite the value of the latest imaging technologies, plain x-ray images remain necessary for preoperative planning.[17]

There are several useful projections:

- *Anteroposterior view:* useful in assessing bone quality, osteophytes, and the humeral canal.
- *Axillary view:* useful for studying posterior erosions and subluxations. This view, however, can lead to overestimating retroversion in up to 86% of cases.[18]
- *Y scapula view:* useful for evaluation of anterior or posterior subluxation.

In planning revision surgeries, it can be helpful to have radiographs of both the glenohumeral joint and the entire humerus, in order to appreciate shortening or medialization at the glenohumeral joint level.[19]

Computerized tomography (CT)

The CT is considered the gold standard for the imaging of bone defects. It offers extensive information on both inclination of the glenoid surface and possible bone defects. However, despite the advantages a CT can offer, potential variability has been described regarding measurements obtained by this system, as a function of scapular rotation in the coronal plane.[20]

Seidl et al. described the importance of obtaining images in the scapular plane, to execute an accurate study of the glenoid surface.[11] In an effort to avoid variability, corrective systems have been described, based on the main plane of the scapula. Friedman et al. studied 20 shoulders in 13 patients (10 with osteoarthritis, 10 with inflammatory arthritis). Their study compared these 20 shoulders with 63 controls. They defined the transverse axis of the scapula as a line drawn from the midpoint of the glenoid fossa to the medial end of the scapula.[21]

Three-dimensional computed tomography (3D CT)

Use of 3D CT for preoperative planning has been validated, both in clinical and cadaver studies.[22–25] This system allows deeper study of glenoid morphology, inclination, version, and available bone stock. Preoperative planning using 3D reconstruction has been shown to improve the precision of implant orientation.[3]

Resolution of clinical scenario

- Preoperative planning plays a critical role in shoulder arthroplasty, helping to improve functional outcomes and prosthesis survival.
- The plain radiographic study remains relevant for such planning, allowing collection of a variety of valuable information.
- The CT is reliable and widely used; it allows precise assessment of glenoid version and bone stock. Caution should be exercised with regards to ensuring measurements are made in the scapular plane.
- The 3D CT allows deep study of glenoid morphology, and seems to improve preoperative planning.

Question 2: In patients with glenohumeral bone loss, does reverse total shoulder arthroplasty (rTSA), compared to other treatment options, result in better outcomes?

Rationale

Glenohumeral stability is determined by dynamic compressive forces of the humeral component on the glenoid component. Minor displacements of as little as 2.5° can lead to subluxation of the humeral component.[26] Failure in correction of glenoid version, with a retroversion of >15°, may lead to osteolysis, posterior translation of the humeral head, and eccentric PE wear of the prosthesis.[27]

There are multiple options for managing glenoid retroversion secondary to bone defect, depending on defect location and type. These therapeutic options can be grouped generally as: implantation of an anatomical

prosthesis, implantation of an inverted prosthesis, associating such implants with eccentric reaming, augmented or personalized implants, and resorting to bone grafts. Careful consideration of the potential benefits and disadvantages of each option is essential to arriving at a customized decision for each patient.

Clinical comment

Before addressing rTSA, it is necessary to outline the other treatment alternatives.

Eccentric reaming and implantation of anatomical prosthesis

There is no clear consensus on the optimal management of retroversion in this patient profile. One of the most frequently chosen options for patients with relatively minor retroversion is eccentric reaming. However, the technique has many detractors. Gillespie and colleagues concluded that in the presence of a retroversion of greater than 15° the probability of successful correction was 50%.[28] Subchondral bone reduction can increase the risk of implant loosening, as well as the risk of excessive medialization.[11,29–32] Other authors, however, argue that this is a good option when retroversion is minor. Nyffeler et al. reported favorable results, with a good capsulolabral release and adequate mobilization of the musculotendinous subscapularis unit.[18]

Augmented or customized implants

Augmented or customized implants have been proposed as an alternative to eccentric reaming or bone grafting. Studies to date report controversial results. Sabesan and colleagues report favorable corrections of glenoid retroversion with augmented implants, in cases of less than

16°. When retroversion is greater than 16°, the same authors recommend the use of bone grafts.[30] They concur with the view that it is a difficult and demanding technique. Incorrect implantation can foster a predisposition to micro-movements and consequent loosening.[30,33]

Available literature and quality of evidence

The quality of the literature on appropriate investigations into rTSA for glenoid loss management is widely varied, and offers only level IV–V evidence. The majority of outcome papers are case series or retrospective cohort studies. There are no randomized trials reported.

Findings

The usefulness of rTSA in treatment of osteoarthritis in the context of CTA has been widely described.[34–36] However, this is not the only indication for such an implant. Mizuno et al. studied 27 cases of rTSA for treatment of primary glenohumeral osteoarthritis and biconcave glenoid (Walch type B2). Their study's patient profile included a mean patient age of 74.1 years, and a mean preoperative retroversion of 32°. After 44 months of follow-up, the mean Constant score increased by 45 points. They reported a 15% complication rate, including early loosening of the glenoid component and neurologic problems. There was a 37% incidence of scapular notching; no radiolucent lines were observed.[37]

Similarly, McFarland et al. reported favorable results in their own series, a review of 42 patients with primary osteoarthritis and intact rotator cuffs. The patients presented with a different range of retroversion grades (A2, B2 and C Walch type glenoids), and were treated with rTSA without bone grafting. Objective improvements in pain level and range of motion were observed, as well as

improved subjective scores. One baseplate failure was reported, requiring revision surgery.[38] These favorable results may be explained by the greater degree of constraint afforded by the technique, avoiding posterior subluxation of the humeral head.[39] RTSA can offer more positive fixation and greater constraint than the use of an anatomical prosthesis. However, this procedure is associated with secondary complications. For this reason, it may be more appropriate for older and more sedentary populations, with severe erosions and subluxations.[16,17,39,40]

Resolution of clinical scenario

- The current evidence does not recommend adopting a firm position on the degree of retroversion which must be present to indicate intervention with rTSA.
- Although there is poor evidence, the studies cited recommend that in Walch type B2 cases rTSA may be considered if other relevant factors permit it.

Question 3: In patients undergoing rTSA, do any bone graft options, compared to others, result in the best outcomes?

Rationale

Use of rTSA in a glenoid with bone defects and secondary retroversion can lead to complications such as notching and joint kinematic disturbance, with reduced uptake of deltoid fibers.[41] These defects may be present in up to 10–15% of cases, complicating correct prosthetic implantation.[42] As previously mentioned, there are varied

approaches to glenoid defect management. An alternative to the techniques described previously is *bone grafting* with the objective of filling the defect.

Clinical comments

It can be difficult to avoid prosthetic orientation failure in patients with extensive erosions and glenoid retroversion. Uncorrected superior bone loss can result in scapular impingement, instability, lower-scapular notching, and medial PE wear.[43,44] Inadequate correction of a posterior defect may lead to reduced external rotation, scapular notching, and posteromedial PE wear.[14,45] Bone grafting has been found to be effective as an alternative treatment, to preserve the kinetic and mechanical characteristics of the joint. Indications for grafting include presentation with a version that cannot be corrected by adjusting the version of the different components, insufficient bone stock to support the glenoid component, retroversion >15°, potential penetration of the glenoid vault following version corrections, or a baseplate with less than 80% native bone support.[46–50]

Bone graft options can be classified as structural or nonstructural. Cancellous graft is a nonstructural option; structural grafts include allografts, and hybrids of allograft and autograft.

Donor-site options include the humeral head, the iliac crest, the femoral head, and the femoral neck.[17,34,35,51–53] Use of rTSA and its fixation system could increase the effectiveness of bone grafts in improving bone stock.[42,54,55]

Medium- and long-term results depend on the technique employed. Neer and Morrison found no glenoid loosening or migration at two year follow-up in their 16-patient series.[46] Steinmann et al. reported that 54% of patients had

some degree of radiographic lucency in their 28-patient series, with 5.3 years of follow-up.[47] Hills and Norris reported on 17 shoulders with posterior bone grafts; five presented with glenoid failure. Each of these studies reported high levels of patient satisfaction.[48] Boileau et al. suggested that one cause of these favorable results could be the effect of a fixed and medialized fulcrum.[56] However, the technique has its drawbacks: it is technically demanding, the fixation may fail, and resorption may occur.[49]

Available literature and quality of evidence

Literature addressing investigations into use of bone grafting for glenoid loss management is widely varied, offering only level IV–V evidence. Most outcome papers available are case series or cohort studies. There are no randomized trials reported.

Findings

The literature includes numerous reports on results with this technique. Neyton et al. reported good results in nine rTSA cases, using iliac crest autografts. In all cases the grafts had been integrated at two years, but functional results could have been more favorable.[55]

Lopiz et al. reported the results of a 20-patient study with a mean follow-up of two years. Their mean Constant score improved from 30.7 ± 9.4 to 51.3 ± 13.4, with osseointegration in 95% of the cases. They reported a 20% complication rate: one case of aseptic glenoid component loosening, one surgical wound hematoma, one acromial fracture, and one symptomatic grade 3 scapular notching.[49]

Wagner et al. reported the functional results of 40 bone-graft revision rTSAs at two-year follow-up. Of these

patients, 18% required a second revision surgery.[57] Mahylis et al. reported a retrospective cohort study of 30 patients treated with rTSA, divided into two groups: one with iliac crest autografts, the other with less extensive erosion and no need for structural bone grafts. At two-year follow-up, no statistically significant differences were found in terms of implant position, scapular notching, implant shift, or fixation failure. Likewise, at least partial osseointegration of 93% of the grafts was observed; 40% had some degree of resorption. No differences were found in range of motion or functional scales.[52]

Boileau et al. presented their work with what they described as a *bio-rTSA technique*. This operative technique was designed primarily to lateralize the center of rotation as the main objective, rather than correction of glenoid version. They reported on a retrospective study of results in 54 patients with a two-year follow-up. In these patients, a trapezoidal graft of the humeral head was used to graft B2 and C (Walch), and E2, E3, and E4 defects. Fifteen of the patients had multiplanar deficits. An integration rate of 94% was observed, with 5% glenoid loosening and 25% scapular notching. In this paper, the authors reported the advantages of the humeral head autograft, including low co-morbidities in the donor area, no risk of disease transmission, and low cost as compared with use of allografts and augmented implants.[51]

They presented their treatment system, consisting of use of standard instrumentation to correct up to 15° of the defect with eccentric milling, and the remainder with graft, in patients with simple defects and less than 25° retroversion deficits. For severe (>25°) or multiplanar defects, they performed correction and realignment with bone graft.[51]

Resolution of clinical scenario

- In patients with extensive bone erosion and severe retroversion, achieving proper prosthesis orientation can present challenges. In such patients, bone grafting may provide the structural support necessary to correct the defects.
- The complication rate in rTSA with bone grafting ranges between 9 and 30%, with a resorption rate of up to 40% in surgical patients.
- Although there is poor evidence with short-term follow-up, patients may have functional results as favorable as those in patients operated on with rTSA without bone grafting.

Summary of answers

- Preoperative planning is critical in shoulder arthroplasty.
- 3D CT scan is an excellent resource for precise assessment of glenoid morphology and likely improves preoperative planning.
- rTSA may be considered for Walch Type B2 glenoid, although there is poor evidence on this .
- Bone grafting may provide structural support in those with extensive bone loss and severe retroversion .
- Complication rates can be up to 30% in patients requiring bone grafting, though functional results may not be affected

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Reverse Total Shoulder Arthroplasty

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Clinical scenario

- A 75-year-old woman who is living independently is seen with complaints of right shoulder pain and loss of motion.
- She has no history of trauma and the pain has been progressive over the past 2–3 years.
- On examination, she has very limited active movement and crepitus. She is neurovascularly intact.

Relevant anatomy

A rotator cuff tear can be classified as acute (no irreversible muscular fatty atrophy and generally reparable) or chronic (with irreversible muscular fatty atrophy and generally irreparable). Instability of the glenohumeral joint due to a long-standing irreparable rotator cuff tear often occurs in an anterior and superior direction, called *anterosuperior escape*, often leading to a pseudoparalysed shoulder, generally defined as a loss of active forward elevation with maintained passive movement. These abnormalities can eventually lead to arthritic changes at both the glenohumeral and acromiohumeral articulations.

Importance of the problem

Shoulder arthritis can include osteoarthritis, rheumatoid arthritis, post-traumatic arthritis, and cuff tear arthropathy. Each type of arthritis is not infrequently seen in combination with a rotator cuff tear. A conventional anatomic total shoulder arthroplasty (TSA) is used to relieve pain and improve function in arthritic shoulders. The articular surfaces are unconstrained and allow the healthy rotator cuff and extrinsic shoulder muscles to restore shoulder function. In most arthritic shoulders, with or without a rotator cuff tear, the *ball-and-socket* biomechanics of the glenohumeral joint are maintained. However, each type of arthritis may present in combination with rotator cuff dysfunction and loss of the normal biomechanics, often leading to instability and pseudoparalysis. In this situation, the outcome of a traditional shoulder arthroplasty is substantially compromised.[1–3]

The incidence of rotator cuff tear dysfunction in the population of shoulder arthritis patients is difficult to determine, but occurs in a minority of patients. Although shoulder arthritis is much less common than hip or knee arthritis, the incidence and indications for shoulder arthroplasty continue to increase.

Top three questions

1. Among patients with shoulder pain and dysfunction, which indications, compared to others, are most relevant for reverse total shoulder arthroplasty (rTSA)?
2. In patients undergoing rTSA, do some surgical techniques, compared to others, result in better outcomes?

3. In patients undergoing rTSA, what are the clinical outcomes?

Question 1: Among patients with shoulder pain and dysfunction, which indications, compared to others, are most relevant for reverse total shoulder arthroplasty (rTSA)?

Rationale

In general, rTSA is an implant that provides increased stability for a shoulder that has lost, or is at increased risk of losing, its normal ball-and-socket function. This most commonly occurs due to soft tissue (usually rotator cuff) or bony deficiency. However, as experience with this implant increases and with newer research, the indications for rTSA are expanding.

Clinical comment

The traditional indication for rTSA has been rotator cuff tear arthropathy with pseudoparalysis in elderly low demand patients. However, indications have rapidly expanded to now include younger high demand patients, other causes of arthritis, cuff insufficiency, or impending insufficiency, as well as some types of proximal humerus fractures.

Available literature and quality of the evidence

- Level I: 1 randomized control study.[4]
- Level II: 1 nonrandomized control study[5] and 2 economic analyses.[6,7]

- Level III: 1 case-controlled study[8] and 2 retrospective cohorts.[9,10]
- Level IV: 2 systemic reviews[11,12] and 4 case series.[13–16]

Findings

Cuff tear arthropathy

RTSA may be considered when the patient presents with a clinically symptomatic, irreparable rotator cuff tear associated with anterosuperior escape and an irrecoverable pseudoparalysis. However, deltoid function must be preserved and there must be adequate glenoid bone stock to allow secure glenoid component fixation.[17,18]

Rheumatoid arthritis

RTSA in patients with rheumatoid arthritis is considered a reliable treatment option, with similar results to rTSA in rotator cuff arthropathy without a higher complication rate.[11]

Cuff tear arthropathy in younger patients

The use of rTSA for cuff tear arthropathy in patients younger than 65 years of age generates some treatment controversy. However, rTSA is now emerging as a reasonable treatment option for these patients, providing subjective functional improvements, but with higher complication rates and implant longevity concerns.[913–16]

Failed arthroplasty

RTSA is also used as a revision procedure for shoulder arthroplasty associated with instability, this is associated with reasonable survival rates and higher complication rates than other indications. Instability can still remain an issue for one in seven patients.[10]

Proximal humerus fractures

RTSA can be used for the treatment of complex proximal humerus fractures in elderly patients. Patients show better forward flexion and abduction, with lower revision rates when compared with hemiarthroplasty.[4,12,19,20] RTSA has also been shown to be more cost-effective when compared with hemiarthroplasty.[7]

Resolution of clinical scenario

- In patients greater than 70 years of age, rTSA can be considered when rotator cuff dysfunction leads to anterosuperior humeral escape and shoulder pseudoparalysis.
- However, when all other options are exhausted, rTSA may also be considered in patients with rheumatoid arthritis, cuff tear arthropathy in patients less than 65 years of age, failed anatomic TSA, and complex proximal humerus fractures in the elderly.

Question 2: In patients undergoing rTSA, do some surgical techniques, compared to others, result in better outcomes?

Rationale

There has been a dramatic increase in rTSA implant design and surgical techniques over the past 10 years. This has led to debate within the literature regarding many factors, including optimal positioning of the glenosphere and baseplate and humeral stem as well as size and design of the glenosphere. The effects of subscapularis muscle repair also show discordance within the literature.

Clinical comment

rTSA has enjoyed tremendous success considering its relatively short proliferation. This implant design provides a surgical option in difficult situations that previously were inadequately addressed with other surgical options. However, the pain and functional outcomes, survival, and complication rates have been somewhat inconsistent and concerning long term. As a result, authors have searched for implant design and technique methods to optimize the outcomes.

Available literature and quality of the evidence

- Level I: 4 randomized controlled trials.[21–24]
- Level II: 1 prospective case series.[25]
- Level III: 5 retrospective cohort designs, 2 prospective case-control studies, and 2 retrospective case-control studies.[26–34]
- Level IV: 1 systematic review and 3 retrospective case series.[35–38]
- Level V: 4 biomechanical studies.[39–41]

Findings

Humeral component neck-shaft angle

Utilizing a lower neck-shaft angle (135°) on the humeral component leads to a greater impingement free range of motion (ROM) and decreases the rate of scapular notching when compared with a higher angled (155°) design ($p = 0.0081$).[30,39,40] The neck-shaft angle does not appear to affect the rate of postoperative dislocation.[35]

Larger diameter glenosphere

Use of a larger diameter glenosphere (>42 mm) decreases the rate of scapular notching ($p < 0.001$) and improves ROM (forward flexion and external rotation) ($p < 0.05$).[31,33] However, both the size of the glenosphere and the presence of notching does not appear to affect the clinical outcome at short-term follow-up.[22,29,32]

Inferior glenoid component tilt and positioning

Inferior glenoid tilt of >10° does not reduce the rate of scapular notching and does not appear to confer a clinical benefit.[23,30] Inferior glenoid positioning is desirable to decrease the rate of scapular notching and may improve clinical outcome scores.[22,25,41,42]

Glenoid lateralization

No differences in functional outcome scores, ROM, or strength have been identified when comparing bony lateralization (i.e. bony-increased offset rTSA) of the glenosphere with medialized designs.[21,32] Higher rates of scapular notching have been shown in medialized designs ($p = 0.022$); however, clinical outcome scores were not affected.[32,36] In a lateralized glenosphere design without bony-offset augmentation there is a risk of base plate failure secondary to increased shear stress at the baseplate–bone interface.[37] More robust baseplate fixation with the use of multiple peripheral locking screws has been shown to eliminate failure at medium-term follow up.[38]

Subscapularis repair

Repair of the subscapularis has been shown in some series to improve clinical outcome scores ($p < 0.05$).[29] However the differences identified are not likely to be clinically meaningful. Other series have not identified any differences in objective and subjective outcome measures,

ROM, strength, or complication rates.[27,28] Repair of the subscapularis may be desirable in medialized designs to decrease postoperative dislocation rates.[28]

Resolution of clinical scenario

- A lower neck shaft angle leads to lowers rates of scapular notching and greater impingement-free ROM.
- Larger diameter glenospheres are preferable.
- Ideal glenosphere positioning is inferior on the glenoid face.
- Component design offset can be determined by surgeon preference but improvements in ROM can be seen in lateralized offset with an intact teres minor.
- Repair of subscapularis is desirable in medialized designs for decreased dislocation rate; however, in a lateralized design subscapularis repair is the surgeon's preference.

Question 3: In patients undergoing rTSA, what are the clinical outcomes?

Rationale

RTSA has been widely accepted for a variety of indications. Overall, early results have been good but appear to be significantly impacted by the indication for use. Long-term outcome data are uncertain at this time.

Clinical comment

RTSA is generally a last resort in a difficult situation. As such, this implant provides an alternative to many problems that previously did not have a good option. Generally, the

results of rTSA are very good for pain relief and improved motion. However, the results depend on several factors, including the indication, age, gender, and preoperative level of function.

Available literature and quality of the evidence

- Level I: 1 randomized controlled trial.[43]
- Level II: 1 retrospective study[44] and 2 prospective cohort studies.[5,45]
- Level III: 3 retrospective studies.[46–48]
- Level IV: 1 case series,[49] 1 therapeutic study,[17] and 8 meta-analyses.[12,18,50–56]

Findings

Overall

Short- to medium-term results of rTSA show substantial improvements in pain, quality of life, ROM (forward elevation and abduction), functional outcome, and patient satisfaction.[18,46,47,49,50] Overall, absolute constant score improved from a preoperative score of 23 ± 12 to a postoperative score of 63 ± 14.[17]

The largest improvements in ROM are with active forward elevation with postoperative values of 138 ± 26° compared to 81 ± 43° preoperatively.[17,18] The majority of patients will be able to return to their preoperative activity level within six months.[48,51,52] However, patients with a lower preoperative level of function displayed longer recovery times.[44,45]

According to the indication

RTSA for rotator cuff arthropathy is associated with the highest absolute Constant score of 70 ± 11. This is compared to other indications, including revision arthroplasty (55 ± 16), massive cuff tear (63 ± 11), and post-traumatic arthritis (55 ± 20).[17,18]

Long-term results

Long-term studies of rTSA show high functional outcome scores and survival rates. At 10 years, the overall mean absolute constant score is 55 ± 16, which is a significant improvement compared with preoperative values.[17] However, there appears to be a significant functional deterioration between medium- to long-term scores ($p < 0.001$).[17] RTSA for revision arthroplasty and post-traumatic arthritis show lower long-term functional outcome scores when compared to rotator cuff arthropathy. Nonetheless, the 10 year overall implant survival rate is 93%.[17]

Proximal humerus fractures

RTSA for complex proximal humerus fractures in elderly patients have shown improved forward flexion and abduction, but decreased external rotation when compared with hemiarthroplasty.[4,12,19,20] Revision rTSA for failed proximal humerus internal fixation showed improved pain, ROM, and functional outcome scores when compared to preoperative values. However, functional scores were lower than patients who underwent primary rTSA for proximal humerus fractures.[4,20]

Resolution of clinical scenario

- Overall, rTSA results in improved pain and functional outcomes, but these results decrease between medium- and long-term follow-up.

- Results are dependent on the indication, with rotator cuff tear arthropathy showing the best results, and revision arthroplasty the worst.
- rTSA for proximal humerus fractures leads to improved function compared to hemiarthroplasty.

Summary of answers

- In patients greater than 70 years of age, rTSA can be considered in the setting of rotator cuff dysfunction.
- A lower neck-shaft angle leads to lower rates of scapular notching and greater impingement free range of motion.
- rTSA results in improved pain and functional outcomes, but outcomes are less reliable at medium and long-term follow-up.

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Glenoid Components in Total Shoulder Arthroplasty

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Clinical scenario

- A 72-year-old right-hand-dominant male has been experiencing three years of right shoulder pain. The pain has been insidious in onset and has failed nonoperative treatment.
- Radiographic studies including conventional radiographs and computed tomography (CT) scan show considerable degenerative changes with loss of joint space, marginal osteophytes, subchondral sclerosis, and significant posterior glenoid erosion.

Top three questions

1. In patients with primary osteoarthritis, do keeled or pegged glenoid components correlate with lower revision rates?
2. In patients with primary osteoarthritis, do patient-specific components or intraoperative navigation, compared to traditional techniques, improve accuracy compared to traditional instrumentation?

3. In patients with primary osteoarthritis, do all-polyethylene cemented or metal-backed uncemented glenoid components result in lower failure rates?

Question 1: In patients with primary osteoarthritis, do keeled or pegged glenoid components correlate with lower revision rates?

Rationale

As the number of primary total shoulder arthroplasties continues to increase worldwide, the decision to use a particular style of glenoid component remains an important one in the effort to improve outcomes and prevent future revision surgery. Two glenoid component designs are most commonly used: keeled and pegged.

Clinical comment

One of the most important outcome measures for any joint replacement procedure is the rate of revision-free survivorship. In total shoulder arthroplasty (TSA), a frequent cause for revision in medium- and long-term follow-up is glenoid component failure.[1–4] It is important, then, to identify the best component design as well as clinical markers that can help identify component failure.

Available literature and quality of the evidence

There is a growing body of peer-reviewed literature exploring keeled versus pegged glenoid component design and correlation with implant survivorship and clinical outcomes. The current literature is limited by the variety of glenoid components used, analytic approaches, and outcome reporting. However, there are two level I studies

as well as some level III and IV studies to help us answer this question.

Findings

Level I studies

Two level I studies address radiolucency about the glenoid component in an attempt to use radiographic parameters to establish whether pegged or keeled components perform best. Rahme et al. performed radiostereometric analysis on 26 shoulders comparing results of inline pegged and keeled all-polyethylene components.[5] They found that only one glenoid (keeled) had any radiolucency on immediate postoperative radiographs. Nine of 12 keeled and 8 of 14 pegged glenoids showed radiolucency at two-year follow-up ($p = 0.429$), but that none of these showed Grade 4 or 5 lucency using the Gartsman classification. There was a trend toward glenoids with Grade 2 or 3 radiolucency showing more micro-migration than glenoids with Grade 0 or 1 radiolucency. However, this study was not powered to directly correlate radiolucency to micro-migration.

Edwards et al. report a prospective randomized trial of pegged versus keeled all-polyethylene components including 46 shoulders at 26 months to determine the effect of glenoid component design on immediate and follow-up radiographs.[6] For both immediate and follow-up radiographic evaluation, they selected the presence of at least Grade 2 lucency as their outcome. They concluded that there was no statistically significant difference between pegged and keeled glenoids on immediate postoperative radiographs ($p = 0.128$). They did find statistically significant differences between the two designs at 26 months, with 46% of keeled and 15% of pegged glenoids showing at least Grade 2 radiolucency ($p = 0.044$).

Level III studies

Vavken et al. did a meta-analysis looking at rates of loosening and radiolucency in keeled versus pegged glenoids.[7] They found a small difference between the component styles. The pooled risk ratio for revision was 0.27 (95% confidence interval [CI]: 0.08–0.88) in favor of pegged glenoids.

Throckmorton et al., in a retrospective case-control study, looked at 50 keeled and 50 inline pegged glenoids at approximately four-year follow-up.[8] There was no difference in glenoids that were at risk for loosening based on radiographic evaluation ($p = 0.74$). There was also no difference in clinical outcomes as measured by improvements in pain and range of motion from preoperatively ($p \geq 0.20$).

Level IV studies

Papadonikolakis et al. performed a systematic review of failures of anatomic total shoulder arthroplasties.[3] In this study, they noted limitations of the wide variability of reporting measures, but that overall, there was no detectable difference between pegged and keeled glenoids with respect to component failure. They did note that for asymptomatic radiolucent lines, there was a greater rate for keeled versus pegged glenoids (overall odds ratio = 2.37; $p = 0.01$).

Resolution of clinical scenario

- Based on the current literature, either keeled or pegged glenoid components may be used with equivalent revision rates.
- Keeled glenoids likely have a higher rate of radiolucency that develops over time. However, caution

must be used linking findings of radiolucent lines (RLL) to clinical outcome measures or to revision rates.

Question 2: In patients with primary osteoarthritis, do patient-specific components or intraoperative navigation, compared to traditional techniques, improve accuracy compared to traditional instrumentation?

Rationale

In efforts to improve survivorship of glenoid components, some authors recommend the use of newer patient-specific components or of intraoperative navigation technology. The hope is that, by improving the accuracy of placing the glenoid component, failure rates will improve.

Clinical comment

Glenoid morphology can be difficult to assess and alignment difficult to recreate and optimize in the placement of glenoid components during TSA. Authors hypothesize that use of the new technology will improve the surgeon's ability to accurately place the glenoid component intraoperatively.

Available literature and quality of the evidence

There are few studies looking at patient-specific systems or intraoperative navigation for glenoid placement, but there is one level I and one level II study that investigates the effectiveness over standard techniques for glenoid

placement. Several biomechanical studies also provide information.

Findings

Level I studies

Hendel et al. performed a randomized prospective clinical trial evaluating standard surgical technique compared to the use of patient-specific instrumentation for placement of the glenoid in TSA.[9] They found that patient-specific instrumentation led to improved inclination and mediolateral offset ($p < 0.05$), but there was no statistical difference for version. In glenoids with the most retroversion preoperatively (>16°), the patient-specific instrumentation showed the greatest benefit with only 1.2° deviation from optimal position versus 10° with standard instrumentation. There was also a significant reduction in the incidence of significant malpositioning (>10° of either version and/or inclination from the optimal preoperative plan) from 75 to 27% ($p < 0.01$).

Level II studies

Kircher et al. performed a small prospective randomized clinical trial using intraoperative navigation comparing glenoid positioning with traditional techniques.[10] Correction of preoperative to postoperative glenoid retroversion assessed on CT imaging showed improvement from 15.4° to 3.7° for navigation, and from 14.4° to 10.9° without navigation ($p = 0.021$).

Level III studies

Heylen et al. found that patient-specific instrumentation did not improve glenoid component inclination ($p = 0.093$), but extreme values of glenoid positioning were decreased with

patient-specific guides ($p < 0.001$).[11] They did not assess component version as an outcome in their study.

Biomechanical studies

Nguyen et al. compared computer-assisted navigation to traditional placement of glenoid components in 16 paired cadaveric specimens.[12] Glenoid version with computer assistance was significantly improved at all stages of positioning (initial guide pin insertion, reaming, drilling of the peg holes, and final component implantation) with respect to glenoid version ($p < 0.05$). With navigation, final version was 1.5° compared to 7.4° without navigation ($p < 0.05$). In this study, though inclination was improved with navigation, it did not achieve statistical significance ($p > 0.05$).

Throckmorton et al. showed that, with patient-specific targeting guides, the glenoid was placed in significantly more accurate version ($p = 0.04$) and inclination ($p = 0.01$) with respect to the intended position of the implant.[13] They also showed that significant malposition, defined as being more than 10° off the intended version or more than 4 mm off the intended starting point, was higher for standard compared to patient specific instrumentation. These results applied to low-volume, medium-volume, and high-volume surgeons equally.

Iannotti et al. evaluated the version, inclination, and location of guide pin placement using traditional techniques and patient-specific instrumentation.[14] They found that version improved by 8.2°, inclination improved by 11.4°, and location improved by 1.7 mm. These were each statistically significant ($p < 0.001$).

Resolution of clinical scenario

- Patient-specific instrumentation and intraoperative navigation reduce the likelihood of significant malposition of the glenoid component.
- Patient-specific instrumentation and intraoperative navigation improve component positioning compared to standard component placement techniques.
- Clinical outcomes and improvement in revision rates have not yet been studied or established with either patient-specific instrumentation or intraoperative navigation.

Question 3: In patients with primary osteoarthritis, do all-polyethylene cemented or metal-backed uncemented glenoid components result in lower failure rates?

Rationale

Durable fixation of the glenoid component remains a challenge given the small bone stock of the native glenoid. Revision rates also drive the need to find improved fixation methods to decrease loosening. While there is current interest in so-called hybrid glenoid designs, few studies exist at present to evaluate these implants. Two main categories of implant design have been widely used and studied to date: cemented all-polyethylene components or uncemented metal-backed components.

Clinical comment

The theoretical advantage of the uncemented designs is that the initial stability afforded by screw fixation ultimately allows for durable bone in-growth or bone on-

growth with the hope of more lasting fixation.[15] The theoretical disadvantage of cemented components is that temperatures generated with methyl methacrylate may rise to levels risking bone necrosis leading to higher rates of loosening.[16]

Available literature and quality of the evidence

The available literature investigating metal-backed versus all-polyethylene components is low in quality and is confounded by multiple implant types and outcome measures. Only one level II study exists and it is the only study looking at a direct comparison of results of these two component designs. Multiple level IV case series and one level IV systematic review are available.

Findings

Level II studies

In a prospective, randomized study, Boileau et al. compared 20 shoulders in each of two groups: cemented all-polyethylene keeled glenoids and uncemented metal-backed glenoids.[17] Clinical outcome measures included the Constant score, forward elevation, and external rotation. There was no statistical difference between the two groups at any time point, including at final follow-up for any of these outcome measures. Radiographic lucency was noted in 85% of polyethylene components versus 25% of metal-backed components and this was a significant difference ($p < 0.001$). Progression to radiographic loosening and need for revision surgery did not occur in the polyethylene group, but did occur in four shoulders (20%) of the metal-backed group. This difference in revision surgery rate (0–20%) was statistically significant. Ultimately, despite equivalent clinical results between the two glenoid component types in this short-term follow-up study, the

higher revision rate for metal-backed glenoids led the authors to conclude that use of metal-backed components should be abandoned.

Level III studies

A retrospective cohort by Friedman et al. reviewed 632 primary anatomic TSA cases, 316 of whom received hybrid cage glenoids and 316 age, sex, and follow-up matched controls who received cemented all-polyethylene peg glenoids. They found significantly lower rates of radiolucent glenoid and humeral lines (9/3% vs 37.6/9.1%, $p < 0.01$) and revision rates in metal cage glenoids compared to polyethylene glenoids (2.5% vs 6.9%, $p = 0.0088$).[18]

Level IV studies

Papadonikolakis et al. performed a systematic review including 21 studies on metal-backed and 23 studies on all-polyethylene glenoids.[19] Metal-backed glenoids showed lower rates of radiolucency and of radiographic loosening ($p = 0.0026$ and $p = 0.0005$, respectively). However, there was a much higher revision rate for the metal-backed components of 14% compared to 3.8% ($p < 0.0001$). Revisions in the all-polyethylene group were predominantly for loosening, whereas the metal-backed group revisions were for other reasons ($p < 0.0001$). These data suggest that metal-backed glenoids, then, have a higher rate of revision than all-polyethylene glenoid components.

Boileau et al. assessed 165 patients with metal-backed glenoids at a minimum of two years.[20] Revision-free survival rate at 12 years was only 46% (100% CI: 32–54%). At a mean of 8.5 years, 37% of patients required revision and, of those, 80% showed wear of the polyethylene. They

concluded that this style of implant is not a viable long-term therapeutic option.

Montoya et al. evaluated a metal-backed glenoid at medium-term follow-up of 64 months in 65 shoulders.[21] They noted the Constant score improved from 49 to 89.8 ($p < 0.001$) and there were also significant improvements in flexion, abduction, and external rotation (all $p < 0.001$). There were 9.4% with broken cage screws that loosened and a revision rate of 11.3% during the study. They felt this was too high a revision rate and the implant was removed from the market.

Tammachote et al. followed cemented metal-backed glenoids for a mean of 10.8 years with notable conclusions that the results were not better than comparable results for all-polyethylene cemented components.[22] They showed improvements in pain, abduction, and external rotation (all with $p < 0.001$). However, they showed 83% of components with radiolucency at most recent radiographic follow-up. They felt this was concerning and merited further follow-up.

Clement et al. looked at metal-backed glenoids in a specific patient population of only rheumatoid arthritis patients with 8- to 14-year follow-up.[23] At a mean of 10 years, their glenoid component survivorship was 89%. The Constant score improved postoperatively ($p < 0.001$) from 20.6 to 33.5.

In a later study, Clement et al. looked at the same component design in patients (mean age of 67) with osteoarthritis with 95-month mean follow-up.[24] Here the Constant score improved by 22 points ($p < 0.001$) and the survivorship was 93%.

Fucentese et al. reviewed their results with a soft metal-backed component at 50 months and showed significant

postoperative improvement in mean absolute Constant scores (29.1–65.9, p <0.001), age- and sex-adjusted Constant scores (40.1–87.7, p <0.001), but a high failure rate of 13.6% at this short follow-up.[25] Failures occurred with glenoid component fractures. They concluded that this was too high despite encouraging results with no other cases of observed loosening.

Resolution of clinical scenario

- At this time, the literature is of relatively low quality and mixed in terms of which design has higher revision rates.

Summary of answers

- Based on the current literature, either keeled or pegged glenoid components may be used with equivalent revision rates.
- Keeled glenoids likely have a higher rate of radiolucency that develops over time. However, caution must be used linking findings of RLL to clinical outcome measures or to revision rates.
- Patient-specific instrumentation and intraoperative navigation reduce the likelihood of significant malposition of the glenoid component.
- Patient-specific instrumentation and intraoperative navigation improve component positioning compared to standard component placement techniques.
- Clinical outcomes and improvement in revision rates have not yet been studied or established with either patient-specific instrumentation or intraoperative navigation.

- At this time, the evidence is mixed and of low quality, thus it is unclear which design has lower failure rates.

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Periprosthetic Joint Infection in Shoulder Arthroplasty

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Clinical scenario

- A 55-year-old man with advanced glenohumeral arthrosis has failed nonoperative treatment. He is seeking pain relief and improved function and is considering shoulder arthroplasty.
- Five years following the index anatomic total shoulder arthroplasty, he presents with three months of increasingly severe shoulder pain.
- The pain occurs deep in the joint, is worse with movement, and is not associated with systemic symptoms including fevers, chills, or sweats. Preoperative serum indices reveal an erythrocyte sedimentation rate (ESR) of 6 and a C-reactive protein (CRP) of 4. Plain films and computed tomography (CT) scan reveal significant lucencies around the glenoid component suggestive of loosening. The patient is seeking definitive management and pain relief.

Top three questions

1. Are infection prevention strategies, including modifiable patient factors and perioperative interventions, effective in reducing periprosthetic joint infection (PJI) in patients who undergo shoulder arthroplasty procedures?
2. In patients with possible PJI, do preoperative serum indices, aspiration, or imaging aid in establishing the diagnosis of infection compared with preoperative tissue culture?
3. In patients with shoulder PJI, does a two-stage revision result in lower reinfection rates compared with one-stage revision?

Question 1: Are infection prevention strategies, including modifiable patient factors and perioperative interventions, effective in reducing periprosthetic joint infection (PJI) in patients who undergo shoulder arthroplasty procedures?

Rationale

Infection continues to be a devastating complication following shoulder arthroplasty procedures. Preventative strategies, including optimization of patient modifiable risk factors and perioperative interventions, have varying degrees of success. Optimization of these preventative strategies is essential for reducing infection following shoulder arthroplasty procedures.

Clinical comment

Shoulder arthroplasty continues to show significant growth with the number of procedures performed annually projected to increase by 150% by 2020.[1] The incidence of PJI following shoulder arthroplasty is between 0.4 and 2.9% in the literature.[2,3] Although rare, infection following shoulder arthroplasty results in significant morbidity to the patient and cost to the health care system.[4,5] Risk factors for PJI after shoulder arthroplasty include age, sex, medical co-morbidities, inflammatory arthritis, corticosteroid use, duration of procedure, and blood transfusion. There has been significant attention placed on the development of preventative strategies to reduce the rates of PJI. Identifying effective methods for reduction of infection will result in significant benefit to patients and society. The optimization of patient modifiable risk factors, and the development of effective perioperative interventions that reduce contamination are both important aspects of infection prevention. Developing effective prevention strategies in shoulder arthroplasty is challenging, due to the low incidence of PJI and the prevalence of infection with low virulent organisms.

Available literature and quality of the evidence

There are many studies evaluating different infection prevention strategies in shoulder surgery. Several modifiable patient factors including blood glucose control, obesity, smoking, and substance abuse are commonly thought to influence the risk of PJI in shoulder arthroplasty. Several cohort studies have evaluated the influence of these factors on patient outcomes and complications. There are no level I randomized control studies regarding modifiable risk factors. There is limited evidence that

optimization of patient modifiable risk factors influences the risk of PJI in shoulder arthroplasty.

Findings

Modifiable risk factors

Obesity The best evidence in this area is level II. Richards et al. did not observe any difference in deep infection rate based on body mass index.[6]

Blood glucose control The evidence for glucose control is level III. The influence of diabetes and glycemic control has had mixed results in the literature. In a large retrospective database study of patients who underwent joint replacement surgery, Marchant et al. demonstrated increased risk of wound infection in patients with uncontrolled diabetes (odds ratio = 2.28; 95% confidence interval [CI]: 1.36–3.81; p = 0.002).[7] In a large retrospective study of lower extremity joint arthroplasty at a single institution, Iorio et al. confirmed the increased rate of infection in diabetic patients compared to nondiabetics (3.43% vs 0.87%) but found no association with HbA1c levels.[8] In contrast, a large database study of total knee arthroplasty failed to identify an increased rate of infection in diabetic patients, or in poorly controlled diabetic patients, when compared to patients without diabetes.[9]

Smoking Smoking has been identified as a risk factor for multiple complications following open and arthroscopic shoulder procedures (level III).[10,11] In a retrospective review of 1834 shoulder arthroplasty procedures, Hatta et al. found there was a deep infection rate of 4.7% at 10 years' follow-up for smokers versus 0.6% in nonsmokers(11).[11] In this study smoking cessation was found to decrease the risk of infection but not to the level

of a nonsmoker. The hazard ratio for deep infection decreased from 7.27 in smokers to 4.26 in patients who were classified as former smokers.

Substance abuse Alcohol abuse is a risk factor for complications following total joint arthroplasty.[12] Evidence is level IV. There are no studies specifically regarding alcohol consumption in patients undergoing shoulder arthroplasty. The timing or efficacy of alcohol cessation prior to joint replacement surgery has not been reported in the literature. Despite limited evidence, surgeons should counsel patients regarding alcohol cessation prior to shoulder arthroplasty.

Intravenous drug abuse has been associated with unacceptably high rates of infection following joint replacement surgery. Two small retrospective series have demonstrated infection rates greater than 25%.[13,14]

Perioperative prevention strategies

Skin preparation Evidence for skin preparation is level I based on skin cultures. Saltzman et al. reported decreased rates of superficial skin culture after use of ChloraPrep compared with DuraPrep or povidone-iodine solution.[15] However, all three agents demonstrated limited efficacy against formerly *Propionibacterium acnes* (now known as *Cutibacterium acnes*) with positive cultures in 7–22% of patients after skin preparation.

Preoperative skin preparation In a level I study, the use of chlorhexidine wipes showed significant decrease in the culture rate of coagulase negative staphylococcus prior to skin preparation compared to standard soap and water washing. However, there was no significant decrease in the rate of *P. acnes* cultures.[16] Dizay et al. evaluated the use of

benzoyl peroxide with clindamycin gel application in a level II study and reported reduction of deep cultures at the time of arthroscopic surgery to less than 4%.[17]

Hair removal There are no studies specific to the orthopedic literature regarding clipping versus shaving, but several studies from the general surgical literature support this practice (level I).[18,19] The removal of axillary hair does not have any influence on the bacterial burden of *P. acnes* following skin preparation with chlorhexidine.[20]

Antibiotics The efficacy of antibiotic prophylaxis in joint replacement surgery has been demonstrated with level III evidence.[21] The exact timing of antibiotics has been debated. The current guidelines indicate that administration should be performed with in one hour prior to surgical incision. The available level III evidence indicates increased infection risk if antibiotics are administered >1 hour before, or after skin incision. Conflicting evidence exists regarding the administration between 0–30 minutes and 31–60 minutes prior to incision.[4,22,23]

Local antibiotic administration The only prospective randomized trial in the spine literature (level I) with this technique failed to demonstrate a significant decrease in infection rate compared to standard intravenous antibiotic prophylaxis.[24]

Intraoperative irrigation A prospective randomized control trial of hemiarthroplasty for hip fractures demonstrated a decreased incidence of PJI with the use of pulsatile lavage compared to bulb syringe irrigation.[25]

Betadine lavage A retrospective study (level III) of total knee and hip arthroplasty demonstrated a decrease in the

90-day infection rate with the addition of a dilute betadine lavage at the time of closure (0.97% vs 0.15%).[26]

Resolution of clinical scenario

Antibiotic prophylaxis with a first-generation cephalosporin administered within one hour of the surgical incision has demonstrated efficacy. Topical skin treatments prior to admission and the use of a chlorhexidine-based solution at the time of surgery reduces positive culture rates, but the role of either intervention in reducing PJI is unproven. Local use of antibiotics at the time of routine primary shoulder arthroplasty for the reduction of PJI is not supported. Intraoperative irrigation and betadine lavage use are both supported.

Question 2: In patients with possible PJI, do preoperative serum indices, aspiration, or imaging aid in establishing the diagnosis of infection compared with preoperative tissue culture?

Rationale

P. acnes, a gram-positive anaerobic bacteria, is the most common infecting organism in periprosthetic shoulder infection (PPSI).[27–32] It is very indolent and slow-growing, and does not elicit an inflammatory reaction or clinical features of typical of infection. Establishing the diagnosis of infection with a painful shoulder after arthroplasty is extremely difficult.

Clinical comment

Establishing the diagnosis of infection with a painful shoulder after arthroplasty is extremely difficult and other than arthroscopic tissue biopsy, few reliable preoperative tests exists. This may lead to highly invasive operations in order to treat shoulder infections that may or may not be present. The current lack of a reliable diagnostic tool for infection may lead to delays in diagnosis, additional operations that could have been avoided, or inappropriate surgery in the presence of an undiagnosed infection.

Available literature and quality of the evidence

- CRP – retrospective cohort studies, level III.[30,33,34]
- ESR – prospective and retrospective cohort studies, level II and III.[3033–35]
- White blood cell count (WBC) – prospective cohort study, level II.[35]
- Serum IL-6 – prospective cohort study, level II.[35]
- Synovial fluid IL-6 – prospective cohort studies, level II.[36,37]
- Alpha defensin – prospective cohort study, level II.[38]
- PCR – mechanism-based reasoning, level V.[39,40]
- MALDI-TOF MS – retrospective cohort studies, level III.[41–44]
- Leukocyte esterase – prospective cohort study, level II.[45]
- Synovial fluid culture – case series, level IV.[46]
- Frozen section – retrospective cohort studies, level III.[29,30,34,47,48]
- Tc-labelled leukocyte scan – case series, level IV.[49]

- Preoperative tissue cultures – retrospective cohort study, level III.[50]

Findings

C-reactive protein (CRP)

Evidence for CRP is level III. Piper et al. reported that the CRP level had a sensitivity of 63% and a specificity of 73% with an optimized cut-off of 7 mg/L for shoulder PJI for all organisms.[33] With a more standard threshold value of 10 mg/L, the sensitivity and specificity was 42 and 84%, respectively. In another study of 45 patients undergoing revision shoulder arthroplasty, Grosso et al. found that CRP had a sensitivity of 33% and a specificity of 85% with a cut-off value for a positive CRP of >1 mg/L.[34]

Erythrocyte sedimentation rate (ESR)

Evidence for ESR is level II. ESR frequently occurs in the normal range in the setting of shoulder PJI. The sensitivities and specificities have been reported 21 and 65%, respectively.[35] In a series of 193 revision shoulder arthroplasties, only 17% of patients with positive *P. acnes* cultures had elevated ESR.[30]

White blood cell count

Evidence for WBC is level II. Villacis et al. found a sensitivity and specificity of 7% and 95%, respectively, in a series of patients undergoing revision shoulder arthroplasty with infection.[35]

Serum interleukin-6

Evidence for serum IL-6 is level II. Villacis et al. reported values for sensitivity, specificity, positive and negative predictive values of 14, 95, 67, and 61%, respectively.[35]

Similarly, in a larger study of 69 patients of which 24 had definite or probable infection, Grosso et al. reported values of sensitivity 12%, specificity 93%.[51]

Synovial markers: synovial fluid IL-6

Evidence for synovial fluid IL-6 is level II. IL-6 synovial fluid IL-6 has been the subject two recent studies. Frangiamore et al. reported that IL-6 had sensitivity, specificity, positive and negative likelihood ratios of 87%, 90%, 8.45, and 0.15, respectively.[36] In a subsequent study,[37] IL-6 was used in 75 cases of revision shoulder arthroplasty with a multiplex immunoassay in which IL-6, IL-1 beta, IL-8, and IL-10 showed the best combination of sensitivity and specificity for predicting infection, and a combined cytokine model that consisted of IL-6, tumor necrosis factor-alpha, and IL-2 had superior diagnostic test characteristics that any individual test with sensitivity of 0.80, specificity of 0.93, positive and negative predictive values of 0.87 and 0.89, and positive and negative likelihood ratios of 12.0 and 0.21.

Alpha defensin

Evidence for alpha defensin is level II. Synovial fluid alpha defensin levels were evaluated for diagnostic utility in identifying the presence of shoulder PJI in 30 patients undergoing revision surgery. There were 11 infected cases. The sensitivity, specificity, and positive and negative likelihood ratios were 63%, 95%, 12.1 and 0.38, respectively.[38]

Polymerase chain reaction (PCR)

Evidence for PCR utilization in shoulder infection is level V. This approach[39] has been investigated along with PCR analysis of fluid from sonicated implants[52] for the diagnosis of musculoskeletal infection. Although the approach

appears promising, the main current limitation is the time delay for analysis of samples, along with the potential for false positive results. A study by Holmes et al. demonstrated the potential viability of a rapid-sequence test that has been validated in vitro;[40] further clinical validation is required.

Matrix-assisted laser desorption ionization time-of-flight mass spectrometry (MALDI-TOF MS)

MALDI-TOF MS is an inexpensive approach to detecting the presence of *P. acnes* by applying the sample of synovial fluid onto a crystal matrix to assess the fragmented ions by mass spectroscopy.[41] Evidence for MALDI-TOF MS is level III. Walter et al. reported on 61 patients with bone and joint infections. Ninety-eight percent were detected with MALDI-TOF MS, including 20 cases involving *P. acnes*.[41] In a prior study, La Scola et al. were able to isolate 75% of *P. acnes* infections with MALDI-TOF MS, most of which were osteoarticular infections.[42] Coltella et al. found that MALDI-TOF MS had high concordance rates for the detection of other bacterial species but only correctly isolated specimens of *P. acnes* in 16 of 21 (76%) of patients.[43] The authors hypothesized that the relatively poor performance of MALDI-TOF MS in identifying the *Propionibacterium* genus was due to few spectra available in the database and the relatively large number of intra-species genetic variability in *Propionibacterium*. Barreau et al. reported significant improvement in the MALDI-TOF MS technology with successful identification of 350 of 375 *Propionibacterium* species, of which 84% were *P. acnes*.[44]

Leukocyte esterase (LE)

LE can be detected by a test strip and is commonly used for the diagnosis of urinary tract infections. In a level II study,

LE was investigated in patients undergoing primary shoulder arthroplasty (45 patients) and patients undergoing revision shoulder arthroplasty (40 patients).[45] The LE sensitivity was 28.6% sensitive, 63.6% specific, and had a PPV of 28.6% and an NPV of 87.5%.

Joint aspiration

Synovial leukocyte counts Bauer et al. suggested that leukocyte counts of >500 cells/μL is highly suggestive of infection,[53] although the threshold is likely joint or organism specific. The evidence for leukocyte counts in shoulder PJI is level IV; authors have reported that there is rarely enough fluid to complete leukocyte counts[54] and when it possible results are often normal.[48]

Synovial fluid culture Kowalski et al. reported on data from five studies on infection following shoulder arthroplasty.[46] In two-thirds of cases, preoperative aspiration was positive for infection. Patients included in this series had overt signs of infection, however; overt signs of infection are rarely present with *P. acnes* infection and are usually consistent with other more virulent organisms. This evidence is level IV.

Frozen section

Evidence for frozen section is level III. However, only one study has reported on frozen section specific to *P. acnes* PJI.[34] This study recommended using a threshold of 10 or more polymorphonuclear leukocytes per five high-power fields. This new specification carried a sensitivity or 72% and a specificity of 100%, which was considerably higher than the accuracy of this test when the traditional thresholds used in hip and knee infection are applied. In a large retrospective review of 193 revision arthroplasty

cases, 108 patients developed positive cultures, 70% of which consisted of *P. acnes*.[30] There was no association between the presence of inflammation on histopathological examination and the presence of positive *P. acnes* cultures.

Imaging: Tc-labelled leukocyte scan

In a level IV study of Tc-labelled leukocyte scintigraphy for endoprosthetic infections, all infections in the knee, hip, and shoulder were identified.[49] However, only two patients in this series had shoulder endoprosthesis.

Preoperative tissue cultures

In a level III study, preoperative tissue biopsy was obtained by arthroscopic means. Dilisio et al. reported on 19 patients who underwent arthroscopic biopsies prior to revision surgery with 100% sensitivity, specificity, positive predictive value, and negative predictive values compared with open biopsy cultures.[50]

Resolution of clinical scenario

- Serum indices including CRP, ESR, WBC, and serum IL-6 have poor ability to detect the presence of infection in shoulder PJI.
- IL-6 and alpha defensing synovial fluid markers are highly accurate, and synovial fluid IL-6 appears to be more sensitive than alpha defensin.
- There is currently no clinical evidence to suggest that PCR has utility in the diagnosis of shoulder PJI.
- MALDI-TOF MS has potential in the diagnosis of shoulder PPI, but there is currently little evidence to support its use.

- LE has demonstrated poor accuracy in the diagnosis of shoulder PPI.
- Synovial fluid leukocyte counts are typically normal and synovial fluid for aspiration is often absent; current evidence suggests that neither is reliable.
- Studies on frozen section demonstrate that in most cases, there is no evidence of inflammatory response on histologic examination.
- There is little evidence that Tc-labelled leukocyte scanning has utility as a diagnostic modality in shoulder PPI due to paucity of the literature.
- Preoperative tissue cultures obtained by arthroscopy correlate highly with intraoperative cultures.

Question 3: In patients with shoulder PJI, does a two-stage revision result in lower reinfection rates compared with one-stage revision?

Rationale

Successful eradication of shoulder PJI lends itself to considerable morbidity including a lengthy treatment course and the need for multiple surgical procedures. If a one-staged revision has comparable clinical results and infection eradication rates as a two-stage procedure, this treatment approach would be of significant benefit to patients.

Clinical comment

The potential risks of multiple-staged surgical procedures in patients with prosthetic shoulder arthroplasty must be

weighed against the potential benefits of improved infection eradication rates and implant durability. Given the known difficulty of successful eradication of PJI with implant retention, removal of implants followed by surgical debridement and intravenous antibiotics is generally recommended. The potential benefits and success of immediate prosthetic reimplantation at the time of index revision compared to a staged strategy remains unknown.

Available literature and quality of the evidence

Multiple studies exist reporting the clinical results of the management of shoulder PJI for both one- and two-staged procedures. All series are retrospective, consist of nonstandardized treatments and the majority lack control groups. The recommended treatment is inconclusive based on current level III/IV evidence.

Findings

Revision surgery performed in two stages theoretically maximizes the chance of complete infection eradication; however, it is associated with the morbidity of multiple surgeries and the potential for poorer clinical outcomes given the deleterious effects on the bone and soft tissues of the shoulder. Two-staged surgery typically involves placement of an antibiotic Prostalac cement spacer and a course of intravenous antibiotics with eventual reimplantation of the prosthesis.

Two retrospective studies have compared the results of single and two-stage revisions for the treatment of shoulder PJI. In the first (level IV) series, 22 shoulders were treated with removal of the prosthesis, extensive debridement, an intravenous antibiotic course, and either immediate reimplantation (n = 10) or a stage reimplantation (n = 12).[55] The authors noted no recurrence of infection in

either group and no significant difference in final active range of motion, American Shoulder and Elbow Surgeons (ASES) scores, or Visual Analog Scale (VAS) pain scores between groups. Recently, in a level III study, 79 cases of shoulder PJI were treated with either one-stage revision (n = 45), two-stage revision(n = 19) or debridement with incomplete component exchange (n = 15).[56] Revision for infection was significantly less likely in the one-stage revision (4%) compared to the two-stage (21%) and partial revision (27%) shoulders. The authors noted the groups were similar in all characteristics. The rate of noninfectious complications and the improvements in shoulder active range of motion (113–137) and ASES scores (60–68) were similar between groups.

Resolution of clinical scenario

- There is no clear advantage of two-stage compared to one-stage revision arthroplasty for the treatment of shoulder PJI.
- The decision between one and two-staged surgery should consider patient and shoulder related variables including patient medical co-morbidities, the quality of remaining bone stock and associated soft tissues, and the type of infectious organism.

Summary of answers

- Antibiotic prophylaxis with a first-generation cephalosporin, topical skin treatments prior to admission, and the use of a chlorhexidine-based solution at the time of surgery reduces positive culture rates, but the role of either intervention in reducing PJI is unproven. There is weak evidence for the use of local

antibiotics at the time of routine primary shoulder arthroplasty for the reduction of PJI.

- Based on limited level II evidence, synovial fluid IL-6 and alpha defensin appear to be highly accurate in the detection of infection preoperatively compared with arthroscopic tissue biopsy. The main limitation of this approach appears to be a paucity of synovial fluid.
- There is no advantage based on current level III evidence that two-stage revision yields better functional outcomes or improved infection eradication rates than one-stage revision.

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Ankle Osteoarthritis

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Clinical scenario

- A 54-year-old physically active male presents with painful post-traumatic ankle osteoarthritis. No osteoarthritis is observed in the adjacent hindfoot joints.
- He sustained a bimalleolar fracture more than 20 years ago, which was surgically treated, and has been pain-free up until now.
- Conservative treatment has failed and the patient seeks surgical options.

Top three questions

1. In patients with ankle osteoarthritis, does age predict different outcomes for ankle fusion (AF) versus total ankle replacement (TAR)?
2. For patients with ankle osteoarthritis, what is the best evidence to assess for AF or TAR according to the underlying cause of arthritis?
3. For patients with ankle osteoarthritis who are treated surgically, how do medium- and long-term outcomes compare between AF and TAR?

Question 1: In patients with ankle osteoarthritis, does age predict different outcomes for ankle fusion (AF) versus total ankle replacement (TAR)?

Rationale

AF or TAR should be reserved for cases when joint-preserving procedures have failed or cannot be performed.[1] Traditionally, it has been recommended that young, active, high-demand patients with ankle arthritis may be better candidates for AF than for TAR, which causes minimal limitations and activity restrictions.[2] According to a review, age is a major criterion when considering AF versus TAR.[3]

Clinical comment

Age is probably one of the most important criteria when choosing between AF and TAR, as there is evidence suggesting that age substantially affects the outcomes of TAR.[3] Young patients generally have higher demands in terms of functional outcomes, return to work, return to sports, etc. According to the literature, TAR should mostly be considered in patients over 50 years.

Available literature and quality of the evidence

Several level II and III meta-analyses and reviews, especially national registries are available to answer this question.[4–9] To our knowledge, there is one randomized controlled trial (RCT) currently registered, with results pending.[10]

Findings

Currently, the RCT TARVA (total ankle replacement vs arthrodesis) is to our knowledge the first RCT and has completed the data collecting, although results have not yet been published.[10]

A level II prospective controlled trial comparing outcomes following TAR versus AF found that the arthroplasty group was, on average, six years older than the arthrodesis group.[9] A meta-analysis of comparative studies between TAR and AF found that age at implantation of the compared studies was younger in the AF group; however, no conclusions were drawn regarding age and outcomes.[4] In a level IV systematic review of the literature (therapeutic studies), patients with TAR were older than patients with AF (mean 58 years vs 50 years, respectively).[7]

Spirt et al., in a retrospective review, reported that age was the only significant predictor of failure and reoperation after TAR.[6] The five-year reoperation rate with failure was 80% for all patients and 89% for patients over 54 years. The authors concluded that every one-year increase in age at implantation of the TAR resulted in a 3.5% decrease in failure hazard.[6]

A Swedish report with 780 TARs showed that patients under 60 years had a 1.8 times higher chance of revision compared to older patients; however, the difference was only found to be significant for women.[5] The same Swedish study group associated younger age with osteolysis, loosening, and therefore increased risk of revision surgery. However, other national registries, such as the Finnish and the New Zealand Register, have not found a relationship between age and survival rate.[11,12]

In an epidemiological study of TAR by Seaworth et al.,[13] younger age at implantation was found to be a risk factor for failure (patients <60 years). Similarly, the Swedish

Ankle Arthroplasty Register observed that lower age at surgery implied an increased risk of undergoing revision surgery.[8]

In a recent case series, the authors compared five-year outcomes of TAR according to age or diagnosis.[14] They observed that the age group of patients <60 years had significantly worse mean Foot and Ankle Outcome Score (FAOS) scores both preoperatively and at five years.

Lower age at surgery has also been associated with higher risk of revision in a study of outcomes with long-term follow-up after TAR.[15] However, TAR is occasionally proposed for younger people in cases of rheumatoid arthritis, bilateral ankle osteoarthritis or low activity level.[3]

Resolution of clinical scenario

- Both AF and TAR should be considered only when conservative measures have failed and other joint-preserving options cannot be offered.
- AF remains a good surgical option for end-stage ankle arthritis.
- Younger age should remain a contraindication for TAR; however, rather than considering a specific age group as a limit for AF, the desired activity level and the patient's activity demands should be more important.
- TAR could be considered in younger patients with rheumatoid arthritis or other inflammatory diseases.
- If considering TAR for a younger patient, an explanation of possible future revisions should be addressed.
- TAR in younger patients should also be considered in cases of bilateral ankle arthritis.

Question 2: For patients with ankle osteoarthritis, what is the best evidence to assess for AF or TAR according to the underlying cause of arthritis?

Rationale

The underlying cause of ankle arthritis is considered a major criterion to indicate AF versus TAR, and is closely related to age.[3] As opposed to hip or knee osteoarthritis, a minority of ankle arthritis is primary, and is most frequently secondary to trauma (65–80%) and rheumatoid disease (12–15%).[16]

Clinical comment

In cases of ankle arthritis secondary to trauma, the surgeon may have to deal with deformities in varus or valgus, loss of bone stock, or severe ankylosis.

Higher revision and reoperation rates have been reported for patients with posttraumatic ankle arthritis undergoing a TAR.[17] Satisfaction rates among these patients are lower than in patients with primary or rheumatoid arthritis, likely due to a younger age, higher demand, and previous surgeries.

Available literature and quality of the evidence

No RCTs have been performed regarding diagnosis and TAR or AF. Survivorship studies, level II and III prognostic studies, and comparative studies have been found regarding the subject that matters.[7,14,18–22]

Findings

A systematic review observed that rheumatoid arthritis was the primary indication for TAR (39%), whereas post-traumatic arthritis was the primary indication for the arthrodesis (57%).[7] Arthroplasty clinical outcomes have been shown to be poorer in patients with post-traumatic arthritis than in those with rheumatoid arthritis.[2]

Regarding post-traumatic arthritis, the extent of residual deformities and instabilities that can be corrected with TAR is increasing.[1,3,23,24] However, coronal plane deformity exceeding 10–15° remains a contraindication to TAR as implant failure is correlated with increasing preoperative deformity. In fact, survival rates are less than 50% for patients with significant preoperative varus or valgus deformity and almost 90% for patients with neutral preoperative alignment.[3,19] Realignment hindfoot osteotomies or arthrodesis and supramalleolar osteotomies during TAR are recommended to prevent early TAR failure.[3]

A retrospective single-center study reported on the five-year outcomes of TAR in relation to type of arthritis.[14] Preoperatively, no differences were observed according to the type of arthritis, although patients with rheumatoid arthritis showed a trend toward higher baseline scores. Interestingly, this group was the only group not to experience a significant increase in their scores at five years.

A comparative prospective study comparing TAR after post-traumatic or primary arthritis concluded that clinical and radiographic outcomes were comparable; however, the incidence of complications was higher in the post-traumatic group.[18] This group required more additional surgical procedures than the primary group (i.e. deformity correction, instability).

A level III therapeutic study compared medium- and long-term outcomes of TAR according to preoperative deformity.[22] Results were found comparable between groups postoperatively, as long as a good neutral alignment was achieved. Varus and valgus malalignment up to 20° were included.

A level III prognostic study analyzing TAR outcomes in patients with rheumatoid arthritis and patients with noninflammatory arthritis found similar outcomes between the two groups.[20] The overall pain and disability scores were significantly worse for patients with rheumatoid arthritis before surgery, but were similar following surgery.

Van Heiningen et al. performed a systematic review of observational and noncontrolled clinical trials regarding medium-term outcomes in patients with rheumatoid arthritis following AF or TAR.[21] Authors concluded that, despite the methodological quality of the studies was low, both procedures showed clinical improvement and neither procedure was superior to the other. The failure rate was 11% for TAR and 12% for AF.

Resolution of clinical scenario

- Patients with post-traumatic arthritis and concomitant deformity may be more suitable for AF than TAR.
- In patients with preoperative deformity undergoing arthroplasty, surgical correction should be addressed before or during in order to reduce failure rate.
- TAR has shown good clinical outcomes for patients with rheumatoid arthritis.

Question 3: For patients with ankle osteoarthritis who are treated surgically, how do medium- and long-term outcomes compare between AF and TAR?

Rationale

The available data on outcomes of AF and TAR are mostly based on retrospective, uncontrolled case series from single institutions.

Clinical comment

The lack of knowledge of the medium- and long-term outcomes of AF and TAR limits the ability of physicians to counsel their patients appropriately when they are faced with the decision of whether to undergo one procedure or another.

Available literature and quality of the evidence

No RCT was found. Several level II, III, and IV therapeutic and systematic reviews were gathered for their findings.[5,7,15,25–28]

Findings

A multicenter study (level II therapeutic study) performed in Canada evaluated medium-term results of TAR and AF (mean follow-up 5.5 years).[26] Of the 388 ankles included, 281 had a TAR and 107 an AF, and 7% of the arthrodeses and 17% of the replacements underwent revision surgery. The complication rate was also higher in the replacement group (19 vs 7%, respectively).

The systematic review by Haddad et al. described medium- and long-term outcomes of TAR and AF, including a total of 852 TAR and 1262 AF.[7] The five-year implant survival rate was 78 and 77% at 10 years. The revision rate was slightly higher for the arthrodesis group (9 vs 7%).

Regarding AF, periarticular degeneration is one of the most important downsides. Long-term studies of ankle arthrodesis have suggested accelerated periarticular joint degeneration; however, no definite causation has been proved.[25,27] The pathophysiology may be similar to adjacent-segment disease seen in the spine.

Coester et al. performed a 22-year follow-up in AF.[25] Authors observed a consistently more severe osteoarthritis in the adjacent hindfoot and midfoot joints. Significant differences between the two sides were found regarding overall activity limitation, pain, and disability.

The Swedish Ankle Register reported on 780 cases of TAR along 10 years of follow-up.[5] Twenty-two percent of patients had been revised and the estimated overall five-year survival rate was 0.81 (95% confidence interval [CI]: 0.79–0.83) and the 10-year survival rate was 0.69 (95% CI: 0.67–0.71). Clough et al. found TAR implant survival at 15.8 years was 76%.[28]

In a therapeutic level IV study with 77 TARs, long-term follow-up (11–15 years) of the Scandinavian total ankle replacement (STAR) was analyzed.[15] While the medium- to short-term results for the same sample of patients was encouraging, authors found that long-term survivorship of the same cohort was considerably inferior. Thirty-eight percent had a revision of at least one component, and implant survival at 10 years was 70.7% and 45.6% at 14 years.

Resolution of clinical scenario

- There is a lack of RCTs in order to draw clearer conclusions.
- Ankle arthrodesis is associated with periarticular joint degeneration in a long-term follow-up; however, the clinical relevance is not clear.
- TARs have good clinical outcomes but higher revision rates. Younger patients undergoing a TAR should be advised that chances are they will have a revision surgery.

Summary of answers

- Age must be taken into account when considering AF (generally younger patients) or TAR.
- AF should be recommended for patients with post-traumatic arthritis, especially when deformity is associated. Patients with rheumatoid arthritis should be considered for TAR.
- Currently, evidence regarding AF vs TAR is limited, and further RCTs should be performed to draw clearer conclusions.

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Osteoarthritis of the 1st Metatarsophalangeal Joint

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Clinical scenario

- You see a 45-year-old female patient in your office with a painful 1st metatarsophalangeal (MTP) joint. She is quite symptomatic, and after examination and radiographs, you confirm the diagnosis of 1st MTP arthritis.
- The patient is an active duty military service member who continues to be physically active both at work and recreationally. She would like to continue to be active for many years to come.
- You consider which nonoperative treatment you can offer to this patient, and if any are particularly more effective than others.
- You also think ahead to what will happen if the patient fails nonoperative management. You wonder which type of surgery would be the best option for her to continue her current lifestyle.

Top three questions

1. In patients with 1st MTP joint osteoarthritis (OA), do any nonoperative treatment modalities result in better

functional outcomes compared to other nonoperative treatment modalities?

2. In patients undergoing surgery for 1st MTP OA, does arthroplasty result in better functional outcomes compared to arthrodesis?
3. In patients undergoing surgery for 1st MTP OA, do some procedures offer faster or higher rates of return to activity compared to other procedures?

Question 1: In patients with 1st MTP joint osteoarthritis (OA), do any nonoperative treatment modalities result in better functional outcomes compared to other nonoperative treatment modalities?

Rationale

Nonoperative management is the first-line treatment for most joints affected by OA, including the 1st MTP joint. It is important to understand which nonoperative treatment modality, if any, is most effective.

Clinical comment

Success rates of over 50% have been reported previously in the literature for nonoperative management of 1st MTP OA, also known as *hallux rigidus*.[1] Many different nonoperative treatments exist, including nonsteroidal anti-inflammatory drugs (NSAIDs), intra-articular injections, orthotics, and shoe modifications.[2] Given that none of these treatments will reverse or cure the disease, it is important to understand what the typical and best-case scenarios are for

each of these modalities. This will help clinicians to have honest and value-based discussions with their patients about nonoperative management.

Available literature and quality of the evidence

A single systematic review of levels I–IV evidence (level IV) summarizes the vast majority of evidence on nonoperative treatment of 1st MTP OA. King et al. reviewed 11 studies on this topic, including one randomized controlled trial (RCT), two level II studies, and one level IV study.[3] The review included a total of 1600 patients. The modalities included in this review were intra-articular injections, manipulation and physical therapy, and orthotics and footwear modifications. There is no clinical evidence for the use of oral NSAIDs in 1st MTP OA; in fact, a recent review on this topic extrapolated from hip and knee OA evidence.[4]

Findings

The systematic review by King et al. found that, overall, the evidence was consistent in supporting the efficacy of physical therapy and footwear modification/orthoses, but more mixed when it came to intra-articular injection in terms of treating 1st MTP OA.[3]

In terms of modification in footwear, insoles, and orthotics, there was only level III and IV evidence available. Success of orthoses was found to be 55% in a large study of 772 patients.[1] Similarly, 63% of patients in a longitudinal case series with over 14 years of follow-up reported that they were satisfied with footwear modification as a first-line therapy and would make the same decision again given the opportunity.[5] Overall, King et al. made a Grade C recommendation (poor level evidence with consistent findings) for the use of orthotics or footwear modifications in the treatment of 1st MTP OA.[3]

Physical therapy is another mainstay in the treatment of most forms of OA. King et al. found two studies looking at the treatment of 1st MTP OA with physical therapy and/or manipulation.[3] A downgraded RCT (level II) which used birthdates to randomize patients to physical therapy or control groups found that the intervention group had significantly better range of motion (42.7° ± 7.8° vs 14.4° ± 8.0°, p <0.001), flexor hallucis longus strength (3.5 ± 1.0 kg vs 0.7 ± 0.4 kg, p <0.001), and pain reduction (6.4 ± 1.3 vs 2.6 ± 1.1 kg, p <0.001).[6] A small retrospective case series (level IV) found that duration of pain relief after manipulation was dependent on radiographic OA grade according to the Karasick and Wapner classification (Grades 1–3, 1 being least severe). Patients with Grade 1 OA had symptom relief for a median of six months, compared to only three months for Grade 2 and no relief for Grade 3.[7] Overall, King et al. also assigned a Grade C recommendation (poor level evidence with consistent findings) for physical therapy/manipulation.[3]

There were six studies looking at various types of injectable therapies for 1st MTP OA. King et al. found that the higher-quality evidence available for injection therapy (levels II and III) suggested either no benefit for injection, or a benefit that lasted three months or less.[3] In their meta-analysis of hyaluronic acid injection studies specifically, they did find that the standardized mean difference (SMD) showed a benefit for both rest pain (SMD = −0.52; 95% confidence interval [CI]: −0.77 to −0.28) and walking pain (SMD = −0.44; 95% CI: −0.83 to −0.05) with low heterogeneity (I^2 = 10.2%). Interestingly, despite the results of this meta-analysis, King et al. made a Grade B recommendation (fair evidence with consistent findings) *against* injection as an effective treatment for hallux rigidus.[3]

Resolution of clinical scenario

- Overall, there is scarce, low-quality evidence for nonoperative treatment of 1st MTP OA.
- Based on consistent findings among level II–IV evidence, physical therapy, footwear modification, and orthoses *are* effective in providing symptom relief in the treatment of 1st MTP OA. In addition, these therapies may be more effective in patients with milder disease.
- Evidence for injection therapy in 1st MTP OA is mixed, with some moderate-quality evidence suggesting no benefit, especially beyond three months. Lower-quality evidence suggests there may be a benefit, particularly when it comes to hyaluronic acid injection.

Question 2: In patients undergoing surgery for 1st MTP OA, does arthroplasty result in better functional outcomes compared to arthrodesis?

Rationale

Many different surgical options exist for the treatment of 1st MTP OA. Broadly, these can be categorized into joint preservation surgery (e.g. cheilectomy, Valenti procedure), arthroplasty (e.g. hemiarthroplasty, implant arthroplasty, interposition arthroplasty), and arthrodesis. Traditionally, arthrodesis and arthroplasty have been the primary treatment options for end-stage 1st MTP OA that is not responsive to nonoperative or joint preservation treatments.

Clinical comment

Similar to wrist and ankle OA, 1st MTP OA that is not suitable for nonoperative or joint preservation surgeries may be amenable to either arthrodesis or arthroplasty.[8,9] Given that arthrodesis can actually provide reasonable function in these joints, and that arthroplasty options are not as well developed as those for knee or hip OA, it is important to understand the evidence behind these various surgical options in order to help patients and surgeons make the most appropriate decision on a case-by-case basis.

Available literature and quality of the evidence

There are four systematic review and meta-analyses (levels III–IV) that summarize the evidence on arthroplasty versus arthrodesis for 1st MTP OA. Patel et al., in their systematic review and meta-analysis of 15 studies (340 patients), compared interposition arthroplasty to arthrodesis (level IV).[10] A systematic review by Stevens et al. analyzed 33 studies, including a meta-analysis of 12 studies looking at total joint arthroplasty versus arthrodesis (level IV).[11] Finally, there was a systematic review and meta-analysis of 11 studies (level IV) and a retrospective cohort study (level III) of 102 patients who had undergone surgery for 1st MTP OA.[12]

Findings

In their systematic review and meta-analysis (level IV) on interposition arthroplasty compared to arthrodesis, Patel et al. included 15 studies, with a total of 340 patients (369 feet). The patients had a mean age of 57.4 with a mean follow-up of 38.1 months. All studies were either level III or level IV evidence. The American Orthopaedic Foot & Ankle Society (AOFAS) score was the most commonly used (14

studies). Mean AOFAS score increased from a pooled preoperative mean of 41.4 (range: 25–63.9) to 83.2 (71.6–93.6) postoperatively. As expected, range of motion was also quite good postoperatively, with increases in dorsiflexion from 21.3° to 42.0°. Among patients asked about satisfaction, 87% were happy and would choose the same surgery again given the opportunity. Importantly, all patients who failed interposition arthroplasty and were converted to arthrodesis had good or excellent results.[10] Thus, the authors felt that interposition arthroplasty provided a comparable alternative to arthrodesis, while not "burning any bridges" with a view to future arthrodesis.

In the most comprehensive review to date on this topic, Stevens et al. completed a systematic review of 33 studies, which included 1160 patients (1296 feet) undergoing arthrodesis or total joint replacement for 1st MTP OA (level IV).[11] Overall, they found that while both interventions improved patient-reported outcomes compared to preoperative status. The results of 12 studies were pooled in a meta-analysis looking at the AOFAS-HMI (American Orthopaedic Foot & Ankle Society hallux metatarsophalangeal interphalangeal) and Visual Analog Scale (VAS) pain scores. This analysis revealed that the treatment effect of arthrodesis was significantly greater than arthroplasty for both AOFAS-HMI (43.8 vs 37.7 points, $p < 0.0001$) and VAS pain scores (6.6 vs 4.7, $p < 0.0001$). The authors concluded that this represented a significant advantage in favor of arthrodesis.[11] It should be noted, however, that the minimal clinically important difference (MCID) for the AOFAS-HMI has been reported at ranging from 7.9 to 30.2,[13] and for the VAS in hallux surgery ranging from 1.8 to 5.2.[14] Thus, only the VAS treatment effect would fall within the MCID, and even then, it would be at the lower end of this range.

In their systematic review and meta-analysis of 11 studies (level IV), Stibolt et al. reviewed a total of 323 patients (350 feet) undergoing hemiarthroplasty, who were being compared with either controls, arthrodesis, or total joint arthroplasty.[15] All studies reported improvement in AOFAS scores regardless of surgical technique. In their meta-analysis, they found a greater treatment effect for hemiarthroplasty versus total joint arthroplasty (mean difference −51.5 vs −40.6, respectively). In contrast, range of motion was comparable for the two groups (24.5 for hemiarthroplasty vs 24.8 for total joint arthroplasty), as were VAS pain scores (6.1 for hemiarthroplasty and 6.3 for total joint arthroplasty). Finally, Beekhuizen et al. performed a retrospective cohort (level III) directly comparing hemiarthroplasty with arthrodesis in 78 patients with a mean follow-up of 8.3 years (range 5–11.8).[12] They found that patients undergoing hemiarthroplasty had significantly better AOFAS-HMI scores (72.8 ± 14.5 vs 89.7 ± 6.6, $p = 0.005$), and pain scores (30.9 ± 9.7 vs 37.4 ± 4.4, $p < 0.001$) than arthrodesis patients. Furthermore, on satisfaction and likelihood to recommend surgery scales (lower score = better), hemiarthroplasty patients did better than arthrodesis (satisfaction: 2.5 ± 1.2 vs 1.3 ± 0.6, $p < 0.001$; recommendation: 1.7 ± 0.8 vs 1.0 ± 0.2, $p < 0.001$).

Resolution of clinical scenario

- Overall, despite the fact that arthrodesis has long been the gold standard operative treatment for end-stage 1st MTP OA, numerous arthroplasty options exist including interposition arthroplasty, implant arthroplasty, and hemiarthroplasty.
- All arthroplasty options are successful in achieving improvements in pain, patient-reported outcomes, and patient satisfaction (level III–IV).

- On direct comparison, hemiarthroplasty appears superior to arthrodesis with long-term follow-up (level III). In contrast, arthrodesis appears inferior to total joint arthroplasty (level IV) and comparable to interposition arthroplasty (level IV).

Question 3: In patients undergoing surgery for 1st MTP OA, do some procedures offer faster or higher rates of return to activity compared to other procedures?

Rationale

OA of the 1st MTP joint can affect patients at a wide range of ages and activity levels. In patients who are active or hoping to return to an active lifestyle, it is important to understand which surgical options provide the greatest likelihood of a timely return to activity.

Clinical comment

Surgical procedures for 1st MTP OA are most often performed for middle-aged patients, and thus rarely considered in the realm of sports surgery. Nonetheless, as a major weightbearing joint of the forefoot, the 1st MTP can play an important role in patients being able to meet their various workplace and recreational activities. As with any arthritic joint, it is important to consider and discuss realistic postoperative expectations and timelines with patients.

Available literature and quality of the evidence

Two retrospective case series (level IV) and one retrospective cohort (level III) study reported on the rates and timelines for return to work and sport in patients undergoing surgery for 1st MTP OA. The retrospective cohort study, discussed above, is a study of patients undergoing hemiarthroplasty versus arthrodesis (level III).[12] The other two studies are retrospective case series with a total of 160 patients.[16,17]

Findings

In the previously discussed study, Beekhuizen et al. found that all patients undergoing hemiarthroplasty or arthrodesis returned to work (level III), with no significant difference in time to return between the two procedures (6.2 ± 6.2 weeks vs 4.3 ± 2.4 weeks, $p = 0.202$).[12] Interestingly, they found that hemiarthroplasty allowed for significantly faster return to sport than arthrodesis (6.7 ± 4.6 weeks vs 11.7 ± 5.1 weeks, $p = 0.002$), though there was no significant difference in rate of return (63% vs 54%, $p > 0.05$).[12]

Da Cunha et al. assessed return to sport in young patients (mean age 49.7, range 23–55) undergoing 1st MTP arthrodesis (level IV).[16] They found that, postoperatively, patients returned to 45% of their preoperative activities within six months, and reached maximal level of participation in 88.6% of activities. Ninety-six percent of patients were satisfied with their postoperative level of return to sport.[16] Jones and Sweet specifically compared return to work outcomes in active duty military service members undergoing three different procedures (cheilectomy, decompressive osteotomy, and arthrodesis) (level IV).[17] They found the highest rate of return to duty with decompressive osteotomy (94.4%) as compared to cheilectomy (80.8%) and arthrodesis (78.8%). Return to

activity was fastest for cheilectomy (12.9 weeks), followed by decompressive osteotomy (19.4) and arthrodesis (20.8 weeks). Subjective satisfaction was not significantly different between the three groups.

Resolution of clinical scenario

- There are generally high rates of return to work and sport regardless of the specific procedures performed for 1st MTP OA.
- Arthrodesis allows for reliable and timely return to activity, though decompressive osteotomy may be even better in this regard. The potential need for future surgery and time missed should be taken into account when deciding between the two.

Summary of answers

- Physical therapy, footwear modification, and orthotic use are supported by weak evidence for the first-line treatment of 1st MTP OA. Nonetheless, nonoperative options should always be exhausted first.
- There is no definitive answer as to which surgical procedure provides the best outcomes, though direct comparison does suggest an advantage for hemiarthroplasty over arthrodesis.
- Most patients return to work and/or sport in a timely manner following 1st MTP OA surgery. Decompressive osteotomy may give patients the best possible chance at this goal.

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Hallux Valgus

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Clinical scenario

- A 45-year-old woman presents with medial sided forefoot pain.
- This has worsened over the last few years. She is otherwise healthy and practices trail running frequently.
- On examination she has a bunion and some hypermobility of the 1st tarsometatarsal joint, with no metatarsalgia. She doesn't have clawing of her toes.
- On x-rays, she has severe hallux valgus (HV), with HV angle of 48° and intermetatarsal angle of 18°. There is no evidence of 1st tarsometatarsal sag on x-rays.

Top three questions

1. In adult patients with HV, does percutaneous correction result in quicker recovery versus open surgery?

2. In adult patients with HV, does long chevron (LC) osteotomy result in fewer complications versus scarf (SC) osteotomy?
3. In adult patients with severe HV, does modified Lapidus result in better functional outcomes than 1st metatarsophalangeal joint arthrodesis (MTP)?

Question 1: In adult patients with HV, does percutaneous correction result in quicker recovery versus open surgery?

Rationale

Percutaneous surgery for HV is performed through the smallest possible incision, usually punctate incisions. Performing percutaneous surgery requires a combination of tactile sensation, clinical appearance, and fluoroscopic imaging to evaluate the correction achieved.

Clinical comment

The patient could have smaller wounds, and faster recovery, with percutaneous surgery, but given that it is technically more difficult, it is unclear which choice is optimal.

Available literature and quality of evidence

Three randomized controlled trials (RCTs) exist on this topic, comparing percutaneous versus open surgery for HV.

Findings

Radwan et al. randomized 53 patients (64 feet) with mild to moderate HV. Interventions were percutaneous distal

metatarsal osteotomy (modified Bosch osteotomy) (29 feet), and distal chevron osteotomy (31 feet).[1] Operative time was seven minutes shorter in the percutaneous group. There was no difference in time to union, hallux valgus angle (HVA), intermetatarsal angle (IMA), range of motion of the 1st MTP, pain, and American Orthopaedic Foot & Ankle Scores (AOFAS). They did not evaluate recurrence (I).

Kaufmann et al. performed an RCT comparing open chevron (OC) versus percutaneous V-shaped osteotomy (PVO).[2] There were 22 and 25 cases, respectively. There was no difference in pre- and postoperative HVA, IMA, or range of motion between the groups. There was significantly better patient satisfaction in the PVO osteotomy at 12 weeks' postsurgery. At six weeks and nine months, patient satisfaction did not show any significant differences. One patient of each group reported poor satisfaction. Complications in the OC group were two hardware removals and one case of hallux varus that did not need revision surgery. Complications in the PVO group consisted in 12 cases of soft tissue irritation, caused by the Kirschner wire (K-wire) which was removed. Recurrence occurred in three feet of the OC group and one foot of the PVO group; these were mild and did not require revision (level I).

Lam et al. reported an RCT of 51 patients undergoing surgical correction of HV, comparing scarf-akin (SCA) osteotomies versus percutaneous modified chevron-akin (PECA) osteotomy.[3] There were 26 subjects (27 feet) and 25 subjects (33 feet), respectively. Operative time was four minutes shorter in the PECA group, pre- and postoperative IMA and HVA were not significantly different between groups. The AOFAS scores did not show any significant differences between the two groups. In the SCA group,

there were two subjects who developed mild second metatarsalgia postoperatively. This was managed successfully with orthotics, with no revision required. In the PECA group, six required screw removal. This complication was almost completely eliminated when the authors started using the internal oblique view to confirm that the screw was fully engaged in the bone at the time of screw insertion (level I). Two other studies are consistent with these findings.[1,3]

Resolution of the clinical scenario

- There is no demonstrated difference in the rehabilitation time comparing open versus percutaneous surgery for HV correction (level II).
- Radiologic outcomes and functional scores are similar between patients (level I).
- Percutaneous surgery is 4–7 minutes shorter than open surgery (level I).

Question 2: In adult patients with HV, does long chevron (LC) osteotomy result in fewer complications versus scarf (SC) osteotomy ?

Rationale

Chevron and SC are the most performed osteotomies for the treatment of HV. Both have good outcomes, but SC osteotomy can present a complication called *troughing* that occurs as the cortex of the dorsal half of the first metatarsal shaft collapses and wedges into the softer cancellous bone, leading to pronation and lesser metatarsal overload.

Clinical comment

The most common complication in the HV treatment is *recurrence*. Preventing complications is a key goal in the HV surgery.

Available literature and quality of evidence

Multiple RCTs have compared chevron and SC osteotomies attempting to answer this question.

Findings

Elshazly et al. performed an RCT on patients with HV and IMA between 10° and 20°.[4] Twenty-one patients underwent SC osteotomy and 22 patients underwent LC osteotomy. There was one superficial infection and one wound dehiscence in each group. There was one case of recurrence in the LC group due to a technical error of unintended valgus angulation during translation of the capital fragment leading to alteration of the distal metaphyseal articular angle (DMAA). Mean operative time was not significantly different (SC 69 minutes ± 5.59 minutes vs LC 45.8 minutes ± 8.36 minutes, p = 0.86). Pre- and postoperative HVA and IMA between groups did not show any differences. Preoperative IMA was 18.48 ± 4.5 in the SC group and 20.36 ± 3.54 in the LC group (p = 0.14), postoperative IMA was 9.24 ± 2.98 in the SC group and 9.10 ± 2.31 in the LC group (p = 0.86). HVA correction was 24.71 ± 11.96 in the SC group, and 23.64 ± 12.86 for LC group (p = 0.78) (level I).

Mahadevan et al. performed an RCT on 84 patients (109 feet) with HV and IMA between 10° and 21°.[5] They compared 46 patients (60 feet) with LC versus 38 patients (49 feet) with SC osteotomy. One case of hallux varus was identified in each group. There were no recurrences during the study period (one year). Preoperative HVA and IMA

was not significantly different (p = 0.214). Postoperative IMA was better in the LC group (5.8 ± 2.5) versus the SC group (6.9 ± 2.8, p = 0.045). Postoperative HVA was not different between groups. Patient satisfaction was improved in both groups equally (level I).

Deenik et al. performed an RCT in patients with HV, comparing 47 feet undergoing chevron (CH) osteotomy and 49 feet undergoing SC osteotomy.[6–8] In the CH group, two patients developed superficial pin tract infections. Four patients in the SC group developed a grade I complex regional pain syndrome (CRPS), while one patient in the CH group developed CRPS. Three patients in the CH group developed partial osteonecrosis of the metatarsal head, with subchondral cysts but no collapse of the metatarsal head. One of these patients was asymptomatic. After the authors modified the surgical technique of CH, protecting the plantar blood supply, there were no more cases of osteonecrosis. The final follow-up was 14 years, at which point 78% of patients in SC group and 73% of patients in CH group had recurrence of HV (p = 0.48), and only one person in the SC group had revision surgery. Compared with the preoperative measurements, the CH group retained significantly greater IMA correction (p = 0.007) than SC group. AOFAS and Short Form 36 (SF-36) scores were not different between both groups. Patients with severe HV obtained a better HVA correction with CH osteotomy (20 ± 4.6) than patients who received a SC osteotomy (11.8 ± 5.0, p = 0.01). There was no difference in the IMA correction. Operative time was five minutes faster in the CH group (level I).

Ma et al.[9] performed a meta-analysis including four publications,[5,6,8,10] comparing SC and CH. Complication rates did not show a significant difference (p = 0.39). There was no difference in HVA (p = 0.77), IMA (p = 0.97), or

AOFAS scores (p = 0.91). Publication bias for HVA, IMA, AOFAS scores, and complications were determined using Egger's test. The results indicated likelihood of publication bias (level I). There is no significant difference between SC and CH, when comparing complication rates (p = 0.39), postoperative HVA (p = 0.77), postoperative-IMA (p = 0.97) and AOFAS scores (p = 0.91).[9] At 14-year follow-up, recurrence occurs in 78% of patients undergoing SC and 73% of patients undergoing CH (p = 0.48). There is a risk of avascular necrosis when performing CH that can be controlled protecting the plantar blood supply, especially during the plantar cut.[6–8]

Resolution of clinical scenario

- SC and CH have similar complication rates (level I).
- SC and CH have similar outcomes comparing postoperative HVA and IMA (level I).
- Surgeon's preference and expertise should be considered in choosing between SC and CH (level V).

Question 3: In adult patients with severe HV, does modified Lapidus result in better functional outcomes than 1st metatarsophalangeal joint arthrodesis (MTP)?

Rationale

- Lapidus and 1st MTP arthrodesis are the procedures of choice in the treatment of severe HV.[11]

- Severe HV in adults is a challenging problem because they usually require an arthrodesis.

Clinical comment

Clear understanding of the functional outcomes is a key factor to consider which procedure to offer in patients with severe HV.

Available literature and quality of the evidence

There are no comparative studies between 1st MTP arthrodesis and Lapidus. Lapidus has been prospectively evaluated as part of a RCT comparing Lapidus versus a distal osteotomy. There is a retrospective evaluation of young patients that has shown acceptable results. On the other hand, 1st MTP arthrodesis for HV has been evaluated in three case series with acceptable results.

Findings

MacMahon et al. performed a retrospective case series of 48 patients with HV that underwent modified Lapidus procedure, with a mean age of 37.3 years old (range 14.1–49.3 years).[12] Mean follow-up was 2.8 years (range 1.0–6.1 years). Preoperatively, 40% (84/212) of the total physical activities were high impact and postoperatively 38% (80/209) were high impact. Seventy-nine percent of the patients returned to their preoperative physical activity level. Compared to preoperatively, among the 97 patient-specific sports and physical activities, patients rated 29% as less difficult, 52% as the same, and 19% as more difficult. They rated participation levels as improved in 40%, the same in 41%, and more impaired in 19%. Eighty-ne percent of patients were satisfied with their surgery regarding to return to physical activities (level IV).

Faber et al. reported an RCT comparing Hohmann procedure versus Lapidus procedure for HV.[13] Fifty-one feet had Lapidus procedure that was fixed with two 3.5 mm cortical lag screws. Mean follow-up was 111 months (87–137). Mean age was 41 years (16–63). Mean AOFAS score improved from 57.1 preoperatively, to 88.2 postoperatively at wo years, and was 78 at 10 years. In the Lapidus group 83% of the procedures were considered satisfactory by the patients, 4% were uncertain, and 13% were considered unsatisfactory. The mean pain score on the VAS (Visual Analogue Scale) improved. Complications in the Lapidus group were: 4% superficial infections; 4% CRPS cases; 12% non-union with 2% requiring revision; 10% presented recurrence, 2%, an acute recurrence, required revision; 6% cases of hallux varus with no re-operations; 4% transfer metatarsalgia, with no re-operations (level II).

Coughlin et al. performed a retrospective report of 16 patients (21 feet) with severe HV that underwent 1st MTP arthrodesis.[14] They used a mini fragment plate and trans-articular K-wire or screw. Their mean age was 71 years old (range 60–82 years). Average follow-up was 8.2 years. Patient satisfaction was excellent in 80% of feet, and good in 20%. No foot was rated as fair or poor. After surgery, 12 patients (10 feet) were able to wear conventional or fashionable shoes, while six patients (nine feet) required shoe inserts or comfort wear. No patients required custom shoes or bracing. All of the patients maintained equal or increased level of activity compared to preoperatively. The average AOFAS was 84 out of 90 points. Patients were advised that it is difficult to tolerate heel heights greater than 1.5 inches. Complications were: 14% nonunion, 29% superficial infection, and 10% hardware removal (level IV).

Tourné et al. reported a retrospective study of 32 patients (40 feet) with HV with a mean age of 67 years old (range

57–78 years).[15] Preoperative HVA was 43° (range 26–68°). Preoperative IMA was 15° (range 7–25). They treated them with 1st MTP arthrodesis using crossed screws and quarter-inch tubular screwed plate. Sixty-eight percent of the patients were very satisfied, 27% were satisfied, and 5% were unsatisfied. Normal gait regardless of surface was seen in 35 cases (86%), three cases (7%) had restrictions on uneven surfaces, and 7% had difficulties on flat surfaces. Complications were: inflammatory scar, deep venous thrombophlebitis. There were no nonunions (level IV).

Ellington et al. performed a retrospective evaluation of 145 patients (155 feet) that underwent 1st MTP arthrodesis.[16] They used a nonlocking plate with trans-articular screw. Fifty-four percent of the patients presented with HV, and 12.1% of patients underwent revision surgery. Mean age was 61.4 years (range 24.5–79.8 years). Mean follow-up was 61 weeks (range 27–127 years). Technique included dome-shaped reamer preparation, followed by fixation with trans-articular screw and nonlocking plate. Eighty-three percent of patients reported good to excellent results. Postoperative AOFAS score was 79.7 (out of 90). Complications were as follows: 12% nonunions, 11% superficial infections, 4% deep infection, others 4% (level IV).

Resolution of clinical scenario

- Lapidus (level II) and 1st MTP arthrodesis (level IV) lead to 80–90% of patient satisfaction in the treatment of severe HV. Populations included in Lapidus studies are younger (mean 40 years old) than 1st MTP arthrodesis studies (mean 69 years old). These are effective and predictable procedures for the treatment of severe HV.

- Nonunion and complication rates are comparable between these two procedures (level IV).

Summary of answers

- There is no difference in the rehabilitation time comparing open versus percutaneous surgery for HV correction (level I).
- Percutaneous surgery is 4–7 minutes shorter than open surgery for HV (level I).
- SC and CH have similar outcomes and complication rates (level I), surgeon's preference and expertise should be considered in choosing between SC and CH (level V).
- Lapidus in young adult patients (level II) and 1st MTP arthrodesis in older patients (level IV) have similar outcomes for severe HV.

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Cavovarus Foot

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Clinical scenario

- A 35-year-old man presents with ankle instability and overload of the lateral border of his foot.
- This has worsened over the last few years. He is otherwise fit and well. His father had a similar problem, with a similar foot shape.
- On examination he has bilateral high arches and varus heels with callosities under the lateral borders of his feet. He has some clawing of the toes.

Top three questions

1. In patients with cavovarus foot and Charcot-Marie-Tooth (CMT), does physiotherapy result in better functional scores compared to no physiotherapy?
2. In patients undergoing peroneus longus (PL) to peroneus brevis (PB) tendon transfer, does running locked suture result in improved construct strength compared to vertical mattress sutures?

3. In patients undergoing lateralizing calcaneal osteotomy, does prophylactic tarsal tunnel release result in less neurologic deficit compared to no tarsal tunnel release?

Question 1: In patients with cavovarus foot and Charcot-Marie-Tooth (CMT), does physiotherapy result in better functional scores compared to no physiotherapy?

Rationale

Lateral ligament instability, foot drop, and/or Achilles tendon tightness can be manifestations of CMT disorders which conventionally are referred for physiotherapy.

Clinical comment

Physiotherapy is a simple intervention that may be useful to improve the function of CMT patients.

Available literature and quality of evidence

- Two randomized controlled trials (RCTs) and two cohort studies exist to answer this question.

Findings

Lindeman et al. found in their RCT that a strengthening program directed to proximal musculature improves strength and functional performance in patients with CMT.[1,2] This study completed 24 weeks of follow-up (level I).

Rose et al., also in an RCT, reported an improvement of dorsiflexion range with serial night casting over four weeks.[3] Following those four weeks, the patients performed gentle stretching exercises and maintained the dorsiflexion range obtained. This study was conducted in CMT patients (level I).

El Mhandi et al., in a cohort study, showed that a 24-week interval-training stationary bike program performed three times per week was well tolerated by all patients.[4] In addition, it was significantly beneficial to their subjective perception of pain/fatigue; improved the functional capacity of these CMT patients; and although there was no reduced fatigability when tested in isometric mode, all patients increased their dynamic strength and physiological capacities (level II).

Chetlin et al., in a retrospective analysis of an RCT, found that a progressive resistance training program improved strength and activities of daily living in patients with CMT.[5] This study is important because it shows that patients with CMT can improve significantly with a simple, cost-effective, and home-based program (level II).

Resolution of the clinical scenario

- Periodic rehabilitation exercises directed to strength[1,2] (level I), stretching[3] (level I), and aerobic capacity[5] (level II) improve strength and activities of daily living.
- Physiotherapy is a mainstay in CMT treatment (level I).[6]
- A period of physiotherapy or home exercises supervised by physiotherapist is recommended (level I). They may be directed to proximal musculature strengthening, stretching, and aerobic capacity.

Question 2: In patients undergoing peroneus longus (PL) to peroneus brevis (PB) tendon transfer, does running locked suture result in improved construct strength compared to vertical mattress sutures?

Rationale

Most authors recommend using PL to PB tendon transfer in the surgical treatment of cavovarus foot to correct forefoot pronation, reduce the first ray plantarflexion and reinforce the weak eversion of the hindfoot.[7,8] The PL to PB transfer usually requires side-to-side tenorrhaphy, as this is stronger than Pulvertaft weave technique.[9]

Clinical comment

Early active mobilization of tendon repairs promotes better joint motion and limits adhesion of neighboring structures, thus a strong repair is needed.

Available literature and quality of the evidence

- The only evidence available consists in a cadaveric model. Wagner et al. performed a biomechanical evaluation of various suture configurations in side-to-side tenorrhaphy (level V).[10]

Findings

Wagner et al. evaluated the resistance to cyclic forces and monotonic loading.[10] The construct consisted of different side-to-side suture configurations on porcine flexor

digitorum tendons harvested from the forefeet. They tested four vertical mattress sutures, running locked sutures, four figure-of-eight sutures on each side of the tenorrhaphy, and four pulley sutures.

No tenorrhaphy failed during the cyclic loading. Nevertheless, during the monotonic loading, vertical mattress suture failed at a lower load than all the others. Running locked suture, four figure-of-eight sutures on each side of the tenorrhaphy and four pulley sutures are stronger than four vertical mattress sutures on monotonic load. They provide a larger safety margin that provides assurance to surgeons who advocate immediate loading or motion at the repair site**.**

Resolution of clinical scenario

- Side-to-side tenorrhaphy is stronger than Pulvertaft weave tenorrhaphy.[9]
- Running locked suture, four figure-of-eight sutures on each side of the tenorrhaphy and four pulley sutures are recommended over four vertical mattress, for side-to-side tenorrhaphy.[10]

Question 3: In patients undergoing lateralizing calcaneal osteotomy, does prophylactic tarsal tunnel release result in less neurologic deficit compared to no tarsal tunnel release?

Rationale

- In cadaveric research, tarsal tunnel volume diminishes after lateralizing calcaneal osteotomy, despite the amount of translation or the osteotomy placement in the calcaneus.[11,12]
- Neurologic deficit after lateralizing calcaneal osteotomy has been reported in up to 33.8% of patients. The mechanism can include direct surgical trauma, traction, and perioperative compression.[13]

Clinical comment

Lateralizing osteotomy is one of the most frequently used osteotomies in the treatment of cavovarus foot.[7,8]

Available literature and quality of the evidence

- No RCTs exist on this topic. The available evidence ranges from levels III to V.

Findings

VanValkenburg et al. performed a retrospective cohort study of 80 feet in 72 patients with cavovarus foot deformity, with average follow-up of 19 months.[13] They found a 33.8% rate of tibial nerve injury. Major injury was defined as encompassing two or more nerve branches. This occurred in 16.2% of cases. Minor injury, defined as injury to only one nerve branch, occurred in 17.5% of cases. The rate of injury when the tarsal tunnel was released prior to the calcaneal osteotomy (21.4%) was comparable to that of those without a release (29.8%, $p = 0.531$). However, the rate of injury when the release was performed after the osteotomy (77.8%) was significantly greater compared with those without a release (29.8%, $p = 0.006$). None of the neurologic deficits found after tarsal tunnel release was

observed to be a major injury, whereas 48.1% of nerve injuries overall were classified as major (level III).

Jaffe et al. reported a case series of 24 feet in 24 patients that underwent cavovarus foot reconstruction with lateralizing calcaneal osteotomy through the medial approach.[14] They performed tarsal tunnel release in only one patient because of previous symptoms. None of the patients developed neurologic deficit in the tibial nerve distribution after surgery (level IV).

Krause et al. reported a case report of two cases, mother and son, with CMT type 2.[15] Both underwent lateralizing calcaneal osteotomy. Both presented with acute tarsal tunnel syndrome in the immediate period after surgery. Both were advised for surgical tarsal tunnel release. The mother accepted the surgery, and the sensory deficit fully recovered by 12 weeks following this procedure. The son did not accept the procedure, and the disturbance had not resolved at 18 months postoperatively (level V).

Stødle et al. reported a case series of 18 feet in 15 patients with cavovarus foot, treated with lateralizing calcaneal osteotomy as a single procedure or in conjunction with other procedures.[16] Seventeen percent of patients presented with tibial nerve deficit at final follow-up of 51 months. They identified four patients with CMT, of whom two presented with deficits in the tibial nerve distribution of the foot at the final follow-up (level IV).

Bruce et al. performed lateralizing and medializing calcaneal osteotomies in eight cadaveric specimens. They measured the tarsal tunnel volume using magnetic resonance imaging (MRI).[11] The tarsal tunnel volume was reduced significantly after lateralizing calcaneal osteotomy. Medializing calcaneal osteotomy did not reduce tarsal tunnel volume (level V).

Resolution of clinical scenario

- Tarsal tunnel release is recommended before conducting a lateralizing calcaneal osteotomy through lateral approach (level III). This order is specifically important in CMT patients, who are at increased risk of tibial nerve damage during the procedure (level IV).
- Medial approach, with no tarsal tunnel release, is an alternative to diminish neurologic risk during lateralizing calcaneal osteotomy (level IV).
- Prophylactic tarsal tunnel release is recommended before performing a lateralizing calcaneal osteotomy (level III).

Summary of answers

- A period of physiotherapy or home exercises supervised by physiotherapist is recommended for CMT patients (level I).
- Running locked suture, four figure-of-eight sutures on each side of the tenorrhaphy and four pulley sutures are recommended over four vertical mattress, for side-to-side tenorrhaphy (level V).
- Tarsal tunnel release is recommended before conducting a lateralizing calcaneal osteotomy through lateral approach (level III).
- This order is specifically important in CMT patients, who are at increased risk of tibial nerve damage during the procedure (level IV).

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IV Trauma

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Damage Control Orthopedics

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Clinical scenario

- After a severe accident you see a multiply injured 45-year-old male patient in the trauma bay.
- The patient is in critical condition: hypotensive, tachycardic, temperature 34.6 °C, lactate 3.8 mmol/L, INR 2.5, pH 7.28; hemopneumothorax with lung contusion and rib fractures, minor traumatic brain injury.
- The patient has severe major fractures that need stabilization: pelvic-ring fracture, femoral shaft fracture, Gustilo–Anderson Grade 3 open ankle fracture.

Top three questions

1. In patients with multiple injuries in a borderline or unstable condition, what parameters best describe a patient in danger for complications?
2. In patients with multiple injuries in a borderline or unstable condition, which fracture is associated with the most complications?
3. In patients with multiple injuries after placement of an external fixation on long-bone fractures, does early or late conversion to intramedullary nailing lead to increased infections?

Question 1: In patients with multiple injuries in a borderline or unstable condition, what parameters best describe a patient in danger for complications?

Rationale

One of the most difficult tasks for a treating physician is to decide about clearance for surgery – and what type, depending on the patient`s condition. Previous studies have shown that early definitive surgery is beneficial in most patients, but lengthy operations, or overzealous blood loss, may trigger complications.

Clinical comment

Around the turn of the century, *damage control orthopedics* (DCO) was introduced to the care of the severely injured patient (level II and III).[1,2] This implies the application of an external fixator to stabilize major fractures of the extremities, or the pelvis, whenever the patient's condition is critical (*borderline* or worse). This technique is in contrast to *early total care*, where the fracture is stabilized definitively in one surgical session. The most relevant advantage of DCO is the substantial decrease of mortality[3] (level III) resulting from minimal invasive surgery minimizing the *second hit*, a theory that indicates the surgery to be a second traumatic hit that might overwhelm the inflammatory response and lead to sepsis, multiple organ failure, and death[4] (level III). However, DCO implies further surgical interventions to perform the definitive fixation and prolonged hospitalization with their associated increased risks of complications and adverse events.

Table 70.1 Defining the condition of a multiple injured patient[3]

	Parameter	Stable (Grade 1)	Borderline (Grade 2)	Unstable (Grade 3)	In Extremis (Grade 4)
Shock	systolic Blood pressure (mmHg)	100 or more	80-100	60-90	<50-60
	Blood units received within 2h after admission	0-2	2-8	5-15	>15
	Lactate (mmol/l)	norm	<2.5	>2.5	severe acidosis
	Base deficit	norm	no data	no data	> -18 - (-6)
	ATLS Shock class	1	2-3	3-4	4
	Urine output (ml/h)	>150	50-150	<100	<50
Coagulation	Platelet count (mug/ml)	>110.000	90.000-110.000	<70.000-90.000	<70.000
	Factor II/V(%)	90-100	70-80	50-70	<50
	Fibrinogen (g/dl)	>1	approx. 1	<1	DIC
	D-Dimer	norm	abdnormal	abdnormal	DIC
Temperature	°C	<>34	33-35	30-32	<30
Soft Tissue injury	Lung function (PaO2/FiO2)	>350	300	200-300	<200
	AIS Chest	1-2	>2	>2	>3
	TTS	0	1-2	2-3	4

	Parameter	Stable (Grade 1)	Borderline (Grade 2)	Unstable (Grade 3)	In Extremis (Grade 4)
	Moore Abdomen	<2	<3	3	>3
	AO Pelvis	A type	B or C	C	C (crush, rollover abd.)
	AIS Extremities	1-2	2-3 ETC if stable or	3-4	Crush, rollover
Recommended Surgical Strategy		ETC	stabilized In doubt: DCO	DCO	DCO

norm = normal range

AIS = Abbreviated injury Scale

TTS = Thoracic Trauma Score

DCO = Damage control orthopedic

ETC = Early Total Care

Available literature and quality of the evidence

Several studies have been performed to evaluate which is the best parameter – or combination – to describe patients at risk. For two decades, the triad of death, using indicators of shock, acidosis, and coagulopathy has been used to assess trauma patients (level III).[5] One of the earliest classification method that is still in use in routine clinical practice is the Injury Severity Score (ISS), that merely describes injury severity and distribution without giving recommendations on treatment strategy (level III).[6] Rotondo et al. described pathological values of acid–base, temperature, and coagulation as the *triad of death* that should be treated as early as possible (level III).[5] Nahm et al. proposed the stratification of patients depending on only three laboratory values (all from the acid–base group) into low- and high-risk patients; they postulated definitive surgery to be safe in low-risk patients (level III).[7] A further scoring system includes the injury severity and stratifies the patient's condition based on the mortality rate (level III).[8] Based on published evidence, the clinical grading scale categorizes the severely injured patient based on parameters of shock, coagulation, temperature, and soft tissue injuries, and recommends appropriate treatment strategies based on the patient's condition (level II).[9]

Findings

Overall, no level I evidence exists that clearly presents recommendations on what parameter, or which combinations of parameter, are to be used in defining the condition of the severely injured patient. Studies investigating this topic draw their conclusions mainly based on retrospective data analysis[8,10,11] and one on the combination of a profound literature review and expert opinion.[2] However, what most of these findings have in common are the evaluation of parameters from the same physiologic systems: shock and hemorrhage, acid–base, coagulation, temperature, and injury severity.

Resolution of clinical scenario

The current literature suggests that this patient is to be graded as *borderline* based on the pathological parameters of shock, acid–base, coagulation, temperature, and injury severity (Table 70.1).

This patient should be treated according to damage control principles until the relevant parameters are physiologic range and the patient is stabilized.

Question 2: In patients with multiple injuries in a borderline or unstable condition, which fracture is associated with the most complications?

Rationale

Initial emergency intervention is based on the principle: stop the bleeding and treat first what kills first. In the presence of multiple fractures, the treating team has to decide which one is associated with the biggest impact on the patient's physiology. These fractures should be addressed first.

Clinical comment

The treatment strategy of severely injured patients with multiple fractures includes planning the definitive treatment of fractures as soon as the patient's condition is stable enough. However, a major issue is the sequence of fracture fixation. Fractures that are associated with the most complications should be addressed earlier. These complications might be stratified into early complications, such as bleeding; medium-term complications, such as infection; pulmonary embolism; and late

complications, such as pneumonia, sepsis, or multiple organ failure (all level III).[4,12,13] Each fracture comes with its own set of possible complications; the clinical challenge is to prevent complications with early appropriate treatment without compromising the patient's overall condition.

Available literature and quality of the evidence

Historically, major fractures have been categorized to represent mainly the long bones (level 2).[14] Moreover, pelvic ring injuries were thought to have a major impact, and both entities have been closely examined recently. Fractures of pelvic ring and fractures of the femur are associated with major bleeding in the acute phase (level II).[15] Severe femoral fractures have been identified to be associated with an increased risk for pre-hospital hemorrhagic shock, higher resuscitation requirements, multiple organ failure, and longer in-hospital and intensive care stay (level III).[16] Moreover, pelvic ring fractures appear to benefit from emergency fixation with associated hemorrhage control (level III).[17] The soft tissue injury associated with a major extremity fracture seems to represent a crucial issue (level III).[18] Open fractures substantially increase the risk of infections (level I) and should be addressed accordingly.[19–21] Over the last decade, there has been only one clinical study that looked at the complications specifically in multiple injured patients in the ICU (level III).[22] The aim of the study was to compare the risk of local complications in patients after DCO for femoral shaft fractures. They showed that even the rate of superficial infection is higher in the DCO group (18.7% vs 1.9%, $p < 0.05$), the rates of deep surgical site infection were comparable in those groups (DCO 1.2% vs early total care [ETC] 1.1%). That led to the conclusion of comparable relevant infection rates, open fractures with severe local tissue damage to be an independent risk factor for infections, and an increase of contamination rate in external fixators when the fixator was placed for longer than two weeks.[22]

A recently published meta-analysis confirmed that in isolated femur fractures there are improved outcomes and fewer embolic events after early stabilization of the femoral shaft compared to delayed management. (level I).[23] Pooling data of one RCT and four retrospective studies, no statistically significant association between timing of intramedullary nailing (IMN) and odds of pulmonary embolism (odds ratio [OR] = 0.71; 95% confidence interval [CI]: 0.21–2.39). However, early IMN is associated with a statistically significant reduction of the odds of deep vein thrombosis (OR = 0.39; 95% CI: 0.21–0.71). Further,

early IMN reduces the odds for decubitus ulcer significantly (OR = 0.17; 95% CI 0.08–0.36).[23]

Even though they described little confidence in the effect estimate, this conclusion is drawn by several other studies as well.[24,25]

Findings

Pelvic fractures and femoral shaft fractures are associated with increased blood loss and hemorrhage and should be treated expeditiously. The most common fractures associated with complications are open fractures (Gustilo–Anderson 2 and above).

Resolution of clinical scenarios

Treatment of thoracic trauma and stabilization of the pelvis and the femoral shaft to facilitate breathing and stop the bleeding.

Level I evidence suggests high risk of infection in open fractures; treatment should include irrigation, surgical debridement, and antibiotic treatment.

Question 3: In patients with multiple injuries after placement of an external fixation on long-bone fractures, does early or late conversion to intramedullary nailing lead to increased infections?

Rationale

The external fixator usually is used during DCO as a temporary, minimal-invasive technique to stabilize a fracture. The timepoint at which the external fixator should be replaced with the definitive fixation is controversial.

Clinical comment

Multiply injured patients are being treated with external fixation and other measures of DCO. Afterward, their physiologic systems are stabilized and treated in the intensive care unit, until definitive surgery of the fractures can be performed.

A prolonged treatment with an external fixator is associated with several complications and should only be used for definitive treatment in

selected cases. However, it still remains difficult to define the best timepoint on when to replace the external fixator.

Available literature and quality of the evidence

Reasons for temporary fracture fixation with external fixators are very individual. In severely injured patients, the aim is to minimize the load of the first surgery in order not to overwhelm the inflammatory system (level III).[26] A systematic review summarized infection rates and the investigated a possible association of conversion time with complications in femoral and tibial shaft fractures.[27] They summarized 185 acute open fractures of the femur (six level IV studies) and 268 fractures of the tibia (seven level IV, one level I studies). With regards to sequential femoral nailing following external fixation of femoral fractures they found a plausible infection rate average of 3.6% (95% CI: 1.8–7.4%). With regards to sequential nailing of tibial fractures after external fixation, they found infection rates of 9% (95%: CI: 7–12%). They also found that length of external fixation ≤28 days reduces the risk of infection by 83% (95% CI: 62–93%). Additionally, interval time in external fixation <14 days resulted in a significant reduction in the infections rates than longer times.[27]

The soft tissue status around the fracture presents as a limiting factor. This has led several groups to the development of a staged protocol in the treatment of fractures with substantial soft tissue damage (level II).[28,29]

These recommendations were published in order to avoid infectious complications at the time of conversion (level II).[29] Also, there are reports about the use of external fixation for definitive fracture care, without conversion to internal fixation (level III)[30] and has been proposed as an safe alternative to intramedullary nailing (level II).[31]

Findings

Evidence is sparse on defining the most appropriate timepoint on when to convert to an internal fixation from an external fixation. However, studies agree on two limiting parameters: the status of the surrounding soft tissue and the patient's general condition.

Resolution of clinical scenario

The timepoint of conversion is defined by the patient's condition and the soft tissue status.

The patient's condition should be remeasured regularly to show treatment effects.

Summary of answers

- Currently, parameters of shock, coagulation, temperature, acid–base, and injury severity most accurately describe the condition of the severely injured patient.
- Each fracture has its unique complications based on injury severity, concomitant injuries to surrounding tissue, or open and closed fractures.
- Early fracture treatment in severely injured patients should stop hemodynamic relevant bleeding, and decrease mid-term and long-term complications.
- The timepoint of conversion from external to internal fixation should occur as early as the patient's condition and soft tissues allow, as longer times in external fixation (>14 days) have been shown to increase infection rates.
- A staged protocol in the treatment of fractures with substantial soft tissue damage has been recommended by several authors.

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Open Fractures

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Clinical scenario

- A 32-year-old female unrestrained driver versus a tree.
- Nonorthopedic injuries include multiple rib fractures, left pneumothorax, and a subarachnoid hemorrhage. The patient was intubated in the trauma bay due to respiratory compromise.
- Orthopedic injuries include a left open comminuted tibial shaft fracture with associated fibula fracture. The patient has a 2+ dorsalis pedis pulse; however, motor and sensory exam are difficult to evaluate secondary to patient intubation.

Top three questions

1. In trauma patients with open fractures, does early antibiotic administration result in lower infection rates as compared to delayed antibiotic administration?
2. In polytrauma patients with open fractures, does timely irrigation and debridement result in decreased complications and infection rates as compared to delayed irrigation and debridement?

3. In patients with open fractures, does irrigation with normal saline versus an additive solution, and high pressure versus low pressure, result in lower infection/complication rates?

Question 1: In trauma patients with open fractures, does early antibiotic administration result in lower infection rates as compared to delayed antibiotic administration?

Rationale

Proper early management of open fractures in the trauma bay is essential to afford patients the best orthopedic outcome. This includes application of splints and bedside irrigation, as well as administration of proper medications and appropriate resuscitation techniques.

Clinical comment

Early administration of antibiotics and resuscitation efforts can help reduce complications.

Available literature and quality of the evidence

- Level I: 10
- Level II: 16
- Level III: 11.

Findings

Open fractures are initially managed in the trauma bay with local irrigation, splinting, and administration of antibiotics. Tetanus is administered as indicated as well. As

experiments have suggested, antiseptics (such as povidone iodine) may be toxic to the host cells;[1,2] therefore, gauze dressings moistened with normal saline may be the safest, least destructive choice for short-term coverage.

The administration of systemic antibiotics for open fractures has been the standard of care since 1974.[3] A Cochrane review by Gosselin et al. showed that antibiotics given for open fractures reduce the infection risk by 59%.[4] The current antibiotic recommendations stem from the original Gustilo and Anderson articles.[5,6] Several studies agree that the single-most-important factor in reducing infection is early administration of the appropriate antibiotics.[2–4,7–9] A 2015 journal article showed that antibiotics given >66 min after arrival in type III fractures were associated with increased infection rates (odds ratio [OR] = 3.78; 95% confidence interval [CI]: 1.16–12.31; p] = 0.03).[10] Contrary to this, a prospective cohort study showed that timing of antibiotic of administration may be less important than Gustilo type for developing deep infection in open fractures.[11] In current protocols, a first-generation cephalosporin (usually cefazolin) is given for type I and II fractures, while an aminoglycoside (usually gentamicin) is often added for type III fractures or fractures with gross contamination based upon the work of Patzakis et al.[7] Penicillin is also recommended for highly contaminated wounds or in areas with poor vascularity.

Some exceptions to early systemic antibiotic therapy do exist, but these studies are primarily focused on hand fractures. For example, a systematic review and a randomized placebo-controlled trial found that prophylactic antibiotics did not add to the prevention of infection in conjunction with routine treatment of open distal phalanx fractures with irrigation and debridement.[8,12] Although these studies suggest that antibiotics may not be

necessary, phalanx fractures are in highly vascular areas, lend to easier bedside irrigation/debridement, and are typically low-energy injuries.

Few articles give length of dosing recommendations for antibiotic therapy, although most surgeons agree that antibiotics should be continued for at least 24 hours after the final irrigation and debridement, similar to antibiotic prophylaxis recommendations for elective surgery.[9]

Resolution of clinical scenario

- Early administration of intravenous (IV) antibiotics is the most important factor for initial management of open fractures; however, subsequent evidence indicates that Gustilo type may be the most important predictor of future infection.
- In our clinical scenario, treatment with a first- or second-generation cephalosporin is recommended with the addition of an aminoglycoside for type III open fractures.

Question 2: In polytrauma patients with open fractures, does timely irrigation and debridement result in decreased complications and infection rates as compared to delayed irrigation and debridement?

Rationale

The importance of this question lies in determining the optimal time from when patients arrive at the hospital to

when a formal irrigation and debridement should be conducted.

Clinical comment

Polytrauma patients are nonelective surgeries; however, operating within the *six-hour rule* for irrigation and debridement should be balanced with the patient's overall physiologic status, operating room availability, and reasonable demands on the surgeon.

Available literature and quality of the evidence

- Level I: 0
- Level II: 9
- Level III: 8.

Findings

Based on the Gustilo/Anderson articles, open fractures have been considered emergent cases that need to undergo operative debridement within six hours of injury. However, only one study supports the idea of debridement of open fractures within six hours of injury; Kindsfater and Jonassen reviewed open tibial fractures and found a significant increase in infection rate in fractures that were delayed greater than five hours. One in fifteen open fractures (7%) became infected if debrided in <5 hours versus 12/32 open fractures (38%) debrided >5 hours after injury ($p < 0.03$).[13]

On the contrary, many studies question the need for urgent irrigation and debridement (I and D) within six hours and some have even suggested no debridement is necessary for isolated type 1 open injuries in the pediatric population.[14] Pollack concluded in a review article that within the modern era of antibiotics timing to I and D is not an

independent predictor of postinjury infection.[15] Later in the Lower Extremity Assessment Program (LEAP) study, he showed that there was no difference in outcomes when debridement occurred within the first 24 hours.[16] In 2012, a systematic review showed no difference in time to operation and infection risk regardless of subtype. Overall infection rates ranged from 4 to 63%, with an OR of late compared to early debridement of 0.91 (95% CI: 0.70 to 1.18).[17] Weber, in 2014, also released a cohort study of 736 patients which showed no difference in time to surgery on infection risk of open fractures.[11] Dr. Srour and the University of Southern California examined 315 patients and again saw no difference in early or late infections when the index procedure was performed <6 hours after injury or between 6 and 24 hours.[18] Lastly, a 2016 systematic review showed there was no difference in infection risk with debridements done before or after six hours. Meta-analysis showed no statistical difference between groups with regards to overall infection rates (risk ratio [RR]] = 1.32; 95% CI: 0.54–3.23; p] = 0.55), deep infection rates (RR] = 0.99; 95% CI: 0.48–2.07; p] = 0.98), and nonunion rates (RR] = 1.49; 95% CI: 0.64–3.49; p] = 0.36).[19]

In summary, many recent studies have examined early initial debridement (<6 hours) versus debridement (6–24 hours), and the consensus has revealed no difference in infection rates. Initial debridement when the patient has been medically optimized, and preferably within 24 hours, has been the current thought process at most level I trauma centers.

Resolution of clinical scenario

- In this specific scenario, a patient should be stabilized from a medical standpoint prior to proceeding for

irrigation and debridement as this can be safely done within 24 hours of admission.

- All cortical bone with no soft tissue should be removed at the time of the initial debridement in this patient to minimize sources of infection.
- Gustilo type appears to correlate more closely with infection risk as opposed to the urgency of which initial debridement is performed.

Question 3: In patients with open fractures, does irrigation with normal saline versus an additive solution, and high pressure versus low pressure, result in lower infection/complication rates?

Rationale

Many options exist with irrigation. Whether or not to use additives, high pressure versus low pressure versus gravity flow, and amount of fluid are all questions that orthopedic surgeons will face in managing open fractures in an effort to improve surgical outcomes and minimize infection risk.

Clinical comment

The choice for irrigation solution, additional additives, volume, and method of delivery (pressure) until recently has been unclear. These choices can affect the cost of the procedure and can have potentially harmful effects to the patient. The safest and most cost-effective irrigation solution and delivery system should be used to yield the best outcome for the patient.

Available literature and quality of the evidence

- Level I: 2
- Level II: 4
- Level III: 3.

Findings

No clear consensus until recently existed for the choice of irrigation solution or method of administration during the initial or subsequent procedures. A previous international survey found 70.5% of respondents favored normal saline as an irrigation solution, 71% of surgeons used low pressure systems, and only 1.3% of the surgeons routinely used a soap additive.[20] Experimental data suggest some toxicity to the host cells from antiseptic solutions. Other concerns for solutions other than normal saline include allergic reactions, additional cost, promotion of resistance, and unproven efficacy.

Volume of irrigation

The volume of solution used to irrigate a wound after adequate debridement is rooted in tradition, with one animal study showing increased bacterial removal with increased volume of irrigation but the correlation plateaued for normal saline alone.[21,22] The traditionally accepted minimum volume is 3 L for type I, 6 L for type II, and 9 L for type III injuries.

Irrigation additives

The efficacy of antiseptic additives in eliminating bacterial loads must be weighed against the potentially toxic side effects to normal host cells in the wound bed. For example, although povidone iodine solution has demonstrated

efficacy in reducing infection in surgical wounds,[23] undiluted povidone iodine is toxic to bone cells.[1] Furthermore, there is continued concern over local antibiotic resistance[24] and anaphylactic reactions.[25,26] Animal models have shown that irrigation with an antibiotic reduces the rate of infection compared with the use of saline solution alone.[27]

Anglen reported the results of a prospective, randomized, controlled trial of 398 lower extremity open fractures comparing castile soap with bacitracin solution.[28] Despite equivalent infection and bone-healing rates, bacitracin was more problematic in terms of wound-healing issues (9.5% vs 4%; p] = 0.03). Soap solutions have been shown to be more effective than normal saline in removing bacteria from stainless-steel screws, while antibiotic solutions showed no advantage (p >0.05).[27] This clinical benefit has been challenged by the conclusion of the FLOW study which examined 2447 patients with open fractures and compared re-operation rates in castile soap irrigation versus normal saline. The re-operation rate with use of castile soap was 182/1229 (14.8%) as opposed to normal saline 141/1218 (11.6%) (p] = 0.01), indicating castile soap may not be as safe or effective as was once thought.[29]

Other potential additives not systematically studied in well-controlled trials include hydrogen peroxide, hexachlorophene, sodium hypochlorite, benzalkonium chloride, and various alcohol-containing solutions.[4]

Method of irrigation delivery

Multiple studies have promoted the superior mechanical properties of high-pressure irrigation, while many others have addressed the more tissue-friendly approach of low-pressure methods. While high-pressure lavage systems may be more effective in reducing bacterial cell counts and

protective biofilm barriers,[30,31] macro- and microscopic damage to both host soft tissues and bone occurs[32–34] and may result in deeper seeding of bacterial colonies.[35,36] These data are limited by lack of human *in vivo* testing of lavage systems. In general, the bulk of experimental evidence suggests an inverse relationship between efficacy of removal of contamination and potential tissue damage with the various methods of wound irrigation.

The FLOW study also evaluated re-operation rate at one year in patients with open fractures with regard to high-pressure irrigation, low-pressure irrigation, and very low-pressure irrigation (gravity flow). Re-operation occurred in 109/826 patients (13.2%) in the high-pressure group, 103/809 (12.7%) in the low-pressure group, and 111/812 (13.7%) in the very low-pressure group. Hazard ratios were conducted in high versus low pressure (0.92; 95% CI: 0.70–1.2; p] = 0.53), high versus very low pressure (1.02; 95% CI: 0.78–1.33; p] = 0.89), and low versus very low pressure (0.93; 95% CI: 0.71–1.23; p] = 0.62). Their conclusion showed no difference in re-operation rates between the three groups. This study further confirms the trend toward use of very low-pressure irrigation for open fractures as a safe and effective approach. While the pendulum has swung toward lower-pressure lavage systems, newer innovations, such as the Versajet™ (Smith and Nephew, Inc., London, UK), claim to provide controlled surgical debridement of tissues. However, there is no high-grade evidence that these newer systems have resulted in improved outcomes and may be reserved for specific situations of severely ground-in contamination as opposed to a thorough surgical debridement and gravity flow irrigation used for most open fractures.

Resolution of clinical scenario

- The FLOW study on human subjects showed that irrigation with normal saline led to lower re-operation rates compared to castile soap in the management of open fractures.
- In our clinical scenario, it is completely acceptable to irrigate the wound thoroughly with gravity flow normal saline, as higher pressure and additives have shown no increased benefit.
- There is no convincing evidence for, or against, using alternative technologies to perform irrigation and debridement of open fractures.

Summary of answers

Initial open fracture management

- Prompt IV antibiotics should be given to patients with open fractures.
- Tetanus toxoid should be administered based on immunization history.
- Initial wound management should consist of placing a sterile normal saline moistened dressing and temporary stabilization of fractures.

Timing to operative intervention

- Timing of operative intervention should be done as soon as possible based on the overall patient's physiologic status.
- The timing of irrigation and debridement, although not as important as early antibiotic delivery, should occur within 24 hours to optimize the outcomes.

Open fracture irrigation management

- Normal saline is the irrigation of choice for most open fractures.
- Additives, including soap, have shown no benefit and have potential risks to the host resulting in increased re-operation rates.
- Very low-pressure irrigation (gravity flow) has shown to be equivalent to higher-pressure irrigation; therefore, current recommendations are for very low-pressure irrigation.

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The Mangled Extremity

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Clinical scenario

- A motorcyclist collides with a car at high speed. He is brought to the Emergency Department with a severe open injury to his leg.
- He has been experiencing financial difficulties and would like to return to work (RTW) as soon as possible. With this goal in mind, he asks whether amputation or limb salvage would be the best option for him.
- He looks at his mangled leg and wonders about the long-term consequences of his injury.

Top three questions

1. In patients with a mangled extremity injury, does limb salvage necessitate greater resource investment than amputation?
2. In patients with a mangled extremity injury, what patient factors influence the success of therapy and the rate of RTW?
3. In patients with a mangled extremity injury, is limb salvage associated with better long-term outcomes when compared to amputation?

Question 1: In patients with a mangled extremity injury, does limb salvage necessitate greater resource investment than amputation?

Rationale

Limb salvage and amputation impose different stressors on a patient's financial and emotional well-being. An understanding of the investment required in each intervention enables the clinician to better counsel patients.

Clinical comment

Salvage may require multiple, costly procedures, and may result in failure rates as high as 40%.[1–5] More than half of patients develop mental health conditions after a failed limb salvage and many would not opt for it again.[2–6] However, at time of injury, 92% prefer an attempt at salvage.[3] Appreciating the financial and psychological costs of limb salvage compared with amputation may assist patients with decision-making.

Available literature and quality of the evidence

The most current relevant literature consists of:

- Level II: 2 cost-analysis studies based on prospectively collected data.[7,8]
- Level III: 3 retrospective chart reviews.[3,9,10]

Findings

Financial cost of limb salvage and amputation

Georgiadis reported a lower acute hospitalization charge (US$65,624) for amputation than for salvage ($109,044) (p <0.006)(level III).[4] Hertel reported equal mean annual hospital cost, based on four years, for amputation (15 112 CHF and salvage (17 365 CHF) (level III).[9] MacKenzie reported equal long-term hospital costs for amputation ($78 221) and salvage ($81 091) (level II).[8] Hertel reported higher total cost, including pension and loss of wage benefits for amputation (64 000 CHF) compared to salvage (33 000 CHF) (p <0.01).[9] When considering lifetime prosthesis-related costs, MacKenzie reported that amputation is three times more costly ($509 275) than salvage ($163,282).[8] Chung calculated cost as amount of money paid for a single extra quality-adjusted life years (QALYs). Assuming the patient has 40 years of life remaining, the average cost is $91 105 for amputation and $81 316 for salvage at two years after injury (level II).[7] The remaining lifetime cost is again higher for amputation ($350 465) than for salvage ($133 704).[7]

Duration of hospitalization for limb salvage and amputation

Georgiadis reported a shorter acute hospitalization for amputation (48 days) than salvage (71 days) (p <0.05).[4] Dagum reported equal stays for amputation (28 days) and salvage (25 days) (level III).[3] Georgiadis reported shorter readmission for amputation (5 days) than for salvage (18 days).[4] Hutchins reported equal total hospital stays, including readmission, for amputation (14 weeks) and for salvage (14.8 weeks) (level III).[10] Additionally, it is important to account for the time spent in rehabilitation centers. Hutchins reported that total acute and rehabilitation admission times were equal for amputation (101 days) and for salvage (129 days).[10] Shorter outpatient

rehabilitation time was required for amputation (12 months) than for salvage (30 months), although this was self-reported by patients ($p < 0.009$).[10]

Resolution of clinical scenario

Level II and III evidence suggests that the cost of limb salvage is:

- Less than amputation, when considering lost wages, pension, lifetime prosthesis-related charges, and QALYs.
- Equal to amputation in regard to in-hospital charges, duration of hospitalization, and duration of inpatient rehabilitation in most studies.
- More than amputation in regard to duration of outpatient rehabilitation.

Question 2: In patients with a mangled extremity injury, what patient factors influence the success of therapy and the rate of RTW?

Rationale

A severe extremity injury is a life-altering event that affects quality of life and function. An important aspect of treatment includes managing patient expectations regarding recovery and ability to RTW.

Clinical comment

Patient factors are often overshadowed by the urgency of the situation, but current opinion suggests that certain factors, such as education level and presence of social

support, can influence success of therapy.[1] It is important to appreciate predictors of outcome and ability to RTW, as they may guide necessary counseling.

Available literature and quality of the evidence

The most current relevant literature consists of:

- Level II: 3 studies from the LEAP (Lower Extremity Assessment Project) group, which retrospectively analyzed a large body of prospectively collected data.[1,11,12]
- Level III: 2 retrospective chart reviews.[3,10]

Findings

Predictors of poor outcome

The LEAP studies measured outcome with the Sickness Impact Profile (SIP) (level II).[1,11] The following patient characteristics predicted poor outcome at two years: less than high school education ($p < 0.05$), household income below the poverty level ($p < 0.1$), non-Caucasian ethnicity, lack of insurance, poor social support network, low level of self-efficacy (confidence in one's ability to resume chief life activities), smoking, and involvement with the legal system for injury compensation ($p < 0.01$).[1] The following predicted poor outcome at seven years: low education level, older age, female gender, non-Caucasian ethnicity, household income below poverty line, smoking, low self-efficacy, poor self-reported health status before injury, and involvement with the legal system for injury compensation ($p < 0.05$).[11] In a small study, Dagum reported that patient involvement with legal action was not associated to Short Form 36 (SF-36) mental component scores or Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) pain

scores (level III).[3] Success of salvage and amputation was equally influenced.

Predictors of return to work (RTW)

Hutchins reported older age to be inversely related to RTW (level III).[10] The LEAP study found the following predictors of RTW: age less than 55, Caucasian ethnicity, high school or college education, nonsmoking status, as well as average to high self-efficacy and motivation (high job involvement and being in a preinjury job for one or more years) ($p < 0.05$) (level II).[12] Involvement with the legal system for compensation predicted lower RTW ($p < 0.01$).[12]

Resolution of clinical scenario

- Level II evidence suggests the following patient characteristics predict poor outcome and difficulty with RTW: lack of education, older age, non-Caucasian ethnicity, poverty, smoking, involvement in disability-compensation litigation, and low self-efficacy.
- Level III evidence had similar findings.

Question 3: In patients with a mangled extremity injury, is limb salvage associated with better long-term outcomes when compared to amputation?

Rationale

A severely injured extremity has life-altering consequences and, as such, the degree of long-term disability associated

with each intervention may be the most important factor to consider.

Clinical comment

Before proceeding with definitive management, patients and physicians must be aware of the outcomes of both limb salvage and amputation. Although there are multiple factors to consider in decision-making, the degree of long-term disability associated with each treatment may be the most significant.

Available literature and quality of the evidence

The most current relevant literature consists of:

- Level II: 3 studies from the LEAP group, which assessed outcome based on prospectively collected data.[1,11,13]
- Level III: 3 retrospective chart reviews.[3,4,14]

Findings

Outcome

The LEAP studies measured outcome with the SIP based on prospectively collected data. At two years after injury, the SIP was the same for salvage and amputation; 42% of all patients had a SIP greater than 10, indicating severe disability (level II).[1] RTW was 49% after salvage and 53% after amputation ($p = 0.48$).[1]At seven years, 49.4% of all patients had a SIP greater than 10 (level II).[11] Rehospitalization was more likely in patients after salvage than for amputation (47.6 vs 33.3%, $p = 0.002$).[1] Through-the-knee amputees had a worse outcome ($p < 0.05$).[11] Most other retrospective studies support these findings,[2–5] with minor exceptions.[3,4] Dagum reported better SF-36 physical

function scores after successful salvage ($p < 0.007$) (level III).[3] Georgiadis reported longer time to weightbearing, and more interference of health on work and recreation after salvage (level III).[4] Melcer reported that in military patients the incidence of mental health disorders was similar after amputation and salvage (level III).[14]

Complications

The most common complication after salvage is nonunion (31.5%), usually diagnosed at six months (level II).[13] The most common complication after amputation is wound infection (34.2%), which usually occurs at three months.[13,14] Salvage patients have more complications ($p < 0.001$), longer time to complication, and require more interventions.[13]

Resolution of clinical scenario

- Level II evidence demonstrates that outcomes after salvage and amputation are equal and do not improve from two to seven years after injury.
- Level II evidence suggests that limb salvage is associated with higher risk of complications and requires more interventions after the index operation.
- Level III evidence suggests similar incidence of mental health disorders with both interventions.

Summary of answers

- Limb salvage costs less than amputation, when considering lost wages, pension, lifetime prosthesis-related charges, and QALYs.

- Salvage and amputation are equal in regard to in-hospital charges, duration of hospitalization, and duration of inpatient rehabilitation in most studies. The duration of outpatient rehabilitation is longer after salvage.
- Patient characteristics predicting poor outcome and difficulty with return to work are as follows: lack of education, older age, non-Caucasian ethnicity, poverty, smoking, involvement in disability-compensation litigation, and low self-efficacy.
- Outcomes after salvage and amputation are equal, and the outcome does not improve from two to seven years after injury.
- Limb salvage patients have a higher risk of complications.

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Acute Compartment Syndrome

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Clinical scenario

- A 34-year-old healthy male pedestrian, struck by a motor vehicle, sustaining an open comminuted fracture of right tibia (Gustilo grade IIIA).
- Patient receives antibiotics (cephalosporin, aminoglycoside); right tibia treated with intramedullary nail fixation following irrigation and debridement.
- Several hours later, patient complains of pain (with progressive increase in analgesic requirements), pain on passive stretch, progressive hypoesthesia, and paresthesia.
- Clinical examination reveals swollen, palpably tense anterior, and lateral compartments; acute compartment syndrome (CS) confirmed by intracompartmental pressure (ICP) measurement.

Top three questions

1. In patients with CS, do open fractures pose greater risk of missed diagnosis and delayed fasciotomy compared to closed fractures?

2. In patients with CS, are patients who undergo compartment pressure monitoring diagnosed faster than patients undergoing clinical assessment?
3. In patients with anterior CS of the leg, does a one-incision fasciotomy of the anterior compartment achieve better decompression and fewer complications compared to the full two-incision/four-compartment release?

Question 1: In patients with CS, do open fractures pose greater risk of missed diagnosis and delayed fasciotomy compared to closed fractures?

Rationale

Acute CS is caused by elevated pressure within a closed osteofascial compartment. CS can develop in response to a multitude of traumatic injuries and medical comorbidities: fractures, burns, exercise, crush injuries, and ischemia-reperfusion injury;[1] less common causes may include bleeding disorders,[2] diabetes, administration of statins,[3,4] infection,[5] hypothyroidism,[6] lithotomy position,[7] snake bites,[8] arterial rupture,[9] and blast injuries.[10]

Clinical comment

A high index of suspicion for CS is required for all fractures, in particular those within the forearm and leg, regardless of whether the fracture(s) are closed or open. Serial examination is the key to diagnosis and avoidance of a missed CS.

Available literature and quality of the evidence

- Level I: 2 randomized controlled trials (RCTs)
- Level III: 1 retrospective cohort.

Findings

McQueen, Gaston et al. (level I evidence) evaluated the occurrence of acute CS; they reported that CS can occur in every muscle compartment of the upper extremity, lower extremity, and trunk; leg (80% of all cases) and forearm are most frequently involved.[1] Age and sex play a role in the likelihood of CS development: male patients under 35 years of age are prone to developing CS more often.[1]

CS is most commonly due to closed long-bone fractures (75% of cases),[11,12] in which the fascia is maintained. Comminuted fractures increase the risk further.[12] In adults, the most common cause of CS is tibial fracture (approximately 1–10%),[11,13] followed by the fractures of forearm bones (distal radius). In children, supracondylar humerus fractures are the most common cause.[14]

Open fractures can result in CS development if a sufficient portion of the deep fascia or skin remains intact (level III evidence).[15] In both volar plating of distal radius fractures and intramedullary nailing of tibial fractures, ICP has been found to peak during the procedure, followed by a decrease postoperatively over 24 hours,[16] and 36 hours,[17] respectively.

Trauma patients without fracture may be at significantly greater risk of delayed CS diagnosis and fasciotomy (level I evidence)[2]: 20% of patients without fracture had muscle necrosis that required debridement, versus debridement being necessary in 8% of patients with fractures.

CS appears to be less frequent in nontraumatic cases. It may be caused by ischemia-reperfusion injury, thrombosis, and bleeding disorders, among a variety of other conditions. Sustained external pressure on an extremity can precipitate CS.[18,19] This can occur in an unconscious patient (i.e. drug overdose, poor surgical position technique). CS is less frequent in nontraumatic cases, and is usually caused by a sustained external pressure on an extremity.[18,19]

Resolution of clinical scenario

- Watchfulness is necessary in all types of fractures (particularly in open fractures and fractures of the leg and forearm). Rapid progressive worsening signs and presence of multiple findings indicate CS development.
- The suspicion of CS should be confirmed by measurement of ICP; the presence of unequivocal signs requires emergency decompression via fasciotomy as the case of our patient in our clinical scenario.

Question 2: In patients with CS, are patients who undergo compartment pressure monitoring diagnosed faster than patients undergoing clinical assessment?

Rationale

Diagnosis of acute CS is challenging, as there is no true diagnostic test; instead, the surgeon must rely on the clinical examination and observation of CS signs and symptoms.[20] Although the timing of the appearance of

specific signs and symptoms varies, they all tend to appear in stepwise fashion.

Clinical comment

Clues indicating a developing CS include the rapid progression of symptoms over a few hours, as well as the presence of multiple findings that are consistent with impending CS. Thus, all patients at risk of CS should be serially evaluated; special attention must be paid to any tense and painful muscle compartment. If acute CS is suspected on the basis of risk factors and clinical findings, ICP measurements should be obtained without delay.[21]

ICP measurements are of particular use in intubated, sedated, and/or obtunded patients. CS remains a clinical diagnosis; history and repeated physical exams are critical to timely diagnosis. A low threshold for fasciotomy should be maintained when clinical signs are present. Obtaining ICP measurements should not delay a patient being brought to the operating room.

Available literature and quality of the evidence

- Level II: 2 studies.

Findings

Level II evidence indicates that the first symptoms of acute CS are disproportionate pain relative to the injury and pain on passive muscle stretch (PPS),[22,23] often coupled with a progressive increase in analgesia requirements.[24] Both pain out of proportion to what is expected of the injury (based on the physical examination) and PPS are the most sensitive clinical findings (19%) and are often the *only* observation that precedes ischemic dysfunction in the nerves and muscles of the affected compartment.[22,23] While

the specificity of both pain measures is high (97%), the sensitivity is very poor (19%); thus, absence of pain may be a useful measure in *ruling out* acute CS.[22]

Approximately one hour after the onset of ischemia, the patient may experience the first sensory changes (level II evidence).[23] As a clinical measure of acute CS, paranesthesia has a sensitivity of 13% and a specificity of 98%.[22] Unfortunately, paresis and/or paralysis of the muscles of the involved compartment are considered signs of a late acute CS; at this stage, the patient is less likely to respond to fasciotomy.[22,25]

The lack of a pulse rarely occurs in CS patients; alternatively, the presence of a pulse does not exclude CS.[26] While congestion of the digits and prolonged capillary refill time may also indicate acute CS, these should not be relied upon, as they may be affected by many different external factors (e.g. shock, dehydration, decreased peripheral perfusion).[26]

Although controversial, level II evidence suggests that the role of ICP measurement in acute CS remains a valuable tool for providing objective criteria for the diagnosis,[27] decreasing the delay to fasciotomy (and thus the long-term complications).[28] In order to capture the peak ICP value, measurements should be taken at the level of the fracture, as well as at sites up to 5 cm proximal and distal to injury.[29]

The indications for ICP measurement include unconscious patients;[30–32] difficult-to-assess patients (e.g. young children, patients with psychiatric problems, or those under the influence of narcotics);[33] patients with equivocal signs and symptoms,[30] especially when accompanied by nerve injury;[33,34] and patients with multiple injuries.[32]

There is no clear protocol for a specific pressure threshold at which fasciotomy should be carried out. Normal tissue pressure within a compartment is 0–8 mmHg.[33] The threshold ICP for decompression is variable in the literature (i.e. 30–45 mmHg). Differential pressure (ΔP) may be a better indicator of tissue ischemia.[33] Level II evidence suggests that the threshold ΔP be 30 mmHg, based on the retrospective observation that this value lead to no apparent missed cases of acute CS.[27] The advantages of a differential pressure threshold include better utility in hypotensive trauma patients and a lower overall fasciotomy rate, compared to an absolute pressure threshold.[27,35]

Clinical findings associated with CS tend to correlate with the degree to which tissue pressure within the affected compartment approaches systemic blood pressure. It has been demonstrated that the capillary blood flow becomes compromised at ΔP of 25–30 mmHg of mean arterial pressure,[36] leading to the development of pain. Once the tissue pressure approaches diastolic pressure, tissue ischemia will occur.[37,38]

Resolution of clinical scenario

- Pain (including pain on passive stretch of muscles) is the earliest and most common finding in all CS cases.
- A suspected CS diagnosis should be confirmed by measuring ICP; ΔP of less than 30 mmHg indicates the need for emergency surgical decompression.

Question 3: In patients with anterior CS of the leg, does a one-incision fasciotomy of the anterior compartment achieve better decompression and fewer complications compared to the full two-incision/four-compartment release?

Rationale

Goals of management in acute CS are to minimize permanent injury of the affected limb by restoring microcirculation to the muscle and nerve, and therefore avoid the sequelae of ischemic contracture. As such, the current gold standard therapy for confirmed acute CS is fasciotomy, where the skin and underlying fascia are incised in order to relieve the limb ischemia generated by the elevated ICP, provided the diagnosis of CS is made within the recommended surgical window of 6–8 hours.[27,35,39] The consequences of delaying fasciotomy are severe; therefore, nonoperative measures are restricted to an adjunctive role supplemental to fasciotomy.

Clinical comment

While the acute CS may be localized to one compartment, it is always safer to release all compartments at the same time. CS may evolve with the passage of time from the inciting event, injury, or surgical intervention, to ultimately affect all compartments. Sufficient extensile skin incision is crucial to complete decompressive fasciotomy of superficial, intermediate, and deep compartments. There is

no role for minimally invasive or percutaneous fasciotomies in the trauma setting.

Available literature and quality of the evidence

- Level III: 1 study
- Level IV: 2 studies
- Level V: 3 studies.

Findings

Three techniques for fasciotomy are most commonly used in the leg: two-incision fasciotomy, one-incision perifibular fasciotomy, and fibulectomy; these have been shown to be sufficiently effective at decreasing ICP. The two-incision technique performed on cadaver specimen (level IV evidence) allows for adequate visualization of all compartments, assessment of muscle viability, and sufficient surgical control to avoid neurovascular structures.[40] A four-compartment release with fibulectomy performed through one lateral incision[41] (level IV evidence) takes advantage of the fascial anatomy, as all fascial membranes insert onto the fibula. This method is technically challenging, places the peroneal vessels at risk, and sacrifices the fibula. Both the two- and one-incision techniques are sufficiently effective at decreasing ICP;[40,42] the one-incision four-compartment fasciotomy without fibulectomy can be useful in cases where soft tissue trauma or contamination is of concern, including situations in which only a single vessel perfuses the leg, or when flap coverage may be necessary.

Level III evidence suggests open fasciotomies (performed by two-incision, one-incision, and fibulectomy techniques) for compartment decompression maximize postischemic tissue viability,[43] although they slightly increase the risk of

minor wound morbidity (superficial wound complications arose in 2 out of 19 patients).

Subcutaneous fasciotomy techniques have been described using cadaver specimens (level IV evidence), in which the fascia is incised blindly with dissecting scissors through a small skin incision.[44,45] Advantages include technical ease and cosmesis; however, access is limited to the deep posterior compartment and the neurovascular bundle (31% of specimen). In acute CS, the skin is an important boundary of all compartments that must be released to achieve the greatest decrease in ICP. While small incision fasciotomy and endoscopically assisted fasciotomy may have a role in chronic exertional CS, cadaver specimen studies have demonstrated that these techniques achieved adequate decompression in only 82% of cases,[46] suggesting that the recurrence of limb-threatening ischemia may occur despite fascial release when the skin is left intact.[45–48]

Resolution of clinical scenario

- In this clinical scenario, to avoid the potential for recurrence of CS, two-incision/four-compartment fasciotomy should be the preferred decompression method of choice in this acute leg CS.
- Level IV evidence suggests that small incision and endoscopically assisted fasciotomies do not provide sufficient decompression and should not be used in *acute* CS.

Summary of answers

- Open fractures can result in CS development if a sufficient portion of the deep fascia or skin remains

intact. Adequate suspicion must be maintained for all fractures (simple *and* compound).

- Compartment pressure monitoring is a valuable tool in confirming a diagnosis of acute CS. The threshold for decompression is a ΔP of 25–30 mmHg of mean arterial pressure.
- Two-incision/four-compartment fasciotomy is the safest choice in the leg for the release of ICP, allowing for adequate visualization of all compartments, assessment of muscle viability, and sufficient surgical control to avoid neurovascular structures.

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Noninvasive Technologies for Fracture Repair

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Clinical scenario

- You see a 32-year-old male who has sustained a comminuted open tibial shaft fracture as a result of a motor vehicle accident two months after the internal fixation.
- Radiographs show no sign of callus formation. There is no clinical, biochemical or radiographic evidence of infection. He has mild tenderness at the fracture site.
- Previously, he worked as a construction worker and wishes to return to his previous work as soon as possible. He does not wish to undergo secondary surgical intervention.

Top three questions

1. In patients with acute tibial fractures, does low-intensity pulsed ultrasound (LIPUS) accelerate fracture healing and improve health-related quality of life (QOL) of the patient compared to no treatment to accelerate fracture healing?

2. In patients with chronic tibial nonunion, does LIPUS promote fracture healing of nonunion and improve health-related QOL of the patient compared to no treatment to accelerate fracture healing?
3. In patients with acute tibial fractures, does pulsed electromagnetic field (PEMF) treatment and extracorporeal shockwave therapy (ESWT) accelerate fracture healing and improve health-related QOL of the patient compared to no treatment to accelerate fracture healing?

Question 1: In patients with acute tibial fractures, does low-intensity pulsed ultrasound (LIPUS) accelerate fracture healing and improve health-related quality of life (QOL) of the patient compared to no treatment to accelerate fracture healing?

Rationale

Length of time to fracture healing is of paramount importance to avoid prolonged periods of pain and disability. In vitro and in vivo studies have revealed that LIPUS increases cell proliferation, protein synthesis, membrane permeability, integrin expression, and cytosolic Ca^{2+} levels, which indicates bone repair response.[1] Several clinical studies support the use of LIPUS and it has been widely used to accelerate fracture healing in acute fractures and to prevent nonunion.[2–5] Clinical effectiveness of LIPUS on fracture healing and QOL of the patient has to be clarified.

Clinical comment

Approximately, 5% of fractures go on to nonunion.[6] Due to limited soft tissue coverage, the risk of developing nonunion is higher in tibia compared to other bones. In addition, the risk of nonunion is increased with increasing Gustilo–Anderson grades.[7]

Available literature and quality of the evidence

There are three randomized controlled trials (RCTs) of acute tibial fractures and two meta-analyses including other bones that are available to answer this question (all level I).[2–4,8–10] Earlier RCTs showed an effectiveness of LIPUS on radiographic union, but limitations of those studies are small sample size, risk of bias, inconsistent results, and lack of evaluation of patient-based outcome measures. Previous meta-analysis by Griffin et al. was based on those RCTs.[4] An RCT in 2016 which evaluated the functional outcome of patients who had sustained acute tibial fracture and subsequent meta-analysis has cast doubt on the effectiveness of LIPUS in acute fractures.[9,10]

Heckman et al. (level I) conducted an RCT in simple closed or Gustilo I open tibial fracture treated by cast.[2] Patients in the LIPUS group healed significantly faster both on radiographs and overall healing compared to the control group (86 ± 5.8 days vs 114 ± 10.4 days, $p = 0.01$, 96 ± 4.9 days vs 154 ± 13.7 days, $p = 0.0001$, respectively). The weakness of this study is that there is a 31% loss to follow-up. Leung et al. (level I) investigated the effect of LIPUS on fracture healing for open and/or severely comminuted tibial shaft fractures fixed by intramedullary nail or external fixator.[3] They concluded that the LIPUS-treated group showed statistically significantly better healing as demonstrated by all assessments. The downside of this study was high risk of bias such as selection bias and

detection bias. However, in the study of fresh tibial fractures treated with reamed and statically locked intramedullary nail by Emami et al. (level I), the average healing time was 155 ± 22 days (median 113 days) for the active treatment group and 125 ± 11 days (median 112 days) for the placebo group ($p = 0.76$).[8] It was concluded that LIPUS treatment did not shorten healing time. None of these studies measured the functional outcome and pain score of the patients. Based on the inconsistency and lack of patient-based outcomes in the result and high risk of bias, Busse et al. (level I) reevaluated the effectiveness of LIPUS compared with sham treatment in acute tibial fractures by randomized trial with a parallel group design of 501 patients.[9] According to their study, postoperative use of LIPUS after tibial fracture fixation did not accelerate radiographic healing as well as functional outcome. There was also no difference in time to radiographic healing (hazard ratio [HR] = 1.07; 95% confidence interval [CI]: 0.86–1.34; $p = 0.55$) and there was no improvement of functional outcome such as 36-item Short Form Health Survey (SF-36), time to return to work without limitations, time to return to household activities without limitations, time to full weight bearings, time to return to ≥80% of function before injury, and time to return to leisure activities without limitations. The risks of unplanned secondary procedures related to bone healing, infection, and nonunion were similar. Subsequent meta-analysis by Schandelmaier et al. (level I), including studies in fractures in other sites, stated that, from studies with a higher quality of evidence, LIPUS does not accelerate radiographic fracture healing, does not affect the risk of subsequent operation related to fracture healing, and does not affect outcomes important to patients.[10]

Findings

Overall, the RCT by Busse et al., which is larger and less biased compared to other RCTs, demonstrated that in the acute phase of tibial fractures LIPUS failed to show the acceleration of radiographic fracture healing and failed to show the prevention of nonunion. The same study suggests that LIPUS does not improve the functional outcome, such as SF-36 and the period going back to the work.

Resolution of clinical scenario

In this acute phase of fracture, there is high-quality evidence to support that the patient would not be benefit from LIPUS treatment in terms of accelerating radiographic union, preventing nonunion, and improvement of functional outcome.

Question 2: In patients with chronic tibial nonunion, does LIPUS promote fracture healing of nonunion and improve health-related QOL of the patient compared to no treatment to accelerate fracture healing?

Rationale

LIPUS has been used in chronic nonunion as well. Compared to secondary surgery for nonunion, LIPUS treatment is less invasive. However, there is also a failure of union after the use of LIPUS in the treatment of chronic nonunion.[11] Effectiveness of LIPUS in avoiding surgical treatment in chronic nonunion has to be clarified.

Clinical comment

In the event of established nonunion, patients normally require a secondary surgery for treatment. It is important for patients to know whether they can avoid the secondary surgery if they use LIPUS. If LIPUS is effective for established nonunion, it is less invasive for patients. In addition, it is more cost-effective, considering the cost of secondary surgery.

Available literature and quality of the evidence

Schofer et al. conducted an RCT (level I) in delayed unions of tibia and concluded that mean improvement in bone mineral density was 1.34 (90% CI: 1.14–1.57) times greater for LIPUS-treated subjects compared to sham subjects ($p = 0.002$).[12] A mean reduction in bone gap area also favored LIPUS treatment ($p = 0.014$). However, in this study there is no statistical difference of the healing rate between two groups: 65% (33 out of 51) of LIPUS and 46% (23 out of 50) of placebo treatment ($p = 0.07$).

Most of the studies related to the use of LIPUS in chronic nonunion are retrospective cohort studies, and those studies as well as RCT by Schofer et al. were summarized as meta-analysis by Leighton et al. (level 1).[13] By this meta-analysis, overall pooled estimate of effect size for healing was 82% (95% CI: 77–87, $I^2 = 71$) for any anatomical site. Subgroup analysis of the tibial nonunion with 354 patients showed 86% of healing rate (95% CI: 79–93) but with considerable heterogeneity($I^2 = 81$). Hypertrophic nonunion had more favorable results compared to atrophic nonunion (odds ratio [OR] = 2.11; 95% CI: 1.26–3.54, $I^2 = 6$). There is no study which compares LIPUS treatment and surgical intervention for nonunion.

Findings

Although one RCT showed the improvement of bone mineral density, this study failed to show the difference of healing rate between the LIPUS treatment group and the placebo treatment group.

Meta-analysis showed an 86% healing rate in chronic tibial nonunion using LIPUS. However, there was a high heterogeneity between studies. It is difficult to test the efficacy of LIPUS for nonunion by RCT. There is no study which evaluated the functional outcome in the use of LIPUS for chronic nonunion.

Resolution of clinical scenario

It is difficult to prove the efficacy of LIPUS over surgical treatment for chronic nonunion. However, given the reported union rate, LIPUS may be useful for treating nonunion, especially in patients who want to avoid secondary surgery.

Question 3: In patients with acute tibial fractures, does pulsed electromagnetic field treatment (PEMF) and extracorporeal shockwave therapy (ESWT) accelerate fracture healing and improve health-related QOL of the patient compared to no treatment to accelerate fracture healing?

Rationale

PEMF and ESWT are other types of bone stimulators. Electric and electromagnetic fields regulate the expression

of genes in connective tissue cells for extracellular matrix proteins, which results in an increase in cartilage and bone.[14] Shockwaves have been shown to produce oxygen radicals, which are supposed to play a key role in translating the mechanical energies of the shockwaves into biological effects.[15] Clinical effectiveness to support the use of PEMF and ESWT on bone union has to be determined.

Clinical comment

Although LIPUS is the most widely used method to accelerate fracture healing, it is important to evaluate the efficacy of other methods such as PEMF and ESWT to the patients.

Available literature and quality of the evidence

PEMF There is only one randomized trial (level I) testing the efficacy of PEMF treatment in acute tibial fractures. Adie et al. conducted a multicenter double-blind randomized trial with 259 acute tibial fracture patients and demonstrated that PEMF does not reduce the secondary intervention for nonunion. In their study, 16 out of 106 in the treatment group and 15 out of 112 in the placebo group needed surgical intervention because of delayed union or nonunion (risk ratio [RR]: 1.02; 95% CI: 0.95–1.14; p = 0.72).[16] They also tested the functional outcomes using the SF-36 and Lower Extremity Functional Scale scores at 12 months and found no difference between groups.

Aleem et al. conducted a meta-analysis (level I) to assess the efficacy of electrical stimulator for bone healing.[17] They included other bones and trials treating spinal fusion. In the subgroup analysis focused on fresh fractures, there was no difference of radiographic nonunion at last reported follow-up to 12 months (RR: 0.83; 95% CI: 0.51–1.35).

ESWT Wang et al. tested the efficacy of ESWT on acute fracture of the tibia and femur in 59 fractures by quasi-randomized trial (level I).[18] The rate of nonunion was 11% (3 out of 27) in the study group versus 20% (6 out of 30) in the control group ($p < 0.001$). Significantly better rates of fracture healing were noted in the study group than in the control group at 3, 6, and 12 months ($p < 0.001$). In addition, the Visual Analog Scale (VAS) score was better in the study group at 3, 6, and 12 months ($p < 0.001$). However, this study was quasi-randomized and the mode of the treatment was selected according to the days of the week, therefore increasing the risk of selection bias.

Findings

Level I studies showed that PEMF did not reduce the risk of nonunion rate of acute tibial fracture and did not improve the functional outcome of the patients. ESWT seems to reduce the nonunion rate of acute fractures of the tibia and femur and improve the VAS score. However, RCTs with better quality are needed.

Resolution of clinical scenario

ESWT but not PEMF might be beneficial to the patient in accelerating union of acute tibial fracture.

Summary of answers

- In acute tibial fractures, LIPUS does not improve the functional recovery of the patients, does not accelerate radiographic union of acute fractures, and does not change the risk of secondary surgery related to fracture healing.
- In chronic nonunion, patients might be able to avoid secondary surgery with LIPUS treatment.

- PEMF does not change the functional outcome of the patients.
- PEMF is unlikely to reduce the risk of radiographic nonunion in acute fractures or reduce the pain caused by fractures.
- ESWT seems promising to reduce the nonunion rate of acute fractures of the tibia and femur and improve the VAS score.

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Calcium-Based Bone Substitutes

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Clinical scenario

- A 54-year-old female presents with a fractured tibial plateau following a low energy injury at home.
- The patient's X-rays indicate a split depression injury laterally, with an associated medial condylar injury with a posterior medial split.

Top three questions

1. In periarticular fractures with joint depression, can calcium phosphate bone substitutes enhance the standard fixation when compared with autogenous bone grafting and fixation or fixation alone?
2. In patients with a fracture requiring bone graft augmentation, does the use of calcium phosphate

cement instead of autogenous iliac crest bone graft result in fewer complications?

3. In osteoporotic fractures, does calcium phosphate augmentation improve fixation of implants when compared with no augmentation of fixation?

Rationale

Periarticular fractures are common injuries that result from indirect coronal and/or direct axial compressive forces. As the patient ages, the fracture pattern is usually a split depression type without associated ligamentous injury. Surgical guidelines advocate anatomic reduction, re-establishment of the long bone alignment, subchondral bone grafting to support the articular cartilage, and stable internal fixation.[1]

Clinical comment

Metaphyseal fractures are among the most difficult fractures to treat. Depressed articular fragments can crush the underlying weak subchondral cancellous bone, leaving a void when the articular segments are reduced surgically. Potential long-term problems including pain, post-traumatic arthritis secondary to apoptosis of the chondrocyte, and limitation of motion and function might occur if joint surface subsidence cannot be prevented or at least limited.

Available literature and quality of the evidence

Russell et al. compared the treatment of subarticular bone defects in tibial plateau fractures with conventional autogenous iliac bone graft (AIBG) to bioabsorbable calcium phosphate paste (alpha-BSM, Etex Corporation) in a randomized controlled trial (RCT).[1] All fractures united in both groups within the same time periods.

There was an unexpected statistically significant (p = 0.009, Fisher's exact two-tailed test) higher rate of articular subsidence in the AIBG group compared to the alpha-BSM group. Subsidence of equal to or greater than 2 mm on the anteroposterior radiographs was found in 31% of patients in the AIBG group compared to 8% in the alpha-BSM group in the final evaluation. This provided level I evidence that bioabsorbable calcium phosphate material, such as alpha-BSM, appeared to be a better choice for the treatment of subarticular defects than AIBG in tibial plateau fractures.

Johal et al. performed a similar RCT on os calcis fractures comparing open reduction and internal fixation (ORIF) plus alpha-BSM to ORIF alone in the treatment of calcaneal bone voids encountered after operative treatment of displaced intra-articular fractures of the calcaneous.[2] There was no difference between the groups in the degree of collapse of Bohler's angle at six weeks and three months when compared to initial postoperative values. However, at six months the mean collapse of the alpha-BSM and ORIF group was 5.6° (standard deviation [SD] 4.5) and ORIF alone was 9.1° (SD 5.8). This was statistically significant (p <0.01).

Findings

Level I evidence suggests that the addition of calcium phosphate to internal fixation in periarticular fractures is more supportive than fixation alone or fixation with autologous bone graft. Although the radiographic outcomes were better with calcium phosphate, these studies were not powered to detect differences in patient-reported outcome scores.

Resolution of clinical scenario

- For ORIF of tibial plateau fractures, calcium phosphate reduces articular subsidence better than autogenous iliac crest bone graft.
- For ORIF of os calcis fractures, calcium phosphate reduces articular subsidence better than fixation alone.

Question 2: In patients with a fracture requiring bone graft augmentation, does the use of calcium phosphate cement instead of autogenous iliac crest bone graft result in fewer complications?

Rationale

Autogenous bone graft, typically from the iliac crest, has been stated in the past to be the gold standard of bone grafting. However, it is associated with donor site morbidity including chronic pain and wound complications.[3–9] Calcium phosphate cement has increased compression strength and improved custom-filling of bone defects. However, any alternative graft material should have a better risk/benefit profile than the current standard.

Clinical comment

Alternative grafting materials for filling fracture voids include allograft and synthetic bone materials. While using allograft avoids the donor site morbidity associated with autograft, it also can lead to complications including potential disease transmission, host–donor incompatibility, and possibly lower union rates.[10–12] Therefore, synthetic bone materials, such as calcium phosphate bone cement, appear to be an attractive alternative. They perform better

acutely and over the first year and lack the disadvantage of bone site morbidity or the potential for infection and disease transmission associated with allograft.

Available literature and quality of the evidence

There are several narrative review articles that address the use of bone grafting in fractures and trauma situations.[3–16] In addition, Bajammal et al. have completed a meta-analysis (level I evidence) of studies comparing calcium phosphate bone cement to bone graft.[17] The meta-analysis included 14 RCTs. The studies had documented outcomes that included pain, maintenance of fracture reduction, infection, and functional outcomes.

Findings

The meta-analysis found there was a lower prevalence of pain at the fracture site in the calcium phosphate group (n = 455 patients) (relative risk = 0.57; 95% confidence interval [CI]: 0.33–0.99]; relative risk reduction = 43%; 95% CI: 1–67%; p = 0.04; heterogeneity tests, p = 0.39, I^2 = 0%). They were not able to pool the functional outcomes across the studies; however, the results of individual studies suggested improved functional outcomes in association with the use of calcium phosphate cement.

There was no significant difference in the prevalence of infection between the calcium phosphate bone cement group and the control group (relative risk = 0.74; 95% CI: 0.19–2.87], p = 0.66; heterogeneity, p = 0.03, I^2 = 59%); however, the use of calcium phosphate significantly reduced the risk of infection in patients with distal radial fractures (relative risk = 0.15; 95% CI: 0.15–0.42; p <0.0001; relative risk reduction = 85%; 95% CI: 58–85%).

Calcium phosphate reduced the risk of loss of reduction compared with autogenous bone graft by 68% (n = 166,

relative risk = 0.32; 95% CI: 0.14–0.70; p <0.001; relative risk reduction = 68%; 95% CI: 30–86%]; number needed to treat, 6; heterogeneity, p = 0.87, I^2 = 0%) and in patients with tibial plateau fractures specifically, the benefits were similar (relative risk = 0.3; 95% CI: 0.13–0.72], p = 0.007; relative risk reduction = 70%; CI: 28–87%; number needed to treat, 6; heterogeneity, p = 0.64, I^2 = 0).

The cost of autogenous bone graft harvesting was investigated in a study by St John et al.[18] The direct and indirect costs involved in harvesting iliac crest were gathered from a cross-section of hospitals in the United States via a questionnaire completed by both finance and surgical personnel. The study concluded the mean cost of autologous bone graft is estimated to be $4154, assuming a hospital stay extended by one day. In comparison, 10 cc of alpha-BSM, a common amount used in Russell's trial,[1] has an average cost of $1270. Additional cost savings include no additional tray instrumentation and a reduction in operating time and postoperative complications.

Resolution of clinical scenario

- Anterior iliac crest bone grafting (AICBG) often results in donor site pain and morbidity.
- Calcium phosphate cement is associated with less pain.
- Calcium phosphate cement decreases the risk of losing fracture reduction.
- Calcium phosphate cement lowers the infection rate in distal radius fractures.
- Some studies have reported better functional outcomes with calcium phosphate cement.
- Inclusive healthcare costs are actually less with calcium phosphate than iliac crest autograft if it saves

the patient a day or more in hospital.

Question 3: In osteoporotic fractures, does calcium phosphate augmentation improve fixation of implants when compared with no augmentation of fixation?

Rationale

Osteoporotic cancellous bone has high porosity and low mechanical strength. Calcium phosphate can be manufactured into various forms, including ceramics, powders, and cements. These can also be manufactured with varying porosity structures and therefore variable compressive strengths from 4 MPa to 60 MPa. In addition, calcium phosphate cements may be molded or injected to custom-fill defects.

Clinical comment

Osteoporotic fractures remain difficult to treat. Calcium phosphate bone substitute material (BSM) can be used to provide a scaffold for new bone ingrowth and also augment fracture hardware, such as bone screws. With the advances in minimally invasive surgical stabilization of fractures, the need for less invasive delivery systems for bone graft substitutes has driven new research into the fluid dynamics of self-setting bone graft substitutes to allow percutaneous application without the previous necessity of large dissections to open the fracture cavities.[19] The previous generations of calcium phosphate synthetic BSM were nonintrusive nonnewtonian fluids that were not amenable to conventional needle injection techniques. The addition of viscosity modifiers such as carboxymethylcellulose and

surfactants/biodegradable oils to calcium phosphate cements changes their flow characteristics to allow controlled flow and good trabecular intrusion.[19] N-Force Blue (Zimmer Biomet, Warsaw, IN) and IN3 (Innoterre, Radebeul, Germany) have received regulatory clearances and marketed in the United States and Europe, respectively, permitting controlled augmentation of the osteopenic bone around implants. An example of this augmentation is a new development of a fenestrated screw or intraosseous implant optimized for hydraulic flow of calcium phosphate cement to fill the defective cancellous bone architecture but also to permit augmentation of the overlying cortex at the implant insertion site. This technique serves to reinforce the structural stability of the implant along its length and not just at one location. The N-Force Fixation System (Zimmer Biomet, Warsaw, IN) was the first FDA-cleared fracture implant with this ability and has been available in Europe and the United States. Cortical replacement by synthetic bone substitutes in diaphyseal fractures is not yet possible, but three-dimensional printing developments may yield such materials in the near future.

Available literature and quality of the evidence

Literature is available for calcium phosphates use in osteoporotic fractures of the proximal humerus, distal radius, vertebra, hip, and tibial plateau. Unfortunately, much of the literature reports retrospective studies or case series (level III–IV).[20–23]

Some level I evidence is available for osteoporotic distal radius fractures,[24] hip fractures,[25] and tibial plateau fractures.[26]

Findings

Cassidy et al. performed a randomized trial of distal radius fractures treated with closed reduction and casting or external fixation versus the same augmented with calcium phosphate cement.[24] They found early benefits such as increased grip strength and range of motion in the augmented group but by one year there were no clinical differences between groups.

Lindner et al. performed a systematic review of the role of bone substitutes in the treatment of osteoporotic hip fractures.[25] They only identified two randomized trials each related to the use of calcium phosphate in displaced femoral neck fractures and unstable intertrochanteric fractures. In femoral neck fractures they recommend against the use of calcium phosphate augmentation due to a trend toward more reoperations in the augment group with no long-term advantages. For intertrochanteric fractures they found a modest reduction in pain and a slight improvement in quality of life, but follow-up was only six months.

Goff et al. reviewed the use of bone graft substitutes in tibial plateau fractures.[26] Overall, results favored the use of bone graft substitutes. Osteoporotic fractures were included in the trials reviewed, but none of the trials was on solely osteoporotic fractures.

Robinson et al. reported good functional outcome with calcium phosphate as an augment in a series of severely impacted valgus fractures of the proximal humerus.[22] Ryu et al. found that early benefits, such as decreased pain and disability scores after using injectable calcium phosphate in balloon kyphoplasty for osteoporotic vertebral fractures, decreased within six months as vertebral height loss decreased and kyphotic angle increased.[27]

Resolution of clinical scenario

- There is not enough evidence to recommend the routine use of calcium phosphate to augment osteoporotic fractures.
- Short-term results of calcium phosphate use in intertrochanteric fractures favor the use of calcium phosphate, but long-term evidence is not available.
- Results with femoral neck fractures have not been favorable to date but low numbers and no long-term follow-up are limitations with this literature.

Summary of answers

- Calcium phosphate provides stronger support to subchondral bone than autogenous bone graft or fixation alone.
- Calcium phosphate decreases the risk of losing fracture reduction.
- Calcium phosphate results in less pain than AICBG.
- Calcium phosphate lowers the infection rate in distal radius fractures.
- There is not enough evidence to recommend the routine use of calcium phosphate as an augment to osteoporotic fractures but as an addition to a good construct it may add support.

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76
Scapula Fractures

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Clinical scenario

- A 28-year-old snowboarder crashed into a tree and was dazed at the scene, had labored respirations, and carried off via stretcher and airlifted to a level I trauma center.
- A trauma work-up revealed a Glasgow Coma Score of 13 in a mildly disoriented male who complained of severe shoulder, chest, and back pain.
- History revealed that he was a right-handed warehouse stockman who was otherwise healthy. Physical exam revealed left-sided facial lacerations and an abrasion over a tender mass at the acromion. He had a strong grip, intact sensation of C5–T1, but an inability to forward elevate or externally rotate the shoulder.

Radiography

A chest X-ray revealed four consecutive left-sided rib fractures and a pneumothorax, prompting dedicated shoulder X-rays. A fracture of the scapula in the region of the glenoid neck in addition to a displaced acromioclavicular (AC) joint was diagnosed. Moderate displacement at the lateral scapula border, and a glenopolar angle (GPA) of 63° as seen on the anteroposterior (AP) view, with an angular deformity of 21° measured on the scapula Y X-ray, prompted a computed tomography (CT) scan.

On three-dimensional (3D) CT, the patient had 20° of angulation, 150% translation and 0.5 cm of displacement of the lateral border. Fracture lines propagated into the spinoglenoid notch, and out the scapular spine, and vertebral border. A two-dimensional (2D) CT revealed no intra-articular involvement, however there was significant displacement at the base of the coracoid, and a retroverted glenoid neck of 11°.

Top three questions

1. For patients with a scapula fracture, does CT, compared to plain X-rays, provide an advantage in terms of diagnosis and management?
2. In patients with scapula fractures, does operative management, compared to nonoperative management, result in better outcomes?
3. In patients with scapula fracture, do rehabilitation protocols differ for those who have undergone surgery compared to those managed nonoperatively?

Question 1: For patients with a scapula fracture, does CT, compared to plain X-rays, provide an advantage in terms of diagnosis and management?

Rationale

Scapula fractures account for approximately 1% of all fractures, about the same percent as calcaneus fractures and exceeding that of the talus fractures. Therefore, this injury is quite relevant; particularly for trauma centers, where such injuries are filtered with regularity.

Clinical comment

A history should render the patient's job description and recreational activities. The shoulder can compensate adequately for lower functioning individuals; therefore, not every displaced scapula fracture requires surgery. A physical exam should include whether abrasions exist over the shoulder, palpation of the AC and sternoclavicular joints, and a neurovascular exam of the extremity. When the patient can be upright, they must be examined disrobed to appreciate shoulder drooping, which is bothersome in severe cases.

Available literature and quality of the evidence

There are level IV and level V studies available to answer this question.

Findings

Shoulder X-rays yield the detail necessary to determine whether or not there is displacement of a fracture. If on the

radiographs, there is displacement of a fracture greater than one centimeter, a 3D CT should be obtained to specifically measure displacement and angulation. In nondisplaced fractures in which nonoperative treatment has been selected, weekly follow-up films over two weeks should be obtained due to the risk of displacement (level IV).[1]

Oftentimes, scapula fractures are delayed in referral or workup, either because of missed injury, or treatment of other bodily injuries, or the time it takes to refer to an appropriate medical center (level IV).[2] In cases when such delay is greater than two weeks, an EMG and nerve conduction study should be performed due to a high association with nerve injuries (level V).[3] This information is helpful for preop planning and prognostication. A 2D CT scan is useful when there is intra-articular involvement to determine step, gap, and number of fragments.

Resolution of clinical scenario

- Medialization, angulation, GPA, and intra-articular step-off should be measured. Medialization is often misunderstood, and represents the displacement at the fractured lateral border, or the position of the proximal relative to the distal main fragments.
- *Angulation* refers to the angle measured between the lateral borders on the scapula Y view.
- GPA measures the inferior rotation of the glenoid (on its proximal fragment) relative to the body as measured off an AP image.
- A 3D CT scan is vital for accuracy since this modality allows for the perfect rotation of the images to get an accurate *AP and Y view*.

Question 2: In patients with scapula fractures, does operative management, compared to nonoperative management, result in better outcomes?

Rationale

There are multiple opinions on the degree of displacement or angular deformity which warrant open reduction and internal fixation (ORIF). It is important to understand when to operate on patients with scapula fractures.

Clinical comment

It is important to understand which fractures require surgical treatment. For those which do require operative management, it is also important to understand which surgical approach is optimal.

Available literature and quality of the evidence

There are level IV and V studies available to answer this question.

Findings

Though nonoperative treatment of double lesions of the superior shoulder suspensory complex have been shown to eventuate in good or excellent outcomes, it is likely that such series reflected minimally displaced injuries since almost no malunions were reported (all level IV) (Table 76.1).[4–7] Nonoperative series to date have not stratified data based on measured displacement, and rigorous outcomes assessment of strength, motion, and function are lacking in those series (all level IV) (Table 76.1).[4–8]

Furthermore, other authors have reported patients with malunion which eventuated in poor outcomes, indicating that not all malunions are benign (all level IV).[9–11] One study demonstrated increased pain and dysfunction and/or decreased motion in almost half of patients who were malunited.[7]

These have included displaced articular injuries between 4 and 10 mm (all level IV),[2,19–21] fractures with lateral border displacement (*medialization*) of 10–20 mm (all level IV),[2,11,19,22] angular deformity of 25–45°,[2,11,19,22] and a GPA of <20°.[9,10] Some authors feel that excessive translation and version of the proximal relative to the distal fragment should be considered a relative indication for surgery (level IV and V, respectively).[1,23] Though there is no “high level” evidence to date, deductive reasoning would lead us to believe that some degree of displacement and angular deformity will yield an adverse clinical result. If function and form are interdependent then malunion results in compensation, and by definition compensation has some physiologic cost. Experts differ as to what amount and type of displacement warrants intervention, but there is growing consensus, given the positive surgical results on record, that operative correction of displaced scapula fractures is beneficial for a subset of patients.

Table 76.1 Current evidence in floating shoulder fractures.

Author	**Level of Evidence # of Patients # Followed/Total (% Follow-up)**	**Summary**
Therapy		
Herscovici D, et al. (1992)	IV 2 Nonop/7 Op/2 LTF 9/11 (82%)	The authors reviewed 9 patients having double lesion injuries and recommended the use of anteroposterior radiographs of the clavicle and scapula, and trans-scapular views. Internal fixation of the clavicle should be performed as soon as possible to prevent malunion of the scapular-neck fracture.
Leung KS and Lam TP (1993)	IV 15 Operative 15/15 (100%)	The authors found that operative treatement for ipsilateral fractures of the scapular neck and the clavicle is safe and that functional recovery is predictably good with most patients regaining normal function of the shoulder soon after injury. With fixation of both fractures, postoperative rehabilitation is greatly facilitated.

Author	**Level of Evidence # of Patients # Followed/Total (% Follow-up)**	**Summary**
Rikli D, et al. (1995)	IV 12 Operative 12/12 (100%)	The authors found that in an unstable shoulder girdle, the therapeutic goal can be reached with ORIF of the clavicle alone. The fracture of the scapular neck is usually reduced indirectly and sufficiently stable for functional aftertreatment. ORIF of the scapula is therefore, only necessary in displaced intra-articular fractures.
Oh CW, et al. (2002)	IV 3 Nonop/10 Op 13/13 (100%)	The authors found that surgical treatment for double disruption of the SSSC is a good option, allowing for early rehabilitation and giving good functional results.
Prognosis		

Author	Level of Evidence # of Patients # Followed/Total (% Follow-up)	Summary
Ramos L, et al. (1997)	IV 16 Nonoperative 13/16 (81%)	The authors found that after a mean follow-up of 7.5 years, the functional results were good or excellent in 92% of the cases and propose that successful nonoperative treatment was due to intense physical therapy, and to the fact that most clavicular and scapular fractures do not require formal reduction for healing, and vicious callus are well tolerated by most patients.
Edwards SG, et al. (2000)	IV 36 Nonoperative 20/36 (56%)	The authors concluded that many floating shoulder injuries are not as unstable as was previously thought and do not require operative fixation. None of the functional assessments utilized identified poor outcomes and thus, it is difficult to identify factors that might predict which fractures will do well with nonoperative treatment and which will have a better result with surgery.

Author	Level of Evidence # of Patients # Followed/Total (% Follow-up)	Summary
Egol KA, et al (2001)	IV 12 Nonop/7 Op/4 LTF 19/23 (83%)	The authors concluded that good results may be seen both with and without operative treatment, and therefore do not universally recommend operative treatment for double disruption of the superior suspensory complex. Treatment must be individualized for each patient.
Van Noort A, et al. (2001)	IV 31 Nonop/4 Op/11 LTF 35/46 (76%)	The authors conclude that ipsilateral fractures of the neck of the scapula and of the clavicle is not inherently unstable and, in the absence of caudal dislocation of the glenoid, conservative treatment gives a good functional outcome.

Author	Level of Evidence # of Patients # Followed/Total (% Follow-up)	Summary
Hashiguchi H and Ito H (2003)	IV 5 Operative 5/5 (100%)	The authors conclude that for a patient with a floating shoulder, it is important to determine the severity of fracture displacement accurately and the presence or absence of coraclavicular ligament rupture radiographically. On the basis of those factors, an appropriate treatment for both fractures that may lead to a satisfactory clinical outcome can be determined.
Labler L, et al. (2004)	IV 8 Nonop/9 Op 17/17 (100%)	The authors concluded that nondisplaced or less displaced floating shoulders are expected to give good results after nonoperative treatment and recommend operative treatment in cases of displacement of scapular neck fracture of more than 25mm and/or reduction of the glenopolar angle less than 30 degrees as an indirect sign for ruptured associated ligaments.

Fractures of the scapula neck and body should be addressed through a posterior approach. There have been a number of modifications to the posterior Judet approach,[24] which are variations on the theme of invasiveness (level IV and V).[19,25,26] Either the entire rotator cuff (and deltoid) can be mobilized from the vertebral border to the lateral border on the neurovascular pedicle or muscular intervals between the infraspinatus and teres minor can be utilized to spare the muscles of detachment from their origins. Such an interval allows good access to the articular surface (level IV).[26] A straight posterior approach to the glenoid neck can be used for fractures isolated to the posterior glenoid or those lateral to the acromial base. The only glenoid fracture associated with the scapula body, which should be addressed from anterior rather than posterior, are those involving the superior coronal half extending into the superior fossa, usually inferior to the coracoid. Sometimes the coracoid itself is detached at the base in these variants.

Most articular fractures, however, are best accessed through a deltopectoral approach, as the version of the glenoid allows for better visualization from anterior, either through an arthrotomy or through a fracture interval. A transaxillary approach has also been described for inferior glenoid fractures in the frontal plane (level V).[27]

Resolution of clinical scenario

- Displacement and intra-articular disruption are key considerations in terms of deciding on a management plan.
- Most articular fractures, however, are best accessed through a deltopectoral approach.

Question 3: In patients with scapula fracture, do rehabilitation protocols differ for those who have undergone surgery compared to those managed nonoperatively?

Rationale

Eighteen muscles insert on, originate from, or traverse the scapula. This bone provides interplay between the clavicle, humerus, and the thoracic cage, as well as provides the conduit for the suprascapular nerve and protection of the brachial plexus. Thus, appropriate rehab is critical to recovery.

Clinical comment

It is important to mobilize patients as soon as safely possible. However, it is unclear how long this timeline should be for operative versus nonoperative management.

Available literature and quality of the evidence

Only level IV evidence exists to answer this question.

Findings

One of the goals of surgery is to achieve stability, which means that the fixation can withstand physiologic motion. Intraoperatively, the patient should be taken through a range of motion to prove such stability has been accomplished. To our knowledge, different rehabilitation regimens have not been studied or compared after scapula fractures.

The only caveat for physical therapy and rehabilitation in nonoperated scapula fractures is that the patient requires a

period of immobilization due to the instability of the fragments. Not only are they too painful for a few weeks to begin motion, but there is a risk of further displacement if motion ensues too early.[1] This period of immobilization is not benign, as extrinsic adhesions establish, and must be overcome.

Resolution of clinical scenario

- Physical therapy protocols are generally similar for operative and nonoperative management.
- Little evidence exists on this topic.

Summary of answers

- Displacement and intra-articular disruption are key considerations in terms of deciding on a management plan.
- Most articular fractures, however, are best accessed through a deltopectoral approach.
- Physical therapy protocols are generally similar for operative and nonoperative management.
- A 3D CT scan is vital for accuracy since this modality allows for the perfect rotation of the images to get an accurate *AP and Y view*.

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77
Sternoclavicular Joint

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Clinical scenario

- A 30-year-old male passenger presents status post T-bone motor vehicle collision with right-sided anterior superior chest pain, ecchymosis, and swelling.
- Reports difficulty swallowing, guarded right shoulder range of motion, and tenderness at the right sternoclavicular (SC) joint.
- Computed tomography (CT) scan with three-dimensional (3D) reconstructions show a posterior SC joint dislocation.

Top three questions

1. In patients with posterior SC joint dislocations does CT provide a better understanding of the injury severity when compared to plain radiographs?
2. In patients with an SC joint dislocation undergoing closed reduction, is the shoulder abduction and traction technique more successful and have fewer complications than other closed reduction techniques?
3. In patients with an SC joint dislocation, does open fixation with allograft or autograft result in improved

patient outcomes when compared to open fixation with metal implants?

Question 1: In patients with posterior SC joint dislocations does CT provide a better understanding of the injury severity when compared to plain radiographs?

Rationale

The clinical anatomy and mechanism of injury associated with posterior SC joint dislocations is complex. A thorough understanding is the first step in evaluating the injury and directing treatment.

Clinical comment

Posterior SC joint dislocations are morbid and, in some cases, life threatening.

Available literature and quality of the evidence

- 1 level IV
- 8 level V.

Findings

The SC joint, an inherently unstable diarthrodial synovial joint, requires stabilization by intrinsic and extrinsic structures to maintain congruency.[1–3] In the event of traumatic injury, thorough evaluation of the joint capsule and surrounding structures must be completed to determine joint stability and injury extent.

The articulating surface of the SC joint is oriented in an anterior lateral to posterior medial sloping direction with a relatively flat articular surface in the axial plane (Figure 77.1)[1] Intrinsic and extrinsic stabilizers as well as the surrounding musculature provide added stability.[1,4] The posterior ligamentous complex is crucial for joint stability regardless of dislocation direction.[1,5] When the posterior capsule is disrupted there is an estimated 41% increase in anterior translation and 106% increase in posterior translation of the joint.[5] Only 25% anterior and 0.7% posterior translation of the SC joint occurs with anterior capsule disruption.[5] When all but the capsular ligaments were disrupted, no significant instability was reported.[6] Subclavius adds additional protection by reducing the upward displacement of the clavicle under compressive loads.[2]

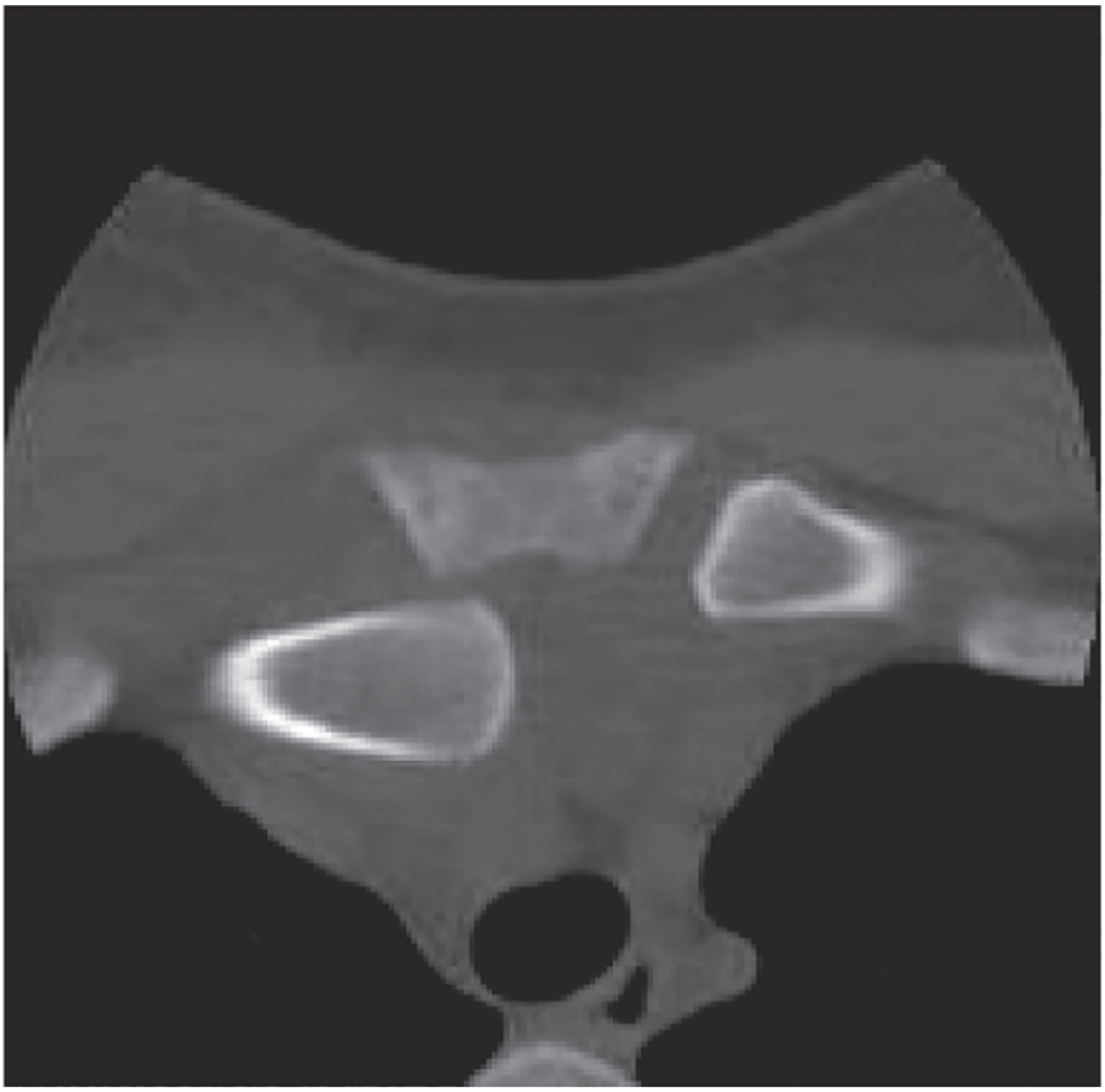

Figure 77.1 CT axial image of a posteriorly dislocated SC joint. Source: Image adapted from Bontempo and Mazzocca.[10]

Traumatic posterior SC joint dislocations occur due to a direct anteromedial force over the medial clavicle or an indirect force onto the posterior lateral shoulder. The amount of initial displacement reflects the magnitude of the applied force and degree of soft tissue injury.[4] Of note, the medial clavicular physis is the last to fuse.[1] Therefore, a

physeal fracture dislocation is more common in individuals under 25 years of age.[1]

Posterior SC joint dislocations are associated with a 3–4% mortality rate secondary to life-threatening neurovascular, tracheal, and esophageal injuries.[7] The brachiocephalic veins lie immediately posterior to the SC joints bilaterally increasing the risk for massive hemorrhage after dislocation or during reduction. Literature review of 60 cases of SC dislocations report a 26% incidence of mediastinal complications.[8] Common compressive symptoms include dysphagia, dyspnea, or vascular/neurologic compromise.[1,7] Urgent reduction of posterior dislocations are recommended.

CT scans should be obtained for any patient with concern of posterior SC dislocation. CT scans provide valuable information on displacement and the integrity of surrounding structures.[4] CT angiograms provide excellent visualization of vascular structures and 3D reconstructions prove beneficial in determining the degree of vertical displacement (Figure 77.2).[4] Chest X-rays or dedicate clavicular films may provide additional information about associated intrathoracic injuries or increase the suspicion for an SC joint dislocation; however, CT scans provide better diagnostic images.[2,9]

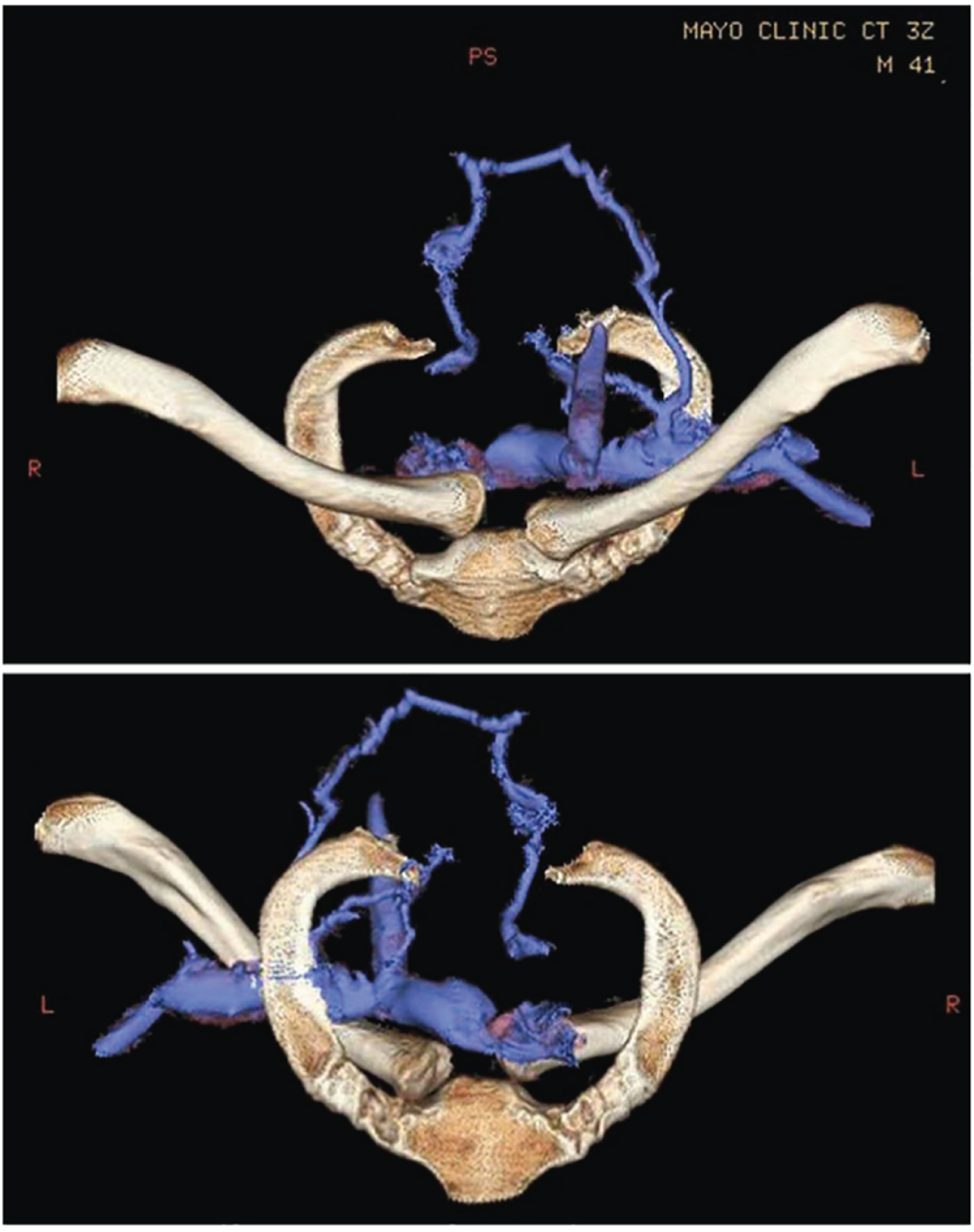

Figure 77.2 3D CT reconstruction of a right posteriorly dislocated SC joint with venous compression. Source: Imaged adapted from: Hoekzema.[11]

Resolution of clinical scenario

- The posterior ligamentous complex is crucial for SC joint stability. Their structural integrity is best appreciated on a CT scan.
- Visualization of posterior structures is best on a CT scan, which can help evaluate potentially life-threatening injuries.
- All suspected SC joint dislocations should be evaluated with CT as the diagnostic sensitivity of plain radiographs are low.

Question 2: In patients with an SC joint dislocation undergoing closed reduction, is the shoulder abduction and traction technique more successful and have fewer complications than other closed reduction techniques?

Rationale

Multiple closed reduction techniques exist for posterior SC joint dislocations. Therefore, knowledge of the unique set of complications and outcomes for each technique is imperative for successful reduction and patient communication.

Clinical comment

Traumatic posterior SC joint dislocations are rare. Missed or unsuccessfully managed dislocations can lead to devastating complications. Correctly identifying patients

who need transfer to a tertiary care center is paramount to successful management.

Available literature and quality of the evidence

- 4 level IV
- 4 level V.

Findings

Unlike anterior dislocations, all posterior SC joint dislocations require reduction.[12] Closed reduction is considered first line management of acute posterior SC joint dislocations without mediastinal compression.[1] Close reductions should be performed under general anesthesia in an operating room; consideration of the posterior vascular structures must be taken; blood products should be available; a cardiothoracic surgeon should be on standby; and most importantly, if attempted closed reduction is unsuccessful, the surgeon must be comfortable performing an open reduction and internal stabilization. If cardiothoracic support or orthopedic expertise is not available, transfer of a stable patient to a tertiary care facility is crucial to provide appropriate treatment. After reduction, CT scans are mandatory to confirm SC joint relocation.[4]

Several closed reduction techniques are reported in the literature, including the shoulder abduction and traction technique, the Buckerfield et al. technique and the Rockwood percutaneous sterile towel clamp assisted technique.[1,13] During the shoulder abduction and traction technique, traction should always precede extension of the arm to prevent the anterior clavicle from binding on the posterior surface of the manubrium.[12] Buckerfield et al. found that the use of an interscapular bolster and caudal

traction applied to an adducted ipsilateral arm achieved reduction of SC joint dislocations in six of seven patients who failed prior reductions.[13] Of note, this study included patients aged 13–26 and did not distinguish between physeal fracture dislocations and pure ligamentous dislocations.

The Rockwood technique utilizes a percutaneously placed towel clamp to apply an anteriorly directed force on the medial clavicle and is typically utilized after failure of a purely closed technique.[14] Significant swelling associated with SC joint dislocations is common and errant clamp placement can cause considerable damage to surrounding structures.[4] The authors do not use this and advise extreme caution with this technique.

Groh et al. reported a closed reduction success rate of ~52% in 21 patients within 10 days of initial injury.[15] Nine reductions were performed with purely closed techniques and two with the aid of a sterile towel clamp.[15] Three of the 11 initially successful reductions re-dislocated.[15] The remaining 13 either had a failed reduction or had symptoms secondary to posterior compression and subsequently underwent successful open reductions.[15] Final evaluation showed good to excellent results in 18 of the 21 patients reviewed.[15] Laffosse et al. reported a purely closed reduction technique success rate of 50% in 10 patients.[16]

Post-reduction protocol should include post-reduction CT scan and immobilization with gradual return to activity. Proposed protocols include figure-of-eight clavicular brace for at least six weeks and active strengthening and range of motion exercises at ~12 weeks.[17]

Resolution of clinical scenario

- Case reports show closed reduction attempts of posterior SC joint dislocations are successful less than 50% of the time regardless of technique.
- The percutaneous towel clamp technique can be utilized after failure of a purely closed reduction attempt.
- The surgeon performing the closed reduction must be able to perform an open reduction or the patient should be transferred.

Question 3: In patients with an SC joint dislocation, does open fixation with allograft or autograft result in improved patient outcomes when compared to open fixation with metal implants?

Rationale

There is no universally accepted open reduction method for posterior SC joint dislocations. A thorough knowledge of successful and unsuccessful techniques, complications, and outcomes is imperative for successful treatment.

Clinical comment

There are a wide variety of internal stabilization methods with the primary goal of recreating joint forces that mimic the native intrinsic and extrinsic stabilizers.

Available literature and quality of the evidence

- 2 level IV

- 7 level V.

Findings

Understanding the morbidity associated with persistent posterior SC dislocations, the authors prefer open reduction of all posterior SC dislocations. As exsanguinating hemorrhage is possible, we recommend all patients be typed and crossed for four units of blood, large bore IV access is established, and cardiovascular surgeons are available for possible vascular control. All patients are consented for open reduction and internal stabilization and risks to damage of posterior structures are discussed.

No gold standard technique for internal stabilization of posterior SC joint dislocations exists. All proposed techniques are technically demanding and should be performed by experienced surgeons. The authors prefer the patient supine with a *horseshoe headrest*. An incision is made over the medial clavicle and manubrium in Langer's lines. A large part of the dissection is typically already completed by the trauma, with the pectoralis major avulsed from the inferior clavicle. A malleable retractor is carefully placed behind the manubrium and clavicle, as a safe stop for the drill. Doubled #5 suture or tendon allograft in a figure-of-eight configuration is passed with looped dental/surgical wire from medial to lateral through two 3.2 mm or 4.5 mm sternal drill holes. The graft is sewn into itself in a Pulvertaft weave anteriorly.[18,19]

Case series and biomechanical studies have been reported on the use of soft tissue allografts for SC joint stabilization. Booth et al. described a technique to reconstruct the costoclavicular ligament in which the distal attachment of the sternocleidomastoid (SCM) along with a strip of local periosteum is passed under the first rib and through a drill

hole located in the medial clavicle. The SCM is then reattached to itself proximally.[20]

Spencer et al. performed a biomechanical study examining the joint stiffness and peak loads to failure of an intramedullary ligament reconstruction versus subclavius tendon reconstruction versus a figure-of-eight semitendinosus graft.[18] The semitendinosus reconstruction restored native joint stiffness better than the other two techniques, especially in the posterior direction (241.4 ± 49.7 N: semitendinosus reconstruction, 85.0 ± 22.8 N: intramedullary ligament reconstruction, 51.5 ± 28.9 N: subclavius tendon reconstruction [$p = 0.004$]).[18] No clinical outcomes could be extrapolated, but it is predicted from the biomechanical data that the semitendinosus reconstruction may produce superior clinical results.

Abiddin et al. reported on a cohort of eight patients with symptomatic SC joint instability stabilized capsular plication and medial clavicular and lateral manubrial suture anchors.[21] The mean follow up was 4.5 years, with no subsequent instability events; seven of eight patients returned to work and only one reported poor results (constant score of 33).[21]

Franck et al. described the Balser plate technique in nine patients after traumatic instability of their SC joint.[22] The goal of this technique is to avoid prolonged postoperative immobilization and allow early physiotherapy.[22] The plate, similar to a hook plate, is placed on the posterior aspect of the manubrium and anterior aspect of the medial clavicle.[22] There were no reported re-dislocations. All plates were removed to avoid migration.[22] Brinker et al. reported on the use of two seventy-five-millimeter 7 mm cannulated screws in a small two-patient cohort with unstable posterior SC joint dislocations.[23] Both patients returned to

the operating room in three months for hardware removal.[23] Both were noted to have a strong neocapsule formation.[23] During recovery, no precautions were taken to limit stress across the SC joint.[23] At 10 months patients had painless full range of motion.[23]

Wallace et al. described a technique using a synthetic braided polyester mesh device to reconstruct the costoclavicular ligament.[1] A histological examination of the tissue created around the mesh in acromioclavicular joint reconstructions was likened to the creation of a fibroblast outer capsule.[1] Overall, this technique has been used for more than 15 years with over 11 000 implanted with very few reported explants or devices failures.[24]

Historically, Kirschner wires (K-wires) were used for stabilization of SC joint dislocations. However, catastrophic failure resulting in a high mortality rate made the use of K-wires contraindicated. Lyons et al. described K-wire stabilization in 21 SC joint dislocations.[25] The results were disastrous with eight deaths due to K-wire migration into major vascular structures and six reports of postsurgical cardiac tamponade requiring cardiac surgery intervention.[25]

Similarly, medial clavicle excisions for posterior SC joint dislocations are looked upon skeptically. Rockwood et al. evaluated 15 patients who underwent ~1.5 cm medial clavicle excision.[26] Outcome were based on a 15-point rating scale that included pain, range-of-motion, strength, reported limitations, and subjective patient outcomes. Each category was assigned a score between 0 and 3. An overall score of ≥13 was an excellent, 10–12 good, 7–9 fair, and <7 poor. The group with intact costoclavicular ligaments reported excellent results. Only three of seven patients in the disrupted costoclavicular ligaments group (equivalent

to patients with traumatic SC joint dislocations) had excellent results and the remaining four patients had fair to poor results. This study suggests resection arthroplasty alone without ligament reconstruction is unsatisfactory.[26]

Resolution of clinical scenario

- Multiple successful open reduction and stabilization techniques reported with no clear answers to which technique is superior.
- K-wires should never be used as a final means to stabilize the SC joint.

Summary of answers

- The SC joint relies on surrounding structures for stability.
- Injury to the posterior structures can be life threatening.
- Closed reduction of posterior SC joint dislocations has a low success rate.
- Readiness to perform an open reduction and stabilization must always be prepared for prior to reduction attempt.
- There are many viable reconstruction options for open reduction and internal stabilization of the SC joint; however, K-wire fixation and joint resection alone should be avoided.

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78
Clavicle Fractures

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Clinical scenario

- A 30-year-old left-hand-dominant male, laborer, presents with isolated intense pain in his shoulder after falling off his mountain bike.
- On examination, his left shoulder is deformed, appearing shortened and *ptotic*. It is a closed, isolated injury and his left upper extremity is neurovascularly intact (Figure 78.1).

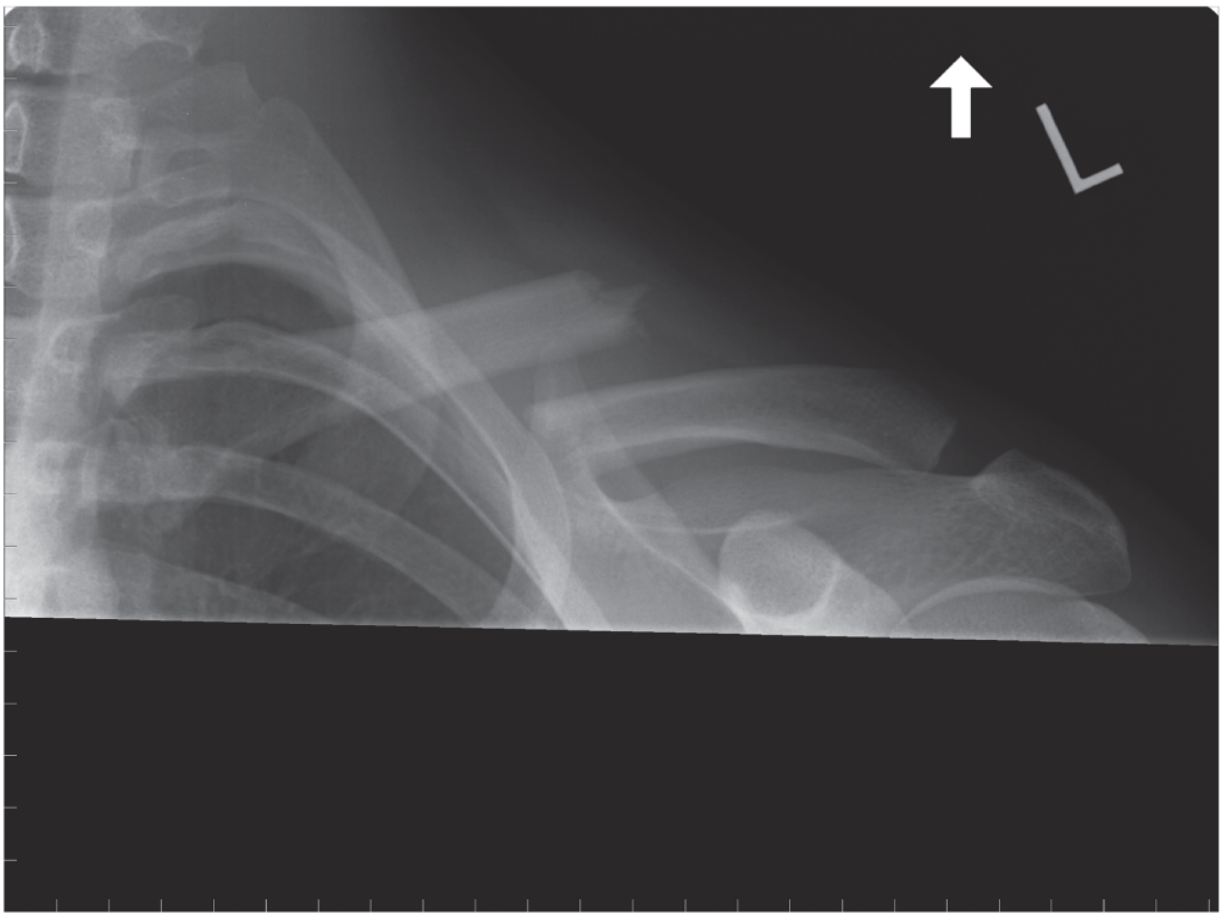

Figure 78.1 Radiograph of a 30-year-old man who fell off his mountain bike and sustained a midshaft clavicle fracture. Displacement and shortening is evident.

Top three questions

1. In patients with clavicle fractures managed nonoperatively, do displaced fractures have worse outcomes than nondisplaced fractures?
2. In patients with displaced clavicle fractures, does open reduction and internal fixation offer improved outcomes compared to nonoperative management?
3. In patients with clavicle fractures managed operatively, does intramedullary nailing result in improved outcomes compared to plating?

Question 1: In patients with clavicle fractures managed nonoperatively, do displaced fractures have worse outcomes than nondisplaced fractures?

Rationale

In order to optimize care, it is important to identify the minority of patients who are at risk for poor outcomes with nonoperative management.

Clinical comment

Nonoperative management is not without risks, so physicians and patients should understand fracture and patient characteristics that negatively affect the outcome in nonoperatively treated fractures.

Available literature and quality of the evidence

After searching the literature, nine studies were utilized to answer this question including: two level I studies and further supported with level II–IV data.

Findings

The majority of patients with a clavicle fracture will heal uneventfully with satisfactory function with nonoperative treatment. However, a minority of patients will have ongoing sequelae from a displaced midshaft clavicle fracture as shown in a recent randomized clinical trial (RCT) reporting 23.1% nonunion with nonoperative management of midshaft displaced fractures.[1] In addition to the unexpected 15% nonunion rate reported by Hill in 1997, a 31% dissatisfaction rate, related to 25% of patients

complaining of deformity and a 29% incidence of thoracic outlet syndrome, was reported. They found initial shortening >2 cm was significantly associated with nonunion and unsatisfactory results ($p < 0.0001$).[2] McKee looked at 30 healed, displaced fractures using patient-based outcomes and strength testing. They showed 27% dissatisfaction, Constant score of 71, and a Disabilities of the Arm, Shoulder, and Hand (DASH) score of 25. There was a trend toward worse DASH scores for shortening >2 cm and there was a statistically significant inverse correlation between abduction endurance strength and shortening.[3] Lazarides found a 25.8% dissatisfaction rate in patients with a healed midshaft clavicle fracture, significantly associated with shortening >18 mm in males and >14 mm in females.[4] This phenomenon has recently been challenged by Goudie, but with an average of only 11 mm shortening and only five patients with >2 cm shortening, this study was underpowered to detect a statistical difference.[5]

In a systematic review, Zlowodzki reported an overall nonunion rate of 5.9% which increased to 15.1% for completely displaced fractures.[6] Robinson's study employing multivariate analysis found increasing fracture displacement, comminution, advancing age, and female gender all to be independent predictors of nonunion in shaft fractures.[7] Nowak also found that displacement, comminution, and older age were predictors for sequelae (pain and deformity) following clavicle fracture.[8] Murray reviewed 941 diaphyseal fractures managed nonoperatively and identified smoking (odds ratio [OR] = 3.76; 95% confidence interval [CI]: 2.39–5.89; $p < 0.001$), displacement (OR = 1.17; 95% CI: 1.13–1.21; $p < 0.001$), and comminution (OR = 1.75; 95% CI: 1.11–2.76;

p = 0.015) to be statistically significant risk factors for nonunion.[9]

Resolution of clinical scenario

- The patient should be counseled that nonoperative management of displaced midshaft clavicle fractures results in a 15% nonunion rate and 25–30% dissatisfaction rate.
  - Major reasons for dissatisfaction: 15% nonunion, 15–20% malunion, 25% deformity, 29% thoracic outlet syndrome.
- This patient should understand this clavicle fracture has no cortical contact and has shortening which are both prognostic for poor outcome (nonunion or symptomatic malunion).
  - Poor prognostic factors include:
    - no cortical contact (displacement)
    - comminution
    - shortening >20 mm
    - smoking status
    - advanced age
    - female gender.

Question 2: In patients with displaced clavicle fractures, does open reduction and internal fixation offer improved outcomes compared to nonoperative management?

Rationale

Multiple high-quality RCTs have suggested potential benefits to primary operative fixation of displaced midshaft clavicle fractures.

Clinical importance

Shared clinical decision-making between patient and provider demand an unbiased, accurate understanding and communication of the literature.

Available literature and quality of the evidence

After searching the literature, 11 studies were utilized to answer this question. Of these, six were level I studies including multiple high-quality RCTs.

Findings

Zlowodzki et al. performed a systematic review of 2144 clavicle fractures. In a subset analysis of only displaced fractures, 460 plated fractures had a nonunion rate of 2.2% versus 15.1% for nonoperatively treated displaced fractures. They reported a nonoperative relative risk (RR) 6.9 (95% CI: 3.4–14.2) for nonunion and an absolute risk reduction (ARR) OF 12.9%, with a number need to treat of 7.8 patients to avoid one nonunion for plating; relative risk reduction (RRR) of 86% (95% CI: 71–93%; $p < 0.001$).[6] In 2007, an RCT comparing plate fixation versus nonoperative treatment for displaced midshaft clavicle fractures demonstrated statistically significant differences including a shorter time to union (16.4 vs 28.4 weeks; $p = 0.001$), improved Constant and DASH scores, as well as improved patient satisfaction ($p = 0.002$) and appearance ($p = 0.001$) in the operative arm.[10] Complications for the operative group were 37% versus 63% for nonoperative treatment. The operative group's complications included hardware

irritation, removal of hardware (ROH), transient brachial plexus irritations, and wound complications (4.8%). The nonoperative group had complications predominated by nonunion (7/49; 14.3%), malunion requiring corrective surgery (9/49; 18.4%), and brachial plexus irritation. The only statistically significant difference in complications were lower nonunion (15% vs 3.2%; p = 0.04) and malunion (22.5% vs 0%; p = 0.001) in the operative group.[10] Smith and Smekal noted similar results following operative fixation of displaced midshaft clavicle fractures in two other RCTs.[11,12]

In 2012, McKee et. al. published a meta-analysis of nonoperative versus operative management for midshaft displaced fractures including six RCTs (412 pts) and showed an overall reduction of non- and malunions from 23 to 1.5% with fixation.[13] Robinson performed an RCT of 178 patients finding a significantly lower nonunion with open reduction and internal fixation (ORIF) (1.2% vs 17%; p = 0.007) with an ARR of 15.8 for ORIF and an number needed to treat (NNT) of 6.2 to prevent one nonunion (RRR = 93%; p = 0.007). The surgical group was more satisfied with the shoulder contour and had better DASH (3.4 vs 6.1; p = 0.04) and Constant scores (92 vs 87.8; p = 0.01) at all time points but this lost significance after exclusion of nonunions.[14] In order to better predict these nonunions and to optimize treatment choice, the same group used a retrospective review of 941 diaphyseal fractures to create a *ready reckoner* table to aid clinical decision-making in real time. Their table uses displacement, comminution, and smoking status to predict risk of nonunion. If the ready reckoner computes the risk for nonunion to be >40%, the fracture is associated with an NNT of 1.7 to prevent a single nonunion with fixation.[9] A meta-analysis in 2017 including 8 RCTs and 12 observational studies (1760 patients) showed lower

nonunion (OR = 0.18; 95% CI: 0.10–0.33; p <0.01) with operative treatment. Looking only at high-quality studies, they found a lower malunion (OR = 0.26; 95% CI: 0.07–0.92), better DASH (mean difference [MD]: −2.04; 95% CI: 23.56–20.52; p = 0.01) and Constant score (MD: 3.23 95% CI: 1.52 to 4.95; p <0.01), and return to work 8.6 days earlier (95% CI: −16.22 to −1.05) with fixation compared to nonoperative treatment.[15] While several studies cite primary fixation being more expensive than nonoperative care.,[14,16] these studies only include direct costs. In a retrospective review comparing 204 operatively and nonoperatively treated displaced fractures, Althausen et al. found ORIF to be $5000 cheaper mostly as a function of less secondary lost wages from earlier return to work (8 vs 35 days).[17] While there is variability of such cost data in the literature, especially in meta-analysis, this internal database study may better capture the total cost of care.

Resolution of clinical scenario

- Literature supports improved function, a lower nonunion and symptomatic malunion rate, improved cosmetic perception, and overall higher satisfaction level with operative versus nonoperative treatment of this displaced, shortened fracture (Figure 78.2).
- Clinical decision-making tools should be used to help understand and communicate the patient's risk for nonunion with nonoperative treatment for this patient.

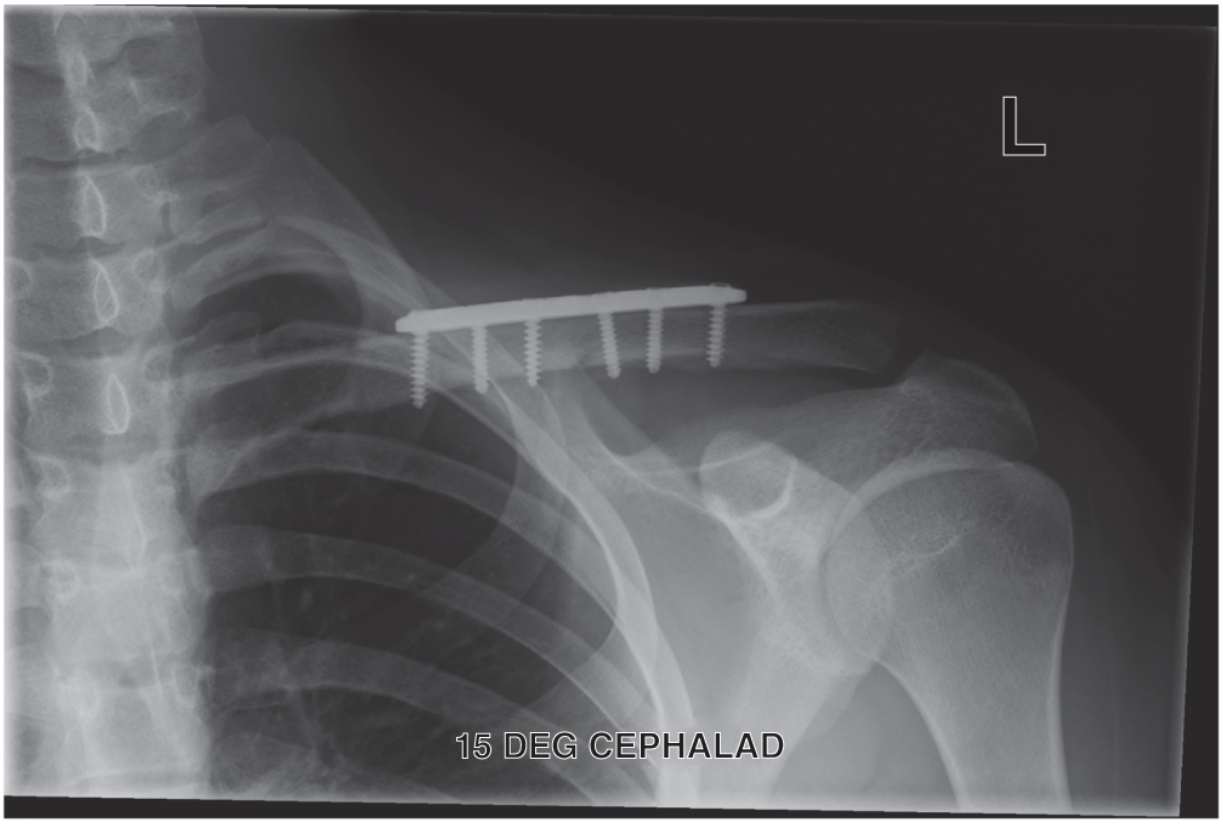

Figure 78.2 The patient in the case scenario elected to have operative treatment. This radiograph was obtained during follow-up and demonstrates fixation with a precontoured clavicle plate.

Question 3: In patients with clavicle fractures managed operatively, does intramedullary nailing result in improved outcomes compared to plating?

Rationale

There are a variety of fixation options available to surgeons, including intramedullary nails or pins (IMN) and

plate fixation. In addition, plates can be placed on the superior or anteroinferior surface.

Clinical comment

Several clavicle fixation options are available. There is debate as to which method is superior and each has unique risks and benefits.

Available literature and quality of the evidence

After searching the literature, 14 studies were utilized to answer this question. Of these, seven were level I studies.

Findings

Compared to the results of plates, there is more variability in the published outcomes for IMN but larger, higher-quality, studies paint a more balanced picture. Ferran performed an RCT comparing IMN versus plate fixation and found no difference in functional scores (Constant score or Oxford score) but with higher hardware removal rate in the IMN group (100% vs 53%).[18] A similar RCT of 120 patients by Hulsmans in 2017 confirmed these same results with no difference in Quick Dash (at all time points except three months) and higher hardware removal rates in the IMN group (RR = 1.65; 95% CI: 1.24–2.19; p <0.001).[19] The same year, Funglesang published an RCT of 123 patients randomized to flexible intramedullary nail versus plate. Operative time was faster for IMN. Plate fixation showed faster functional recovery (DASH p <0.001, and Constant score p <0.001) between 0 and 6 months but no difference at 12 months. Those with comminuted fractures treated with an IMN had the slowest recovery. IMN had a higher hardware removal rate.[20] A systematic review of 20 studies (six RCTs) reported no statistical difference in re-intervention rate (OR = 1.21; 95% CI: 0.71–2.04; p = 0.48),

Constant scores (p = 0.85), nonunion (p = 0.19) or infection (p = 0.13) between plate and IMN. Plate fixation had higher major complication rate while IMN had higher removal of hardware (73% vs 38%). Re-fracture occurred more commonly after plate removal (OR = 3.42; 95% CI: 1.12–10.24; p = 0.03).[21] Hussain published a systematic review and meta-analysis in *Nature* in 2016 comparing IMN versus plate fixation using seven RCTs and three quasirandomized trials showing no statistical difference in long-term function (MD: −0.66; 95% CI: −2.03 to 0.71; I^2 = 62%; p = 0.34). Plating had a statistically significant twofold risk of operative complications (95% CI: 1.38–3.23; I^2 = 53%; p = 0.0006) as well as prolonged operative time by 20 minutes (95% CI: 16.87–23.44; I^2 = 56%; p <0.00001) and a twofold statistically insignificant increase in treatment failure (95% CI: 0.03–5.15; I^2 = 0%; p = 0.07).[22]

Superior plating is accepted to be biomechanically superior to anteroinferior plating.[23] More importantly, both options appear to have adequate efficacy clinically.[24] Serrano looked at the more relevant question of plate irritation in a retrospective review of 252 fixations comparing both plate positions. Superior plates were more likely to undergo secondary intervention (ROH: 5.9% anteroinferior vs 22.3% anterosuperior; OR = 4.6; 95% CI: 1.9–10.9; p <0.001).[25] Using the same economic model as Walton, secondary surgery increased the cost an incremental $5173. They postulated that anteroinferior plating would avoid 17 additional surgeries for every 100 ORIFs and with a cost savings of $87 000.[16,25] Nourian et al. performed a meta-analysis using 34 articles to compare these techniques. They found no difference in functional score, union, malunion, or implant failure; however, superior plate had significantly higher symptomatic hardware (17% vs 8%;

p = 0.005) and significantly higher removal of hardware (11% vs 5%; p = 0.008).[24] In a large national database, Naimark et al. showed a 12.7% ROH rate within two years postoperatively. In a retrospective study of 73 plate fixations as part of the same report, they showed plate removal to be more likely in females (p = 0.009) and with non-precontoured plates (ROH: 25.5% non-precontoured vs 12.5% precontoured; p = 0.27) but the study was underpowered to show a statistical difference.[26] Those who required hardware removal had lower DASH scores, EQ-5D, and lower satisfaction.[26] However, a 2015 Cochrane review found the current evidence comparing clavicle operative treatment methods to be of low or very low quality. This was due to the risk of bias due to flawed methods, or such low numbers that a type I error may be possible. They support surgeon discretion in decision-making of implant choice and location: “There is very limited and low quality evidence available from RCTs regarding the effectiveness of different surgical methods of surgical fixation of fractures and nonunion of the middle third of the clavicle.”[27]

Resolution of clinical scenario

- When choosing between various surgical options, there is level I evidence that plate and IMN fixation are both viable options and offer similar union rates and functional outcome.
- There is level I evidence that plate fixation may offer earlier return to function, especially in comminuted fractures and that IMN fixation is associated with higher removal of hardware rates.
- Removal of hardware is associated with increased cost and inferior outcomes.

Summary of answers

- Nonoperative management of displaced midshaft clavicle fractures results in a 15% nonunion rate and a 25–30% dissatisfaction rate.
- Factors prognostic for poor outcome (nonunion or symptomatic malunion) following nonoperative management of clavicle fractures include: no cortical contact (amount of displacement), comminution, shortening >20 mm, smoking status, advanced age, female gender.
- In patients with a displaced clavicle fracture, there is a functional benefit, lower nonunion rate, improved cosmetic perception, and overall higher satisfaction level with operative versus nonoperative treatment.
- Clinical decision-making tools should be used to help understand and communicate the patient's risk for nonunion with nonoperative treatment for this patient.
- Plate and IMN fixation are both viable options and offer similar union rates and functional outcome.
- Plate fixation may offer earlier return to function, especially in comminuted fractures.
- Precontoured plates lower the rate of hardware removal.
- IMN fixation is associated with a higher removal of hardware rates.
- Removal of hardware is associated with increased cost and inferior outcomes.

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Acromioclavicular Joint

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Clinical scenario

- A 23-year-old man comes to the Emergency Department after being tackled during a football game and injuring his left shoulder.
- On examination, he has swelling and deformity at the distal end of his clavicle. His upper extremity is neurovascularly intact. It is an isolated injury.
- Radiographs reveal a high-grade (Rockwood type V) acromioclavicular (AC) joint dislocation.

Top three questions

1. In patients with AC joint injuries undergoing operative repair, do those with low-grade injuries have worse functional outcomes compared to those with high-grade injuries?
2. In patients with high-grade AC joint injuries treated operatively, do reconstruction methods offer improved results over temporary hook plate fixation?

3. In patients with AC joint injuries treated operatively, does early intervention offer improved outcomes compared to delayed surgery?

Question 1: In patients with AC joint injuries undergoing operative repair, do those with low-grade injuries have worse functional outcomes compared to those with high-grade injuries?

Rationale

Patients with high- and even low-grade AC joint injuries often present with pain, deformity, and expectations of returning to normal. Understanding of our ability to improve clinical outcomes continues to evolve and surgeons should carefully deliver realistic expectations in counseling.

Clinical comment

Most AC injuries are best treated symptomatically with or without physical therapy, while some may benefit from operative intervention, either acutely or secondarily.

Available literature and quality of the evidence

This clinical question was answered with nine studies, of which four were level I studies.

Findings

Increasing soft tissue damage with increasing grades of AC joint injury lead to greater functional deficits and pain. Particularly poor outcomes have been noted in higher grades that are associated with deltotrapezial fascia disruption and horizontal plane instability. Authors have

reported concomitant intra-articular glenohumeral pathology in up to 84% of patients with an acute AC injury, which impacts treatment and outcome in select patients.[1]

There are no prospective comparison studies specifically looking only at *low grade* (Rockwood type I–III) injuries and nonoperative treatment is considered standard of care for type I and II AC separations. However, Bergfeld et al. reported persistent pain and activity limitations in 9% of type I and 23% of type II AC injuries in an active military population.[2]

Type III injuries have been the center of debate. Gstettner et al. performed a retrospective cohort study comparing patients with type III injuries treated either with hook plates (n = 24) or nonoperatively (n = 12). Treatment choice was based on patient's preference. They found improved Constant scores (90.4 vs 80.7; p <0.05) and AC joint reduction in the operative group but no difference in return to sport.[3] Smith performed a meta-analysis comparing operative (trans-acromial Kirschner wires [K-wires], coracoclavicular screws, or hook plates) and nonoperative treatment of type III separations. The operative group had improved cosmesis (risk difference [RD] = 0.64; 95% confidence interval [CI]: 1.09, 0.19; p <0.0001), slower return to work (RTW) (mean difference [MD]: 3.3 days' sick leave; 95% CI: 2.10–4.50; p <0.001), similar function, but there was no difference in strength, throwing ability, and AC arthritis.[4] A more recent systematic review of 22 low-quality studies showed a 14% loss of reduction in type III injuries with fixation and no difference in Constant score (87.3 operative vs 88 nonoperative; p = 0.6832), or arthritic change (38.4% operative vs 40.5% nonoperative; p = 0.9413). There was a trend toward lower persistent pain with operative treatment (11% vs 25%; p = 0.07).[5] These analyses should

be interpreted with caution due to the inclusion of heterogeneous (and sometimes outdated) techniques, but in general they support the conservative management of most type III separations with acceptable outcomes. However, a portion of patients treated nonoperatively will have persistent symptoms.[4,5] In general, operative management is reserved for those who fail nonoperative management. This is most commonly due to persistent pain and weakness. Other causes of failure include intra-articular glenohumeral pathology, dynamic posterior instability, scapular dyskinesia, thoracic outlet syndrome, deformity, or cosmetic concerns.

Operative indications have remained largely unchanged since the first randomized trial by Bannister in 1989.[6] They randomized 54 patients with *AC dislocations* of various grades to nonoperative treatment versus fixation with a coracoclavicular screw. They noted significantly faster RTW (manual workers RTW average 4 vs 11 weeks; clerical workers RTW average 1 vs 4 weeks; $p < 0.01$), return to sport (7 vs 16 weeks; $p < 0.05$), and fewer unsatisfactory results in the conservative management group (0% vs 16% fair at 4 years). Better results were noted with early surgical fixation for *severe displacement* of ≥2 cm displacement (consistent with Rockwood type V).[6] Bannister confirmed these results in another prospective study of 48 patients, showing the highest benefit for early surgery in those with displacement ≥2 cm.[7]

The Canadian Orthopaedic Trauma Society performed an RCT of 83 patients with grade III–V AC separations comparing hook plate versus nonoperative treatment.[8] Hook plate offered better radiographic reduction ($p < 0.05$) but more frequent complications. Nonoperative treatment yielded better early function – DASH up to three months 16.03 (standard deviation [SD]: 17.03) vs 28.76 (SD: 15.3);

p = 0.005, Constant score up to six months – 91.53 (SD: 7.09) vs 80.22 (SD: 17.56); p = 0.0001 – earlier RTW (76% vs 43% at three months; p = 0.004) and lower re-operation rate (38 planned and 2 unexpected in the operative group vs 2 conversion to surgical in the conservative group; p <0.05). This is biased by the standardized removal of hardware necessitated by this procedure which occurred in 38 (79%) of the patients during this study. There was no difference in perceived cosmesis at one year (p = 0.091) or function from six months through two years.[8] A follow-up study of this data analyzing health-related quality of life showed these patients have pre-injury function higher than population norms and they return to this physical function faster with nonoperative management (six months vs two years), concluding that hook plate fixation does not lead to improved general health status.[9] Although there were patients in the nonoperative group who had a poor outcome and required later reconstruction, the authors were unable to predict factors associated with nonoperative failure. Despite the rigorous nature of this multicenter trial, they were unable to show a benefit in high-grade injuries due to lower recruitment of these rare entities.

Resolution of clinical scenario

- Low-quality evidence and common practice supports conservative management for Rockwood type I and II injuries.
- Patients with type III injuries are best managed with nonoperative treatment initially and delayed reconstruction on rare clinical occasions when required.
- This active patient with type V AC separation is likely best treated with primary operative repair but RCTs focusing specifically on this entity are lacking.

Question 2: In patients with high-grade AC joint injuries treated operatively, do reconstruction methods offer improved results over temporary hook plate fixation?

Rationale

There are currently over 60 techniques described for AC joint fixation with variable success, and new variations are continuously being reported. This speaks to the lack of consensus, and clouds the ability to identify a gold standard.

Clinical comment

This is a case of a young, active patient who has sustained a grade V AC joint injury for which the current standard is early surgical reduction. However, the ideal surgical treatment is still being debated.

Available literature and quality of the evidence

This question is addressed using 11 low- to high-quality studies clinical studies, of which there was one systematic review (level I) and three level III studies included.

Findings

Active patents with type V injuries have mediocre outcomes when managed nonoperatively (Disabilities of the Arm, Shoulder, and Hand [DASH] score 27.8 ± 17.7, American Shoulder and Elbow Surgeons [ASES] score 62 ± 17.1).[10] No RCTs exist in the literature comparing fixation techniques for AC joint dislocations. Result of meta-

analyses show heterogeneity of indications and techniques and should be interpreted with caution.

Contemporary literature has seen multiple low-quality (level III–IV) studies reporting novel techniques. These techniques can be broken down into biologic and nonbiologic fixation, each of which may be anatomic or nonanatomic. Nonbiologic fixation is used acutely to reduce the joint long enough to allow permanent ligament and capsule scarring. The hook plate has been widely used and studied for this indication since its introduction in the 1980s as a more durable alternative to K-wire fixation. It is biomechanically powerful, but currently available designs have high rates of acromial erosion, impingement, and hardware irritation. This results in the need for subsequent plate removal which usually performed 3–6 months postoperatively.[3] More recently coracoclavicular cortical suture buttons have been introduced as an alternative method with the added theoretical benefits of anatomic motion, the possibility for arthroscopic glenohumeral treatment of concomitant pathology, and lower removal of hardware rates. Unfortunately, early reports showed loss of reduction (failure) as high as 100% secondary to suture breakage/slippage with mediocre clinical results.[11,12] A prospective multicenter study by Clavert et al. of 116 early suture button fixations for grade III–V injuries showed a 22% complication rate and a 41% loss of reduction (>150% coracoclavicular [CC] distance), which was associated with decreased overall function (Constant score 71 vs 93; $p < 0.0001$). Persistent dislocation (radiographic failure) occurred in 48/116 (41.3%) of patients and was associated with worse overall constant score (88.4 vs 82.8; $p = 0.024$), mainly the subgroups of pain (9.7 vs 13.8; $p = 0.023$) and activity level (14.9 vs 18.9; $p = 0.044$). Those with complications had significantly decreased overall function (Constant score 71 vs 93; $p < 0.0001$).[13] A systematic

review and meta-analysis of 38 level III and IV studies (with highly heterogeneous results) compared suture button repair to hook plate fixation. The authors found suture button to have significantly lower pain (Visual Analog Scale [VAS]: 0.32 [95% CI: 0–0.64] vs 1.51 [95% CI: 0.73–2.00]), a trend toward improved Constant scores but a higher complication rare (RR = 1.7; 95% CI: 1.07–2.6) including loss of reduction, implant migration and osteolysis.[14] Natera-Cisneros et al. performed a retrospective cohort study comparing arthroscopically assisted suture button to hook plate fixation for 31 type III–V injuries. They found significantly improved quality of life (SF-36 Physical; 58.2 ± 2.2 vs 53.7 ± 4.3; p <0.001, SF-36 Mental; 56.2 ± 2.2 vs 53.1 ± 6.1; p = 0.049), VAS (0.4 ± 0.5 vs 1.5 ± 1.5; p = 0.007), Constant score (95.3 ± 2.5 vs 91.4 ± 6.8; p = 0.026), and patient satisfaction (8.9 ± 0.9 vs 8.0 ± 1.2; p = 0.035) with the suture button technique. Both groups had comparable rates of scapular dyskinesia and persistent vertical instability (40% suture vs 36.4% hook plate).[15] Although mechanically highly effective, subacromial pain and erosion remain common with older designs of hook plates that do not match the undersurface of the acromion. Newer designs may offer improved results.

The Weaver–Dunn technique is a biological, nonanatomic, coracoacromial (CA) ligament transfer performed with or without augmentation. This technique has been criticized due to the strength of this transfer being inferior to physiological demand.[16,17] Boström Windhamre et al. retrospectively compared 23 CA transfers with PDS-Suture to 24 CA transfers with temporary hook plate for mostly type V separations. They found no difference in function or stability but more pain with movement – VAS 32 (range 0–86) vs 10 (range 0–47); p = 0.003 – with hook plate and a trend towards lower function.[18] *Anatomic reconstruction* traditionally refers to biologic reconstruction of both the

conoid and trapezoid, but it is often misused in the literature when referring to nonbiologic suture button fixation. In 2010, Carofino and Mazzocca popularized anatomic reconstruction with tendon autograft in a series of 18 cases. They showed good to excellent results (ASES improved from 53 to 92, Constant score improved 76 to 95), but also an 18% failure rate.[19] In a cadaver study looking at load to failure, this anatomic reconstruction technique with ligament graft (948N) was found to be biomechanically superior to suture button fixation (578N; p = 0.01), Weaver–Dunn (523N; p = 0.001), and nonanatomic graft (591N; p = 0.003).[17]

Rush performed a multicenter retrospective cohort study comparing suture button fixation with anatomic tendon reconstruction in 38 cases.[20] The anatomic tendon reconstruction resulted in lower failure (38.8% symptomatic loss of reduction with suture button vs 15% asymptomatic loss of reduction with tendon graft; p = 0.002) and complications (61% vs 25%; p = 0.0243). They concluded that the suture button fails to provide horizontal stability.[20] A dynamic cadaver study showed less laxity and anterior–posterior translation with anatomic graft reconstruction compared to Weaver–Dunn or suture fixation.[21] Tauber performed a prospective cohort study comparing 12 modified Weaver–Dunn procedures vs 12 anatomic autograft reconstructions in type III–V injuries. The anatomic autograft reconstruction group had improved functional scores (p <0.001) and significantly less radiographic displacement with stress loading (2.6 mm vs 0.4 mm; p = 0.027).[22] This was confirmed in a cohort study of 10 chronic type III injuries.[23] Anatomic reconstruction does have limitations, particularly loss of reduction, which has been noted to be as high as 47% and a distal clavicle fracture rate as high as 10%.[24]

Resolution of clinical scenario

- Low-quality evidence supports the use of hook plates as a biomechanically sound option for early AC joint reduction in high-grade AC separations but almost universally require removal of hardware due to symptomatology.
- Moderate- to high-quality evidence shows suture button fixation to have a higher overall complication rate and loss of fixation.
- Low- to moderate-quality evidence shows anatomic reconstruction with tendon autograft has clinically superior maintenance of reduction, lower complications, and improves horizontal stability compared to suture button and Weaver–Dunn but with a 10% distal clavicle fracture rate.

Question 3: In patients with AC joint injuries treated operatively, does early intervention offer improved outcomes compared to delayed surgery?

Rationale

Not all patients with grade III–V require or undergo early reconstruction. It is important to understand the role for delayed reconstruction in those who fail nonoperative treatment.

Clinical importance

Most patients with type III should undergo a nonoperative trial and some patients with type V may elect this course as

well. Patients and surgeons should understand the differences in outcome between acute and delayed reconstruction if they fail conservative treatment.

Available literature and quality of the evidence

This question was answered with four studies utilizing multiple level III studies and systematic review.

Findings

Rolf looked retrospectively at 49 patients, 20 with delayed repair of their AC joint injury and 29 with acute repair using different techniques.[25] Acute repair resulted in improved Constant scores (87.17 vs 78.10; p = 0.019) (minimal clinically important difference [MCID] of 8), lower loss of reduction (34% vs 58%; p = 0.037) and a lower complication rate with acute repair.[25] Von Heideken et al. performed a retrospective cohort study comparing early (<4 weeks) and late (>4 months) Weaver–Dunn and hook plate for type V injuries. There was no difference in Constant score, but acute reconstruction offered superior Shoulder Pain and Disability Index (0 vs 14; p = 0.006), QuickDASH (0 vs 18; p = 0.002), subjective shoulder value (p = 0.032), less pain with movement (p = 0.005) and rest (p = 0.014), and less subluxation on weighted images (p = 0.011).[26] Virk looked at early versus late reconstruction in five retrospective studies including 135 patients in five level III studies showing favorable outcome (defined specifically in each investigation as a tool for subjective evaluation) in 91% of those treated acutely vs 73% of those treated delayed.[27] This was low-quality evidence. A recent systematic review including eight studies showed early reconstruction had better functional outcomes using the Constant score and subjective shoulder value (p <0.05) and lower partial-dislocation or redislocation (39/150 [26%] vs

40/150 (38.1%); p <0.05) but no statistical difference in complications (12.5% early vs 17.7% delayed).[28]

Resolution of clinical scenario

- Early reconstruction is warranted in this active patient with a high-grade AC injury and is supported in the literature with superior functional outcomes, less loss of reduction and lower complications compared to late reconstruction.

Summary of answers

- Patients with Rockwood type I and II injuries are best managed nonoperatively.
- Patients with type III injuries are best managed with nonoperative treatment initially.
- Patients with a type V AC separation are probably best treated with primary operative repair.
- Hook plates are a biomechanically sound option for early AC joint reduction in high-grade AC separations but usually require removal of hardware due to symptomatology.
- Coracoclavicular suture button repair can result in good function but has a high complication and loss of reduction rate.
- Anatomic reconstruction with tendon autograft is biomechanically superior to suture button, Weaver–Dunn, and nonanatomic graft.
- Anatomic reconstruction with tendon autograft is clinically and biomechanically superior and has lower complications and loss of reduction compared to suture button and Weaver–Dunn.

- Anatomic reconstruction with tendon autograft is associated with up to a 10% distal clavicle fracture rate.
- Early reconstruction is associated with superior functional outcomes, less loss of reduction and lower complications compared to late reconstruction.

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Proximal Humeral Fractures

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Clinical scenario

- A 69-year-old woman presents to the Emergency Department after a slip and fall at home. She is an avid golfer and does not take any medication. On examination, she has pain, swelling, and ecchymosis of her right dominant shoulder and arm and a normal neurovascular exam. Radiographs reveal a minimally displaced fracture of the proximal humerus. She is concerned about radiation exposure, and asks whether a computed tomography (CT) scan is necessary.
- She is anxious to get back to golf and would like to know when she should start exercises to most effectively regain function.
- A friend of hers recently had surgery. She is wondering if she should have surgery too.

Top three questions

1. In patients with a proximal humerus fracture, does adding CT imaging improve classification of fractures or improve patient outcomes compared with radiographs alone?

2. In patients choosing nonoperative treatment of a fracture of the proximal humerus, does early initiation of exercises (before one week) improve pain or patient-reported function compared with delayed exercise programs (after three weeks)?
3. In patients with displaced three- or four-part humerus fractures, does nonoperative treatment lead to better outcomes than surgical treatment (open reduction and internal fixation, hemiarthroplasty, or reverse total shoulder arthroplasty)?

Question 1: In patients with a proximal humerus fracture, does adding CT imaging improve classification of fractures or improve patient outcomes compared with radiographs alone?

Rationale

Surgeons and patients hope that more detailed imaging will better guide management and lead to improved outcomes.

Clinical comment

Due to complex three-dimensional (3D) anatomy of proximal humerus fractures, some can be challenging to characterize on radiographs. CT scans are commonly used to get a more detailed image of the fracture pattern, which could potentially lead to better tailored treatments and improve outcomes.

Available literature and quality of the evidence

Two prospective studies have evaluated the reliability and accuracy of classification using radiographs and CT scans (level II).[1,2] One study assessed interobserver reliability of AO classification between 2D and 3D CT scans (level III).[3] Multiple retrospective studies studied inter- and intraobserver reliability regarding specific fracture characteristics (level III)[4] and fracture classification with AO classification (level III)[5] or Neer classification (level III).[6]

Findings

In a prospective diagnostic study three observers classified 44 consecutive fractures and found better assessment of relevant structures (tuberosities, the glenoid, and humeral head) using a four-grade scoring system (1 = excellent, 2 = good, 3 = fair, and 4 = inadequate) based on CT compared to radiographs (AP view, scapular Y-views, and axillary views) independent of fracture severity (i.e. Neer two-, three-, or four-part fractures) ($p < 0.05$) (level II).[1] A study comparing 2D to 3D CT scans found higher, but still only fair, interobserver reliability for 3D CT scans regarding displacement of the greater tuberosity ($\kappa = 0.35$ vs 0.30, $p < 0.001$).[3]

In a retrospective study three3 observers evaluated 40 nonconsecutive fractures and found better assessment of fracture displacement, impaction, and anatomic neck involvement with CT compared to radiographs, but no influence on AO classification or decision on whether to operate (level III).[5]

In another retrospective study four observers evaluated 40 consecutive fractures and documented better interobserver reliability by adding CT: “moderate” for radiographs ($\kappa = 0.42$) and 2D CT ($\kappa = 0.56$) to “good” for 2D CT with 3D volume renderings ($\kappa = 0.76$) for the Neer classification

system intraobserver reliability improved ($p < 0.001$) from "moderate" for radiographs ($\kappa = 0.48$) and 2D ($\kappa = 0.63$) to "excellent" for 2D CT with 3D volume renderings ($\kappa = 0.84$) for the Neer classification (level II).[2]

In another study, seven observers evaluated 40 consecutive fractures and compared 2D versus 3D CT with no difference in intraobserver reliability.[6] There was a difference in interobserver reliability among the junior resident observers (level III). This difference amongst more junior surgeons was also reflected in a prior study comparing 2D and 3D CT scans where less experienced surgeons had significantly higher levels of agreement with 3D ($\kappa = 0.14$) CT than 2D ($\kappa = 0.17$) ($p = 0.014$).[3]

In another study, three observers reviewed 20 fractures with no difference in diagnosis of fracture characteristics (existence of medial hinge, metaphyseal extension) on radiographs compared to 2D CT (level III).[4]

Resolution of clinical scenario

- Level II evidence suggests that CT does not improve overall classification of proximal humerus fractures, but it may be more reliable for defining specific fracture characteristics and therefore may be helpful when making treatment decisions for patients.
- Level III evidence suggests 3D CT may improve the reliability of classification over 2D CT among less-experienced observers.
- It is not known whether more reliable classification leads to improved outcomes.

Question 2: In patients choosing nonoperative treatment of a fracture of the proximal humerus, does early initiation of exercises (before one week) improve pain or patient-reported function compared with delayed exercise programs (after three weeks)?

Rationale

Immediate initiation of exercises might result in better final shoulder motion but could also theoretically interfere with healing. Controversy exists between early (within one week) or late (three weeks or greater, once healing is underway) initiation of exercises after a proximal humerus fracture.

Clinical comment

Most fractures of the proximal humerus are adequately aligned, stable, and associated with limited functional impairment after nonoperative treatment.[7,8] Many of these have good results treated in a simple arm sling. Due to the impact on activities of daily living in the generally older patient population, early return of function is important for maintaining independence.[9]

Available literature and quality of the evidence

Three prospective randomized controlled trials (RCTs) (level II) have studied the effect of mobilization within one week of injury on multiple patient-reported outcome measures (PROMs).[9–11]

Findings

Shoulder function

Two prospective RCTs (160 patients) with methodological limitations (possible bias; allocation concealment unclear, some blinding outcome assessors, blinding patients impossible, inclusion/exclusion criteria not clearly defined) showed that early mobilization within one week resulted in significantly better Constant Shoulder Scores at 12 weeks[9] for impacted (stable) proximal humeral fractures (weighted mean difference [MD]: 9.9; 95% confidence interval [CI]: 2.1–17.7; $p < 0.05$) and 16 weeks[10] for non- and minimally displaced two-part fractures (MD: 16.0; 95% CI: 7.1–24.9; $p < 0.001$). There were no significant differences at six months[9] (MD: 6.1; 95% CI −0.2–12.4, $p = 0.06$) and one year[10] (MD: 7.0; 95% CI: −3.4–17.4; $p = 0.19$) after fracture (level II).

General health status (Short Form 36)

One prospective RCT (86 patients) showed that early mobilization within one week for patients with non- and minimally displaced proximal humerus fractures resulted in significantly better health-related quality of life scores at 16 weeks in two dimensions of the SF-36 (role limitation physical: MD: 22.2; 95% CI: 3.8–40.6; pain: MD: 12.1; 95% CI: 3.2–20.9).[10] There were no statistically significant differences between the two treatment groups in the other six dimensions (e.g. physical functioning) of SF-36, nor in any of the eight dimensions at one year (level II).

Pain

One prospective controlled trial by Lefevre-Colau and colleagues of patients with impacted proximal humeral fractures (64 patients) reported significantly less pain in

patients that started pendulum exercises immediately compared to those that were immobilized for a month as measured on a 100 mm Visual Analog Scale (VAS) pain score at three months (MD: 15.7; 95% CI: 0.52–30.9; p <0.05), but not at six weeks (MD: 3.6; 95% CI: −13.6–20.8; p = 0.68) or six months (MD: −0.20; 95% CI: −14.4–14.0, p = 0.98) (level II).[9]

Resolution of clinical scenario

- Evidence suggests that for the above-mentioned patient with a minimally displaced two-part fracture or an impacted fractures of the proximal humerus, early initiation (within one week) of exercises does not influence impairment or disability six months or more after fracture of the proximal humerus, and may facilitate quicker recovery and return to activities like golf.
- No risk of nonunion was seen with early initiation of exercises in patients similar to the patient in this scenario, but these were small studies unable to assess for the risk of uncommon events.

Question 3: In patients with displaced three- or four-part humerus fractures, does nonoperative treatment lead to better outcomes than surgical treatment (open reduction and internal fixation, hemiarthroplasty, or reverse total shoulder arthroplasty)?

Rationale

Multiple surgical treatments are available for displaced proximal humerus fractures, including open-reduction and internal fixation with a locking plate, reverse total shoulder arthroplasty, or hemiarthroplasty. Which surgical option, if any, can improve outcomes for patients with displaced three- or four-part proximal humerus fractures is still unclear.

Clinical comment

Studies have not consistently shown that surgical intervention improves outcomes, and operative interventions come with different sets of complications. Difficulties associated with loss of fixation, nonunion, malunion, and osteonecrosis after open reduction and internal fixation make prosthetic arthroplasty an appealing treatment option. Function is inconsistent after hemiarthroplasty and might be better with reverse arthroplasty.

Available literature and quality of the evidence

Multiple high-quality RCTs (level I) have investigated differences in outcomes between nonoperative and operative management of three- or four-part proximal humerus fractures[12–19] along with an RCT with <80% follow-up.[20] There are two systematic reviews with meta-analysis (level I).[21,22]

Direct comparisons of different operative methods are more limited, but high-quality RCTs (level I)[23,24] have been performed, along with lower-quality RCTs (level II)[25] and a systematic review and network meta-analysis (level II)[26] which combines six RCTs to compare multiple treatment modalities.

Findings

Shoulder function: operative versus nonoperative

Seven prospective controlled trials[12–20] (518 patients) with methodological limitations (unable to blind patients and caregivers, outcome assessors not blinded, one[20] with <80% follow-up) randomized patients to nonoperative treatment versus hemiarthroplasty for displaced fractures[12,13,16] (142 patients), versus locking plate for displaced three-part (60 patients)[17] or displaced three- or four-part (50 patients),[14,15] versus surgeon preference (90 locking plate, 10 hemiarthroplasty) and versus tension-band osteosynthesis for three- or four-part proximal humerus fractures (40 elderly patients, mean age 74 years).[20] Five studies used standardized shoulder-specific outcome measures.[13,14,16,17,20] All five studies measured constant scores, and no individual study or meta-analysis of these studies[21] showed a significant difference at 12[13,14,16,17] or 24 months.[15–17,20] Two studies compared Disabilities of the Arm, Shoulder, and Hand (DASH) scores in nonoperative versus hemiarthroplasty[16] or open

reduction and internal fixation (ORIF) with a locking plate.[17] Both studies showed no significant differences in DASH scores in the operative groups (26 for ORIF, 35 nonoperative; p = 0.19)[17] (30 for hemiarthroplasty, 37 nonoperative; p = 0.25).[16] The Oxford Shoulder Score was also measured in the largest of the level I studies and showed no significant difference at any timepoint during the first two years in the original publication (231 patients) or in three-year (164 patients), four-year (155 patients), or five-year (149 patients) extensions.[14,15]

Complications: operative versus nonoperative

Two meta-analyses showed a higher rate of surgery subsequent to the initial treatment in the operative patients compared to nonoperative (seven studies, 523 patients; risk ratio [RR]: 2.06; 95% CI: 1.18–3.6; p = 0.011; I^2 = 29%).[21,22] The meta-analyses did not find significant differences between operative and nonoperative treatment in any other complications or adverse events including mortality, avascular necrosis, nerve injury, nonunion, nerve injury, or shoulder impingement.

Hemiarthroplasty versus ORIF with locking plate

One RCT (32 patients, two-year follow-up) with methodological limitations (unclear allocation concealment, unclear blinding of patients or outcome assessors) reported significantly higher constant scores (73 vs 60; p = 0.017), lower pain on VAS (3.6 vs 6.4; p = 0.018) and lower DASH scores (9.2 vs 15; p = 0.023) for hemiarthroplasty compared to ORIF with locking plate.[24] No significant difference in strength or range of motion (ROM) was observed.

Reverse shoulder arthroplasty versus hemiarthroplasty

One RCT (62 patients) comparing reverse shoulder arthroplasty (RSA) to hemiarthroplasty in four-part fractures deemed not amenable to ORIF showed significantly superior outcomes for RSA.[23] RSA had significantly higher constant scores (56.1, range 24–80 vs 40.0, range 8–74; p = 0.001), higher UCLA scores (29.1, range 16–34 vs 21.1, range 6–34; p = 0.001), and lower DASH (17.5, range 12–30 vs 24.4, range 13–41; p = 0.001). Shoulders in the RSA group also had significantly better ROM in anterior forward elevation (120° vs 80°; p = 0.01), abduction (113° vs 79°; p = 0.001), and external rotation (4.7 Constant sub-score vs 3.3; p = 0.23). No significant difference was seen in internal rotation. They also noted a nonsignificant higher rate of implant survival at 40 months in the RSA group (97% vs 80%; p = 0.43).

Comparison of multiple surgeries in network meta-analysis

A Bayesian network meta-analysis of seven RCTs was performed to compare nonoperative management, hemiarthroplasty, ORIF, and RSA simultaneously.[26] This analysis did not show any significant difference regarding Constant scores or revision rates between treatments.

Resolution of clinical scenario

- If our patient's fracture was displaced, multiple level I studies show no significant differences in PROMs between operative and nonoperative management.
- Operative treatment of a displaced fracture is associated with a higher risk of needing further surgery than nonoperative management without other significant differences in rates of adverse events.
- Hemiarthroplasty may lead to better PROMs than ORIF in elderly patients with displaced four-part proximal

humerus fractures.

- If our patient's fracture was four parts and displaced, RSA may lead to better PROMs, increased ROM, and increased implant survival rates compared to hemiarthroplasty.

Summary of answers

- CT scans do not significantly increase reliability or accuracy of fracture classification in proximal humerus fractures amongst experienced surgeons, but they may be beneficial to assess particular fracture characteristics, which may change treatment decisions. It is not known whether CT affects outcomes.
- Early mobilization and home exercises within a week of injury have not been shown to negatively impact union rate, and may expedite recovery of function.
- There is insufficient evidence from RCTs to determine the optimal intervention in patients with proximal humeral fractures, but high-quality studies have shown no significant benefit and higher risks with operative management of proximal humerus fractures in the elderly.

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81
Humeral Shaft Fractures

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Clinical scenario

- A 35-year-old man is brought to the Emergency Department following a motor vehicle accident.
- He is complaining of right arm pain and has an obvious deformity of his right upper arm, which appears to be his only orthopedic injury.
- After your resident attempts a reduction application of a hanging cast, the patient reports numbness and weakness in his radial nerve distribution.

Top three questions

1. In adult patients with displaced humeral shaft fractures, does operative treatment result in improved function compared to nonoperative treatment?
2. In adult patients with displaced humeral shaft fractures undergoing operative treatment, how does plate osteosynthesis compare to intramedullary nailing in terms of fracture union and complication rates?
3. In adult patients sustaining humeral shaft fractures with radial nerve palsy, is there a difference in the recovery rate with primary radial nerve palsy, as

compared to secondary radial nerve palsy (i.e. with fracture manipulation) radial nerve palsy?

Question 1: In adult patients with displaced humeral shaft fractures, does operative treatment result in improved function compared to nonoperative treatment?

Rationale

Nonoperative treatment has historically been the standard of care for isolated closed humeral shaft fractures. Similar to clavicle fractures, it has been assumed that the majority of fractures heal with a low level of complication, but level I evidence regarding the treatment of isolated closed humeral shaft fractures is lacking.

Clinical comment

Understanding the outcomes of operative and nonoperative treatment is important in order to recommend treatment and guide patients regarding their expected outcomes.

Available literature and quality of the evidence

To date, only a single level I study has compared operative with nonoperative treatment of humeral shaft fractures.[1]

Findings

Matsunaga and colleagues performed a prospective randomized study of 110 adult patients sustaining humeral shaft fractures treated with either minimally invasive bridge plating or nonoperative treatment with a functional brace. The primary outcome was the Disabilities of the

Arm, Shoulder, and Hand (DASH) score at six months. Secondary outcome measures include the Short Form 36 (SF-36) life-quality questionnaire, Constant–Murley score for the shoulder, pain level, treatment complications, and radiographic results.[1]

Surgical treatment with bridge plating was statistically superior to conservative treatment with respect to the mean DASH at six months (mean scores: 10.9 ± 10.5 for bridge plating and 16.9 ± 18 for conservative treatment; $p = 0.046$), but this difference is of uncertain clinical benefit since other studies suggest that 10 points is the minimal clinically important difference.[2,3] The union rate in the bridge plate group was significantly better than in the nonoperative group (100% vs 85% respectively; $p < 0.05$). Mean residual angular displacement seen on the anteroposterior radiograph was significantly less in the bridge plate group (2.0° ± 4.7° vs 10.5° ± 8.9°; $p < 0.05$). There was no difference between the groups with regard to the SF-36 score, pain level, Constant–Murley score, or angular displacement seen on the lateral radiograph.

Resolution of clinical scenario

- Operative treatment with bridge plating results in a superior mean DASH score at six months, but the clinical importance of this difference is uncertain.
- Operative treatment using a minimally invasive bridge plating technique results in a significant higher union rate compared to nonoperative treatment.
- This recommendation is based on only a single study with low external validity since it was conducted at a single center. There are two randomized clinical trials comparing surgical and nonsurgical treatment of humeral shaft fractures in progress.[4,5]

- Given that the current evidence does not show significant functional differences between operative and nonoperative management, patient preferences such as time to return to activity and feelings toward surgical risk should be considered

Question 2: In adult patients with displaced humeral shaft fractures undergoing operative treatment, how does plate osteosynthesis compare to intramedullary nailing in terms of fracture union and complication rates?

Rationale

There is debate regarding the choice of humeral shaft fracture operative treatment. The main operative treatment options are plate fixation or intramedullary nailing. Plate fixation has traditionally been done through an open reduction approach, but a minimally invasive approach in which the plate is inserted through small incisions has gained popularity.

Clinical comment

A significant number of clinical studies have compared plate fixation or intramedullary nailing of humeral shaft fractures in an attempt to identify the optimal treatment option.

Available literature and quality of the evidence

There have been 16 downgraded randomized controlled trials (RCTs) (level II), including 832 participants,

comparing the different operative treatment options for humeral shaft fractures.[6–21] Individual sample sizes ranged from 28 to 89 participants. A network meta-analysis of these downgraded RCTs (level II) has pooled the results to assess the outcomes of different operative treatment options.[22]

All of these studies have a risk of bias. Blinding was not possible for the participants and clinicians because of the nature of the surgical treatment. None of studies reported whether they received grants in support of their research. None of the studies mentioned whether an *intention to treat* analysis was performed. Based on the Oxford Centre for Evidence-based Medicine Levels of Evidence, all of the trials were assessed as level II evidence.

Findings

The results of a network meta-analysis of these clinical trials showed that shoulder impingement occurred more commonly in the intramedullary nail group than with either open reduction and plate fixation (odds ratio [OR] = 0.13; 95% confidence interval [CI]: 0.03–0.37) or minimally invasive plate fixation (OR = 0.08; 95% CI: 0.00–0.69). Iatrogenic radial nerve injury occurred more commonly in the open reduction and plate fixation group than in the minimally invasive plate fixation group (OR = 11.09; 95% CI: 1.80–124.20). There were no significant differences among the three procedures in nonunion, delayed union, and infection.[22]

Resolution of clinical scenario

- Minimally invasive plate fixation is the preferred treatment method for humeral shaft fractures since it has a lower complication rate than intramedullary nailing or open reduction and plate fixation.

Question 3: In adult patients sustaining humeral shaft fractures with radial nerve palsy, is there a difference in the recovery rate with primary radial nerve palsy, as compared to secondary radial nerve palsy (i.e. with fracture manipulation) radial nerve palsy?

Rationale

When radial nerve palsy develops following fracture manipulation, many surgeons have advocated radial nerve exploration because this scenario suggests that the radial nerve might be trapped within the fracture.

Clinical comment

A survey of current practice among trauma surgeons in England showed that surgeons still differ in the ways of managing radial nerve palsy associated with humeral fractures, with a slightly higher percentage of surgeons preferring conservative treatment.[23]

Available literature and quality of the evidence

No RCTs have been performed to date on the topic of radial nerve palsy secondary to humeral shaft fracture. A single prospective cohort is registered on clinicaltrials.gov, and the status marked as completed, though no publications from the group could be found. Shao et al. performed a systematic review (level IV) of 35 studies which included a total of 1079 patients.

Findings

Shao et al. reported that a spiral fracture pattern of the distal humerus with associated nerve palsy is not an absolute indication for radial nerve exploration and showed no significant difference in the rate of recovery between primary (88.6%) and secondary nerve palsies (93.1%).[24] A limited period of waiting also had no effect on the final recovery. Eleven studies (n = 98 patients) showed that the mean delay to first exploration was 4.3 months (range 1–15). In 101 cases treated expectantly at first, the mean spontaneous recovery onset time was 7.3 weeks, which may indicate the minimum waiting time before exploration.

The rationale for this type of injury is not to be indicated for open reduction unless it constitutes an increase in radial nerve deficit. It is reported that nerve fibers will regenerate in three months' time. When recovery in this time period has failed, further treatment options such as exploration, neurorrhaphy, and tendon transfers may start to be considered. Because irrigation and debridement is required for open fractures, it is reasonable to explore the nerve at this same operation. Shao et al. did not identify a significant difference in the spontaneous recovery of radial nerve palsies in open versus closed fractures.[24]

Resolution of clinical scenario

- Exploration is recommended at 4–6 months if there is no resolution following a primary radial nerve palsy (overall quality: low).
- In patients with indications for earlier operative fixation, exploration of the nerve should be at the time of internal fixation (overall quality: low).
- Primary and secondary nerve palsies show no difference in recovery rate so in this case the patient

should be counseled about the high expected recovery rates with observation alone and the timing to recovery to create appropriate expectations (overall quality: moderate).

Summary of answers

- Operative treatment using a minimally invasive plate fixation results in improved function compared to nonoperative treatment.
- Minimally invasive plate fixation is the preferred treatment method for humeral shaft fractures since it has a lower complication rate than intramedullary nailing or open reduction and plate fixation.
- The recovery rate of radial nerve palsy associated with humeral shaft fractures averages from 88 to 93%. Primary and secondary nerve palsies show no difference in recovery rate.

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Distal Humerus Fractures

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Clinical scenario

- An 81-year-old female patient, who lives independently, presents to the Emergency Department after a fall from standing height on her right arm.
- She is complaining of pain in her right elbow.
- There are no open wounds and her limb is neurovascularly intact.
- The x-rays show a displaced C3-type distal humerus fracture with significant comminution (Figure 82.1).

Top three questions

1. In patients with intra-articular distal humerus fractures, does a triceps splitting approach result in better patient outcomes when compared to an olecranon osteotomy?
2. In patients with distal humerus fractures, does parallel plating result in better outcomes when compared to orthogonal plating?

3. In elderly patients with comminuted, intra-articular, distal humerus fractures does total elbow arthroplasty (TEA) result in better outcomes than open-reduction and internal fixation?

Question 1: In patients with intra-articular distal humerus fractures, does a triceps splitting approach result in better patient outcomes when compared to an olecranon osteotomy?

Rationale

Numerous surgical approaches have been described for the fixation of distal humerus fractures. With the exception of approach strategies for coronal shear fractures, all of these involve a posterior skin incision with various strategies of working through, or around, the triceps. Described approaches include the triceps-splitting, olecranon osteotomy, triceps-reflecting (Bryan–Morrey), triceps-reflecting anconeus pedicle (TRAP), and para-tricipital approaches. Surgeon opinion regarding the optimal surgical approach to distal humerus fractures is widely divergent.

Clinical comment

One goal of surgical fixation of distal humerus fractures is achieving an upper extremity with functional range of motion and strength. The surgical approach of choice would ideally provide the maximum visualization of the joint surface while minimizing negative effects on function postoperatively.

Available literature and quality of the evidence

- Level III: 4 studies[1–4]
- Level IV: 11 studies.[5–15]

The evidence to answer this important question is limited to multiple level III and level IV studies.

Findings

Four level III studies retrospectively compared the triceps-splitting approach and the olecranon osteotomy approach for distal humerus fractures fixation. Three of these studies showed no statistically significant differences between the approaches with regards to either objective elbow strength, range of motion (ROM), or functional outcomes (n = 62 patients).[1,2,4] Other level IV series of patients treated with olecranon osteotomy have reported rates of hardware removal ranging from 6 to 30% and nonunion of the olecranon osteotomy in 0–9% of patients.[5–9] One level III study compared the two approaches for the fixation of open distal humerus fractures and found better functional outcomes and a trend toward improved ROM in the triceps-splitting group (n = 26 patients).[3] Mayo Elbow Performance Score (MEPS) were 84.5 versus 73.5 (p = 0.05), and Disabilities of the Arm, Shoulder, and Hand (DASH) scores were 29.5 versus 64.1 (p = 0.05). Authors hypothesized that this effect was due to the fact that open fractures had a large tear in the triceps that was easily incorporated into the triceps splitting approach. Multiple level IV studies have reported satisfactory results using the olecranon osteotomy, triceps-splitting,[10] triceps-reflecting,[11,12] and triceps sparing[13–15] approaches. A meta-analysis of the literature looked at both the triceps-splitting and Bryan–Morrey approaches independently

compared to an olecranon osteotomy.[16] The authors noted the overall low quality of evidence currently available. When comparing the Brian–Morrey approach with olecranon osteotomy, the MEPS showed no significant difference (standardized mean difference [SMD]: 0.20; 95% confidence interval [CI]: −0.40, 0.80; I^2 = 55%). Similarly, using the flexion extension arc as the performance outcome, there was no significant difference noted between the triceps-splitting approach and olecranon osteotomy (SMD: −0.22; 95% CI: −1.53 to 1.08; I^2 = 86%). Analysis revealed no significant differences in terms of ulnar nerve injury, heterotopic ossification, infection, or post-traumatic arthrosis. They did note a higher rate of re-operation with olecranon osteotomy for hardware removal, although this finding was heavily weighted by one study in the analysis.

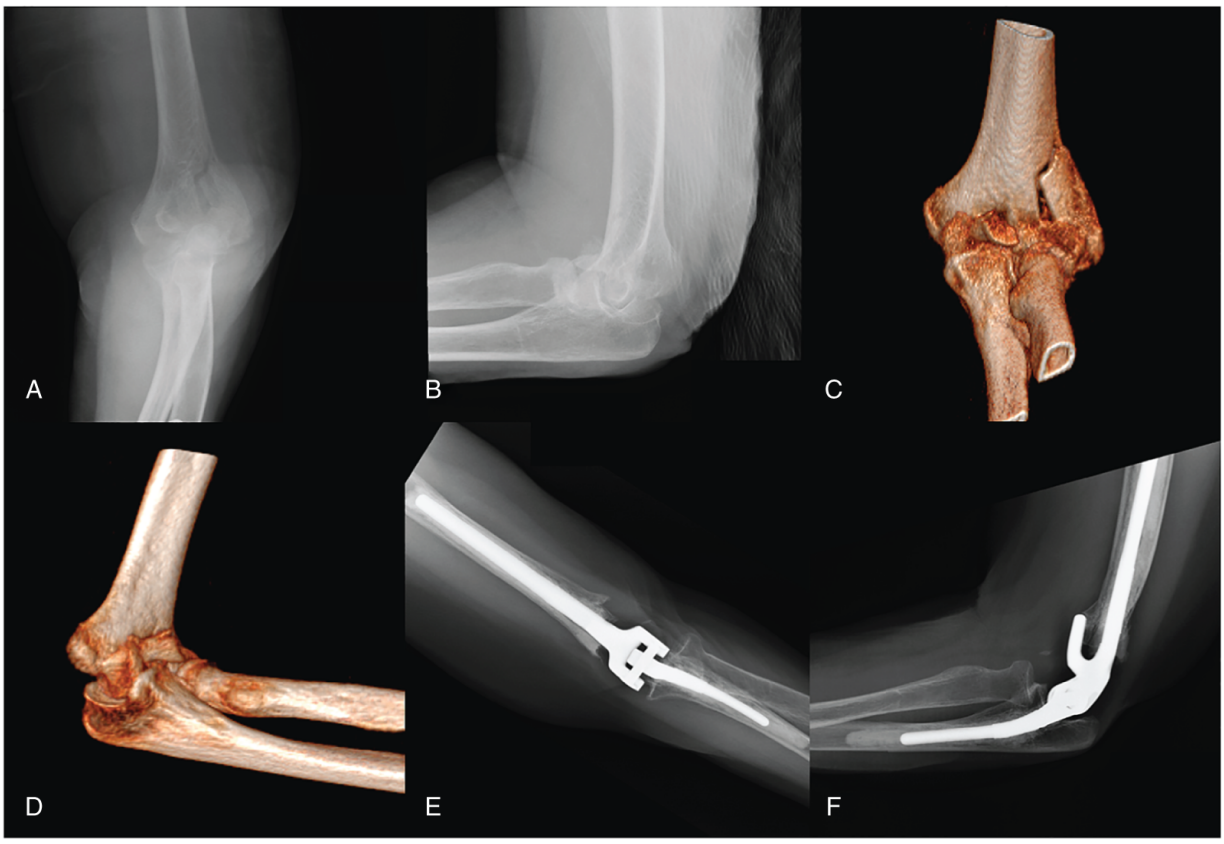

Figure 82.1 Radiographs and three-dimensional (3D) CT scan reconstructions of an 81-year-old female patient with a comminuted intra-articular distal humerus fracture, including a coronal shear component (A–D). Six-month postoperative radiographs following treatment with a semi-constrained total elbow arthroplasty (TEA) performed through a triceps sparing, para-tricipital approach (E and F).

Resolution of clinical scenario

In patients with an intra-articular distal humerus fracture, who are considered candidates for operative fixation of the fracture, it is the authors' approach to use a triceps-splitting technique (Figure 82.2) except in cases where there is extensive articular comminution, particularly those with a coronal shear component to the articular fracture. In these cases, the authors recommend an olecranon

osteotomy to improve visualization based on the evidence that suggests a triceps-splitting approach gives equivalent functional outcomes and a decreased need for removal of hardware when compared to olecranon osteotomy (overall quality: low).

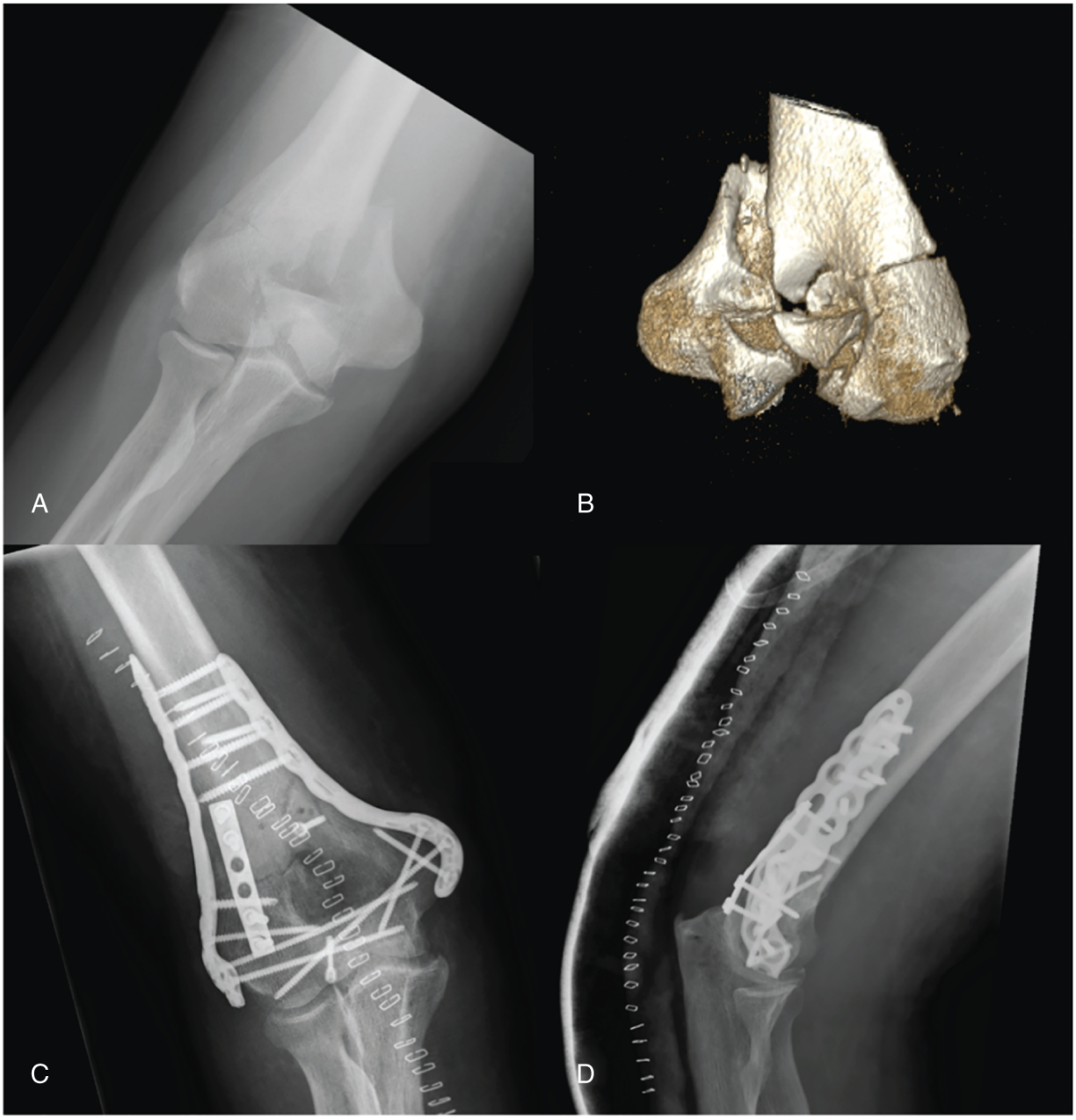

Figure 82.2 AP radiograph and 3D CT scan reconstruction of a 58-year-old male patient with a comminuted intra-articular distal humerus fracture (A and B). Postoperative radiographs following ORIF with parallel plating performed through a triceps-splitting approach (C and D).

Question 2: In patients with distal humerus fractures, does parallel plating result in better outcomes when compared to orthogonal plating?

Rationale

Since the introduction of AO techniques involving dual column plating for the fixation of distal humerus fractures, significant improvements in surgical outcomes have been observed. Evidence shows that plate fixation is superior compared to minimal fixation with screws and/or Kirschner wires (K-wires).[17,18] However, controversy remains regarding the position/orientation of plate fixation and the role of locked plating systems.

Clinical comment

Fixation for distal humerus fractures must achieve anatomic and absolute stability of the articular surface. Fixation strategies must also bridge metaphyseal comminution while allowing for early ROM to avoid significant postoperative stiffness. Research has focused on identifying the ideal dual plating construct to resist early failure while achieving reliable union rates.

Available literature and quality of the evidence

- Level II: 1 study[19]
- Level IV: 22 studies.[20–23]

Limited clinical evidence is available to answer this question. Most data come from a variety of biomechanical

studies using various fracture models to analyze the properties of these two constructs.

Findings

One level II study compared parallel plating to perpendicular plating in a prospective, randomized fashion (n = 35 patients).[19] Although no statistically significant differences were found between the two groups, there were two nonunions in the perpendicular plating group versus no nonunions in the parallel plating group. This study may have been underpowered to detect a clinically significant difference in union rates. Multiple level IV series have reported satisfactory results with perpendicular plating techniques[20–24] and parallel plating techniques.[25–30]

Several biomechanical studies have demonstrated that parallel plate configurations at 180 degrees to each other are biomechanically superior to perpendicular plates when a gap model is used to simulate fracture comminution.[31–33] Specifically, there is a significant increase in internal torsional stiffness with a parallel plating construct, parallel 2.9 ± 0.7 N-m/deg versus orthogonal 2.3 ± 0.6 N-m/deg, $p < 0.0001$, $R^2 > 0.98$.[34] In addition, axial loading of orthogonal plate constructs leads to anterior movement of capitellum relative to the trochlea which can lead to distal screw pull out in the posterolateral plate.[35]

Two clinical level IV studies have reported on the results of locked plating of distal humerus fractures (n = 52 patients).[36,37] Pooled analysis showed good/excellent results in 79% of patients, with only a single case of implant failure.

Biomechanical studies have shown improved stiffness with the use of locked plating constructs in gap models of comminuted distal humerus fractures. When comparing

fixation between an orthogonal locked plating system and orthogonal conventional plates, there was a 52% increase in stiffness ($p < 0.001$).[38]

Resolution of clinical scenario

In the case of our patient, the evidence supports the need for dual column fixation, either in perpendicular or parallel (overall quality: moderate). It is the authors' approach to use a parallel plating technique with pre-contoured, peri-articular, locking plates (Figures 82.2 and 82.3). This maximizes stability in fractures with metaphyseal comminution to allow for early ROM postoperatively. In some cases, with limited metaphyseal comminution but the fracture has a shear component laterally, a posterolateral plate is selected as it allows fixation from a posterior to anterior direction to capture large shear fragments.

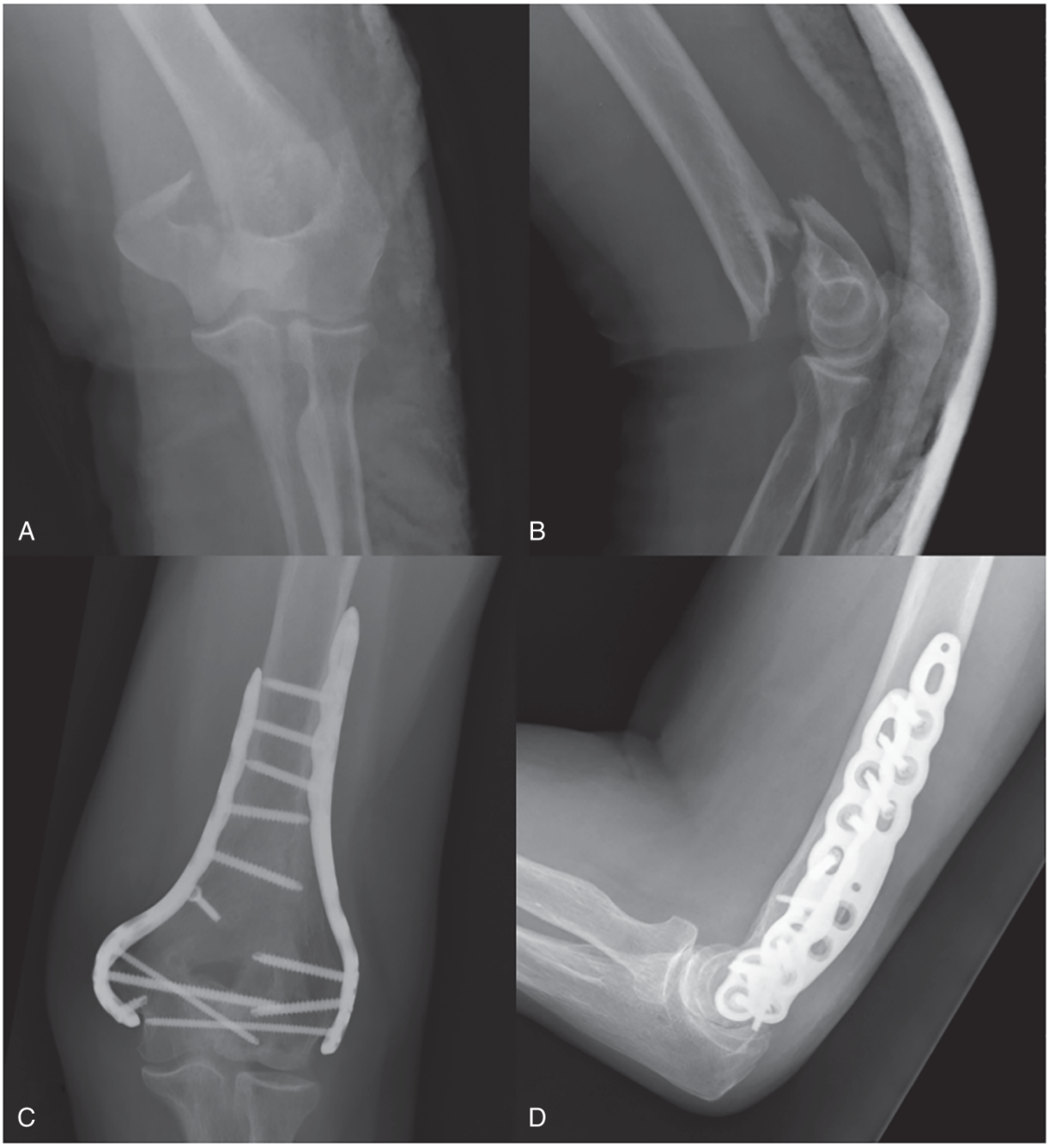

Figure 82.3 Preoperative radiographs of a 67-year-old female patient with an intra-articular distal humerus fracture (simple intra-articular split) (A and B). Six-month postoperative radiographs following ORIF with parallel plating performed through a para-tricipital approach (C and D).

Question 3: In elderly patients with comminuted, intra-articular, distal humerus fractures does total elbow arthroplasty (TEA) result in better outcomes than open-reduction and internal fixation?

Rationale

Distal humerus fractures with comminution of the articular surface can be difficult to manage, even in young patients with excellent bone quality. In elderly patients with poor bone quality and significant articular comminution, this challenge increases exponentially, and surgical outcomes have historically been poor in these patients. This has prompted many authors to investigate, and advocate for, the role of acute TEA in the management of distal humerus fractures in elderly patients, with a 2.6-fold increase in use between 2002 and 2012 in a US-based study.[39]

Clinical comment

In the setting of a comminuted distal humerus fracture, a semi-constrained TEA can be performed through a triceps-sparing, para-tricipital approach. This creates an immediately stable construct, which allows for early functional rehabilitation and avoids the complications of fracture nonunion and post-traumatic osteoarthritis. However, a TEA comes with inherent lifelong limitations in carrying weight (typically restricted to 10–15 pounds) as well as the risk for infectious or aseptic failure requiring revision.

Available literature and quality of the evidence

- Level II: 1 study[40]
- Level III: 7 studies[39–45]
- Level IV: 2 studies.[46,47]

Findings

A prospective, randomized, multicenter study compared ORIF versus TEA for displaced, intra-articular fractures of the distal humerus (OTA/AO type C) in patients over the age of 65 years (n = 40 patients).[40] The authors reported better functional outcomes in the TEA group vs the ORIF group at two-year follow-up. MEPS for TEA versus ORIF at two years were 86 versus 73 (p = 0.015); DASH scores showed a trend toward TEA at 32 versus 43 (p = 0.18). In addition, there was a 25% rate of intra-operative conversion to TEA in the ORIF group due to extensive comminution and inability to achieve stable fixation.

A systematic review and meta-analysis of studies published prior to 2014, involving geriatric distal humerus fractures, looked at outcomes between ORIF and TEA.[45] Based on the 27 studies identified, including 563 patients, the authors reported no clinically significant difference in functional outcomes. The number of patients experiencing at least one complication in the TEA group was 33.3 (CI: 21.6–44.9%) compared to the ORIF group 32.6 (CI: 21.8–43.5%), which did not differ significantly. Total complications were higher overall in the TEA group (37.6 vs 34.2%); however, major complications were higher after ORIF (11 vs 13.7%), resulting in a higher reoperation rate after ORIF (5.7 vs 9.4%).

Two level IV studies reported on 10-year outcomes data for TEA in the setting of distal humerus fractures.[46,47] Pooled analysis shows 47% patient survival at 10 years' follow-up, with a mean age at time of surgery of 71.

One level III study retrospectively compared the outcome of acute TEA for distal humerus fractures versus delayed TEA following failed ORIF or conservative treatment (n = 32 patients).[43] The authors reported a high rate of good/excellent functional outcomes (82%) with no significant differences between the two treatment groups. However, the results showed trends toward increased rates of infection, nerve injury, and implant failure in the delayed treatment group, and the study was likely underpowered to detect clinically significant differences in the rates of these complications between groups.

Resolution of clinical scenario

In the case of an elderly patient with a comminuted intra-articular distal humerus fracture, it is the authors' approach to evaluate the fracture with a computed tomography (CT) scan. This allows for the evaluation of the degree of comminution, presence of coronal shear components, and assessment of the joint for pre-existing osteoarthritis. In highly comminuted fractures, the evidence supports the use of TEA (Figure 82.1). This recommendation is strengthened in the presence of pre-existing osteoarthritis of the elbow. In this setting, elbow stiffness related to arthritis increases the stress through the fractured metaphysis, which may predispose to early hardware failure or nonunion.

Summary of answers

- The use of a triceps-splitting approach may lead to equivalent functional outcomes and a decreased need for re-operation when compared to an olecranon osteotomy (overall quality: low).

- A triceps-splitting approach is preferred over olecranon osteotomy for the treatment of open fractures of the distal humerus (overall quality: moderate).
- All distal humerus fractures involving both columns should be treated with dual plate fixation in either a perpendicular or parallel configuration (overall quality: moderate).
- In elderly patients (>65 years) with displaced, intra-articular distal humerus fractures not amenable to stable internal fixation acute TEA is preferred (overall quality: moderate).

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83
Elbow Dislocations

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Clinical scenario

- You see two patients in the Emergency Department after sustaining complex elbow fractures after falling while downhill biking.
- The first, a 35-year-old male, has an anteromedial facet (AMF) coronoid fracture (O'Driscoll subtype I) and a lateral collateral ligament (LCL) injury that you are not sure requires surgical management.
- The second, a 40-year-old male, has a terrible triad injury with a type I coronoid and severely comminuted radial head fracture. You are not sure if the coronoid requires fixation and want to avoid radial head replacement, if possible.

Top three questions

1. In patients with AMF fractures, does operative management result in improved outcomes compared to nonoperative management?
2. In patients with terrible triad injuries, does surgical management of the coronoid improve clinical outcomes compared to nonoperative management?

3. In patients with terrible triad injuries, does radial head arthroplasty lead to improved clinical outcomes compared to internal fixation?

Question 1: In patients with AMF fractures, does operative management result in improved outcomes compared to nonoperative management?

Rationale

The AMF is an important structure to varus posteromedial elbow stability. Understanding the evidence-based indications for operative and nonoperative treatment is important in properly managing these fractures.

Clinical comment

AMF fractures can be difficult injuries to diagnose and treat. They are often associated with ligamentous injuries that also often require surgical management. If not appropriately treated, they may be associated with poor outcomes, including ulnohumeral arthritis, with limited options for future management. Nonoperative management, however, can be considered in patients that meet specific injury criteria.[1,2] Understanding the implications of operative and nonoperative treatment is essential. O'Driscoll classification separates coronoid fractures into three types with subdivisions. Type I fractures involve the tip, type II fractures involve the AMF while type III involve the base. Type II fractures are further subdivided into those involving the rim, the rim and AMF, and those involving the sublime tubercle.[3]

Available literature and quality of the evidence

No level I or II evidence was found, and only one study, a retrospective cohort classified as level III,[4] while the remainder of the literature are case series with low patient numbers or biomechanical studies.[1,5–8]

Findings

Doornberg et al. followed 18 patients with AMF fractures (O'Driscoll subtype I in one case, subtype II in three cases and subtype III in 13 cases).[4] Fifteen of the cases had associated LCL injuries with two medial collateral ligament (MCL) injuries. Nine patients were treated with coronoid fixation and LCL reconstruction. Functional results were good or excellent in all but one patient with an average Bryan–Morrey elbow score of 97 and range of movement (ROM) of 131° (range 108–145°) and without instability. The other nine patients were characterized with either non- or tenuous fixation of the AMF. Average ROM of this group was 99° (30–140°) with an average score of 83. Seven of these patients had persistent instability in which six developed arthrosis. The authors concluded that all AMF fractures should be addressed surgically, even when small.

Pollock et al. biomechanically tested the stability of 10 cadaver elbows under varus and valgus gravitational loading with simulated type II (all subtypes) AMF fractures.[8] They found isolated LCL repair did stabilize the elbow with subtype I factures 2.5 mm or smaller. However, in the presence of 5 mm subtype I fractures, LCL repair alone did not achieve stability in the varus position (6.2° ± 4.5° internal rotation compared to 3.3° ± 3.1° normal elbow; $p < 0.05$). The authors recommended fixation of AMF fractures larger than 2.5 mm and that LCL repair alone cannot restore normal kinematics in the majority of cases.

Park et al. followed 11 patients with isolated AMF fractures consisting of subtypes I–III for an average of 31 months all of which were associated with an LCL injury, while six cases (mostly subtype I and II) also had a concurrent MCL injury.[7] Two patients with subtype I were treated with isolated LCL repair while the nine patients with subtypes II and III were treated with buttress plating. They documented a mean ROM of 128° and an average Mayo Elbow Performance Score (MEPS) of 89. Outcomes were classified as good or excellent in 10 patients. Rhyou et al. followed 18 patients with O'Driscoll type II AMF fractures (all subtypes) with or without LCL repair for a mean of 37 months.[6] Both cases of subtype I had fragments <5 mm and were treated with isolated LCL repair. Five of the subtype II fractures had open reduction and internal fixation (ORIF) and LCL repair, while six had only ORIF as they were deemed stable to varus and pronation testing after fixation. Two cases had fragments <5 mm and had isolated LCL repairs. Both subtype III fractures were managed with ORIF, while one also had LCL repair. The mean MEPS and Disabilities of the Arm, Shoulder, and Hand (DASH) scores were 98 and 5.6, respectively. There was no statistically significant difference between the outcomes scores, subtype, fixation method, or whether the LCL was repaired. Authors concluded that fragments <5 mm could be treated with isolated LCL repair. They also suggested that even fractures >5 mm with fixation stable to varus testing did not require LCL reconstruction.

Chan et al. specifically looked at fracture patterns that could be treated nonoperatively.[1] Nonoperative treatment was considered if there was concentric joint location, no block to mechanical rotation, a small coronoid fracture and a stable ROM arc to 30° of extension. Nine were classified as subtype II, while one was subtype III with an average size and displacement of 5 and 3 mm, respectively. Early

ROM was performed and all outcomes were reported as good to excellent. There was no significant difference between ROM and strength to the contralateral side at a mean follow-up of 50 months (range 12–81 months). The authors did caution, however, that the nonoperative approach required careful supervision and also cautioned the reliability of proper varus testing in acute elbow injuries.

Resolution of clinical scenario

- Small AMF fractures (subtype I), such as the patient in the clinical scenario, can likely be treated with isolated LCL repair provided the elbow is stable (overall quality: low).
- Elbow stability is of primary importance in AMF fractures and all stabilizing structures (LCL and MCL) should be addressed surgically, if necessary (overall quality: low).

Question 2: In patients with terrible triad injuries, does surgical management of the coronoid improve clinical outcomes compared to nonoperative management?

Rationale

The terrible triad (TT) injury of the elbow consists of a posterolateral ulnohumeral dislocation with fractures of the radial head, coronoid process and LCL. Coronoid fractures that occur in TT injuries tend to be transverse in nature and are often classified as O'Driscoll type I, or type I or II by the Regan and Morrey classification.[9] Fixation of the

coronoid process in TT injury of the elbow is controversial in the literature with early nonoperative studies showing poor outcomes.[10]

Clinical comment

Coronoid fractures accompany TT injuries, and it is important to understand when surgical management is indicated in these injuries as resultant instability contributes to poor outcomes.

Available literature and quality of the evidence

No level I or II evidence was found. One study, a retrospective cohort, is classified as a level III,[11] while the remainder of the literature is case series and cadaveric studies.[2,12–15]

Findings

Several studies have involved coronoid fixation in all cases and generally report good to excellent outcomes in 77–83% of cases with a mean arc of motion reported as 112–19°.[11,13,16] Arthrosis was reported as 28–67% while heterotopic ossification was reported as 8–14%. Recurrent instability was reported as 4–20%.[11,13,16]

Furthermore, Garrigues et al. reported a statistically improved reduction in instability using the suture lasso technique compared to suture anchors or screw fixation.[11] Elbows treated with suture lasso had instability via the hanging arm test in 4%, while suture anchors and screw fixation had instability in 57 and 20%, respectively ($p < 0.05$), which persisted at 18 months.

Papatheodorou et al. looked at TT injuries with type I and II coronoid fractures.[2] After radial head and LCL fixation, intraoperative fluoroscopy was utilized to assess stability,

and none of the coronoid fractures was fixed. The mean Broberg and Morrey score and DASH scores were 90 (range 70–100) and 14 (range 0–38), respectively, indicating good outcomes and no recurrent instability. One patient developed arthritic changes, while one had clinically insignificant heterotopic ossification.[2] The authors suggest that type I and II coronoid fractures may not require fixation provided the LCL, MCL, and radial head are all managed properly. This is in keeping with a cadaver study which showed that type I coronoid fracture suture repair had no effect on elbow biomechanics when the MCL, LCL, and radial head were appropriately managed.[12] Zhang et al. studied 13 TT patients with type I–III coronoid fractures. All coronoids were fixed except type I fractures, which were not attached to the anterior soft tissue complex. Eighty percent of patients had good to excellent outcomes at an average of 28 months. Recurrent instability was noted in two patients while heterotopic ossification and a synostosis were noted in 1 patient.[14]

Chan et al. studied nonoperative treated TT injuries in 12 elbows with the following criteria: the radial head did not cause a block to forearm rotation, the elbow was concentrically reduced, a stable ROM to 30° of extension and type I and II coronoid fractures. The mean MEPS outcomes scores were good to excellent in 10 elbows with only one recurrent instability while the mean DASH score was 7. Four patients developed arthritic changes, while one developed heterotopic ossification.[15] Another study reported a DASH and MEPS scores of 4.76 and 95, respectively, in 10 patients followed nonoperatively involving type I and II coronoids. Post-traumatic arthritis was noted in 30% of patients.[17] Both of these studies emphasized the importance of very careful surveillance for failure, which may not be available in every center.

Resolution of clinical scenario

- Some TT injuries can be managed nonoperatively if specific injury criteria are confirmed.
- Patients with type I coronoid fractures in the setting of a TT do not require coronoid fixation in the setting of a stable elbow.
- Although some studies suggest type II coronoid fractures do not require fixation, most authors advocate for surgical management as it is likely associated with improved outcomes.

Question 3: In patients with terrible triad injuries, does radial head arthroplasty lead to improved clinical outcomes compared to internal fixation?

Rationale

Radial head fractures are part of the TT elbow injury and often have multiple fragments. Fixation and arthroplasty are common treatment methods, and some debate exists on the optimal treatment.

Clinical comment

Arthroplasty and fixation are both methods utilized in the treatment of radial head fractures associated with TT injuries. Arthroplasty has become more common; however, some centers still prefer an attempt at ORIF prior to arthroplasty. Understanding the complications and technical considerations of these treatment methods is important to optimize outcomes.

Available literature and quality of the evidence

There are two level I randomized controlled trials (RCTs) as well as a meta-analysis.[18–20]

Findings

Chen et al. performed an RCT comparing ORIF versus arthroplasty in Mason III radial head fractures in the setting of complex elbow dislocations.[18] They enrolled 45 cases with a two-year follow-up. Either plates and/or screws or a monopolar implant were utilized. The overall satisfaction for the arthroplasty and ORIF groups were 91 and 65.2%, respectively ($p < 0.01$). There was a significantly higher complication rate in the ORIF group (47.9%) compared to the arthroplasty group (13.6%). Common complications in the ORIF group included stiffness, nonunion, hardware failure, and heterotopic ossification. The complication in the arthroplasty group included stiffness. The authors concluded that Mason III radial head fractures in the setting of a complex elbow dislocation should be managed with arthroplasty. Interestingly, they did not report any radiocapitellar arthrosis at two years.

Yan et al. also conducted an RCT involving Mason III fractures in the setting of a TT injury. Thirty-nine patients were randomized to ORIF or arthroplasty and followed for three years. They reported significantly longer surgical times for ORIF ($p < 0.001$). The MEPS was significantly improved in the arthroplasty group (85.8 vs 77.9; $p < 0.009$). The flexion–extension arc was also improved in the arthroplasty group (101 vs 92°; $p = 0.01$) as was the pronation–supination arc (114° vs 103°; $p = 0.04$). Furthermore, the overall complication rate for arthroplasty was lower ($p = 0.04$). Two patients in the arthroplasty group required revision, one for stiffness due to

overstuffing and one for heterotopic ossification. Four patients in the ORIF group had stiffness that required re-operation. In addition, two patients developed heterotopic ossification that required revision, while one had failed hardware that also required revision. As with the other study, no radiocapitellar erosion was seen.

A meta-analysis which included the two randomized trials as well as six other nonrandomized studies compared ORIF versus arthroplasty.[20] There were 138 fractures managed with ORIF and 181 with arthroplasty. The satisfaction rates for radial head arthroplasty (RHA) and ORIF were 94.6 and 72.9%, respectively (risk ratio = 0.72; 95% confidence interval [CI]: 0.44–1.18; p = 0.20), with high heterogeneity (I^2 = 89%). The MEPS (MD −7.08; 95% CI: -12.93 to −1.24; p = 0.02) and elbow score (−15.53, 95% CI: −23.16 to −7.91; p <0.001) showed statistically significant improvement with arthroplasty with low (I^2 = 0%) and high (I^2 = 93%) heterogeneity, respectively. The revision rate for arthroplasty and ORIF was 16.7 and 20.1%, respectively, and did not reach statistical significance. Common complications associated with ORIF was failure of fixation (15.5%), nonunion, and resorption (18.5%). Complications associated with arthroplasty were overstuffing and subluxation. There were no significant differences between infection, heterotopic ossification, stiffness, or nerve injury. The methodology for the studies was considered moderate to low and thus caution should be employed when generalizing these results.

Resolution of clinical scenario

- Level I literature suggests that unstable and comminuted radial head fractures associated with complex elbow dislocations (terrible triad injuries),

such as the one in the clinical scenario, are better managed with arthroplasty.

- Technical considerations for proper arthroplasty are critical for optimal outcome.

Summary of answers

- O'Driscoll type II/III AMF fractures are better treated with ORIF and concurrent LCL and MCL reconstruction, if necessary. Elbow stability in this setting is critical.
- Type I coronoid fractures in the setting of a terrible triad injury often do not require fixation. There is some evidence that type II and III fractures should be surgically addressed.
- Level I evidence shows that in the setting of a TT injury, radial head arthroplasty is associated with improved outcomes.

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84
Radial Head Fractures

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Clinical scenario

- A 36-year-old woman arrives at the Emergency Department with elbow pain after a fall onto her outstretched left hand while skating.
- On examination, her range of elbow motion is limited due to pain, and she has tenderness over the radial head.

Top three questions

1. In patients with radial head fractures, does aspiration/injection aid in the initial management compared to radiographs alone?
2. In patients with displaced isolated partial radial head fractures, does operative treatment result in better outcomes compared to nonoperative treatment?
3. In patients with unstable or displaced fractures of the radial head that are part of a complex injury, does open reduction internal fixation (ORIF) have better outcomes compared with excision with or without prosthetic replacement?

Question 1: In patients with radial head fractures, does aspiration/injection aid in the initial management compared to radiographs alone?

Rationale

Aspiration of the hemarthrosis and injection of local anesthesia might help determine if some radial head fractures are hindering forearm rotation, and thus change the treatment strategy to follow. The role of aspiration for pain relief alone is debatable.

Clinical comment

The patient's radiographs reveal a minimally displaced partial articular radial head fracture. Forearm motion is limited by pain. You would like to know if the patient has any blockage while moving the forearm from pronation to supination.

Available literature and quality of the evidence

- Level I: 2 systematic reviews and 1 randomized trials.
- Level III: 1 retrospective cohort study.

Findings

In one study, 80 patients with minimally displaced partial articular radial head fractures treated nonoperatively were randomized to aspiration and injection of bupivacaine with initiation of exercises or exercises alone.[1] Aspiration was associated with improved initial comfort and motion, but there was no difference in final motion.

A randomized trial of 40 patients with minimally displaced radial head and neck fractures treated nonoperatively to aspiration alone versus aspiration with intra-articular injection of bupivacaine. The authors found there was instant relief with aspiration with or without bupivacaine ($p < 0.001$). In both groups on average the Visual Analog Score (VAS) dropped from a VAS of 8 (IQR 7 to 8) in Group A (aspiration only) and 8 (IQR 7 to 9) in Group B (aspiration with bupivacaine injection) to an average of 1.5 and 1, respectively, following intervention. But at all time points thereafter there was no difference in pain with both groups having a VAS of 0 (no pain) at six weeks. ROM (flexion, extension, supination, and pronation) additionally had significant improvement one day after intervention in both groups but had very similar results at six weeks.[2]

A meta-analysis concluded that the quality of evidence for aspiration of a traumatic elbow effusion was low and insufficient to recommend it as a routine procedure.[3]

Resolution of clinical scenario

- Aspiration of the hematoma of the elbow joint might aid in pain relief in the acute setting (overall quality: moderate).
- There is insufficient evidence to determine whether joint aspiration and/or injection can improve final elbow motion.

Question 2: In patients with displaced isolated partial radial head fractures, does operative treatment result in better outcomes compared to nonoperative treatment?

Rationale

In the acute setting, patients often wonder what, if any, limitations they will have in the future due to their injury, and how this may relate to treatment options. Nonoperative treatment of displaced partial articular fractures of the radial head without elbow dislocation or associated fractures is associated with good recovery. Operative treatment is straightforward; has similar outcomes; and is associated with some operative risks, discomforts, and inconveniences.

Clinical comment

The patient radiographs reveal an isolated, displaced (2 mm step in the articular surface) partial articular radial head fracture. What evidence exists to inform the decision between operative and nonoperative treatment?

Available literature and quality of the evidence

- Level II: 1 systematic review.
- Level IV: 1 systematic review and 2 retrospective case series.

Findings

A systematic review of 28 studies identified 14 studies involving 519 patients treated operatively and 7 studies involving 430 patients treated nonoperatively. Fifty-two percent of patients treated nonoperatively and 88% of patients treated operatively had satisfactory Broberg and Morrey ratings (reported as good to excellent with scores ranging from 80 to 100). Residual pain was reported in 42% of patients treated nonoperatively and 32% of the patients treated operatively. Authors noted high

heterogeneity in the review and refrained from pooling all the results of the study.[4]

In a second review limited to nine retrospective case series with an adequate description of the treatment method and a well-defined rating system (Broberg and Morrey, Mayo Elbow Performance, or Riseborough and Radin scores), 142 patients were treated nonoperatively and 82 were treated with open reduction and internal fixation (ORIF). Treatment was rated successful in 80% of patients treated nonoperatively and 93% treated operatively with ORIF. Complications were not reported in any of the studies.[5]

In 2005, Herbertsson and colleagues examined 32 patients treated nonoperatively for stable, isolated, minimally displaced fractures of the radial head or neck an average 21 years after injury.[6] Twenty-nine of the patients had no symptoms and three had occasional elbow pain.

In 2006, the same group published an average 19-year evaluation of 49 patients with isolated, displaced, partial articular fractures of the radial head (2–5 mm displacement) treated nonoperatively.[7] At the final evaluation, 40 patients had no symptoms, 8 had occasional elbow pain, and 1 had daily pain. On average, there was a slight decrease in flexion (mean/standard deviation [SD]: 138 deg ± 8 compared with 140 deg ± 7), and extension (mean/SD: −4 ± 8 compared with −1 ± 6), compared with the contralateral side ($p < 0.001$).

In 2012, a cohort study of 100 patients described the long-term results of isolated, stable radial head fractures both nondisplaced (Mason 1) and displaced (Mason 2) treated nonoperatively. Ninety-two patients were satisfied with the result. Only 1 of 43 patients with a Mason 2 fracture (average displacement 2.5 mm, range 2–5 mm) had surgery, because the fracture was thought to be restricting forearm rotation. Stiffness (14%) and residual pain (24%) were the

most common problems an average of 10 years after injury. Factors independently associated with greater symptoms and limitations (higher Disabilities of the Arm, Shoulder, and Hand [DASH] score) included older age, comorbidities, greater socioeconomic deprivation, greater fracture displacement, and a legal dispute.[8]

Resolution of clinical scenario

- There are no randomized trials comparing operative and nonoperative management of displaced partial articular radial head fractures.
- In the long-term, patients with non- or minimally displaced fractures of the radial head and neck can expect minimal impairment or discomfort with slight radiographic arthrosis (overall quality: low).
- Patients with displaced partial articular fractures that are not part of a more complex injury can expect some limitation of range of motion and some pain whether treated operatively or nonoperatively. (overall quality: low).
- The relative advantages and disadvantages of surgery for isolated, stable, partial articular fractures displaced more than 2 mm are uncertain.

Question 3: In patients with unstable or displaced fractures of the radial head that are part of a complex injury, does open reduction internal fixation (ORIF) have better outcomes compared with excision with or without prosthetic replacement?

Rationale

Treatment of displaced and unstable radial head fractures is debated. Fractures that were once treated with excision are now often treated with ORIF or prosthetic replacement, particularly in a complex injury that includes an associated coronoid fracture.

Clinical comment

The patient had a concomitant elbow dislocation that was reduced. Her radiographs reveal a displaced, unstable articular fracture of the radial head. You plan to treat her operatively.

Available literature and quality of the evidence

- Level I: 1 meta-analysis.
- Level II: 1 randomized controlled trial (RCT).
- Level III: 4 retrospective comparative studies.

Findings

Our review of published evidence identified one small RCT evaluating ORIF versus prosthetic replacement of the radial head for displaced, unstable radial head fractures.[9]

Fourteen patients were randomized to radial head replacement and eight patients received ORIF. Patients were followed for an average of 16 and 14 months, respectively. Using the Broberg and Morrey score, the authors found good to excellent results in 12 out of 14 (93%) patients treated with radial head replacement, compared to 1 of 8 (12.5%) patients treated with ORIF. Despite the small numbers, the magnitude of this difference was enough to achieve statistical significance ($p = 0.0004$).

A study using claims data identified 58 000 radial head fractures: 2981 treated operatively including 57% treated with ORIF, 38% with radial head arthroplasty (RHA), and 5% with radial head excision. Radial head fractures initially treated with ORIF were more likely to have a second surgery within two years compared to those treated initially with RHA (12.7% at one year and 14.4% at two years compared to 8.6 and 10.7% for RHA ($p < 0.05$). The study also suggests that radial head arthroplasty is utilized more frequently as the complexity of injury increases and has lower rates of revision surgery.[10]

A meta-analysis of nine studies with 365 patients with displaced fractures of the entire radial head (169 treated with radial head replacement and 196 treated with ORIF) found that patients who received radial head replacement had a significantly higher percentage of good to excellent categorical results (odds ratio [OR] = 3.48; 95% confidence interval [CI]: 1.98–6.11; $p < 0.0001$; I^2 4%; $p = 0.40$ better Broberg and Morrey elbow scores (weighted mean difference [WMD] = 9.79; 95% CI: 4.22–15.36; $p = 0.0006$; I^2 94%; $p < 0.0001$), and significantly fewer postoperative complications (OR = 0.33; 95% CI: 0.16–0.69; $p = 0.003$; I^2 0%; $p = 0.64$).[11]

A cohort study of operative management of displaced, unstable radial head fractures in young, active, high-demand patients compared 67 treated with ORIF and 10 treated with RHA. Injury complexity had a negative impact on motion, complications, and reoperation, but RHA versus ORIF did not. RHA was associated with more heterotopic ossification (30 vs 14%), implant loosening (20%), and neurologic injury (10%).[12]

Resolution of clinical scenario

- Limited retrospective and prospective data also support prosthetic replacement over ORIF for complex, displaced fractures of the entire head of the radial head (overall quality: moderate).

Summary of answers

- Aspiration of the hematoma of the elbow joint might aid in pain relief in the acute setting, but there is insufficient evidence to determine whether joint aspiration and/or injection can improve final elbow motion.
- Limited retrospective and prospective data also support prosthetic replacement over ORIF for complex, displaced fractures of the entire head of the radius (overall quality: moderate).
- In the long-term, patients with a minimally displaced fracture of the radial head or neck can expect minimal impairment (overall quality: low).
- Patients with a displaced, isolated, stable partial articular fracture can expect some limitation of range of motion and some pain whether treated operatively or nonoperatively (overall quality: low).

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85
Olecranon Fractures

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Clinical scenarios

Cases 1 and 2

- A 76-year-old female presents to the Emergency Department with left elbow pain after a fall from standing height after tripping on the carpet in her nursing home.
- On physical examination, she is tender about the elbow with a palpable defect over the proximal ulna.
- She has no active elbow extension.
- Figures 85.1 and 85.2 show what the radiographs reveal.

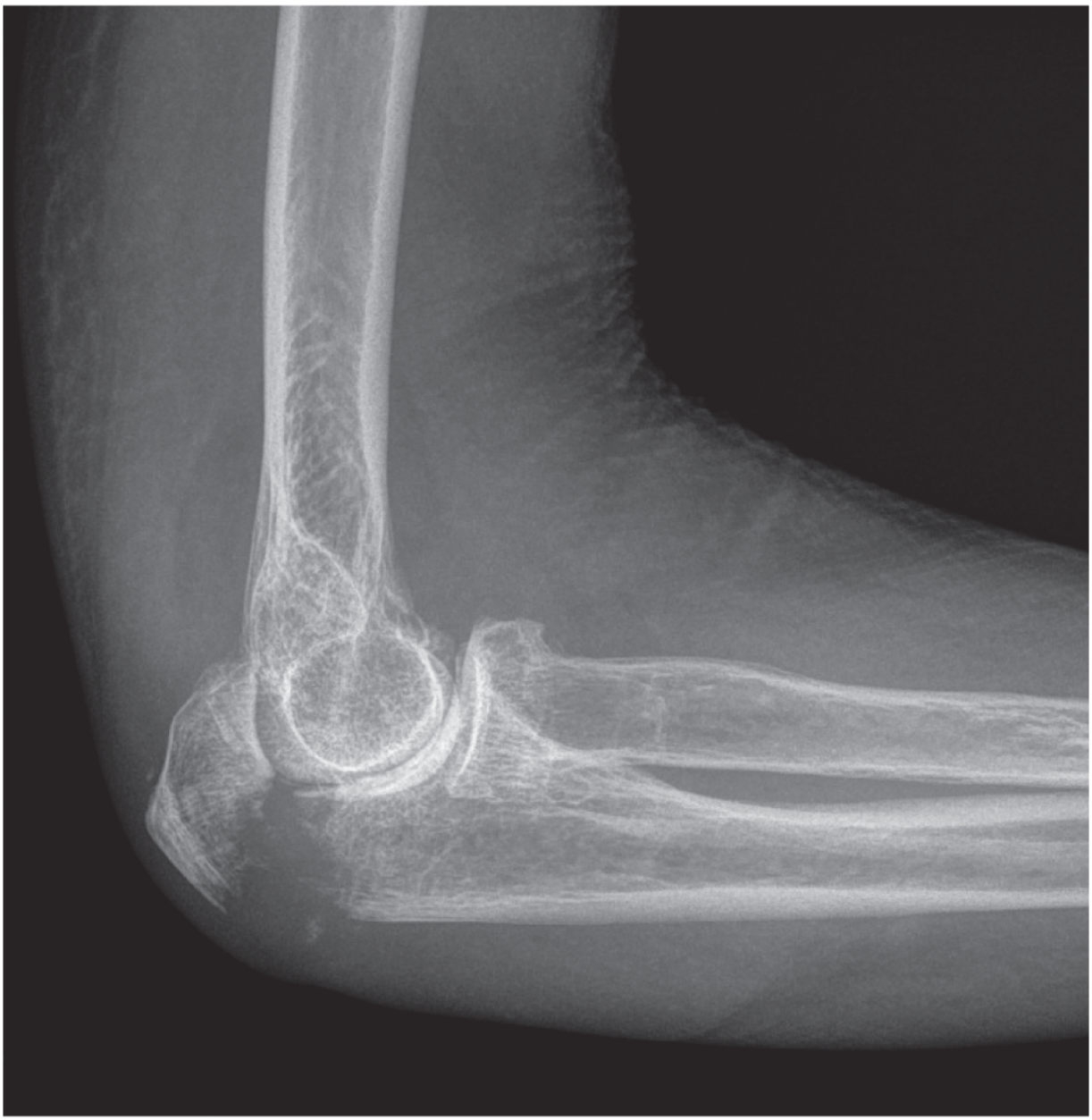

Figure 85.1 Case 1.

Case 3

- A 43-year-old male motorcyclist presents to the Emergency Department with right elbow pain after a collision.
- On physical examination, he is swollen and tender about the elbow with a palpable defect over the

proximal ulna.

- He has no active elbow extension.
- Figure 85.3 shows the lateral radiograph (case courtesy of Chaitanya Mudgal, MD).

Top three questions

1. In patients with displaced olecranon fractures treated surgically, how do the outcomes compare between those treated with internal fixation vs fragment excision and triceps advancement?
2. In low-demand elderly patients with displaced olecranon fractures, does surgery result in improved outcomes compared with nonsurgical treatment?
3. In patients with simple or minimally comminuted, stable, displaced olecranon fractures treated with surgery, how does tension-band wiring (TBW) compare with dorsal plating in terms of outcomes, complications, and costs?

Question 1: In patients with displaced olecranon fractures treated surgically, how do the outcomes compare between those treated with internal fixation vs fragment excision and triceps advancement?

Rationale

As internal fixation implants and surgical techniques have been refined, our ability to achieve stable fixation constructs in comminuted fracture patterns has improved.

As a result, more fractures are being treated with open reduction and internal fixation, including olecranon fractures that may have previously been treated with fragment excision.

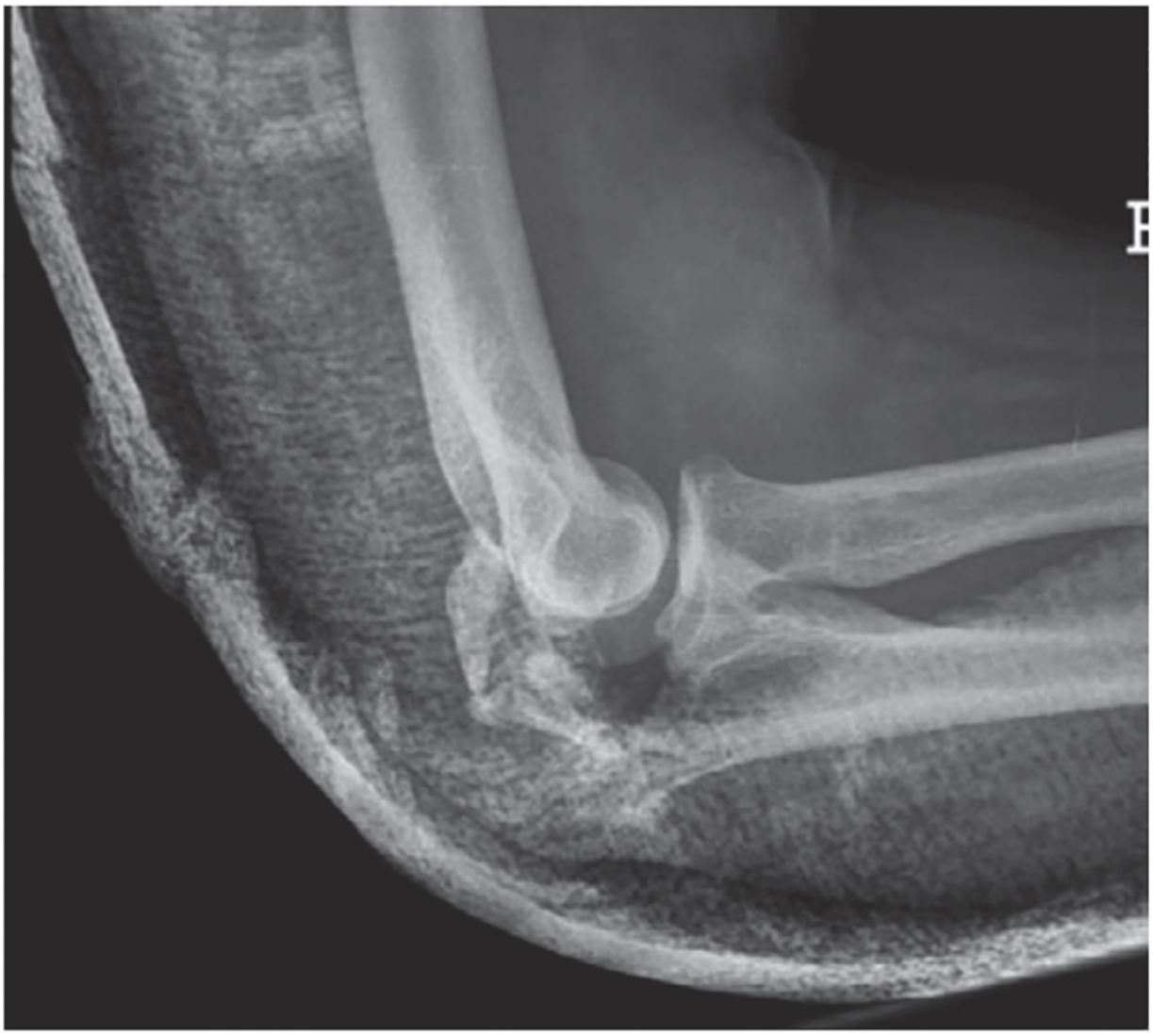

Figure 85.2 Case 2.

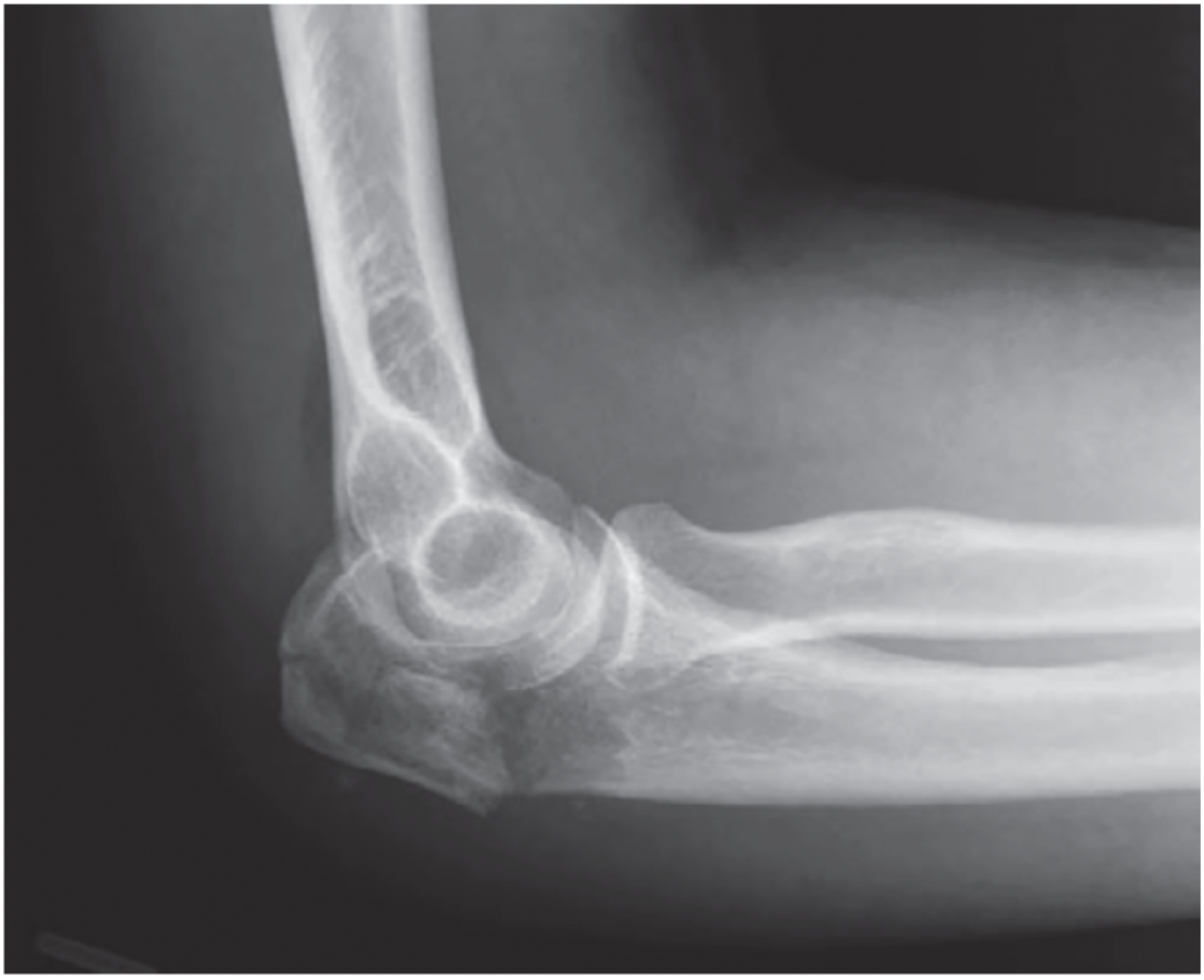

Figure 85.3 Case 3.

Clinical comment

Fragment excision with triceps advancement is usually now reserved for elderly patients with low functional demands and olecranon fractures with small proximal fragments and/or extensive comminution not amenable to internal fixation. Otherwise, internal fixation is typically the treatment of choice for acute displaced olecranon fractures.

Available literature and quality of the evidence

- Level III: 2 retrospective studies comparing excision versus internal fixation.[1,2]
- Level IV: 4 retrospective case series.[3–6]

Findings

Since the 1940s, fragment excision with triceps advancement has been considered in the management of select olecranon fractures, especially in low-demand elderly patients and injuries with extensive comminution not amenable to internal fixation.[1–6]

As the olecranon process contributes to the osseous constraint and stability of the ulnohumeral articulation,[7] partial excision of the olecranon raises concern for creating iatrogenic elbow instability. There are conflicting reports in the literature as to how much of the olecranon may be excised. Clinical studies suggest that up to 50%[2] (or perhaps as much as 60%,[8] 70%,[6] or 80%[4]) of the semilunar notch of the olecranon may be safely excised without causing clinically relevant instability of the elbow, assuming an intact coronoid, radial head, and collateral ligaments.[2,4,6,8] Cadaver studies of sequential olecranon resection have demonstrated increasing elbow angular and rotational laxity with increasing olecranon resection.[9,10] While the landmark study by An and Morrey suggests up to 50% of the olecranon may be removed without adversely affecting ulnohumeral joint stability,[7,9] a subsequent biomechanical study by Bell et al. suggested up to 75% of the olecranon articular surface can probably be removed, provided there are no concurrent injuries to the coronoid, radial head, or collateral ligaments.[10] In the same study, however, Bell et al. also demonstrated that elbow instability became evident following even small amounts of olecranon resection. The authors therefore cautioned against

olecranon resection if internal fixation is possible or alternative reconstructive options exist.[10]

Rettig et al. reported comparable range of motion (ROM) among four patients treated with excision and 34 patients treated with internal fixation, and a higher rate of complications (15% reoperation rate) with internal fixation. Despite these findings, the authors recommended excision only when internal fixation is not possible.[1]

Gartsman et al. compared primary excision (n = 53) with internal fixation (n = 54) for olecranon fractures.[2] Excision was used for all severely comminuted and small avulsion fractures; patients with two-part fractures were equally distributed between the excision and internal fixation groups. Twenty-nine patients were reviewed at minimum two-year follow-up (range 2–15 years); of the 15 patients who underwent primary excision, nine had 33–50% of the articular surface excised, and the six had ≥50% of the articular surface excised. Comparing patients treated with primary excision versus internal fixation at two years' minimum follow-up, there was no difference in pain, instability, ROM, or elbow extension strength.[2]

Resolution of clinical scenario

In Case 2, a low-demand elderly patient presented with a stable displaced olecranon fracture with small proximal fragments and extensive comminution (Figure 85.2). Key takeaways:

- For fractures involving up to 50% (and possibly up to 75%) of the articular surface, fragment excision and triceps advancement can be considered with the expectation of similar postoperative elbow strength compared to fracture fixation.

- Associated injuries to the primary or secondary stabilizers of the elbow may lead to instability with fragment excision; therefore, this technique may be best reserved for isolated, stable, severely comminuted fractures not amenable to fixation.

Question 2: In low-demand elderly patients with displaced olecranon fractures, does surgery result in improved outcomes compared with nonsurgical treatment?

Rationale

The literature regarding the management of displaced olecranon fractures is replete with studies debating the virtues of various surgical fixation constructs. Yet the more fundamental question has remained largely unanswered: which patients do better with surgery as compared with no surgery?

Clinical comment

Although displaced olecranon fractures are typically treated surgically, a recent prospective randomized trial comparing operative with no-operative care suggested comparable outcomes and fewer complications with nonsurgical management in low-demand elderly patients.[11]

Available literature and quality of the evidence

- Level II: 1 underpowered prospective randomized trial.[11]
- Level IV: 5 retrospective case series.[12–16]

Findings

Duckworth and colleagues published a prospective randomized trial comparing surgical and nonsurgical management for acute, closed, stable displaced (MEPS type 2A or 2B)[16] olecranon fractures in adults ≥75 years of age.[11] Nineteen patients were randomized to operative (n = 11) or nonoperative (n = 8) treatment. Patients were surgically treated with TBW (n = 9) or precontoured nonlocking plate (n = 2) fixation depending on fracture configuration, with plates being used for the more comminuted fractures. The decision on surgical technique was made by the treating surgeon.

Though 25 patients were needed in each arm according to a priori power analysis, the study was stopped prematurely due to the high rate of complications in the operative arm which caused loss of equipoise among surgeons involved in the study. With only six in the nonoperative group (two patients died from unrelated causes before they could be analyzed at one year postop) and only 11 in the operative group included in the final analysis, the study is underpowered: conclusions regarding the noninferiority of nonoperative management cannot be drawn based on this trial.

Outcomes

Although the study was underpowered, analysis of available data showed no difference ($p \geq 0.05$) in Disabilities of the Arm, Shoulder, and Hand (DASH) score at one year, or at any time point. Mean DASH at one year was 23 (range 0–59.6) in the nonoperative group and 22 (range 2.5 – 57.8) in the operative group ($p = 0.763$). At one year, mean elbow flexion arc was better in the operative group (129° [range 105–145°]) compared with the nonoperative group (106° [range 75–140°]) ($p = 0.049$). Otherwise, there was

no significant difference between groups for pain, forearm ROM, or surgeon-reported outcomes (Broberg and Morrey score,[17,18] Mayo Elbow Performance Score [MEPS][19] at any assessment point after injury (all p ≥0.05).

Complications

There were 13 complications in 10 patients, with significantly more complications in the operative group (9 of 11 patients = 81.4%) compared with the nonoperative group (one of seven patients = 14.3%) (p = 0.013). The one patient in the nonoperative group had an associated radial head subluxation (MEPS type III), which was initially missed and then ultimately treated with ORIF; this was complicated by failure of fixation due to infection requiring additional surgical irrigation and debridement, sinus tract excision, removal of hardware, and a prolonged course of antibiotics. The infection resolved and this patient developed a fibrous nonunion with a pain-free functional ROM at one year. Six of 11 patients (54%) in the operative group had loss of reduction of the fracture (all TBW). Three of 11 patients (27.3%) required removal of prominent metalwork (two plates, one TBW). One additional patient (plate) developed infection requiring excision of a chronic sinus.

Resolution of clinical scenario

In Case 1, a low-demand elderly patient presents with a stable displaced olecranon fracture (Figure 85.1). Key takeaways:

- An underpowered prospective randomized trial of low-demand elderly patients with stable displaced olecranon fractures suggests nonsurgical management results in comparable outcomes and fewer complications as compared with surgery

(predominantly TBW fixation).[11] These results, in combination with the results from retrospective case series,[12–16] suggest nonsurgical management of stable displaced olecranon fractures may be reasonable in older patients with lower functional demands.

Question 3: In patients with simple or minimally comminuted, stable, displaced olecranon fractures treated with surgery, how does tension-band wiring (TBW) compare with dorsal plating in terms of outcomes, complications, and costs?

Rationale

Although surgical fixation is often used for managing simple or minimally comminuted stable displaced olecranon fractures in young active patients, the choice of surgical technique remains controversial and there is no clear consensus.

Clinical comment

While stable displaced olecranon fractures in young active patients are often treated with TBW fixation, a recent prospective randomized trial comparing nonlocking plate with TBW fixation suggests comparable outcomes and costs and fewer complications with nonlocked plating.[20]

Available literature and quality of the evidence

- Level I: 1 prospective randomized trial.[20]

- Level II: 1 prospective randomized trial with methodological limitations.[21]

Findings

Duckworth and colleagues recently published a prospective randomized trial comparing nonlocking plate versus TBW fixation for acute, closed, stable displaced (MEPS type 2A)[16] olecranon fractures in adults ≥16 and <75 years of age.[20] Sixty-seven patients were randomized to treatment with either a pre-contoured nonlocking dorsal proximal ulnar plate (n = 33) or TBW (n = 34) fixation. The TBW group was significantly younger (43 ± 16 vs 52 ± 17 years, p = 0.028) with a trend toward fewer comorbidities (p = 0.100); otherwise baseline characteristics were comparable. Data were analyzed according to intention-to-treat principles and crossover was minimal. Based on *a priori* power analysis, the study was adequately powered to detect a clinically relevant mean difference of 10 points in DASH score 1 year after surgery.[22]

Outcomes

There was no significant difference in DASH at any time point. Mean DASH at 1 year was 12.8 ± 20 (range 0–79; 95% CI 5.3–20) in the TBW group and 8.5 ± 10 (range 0–41; 95% CI 4.4–12.5) in the plate group (p = 0.315). There was no statistically significant difference between groups in ROM, Broberg and Morrey score, or MEPS at any time point after surgery (all p≥0.05). Though these comparisons technically did not achieve statistical significance, there was a trend toward better surgeon-reported outcomes in the plate group (Broberg and Morrery score 95 vs 89, p = 0.072; MEPS 96 vs 90, p = 0.05). In their multivariate analysis controlling for covariates, increasing ASA grade was the only independent predictor of worse outcome.

Complications

Among the 62 patients (32 plate; 30 TBW) assessed for complications, the authors reported 41 complications in 31 patients, yielding an overall complication rate of 50%. Complications were significantly more common with TBW—19 of 30 patients (63.6%) had a complication in the TBW group, compared with 12 of 32 patients (37.5%) in the plate group ($p = 0.042$). The rate of removal of symptomatic implants was more than twice as high with TBW (15 of 30 patients [50%]) compared to plating (7 of 32 patients [21.9%]) ($p = 0.021$). Loss of reduction also occurred more than twice as often with TBW (8 of 30 patients [26.7%]) as compared with plating (4 of 32 patients [12.5%]), though this did not reach statistical significance ($p = 0.206$). Four patients (12.5%) had infections (two superficial infections that responded to antibiotics; two deep infections that required revision surgery) in the nonlocked plate group; no infections occurred in TBW group ($p = 0.114$).

Costs

Costs were analyzed for 62 patients taking into account number of days in hospital as well as the costs of inpatient and outpatient treatment, including the costs associated with complications (e.g., additional trips to the operating room, antibiotics, etc.). Despite the higher initial cost of the nonlocking plate and screws ($836.72) compared with the cost of the tension band wire ($30.28), the overall median cost per patient was higher in the TBW group ($8374 [range $4471–$42183, IQR $4471–$8538]) compared to the plate group ($7812 [range $5249–$34815, IQR $5273–$10310]), though this did not reach statistical significance ($p = 0.131$).[20]

In contrast, Amini et al retrospectively compared locking plate (n = 10) and TBW (n = 10) fixation for simple isolated transverse olecranon fractures and found significantly higher overall operative costs with locked plating ($14333.46 vs $6598.36, p<0.001), despite a higher rate of hardware removal in the TBW group (40% vs 10%).[23] The difference in cost analysis between the two studies may be at least partly explained by the fact that Amini et al did not consider other costs (e.g., length of inpatient stay, cost of outpatient follow-up) and the implants they used were locking plates which were much more expensive than the nonlocking plates used by Duckworth et al ($6688.52 vs $836.72).[21,23]

In 1992, Hume and Wiss published the only other prospective randomized trial comparing plate (n = 22) and TBW (n = 19) fixation for displaced olecranon fractures.[21] They included comminuted fractures and open fractures. Power analysis was not performed; patient-rated outcome measures were not utilized; costs were not analyzed. Similar to the results reported by Duckworth et al, Hume and Wiss found comparable ROM between groups at six months after surgery, with loss of reduction and symptomatic implant prominence significantly more common in the TBW group (both p <0.05).[20,21] Unlike the trial by Duckworth et al, Hume and Wiss found clearly superior surgeon-rated clinical results in the plate fixation group (86% good results with plate, vs 47% good results with TBW).[21] In contrast to these findings, the trial by Duckworth et al showed no significant difference in outcome between plate and TBW groups at 1 year, though there was a trend toward better outcomes in the plating group for patient- and surgeon-reported outcome measures.[21]

Resolution of clinical scenario

In Case 3, a young active patient presents with a stable displaced olecranon fracture with minimal comminution (MEPS 2A) (Figure 85.3). Key takeaways:

- In the only adequately powered prospective randomized trial of stable displaced olecranon fractures in young active patients (<75 years of age), there were no significant differences in outcomes between nonlocking plate and TBW groups at one year, though there was a trend toward better outcomes in the plating group for patient- and surgeon-reported outcome measures.[20] The authors also demonstrated nonlocking plate fixation had comparable costs and a significantly lower rate of complications as compared to TBW fixation.[20]
- In young active patients, both plate and TBW fixation result in functional elbow ROM; compared to plating, loss of reduction and symptomatic implants are more common with TBW fixation.[20,21]

Summary of answers

- For fractures involving up to 50% (and possibly up to 75%) of the articular surface, fragment excision and triceps advancement can be considered with the expectation of similar postoperative elbow strength compared to fracture fixation.
- Associated injuries to the primary or secondary stabilizers of the elbow may lead to instability with fragment excision; therefore, this technique may be best reserved for isolated, stable, severely comminuted fractures not amenable to fixation.
- For low-demand elderly patients (≥75 years of age) with stable displaced olecranon fractures (MEPS 2A or

2B): an underpowered prospective randomized trial suggests nonsurgical management results in comparable outcomes and fewer complications as compared with surgical fixation (predominantly TBW fixation).[11]

- For young active patients (<75 years of age) with stable displaced olecranon fractures (MEPS 2A): the only adequately powered prospective randomized trial showed no significant difference in outcomes between nonlocking plate and TBW groups at one year, though there was a trend toward better outcomes in the plating group for patient- and surgeon-reported outcome measures. The authors also demonstrated plate fixation had comparable costs and a significantly lower rate of complications as compared with TBW fixation.[20]
- In young active patients, both plate and TBW fixation result in functional elbow ROM; compared to plating, loss of reduction and symptomatic implants are more common with TBW fixation.[20,21]
- Placing Kirschner wire (K-wire) TBW fixation implants deep to triceps tendon and engaging K-wires into the anterior ulnar cortex distal to the coronoid may reduce symptomatic implants, implant removal, and fracture displacement.[24–26]

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Forearm Fractures

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Clinical scenarios

Case 1

- Patient A, a 42-year-old male carpenter, fell from a ladder and landed on his dominant right forearm.
- He was taken to the local Emergency Department, where radiographs showed a displaced fracture of the distal radial shaft.
- Physical examination showed a step deformity in the distal third of the forearm. No neurological or vascular deficits were found.
- He was treated with an open reduction and internal fixation (ORIF).

Case 2

- Patient B, a 38-year-old male construction worker, was struck on the ulnar aspect of his left forearm by a falling metal rod at a construction site.
- He was taken to the local Emergency Department, where radiographs showed an isolated minimally displaced midulnar shaft fracture.
- On examination, he was neurovascularly intact.
- Treatment recommendation was immobilization with a short arm cast for six weeks.

Top four questions

1. In patients with radial shaft fractures/Galeazzi-type fracture-dislocations, does radiological radial shortening more accurately predict distal radioulnar joint (DRUJ) injury compared with radial shaft fracture location?
2. In patients with isolated ulnar fractures, does surgical treatment lead to better functional outcomes compared with nonsurgical treatment?
3. In patients with Galeazzi-type fractures, does surgical reconstruction or temporary transfixion of the DRUJ prevent decrease in range of motion (ROM) of the forearm compared to nonsurgical treatment?
4. In patients with forearm fractures treated with plate fixation, does plate removal after bony union lead to higher refracture/complication rates compared with patients who retain their hardware?

Question 1: In patients with radial shaft fractures/Galeazzi-type fracture-dislocations, does radiological radial shortening more accurately predict distal radioulnar joint (DRUJ) injury compared with radial shaft fracture location?

Rationale

One of the most common causes for residual wrist disability after distal radial fractures is DRUJ instability.[1] As they are not always obvious on radiographs, DRUJ injuries may be missed during the initial assessment and treatment of a radial fracture; potentially delaying a patient's return to full function. Thus, defining radiographic parameters to identify DRUJ involvement in radial shaft fractures would be beneficial to form an optimal treatment plan for the patient.

Clinical comment

In the rehabilitation period, patient A continued to experience pain in his right wrist, as well as weakness during pronosupination. He also complained of decreased grip strength. This was affecting his ability to continue his work as a carpenter. Detailed repeat examination revealed an unstable DRUJ.

Available literature and quality of the evidence

- Level III: 2 retrospective cohort studies.

Findings

Tsismenakis and Tornetta assessed the predictive value of various radiographic parameters of DRUJ injuries (Table 86.1).[2] These included: (i) >5 mm radius shortening on standard PA radiographs, (ii) radial fracture within 7.5 cm from the lunate facet, and (iii) ulnar styloid fracture. Sixty-six patients were assessed. Radiographs of 21 patients showed radial shortening >5 mm; six of these patients had DRUJ instability. Twenty-six of the radial fractures were within 7.5 cm of the lunate facet; five of these had DRUJ instability. Ulnar styloid fractures were seen in 13 patients; DRUJ instability was present in four of these patients. Thus, they concluded that radiographs alone are insufficient to diagnose DRUJ instability preoperatively. However, due to the high negative predictive value (NPV) of the parameters, it is unlikely for DRUJ instability to occur in patients with <5 mm shortening or fractures >7.5 cm from the lunar facet.

Additionally, Ding et al. assessed radial shaft fracture obliquity, in addition to the previously mentioned radiographic parameters (Table 86.1).[3] A total of 102 patients were assessed. Radiographs of 59 patients showed fracture obliquity >30°; 35 of these had DRUJ instability. Forty-four fractures were <7.5 cm from the midarticular surface of the radius; 25 of these were associated with DRUJ instability. Radial shortening of >5 mm was seen in 35 patients; 29 of these had DRUJ instability. Twenty-nine ulnar styloid fractures were seen; 19 were associated with DRUJ instability. They concluded that the most sensitive radiographic parameter to

predict DRUJ instability was radial shaft fracture obliquity >30°, while radial shortening <5 mm was the most specific parameter to exclude DRUJ instability.

Resolution of clinical scenario

- Due to the low sensitivity of radiographic parameters (fracture obliquity >30°, fracture distance >7.5 cm from lunate facet, radial shortening >5 mm, and ulnar styloid fracture) in predicting DRUJ instability, radiographs alone are insufficient to diagnose DRUJ injuries.
- Along with careful physical examination, the above-mentioned parameters may be helpful in ruling out DRUJ injuries.
- Fractures of the middle and proximal thirds of the radial shaft (>7.5 cm from lunate facet) are less likely to be associated with clinically significant DRUJ injuries.
- In both cases, given that the injuries are distal, DRUJ injury should be considered. All radiographic parameters should be considered and assessed, though given their poor diagnostic performance further imaging may be needed .

Question 2: In patients with isolated ulnar fractures, does surgical treatment lead to better functional outcomes compared with nonsurgical treatment?

Rationale

There is currently no consensus as to the best treatment plan for isolated ulnar shaft fractures, which may lead to complications such as nonunion, radioulnar synostosis, and decreased forearm ROM.[4]

Clinical comment

The recommended treatment plan for patient B was immobilization with a short arm cast for six weeks. However, the patient was interested in surgical treatment options as he believed he could return to work sooner, and have better stability and functional outcomes with a surgical fixation.

Table 86.1 Radial shaft fracture obliquity and radiographic parameters.

	Tsismenakis and Tornetta				Ding et al.			
	Sensitivity	**Specificity**	**PPV**	**NPV**	**Sensitivity**	**Specificity**	**PPV**	**NPV**
Fracture distance <7.5 cm	71%	64%	19%	95%	54.3%	66.1%	56.8%	63.8%
Radial shortening >5 mm	86%	69%	29%	97%	63.0%	89.3%	82.9%	74.6%
Ulna styloid fracture	57%	85%	31%	94%	41.3%	82.1%	65.5%	63.0%
Fracture obliquity >30°	—	—	—	—	76.1%	57.1%	59.3%	74.4%

NPV: negative predictive value; PPV: positive predictive value.

Available literature and quality of the evidence

- Level II: 1 randomized controlled trial (RCT).
- Level III: 1 retrospective case control study and 1 retrospective cohort study.

Findings

Hussain et al. randomized 30 patients with isolated ulnar shaft fractures to two groups; one group was treated nonoperatively (n = 16), and the second group surgically (n = 14).[5] The nonoperative group was treated by an above elbow cast for six weeks. Acceptable reduction was defined as <50% of displacement and <10° of angulation on anteroposterior and lateral x-rays. The surgical group was treated with ORIF with a low-contact dynamic compression plate (LC-DCP), with mobilization when pain decreased postoperatively. At the 12-month follow-up, they found no difference between the two groups with regards to VAS (Visual Analog Score) score, grip strength, DASH (Disabilities of Arm, Shoulder, and Hand) score, and elbow/wrist ROM. Mean time to union was 18 weeks in the cast group, and 13 weeks in the ORIF group. There was one nonunion in the cast group and two nonunions in the ORIF group. They thus concluded that ORIF of isolated ulnar shaft fractures can result in anatomical restoration of the ulna; however, this does not translate to improved functional outcomes in short-term follow-up.

Coulibaly et al. retrospectively reviewed 70 patients with isolated ulnar shaft fractures.[6] Thirty-three patients were treated nonoperatively with a long or short arm cast, splint, or brace for 4–6 weeks; 37 patients were treated surgically with various fixation techniques, depending on fracture pattern and surgeon preference. Recorded complications included eight delayed unions in the surgical group versus nine in the nonoperative group; two malunions in the surgical group versus 15 in the nonoperative group; two nonunions in the surgical group versus 12 in the nonoperative group; and one secondary displacement in the surgical group versus 10 in the nonoperative group. Mean time to healing was 116 days in the surgical

group versus 145 days in the nonoperative group. They thus concluded that nonoperative treatment of isolated ulnar shaft fractures is prone to more complications.

Szabo and Skinner retrospectively reviewed 46 patients with isolated ulnar shaft fractures.[7] Eighteen patients were treated with ORIF and 28 were treated nonoperatively. From the ORIF group, one open fracture became infected with subsequent hardware loosening and nonunion. From the nonoperative group, there were seven nonunions after 4–12 months of treatment. All nonunions occurred in high energy fractures (six motor vehicle accidents, one gunshot wound, one fall from 13 m). None of the proximal third fractures that were treated nonoperatively healed. They recommended ORIF for proximal third fractures, as well as high-energy distal two-thirds fractures with 5 mm or more of displacement.

Resolution of clinical scenario

- Based on the literature reviewed, there remains no clear consensus regarding the recommendations for treating isolated ulnar shaft fractures. Treatment choices should be made based on the individual case and patient's preferences.
- A discussion should be had with the patient based on fracture pattern, the patient's lifestyle, and their values in terms of early stability versus tolerance for surgical risk.

Question 3: In patients with Galeazzi-type fractures, does surgical reconstruction or temporary transfixion of the DRUJ prevent decrease in range of motion (ROM) of the forearm compared to nonsurgical treatment?

Rationale

Inadequate treatment of DRUJ injuries can lead to continuing wrist pain, decreased grip strength, and limited pronosupination. There is currently no consensus on the best treatment for DRUJ injuries that leads to improved functional outcomes.

Clinical comment

On follow-up for the ORIF for his distal radius fracture, patient A was noted to have DRUJ instability. He wanted to know if treating the DRUJ injury surgically would allow him to return to full function earlier than conservative treatment.

Available literature and quality of the evidence

- Level I: 1 RCT.

Findings

Lee et al. evaluated 157 patients with distal radius fractures with confirmed DRUJ instability by intraoperative manual stress test.[8] All radius fractures were treated using volar locking plates. These patients were divided into three groups: Group A

consisted of patients without ulnar styloid fractures, Group B of patients with ulnar styloid tip fractures, and Group C of patients with ulnar styloid base fractures. Patients in each group were further randomized into subgroups. Subgroup 1 (A-1, B-1, C-1) was treated with sugar-tong splinting (conservative treatment). Subgroup 2 (A-2, B-2, C-2) was treated surgically. Subgroups A-2 and B-2 were treated with Kirschner wire (K-wire) transfixion. Subgroup C-2 was further divided into groups C-2-a, treated with K-wire transfixion, C-2-b treated with tension-band wiring of the ulnar styloid fracture, and C-2-c treated with hook plating of the ulnar styloid fracture. Group A had an additional subgroup (A-3) consisting of patients treated with arthroscopic TFCC (triangular fibrocartilaginous complex) repair. At three-month follow-up, the operative groups showed significantly greater ROM than the nonoperative groups (mean group ROMs not reported; $p = 0.028$ for flexion-extension, $p = 0.036$ for supination-pronation). However, there was no difference in ROM between the different surgical techniques. At 12-month follow-up, there was no significant difference in ROM, DASH score, modified Mayo Wrist Score, and grip strength between the operative and nonoperative groups. At final follow-up (mean 16.9 months), they found that clinical outcomes were not affected by the presence/absence of ulnar styloid fracture, fracture level, displacement, or the union rate. There was also no difference noted between the operative and nonoperative groups. Chronic DRUJ instability was noted in two patients from the operative groups; however, both patients refused further treatment as they were not bothered by their symptoms.

Resolution of clinical scenario

- Surgical treatment of DRUJ injuries in Galeazzi fractures provides better short-term outcomes than nonsurgical treatment.
- Long-term outcomes are similar for DRUJ injuries treated surgically or conservatively.
- Given that, based on the provided information, neither patient had sustained a Galeazzi fracture, if there was a DRUJ injury in either case, it could be treated surgically or conservatively based on patient values and other contextual considerations.

Question 4: In patients with forearm fractures treated with plate fixation, does plate removal after bony union lead to higher refracture/complication rates compared with patients who retain their hardware?

Rationale

After bony union has been achieved with plate fixation, many patients may wish to remove the implant. This may be due to a belief that the implant is causing them pain, or even if they are asymptomatic they may be uncomfortable with the idea of keeping metal in their bodies. There is currently no consensus regarding plate removal after bony union in forearm fractures.

Clinical comment

Patient A returned to clinic 20 months after his initial injury. He continued to have minimal pain in his forearm, and requested to have the plate removed.

Available literature and quality of the evidence

- Level III: 3 retrospective cohort studies.
- Level IV: 1 case series.

Findings

Yao et al. retrospectively reviewed 122 patients (170 fractures) with forearm fractures treated with plate fixation.[9] The plate implant was removed after bony union in 62 fractures and retained in 108 fractures. The incidence rate of refracture was significantly higher in the implant removed group ($p = 0.013$). Refracture occurred in eight bones after implant removal (12.9%), all without high-energy trauma. Refracture occurred three bones in the implant retained group (2.7%), all caused by high-energy trauma. For the implant removal group, the mean time from implant placement to removal was 14.8 months in patients who refractured and 19 months in patients who did not refracture, although no statistically significant relationship was noted between refracture rate and time to implant removal ($p = 0.792$). Additionally, within the implant removed group, refracture rate was found to be significantly higher in AO/OTA type B fractures $p = 0.049$). They concluded that routine implant removal is not recommended, and when they are removed, they recommend removal >18 months after surgery.

Mih et al. retrospectively reviewed 175 forearm fractures that were treated with plate fixation.[10] These included 122 acute fractures, 38 nonunions, and 15 malunions. Sixty-two implants were removed at an average of 19 months after plate insertion. In this group, there were seven refractures (11%). They occurred at an average of six months after plate removal. No refractures occurred nine months after plate removal. Other complications in this group included compartment syndrome and infection. The overall complication rate in this group was 16%. Additionally, 12% of patients in this group reported having continued discomfort and decreased ROM after the index surgery. After plate removal, 33% believed their symptoms improved, while 58% reported no improvement in symptoms. Many patients (113) retained their implant. In this group, six patients had complications needing surgery: one deep infection, three plate failures, one plate loosening with fracture, and one nickel sensitivity. The overall complication rate in this group was 4.4%; 96% of patients in this group remained asymptomatic; 4% reported pain or loss of function. The difference in complication rates between the two groups was statistically significant ($p <0.008$).

Wolvetang et al. retrospectively reviewed 929 forearm fractures treated with plate fixation.[11] Sixty-nine plates were removed after a median of 12.7 months from surgery. Within six months of plate removal, three of these patients (4.6%) had a refracture at the screw holes secondary to low-energy trauma. Of the remaining 860 fractures with the implant retained, 17 (2%) refractured at the screw holes and at the edge of the plate.

Vos et al. followed patients scheduled for implant removal after bony union.[12] This included 52 radius plates, 19 ulnar plates, and eight radius and ulnar plates. Follow-up at six months was 85%. The most common complications were sensory nerve injuries and wound infections. They reported no refractures and suggested that the risk of refracture after adequate fracture healing is of no importance. They concluded that for upper-extremity fractures treated with plate fixation implant removal after ≥8 months has a low risk of refracture, and had good clinical outcomes. However, this was based on very low-quality evidence.

Resolution of clinical scenario

- Plate removal is not recommended in asymptomatic patients.
- Plate removal should only occur 12–18 months after plate placement.
- For Case 1, if the patient has plate-related symptoms, removal should be delayed until 12–18 months postoperatively.
- For Case 1, if the patient is asymptomatic, there is no indication for plate removal.

Summary of answers

- In distal radius fractures, the radiographic parameters of fracture obliquity >30°, fracture distance >7.5 cm from lunate facet, radial shortening >5 mm, and ulnar styloid fracture have a low sensitivity in predicting DRUJ instability.
- Radiographs alone are insufficient to diagnose DRUJ injuries.
- In addition to a detailed physical examination of the wrist joint, fracture obliquity >30°, fracture distance >7.5 cm from lunate facet, radial shortening >5 mm, and ulnar styloid fracture may be helpful in ruling out DRUJ injuries in patients with distal radius fractures.
- Fractures of the middle and proximal thirds of the radial shaft (>7.5 cm from lunate facet) are less likely to be associated with clinically significant DRUJ injuries
- There remains no clear consensus regarding the best method for treating isolated ulnar shaft fractures.
- Surgical fixation of DRUJ injuries in Galeazzi fractures provides better short-term outcomes than conservative treatment.
- Long-term outcomes are similar for DRUJ injuries treated surgically or conservatively.
- In asymptomatic patients with plate fixation of forearm fractures, removal of hardware is not recommended.
- In symptomatic patients with plate fixation of forearm fractures that would like the plate removed, plate removal should not occur earlier than 12–18 months after index surgery.

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Distal Radius Fractures

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Clinical scenario

- A 48-year-old female patient, who works as a waitress, presents to the Emergency Department after a fall onto her outstretched right hand.
- The radiographic evaluation shows a displaced and comminuted distal radius fracture with approximately 30° of dorsal angulation, significant shortening, and intra-articular involvement.
- The treating orthopedic surgeon recommends surgical treatment of the distal radius fracture.

Top three questions

1. In patients with displaced intra-articular distal radius fractures, does open reduction and internal fixation (ORIF) with a plate result in improved outcomes as compared to temporary spanning external fixation with or without supplementary pin fixation?
2. In patients with displaced intra-articular distal radius fractures, does dorsal plating result in higher complication rates as compared to volar plating?
3. In patients with displaced intra-articular distal radius fractures, does arthroscopic reduction improve the outcomes over fluoroscopic reduction?

Question 1: In patients with displaced intra-articular distal radius fractures, does open reduction and internal fixation (ORIF) with a plate result in improved outcomes as compared to temporary spanning external fixation with or without supplementary pin fixation?

Rationale

Unstable intra-articular distal radius fractures frequently undergo surgical fixation. Surgical fixation options include the concepts of internal fixation versus external fixation. Temporary spanning external fixation with or without supplementary percutaneous pin fixation is a widely used standard treatment method. Similarly, open reduction and internal plate (dorsal or volar) represents a commonly used standard treatment method.

Clinical comment

External fixation relies on indirect reduction of the fracture, but it can be applied in a minimally invasive fashion. Open reduction and internal fixation (ORIF) offers the benefit of a direct reduction with appropriate visualization of the fracture site. However, it also represents a more invasive treatment method as compared to external fixation.

Available literature and quality of the evidence

In 2013, Esposito et al. published a meta-analysis of all randomized clinical trials that were published prior to

January 2011 (level I evidence).[1] A total of nine randomized clinical trials were included in their analysis. Since then an additional four level I studies comparing temporary spanning external fixation with or without supplementary pin fixation versus ORIF with a plate have been published in the literature.[2–5]

Findings

In their meta-analysis, Esposito et al. reported on the pooled results from nine publications with a total of 707 distal radius fractures treated with ORIF with a plate (n = 356) versus external fixation (n = 351).[1] These authors reported favorable functional results regarding upper extremity function as measured by the Disability of the Arm, Shoulder, and Hand (DASH) score in patients undergoing ORIF with a plate (mean difference [MD]: −5.92; 95% confidence interval (CI): −9.89 to −1.96; p <0.01). Moreover, they reported favorable radiographic results as measured by ulnar variance in patients undergoing ORIF with a plate (MD: −0.70, 95% CI: −1.20 to −0.19; p = 0.006). In addition, the risk of infection was lower in the ORIF with a plate group (risk ratio [RR] = 0.37; 95% CI: 0.19–0.73; p <0.01).

Subsequent randomized clinical trials confirmed these findings. Jeudy et al. reported on 75 patients undergoing ORIF with a plate (n = 36) versus spanning external fixation (n = 39).[2] Patients undergoing ORIF were found to have improved wrist function, as measured by the Green and O'Brien rating scale, at six months after surgery. Moreover, the ulnar variance trended toward superior results in the ORIF group, but this trend was not statistically significant. Williksen et al. reported on 91 patients who were followed for a minimum of five years.[5] They reported significantly less radial shortening in the

ORIF group. Moreover, a subgroup analysis showed favorable functional outcomes, as measured by the Mayo Wrist Score, in patients with C2 type fractures. Roh et al. reported on 74 patients, who were randomized to ORIF with a plate versus external fixation, with a 12-month follow-up.[4] These authors reported improved functional outcomes in the ORIF group at three months after surgery, as measured by the Michigan Hand Questionnaire score. At 12 months after surgery the difference between the two groups was no longer significant. However, the ORIF group showed superior radiographic outcomes as measured by the ulnar variance. Recently, Mellstrand Navarro et al. reported on 140 patients, who were randomized to the two treatment groups.[3] The authors did not identify any statistically significant differences regarding the functional outcomes at the final follow-up. However, the ORIF group showed favorable radiographic outcomes with regards to ulnar variance and restoration of volar tilt.

Resolution of clinical scenario

- Consistent level I evidence suggests that ORIF with a plate results in favorable clinical and radiographic outcomes as compared to temporary spanning external fixation with or without supplemental pin fixation.

Question 2: In patients with displaced intra-articular distal radius fractures, does dorsal plating result in higher complication rates as compared to volar plating?

Rationale

Contemporary implants allow for placement of plates over the dorsal surface of the radius as well as for placement of plates over the volar surface. Precontoured plates are available to the surgeon for both the volar and the dorsal surface. The choice of approach and implant needs to be based on the best available evidence.

Clinical comment

The concept of dorsal plating seems appealing as it provides a posterior buttress for fractures with dorsal displacement. However, there remains the concern of potential extensor tendon irritation and rupture.

Available literature and quality of the evidence

A total of three randomized clinical trials (all level II) have been published in the literature.[6–8]

Findings

A total of 192 patients were enrolled within these three trials. A total of 95 patients underwent dorsal plate fixation, whereas 97 patients underwent volar plating. Within these three trials, a total of four postoperative tendon ruptures were observed, including three patients in the dorsal plate fixation group and one patient in the volar plate fixation group. Pooled data analysis from these three trials did not show a significantly increased risk of tendon rupture in patients undergoing dorsal plate fixation (odds ratio [OR] = 3.1304; 95% CI: 0.3198–30.6422; p = 0.3268). Of note, all patients enrolled in the study by Jakubietz et al. underwent routine hardware removal at six months after surgery as per their treatment protocol, which potentially minimized the risk of local tendon irritation.[6]

All three trials reported significantly better range of motion (ROM) in patients undergoing volar plate fixation as

compared to patients with dorsal plate fixation. Two trials also reported on significantly better grip strength in patients undergoing volar plate fixation.[6,7]

Resolution of clinical scenario

- Both dorsal and volar plating can be considered safe surgical techniques.
- There is no evidence that dorsal plating with contemporary implants increases the risk of local tendon irritation and tendon rupture.
- There is also evidence to suggest there is improved wrist function during the early postoperative period in patients undergoing volar plate fixation, but further study of this issue seems warranted.

Question 3: In patients with displaced intra-articular distal radius fractures, does arthroscopic reduction improve the outcomes over fluoroscopic reduction?

Rationale

One of the major goals of surgical treatment of patients with distal radius fractures is to restore the anatomy of the distal radius and the articular congruency. Intra-articular distal radius fractures may potentially benefit from arthroscopically assisted surgery as it may allow for visualization of the joint surface as well as visualization of associated wrist joint pathology, such as tears of the scapholunate ligament.

Clinical comment

Wrist arthroscopy techniques continue to be refined and have become more widely available. A surgical technique that allows for more precise articular visualization and reduction seems desirable. However, arthroscopically assisted surgery may require additional equipment, increased surgery time, and costs.

Available literature and quality of the evidence

Two studies compared arthroscopic versus fluoroscopic reduction in patients undergoing temporary spanning external fixation with percutaneous pin fixation.[9,10] This included one level I study[10] and one level II study.[9]

One level I study compared arthroscopic versus fluoroscopic reduction in patients undergoing open reduction and internal volar plate fixation.[11]

Findings

In a prospective randomized clinical trial including 40 patients and with 24 months follow-up, Varitimidis et al. reported favorable results in patients undergoing external fixation plus percutaneous pin fixation with arthroscopic assistance as compared to patients undergoing external fixation plus percutaneous pin fixation using fluoroscopically assisted fracture reduction.[10] At final follow-up, the arthroscopic group demonstrated significantly better Mayo Wrist Scores than the fluoroscopic group (91.2 vs 86.7; $p < 0.01$). The DASH scores did not show any significant difference between the two groups. Moreover, the authors recorded a significantly smaller intra-articular step-off in the arthroscopic group (0.3 mm vs 0.8 mm, $p < 0.01$) as a measure of the quality of fracture reduction. Moreover, better wrist ROM was

observed in the arthroscopic group. In a level II study including 30 patients, Ruch et al. did not find any significant differences regarding DASH scores and quality of fracture reduction between these two patient groups.[9] However, they also recorded significantly improved wrist ROM in patients undergoing arthroscopically assisted fracture reduction. Data pooling between these two studies was not possible due to inconsistent reporting of study results.

In a prospective randomized clinical trial including 74 patients, Yamazaki et al. compared open reduction and internal volar plate fixation using arthroscopically guided versus fluoroscopically guided fracture reduction.[11] These authors did not identify any differences between the two groups with regards to DASH scores, quality of fracture reduction, and wrist ROM.

Resolution of clinical scenario

- Level I and level II evidence suggests that arthroscopically assisted fracture reduction may improve the clinical and radiographic outcomes if an external fixation plus percutaneous pin fixation construct is chosen.
- Level I evidence also suggests that patients undergoing open reduction and internal volar plate fixation do not benefit from arthroscopically assisted fracture reduction.

Summary of answers

- Level I evidence suggests that ORIF with a plate results in favorable clinical and radiographic outcomes as

compared to temporary spanning external fixation with or without supplemental pin fixation.

- There is no evidence to suggest that dorsal plating with contemporary implants increases the risk of local tendon irritation and tendon rupture. Both dorsal and volar plating can be considered safe surgical techniques.
- Level I evidence suggests that patients undergoing open reduction and internal volar plate fixation do not benefit from arthroscopically assisted fracture reduction.
- However, level I and level II evidence suggest that arthroscopically assisted fracture reduction may improve the clinical and radiographic outcomes if an external fixation plus percutaneous pin fixation construct is chosen as the treatment method.

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Carpal Dislocations

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Clinical scenario

- A 30-year-old man presents to the Emergency Department after a high-energy motorcycle collision.
- His only injury is to his right-dominant wrist, which is painful, swollen, and deformed.
- Radiographs reveal a dorsal perilunate dislocation of the wrist.
- The neurovascular examination is unremarkable.

Top three questions

1. In patients with perilunate dislocations, does advanced imaging (such as CT scan, US, MRI, or arthroscopy) lead to changes in diagnosis or operative planning compared to radiographs alone?
2. In patients with reducible perilunate dislocations, does delay in operative fixation lead to worse functional

outcomes compared with early fixation?

3. In patients with perilunate dislocations, does temporary fixation of the carpus with screws achieve better functional and radiographic outcomes than Kirschner wire (K-wire) fixation?

Question 1: In patients with perilunate dislocations, does advanced imaging (such as CT scan, US, MRI, or arthroscopy) lead to changes in diagnosis or operative planning compared to radiographs alone?

Rationale

Perilunate dislocations are usually treated with open reduction and it is not clear that computed tomography (CT) scanning or magnetic resonance imaging (MRI) helps with preparation or understanding of the injury beyond that gained with open visualization of the injury.

Clinical comment

Lateral and posteroanterior radiographs suggest a lesser arc perilunate injury without major fracture, but the anatomy is distorted and there are some bone fragments of unclear source.

Available literature and quality of the evidence

- Level IV: 2 case series.[1]
- Level V: 2 expert opinions[2] and 1 case report.[3]

Findings

Despite the fact that posteroanterior and lateral radiographs are almost always sufficient to diagnose carpal dislocations, up to 25% of these injuries are missed at presentation, as shown by Herzberg et al. (level IV).[1] One case report describes a delayed diagnosis of perilunate dislocation via ultrasonographic workup of median neuropathy (level V).[3] Advanced imaging is not routine, but according to Kaewlai et al. (level V) CT with multiplanar and volumetric reformation can be a useful technique to demonstrate the complexity and extent of fractures and dislocations.[2] There are no methodological studies comparing plain radiographs to ultrasound (US), CT imaging, MRI, or diagnostic arthroscopy for carpal dislocations.

Resolution of clinical scenario

- Advanced imaging would not be helpful in the management of this patient's perilunate wrist dislocation. Two- (2D) and three-dimensional (3D) CT might be helpful to nonspecialists and can occasionally assist in evaluating of complexity (overall quality: very low).

Question 2: In patients with reducible perilunate dislocations, does delay in operative fixation lead to worse functional outcomes compared with early fixation?

Rationale

After achieving closed manipulative reduction of a perilunate fracture dislocation, definitive surgery can be planned as an outpatient when median nerve compromise is ruled out. This introduces the potential for a delay in treatment due to access to care or logistical issues. It's not clear that such delays after closed reduction influence the final result.

Clinical comment

If closed reduction can be achieved, surgery can be delayed for up to a week or so after injury in the absence of acute carpal tunnel syndrome, forearm compartment syndrome, or an open wound.

Available literature and quality of the evidence

- Level III: 1 case control study.[4]
- Level IV: 2 case series.[1,5]
- Level V: 4 expert opinions[6–9] and 1 case report.[10]

Findings

In a large retrospective series of 89 patients with closed perilunate dislocations or fracture dislocations reported by Herzberg et al (level IV), 19 patients with delayed diagnosis of perilunate dislocations treated between 7 and 45 days after injury showed a trend toward worse results at >1 year of follow-up using a modified Green and O'Brien scoring system (71 – “fair”) compared to 51 patients treated within seven days (80 – “good”; $p = 0.07$).[1] Delay in treatment of more than 45 days showed significantly worse results (57 – “poor”; $p < 0.05$).

In a study by Komurcu et al. (level III) comparing the outcome of early versus delayed treatment in 12 patients

with greater arc injuries, the six patients treated between 7 and 45 days after injury trended toward reduced flexion/extension arc (95.5°±18.1°), grip strength measured by Jamar dynamometer (26.3 ± 13.5 kg) and modified Green and O'Brien scores (72.5 – “fair”) compared to the six patients treated within seven days. The “early” treatment group was found to have a motion arc of 129.5° ± 20.4°, grip strength of 34.0 ± 12.8 kg and modified Green and O'Brian score of 89.2 (“good”). None of the aforementioned measures reached statistical significance between groups.[4]

Most surgeons suggest surgery when convenient within the next week after injury when the dislocation can be manipulatively reduced in the Emergency Department and within a few days for those that cannot be reduced.[6–10]

Resolution of clinical scenario

- The optimal timing of definitive surgery following closed reduction, in this patient is within a week after injury (overall quality: moderate).

Question 3: In patients with perilunate dislocations, does temporary fixation of the carpus with screws achieve better functional and radiographic outcomes than Kirschner wire (K-wire) fixation?

Rationale

Temporary K-wire fixation of the carpus is standard after open reduction and internal fixation of perilunate

dislocations. Wires are more readily available and are easier to place. Temporary screws may reduce the likelihood of skin problems or infection and may allow earlier mobilization potentially improving functional results.

Clinical comment

Radiographic alignment is easier to restore after open reduction and internal fixation of a perilunate than wrist motion. It is felt that it can take about three months for the wrist ligaments to heal sufficiently to go without the support of internal fixation. The result is that a wrist treated with open reduction and pin fixation will be immobilized for up to three months until the K-wires are removed. Herbert (level V) suggested using temporary screws between the scaphoid and lunate and between the lunate and the triquetrum as an alternative to K-wire fixation.[11] The screws are sturdier and do not cross the midcarpal joint.

Available literature and quality of the evidence

- Level III: 1 case control studies.[12]
- Level IV: 1 case series.[13]
- Level V: 1 expert opinion.[11]

Findings

In the retrospective review by Souer and colleagues (level III) there were no significant differences between small cohorts of nine patients treated with temporary intercarpal screws and nine treated with temporary intercarpal K-wires, at average follow-up of 44 months[12] in arc of wrist flexion and extension (mean 87° for screws, range 50–135° compared mean 73° for wires, range 50–100°; p = 0.34);

grip strength as percentage of the other hand (mean 76% for screws; range 55–90% compared to mean 67% for wires, range 40–96%; p = 0.33); and Mayo Wrist Score mean of 71 for screws (range 60–100) compared to a mean of 66 for wires (range 45–65; p = 0.47). The prevalence of midcarpal arthritis was lower (29% vs 71%) in the screw fixation group. There were two pin infections in the K-wire cohort and the only pin in the screw fixation cohort (used to address ulnocarpal translocation) also became infected, with two patients developing septic arthritis of the wrist.[13]

Resolution of clinical scenario

- Treatment of this patient's perilunate dislocation with temporary intercarpal screws is an alternative to Kirschner wires (overall quality: low).

Summary of answers

- Advanced imaging is not helpful in the diagnosis of perilunate dislocations among experts, but 2D and 3D CT might be helpful to nonspecialists and can occasionally assist in evaluating of complexity (overall quality: very low).
- The optimal timing of definitive surgery for a reducible dislocation is within a week or so after injury in the absence of acute carpal tunnel syndrome or median neuropathy (overall quality: low).
- Treatment with temporary intercarpal screws is an alternative to temporary K-wires (overall quality: low).

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Carpal Fractures

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Clinical scenario

- A 30-year-old laborer fell from his truck and landed on his right upper extremity with the wrist in dorsiflexion.
- He presents to the Emergency Department with pain and swelling of the right wrist, at the anatomical snuffbox.
- Range of motion of the wrist is limited by pain. Radiographs are taken and are shown in Figure 89.1.

Top three questions

1. In patients with a suspected scaphoid fracture but negative findings on initial x-rays, is magnetic resonance imaging (MRI) more sensitive and cost-effective than temporary immobilization and repeated x-rays after two weeks?
2. In patients with a nondisplaced scaphoid fracture undergoing conservative treatment, does a short arm thumb spica cast achieve higher union rates compared to a below-elbow casting without thumb?

3. In patients with a nondisplaced fracture of the scaphoid, does conservative treatment achieve similar union rates to surgical treatment of the scaphoid?

Question 1: In patients with a suspected scaphoid fracture but negative findings on initial x-rays, is magnetic resonance imaging (MRI) more sensitive and cost-effective than temporary immobilization and repeated x-rays after two weeks?

Rationale

A missed scaphoid fracture can have adverse outcomes. It is generally accepted that a delay in diagnosis and treatment of scaphoid fractures can lead to nonunion or malunion resulting in symptomatic osteonecrosis, carpal collapse, or secondary osteoarthritis. This underlines the importance of an accurate and prompt diagnosis.

Clinical comment

Patients presenting with a clinically suspected scaphoid fracture, but negative initial radiographs, are treated with temporary cast immobilization for 10–14 days before a second set of radiographs is performed.

The patient's radiographs are initially negative. You are planning to immobilize the patient in a cast and reassess him in two weeks with repeat radiographs (Figure 89.2), but you are wondering if an immediate bone scan, computed tomography (CT) scan, or MRI would be more appropriate.

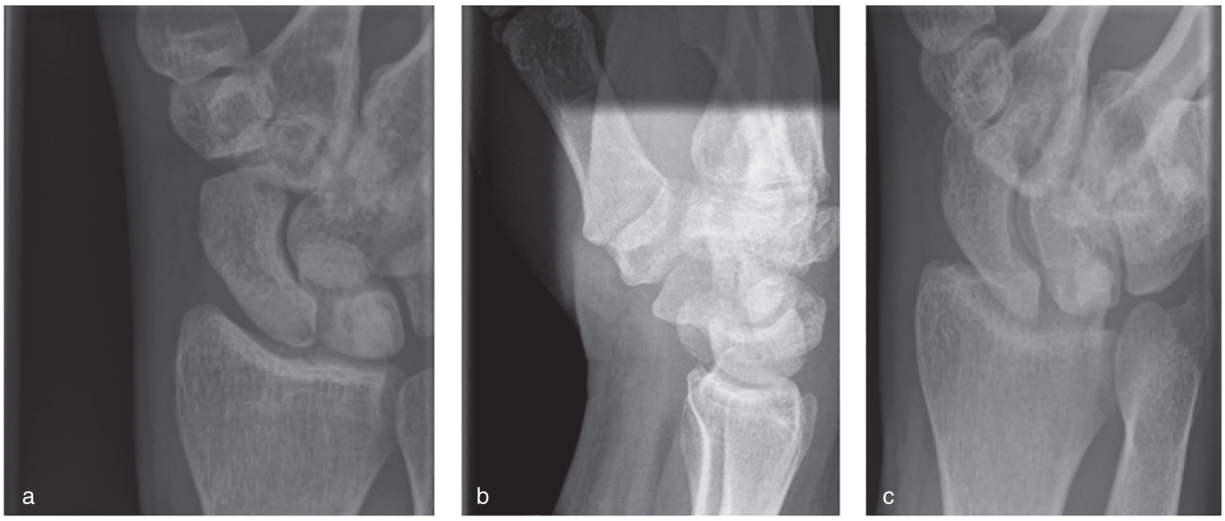

Figure 89.1 PA in ulnar deviation (A), lateral (B), and scaphoid (C) view of the right scaphoid.

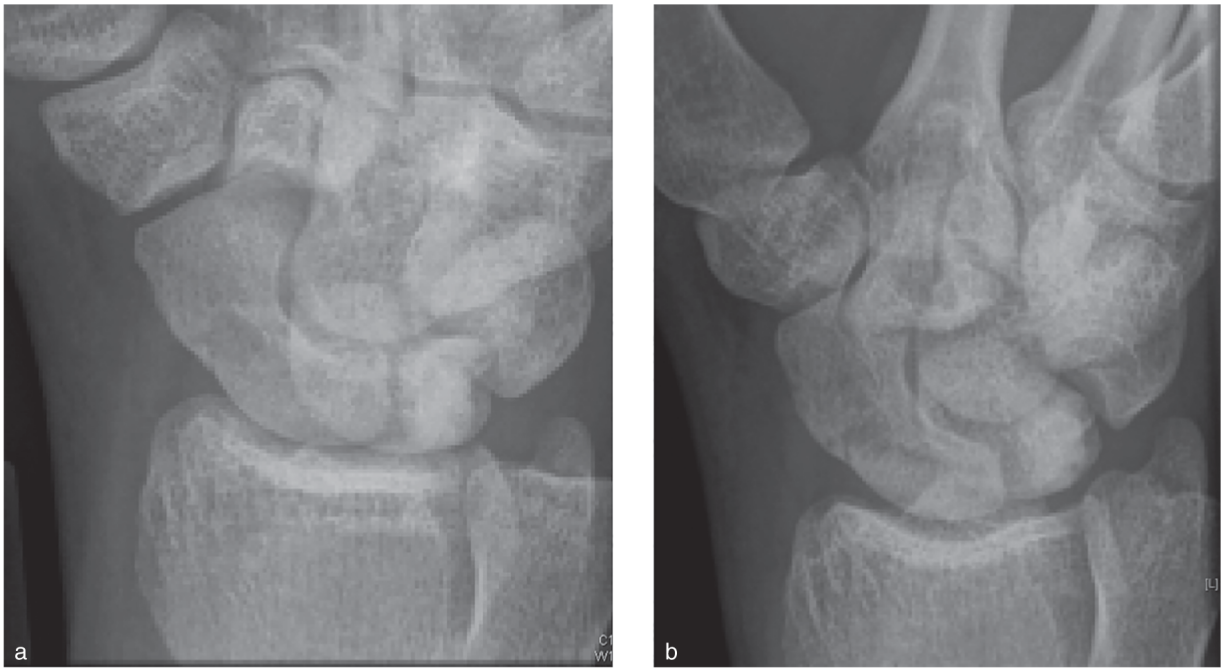

Figure 89.2 Pronated oblique view of the same patient in Figure 89.1: (A) following the injury, there was a doubt about a waist fracture; (B) 10 days later, radiograph reveals more clearly the waist fracture.

Available literature and quality of the evidence

This search produced the following level I studies: a Cochrane meta-analysis,[1] one randomized controlled trial (RCT) comparing the suitability of two imaging techniques (conventional radiography vs a CT scan),[2] two RCTs comparing the cost-effectiveness of MRI versus conventional management,[3,4] and two meta-analyses of mostly prospective cohorts.[5,6]

Whenever possible, these level I studies will be used to answer the question.

Studies with a lower level of evidence will be used to address the role of other imaging modalities that lack high-quality evidence.

Findings

Sensitivity and negative predictive value (NPV) of initial and repeated radiographs

The NPV of initial radiographs varies greatly between studies. One large prospective multicenter study of moderate quality showed a sensitivity of 93.7% (95% CI: 0.88–0.96) and a specificity of 100% (95% CI: 0.99–1.00) for patients with clinical suspicion and after five standardized projections.[7] A collection of smaller studies shows a range of NPV between 50 and 93% with a mean of 82%.[2,3,8–10] To compensate for this variation, patients with clinically suspected acute scaphoid fractures but negative initial x-rays are typically treated with two weeks of cast immobilization followed by repeated examination and radiographic studies.

A meta-analysis by Yin et al. demonstrated that radiographs repeated in less than six weeks have a sensitivity of 91% (95% CI: 0.810–0.978) and a specificity of 99% (95% CI: 0.99–1.00).[11]

Other diagnostic modalities and their utility in avoiding significant, unnecessary immobilization time

Bone scan

The latest Cochrane review reveals that bone scan is sensitive but not specific for diagnosing scaphoid fractures. Sensitivity and specificity of bone scan were 99% (95% CI: 0.69–1.00) and 86% (95% CI: 0.73–0.94).[1] Moreover, it requires a delay of at least 72 hours following the injury to capture the osteoblastic activity of the fracture site[5] and is also the most invasive test with the need for intravenous radioactive isotopes and a higher dose of radiation compared to CT scan.[12]

Magnetic resonance imaging

According to the latest Cochrane meta-analysis, MRI has shown to have a sensitivity of 88% (95% CI: 0.64–0.97) and a specificity of 100% (95% CI: 0.38–1.00) (Figure 89.3).[1] Previous meta-analyses coincide with this high specificity value but grant higher values for sensitivity; 96% (95% CI: 0.91–0.99) and 97% (95% CI: 0.95–0.99).[5,11] This decrease in sensitivity value observed in the latest Cochrane meta-analysis is due to the selection of only high- and moderate-quality studies for this calculation which omitted poor-quality studies.

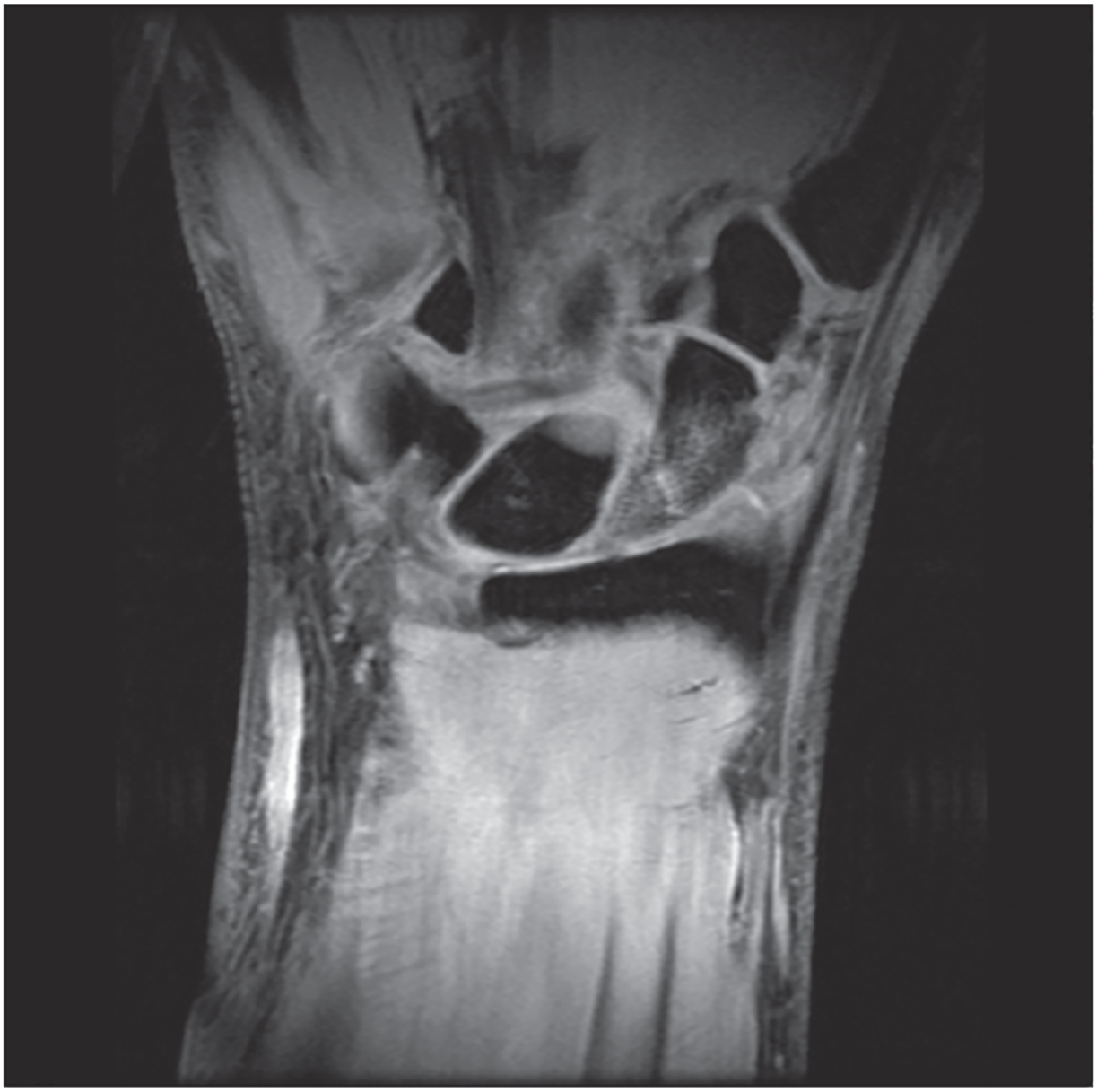

Figure 89.3 Coronal Fat Sat T2 MRI confirming a suspected proximal pole fracture of the scaphoid.

MRI also allows for the ability to detect associated soft tissue injuries.

Computed tomography

CT scan can also identify occult fractures (Figure 89.4) but is more useful in defining the fracture pattern and the angular deformity.[13] According to the Cochrane review it

has a sensitivity and specificity of 72% (95% CI: 0.36–0.92) and 99% (95% CI: 0.71–1.00), respectively. Similarly to the MRI findings, sensitivity is lower than the one from an earlier meta-analysis which granted it a sensitivity between 93% (95% CI: 0.83–0.98) and 85% (95% CI: 0.73–0.94).[5,11] This reduction in sensitivity is due to the same reasons as the MRI decrease.

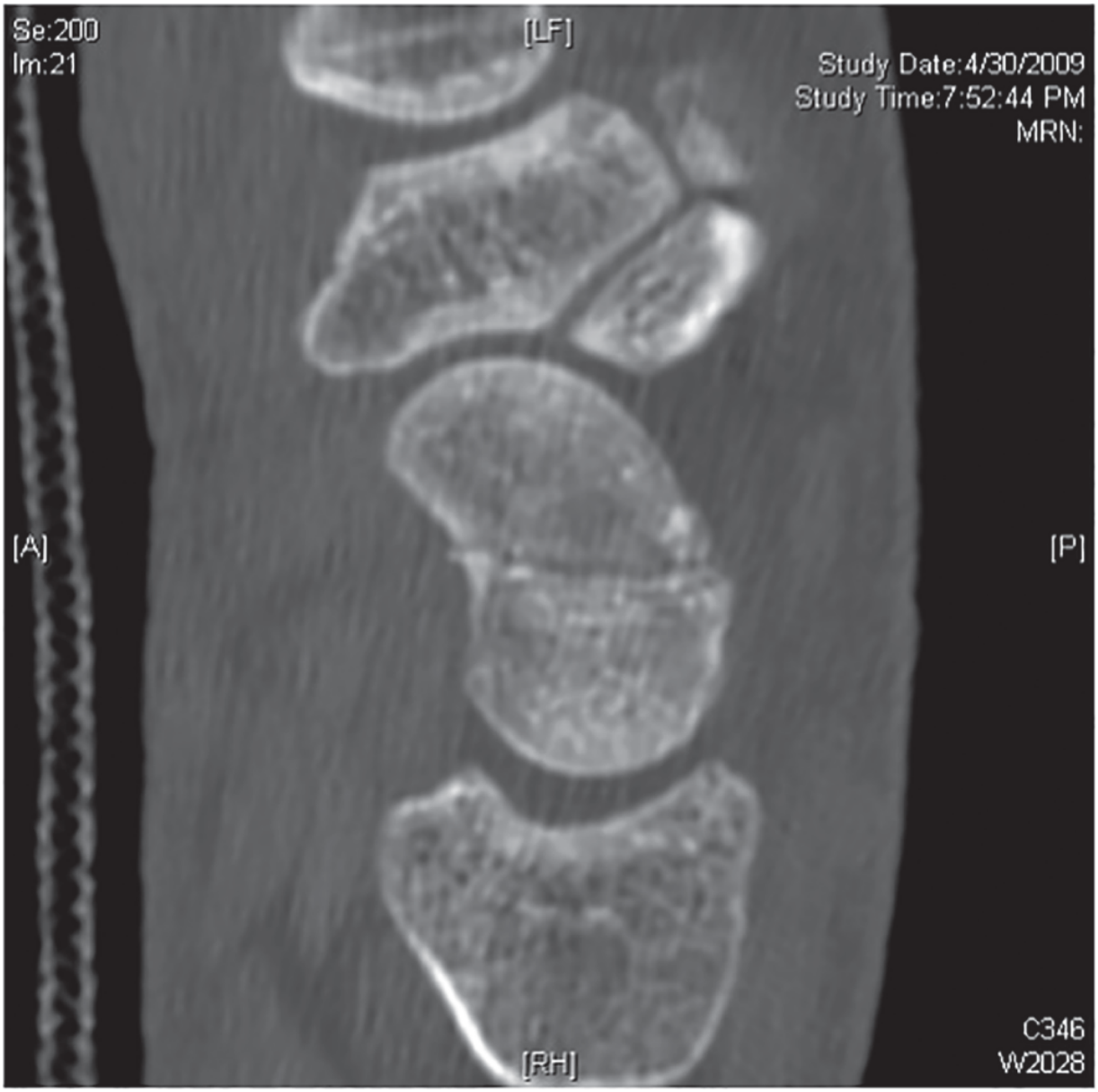

Figure 89.4 CT scan of the same patient in Figure 89.1. CT can identify occult fracture but is more useful in assessing fracture displacement and angulation.

Cost-effectiveness of early MRI as an alternative to repeated x-rays

Two high-quality level I diagnostic RCTs are used to answer this question.[3,4] Brooks investigated the cost-effectiveness of MRI by randomizing 28 patients with a suspected

scaphoid fracture to either MRI or immobilization with radiographs at 10–14 days.[3] Of the patients without fracture, the MRI group had significantly fewer days immobilized: a median of three days (interquartile range 3.0–3.0) versus 10 days (7–12) in the control group (p = 0.006). The total expenditure in the two groups was similar (MRI group = AUS$594, control group = $428; p = 0.19), owing to the direct cost of MRI. Costs from productivity loss and income loss secondary to immobilization were not included in the calculation; however, if considered these may have swayed the conclusion in favor of MRI. Similar results, but with a slight monetary advantage to MRI, were recorded by Patel et al. in the UK, who also showed that the early use of MRI exhibited increased patient satisfaction and fewer fracture clinic appointments and radiographs.[4]

Comparison between follow-up radiographs, bone scan, CT scan and MRI

Eleven level I diagnostic studies looked at diagnostic accuracy of one or two of these tests. In 2015, a Cochrane review pooled the results of the studies to show that CT scans and MRI are not as sensitive as bone scans for diagnostic accuracy.[1] However, since the prevalence of true fractures among suspected fractures is around 20%, the lower specificity of bone scan becomes problematic and would mean overtreatment in 1 out of 10 patients. With its better specificity and sensitivity, MRI is the test of choice in the diagnosis of occult scaphoid fractures. CT scan and follow-up radiographs are less sensitive tests.[6,12]

Resolution of clinical scenario

- An initial normal radiograph cannot accurately guarantee absence of a scaphoid fracture: it is

therefore recommended to proceed with further imaging, either acutely or two weeks later (overall quality: high).

- MRI is the study of choice to diagnose occult scaphoid fracture in the acute setting and has the advantage of avoiding unnecessary immobilization. There is good evidence to support its cost-effectiveness. The availability of this modality may limit its application (overall quality: high).

Question 2: In patients with a nondisplaced scaphoid fracture undergoing conservative treatment, does a short arm thumb spica cast achieve higher union rates compared to a below-elbow casting without thumb?

Rationale

Many casting options are suggested in the literature. The ideal casting method should be one that protects the fracture fragments from moving while providing maximum function to the patient.

A short arm thumb spica cast remains the most widely accepted treatment of nondisplaced scaphoid fracture.

Clinical comment

The patient radiographs reveal a nondisplaced fracture of the waist of scaphoid (Figure 89.5). After discussing the nonsurgical and surgical options with the patient, you decide to treat him conservatively.

Available literature and quality of the evidence

This search produced the following level I studies:

- 3 meta-analyses[14–16]
- 5 high-quality RCTs.[17–21]

Findings

Long-arm versus short-arm cast

There was only one meta-analysis that specifically focused on conservative treatments without comparing it to surgery.[14] The results of two RCTs were pooled comparing below-elbow and above-elbow casting for rates of nonunion and time to union. There were no significant differences in the rates of nonunion between below-elbow casting (four events of nonunion in 76 patients) and above-elbow casting (six events of nonunion in 75 patients); risk ratio (RR) 1.02; 95% CI: 0.05–19.23; p = 0.99).[14] The other two meta-analyses found no difference between the two immobilization techniques.[15,16]

A cadaveric study used CT scan to evaluate the amount of fracture displacement during pronation-supination between nonimmobilized scaphoids and scaphoids immobilized in below-elbow thumb spica cast. Long-arm casting was not tested.[22] Less than 1 mm of displacement was judged to be acceptable. The total magnitude of motion from pronation to supination averaged 0.2 mm in the specimens immobilized with a below-elbow thumb spica cast, suggesting that a short arm cast would be appropriate in preventing motion at the fracture site.

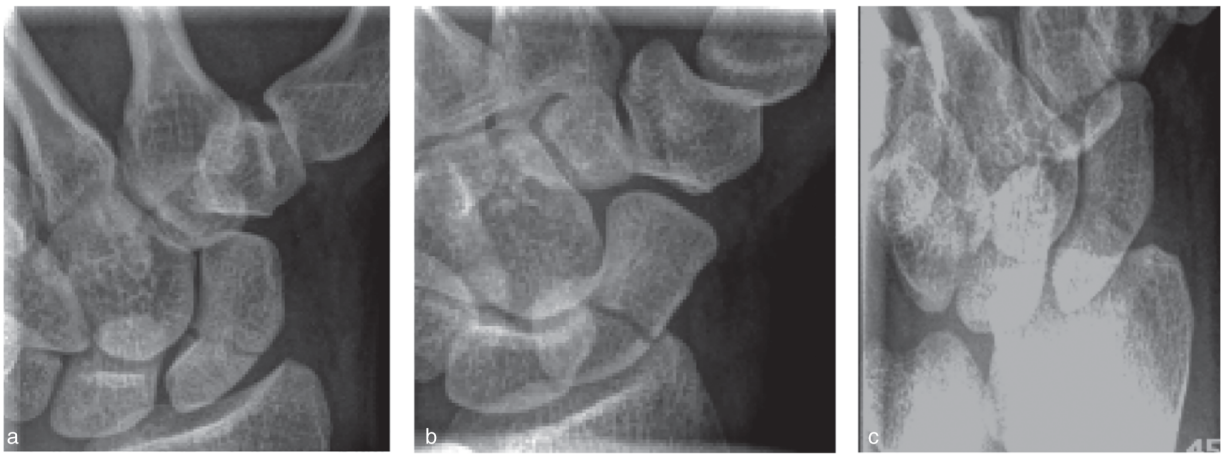

Figure 89.5 (A) AP, (B) pronated oblique, and (C) scaphoid view of a nondisplaced scaphoid fracture.

Lawton et al. compared the forearm rotation allowed by a long-arm thumb spica cast versus an epicondylar-bearing (Munster) thumb spica cast on healthy individuals with no fracture.[19] The authors suggested that the Munster cast could still limit enough forearm rotation to avoid healing complications while allowing more elbow flexion/extension than a long-arm cast; however, the clinical advantages of this type of casting have not been demonstrated.

Inclusion of the thumb

Clay et al. showed, in a RCT, that there was no significant difference in the rate of nonunion between casts that included the thumb (14 events of nonunion in 143 patients) or did not include the thumb (15 events of nonunion in 148 patients); RR 0.97; 95% CI: 0.48–1.93; p = 0.92.[17] This was later confirmed in another level I RCT using CT scan to assess union.[20]

Resolution of clinical scenario

- The evidence does not support the use of a long-arm cast in the treatment of a nondisplaced scaphoid fracture (overall quality: high).

- Inclusion of the thumb in the cast is not critical for scaphoid fracture healing and leads to greater functional impairment during the period of casting (overall quality: high).

Question 3: In patients with a nondisplaced fracture of the scaphoid, does conservative treatment achieve similar union rates to surgical treatment of the scaphoid?

Rationale

Scaphoid fractures can escape early detection because the initial symptoms can be minimal, and the clinical and radiographic signs can be subtle. Many authors suggest that any fracture that presents greater than four weeks from injury is at high risk of nonunion, so when there is a delay in diagnosis some advocate that most scaphoid fractures should be treated operatively.

Clinical comment

The patient presents five weeks following injury to his wrist. Radiographs show a nondisplaced scaphoid waist fracture.

Available literature and quality of the evidence

The highest level of evidence produced by this search was five level IV studies.[23–27]

Findings

Russe reported 27 cases of delayed presentation of scaphoid fractures (range three weeks to three years).[25] All fractures eventually achieved union with cast treatment; however, the duration of immobilization was considerable.

Eddeland et al. reported that the rate of nonunion was 73.3% (11/15) when immobilization was initiated between four weeks to one year, and 96.3% (26/27) when it was initiated at greater than one year.[23] They concluded that a delay in treatment of greater than four weeks from injury is highly predictive for the development of scaphoid nonunion.

Another retrospective review of 285 scaphoid fractures demonstrated that, while the incidence of nonunion was negligible if treatment was initiated within 28 days of injury, the frequency of nonunion significantly increased with a delay in treatment of greater than four weeks ($p < 0.01$).). Of the fractures that eventually healed, a treatment delay of greater than four weeks was associated with a significantly increased time to union from nine weeks in early detection to 17 weeks in delayed fractures ($p < 0.001$).[27]

Finally, Grewal et al. reviewed 28 cases of subacute scaphoid fractures presenting between six weeks and six months of injury.[26] They found an 82% union rate with casting with a mean length of time to union of 11 weeks for waist fractures and 14.2 weeks for proximal pole fractures. Risk factors with significant association to nonunion were diabetes, humpback deformity, and comminution. Exclusion of patients with these risk factors resulted in a union rate of 96%, suggesting that subacute scaphoid fractures can be successfully treated with casting alone.

Resolution of clinical scenario

- Delay in treatment exceeding four weeks from time of injury is associated with higher risk of nonunion or delayed union; however, it is unclear if surgical intervention should be favored over prolonged cast treatment in the absence of comminution, humpback deformity, and diabetes (overall quality: low).

Summary of answers

- An initial normal radiograph cannot accurately guarantee absence of a scaphoid fracture: it is recommended to proceed with further imaging, either acutely or two weeks after injury.
- MRI is the study of choice to diagnose occult scaphoid fractures in the acute setting and has the advantage of avoiding unnecessary immobilization. There is good evidence to support its cost-effectiveness. However, the availability of this modality may limit its application.
- Evidence does not support the use of a long-arm cast in the treatment of a nondisplaced scaphoid fracture.
- Inclusion of the thumb in the cast is not critical for scaphoid fracture healing and leads to greater functional impairment during the period of casting.
- Delay in treatment exceeding four weeks from time of injury is associated with higher risk of nonunion or delayed union; however, it is unclear if surgical intervention should be favored over prolonged cast treatment in the absence of comminution, humpback deformity, and diabetes.

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90
Metacarpal Fractures

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Clinical scenario

- An adult 22-year-old male injures his dominant right hand in a bicycle accident.
- He has a closed small finger metacarpal neck fracture with radiographs showing 45° of apex dorsal angulation.
- There is no rotational deformity on clinical examination.

Top three questions

1. In adult patients with angulated fifth metacarpal neck fractures, does surgical treatment offer better final range of motion (ROM) or grip strength than nonsurgical treatment?
2. In adult patients with angulated fifth metacarpal neck fractures, does closed reduction and casting improve ROM, grip strength, or patient-reported outcomes compared to less rigid immobilization?
3. In adult patients with a metacarpal neck fracture, does correction of angulation result in improved ROM or grip strength compared to consolidation without angulation correction?

Question 1: In adult patients with angulated fifth metacarpal neck fractures, does surgical treatment offer better final range of motion (ROM) or grip strength than nonsurgical treatment?

Rationale

Many patients with metacarpal neck fractures do well with nonsurgical treatment. Surgical intervention may improve radiographic alignment, but it is associated with additional direct costs and may expose the patient to additional complications such as stiffness, infection, and hardware problems.

Clinical comment

When patients see an angulated fracture on radiographs, they often question whether the fracture should be “fixed” surgically.

A wide variety of fixation methods can be used to treat metacarpal neck fractures including percutaneous pinning (antegrade, retrograde, and transverse), intramedullary fixation, and open reduction internal fixation with plating.

Available literature and quality of the evidence

Several studies compare different types of surgical fixation to one another, but only two studies directly compare surgical treatment with nonsurgical treatment. These include one level I randomized controlled trial (RCT) and one level III prospective cohort study.

Findings

Sletten et al. randomized 85 patients with small finger metacarpal neck fractures angulated >30° into surgical and nonsurgical treatment groups. The surgical group was treated with antegrade intramedullary pinning (aka bouquet pinning).[1] No attempt of closed reduction was made for the patients with metacarpal fractures randomized to the nonsurgical treatment group. Both groups were treated in a plaster splint for one week, followed by a functional brace for three weeks. There was no statistically significant difference between the two groups at one-week, six-week, three-month, or one-year follow-up with regard to QuickDASH scores, grip strength, total active ROM, or patient satisfaction Visual Analog Score (VAS). At three months, 46.5% (20 of 43) patients in the nonsurgical group reported that they were discontent with their hand function compared to 31% (13 of 42) of those who underwent surgical treatment, but these differences resolved at the one-year follow-up. However, at one year, 17.5% (7 of 40) conservatively treated patients reported that they were not content with their hand appearance, compared to 1 of 36 operatively treated patients (2.8%). Patients in the operative group experienced more complications (19 compared to 10) including complex regional pain syndrome, superficial infection, pin migration, and bent pins.

Strub et al. prospectively followed 40 patients for 12 months undergoing either antegrade intramedullary (aka bouquet) pinning or functional bracing without reduction for small finger metacarpal neck fractures angulated 30–70°.[2] There was no difference between the two groups in MP joint ROM at two weeks, six weeks, three months, six months, or one year. Grip strength was only measured at one year after injury and was equal between the two groups. All of the operative patients underwent pin removal at three months. Complications in the operative group

included delayed wound healing after pin removal (one patient), secondary displacement (one patient), and dissatisfaction with scarring (three patients). In the nonsurgical group, 55% (11 of 20) patients reported dissatisfaction with the aesthetic appearance of the knuckle, and four patients complained of feeling the metacarpal head in their palm with heavy grip. Overall patient satisfaction was equivalent in the two groups. Compared to the study by Sletten et al, the Strub et al. study had a smaller sample size and no patient-reported outcome measures. In addition, the authors did not report how they ascertained the patient's opinion of the appearance of their hand, which was one of the few differences between the two groups.

Resolution of clinical scenario

Nonsurgical and surgical treatment for metacarpal neck fractures result in similar patient reported outcomes, grip strength, and ROM.

Surgical intervention may improve patient satisfaction with the appearance of their hand, but also carries an increased risk of complications when compared to nonsurgical treatment.

Question 2: In adult patients with angulated fifth metacarpal neck fractures, does closed reduction and casting improve ROM, grip strength, or patient-reported outcomes compared to less rigid immobilization?

Rationale

Surgeons utilize a wide variety of immobilization methods for metacarpal fractures, ranging from short-arm ulnar gutter casts that include the whole ray to removable braces to elastic bandage wraps.

Clinical comment

Each immobilization method carries different direct costs, as well as varying degrees of interference with patient activities, but controversy exists regarding which method is superior.

Available literature and quality of the evidence

Four level I RCTs compare different types of immobilization for metacarpal neck fractures. The inclusion criteria vary somewhat from study to study with regard to fracture type and location and maximal fracture angulation.

Findings

Van Aaken et al. randomized adult patients with a fifth metacarpal neck fracture angulated ≤70° to either no reduction and soft wrap with buddy taping for three weeks or closed reduction and metacarpophalangeal (MCP) extension casting for four weeks.[3] At four months, they found no significant difference between the two groups with respect to ROM, grip strength, satisfaction with aesthetic appearance, Visual Analog Scale (VAS) score, or Disabilities of the Arm, Shoulder, and Hand (DASH) score. Those patients who had undergone closed reduction experienced gradual loss of reduction, such that the final fracture angulation was equivalent between the two groups. Patients in the soft wrap group reported fewer days out of work than those treated with casting (22 days vs 33 days).

The results of the Van Aaken et al. study are supported by several other studies, although the inclusion criteria for these studies vary slightly from the Van Aaken study. Braakman et al. randomized 50 patients to either functional taping or an ulnar gutter cast for fifth metacarpal fracture (including shaft and neck fractures).[4] Patients treated with functional taping had better grip strength, better pulling strength, and less extensor lag at one week and four weeks after injury. At four weeks, 11 of 25 patients in the casting group had an extension deficit, compared to 0 of 25 patients in the taping group. All patients in the taping group had restoration of 50% pulling strength by four weeks, compared to 52% from the casting group. Likewise, Hansen and Hansen compared randomized patients with ring or small finger metacarpal neck fractures angulated <60° to either an elastic bandage, a functional brace, or a plaster cast.[5] At one month, patients in the plaster cast had less MCP motion than the other two groups, but at three months demonstrated equal motion to the functional brace group. At one month and three months, patients in the elastic bandage group had slightly less MCP motion than those treated with a functional brace, and these patients also reported more pain.

Statius Muller et al. randomized 40 patients with metacarpal neck fractures to either a plaster cast for three weeks or a pressure bandage for one week followed by mobilization as tolerated.[6] They found no significant differences in MCP ROM or pain between the two groups. Twelve weeks after injury, 80% of patients in each group reported “good” satisfaction with their treatment and outcome.

Resolution of clinical scenario

Rigid casts do not appear to be superior to functional bracing or soft wrap with regard to maintenance of fracture alignment, DASH outcome scores, or MCP motion for small finger metacarpal neck fractures. Correction of angulation with closed reduction was not maintained with cast immobilization. With that information, the type of immobilization can be chosen based on patient needs, cost, and ease of use.

Question 3: In adult patients with a metacarpal neck fracture, does correction of angulation result in improved ROM or grip strength compared to consolidation without angulation correction?

Rationale

Some surgeons advocate surgical intervention for angulated small finger metacarpal neck fractures based on the idea that a metacarpal neck fracture that heals in an angulated position interferes with hand function.

Clinical comment

Residual angulation of a metacarpal neck fracture can result in a visible change in hand appearance, but the impact on hand function is not completely understood. Given the lack of high-quality studies, surgeons struggle to know when to intervene to correct angulation in a metacarpal neck fracture.

Available literature and quality of the evidence

No clinical study directly addresses this question as a primary outcome. Information from two biomechanical studies has not clearly been corroborated with clinical findings. Two level I RCTs are also available which indirectly answer this question.

Findings

Historically, two biomechanical studies have significantly influenced treatment of metacarpal neck fractures. One cadaver study by Ali et al. examined the excursion of the flexor digiti minimi and third volar interosseous muscles with changes in metacarpal neck angulation.[7] They concluded that angulation >30° would decrease grip strength by creating slack in flexor digiti minimi. Based on their model, they reported a 30° angulation would result in 92% flexor digiti minimi strength and 78% small finger total ROM compared to an intact small finger metacarpal. A second cadaver study by Birndorf et al. also looking at work of flexion also identified 30° of angulation as the point at which work of flexion increased significantly.[8]

Despite these biomechanical models, clinical studies have not reported significant deterioration of function with >30° of angulation. For example, Van Aaken et al. reported low QuickDASH scores, good grip strength, and ROM for their patients who had a mean fracture angulation >45°.[3]

Although no clinical study directly addresses the correlation between fracture angulation and function, two studies provide some analysis as part of their secondary aims. Sletten et al. found no correlation between QuickDASH score, total active motion deficit, or relative grip strength and the degree of angulation in healed fractures at one year. In addition, they reported no correlation between the final VAS score for satisfaction and the degree of fracture angulation.[1] The mean angulation in

their nonoperatively treated fractures was 41° (range 30–58°).

In their report on patients treated nonoperatively, Statius Muller et al. found no difference in the mean fracture angulation between patients who had full ROM and patients who had decreased ROM.[6] Likewise, there was no difference in the mean fracture angulation between patients who were satisfied with their hand function and those who were not satisfied. However, there were very small numbers in both the decreased ROM and dissatisfied with function groups, limiting any strong conclusions from these data.

Resolution of clinical scenario

The degree of metacarpal neck angulation that results in clinical impairment is not known. Despite biomechanical models suggesting impaired function with greater than 30° of angulation, clinical studies report relatively normal grip strength and ROM in fractures angulated approximately 45°, such as the fracture in this clinical scenario.

Summary of answers

- Nonsurgical and surgical treatment for metacarpal neck fractures result in similar patient reported outcomes, grip strength and range of motion.
- Rigid casts do not appear to be superior to functional bracing or soft wrap with regard to maintenance of fracture alignment, DASH outcome scores, or MP motion for small finger metacarpal neck fractures.
- The degree of metacarpal neck angulation that results in clinical impairment is not known.

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Pelvic Fractures

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Clinical scenario

- A 37-year-old woman is severely injured in a motor vehicle accident and is brought to the Emergency Department with complaints of pelvic pain.
- She is unresponsive to initial volume resuscitation.
- On examination, her left and right thighs are swollen and bruised. Blood pressure is 90/60 with tachycardia of 130/min.
- The neurological exam, the chest x-ray, and the abdominal ultrasound are negative.

Top three questions

1. During the initial management of patients with suspected pelvic bleeding, does the application of an invasive external fixator provide superior pelvic hemorrhage control when compared to a noninvasive external pelvic binder (PB)?

2. For patients with ongoing pelvic bleeding after resuscitation, does giving priority to pre-peritoneal pelvic packing (PPP), before angioembolization (AE), reduce mortality?
3. In pelvic fracture patients at high risk of bleeding and pulmonary embolism (PE), is mechanical thromboprophylaxis or even prophylactic inferior vena cava (IVC) filter insertion safer than a chemical strategy?

Question 1: During the initial management of patients with suspected pelvic bleeding, does the application of an invasive external fixator provide superior pelvic hemorrhage control when compared to a noninvasive external pelvic binder (PB)?

Rationale

Temporary stabilization is crucial for the survival of patients with a life-threatening pelvic ring injury. Until recently, urgent application of external fixation was widely used. Experimental studies have shown that the retroperitoneal compartment is an open space[1] and that the *tamponade effect* of the pelvis is minimal. According to the ATLS (acute trauma life support)guidelines, a PB should be applied before mechanical fixation.

Clinical comment

During the immediate resuscitative period, the trauma team can quickly wrap a simple bedsheet around her pelvis and thighs before the orthopedic surgeon arrives. Blood pressure and heart rate improve dramatically 10 minutes post application.

Available literature and quality of the evidence

- Level I–II: 0 randomized controlled trials (RCT).
- Level III: 3 case-controls.
- Level III and IV: 2 systematic reviews.

Findings

Two systematic reviews have been published on the effectiveness of circumferential pelvic compression devices for unstable pelvic fractures.[2,3] The most recent, published in 2016, found sufficient evidence to suggest that external compression mechanically reduces disrupted pelvic rings. Although the short-term physiological effectiveness of PB has been shown, the long-term outcome regarding mortality remains unclear.[2] Similar conclusions were reported in the other systematic review that included 17 articles with only one level III study. Authors concluded that, although PB appears to be effective, there was a lack of prospective data.[3]

A trauma registry analysis by Croce et al. compared external fixators to PB in a cohort of 186 patients and found a lower mortality rate in the PB group but the results were not statistically significant ($p = 0.011$).[4] However, blood transfusions at 24 (4.9 vs 17.1 units) and 48 hours (6 vs 18.6 units) were statistically lower for the PB group than for the external fixation group ($p < 0.0001$). In a retrospective study of 585 patients treated with and without PB upon arrival at a trauma center, Fu et al.

reported a significant reduction in transfusion rates (398 ± 417 ml vs 1954 ± 249 ml, p = 0.006) and a shorter intensive care length of stay (6.6 vs 11.8 days, p = 0.02).[5] Another retrospective analysis on 118 patients treated with PB upon patient arrival and continued for 24 to 72 hours, compared them with historical controls in the preceding year (n = 119).[6] PB had no effect on mortality (23% vs 23%, p = 0.92), need for pelvic AE (11% vs 15%, p = 0.35), or 24-hour transfusions (5.2 ± 10.0 vs 4.6 ± 9.0 U, p = 0.64).

Resolution of clinical scenario

In the hemodynamic unstable pelvic fracture, evidence suggests (overall quality: low):

- Emergent stabilization of the pelvis is beneficial.
- External fixation is not superior to noninvasive stabilization devices. Therefore, we recommend the immediate application of a PB during resuscitation from life-threatening hypovolemic shock in patients with unstable pelvic injuries.

Question 2: For patients with ongoing pelvic bleeding after resuscitation, does giving priority to pre-peritoneal pelvic packing (PPP), before angioembolization (AE), reduce mortality?

Rationale

Reducing blood loss is crucial for the survival of patients with a pelvic injury and hemodynamic instability. In conjunction with bone stabilization, there are two possible

methods of hemorrhage control: PPP and AE. Guidelines currently provide contradictory recommendations over which treatment should be preferred.

Clinical comment

After temporary hemodynamic stabilization, the patient undergoes a secondary drop in blood pressure to 85/50. Repeated secondary survey does not reveal any other source of bleeding. The general surgeon wants to perform PPP while the orthopedic team would prefer beginning with AE. Following a publication from the American Association for Surgery of Trauma, embolization (10%) is used much more frequently than PPP (5%) to control bleeding in unstable pelvic injuries in the USA,[7] whereas PPP is more frequently reported in European literature. The most common complication for PPP is infection in 15% of cases. The unique complications reported for embolization are ischemia of the gluteus muscles and those related to IV contrast.[8]

Available literature and quality of the evidence

- Level I–II: 1 RCT
- Level III: 2 case-controls.
- Level IV: 2 retrospective studies of prospective database.

Findings

- Level II: a quasi-randomized study on 56 patients with a pelvic fracture and instability showed that PPP was quicker than angiography (60 ± 14 minutes vs 84 ± 12 minutes, $p < 0.001$) and that the delay was shorter (77 ± 19 minutes vs 102 ± 27 minutes, $p = 0.01$). However, there was an important limitation to this study because

the randomization was done according to the time of day with significantly higher ISS for overnight cases which all received PPP. The authors were not able to demonstrate differences in mortality ($p = 0.449$), length of stay in intensive care ($p = 0.214$), or transfusion between both groups ($p = 0.124$).[9]

- Level III: case control study. Osborn et al. published a retrospective study in 2009 comparing 20 patients treated with PPP to 20 patients treated with embolization.[10] From 1998 to 2004, first line treatment for patients was angiography, changing to PPP from November 2004 to June 2006. The groups were not comparable with patients in the angiography group having lower ISS scores (46 ± 9 vs 55 ± 13, $p = 0.014$). Delay between admission and treatment was shorter for the PPP group (45 vs 130 minutes, $p < 0.01$) with fewer transfusions in the PPP group in the first 24 hours after treatment (7 vs 12 units, $p < 0.01$).
- Level III: case control study. Another comparative historical case control study was published by Tai et al.[11] Thirty patients were studied in the angiography group and 11 in the PPP group after a protocol modification at their level I trauma. Time to angiography was longer than time to the odds ratio (OR) for PPP (140 ± 95 vs 79 ± 24 minutes, $p = 0.248$). Mortality was also greater in the angiography group (69% vs 36%, $p = 0.107$). However, both results were not significant as this study was underpowered.
- Level IV: a Japanese study comparing *laparotomy first* to *embolization first* for patients with pelvic fractures and positive FAST used data from a national database between 2004 and 2010. Among the 317 eligible patients, 51% were hypotensive upon arrival. After adjusted regression analysis, they demonstrated that

there was no difference in mortality between both methods.[12] The adjusted OR was of 1.20 (95% confidence interval [CI]: 0.61–2.39).

Resolution of clinical scenario

In the hemodynamic unstable pelvic fracture, poor to modest evidence suggests that:

- Access to PPP is faster than AE.
- Time needed for the procedure is less for PPP than AE.
- There were no conclusive data to help prioritize one method over the other. However, PPP seems promising.
- Every level I trauma center should establish a clear algorithm for management of pelvic fractures with hemodynamic instability, based on local accessibility to embolization and the operating room.

Question 3: In pelvic fracture patients at high risk of bleeding and pulmonary embolism (PE), is mechanical thromboprophylaxis or even prophylactic inferior vena cava (IVC) filter insertion safer than a chemical strategy?

Rationale

Patients with pelvic fractures are at high risk for both bleeding and DVT (deep vein thrombosis). Choosing appropriate thromboprophylaxis is essential to minimize bleeding complications while still protecting against potential DVT and PE.

Clinical comment

With current insertion techniques performed by experienced clinicians, the short-term complication rates associated with IVC filter use are lower than historical results. Without thromboprophylaxis, patients with a pelvic fracture have a DVT risk that is as high as 60%,[13] and PE is the third-leading cause of death in those who survive beyond the first day.[14] Current prophylaxis guidelines for thromboprophylaxis are directed toward major trauma patients, but their effectiveness, especially in the patient with an injured pelvis, is still debated.

Available literature and quality of the evidence

- Level II: 4 systematic reviews/meta-analyses; 1 randomized control.
- Level III: 1 propensity matched; 2 retrospective cohort studies.
- Level IV: 3 case series.

Findings

One small retrospective study[15] (level IV) and one systematic review[16] of the prophylactic use of IVC filter in trauma patients showed no significant difference in PE rate compared to patients without filter placement (level II). Two more recent systematic reviews found that while IVC filters may be an appropriate alternative in patients unable to receive chemical thromboprophylaxis, the paucity of high level data did not justify the use of prophylactic IVC filters.[17,18] These findings may have influenced the use of these implants as a recent National Trauma Databank study reveal a sharp decline in use (22–78% decrease) with no observable change in PE rate (level III).[19]

A systematic review by Slobogean et al. in 2009 (level II) found that no strong evidence-based recommendations for venous thromboembolism prevention in patients with pelvic and acetabular fractures can be made.[20] This was mostly due to a lack of prospective studies, small sample sizes, and nonstratified larger studies where pelvic/acetabular data could not be isolated. One prospective study evaluated the effect of timing of administration of LMWH for patients with pelvic fractures (level III).[21] They found a significantly increased rate of PE and DVT when low-molecular-weight heparin (LMWH) was administered at >24 hours from injury. The efficacy of LMWH compared to unfractionated heparin (UH) was confirmed in trauma patients in a large retrospective cohort study by Byrne et al. (level III).[22] They found an OR of 0.56 (0.50–0.63) for PE using LMWH compared to UH. One significant issue with LMWH is postdischarge compliance, as one prospective study found patients with LMWH were significantly less likely to adhere to prophylaxis compared to twice daily aspirin use (OR = 2.34)[23] (level II). This issue is currently being investigated as part of a larger study evaluating the effect of twice daily aspirin compared to LMWH for thromboprophylaxis in trauma patients (PREVENTion of Clot in Orthopaedic Trauma, PREVENT CLOT). Currently, available data are not robust enough to support routine use in these patients.[24,25]

Resolution of clinical scenario

For pelvic trauma patients, evidence suggests.

- Early administration of LMWH demonstrated a clear reduction in DVT and PE (overall quality: moderate).
- LMWH prophylaxis significantly protects against DVT in the major trauma patient (overall quality: moderate).

- Systematic use of prophylactic vena cava filters does not significantly reduce the risk of PE or mortality (overall quality: low).
- Routine use of an IVC filter as thromboprophylaxis is not recommended (overall quality: low).
- Use of IVC filters in patients with contraindications to chemical prophylaxis may result in a decreased rate of PE with an acceptable complication rate (overall quality: low).

Summary of answers

- The priority is saving the patient's life and then managing the pelvic fracture in order to reduce the high morbidity associated with pelvic fractures.
- Every Emergency Department, together with the surgical and radiological team, must create and apply a simple algorithm based on available resources for unstable patients with a pelvic fracture, to prevent confusion and the loss of precious time in cases of life-threatening pelvic injury.

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Acetabular Fractures

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Clinical scenario

- An 80-year-old woman with a pathological history of epilepsy is brought to the Emergency Department due to pain in her left hip and functional disability after falling from standing height.
- Anteroposterior (AP) pelvis x-ray shows an incongruity at the level of the articular surface of the left hip, without alterations in the morphology of the proximal femur. The diagnosis of suspicion is acetabular fracture.
- Judet projections inclined at 45° (alar and obturator views) are performed, in addition to computed tomography (CT). The presence of a fracture of the left acetabulum, simple posterior wall pattern, is confirmed. In addition, there is a fracture of the femoral head that had gone unnoticed on the initial radiographs.

Top three questions

1. In elderly patients (over 65 years old) with acetabular fractures, does surgical treatment achieve better functional outcomes compared to conservative treatment?

2. In elderly patients (over 65 years old) with acetabular fractures, does surgical fixation delay the need for total hip arthroplasty (THA) compared to conservative treatment?
3. In elderly patients (above 65 years) with acetabular fractures, does acute THA achieve better patient-reported outcomes and fewer surgical complications compared to a delayed THA?

Question 1: In elderly patients (over 65 years old) with acetabular fractures, does surgical treatment achieve better functional outcomes compared to conservative treatment?

Rationale

The number of acetabular fractures in the elderly is on the rise, due to an aging population, greater functional demands, and patients remaining active later into life. Although nondisplaced and stable fractures in older patients can be treated conservatively, the gold standard for the treatment of acetabular fractures is surgical osteosynthesis.[1] The goal is to preserve the survival and function of the native hip as much as possible.

Clinical comment

The incidence of acetabular fractures has increased 2.4 times over the past decade. They are associated with a mortality rate of between 8 and 25%.[2] The main purpose of surgical treatment is to restore the function of the hip, accelerate recovery, and avoid future complications.

Deciding which is the best treatment of these fractures requires considering several factors. Apart from fracture pattern and the surgeon's ability to achieve the best possible reduction, there are also important patient-related factors to consider. In addition, an aging population with multiple co-morbidities might mean that some patients are not ideal candidates for surgical treatment.

Available literature and quality of the evidence

- Level II: 1 study
- Level III: 9 studies
- Level IV: 1 study.

Findings

When operative management is required for anterior column fractures, minimally invasive techniques result in lower mortality, morbidity, and complications, compared to open surgery.[3] With operative treatment compared to nonoperative treatment, the recovery of function is much faster, allowing early weightbearing in elderly patients.[4] Sixty-five percent of patients recover their previous functional level, although in many cases with persistent pain.[5] Conversely, results obtained by Daurka et al. showed that results are worse for percutaneous osteosynthesis when compared with open reduction and internal fixation (ORIF).[6]

Fractures compromising the acetabular roof are usually managed surgically. In older patients it will depend on the medical condition.[7] In patients with low functional demands or those who are at high surgical risk because of co-morbidities, nonsurgical treatment can be chosen, followed by THA if secondary osteoarthritis develops. Patients should be mobilized as soon as possible if pain

management allows, to avoid prolonged periods of rest or traction in bed. Optimal outcomes are achieved when patients start with flat foot weightbearing for 6–8 weeks, and then progress gradually from there to full weightbearing.[8]

Posterior wall fractures are the most frequent acetabular fractures, representing around 30–47%.[1] They are generally associated with poorer prognosis, particularly when associated with a posterior dislocation, which is often associated with femoral head damage as well.

Other fractures that occur more inferiorly in the acetabulum that do not affect the weightbearing surface can be treated conservatively. Similarly, bi-columnar fractures can be successfully treated nonoperatively if secondary congruence of the femoral head respect to the acetabular roof is maintained without traction.

Ryan et al. reported similar functional results in patients with high surgical risk who were treated nonoperatively and those who underwent ORIF. No differences were found in overall Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) or Short Form 8 (SF-8) scores at one-year follow-up.[8]

Resolution of clinical scenario

- In older or younger patients with co-morbidities and surgical risk, nonsurgical treatment of acetabular fractures is associated with worse outcomes in terms of pain and morbidity.
- Mortality is similar in patients with high risk who undergo nonsurgical treatment compared to those in which surgical treatment was performed.

- In older patients with high surgical risk, it is reasonable to opt for nonoperative management and reserve arthroplasty as a rescue alternative. Patients should be counselled about this possibility at time of injury.

Question 2: In elderly patients (over 65 years old) with acetabular fractures, does surgical fixation delay the need for total hip arthroplasty (THA) compared to conservative treatment?

Rationale

Acetabular fractures are commonly associated with marked joint injury making articular surface reconstruction very challenging. Even when a satisfactory reduction is achieved, results are variable, and in many cases poor. In addition, failure rates are high, so some patients need to undergo rescue procedures (i.e. THA). It is controversial whether surgical fixation allows patients to delay the time to THA compared to conservative treatment.

Clinical comment

The goal of ORIF is to restore joint anatomy by reducing both columns, the quadrilateral plate, and the acetabular rim, thereby maximizing native hip function and survival. If anatomic reduction is not achieved, there is a higher likelihood of THA being required in the future.[9–12] Studies have shown that proper reduction delays the need for THA. Nonetheless, even nonanatomic reductions outside the weightbearing zone are generally well-tolerated.[2,13]

Available literature and quality of the evidence

- Level II: 2 studies
- Level III: 12 studies
- Level IV: 6 studies
- Level V: 1 study.

Findings

Classically, it has been reported that 10–37% of patients will eventually require THA following ORIF for an acetabular fracture,[14,15] and as mentioned above, fractures that affect the posterior wall have a poorer prognosis.[9,16]

According to Giannoudis et al., 20–25% of acetabular fractures will have poor results in the medium term, with the quality of reduction being a key predictor. Minimal step-off (step-offs <2 mm) are associated with a failure rate of 14%, while a step-off >2 mm can reach failure rates of up to 40%.[17] Even when satisfactory reduction is achieved, one of the important factors to consider is the cartilage damage sustained at the initial trauma, and this must be assessed in the medium-long term.

Ding et al. found that if the fracture affected the posterior wall, 36% of patients required delayed THA compared to only 17% patients in whom the fracture did not affect the posterior wall.[18] Kreder et al. reported the need for arthroplasty in 56% of elderly patients with posterior wall fractures they treated within the first two years surgery.[19]

Fractures of the anterior component of the acetabulum associated with femoral head protrusion are frequent in older patients. Archdeacon et al. showed a case-series of patients over 70 years in which they reported a conversion rate to THA of 19% in the first 18 months.[14,20]

Resolution of clinical scenario

- If a fracture has poor prognostic factors, the rate of secondary osteoarthritis is high. In addition, even following ORIF, these fractures have a relatively high rate of failure.
- The gold standard in surgical treatment through osteosynthesis is to obtain an anatomical reduction, with fractures that are not well reduced being at greater risk of failure.
- Failure is usually early, within the first two years, and there are associated high rates of morbidity and mortality in elderly patients.

Question 3: In elderly patients (above 65 years) with acetabular fractures, does acute THA achieve better patient-reported outcomes and fewer surgical complications compared to a delayed THA?

Rationale

The gold standard for acetabular fractures is surgical treatment. Given the poor prognosis presented by these fractures and the group of fragile patients in which they occur, it is not clear which is the best surgical treatment option. Due the high rates of failure with internal fixation, hip replacement could play an important role in this group of patients.

Clinical comment

Surgical treatment of acetabular fractures in the elderly has evolved over time. There is a trend toward performing early THA as a definitive procedure, although it is not clear whether to carry it out in one or two stages. The goal of the two-step approach is to reconstruct the joint using osteosynthesis to facilitate future arthroplasty. Meanwhile, one-step arthroplasty aims to avoid future reinterventions in this fragile patient population.

Available literature and quality of the evidence

- Level II: 1 study
- Level III: 13 studies
- Level IV: 2 studies.

Findings

Normally, THA occurs in the first two years after osteosynthesis of an acetabular fracture.[21,22] Ding et al. reported a 28% rate of THA in the first 2.5 years following index ORIF.[2,18] There are no differences in the need to perform a rescue THA depending on the type of fixation; Daurka et al. showed that the rates of THA were 22 and 25% following ORIF and percutaneous osteosynthesis, respectively.[6]

If it is difficult to reconstruct the posterior wall and the fracture presents risk factors for poor outcomes with surgical fixation such as marginal impaction ($p = 0.01$) or wall comminution ($p = 0.005$), primary THA should be considered as an option, especially in patients older than 50–60 years ($p = 0.01$).[15,19]

Placement of the acetabular component can be difficult depending on the size and location of posterior wall fragments (e.g. large fragments located near the roof are

technically more difficult to fix). If the prosthesis is indicated as the initial procedure, it is not clear whether it is better to do it with osteosynthesis and conventional prosthesis, or with complex prostheses (revision cups, cup cage, graft, etc.). In the former case, the objective of osteosynthesis is not necessarily anatomic reduction but rather to provide stability to the arthroplasty components.

If a combined procedure is carried out, the failure rates range from 13 to 45%.[23,24] Reconstruction rings can also be used, but it can be difficult to place them in bi-columnar fractures. The main problems with acetabular components are proximal migration and medialization, along with malpositioning leading to dislocation. Failure rates of the acetabular component for acetabular fracture are four to five times higher than in primary elective THA.[25]

Early arthroplasty in acetabular fractures has better results than late conversion to arthroplasty of a failed osteosynthesis.[26] The results of arthroplasty as a rescue of a failed osteosynthesis, based on the Harris Hip Score, are worse than the results of a nontraumatic primary arthroplasty.[27,28]

Data on survival are somewhat mixed. Morison et al. reported that in rescue THA failure was seen about five years earlier than primary arthroplasties.[29] However, other authors showed high survival rates in their articles. Lizaur-Utrilla didn't see differences in terms of aseptic loosening of a cementless acetabular component in patients undergoing THA after an acetabular fracture or compared to primary elective THA.[27] Ranawat et al. reported that five-year survival with revision, loosening, dislocation, or infection as an endpoint was 79%.[30]

Resolution of clinical scenario

- If the acetabular fracture associates to extensive impaction and comminution, and/or there is damage to the articular cartilage of the femoral head, an early THA should be considered in elderly patients.
- Early arthroplasty seems to have better results than late THA after osteosynthesis failure in elderly patients.
- The results of rescue arthroplasties are inferior to those of nontraumatic arthroplasty in terms of function, though it's unclear if there is a significant difference in implant survival.

Summary of answers

- Non-surgical treatment of acetabular fractures is associated with worse outcomes
- The gold standard with open reduction internal fixation is to achieve anatomic reduction, particularly of the joint surface
- Early THA should be considered in elderly patients with extensively impacted and/or comminuted fractures

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Hip Dislocations

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Clinical scenario

- A 40-year-old male is brought to the Emergency Department after a motor vehicle crash. He was an unrestrained passenger in the front seat.
- He is complaining of significant pain in the left hip and buttock region. His left extremity is slightly flexed, adducted, and internally rotated, and appears to be his only injury.
- X-ray demonstrates a posterior left hip dislocation with a small posterior wall acetabular fracture.
- After uneventful reduction in the Emergency Department, his hip remains concentrically reduced. Stress examination reveals that the hip is stable through range of motion. Nonoperative management is selected.
- Due to persistent pain two weeks later, he undergoes magnetic resonance imaging (MRI), and is diagnosed with a labral tear.

Top three questions

1. In patients with a traumatic dislocation of the hip, does a delay in hip reduction increase the risk of femoral head osteonecrosis (avascular necrosis [AVN]) as compared with an earlier reduction?
2. In patients with an isolated traumatic hip dislocation, do advanced imaging examinations (computed tomography [CT] and/or MRI) change treatment approach, as compared with X-rays alone?
3. In patients with hip dislocations who are diagnosed with an acetabular labral tear after closed reduction, does surgical treatment (with debridement and/or repair) achieve better functional outcomes than nonsurgical management?

Question 1: In patients with a traumatic dislocation of the hip, does a delay in hip reduction increase the risk of femoral head osteonecrosis (avascular necrosis [AVN]) as compared with an earlier reduction?

Rationale

- Traumatic hip dislocations are uncommon but severe injuries mainly observed after motor vehicle crashes and occasionally associated with sporting injuries. They represent 5.2% of all traumatic joint dislocations.[1]
- Posterior dislocations are more common (accounting for nearly 90% of all hip dislocations)[2] and tend to occur after what is known as a *dashboard injury* (the

seated driver/passenger's knee strikes the dashboard during sudden deceleration, causing the hip to dislocate posteriorly).

Clinical comment

Femoral head AVN – an undesirable complication after a traumatic hip dislocation – can lead to significant morbidity.[3] It may be caused by disruption and/or kinking of retinacular vessels supplying the femoral head.[4] Most surgeons believe that rapid reduction of hip dislocations is important to minimize AVN risk, but this is unproven. Knowledge regarding whether type of dislocation and timing to hip reduction is achieved may have an impact upon development of osteonecrosis and post-traumatic arthritis can assist orthopedic surgeons when informing hip dislocation patients about their prognosis and offering them the appropriate treatment.

Available literature and quality of the evidence

This search produced the following results: one level III meta-analysis[1] and one level IV systematic review and meta-analysis.[5] Numerous case series and case reports are already included in the previous two articles.

Findings

Femoral head osteonecrosis and hip dislocations

Kellam et al. performed a systematic review and meta-analysis that assessed femoral head osteonecrosis and post-traumatic osteoarthritis (PTOA) rates after traumatic hip dislocation.[5] They included 13 retrospective observational cohort studies (level of evidence: IV) with 795 posterior hip dislocations and 86 anterior hip dislocations, and found that, for both anterior and posterior dislocations, the event

rate of AVN and PTOA was higher as the severity of the injury increased. On the other hand, Ahmed et al. conducted a meta-analysis where they found that time to hip reduction was unimportant, and data pooled from the selected studies showed a trend toward higher femoral head AVN in high-grade traumatic hip dislocations (Thompson and Epstein grade IV–V) when compared to low-grade traumatic hip dislocations (Thompson and Epstein grade I–III), but this did not reach statistical significance (odds ratio [OR] = 1.71; 95% confidence interval [CI]: 0.22–13.22; I^2 = 68.9%; p = 0.012).[1]

Time to reduction and AVN

From the 13 studies included by Kellam et al.,[5] only two reported data about time to hip reduction. Sahin et al. showed that patients developed AVN after hip dislocation less frequently when reduction was performed within the first 12 hours (1/35, 2.9%), as compared to later than 12 hours (4/27, 14.8%) after the injury.[6] However, when comparing traumatic hip dislocations reduced in <6 hours and those reduced between 6 and 12 hours from the injury, they did not find any difference in AVN rates. Brav et al. reported AVN in 3/204 (1.47%) versus 33/58 (56.9%) cases when comparing patients who underwent articular reduction within or after 12 hours, respectively.[7] Although the number of studies reporting on timing was small, Kellam et al. calculated an increased risk (OR = 5.63; 95%CI: 2.97–10.67; p <0.005) for development of AVN for all types of hip dislocations when reduction is performed after 12 hours.[5]

Ahmed et al. considered a different timeframe in their study. They compared femoral head AVN rates when hip reduction was done early (considered to be <6 hours from the time of injury) versus late (>6 hours).[1] They included

five studies (all retrospective cohort studies) encompassing 236 traumatic hip dislocations. Patients who underwent late hip reduction had a significantly higher risk of femoral head AVN (OR = 5.00; 95% CI: 1.30–19.29; I^2 = 48.6%), as compared to those who had an early reduction. Dreinhöfer et al., in a cohort of 50 patients who underwent hip reduction after a traumatic hip dislocation, found an overall femoral head AVN rate of 12%, but found no difference in the rates between patients who underwent reduction within one hour compared to between one and six hours after injury.[8]

Resolution of clinical scenario

In this clinical scenario, considering the best available evidence, the orthopedic surgeon should be prepared to perform a reduction of a dislocated hip within six hours from injury. However, as evidence associating femoral head AVN with time to reduction of a hip dislocation is moderate, the recommendation remains to perform reduction as soon as possible in order to avoid further articular damage and, possibly, femoral head AVN (overall quality: moderate).

Question 2: In patients with an isolated traumatic hip dislocation, do advanced imaging examinations (computed tomography [CT] and/or MRI) change treatment approach, as compared with X-rays alone?

Rationale

- Hip dislocations are normally diagnosed with orthogonal plane x-rays. Traditionally, after closed

reduction is achieved, CT scans have been the imaging technique of choice to assess for associated fractures and/or intra-articular fragments.

- Controversy exists about the best imaging modality for evaluation of patients after closed reduction of hip dislocations, due to concern for associated soft tissue injuries and/or intra-articular fragments that may be missed by CT scan.[9]

Clinical comment

Arthroscopy has emerged as an important therapeutic tool after traumatic hip dislocation to treat some patients with persistent pain or mechanical symptoms associated with intra-articular loose bodies or other injuries, such as labral tears. Arthroscopy has been used as the gold standard when comparing the accuracy of different imaging techniques for the identification of intra-articular pathology.

Available literature and quality of the evidence

This search identified a level IV systematic review including 14 case series and 17 case reports. evaluating the diagnostic precision of CT and against arthroscopy as the gold standard.[10] Whenever possible, this review was used to answer the question, but when assessing the role of advanced-imaging techniques compared to conventional x-rays, five small retrospective studies (level IV) were used to help answer this question.

Findings

Arthroscopy after traumatic hip dislocations

No specific study answering the specific clinical question was found. However, some studies compared advanced

imaging findings after hip dislocation, with arthroscopy as a gold standard, because of persistent pain or mechanical symptoms.

Mandell et al. included 31 studies in a systematic review including 151 patients who underwent hip arthroscopy after a traumatic hip dislocation.[10] Patient mean age was 25.2 years (range 8–54) and 74% were males, with most dislocations being secondary to a motor vehicle crash (57%). The median time to arthroscopy from injury was 37.5 days. Specific findings about the presence or absence of intra-articular fragments were described in 119 patients. CT scan identified loose bodies in 89 cases (74.8%), compared to 102 cases (85.7%) identified by arthroscopy, thus CT had a sensitivity of 87.3%. From the 30 patients without intra-articular fragments identified on CT scan, 13 (43.3%) had chondral, osteochondral, or osseous intra-articular fragments seen during arthroscopy. This is also consistent with the findings of Khanna et al., in which CT scans identified only 2 of the 17 intra-articular bodies (12%) found in a cohort of 29 patients who underwent hip arthroscopy.[11]

On the other hand, 23 patients received a preoperative MRI with labral appearance being described in 21 cases. Nineteen labral tears were diagnosed by MRI, and all of them were confirmed by arthroscopy. One false-negative and one true-negative were identified. Thus, MRI had a sensitivity of 95% and a specificity of 100%. Additionally, the presence of intra-articular bodies was evaluated by MRI and in the six cases with MRI-identified loose bodies, arthroscopy confirmed the findings.[10]

Conventional x-rays versus CT

Hougaard et al. reviewed 15 cases in which both a CT and plain radiographs were performed after reduction of a

posterior hip dislocation.[12] Loose fragments were identified in five cases with CT scan (fragment of between 1 cm^2 and 6 cm^2), all of which were removed by open surgery. Plain radiographs only identified loose fragments in one case. Additionally, in six cases, CT scans demonstrated a fracture that would otherwise have been overlooked based on radiographs. Sauser et al. reported that, in a series of 13 patients with hip and pelvis injuries (six hip dislocations), CT scans provided useful information not seen on radiographs, modifying the treatment in four patients (30.8%).[13] Harley et al. and Shirkhoda et al. found both superior sensitivity and specificity when assessing intra-articular bodies with CT scans compared to x-rays, leading to identification of intra-articular loose bodies that were surgically removed and would have been otherwise overlooked.[14,15]

Resolution of clinical scenario

When plain radiographs reveal the presence of pathology requiring surgical intervention, advanced imaging techniques may not be necessary. However, in patients with apparently normal hip radiographs following uneventful closed reduction of an isolated hip dislocation, current evidence appears to support adding advanced imaging techniques (CT scan or MRI) in order to increase the likelihood of identifying associated injuries and perhaps changing treatment strategies. However, owing to small sample sizes and poor study design, it is not clear which method should be selected when choosing between CT or MRI. There is minimal evidence that MRI may be superior for the detection of injuries that could cause mechanical symptoms or persistent pain (such as labral injuries or intra-articular fragments) (overall quality: low).

Question 3: In patients with hip dislocations who are diagnosed with an acetabular labral tear after closed reduction, does surgical treatment (with debridement and/or repair) achieve better functional outcomes than nonsurgical management?

Rationale

- Hip dislocations are associated with a broad spectrum of intra-articular pathology, including labral tears, ligamentum teres disruption, intra-articular loose bodies, and chondral injuries. The presence of these types of injuries may explain persistent pain and/or mechanical symptoms after hip reduction is achieved.
- None of the current hip dislocation classification systems (Thompson and Epstein,[16] Stewart and Mildford,[17] Levin[18]) includes these injuries as a component of the classification.

Clinical comment

Associated injuries after a traumatic hip dislocation may slow recovery and potentially lead to future PTOA. Intra-articular bodies and labral tears can both cause chondral damage and increase the risk of hip osteoarthritis.[19,20] Traditionally, open reduction has been the standard of care for the treatment of hip dislocations that require surgery. However, recent sports medicine literature has focused on these hip conditions and their treatments,[21] with hip arthroscopy gaining in popularity in the context of

traumatic hip dislocations as an effective and less invasive approach for evaluation of periarticular soft tissues.

Available literature and quality of the evidence

This search identified one level IV systematic review including 14 case series and 17 case reports[10] evaluating CT and MRI diagnostic precision compared with arthroscopy; a review about the use of hip arthroscopy to treat sequelae of traumatic hip dislocations;[22] another review including the mechanism of injury, epidemiology, associated injuries, evaluation, treatment, and functional outcomes of simple hip dislocations;[23] and a retrospective study including patients who underwent arthroscopic treatment after acetabular fracture or hip dislocation.[21]

Findings

Labral tears after traumatic hip dislocations are a common finding. The use of arthroscopy to evaluate the hip joint after traumatic hip dislocations is increasing.[22] Philippon et al. identified that, in a series of 14 professional athletes who sustained traumatic hip dislocations, all had a labral tear during hip arthroscopy for continued hip pain, at a mean of 125 days postinjury.[24] Khanna et al. used hip arthroscopy to investigate the prevalence of intra-articular pathologic findings after a traumatic injury of the hip, reporting a presence of 93% of labral tears (27 of 29 hips).[11]

Hwang et al. carried out a retrospective study of 13 hip arthroscopy cases.[21] All patients had major hip trauma (acetabular fracture and/or hip dislocation), and were treated by a single senior surgeon due to persistent or aggravating pain and/or intra-articular pathologies such as loose fragments, labral tears, or ligamentum teres injury identified on advanced imaging. Labral tears were debrided

or repaired, loose fragments removed, and torn ligamentum teres debrided. Visual Analog Scale (VAS) and modified Harris Hip Score (mHHS) improved significantly at the final follow-up, from 6.3 and 53.4 to 3.0 and 88.3, respectively ($p = 0.002$ and $p < 0.001$, respectively). However, there were no significant differences in final hip flexion ($p = 0.07$), abduction ($p = 0.414$), adduction ($p = 0.317$), external rotation ($p = 0.084$), and internal rotation ($p = 0.136$).

Of all patients who underwent hip arthroscopy, eight had preoperative Tönnis grade 0 changes and five had grade 1 changes; none showed progression of hip osteoarthritis at the final follow-up (mean follow-up 59.8 months).

Overall, good outcomes have been achieved with arthroscopic labral debridement and repair.[10,21,25] The rest of the available literature appears to address arthroscopic treatment of labral tears not associated with hip dislocations. For instance, Kelly et al. reviewed early outcomes of labral tear debridements in the management of hip injuries in more than 500 athletes reporting good to excellent results in almost 90% of patients.[26] Byrd et al. reported a statistically significant increase in mHHS after arthroscopic labral debridement.[27] A median improvement of 25 points (preoperative, 56 points; postoperative, 81 points) at 10-year follow-up was observed.

Conservative management of labral tears is associated with an accelerated onset of osteoarthritis.[28,29] However, Clegg et al. recommend involving patients in a conservative management program, including physical therapy that involves specific strengthening exercises for the muscles around the hip joint.[23] Additionally, a review of nonsurgical rehabilitation for the treatment of labral tears in athletes has demonstrated a decrease in pain, increase in strength,

increase in function, and return to sport at preinjury levels.[30]

Resolution of clinical scenario

The arthroscopic treatment of intra-articular pathology with debridement and/or repair after traumatic hip dislocations appears to be safe and effective. Arthroscopic treatment significantly improves VAS and mHHS, and may help to stop or slow the progression of hip osteoarthritis. However, the bulk of studies to date include both simple and complex hip dislocations, or do not include traumatic hip dislocations. Long-term studies, including patients with hip dislocations and labral tears treated with hip arthroscopy, are necessary for a more complete evaluation of this technique. Although nonoperative management of acetabular labral tears may alleviate symptoms, the risk of accelerated arthritis may still persist (overall quality: low).

Summary of answers

- When treating a patient with a hip dislocation, based upon moderate-quality evidence, the recommendation is to perform a closed reduction as soon as possible within six hours of the injury to avoid further articular damage and femoral head AVN.
- After hip reduction is achieved, routine use of CT scan may change treatment of patients by increasing the ability to detect intra-articular loose bodies, based upon low-quality evidence.
- For patients with persistent pain or mechanical symptoms after traumatic hip dislocations, MRI may be superior to CT scans and plain radiographs for detecting intra-articular pathology, based upon low-quality evidence.

- Arthroscopic debridement of labral tears appears to be a safe and effective procedure for hip preservation after traumatic hip dislocations but long-term studies are needed. Conservative management of labral tears after hip dislocation may decrease symptoms, but does not appear to reduce the future risk of hip osteoarthritis.

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Femoral Head Fractures

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Clinical scenario

- A 48-year-old male is involved in a motor vehicle collision.
- Upon presentation he is awake and alert and complains primarily of left hip pain.
- His left lower extremity is flexed, adducted, shortened, and internally rotated.

Top three questions

1. In patients with femoral head fractures, which types benefit from operative intervention more than others?
2. In patients with operatively treated femoral head fractures, does a surgical dislocation utilizing an anterior surgical approach result in improved outcomes compared to the digastric trochanteric flip osteotomy?
3. In patients with femoral head fractures, are there situations in which hip arthroplasty may have improved outcomes compared to open reduction and internal fixation?

Question 1: In patients with femoral head fractures, which types benefit from operative intervention more than others?

Rationale

Although operative reduction and fixation are recommended for most displaced femoral head fractures, the treating physician must know which injury types are best managed nonoperatively. The primary goal of treatment is to achieve/maintain a healed, viable, comfortable, functional, stable, and congruent hip joint.

Clinical comment

Femoral head fractures are uncommon injuries occurring in only 10–15% of native hip dislocations, and are usually due to a high-energy traumatic event such as a head-on motor vehicle collision.[1] The most commonly used classification system is that described by Pipkin, who initially divided femoral head fractures into four types.[2] Type I fractures are those caudal to the fovea capitis, type II fractures are those cephalad to the fovea capitis, type III fractures were those associated with a femoral neck fracture, and type IV fractures were those associated with a fracture of the acetabular rim. The treatment options for displaced femoral head fractures with associated hip joint instability are almost always operative unless the intervention would pose a significant risk to the patient's life. Urgent management should include a prompt and concentric manipulative reduction. Outcomes following femoral head fracture have historically been evaluated using the Thompson and Epstein scale.[3] This system divides the

radiographic outcomes into excellent, good, fair, and poor based on the following criteria:

- Femoral head position.
- Amount of cartilaginous space narrowing.
- Variations in femoral head bone density.
- Subchondral irregularities of the head.
- Acetabular sclerosis.
- Capsular calcification.
- Spur formation.

Available literature and quality of the evidence

High-quality evidence pertaining to the treatment of femoral head fractures is limited due to the low incidence of the injury. Two randomized controlled trials[4,5] (level I) and a systematic review of 29 retrospective studies reporting on 453 femoral head fractures[1] (level II) constitute the best available evidence.

Findings

Chen et al. randomized 24 patients aged 18–60 with suprafoveal Pipkin II fractures to operative versus nonoperative treatment.[4] The operative patients were treated using a Smith-Petersen exposure within 12 hours of injury (without attempted preoperative closed reduction) followed by skin traction for six weeks to restrict hip motion. The nonoperative patients had manipulative closed reductions within 12 hours of injury and were placed in skeletal traction for six weeks. The patients were then followed for a minimum of two years after injury. According to the Thompson and Epstein scoring system,[3] there were two excellent, three good, five fair, and two poor outcomes

in the nonoperative group compared to five excellent, five good, and two fair outcomes in the operative group. One patient in the nonoperative group and five in the operative group developed heterotopic ossification. Two patients developed femoral head aseptic necrosis, both of which were in the nonoperative group. The results from this study concluded that patients with Pipkin type II fractures have improved outcomes when treated operatively.

Lin et al. randomized 36 patients with infrafoveal Pipkin type I fractures into an emergent surgical reduction and fixation group (group one, less than six hours to surgical intervention) and a secondary operative fixation group (group two, closed reduction followed by surgery more than two days after injury).[5] All patients underwent a Smith-Petersen surgical exposure. Patients in group one had 10 excellent, 4 good, 2 moderate, and 2 poor outcomes on the Thompson and Epstein scale compared to 3 excellent, 7 good, 3 moderate, and 5 poor outcomes in group two. Although these data suggest that expeditious treatment of Pipkin I fractures may improve overall clinical outcome, 9 of the 18 patients in group two had a nonconcentric hip after the initial closed reduction due to large fragments interposed in the articular surface. This group of patients had decreased Thompson and Epstein scores and a higher rate of femoral head aseptic necrosis (4/9 in those with a nonanatomic initial reduction compared to 1/9 in those with an anatomic reduction). The study concluded that surgery should be performed on an urgent basis in hips that remain nonconcentric following an emergent closed reduction.

Giannoudis et al. performed a systematic review of 29 retrospective clinical studies involving 453 femoral head fractures.[1] Outcomes data were available for 256 total cases. Criteria noted for conservative treatment included anatomical, concentric closed reduction of the hip

dislocation and femoral head fracture, absence of intra-articular osteochondral fragments, and a stable hip joint. Those patients treated conservatively (54 cases) resulted in 7 (13%) excellent, 16 (29.6%) good, 15 (27.8%) fair, and 16 (26.9%) poor outcomes while those treated operatively (202 cases) resulted in 31 (15.3%) excellent, 92 (45.5%) good, 32 (15.8%) fair, and 47 (23.3%) poor outcomes. Pipkin type I fractures represented the largest percentage of the nonoperative group at 25.3%. Of those Pipkin type I fractures that were managed operatively, 86.7% that had fragment excision had excellent or good results.

Resolution of clinical scenario

- Insufficient evidence exists to make a definitive recommendation regarding nonoperative treatment.
- Infrafoveal (Pipkin type I) fractures that are essentially nondisplaced with concentric hip joints radiographically, which are stable to examination under anesthesia are good candidates for nonoperative management.
- If treated operatively, fragment reduction and fixation is recommended when possible. Fracture fragment excision is performed for stable and concentric Pipkin type I fractures.
- The mainstay of treatment for Pipkin types II, III, and IV injuries is operative to restore a stable and congruent reduction of the hip joint.

Question 2: In patients with operatively treated femoral head fractures, does a surgical dislocation utilizing an anterior surgical approach result in improved outcomes compared to the digastric trochanteric flip osteotomy?

Rationale

The treating surgeon must be familiar with the advantages and disadvantages for each surgical approach when formulating a surgical plan for femoral head fractures.

Clinical comment

The most common surgical approaches for fixation of femoral head fractures include an anterior Smith-Petersen/modified Heuter approach or a posterior digastric trochanteric flip osteotomy, both of which involve surgical dislocation of the hip.[6] More recently, hip arthroscopy has been utilized for certain selected patients.

Available literature and quality of the evidence

One systematic review of 29 retrospective studies (level III),[1] one retrospective case-matched comparison study (level III),[7] and three retrospective studies (level IV) constitute the best available evidence for evaluating an anterior compared to a posterior approach.[15–17] Four studies involving small case series or case reports describe techniques utilizing hip arthroscopy for treatment of femoral head fractures (level IV).[8–11]

Findings

Giannoudis et al. performed a systematic review of 29 retrospective studies involving 453 femoral head fractures.[1] Outcomes data according to the surgical exposure utilized were present in 11 articles for a total of 153 cases. An anterior approach was associated with heterotopic ossification (all Brooker classes) in 17/38 (44.7%) and avascular necrosis (AVN) in 2/38 (5.3%) cases. A Kocher-Langenbeck approach had been reported in several studies and was associated with heterotopic ossification (all Brooker classes) in 21/65 (32.3%) and avascular necrosis in 11/65 (16.9%) cases. With the digastric trochanteric-flip osteotomy 17/36 (47.2%) developed heterotopic ossification (all Brooker classes) and 3/36 (8.3%) developed AVN. They found that there was a 1.87 times higher incidence of heterotopic ossification after a trochanteric-flip osteotomy when compared to a posterior approach (did not reach significance). The authors did not quantify what percentage of those patients with heterotopic ossification with each approach was actually symptomatic. The likelihood of AVN was 3.67 and 2.24 times higher when using a posterior approach compared to a trochanteric-flip osteotomy or anterior approach (did not reach significance). Post-traumatic arthritis was more common when using an anterior (20.3 times, $p = 0.04$) or posterior approach (30.6 times, $p = 0.018$) compared to a trochanteric osteotomy.

Four studies reported complications unique to the digastric trochanteric flip osteotomy.[6,12–14] Out of a total of 306 reported patients that underwent a trochanteric osteotomy (with or without a surgical dislocation), six (2.0%) patients had persistent pain at the site of fixation requiring screw removal, while four (1.3%) had fixation failure and/or nonunion at the site of the osteotomy.

In a case matched comparison of Smith-Petersen (12 patients) versus Kocher-Langenbeck approaches (12 patients) for Pipkin I and II femoral head fractures, Swiontkowski et al. found that the Kocher-Langenbeck approach was often associated with limited visualization of fracture fragments.[7] Three patients in this group developed heterotopic ossification and two developed AVN compared to seven with heterotopic ossification and none with AVN in the Smith-Petersen group. Eight of 12 patients in both groups had good or excellent results.

In the largest retrospective study to date by Scolaro et al. evaluating the outcomes of 78 operatively treated patients, 76 (97%) were treated with a Smith-Petersen approach.[15] Their overall results demonstrated a femoral head union rate of 89.9%. Six patients (9%) developed AVN, while heterotopic ossification developed in 28 (40.6%). Of the 28 patients that developed heterotopic ossification, 17 (60%) were Brooker class I, four (14%) were Brooker class II, four (14%) were Brooker class III, and three (10%) were Brooker class IV. Only two patients required a return to the operating room for heterotopic ossification excision.

Two other clinical manuscripts evaluated the outcomes of the digastric trochanteric flip osteotomy in 25 total patients.[16,17] Solberg et al. looked specifically at 12 patients with Pipkin type IV injuries.[17] Outcomes with the Thompson and Epstein scoring scale involved 10 with good or excellent outcomes, 1 with a fair outcome, and 1 with a poor outcome. Eleven of the femoral head fractures healed, one developed AVN, and four patients developed heterotopic ossification (three with Brooker class II and one with Brooker class III). There was no group for comparison in this study.

Masse et al. reported on 13 patients with femoral head fractures (five Pipkin I, two Pipkin II, six Pipkin IV).[16] This

cohort included eight patients with anatomic hips and five with imperfect hips according to the Matta radiographic criteria.[18] The mean Harris Hip Score at minimum follow-up of two years was 82.[19,20] One patient developed AVN and two others developed asymptomatic heterotopic ossification.

Four studies report on seven patients treated with arthroscopic reduction and fixation of a femoral head fracture.[8–11] No objective outcomes data are available, although the patients were reported to do well postoperatively.

Resolution of clinical scenario

- The chosen approach should be based on fracture morphology, size, and the presence of an ipsilateral acetabular fracture.
- The Smith-Petersen surgical exposure is most commonly used because it allows an anterior surgical hip dislocation with complete visualization of the femoral head fracture, but may be associated with higher rates of heterotopic ossification formation.
- The Kocher-Langenbeck surgical exposure is not recommended for the majority of femoral head fractures because direct visualization of the anterior femoral head fracture is not possible, and it has been associated with higher rates of aseptic necrosis. This exposure can be used to operatively reduce and stabilize an associated unstable posterior wall acetabular fracture.
- The digastric trochanteric flip osteotomy is advocated for those patients with unstable posterior wall acetabular fractures and femoral head fractures.

- A recommendation for or against hip arthroscopy cannot be made based on the current evidence.

Question 3: In patients with femoral head fractures, are there situations in which hip arthroplasty may have improved outcomes compared to open reduction and internal fixation?

Rationale

Femoral head fractures have variable outcomes based on Pipkin classification, as certain fracture types are associated with high complication rates. Therefore, there may be a subset of this patient population that would be better managed with acute hip arthroplasty.

Clinical comment

Outcomes following femoral head fractures are variable depending on the type of fracture and can be devastating for the native hip if AVN occurs. This complication seems to most often occur in Pipkin type III fractures, which also involve a fracture of the femoral neck. Although most young, healthy patients should typically receive attempted operative fixation following femoral head fractures when surgical indications are met, this specific subset may have better outcomes if treated primarily with hip arthroplasty.

Available literature and quality of the evidence

One systematic review of 29 retrospective studies (level III)[1] and two large retrospective case series (level IV).[15,21]

Findings

In the systematic review by Giannoudis et al.,[1] outcomes data according to the Thompson-Epstein criteria were available in a total of 18 articles involving 291 femoral head fractures. Overall, outcomes were found to be excellent in 14.3% of cases, good in 39.8%, fair in 19.3%, and poor in 26.5%. Data from 26 articles involving 405 femoral head fractures showed an overall AVN rate of 11.8%, post-traumatic arthritis in 20%, and heterotopic ossification in 16.8%. This systematic review did not find any significant difference in outcomes among Pipkin subtypes but did note a nearly significant difference when Pipkin types I and II were compared to Pipkin types III and IV ($p = 0.057$). Functional outcomes were available in 11 articles reporting on 155 fractures. Thompson and Epstein scores according to Pipkin subtypes were:

- Pipkin I (n = 34): 5 (14.7%) excellent, 17 (50%) good, 8 (23.5%) fair, 4 (11.8%) poor.
- Pipkin II (n = 56): 14 (25%) excellent, 27 (48.2%) good, 6 (10.7%) fair, 9 (16.1%) poor.
- Pipkin III (n = 8): 0 excellent, 4 (50%) good, 2 (25%) fair, 2 (25%) poor.
- Pipkin IV (n = 57): 9 (15.8%) excellent, 21 (36.8%) good, 8 (14%) fair, 19 (33.3%) poor.

Tonetti et al. performed a retrospective study of 110 patients with femoral head fractures, 78 of which were treated operatively.[21] They reported specifically on rates of conversion to total hip arthroplasty as the primary outcome measure. They found that only Pipkin III fractures were predictive of conversion to total hip arthroplasty. There were a total of four in their study, one of which underwent primary arthroplasty, while the other three underwent secondary arthroplasty following failure of initial

treatment. In their series of 78 operatively treated Pipkin fractures, Scolaro et al. noted a 100% failure rate in Pipkin III fractures (five patients) of the femoral head and also suggested that arthroplasty should be strongly considered as an initial treatment option.[15]

Resolution of clinical scenario

- Strong consideration should be given to primary total hip arthroplasty in Pipkin type III fractures in all adult patients due to high failure rates of open reduction and internal fixation (ORIF).
- For older patients with injuries that need operative treatment, primary total hip arthroplasty may be considered.

Summary of answers

- Insufficient evidence exists to make a definitive recommendation regarding nonoperative treatment.
- Infrafoveal (Pipkin type I) fractures that are essentially nondisplaced with concentric hip joints radiographically, and are stable to examination under anesthesia are good candidates for nonoperative management.
- If treated operatively, fragment excision can be considered in Pipkin type I fractures that are congruent and stable following fragment excision. If instability is identified following fragment excision, the surgeon should fix the femoral head fragment.
- Displaced and unstable Pipkin types II, III, and IV injuries warrant operative treatment.

- Selection of the proper surgical exposure should be based on the fracture morphology and the presence of an associated ipsilateral unstable acetabular fracture.
- The Smith-Petersen surgical exposure is most commonly used but may be associated with a higher incidence of heterotopic ossification.
- The Kocher-Langenbeck is not recommended for femoral head fractures because direct visualization of the anterior femoral head fracture is not possible and it has been associated with higher rates of aseptic necrosis.
- A recommendation for or against hip arthroscopy cannot be made based on the current evidence.
- Strong consideration should be given to primary total hip arthroplasty in Pipkin type III fractures, especially in elderly patients.

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95
Femoral Neck Fractures in Younger Patients

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Clinical scenario

- A 26-year-old healthy, nonsmoking male presents to the Emergency Department after a five-foot fall off a trailer.
- Initial radiographs demonstrate a displaced femoral neck fracture (Figure 95.1). On exam the patient's affected hip is flexed, externally rotated, and neurovascularly intact.
- He was treated with open reduction and internal fixation (ORIF) with a sliding hip screw (SHS) four hours after initial injury (Figure 95.2). The patient demonstrates appropriate healing and maintenance of fixation at six-month follow-up (Figure 95.3).

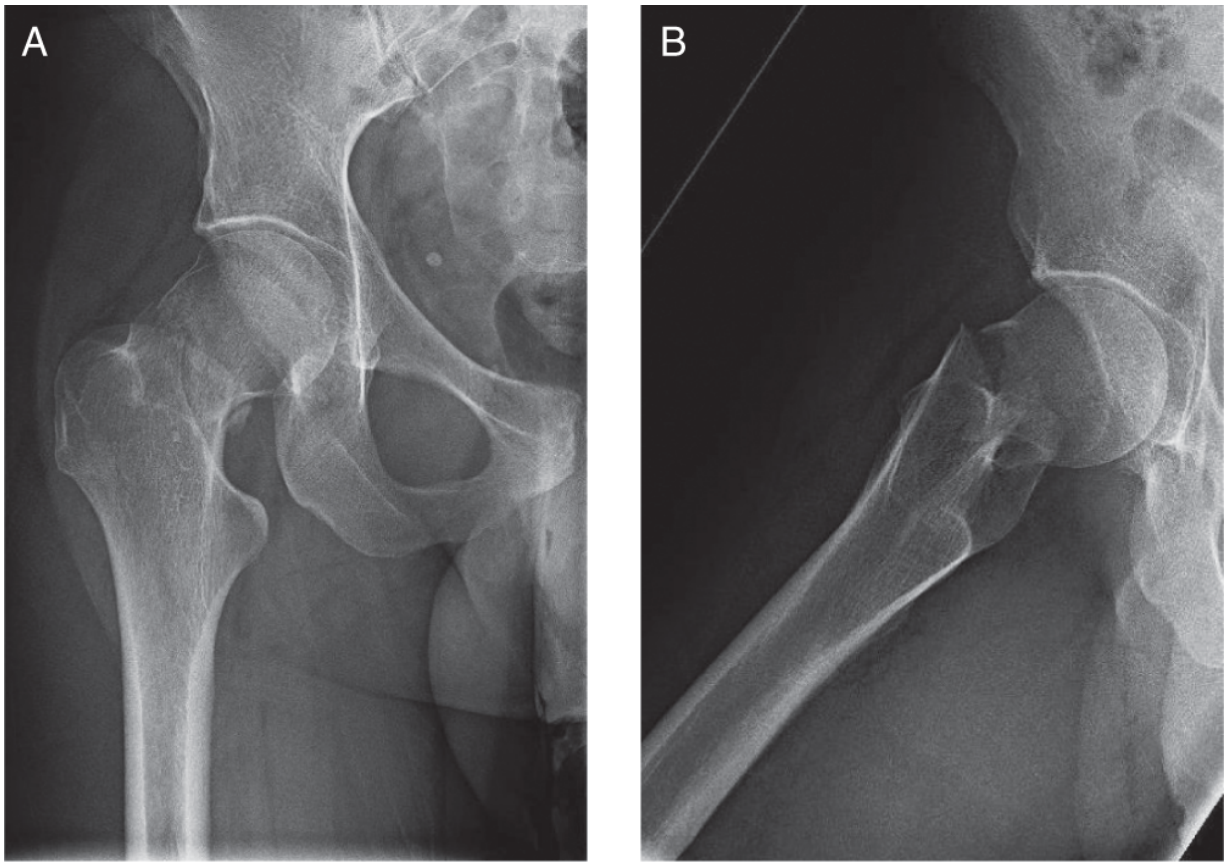


Figure 95.1 Radiographs on presentation showing right femoral neck fracture: (A) AP right hip; (B) lateral right hip.

Top three questions

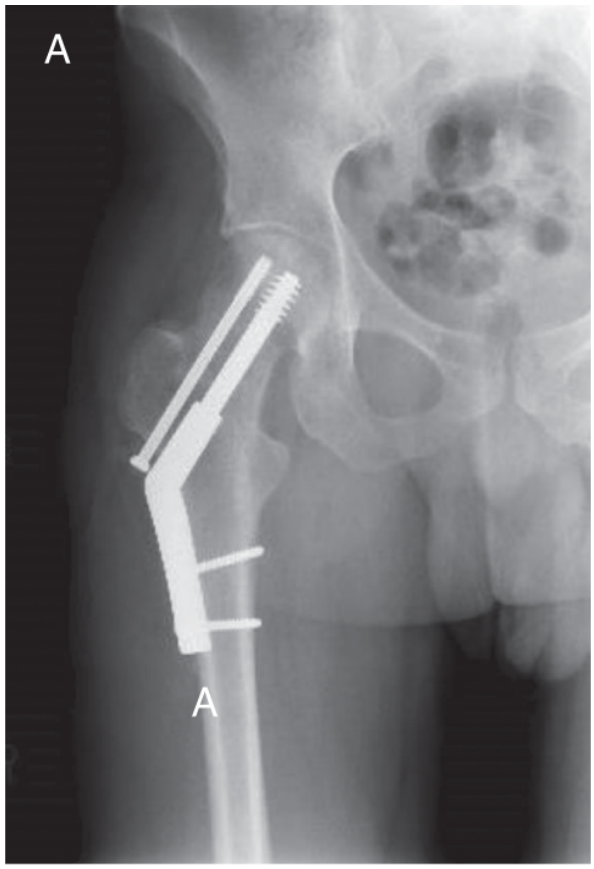
1. In young adult patients with displaced femoral neck fractures, does time to surgery of <6 hours result in lower rates of avascular necrosis (AVN) compared to surgery performed 6–24 hours from injury?
2. In young adult patients with displaced femoral neck fractures, does treatment with open reduction provide superior outcomes compared to treatment with closed reduction?
3. In young adult patients with displaced femoral neck fractures, does implant choice of cannulated screws

(CS) result in higher complication rates when compared to an SHS?

Question 1: In young adult patients with displaced femoral neck fractures, does time to surgery of <6 hours result in lower rates of avascular necrosis (AVN) compared to surgery performed 6–24 hours from injury?

Rationale

Urgent or emergent reduction and fixation of displaced femoral neck fractures has been postulated to decrease postoperative rates of AVN of the femoral head. Optimal timing of intervention is an ongoing debate.



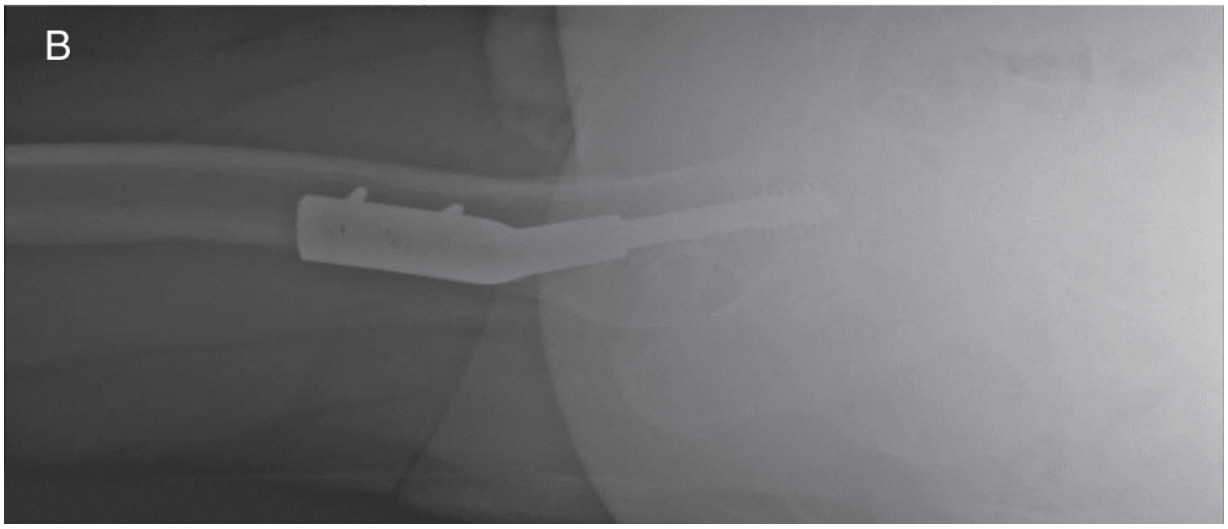
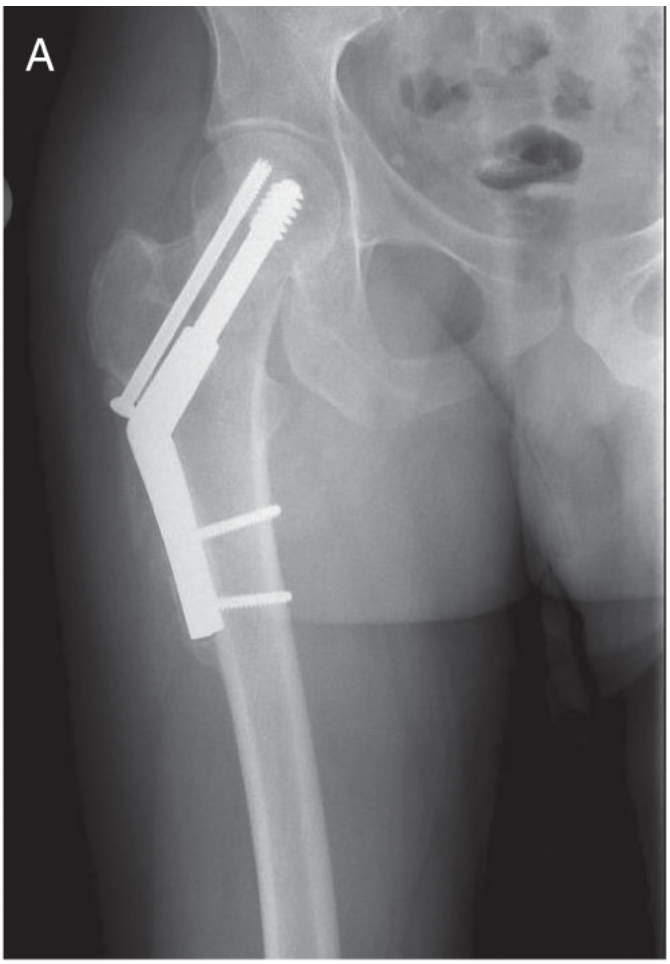


Figure 95.2 Postoperative open reduction and internal fixation with a sliding hip screw and anti-rotational screw: (A) AP right hip; (B) lateral right hip.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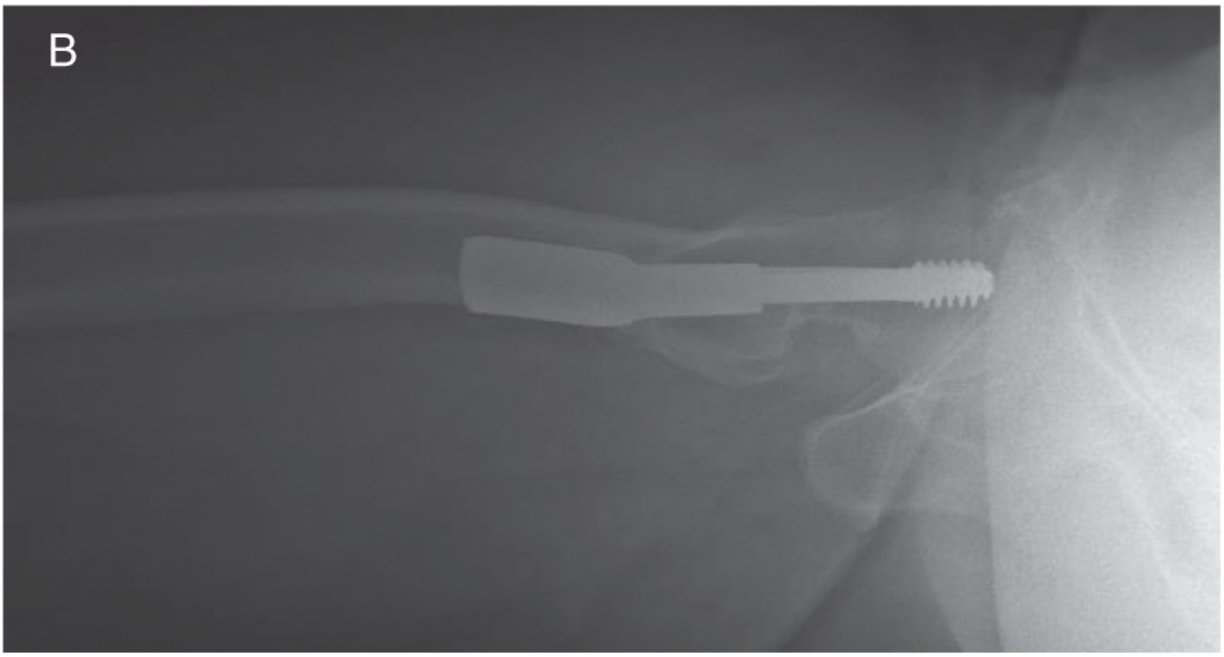
B

Figure 95.3 Six-month follow-up demonstrating interval healing and maintained reduction: (A) AP right hip; (B) lateral right hip.

Clinical comment

Proper management of displaced femoral neck fractures in young adult patients remains controversial. Treatment is associated with historically high complication rates including AVN, malunion, nonunion, and implant failure.[1–4] With the treatment goal being joint preservation, the most feared complication is AVN of the femoral head. Efforts have been made to reduce and stabilize the fracture in an urgent or emergent fashion to decrease this risk. However, there are currently no studies that can support the routine practice of emergent (<6 hours) surgical fixation in these patients.

Available literature and quality of the evidence

There is a lack of literature investigating optimal timing of fixation in young adult patients with femoral neck fractures. Recent literature includes a level I prospective randomized study comparing outcomes and complications in young patients with displaced femoral neck fractures.[5] Additionally, there is one retrospective cohort and one meta-analysis (level II), which both analyze the correlation of time to fixation with rates of AVN.[6,7]

Findings

Upadhyay and colleagues performed a prospective randomized multicenter study on 92 patients with Garden grades III and IV femoral neck fractures.[5] Patients aged 15–50 years who underwent closed or open reduction with internal fixation were followed clinically and radiographically for two years. Secondary measures

included risk factors affecting the development of AVN and nonunion. Forty-two patients had a delay of femoral neck fixation of >48 hours, and 15 femoral heads developed AVN. Of the 16 femoral necks that developed nonunion, 7 (43.8%) consisted of a delay of fixation of >48 hours (odds ratio [OR] = 1.37; 95% confidence interval [CI]: 0.20–9.50). They concluded that no factors investigated, including time of surgery, increased the risk of developing AVN.[5]

Razik et al. performed a retrospective study investigating effect of time delay to fixation in patients with femoral neck fractures.[6] Patients underwent fixation with either SHS, CS, or SHS with a de-rotation screw. Ninety-two patients under the age of 60 followed for a mean of two years were retrospectively analyzed. Time to fixation was divided into intervals including ≤ 6 hours, 6–12 hours, 12–18 hours, 18–24 hours, 24–48 hours, and >48 hours. The percentage of patients who developed AVN was 14.1%. Two had nondisplaced fractures and 11 had displaced fractures. Utilizing a binary logistic regression model, incidence of AVN did not increase significantly past the six-hour time to surgery interval, with no significant difference demonstrated between time intervals and rate of AVN.[6]

A meta-analysis performed by Papakostidis et al. reported on timing of internal fixation of femoral neck fractures.[7] Out of 492 studies that investigated outcomes of acute femoral neck fractures, seven met final inclusion criteria and six consisted of young adult patients. A meta-analysis was performed to compare time of internal fixation with rates of AVN and nonunion. Groups included fixation within six hours versus fixation after six hours, fixation within 12 hours versus fixation after 12 hours, fixation within 24 hours versus fixation after 24 hours, and fixation within 6 hours versus fixation after 24 hours. There was no association between AVN and any time interval. However,

the odds of nonunion tripled with patients who underwent internal fixation after 24 hours ($p = 0.004$).[7]

Resolution of clinical scenario

- In young patients with a femoral neck fracture, time to fixation may not be as crucial as previously thought.
- In young patients with a femoral neck fracture, time to fixation even >24 hours from injury has not been shown to increase the risk of AVN.
- Other factors should be considered to minimize complications including optimal operative environment and fixation method.

Question 2: In young adult patients with displaced femoral neck fractures, does treatment with open reduction provide superior outcomes compared to treatment with closed reduction?

Rationale

No standard of care exists regarding closed versus open reduction of femoral neck fractures. These fractures can be difficult to reduce and have high rates of osteonecrosis and nonunion if not reduced acceptably; for this reason, controversy remains regarding the best method of reduction.

Clinical comment

In the treatment of displaced femoral neck fractures in young patients, obtaining an anatomic reduction is

paramount, as a poorly reduced fracture is a major risk factor for nonunion and AVN.[5,8] While open reduction most easily facilitates anatomic fracture reduction, a closed reduction using fluoroscopy can often lead to a radiographically acceptable result without the need for direct open exposure. This leads to less invasive surgery, improved postoperative recovery, and results in indirect cost reduction.[9] Given that no consensus opinion exists on which method is superior, it is important to explore risks, benefits, and outcomes associated with each reduction method.

Available literature and quality of the evidence

Current literature includes a meta-analysis (level I) of closed versus open reduction investigating rates of union and AVN between reduction methods.[10] There is also a prospective, randomized study (level I)[5] and multicenter retrospective cohort study (level III)[11] comparing the results and complications between closed and open reduction in young adults with displaced femoral neck fractures.

Findings

A meta-analysis performed by Ghayoumi et al. investigated outcomes including nonunion, AVN, and deep infection after treatment of femoral neck fractures with ORIF or closed reduction with internal fixation (CRIF) in patients 50 years old or younger.[10] Twenty-one studies were included in the analysis. The incidence of nonunion and AVN was not found to be statistically significant between ORIF and CRIF ($p = 0.25$, 0.91, respectively). Incidence of deep wound infection was found to be higher in the ORIF patients compared to CRIF ($p = 0.0019$).[10] However, it is important to note possible bias in the included studies. Treating

surgeons are likely to perform closed reduction on minimally displaced fractures, which would likely go on to do well regardless of approach. Similarly, fractures with high degrees of displacement, which are more likely to do poorly, are more often treated with an open approach.

In a prospective, randomized study by Upadhyay et al., results and complications were compared after closed and open reduction with internal fixation in young adults with Garden grades III and IV femoral neck fractures.[5] Secondary outcomes included risk factors which influenced nonunion and development of AVN. There were 102 patients between 15 and 50 years who were randomized to receive closed or open reduction. There was no significant difference between fixation methods in union ($p = 0.93$) or AVN at two years ($p = 0.85$). Posterior comminution, poor reduction, and improper placement of the screws were the major risk factors which contributed to nonunion; however, incidence of AVN was not found to be influenced by these risk factors.[5]

A multicenter retrospective cohort study by Ishii et al. investigated 239 patients from 13 academic institutions that were treated with ORIF versus CRIF for OTA 31-B2 (femoral neck) or 31-B3 (basicervical) fractures with a minimum of six-month follow-up.[11] Primary outcome was reoperation with secondary outcomes including nonunion, malunion, AVN, infection, osteoarthritis, heterotopic ossification, and fracture fixation failure. There was no statistically significant difference in total reoperation rate between ORIF and CRIF (37.3% vs 27.4%, $p = 0.14$), although ORIF patients did show a higher incidence of reoperation due to nonunion when compared to CRIF patients (16.7% vs 5.3%, $p = 0.01$). Incidence of AVN (18.5% vs 8.7%) and post-traumatic osteoarthritis (12% vs 3.8%) was higher in the CRIF versus ORIF group ($p =$

0.034 and 0.027, respectively). When comparing the cohorts, CRIF patients were older, had more co-morbidities, and were more likely to have sustained OTA type B3 (displaced subcapital) injuries, while ORIF patients were more likely to have Pauwels type III injuries and coincident femoral shaft fractures.[11]

Resolution of clinical scenario

- In young adult patients with a displaced femoral neck fracture, open reduction has not been shown to decrease the risk of nonunion or AVN.
- Poor reduction of a displaced femoral neck fracture in a young patient, achieved by either open or closed reduction, is a risk factor for nonunion and poor outcome.
- Closed reduction and internal fixation will decrease overall risk of deep wound infection compared with open reduction.

Question 3: In young adult patients with displaced femoral neck fractures, does implant choice of cannulated screws (CS) result in higher complication rates when compared to an SHS?

Rationale

Controversy exists regarding the ideal implant for treatment of young patients with displaced femoral neck fractures. The two most commonly used devices are partially threaded 6.5 or 7.3 mm CS in an inverted triangle

configuration, and an SHS device with or without a de-rotational screw. The CS implant provides rotational control and are less invasive to perform, while the SHS provides axial compression along a fixed angle support. No consensus currently exists regarding which implant configuration is superior.

Clinical comment

Many young adult femoral neck fractures can undergo fixation with three cancellous screws in an inverted triangle formation with perpendicular placement to the fracture line. Proponents for this type of fixation reason that the orientation of three CS allows rotational stability while resulting in less bone loss than SHS if revision is required.

Significantly displaced femoral neck fractures are more controversial when considering fixation due to the degree of displacement and the desire for fixed angle support. Fixation with an SHS versus three CS has been shown to result in less inferior femoral head displacement, less shearing displacement, and greater load to failure in short-term follow-up studies.[12,13] While the fixed-angle SHS has been shown to be biomechanically superior to CS, this advantage is not demonstrated in current clinical studies.[12–15]

Available literature and quality of the evidence

There are two prospective randomized controlled trials (RCTs; level I) comparing fixation methods for nondisplaced femoral neck fractures. It is worth noting that patient population age was over 50 years in the FAITH trial.[16,17] Current literature beyond this is limited to retrospective cohort review studies (level III) comparing

outcomes of fixation methods for both nondisplaced and displaced young femoral neck fractures.[12]

Findings

In a prospective, international, multicenter, RCT by Nauth et al., known as the FAITH trial, 1108 patients with nondisplaced femoral neck fractures were recruited over six years.[16] Each patient was randomized to receive CS or SHS fixation and were followed up to two years postoperatively. Primary outcome was hip reoperation within 24 months after initial surgery. Analyses followed the intention-to-treat principle. AVN was more common in the SHS group compared to CS group (9% vs 5%; 95% CI: 1.06–3.44; p = 0.0319). Hip reoperation within 24 months did not demonstrate a statistically significant difference between methods of fixation (20% vs 22%; 95% CI: 0.63–1.09; p = 0.18). Similarly, nonunion rate, implant failures, infections, fracture shortening, and fracture healing did not show a statistically significant difference between surgical fixation method. Sub-group analyses favored SHS in patients with displaced fractures, fractures at the base of the femoral neck, and in those who were current smokers.[16]

In a second RCT by Siavashi et al., 58 patients with Garden type III or IV femoral neck fractures were randomized to receive CS or SHS treatment with minimum follow-up of one year evaluating union, AVN, infection rate, with clinical outcomes including Harris Hip Score (HHS).[17] There was a total of five (18%) versus zero patients that experienced reduction and fixation failures in the CS versus SHS treatment group (p <0.001). The patients who received CS fixation had statistically significant lower HHS outcomes compared to SHS (p <0.01). There was no statistically

significant difference between the rate of AVN and infection.

In a retrospective study by Gardner et al., early failure rates of SHS and CS constructs were evaluated in 68 patients aged <60 years. Primary aim was to compare rate of fixation loss in younger patients with displaced femoral neck fractures treated with either SHS or CS constructs.[12] A secondary aim was to identify risk factors associated with early or late fixation failure, AVN, or nonunion. Univariate comparisons suggested that CS fixation is associated with a significantly higher early fixation failure rate compared to SHS (21% vs 3%, p = 0.04). All early failures in the CS group were of intermediate verticality and were classified as Pauwels type II fractures. There was no significant difference between the two groups in nonunion rate (p = 0.39) and symptomatic AVN (p = 0.69).

Resolution of clinical scenario

- Nondisplaced femoral neck fractures treated with CS fixation provide a rotationally stable construct with less bony loss compared to SHS.
- Displaced femoral neck fractures treated with SHS fixation have shown lower rates of reduction loss and fixation failure when compared to CS.
- There is conflicting literature regarding complication rates in displaced femoral neck fractures treated with SHS versus CS. However, recent randomized controlled data suggest there is a higher rate of osteonecrosis in patients treated with SHS.

Summary of answers

- When treating femoral neck fractures in young patients, the current body of literature does not support emergent (<6 hours) fixation compared to fixation within 24 hours.
- Open versus closed reduction of a young femoral neck fracture should be based on fracture morphology with the goal being anatomic reduction. There are benefits to closed reduction; however, a closed reduction should not be performed at the cost of an acceptable reduction.
- SHS and CS fixation for young femoral neck fractures are both currently acceptable implant options, and there are pros and cons to both fixation methods.

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Femoral Neck Fractures in the Elderly

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Clinical scenario

- You see a 71-year-old male patient who is a community ambulator and slipped while shoveling his driveway after a snowstorm. He was transported to the Emergency Department by emergency medical services. He is unable to bear weight. On examination, his right leg is shortened and externally rotated. He is neurovascularly intact.
- The patient's x-ray reveals a displaced femoral neck fracture (Garden type IV). You present treatment options to your patient: arthroplasty or internal fixation.

Top three questions

1. In patients over the age of 65 undergoing treatment of a displaced femoral neck fracture, does arthroplasty result in decreased mortality and re-operation rates compared to internal fixation?
2. In patients over the age of 65 undergoing internal fixation for a displaced femoral neck fracture, does use of cancellous screws result in reduced risk of

complications and re-operation compared to sliding hip screws (SHSs)?

3. In patients over the age of 65 undergoing arthroplasty for a displaced femoral neck fracture, does use of total hip arthroplasty (THA) result in decreased complications and improved outcomes compared to hemiarthroplasty?

Question 1: In patients over the age of 65 undergoing treatment of a displaced femoral neck fracture, does arthroplasty result in decreased mortality and re-operation rates compared to internal fixation?

Rationale

Maintaining the patient's original hip with a fixation device versus removing the femoral head and replacing the hip with a prosthesis has important implications for outcome and function. Current opinion is highly divergent among orthopedic surgeons on whether to fix or replace the hip.

Clinical comment

The disability adjusted life-years lost as a result of hip fractures ranks in the top 10 of all cause disability globally. Over 4.5 million persons sustain hip fractures around the world each year. By the year 2040, the number of people aged 65 or older will increase from 34.8 million to 77.2 million. The number of hip fractures is likely to exceed 500 000 annually in the United States and 88 000 in Canada over the next 40 years.[1–4] Hip fractures are associated with a 21% mortality rate at one year and

profound temporary, and sometimes permanent, impairment of independence, and quality of life.[5] Furthermore, approximately 30% of surgically treated hip fractures require revision surgery.[6] These revisions are associated with a large burden of morbidity and mortality. Arthroplasty has the potential to achieve reduced re-operation and mortality.

Available literature and quality of the evidence

Multiple randomized controlled trials (RCTs) have investigated the difference in mortality and re-operation rate between internal fixation and arthroplasty for displaced femoral neck fractures in patients over the age of 65. The most relevant literature consisted of a systematic review of the literature and meta-analysis (level I evidence).

Findings

In 2003, Bhandari et al. reported the results of a meta-analysis of 14 randomized trials comparing outcomes of internal fixation and arthroplasty (level I).[7] Nine trials (n = 1162 patients) provided postoperative mortality data at four months or less, twelve trials (n = 1767) provided one-year mortality data, and all 14 trials (n = 1901) provided information on revision surgeries. They found no difference in the risk of mortality between arthroplasty and internal fixation, but did find that arthroplasty was associated with significantly lower risk of revision and the results were consistent study to study (risk ratio [RR] = 0.23; 95% confidence interval [CI]: 0.13–0.42). Information on secondary outcomes of pain, function, and infection rate was available for some studies. Information on secondary outcomes was available for six studies (n = 1153 patients) reporting on pain relief and 12 on function (n = 1179

patients). Pain relief and function were similar in patients treated with arthroplasty or internal fixation (RR of no/little pain 1.12; 95% CI: 0.88–1.35 and good function 0.99; 95% CI: 0.90–1.10). Arthroplasty significantly increased the risk of infection (12 studies, n = 1822) compared to internal fixation (RR = 1.81; 95% CI: 1.16–2.85, p = 0.009, homogeneity p = 0.16). The risk difference between the two treatments was 3.4%. This meant that for every 29 patients treated with internal fixation one infection could be prevented (number needed to treat [NNT] = 1/0.034 = 29.4). Relatively fewer data were available for secondary outcomes of blood loss and surgical time. Four studies (n = 343 patients) reported on estimated blood loss, and five (n = 447 patients) and surgical time. Patients who underwent arthroplasty experienced greater blood loss than those who were treated with internal fixation (weighted mean difference = 176.4 mL; 95% CI: 132.4–220.4, p <0.05). Similarly, surgical time in the arthroplasty-treated patients was greater than the patients treated with internal fixation (weighted mean difference = 29.0 minutes; 95% CI: 23.2–34.8, p <0.05).

Overall, level I evidence suggests that arthroplasty is associated with significantly lower risk of re-operation compared to internal fixation, but there is no difference in risk or mortality.[7] Additionally, arthroplasty was associated with significantly greater blood loss, operative time, and risk of infection. There are limitations to these data though as they lacked the power to demonstrate whether there was an increased risk of mortality with arthroplasty. The review did raise a possible concern for increased risk of early mortality (relative risk of death at four months 1.27); however, this was not statistically significant.

Resolution of clinical scenario

- Level I evidence suggests that arthroplasty *does* significantly reduce the risk of revision surgery at one year compared to internal fixation.
- Level I evidence suggests arthroplasty *does not* result in significantly different risk of mortality at one year compared to internal fixation.
- Level I evidence suggests arthroplasty *does* significantly increase the risk of infection, blood loss, and operative time at one year compared to internal fixation.

Question 2: In patients over the age of 65 undergoing internal fixation for a displaced femoral neck fracture, does use of cancellous screws result in reduced risk of complications and re-operation compared to sliding hip screws (SHSs)?

Rationale

As much of the focus in the literature is concerned with comparing internal fixation to arthroplasty, what is less well understood is which method of fixation generates superior results. It is suggested that bias in certain study designs has caused outcomes for arthroplasty to fair better. For this reason, internal fixation cannot be overruled and further scrutiny of fixation methods are in order.[8]

Clinical comment

The literature has demonstrated that the most critical component to avoiding complication in femoral neck

fracture fixation is the quality of reduction. An optimal reduction far outweighs implant choice and it is our preference to perform an open reduction of all displaced femoral neck fractures that undergo internal fixation. With nondisplaced fractures, current opinion suggests that the majority of surgeons are using internal fixation with cancellous screws. When internal fixation is chosen for displaced fractures, SHS shows a reduced risk of re-operation.[9] It is important to understand the relative risks of complications, such as avascular necrosis (AVN), and re-operation to determine the optimal fixation method for patients; however, the quality of reduction must be the surgeons primary focus.

Available literature and quality of the evidence

Multiple RCTs have compared the use of SHSs and cancellous screws for fixation of displaced femoral neck fractures; however, many current studies lack methodological rigor. The most relevant current literature consisted of: (i) a systematic review of the literature with meta-analysis (level I evidence), (ii) a Cochrane review of the literature (level I evidence), and (iii) an international, multicenter, RCT (level I evidence).

Findings

A review from 2009 by Bhandari et al. summarized the results from four randomized trials (n = 516 patients) comparing SHSs to cancellous screws for fixation of displaced femoral neck fractures (level I).[8] They found no statistically significant difference in revision surgery using SHSs compared to cancellous screws (relative risk ratio [RRR] = 27%; 95% CI: 48 to −4). Similarly, a Cochrane review of internal fixation (using screws, pins and/or plates) in intracapsular hip fractures included 28 trials (n =

5547) (level I).[10] The authors concluded that due to the variability in study designs, outcomes, lack of methodological rigor, and small sample sizes no definitive statements could be made to support the use of certain types or methods of fixation over others. Pooled results from five trials (n = 565 patients) comparing SHS to cancellous screws showed that point estimates for AVN favor SHSs (RR = 0.62; 95% CI: 0.38–1.01). An international, multicenter, RCT by Bhandari et al. suggested SHSs reduced re-operations in patients with displaced fractures compared to cancellous screw fixation (re-operation 43/179 with SHS vs 57/167 with cancellous screws; hazard ratio [HR] = 0.57; 95% CI: 0.38–0.87) (level I).[9]

Overall, current studies comparing different implants for fixation of femoral neck fractures lack methodological rigor. While several studies did find significant results for certain outcomes, these results are questionable due to the multiple analyses performed. SHSs may reduce re-operations in patients with displaced fractures (level I).[8,10] SHSs have a tendency toward increased rates of AVN compared to cancellous screws (level I).[9]

Resolution of clinical scenario

- Current studies comparing different implants for fixation of femoral neck fractures lack methodological rigor. SHSs *may* reduce re-operations in patients with displaced fractures.
- Level I evidence suggests SHSs have a tendency toward *increased* rates of AVN compared to cancellous screws.

Question 3: In patients over the age of 65 undergoing arthroplasty for a displaced femoral neck fracture, does use of total hip arthroplasty (THA) result in decreased complications and improved outcomes compared to hemiarthroplasty?

Rationale

In making operative decisions about arthroplasty, it is important, for example, to know whether bipolar compared to unipolar hemiarthroplasty does in fact decrease acetabular wear and improve function. Also, what patient and implant risk factors should be considered when choosing between hemiarthroplasty and THA?

Clinical comment

Once arthroplasty has been chosen, it is important to select the technique that is most appropriate for the patient's age and functional status. Pre-existing hip pain and radiographic evidence of osteoarthritis has been an indication for THA. Determining the activity threshold when deciding between THA and hemiarthroplasty is nuanced, with the goal to avoid a second procedure in the future. THA is generally considered a better option for patients who are active and capable of following postoperative instructions. Hemiarthroplasty is more optimal for patients with limited demands or cognitive impairment due to the lower risk of hip dislocation compared with THA.

Available literature and quality of the evidence

Multiple systematic reviews are available to answer questions about arthroplasty in femoral neck fracture treatment. The most relevant current literature consisted of: (i) a Cochrane review of the literature (level I), (ii) another Cochrane review of current studies (level I), (iii) a meta-analysis of published RCTs (level I evidence), and (iv) a recently published large RCT (level I).

Findings

A Cochrane review of 19 trials (n = 2115) of arthroplasties in hip fractures provided the highest level of evidence (level I).[11] Two trials (n = 232 patients) compared uncemented hemiarthroplasty to THA. They found no difference in dislocation, re-operation, or failure to regain mobility. Additionally, one trial (n = 180 patients) found no difference in early mortality (3–4 months) or late mortality (one year). One trial (n = 135) did find a significant increase in postoperative residual pain following hemiarthroplasty compared to THA (RR = 34.91; 95% CI: 2.15–565.58). This trial compared the Austin Moore hemiarthroplasty to THA. A study by Ravikumar et al. (level I) also reported high rates of pain in patients with the Moore implant (27% at 1 year; 45% at 13 years) compared to hemiarthroplasty (0% at 1 year; 6% at 13 years).[12] The Austin Moore prosthesis was introduced in the 1950s as a monoblock cementless option for femoral neck fractures. With a lack of modularity as well as neither a fit and fill or wedge taper, the implant has had poor long-term results with thigh pain and loosening frequently reported. Cemented hemiarthroplasty was compared to THA in four trials (n = 415 patients).[11] They found significantly reduced rates of dislocation and minor re-operation associated with hemiarthroplasty compared to THA. A second Cochrane review of seven trials (n = 734) compared hemiarthroplasty to THA (level I).[13] They found similarly that

hemiarthroplasty was associated with lower risk of dislocation and minor re-operation compared to THA. Another meta-analysis from 2014 by Liu et al. summarized nine trials (n = 1100 patients) comparing unipolar and bipolar hemiarthroplasty (level I).[14] They found no difference in risk of complications, acetabular erosion, return to function, or mortality. Six clinical trials (n = 549 patients) compared cemented to uncemented arthroplasty in adults with hip fractures. The results revealed decreased risk of pain (RR = 0.51; 95% CI: 0.31–0.81) and failure to regain mobility (RR = 0.60; 95% CI: 0.44–0.82, respectively) in the cemented group. The Hip Fracture Evaluation with Alternatives of Total Hip Arthroplasty versus Hemi-arthroplasty (HEALTH) trial randomized 1495 patients to THA or HA and followed them for two years. They found no significant difference in the primary outcome of revision surgery (HR: 0.95; 95% CI: 0.64–1.40, p = 0.79). Patients in the THA group had significantly better function scores as measured on the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), though the difference was modest (mean difference = −6.37; 99% CI: −9.18 to −3.56).[15]

Overall, there is a lack of evidence of a difference in many outcomes between cemented or uncemented hemiarthroplasty and THA (level I).[11] There is, however, level I evidence that, when cemented and uncemented hemiarthroplasty is compared, cemented hemiarthroplasty is associated with a significantly lower risk of pain at one year post surgery and a significantly greater risk of failure to regain mobility (level I).[14] Additionally, there is no difference in outcome associated with unipolar versus bipolar hemiarthroplasty implants (level I).[14] The risk of dislocation and minor re-operation is higher in THA compared to hemiarthroplasty (level I).[11,13]

Resolution of clinical scenario

- Level I evidence demonstrates *increased risk* in dislocation and minor re-operation rates for THA versus hemiarthroplasty.
- Level I evidence demonstrates *no difference* between uncemented hemiarthroplasty compared to THA for any other outcome.
- Level I evidence demonstrates patients with the Moore implant were *significantly more* at risk for residual pain compared to those with THA.
- Level I evidence demonstrates patients with uncemented hemiarthroplasty were at *significantly increased* risk of residual pain and failure to regain mobility compared to cemented hemiarthroplasty.
- Level I evidence demonstrates there is *no difference* in the risk of complications, acetabular erosion, return to function, or mortality between unipolar and bipolar hemiarthroplasty in femoral neck fractures.

Summary of answers

- Arthroplasty does significantly reduce the risk of revision surgery at one year compared to internal fixation.
- Arthroplasty does not result in significantly different risk of mortality at one year compared to internal fixation.
- Arthroplasty does significantly increase the risk of infection, blood loss, and operative time at one year compared to internal fixation.

- Current studies comparing different implants for fixation of femoral neck fractures lack methodological rigor. SHSs may reduce re-operations in patients with displaced fractures.
- SHSs have a tendency toward increased rates of AVN compared to cancellous screws.
- THA is associated with an increased risk of residual pain at one year and minor re-operation compared to hemiarthroplasty.
- There is no difference between uncemented hemiarthroplasty compared to THA for any other outcome.
- Patients with the Moore implant were significantly more at risk for residual pain compared to those with THA.
- Patients with uncemented hemiarthroplasty were at significantly increased risk of residual pain and failure to regain mobility compared to cemented hemiarthroplasty.
- There is no difference in the risk of complications, acetabular erosion, return to function, or mortality between unipolar and bipolar hemiarthroplasty in femoral neck fractures.

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Extracapsular Hip Fractures

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Clinical scenario

- A 76-year-old community ambulatory female has a mechanical fall and sustains a right intertrochanteric hip fracture.
- The patient arrives at your Emergency Department that evening after a friend found her at home, complaining of right hip pain and unable to ambulate.

Top three questions

1. In patients with extracapsular hip fractures undergoing fixation, does a cephalomedullary nail (CMN) result in a lower rate of re-operation when compared with sliding hip screw (SHS) and stratified by fracture pattern?
2. In patients with extracapsular hip fractures, do comprehensive *orthogeriatric* co-management programs, compared to usual care, improve outcomes after hip fracture surgical fixation?

3. In patients with failed fixation of an extracapsular hip fractures, does revision fixation compared to arthroplasty lead to better long-term function?

Question 1: In patients with extracapsular hip fractures undergoing fixation, does a cephalomedullary nail (CMN) result in a lower rate of re-operation when compared with sliding hip screw (SHS) and stratified by fracture pattern?

Rationale

There are numerous implant options available and a growing trend toward the use of CMNs.[1] Implant options can be roughly separated into extramedullary implants (of which the SHS is the most common) and intramedullary implants (of which a CMN is the most common). Choosing the most appropriate implant for a specific patient allows the surgeon to optimize the patient's outcome while controlling cost.

Clinical comment

Many hip fracture failures stem from an inappropriate implant utilization, which leads to failure, typically represented by cutout, varus collapse, or medialization of the femoral shaft.

Available literature and quality of the evidence

Numerous prospective, randomized controlled trials (RCTs) have evaluated implants for treatment of extracapsular hip fractures. We focused on those carried out after the year 2000 to focus on current implant design.

Cephalomedullary nail versus sliding hip screw

- Level I data: 10 modern implant design prospective randomized clinical trials and 2 systematic reviews/meta-analyses.

Findings

Early studies suggested an increased rate of complications, specifically periprosthetic fractures, in hip fractures treated with a short CMN.[2,3] However, after design modifications were made to these devices, Bhandari et al. conducted a meta-analysis in 2009 to re-evaluate this.[4] They found in early studies (conducted before 2000) that short nails had an increased relative risk of fracture of 4.5 (95% confidence interval [CI]: 1.78–11.36), but that in studies performed after 2000 the relative risk (RR) was not significantly increased (RR = 1.65; 95% CI: 0.50–5.44, p = 0.41). They advise that early studies comparing nails to SHSs for the treatment of extracapsular hip fractures should be interpreted with caution as they may not be applicable to current technology.

Small differences or trends in secondary outcomes such as blood loss, operating room time, early mobilization, or pain have varied in significance depending on the study evaluated. However, our main outcome of interest (implant failure necessitating re-operation) has repeatedly been shown to be equivalent in most fracture patterns. Harrington compared a hip screw (n = 52) to an intramedullary device (n = 50) for unstable intertrochanteric hip fractures and found no difference in

the rate of re-operation relative to implant used.[5] They noted in all cases of cut-out the tip–apex distance was greater than 25 mm, suggesting surgical technique was more important than implant choice. Little compared a long, statically locked CMN (n = 92) to an SHS (n = 98) in a prospective randomized trial of AO/OTA type 31A fractures excluding only those with subtrochanteric extension. They found no difference in the rate of union, implant failure, or re-operation.[6] A Cochrane review of 43 trials performed in 2010 evaluated intramedullary versus extramedullary implants for extracapsular hip fractures. They found no compelling data to suggest intramedullary fixation provided better outcomes than the SHS, and instead found it may increase complications.[7]

Since this review, several RCTs have found no difference in revision or re-operation rates between CMN and SHS.[8–12]

A common belief is that fractures with subtrochanteric extension, reverse obliquity, an incompetent lateral wall, or incompetent calcar (the AO/OTA 31A3 fractures) benefit from intramedullary fixation. Sadowski et al. compared intramedullary versus extramedullary fixation in the treatment of AO/OTA 31A3 injuries.[13] Thirty-nine patients were randomized to CMN (n = 20) or a 95° fixed angle extramedullary device (n = 19). There were six implant failures and one nonunion in the 19 patients treated with the extramedullary device versus zero implant failures and one nonunion in the CMN group at one year (p = 0.007). Kuzyk et al. performed a meta-analysis of studies looking at subtrochanteric or intertrochanteric fractures with subtrochanteric extension.[14] They identified three level I studies and nine level IV studies. A pooled analysis of fixation failure in the level I studies trended toward a decreased risk of failure with intramedullary fixation (RR = 0.287; 95% CI: 0.062–1.327). Matre et al. reviewed the

Norwegian registry data of 2716 patients with AO/OTA 31–A3 or subtrochanteric fractures treated with an SHS (n = 1792) or an intramedullary nail (IMN) (n = 924).[15] At one year, the rate of re-operation was increased in the SHS (6.4%) than nail group (3.8%). A Cox regression analysis found the use of an SHS carried an RR of 1.43 for re-operation (95% CI: 1.01–2.03). Finally, in 2015, the American Academy of Orthopaedic Surgeons released evidence based clinical practice guidelines on the management of hip fractures in the elderly.[16] In their final report, they used three high and two moderate strength studies to conclude that there is strong evidence to support the use of a cephalomedullary device in the use of subtrochanteric and reverse obliquity intertrochanteric hip fractures.

Swart et al. used these data to ask whether cost-effective decision-making could guide implant choices based on fracture pattern. They used an expected-value decision-analysis model to compare SHS versus nail for the treatment of AO/OTA 31 injuries. Their model was sensitive to the failure rate and implant cost. For A1 fractures, the SHS and for A3 fractures the nail always provided more value.[17] For A2 injuries, there was discrepancy, depending on the fixation failure rate used, but under most conditions, the SHS was favored.

Lastly, Palm et al. reported an impressive series of data looking at 1000 geriatric hip fractures before and after the implementation of a defined treatment algorithm. Implant choice was dictated by fracture pattern with AO/OTA 31A1 and 31A2.1 injuries treated with an SHS and 31A2.2, 31A2.3, and 31A3 injuries treated with a short CMN. Total re-operation rate for extracapsular fractures was reduced from 13 to 7% (p = 0.002) with most of that decrease

coming from the unstable intertrochanteric fracture group (17% vs 8%, p <0.001).[18]

Resolution of clinical scenario

- In the absence of extenuating circumstances, AO/OTA 31A1 injuries should be treated with an SHS, and 31A3 injuries with an intramedullary device.
- For most 31A2 injuries, an SHS is the optimal implant, but certain patterns may benefit from intramedullary fixation, including severe posteromedial comminution.

Question 2: In patients with extracapsular hip fractures, do comprehensive orthogeriatric co-management programs, compared to usual care, improve outcomes after hip fracture surgical fixation?

Rationale

Geriatric hip fractures have a significant impact on patient morbidity and mortality. Coordinated care between orthopedic surgeons, geriatricians, endocrinologists, physical and occupational therapists, dieticians, and social workers may improve a variety of outcomes for older patients who suffer a hip fracture.

Clinical comment

Often, the decision to operate is the least complex aspect of managing a geriatric hip fracture patient. Optimizing a patient's medical and nutritional status, early mobilization, and appropriate transition to the next level of care may

play as large a role as surgical care in improving outcomes for these patients.

Available literature and quality of the evidence

- Level I: 3 systematic review/meta-analyses and 2 RCTs.
- Level II: 1 population-based longitudinal study.

Findings

A Cochrane review of five studies (n = 316) comparing enhanced rehabilitation care models (including orthogeriatric co-management teams) to usual care found a lower frequency of some complications (urinary tract infections, nutritional problems, postoperative delirium, recurrent falls), reduced length of stay, decreased risk of institutional placement at three months, better activities of daily living (ADLs) function, and higher probability of regaining preinjury walking capability. They found no differences in cognitive deterioration or mortality,[19] but admittedly was limited by inadequate reporting and low sample size. A second Cochrane review of 13 trials (n = 2498) comparing multidisciplinary rehabilitation models in geriatric hip fractures to usual care showed no difference in mortality at the end of follow-up.[20] Return to functional status, length of hospital stay, and costs varied between the studies.

Prestmo et al. reported a single-center RCT (n = 397) of patients 70 years or older able to walk 10 m before their fracture assigned to either comprehensive geriatric care or orthopedic care (usual care).[21] Those with comprehensive geriatric care demonstrated improved mobility at four months after surgery. Watne et al. randomized patients

(n = 329) to treatment in an acute geriatric ward or a standard orthopedic ward.[22] They found no significant difference in cognitive function or delirium rates four months after surgery.

A multicenter retrospective population-based longitudinal study (n = 33 152) demonstrated that introducing an orthogeriatrician decreased 30-day (hazard ratio [HR] = 0.73; 95% CI: 0.65–0.82) and one-year mortality (HR = 0.81; 95% CI: 0.75–0.87). Introduction of a nurse-led fracture liaison service had similar reduction on 30-day (HR = 0.80; 95% CI: 0.71–0.91) and one-year mortality (HR = 0.84; 95% CI: 0.77–0.93).[23] Grigoryan et al. conducted a meta-analysis of 18 studies (n = 9094 patients) and found a significant reduction in in-hospital mortality (RR = 0.60; 95% CI: 0.43–0.84) and long-term mortality (RR = 0.83; 95% CI: 0.74–0.94) with geriatric intervention during hospitalization for hip fractures.[24] A shared-care model also demonstrated a reduction in length of stay and time to surgery.

Resolution of clinical scenario

- Comprehensive care models, which include medical co-management, liaison services, and discharged planning, should be utilized in caring for geriatric hip fracture patients.
- Benefits appear to include improved functional status and decreased postoperative complications and may lead to decreases in mortality rates and length of hospital stay.

Question 3: In patients with failed fixation of an extracapsular hip fractures, does revision fixation compared to arthroplasty lead to better long-term function?

Rationale

Despite best efforts, some fixation failures of extracapsular hip fractures will result in patients who will need further surgical management.

Clinical comment

Deciding whether to attempt revision fixation or arthroplasty is a complex choice that often hinges on patient characteristics, remaining bone stock, and method of failure.

Available literature and quality of the evidence

- Numerous level III case series and retrospective reviews, 6 of which are reviewed below.
- No high-level data that directly compare attempted salvage to arthroplasty in similar patient populations.

Findings

Haidukewych et al. reported a case series of 20 failed intertrochanteric hip fractures treated with revision open reduction and internal fixation (ORIF) and bone grafting. Nineteen of the 20 patients ultimately went on to union and were ambulatory, demonstrating that success can be obtained with salvage procedures.[25] Haidukewych et al. also reviewed patients who underwent arthroplasty for

failed intertrochanteric fractures. Of the 44 patients available for follow-up, 39 had no or mild pain with ambulation and the implant survivorship at 10 years was 87.5% (95% CI: 67.3–100%).[26]

Yuan et al. reviewed 111 patients converted to arthroplasty after previous failed intertrochanteric fracture treated with an extramedullary device (n = 70) or an intramedullary device (n = 41). They found overall implant survivorship and function to be similar between groups. Complications were similar with the exception of increased intraoperative femoral fractures in the intramedullary group (12% vs 1%, p = 0.02).[27] Pui et al. looked at complications from conversion total hip arthroplasty (THA) following failed intertrochanteric hip fracture fixation. In a multicenter, retrospective review, they evaluated 91 conversion THA hips from a failed CMN (n = 31) or SHS (n = 60). Their primary outcome was Harris Hip Score, which showed no difference. The overall perioperative complication rate in CMN conversion was significantly higher (41.9% vs 11.7%, p = 0.001) as was the orthopedic complication rate (29.0% vs 8.3%, p = 0.014).[28] However, Zeng et al. reviewed patients who underwent conversion THA from either failed SHS (n = 70) or CMN (n = 72) and found contradictory results. They found a higher rate of complications in those converted from SHS (42.9% vs 20.8%, p = 0.003), specifically for periprosthetic fracture (15.7% vs 4.2%, p = 0.021).[29]

Said et al. reviewed 26 patients with failed SHS fixation of intertrochanteric hip fractures.[30] Eighteen patients underwent revision fixation and eight underwent arthroplasty (for irreparable femoral head and/or acetabular damage). All patients in the revision fixation group eventually achieved union at an average of 17 weeks, with one patient having avascular necrosis. Six of the eight

patients who underwent arthroplasty had good outcomes with pain-free gait.

Resolution of clinical scenario

- Revision fixation and arthroplasty are both options in the case of a failed original ORIF for a hip fracture.
- There is mixed evidence as to whether conversions from a failed CMN or SHS are at higher risk of failure.

Summary of answers

- Appropriate implant choice based on fracture pattern can reduce the rate of failure and help reduce cost.
- Multidisciplinary care models improve a variety of outcomes in geriatric hip fracture patients.
- Both revision fixation and conversion arthroplasty can produce good results. Surgeons should be aware of the risk of intra-operative fracture with respect to revision of CMNs.

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98
Subtrochanteric Femur Fractures

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Clinical scenario

- A 45-year-old obese patient who is otherwise well presents to the Emergency Department after a motor vehicle accident.
- X-rays show a proximal femur fracture (Figure 98.1a and b). There is significant abduction, external rotation, and flexion deformity of the proximal fragment in relation to the distal fragment. The AO/OTA classification is a 31A3.1.

Top three questions

1. In patients with subtrochanteric femur fractures treated with an intramedullary nail (IMN), does a trochanteric start point provide superior outcomes to a piriformis fossa start point?
2. In patients with subtrochanteric femur fractures treated with an IMN, does a nonanatomic reduction result in higher failure rates and higher mal/nonunion rates than anatomic reduction?

3. In patients with subtrochanteric femur fractures treated with an IMN, does open reduction lead to increased complication rates (i.e. infection, nonunion) when compared to closed reduction and intramedullary nailing?

Question 1: In patients with subtrochanteric femur fractures treated with an intramedullary nail (IMN), does a trochanteric start point provide superior outcomes to a piriformis fossa start point?

Rationale

When performing intramedullary nailing of subtrochanteric fractures, there has been debate over different aspects of the surgical technique including the starting point.

Clinical comment

The insertion site for anterograde nailing of subtrochanteric femur fractures can be located in the piriformis fossa or the tip of the trochanter. It should be noted that the term *piriformis fossa* is actually a misnomer and anatomically incorrect, although this has been propagated as the start point for femoral nailing in the literature for decades.[1,2] The correct name is the *trochanteric fossa*, but to keep the nomenclature consistent with North American literature we have chosen to keep with the term *piriformis fossa*.

A piriformis fossa starting point offers colinear access to the shaft for reaming and nail insertion of a straight nail and possible decreased risk of varus malalignment.

Fracture reduction is important when dealing with a subtrochanteric femur fracture; however, this insertion site may involve more soft tissue compromise than a start point at the tip of the trochanter.[3,4] A start point at the tip of the trochanter may be technically easier to obtain; however, anatomic variability in the start point and varying proximal nail geometry may add complexity when choosing this start point. One study observed that the tip was ideal as a start point in only a minority of cases, and recommended preoperative templating of the contralateral intact femur to identify the appropriate start point to prevent malreduction of the fracture.[5,6]

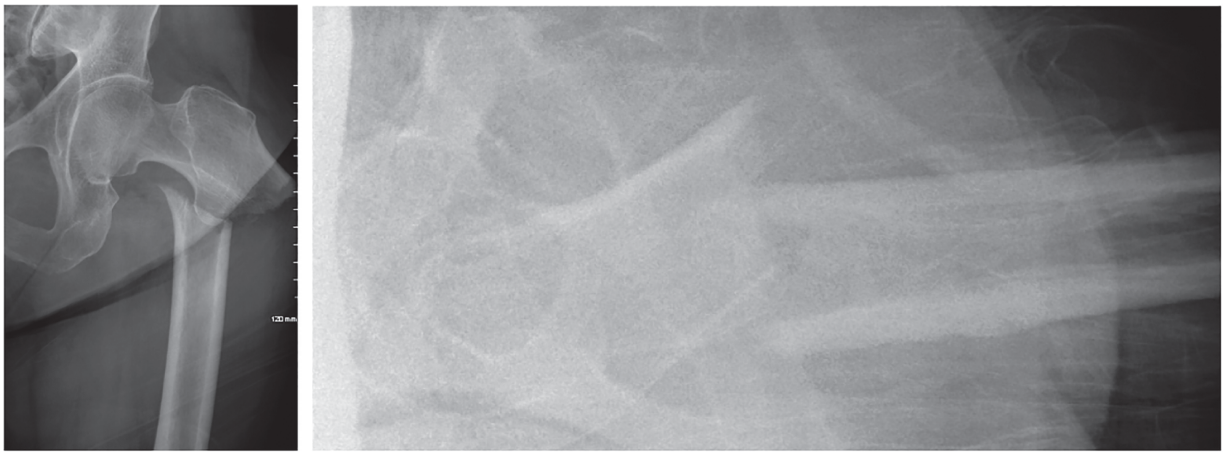

Figure 98.1 AP and lateral x-ray of a proximal femur fracture. This is an OTA 31A3.1 type femur fracture with typical noted deformity.

Available literature and quality of the evidence

There is one prospective randomized trial (level I), one prospective cohort study (level II), and one retrospective cohort study (level III) that specifically addresses this question.

Findings

The only randomized study to date included 34 patients who were randomized to one of two implants that had a piriformis start or a trochanteric start respectively (level I).[7] This study was powered to detect a significant difference (200 mL) in blood loss and there was no difference between the two groups in this regard. With respect to varus malalignment, this study showed 2 of 17 patients in the piriformis fossa group and 4 of 17 patients in the trochanteric group had varus malalignment on follow-up x-rays. This was not statistically significant; however, this study was underpowered for this outcome. Several other outcomes were compared, including duration of surgery, union rate, complication rate, and functional outcomes, and there were no differences between the two groups for these outcomes in this small patient sample.

The other prospective study was a multicenter cohort study that included 108 patients treated with a single implant that differed only in proximal lateral bend which was used either through a piriformis or trochanteric entry.[8] This study showed that piriformis entry nails had a mean 12-minute longer operative time – 75 minutes (range 31–131) versus 62 min (range 14–193), ($p = 0.08$) – and a 61% increase in fluoroscopic time – 153 seconds (range 16–662) versus 95 seconds (range 20–375). These differences were amplified in obese patients where operative time was 30% longer and fluoroscopy time was 73% higher. There were no varus malreductions in either group and only one patient in each group needed further intervention (exchange nailing) for nonunion. Functional outcomes were recorded using the lower-extremity measure which showed no difference between the groups at any time point (4, 6, and 12 months). It should be noted that the authors used a modified greater trochanteric (GT) start point (either slightly medial or lateral to the tip of the GT) that was individualized for each patient, taking into account the

anatomy of the patient's proximal femur as well as the geometry of the nail. This idea of a variable trochanteric start point is supported in other anatomic and radiographic studies, and it is accepted that a correct trochanteric entry point is slightly medial to the tip of the greater trochanter in the anteroposterior (AP) view and slightly posterior in line with the shaft on the lateral view (due to the anterior offset of the GT).[5,6,9,10]

There is one retrospective cohort study that compared the two starting points with respect to nerve and muscle function postoperatively with outcomes out to a mean of 22 months.[11] This study included only 17 patients (9 in the piriformis group and 8 in the trochanteric entry group). They looked at whether the patients had a Trendelenburg gait, electromyographic (EMG) changes in their hip musculature, differences in their Harris Hip Score and Visual Analog Scale (VAS), magnetic resonance imaging (MRI) changes of the soft tissues, and differences in muscular endurance around the hip. Overall, five patients in the piriformis group had a Trendelenburg gait and four had EMG evidence of injury to the superior gluteal nerve which had since recovered. The piriformis group had decreased endurance on the isokinetic testing of the hip range of motion; however, the clinical relevance is unknown. Overall, this was a very small retrospective study with fragile results and the clinical relevance is questionable, although it does fuel the need for larger studies.

Resolution of clinical scenario

- Both start points can be used and varus malalignment is relatively uncommon with either start point. Anatomical differences may require modification of the

GT start point from the radiographic tip to a position slightly medial and posterior.

- With modern intramedullary implants, there is no conclusive evidence that one start point leads to a better outcome with respect to blood loss, fracture healing, and complication rates when variations in proximal femoral anatomy and nail geometry are accounted for.
- Trochanteric start nailing may decrease operative and fluoroscopy time, especially in obese patients.
- There is very weak evidence that a piriformis entry point, when compared to a GT entry, causes some weakness (neuromuscular and tendon injury) around the hip but the clinical relevance of this has not been definitively shown.
- In this obese patient, a trochanteric start nail, with a slightly medial and posterior starting point, may be ideal.

Question 2: In patients with subtrochanteric femur fractures treated with an IMN, does a nonanatomic reduction result in higher failure rates and higher mal/nonunion rates than anatomic reduction?

Rationale

Because of the difficulty of treating this fracture and the relatively high failure rate of fixation in early studies, there

has been focus on trying to improve these results with emphasis on the importance of fracture reduction.

Clinical comment

In 2018, intramedullary nailing is the preferred method of treatment for subtrochanteric femur fractures. Many plating options exist and are useful for fractures that extend into the nail insertion site or femoral neck; however, proximal femoral locking plates have been shown to have high failure rates and blade plates are technically demanding, especially in an already challenging fracture pattern.[12,13] When consideration is given for nailing these fractures, the short proximal segment, capacious size of the metaphyseal component, and the multidirectional deforming forces create a perfect environment for a less-than-ideal reduction. But does an anatomic reduction matter when you are aiming for relative stability and secondary bone healing with an intramedullary implant? So, the question remains, does a nonanatomic reduction result in higher failure rates when compared with an anatomic reduction for subtrochanteric fractures treated with an IMN?

Available literature and quality of the evidence

There are two retrospective studies (level III) that specifically address reduction quality in intramedullary fixation of subtrochanteric femur fractures.

Findings

Shukla et al. performed a retrospective review that included 60 patients treated with a cephalomedullary nail.[14] They examined the effect of coronal plane (varus/valgus) reduction on union and complication rates. They found that 19 out of 60 fractures were malreduced in

varus (>10° as compared to the contralateral femur). Of these, 74% (n = 14) had a complication of malunion (n = 9), nonunion (n = 3), or hardware failure (n = 2). This was in contrast to the anatomically reduced group which only had one complication (a varus malunion) in 41 cases.

Riehl et al. performed a retrospective cohort study of 35 patients who were treated with an IMN for a subtrochanteric femur fracture and compared those nailed with a malreduction and those without.[15] Their main outcome measure was fracture healing. They found 7 of 35 fractures had a malreduction, either varus >10° (n = 2), flexion (n = 4), or both (n = 1). Of the fractures with a malreduction, all developed a delayed union (n = 6) or nonunion (n = 1). The presence of a malreduction greater than or equal to 10° in any plane significantly increased the rate of delayed or nonunion (p = 0.0005).

Resolution of clinical scenario

Malreduction (especially varus malreduction) of subtrochanteric fractures increases implant failure rates, increases malunion rates, and increases nonunion rates.

Question 3: In patients with subtrochanteric femur fractures treated with an IMN, does open reduction lead to increased complication rates (i.e. infection, nonunion) when compared to closed reduction and intramedullary nailing?

Rationale

In subtrochanteric femur fractures, the personality of the fracture is determined by the deforming forces of muscular action on the proximal and distal fragments (Figure 98.2) and closed reduction is often unable to achieve a satisfactory reduction. An open reduction would be needed to obtain a more accurate reduction.

Clinical comment

Malreduction is associated with higher delayed and nonunion rates as well as hardware failure (see Question 2). Open reduction can improve the reduction to acceptable parameters; however, it has been suggested that open reduction techniques (clamping, provisional plating [PP], cerclage wires/cables) may be associated with increased infection rates as well as increased nonunion rates secondary to soft tissue stripping.

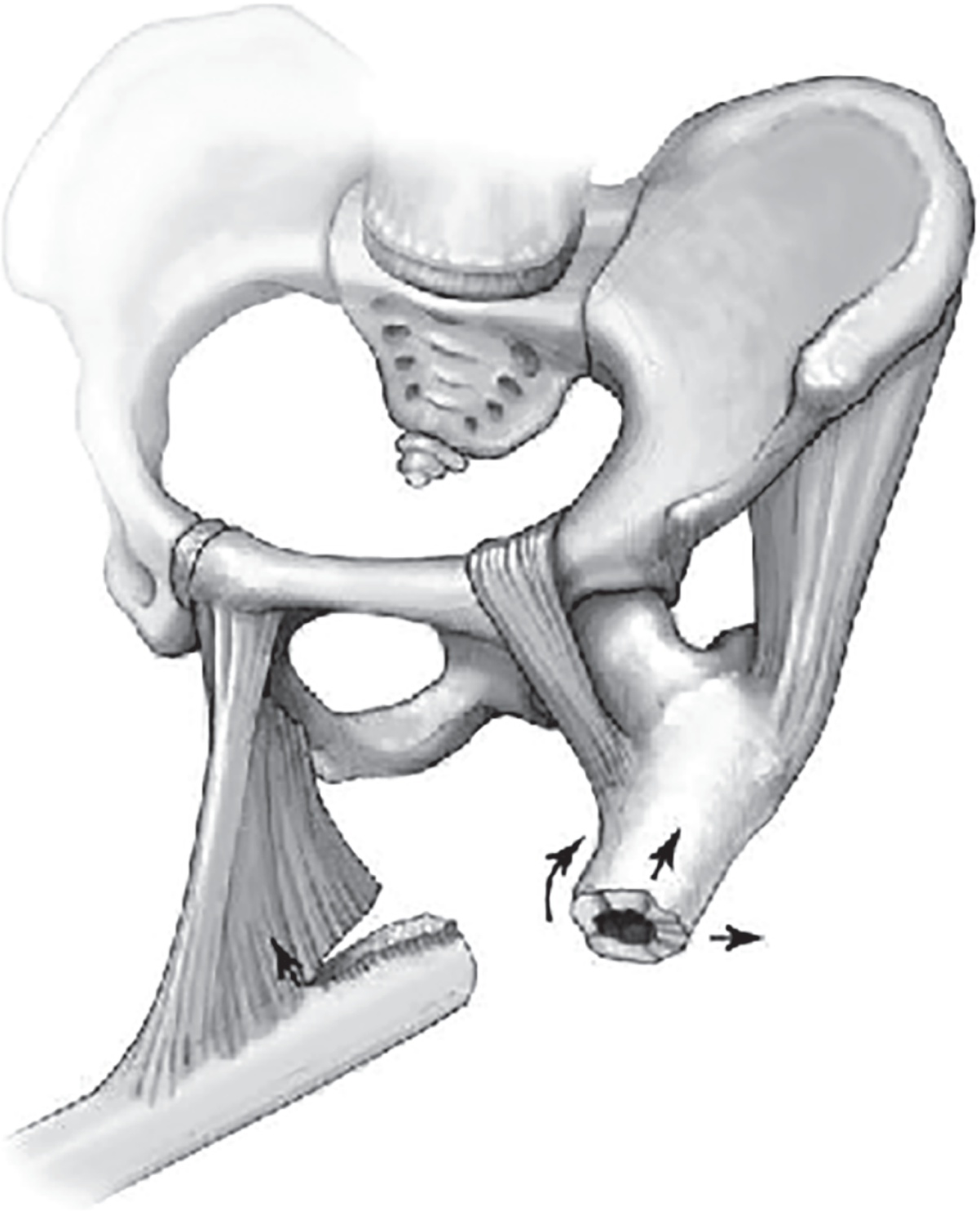

Figure 98.2 Schematic diagram of the muscular forces that deform a typical subtrochanteric femur fracture.

Available literature and quality of the evidence

There have been several recent studies examining open reduction techniques of subtrochanteric femur fractures including three retrospective cohort studies (level III) and four case series (level IV).

Open reduction

Three studies looked at open reduction and nailing with the highest-quality study (level III) from Beingessner et al.[16] This was a retrospective cohort study including 56 patients who underwent open reduction and intramedullary fixation compared to 40 that underwent closed reduction and intramedullary (IM) fixation. There were no nonunions or infections in the open group, whereas the closed group had one nonunion and one early fixation failure. There was no difference in time to union.

A retrospective case series by Afsari et al. of 44 patients treated with clamp-assisted nailing (either clamp reduction of oblique or spiral fractures or simply clamp control of the proximal segment fractures not amenable to clamp reduction).[17] Nonunion was only reported in 1/44 cases (2.3%) and there were no reported infections or wound complications.

Another retrospective series, by Mingo-Robinet et al., looked at open reduction of 26 geriatric subtrochanteric fractures and had no cases of nonunion and one case of deep infection.[18]

Open reduction and cerclage wire

Cerclage wiring was once considered orthopedic trauma heresy due to periosteal stripping and strangulation of bony vascularity; however, it is gaining momentum as an adjunct to intramedullary nailing of subtrochanteric fractures. There are three recent studies that support the use of open reduction and cerclage wiring. Hoskins et al.

provided a retrospective cohort study of 134 cases of which 20 were treated with cerclage wire.[19] Of these, there were no major complications (nonunion, loss or failure of fixation, or cutout). If a cerclage wire was not used there was a major complication rate of 11.4%. This study did not look at infection. Another retrospective cohort study examined the use of cerclage wiring and nailing compared with closed nailing in a geriatric cohort of 90 patients and found that there was a significantly superior reduction in the cerclage group (n = 30). There were no differences in the complication profile between the two groups and the cerclage group had a significantly shorter time to union (4.4 months vs 6.9 months p <0.001).[20]

Open reduction and provisional plating

One retrospective cohort study examined their series of 22 cases of open reduction and PP in the lateral position compared with 48 cases of closed reduction.[21] There were no malunions in the PP group; however, there was a 27.7% rate of malreduction (defined as >5° of angulation on postoperative radiographs) in the closed nailing group. There was no difference in time to union and there was only one case of nonunion in each group. However, there was increased blood loss (392 vs 293 mL, p = 0.007) and operative time (128 vs 105 min) in the PP group.

Resolution of clinical scenario

In patients with displaced subtrochanteric fractures where closed manipulation does not achieve a satisfactory reduction, evidence suggests open reduction and the use of reduction adjuncts such as clamps, wires, or provisional plates:

- Reduces the risk of malunion.

- Does not increase the risk of nonunion.
- Does not increase the risk of infection.

Summary of answers

- When treating subtrochanteric femur fractures with an IMN, reduction of the fracture prior to nail insertion and a proper start point are essential.
- There is no difference between a piriformis and trochanteric start point implant; however, when choosing a trochanteric start point the surgeon must pay close attention to the start point as this commonly *does not* correspond to the tip of the trochanter and is usually slightly medial and posterior.
- Malreduction (especially varus malreduction) of subtrochanteric fractures increases implant failure rates, increases malunion rates, and increases nonunion rates. One should strive for anatomic reduction, and if an open reduction is necessary, be reassured that, with respectful soft tissue principles, infection and nonunion rates are not increased.

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99
Femoral Shaft Fractures

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Clinical scenario

- A 30-year-old male victim of a road traffic accident (RTA) is admitted to the Emergency Department.
- He is suffering from bilateral femur fractures, one of them being Gustilo II open, minor contusion of the right lung, and his Glasgow Coma Scale is 14/15.
- He is cleared of any other injuries of his abdomen and pelvis.
- Femoral shaft fractures frequently occur within the context of polytrauma and might result in considerable morbidity and mortality.
- Bilateral as well as open femur fractures constitute high energy injuries and have been associated with higher mortality and morbidity rates as compared to unilateral femur fractures.
- The optimal timing and type of definitive treatment of femoral shaft fractures in the above scenario are still controversial.

Top three questions

1. In polytrauma patients with femoral shaft fractures, does early definitive fixation of the femoral fracture result in lesser systematic complications and decreased mortality compared to the damage control orthopedics (DCO) approach?
2. Does early, simultaneous intramedullary nailing (IMN) of bilateral femur fractures predispose the patient to increased complication rates compared to the DCO approach?
3. In open femur fractures, does early IMN result in increased complication rates compared to delayed IMN?

Question 1: In polytrauma patients with femoral shaft fractures, does early definitive fixation of the femoral fracture result in lesser systematic complications and decreased mortality compared to the damage control orthopedics (DCO) approach?

Rationale

Multiply injured patients with concomitant femoral shaft fractures are at increased risk of systemic complications that could cause considerable morbidity and mortality.[1,2] These adverse outcomes could be attributed not only to the patient's related factors (such as age, co-morbidities, associated injuries, etc.) but also to the type of the initial therapeutic intervention.[3] There is a diversity of recommendations regarding the optimal treatment plan in this cohort of patients. Neither early total care (ETC), entailing early internal fixation of femur fractures, nor DCO, combining initial temporary stabilization of the femoral fractures by means of external fixation and secondary conversion of the ex-fix to definitive internal fixation, have emerged as the unequivocal treatment methods for all trauma patients.

Clinical comment

DCO combines the benefits of early fracture stabilization, allowing for ongoing patient resuscitation, with the minimal risks of complications.[4] However, some skepticism exists with the DCO practice for potential septic complications at the stage of conversion of the temporary external fixation to definitive IMN.[5,6] On the other hand, early definitive fixation of femoral fractures leads to decreased rates of pulmonary complications (adult respiratory distress syndrome [ARDS], fat embolism, pulmonary embolism, and pneumonia), shorter duration of ventilation, decreased length of hospital stay (LOS), and overall lesser costs of treatment.[7] Emphasis has also been given on the detrimental effect of early fixation in the presence of subclinical tissue hypoperfusion as this might increase systemic complications.[8–10]

Table 99.1 Results by outcome of interest. Source: Modified from El-Menyar et al.[11]

Outcome	n-studies (refs)	n-pts Early IMN	n-pts Delayed IMN	Odds ratio (95% CI)	p	I^2	Favors
ARDS	10	2133	791	0.39 (0.26, 0.57)	p <0.0001	0%	Early IMN
FE	4	1150	420	0.65 (0.26,1.62)	0.35	0%	ns
Pneumonia	5	1468	399	0.71 (0.21, 2.39)	0.58	0%	ns
PE	2	1440	428	0.39 (0.21, 0.71)	0.002	11%	Early IMN
MOF	2	502	155	0.34 (0.03, 3.95)	0.39	90%	ns
Mortality	11	6370	2230	0.46 (0.26, 0.82)	0.008	51%	Early IMN

ARDS: Adult Respiratory Distress Syndrome, CI: confidence interval, FE: fat embolism, PE: pulmonary embolism, MOF: multiple-organ failure.

Available literature and quality of the evidence

The most relevant current literature consisted of:

- Level III: 1 systematic review of the literature and meta-analysis.[11]
- Prognostic level II: 1 prognostic study (statistical modeling based on retrospective database.[12]

Findings

The systematic literature review and meta-analysis attempted to critically assess early versus delayed IMN of femur fractures in polytrauma patients.[12] It included relevant studies up to mid-2016. Based on eligibility criteria, the authors recruited 15 component studies (2 RCTs and 13 retrospective cohort studies). The distinction between early and delayed IMN across component studies was based on variable timeframes, but 24 hours was the most frequently used cutoff. The main results of the study, categorized per outcome of interest, are shown in Table 99.1.

The study documented significantly reduced odds of ARDS, pulmonary embolism, and mortality in the group of early IMN compared with delayed IMN (Table 99.1). As for fat embolism, pneumonia and MOF, no statistically significant difference between the two groups could be established. Based on the GRADE (Grading of Recommendations, Assessment, Development and Evaluations) system, the strength of evidence for every outcome of interest of this meta-analysis was low.

Finally, in the prognostic study mentioned above, a protocol termed *early appropriate care* (EAC) was developed aiming at quantifying the response of the multitrauma victim to the resuscitative measures for the management of metabolic acidosis.[12] A complex statistical model, incorporating univariate and multivariate analysis of variance, logistic predictive analysis and calculation of receiver operating characteristic (ROC) curves, was developed and showed that correction of metabolic acidosis within the first eight hours, as indicated by lactate levels <4.0 mmol/L, pH >7.25, or BE less than −5.5 mmol/L was associated with a reduced risk of pulmonary complications. Early (within 36 hours of injury) definitive fixation of unstable fractures in adequately resuscitated polytrauma patients reduces systematic complications, shortens LOS, and reduces costs of treatment. If metabolic acidosis persists despite resuscitative measures, a DCO approach is recommended.

Resolution of clinical scenario

- Early (within 24 hours from injury) definitive fixation of femur fractures in stable polytrauma patients reduces the risks of systematic complications and mortality.
- Optimal timing of definitive femoral fracture fixation in trauma patients should be balanced between patient physiologic condition and adequacy of resuscitation.
- A delay of definitive fracture treatment of up to 36 hours is justified in order to correct metabolic acidosis, due to occult tissue hypoperfusion.

Question 2: Does early, simultaneous intramedullary nailing (IMN) of bilateral femur fractures predispose the patient to increased complication rates compared to the DCO approach?

Rationale

Respiratory complications in the form of fat embolism, ARDS, pulmonary embolism, or pneumonia occur in approximately 2–3% of patients with isolated femur fractures and up to 10–75% of polytrauma patients with femur fractures, following IMN. Two independent risk factors for developing serious respiratory complications following IMN of the femur have been identified: thoracic injury and multiple IMN procedures in the same sitting.[13] Furthermore, a statistical predictive model was developed to predict the likelihood of respiratory failure (RF) in the presence of the above parameters. According to this model, only 2% of patients with femur fractures are likely to develop RF when both risk factors are absent, 33% will develop RF following multiple nailing procedures and in the absence of thoracic injury, whereas the likelihood of developing RF increases dramatically to 95% in the presence of both risk factors.[13]

Clinical comment

Simultaneous IMN of bilateral femoral fractures, particularly in trauma victims with concomitant thoracic injuries, could potentially predispose to systemic complications and increased mortality.

Available literature and quality of the evidence

The most relevant current literature included:

- Level IV: 4 retrospective comparative studies.[14–17]
- Level III: 1 longitudinal cohort study.[18]

Findings

All four retrospective studies[14–17] provided data of direct comparison between patient cohorts with bilateral and unilateral femoral fractures. We performed a pooled analysis of the following outcomes of interest: intensive care unit/high dependency unit (lCU/HDU) stay, LOS, ARDS, and mortality (Table 99.2).

Table 99.2 Results of pooled analysis.[14–17]

		Participants					
Outcome	**Studies**	**BFF**	**UFF**	**Statistical method**	**Effect estimate**	**Heterogeneity (I^2)**	**Favors**
ICU/HDU stay	3[15–17]	186	1505	Mean Difference (IV, Fixed, 95% CI)	3.30 (1.82–4.77)	0%	UFF
LOS	3[15–17]	186	1505	Mean Difference (IV, Fixed, 95% CI)	5.22 (2.30–8.13)	11%	UFF
ARDS	3[14,15,17]	171	1365	Odds Ratio (M-H, Random, 95% CI)	2.71 (1.39–5.29)	53%	UFF
Mortality	4[14–17]	271	2305	Odds Ratio (M-H, Fixed, 95% CI)	2.44 (1.71–3.49)	0%	UFF

BFF: bilateral femur fracture, UFF: unilateral femur fracture, IV: inverse variance, Fixed: fixed effects model, Random: random effects model, M-H: Mantel-Haenszel analysis method.

Table 99.3 Comparison of outcomes among DCO, ETC, and mixed approach for bilateral femur fractures.[18]

	DCO	ETC	Mixed	P (DCO vs ETC)
ISS, mean (SD)	31.1 (15.0)	23.5 (12.0)	19.9 (10.9)	<0.001
NISS, mean (SD)	37.5 (12.9)	31.2 (9.9)	42.5 (16.4)	<0.001
ICU stay, mean (SD), d	19.4 (25.6)	11.5 (9.9)	13.3 (15.1)	<0.001
Ventilation time, mean (SD), days	11.6 (15.6)	7.3 (9.4)	11.3 (14.9)	
OF (%)	55.3	39.6	37.5	0.02
MOF (%)	40.2	25.3	23.2	0.016
Sepsis (%)	21.6	12.0	13.5	0.081
Hospital mortality, n (%)	26 (13.5)	8 (8.4)	1 (1.7)	

The results of the pooled analysis demonstrate that the odds of ARDS and mortality are about 2.5 times higher in patients suffering from bilateral femur fractures as compared to patients with unilateral femur fractures. Moreover, patients with BFF have significantly protracted ICU/HDU and LOS stay compared to UFF patients.

A longitudinal cohort study conducted over a 15-year period (1993–2008), and based on the German registry for polytrauma patients, investigated the effect of the initial therapeutic approach on the final outcome of polytrauma patients suffering from bilateral femur fractures.[18] All included patients had been managed with a risk-adapted approach, meaning that there was a trend for primary definitive osteosynthesis of both fractured femora in less injured patients and for DCO in more severely injured ones. Thus, out of the initial cohort of 379 multiply-injured patients with bilateral femur fractures, almost half of them (51%, n = 193 patients) had been treated with DCO (bilateral temporizing ex-fix of both femora), 25% of them (n = 95 patients) with ETC (primary definitive IMN of both femora), 15.6% (n = 59 patients) with IMN on one side and temporary ex-fix on the other side (mixed subgroup), while 32 patients (8.4%) had not received any osteosynthesis of their fractured femora, because of their critical condition (*No* subgroup).

Compared with the ETC and mixed groups, patients of the DCO group were more severely injured (increased Injury Severity Score [ISS] and New Injury Severity Score [NISS] and more severe thoracic injuries) and required significantly longer stay in the ICU, significantly longer time of ventilation, while their complication and mortality rates were increased. Adjusted for injury severity, the standardized mortality rates between DCO and ETC subgroups did not differ significantly. Based on their results the authors

concluded that it was reasonable to treat the clearly stable patient with primary IMN of both femora (Table 99.3). It would be better to treat the potentially unstable patient with the DCO approach. When in doubt, it seems to be safer to use DCO as a risk-adapted approach.

Resolution of clinical scenario

- Bilaterality of femur fractures is a clear risk factor for systemic complications, and increased mortality.
- Adequately resuscitated, stable patients suffering from bilateral femur fractures could be safely treated with simultaneous IMN of both fractured femora.
- For the potentially unstable patient with bilateral femoral fractures, or when in doubt, the best treatment option seems to be a DCO approach.

Question 3: In open femur fractures, does early IMN result in increased complication rates compared to delayed IMN?

Rationale

Open femur fractures constitute high-energy injuries usually occurring within the context of polytrauma. Their prevalence among the cohort of multiply-injured patients with femur fractures has been recently estimated as high as 23%.[19] In this longitudinal cohort study including 5761 individuals with femoral fractures (77% closed and 23% open fractures) open femoral fractures demonstrated increased incidence of hemorrhagic shock in the prehospital setting, and required significantly more IV fluids and transfusions compared with the closed femur fractures.[19] Moreover, open femur fractures were associated with longer hospital and ICU stay, and increased risk of MOF. In a further subgroup analysis, based on the Gustilo classification, an increasing risk of sepsis, mortality, and MOF with increased grade of open injury was documented.

Clinical comment

While IMN is the gold standard treatment of closed femur fractures even in multiply-injured patients, its role in the subgroup of open femur fractures has to be critically evaluated.

Available literature and quality of the evidence

The most recent evidence on this topic was provided by:

- Level IV: 1 systematic review of the literature and meta-analysis.[20]

Findings

This review included 17 primary studies, mostly retrospective observational, with only two prospective studies reporting on the treatment of open femur fractures with intramedullary nails. The study documented a summarized estimate of union rate at 97% (95% confidence interval [CI]: 94–99%, I^2 = 68.5%). As for complication rates, the pooled estimates of effect size for deep infection and malunion rates were 6% (95% CI: 1.5–6%) and 3% (95% CI: 1–5.6%), respectively. The overall rate of bone grafting was 3.5% (95% CI: 1.8–5.8%, I^2 = 34.5%).

Timing of nail fixation (*early fixation*– within 72 hours of injury vs *delayed fixation* –after 72 hours of injury) did not seem to affect the final outcome in terms of union or infection rates. However, increasing Gustilo grade of the open injury resulted in an increase of the odds of infection (3.5 times for Gustilo III open fractures as compared to grade I + II open femur fractures).

This review provided a low level of evidence due to the inclusion of low-quality component studies. However, these studies were the only available relevant material in the current literature.

Resolution of clinical scenario

- Treatment of open femoral fractures with IMN results in satisfactory union and acceptable infection rates, comparable to those observed in the management of closed counterparts.
- Scheduled secondary grafting, when needed due to traumatic bone loss, should be promptly addressed and, if so, satisfactory healing should be expected.
- While early IMN does not adversely affect union or infection rates, Gustilo grade III injuries predispose to higher deep infection rates, and strict adherence to established surgical debridement and fixation protocols is advocated.

Summary of answers

- Optimal timing of definitive femoral fracture fixation in trauma patients depends on the patient's physiologic condition and adequacy of resuscitation. A protocol of early (within 36 hours) definitive stabilization of femoral fractures after appropriate management of occult tissue hypoperfusion (and subsequent metabolic acidosis) seems to be feasible in most trauma patients. In the small proportion of patients not responding early to the resuscitation measures, a DCO approach is preferable.
- Bilateral femur fractures can be treated with simultaneous IMN, provided the patient is adequately resuscitated and physiologically stable. In case the patient's physiologic stability is in doubt, the DCO approach should be undertaken.

- Immediate IMN is the hallmark of the treatment of open femur fractures. Extreme vigilance should be paid in in Gustilo III open femur fractures as their odds of being infected is 3.5 times higher than Gustilo I + II open fractures.

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Distal Femur Fractures

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Clinical scenario

- A 66-year-old woman presents to the Emergency Department with significant pain and deformity to her right lower thigh after falling off a step ladder. X-rays demonstrate a distal femur fracture. You are consulted as the orthopedic surgeon on call.
- She would like to know what the best way to fix her fracture is and is quite insistent on doing everything possible to avoid a second operation.
- She has also recently heard about the expedited surgery of hip fracture are receiving on the news and wonders if this is applicable to her as well.

Top three questions

1. In patients undergoing distal femoral fixation, do locking plates result in less construct failures and nonunions than nonlocking constructs?
2. In geriatric patients with distal femur fractures, does early surgery result in improved morbidity and mortality in comparison with delayed surgery?

3. In patients undergoing lateral locking plate fixation, are some patient and surgical factors, such as patient BMI, plate length, etc., more likely to result in nonunion and mechanical failure compared to other factors?

Question 1: In patients undergoing distal femoral fixation, do locking plates result in less construct failures and nonunions than nonlocking constructs?

Rationale

Locking plates have become widely used throughout trauma orthopedics because of their assumed increased stability, ability to find fixation in osteoporotic bone, and often their precontoured nature.[1] However, there is concern regarding a potential for nonunion when applied to distal femoral fractures.

Clinical comment

Distal femoral fractures have been reported to go onto nonunion at a rate of 6–24%.[1–3] Nonunions have been demonstrated to have devastating consequences for patients' physical, psychosocial, and financial wellbeing as well as lead to significant healthcare system costs.[4–6] Additionally, mechanical failure (often contributory to nonunion) has been identified as a significant problem in distal femoral fractures, resulting in the need for re-operation in 4% of cases.[7] With this in mind, the surgical techniques used to fix distal femoral fractures should

attempt to minimize the nonunion rate and requirement for re-operation.

Available literature and quality of the evidence

A 2015 Cochrane review by Griffin et al. (level II) for distal femoral fractures included six studies examining surgical fixation methods, including preliminary data from two studies that compared locking plates versus intramedullary (IM) nailing and the dynamic condylar screw (DCS), respectively.[8] No differences were found between locking plates and other interventions in this review in terms of union rates or mechanical failures. Similarly, a small randomized controlled trial (RCT) (level II) by the Canadian Orthopaedic Trauma Society of 52 patients with distal femoral fractures were randomized to either locked plating with the Less Invasive Stabilization System (LISS) or DCS.[9] Significantly more DCS patients achieved bony union without subsequent intervention in comparison to LISS plating.

A meta-analysis (level II) by Koso et al. synthesized the results of 11 level II and 3 distal femoral fracture studies including 505 patients.[7] They found no significant differences in nonunion rates, reoperation rates, or mechanical failures when comparing plating constructs versus IM nails – they did not differentiate between locking and nonlocking plates. The LISS was compared specifically to other constructs, which included IM nails, other locking plates, DCS, and nonlocking plate constructs and was found to have significantly fewer mechanical failures.

The Southeast Fracture Consortium compared locking compression plating to LISS for distal femoral fixation in a retrospective review (level III) of 339 patients.[10] No significant difference was found between the two constructs for mechanical failure or nonunion rates.

Findings

Based on the current available evidence, it is unclear if locking plates provide any benefit over other constructs. This is especially apparent as the predominant locking plate option reported on in the literature is the LISS, which is no longer as widely used with the advent of other commercial locking plates that are marketed as less rigid to avoid nonunion.[9,11] There is a need for high-quality evidence examining the optimal fixation method for distal femoral fractures.

Resolution of clinical scenario

- Level II and III evidence provides mixed results for the benefit of locking plates over other constructs for distal femoral fractures. Given the current literature, no resolution was reached.

Question 2: In geriatric patients with distal femur fractures, does early surgery result in improved morbidity and mortality in comparison with delayed surgery?

Rationale

Increasingly, attention has been drawn to the effect of surgical delay on the morbidity and mortality of geriatric orthopedic patients. Definitive evidence to this effect for hip fracture patients has changed the clinical landscape with clinical practice guidelines recommending early surgery.[12,13] Whether or not a similar action should be applied to distal femur fractures in the geriatric population is an important question to answer.

Clinical comment

Distal femur fractures occur in a bimodal distribution in the population, with an increased frequency in young trauma patients and in elderly patients with osteoporotic bone.[14,15] The patient profile of low-energy distal femur fractures is similar to the hip fracture population in terms of demographics and comorbidities. Elderly patients who suffer a distal femur fracture are at significant risk of postoperative complications and/or mortality. The one-year mortality rate has been reported as up to 38% post distal femur fracture,[16–18] which is similar to hip fractures.[19] Several studies have evaluated patient and surgical factors affecting mortality of patients with distal femoral fractures, including surgical delay.

Available literature and quality of the evidence

Evidence from retrospective reviews has produced mixed results as to whether surgical timing has an impact on patient mortality for distal femur fractures. In 2018, Myers et al. reviewed 283 elderly patients with distal femur fractures (level III) and found significantly higher 30-day, 60-day, and one-year mortality when surgery occurred more than two days after admission.[20] Moloney et al. also examined 176 elderly patients with distal femur fractures in a retrospective cohort (level III) and similarly found a significantly higher one-year mortality in patients with delay to surgery greater than two days.[21] Streubel et al. (level III) found a similar association between surgery delayed more than four days from injury and six-month and one-year mortality in their review of 92 elderly patients with distal femur fractures.[16]

However, the impact of surgical delay on mortality has not been found consistently by other studies; however, a 2017 retrospective study using the Danish fracture database

(level III) examined 90-day mortality of patients aged >50 and found no association with surgical timing.[22] Kammerlander et al. (53 patients, level III) and Brogan et al. (80 patients level III) also did not demonstrate a mortality difference between early and delayed surgery.[23,24]

Findings

Based on the current available evidence, it is unclear if early surgery provides any mortality benefit for geriatric patients with distal femur fractures. There is a need for large, multicenter, population-based studies examining surgical timing, as well as meta-analyses of the currently available data for a more conclusive answer to this problem.

Resolution of clinical scenario

- Level III evidence provides mixed results if delay to surgery affects postoperative mortality in geriatric patients with distal femur fractures. Thus, given the current literature, no resolution can be reached.

Question 3: In patients undergoing lateral locking plate fixation, are some patient and surgical factors, such as patient BMI, plate length, etc., more likely to result in nonunion and mechanical failure compared to other factors?

Rationale

The postoperative nonunion rate in distal femoral fractures has been estimated to be 6–24%.[1–3] Significant attention should be given to ways to reduce nonunions in these patients, and as such an understanding of patient and provider risk factors for developing nonunion must be understood.

Clinical comment

In recent years, lateral locked plating has become the predominant means of fixation for distal femoral fractures over previously popular fixed angle devices such as DCS, blade plates, and retrograde IM nails.[25] Early results of studies examining lateral locking plates showed very promising results with possible improvements in nonunion rates in comparison to other fixed angle devices.[26,27] However, other studies have since reported higher nonunion rates and called into question whether locking plate are contributory to nonunions in this patient population.[28–30] Understanding patient and surgical risk factors for developing nonunion, as well as strategies to mitigate these factors are important in avoiding postoperative complications.

Available literature and quality of the evidence

Several large retrospective reviews and biomechanical studies have examined risk factors for nonunion after distal femoral fixation with a lateral locking plate. A large population-based review by Ricci et al. (level III) of 335 patients found that diabetes and open fractures were risks for developing nonunion, and that open fractures, smoking, obesity, and shorter plate length (eight or fewer holes) to be associated with implant failure.[25] Similarly, Rodriguez et al. (level III) performed a retrospective case control study of 283 distal femoral fracture patients after lateral locked plate fixation.[31] They found that obesity, open fracture, and

occurrence of infection were patient risk factors for developing nonunion. Additionally, the use of stainless-steel plates resulted in significantly more nonunions than titanium plates attributable to construct rigidity. In a separate analysis on a similar dataset, the authors examined other construct factors and once again demonstrated the use of stainless steel as a risk factor but did not find a significant difference for screw density or plate length.[3]

Peschiera et al. (level III) examined surgical factors that contributed to nonunions in 116 distal femoral fractures and found that malreduction, particularly with varus malalignment, as well as medial cortical bone defect were associated with developing nonunion.[2] This led to the authors' recommendation that if medial cortical bony contact could not be achieved with primary fixation bone grafting be used to avoid nonunion, though this method itself has not been well studied.

Findings

Level III studies are the best available evidence for answering which factors are more likely to lead to nonunion in distal femoral fractures. Patient factors of obesity and smoking result in more nonunions and mechanical failures, respectively. Injury factors such as open fractures and the development of infection have also been shown to increase the likelihood of nonunions. Stainless-steel plates, failure to obtain adequate reduction, and the lack of medial cortical support are surgical factors that have been shown to increase nonunion rates.

Resolution of clinical scenario

- Level III evidence demonstrates obesity, smoking, open fractures, infection, medial cortical gaping, and use of

stainless-steel plates result in a greater risk of nonunion and/or mechanical failure after locked plating for distal femoral fractures.

Summary of answers

- A lack of high-quality evidence exists comparing lateral locked plating of distal femoral fractures with other constructs.
- The effect of using locking plates on the nonunion rates for distal femoral fractures is unclear.
- Based on current literature, it is unclear if delay to surgery affects postoperative mortality of geriatric patients with distal femur fractures.
- Obesity, smoking, open fractures, infection, malunion, medial cortical gaping, and use of stainless-steel plates result in greater risk of nonunion and/or mechanical failure after locked plating for distal femoral fractures.

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Proximal Tibia Fractures

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Clinical scenario

- You are an orthopedic staff on call and are asked to see a 48-year-old male who has fallen from a ladder. He has sustained a closed injury to his right proximal tibia. Radiographs reveal a bicondylar tibial plateau fracture.
- You review the case and decide that this patient will require an operation. When considering the operative treatment options, you wonder if treatment with external fixation leads to a decreased rate of complications when compared to open reduction and internal fixation.
- When considering treatment for this patient, you anticipate he will require bone graft to fill a bone defect after reducing the fracture fragment. Should you use bone substitute, iliac crest bone graft, or neither?
- Lastly, you are describing the likely postoperative course for this patient. He asks if he will return to having full preoperative range of motion (ROM). Unsure, you review the most recent evidence on

predictive factors for postoperative knee stiffness in patients treated operatively for tibial plateau fractures.

Top three questions

1. Amongst adult patients presenting with bicondylar tibial plateau fracture, does open reduction and internal fixation, when compared to external fixation with use of limited open techniques, lead to fewer operative complications?
2. Amongst adult patients who have proximal tibial fractures with metaphyseal bone defects, does iliac crest bone grafting (ICBG), when compared to bone substitute (calcium phosphate or other), improve patient-reported and radiographic outcomes?
3. Amongst adult patients who have undergone operative treatment for a tibial plateau fracture, what patient and injury-specific factors, when compared to the general population, yield improvement in knee ROM at one-year follow-up?

Question 1: Amongst adult patients presenting with bicondylar tibial plateau fracture, does open reduction and internal fixation, when compared to external fixation with use of limited open techniques, lead to fewer operative complications?

Rationale

There are a number of treatment options for complex proximal tibia fractures.1 External fixation, combined with limited open techniques can potentially reduce complications but potentially limit the ability to obtain optimal reductions.2 Open plating techniques can allow a more precise reduction, but risk complications. When performing an open reduction and internal fixation (ORIF), the surgeon must consider choice of incision and approach(es) to achieve surgical goals while limiting complications as well as considering the need for future procedures.

Clinical comment

In patients with orthopedic injuries, it is often a challenge to decide amongst treatment options, as it is often unknown which treatments offer the lowest acceptable rate of complications, while still remaining a cost-effective option. Treatment with ORIF with two plates inserted via an anterior or two incisions may have a higher complication and re-operation rate. Patients often prefer to avoid the prolonged use of external devices as is necessary compared with limited ORIF with circular external fixator. There is insufficient evidence to definitively guide choice between ORIF, hybrid external fixation, and unilateral locked plating in proximal tibia fractures.

Available literature and the quality of the evidence

Level I: 2 prospective comparative trials were identified in the literature.

Level II: 1 meta-analysis of both randomized and nonrandomized trials.

Findings

A trial from the Canadian Orthopaedic Trauma Society (COTS) compared closed/limited open reduction and circular external fixation with ORIF via midline or two-incision methods using nonlocking implants.[3] The patients were limited to high-energy fractures classified as Schatzker 5/6 injuries (AO 41-C). The authors identified Hospital for Special Surgery knee scores at two years postoperatively as their primary outcome with an a priori power calculated to predict a 25% difference with their sample size of 82 patients. There was no significant difference in HSS knee scores at two years (primary outcome) between groups ($p = 0.31$). However, the external fixation group was found to have a trend to earlier functional recovery with better HSS knee scores at six months postoperatively ($p = 0.064$). The ORIF group was found to have a 17% (8/40) infection rate versus 4.7% (2/43) in the external fixation group ($p = 0.032$). The ORIF group was found to have a larger number of unplanned procedures (37 vs 16, $p = 0.001$) which were often of significant magnitude, including one above-knee amputation. Other secondary outcomes of Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) scores, quality of reduction, development of osteoarthritis, and Short Form 36 (SF-36) scores were similar between groups.

Jiang et al. randomized 84 patients with bicondylar tibial plateau fractures to either double plating through two incisions or lateral locked plating with the LISS device.[4] Some limitations of this study include concerns that details of the randomization process were not clear and that a priori primary and secondary outcomes were not discussed. However, a power calculation for HSS scores was presented, which is presumably the primary outcome. This group found no significant difference in HSS score at 12 or 24 months postoperatively ($p = 0.215$ and $p = 0.84$). They

also found no significant difference in infection rate (2/43 using double plating vs 3/41 using LISS p = 0.96) or other complications.

A recent meta-analysis was completed comparing patients receiving external fixation versus ORIF for complex tibial plateau fractures.[5] In summary, patients treated with external fixation tended to return to preinjury level faster than those treated with ORIF, but ultimately there was no difference in functional score at final follow-up. Conversely, ex-fix patients had higher pooled rates of superficial infection (odds ratio [OR] = 1.93; 95% confidence interval [CI]: 0.17–22.53; p = 0.01), venous thromboembolism (OR = 1.56; 95% CI: 0.49–4.96; p = 0.45) and higher re-operation rate (OR = 0.77; 95% CI: 0.40–1.49; p = 0.44) and lower rates of compartment syndrome (OR = 0.61; 95% CI: 0.12–3.20; p = 0.56). However, only superficial infection risk was found to be significantly different between groups.

There is insufficient evidence to recommend external fixation with limited open reduction over open reduction and internal fixation (overall quality: moderate).

Resolution of clinical scenario

- The best available data suggest no obvious difference between limited open reduction with external fixation versus formal open reduction.
- Surgeon experience and patient choice can be used to determine a preferred approach for each particular patient scenario
- Large prospective studies are required to determine which groups of patients will do better with each intervention

Question 2: Amongst adult patients who have proximal tibial fractures with metaphyseal bone defects, does iliac crest bone grafting (ICBG), when compared to bone substitute (calcium phosphate or other), improve patient-reported and radiographic outcomes?

Rationale

Proximal tibia fractures are often associated with a component of joint surface depression.6 Elevation of the joint surface to its anatomic location leaves behind a metaphyseal bone void of variable size. It is common practice to fill this resultant void with supportive material to augment internal fixation and support elevated articular bone fragments.7 Autograft bone, usually from the iliac crest, has been used historically. Several bone graft substitute materials have been introduced recently, in part due to the known morbidity of bone graft harvest.8

Clinical comment

The development of substitutes is a widely developing practice with multiple companies offering various branded options. However, the safety of these bone substitutes, as well as their effectiveness, remains unclear. ICBG is widely considered the gold standard for filling substantial bone defects, though the donor site morbidity is significant. The choice to use one or the other presents a challenging decision for the patient and the surgeon.

Available literature and quality of the evidence

- Level I: 2 randomized controlled trials (RCTs).
- Level II: 1 systematic review and meta-analysis of comparative studies.
- Level II: 4 prospective cohort studies.
- Level IV: multiple case series and case reports.

Findings

Multiple recent trials have compared use of bone substitutes, of various kinds, to ICBG. In 2008, Russell et al. published a prospective RCT comparing calcium phosphate bone substitute to ICBG.[9] In this trial, 120 acute tibial plateau fractures were randomized to either ICBG or alpha-BSM (a type of calcium phosphate bone substitute). In this study, alpha-BSM was significantly more likely to prevent radiographic subsidence of the tibial plateau ($p = 0.009$, no CI: reported). However, no patient-reported outcomes were measured or compared.

Nusselt et al. . completed an RCT in 2014 comparing a bioabsorbable calcium phosphate cement to ICBG.[10] Unpublished results from conference abstracts relay that this bone substitute was noninferior to ICBG in SF-12 scores at six-month follow-up.

Lastly, the most recent systematic review evaluating use of bone substitutes used in the management of bone defects in the tibial plateau fractures was completed in 2013.[11] This review described that overall subsidence rates were lowest in calcium phosphate substitutes (3.6%) and highest in calcium sulphate groups (11.1%) when a radiographic cut-off of >2 mm was used to qualify as subsidence (no p values or CI: were reported). The rate of complications was not measurably different between groups, while patient pain scores in the early postoperative period favored bone

substitute. Overall, the review supported the use of bone substitutes in depressed tibial plateau fractures.

Resolution of clinical scenario

- Level I evidence support the use of calcium phosphate bone graft over ICBG to improve radiographic subsidence. Additionally, the donor site morbidity from ICBG should remain a consideration when choosing bone substitute. Similar results would be expected when evaluating allograft ICBG, though minimal head-to-head evidence exists.
- Level IV evidence suggesting patient functional scores are equivocal when considering bone substitute or ICBG.

Question 3: Amongst adult patients who have undergone operative treatment for a tibial plateau fracture, what patient and injury-specific factors, when compared to the general population, yield improvement in knee ROM at one-year follow-up?

Rationale

Knee stiffness following operative fixation of tibial plateau fractures is an unfortunate but relatively common complication.[12] Knee stiffness can result from injury to the soft tissue envelope, muscle atrophy, or arthrofibrosis.[13] Significant intra-articular adhesions may require a secondary arthroscopic lysis of adhesions to improve ROM.

Clinical comment

Stiffness is always considered a potential complication of any articular or periarticular injury, particularly those involving the tibial plateau. Patient and injury-specific factors could provide insight into which patients will predictably have better or worse recovery of knee ROM.

Available literature and quality of the evidence

- Level II: 1 prospective cohort study.
- Level II/III: 2 retrospective cohort studies.
- Level II /III: 2 systematic reviews of nonrandomized studies.
- Level III: 2 case control studies.

Findings

Kugelman et al. reported on a prospectively collected cohort of patients followed at a single academic center over 11 years.[14] The 266 patients involved in this study completed a mean of 17 months of follow-up. After regression analysis, bilateral injuries ($p = 0.02$, 1.16–9.12), increasing age ($p = 0.004$; 95% CI: −0.71 to −0.15), postoperative deep infection ($p = 0.003$; 95% CI: −15.12 to −3.01) were all significantly associated with decreased ROM, while increased time in external fixator ($p < 0.0001$; 95% CI: 1.29 to −1.7) reduced knee stiffness. A total of 10 patients (3.7%) required secondary procedure for arthrofibrosis.

Konda et al. examined 293 patients in a retrospective case series of patients with tibial plateau fractures, and found that patients with associated tibial eminence fractures had poorer ROM and functional scores at three months, six months, and one-year following injury than a matched

cohort of patients without tibial eminence fractures (p <0.01; ROM of 118.7 vs 126.9).[15] Reahl et al. described risk factors for postoperative knee stiffness in a case-control study.[16] The 110 patients who underwent subsequent surgery for knee stiffness following a tibial plateau fracture were matched with 319 patients who did not have any postoperative stiffness. Weeks in an external fixator (OR = 1.5 per week; 95% CI: 1.3–1.7; p <0.001) and presence of bilateral tibial plateau fractures (OR = 3.3; 95% CI: 1.2–9.1; p = 0.02) were implicated as significant risk factors for postoperative stiffness. Gittings et al. described in a retrospective case series that patients who underwent arthroscopic lysis of adhesions for knee stiffness following surgery for periarticular fractures improved significantly immediately postoperatively (from 72° to 127°).[17] However, these patients lose approximately half of their gains in ROM by final follow-up (mean ROM of 104°).

Christiano et al. reported on 117 patients assess in a case series.[18] In this group, patients were able to measurably increase short musculoskeletal functional assessment (SMFA) scores (p <0.01) until a plateau at six months – with no subsequent improvements afterwards (p = 0.92).

Resolution of clinical scenario

- Level II evidence that tibial eminence fractures, age, and deep infection are risk factors for postoperative knee stiffness in patients undergoing operative treatment for tibial plateau fractures. There is conflicting evidence on length of use of external fixators and whether it leads to better or worse postoperative ROM.
- Level IV quality evidence suggests patients continue to improve functional scores (SMFA) until six months

postoperatively (overall quality: low).

Summary of answers

- There is no measurable difference in outcomes between ORIF when compared to external fixation with limited open reduction for management of tibial plateau fractures.
- Bone substitute provides lower rates of plateau subsidence than ICBG without differences in complications.
- Tibial eminence fractures, bilateral tibial plateau fractures, older age, and presence of deep infection are risk factors for postoperative knee stiffness following fixation for tibial plateau fractures.

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Tibial Shaft Fractures

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Clinical scenario

- A 32-year-old male presents to the Emergency Department following a motorcycle collision.
- On examination, swelling and deformity of the left lower extremity are noted. There is a small open wound that probes to fracture.
- Neurovascular exam is normal, and there are no signs of acute compartment syndrome.

Top three questions

1. In tibial shaft fractures, does intramedullary (IM) nailing offer better outcomes compared with open reduction and internal fixation (ORIF)?
2. In open tibial shaft fractures, does IM nailing offer improved outcomes compared to external fixation?
3. In tibial shaft fractures (open and closed), what is the effect of reamed versus unreamed intramedullary (IM) nailing in the rates of major re-operations and secondary complications?

Question 1: In tibial shaft fractures, does intramedullary (IM) nailing offer better outcomes compared with open reduction and internal fixation (ORIF)?

Rationale

Although the patient in the example provided has an open tibial shaft fracture, it is important to know which intervention (casting, external fixation, plating, IM nailing) is supported by the evidence across a variety of clinical scenarios.

Clinical comment

Tibial shaft fractures are among the most common long bone fractures encountered by orthopedic surgeons with almost 500 000 occurring annually.[1,2] Tibial shaft fractures often represent high-energy injuries and account for a significant proportion of open fractures.[3,4] The management of these injuries is challenging, and complication rates can be high. Further, the economic impacts, in terms of disability and utilization of healthcare resources, are broad.[5,6] Thus, command of current literature is critical with respect to the provision of safe and effective care to patients with tibial shaft fractures. This enables the clinician to choose the best intervention for the patient and clinical scenario while offering appropriate counseling and education regarding the treatment options.

Available literature and quality of the evidence

There is limited literature available that directly compares ORIF to IM nailing in closed, diaphyseal tibial shaft fractures. In general, IM nailing has supplanted ORIF as the preferred method of treatment for the majority of practicing orthopedic surgeons as ORIF has been associated with significant soft tissue concerns.[2,7] It should be noted that there is additional controversy in the setting of extra-articular proximal and distal metaphyseal tibial fractures due to higher rate of malunion with IM fixation.

This question was answered based on three systematic reviews/meta-analyses and two randomized clinical trials with limitations:

- Level I: 3 systematic reviews/meta-analyses.
- Level II: 2 randomized controlled trials (RCTs) with limitations.[8,9]

Findings

The two reviews utilized pooled data from primarily observational studies to evaluate treatment options in closed tibial shaft fractures. With regard to surgical options, Littenberg et al. demonstrated faster time to union in plate fixation without differences in rates of nonunion. Rates of deep infection were lower with the use of IM nail.[10] Coles and Gross performed a systematic review and meta-analysis, including 13 studies with 895 tibial shaft fractures.[11] They reported that plate fixation resulted in lower rates of delayed union and nonunion (2.6% with plate fixation, 8.0% with reamed nailing, and 16.7% with unreamed nailing), but higher rates of infection (9% for plate fixation, 2.9% for reamed nailing, and 0.5% for unreamed nailing).[11] In general, survey data suggest that the benefits in terms of time to union do not offset the

perceived risks of soft tissue and infectious complications.[7] As a result, IM nailing is the preferred method of operative treatment for closed diaphyseal tibial shaft fractures.

With regards to distal metaphyseal tibial shaft fractures, data are derived from one systematic review of 11 randomized control trials evaluating ORIF versus IM nail.[12] This systematic review demonstrated that there were no significant differences between IM nail and locking plate fixation with regards to nonunion, delayed union, deep infection, union time, AOFAS score, and Disability Rating Index. However, IM nail fixation was associated with a higher rate of malunion (relative risk [RR] = 1.76; 95% confidence interval [CI]: 1.21–2.57; p = 0.003), a lower rate of superficial infection (RR = 0.29; 95% CI: 0.13–0.63; p = 0.02), and a higher foot function index (mean difference [MD] = 0.09; 95% CI: 0.01–0.17; p = 0.02).[12]

Resolution of clinical scenario

Although ORIF is associated with lower rates of nonunion and faster time to union, IM nailing is the consensus surgical option for the management of closed diaphyseal tibial shaft fractures primarily due to concerns regarding soft tissue and infection. The quality of the evidence is poor as direct comparative studies are limited.

Question 2: In open tibial shaft fractures, does IM nailing offer improved outcomes compared to external fixation?

Rationale

Open tibial shaft fractures are challenging injuries faced by orthopedic surgeons regularly. These injuries are often

associated with significant soft tissue injury as classified by the Gustilo and Anderson system. It is imperative that surgeons are aware of evidence-based treatment options to avoid complications and disability.

Clinical comment

There are many controversies in the treatment of open tibial shaft fractures. High-energy open tibia fractures present a significant clinical challenge with high rates of hospital re-admission for complications and poor longer-term outcomes associated with these complications.[13,14] Traditional treatment protocols typically utilize IM nails or plates for fracture fixation, which has the disadvantage of placing metal within the fracture site. Multiple studies demonstrate that infection rates tend to increase whenever hardware is placed within a wound[15,16] Use of definitive external fixation (either traditional uniplanar frames or circular multiplanar frames) for treatment of open tibial shaft fractures does not place any hardware at the fracture site. However, in the past, there have been issues with malunion, nonunion, and limitations in patient mobility.[17] It is important to consider the relative risks and benefits of these treatment options in an effort to avoid complications which can be prevalent with these injuries.

Available literature and quality of the evidence

This question was answered based on a systematic review and meta-analysis, one randomized trial, and two prospective studies.

- Level I: 2 systematic reviews and meta-analyses, 1 randomized trial.[18–20]
- Level II: 2 prospective cohort studies.[21,22]

Findings

Foote et al. conducted a recent meta-analysis primarily evaluating the rate of re-operation for different fixation strategies in open tibial shaft fractures.[19] Five studies assessing unreamed IM nailing versus external fixation were included. These studies demonstrated a lower odds of re-operation in the unreamed nailing group compared to external fixation (OR = 0.38; 95% CI: 0.23–0.62). They also completed a meta-regression to assess the effect of Gustilo grade on odds of re-operation in these groups which revealed no difference in effect (p = 0.84), indicating consistency across Gustilo grades. These findings were consistent with a prior systematic review and meta-analysis by Bhandari and colleagues in 2001.[18]

Inan et al. performed a randomized trial of type IIIA open tibial shaft fractures treated by circular wire external fixation versus unreamed IM nails.[20] Their results demonstrated shorter time to union (19 weeks vs 21 weeks; p = 0.04) and fewer knee contractures in the IM nail group. They did not detect a significant difference in the rate of deep infection. Kakar and Tornetta performed a prospective cohort study of 143 type I–III open tibial shaft fractures treated with immediate unreamed IM nails that showed a low incidence of deep infections (3%) and implant failures (3.5%).[21] Henley et al. demonstrated decreased risk of re-operation without difference in infection rate in a quasi-randomized comparative study of type II, IIIA, and IIIB open tibial shaft fractures.[22] There is good evidence to support the use of IM nailing in open tibial shaft fractures. This should be applied with caution with regard to injuries with more extensive soft tissue damage such as types IIIB and IIIC as further study is warranted.

O'Toole et al. in association with the Major Extremity Research Consortium (METRC) is actively enrolling patients into a randomized pragmatic trial designed to address this issue in severe open tibia fractures.[23] In this

study patients with severe open tibia fractures are randomized into circular external fixation versus internal fixation arms (IM nail and/or plate). Patients who decline randomization may enroll into the observation arm of the study in which the patient chooses their fixation strategy (external vs internal fixation) and identical follow-up data are collected. The primary outcome is rehospitalization for major limb complications and secondary outcomes include infection, fracture healing, limb function, and patient-reported outcomes regarding function and pain. This study, with its rigorous methodology, will provide important high-quality guidance regarding optimal management of these severe injuries in coming years.

Resolution of the clinical scenario

- In the case of open diaphyseal tibial shaft fractures, IM nailing is supported overuse of plating or external fixation due to lower re-operation rates and shorter time to union without changes in rate of deep infection.
- Extent of soft tissue injury is an important consideration. Further studies are required with regard to more severe soft tissue damage in type IIIB and IIIC injury patterns.

Question 3: In tibial shaft fractures (open and closed), what is the effect of reamed versus unreamed intramedullary (IM) nailing in the rates of major re-operations and secondary complications?

Rationale

The patient has an open tibial shaft fracture that will be treated with IM nailing. You are unsure whether reaming will result in better outcomes for your patient.

Clinical comment

The use of reamed versus unreamed IM nailing of long bone fractures has long been a topic of discussion. Unreamed nails may preserve endosteal blood supply and improve fracture healing rates. Reamed nails, however, offer greater mechanical stability at the fracture site due to their larger size at the expense of the endosteal blood supply.

Available literature and quality of the evidence

Several randomized control studies and the pooled results of a meta-analysis were used to address the question.

- Level I: 3 systematic reviews/meta-analyses (one includes all long bones – tibia and femur).[24–26]
- Level I: 3 randomized trials (level I).[13,15,27]

Findings

Multiple level I studies show no clear difference in major re-operations or complications between reamed and unreamed IM nailing of combined open and closed tibial shaft fractures. Sub-analyses between open and closed fractures, however, have shown that reamed closed tibial fractures may have a reduction in re-operation compared to open fractures. Studies measuring patient function and quality of life corroborate these findings.[24–27]

- Moderate quality evidence has shown no statistically significant differences between reamed and unreamed tibial nailing groups for combined open and closed

fractures in “major” re-operations (RR = 0.88; 95% CI: 0.64–1.21; five trials), or in the secondary outcomes of nonunion, pain, deep infection, malunion, and compartment syndrome. Subgroup analysis, however, suggests that reamed nailing reduces the incidence of re-operations related to nonunions in closed fractures compared to open fractures.[25]

- Benefits of reaming for closed fractures were also supported by a large multicenter RCT that found a 33% reduction in having a re-operation with reamed versus unreamed IM (RR = 0.67; 95% CI: 0.47–0.96; p = 0.03) in closed tibial fractures. This reduction was largely due to differences in dynamization.[15]
- No significant differences in adverse effects were found between reamed and unreamed nails in open tibial fractures. A pooled meta-analysis of four studies found no difference in healing rate, secondary surgery rate, implant failure rate, compartment syndrome, and infection between reamed and unreamed nails in open tibial fractures (p >0.05 for all outcomes).[26]
- There were no differences between the reamed and unreamed groups at 12 months for either the Short Form 36 (SF-36) physical component score (42.9 vs 43.4; 95% CI: 22.1–1.1; p = 0.54) or the short musculoskeletal functional assessment (SMFA) dysfunction index (18.0 vs 17.6; 95% CI: –2.2 to 2.9; p = 0.79).[13]

Resolution of clinical scenario

- There is no difference in major re-operations or complications between reamed and unreamed IM nailing of tibial shaft fractures (combined open and closed).

- Closed tibial fractures treated with a reamed IM nail appear to have decreased re-operations related to nonunions.

Summary of answers

- IM nailing is the preferred method of operative treatment for closed diaphyseal tibial shaft fractures.
- IM nailing is the preferred method of treatment for open diaphyseal tibial shaft fractures.
- There is no demonstrable difference in major re-operations or complications between reamed and unreamed nails for tibial shaft fractures (combined open and closed). Subgroup analyses, however, show reamed nails appear to have a lower risk of re-operation for closed fractures.

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Intra-Articular Distal Tibia (Pilon/Plafond) Fractures

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Clinical scenario

- A 30-year-old man who was involved in a motor vehicle accident comes in as a trauma team activation. He has been cleared on primary and secondary survey. He has suffered an isolated injury to his right ankle. His chief complaint is pain, swelling, and inability to weightbear on his right lower extremity. He is diagnosed with a distal tibia intra-articular fracture (i.e. *pilon* or *plafond*) on x-ray.
- On physical examination, there are no open wounds, there are intact dorsalis pedis and posterior tibial pulses with only moderate swelling. Computed tomography (CT) scan confirms an intra-articular multifragmentary distal tibia fracture with proximal displacement of the talus, an AO43 type C fracture.[1]
- As the most responsible physician caring for this patient, you consider the most appropriate management plan in terms of operative approach, immediate versus delayed fixation, and the use of external fixator in the treatment for pilon fractures.

Top three questions

1. In patients undergoing operative management for distal tibia intra-articular fractures, does staged open reduction and internal fixation (ORIF) result in better clinical and postsurgical outcomes compared to acute fracture management?
2. In patients undergoing operative management for distal tibia intra-articular fractures, does definitive management with limited internal fixation with external fixation result in better clinical and postsurgical outcomes compared to ORIF (early or delayed)?
3. In patients undergoing operative management for distal tibia intra-articular fractures, does any specific surgical exposure result in better clinical and postsurgical outcomes compared to other exposures?

Question 1: In patients undergoing operative management for distal tibia intra-articular fractures, does staged open reduction and internal fixation (ORIF) result in better clinical and postsurgical outcomes compared to acute fracture management?

Rationale

Intuitively, ORIF is easiest to perform immediately after injury and before the development of organizing hematoma, soft tissue contraction, callus formation, and inflammatory osteopenia. However, the timing of definitive surgery depends on soft tissue integrity. Appropriate surgical

timing decreases the risk of wound complications, including skin slough and superficial and deep infection.

Clinical comment

The decision on when to operate depends on multiple factors such as age, general and current health, soft tissue integrity, and other injuries that influence the safe administration of anesthesia.[2]

Surgical intervention during maximal soft tissue swelling will lead to a higher risk of wound necrosis and infection. Early surgical intervention or delayed surgery as part of two-stage management is carried out when the soft tissue envelope is *favorable*. Specific clinical signs that help the surgeon decide if the soft tissue is ready include resolution of edema and fracture blisters and the return of skin wrinkling.

Available literature and quality of the evidence

Overall, there is limited high-quality evidence on the topic of acute versus delayed management of pilon fractures. There is one prospective cohort study (level II) and two retrospective cohort studies (level III) that specifically seek to answer this question.

Tang et al. retrospectively compared a cohort of 46 patients with closed type C pilon fractures who underwent surgery either within 36 hours of injury or had delayed treatment (level III).[3] Sajjadi et al. retrospectively studied 41 closed tibial pilon fractures, half of which were treated definitively within 24 hours, and the other half of which were treated with an external fixator within 24 hours then subsequent ORIF once soft tissues were amenable (level III).[4] In a prospective cohort study, Conroy et al. reported the results of early ORIF in 32 patients who suffered from open type B (21 patients) and type C pilon fractures (11 patients) (level

II).[5] They followed a *fix and flap* protocol by managing pilon fractures with early bone stabilization and flap coverage at the same time. In this study 28 patients were managed with early ORIF and early coverage using free muscle flaps and split skin graft, and four patients were managed with application of external fixation.

Findings

In their retrospective cohort (level III), Tang et al. found that there was no significant difference between groups regarding the rate of soft tissue complications, fracture union, and final functional outcome score. Further, the early fixation group had a significantly shorter mean time to fracture union and hospital stay.[3] Sajjadi et al. (level III) reported no significant difference in rate of infection (superficial or deep infection, osteomyelitis), malunion/nonunion, and patients' satisfaction with American Orthopaedic Foot and Ankle Society (AOFAS) score. Similar to Tang's study, Saijadi et al. reported significantly decreased length of stay with early ORIF.[4] In their study, Conroy et al. (level II) reported two amputations (6.2%), two deep infections (6.2%), and three malunions (9.3%).[5] After exclusion of the two amputees, all 30 remaining patients progressed to clinical and radiological union. They concluded their *aggressive protocol* showed excellent union rate, low rate of infection, and good functional outcome.

At least two major differences can be identified between the studies above that endorse the use of early ORIF, and the lower-quality studies that historically reported much higher complication rates[6–9]: the mechanism of injury and status of the soft tissues. In the more recent, higher-quality evidence, when soft tissue integrity and fracture type are taken into account, early ORIF represents a reasonable and comparable option to delayed fixation.

The approach most commonly used to treat high-energy pilon fractures is a two-stage procedure involving initial reduction and application of external fixator followed by definitive fixation about 10–21 days later when the soft tissue envelope is amenable (level II–III). There is, however, mounting moderate-quality evidence that tibial pilon fractures treated acutely within 12–24 hours, without evidence of extensive soft tissue trauma, do as well as those treated in delayed fashion (level II–III).

Resolution of clinical scenario

- Level II–III evidence suggests that acute ORIF of pilon fractures is a viable treatment option if: definitive management occurs within 48 hours, the injury is relatively lower energy (or torsional) with amenable soft tissues, by an experienced surgeon at a well-resourced facility with ability for *flap* management of soft tissue coverage issues.
- Level II evidence suggests acute ORIF decreased hospital length of stay.
- Two-stage protocol involves an ankle-spanning external fixation and delayed internal fixation once the soft tissue injury resolves.
- A two-stage approach is most appropriate for high-energy injuries with extensive soft tissue disruption including open injuries and those with extensive hemorrhagic fracture blisters (level II–III).

Question 2: In patients undergoing operative management for distal tibia intra-articular fractures, does definitive management with limited internal fixation with external fixation result in better clinical and postsurgical outcomes compared to ORIF (early or delayed)?

Rationale

In high-energy pilon fractures, the soft tissue envelope has been damaged by the injury. A second insult from surgical dissection may increase soft tissue complications. Maintenance of fracture length and stability decreases soft tissue swelling by helping to maintain vascular flow. In addition, with minimal dissection, the surgeon will avoid more insult to the vulnerable soft tissue envelope.

Clinical comment

As mentioned above, historically, poor outcomes have been reported with primary ORIF of high-energy pilon fractures and external fixation, and therefore became a popular treatment alternative. Fracture reduction through ligamentotaxis will maintain fracture length, provide fracture stabilization, and eventually promote soft tissue healing. Limited ORIF of the joint surface is utilized for articular fragments not anatomically reduced by ligamentotaxis.

Available literature and quality of the evidence

Two downgraded prospective randomized controlled trials (RCTs) and one meta-analysis (all level I) aim to answer this question.

In their RCT, Wyrsch et al. compared 18 patients who were treated with ORIF between 2 hours and 10 days of index injury, with 20 patients who were treated with external fixation with limited internal fixation. Patients were randomized using a quasi-random method (odd and even numbers) (level II).[10] Wang et al., in their 2015 meta-analysis in comparing ORIF and limited internal fixation combined with external fixation, analyzed nine studies (three RCTs and six non-RCTs) with 498 fractures (level II).[11] Wang et al. most recently evaluated patients closed B3- and C-type tibial pilon fractures randomized to either two-stage ORIF (27 patients) or limited incision and external fixation (29 patients)(level II).[12]

In their RCT, Wyrsch et al. reported 15 major complications in seven patients who had ORIF, necessitating 28 additional operations.[10] In the external fixation group there were four major complications in four patients, necessitating five additional operations. The authors found no significant difference in post-traumatic arthritis and concluded that external fixation with limited internal fixation was a satisfactory method of treatment of pilon fractures and was associated with fewer complications than early ORIF. Wang et al.'s meta-analysis found no significant differences in bone healing complications (risk ratio [RR] = 1.17; 95% confidence interval [CI]: 0.68–2.01; p 1/4 0.58]), nonunion (RR = 1.09; 95% CI: 0.51–2.36; p 1/4 0.82), malunion or delayed union (RR = 1.24; 95% CI: 0.57–2.69; p 1/4 0.59), superficial (RR = 1.56; 95% CI: 0.43–5.61; p 1/4 0.50), or deep (RR = 1.89; 95% CI: 0.62–5.80) infections, arthritis symptoms (RR = 1.20; 95% CI: 0.92–1.58; p 1/4 0.18), or chronic osteomyelitis (RR = 0.31; 95% CI: 0.05–1.84; p 1/4 0.20) between the two groups.[11]

Finally, in their RCT of 56 patients, Wang et al. reported two wound infections, one requiring reoperation, and one pin-tract infection in the two-stage ORIF group compared to no wound infections and 12 pin-tract infections in the limited incision and external fixation group ($p < 0.05$).[12] The external fixation group had higher rates of malunion, delayed union, and arthritis symptoms, but no statistical significance was demonstrated. Both groups resulted in similar ankle joint function. Logistic regression analysis, however, indicated that smoking ($p < 0.01$), increasingly severe fracture pattern ($p < 0.01$), and age ($p = 0.026$) were the factors significantly influencing the final outcomes.

Findings

When considered in the context of the aforementioned meta-analysis, there is no clear treatment that can be strongly recommended. External fixation appears to have fewer deep wound complications than ORIF, but it may be more prone to impaired union. Wang et al.'s more recent, methodologically sound quasi-RCT, however, suggested a trend toward a treatment advantage for ORIF, however not significant, over external fixation.[12] This study also illustrated that a number of variables important to the final outcome are not within the surgeon's locus of control, including the degree of fracture comminution, smoking status, and age.

Resolution of clinical scenario

- External fixation with limited internal fixation is a widely accepted mode of definitive treatment in pilon fracture management.
- The existing literature suggests that outcomes are better with ORIF at the expense of elevated infection

events, compared to the elevated malunion/nonunion events associated with external fixation and limited ORIF (level III/IV).

- There is not enough evidence to conclude whether two-stage ORIF or definitive management with an external fixator is superior; this is likely fracture-, surgeon- and patient-dependent.

Question 3: In patients undergoing operative management for distal tibia intra-articular fractures, does any specific surgical exposure result in better clinical and postsurgical outcomes compared to other exposures?

Rationale

The ankle soft tissue envelope is thin and vulnerable to wound complications.[13] Extensive soft tissue dissection may result in wound breakdown. The approach that allows for satisfactory fixation while causing the least amount of soft tissue compromise should be chosen.

Clinical comment

The surgical approach to a pilon fracture is primarily dictated by the fracture pattern and soft tissue status. The CT scan must be reviewed carefully as part of surgical planning for both reduction and fixation strategies. The goal is to achieve anatomic reduction of the joint surface, restoration of axial alignment of the nonarticular component, and application of appropriate fixation with meticulous soft tissue handling.

The classic approaches to distal tibia and fibula are: (i) anteromedial (1cm lateral to the anterior tibial crest), (ii) anterolateral (between the peroneal and extensor muscles), (iii) posterolateral (Harmon), (iv) posteromedial, (v) anterior, and (vi) direct lateral. The traditional surgical approach, described and recommended by the AO Group, is the *anteromedial approach* for the tibia and lateral for the fibula.[1]

Available literature and quality of the evidence

A prospective cohort (level II) and a comprehensive systematic review (level IV) have assessed the impact of surgical approach on wound and fracture healing in pilon fractures.

Howard et al. performed a prospective cohort (level II) which reported a low rate of wound complications in 46 pilon fractures with less than a 7 cm skin bridge between two or three skin incisions.[14] The authors concluded that, with careful attention to soft tissue management and surgical timing, incisions for pilon fractures may be placed less than 7 cm apart, allowing the surgeon to optimize exposures on the basis of the injury pattern.

More recently, Liu et al. (2016) conducted a systematic review (level IV) on the same topic. A total of 733 patients were included with type B and C fractures. The anterolateral approach was most common, accounting for one-third of the entire study population. The anterior approach had one of the lowest complication rates with a patient base that had a high proportion of type C fractures. The posterolateral and anteromedial approaches had markedly higher complication rates, although no formal statistics were displayed in that review.[15]

Findings

Weak evidence suggests that there are decreased complications associated with the anterior approach to pilon fractures. Nonetheless, given the weak evidence and complexity of these fractures, the approach to the fracture should be dictated by the fracture pattern and surgeon comfort.

Resolution of clinical scenario

- The surgical approach is dictated by anatomy of fracture and the status of the soft tissue.
- Careful physical examination and review of the CT scan will help the surgeon to choose the most appropriate surgical approach. Weak evidence suggests that the anterior approach is useful for type C fractures and is associated with lower complication rates (level IV).

Summary of answers

- Acute ORIF of tibial pilon fractures is a viable treatment option if: definitive management occurs within 48 hours, relatively lower energy (or torsional) injury with manageable soft tissue status.
- A two-stage approach is most appropriate for high-energy injuries with extensive soft tissue disruption including open injuries and those with extensive hemorrhagic fracture blisters.
- External fixation with limited internal fixation is a widely accepted mode of definitive treatment in pilon fracture management.
- The surgical approach is dictated by anatomy of fracture and the status of the soft tissue.

- Weak evidence suggests that the anterior approach is useful for type C fractures and is associated with lower complication rates.

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Malleolar Fractures

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Clinical scenario

- You are on call and are asked to see a 23-year-old male who has suffered a rotational ankle injury after slipping on ice. The triage nurse asks if he should receive an x-ray before you see him and what clinical tools might be appropriate to decide that.
- Once the x-rays have been completed and you speak to the patient, you mention that he may have an injury to his ankle syndesmosis. The patient asks what various options there may be for treatment.
- You also notice on the lateral x-ray that the patient has a small posterior malleolus fracture. You are unsure if you should fix the posterior malleolus as it seems small. You wonder if adding additional fixation will improve this patient's outcomes.

Top three questions

1. Amongst adult patients presenting with low-energy inversion ankle injuries, are the Ottawa Ankle Rules (OAR), when compared to other ankle injury screening

tools, more accurate in diagnosing patients with ankle fractures?

2. Amongst adult patients, who have syndesmotic injuries proven with intraoperative stress testing, do novel suture button devices, when compared to standard screw fixation, improve the reduction of syndesmosis and patient-reported outcomes?
3. Amongst adult patients who have posterior malleolar ankle fracture, at what percentage of articular surface involvement does operative intervention, when compared to nonoperative management, yield improvement in patient-reported outcomes at one-year follow-up?

Question 1: Amongst adult patients presenting with low-energy inversion ankle injuries, are the Ottawa Ankle Rules (OAR), when compared to other ankle injury screening tools, more accurate in diagnosing patients with ankle fractures?

Rationale

Ankle injuries are among the most common reasons for visits to the Emergency Department.[1] Many patients do not require radiographic imaging, adding unnecessary cost and increasing wait times in the Emergency Department. Multiple screening tools have been developed to triage which injuries are at high risk for fractures and will require radiological investigation.[2]

Clinical comment

In order to deliver healthcare effectively, it is important to identify which patients require imaging in the Emergency Department and those that can be managed conservatively and discharged immediately. Furthermore, the most utilized decision-making tool (the OAR) was initially validated more than 25 years ago and primarily used at that time by emergency physicians.[3] Modern primary care involves associated healthcare professionals, including nurse practitioners and physiotherapists. Accordingly, the most accurate screening tool needs to be one that is appropriately utilized by all healthcare professionals.

Ottawa Ankle Rules[3]

Ankle radiographs are indicated if there is pain in the malleolar area and any of the following:

- Bone tenderness along the distal 6 cm of the posterior edge of the tibia or tip of the medial malleolus.
- Bone tenderness along the distal 6 cm of the posterior edge of the fibula or tip of the lateral malleolus.
- An inability to bear weight, both immediately and in the Emergency Department, for four steps.

Available literature and the quality of the evidence

The most relevant current literature consisted of:

- Level I: 2 randomized trials.[2,4]
- Level I: 2 systematic reviews of the literature and meta-analysis of comparative studies.[5,6]

Findings

Various decision-making tools regarding ankle fracture assessment have been reviewed in a number of prospective studies and a recent systematic review. In a 2015 randomized controlled trial (RCT), the OAR were shown to have better specificity than the Bernese Ankle Rules, at 0.97 and 0.69.[2] In a 2018 RCT, triage nurses using the OAR were able to detect ankle fractures more often than physicians using expertise alone.[3] Additionally, the proportion of ankle fractures missed was lower in the triage nurse group than the physician group. This study highlighted the ability to apply the OAR to a variety of healthcare professionals, not just emergency room physicians.[4]

Additionally, 66 studies evaluating the OAR were included in the most recent systematic review and meta-analysis.[5] Overall sensitivity of the OAR was found to 99.4%, while use of the OAR was found to reduce unnecessary medical imaging by ~30% across all settings and by 49% in sports centers.

When compared to other screening tools, a recent meta-analysis showed the OAR, Bernese Ankle Rules, and the Malleolar Zone Algorithm to result in a negative likelihood ratio of 0.12, 0.14, 0.39, and 0.23, respectively – highlighting that the OAR remains the most accurate decision tool for excluding fractures in the setting of an acute injury.[6]

Resolution of clinical scenario

- Level I evidence that the OAR are an accurate screening tool to exclude fracture in adult patients presenting with ankle fractures. These rules decrease use of radiography with a low likelihood of missing a fracture (overall quality: high).

- Level I evidence that the OAR are superior to other screening tests in excluding ankle fractures(overall quality: high).

Question 2: Amongst adult patients, who have syndesmotic injuries proven with intraoperative stress testing, do novel suture button devices, when compared to standard screw fixation, improve the reduction of syndesmosis and patient-reported outcomes?

Rationale

One of the promising aspects of suture button fixation for syndesmotic injuries is the ability to maintain reduction while allowing a small degree of motion of the syndesmosis once patients begin to weight bear, and a relative reduction in hardware-related complication compared to screw fixation.[7] Accordingly, it is important to understand if suture button fixation achieves its purported goals.

Clinical comment

The distal tibiofibular syndesmosis is a primary stabilizer of the ankle joint. Instability of this articulation has been shown to significantly increase joint contact pressures and thus predispose to secondary arthrosis and poor functional outcomes.[8] Suture button fixation is a relatively novel technique that has shown excellent functional outcomes when using in other operations, including anterior cruciate ligament reconstruction and distal biceps repairs.[9]

Common complications following syndesmotic fixation in ankle fractures with screws include failure to maintain reduction and hardware failure.[10] It has been proposed that a suture button technique allows for a more physiologic relationship between the distal tibia and fibula and thus retains syndesmotic reduction once patients begin to weight bear. However, the per-unit cost of a given suture button system far exceeds that of typical screw fixation and thus excellent evidence is required to support the use of this implant.

Available literature and quality of the evidence

The most relevant current literature consisted of:

- Level I: 3 randomized trials.[11–13]
- Level I: 1 systematic reviews of the literature and meta-analysis of comparative studies.[14]

Findings

There has been significantly increased interest in suture or dynamic fixation of the syndesmosis in the past 10 years. A recent multicenter RCT found dynamic fixation of acute ankle syndesmosis to result in better clinical and radiographic outcomes at minimum two-year follow-up, with lower re-operation rates.[11] Laflamme et al. described the results following their prospective RCT. They noted that dynamic fixation of acute ankle syndesmosis rupture with a suture button device seems to result in modestly better clinical outcomes (Olerud Molander scores 93.3 vs 87.6, $p = 0.046$) and lower rate of hardware failure (36.1% vs 0%, $p < 0.05$).[12]

In 2015, Kortekangas published an RCT comparing suture button and screw fixation for accuracy and maintenance of syndesmotic reduction assessed with bilateral computed

tomography. Twenty-one patients were randomized to TightRope (a type of suture button fixation), while 22 were randomized to syndesmotic screw fixation. They reported that syndesmotic screw and suture button fixation had similar postoperative malreduction rates. Neither the incidence of ankle joint osteoarthritis nor the functional outcome significantly differed between the fixation methods. The results of the study pointed to similar overall outcomes in all techniques.[13]

Additionally, a recent meta-analysis commented that suture button fixation yielded improvement in functional scores over screw fixation, but clinical significance is doubtful.[14] Future trials are in progress, and an updated meta-analysis will be required to answer this clinical question.

Resolution of clinical scenario

- Level I evidence suggests that screw fixation is not inferior to suture button fixation when focusing on clinical outcomes, though it may lead to worse radiographic outcomes when measuring syndesmotic reduction.

Question 3: Amongst adult patients who have posterior malleolar ankle fracture, at what percentage of articular surface involvement does operative intervention when compared to nonoperative management, yield improvement in patient-reported outcomes at one-year follow-up?

Rationale

A high proportion (>10%) of rotational ankle injuries will involve a bony injury to the posterior malleolus.[15] The clinical importance of this fragment remains unclear. Biomechanical studies have suggested that the posterior malleolus can prevent posterior tibial subluxation over the talus,[15] but should all posterior malleolar fractures be treated? Is there a meaningful clinical benefit to patients?

Clinical comment

It is generally accepted that fractures involving the posterior malleolus have a worse prognosis than those with intact posterior malleoli.[16] The literature remains divided with respect to the indications for surgical intervention. Open reduction and internal fixation (ORIF) of this piece often requires a separate incision and approach than the standard bimalleolar fracture approaches. Given the potential morbidity and complications associated with a longer and more complex operation, should all posterior malleolar fractures be anatomically reduced and undergo internal fixation? Is there an optimal size to which the fragment can be successfully treated without an operation? Lastly, if treated with ORIF, should one use screw fixation from anterior to posterior or buttress plating from a posterolateral approach?

Available literature and quality of the evidence

The most relevant current literature consisted of:

- Level I: 1 randomized trial.[17]
- Level III: 1 systematic review and meta-analysis of biomechanical studies.[18]
- Level III: 1 systematic reviews of the literature and meta-analysis of both comparative and noncomparative

studies.[19]

- Level III: 1 retrospective cohort with medium to high risk of bias.[20]

Findings

Biomechanical studies

In a recent meta-analysis,[18] eight biomechanical studies were reviewed. Unfortunately, the findings of the studies were very heterogenous. Scheidt et al. showed that a posterior malleolar fragment 25% of the articular led to posterior tibial subluxation, and that subsequent fixation reduced instability.[21] In contrast, other studies found that osteotomized as much as 40% of the posterior malleolus did not change tibiotalar alignment.[18] However, more recent literature supports fixation of the posterior malleolus to regain stability of the syndesmosis.[22,23] Miller et al. described that fixation of posterior malleolus offered stability to the syndesmosis due to the ligamentous attachments to the malleolus itself,[22] while Fitzpatrick et al. demonstrated in a cadaveric study that malreduction of the posterior malleolus led to malreduction of the syndesmosis itself.[18]

Clinical studies

Fragment size

No randomized or prospective cohort studies have been undertaken to compare operative and nonoperative treatment of posterior malleolar fractures at a given size of the articular surface. Mingo-Robinet conducted a retrospective cohort study of 45 patients, and found that patients with small fragments (defined as less than 25% of the articular surface on a lateral radiograph) had similar outcomes regardless of whether they had an anatomic or

nonanatomic reduction.[20] However, in a meta-analysis comprising 12 other nonrandomized studies, the decision to pursue nonoperative treatment was based on fragment size, though that was only defined in 2 of 12 studies.[16] Additionally, no retrospective studies have shown a relationship between fragment size and development of osteoarthritis. Higher-level evidence is required to definitively state that certain fragment sizes can be treated with or without an operation.

Fixation strategy

O'Connor randomized 37 patients with posterior malleolar fractures to either anterior to posterior screws or an ORIF with a posterolateral buttress plate. Though the study was small, buttress plating was shown to have superior clinical outcomes at follow-up.[17] A recent meta-analysis supported this finding, but commented that the postoperative articular step was the most important predictor of clinical outcomes,[19] and that posterolateral plating offered a lowered risk of leaving an articular step.

Resolution of clinical scenario

- Level III evidence that surgical fixation for fragments that are nondisplaced, with no articular step-off, regardless of size, may not affect patient outcomes (overall quality: poor).
- Level III evidence that malreduction of a displaced posterior malleolus fragment may lead to malreduction of the syndesmosis (overall quality: poor).
- Level III evidence that posterior malleolar fractures comprising less than 25% of the articular surface may not require operative fixation (overall quality: poor).

- Level II evidence supporting use of posterolateral buttress plate over anterior to posterior screws for fixation of posterior malleolar fragments (overall quality: moderate).

Summary of answers

- The Ottawa Ankle Rules are a reliable tool for determining which patients require ankle radiographs, and are superior to other tools used for the same purpose.
- Suture button and screw fixation for syndesmotic disruption have similar clinical outcomes.
- For posterior malleolar fractures requiring operative fixation (usually >25% articular surface), posterolateral buttress plates are preferred over anterior to posterior screws.

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Talus Fractures

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Clinical scenario

- A 21-year-old male suffered a motor vehicle accident. He presents to the Emergency Department with a painful and swollen left ankle but no other injuries.
- Edema and tenderness over left hindfoot is noted. The skin has some small blisters but otherwise the physical exam is normal. X-rays show a displaced talar neck fracture with a subtalar joint dislocation.

Top three questions

1. In patients with displaced talar neck fractures, does urgent definitive fixation result in better outcomes and fewer complications, compared with delayed definitive fixation?
2. In patients with displaced talar neck fractures, does surgery with dual approaches (anteromedial and anterolateral) result in better outcomes and fewer complications, compared with surgery with percutaneous fixation or arthroscopic-assisted reduction and fixation?

3. In patients with displaced talar neck fractures, does plate fixation result in better biomechanical stability compared with fixation using only screws?

Question 1: In patients with displaced talar neck fractures, does urgent definitive fixation result in better outcomes and fewer complications, compared with delayed definitive fixation?

Rationale

Talar neck displaced fractures have been historically considered surgical emergencies due to their frequent association with peritalar joint dislocations or subluxations. It is also believed that early surgery will decrease vascular impairment and subsequent risk of osteonecrosis.[1] However, given the high-energy characteristics commonly associated with this injury, soft tissue conditions make immediate definitive fixation challenging and significantly increases complications.[2]

Clinical comment

Even when displaced talar neck fractures are considered to need an urgent surgery, there has recently been a trend toward performing a closed reduction of the fracture-dislocations and wait until soft tissues are in a good enough condition to perform a delayed final open reduction and internal fixation (ORIF). There is a need to analyze which treatment paradigm has better outcomes and fewer complications.

Available literature and quality of the evidence

This search produced no systematic reviews or randomized controlled trials. There are five retrospective studies (level III). Whenever possible, these level III studies will be used to answer the question.

Findings

Lindvall et al. compared different aspects of 26 talar body and neck fractures (8 body and 18 neck) treated within six hours from injury or after six hours and found no difference regarding American Orthopaedic Foot and Ankle (AOFAS) score, nonunions, osteonecrosis or post-traumatic arthritis.[3] Sanders et al. review 70 cases of displaced talar neck fractures and although they did not list the detailed times in which surgeries were performed, they stated that surgical timing showed no difference in the need of secondary procedures.[4]

Vallier et al. reviewed 60 displaced talar neck fractures. Although the numbers in the study were small, no correlation was found between the timing of reduction and the development of osteonecrosis.[5] Despite this, the authors advocate for urgent reduction because it may help to preserve any remaining blood supply. Once reduction has been achieved, a delay in fixation could be done and potential complications derived from severe soft tissue injury as skin necrosis, wound dehiscence, and infection could be avoided.

In another more recent cohort, Vallier et al. reviewed 81 talar neck fractures. This cohort had 2 Hawkins type I fractures, 44 Hawkins type II fractures – 21 were type II-A (without subtalar joint dislocation) and 23 were type II-B (with subtalar dislocation) – 32 Hawkins type III fractures, and 3 Hawkins type IV fractures.[6] Treatment consisted of emergent closed reduction for dislocation patterns.

Irreducible dislocations and open fractures underwent definitive surgical treatment immediately. From the total cohort, 46 (57%) were treated with urgent definitive fixation and 35 (43%) were treated with delayed ORIF. They found that emergent closed reduction within 6, 8, 12, or 18 hours did not correlate with osteonecrosis and the time to definitive fixation did not correlate with avascular necrosis (AVN) rates. Actually, patients who developed osteonecrosis underwent ORIF earlier than those without AVN (1.7 days vs 4.8 days; $p < 0.001$). Authors believed that this difference might be attributed to a difference in the severity of fractures in both groups as there were more open fractures in the group that underwent urgent fixation. They declared that their analysis did not account for that potential confounding effects.

In addition, even when prior studies have suggested no association between the timing of definitive fixation and osteonecrosis,[3],[5] none of those studies specifically included the timing of reduction. Because of the small sample they were unable to determine an association between the timing of the reduction of dislocations and the development of osteonecrosis, but they stated that achieving an expeditious closed reduction is mandatory.[6]

Similarly, another study reviewed 106 talus fractures and fracture-dislocations and found that there was no effect from the time since the injury to surgical reduction on rates of AVN and posttraumatic osteoarthritis.[7] However, all these studies are retrospective and have relatively small sample sizes, so statistical power to reject the correlation between complication rates and surgical timing is limited.[8] In spite of this, these series consistently show that displaced talar neck fractures might not need to be treated as surgical emergencies. However, if dislocations are present, they must be reduced even if this requires an open reduction.

Resolution of clinical scenario

Even when urgent reduction and definitive fixation has been advocated for talar neck fractures, current evidence suggests that there is no difference in AVN rates, post-traumatic arthritis, union rate, or AOFAS hindfoot scores. Moreover, it seems that urgent open management gives rise to concerns regarding wound complications given the often severely traumatized soft tissues. With this in mind, in this case it seems reasonable to perform a closed reduction and, if congruence of the subtalar joint is restored, wait for the soft tissues to recover before performing the definitive fixation.

Question 2: In patients with displaced talar neck fractures, does surgery with dual approaches (anteromedial and anterolateral) result in better outcomes and fewer complications, compared with surgery with percutaneous fixation or arthroscopic-assisted reduction and fixation?

Rationale

Different surgical approaches have been used during the last decades to achieve better talar neck fracture reduction with the hope of reducing AVN rates and post-traumatic arthritis. Nevertheless, there is controversy about which surgical approach should be used. Some authors advocate for internal fixation under direct visualization by utilizing two surgical approaches, and others prefer smaller

percutaneous surgical approaches to preserve the soft tissues with the idea to protect vascular supply to the talus.

Clinical comment

Talar neck fractures often occur in high-energy trauma context so they are commonly presented as either fractures associated with some degree of soft tissue damage or as open fractures. However, nowadays there is no agreement about which surgical approach is better to perform the reduction and fixation, but there is a trend toward doing less-invasive approaches.

Available literature and quality of the evidence

This search produced no systematic reviews or randomized controlled trials. There are three retrospective studies (level III) related to this question. Whenever possible, these level III studies will be used to answer the question.

Findings

Even when there are not specific studies addressing this specific clinical question, different studies have been published showing the functional outcomes and complication rates with the different aforementioned techniques.

Beltran et al. did a retrospective review of 24 patients with talar neck fractures treated with a percutaneous posterior-to-anterior (PA) screw fixation finding an average AOFAS hindfoot score of 78.5 (range 28–100), an average Visual Analog Scale (VAS) for daily pain of 0.8 (range 0–4) and a Short Form 36 (SF-36) mental component score (MCS) and physical component score (PCS) averaging 49.1 ± 13.1 and 47.5 ± 12.4, respectively.[9] They reported one superficial surgical site infection, five transient, and one permanent numbness and paresthesias of the sural nerve. Besides,

62% of the patients developed subtalar arthrosis and 42% showed AVN but without joint collapse. These outcomes compare favorably to a previously published systematic review and meta-analysis.[10]

Xue et al. followed 28 patients treated with plate fixation through dual approaches for an average period of time of 25 months.[11] Their cohort showed a mean AOFAS hindfoot score of 78 (range 65–91). SF-36 PCS and MCS domains averaged 68 (range 59–81) and 74 (range 63–85), respectively. Although SF-36 scores differ between both series and are higher in the group of patients treated with dual approaches compared with the group that underwent percutaneous fixation, both populations are not comparable because they did not have the same fracture characteristics (Beltran et al. series had four open fractures and one Hawkins type IV fracture, compared with no open fractures or Hawkins type IV fractures in Xue et al.'s series).

Wagener et al. published a case series of seven patients with a Hawkins type II talar neck fractures treated arthroscopically.[12] Patients did not suffer any complications or AVN at a mean follow-up of 2.2 years. Unfortunately, they did not report on SF-36 or AOFAS scores, so it makes it hard to compare the results with previous published series.

Resolution of clinical scenario

As current evidence does not allow for a precise conclusion of which intervention has better functional outcomes and fewer complications for displaced talar neck fractures, probably the best recommendation for surgeons is that they should perform the surgical fixation they feel more comfortable with and experienced at until new evidence arises on less invasive methods (overall quality: low).

Question 3: In patients with displaced talar neck fractures, does plate fixation result in better biomechanical stability compared with fixation using only screws?

Rationale

Varus malunion is a common source of late morbidity from talar neck fractures. Rates higher than 30% have been reported.[4,13] Varus malunion shortens the medial column, locking the hindfoot in varus and internal rotation causing altered gait patterns and lateral column overload.[14]

As little as 3° of malunion produces a significant loss of motion in the subtalar joint.[14] Avoiding this problem is essential in talar neck fracture management and in order to do so there is a need to achieve stable fixation. Controversy exists whether screws or plates have better biomechanical properties to treat these fractures, both with and without associated comminution.

Clinical comment

Traditionally, it has been taught that these fracture fixations have a tension failure side (simple fracture pattern) and a compression failure side (comminuted fracture patterns). It is believed that screws are good for simple fracture patterns and comminuted fracture patterns are better fixed using a plate over the comminuted side.

Available literature and quality of the evidence

This search produced no systematic reviews or randomized controlled trials. There are five mechanical studies comparing different fixations techniques (level II).

Findings

Swanson et al. compared four different fixations (crossed 2.0 mm Kirschner wires [K-wires], two anterior-to-posterior [AP] 4.0 mm screws, two PA 4.0 mm screws, and one PA 6.5 mm screw plus a 2.0 antirotatory K-wire) on a model with minimal dorsal comminution.[15] Yield load, yield deformation, stiffness, and energy absorbed were significantly higher for both PA techniques with the best results for the two screws technique ($p < 0.001$).

Charlson et al. assessed the biomechanical properties of either 4.0 mm partially threaded cancellous screws placed PA and a four-hole 2.0 mm mini-fragment plates secured with 2.7 mm screws on a comminuted talar neck model.[16] PA screw fixation had statistically higher load to failure (120.7 ± 68.5 N vs 89.7 ± 46.6 N; $p < 0.05$) in a model of comminuted dorsal talar neck fractures. Nevertheless, the magnitude of the difference of around 30 N might not be that relevant (about six pounds). Interestingly, they compared the ultimate strength with previousfindings[15] and noticed that comminution greatly decreased construct strength by an order of magnitude.

Attiah et al. compared three techniques: three AP screws (one 3.5 mm cortical, and two 4.0 mm cancellous screws), two PA 4.0 mm cannulated cancellous screws and one 4.0 mm cancellous screw with a medially applied 2.7 mm mini-fragment blade plate (BP) on a model with dorsal medial comminution.[17] They did not find any statistical difference but a 25% decrease in fixation strength was observed in the group of three AP screws compared to the other two methods of fixation. The yield points (kN) for AP screws, PA screws, and BP were 1.48 ± 1.06 vs 1.88 ± 0.49 vs 1.83 ± 0.96, respectively ($p > 0.05$). Loads to 3 mm deformation were 1.26 ± 0.88 vs 1.48 ± 0.47 vs 1.41 ± 0.66 for the AP, PA, and BP groups, respectively ($p > 0.05$).

Capelle et al. performed biomechanical testing in a talar neck fracture model comparing headless variable-pitch screws with conventional screws.[18] The interventions compared were: fixation of the talar neck fractures with two cannulated headless variable-pitch 4/5 screws or two 4.0 mm conventional screws. In all cases the screws were inserted from AP. Results showed that fixation with headless variable-pitch screws had significantly lower failure displacement than the conventional screws. Besides, no significant differences were found between both fixation techniques for the energy absorbed, failure stiffness, or load at failure. However, differences in stiffness ($p = 0.058$) and energy absorption ($p = 0.065$) between screw types were quite large and very close to statistical significance favoring headless variable-pitch screws.

Karakasli et al. compared mechanical properties of headless screw fixation and locking plate fixation for talar neck fractures on a model with a simple transverse fracture.[19] They used two AP cannulated headless variable-pitch 4 mm/5 mm screws and a 2.7 mm locking plate. Headless variable-pitch screw fixation had lower failure displacement than the locking plate fixation. There were no significant differences in failure stiffness, yield load, yield stiffness ($p = 0.065$), or ultimate load between the two fixations techniques.

Resolution of clinical scenario

Many fixation options have been compared showing similar biomechanical properties. PA screws are superior to AP screws, and they seem to have at least similar biomechanical stability compared to plate fixation, even in comminuted talar neck models. Also, there is some evidence showing that headless variable-pitch screws might be superior to traditional cancellous screws.

With current evidence, it appears that talar neck fracture fixation using either plates or screw-only constructs provide appropriate biomechanical stability (overall quality: low).

Summary of answers

- Best current evidence shows that there is no difference in AVN rate, post-traumatic arthritis, union rate, or AOFAS hindfoot scores when comparing urgent versus delayed ORIF in displaced talar neck fractures.
- Urgent ORIF seems to be related with increased early wound complications so, even when the quality of evidence is low, currently it is reasonable to wait for the soft tissues to recover before performing the definitive fixation in patients with displaced talar neck fractures, if peri-talar joints are congruent.
- Existing evidence does not allow for precise conclusion of which kind of approach results in better outcomes and fewer complications in patients with displaced talar neck fractures.
- PA screws are biomechanically superior to AP screws in talar neck fracture models.
- Both plates and screw fixation provide appropriate biomechanical stability for displaced talar neck fractures.

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Calcaneal Fractures

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Clinical scenario

- A 35-year-old male construction worker is brought to the Emergency Department following a 3 m fall at work. He complains of left heel pain and is unable to weight bear on the left.
- Initial trauma workup reveals an isolated injury to the left calcaneus, with no spinal or ipsilateral lower limb fractures. His left foot is very swollen and tender posteriorly with a few blisters.
- This man has no medical problems except he has smoked one pack/day for 20 years.

Top three questions

1. In adults with displaced intra-articular calcaneal fractures, does nonoperative treatment provide long-term functional outcomes as good as operative care (open reduction and internal fixation [ORIF])?
2. In adults with displaced intra-articular calcaneal fractures, does minimally invasive reduction and percutaneous fixation provide long-term functional outcomes as good as ORIF?
3. In adults with displaced intra-articular calcaneal fractures, does primary fusion provide long-term functional outcomes as good as ORIF?

Question 1: In adults with displaced intra-articular calcaneal fractures, does nonoperative treatment provide long-term functional outcomes as good as operative care (open reduction and internal fixation [ORIF])?

Rationale

Operative treatment of calcaneal fractures is associated with a significant risk of serious complications. As such, it is important that both the treating surgeon and the patient are aware of the expected outcome of the three options of operative treatment (ORIF, minimally invasive reduction, and primary fusion) and nonoperative treatment so that this can be accurately balanced against the risks involved with the chosen treatment.

Clinical comment

Most trauma surgeons would currently suggest operative treatment of a displaced intra-articular calcaneal fracture in an otherwise healthy young male manual worker. Clinical features that would push a surgeon to do an ORIF in a patient with a displaced intra-articular calcaneal fracture are young age, active lifestyle, simple fracture, good soft tissue envelope, nonsmoker, and good clinical expertise.

Available literature and quality of the evidence

A literature search provided us with eight randomized controlled trials (RCTs)[1–8] and four meta-analyses.[9–12] All of these RCTs are of level II strength (as they each have some methodologic flaws) and none of them is of the size to accurately answer this tough problem alone. However, together they create a good body of work and can provide some clinical direction to answer this tough question.

The four meta-analyses were done between 2009 and 2017 and thus reflect the difference in timing of the appearance of the above RCTs.[9–12] When combined, these four papers have very similar summaries.

Findings

These papers state that we are still in need of a large RCT to answer this question definitively.[1–12] They also state that surgical complications are the big downside of ORIF but that clinical outcomes are somewhat better with ORIF.

Pooled results of the eight RCTs showed that patients managed nonoperatively failed to resume pre-injury work (risk ratio [RR] = 0.60; 95% confidence interval [CI]: 0.37–0.98; p = 0.04). However operative intervention was associated with more complications (RR = 1.74; 95% CI: 1.28–2.37; p = 0.0005). There was no statistically significant difference in residual pain (RR = 0.73; 95% CI: 0.40–1.36; p = 0.33) and re-operation (RR = 0.75; 95% CI: 0.48–1.16; p = 0.20) between the two groups.

Surgically managed patients are more likely to resume their pre-injury work. Buckley et al. noted that patients with light-to-moderate work may lead to better recovery with surgery.[4] However, patients with heavy workloads are unlikely to recover well regardless of the treatment type. Buckley et al. and others reported better functional results and less pain when Bohler's angle was restored and anatomic reductions were achieved. On the other hand, Ibrahim et al. found no association between radiographically measured restoration of the angle and clinical outcome.[5]

Operatively managed patients had fewer problems while wearing shoes. This may be due to the fact that surgery results in the restoration of preinjury calcaneal width. Patients who underwent surgery were likely to have less pain as compared to those who underwent nonoperative management, although the difference did not reach statistical significance.

Although operative intervention showed good outcomes, they also had a significantly higher incidence of complications. Complication rates were much higher with surgery with the most frequent complication being infection with rates between 5 and 15%.

Resolution of clinical scenario

- Complications must be avoided for the best results when managing these patients (RR = 1.74; 95% CI: 1.28–2.37, p = 0.0005).
- Operative care is slightly better in younger patients as they have fewer complications than the older patient with more medical problems (overall quality: moderate).
- Functional outcome is slightly better in the operatively managed patient provided complications are not encountered (overall quality: moderate).
- Return to heavy labor is unlikely after a displaced intra-articular calcaneal fracture regardless of treatment type; return to work may be improved with operative treatment (overall quality: moderate).
- Better restoration of anatomy can lead to a better clinical result as footwear is easier to manage in the operatively treated patient (overall quality: moderate).

- No statistically significant difference in pain or functional outcome between operative treatment modalities and nonoperative treatment (overall quality: moderate).
- Subtalar arthrodesis rates are significantly decreased after operative treatment (overall quality: moderate).
- This young laborer should undergo ORIF of his calcaneal fracture.

Question 2: In adults with displaced intra-articular calcaneal fractures, does minimally invasive reduction and percutaneous fixation provide long-term functional outcomes as good as ORIF?

Rationale

With minimally invasive reduction and fixation techniques becoming widely accepted in orthopedic trauma practice, the role of this technique in calcaneal fracture fixation is becoming clearer. Complications certainly are less with smaller incisions, and with less surgery, range of motion may be better, providing better long-term outcomes for patients.

Current opinion

Currently, over the last five years, there has been a real swing in popularity for surgeons to routinely use minimally invasive techniques for the treatment of displaced intra-articular calcaneal fractures rather than the classic extensile lateral calcaneal exposure. Fewer complications and better range of motion with less postoperative pain are pushing surgeons to move toward less invasive surgery to accomplish the same goals for patients.

Available literature and quality of the evidence

A literature search provided us with:

- Level II: 5 randomized trials[13–17] and 2 systematic reviews.[18,19]
- Level III: 3 prospective cohort or retrospective reviews.[20–22]

Findings

There are no level I studies comparing minimally invasive techniques to any other form of treatment but there are 10 level II or III studies and 2 systematic reviews.

The most recent RCT provided these findings: operative time in the minimally invasive percutaneous osteosynthesis (MIPO) group was 52.5 ± 11.1 min, which was significantly shorter than 82.8 ± 16.2 min in the conventional treatment group ($p < 0.001$).[17] One week postoperatively, the Visual Analog Scale (VAS) value was 3.2 ± 1.4 in the MIPO group, which was lower than that in the conventional treatment group, 3.9 ± 1.3 ($p = 0.038$). In the conventional treatment group, 13 of 35 fractures (37.1%) had wound healing problems, whereas this issue occurred in only 2 of 29 fractures (6.7%) in the MIPO group ($p = 0.004$). In the MIPO group, deep and superficial infections occurred in none of the cases and 1 of 29 (3.4%) patients, respectively. Length of incision in the MIPO group was shorter than that in the conventional treatment group (4.2 ± 0.6 vs 10.9 ± 1.5 cm; $p < 0.001$). Hospital stay was 9.7 ± 2.8 days in the MIPO group and 11.7 ± 2.6 days in the conventional treatment group ($p = 0.004$). At the last follow-up, the Short Form 36 (SF-36) scores and AOFAS scores in the two groups were comparable ($p > 0.05$). The postoperative radiographic data, the Bohler's angle, Gissane's angle, and calcaneal height, width, and length in the two groups were comparable ($p > 0.05$).

A systematic review states that the results from the current data appear to be promising;[18] however, the lack of statistical power and inconsistent documentation have made it difficult to determine any superiority. The complication rates were much lower than those with open procedures, regardless of the technique. The percutaneous fixation technique appears to be a favorable option for displaced intra-articular calcaneal fractures.

Resolution of the clinical scenario

- At present, there is strong and growing evidence regarding the use of minimally invasive techniques for calcaneal fracture fixation.
- Functional outcomes are at least equal, complications are much less with smaller incisions, time in hospital is less, and early postoperative pain is also less.
- The sinus tarsi approach is the approach of choice for reduction of the joint with percutaneous fixation with screws and/or plates and screws.
- This 35-year-old laborer (also a smoker with potential wound problems) should have minimally invasive reduction with percutaneous fixation using the sinus tarsi approach.

Question 3: In adults with displaced intra-articular calcaneal fractures, does primary fusion provide long-term functional outcomes as good as ORIF?

Rationale

Should the preoperative CT scan demonstrate that this patient has a Sanders type IV comminuted displaced intra-articular calcaneal fracture, then besides the option of ORIF, this patient may be served by a primary subtalar fusion. The more severe the fracture, the more that this option can become relevant because of the difficulty with obtaining a satisfactory ORIF.

Clinical comment

It is difficult to obtain an anatomic reduction in this type of fracture. Some surgeons would recommend immediate subtalar arthrodesis given that this fracture pattern is often associated with poor functional results after an ORIF and a high rate of late subtalar arthrodesis regardless. The argument is that why would a surgeon ever do an ORIF for a patient with a Sanders type IV fracture if a second operation (secondary fusion) is needed in a high percentage of patients anyway.

Available literature and quality of the evidence

- 2 level II studies[23,24]
- 2 level III studies[25,26]
- 3 level IV studies[27–29]
- 1 systematic review.[30]

Findings

There are two level II studies that compare reconstruction and primary subtalar arthrodesis (PSTA) with reconstruction for severe (Sanders type IV) fractures. In a study by Buckley, 26 patients (26 displaced intra-articular calcaneal fractures) were followed

for a minimum of two years (81% follow-up).[23] No statistical difference was found between the results for ORIF compared with ORIF + PSTA: the mean SF-36 physical component scores were, respectively, 30.2 (standard deviation [SD] = 11.4) and 37.8 (SD = 10.4) ($p = 0.10$); the mean Musculoskeletal Functional Assessment Survey scores were 44.2 (SD = 25.6) and 37.9 (SD = 21.5) ($p = 0.50$); the mean Ankle-Hindfoot Scale scores were 62.5 (SD = 19.6) and 65.8 (SD = 19.2) ($p = 0.68$); and the mean VAS scores were 36.8 (SD = 34.7) and 36.0 (SD = 30.7) ($p = 0.82$). A Korean study showed that the results for ORIF did not differ from those for PSTA based on the last follow-up AOFAS scores or the VAS scores ($p > 0.05$).[24] However, patient satisfaction was significantly higher in the PSTA group ($p = 0.008$). Secondary subtalar arthrodesis was conducted in five patients (45.5%) of the ORIF group within two years postoperatively.

Resolution of clinical scenario

- There is some evidence to support acute subtalar arthrodesis as an appropriate treatment for Sanders type IV displaced calcaneal fractures.
- It can help prevent late secondary fusion after primary ORIF, and when done primarily, results in earlier return to work with good satisfaction.
- This patient should not have a subtalar fusion unless he has a Sanders type IV fracture.

Summary of answers

- No statistically significant difference in pain or functional outcome between operative treatment modalities and nonoperative treatment (overall quality: moderate).
- Minimally invasive surgery creates less complications and less pain with equal late functional outcomes (overall quality: moderate).
- Subtalar arthrodesis is a viable option for Sanders type IV fractures and prevents the need for secondary fusion (overall quality: moderate).
- Current evidence suggests that treatment of displaced intra-articular calcaneal fractures be tailored to the individual, as summarized in Table 106.1.

Table 106.1 Important recent studies of high quality about displaced calcaneal fractures.[9]

Study year	Country	Cases Operative (O)/Nonoperative (NO)	Sex Male/ Female	Mean Age O/NO Years	Followup Years O/NO	Important conclusions of study	Jadad Score (quality of study)
O'Farrell 1993[1]	Ireland	12/12	20/4	33/38	1.3/1.2	Surgery improved functional results	2
Parmar 1993[2]	UK	25/31	48/8	48/48	2.1/1.8	No difference in functional outcomes between groups	2
Thordarson 1996[3]	USA	15/11	21/5	35/36	1.4/1.2	Improved walking ability after surgery	5.5
Buckley 2002[4]	Canada	206/218	381/43	41/39	3.0/3.0	No difference between outcome in the two groups but trends evident in RCT	6.5
Ibrahim 007[5]	UK	15/11	21/5	61/58	15.2/14.8	No difference between groups	4
Nouraei 2011[6]	Iran	31/30	No data	46/52	3.0/3.0	Surgery group more likely to resume pre-injury work	4
Griffin 2014[7]	UK	73/78	127/24	45/48	2.0/2.0	No difference between outcome in the two groups but more complications in the operative group	6

Study year	Country	Cases Operative (O)/Nonoperative (NO)	Sex Male/ Female	Mean Age O/NO Years	Followup Years O/NO	Important conclusions of study	Jadad Score (quality of study)
Agren 2013[8]	Sweden	42/40	59/23	49/48	10.0/10.0	No difference with short-term outcomes but operative group was superior over time	7

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107
Lisfranc Injuries

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Clinical scenario

- A 19-year-old motorbike rider attempts a large jump whilst off-road racing in a country competition.
- He lands poorly and feels his right foot get hyperextended with his foot against the foot pedal as he hits the ground and falls from his bike.
- There is immediate pain and he is unable to fully weight bear. He then rides home in pain, and walks with difficulty for the next few days until seeking medical attention. The local doctor sees a swollen foot with bruising on the plantar surface and does an x-ray that shows an avulsion fracture at the base of the second metatarsal but no obvious displacement.
- He is then placed in a controlled ankle motion (CAM) walker, allowed to weight bear as tolerated, and asked to present to the local fracture clinic in several weeks' time.

Top three questions

1. In a patient with a Lisfranc injury, does an anatomical reduction and fixation result in better outcomes than primary arthrodesis?

2. In a patient with a Lisfranc injury, does delayed or misdiagnosis adversely affect the outcomes compared to successful diagnosis and treatment?
3. In the active patient with a Lisfranc injury does, operative treatment allow for return to preinjury level of sport compared to nonoperative treatment?

Question 1: In a patient with a Lisfranc injury, does an anatomical reduction and fixation result in better outcomes than primary arthrodesis?

Rationale

A Lisfranc joint fracture dislocation is relatively rare, 0.1–0.9% of all fractures.[1] It is associated with significant morbidity and it is reported up to one-third of these injuries are missed. In contrast, midfoot sprains are commonly seen in athletes.[2] Unfortunately, a Lisfranc injury is a commonly missed diagnosis and this type of injury has the potential to lead to significant morbidity.[3] Key to this is the reduction of the articulation between the second metatarsal and the middle cuneiform and fixation which replicates the function of the Lisfranc ligament, tying the medial cuneiform to the second metatarsal.

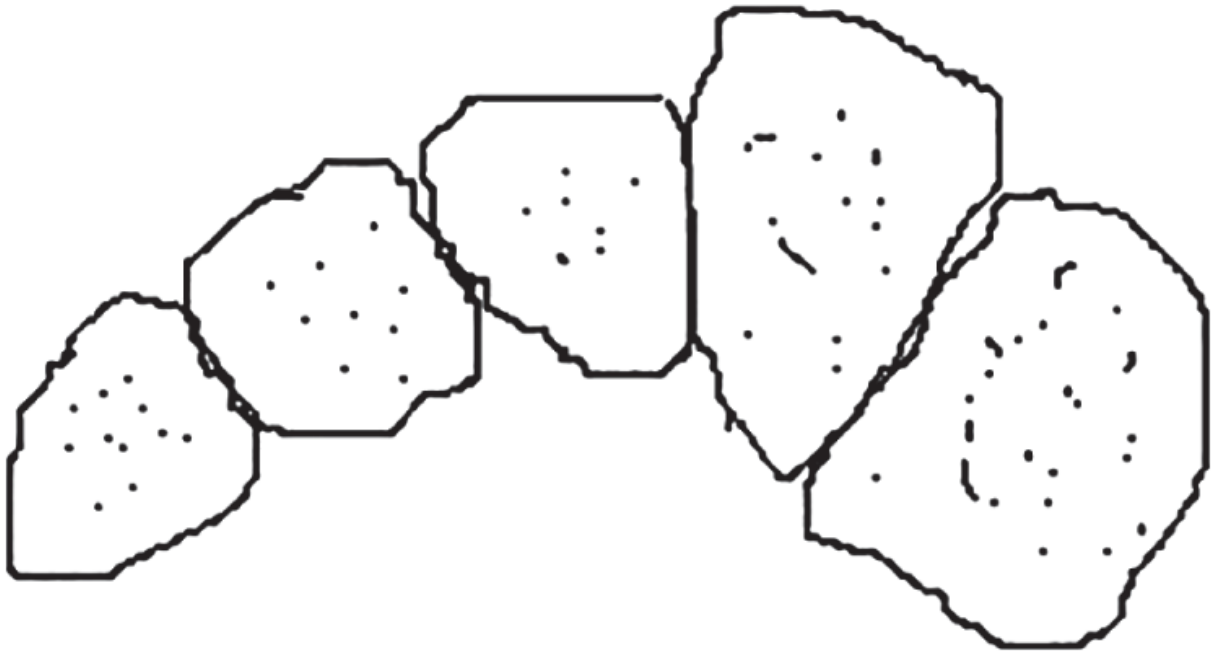

Figure 107.1 The Roman arch configuration of the Lisfranc complex.

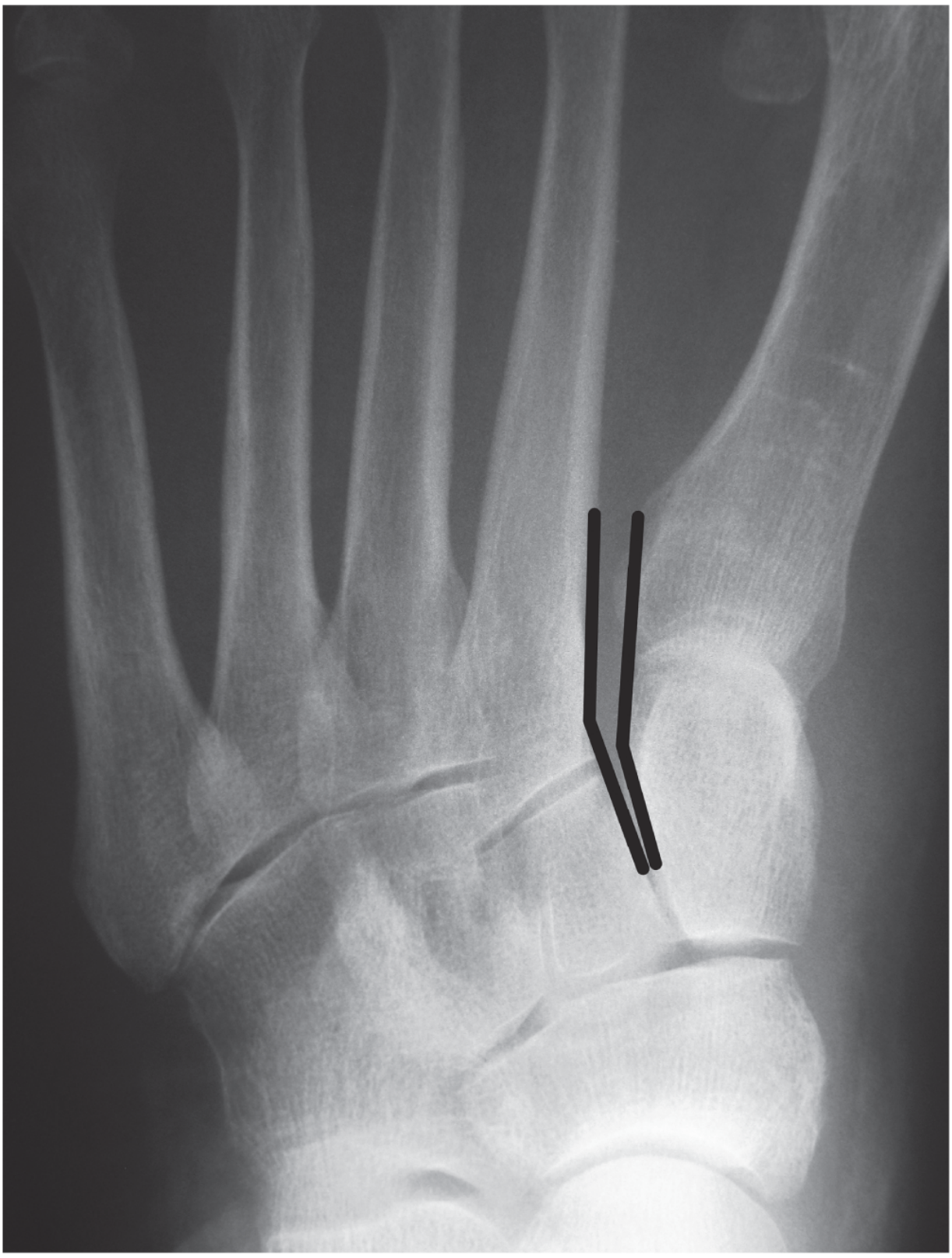

Figure 107.2 Anteroposterior view showing alignment of the lateral borders of the first metatarsal and the medial cuneiform as well as the medial borders of the second metatarsal and the middle cuneiform.

Clinical comment

Lisfranc injuries require prompt anatomical reduction and surgical fixation with plates and screws. There is some debate regarding the effectiveness of primary arthrodesis as treatment for these injuries, but this has not become mainstream treatment. It is important to recognize purely ligamentous Lisfranc injuries, as these can be underappreciated, and there is emerging evidence to suggest primary arthrodesis can have a more favorable outcome in these select patients.

Available literature and quality of the evidence

A recent meta-analysis (level I) concluded that there was no difference in outcomes or quality of anatomic reduction between open reduction and internal fixation (ORIF) and primary arthrodesis.[4] Three studies were considered eligible for inclusion, and demonstrated similar patient reported outcomes, revision surgery rates, and anatomic reduction. It was demonstrated that there are greater rates of hardware removal with the ORIF group, which needs to be considered in the discussion with the patient,[4] which is also supported by other studies.[5]

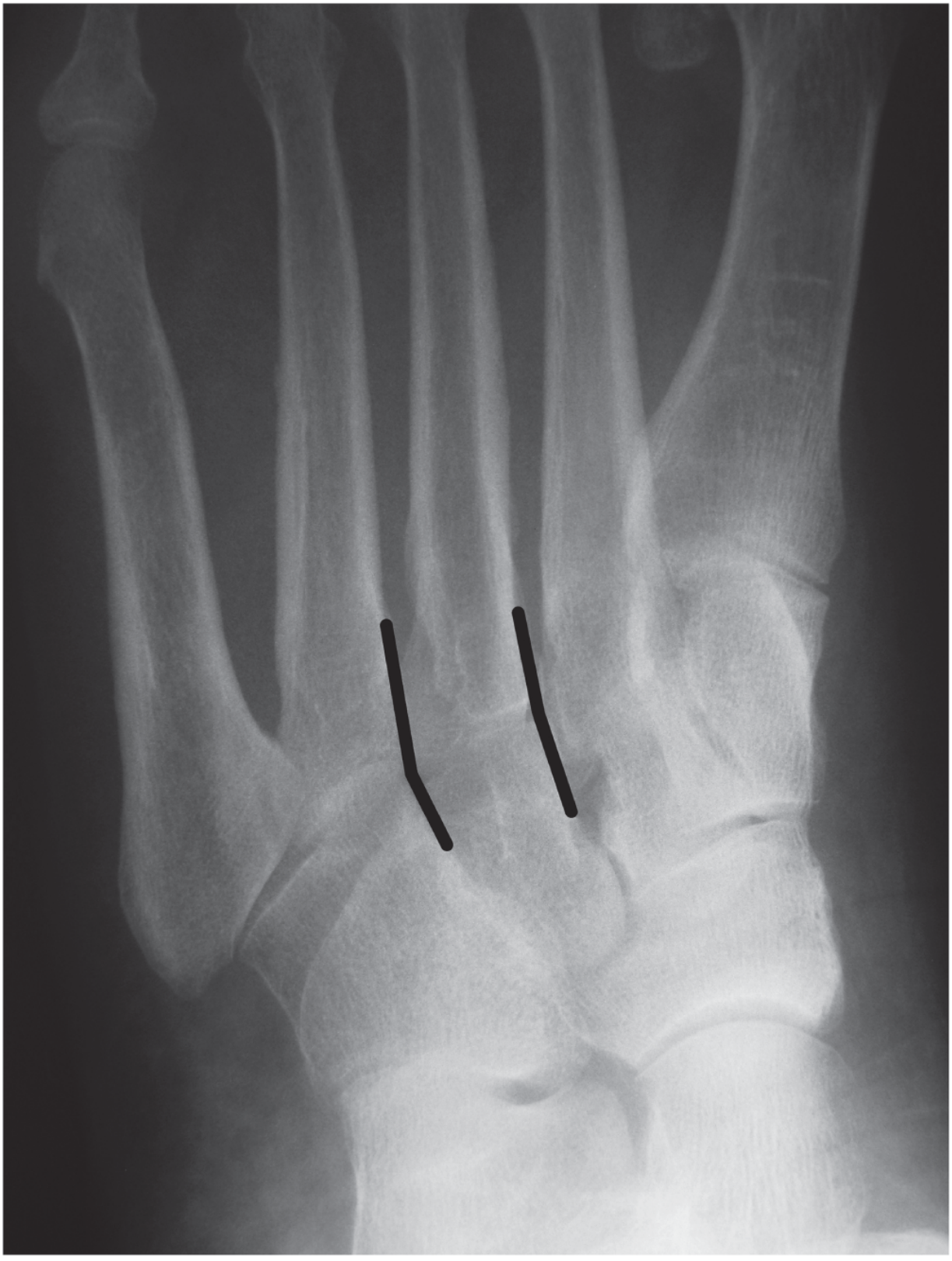

Figure 107.3 30° oblique view showing alignment of the medial borders of third metatarsal and the lateral cuneiform as well as the medial borders of the fourth metatarsal and the cuboid bone.

A prospective randomized study (level I) has also demonstrated no difference,[5] whereas a similarly constructed prospective, randomized study by Ly and Coetzee have shown improved short- and medium-term outcomes in the arthrodesis group.[6] Ly and Coetzee compared 41 patients with primarily ligamentous injuries for 42.5 months, and demonstrated an improved AOFAS midfoot score of 88 in the arthrodesis group and 68.6 in the open-reduction group ($p < 0.005$). The primary arthrodesis group estimated that their postoperative level of activities was 92% of their preinjury level, whereas the open-reduction group estimated that their postoperative level was only 65% of their preoperative level ($p < 0.005$).[6]

A comparative cohort study (level III) by Rammelt et al. compared 44 patients that underwent primary open reduction (22 patients) with delayed, corrective arthrodesis (22 patients) with a follow-up of 22 months and found that the primary fixation leads to improved functional results, earlier return to work, and greater patient satisfaction than secondary corrective arthrodesis ($p = 0.03$).[7]

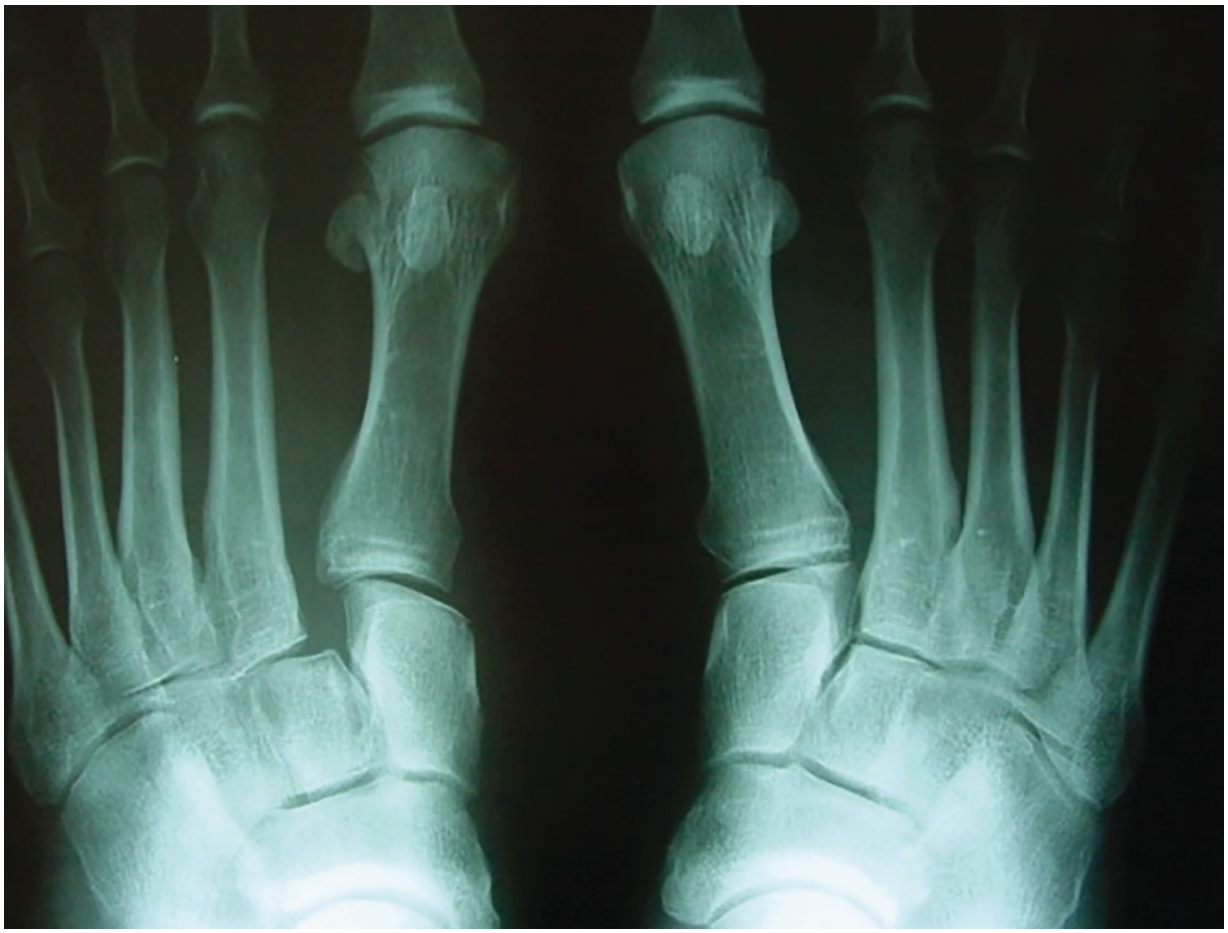

Figure 107.4 Weightbearing views showing instability of the left first and second tarsometatarsal joints and widening of the space between the first and second rays.

Numerous level IV case series are available to demonstrate the importance of accurate reduction and internal fixation. In Myerson's case series of 55 patients the major determinant of unacceptable results was identified as the quality of the initial reduction.[8] Goossens and De Stoop's case series of 20 patients showed that 70% of patients who were treated conservatively in an unreduced position had a poor outcome compared with only 18% of those who had reduction and pinning.[9] Arntz et al. showed in a consecutive series of 40 patients that good or excellent results were obtained in 95% of patients with an anatomical reduction but only 20% of those in whom the

reduction was nonanatomic.[10] One case series suggested that anatomical reduction was not a guarantee of satisfactory outcome: Teng et al. reported that the subjective functional outcome in their series of 11 patients was not very good despite successful restoration of normal anatomy.[11]

Findings

Overall, level I evidence has shown mixed support for undertaking a primary arthrodesis for Lisfranc injury. Ly and Coetzee have demonstrated favorable outcomes for patients with a primarily ligamentous injury treated with a primary arthrodesis with a significant improvement in midfoot AOFAS scores in the arthrodesis group at two years.[6] Whereas, Henning et al. demonstrated in 40 patients no significant difference in Short Form 36 (SF-36) and short musculoskeletal functional assessment (SMFA) score.[5]

Level III evidence also demonstrates no difference in outcomes or quality of anatomic reduction between ORIF and primary arthrodesis.[7] Level IV studies have demonstrated the need for anatomical reduction and rigid internal fixation has been shown to be an important factor in the eventual outcome.[5–11]

Resolution of clinical scenario

- Level IV evidence suggests restoration of normal anatomy and surgical fixation gives the best chance of a favorable long-term outcome.
- Level I evidence suggests similar outcomes can be expected with anatomic reduction and primary arthrodesis, though a higher rate of removal of hardware in the anatomic reduction group.

- Level I evidence suggests that, in the primarily ligamentous injury group, consideration for primary arthrodesis should take place.

Question 2: In a patient with a Lisfranc injury, does delayed or misdiagnosis adversely affect the outcomes compared to successful diagnosis and treatment?

Rationale

Lisfranc injury is a commonly missed diagnosis in the acute setting, and although it is a rare injury, the potential for a poor outcome is significant, especially if mismanaged.[12,13] A missed Lisfranc injury is reported to lead to progressive planovalgus deformity, instability, and post-traumatic arthritis.[14]

Clinical comment

In this case, the diagnosis was not significantly delayed, surgical intervention would not be recommended before the swelling had settled, and there is only evidence in the literature that a significant delay (six months) in treatment would affect outcome (level IV).[15] Nevertheless, clinicians who regularly attend to patients with acute foot trauma should always be alert to the possibility of a Lisfranc injury in order to expedite prompt further investigation and management. Clues to aid in diagnosis include a mechanism of injury including hyperplantarflexion (toe catching the ground in a motorbike, foot plantarflexing of a rigid surface like stairs/curbside, or caught in a horse's stirrup), midtarsal pain, swelling, and plantar ecchymoses.[16]

Lisfranc injuries often occur with significant trauma to the foot. Most specialists would advocate a period of elevation, icing, and observation in the initial 24–48 hours. At the same time further investigations should be arranged, if necessary, to assess tarsometatarsal stability. Plain radiographs and weightbearing/stress radiographs are appropriate initial investigations. If these are normal or equivocal and there is ongoing clinical suspicion of a Lisfranc injury then further investigation with computed tomography (CT) or magnetic resonance imaging (MRI) should be arranged. Both study mediums are more sensitive in identifying midfoot fractures and malalignments than plain and stress radiographs.[17]

Available literature and quality of the evidence

Multiple case reports and case series have reported on the sequelae of delayed or missed diagnosis in Lisfranc injuries (level IV). Loss of range of movement in the midfoot is well recognized after this injury. Wilson found that almost all patients in his series displayed some degree of stiffness and this was related to the quality of the initial reduction.[18] Complex regional pain syndrome (CRPS) has been reported in 25% of the patients in his series, and missed or delayed diagnosis was thought to be an important factor in many of those cases.[9] Disruption of the Lisfranc complex can result in a planovalgus deformity. There is conflicting evidence as to whether this is significant in terms of outcome. Aitken and Poulson reported good functional outcomes in their case series despite obvious residual deformity.[19] This is contrary to the findings of Faciszewski et al., who reported that maintenance of the longitudinal arch is a major determinant of outcome.[20] Post-traumatic arthritis is the most common long-term complication in Lisfranc injuries. In many series this is reported to occur in a significant number of cases and is a significant cause of long-term

morbidity.[8,21] Calder et al. retrospectively analyzed 46 patients with Lisfranc injury and demonstrated there was a worse outcome in terms of return to work when there was delay in diagnosis of greater than six months ($p = 0.01$), with age, gender, mechanism, or occupation prior to injury not appearing to affect outcome.[15]

Findings

Overall, published data reporting on the sequalae of missed diagnosis are restricted to case reports and small case series (level IV). These studies demonstrate that postinjury stiffness is related to the quality of initial reduction.[18] Missed or delayed diagnosis of injury can have an important influence on the development of CRPS,[9] planovalgus deformity,[19,20] and post-traumatic arthritis.[8,21]

Resolution of clinical scenario

- Level IV evidence Lisfranc injuries are best treated acutely to avoid potential problems associated with missed or delayed diagnosis.
- Level IV evidence suggests that missed or delayed diagnosis can have an important influence on the development of CRPS, planovalgus deformity, post-traumatic arthritis, and ability to return to work.

Question 3: In the active patient with a Lisfranc injury does, operative treatment allow for return to preinjury level of sport compared to nonoperative treatment?

Rationale

Managing expectations is an important aspect of treating surgical patients, and a thorough knowledge of prognosis helps in this respect.

Clinical comment

Return to a preinjury level of sporting activity is difficult to predict with Lisfranc injuries, and become increasingly less likely in those with missed diagnosis of a Lisfranc injury.

Available literature and quality of the evidence

Retrospective cohort studies (level III) have demonstrated high rates of return to sport (and preinjury levels) in both operatively and nonoperatively treated Lisfranc injuries. Nunley and Vertullo reported on 15 patients with Lisfranc injuries sustained playing sport.[22] Seven of these injuries were diagnosed as sprains and treated conservatively and eight required operative treatment. All patients in their series returned to sport (average 15.2 weeks) and an excellent result in 93%.[22] McHale et al. found that of 28 NFL athletes treated for a Lisfranc injury 26 returned to sport, though at longer time period compared to other studies, up to 15 months. Those that were treated nonoperatively (six patients) returned at a mean of 6.2 months compared to those treated operatively (22 patients) returning at a mean of 11.1 months. Importantly, their study reported on performance (Offensive Power Rating, Defensive Power Rating), positional demands and durability matched against 162 players in a control group.[23]

Multiple level IV studies have assessed return to preinjury levels of function with mixed levels of success. Hawkinson et al. published a retrospective review of 171 military personnel treated for Lisfranc fracture/dislocation.[16] Of 111 who had complete data, 91 underwent an ORIF and 20

a primary arthrodesis. Overall 75 (68%) returned to full active duty, 5(4%) to limited duty, and 31 (28%) were discharged from service due to pain and/or disability. This study had many limitations, no radiological or surgical records were available to the authors, the information they had was limited to medical notes through the military database.[15] Other level IV studies have reported a case series including five gymnasts with Lisfranc injuries, only one returned to full competition[24] and a reported 3 of 19 patients with Lisfranc injury were unable to return to their sports.[25]

Doel et al. undertook a retrospective review of English premier league and championship rugby players, with 16/17 surgically managed players returning to full competition between 21–31 weeks post injury (level IV).[26] The authors attribute the excellent outcomes to avoiding metalware across joint surfaces and access to prompt, high-quality rehabilitation.

Findings

Overall, there is difficulty in predicting postinjury levels of activity and satisfaction. There is, however, level III and level IV evidence that suggests elite level athletes who have sustained an injury in their sport have high rates of returning to preinjury levels.[22,23,26] However, other level IV evidence suggests that these rates of return are not as reliable in predicting return to preinjury levels of ability.[16,24,25] This may reflect the difference in injury mechanism, injury type, treatment type and postinjury rehabilitation access, as well as study design and quality. Recent studies are becoming more optimistic in predicting outcomes after Lisfranc injury, which may reflect improved imaging, increased suspicion for injury, and a focus on anatomic reduction and surgical technique.

Resolution of clinical scenario

- The outcome of Lisfranc injuries is not predictable from the current literature, although recent studies are more optimistic than older ones.
- Level III and level IV evidence suggests that those patients injured playing sport can have reasonable expectations to return to similar levels of preinjury ability and satisfaction, though this may take up to 15 months.

Summary of answers

- Lisfranc injuries are best treated acutely to avoid potential problems associated with missed or delayed diagnosis.
- In treating Lisfranc injuries restoration of normal anatomy and surgical fixation gives the best chance of a favorable long-term outcome.
- Primary arthrodesis is a viable treatment option, and has less cases of a need to remove hardware than those patients treated with internal fixation.
- Primary arthrodesis should be considered in the primarily ligamentous Lisfranc injuries.
- Awareness of the immediate and late complications of Lisfranc injuries is essential.
- Patients injured playing sport can have reasonable expectations to return to similar levels of preinjury ability and satisfaction

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Fifth Metatarsal Fractures

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Clinical scenario

- A 30-year-old football player attempts a tackle and “rolls” her ankle in the process.
- She has immediate pain but manages to finish the game with a limp.
- The pain worsens on the lateral border of the foot over the next few days and she presents to the Emergency Department complaining of pain, swelling, and difficulty mobilizing.
- A radiograph is taken showing a base of fifth metatarsal fracture and she is given a controlled ankle motion (CAM) walker to weight bear in for the next six weeks.
- She is gradually weaned from the CAM walker and finds she still has pain with weightbearing at the three-month mark with no radiological signs of fracture union.

Top three questions

1. In patients with a proximal fifth metatarsal fracture, does the pattern of injury affect the clinical and radiological outcome?

2. In patients with a proximal fifth metatarsal fracture, does operative fixation result in better outcomes than nonoperative management?
3. In patients with a proximal fifth metatarsal fracture, does intramedullary screw fixation lead to better biomechanical and clinical outcomes than other operative treatment options?

Question 1: In patients with a proximal fifth metatarsal fracture, does the pattern of injury affect the clinical and radiological outcome?

Rationale

Fractures of the fifth metatarsal are the most common fractures sustained in the foot.[1,2] Fractures of the base are classified into three zones, which have been found important for prognosis and determining fracture management.[2,3]

Clinical comment

The classification and description of fractures of the proximal fifth metatarsal can be confusing and central to this has been the regular mis-use of the term *Jones' fracture*. Sir Robert Jones was one of the forefathers of British orthopedics and founder of the British Orthopaedic Association. In 1902, he wrote a case series on fractures of the fifth metatarsal, one of which was his sustained through dancing.[3,4] A zone 1 (avulsion) fracture is proximal to the fourth/fifth intermetatarsal joint and represents an avulsion of the tuberosity. A zone 2 (Jones) fracture is in the vascular watershed zone between the diaphysis and metaphysis, at the level of the intermetatarsal joint. A zone

3 (diaphyseal stress) fracture is distal to this in the proximal diaphysis (Figure 108.1).2 Zone 3 fractures were qualified further by Torg et al., who described a classification system with a type 1 indicating an acute fracture, a type 2 representing delayed union with a wide fracture line and intramedullary sclerosis, and type 3 is a nonunion with a wide fracture line and extensive intramedullary sclerosis.5 Further work has differentiated fractures into complete and incomplete fractures, where an incomplete fracture is more likely to progress to nonunion in weightbearing as there are tensile forces over the lateral cortex and compressive forces medially.6

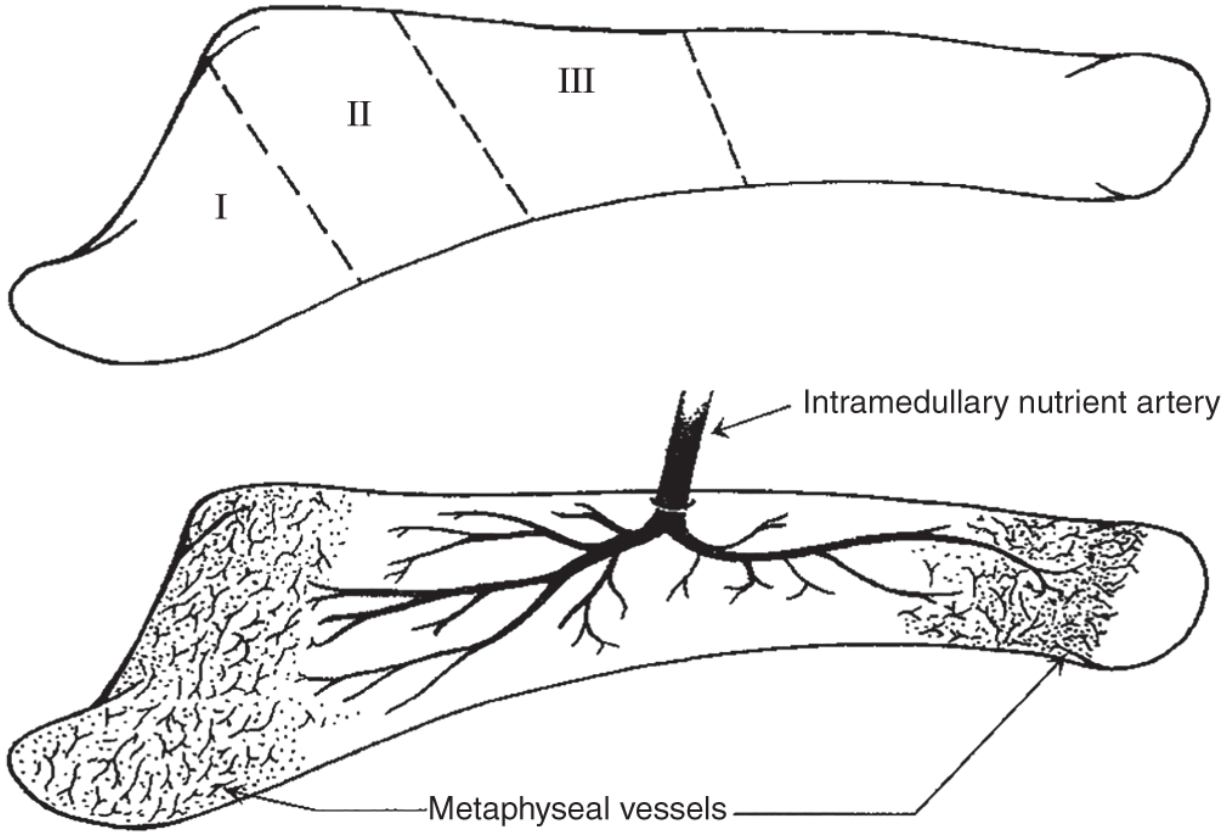

Figure 108.1 (Top) Dameron's three zones of the proximal fifth metatarsal. Zone 1 injuries are avulsion fractures of the tuberosity. Zone 2 injuries are fractures involving the intermetatarsal facet (as described by Jones). Zone 3 injuries are proximal diaphyseal fractures. (Bottom) Blood supply.9

Available literature and quality of the evidence

Level IV studies have further demonstrated the anatomical location affecting fracture location and union. Clapper et al. reviewed a series of 100 patients with fifth metatarsal fractures which were followed prospectively to determine outcomes of their injuries: three distinct subgroups were identified depending on fracture location.7 The study showed 68 zone 1 (avulsion), 25 zone 2 (Jones), and 7 zone 3 (diaphyseal stress) and provided a treatment algorithm, which yielded 100% union at 4.7 weeks for zone 1

(avulsion) injuries treated nonoperatively, and 100% union at 5.8 weeks for zone 3 (diaphyseal stress) injuries treated nonoperatively, and only 72% union at an average of 21.2 weeks for zone 2 (Jones) injuries treated nonoperatively.[7] A similar union rate was demonstrated by Kavanaugh et al., with a series of 22 zone 2 (Jones) fractures having delayed healing in two-thirds of those cases treated conservatively.[8]

Other level IV studies have reported on union rates in zone 1 (avulsion) fractures. Dameron reported a case series of 100 tuberosity fractures (zone 1) treated conservatively, all but one healed clinically within three weeks.[9] Vorlat et al. reported on a case series of 38 patients with zone 1 (tuberosity) fractures, and found the most significant predictor of poor functional outcome was prolonged nonweightbearing. Gender, age, and fracture type did not affect outcome.[10] A single level II study has also demonstrated 100% union rates in 60 patients with zone 1 (avulsion) fractures with nonoperative treatment.[11]

Lee et al. reviewed a cohort of 75 patients (level III), and introduced the concept of the plantar gap in the zone 3 (diaphyseal stress) injury; the distance between the fracture margins, measured on the lateral cortex of an oblique radiograph. The mean time for bone union in those patients with a plantar gap <1 mm was 71.21 ± 29.95 days compared to 126.4 ± 51.99 days in those with a plantar gap >1 mm ($p < 0.001$).[6]

Findings

Overall, there are many level IV studies that have been used to define proximal fifth metatarsal fractures, with Clapper et al. reporting on fracture pattern and union rates in 100 proximal fifth metatarsal fractures.[7] Torg et al. provided further understanding and classification with

description of the acuity of zone 3 injuries,[5] and Lee et al. introduced the concept of plantar gap distance having an effect on time to union.[6]

Multiple level IV studies[9,10] and a single level II[11] study have demonstrated excellent union rates in zone 1 (avulsion) fractures treated nonoperatively. Other level IV studies have shown that union rates in zone 2 (Jones) and zone 3 (diaphyseal stress) fractures are far less reliable with nonoperative treatment.[6–8] A retrospective study of 22 patients with zone 2 (Jones) fractures or zone 3 (diaphyseal stress) fractures treated surgically showed all fractures united (mean 6.25 weeks) with no to rare pain reported during athletic activity.[12]

Resolution of clinical scenario

- Zone 1 (avulsion) fractures should be treated nonoperatively, with symptomatic treatment being sufficient, with patients resuming normal activities as their symptoms permit irrespective of radiological appearance.
- Zone 2 fractures (Jones fracture) are slower to heal and more prone to re-fracture. A short leg cast or a functional brace may be used; however, surgical fixation should be considered, particularly in an athletic population.
- Zone 3 (diaphyseal stress) fractures are prone to nonunion and surgical fixation results in a quicker time to union and return to sport and this may be beneficial in selected patients.

Question 2: In patients with a proximal fifth metatarsal fracture, does operative fixation result in better outcomes than nonoperative management?

Rationale

The majority of proximal fifth metatarsal fractures heal with conservative management.[8,9] There is a small group which are prone to delayed healing and nonunion, which have been subclassified by Torg[5] and added to by Lee et al.[6] Identifying those patients which are best suited for operative management can be challenging. Return to a preinjury level of sporting activity can almost always be expected after a proximal fifth metatarsal injury.

Clinical comment

Zone 1 (avulsion) fractures and distal metatarsal fractures are commonly treated symptomatically, with evidence indicating weight bearing helps with fracture healing. Zone 2 (Jones) and 3 (diaphyseal stress) injuries, when treated conservatively, should be put in a CAM walker or plaster. Current recommendation in most patients would be to nonweightbear initially then consider changing at 4–6 weeks to weightbearing in a CAM walker until radiological union. In an athlete with an acute zone 2 (Jones) fracture or zone 3 (diaphyseal stress) fracture, most specialists would advise operative fixation to achieve a more rapid time to union and return to sport. Return to a preinjury level of sporting activity can almost always be expected after a fifth metatarsal injury.

Available literature and quality of the evidence

A randomized controlled trial (level I) compared cast treatment (n = 18) to screw fixation (n = 19) in acute zone 2 (Jones) fractures, which demonstrated 5/18 fractures treated with immobilization resulted in nonunion, 1/18 in delayed union (68 weeks), and 2/18 re-fracturing.[13] Time to union (7.5 weeks vs 22.1) was also significantly ($p < 0.01$) decreased in the surgical group.[13]

A recent systematic review (level II) of treatment of zone 2 (Jones) fractures found nonoperatively managed acute fractures had a union rate of 76% compared to 96% of those fractures treated with an intramedullary screw.[3] Most of the 26 studies were case series (level IV) with one randomized controlled trial (level I), and included 358 (of 630 patients, total) surgically treated fractures, but the authors concluded that union was quicker and more likely to be achieved in those treated operatively. The complication rate reported was 1.7% infection, 0.8% sural nerve damage, 1.4% intraoperative fracture, and 20 removal of screws.[3]

Multiple level four studies have assessed operative fixation in proximal fifth metatarsal fractures and time to union and return to sport. Japjec et al. series of 42 athletes with zone 2 and 3 fractures, supported operative fixation.[14] Porter et al. reported a case series of 23 athletes treated with internal fixation of the fifth metatarsal, all returned to sport (mean 7.5 weeks) (level IV).[15] A retrospective study of 22 patients with Jones fractures or proximal diaphyseal stress fractures treated surgically showed all fractures united (mean 6.25 weeks) with no to rare pain reported during athletic activity.[12] Another series reported union in 64% of patients at six weeks, with the remainder uniting by 12 weeks with one partial union. All patients returned to their previous levels of sporting activity.[16] De Lee et al. achieved union (mean 7.5 weeks) in all patients in their series (10 pts) with screw fixation.[17] Mindrebo reported

nine patients fixed surgically with mean time to return to running of 5.5 weeks, all fractures clinically and radiologically united.[18] Lareau et al. reviewed 25 professional NFL players with an operatively treated zone 2 (Jones) fracture and demonstrated 100% return to play, with an average time between 8 and 10 weeks.[19] O'Malley et al. demonstrated 100% return to play in 10 professional NBA athletes treated surgically with zone 2 (Jones) and zone 3 (diaphyseal stress) injuries at a mean time of 9.8 weeks.[20]

Level IV evidence has shown that of 38 patients with zone 1 (avulsion) fractures, the most significant predictor of poor functional outcome was prolonged nonweightbearing. Gender, age, and fracture type did not affect outcome.[10] Level II evidence has also demonstrated, with a review of 60 patients with zone 1 (avulsion) fractures, all fractures healed; however, those treated in a soft dressing returned to preinjury levels of activity faster (average 33 days vs 46 days).[11]

Findings

Level I evidence shows significantly faster time to union with operative fixation (7.5 weeks) compared to nonoperative treatment (22.1 weeks).[13] A systematic review (level II) found faster return to sport with fixation of Jones fractures, with slower time to union and function in those treated in a cast.[3] Furthermore, it was concluded that these fractures should be managed operatively and return to full function should be delayed until radiological union to reduce the risk of re-fracture.[3] There is increasing literature in support of operative management of zone 2 fractures, particularly amongst athletic individuals. The bulk of the supporting evidence is formed by retrospective case series (level IV), but shows faster rates of return to sport in the athlete in operatively treated zone 2 (Jones)

fractures,[12],[14]–[18] and an ability to reach preinjury activity levels.[19],[20]

In those patients with zone 1 (avulsion) fractures, more favorable outcomes were achieved with weightbearing (level IV),[20] and avoidance of cast immobilization (level II).[10]

Resolution of clinical scenario

- Patients with fifth metatarsal injuries can be reassured that they should be able to return to their preinjury sport.
- Athletes with zone 2 (Jones) and zone 3 (diaphyseal stress) fractures should have strong consideration for operative fixation.
- Zone 1 (tuberosity) fractures achieve union with nonoperative treatment, with faster union rates associated with weightbearing and avoidance of cast immobilization

Question 3: In patients with a proximal fifth metatarsal fracture, does intramedullary screw fixation lead to better biomechanical and clinical outcomes than other operative treatment options?

Rationale

Managing expectations is an important aspect of treating surgical patients and a thorough knowledge of prognosis helps in this respect. Most surgeons use an intramedullary screw to fix these fractures. However, the rate of nonunion

and re-fracture after this procedure remains a concern. Guidelines for treatment should be individualized depending upon type of fracture and sporting or functional demands.

Clinical comment

The optimal fixation method for proximal fifth metatarsal fractures has a bearing on radiological union rates, clinical outcomes, and potential complications.

Available literature and quality of the evidence

Level IV and V studies have utilized cadaver models to demonstrate the hardware failure and number of cycles to failure. Shah et al. used a cadaveric model to compare 4.5 mm and 5.5 mm screws to fix proximal fifth metatarsal fractures, with no difference in initial load to failure or ultimate load to failure.[21] Reese et al. cautioned against the use of screws of 4 mm and less due to the low number of cycles to failure in their cadaveric models fixed with these screws. They also found that solid screws displayed twice the number of cycles to failure when compared to cannulated screws.[22] Sides et al. compared bending stiffness and pull-out strength of tapered, variable pitch screws, and 6.5 mm cancellous screws in acute zone 2 (Jones) fractures using a cadaveric model. There was no demonstrable difference in bending stiffness between metatarsals fixed with the two types of screws ($p = 0.688$).[23] The 6.5 mm screw provided significantly higher resistance to pull-out ($p = 0.001$), a finding replicated in Kelly et al.'s cadaveric study.[24] The importance of torsional restraint was suggested by the findings of a cadaveric study by Vertullo et al.[25] Horst et al. tested torsional resistance of 5 mm and 6.5 mm screws used to fix simulated Jones fractures in cadaveric models. They found that both 5 mm or 6.5 mm screws provide equal torsional rigidity, but

5 mm screws needed to be longer to achieve stability and this could potentially cause problems in patients with curved metatarsals.[26] Moshirfar et al. studied strength of fixation comparing a bicortical lag screw with an intramedullary screw the lag screw technique resulted in a significantly greater mean (±SD) load to failure (150 ± 90 N) (level V).[27] Huh et al. compared biomechanical outcomes in eight cadavers which demonstrated intramedullary screw fixation had a greater bending stiffness and less fracture site angulation than plantar plate fixation during plantar-to-dorsal and lateral-to-medial bending, though this did not reach statistical significance.[28]

Level IV clinical studies have investigated optimal screw size and diameter. Porter al. compared the use of 4.5 mm and 5.5 mm screws to fix proximal fifth metatarsal fractures, which demonstrated no difference in union rates or return to sport in 20 athletes (mean 9.3 weeks), though there were three bent screws in the 4.5 mm group.[29]

Level IV studies have also investigated the outcomes of plantar plate internal fixation. Bernstein et al. demonstrated 100% union and return to play in eight elite athletes with acute metatarsal fracture (four patients) and acute re-fracture (four patients) treated with plantar plating and autologous bone grafting, with a mean time to union 6.5 weeks and return to sport at 12.3 weeks.[30] Sarimo et al. presents a series of zone 3 (diaphyseal stress) injuries treated successfully with a tension band wire construct. There were no re-fractures or hardware failures in their series of 27 patients, with a mean return to activity of 14.1 weeks.[31] Lee et al. retrospectively reviewed 168 patients with zone 3 (diaphyseal stress) fractures treated with tension band wiring, with mean 23.6-month follow-up, with 11 nonunion and 18 re-fracture, and found that surgical technique was reproducible, but a higher risk of

complications was present for patients with an increased body weight, wide fourth/fifth intermetatarsal angle, and curved metatarsal head.[32]

Findings

Overall, the evidence for fixation type is limited to level IV and V studies. There exist biomechanical studies which have shown no clear differences between 4.5 and 5.5 mm intramedullary screws,[21] and clinical studies with a similar outcome.[29] Other biomechanical evidence suggesting no difference between 5 and 6.5 mm screws, other than the 5 mm screw requiring a longer time period to achieve union.[26] Further biomechanical studies have shown no difference between intramedullary screw fixation and plantar plating.[28]

Clinical studies are restricted to case series (level IV), with Bernstein et al. showing successful union and return to sport in small numbers of patients treated with plantar plating,[30] and Sarimo et al. showing similar successful treatment outcomes with tension band construct.[31] Lee et al. reviewed 168 patients with zone 3 (stress) fracture with uncomplicated union in 82.7% of patients, and identified anatomic risk factors for poor union and patient factors including increased body weight.[32]

Resolution of clinical scenario

- A solid screw of adequate size such that the threads gain purchase in the cortical diaphyseal bone should be used.
- Cannulated screws and screws 4 mm and smaller risk failure; bending of the screw and re-fracture (Figure 108.2).

- Tension band wire and plantar plating remain options for fixation.
- No clear difference in biomechanical outcomes with 4.5 mm and 5.5 mm intramedullary screws.

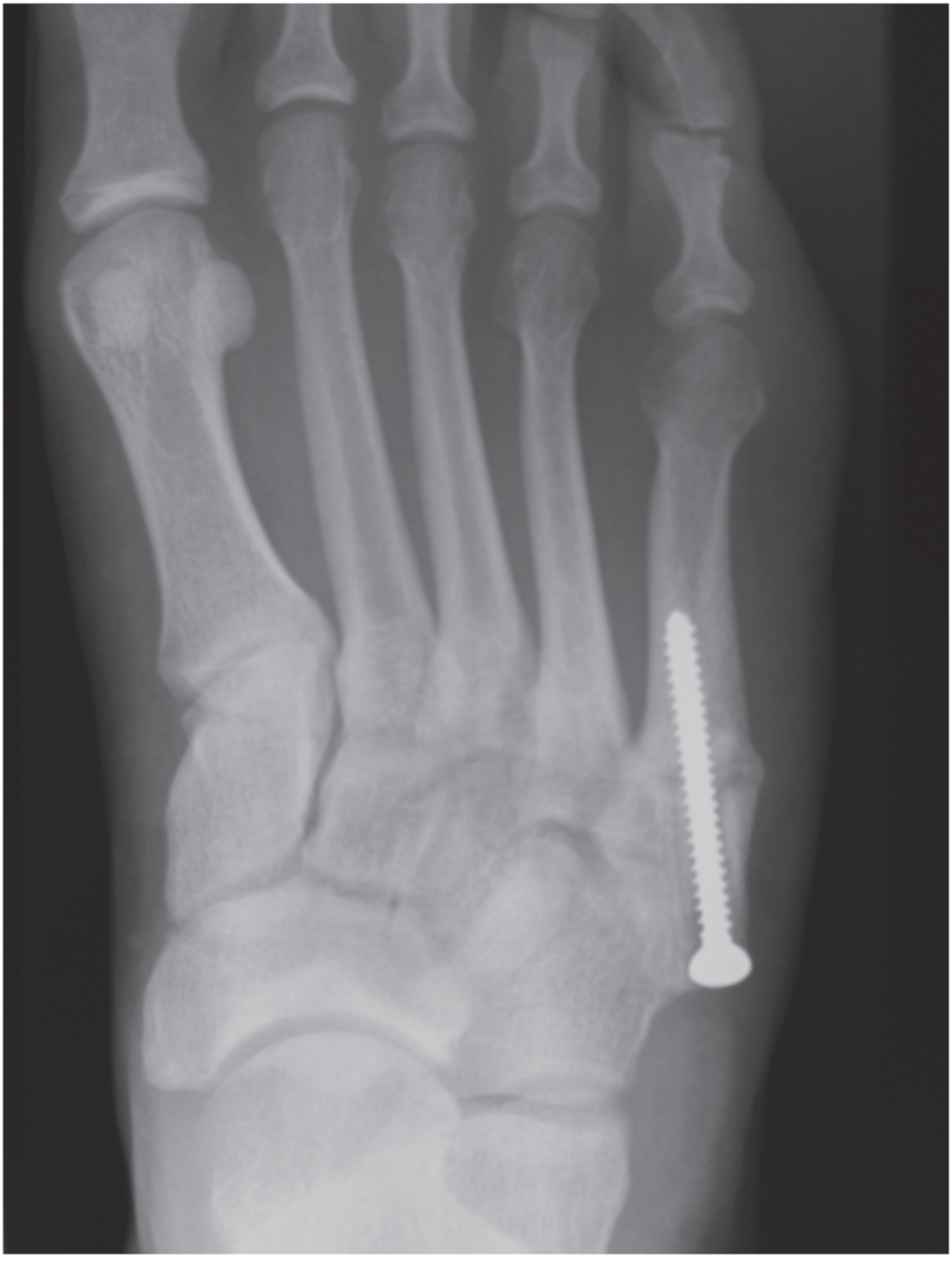

Figure 108.2 4.5 mm screw fixation of proximal fifth metatarsal fracture.

Summary of answers

- It should be appreciated that there are three types of proximal fifth metatarsal fracture that may require different treatments and which have different prognoses.
- The prognosis of proximal fifth metatarsal fractures is good.
- When conservatively treating proximal fifth metatarsal fractures treat zone 1 injuries symptomatically and zone two-thirds of injuries in a plaster or boot: weightbearing should be encouraged as tolerated.
- Operative fixation of zone 2 and zone 3 proximal metatarsal injuries leads to a quicker time to union and return to sport and this may be beneficial in selected patients.
- Intramedullary screw fixation with a diameter of 4.5 mm and greater has good biomechanical and clinical evidence.
- There is no clear difference with the use of plantar plates, tension band constructs, or intramedullary screws.

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V Spine

109
Mechanical Neck Pain

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Clinical scenario

- A 50-year-old woman presents with acute neck pain, which she attributes to sleeping in an awkward position.
- The pain is sharp and tight, and located over the right posterolateral aspect of her neck, upper back, and shoulder.
- She denies radiating arm pain, impaired hand dexterity, or gait. She denies associated headaches. She denies antecedent trauma.

Top three questions

1. In adults with nonwhiplash-associated mechanical neck pain, do patient education strategies improve pain, function, and/or quality of life compared to no treatment?
2. Have nonsteroidal anti-inflammatory drugs (NSAIDs), muscle relaxants, or analgesics demonstrated efficacy compared to placebo or other treatments in treating patients with nonspecific neck pain?

3. In adults with nonwhiplash-associated mechanical neck pain, does the addition of exercise to mobilization/manipulation improve pain and function compared to mobilization/manipulation alone?

Question 1: In adults with nonwhiplash-associated mechanical neck pain, do patient education strategies improve pain, function, and/or quality of life compared to no treatment?

Rationale

Although the efficacy of patient education for mechanical low back pain is controversial, it is often recommended. Initially, a considerable amount of faith was placed in its potential benefits.[1] However, subsequent robust research has moderated these expectations.[2,3] However, a systematic review reported on the effectiveness of back schools, particularly in the occupational setting.[4]

Clinical comment

Because of reports recommending educational strategies for mechanical low back pain, providers often recommend such strategies for mechanical neck pain as well.

Available literature and quality of the evidence

- Level I: 6 randomized studies.[5–10]

Findings

Two trials compared advice focused on activation to no treatment and found no benefit for subacute and chronic mechanical neck disorders in pain at up to six months and immediately after completing treatment, respectively.[5,7] One study compared advice focused on activation to home exercise and found no difference in pain and self-reported ability to work at one year.[10] Two studies compared advice focused on activation to cognitive behavioral therapy (CBT) and found no difference in pain at one year; however, activation was inferior to CBT regarding functional disability and work-related outcomes at one year according to one study.[10] Kamwendo et al. found no difference in sick leave taken between both groups.[7] Two trials compared advice focused on activation to usual physiotherapy care and found activation was marginally inferior in pain relief; function, disability, or work-related outcomes; and quality of life at one year.[8,9]

One trial compared advice focused on pain and stress comping skills to no treatment and reported no benefit in pain or disability reduction.[6]

One trial compared neck school to no treatment and showed no benefit in pain, and function, disability, or work-related outcomes at six months.[7]

Resolution of clinical scenario

Patients with nonwhiplash-associated mechanical neck pain will likely not benefit from educational interventions, especially advice to activate, advice on pain and stress coping skills, and neck school.

Question 2: Have nonsteroidal anti-inflammatory drugs (NSAIDs), muscle relaxants, or analgesics demonstrated efficacy compared to placebo or other treatments in treating patients with nonspecific neck pain?

Rationale

Conservative treatments, specifically oral pharmacological agents, are often considered first-line treatments for most musculoskeletal conditions. To justify their use, these modalities should allow patients to maintain activities related to work and daily living, and a good quality of life.

Clinical comment

NSAIDs, muscle relaxants, and analgesics are often recommended and widely prescribed for nonspecific neck pain. These recommendations were extrapolated from literature addressing other musculoskeletal conditions, including low back pain.

Available literature and quality of the evidence

- Level I: 1 systematic review.[11]
- Level I: 1 best-evidence synthesis.[12]
- Level I: 1 randomized trial.[13]

Findings

A Cochrane review concluded that muscle relaxants, opioid analgesics, and NSAIDs have limited evidence and unclear

benefits for nonspecific neck pain.[11] The Task Force on Neck Pain found no evidence to suggest that one medication is superior to any other medication or nonmedication intervention.[12] Based on six clinical trials considered scientifically admissible, the Task Force on Neck Pain concluded that the short-term management of symptoms with nonnarcotic analgesics may be helpful for grade II neck pain.[14]

A subsequent trial found that oxycodone was effective for recurrent episodes of neck pain.[13] However, the use of oxycodone for noncancerous pain is controversial due to limited evidence for long-term efficacy, poor side-effect profile, and a potential for abuse and addiction.[15]

Resolution of clinical scenario

A short course of nonopioid analgesics or NSAIDs may be helpful for the short-term management of grade II neck pain symptoms.

Question 3: In adults with nonwhiplash-associated mechanical neck pain, does the addition of exercise to mobilization/manipulation improve pain and function compared to mobilization/manipulation alone?

Rationale

Chiropractors, often considered the gatekeepers between patients with musculoskeletal conditions and clinicians, including surgeons, have repeatedly demonstrated high value in the services they provide.[16–19]

Clinical comment

There is a general consensus that spinal manipulation and mobilization is highly cost-effective for spinal pathologies. However, one recent high-quality UK systematic review reported inconclusive evidence for cervical manipulation alone.[20] In addition, reports of increased incidence of stroke following cervical manipulation were concerning,[21],[22] although these reports were subsequently refuted by a systematic review in 2012.[23]

Available literature and quality of the evidence

- Level I: 2 systematic reviews.[24],[25]
- Level I: 1 clinical guideline.[26]

Findings

Gross et al., in a Cochrane review, reported on 33 randomized trials, of which 42% were considered high quality. They found no benefit of manipulation or mobilization to alleviate mechanical neck pain with or without headaches, compared to control groups, placebo, or other treatment modalities. However, they reported strong evidence supporting manipulation and/or mobilization combined with exercise toward improving pain, disability, and global perceived effects.[25]

The aforementioned study was fortified by a subsequent systematic review that reported on 88 randomized trials, of which 59% were considered high quality.[24] It reported strong evidence of maintained benefit for pain reduction, functional improvement, and global health improvement in patients that received manipulation and/or mobilization, and exercise compared to a control cohort of patients with mechanical neck pain

A *Clinical Practice Guidelines* regarding assessment and management of neck pain was subsequently published, concisely synthesizing the results from the above studies and others. They endorsed that clinicians should consider cervical manipulation and/or mobilization. Furthermore, it reported that exercise and manipulation and/or mobilization proved more effective for improving pain, disability, and global health.[26]

Resolution of clinical scenario

In patients with mechanical neck pain with or without headaches, manipulation and/or mobilization with exercise is likely to be beneficial and should be recommended.

Summary of answers

- Patients with nonwhiplash mechanical neck pain will likely not benefit from educational interventions such as neck school.
- A short course of nonopioid analgesics may be helpful for short-term symptomatic management.
- In patients with mechanical neck pain, manipulation and/or mobilization is likely to be beneficial.

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110
Whiplash

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Clinical scenario

- A 21-year-old college football players sustains a helmet-to-helmet collision and has immediate onset of neck pain.
- The patient previously had one episode of transient weakness in his right upper extremity after a football collision in high school, but he has never had symptoms like this.
- Initial evaluation reveals tenderness to palpation about the cervical spine, limited neck range of motion (ROM), and no neurological deficits.
- He is concerned about his ability to return to play this season and the effects of this injury on his long-term career prospects.

Top three questions

1. In athletes with whiplash and/or cervical spine injuries, what are the return-to-play criteria, and what injuries/conditions are contraindications to return to play?
2. In athletes who sustain a cervical disc herniation, do those who undergo surgery have higher return-to-play rates than individuals treated nonoperatively?

3. In athletes who sustain a burner/stinger injury, do preexisting factors contribute to an increased risk of this condition, and how do these factors impact resolution of symptoms and return to play?

Question 1: In athletes with whiplash and/or cervical spine injuries, what are the return-to-play criteria, and what injuries/conditions are contraindications to return to play?

Rationale

Sports-related cervical spine injuries are common and can range from minor cervical strains to catastrophic fractures/dislocations resulting in permanent neurological impairments and even death. Although severe neurological injuries are rare, many competitive athletes are quite motivated to return to sport. Therefore, the treatment for these injuries and criteria for return to play are important considerations for physicians.[1]

Clinical comment

Due to the risk of catastrophic spinal cord injury and persistent neurological dysfunction, certain criteria are absolute contraindications to return to play in intense athletic activity.

Available literature and quality of the evidence

There is a paucity of high-quality studies that guide return to play criteria, likely due to the relative rarity of these injuries. In addition, some athletes with certain spine injuries cannot justify returning to play due to the potential

for catastrophic spinal cord injury. The majority of guidelines that guide treatment decisions are based on retrospective evaluations and expert opinion.[2]

Table 110.1 Guidelines for return to collision/contact sports in patients with a cervical spine condition or injury. Asymptomatic patients are defined as athletes with no neurological deficits, neck pain, pain with ROM, or evidence of pseudarthrosis.[4]

Condition	**Return to Play**
Patients with healed, stable nondisplaced fractures without spinal malalignment	No Contraindication
Successful nonsurgical treatment of asymptomatic disc herniations	No Contraindication
Asymptomatic patients after a previous one-level cervical fusion	No Contraindication
Certain congenital conditions, such as Klippel-Feil type 2 anomoly	No Contraindication
	No Contraindication
Prior fracture of the upper cervical spine with evidence of union [nondisplaced Jefferson fracture, a dens fracture (type 1 or 2)]	Relative Contraindication (If Patient Asymptomatic)
A healed vertebral compression fracture without significant displacement or malalignment	Relative Contraindication (If Patient Asymptomatic)
A stable and healed fracture that involves the posterior elements (not including spinous process fractures)	Relative Contraindication (If Patient Asymptomatic)
Two-level cervical fusion	Relative Contraindication (If Patient Asymptomatic)

Condition	Return to Play
Odontoid abnormalities	Absolute Contraindication
Occipital-cervical arthrodesis	Absolute Contraindication
Atlantoaxial instability	Absolute Contraindication
Klippel-Feil typ 1 abnormalities	Absolute Contraindication
Spear Tackler's Spine	Absolute Contraindication
Subaxial cervical spine instability	Absolute Contraindication
Acute fracture of the body or posterior elements (both with and without instability)	Absolute Contraindication
United subaxial vertebral body fractures with persistent saggital malalignment	Absolute Contraindication
Retropulsed bone fragments	Absolute Contraindication
Continued pain, limited motion, or neurological deficits after a healed fracture	Absolute Contraindication
Acute or chronic disc herniation with associated pain, limited motion, or neurological deficts	Absolute Contraindication

Findings

Whiplash and cervical strains/sprains are common injuries encountered in most sports. Athletes may have localized cervical pain, tenderness to palpation, and decreased ROM *without* neurological deficits. An athlete with full, intact

ROM (including flexion, extension, lateral bending, and rotation) does not require further imaging and may resume activity. If physical examination reveals pain, diminished ROM, or sensorimotor deficits then imaging studies are required.[1]

Certain injuries and/or conditions are career ending, but many athletes can return to play after injuries that have been treated appropriately with minimal risk for significant recurrence or worsening of the injury.[3] Physicians often face extrinsic pressures, and the decision to allow return to competitive activity after cervical spine injuries can be challenging.[4] Table 110.1 summarizes return-to-play recommendations after certain injuries and conditions of the cervical spine.

Resolution of clinical scenario

- Athletes can generally return to contact/collision sports after a cervical spine injury if they have no pain, full ROM, and no neurological deficits.
- Certain injuries or congenital conditions preclude return to sports (Table 110.1). These are generally associated with an unacceptable level of risk for catastrophic spinal cord injury.

Question 2: In athletes who sustain a cervical disc herniation, do those who undergo surgery have higher return-to-play rates than individuals treated nonoperatively?

Rationale

Cervical disc herniations in athletes are relatively common, especially in contact sports, with a constellation of symptoms that can vary from neck pain to radiculopathy, myelopathy, and transient quadraparesis.[5]

Clinical comment

The treatment of cervical disc herniations in athletes is controversial, without a consensus on the optimal treatment approach for these injuries.

Available literature and quality of the evidence

Although neck injuries occur relatively frequently in athletes, these patients represent a small subset of the overall population, and it is difficult to design high-quality studies that can dictate management and return-to-play algorithms specifically for this group of patients. The majority of studies are based on retrospective analysis and expert opinion.[1,5]

Findings

Various studies have evaluated the effect of surgery on return-to-play rates in players who undergo surgery for cervical disc herniations. Hsu et al. retrospectively reviewed 99 National Football League players. Fifty-three of these 99 athletes underwent surgical treatment, and the athletes treated operatively were significantly more likely to return to professional football (72% vs 46%, $p = 0.04$). However, in the athletes that did return to play, there was no significant difference in number of games played and positional performance scores in the patients treated operatively and nonoperatively.[5,6]

Another study evaluated 15 athletes who underwent a single level anterior cervical discectomy and fusion (ACDF). Thirteen of these patients were able to return to

activity after demonstrating full, painless neck ROM, a solid radiographic fusion, and a normal neurological examination.[7] Several other studies validate these findings, although the data are somewhat limited due to the relative infrequency of this condition in athletic individuals.[5]

No studies have been able to effectively determine whether it is safe to return to play after multilevel cervical fusions. In general, a two-level ACDF is considered a relative contraindication and a 3+ level ACDF is considered an absolute contraindication to athletic activity.[5]

Resolution of clinical scenario

- In general, athletes with a cervical disc herniation can safely return to play after a one-level ACDF if they have evidence of a solid fusion, normal neurological examination, and normal neck ROM.
- Multilevel cervical fusions are considered contraindications to return to sport.
- Some literature suggests that athletes with symptomatic cervical disc herniations treated operatively have higher rates of return to athletic activity than patients treated nonoperatively.

Question 3: In athletes who sustain a burner/stinger injury, do preexisting factors contribute to an increased risk of this condition, and how do these factors impact resolution of symptoms and return to play?

Rationale

Stingers, also known as *burners*, are very common injuries, particularly in contact sports. One study found that they occur in approximately 65% of American college football players at least once during their four-year college football tenure.[5]

Clinical comment

Recognizing this injury is important, as the symptoms can coincide with more severe cervical spine injuries that require further workup and more stringent return-to-play criteria.[5] Although they are quite common, the mechanisms of injury associated with stingers can vary, which can influence the risk of recurrent injuries.

Available literature and quality of the evidence

Similar to other cervical spine injuries in athletes, the majority of evidence that guides treatment is based on retrospective evaluations and expert opinion.

Findings

Athletes who sustain a stinger injury typically experience pain, paresthesias, and occasionally weakness in a *single* extremity. The symptoms do not always follow a dermatomal pattern and often resolve after a short period of time.[1]

Several mechanisms responsible for the pathophysiology associated with stingers have been proposed. Some authors believe they are the result of foraminal compression of the exiting cervical nerve root as the neck is extended and bent laterally, causing an injury to the nerve root itself.[5] Several studies have popularized this proposed mechanism. For instance, Meyer et al. found that college football players with a Torg–Pavlov ratio less than 0.8 were over three times more likely to develop a stinger.[5,8] Another study

found that high school football players who had previously suffered from a stinger had significantly smaller Torg–Pavlov ratios relative to asymptomatic controls (0.88 vs 0.94; p = 0.02).[9]

Other authors believe that stingers are more commonly the result of traction injuries to the brachial plexus that occur when lateral impact to the head causes contralateral neck flexion and ipsilateral shoulder depression. Studies supporting this theory have described brachial plexus neuropraxia, such as axonotmesis, in the electromyograms of the majority of athletes who suffer from stingers. Both mechanisms likely contribute to these injuries, with nerve root compression more common in patients with chronic stingers and preexisting cervical spine spondylosis, and neuropraxia more common in acute stingers.[5]

These injuries often resolve quickly, sometimes after a few minutes, and most physicians allow return to play when the athlete has resolution of symptoms with full strength and full ROM of both the neck and the involved extremity. When symptoms persist, or an athlete has more than three episodes in less than one year, additional workup is required.[1]

Persistent symptoms or recurrent episodes (more than three stingers in less than a year) generally require further workup with an electromyograph (EMG) or magnetic resonance imaging (MRI) prior to return to play. Physicians must always differentiate stingers from transient neuropraxia, which involves more than one extremity and generally does not resolve quickly. These injuries require immediate workup and further treatment.[5]

Resolution of clinical scenario

- Stingers/burners are common conditions seen in contact athletes.

- When symptoms are localized to a single extremity and resolve after a short period (demonstrated by full strength and ROM of the neck and the involved extremity), the athlete may return to play.
- When symptoms persist, or an athlete has more than three episodes in less than one year, further workup is required.

Summary of answers

- Athletes can return to contact sports after cervical spine injury if they have full ROM, no pain, and no neurological deficits.
- Athletes with a cervical disc herniation can return to play after single-level ACDF if there is solid fusion, no neurological deficits, and normal neck ROM.
- Multilevel ACDF is a contraindication to return to contact sports.
- Stingers/burners are common, and when symptoms persist or recur, further workup is indicated.

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111
Cervical Radiculopathy and Myelopathy

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Clinical scenario

- A 53-year-old male presents to an ambulatory clinic with a history of bilateral hand numbness and clumsiness, leading to great difficulty with manual tasks, as well as gait difficulty.
- Examination reveals diminished power in bilateral hand grip and finger abductors, hyperreflexia, a positive Hoffmann's sign, upgoing plantar responses, and unsteadiness on tandem gait testing.
- Magnetic resonance imaging (MRI) of the cervical spine reveals multilevel cervical spondylosis with moderate central canal narrowing and spinal cord compression; there is T2 hyperintense signal within the cord at C4.

Top three questions

1. In patients with mild, moderate, or severe degenerative cervical myelopathy (DCM), does surgical decompression provide superior functional outcomes, as graded by the modified Japanese Orthopaedic

Association (mJOA) scale, compared to nonoperative management strategies?

2. In patients with asymptomatic cervical spinal cord compression (imaging evidence of cervical spinal cord compression without signs or symptoms of myelopathy or radiculopathy), what is the role of prophylactic surgery, and what are the frequency and timing of symptom development and clinical, radiological, and electrophysiological predictors of myelopathy development?
3. In patients with imaging evidence of cervical spinal cord compression and clinical and/or electrophysiological evidence of radiculopathy, but without myelopathy, what is the role of surgery, and what are the frequency and timing of symptom development and clinical, radiological, and electrophysiological predictors of myelopathy development?

Question 1: In patients with mild, moderate, or severe degenerative cervical myelopathy (DCM), does surgical decompression provide superior functional outcomes, as graded by the modified Japanese Orthopaedic Association (mJOA) scale, compared to nonoperative management strategies?

Rationale

DCM is a progressive degenerative spinal condition that results in chronic, nontraumatic compression of the cervical spinal cord and ensuing neurological deficits. The spectrum of disease severity is wide in DCM, and the severity of initial presentation dictates the optimal clinical management of affected patients. Classification of patients into severity groups is by the mJOA scale: mild (mJOA 15–17), moderate (mJOA 12–14), and severe (mJOA <12).[1]

Clinical comment

DCM represents the leading cause of spinal cord dysfunction globally.[2] DCM occurs when progressive age-related osteoarthritic changes (e.g. degenerative disk disease, spondylosis, ossification of the posterior longitudinal ligament) narrow the cervical spinal canal, leading to chronic spinal cord compression.[3] There is ischemia and breakdown of the blood–spinal cord barrier, ultimately resulting in neuronal and glial death and a pathological picture consistent with chronic spinal cord injury.[4] The natural history of DCM is thought to involve progressive, stepwise decline, with 20–62% of patients deteriorating at 3–6 years of follow-up, as assessed by the mJOA scale.[5,6] Given the limited potential for repair and recovery of the spinal cord, many of the pathological and clinical changes induced by this process are irreversible. With the aging population, DCM will portend a greater burden of disability on our population. Over 70% of individuals over 60–65 years old demonstrate pathological or radiological evidence of cervical degeneration, and approximately one-quarter of these people become clinically symptomatic from mechanical neural compression.[7–9] The proportion of the United States population 65 years or older is expected to nearly double from 13% in 2010 to 22% in 2050.[10] Orthopedic and neurosurgeons alike therefore should become comfortable

in making decisions related to the management of patients with this clinicopathological entity.

Available literature and quality of the evidence

Clinical practice guidelines for the management of patients with DCM were published in 2017.[11] The evidence for management of DCM is derived primarily from prospective (level II evidence) and retrospective (level III evidence) observational studies. There have been select randomized controlled trials (RCTs); however, these have had several methodological flaws. There have also been several systematic reviews.

Findings

There is a single RCT comparing the clinical outcomes of operative and nonoperative management for DCM. In 2000, Kadanka et al. published the results of a small RCT of 48 patients with mild or moderate DCM (mJOA ≥12) randomized to conservative or operative treatment.[12–16] Surgery consisted of anterior decompression in 22 patients, corpectomy in six patients, and laminoplasty in five patients. Conservative strategies included cervical collar, anti-inflammatory medications, and intermittent bedrest for patients with pain, discouragement from participation in high-risk activities, and avoidance of risky environments (e.g. physical overloading, movement on slippery surfaces, manipulation therapies, or prolonged flexion of the head). No significant difference was observed in mean mJOA score within or between the conservative and surgical cohorts over a 36-month period. At the three-year mark, 24.1% of the surgical cohort had improved two or more points on the mJOA scale, not significantly different from the corresponding proportion in the conservative cohort (23.3%).[13] At the 10-year mark, mean mJOA score was 15.0 in conservatively and 14.0 in surgically treated

patients.[15] However, several criticisms have been levied against this trial, most notably that it was underpowered and lacked a sample size calculation.[17] A recent sample size estimate for an RCT sponsored by the Patient-Centered Outcomes Research Institute (PCORI) indicates 159 patients would be needed to demonstrate a difference using the SF-36 Physical Component Summary (PCS) as the outcome instrument.[18] Hence, based on this study and one retrospective cohort study of 91 Chinese DCM patients,[19] there is low-level evidence that nonoperative treatment results in similar outcomes as surgery for patients with *milder* (mJOA ≥13), single-level DCM and intramedullary signal change on T2 MRI.[20,21]

In another prospective comparative study also published in 2000, Sampath et al. enrolled patients with subacute DCM, defined by at least eight weeks of symptoms. Patients were seen by a Cervical Spine Research Society (CSRS) surgeon and prescribed either medical or surgical therapy.[22] A total of 23 patients received conservative treatment, including a combination of pharmacotherapy, home exercise, physical therapy, bedrest, cervical traction, and neck bracing. By contrast, 20 patients underwent surgery. At a mean follow-up of 29.8 months, the surgical group demonstrated significant improvements in overall functional status as well as work and social activities. Conservatively treated patients, too, exhibited functional improvements, but this did not reach statistical significance. Additionally, surgical patients experienced no change in the number of activities that worsened their symptoms from before to after treatment, whereas the number of activities that exacerbated symptoms in the medical cohort increased from baseline to follow-up (+0.63).

Since then, there have been several contemporary prospective studies to support the safety and efficacy of

operative treatment in patients with DCM with regard to functional status, disability, pain, and complications. A 2017 systematic review of the literature identified 32 prospective investigations.[23] Pooled standard mean differences showed a large effect for improvement in mJOA score from baseline at short-, medium-, and long-term follow-up: 6–12 months (1.92; 95% confidence interval [CI]: 1.41–2.43); 13–36 months (1.40; 95% CI: 1.12–1.67); and >36 months (1.92; 95% CI: 1.14–2.69) (moderate-level evidence). There was also low-level evidence that surgery resulted in significant improvements in Nurick grade, Neck Disability Index (NDI), and Visual Analog Scale (VAS) scores. The cumulative incidence of complications was low (14.1%; 95% CI: 10.1–18.2%). The AOSpine CSM-NA and CSM-I trials represent two of the largest multicenter, prospective studies of surgical decompression for DCM.[24,25] An extensive battery of outcome metrics were evaluated, including functional status (mJOA, Nurick, 30-meter walk test [30MWT]), disability (NDI), and quality of life (SF-36). The CSM-NA study recruited 278 patients with symptomatic DCM and MRI evidence of spinal cord compression from 12 North American centers over a two-year period.[25] At enrollment, patients were classified into mild (mJOA ≥15), moderate (mJOA 12–14), or severe (mJOA < 2) groups based on disease severity. All patients underwent surgical decompression. There was significant improvement in mJOA score, Nurick grade, NDI, and all SF-36 dimensions, except *general health*, from baseline to one-year follow-up ($p < 0.05$). With the exception of mJOA, which exhibited a ceiling effect in patients with mild DCM, the degree of improvement did not depend on the severity of disease. The CSM-I trial enrolled 479 patients with symptomatic DCM with imaging evidence of compression from 16 global sites from 2007 to 2011.[24] At two-year follow-up, there was significant improvement in mJOA (12.5

to 14.9), NDI (36.4 to 23.2), and SF-36 PCS (34.3 to 40.8) and MCS (39.5 to 46.2) scores. The rate of neurological complications was 3.1%.

The primary limitation of the above studies was the absence of a control nonoperative group. However, in considering studies that evaluated structured nonoperative treatment, including therapeutic exercise, manual therapy, cervical bracing, and/or traction, a recent systematic review found very low-level evidence to suggest structured nonoperative treatment results in either a positive or negative change in function, as evaluated by the mJOA scale.[26] A majority of nonoperatively managed patients reported in the literature did not experience significant gains in function with structured nonoperative treatment. Moreover, a substantial proportion (23–54%) eventually underwent surgical treatment.

Distilling the above information, there is moderate-quality evidence to support the recommendation of surgical intervention in patients with moderate or severe DCM.[27] Current guidelines recommend surgical intervention or a supervised trial of rehabilitation in patients with mild DCM; if the latter is pursued, surgery is recommended if there is neurological deterioration or if the patient fails to improve.[27]

Question 2: In patients with asymptomatic cervical spinal cord compression (imaging evidence of cervical spinal cord compression without signs or symptoms of myelopathy or radiculopathy), what is the role of prophylactic surgery, and what are the frequency and timing of symptom development and clinical, radiological, and electrophysiological predictors of myelopathy development?

Rationale

Many patients present with imaging evidence of cervical spinal cord compression, but without clinical signs or symptoms of DCM or radiculopathy.

Clinical comment

In nonmyelopathic patients with imaging evidence of cervical spinal cord compression, it is important to consider the natural history of the disease, rates of disease progression, and myelopathy development, and risks of operative intervention.

Available literature and quality of the evidence

The clinical management of patients with asymptomatic cervical spinal cord compression is guided by prospective (level II evidence) and retrospective (level III)

observational studies. There are no RCTs (level I evidence) to guide decision-making in these patients.

Findings

Wilson et al. conducted a systematic review of the literature to assess the frequency, timing, and predictors of symptom development in patients with radiographic evidence of cervical spinal cord compression, spinal canal narrowing, and/or ossification of the posterior longitudinal ligament (OPLL), but without symptoms of myelopathy.[28] The authors identified five longitudinal cohort studies meeting eligibility criteria. The frequency of myelopathy development was reported to be 8% at one year and 22.6% at a median follow-up of 44 months in patients with cervical spondylosis. This was based on a prospective cohort study by Bednarik et al.[29,30] In this study, the presence of symptomatic radiculopathy (risk ratio [RR] = 3.0; 95% CI: 2.0–4.4), cervical cord hyperintensity on MRI (RR = 1.7; 95% CI: 1.0–2.7), and prolonged somatosensory- (SSEPs) (RR = 2.9; 95% CI: 1.7–5.1) and motor-evoked potentials (MEPs) (RR = 3.2; 95% CI: 1.9–5.6) were found to be significant independent predictors of myelopathy development. Traumatic events were not significantly associated with myelopathy development (RR = 0.9; 95% CI: 0.3–3.2).[30] In patients with OPLL, the rate of myelopathy development reported in three prospective cohort studies ranged from 0 to 61.5%.[31–33] One of these studies reported central canal stenosis ≥60% (RR N/A), lateral deviated OPLL (RR = 2.1; 85% CI 1.4–3.1), and increased cervical range of motion (RR N/A) to be significant predictors of myelopathy development.[32]

There are no studies that directly compare the efficacy of operative nonoperative management in nonmyelopathic patients with cord compression without signs or symptoms of radiculopathy. However, based on expert

recommendation and indirect lines of evidence surrounding rates of myelopathy development (derived from the studies discussed above), current guidelines provide a weak recommendation that prophylactic surgery not be offered to patients with evidence of cervical cord compression without signs or symptoms of radiculopathy.[27] These patients should be counseled about the risks of progression, educated about relevant signs and symptoms of myelopathy, and be followed clinically. If myelopathy were to develop, recommendations would follow that discussed in Question 1.

Question 3: In patients with imaging evidence of cervical spinal cord compression and clinical and/or electrophysiological evidence of radiculopathy, but without myelopathy, what is the role of surgery, and what are the frequency and timing of symptom development and clinical, radiological, and electrophysiological predictors of myelopathy development?

Rationale

Many patients present with clinical and/or electrophysiological evidence of radiculopathy and imaging evidence of cord compression, but without clinical signs or symptoms of myelopathy.

Clinical comment

Similar to Question 2, in nonmyelopathic patients with imaging evidence of cervical spinal cord compression and clinical and/or electrophysiological evidence of radiculopathy, it is important to consider the natural history of the disease, rates of disease progression, and myelopathy development, and risks of operative intervention.

Available literature and quality of the evidence

The clinical management of patients with cervical spinal cord compression and radiculopathy, but without myelopathy, is guided by prospective (level II evidence) and retrospective (level III) observational studies. There are no RCTs (level I evidence) to guide decision-making in these patients.

Findings

The findings presented for Question 2 are relevant to this important and practical question as well. As summarized in the systematic review by Wilson et al.,[28] the prospective study published by Bednarik and colleagues found symptomatic (clinical) radiculopathy (RR = 3.0; 95% CI: 2.0–4.4), prolonged SSEPs (RR = 2.9; 95% CI: 1.7–5.1), prolonged MEPs (RR = 3.2; 95% CI: 1.9–5.6), and EMG signs of anterior horn cell lesion (RR = 2.4; 95% CI: 1.5–3.9) to be significant predictors of myelopathy development on univariate analysis in nonmyelopathic patients with imaging evidence of cervical spinal cord compression.[29,30] Furthermore, a multivariate Cox proportional regression model revealed prolonged SSEPs and MEPs, clinically symptomatic radiculopathy, and lack of MRI hyperintensity to be associated with early (≤12 months) development of DCM.[28] More specifically, 62.5% of patients with clinical radiculopathy developed myelopathy by 12 months,

compared to 26.3% of patients without symptomatic radiculopathy.

Again, there are no studies that directly compare the efficacy of operative versus nonoperative management in nonmyelopathic patients with cord compression and signs or symptoms of radiculopathy. Based on expert opinion and the indirect lines of evidence discussed above, current guidelines offer a weak recommendation that nonmyelopathic patients with cord compression and clinical evidence of radiculopathy with or without electrophysiological confirmation be offered surgical intervention or nonoperative treatment.[27] The latter consists of close serial follow-up or a supervised trial of structured rehabilitation. These patients are at higher risk of developing myelopathy and should be counseled accordingly. If myelopathy were to develop, recommendations would follow that discussed in Question 1.

Resolution of clinical scenario

This patient presents with the signs and symptoms of DCM (i.e. symptomatic myelopathy). From the description, the patient has an mJOA score of 14 at the most; therefore, this patient falls into the *moderate* myelopathy group. Based on best available evidence and guideline recommendations, this patient should be managed with surgical intervention. The goal of surgery is to provide decompression of the cervical spinal cord, which can be achieved through an anterior, posterior, or combined approach, followed by reconstruction and stabilization of the spinal column to address any element of instability, whether degenerative or iatrogenic.

Summary of answers

- There is moderate evidence to support the recommendation of surgical decompression in patients with moderate or severe DCM, considering improvement in functional status. There is very low to low evidence to suggest patients with mild DCM should be offered surgical intervention or a supervised trial of structured rehabilitation. If the latter is opted, operative intervention is recommended if the patient fails to improve or deteriorates neurologically.
- There is low evidence that 22.6% of patients with asymptomatic cervical spinal cord compression will develop myelopathy at a median follow-up of 44 months. There is insufficient evidence to suggest 0–61.5% of patients with OPLL without myelopathy will develop symptomatic myelopathy. Current guidelines recommend against prophylactic surgery in nonmyelopathic patients with imaging evidence of cervical spine cord compression without signs or symptoms of radiculopathy.
- There is moderate evidence that, in nonmyelopathic patients with imaging evidence of cervical spinal cord compression, presence of clinically symptomatic radiculopathy, prolonged SSEPs, and prolonged MEPs are significant predictors of early development of myelopathy (<12 months). Current guidelines offer a weak recommendation that these patients be offered surgical intervention or nonoperative treatment consisting of close serial follow-up or a supervised trial of structured rehabilitation. The patients should be counseled about the higher risk of developing myelopathy. In the event of development of myelopathy, these patients should be managed according to the answer to Question 1.

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Mechanical Low Back Pain: Operative Management

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Clinical scenario

- A 60-year-old male presents with a two-year history of isolated low back pain with no lower extremity radicular component.
- Patient's symptoms are refractory to multiple conservative treatment modalities including oral analgesia, physical therapy, and epidural steroid injections.
- The anesthetic discogram is concordant with pain at the L5–S1 level with normal controls at L3–L4 and L4–L5.
- Physical examination shows diminished range of motion throughout the lumbar spine in terms of flexion and extension, normal gait, and a normal neurovascular exam.

Top three questions

1. In patients with isolated mechanical back pain, does fusion provide improved pain relief compared to nonoperative treatment?
2. In patients with chronic low back pain (LBP), do some diagnostic tests more accurately select the right patient for spine fusion than other tests?
3. In patients undergoing spine fusion, what risk factors are associated with poorer outcomes?

Question 1: In patients with isolated mechanical back pain, does fusion provide improved pain relief compared to nonoperative treatment?

Rationale

The presenting patient has clinical and radiographic findings consistent with degenerative disc disease (DDD). He has exhausted conservative measures and wishes to know if a fusion can reliably improve his low back pain.

Clinical comment

There is a great deal of controversy regarding the treatment of mechanical LBP among orthopedic surgeons. Whether the intervertebral disc is the actual pain generator and operative fusion for treating mechanical low back is warranted remains controversial in both the literature and in clinical practice.

Available literature and quality of the evidence

Multiple randomized controlled trials (RCTs) are detailed below.

Findings

The common measurement outcome employed by four randomized trials was the Oswestry Disability Index (ODI), a validated measure specific for lumbar degenerative disorders. This index is measured from 1 to 100 with higher scores indicating a higher level of disability. Developers of the ODI indicate that a clinically relevant change is 4 points, whereas other studies have suggested thresholds of up to 18 points are required for clinical relevance.[1]

All four of the randomized trials compared surgical treatment of mechanical LBP with nonoperative treatment. Of the four randomized trials reviewed, three of them had structured nonoperative regimens.[2–4] The Fritzell et al. 2002 study did not have a structured regimen of physical therapy. Instead it used any kind of physical therapy as the main component, which could be supplemented with "information and education, TENS (transcutaneous electrical nerve stimulation), acupuncture, injections, cognitive and functional training, and coping strategies."[5]

All four studies showed a similar improvement in the surgical arm of patients, with improvement from baseline ranging from 8.9 to 15.6 points (percent improvement 18.9 to 37.1%).[6] In the nonoperative arm, improvements ranged from 2.8 to 12.8 (percent improvements from baseline were 5.8 to 30.1%). Only in the Fritzell et al. study was the improvement in nonoperative treatment below the clinically relevant threshold of 4 points on the ODI,[5] whereas in the other three studies the improvement seen in the nonoperative patients was similar to that of the operative patients. These three studies used a structured

nonoperative treatment regimen incorporating cognitive behavioral therapy, whereas the Fritzell et al. study did not.

The greatest improvement in surgical patients, when compared to their nonsurgical counterparts, was seen in the Fritzell et al. study (ΔODI surgery group − ΔODI nonsurgical group) at 8.8.[5] The Fairbank et al. study showed improvement in the surgical group of patients as well, with a minor improvement at 4.1 (95% confidence interval [CI]: 0.1–8.1). This value was not considered statistically significant.[2] Neither Brox et al. study showed a statistically significant difference between surgical and nonsurgical intervention for the ODI. The first study, looking at patients without prior surgery, the improvement seen with surgery for this study was 2.3 (95% CI: −6.8 to 11.4).[3] In the second Brox et al. study, looking at patients with a prior discectomy, greater improvements in the ODI were seen with nonsurgical treatment. When adjusted for gender and treatment expectations, this value was −9.7 (95% CI: −21.7 to 1.7).[4] Mannion et al. in their study consisting of three multicenter RCTs of surgery versus multidisciplinary cognitive-behavioral and exercise rehabilitation found no difference in patient self- reported outcomes between fusion and multidisciplinary cognitive-behavioral and exercise rehabilitation for chronic LBP.[7]

Resolution of clinical scenario

- Compared with an unstructured nonoperative treatment regimen, lumbar fusion can be expected to reduce pain by about 63% and improve ODI by about 25% (overall quality: moderate).
- Structured nonoperative treatment regimens that incorporate cognitive behavioral therapy can provide pain relief and improvements in the ODI that are

comparable to, if not better than, lumbar fusion (overall quality: moderate).

- Nonoperative treatment for mechanical back pain should be strongly considered (overall quality: high).

Question 2: In patients with chronic low back pain (LBP), do some diagnostic tests more accurately select the right patient for spine fusion than other tests?

Rationale

Spine surgeons often use diagnostic tests such as discography, magnetic resonance imaging (MRI), facet joint blocks, and brace immobilization to determine patient selection for lumbar fusion for DDD and chronic LBP.

Clinical comment

Understanding the prognostic value of these diagnostic tests can help the surgeon better select patients who may have better outcomes from lumbar fusion for isolated DDD.

Available literature and quality of the evidence

Although this topic has been reported frequently in the literature, few quality studies have been produced to adequately address this question of which diagnostic tests provide prognostic value for patient selection for lumbar fusion. After a thorough review of the literature, systematic reviews prove to be the most reliable and valuable method of understanding these diagnostic tests. Due to the nature of these tests, high-level evidence is not readily available

and systemic reviews consisting of retrospective analysis of prospectively collected data were utilized.

Findings

Patient selection for lumbar fusion due to isolated DDD remains a challenging question but one that is important for clinical success. Several studies have looked at various diagnostics tests to determine if they have validity in providing prognostic value. Diagnostic tests reviewed for prognostic accuracy include MRI, discography, facet joint blocks, pantaloon cast test (PCT), immobilization by orthosis, Modic changes, and a summary of physical symptoms termed *loading factor*.[8,9] Willems et al. compared the results of MRI, provocative discography, facet joint blocks, orthosis immobilization, and temporary external fixation with the clinical outcome of patients who underwent spinal fusion for chronic LBP.[8] The outcome measure was to determine the prognostic accuracy of diagnostic tests in predicting clinical efficacy of spinal fusion in regards to sensitivity, specificity, and likelihood ratios (LRs). In their review, immobilization by an orthosis (median [range] positive LR, 1.10 [0.94–1.13] and negative LR, 0.92 [0.39–1.12]), provocative discography (median [range] positive LR, 1.18 [0.70–1.71] and negative LR, 0.74 [0.24–1.40]), and temporary external fixation (median [range] positive LR, 1.22 [1.02–1.74] and negative LR, 0.58 [0.15–0.94]) did not have clinically relevant prognostic accuracy.[8] Overall, in this review, these tests could not identify a subset of patients with chronic LBP in which a fusion would have predictable and effective outcomes.

Staartjes et al. performed a systematic review investigating the value of prognostic tests following lumbar fusion surgery for DDD with a retrospective analysis of prospectively collected data.[9] The outcome measures were pre- and postoperative Visual Analog Scale (VAS) and ODI

scores. The review found discography, Modic changes, and loading factor were of no value for predicting outcome scores ($p > 0.05$).[9] However, in patients without prior surgery, a positive PCT did correlate with improved outcomes in back pain severity suggesting a possible promising prognostic tool. Furthermore, Willems et al. specifically examined the value of a PCT in surgical decision making with a systematic review supplemented with a prospective cohort study. They found patients with DDD without prior spine surgery and who had significant pain relief with the PCT, had a higher likelihood of a favorable outcome of lumbar fusion compared to conservative management.[10]

Resolution of clinical scenario

- Diagnostic tests such as MRI, discography, facet joint blocks, and immobilization by orthosis have very little prognostic value in terms of identifying the best candidates for lumbar fusion for DDD. However, a positive PCT has been correlated with improved outcomes, highlighting its promise as a prognostic tool.

Question 3: In patients undergoing spine fusion, what risk factors are associated with poorer outcomes?

Rationale

Lumbar fusion is a mainstay in the surgical management of degenerative spine pathologies. Awareness of modifiable risk factors that produce suboptimal outcomes is therefore imperative for any spine surgeon.

Clinical comment

The success of spine fusion depends on efficient bone remodeling and new bone formation. The literature on risk factors is extensive; however, it is somewhat unclear which risk factors are modifiable and are independently causing poor fusion outcomes.

Available literature and quality of the evidence

Multiple RCTs are detailed below.

Findings

Conditions such as osteoporosis, diabetes, smoking, and others can significantly impair bone formation and remodeling, resulting in poor bone quality and lower fusion rates. Patient demographics have also been implicated in fusion outcomes. In a study on twins, Suri et al. found that BMI ≥35, smoking, lack of physical activity and sleep, depression, and post-traumatic stress disorder were associated with LBP.[11] However, when genetic and familial factors were removed, obesity and the presence of mental disorders significantly correlated with LBP.[11]

In a systematic review, Choma et al. looked at the impact of patient risk factors on spine fusion or conservative management of chronic LBP.[12] Based on the few eligible studies in their review, fusion proved only slightly beneficial in patients without risk factors and nonsmokers. In an RCT by Hägg et al. patients were randomized in two groups, fusion or nonoperative, and radiological, personality disorders, sociodemographics, and clinical outcomes were compared.[13] Among the surgical patients with co-morbidities, 66% reported improvement versus 61% without co-morbidities. In the nonoperative group, those percentages were 40 versus 23%. Similar changes were seen with smoking: in the surgical group, improvement was observed in 58% of the patients who

were smokers and in 66% of nonsmokers. For the nonoperative groups, improvement was seen in 32 and 26% of smokers and nonsmokers, respectively. At the same time, the confidence intervals between the different groups were overlapping, suggesting no significant difference in treatment effects. In addition, the nonoperative treatment was not well defined. In another RCT, Fairbank et al. evaluated the effect of smoking on fusion or intensive rehabilitation outcomes at 24 months.[2] Among smokers, the ODI values changed from 47.8 ± 14.5 (baseline) to 40.6 ± 22.2 (24 months) for surgical patients, and from 46.9 ± 14.6 (baseline) to 38.4 ± 22.2 (24 months) for rehabilitation patients. In nonsmokers, the ODI values improved for both the surgical (from 45.5 to 29.5) and nonoperative (from 43.1 to 34.6) patients.[2] Based on the Forest plot analysis, Choma et al. found that nonsmokers in Fairbank's RCT had better fusion outcomes than patients who were smoking.[12]

The effect of mental disorders on the outcomes in patients with spine pathologies has been reported. Daubs et al. found that only one RCT compared the outcomes between surgical and nonoperative groups stratified by physiological condition in chronic LBP patients.[14] The improvements at two years postoperatively were 12% in patients with a personality disorder and 18% in patients without a personality disorder.[14] In the nonsurgical group, the improvement was seen in 27 and 9% of patients with and without personality disorders, respectively. The Zung Depression Scale (ZDS) scores were similar between surgical patients with or without any improvements at two years postoperatively. On the other hand, nonoperative patients who reported improvements had higher ZDS score than the patients without improvements (48 vs 40). Daubs et al. showed significant differences in the ZDS scores among surgical and nonoperative patients who improved at

two years postoperatively (39 vs 48, p <0.009).[14] Hägg and co-workers also reported significant changes in the personality traits scores for neuroticism among the surgical patients.[13] At two years postoperatively the score was 50.1 ± 8.3 in patients designated as *improved* versus 54.1 ± 9.8 in the *nonimproved* group (p = 0.006). An opposite trend was seen in nonoperative groups.

When it comes to sociodemographic factors Mroz and co-workers reported that patients with lighter jobs, pending litigation, and not being on sick leave responded better to fusion than nonoperative treatment.[15] In the RCTs done by Fritzell et al. surgical patients without litigation did better than patients under litigation or compensation at two-year follow-up (70% vs 58%);[5] however, it was not significant. In the nonoperative arm similar trends were seen (50% vs 18%, p = 0.043).[5] Fairbank and co-workers reported a reduction in the ODI values in both surgical and intensive rehabilitation groups.[2] In the surgical group, the ODI scores improved in both patient groups, with litigation (−17.9) and without litigation (−11.6) at two-year follow-up. Compared to the surgical group, the intensive rehabilitation patients had less improvement in the ODI scores −8.8 to −7.6, with or without litigation.[2] Due to the lack of statistical analysis between the treatments, it is unclear if there was a significant effect modification.

Resolution of clinical scenario

- Smoking is perhaps the most well-known risk factor that produces suboptimal outcomes in surgical fusion candidates.

Summary of answers

- Structured nonoperative treatment for LBP can provide pain relief and functional improvement.
- Diagnostic tests have little prognostic value, though a positive PCT has been correlated with improved outcomes.
- Smoking is a major risk factor for suboptimal outcomes in surgical fusion candidates.

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113 Mechanical Low Back Pain: Nonoperative Management

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Clinical scenario

- A 57-year-old male truck driver presents with low back pain (LBP) along the beltline after a recent long drive across the country.
- Symptoms have been present for the last three weeks.
- Pain is described as a dull ache that does not radiate anywhere else. He denies any numbness or tingling. He does note occasional shooting pain that radiates down the lateral right thigh and into the anterolateral lower leg. No reported weakness.
- He has treated himself so far with heating pads and occasional acetaminophen, which is minimally effective.

Top three questions

1. In patients presenting with acute or subacute LBP, does early advanced imaging, e.g. computed tomography (CT) and magnetic resonance imaging (MRI), lead to improved outcomes when compared to delayed imaging?
2. For patients undergoing initial treatment of mechanical LBP, does skeletal manipulation prevent the

progression of symptoms more effectively than medical care?

3. Is there a role for spinal injections in the treatment of patients with mechanical LBP instead of oral medications?

Question 1: In patients presenting with acute or subacute LBP, does early advanced imaging, e.g. computed tomography (CT) and magnetic resonance imaging (MRI), lead to improved outcomes when compared to delayed imaging?

Rationale

In the US, LBP is one of the most common issues leading to medical evaluation. Roughly 85% of the population will experience an episode of mechanical LBP at some point in their lives.[1,2] More than 85% of patients who present to primary care with this symptom will have LBP that cannot reliably be attributed to a specific disease or spinal abnormality.[3] This translates to a significant healthcare expense, with only cancer and heart disease having a larger financial impact.[4–8] A variety of advanced imaging studies can be used to evaluate LBP, but many have high associated costs. However, more expensive tests may be justified if there is a possibility to positively affect outcomes.[9]

Clinical comment

Physicians are burdened with appropriately and effectively treating a patient while also preventing financially wasteful testing. Expensive imaging is difficult to justify if the clinical outcomes are unaffected. In addition to the stress the physician feels to be fiscally responsible, the patient is taxed with potentially having to make another appointment to obtain the advanced imaging. This can lead to decreased patient satisfaction if the additional time within the healthcare system is not justified. Furthermore, unindicated imaging could lead to findings that trigger further intervention without benefit.

Available literature and quality of the evidence

The overwhelming consensus in the treatment of LBP is that advanced imaging is not indicated for acute and subacute symptoms. Multiple clinical guidelines and meta-analyses support this opinion in both the United States and the United Kingdom.[10]

Findings

A 2009 meta-analysis of randomized controlled trials (RCTs) showed that in the primary care setting there was no significant difference in outcomes between early imaging versus no immediate imaging for acute or subacute LBP.[11] This was true for both short-term (up to three months, standardized mean difference 0.19; 95% confidence interval [CI]: –0.01 to 0.39 for pain and 0.11, –0.29 to 0.50 for function; with negative values favor routine imaging) or long-term (6–12 months, –0.04, –0.15 to 0.07 for pain and 0.01, –0.17 to 0.19 for function) follow-up. Imaging in this study was defined as radiography, MRI, or CT.

The American College of Physicians and the American Pain Society released a series of clinical guidelines in 2007

regarding the diagnosis and management of LBP.[12] In their second recommendation, the guidelines state that "Clinicians should not routinely obtain imaging or other diagnostic tests in patients with nonspecific LBP." This was labeled a strong recommendation with moderate quality evidence. They further clarified indications for imaging by delineating neurologic deficits or underlying conditions that could support the administration of injections or surgery as a reason to obtain an MRI or CT.

Several studies have also documented both the overuse and underuse of advanced imaging in the treatment of LBP.[13] When being referred for lumbar spine imaging, 34.8% of referrals (95% CI: 27.1–43.3) were deemed inappropriate by the absence of red flags for serious pathology and 31.6% (95% CI: 28.3–35.1) were determined to be inappropriate by the criteria of no clinical suspicion of pathology. Subsequent research demonstrated how little the actual management of LBP is informed by lumbar MRI, with one study stating only 13% of said MRIs were actionable.[14]

Resolution of clinical scenario

- Immediate advanced imaging (CT, MRI, etc.) is not indicated for this patient who presents without a worsening neurologic deficit or significant underlying medical or traumatic condition relating to his LBP.
- Without any defined injury or trauma, immediate radiographs are also not indicated at the time of initial presentation.

Question 2: For patients undergoing initial treatment of mechanical LBP, does skeletal manipulation prevent the progression of symptoms more effectively than medical care?

Rationale

With most population centers supporting both medical and chiropractic practices, many patients often ask about skeletal manipulations as a form of treatment for LBP. Many physicians do not have any direct experience with or in-depth knowledge of these treatments in order to inform their patients regarding use.

Clinical comment

Once diagnosed with acute or subacute LBP, most patients are typically encouraged to undergo a variety of both pharmacological and nonpharmacological conservative treatments. Commonly used medications include nonsteroidal anti-inflammatories (NSAIDs), acetaminophen, and muscle relaxants. Opioids are typically avoided in these scenarios. Nonpharmacological therapies include a variety of modalities: exercise and physical therapy, spinal manipulation, acupuncture, yoga, and psychological therapies. Chiropractic care is often a popular option among patients with acute or subacute LBP. However, is this extra method of treatment more beneficial than standard medical care?

Available literature and quality of the evidence

Several well-powered meta-analyses and RCTs exist regarding the question proposed previously. Furthermore,

these form the basis for several practice guidelines from the American College of Physicians.

Findings

The American College of Physicians has proposed several recommendations regarding the use of skeletal manipulations in the treatment of LBP. It found that skeletal manipulation was as effective as other active interventions with a moderate strength of evidence. This was comparable to the moderate recommendation endorsing multidisciplinary rehabilitation and exercise.[15,16]

In a 2016 randomized clinical trial, Schneider et al. reported that manual thrust manipulation (MTM) was superior to usual medical care (UMC) in providing greater short-term reduction in self-reported disability and pain scores.[17] In the study's responder analysis, defined as 30 and 50% reductions in Oswestry scores, the authors revealed a significantly greater proportion of responders at four weeks in MTM (76%, 50%) compared to UMC (48%, 39%). These differences were only present in the short-term, however. There were no statistically significant differences between groups at three or six months.

A 2017 meta-analysis also reported that spinal manipulation provided modest improvements in pain and self-reported function for up to six weeks.[18] Fifteen randomized clinical trials (encompassing 1699 patients) provided moderate-quality evidence that spinal manipulation has a statistically significant association with improvements in pain (pooled mean improvement in the 100 mm Visual Analog Scale (VAS), −9.95 (95% CI: −15.6 to −4.3), while 12 randomized clinical trials (1381 patients) produced moderate-quality evidence that manipulation has a significant association with improvements in function (pooled mean effect size, −0.39 (95% CI: −0.71 to −0.07).

Shekelle et al. echoed this finding, demonstrating that in patients presenting with uncomplicated, acute low back pain, the difference in probability of recovery at three weeks in the context of treatment with spinal manipulation was 0.17 (95% probability limits of estimate, 0.07–0.28).[19]

While this evidence suggests that spinal manipulation is effective in alleviating acute LBP, there are relatively few high-quality studies comparing this method of treatment directly to other standard approaches. Assendelft et al. performed a meta-analysis and found no evidence that spinal manipulative treatment was superior to other modalities of conservative treatment for acute or chronic LBP.[20] They defined standard methods of treatment as general medical care, analgesics, physical therapy, exercises, or back school.

To determine who would benefit from spinal manipulation, Flynn et al. proposed a prediction rule that classified patients according to who would demonstrate short-term improvement.[21] They first identified five variables (symptom duration, fear-avoidance beliefs, lumbar hypomobility, hip internal rotation range of motion, and no symptoms distal to the knee) as correlating to an increasing probability of success. The presence of four of five of these variables (positive likelihood ratio = 24.38) increased the probability of success with manipulation from 45 to 95%. This rule was then subjected to a validation study and found to show that a patient who was positive on the rule and received manipulation enjoyed a 92% chance of a successful outcome.[22]

Resolution of clinical scenario

- Spinal manipulation is an effective tool in providing short-term relief for acute LBP.

- There is little evidence to suggest that spinal manipulation is superior to standard medical treatments, however.
- Patient and physician preference should dictate which initial method of treatment is attempted, as both appear to be cost effective.[23]

Question 3: Is there a role for spinal injections in the treatment of patients with mechanical LBP instead of oral medications?

Rationale

Many patients presenting with LBP are very limited in their daily activities while symptoms are present. Patients often ask about and actively seek an immediate and tangible intervention, such as an injection instead of an oral medication.

Clinical comment

Injection therapy has been shown to be moderately effective when treating compressive nerve-related pathology such as that from herniated discs or spinal stenosis, but not so much for nonspecific LBP. While not a surgical procedure in terms of invasiveness, an injection still involves a foreign material entering the body. While this method of treatment is often considered conservative by patient and physicians, there remains the potential for complications to develop. Also, the cost of such a procedure must be weighed against the clinical efficacy it provides over less expensive and more readily accessible alternatives.

Available literature and quality of the evidence

There is little evidence at all, let alone high-level evidence, to suggest that injection therapies should be favored over oral medications for acute LBP.

Findings

While there are a variety of treatment options available in terms of injection therapies, there is simply too much heterogeneity to support the use of such methods as standard treatment of subacute LBP.[24] Some conditions responded equally well to either local anesthetic injections with or without steroids, while nonspecific LBP failed to demonstrate a clinically effective response to facet joint injections.[25],[26]

Oral medications present a readily accessible method for treatment of acute LBP. The literature supports the use of NSAID medications, with multiple studies documenting their efficacy. In a systemic review, four trials found a greater mean improvement for NSAID medications over placebo: (weighted mean difference, 8.39 points on a 0 to 100-point scale [CI: 12.68–4.10 points]; chi-square test, 3.47 points; $p > 0.10$).[27] Surprisingly, the role of acetaminophen is limited.[28] Muscle relaxants can be effective secondary means of treating these acute symptoms as well.[29] With the increasing scrutiny that opioids have developed, the literature now supports only a very limited role for their use in the treatment of LBP.[30],[31]

Resolution of clinical scenario

- First-line treatment should consist of oral medications such as NSAIDs and muscle relaxants.

- Opioids should have an exceedingly limited role, if any, in the management of acute and subacute LBP.
- Injections are likely ineffective for acute and subacute pain if there is no specific radiographic pathology or well-characterized etiology for the pain.

Summary of answers

- Immediate advanced imaging is not indicated for patients without significant trauma or neurologic deficit.
- Spinal manipulation can provide short-term pain relief, but it is unclear whether it is superior to standard medical treatments.
- First-line treatment for LBP should consist of NSAIDs and muscle relaxants, with opioids used very rarely.

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114 Neurogenic Claudication

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Clinical scenario

- A 68-year-old woman presents with leg and buttock pain after walking less than 250 meters, accompanied by lower extremity numbness.
- No severe back pain. Symptoms relieved when bending forward or sitting down. The symptoms have gradually been more intense in the last 2–3 years.
- Clinical examination normal: no sign of muscle weakness in the lower extremity, no sign of numbness or reduced sensibility, normal tendon reflexes.
- Magnetic resonance imaging (MRI) of the lumbar spine reveals severe spinal stenosis at L4/L5, with homogeneous gray signal in the spinal canal with no cerebrospinal fluid signal visible between the rootlets. An anterolisthesis of 4 mm is seen in the sagittal view. X-ray is not revealing any instability on flexion/extension view.

Top three questions

1. In elderly patients with lumbar spinal stenosis, does decompressive surgery result in better patient-reported outcomes compared to nonoperative treatment?
2. In elderly patients with lumbar spinal stenosis, does minimally invasive (midline-sparing) decompression

result in better patient-reported outcomes compared to laminectomy?

3. In elderly patients with lumbar spinal stenosis and concomitant spondylolisthesis, does surgical treatment with decompression and fusion result in better patient-reported outcomes compared to decompression alone?

Question 1: In elderly patients with lumbar spinal stenosis, does decompressive surgery result in better patient-reported outcomes compared to nonoperative treatment?

Rationale

Lumbar spinal stenosis (LSS) is the most common indication for spinal surgery among the elderly. The prevalence of symptomatic LSS is approximately 10%.[1],[2] Classical symptoms are neurogenic claudication accompanied by pain and paresthesia in the back, buttocks, and lower limbs, typically, but not always, relieved by flexion of the spine. The condition represents a significant negative impact on quality of life.[3] The goal of the treatment is pain relief and improved function, and decompressive surgery is a frequently used operative strategy. Nonoperative treatments vary from simple pain medication and physiotherapy to epidural steroid injections. There is no international consensus on when to operate, and studies evaluating the clinical benefit of surgery over conservative treatment are few in number.

Clinical comment

The indication for surgery is relative but remains an option for patients with persistent and severe symptoms that include both back and leg pain. Due to higher age and frequent presence of co-morbidities the risk has to be weighed against benefit. In many patients radiographic findings are consistent with LSS, but the clinical signs and symptoms are not. The clinical history is a prerequisite to conclude whether to operate or not.

Available literature and quality of the evidence

There are four level I evidence studies examining this question, comparing decompressive surgery to physiotherapy and/or to epidural steroid injections. Small size and high crossover rate make the quality of these studies low.

Findings

In a Finnish study from 2007, 94 patients were randomized into decompressive surgery (n = 50) or nonoperative treatment (n = 44). Surgery consisted of laminectomy, in 10 patients combined with fusion.[4] The nonoperative treatment was individually adjusted physiotherapy treatment, with nonsteroidal anti-inflammatory drugs when indicated. The primary outcome was Oswestry Disability Index (ODI) and the follow-up period was two years. In this small study with fewer patients than the a priori power calculation (total participants were 94 vs 104 in the power calculation), and with a crossover of 10% in each group, the results must be interpreted with caution. Mean difference in ODI (95% confidence interval [CI]) after two years was 7.8 (0.8–14.9) in favor of surgery but with improvement in both groups.

In the Spine Patient Outcomes Research Trial (SPORT) Weinstein et al. reported two-year outcomes in patients

with LSS without degenerative spondylolisthesis, randomized to surgical or nonsurgical treatment.[5] A total of 289 patients were enrolled in a randomized cohort and 365 in an observational cohort. In the randomized cohorts, 67% of patients in the surgery group had undergone surgery, whereas 43% in the nonsurgical group also had undergone surgery at two years. Surgery was decompressive laminectomy without fusion. In the intention-to-treat analysis, treatment effects of surgery compared to nonsurgery (95% CI) were 7.8 (1.5–14.1) for Short-Form General Health Survey 36 (SF-36) bodily pain, 0.1 (–6.4 to 6.5) for physical function, and –3.5 (–8.7 to 0.1.7) for ODI. For the as-treated analysis the corresponding numbers were 11.7 (6.2–17.2), 8.1 (2.8–13.5) and –8.7 (–13.3 to –4.0).

A parallel study was done on LSS-patients *with degenerative spondylolisthesis*.[6] Here 304 patients were included in the randomized cohort and 303 in the observational cohort. The surgery group received decompressive laminectomy with or without fusion. The nonsurgical group was given *usual care*. Primary outcomes were SF-36 on pain and physical function and ODI. In the intention-to-treat analysis treatment effects (95% CI) were 1.5 (−4.2 to 7.3) for SF-36 bodily pain, 1.9 (−3.7 to 7.5) for physical function, and 2.2 (−2.3 to 6.8) for the ODI at two years. For the as-treated analysis the corresponding numbers were 18.1 (14.5–21.7), 18.3 (13.4–23.6), and –16.7 (–19.9 to –13.9).

A high rate of crossover was also seen in the study of Delitto et al. randomizing patient to either surgical decompression or physiotherapy treatment.[7] Eligible patients were already assigned for surgery. The physiotherapy treatment program emphasized lumbar flexion exercises, general conditioning exercises, and

patient education. Out of 169 eligible patients, 87 were allocated to surgery and 82 to physical therapy. In the conservative group 57% crossed over to surgery, while two crossed over from surgery to physical therapy. The primary outcome for the study was the physical function score on SF 36 at the two-year endpoint. The mean difference in effect was (95% CI) 1.9 (−7.3 to 11.2).

In conclusion, surgery had a favorable effect on overall disability in three out of the four studies. Improvement also occurred in the nonoperative treatment group. Surgical decompression should be suggested with caution and only after due conservative treatment of the patient. Due to high rate of crossovers and loss to follow-up >20%, the certainty based on these studies is low.

Resolution of clinical scenario

Decompressive surgery is indicated if conservative treatment has been tried and have had no or limited effect.

Question 2: In elderly patients with lumbar spinal stenosis, does minimally invasive (midline-sparing) decompression result in better patient-reported outcomes compared to laminectomy?

Rationale

In the 1950s the pathophysiology of this condition was understood, and laminectomy became the gold standard for surgical treatment of LSS.[8] A new approach was developed in the mid-1990s, and minimally invasive decompression became an alternative procedure. The essence of this

procedure was to spare the midline structures. Theoretically, this will reduce the risk of postoperative instability, and hence improve the results compare to laminectomy. On the other hand, there is a possibility that minimally invasive decompression does not result in sufficient decompression of the nerve roots. A Norwegian cohort study comparing minimally invasive decompression to laminectomy found no difference in outcome in unmatched cohort or propensity matched cohort.[9]

Clinical comment

Minimally invasive decompression can be done in several ways, and has different names, sometimes with confusing overlap. Expressions as bilateral laminotomy, microdecompression, foraminotomy, unilateral approach with crossover technique, and *over the top decompression* are commonly used. Endoscopic technique for minimally invasive decompression is also described. There is, however, little evidence for advocating one surgical technique over another.[10],[11]

The narrowing of the spinal canal is a slow degenerative process and the symptoms usually appear gradually. Patients with persistent severe pain seem to benefit from surgery. On the other hand, some patients with degenerative LSS expose challenging clinical decisions due to high age and co-morbidities. MRI may also show narrowing of the spinal canal in more than one level. This makes the decision on which level to operate more difficult. The main surgical approach is decompression, either by minimally invasive technique or laminectomy. The aim is to remove bone, like the medial aspect of the medial facet and ligamentum flavum, to relieve compression on the spinal nerves.

Available literature and quality of the evidence

There are five randomized prospective studies addressing this question. The timespan is large and the sizes of the studies vary, as do the conclusions.

Findings

In a study from 2010, Celik et al. randomized 71 patients to laminectomy (n = 34) or bilateral *microdecompressive laminotomy* (n = 37).[12] Mean follow-up was five years and primary outcome was Visual Analog Scale (VAS) for back and leg pain in addition to the ODI as a measure of physical disability. A statistically significant reduction in the severity of pain and increased physical function was observed in both groups postoperatively ($p < 0.05$). Although there was less postoperative pain in the microdecompressive laminotomy group, no statistically significant between-group difference was found regarding postoperative pain reduction and physical disability improvement ($p > 0.05$).

Fu et al. compared in a study from 2008 minimally invasive decompression (*windows technique*) to laminectomy in 152 patients.[13] Primary outcome included VAS for back and leg pain, and ODI. All though both groups had significant improvement of pain and disability, the results were significantly better in the minimally invasive group compared to laminectomy at follow-up. After 40 months VAS for back pain was 0.05 compared to 0.63 ($p < 0.001$), VAS for leg pain was 0.01 compared to 0.36 ($p = 0.001$), and ODI was 0.37 compare to 3.37 ($p = 0.003$). A good to excellent result was described for 89% in the minimally invasive group and 63% in the laminectomy group ($p < 0.001$).

In a study published in 2005, Thomé et al. randomized 120 patients to three groups, operated with bilateral laminotomy, unilateral laminotomy with bilateral decompression, or laminectomy.[14] Bilateral laminotomy

and unilateral laminotomy with crossover technique are both midline-sparing techniques and should be considered as minimally invasive decompression as compared to laminectomy. Pain in VAS was primary outcome and follow-up was 12 months. The surgery resulted in a reduction of overall pain in all three groups ($p < 0.001$). There was significantly more residual pain in the unilateral laminotomy group (3.6) and laminectomy group (4.0) compared with patients operated with bilateral laminotomy (2.3) ($p < 0.05$). Neurogenic claudication (leg pain during walking) improved in 92% of patients in the bilateral laminotomy group compared with 74 and 68% in unilateral laminotomy and laminectomy group ($p < 0.05$), respectively.

Postacchini et al. compared in 1993 multiple laminotomy with laminectomy including 67 patients with LSS at two or three levels.[15] The protocol, however, allowed multiple laminotomy to be changed to total laminectomy if preoperatively assumed as necessary to achieve adequate decompression. There were therefore three treatment groups: 26 patients submitted to multiple laminotomy, 9 patients scheduled for laminotomy but submitted to laminectomy, and 32 patients scheduled for, and submitted to, laminectomy. The primary clinical outcome score was the mean of two scores, from the patient and from the clinical examination rated as excellent, good, fair, or poor. The mean follow-up was 3.7 years. There were no significant differences in the mean objective improvement scores for each group.

In conclusion, minimally invasive decompression had favorable effect on pain and overall disability in one out of the four studies. Improvement occurred after both minimally invasive decompression and laminectomy. The choice of technique should mainly be based on the surgeon's preference. Due to concerns with inadequate

allocation concealment and small numbers per group, the certainty based on these studies is low.

Resolution of clinical scenario

- Decompression surgery can be performed as minimally invasive decompression or laminectomy.
- Minimally invasive decompression has shown shorter operation time and shorter length of hospital stay.

Question 3: In elderly patients with lumbar spinal stenosis and concomitant spondylolisthesis, does surgical treatment with decompression and fusion result in better patient-reported outcomes compared to decompression alone?

Rationale

Spinal stenosis is the result of a degenerative process narrowing the spinal canal. Often, there is coexisting degenerative spondylolisthesis, a radiological finding often regarded as a sign of segmental instability. Concomitant arthrodesis has been used in addition with nerve decompression to provide spinal stability and prevent progressive deformity.

Clinical comment

Although it has been disputed, adding surgical fusion in addition to decompression has been recommended to prevent persistent back pain. There is a large and possibly unwarranted practice variation in the use of additional

arthrodesis, implicating higher cost and possible higher complication rate compared to decompression alone.

Available literature and quality of the evidence

There are two randomized controlled studies addressing this issue, both published in 2016.

Findings

In a Swedish randomized controlled study, Försth et al. compared the efficacy of fusion surgery in addition to decompression alone in LSS with or without degenerative spondylolisthesis.[16] In this study 247 patients, aged 50 to 80, were enrolled and primary outcome was the difference in ODI two years after surgery. There were no significant differences from baseline between decompression and fusion (ODI = 27) compared with decompression alone (ODI = 24; p = 0.72).

In a study from the US, Ghogawala et al. compared the effectiveness of instrumented fusion in addition to decompressive laminectomy to decompression alone in patients with symptomatic grade I degenerative spondylolisthesis.[17] There were 66 patients, between 50 and 80 years of age. The primary outcome measure was the change in the physical-component summary score of the SF-36 two years after surgery. In this study the ODI score was planned as the primary outcome, but presented as a secondary outcome. In the primary outcome there was significantly greater increase in the SF-36 physical-component summary score in the fusion group (15.2 vs 9.5, p = 0.046). Reduction in disability measured by ODI was also greater in the fusion group, but did not differ significantly (−26.3 vs −17.9, p = 0.06). The cumulative reoperation rate was lower in the fusion group (14% vs 34%, p = 0.05).

In conclusion, decompression surgery alone is effective in improving symptoms in patients with lumbar spinal stenosis and concomitant spondylolisthesis. Due to some degree of high rate of loss to follow-up and a small number of events, the certainty based on these studies is moderate.

Resolution of clinical scenario

Decompression surgery alone can be performed in LSS in most cases, also when there are concomitant mild spondylolisthesis, as in this case.

Summary of answers

- Decompressive surgery is indicated for lumbar spinal stenosis if conservative treatment has been tried and have had no or limited effect.
- Decompression surgery can be performed as minimally invasive decompression or laminectomy.
- Minimally invasive decompression has shown shorter operation time and shorter length of hospital stay.
- Decompression surgery alone can be performed in lumbar spinal stenosis in most cases, also when there are concomitant mild spondylolisthesis, as in this case.

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115 Lumbar Radiculopathy

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Clinical scenario

- A 48-year-old woman is referred to clinic with pain on the outside of her thigh radiating down her leg for the past nine weeks.
- The symptoms began atraumatically and has been steady in its intensity and location since its onset.
- She reports no problems with leg strength, or bowel or bladder control.

Top three questions

1. In adult patients with lumbar radiculopathy, what work-up is needed to establish a diagnosis?
2. In adult patients with lumbar radiculopathy, do injections alter the natural history of the symptoms compared to noninvasive or surgical treatments?
3. In adult patients with lumbar radiculopathy, does surgical treatment result in superior sustained symptom relief compared to nonsurgical treatment?

Question 1: In adult patients with lumbar radiculopathy, what work-up is needed to establish a diagnosis?

Rationale

A patient's complaint of *sciatica* can originate from myriad pathologies in the lumbar spine and distal to the spine. The clinician must understand the common and rare etiologies of lumbar radiculopathy and the appropriate work-up.

Clinical comment

Radiating leg pain is a common complaint in the outpatient and Emergency Department setting. It is important to understand which exam maneuvers are more sensitive than others in narrowing the differential diagnosis. Additionally, an awareness of the role of advanced imaging avoids unnecessary tests.

Available literature and quality of the evidence

There is level III evidence available regarding the ability of history-taking to establish a diagnosis in patients with lumbar radiculopathy. Level I evidence from multiple prospective studies and subsequent meta-analyses has been published to better understand the diagnostic role of physical exam maneuvers in lumbar radiculopathy. There is level I evidence supporting the use of MRI (magnetic resonance imaging), CT (computed tomography) and CT-myelogram in the work-up of lumbar radiculopathy.

Findings

The history and physical exam steer the clinician toward a diagnosis of lumbosacral pathology if radiculopathy is present, and primary clinicians are trained to search for

red flag symptoms that would prompt a referral to a specialist. However, the diagnostic accuracy of history-taking is low. Verwoerd et al. performed a cross-sectional study investigating the ability of individual questions and a six-question model to predict lumbosacral nerve root compression confirmed by MRI.[1] Questions pertaining to sensory loss were effective, with odds ratios of 2.31 (95% confidence interval [CI]: 1.10–4.85) for nerve root compression and 3.54 (1.64–7.64) for disc herniation. However, the six-question model as a whole was poorly predictive of lumbosacral nerve root compression with an area under the receiver operator characteristic curve (AUC) of 0.65 (0.58–0.71) and 0.66 (0.58–0.74).

Earlier prospective studies argued that physical exam maneuvers and testing could sufficiently diagnose lumbar radiculopathy and even localize the vertebral level of pathology.[2] However, a subsequent Cochrane review concluded the role of diagnostic physical exam tests in lumbosacral radiculopathy was poorly substantiated after reviewing 18 studies on the subject.[3] Iversen et al. performed a prospective study on the accuracy of the physical exam maneuvers recommended by the American Spinal Injury Association (ASIA) to predict nerve root impingement.[4] They reported that no individual test was reliable at predicting the laterality or level of impingement, with low sensitivities and specificities and wide confidence intervals.

A systematic review by Wassenaar provided level I evidence on the role of MRI in diagnosing lumbosacral pathology.[5] The pooled data calculated a sensitivity of 75% (95% CI: 65–83%) and specificity of 77% (95% CI: 61–88%) for diagnosing herniated nucleus pulposus (HNP). Likewise, for nerve root compression, two studies showed sensitivities of 81 and 92% with specificities of 52 and

100%. Importantly, clinicians must be aware that there is poor interrater agreement on MRI findings in degenerative lumbar conditions.[6] A systematic review of the use of CT for diagnosing lumbosacral pathology concluded CT was useful for HNP but not other causes of lumbosacral radiculopathy.[7]

Resolution of clinical scenario

- History is useful to ascertain the presence of radiculopathy as a symptom.
- Both history and physical exam poorly correlate with lumbosacral pathology and localizing the etiology of radiculopathy.
- MRI is a useful tool to diagnose lumbosacral pathology but can be misleading due to the level of detail it provides.
- CT or CT-myelogram is capable of detecting certain lumbosacral pathologies if MRI is unavailable to a patient, but its limitations prevent it from a being a first-line imaging modality.

Question 2: In adult patients with lumbar radiculopathy, do injections alter the natural history of the symptoms compared to noninvasive or surgical treatments?

Rationale

The use of injections for treating pathology causing lumbar radiculopathy is a middle ground between physical therapy modalities and surgical treatment. Although desirable for

its relative minimal morbidity, clinicians must understand the impact of injections on the long-term outcomes of lumbar radiculopathy.

Clinical comment

Patients are commonly referred to clinic and enquire as to the likelihood of injections alleviating lumbar radiculopathy.

Available literature and quality of the evidence

There is level I evidence that evaluates the short- and long-term efficacy of lumbar injections when used for radiculopathy caused by HNP. There is level I evidence comparing the approach and type of injection used to alleviate lumbar radiculopathy from HNP.

Findings

The majority of the evidence addressing injections for lumbar radiculopathy involves HNP as the etiology of radiculopathy. Therefore, we cannot recommend extrapolation of these data to lumbar etiologies of radiculopathy other than HNP. Ackerman et al. performed a randomized controlled trial (RCT) comparing transforaminal, caudal, and interlaminar epidural steroid injections (ESI) in patients with radiculopathy from a HNP.[8] This study demonstrated superior relief from transforaminal injections than the other routes, which was sustained at 12 and 24 weeks. Ghahreman et al. performed a prospective trial of 150 patients who were randomized into five groups: transforaminal with normal saline, transforaminal with local anesthetic, transforaminal with corticosteroid, intramuscular with normal saline, and intramuscular with corticosteroid.[9] Of the transforaminal group that received corticosteroid, 54% of patients

reported >50% improvement in leg pain after one month (95% CI: 0.36–0.72). This was statistically significant compared to the other routes at one month but not sustained at 12 months and therefore the authors advocated short-term use.

The finding of short-term relief was echoed in a study by Nandi et al., who reported the results of a prospective comparative study between caudal ESI with corticosteroid versus saline for HNP.[10] At four weeks there was a significant difference based on a four-part descriptive scale with 17% of the saline group reporting improvement compared to 68% in the corticosteroid group. This difference was not significant at three months. Chou et al. performed a systematic review incorporating nine high-quality studies and concluded that injections provided a moderate short-term benefit for radiculopathy.[11]

Resolution of clinical scenario

- There is high-quality evidence that a transforaminal ESI will provide moderate short-term relief for the patient in the above clinical scenario if HNP is the etiology of her radiculopathy.
- There are published studies of long-term pain relief from ESI but that finding has not been reproducible in larger systematic reviews.

Question 3: In adult patients with lumbar radiculopathy, does surgical treatment result in superior sustained symptom relief compared to nonsurgical treatment?

Rationale

This question addresses the most pressing concern of the patient and the surgeon when making a shared clinical treatment plan. The clinician must be aware of the nuanced data available to help patients make informed decisions.

Clinical comment

The patient must be appropriately counseled about expectations regarding the outcomes of surgery. It is the surgeon's responsibility to adequately translate the scientific evidence to allow the patient to make an informed decision.

Available literature and quality of the evidence

There is level I evidence comparing the outcomes of surgical and nonsurgical treatment for radiculopathy secondary to HNP. There is level IV evidence evaluating the timing of surgery in patient outcomes.

Findings

Buttermann published the results of a prospective RCT evaluating discectomy versus interlaminar epidural steroid injection.[12] The outcomes were leg and back pain measured by Visual Analog Scale (VAS) and function measured by the Oswestry Disability Index (ODI). He reported an improvement in leg pain and ODI scores in both groups but a greater improvement in leg pain and function at the 1–3 month and 4–6 month follow-up time periods ($p < 0.0001$ and $p = 0.03$, respectively).

The Spine Patient Outcomes Research Trial (SPORT) provides prospective, randomized data comparing nonoperative and operative treatment of radiculopathy for HNP.[13] There has been much debate on the results of

intent-to-treat analyses versus as-treated analyses. From a surgical perspective, the as-treated analysis shows long-term statistically significant improvement with surgical treatment. At one year, the Short Form 36 (SF-36) bodily pain score improved by 15.0 points (95% CI: 10.9–19.2) and physical function improved by 17.5 points (95% CI: 13.6–21.5). The ODI scores of the surgical group decreased by 15.0 points (95% CI: 11.7–18.3).

Atlas et al. published the results of the Maine Lumbar Spine Study group at 10-year follow-up, which compared surgical and nonsurgical treatment of HNP.[14] This study found a significant improvement in leg pain and function but similar rates of work status and disability in both groups. Finally, Ng et al. prospectively collected data on a series of patients who underwent discectomy for radiculopathy and concluded that patients who undergo discectomy more than one year after the onset of symptoms have less improvement on the ODI.[15]

Resolution of clinical scenario

- For patients with radiculopathy from HNP who have undergone nonoperative therapy for six weeks without improvement, surgical treatment is a reasonable alternative that can provide reliable pain relief.
- In this clinical scenario, if the patient has an HNP confirmed by MRI and is having radiculopathy affecting her function, discectomy can be offered as treatment if there are no contraindications.

Summary of answers

- Patients that present with radiating lower extremity pain suggestive of lumbar radiculopathy should

undergo a comprehensive history and physical exam to rule out extraspinal etiologies.

- MRI is the modality of choice for investigating lumbar radiculopathy symptoms.
- HNP is the most common cause of lumbar radiculopathy, and transforaminal epidural steroid injections are capable of provided short-term pain relief.
- Surgical discectomy is an option after six weeks of pursuing nonoperative treatment for radiculopathy, and is most effective if done within one year of symptom onset.

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116 Adolescent and Adult Spinal Deformity: Nonoperative Management

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Clinical scenario

- You see an asymptomatic 13-year-old Risser 0 female patient in your orthopedic clinic with a first-time presentation of a right thoracic curve with associated 30° Cobb angle from T7 to L1. She presents with a normal examination and an unremarkable past medical and developmental history.
- The patient, along with her mother and father, wishes to avoid surgical intervention but worries about the effectiveness of bracing therapy and has read about the negative psychosocial effects of bracing.
- The patient's mother is concerned about her daughter becoming short of breath with any type of exertional activity, like her aunt who had untreated scoliosis.
- The patient's father asks how you can be certain her current curve will not progress when she is done growing and cause her “problems” as an adult.

Top three questions

1. In patients with adolescent idiopathic scoliosis (AIS), how does bracing influence health-related quality of life (HRQoL)?
2. In patients with AIS, does nonoperative management result in pulmonary compromise in adulthood?
3. Which risk factors predict patients with adult scoliosis curves will progress and cause low back pain (LBP)?

Question 1: In patients with adolescent idiopathic scoliosis (AIS), how does bracing influence health-related quality of life (HRQoL)?

Rationale

Older reports suggest a negative impact of bracing on psychosocial development and HRQoL. It is important to understand whether bracing therapy for AIS continues to cause negative HRQoL.

Clinical comment

The Bracing in Adolescent Idiopathic Scoliosis Trial (BrAIST) is a landmark multicenter randomized cohort trial demonstrating efficacy of brace treatment in preventing curve progression to surgical thresholds among adolescents with remaining growth and curve magnitudes under 40°.[1] Importantly, brace treatment has traditionally been associated with poor body image, decreased psychosocial wellbeing, and self-esteem when compared to healthy peers.[2] Brace treatment has also been associated with poor psychosocial health due to body image disturbance.[3] Furthermore, Danielsson et al. showed that after brace treatment patients report greater subjective

body distortion than nonbranched peers with similar truncal rotation and curve magnitude.[4]

Available literature and quality of the evidence

BrAIST provides level II evidence on HRQoL among those patients undergoing bracing treatment compared to nonbraced controls.[1] Further available evidence to inform HRQoL predictors related to bracing therapy for AIS comes from level II studies spun off of the BrAIST trial. Schwieger et al. provided two level II prospective cohort studies based on BrAIST analyzing the HRQoL of braced patients at baseline and up to two-year follow-up post initiation of bracing therapy.[5,6] Importantly, Schwieger et al. examined whether HRQoL and body image affected compliance to brace therapy.[6] The largest cohort of braced AIS patients comes from Cheung et al. (level III).[7] Cheung et al. analyzed 652 patients with scoliosis using the refined Scoliosis Research Society 22-item (SRS-22r) and 5-level EQ-5D (EQ-5D-5L) questionnaires. They compared patients undergoing clinical observation to a group of patients in thoracolumbar orthosis and patients who were previously braced.

Findings

In Cheung et al. HRQoL scores were initially higher when bracing was initiated; however, there was a time-dependent deterioration associated with duration of brace treatment.[7] The respective SRS-22r scores were higher for the observation than bracing and previously braced groups ($p < 0.001$). Curves greater than 40° had worse HRQoL ($p < 0.001$). Additionally, previously braced patients had better HRQoL than currently braced patients, with 0.23 higher SRS-22r scores ($p < 0.001$), thus supporting a transient effect to bracing therapy in AIS.

Interestingly, the BrAIST trial found no differences in pediatric quality of life scores between the bracing control group at baseline or follow-up (mean scores in primary analysis 82.9 and 81.9, respectively p = 0.97).[1] Schwieger et al. found no significant differences within or between study arms of observation or braced AIS patients; however, patients with Cobb angles >40° had significantly poorer body self-image.[5] In Schwieger et al., 167 patients undergoing brace treatment were found to have no statistically significant correlation to compliance with brace wear; however, there was a trend toward improved satisfaction with treatment when these patients were involved in their treatment decisions.[6] Therefore, while initial reports suggested that bracing may be associated with poorer psychosocial development, poor body-image, and reduced HRQoL, newer evidence suggested this to not be the case.

Resolution of clinical scenario

- Level II evidence supports that bracing is a safe and effective method of treating scoliosis in patients with growth remaining and curves ranging from 20 to 40° in their coronal cobb angle.
- While initial reports suggested that bracing in scoliosis was associated with a negative effect on self-image and psychosocial health, newer level II reports suggest that HRQoL may not be significantly different between patients receiving brace treatment and those not receiving brace treatment.
- Level II evidence supports improved treatment satisfaction in patients taking on an active role in making decisions regarding their own bracing treatment.

Question 2: In patients with AIS, does nonoperative management result in pulmonary compromise in adulthood?

Rationale

Thoracic curves in AIS can affect respiratory function, leading to restrictive respiratory abnormalities based on alterations to the anatomy of the thorax. It is important to identify nonoperatively treated AIS patients at an early age to best understand who is at greatest risk in adulthood of pulmonary compromise.

Clinical comment

While the causal relationship between spinal deformity and pulmonary function has yet to be fully elicited, there is a known negative correlation between curve magnitude and pulmonary function.[8] Forced vital capacity (FVC) and forced expiratory volume in one second (FEV_1), both measures of pulmonary function, are most significantly reduced with greater thoracic curves and higher apical vertebral levels.[9] Long-term follow-up of patients with AIS has demonstrated clinically relevant pulmonary compromise affecting mortality only in thoracic curves which progress over 100°.[8–10] Importantly, almost two-thirds of AIS patients commonly complain of decreased cardiovascular ability and exercise capacity with increasing significance based on thoracic curve magnitude.[10–14] In patients who undergo nonoperative AIS treatment, it is important to understand the degree of expected pulmonary dysfunction that may occur in adulthood.

Available literature and quality of the evidence

The highest available quality of evidence to inform expected pulmonary capacity in adulthood among nonoperatively managed AIS patients is derived from level III cohort studies. There has been little new long-term longitudinal analyses on the effects of nonoperative AIS management and adult pulmonary compromise. Pehrsson et al. compared a consecutive group of 251 patients with posterior fusion (141) or brace (110) treatment at a mean of 25-year follow-up with a group of 100 age- and sex-matched controls (level III).[15] Similarly, Weinstein et al. provided a 50-year follow-up of an AIS patient cohort treated nonoperatively and followed prospectively, compared to age- and sex-matched controls (level III).[10] In an effort to establish the effects of thoracic curve on cardiopulmonary exercise tolerance, Shen et al. recently analyzed a cohort of 40 AIS patients (level III).[6] All patients had a full radiographic, pulmonary function, and cardiopulmonary bicycle ergometer assessment to maximal exertion. Among included patients, an average 49° coronal thoracic curve was present at analysis among patients ranging from 11 to 35 years at analysis.

Findings

In Pehrsson et al. among brace-treated AIS patients, vital capacity (VC) calculated as a percentage of expected VC based on height and age corrected for height loss related to curve increased from 77% predicted pretreatment to 89% ($p < 0.0001$) 25 years after initiation of treatment, for a mean change of 12.3% (95% confidence interval [CI]: 10.5–14.1).[15] There was no significant difference among all groups in reported dyspnea or wheezing rates.[10],[15] Weinstein et al. demonstrated that patients with thoracic curves >80° or lumbar curves >50° had greater odds of shortness of breath (SOB) than lesser lumbar curves (odds ratio [OR] = 9.75; 95% CI: 1.15–82.98).[10] Of 79 available

patients at all three points of analysis in the study, those with Cobb angles >50° at skeletal maturity were at significantly increased odds of SOB at all time points (OR = 3.67, latest follow-up; 95% CI: 1.12–12.12). Shen et al. found no correlation between kyphosis and exercise tolerance; however, a correlation between kyphosis and pulmonary function was reported, with FVC ($r = 0.366$, $p = 0.043$) and FEV_1 ($r = 0.456$, $p = 0.001$), consistent with previous reports.[16] Patients performing regular aerobic exercise had better physical exertion responses with peak oxygen intake normalized by predicted value ($p = 0.003$), maximum heart rate ($p = 0.020$), and heart rate reserve at maximal exercise ($p = 0.013$). However, there were no differences in pulmonary function results or in parameters related to ventilation and pulmonary gas exchange. These results support the importance of early and consistent aerobic exercise programs for AIS patients regardless of age of diagnosis or degree of curvature at time of diagnosis.

Resolution of clinical scenario

- Level III evidence supports improved pulmonary function in AIS patients treated nonoperatively when compared to prebracing measurements at long-term follow-up.
- Level III evidence provides supportive evidence to emphasize the importance of early intervention of aerobic exercise regimens for all AIS patients, regardless of how minimal a curve is at initial diagnosis.

Question 3: Which risk factors predict patients with adult scoliosis curves will progress and cause low back pain (LBP)?

Rationale

For patients with nonoperatively managed adult idiopathic scoliosis (AIS) it is important for physicians to understand future risks of LBP and curve progression to better inform clinical decision-making and appropriate follow-up of this patient population.

Clinical comment

The most compelling indication for intervention in AIS is curve progression and the effort to prevent such a phenomenon in adulthood.[17] Thus, surgical intervention is often pursued in patients with curves approaching or exceeding 50°. While it is known that as skeletal maturity occurs peak curve progression slows dramatically, the challenge to clinical practice for adult patients with scoliosis is predicting far into the future which patients treated nonoperatively will see progression to their curves and predict those patients who may become symptomatic in the future.[17]

Available literature and quality of the evidence

There is limited literature on the natural history of nonoperative management of AIS. As such, the bulk of the evidence available to practitioners is in the form of longitudinal level III and IV retrospective follow-up studies. The so-called Iowa studies have largely shaped our understanding of the natural history of AIS in nonoperatively managed patients.[10,17–19] Compiled

evidence from the ensuing long-term follow-ups of the Iowa studies demonstrate curves >30° at adulthood progress at a rate of <1° per year, with rates of progression up to curves of ~80° increasing at slightly greater rates annually.[10,17–19] Similarly, quantification of the rates of the prevalence of LBP among AIS patients comes from level III retrospective cohort studies. Mayo et al. assessed the prevalence of LBP among 1476 AIS subjects compared to 1755 age-, sex-, and regional-matched controls in a retrospective cohort (level III).[20] Mayo et al. assessed the prevalence of LBP among this cohort via mailed questionnaires of both the McGill Pain Questionnaire and the Oswestry Disability Index (ODI). In a retrospective level III cohort study Danielsson et al. reported on 142 surgically treated and 110 braced patients at a mean of 23- and 22-year follow-up, respectively, compared to 100 age- and sex-matched control group participants (level III).[21] Recently, Ohashi et al. reported on 56 nonoperatively treated AIS patients with an average follow-up of 25 years ± 7 years in a retrospective case series (level III).[22] Ohashi et al. performed both a Visual Analog Scale (VAS) for LBP as well as the ODI and magnetic resonance imaging (MRI) among included patients.

Findings

Danielsson et al. reported a curve progression of 7.9° in nonoperatively treated patients at last follow-up compared to 3.5° for surgically treated patients ($p < 0.001$).[21] Both surgically treated and braced patients were more likely than control group patients to experience degenerative disc changes ($p < 0.001$). Ohashi et al. reported that patients with a Cobb angle of 37.3° ±7.5° progressed to 47.8° ±12.6° (0.41° per year) at 25-year follow-up.[22] Multivariate analysis demonstrated L3 tilt at skeletal maturity to predict curve progression >0.5° per year (OR = 1.17), while L4 tilt

at skeletal maturity predicted a VAS >3 (OR = 1.20) and an ODI >21% (OR = 1.25) in adulthood. Furthermore, lumbar disc degeneration on MRI was associated with L4 tilt at skeletal maturity and associated LBP in adulthood.

Mayo et al. demonstrated significantly more persons with AIS compared to control subjects reported LBP in the preceding year (73% vs 56%; sex-adjusted risk ratio = 1.28; 95% CI: 1.21–1.35).[20] This relative prevalence was equivalent to a sex-adjusted OR of 2.00 (95% CI: 1.72–2.32). Furthermore, for patients currently experiencing LBP, the association to AIS presence was even stronger with 44% of AIS subjects reporting current LBP compared to 24% of controls (RP = 1.80; 95% CI: 1.63–2.00), in addition to an elevated rate of radicular leg pain (RP = 1.30; 95% CI: 1.13–1.49).

Resolution of clinical scenario

- Level III evidence at long-term follow-up supports the finding that most nonoperatively treated AIS curves do not significantly increase in adulthood.
- Level III evidence supports increased rates of LBP in AIS patients compared to control subjects.
- Degenerative disc changes are more common in patients with AIS than non-AIS patient controls, with significant L3 and L4 tilt at adulthood potentially warranting closer follow-up for further degeneration.

Summary of answers

- Bracing is a safe and effective method of treating AIS in patients with growth remaining and curves ranging from 20–40°.

- HRQoL is not significantly different between patients receiving brace treatment and those who do not receive brace treatment.
- Pulmonary function has been shown to improve in patients receiving bracing treatment, with evidence to support early incorporation of aerobic exercise activities into daily life of all patients with AIS regardless of curve severity to mitigate adulthood pulmonary compromise.
- At long-term follow-up measures, most AIS patients treated nonoperatively do not see significant curve progression in adulthood, though significant L3 and L4 tilt at skeletal maturity may predict increased rates of curve progression.
- Degenerative disc changes and slight increased rates of LBP are expected in AIS patients compared to controls.

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117 Adolescent and Adult Spinal Deformity: Operative Management

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Clinical scenarios

- A 16-year-old girl previously diagnosed and braced for adolescent idiopathic scoliosis (AIS) presents with chronic radiating midback pain. Examination reveals a significant left thoracic prominence and abnormal gait. Radiographs show a 67° primary thoracic Cobb angle and 61° lumbar secondary Cobb angle, an increase from the previous visit. Patient reports bracing noncompliance. Patient is one-year postmenarchal.
- A 57-year-old male presents with progressive spinal deformity (ASD). Patient reports acute lower back and leg pain and difficulty ambulating and sleeping for longer than four hours. Patient has exhausted all conservative treatment options, without any pain or discomfort improvements. Radiographs reveal moderate stenosis at L2/3 and L3/4.

Top three questions

1. Have current classification systems improved preoperative planning and fusion level determination for AIS and ASD patients?

2. For AIS and ASD patients, do minimally invasive surgical techniques have better operative and radiographic outcomes compared to traditional open techniques?
3. For AIS and ASD patients, does operative management achieve better correction and quality of life outcomes compared to patients treated otherwise?

Question 1: Have current classification systems improved preoperative planning and fusion level determination for AIS and ASD patients?

Rationale

Operative management of scoliosis patients begins with clinical and radiographic deformity assessment. Classification systems for AIS and ASD have been developed to reduce treatment inconsistency, guide decision-making, and improve outcomes. While the development of consistent and reliable classification systems has gone through several iterations and arguably progressed, controversy regarding the proper course of action in optimal preoperative planning has persisted.

Clinical comment

Classification system limitations and inconsistencies could result in improper surgical indications, preoperative planning, and execution, namely improper fusion level selection and realignment resulting in several clinical consequences. For instance, suboptimal postural realignment or further coronal or sagittal decompensation

may occur, resulting in issues related to pelvic obliquity, shoulder imbalance, junctional kyphosis, or suboptimal functional outcomes during inappropriate exclusion of curvature segments. Contrarily, unnecessary functional loss of motion, additive surgical duration and risk, and increased adjacent segment pathology may occur for excessive levels fused.

Available literature and quality of the evidence

Level II–IV.

Findings

Regarding AIS, the Lenke classification remains the standard.[1] Comparative studies determined the Lenke classification to have good–excellent (kappa >0.75) interobserver and intraobserver reliability for curve type (kappa 0.92–0.83), lumbar modifiers (kappa 0.80–0.84), and sagittal thoracic modifiers (kappa 0.94–0.97), respectively, revealing significant improvements from the previously universally accepted King–Moe classification.[2–4] Further, a retrospective study investigating 606 AIS patients determined that 90% of operative cases had surgically recognized structural regions of the spine predicted by the Lenke curve type.[5] While the Lenke classification offers comprehensive radiographic evaluation, improved decision-making, and good-excellent reliability, retrospective and comparative studies have suggested that its complexity (42 curvature types) and inability to define end construct levels hinder feasibility for surgical planning.[6,7]

Despite controversy over operative decision-making (31% prevalence),[8] variations in operative management have reduced (18% vs 12%, p = 0.001) since the Lenke classifications implementation.[9] According to the Lenke

classification, major curves should be included in the fusion construct, along with the structural minor curves, leaving nonstructural minor curves to spontaneously correct.[10] Selective fusion involves fusing one of two curves that crosses the midline, and the lower instrumented vertebra (LIV) extending no lower than L2. A meta-analysis determined that for Lenke 1C curves, selective thoracic fusions decreased postoperative main thoracic Cobb angle (mean difference [MD]: −27.78° [−30.71° to −24.85°]; p <0.01), postoperative thoracolumbar/lumbar Cobb angle (MD: −16.24° [−17.99° to −14.48°]; p <0.01), and improved coronal balance (MD: 0.47 cm [0.07–0.87]; p = 0.02).[11] While selective fusion maximizes postoperative mobility, corona -decompensation is a concern. Nonselective thoracic fusion, where LIV may extend past L2, sacrifices mobility to more definitively prevent coronal decompensation. Regarding upper instrumented vertebra (UIV) determination, the primary objective is to minimize shoulder imbalance and prevent proximal junctional kyphosis (PJK) development. UIV caudal to proximal upper-end vertebra (Lenke 1; odds ratio [OR] = 15.91 [2.18–115.95]; p = 0.0063) and cephalad to upper end vertebra (Lenke 5, OR = 9.07 [1.77–46.45]; p = 0.0081) were significant PJK risk factors.[12]

After wide adaptation of the Lenke classification, the Scoliosis Research Society (SRS) classification was established to guide categorization and management of ASD. A comparative study determined the SRS classification to have moderate interobserver (kappa: 0.64), regional sagittal modifier (kappa: 0.73), and degenerative lumbar modifier (kappa: 0.65) classification reliability. Interobserver reliability for determining UIV (kappa: 0.56) and LIV (kappa: 0.77) was substantial.[13] While this system describes structural curvature, it overlooks other important clinical factors relevant to ASD decision-making (e.g. age,

BMI, disability). Building off of the SRS classification, Schwab and colleagues created a system which guides operative decision-making by identifying clinically significant radiographic parameters associated with patient-reported outcome measures (PROMs).[14] Comparative studies have determined the SRS Schwab classification to have good–excellent interobserver (kappa: 0.73–0.87) and intraobserver (kappa: 0.83–0.94) reliability.[15,16] The most clinically significant SRS Schwab radiographic parameters are pelvic incidence minus lumbar lordosis (PI-LL), pelvic tilt (PT), sagittal vertical axis (SVA), and T1 pelvic angle (TPA).[17,18] A prospective comparative study determined PT, SVA, and PI-LL to correlate most strongly with disability in operative and nonoperative cohorts, with PT ≥22° (r = 0.38), SVA ≥47 mm (r = 0.47), or PI-LL ≥11° (r = 0.45) most strongly predictive of ODI >40 (indicative of severe disability).[19] Correlations between age and PROMs also exist (r >0.510, p <0.001), with younger patients requiring more rigorous alignment objectives.[20] Prospective studies have validated the use of SRS Schwab modifiers. Patients with improved PT, PI-LL, SVA, and TPA were associated with improved SRS 22 (total, pain, activity, appearance), ODI, and physical component scale (PCS) (p <0.05).[21,22] SRS Schwab modifiers also correlated with operative decision-making. A prospective study of 527 consecutive patients determined patients with abnormal sagittal spinopelvic modifiers required major osteotomies, iliac fixation, interbody fusions, and/or decompression procedures (p <0.001).[23]

Resolution of clinical scenario

- The Lenke classification offers substantial intra- and interobserver reliability, and comprehensive operative guidelines for multiple AIS curve types. Selective

fusions for Lenke C curves correct deformity and improve coronal balance. Depending on Lenke curve type, UIV placement has been associated with certain complications (PJK, proximal curve progression, shoulder imbalance).

- The SRS Schwab classification offers substantial intra- and interobserver reliability for determining ASD curve types, radiographic sagittal modifiers, degenerative lumbar modifiers, and UIV + LIV placement. Operative decision-making should account for patient age. Sagittal spinopelvic modifiers can guide decision-making regarding instrumentation extending to the ilium, osteotomies, and interbody fusions.

Question 2: For AIS and ASD patients, do minimally invasive surgical techniques have better operative and radiographic outcomes compared to traditional open techniques?

Rationale

Open fusions using hook and/or pedicle screw instrumentation are associated with significant blood loss, soft tissue damage, prolonged rehabilitation, and morbidity. Recent technological advances have increased utilization of minimally invasive surgical (MIS) techniques for both AIS and ASD patients. Emerging evidence gives insight into how MIS techniques compare to open surgical techniques, regarding intraoperative and postoperative outcomes.

Clinical comment

MIS techniques may provide adequate deformity correction, disability improvement, and pain alleviation while minimizing blood loss, hospital length of stay, and complication risks.

Available literature and quality of the evidence

Level I–IV.

Findings

Profound morbidity associated with operative intervention, specifically in elderly ASD patients, and technological advances have driven the development of MIS techniques. A retrospective review utilizing propensity-matched MIS, hybrid, and open operative cohorts observed MIS patients to have less blood loss (669 vs 2322 mL, p = 0.001), intraoperative complications (0.0% vs 25%; p <0.03), PI-LL correction (−3° vs −14°; p = 0.04), similar overall complications (p >0.05), operative time (p >0.05), more fused interbody levels (4.5 vs 1.6, p <0.001), and insignificant improvement to Visual Analog Scale (VAS) leg pain compared to open surgeries.[24] A meta-analysis found no difference in overall complication rates between MIS extreme lateral interbody fusions (XLIF), MIS decompressions, and open surgeries with or without osteotomy.[25] MIS and hybrid operative patients undergoing similar levels of posterior fusion were shown to have similar PJK (48.1% vs 53.8%; p = 0.68) and reoperation rates (11.1% vs 19.2%, p = 0.41).[26] A systematic review found MIS patients to have a 46% complication rate, and postoperatively improved VAS leg pain (avg 18.9; p = 0.009), ODI (9.3–33%), coronal Cobb angle (11–28.5°), coronal balance (avg 14.5 cm; p <0.001), SVA (2.1–14.9 cm; p <0.05), PT (11.4°; p = 0.009), and lumbar lordosis (5–25.1°; p <0.05).[27] A retrospective review of prospective,

consecutively enrolled patients observed MIS patients to have a ceiling effect of 34° curve correction, significantly less than the ceiling effect of 55° curvature correction observed in hybrid patients.[28]

Regarding MIS in AIS, a meta-analysis found that, of 272 patients, the percentage of curvature correction was 62.05% for MIS and 70.0% for open surgeries ($p < 0.001$).[29] A retrospective comparative study found that compared to patients (Lenke Type 5C) undergoing open procedures, patients who underwent MIS with O-arm navigation had less blood loss ($p < 0.001$), longer operation times ($p = 0.002$), better SRS pain and self-image scores ($p = 0.013$, 0.046, respectively), a higher pedicle placement accuracy, and no complications compared to open procedures.[30] A retrospective comparative study of 131 Lenke I and Lenke V curves reported MIS anterior thoracoscopic procedures without thoracoplasty had less decreases to forced expiratory volume in 1 second (FEV_1: −4.40% vs −10.97%), forced vital capacity (FVC; −4.73% vs −12.97%), and greater total lung capacity increases (TLC; 3.19% vs −8.00%) compared to anterior open procedures without thoracoplasty (all $p < 0.05$). Patients undergoing thoracoplasty were associated with worse FEV_1 and FVC.[31]

Resolution of clinical scenario

- Evidence points to less blood loss and less intraoperative complications as benefits from MIS. Open/hybrid techniques appear to have similar overall complication rates, greater correction potential, and VAS leg pain improvement. Elderly ASD patients and those at higher risk of intraoperative complications or of mild deformity may benefit from MIS techniques.

- AIS patients undergoing open procedures have a greater potential for curvature correction. Utilization of MIS techniques with O-arm navigation may reduce intraoperative blood loss and complications, and improve postoperative patient pain and self-image. Optimal pulmonary function may be obtained by implementing MIS thoracoscopic procedures during anterior approach.

Question 3: For AIS and ASD patients, does operative management achieve better correction and quality of life outcomes compared to patients treated otherwise?

Rationale

Surgical intervention for AIS and ASD remains a contentious topic. Advocates of operative intervention emphasize the benefits of deformity correction, which include prevention of curve progression, restoration of balance, improvements to disability, pain, and quality of life. Those opposing operative intervention often highlight complication potential and lack of evidence proving long-term medical benefit.

Clinical comment

Operative treatment, a potentially life-altering intervention, should not be recommended without proper evidence and indication. Undergoing operative management subjects patients to the possibility of neurologic deficit, infection, decreased pulmonary function, sexual dysfunction, and mortality. Is operative intervention an effective and reasonable treatment for AIS and ASD patients?

Available literature and quality of the evidence

Level I–IV.

Findings

Regarding operative intervention for ASD patients, a systematic review reported an average ODI postoperative improvement of −23.3 ± 11.3, reduction in coronal Cobb angle of 48.5% ± 210%, and a 49% complication incidence.[32] A meta-analysis reported postoperative improvements to coronal Cobb angle (−11.1° [−13.85° to −8.40°]), coronal balance (7.674 mm [−10.5 to −4.9°]), VAS pain (−3.24 [−4.5 to −1.98), and ODI score (−27.18 [−34 to −20]). A systematic review showed operative intervention to have a large positive effect on ≥2-year follow-up scores for the SRS questionnaire (Cohens d = 1.35 [0.93–1.76]) and ODI (Cohens d = 0.88 [0.36–1.41]).[33] When compared to conservative management, a systematic review found operative patients had improved ODI (−19.1), back pain (−4.14), leg pain (−3.36), SF36-PCS (11.2), SF36-MCS (9.93), and a 48% complication rate; while nonoperative treatment exerted no effects on pain, disability, complications or quality of life.[34] A prospective comparative study found patients reporting SRS-22 “worst” or “severe” baseline disability were more likely to perceive greater disability improvements at 2-year follow-up, compared to patients reporting less disability.[35]

For AIS, prognostic studies have shown curvature >50° left untreated will progress at least 1° per year after skeletal maturity. Untreated patients with curves >50° are likely to experience chronic or acute back pain, dissatisfaction with self-image, while patients with curves ≥80° main Cobb or ≥50° lumbar curve have significantly increased instances of shortness of breath (OR = 9.75 [1.15–82.98]).[36,37] Cardiorespiratory failure is a possibility in curves ≥110°.[38]

Prospective controlled trials with propensity-matched operative, nonoperative, and control cohorts have demonstrated operative and braced patients to have similar long-term follow-up (>20 years), main Cobb curves (28°–38°, p >0.05), prevention of significant curvature progression, improvements to pulmonary function vital capacity (p <0.001), and reoperation rate of 5.1%.[39–41] Operative patients had less curvature deterioration (3.5° vs 7.9°, p <0.001) and lumbar lordosis (33° vs 45°) compared to braced patients.[41] A retrospective study of 6334 operatively treated patients reported a 5.7% overall complication rate and a 0.03% overall complication-related mortality rate.[42] Operative AIS patients have also exhibited improved postoperative SRS pain, self-image, function, and level of activity scores (p <0.001).[43,44]

Resolution of clinical scenarios

- ASD patients with progressive or severe deformity/disability benefit most from operative intervention. Operative intervention offers correction of deformity, improved balance, quality of life, and reduced pain and disability. Complication occurrence is a significant risk with operative treatment.
- Operative intervention is an effective treatment for skeletally mature AIS patients at risk for curvature progression. Advantages include prevention of curvature progression with associated morbidities, improvements to pulmonary function and quality of life (pain, self-image, disability), and low complication and reoperation rates.

Summary of answers

- The Lenke and SRS Schwab classification systems are beneficial guides to operative decision-making in adolescent and adult scoliosis.
- Higher-risk patients and those of mild deformity reap the greatest benefits from MIS procedures.
- While operative intervention for AIS patients is an effective treatment for advanced curvatures, and has a minimal associated risk of complication or mortality, operative correction of ASD is associated with both significant quality-of-life improvements and high complication rates. Physicians and patients alike should be aware of the highest levels of evidence for appropriate treatment decision-making and proper risk stratification.

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118 Metastatic/Myeloma Disease

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Clinical scenario

- A 78-year-old man with a known history of widely metastatic nonsmall cell lung cancer presents to the Emergency Department with atraumatic back pain and is found to have metastatic spinal cord compression.
- He remains ambulatory with preserved bowel and bladder function, but he is objectively weak on examination.

Top three questions

1. In patients with metastatic carcinoma or myeloma disease resulting in metastatic epidural spinal cord compression, does radiation combined with direct decompressive surgery result in improved functional status for patients compared to radiation alone?
2. In patients with metastatic carcinoma or myeloma disease affecting the spine, does assessment of spinal stability by a scoring algorithm provide reliable and useful prognostic information compared to opinion alone?
3. In patients with metastatic carcinoma or myeloma disease affecting the spine, do simple prognostication algorithms that take patient-specific and tumor-specific

factors into account better predict outcomes than those that do not?

Question 1: In patients with metastatic carcinoma or myeloma disease resulting in metastatic epidural spinal cord compression, does radiation combined with direct decompressive surgery result in improved functional status for patients compared to radiation alone?

Rationale

There are two treatment modalities available for metastatic spinal cord compression: radiation and decompressive surgery. Decompressive surgery for metastatic spinal cord compression is an invasive and risky intervention relative to radiation alone, thus operative intervention may be justified only if the functional outcomes for the patient are improved when decompressive surgery is combined with radiation. This question of whether to offer surgery is pondered over daily by all physicians who regularly care for patients with metastatic spinal cord compression.

Clinical comment

For the patient in this scenario, making a shared, informed decision with his healthcare team of whether to undergo the risks of decompressive surgery versus pursuing radiation treatment alone is a critical branch point in his treatment course and can only be made once he

understands what the benefits might be of taking on the risk of surgical decompression.

Available literature and quality of the evidence

There is one level I randomized controlled trial that addresses the question at hand published by Patchell et al. in 2005 comparing ambulatory function, urinary continence, muscle strength, functional status, corticosteroid and opioid analgesic use, and short-term (30-day) survival between patients undergoing radiotherapy alone and direct decompressive surgery followed by radiotherapy for metastatic extradural spinal cord compression.[1] The study enrolled only adult patients with tissue-proven noncentral nervous system (CNS) origin metastatic spinal cord compression affecting only a single area of the spine with at least one neurological sign or symptom (inclusive of pain) and who had not been paraplegic for greater than 48 hours prior to study enrollment and who did not have a particularly radiosensitive tumor (lymphoma, leukemia, multiple myeloma, germ cell tumor). This is the only level I evidence available.

Findings

The primary outcome from Patchell's study is ambulatory function post treatment.[1] In the radiotherapy alone group, post-treatment ambulatory rate was 57% (29/51) versus 84% (42/50) in the surgery followed by radiotherapy group. The odds ratio (OR) for post-treatment ambulatory function with surgery followed by radiotherapy was 6.2 (95% confidence interval [CI]: 2.0–19.8) with $p = 0.001$. This fell below the predetermined criteria for early termination, so the trial was stopped early. Patients who underwent surgery plus radiation also retained the ability to ambulate

for a longer period of time (median 122 days vs 13 days; p = 0.003).

In terms of secondary outcomes, patients who underwent surgery plus radiation maintained urinary continence for longer (156 days vs 17 days) with relative risk (RR) of 0.47 (95% CI: 0.25–0.87). Surgical patients also maintained their functional status for longer, as measured by the ASIA score (566 days vs 72 days) with RR = 0.28 (95% CI: 0.13–0.61). Survival time was longer in patients undergoing surgery of 126 days vs 100 days with RR = 0.60 (95% CI: 0.38 – 0.96). All differences were statistically significant at $p < 0.05$.

Resolution of clinical scenario

- In patients with metastatic carcinoma resulting in spinal cord compression at a single level who have not been paraplegic for greater than 48 hours, direct decompressive surgery followed by radiation results in an increased rate of ambulation, increased rate of retaining the ability to ambulate (if relevant), decreased rate of urinary incontinence, increased rate of preservation of neurologic functional status, and increased survival time relative to radiation alone.
- Patients who meet these criteria should be offered direct decompressive surgery followed by radiation.
- This recommendation cannot necessarily be made for patients who are deemed to be poor candidates for surgery, have myelomatous disease (or other highly radiosensitive tumors), do not have any neurologic compromise, have had a more extended period of paraplegia, or who have multiple sites of spinal cord compression.

Question 2: In patients with metastatic carcinoma or myeloma disease affecting the spine, does assessment of spinal stability by a scoring algorithm provide reliable and useful prognostic information compared to opinion alone?

Rationale

The local tumor burden within the spine from metastatic disease occupies space within the spinal elements and can thus be a destructive presence that compromises the stability of the spine itself, but determining when spinal stability has been compromised by metastatic disease to the point of potentially benefiting from surgical stabilization is difficult to ascertain.

Clinical comment

For the patient in this scenario, to ascertain whether he has impending spinal instability influences whether surgical intervention is recommended. Assessing impending instability is notoriously difficult for all clinicians, thus having a validated clinical prediction algorithm may prove helpful.

Available literature and quality of the evidence

The Spinal Instability Neoplastic Score (SINS) was developed by the Spine Oncology Study Group (SOSG) and was initially published in 2010.[2] Three subsequent studies have been carried out to assess reliability and validity of SINS: one from members of the SOSG who initially developed SINS,[3] another from a single independent

multispecialty group,[4] and the third from an international group of radiation oncologists.[5] No level I evidence exists evaluating SINS compared to any other method of judging neoplastic spinal instability. Two level II prospective cohort studies have been published evaluating the ability of SINS for predicting symptomatic improvement with radiotherapy and/or surgical stabilization based on the SINS assessment of instability.[6],[7]

Findings

In terms of validating SINS from a reliability perspective, the SOSG found its inter- and intraobserver reliability of total SINS score measured by the kappa statistic to be 0.846 (95% CI: 0.773–0.911) and 0.886 (95% CI: 0.868–0.902), respectively.[3] Assessed by an independent group of clinicians, inter- and intraobserver reliability of total SINS score by kappa was 0.79 (95% CI: 0.69–0.88) and 0.96, respectively.[4] Assessed by an international group of 33 international oncologists, inter- and intraobserver reliability of SINS on a binary scale (“stable” vs “current or possible instability”) by kappa was 0.76 (95% CI: 0.56–0.88) and 0.80 (95% CI: 0.74–0.86), respectively.[5]

In terms of prospective validation, Hussain et al. reported on a prospective cohort of 131 patients who underwent instrumented fusion for metastatic spinal cord compression over a two-year period at a single institution for whom preoperative patient-reported outcomes assessed by the Brief Pain Inventory (BPI) and MD Anderson Symptom Inventory (MDASI) were available, in addition to SINS scores.[6] When patients were stratified by SINS score into three categories (stable, indeterminate, and unstable), there was a statistically significant difference among these three groups in the degree to which pain improved after surgery, as assessed by both the BPI and the MDASI. In the

stable group, the BPI score increased by 1.5 and the MDASI by 2.5. In the indeterminate group, the BPI score decreased by 2.3 and the MDASI by 2.2. In the unstable group, the BPI score decreased by 3.0 and the MDASI by 2.8. The p values were 0.04 for both the BPI and the MDASI.

Van der Velden et al. reported on a prospective cohort of 124 patients from two institutions who underwent palliative radiotherapy for spinal metastases (exclusive of multiple myeloma) for whom pre- and postradiation pain scores were assessed.[7] Patients were defined as having a complete pain response after radiotherapy if the pain score was reported as 0 and the oral morphine equivalent dose was stable or reduced. When SINS was analyzed as a binary variable (stable: 0–6; unstable: 7–18), adjusted OR for complete response with an unstable SINS was 0.21 (95% CI: 0.06–0.67) with p = 0.009. The adjusted OR of any response after radiotherapy with unstable SINS was 0.88 (95% CI: 0.36–2.15) with p = 0.782.

Resolution of clinical scenario

- In patients with metastatic carcinoma or myeloma disease affecting the spine, assessment of spinal stability by the spinal instability neoplastic score (SINS) is a reliable method for assessment of spinal instability among physicians (surgeons and nonsurgeons).
- In patients with metastatic carcinoma or myeloma disease affecting the spine who are assessed to have a SINS >6 may benefit from decreased pain with surgical stabilization and may be less likely to benefit from palliative radiotherapy than patients with lower SINS.

Question 3: In patients with metastatic carcinoma or myeloma disease affecting the spine, do simple prognostication algorithms that take patient-specific and tumor-specific factors into account better predict outcomes than those that do not?

Rationale

In deciding whether surgical intervention for metastatic spine disease is indicated, each patient's overall prognosis must be taken into consideration. Several prognostic scoring systems for spinal metastasis have been developed and reached varying states of validation. Those that take into account both patient-specific and tumor-specific factors may best prognosticate outcomes and determine which patients are best suited to derive benefit from surgery.

Clinical comment

For the patient in this scenario, knowledge of his overall prognosis is an important component in deciding whether to proceed with surgical decompression and stabilization. A patient with very limited life expectancy and poor preoperative assessment of prognosis may be deemed a poor surgical candidate, even if the data presented earlier in the chapter suggest an unstable spine and improved neurologic outcome with surgery.

Available literature and quality of the evidence

No level I evidence exists prospectively validating any prognostic scoring algorithm for patient outcomes with

operative and nonoperative treatment of metastatic spinal cord compression.

Two level III studies published in 2015 retrospectively validated a set of prognostic factors, now known as the New England Spinal Metastasis Score (NESMS), associated with short-term (30- and 90-day) and longer-term (one-year) survival in patients with metastatic spine disease.[8,9]

Two level II studies were subsequently published in 2016 demonstrating the validity of NESMS when applied to a large population dataset – the National Surgical Quality Improvement Program (NSQIP) – and to an independent cohort of patients from a separate center from which NESMS was originally described.[10,11] No validation studies have been published employing cohorts which included patients managed nonoperatively, a significant limitation of the current evidence base given the potential selection bias of patients deemed fit for surgery.

Findings

In terms of retrospective validation of NESMS for one-year survival, 318 patients were included in the cohort with 48% survival rate.[8] Independent predictors of survival were preoperative modified Bauer score with OR = 3.00 (95% CI: 1.90–5.01), ambulatory status with OR = 2.47 (95% CI: 1.48–4.14), and serum albumin with OR = 2.80 (95% CI: 1.66–4.72). The modified Bauer score considers the presence of visceral metastases and lung cancer, the primary tumor histology, and the number of skeletal metastases. The predictive score combining the modified Bauer score with serum albumin and ambulatory status was able to explain 74% of the variation in one-year survival, while the modified Bauer score alone explained 64% of said variation.

A separate study using the same patient cohort evaluated 30- and 90-day mortality, which was 9 and 27%, respectively.[9] In a multivariate logistic regression model of 30-day survival, serum albumin >3.5 g/dL was the strongest predictor of survival with OR = 9.0 (95% CI: 3.1–26.6), followed by ambulatory status with OR = 6.8 (95% CI: 1.5–30.7). At 90 days, replete serum albumin and intact ambulatory status were similarly strong predictors of survival, while lung cancer metastases predicted negative outcome with OR = 0.36 (95% CI: 0.18–0.72) and lymphoma/myeloma portended a more favorable prognosis with OR = 4.5 (95% CI: 1.4–14.5). The final predictive model explained 76% of variation in 90-day survival.

The authors of NESMS applied the model to a cohort of 776 patients undergoing surgery for spinal metastasis from the NSQIP.[10] OR for 30-day mortality for NESMS score 1 patients was 0.46 (95% CI: 0.24–0.87), for NESMS score 2 patients was 0.19 (95% CI: 0.10–0.38), and for NESMS score 3 patients was 0.11 (95% CI: 0.04–0.31) with all ORs being statistically significant at $p < 0.05$. The model explained 71% of variation in 30-day mortality within the NSQIP population.

Independent validation of NESMS by a separate center was reported on a cohort of 161 patients with one-year survival of 45%. In the adjusted, multivariable logistic regression model, 80% of the variation in one-year survival was explained by NESMS.[11]

Briefly, several other prognostic scoring systems in metastatic spine disease exist. The Tokuhashi score is reportedly the most widely used and also takes into account patient- and tumor-specific factors, in addition to numerous other variables which increases its complexity and thus compromises its utility and reliability. The Tomita score is also well known but has not been independently verified as

predictive of patient outcome. The modified Bauer score is improved upon by adding the aforementioned variables to form the NESMS.

Resolution of clinical scenario

- In patients with metastatic carcinoma or myeloma disease affecting the spine, the NESMS is the most simple and well-validated prognostication algorithm and may explain up to 80% of variation in one-year survival by accounting for patient- and tumor-specific factors.
- In patients with metastatic carcinoma or myeloma disease affecting the spine who are otherwise deemed to potentially benefit from surgical decompression and stabilization, accurate assessment of overall prognosis is a vital component of surgical decision-making.

Summary of answers

- In patients with metastatic carcinoma (not myeloma) resulting in spinal cord compression at a single level who have not been paraplegic for longer than 48 hours, direct decompressive surgery followed by radiation results in an improved functional status relative to radiation alone.
- In patients with metastatic carcinoma or myeloma disease affecting the spine, the SINS provides reliable information regarding spinal stability and may provide useful prognostic information with regards to which patients may benefit most from surgical stabilization in terms of pain control.
- In patients with metastatic carcinoma or myeloma disease affecting the spine, the NESMS provides the

simplest and most validated prognostic assessment of patient survival to be used by clinicians and patients when deciding on whether to proceed with surgery.

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119 Spinal Infections

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Clinical scenario

- A 40-year-old man with a history of chronic liver disease and intravenous drug use (IVDU) presents to the Emergency Department with neck pain, midthoracic back pain, and fevers.
- He denies radiating pain, numbness, or weakness.

Importance of the problem

The incidence of vertebral osteomyelitis (VO) and spinal epidural abscess (SEA) are presently on the rise. An aging population with associated co-morbidities, increased IVDU, and the prevalence of spinal instrumentation are among the reasons thought to explain the elevated rates of these spinal infections.[1–5] The incidence of VO has been reported to be 2.2–7.4 per 100 000 population per year,[6–8] and the incidence of SEA has been reported to be 0.2–2.8 per 10 000 hospital admissions per year,[9,10] or 1.8 per 100 000 persons per year.[11]

Top three questions

1. What are the typical presentation, examination findings, and imaging characteristics of patients with VO/epidural abscess?

2. What is the evidence for operative compared to nonoperative management for patients with VO/epidural abscess?
3. What is the prognosis for patients with VO and epidural abscess, including post-treatment morbidity?

Question 1: What are the typical presentation, examination findings, and imaging characteristics of patients with VO/epidural abscess?

Rationale

In order to assess treatment options and prognosis, one must first have the correct index of suspicion for VO and epidural abscess. Understanding the characteristic presentation of the problem permits accurate diagnosis.

Clinical comment

VO and SEA are serious conditions with significant morbidity and mortality. Unfortunately, the diagnosis is often difficult, and as a result delayed, which only increases morbidity and mortality.[12–14] It is essential to understand typical presentation, examination findings, and imaging characteristics in order to correctly diagnose the condition when present and provide efficient management.

Available literature and quality of the evidence

- Level I: 0 studies identified.
- Level II: 0 studies identified.
- Level III: 3 systematic reviews of retrospective observational studies, 1 retrospective case series study.

Findings

A systematic review and meta-analysis of 12 retrospective studies considering the medical and surgical management of SEA found IVDU to be the most frequently reported risk factor (22%), and diabetes (27%) and hepatic disease to be the most commonly reported co-morbidities. The most common symptoms were back pain (67%), motor weakness (52%), and fever (44%). There were significantly more patients with back pain, fever, and motor weakness compared to historical data.[15] The grade of recommendation from this systematic review is low given the retrospective nature of the studies reviewed.

A systematic review of 14 retrospective studies found that back pain was the most common presenting symptom (85% of patients), followed by fever (60%), and neurologic deficit (34%). In the five studies that included duration of symptoms, the mean time from onset of symptoms to diagnosis ranged from 11 to 59 days. Paraspinal or epidural abscesses were found in 44% of cases of VO.[16] A recent retrospective observational study over a 12-year period found local tenderness in <20% of cases of VO.[17,18] Magnetic resonance imaging (MRI) is considered the gold standard for diagnosis of VO, with sensitivity/specificity >90%.[1,3,4,18] The systematic review found MRI to have a sensitivity and specificity of 94% but also noted that plain radiography revealed abnormalities in 89% of cases, though other reviews note its limited utility in early disease.[1,11] Notably, 6% of patients demonstrated continuous lesions spanning multiple levels, and 3% had skip lesions.[16] The grade of recommendation from this review is low based on the low levels of evidence of the included studies.

A retrospective case-control study of 233 adult patients with SEAs who underwent entire spinal imaging over an

18-year period at a tertiary referral healthcare system found 22 patients with skip lesions. Three risk factors were identified: delay in presentation (>7 days), concomitant area of infection outside the spine, and an erythrocyte sedimentation rate (ESR) >95 mm/h at presentation. The predicted probability for the presence of skip lesions was 73, 13, 2, and 0% with the identification of 3, 2, 1, and 0 risk factors, respectively.[19] The grade of recommendation from this single retrospective study is low based on the retrospective nature of the study.

Resolution of clinical scenario

- Axial pain, fever, and neurologic findings are the most common presenting symptoms, but they are not specific, and often not all found at the same time (grade of recommendation: low).
- MRI is the most useful diagnostic imaging modality. Consideration should be given to imaging the entire spine in cases of VO/SEA (grade of recommendation: low).
- Patients with delay in presentation, concomitant area of infection outside the spine, and ESR >95 are at high risk of having skip lesions (grade of recommendation: low).

Question 2: What is the evidence for operative compared to nonoperative management for patients with VO/epidural abscess?

Case clarification

MRI of the cervical spine reveals a large, loculated SEA from C4 to T1 (Figure 119.1) with VO at C5 and C6. The patient expresses a desire to avoid any surgery.

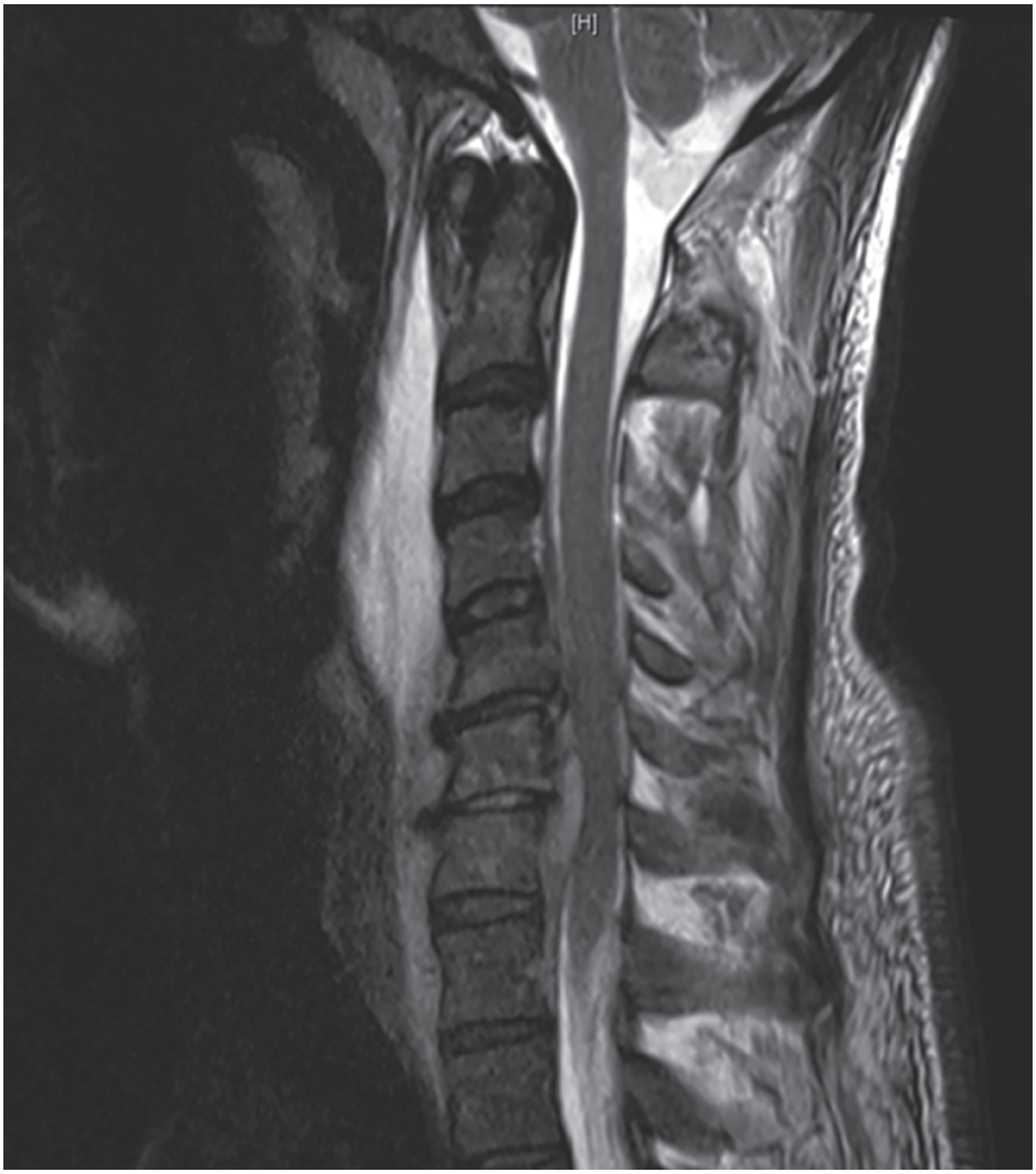

Figure 119.1 Sagittal T-2 weighted MRI image of a patient with a spinal epidural abscess at C4–T1 and vertebral discitis/osteomyelitis at C5 and C6. The patient was treated with a C6 corpectomy, abscess evacuation and C5–7 reconstruction with instrumentation and a titanium cage.

Rationale

Both nonoperative and operative management options exist for the treatment of patients with VO and SEA. Operative management is not without inherent risk and potential complications.

Clinical comment

Historically, SEA has been thought of as a surgical emergency due to the risk of precipitous neurologic decline.[10,13,20,21] More recently, success has been reported with medical management of SEAs.[22,23] Traditionally, medical management has been the mainstay of treatment for VO, with surgery more generally playing a role in diagnosis through biopsy,[1] unless medical treatment fails or fracture/instability is impending.[2,24,25] It is generally accepted that urgent surgical management is necessary in cases of acute or progressive neurological deficit, but it is unclear how best to manage patients without neurologic symptoms.[5,15] Which patients might be successfully treated medically, and in what fashion, remains a subject of great controversy.

Available literature and quality of the evidence

- Level I: 1 randomized controlled trial (RCT).
- Level II: 0 studies identified.
- Level III: 3 systematic reviews of retrospective studies.

Findings

No studies that prospectively compared operative management and nonoperative management for the treatment of SEA were found. A systematic review of 10 retrospective studies found that overall outcomes among

patients treated with operative and nonoperative management were not different, though there was significant allocation bias based on pretreatment neurologic function. In addition, there was significant crossover among the studies. The odds ratio for improvement or stability of neurologic status for operative and nonoperative management was 0.653 ($p = 0.11$), and of good outcome was 1.11 ($p = 0.69$).[26] The grade of recommendation from this review is low based on the retrospective nature of the included studies.

A systematic review of 12 retrospective studies directly comparing surgical to nonsurgical management of SEA found no statistically significant difference between treatment modalities, though it did find a significant increase in the proportion of patients medically managed compared to historical controls. It also found that patients with no neurological deficits were significantly more likely to be treated medically than surgically.[15] The grade of recommendation from this systematic review is low given the retrospective nature of the studies reviewed.

No studies that prospectively compared operative management and nonoperative management for the treatment of VO were found. In a systematic review of 14 retrospective studies of VO management, all patients received antibiotic treatment. Indications for surgery included spinal stabilization, abscess drainage, and decompression for the management of neurologic symptoms.[16] Given the heterogeneity of decisions for surgical intervention, and the retrospective nature of studies, the grade of recommendation is low.

An RCT comparing antibiotic treatment for six weeks versus 12 weeks in patients with pyogenic VO found that six weeks of antibiotic treatment was not inferior to 12 weeks of antibiotic treatment with respect to the

proportion of patients with pyogenic VO cured at one year.[27] Although the RCT was well powered, the lack of additional studies makes the grade of recommendation moderate.

Resolution of clinical scenario

- Nonoperative management may be as effective as operative management of SEA in patients without neurologic symptoms (grade of recommendation: low).
- Nonoperative management is the main treatment modality for VO, unless stabilization or decompression in the setting of neurologic symptoms is necessary (grade of recommendation: low).
- Necessary antibiotic treatment duration for VO may be shorter than that historically employed with six weeks of antibiotics demonstrating similar efficacy to 12 weeks of antibiotics (grade of recommendation: moderate).

Question 3: What is the prognosis for patients with VO and epidural abscess, including post-treatment morbidity?

Clinical clarification

The patient agrees to proceed with surgery after his symptoms fail to improve with a trial of antibiotics and the abscess is found to enlarge on repeat imaging. He undergoes a C6 corpectomy with reconstruction using plate instrumentation and a spanning titanium cage. He is concerned about postoperative complications and the likelihood of full recovery.

Rationale

Both operative and nonoperative management of VO and SEA are not without complications. The prognosis of patients with either condition depends on the timing of diagnosis, clinical presentation, and treatment modality.

Clinical comment

Operative management imparts inherent perioperative risk. Long-term antibiotic use can increase the likelihood of antibiotic resistance and healthcare-related infections.[28–30] Both operative and nonoperative management can fail, or be complicated by a recurrence of disease. Furthermore, patients who receive surgery have additional risks of construct failure, pseudarthrosis, and the need for revision surgery (Figure 119.2). Those who fail medical management, and ultimately require surgical intervention may carry a worse prognosis.[5,31] In the case of VO and SEA, successful management is often assessed through the proxies of mortality and recovery from neurologic deficits.[4] The potential for these events is highly predicated on the location of the spinal infection, its size, duration of symptoms prior to presentation, the patient's nutritional and immunologic status, as well as the presence of other medical co-morbidities.

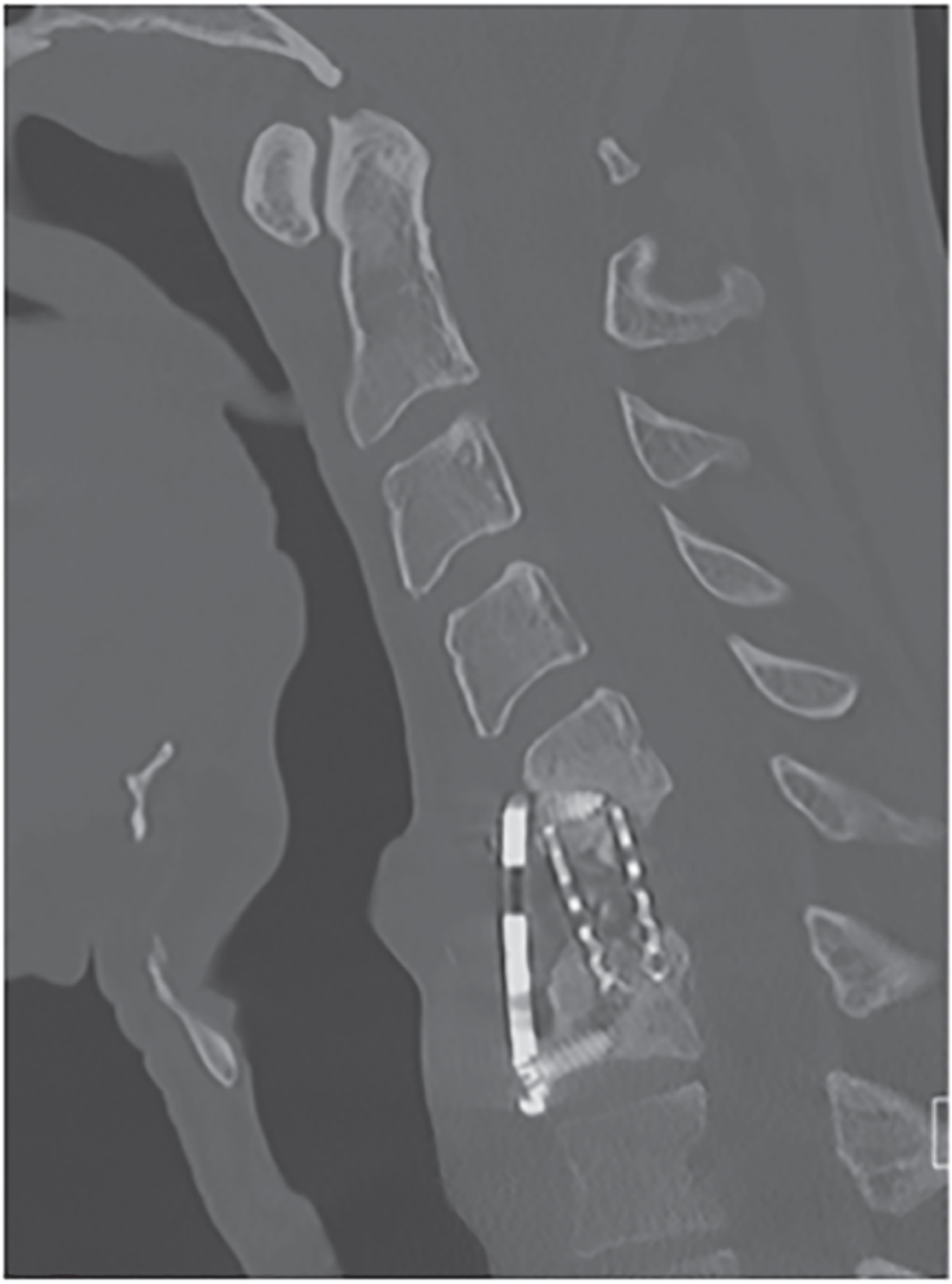

Figure 119.2 Sagittal computed tomography (CT) image of the same patient in Figure 119.1, six months following surgical management. In the intervening period, the patient had developed pseudarthrosis, subsidence of the titanium cage and inferior screw cut-out from the C7 vertebral body.

Available literature and quality of the evidence

- Level I: 0 studies identified.
- Level II: 0 studies identified.
- Level III: 1 meta-analysis of retrospective studies and 4 systematic reviews of retrospective studies.

Findings

A systematic review and meta-analysis of 12 retrospective observational studies of the medical management of SEA – which defined *failed medical management* as persistent severe neurologic deficit, poor clinical outcome, death, or need for surgery – found the overall pooled risk of failed medical management to be 29.3% (95% confidence interval [CI]: 21.4–37.2%). Considering only the six studies which provided data for analysis by intention to treat, the pooled risk of failed medical management was 35.1% (95% CI: 15.7–54.4%).[5] The grade of the recommendation from this systematic review and meta-analysis is low due to the retrospective, observational nature of the included studies, as well as the heterogeneity in reported outcomes.

A systematic review of 10 retrospective studies comparing surgical and medical management found that failure rates after medical management ranged from 10 to 50%, with three studies reporting large effect sizes for neurologic outcome if early surgery was performed.[26] The review found that gender was not significantly associated with patient outcome but that younger age correlated with

better neurologic outcomes, while diabetes mellitus correlated with worse neurologic outcomes. Overall, pretreatment neurologic status correlated strongly with neurologic outcome.[26] The grade of recommendation from this review is low based on the low level of the included studies.

A systematic review of 18 retrospective studies found that cases with a delay in diagnosis had an increased risk of residual weakness versus those with no delay, and that duration and severity of neurological symptoms correlated with ultimate outcome. Mortality rates were found to range from 2 to 20%, and were higher in patients with multiple co-morbidities.[3] The grade of recommendation from this review is low based on the low level of evidence among the included studies.

A systematic review of 14 retrospective studies investigating VO found a mortality rate of 6%, with relapses in 32% of cases. That being said, 27% of patients had complications that seriously affected their quality of life. The six studies that detailed the complications found 28% of patients have persistent pain, 16% have weakness, and 7% have bowel or bladder dysfunction. In the one study that compared the functional outcome of nonoperatively and operatively managed patients, 64% of nonoperatively managed patients experienced disabling pain or relapse, while only 26% of the operatively managed patients did.[16] Given the heterogeneity of outcomes and complications reporting, as well as the retrospective nature of the studies, the grade of recommendation is low.

Resolution of clinical scenario

- Medical management alone of SEA fails approximately one-third of the time (grade of recommendation: low).

- Pretreatment neurologic status in cases of SEA correlates with neurologic prognosis (grade of recommendation: low).
- Approximately one-third of cases of VO recur, and one-third of patients with VO have complications (grade of recommendation: low).

Summary of answers

- The body of evidence that can be used to support evidence-based decision-making in the treatment of VO and SEA is fairly low in both grade and quality.
- Axial pain, fever, and neurologic impairment are the most common presenting symptoms, but they are not specific, and may not be present in all cases.
- MRI is the most useful imaging modality for the diagnosis of VO and SEA.
- Nonoperative management is the usual treatment for VO, unless stabilization is required or neurologic deficits are present.
- Nonoperative treatment may be as effective as surgical intervention for patients with SEA who do not manifest neurologic impairment. In appropriate patients, nonoperative management may still fail 33% of the time.
- There is a single RCT that maintains six weeks of antibiotic therapy for VO is as effective as 12 weeks of antibiotics.
- In the setting of SEA, neurologic status at the time of presentation is one of the most important prognostic factors for post-treatment outcome.

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VI Sports Medicine

120 Ergogenic Aids

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Clinical scenario

- You are performing preseason physicals for a youth hockey team.
- One of the players, a 16-year-old male, asks you about creatine supplementation.
- He states that he has been told he is too small and needs to put on mass to have a chance at a future professional career.
- He wants to know if creatine supplementation will enhance his performance on the ice and in the gym.

Top three questions

1. Do young adults using creatine supplementation experience an enhancement in performance compared to nonsupplemented young adults?
2. In young adults supplementing with creatine, is there resultant physiological change associated with supplementation as compared to nonsupplemented young adults?
3. Do young adults using creatine supplementation experience adverse side effects compared to nonsupplemented young adults?

Question 1: Do young adults using creatine supplementation experience an enhancement in performance compared to nonsupplemented young adults?

Rationale

Dietary nutritional supplements are a multibillion-dollar industry worldwide. The most common legal performance enhancing supplements used by athletes are creatine, protein powders, and caffeine. Creatine, however, is the most popular nutritional supplement used as an ergogenic aid at all levels of competition.[1–3]

Clinical comment

Creatine is predominately stored in skeletal muscle (fast twitch, type II fibers) where it serves as the energy substrate for muscle contraction.[3] In its phosphorylated form, creatine contributes to the re-synthesis of adenosine triphosphate (ATP) from adenosine diphosphate (ADP) which occurs during short-duration and high-intensity exercises.[4] This suggests and therefore serves as the rationale for creatine supplementation as an ergogenic aid.[5]

Available literature and quality of the evidence

A number of randomized controlled trials (RCTs) exist to answer this question.

Findings

A double-blind study tested 12 adult male cyclists pre- and post- a 28-day creatine supplementation regimen. The

changes in plasma volume from pre- to post-supplementation were significantly greater in the creatine group (14.0 ± 6.3%) than the placebo group (−10.4 ± 4.4%; $p < 0.05$) at 90 minutes of exercise.[6]

In short-interval exercise it was concluded that creatine supplementation increases short-terms bursts, such as dribble and power tests (vertical jumping) with young soccer players.[7]

In a double-blinded, placebo-controlled RCT, 14 men ingested 25 g/day of creatine monohydrate for seven days. Subjects performed five sets of bench press to failure and a jump squat (five sets of 10 repetitions using 30% of each subject's one repetition max [RM]). It was concluded that one week of creatine supplementation (25 g/day) enhances muscular performance during repeated sets of bench press and jump squat exercises.[8]

A study on cyclists for five days of 20 g creatine supplementation testing maximal power output to exhaustion found oxygen consumption larger after creatine supplementation (10.40 ± 0.65 L) to (11.82 ± 0.34 L).[9]

Reardon et al. looked at the potential effect of creatine supplementation on aerobic long durance exercise. Subjects completed 45-minute cycling sessions. It was concluded that the ergogenic potential of creatine supplementation in endurance performance does not produce significant results.[10]

A test on 12 regional class triathletes for five days on a 6 g/day creatine dosing and cycling 30 minutes to exhaustion found endurance performance was not influenced as interval power was only increased by 18%.[11]

Fourteen female and eight male collegiate athletes supplemented with seven days of 25 g/day creatine were subjected to three timed 60 m sprints trials. Results showed

creatine supplementation did not enhance speed during 60 m sprints.[12]

Recent literature has illuminated the anabolic/performance-enhancing mechanisms of creatine,[13] suggesting that these effects may be due to satellite cell proliferation, myogenic transcription factors, and insulin-like growth factor-1 signaling.[14] Changes in myogenic transcription factors occur when creatine supplementation and resistance training are combined in young healthy males. It was observed that serum levels of myostatin, a muscle growth inhibitor, were decreased in the creatine group.[15]

Resolution of clinical scenario

The suggestion from various sports and training regimens is that creatine supplementation may be effective as an ergogenic aid in short bursts of intense exercise, but that it does not seem to be beneficial in aerobic, endurance exercises.

Creatine has been demonstrated to be of performance benefit in modes of exercise such as high-intensity sprints or endurance training. The evidence also demonstrates that it appears that the effects of creatine diminish as the length of time spent exercising increases.

Question 2: In young adults supplementing with creatine, is there resultant physiological change associated with supplementation as compared to nonsupplemented young adults?

Rationale

Supplementation with creatine is widely used to increase strength, fat-free mass, and muscle morphology.

Clinical comment

Studies show that creatine supplementation increases intramuscular creatine concentrations, which may help explain the observed improvements during high-intensity exercise.[16]

Available literature and quality of the evidence

A number of RCTs exist to answer this question.

Findings

Twelve weeks of training with creatine supplementation demonstrated increases in heavy resistance exercise in a double-blind, placebo-controlled RCT.[8] Treated subjects improved bench press and squat exercises by 24 and 32%, respectively, versus the placebo group (16 and 24%, respectively) who had training but no supplementation.[8] The gains in mass appeared to be due to an improvement in the ability to recover faster from heavy load workouts and high-intensity training, thereby resulting in greater muscle hypertrophy.

A double-blinded, placebo-controlled RCT, observed the effect of creatine supplementation on anaerobic performance and body composition of American football players evaluating one repetition maximum (1RM) parallel squat, 1RM bench press, dynamic explosive strength test of vertical jump, and high-intensity endurance test of 15 five-second cycling rides with a one-minute rest period between rides. Results showed an 11.6% increase in squat, 10% increase in bench press, and 1.5% increase in vertical

jump. Both hydrostatic (7%) and skin-fold method (2.6%) indicated a substantial gain in lean body mass, and an increase in body mass of 1.4 % over five weeks.[17]

A double-blind RCT studied 24 male resistance trainers taking 20 g/day of creatine for five days followed by 5 g/day for the remaining 23 days and then completed a resistance-training program with four supervised workouts per week which targeted the major muscle groups. It was found that ingestion of creatine promotes increases in lean mass, body composition, and 1RM bench press and leg press.[18]

In a double-blind, placebo-controlled trial, similar results were found in the Birch et al. study utilizing the *Wingate tests* (30 seconds of maximal cycling effort).[19] In the creatine group, the total power output increased by 7.6%.[19]

Multiple studies including double-blind studies demonstrated physiological changes post creatine supplementation regimen.[8],[18] These physiological changes include enhanced muscular performance, increases in lean mass and body composition, as well as increased oxygen consumption.

Resolution of clinical scenario

Enhanced muscular performance, increase in lean body mass and composition, and increased oxygen consumption were the resultant physiological effects during and following creatine supplementation.

Question 3: Do young adults using creatine supplementation experience adverse side effects compared to nonsupplemented young adults?

Rationale

While creatine supplementation has been suggested to be effective in enhancing performance in short, high-intensity athletic-related situations, it is paramount to evaluate whether this supplement has any adverse effects or safety concerns. Creatine is a legal supplement that is readily available over the counter. It is not a banned or regulated substance in any amateur or professional sport.

Clinical comment

Short-term use of creatine has generally been considered safe but can still have potential side effects, which are usually mild.[20],[21] The most common side effects are bloating, cramping, and diarrhea.[22] These effects may be minimized by forgoing the loading dose and staying well hydrated. Creatine does not seem to adversely affect kidney function, but special consideration should be taken for athletes with pre-existing kidney disease. It has not been tested thoroughly for patients under the age of 18; however, for adults it seems to be safe and possibly effective.[16],[23]

Available literature and quality of the evidence

A number of retrospective and cross-sectional studies are available to answer this question.

Findings

Liver changes were studied during medium-term (four weeks) creatine supplementation in young athletes. No evidence of dysfunction based on serum enzymes and urea production was found. There was an increase in body mass during short-term creatine supplementation likely due to

water retention, with a 0.6 L decline in urinary volume after ingestion of creatine 20 g/day for 6 days.[24]

A review on various studies undertaken on the long-term effects of creatine supplementation noted an increased muscle mass which may result because of fluid retention and not increased protein synthesis. An increase of 0.7 to 3 kg in one month has been reported. Weight gain can be maintained on 5 g per day of creatine during a 10-week period of detraining and maintained four weeks after it is stopped. Other adverse effects that are often cited but not proven include anecdotal reports of muscle cramps, strains, dehydration in hot humid weather, diarrhea, migraines, and nausea.[3]

A retrospective study utilized questionnaires and blood samples on 26 athletes from various sports who had used creatine supplementation for 0.8–4 years. All groups fell within normal clinical ranges, and no significant adverse health effects were found with long-term creatine supplementation. Some subjects reported short-terms side effects of gastrointestinal distress, but in this study evidence was anecdotal and relied on athlete recollection.[25]

A study of Egyptians aged 13–18 found that a child's ability to regenerate high-energy phosphates during high-intensity exercise is less than that of an adult. Therefore, creatine supplementation may benefit the rate and use of creatine phosphate and ATP re-phosphorylation. However, performance in short-duration high-intensity exercise can be improved through training; therefore, supplementation may not be necessary.[26]

A survey of 1103 middle and high school athletes aged 10–18 found 62 (5.6%) admitting to creatine use. The main reasons for taking creatine were cited as: performance (74.2%) and improved appearance (61.3%). The most

common reason cited for not taking creatine was safety (45.7%).[27]

Creatine supplementation does not appear to have significant adverse side effects from either short- or long-term use in most young adult athletes. Shortcomings in the current studies available for review include a lack of high-quality, well-designed RCTs. There is also a paucity of data for creatine use in athletes younger than 18 years old.

Resolution of clinical scenario

The current consensus is to recommend against creatine use in athletes with existing renal disease. The current position of the International Society of Sports Nutrition is that, under proper supervision, creatine monohydrate supplementation in children and adolescent athletes is acceptable and may provide a safer alternative to potentially dangerous anabolic androgenic drugs.[16] It is also recommended that creatine supplementation only be considered for use by younger athletes who (i) are involved in competitive supervised training, (ii) are consuming a well-balanced diet, (iii) are educated about the appropriate use of creatine, and (iv) follow recommended dosages.[16]

Summary of answers

- Creatine supplementation may be effective as an ergogenic aid in short bouts of intense exercise.
- Creatine supplementation does not appear to be beneficial in aerobic, endurance exercise.
- Enhanced muscular performance, increased lean body mass, and increased oxygen consumption are the physiological effects of creatine supplementation.

- Current statement is that creatine supplementation should be avoided in those with existing renal disease and supervised in children and adolescents.

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121 First Time Shoulder Dislocation

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Clinical scenario

- A 20-year-old collegiate football lineman sustains an injury to his dominant shoulder while blocking that involves a sudden posteriorly directed force on his forearm while his arm was in a position of abduction and external rotation.
- On examination, he holds his arm at his side and refuses any attempts at range of motion assessment.
- He is neurovascularly intact distally.
- This is the first episode of anterior shoulder instability sustained by the athlete.

Top three questions

1. In patients undergoing reduction of primary glenohumeral dislocations, does intravenous (IV) sedation for closed reduction present a greater chance for successful reduction and fewer complications than other methods of premedication for reduction?
2. In a patient undergoing a primary glenohumeral dislocation reduction, is there an ideal reduction and immobilization method that results in fewer complications and reduced recurrence rates?
3. What is the long-term prognosis for a patient who sustains a primary anterior glenohumeral dislocation?

Question 1: In patients undergoing reduction of primary glenohumeral dislocations, does intravenous (IV) sedation for closed reduction present a greater chance for successful reduction and fewer complications than other methods of premedication for reduction?

Rationale

An athlete with a primary dislocation of the glenohumeral joint will be in obvious discomfort and resistant of closed reduction attempts secondary to pain. In the current medical care setting, there are several options for premedicating patients that range from IV sedation to intra-articular anesthetic to regional nerve block. The treating clinician must decide on the best method of anesthesia delivery (IV sedation vs intra-articular injection) to maximize patient safety while achieving successful reduction and minimizing complications.

Clinical comment

Premedication is an important aspect of reduction as it can allow for a better outcome in regards to patient safety and satisfaction, in addition to aiding the clinician in a more facile reduction.

Available literature and quality of the evidence

- Level I: 4 systematic reviews/meta-analysis[1–4] and 7 randomized trials.[5–11]

Findings

The included trials compared various outcome measures among techniques for premedication that included IV sedation, intra-articular lidocaine injection, and suprascapular nerve block. Outcomes that were compared included reduction success, complications, pain level, time to reduction, and overall time spent in the Emergency Department. In the included studies, no difference was seen in rates of reduction among the different techniques used for sedation. Furthermore, patient pain and satisfaction between the various techniques showed no significant differences.

There were differences found in complication rates between intra-articular lidocaine injection and IV sedation. The most common complication involved respiratory depression in the setting of IV sedation. One meta-analysis found statistically significant increases in rates of respiratory depression, vomiting, and thrombophlebitis in the IV sedation group when compared to the intra-articular lidocaine group. There were no significant differences found in regards to nausea, hypotension, drowsiness, or headache.[4]

Time to reduction and overall time spent in the Emergency Department has also been evaluated by the included studies. In general, studies comparing time to reduction favor IV sedation as the quicker method, while intra-articular lidocaine results in the least overall time spent in the Emergency Department. One systematic review found that mean time spent in the Emergency Department was 109.46 minutes less with intra-articular lidocaine as compared to IV sedation (95% confidence interval [CI]: 84.60–134.32). In terms of time to reduction, IV sedation was favorable with a time of 105 seconds to reduction (95% CI: 84.0–126.1), while intra-articular lidocaine had an average time of 284.6 seconds to reduction (95% CI: 185.3–383.9).[3]

Resolution of clinical scenario

- No significant difference exists among premedication techniques for glenohumeral reduction in regards to success rate for reduction and patient pain level.
- Intra-articular lidocaine significantly reduces the risk of complications, mainly in the form of respiratory depression associated with IV sedation.
- Time to reduction and overall time spent in the Emergency Department were variable with studies favoring IV sedation in time to reduction and intra-articular lidocaine with overall time spent in the Emergency Department.

Question 2: In a patient undergoing a primary glenohumeral dislocation reduction, is there an ideal reduction and immobilization method that results in fewer complications and reduced recurrence rates?

Rationale

The standard of care for the athlete with a dislocated glenohumeral joint is expeditious reduction and immobilization. It is important to select a technique to best achieve reduction and then to place the arm in a position of relative stability. There are numerus techniques for achieving reduction and immobilization of the glenohumeral joint. Each technique utilizes different strategies to overcome muscular forces and allow the humeral head to reduce back into congruent anatomic alignment with the glenoid. Furthermore, immobilization methods are aimed at maximal stability and preventing recurrent dislocation.

Clinical comment

It is important to achieve safe, expeditious reduction in a manner that avoids iatrogenic injury to the anatomic structures of the shoulder. Furthermore, choice of immobilization may be important for postreduction stability and prevention of recurrent dislocations.

Available literature and quality of the evidence

- Level I: 3 systematic reviews/meta-analysis[12–14] and 8 randomized trials.[15–22]
- Level II: 1 observational cohort study[23] and 2 randomized trials.[24,25]

Findings

There are numerous techniques for glenohumeral reduction. Some of these include: Milch technique, Kocher technique, Hippocratic method, FARES (Fast, Reliable, and Safe), Traction–Countertraction, and the Scapular Manipulation technique. The above studies looked at several variables when comparing the techniques with regards to rate of successful reduction, patient pain according to visual analog pain ratings, and reduction time.

Scapular Manipulation was the most successful (97%), fastest (1.75 minutes), and least painful (Visual Analog Scale [VAS] 1.47). FARES was also successful (92%), fast (2.24 minutes), and relatively painless without analgesia (VAS 1.59). Traction–Countertraction showed high rates of success (95%) but was more painful (VAS 4.75). Table 121.1 gives details for each method.[13]

Table 121.1 Techniques for glenohumeral reduction. Source: Modified from Alkaduhimi et al.[13].

Technique	Total Patients (N)	Reduction Success (%)	Reduction Time (min)	Reduction Pain (VAS 1–10)
Hippocratic	51	73	5.55 (SD 0.395)	4.88 (SD 0.54)
Milch	148	80	4.29 (SD 0.14)	5.28 (SD 0.54)
Kocher	317	85	4.19 (SD 1.25)	4.68 (SD 2.00)
FARES	133	92	2.24 (SD 0.27)	1.59 (SD 0.46)
Traction–Countertraction	278	95	6.05 (SD 2.49)	4.75 (SD 0.55)
Scapular Manipulation	78	97	1.75 (SD 0.38)	1.47 (SD 0.44)

SD: standard deviation.

Classically, immobilization in a position of internal rotation has been employed. However, some advocate for immobilization in external rotation to place tension along the anterior capsulolabral structures to improve restoration of preinjury anatomy and decrease likelihood of recurrence. One systematic review found that there was no evidence to show a difference in re-dislocation rates between internal and external rotation immobilization at two years or greater follow-up (relative risk [RR] = 1.06 favoring internal rotation; 95% CI: 0.73–1.54, p = 0.77, 252 participants over three trials). There was also no evidence found to show a difference between the two groups in return to preinjury levels of activity (RR = 1.25 favoring external rotation; 95% CI: 0.71 to 2.2; p = 0.43; 278 participants over two trials).[14]

In regards to length of immobilization, Hovelius et al. followed a cohort of patients for over 25 years comparing time of immobilization in internal rotation. They found that length of time immobilized had no difference in rate of recurrent dislocation. Overall, recurrence rate of dislocation progressively increases over time but plateaus at about five years after the initial injury (29% at 2 years, 45% at 5 years, 48% at 10 years).[18]

Resolution of clinical scenario

- There are several techniques for shoulder reduction that are relatively quick and have a high success rate (FARES, Scapular Manipulation, Traction–Countertraction). These can be employed safely with either IV sedation or intra-articular lidocaine use.
- The FARES and Scapular Manipulation techniques can be used with minimal to no pre-sedation medication and have a high success rate while also producing little pain during the reduction.
- There is no significant difference in recurrent dislocation rate between immobilization for several weeks in internal rotation versus early motion.
- There is no high-level evidence to suggest a difference in immobilization in internal rotation versus external rotation in regards to recurrent dislocation.

Question 3: What is the long-term prognosis for a patient who sustains a primary anterior glenohumeral dislocation?

Rationale

Once a primary anterior glenohumeral dislocation in an athlete has been successfully reduced and immobilized, they will likely enquire about future ramifications for shoulder function later in life. It is important to guide patients on expectations for the short term in regards to immobilization, rehabilitation, and recurrent dislocation risk. However, it is equally important to educate them on the possible long-term sequela of a first-time dislocation.

Clinical comment

The short-term risk of recurrent dislocation is important; however, the long-term sequela of glenohumeral arthritis can be impactful in terms of resultant shoulder dysfunction for the patient.

Available literature and quality of the evidence

- Level I: 1 randomized trial.[26]
- Level II: 1 cross-sectional study.[27]

Findings

One of the biggest concerns is the threat of post-traumatic osteoarthritis and how one dislocation event versus recurrent dislocations impacts this outcome. Ogawa et al. found a high incidence of osteoarthritis in patients with traumatic anterior instability for whom surgery was planned. Incidence of osteoarthritis on plain x-ray was 11%, while incidence was 31% on computed tomography (CT) analysis. The total number of dislocation/subluxation events and frequency of those events in osteoarthritic shoulders were significantly larger and higher than in nonosteoarthritic shoulders.[27]

Hovelius et al. followed 227 patients for 25 years after an initial glenohumeral dislocation event treated no-operatively. He used Disabilities of the Arm, Shoulder, and Hand (DASH) scores to evaluate patients. He found that shoulders

classified as nonrecurrent, stable over time, or surgically stabilized had similar DASH scores and fared better than shoulders classified as persistent, recurrent dislocations.[26]

Resolution of clinical scenario

- DASH scores are comparable amongst groups regardless of treatment, as long as stability is achieved and displayed over time.
- Patients with persistent, recurrent dislocation events have an increased incidence of osteoarthritis and lower DASH scores long term.

Summary of answers

- No difference exists between premedication techniques for glenohumeral reduction regarding success rate for reduction and patient pain level.
- Intra-articular lidocaine significantly reduces the risk of complications, mainly in the form of respiratory depression associated with IV sedation.
- There are several techniques for shoulder reduction that are relatively quick and have a high success rate (FARES, Scapular Manipulation, Traction–Countertraction). These can be employed safely with either IV sedation or intra-articular lidocaine use.
- There is no significant difference in recurrent dislocation rate between immobilization for several weeks in internal rotation versus early motion.
- There is no high-level evidence to suggest a difference in immobilization in internal rotation versus external rotation in regards to recurrent dislocation.
- Patients with persistent, recurrent dislocation events have an increased incidence of osteoarthritis and lower

DASH scores long term.

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122 Recurrent Shoulder Instability

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Clinical scenario

- A 28-year-old soccer keeper had a traumatic anterior dislocation of the right shoulder at the age of 24. He was treated conservatively and has had five recurrences afterwards.
- At physical examination there is no hyperlaxity. The apprehension, relocation, and release tests are positive.
- A computed tomography (CT) scan shows a small defect of the anterior glenoid (Figure 122.1) and a large Hill–Sachs lesion in the posterolateral part of the humeral head (Figure 122.2).

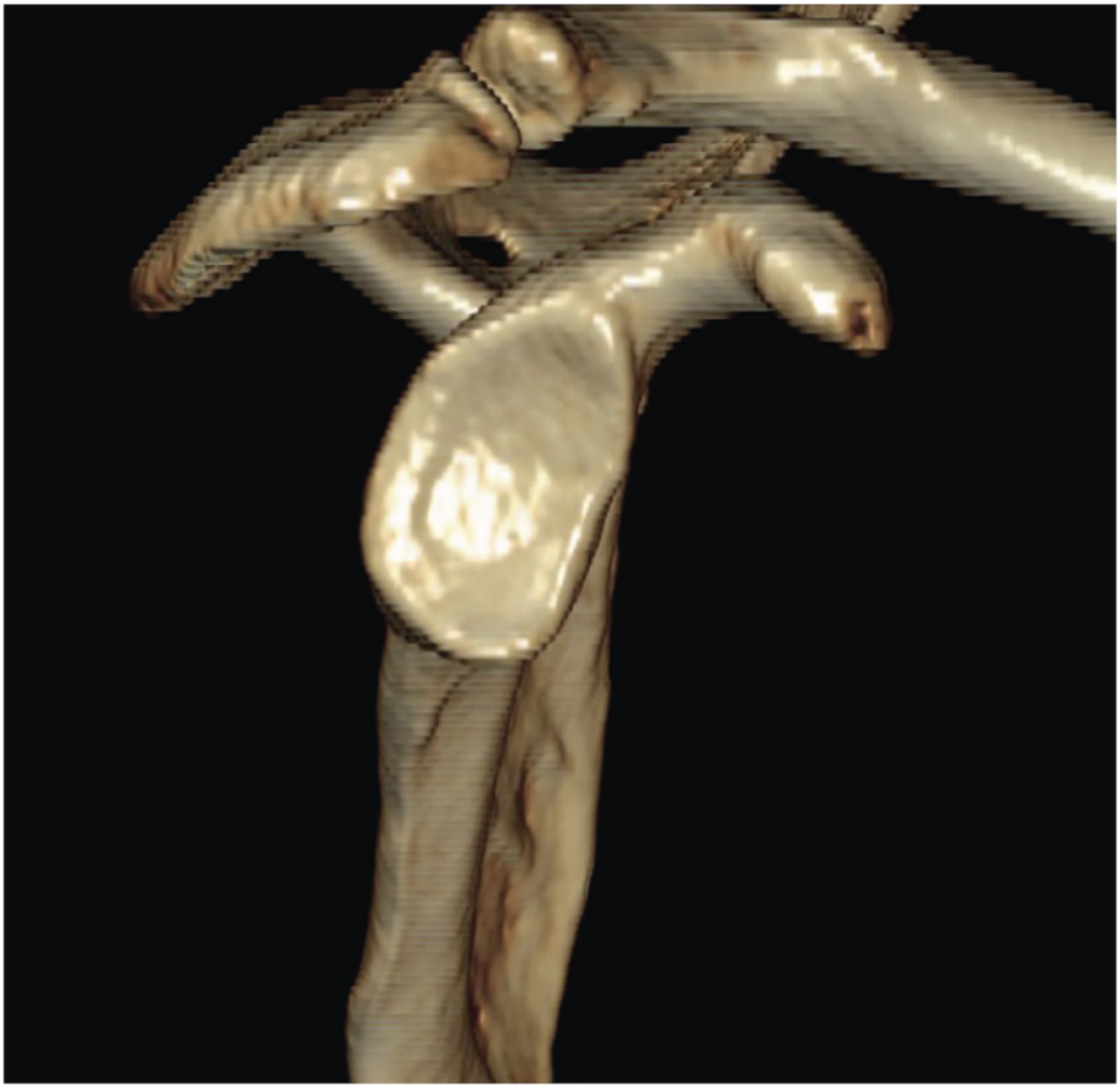

Figure 122.1 CT scan of the right shoulder, with erosion of the anterior glenoid. Source: Joost I. P. Williams, Amber von Gerhardt, W. Jaap Willems, Arthur van Noort.

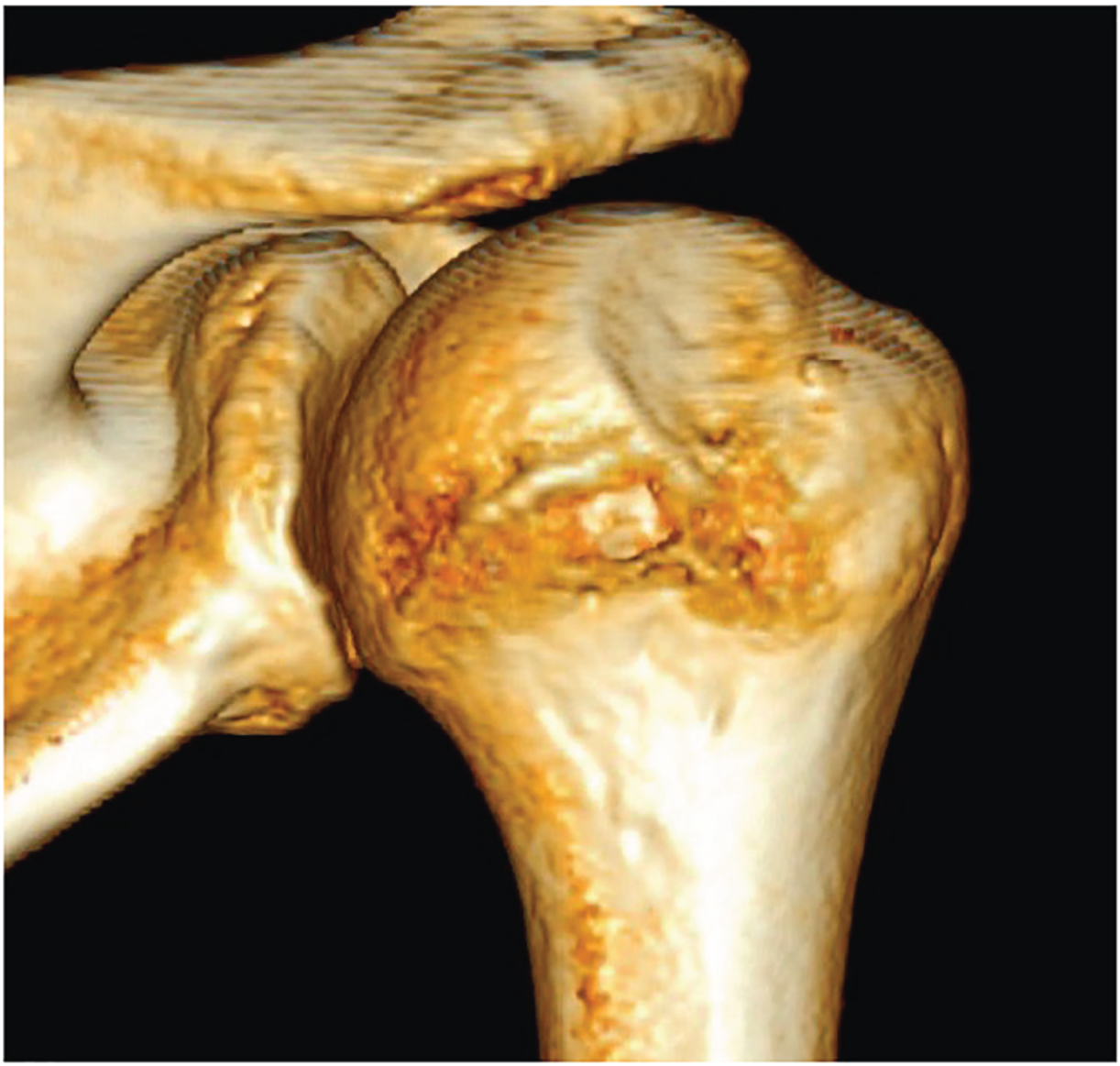

Figure 122.2 CT scan of the humeral head, showing a Hill–Sachs defect on the posterolateral part of the humeral head. Source: Joost I. P. Williams, Amber von Gerhardt, W. Jaap Willems, Arthur van Noort.

Top three questions

1. In patients with recurrent post-traumatic anterior shoulder instability with a bony defect, does a bony

procedure lead to less recurrent instability in comparison to a labrum repair alone?

2. In patients undergoing a bony procedure in shoulder instability, does the original Latarjet procedure (onlay) show superiority to other bony procedures in the prevention of recurrent instability?
3. In recurrent post-traumatic anterior shoulder instability with a large Hill–Sachs lesion without considerable glenoid bone loss, is a remplissage combined with a labrum repair superior to a labrum repair alone?

Question 1: In patients with recurrent post-traumatic anterior shoulder instability with a bony defect, does a bony procedure lead to less recurrent instability in comparison to a labrum repair alone?

Rationale

Historically, an open or arthroscopic labrum repair is the gold standard for treating recurrent anterior instability, but long-term follow-up studies have shown that the rate of recurrence is rather high. Bony procedures seem to show better long-term results with lower recurrence rates, but at the expense of greater number of complications.[1]

Clinical comment

Labrum repair is nowadays mostly performed arthroscopically and is a procedure with low morbidity but high recurrence in cases with considerable bone loss. The bony procedures, of which the Latarjet is the most popular,

are a more difficult operation with potentially less recurrence, but with a higher complication rate.

Available literature and quality of the evidence

In a recent systematic review, including seven studies of level III and one study of level II, 795 patients were evaluated of which 416 underwent an open or arthroscopic Bankart repair and 397 an open Latarjet procedure with a mean range of follow-up of 4.9 to 17.5 years. None of these studies reported on the preoperative bone loss. Latarjet procedure leads to less recurrence and less revision surgery, with no higher complication rate leading to reoperation.[2]

In another recent systematic review with a minimum follow-up of five years, arthroscopic (n = 336) and open Bankart (n = 632), as well as open Latarjet repairs (n = 684), were evaluated. Recurrence rates were respectively 15.1, 7.7, and 2.7%. Only the difference between arthroscopic Bankart repair and Latarjet was statistically significant.

Complication rates were higher in Latarjet repair (9.4% vs 0%) in the arthroscopic Bankart repair (p = 0.002).[1]

One level III study,[3] comparing arthroscopic Bankart versus open Latarjet with a minimum follow-up of six years, showed superior results for the Latarjet procedure regarding any type of recurrent instability (positive apprehension, subluxation, dislocation) (41% vs 11% respectively, p = 0.0001). Small bone lesions were operated by Bankart repair, larger bone defects with a Latarjet. Revision surgery was more frequent in the Bankart repair group (21% vs 5.3%, p = 0.0001).

In two studies, Bankart repair combined with remplissage was compared with Latarjet procedure in patients with

considerable Hill–Sachs lesions.[4,5] Both were retrospective level III studies. With a follow-up of both studies varying between two and four years, the recurrence rate was not significantly different. In one study the rate of complications was higher in the Latarjet group; in the other study, the patients with Bankart plus remplissage showed more pain and loss of external rotation.

Apart from the bony lesions, other clinical factors play a significant role in predicting the chance of recurrence after arthroscopic Bankart repair, especially for those aged <22, male, with a number of preoperative dislocations who participate in competitive sports.[6]

Findings

There is moderate evidence, that labrum repair alone (Bankart repair) is inferior to the Latarjet procedure in recurrent instability.

No high-level evidence data are available if, in minor bony erosions of the glenoid, the labrum repair alone is as effective in preventing recurrence compared to the Latarjet procedure. A randomized controlled trial would be helpful. Following the data at present, with a higher recurrence after labral repair in undefined bone lesions, it is probable, that the Latarjet procedure is superior whenever there is a bone lesion.

Resolution of clinical scenario

- Level III evidence demonstrates that the Latarjet procedure is superior to open or arthroscopic labrum repair regarding re-dislocation and recurrence of instability.
- There is no evidence for a higher complication rate after Latarjet procedure compared to open or

arthroscopic labrum repair.

- Level III evidence demonstrates no difference in recurrence between labrum repair combined with remplissage versus Latarjet procedure.

Question 2: In patients undergoing a bony procedure in shoulder instability, does the original Latarjet procedure (onlay) show superiority to other bony procedures in the prevention of recurrent instability?

Rationale

With many different bony procedures described in literature, the question remains: which technique is the most suitable for shoulders with considerable glenoid bone loss?

Clinical comment

Recurrent shoulder instability is commonly associated with glenoid bone loss.[7] In cases with significant glenoid bone loss, often a soft tissue procedure alone is not sufficient.[8] In the last decade there has been an increasing tendency to perform bony procedures to augment the anterior glenoid. Although some techniques are used more frequently, there is still debate as to which procedure is the best regarding postoperative stability, function, return to activity level, and patient satisfaction.

Multiple types of glenoid augmentation procedures have been described in the literature. The first description of bone augmentation was by Eden, who used an autograft

from the tibia.[9] Hybinette adapted the technique by using an autograft from the iliac crest.[10] In 1954, Latarjet was the first to publish on a technique which describes a transfer of the coracoid with the attached conjoined tendon to the anterior part of the glenoid with mostly two screws, through a split of the subscapularis muscle. It increases the glenoid surface and creates a dynamic sling which prevents dislocation in abduction and external rotation.[11]

The classic onlay technique describes a transfer of the coracoid with the inferior part of the coracoid transferred to the anterior glenoid. A subsequent adaptation of this technique is the congruent arch technique, which describes a transfer of the concave inferior side of the coracoid in the same direction as the articular side of the glenoid.[12]

The classic technique allows the use of a portion of the cut coracoacromial ligament for re-attachment of the articular capsule for increased anterior stability. The congruent arch technique aims to create a better match to the concavity of the glenoid and, because of the flat shape of the coracoid, creates a larger articular surface for the glenoid in comparison to the classic technique.

Although the Latarjet procedure has proven to be a successful procedure in the short and long term,[1] there are some risks involved in this technique, such as bone graft resorption, inadequate placement of the bone block creating increased rates of osteoarthritis, failure of fixation, nonunion, or screw loosening, most of these requiring re-operation.

A variation of the coracoid transfer was developed by Bristow, where the tip of the coracoid is fixed to the glenoid rim with one screw.[13] Other types of bone grafts that have been used for glenoid reconstruction are distal tibia osteochondral allograft[14] and lateral clavicle autograft.[15]

More recent techniques of iliac crest bone graft describe a transfer of the inner table of the iliac crest to the anterior surface of the glenoid, which is a better match with the congruency of the glenoid surface.[16] Another technique is the use of a J-shaped iliac crest bone graft which can be placed as a wedge in the anterior glenoid, without the use of fixation material.[17]

Available literature and quality of the evidence

A systematic review of level IV studies did not show differences in recurrence in different bony procedures.[18] A recent level I study showed no difference in clinical scores and recurrence between the Latarjet procedure and iliac crest graft (J-graft). The Latarjet group had a significant worse internal rotation; the iliac crest group had a high donor site morbidity.[19]

Findings

There is no evidence, that either technique of bone grafting is clinically superior in treating shoulder instability with considerable bone loss.

Resolution of clinical scenario

- Level I evidence demonstrates a similar effect on stability of both the Latarjet procedure and an iliac crest bone graft (J-graft).

Question 3: In recurrent post-traumatic anterior shoulder instability with a large Hill–Sachs lesion without considerable glenoid bone loss, is a remplissage combined with a labrum repair superior to a labrum repair alone?

Rationale

Since the introduction of the remplissage technique, it has not been proven that it leads to less recurrence compared to labrum repair alone.

Clinical comment

In the past, several techniques have been reported to treat the humeral head defect (he Hill–Sachs lesion) in shoulder instability. Osteochondral allograft, humeral head osteotomy, humeroplasty, partial resurfacing arthroplasty are described.[20–23] Connolly introduced a soft tissue procedure, which describes an open approach with a transfer of the infraspinatus tendon with a piece of the greater tuberosity to the Hill–Sachs defect.[24]

Wolf adapted this technique for an arthroscopic approach, whereby filling (remplissage) the humeral head defect through a capsulotenodesis of infraspinatus and teres minor transforms the Hill–Sachs defect extra-articularly, thus preventing engagement.[25]

One study has shown that in most cases only capsule or muscle is attached to the Hill–Sachs defect.[26]

Availability and quality of the evidence

A meta-analysis of three comparative studies (level III) showed superior results in the group of combined labrum repair and remplissage versus the only labrum repair group in shoulders with up to 25% glenoid bone loss, regarding redislocation rate, recurrent instability, and clinical scores. A comparison between postoperative range of motion, especially of external rotation, could not be made.[27]

Findings

There is low evidence that in patients with a large Hill–Sachs lesion a combined procedure of labrum (Bankart) repair combined with remplissage leads to less recurrence than labrum repair alone.

Resolution of clinical scenario

- Level III evidence demonstrates that, with glenoid bone loss of maximally 25%, remplissage combined with labrum repair is superior to labrum repair alone regarding redislocation and recurrent instability. No data are available to demonstrate loss of external rotation in the remplissage group.

Summary of answers

- Two- (2D) and three-dimensional (3D) CT as well as 2D and 3D magnetic resonance imaging (MRI) are equally adequate in measuring glenoid bone defects in shoulder instability. The best-fit circle method is reliable and accurate.
- The Latarjet procedure is superior to open or arthroscopic labrum repair regarding re-dislocation and recurrence of instability. There is no evidence for a higher complication rate after Latarjet procedure

compared to open or arthroscopic labrum repair. There is no difference in recurrence between labrum repair combined with remplissage versus Latarjet procedure.

- An iliac crest bone graft has a similar effect on stability as the Latarjet procedure.
- In glenoid bone loss more than 25% a labrum repair with remplissage is superior to labrum repair alone regarding redislocation and recurrence of instability.

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123 Rotator Cuff Tears

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Clinical scenario

- A 63-year-old man complains of three days of shoulder pain after overexertion when lifting a weight.
- He describes the pain as mostly mechanic, with progressive worsening throughout the day. Furthermore, it wakes him up in the middle of the night.
- The patient is active both in terms of his profession (a painter) and recreationally (swimming).

Top three questions

1. Among patients with rotator cuff tears, does older age, compared to younger age, have an impact on the success of rotator cuff repair?
2. In patients with an acute rotator cuff tear, does early surgery, compared to delayed surgery, result in better functional outcomes?
3. Among patients undergoing rotator cuff repair, does double row repair, compared to single row repair, have an advantage in terms of outcomes?

Question 1: Among patients with rotator cuff tears, does older age, compared to younger age, have an impact on the success of rotator cuff repair

Rationale

When deciding on the management of a rotator cuff tear, the patient's age is an important variable to assess.[1] A number of studies have evaluated the role of age as a prognostic factor when repairing chronic rotator cuff pathology.[2] An analysis of the published evidence about this topic will help us to decide if there is an age limit after which the patient does not benefit from surgical repair.

Clinical comment

In order to focus properly the management of a degenerative rotator cuff tear, we must decide whether the lesion is surgical or should be treated conservatively.[3] In this sense, age has been suggested not only as a predisposing factor but also as prognostic of outcome of the result, being associated with a higher rate of repair failure.[4],[5]

It is critical to first determine if a tear is of a traumatic or degenerative nature. Hybrid lesions often exist, that is traumatic injuries on a background of an already degenerative rotator cuff. The intrinsic structure of the tendon can be affected by many factors, but primarily by professional activity, gender, and age. The degeneration of the tendon fibers not only predisposes the patient to a rotator cuff tear but also has a decisive influence on the tendon's healing after surgical repair.[6]

Given this relationship between age, fibrillar degeneration, and lower healing potential, the question arises regarding the age cutoff, if one exists, above which the net benefit does not exceed the surgical risk. Other critical prognostic factors include size of the lesion, the degree of muscular atrophy, fatty infiltration at the time of diagnosis, and the tendon's retraction distance.[7]

Available literature and quality of the evidence

In spite of the high number of publications that try to offer some light to this question, only a few reach a high level of evidence. Although the majority of the studies are of level IV evidence, in the last 10 years there have been some level III studies, numerous studies of level IIB, a systematic review (IIA), and a randomized controlled trial (RCT; level IB).

Findings

In the only blinded RCT (multicenter study) conducted thus far, Flurin et al. compared bursectomy and subacromial decompression versus bursectomy, decompression, and arthroscopic repair in 143 patients older than 70 years (70 and 73, respectively).[8] This study concluded that both groups presented a significant clinical improvement at one-year follow-up. However, the group undergoing arthroscopic repair obtained better clinical results in all evaluation scales, with a statistically significant difference. Interestingly, this difference was accentuated in the patients who presented a greater retraction of the tendon cape and was smaller in the patients who presented a greater degree of fat infiltration based on the Goutallier classification.[9]

Along the same lines, Dezaly et al. performed a very similar RCT (level IIB) in which they reached the same conclusion

after randomizing 142 patients: acromioplasty and biceps tenotomy group versus acromioplasty, biceps tenotomy, and cuff repair group.[10] The acromioplasty, biceps tenotomy, and rotator cuff group obtained statistically significant improvements in clinical scores and overall satisfaction.

In a 2017 study, Silva et al. conducted a literature review of studies published involving patients over 65 years of age.[11] They concluded that, despite the lack of RCTs, the data obtained in the different studies are consistent. The healing rate after one year varies depending on the studies from 58%[12] to 81.5%,[7] obtaining an average of 71.7%. However, the improvement in the clinical evaluation scales and in overall patient satisfaction is even higher.

Oh et al. published in 2010 a case series that, despite being level IV evidence, was very statistically robust.[13] They demonstrated that in a multivariate regression analysis, age is not an independent determining factor of Constant score, while the degree of retraction of the proximal end and the fatty degeneration of the infraspinatus were indeed independent factors affecting the integrity of the repair.

Resolution of clinical scenario

- Studies published to date show that increasing age is associated with prevalence of larger rotator cuff tears. The size of the tear is closely related to a risk of re-rupture following rotator cuff repair.
- The rate of healing in patients over 70 years after one year exceeds 70% on average, reaching in some studies up to 81%.
- In patients in whom there has been a re-rupture of the repair after one year, the functional and overall patient

satisfaction scores still show a statistically significant increase compared to decompression alone.

- Based on the evidence published thus far, we can affirm that age should not exclude patients from undergoing rotator cuff repair. This indication should be made around other factors, such as the degree of retraction and the degree of fatty infiltration degree.

Question 2: In patients with an acute rotator cuff tear, does early surgery, compared to delayed surgery, result in better functional outcomes?

Rationale

In general terms, when we treat an acute tendon injury, we understand that early repair is a key factor to be taken into account to avoid muscle hypotrophy and tendon retraction.[14] Some clinical guidelines recommend that acute lesions should be repaired in a period of less than three weeks.[15] But is there true evidence to support such a claim? And if so, what is the critical period for treating it?

Clinical comment

Making a distinction between an acute rupture, acute symptoms of a chronic rupture or the acute extension of an existing chronic rupture are very difficult, if not impossible.[16] We define acute ruptures as those in which a previously asymptomatic patient identifies a traumatic incident leading to a sudden onset of symptoms such as severe pain, functional limitation, and loss of strength in the affected limb.[17] However, the diagnosis is rarely immediate, either because it takes time to consult a

physician or due to delays in referrals and wait times for nonurgent issues.[18]

Extrapolating the pathophysiology of tendon lesions in other parts of the body, several studies have tried to provide scientific support to the hypothesis that truly acute tendon ruptures should be treated immediately, similar to how they are for other parts of the body (e.g. Achilles, flexor tendons).[19],[20]

Available literature and quality of the evidence

The majority of the available studies published as far are level IV.[14][16]–[27]

Findings

The first study that directly addressed the issue dates from 1983. Basset et al. conducted a cohort study with 37 patients separating them into three groups: early surgery (ES) <3 weeks, 3–6 weeks, and delayed surgery (DS) >6 weeks.[21] They concluded that the earlier patients underwent surgery, the greater range of motion they ultimately achieved.

In 2011, Hantes et al. conducted a retrospective cohort study with 35 patients (ES <3 weeks vs DS >3 weeks).[22] They found a significantly greater improvement in the University of California Los Angeles (UCLA) and Constant scales in the ES group compared to the DS group. In a very similar study, however, Petersen et al. established that there were no differences among patients operated on any time in the first four months postinjury.[23]

Tan et al. performed a retrospective cohort study with the largest sample size to date.[24] They analyzed the results of 1200 patients divided into two groups: ES <24 months and DS >24 months. They found that patients operated on

within 24 months after the traumatic event had a lower rate of re-rupture (13%) compared to the DS group (20%). In contrast, Zhaeentan et al. demonstrated no advantages between the ES and DS groups.[27] The discrepancy in this case may be due to the fact that the latter study performed repairs using a mini-open approach rather than arthroscopy.

The only systematic review (grade IIIA) to date was carried out by Mukovozov et al. in 2013.[17] For this study they used seven studies in the ES group (<3 months) and eight studies in the DS group (>3 months). They concluded that the patients in the ES groups had a statistically significant increase in the UCLA and Constant scores; however, given that low-quality data were pooled, this should be interpreted with caution.

Resolution of clinical scenario

Common sense leads us to think that early repair has advantages (e.g. less atrophy) compared to delayed repair (e.g. increased lesion size, loss of cuff elasticity). However, true common sense is to apply scientific evidence to our clinical practice. From the studies published to date, it appears early repair increases the rate of healing and clinical outcomes. However, there is currently insufficient evidence, which is often of poor quality and sometimes even contradictory. To determine the balance between benefits and prejudices, higher-quality studies and larger statistical power studies are needed. Likewise, there is no consensus regarding the definition of *early surgery*.

Question 3: Among patients undergoing rotator cuff repair, does double row repair, compared to single row repair, have an advantage in terms of outcomes?

Rationale

The optimal tendon repair technique has been a topic of debate. Single row, double row, transosseous, and bridged repairs are some of the options currently in the therapeutic arsenal and are applied depending on the surgeon's preference.

Clinical comment

The controversy about which suture technique is best suited to repair the cuff arose at the beginning of this century, with the aim of anatomically restoring the insertional footprint.[28] A cadaveric study conducted in by Meier et al. confirmed not only the increase in tendon–bone contact but also the mechanical advantage of the double row repair compared to the single row repair.[29] Despite a plethora of evidence on the topic since then, the question remains: which technique is best for a given patient?

Available literature and quality of the evidence

Seven cadaveric studies were available, which formed the basis for in vivo trials that followed. In vivo, there is abundant level IV and level III evidence (14 studies). There are also six level IIB studies, with their corresponding systematic reviews of level IIA (five reviews and meta-analyses). Focusing on level I evidence, seven RCTs (IB) have been published thus far. In addition, three systematic

reviews/meta-analyses (IA) focusing on these trials have been published.

Findings

Curtis et al. carried out a descriptive anatomical study in cadavers, describing the insertional footprint.[30] It concluded that the footprint followed a consistent and identifiable pattern through anatomical references, which allowed the evaluation of size and location of the cuff lesion. In a subsequent study, Lo et al. formulated the hypothesis that the restoration of the footprint would provide better biology and a biomechanical advantage.[28]

Meier et al. subjected 30 cadaveric shoulders to a cyclic load. The endpoints were established in 10 mm gap or 5000 cycles.[29] Two conclusions were reached from this study: the anchor suture is superior to the transosseous suture, and the double row was biomechanically and anatomically superior to single row. Subsequent cadaveric studies further corroborated these findings.[31],[32]

Grasso et al. performed the first randomized clinical trial (level IB), in which 80 patients were randomized to single row versus double row repair (40 patients in each group).[33] Outcomes included the Disabilities of the Arm, Shoulder, and Hand (DASH) scale, the Constant score, and the Strength score. The study concluded that in the short term there were not clinically significant differences between the two techniques.

In the following years seven further high-quality trials all reached very similar conclusions: no differences in clinical outcome, and marginal (nonsignificant) superiority for healing rate in favor of double row repair.

Carbonel et al. carried out the RCT with the greatest statistical power.[34] They randomized 160 patients, 80 for

each therapeutic group. Outcomes included the UCLA score, American Shoulder and Elbow Surgeons (ASES) scores, and the Constant score. Multiple independent variables were analyzed. Healing was evaluated by magnetic resonance imaging (MRI) and the follow-up was up to two years postoperatively. The study concluded that, although there were no differences in healing rate, patients undergoing double row repair did have better clinical outcomes after two years, a difference that was more evident in lesions >3 cm. These conclusions were in contrast to the previously published studies.

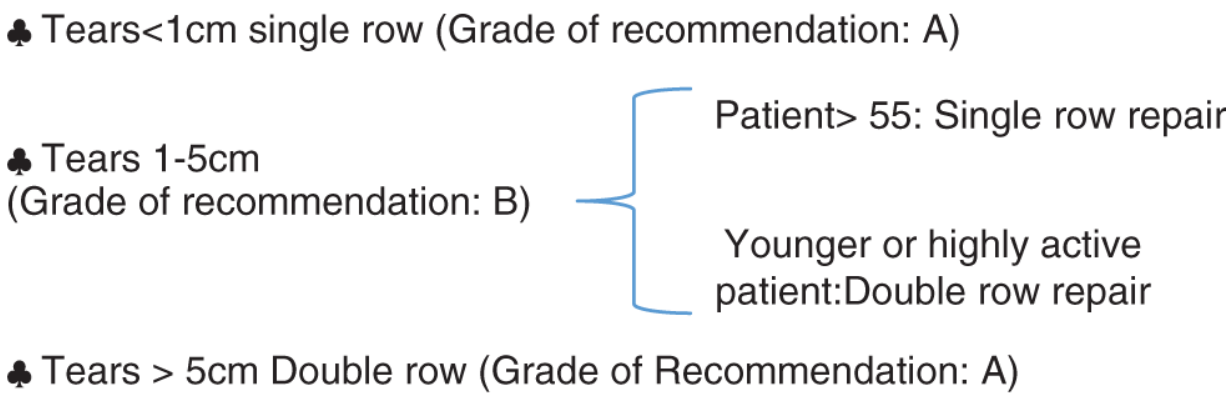
In 2016, Spiegl et al. performed a systematic review of the meta-analyses published until then, including eight papers with level I–III studies.[35] After analyzing all the information, the authors concluded that in the short-term there were no statistically significant clinical differences for small and medium rotator cuff injuries. However, there was a higher re-rupture rate in the single row patients. It also suggested a tendency to obtain better clinical results in large and massive cuff tears.

The most complete meta-analysis performed to date analyzed seven clinical trials.[36] The UCLA score was the only outcome which significantly favored double row repair. Other outcomes (ASES, Constant, Western Ontario Rotator Cuff [WORC], and Single Assessment Numeric Evaluation [SANE]) scores showed no significant differences.

Resolution of clinical scenario

- Double row suture and bridge double row configurations have demonstrated biomechanical, biological, and anatomical superiority in cadavers.

- This superiority does not translate in clinical outcomes as expected, although imaging studies do seem to show a higher rate of healing and lower rates of re-rupture with double row repair.
- The latest systematic reviews also suggest a tendency to obtain better clinical results in large and massive cuff tears with double row repair.
- With the evidence published to date, the recommendations are:



Summary of answers

- Increasing age is associated with prevalence of large rotator cuffs.
- Age alone should not exclude patients from undergoing rotator cuff repair.
- There is currently insufficient evidence to demonstrate that early repair increases rates of healing and/or clinical outcomes.
- Double row suture configurations have demonstrated biomechanical superiority.
- Double row repair has not translated into clinical outcomes.

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124 Massive and Irreparable Rotator Cuff Tears

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Clinical scenario

- A 52-year-old male laborer presents with chronic, dominant shoulder pain.
- Magnetic resonance imaging (MRI) demonstrates a massive rotator cuff tear with retraction of the rotator cuff tendon medial to glenoid, and grade 3 Goutallier atrophy.

Top three questions

1. In active patients with a full thickness, massive, retracted rotator cuff tear, does single row rotator cuff repair (RCR) result in better clinical outcomes than double row RCR?
2. In middle-aged active men with full thickness, massive, retracted rotator cuff tears, does RCR with patch augmentation result in better clinical outcomes than RCR in isolation?
3. In middle-aged men with irreparable rotator cuff tears, does superior capsular reconstruction (SCR) result in better functional outcomes than tendon transfers?

Question 1: In active patients with a full thickness, massive, retracted rotator cuff tear, does single row rotator cuff repair (RCR) result in better clinical outcomes than double row RCR?

Rationale

With the current focus on minimizing expenses in healthcare, it is important to understand when additional costs are truly beneficial to clinical outcomes, and when the cost may be unnecessary. Double row RCR is more costly than single row RCR, so the cost must be justified with improved outcomes.

Clinical comment

The number of RCR performed each year is increasing. There are many ways to perform an RCR, but the most common is either via a single or double row configuration. It is imperative that these RCR techniques be closely compared and scrutinized so treating surgeons can choose the correct procedure that offers the best outcome. Furthermore, the patient in this scenario has a massive, retracted rotator cuff tear. This must be distinguished from an irreparable rotator cuff tear. An irreparable rotator cuff tear is one that, despite soft tissue releases, muscle relaxation, etc., is too degenerated, with too much fatty atrophy, and not enough excursion that it cannot physically be repaired. Other factors that aid in the decision-making process would be co-morbidities that have potentially negative effects on healing. For example, if the tendon were able to be mobilized to the tuberosity but was of poor

quality and the patient was a diabetic smoker with osteoporosis, the tear could also be classified as irreparable (in that it would be unlikely to heal).

Available literature and quality of the evidence

The evidence supporting the answer to this question is good with several level I and II studies.[1–7]

Findings

In the middle-aged patient represented in this scenario with a massive rotator cuff tear, the evidence suggests that a double row RCR offers better results in regards to strength (specifically shoulder abduction and external rotation) and tendon healing than a single row repair.[1,2] Studies found that patients with intact rotator cuff tendons following RCR (as confirmed by MRI) have better clinical outcome scores than patients who had a re-tear following RCR.[2] Furthermore, double row RCR leads to decreased re-tear rates accelerated postoperative rehabilitation.[6] A systematic review of overlapping meta-analyses found improved healing rates in double row RCR compared to single row.[8] These results were similar to a systematic review and meta-analyses that similarly found improved healing rates in double row RCR over single row.[9] In the majority of studies there were no differences in clinical outcome scores between the groups.[7] One level I study did find a significant difference in clinical outcome scores, with patients who underwent double row RCR demonstrating higher scores than those who underwent single row repair.[10] This difference was most pronounced with large and massive rotator cuff tears. Hence, in middle-aged, active, laboring patients who undergo RCR on their dominant shoulder and are at increased risk for re-tear, a double row RCR (transosseous equivalent) would be the

treatment of choice. This would allow a faster rehabilitation process with a decreased chance that the repair would fail.

Resolution of clinical scenario

- In massive rotator cuff tears, double row RCR leads to decreased re-tear rates.
- There are conflicting results with regards to clinical outcome scores between groups. In massive rotator cuff tears, double row RCR may improve clinical outcome scores.

Question 2: In middle-aged active men with full thickness, massive, retracted rotator cuff tears, does RCR with patch augmentation result in better clinical outcomes than RCR in isolation?

Rationale

There has been a significant amount of recent attention given to augmentation strategies for RCR. Prior to recommending a patch augmentation, the surgeon should be familiar with what the evidence shows.

Clinical comment

Several companies have developed patches to be used as augments during RCR. These patches are used in an attempt to promote healing of the RCR. If these patches improve healing rates and functional outcomes following RCR, they may be worthwhile using as an augmentation technique.

Available literature and quality of the evidence

The evidence supporting the answer to this question is mediocre with three level III studies and several level IV studies.[11–15]

Findings

The porcine dermal xenograft used as an augment to supraspinatus tendon repair does not appear to improve radiographic healing or clinical outcomes at two years.[11] The poor performance of the xenograft was seen in multiple studies, and augmentation with this graft should be used with caution.[16] Yoon et al. compared standard RCR to marrow stimulation and patch-augmented RCR.[15] The authors found no difference in clinical outcome scores, but a significantly lower re-tear rate in the patch-augmented group. These results should be evaluated with caution, however, because the patch group also underwent marrow stimulation. Ciampi et al. compared a standard RCR without patch augmentation, an RCR with a collagen patch augmentation, and an RCR with a nonabsorbable, synthetic polypropylene patch augmentation.[12] The authors found a reduced 12-month re-tear rate as well as increased UCLA scores, abduction strength, and elevation at three-year follow-up. In the level IV studies without control groups, all studies reported significant improvements in outcome scores, pain, and shoulder motion following patch-augmented RCR, but given the lack of control groups, it is difficult to discern whether these improvements would be more significant than outcomes following RCR without patch augmentation.[13,14,16] Hence, as the literature currently stands, augmentation of an RCR with a patch in a middle-aged, active laborer may decrease re-tear rates but does not improve clinical outcomes. Good clinical judgment

must be utilized when deciding whether to augment a repair with a patch.

Resolution of clinical scenario

- There does not appear to be a difference in clinical outcome scores between patients who undergo isolated RCR and those who undergo RCR plus patch augmentation.
- Patch augmentation may decrease re-tear rates following RCR compared to patients who undergo RCR without patch augmentation.

Question 3: In middle-aged men with irreparable rotator cuff tears, does superior capsular reconstruction (SCR) result in better functional outcomes than tendon transfers?

Rationale

There are some rotator cuff tears that cannot be fixed. In a young patient who would be a poor candidate for an arthroplasty procedure, the surgeon should choose the treatment option that will afford the patient the best outcome.

Clinical comment

Young, active patients with irreparable rotator cuff tears represent a very difficult patient population for treating surgeons. In this scenario, the rotator cuff, despite soft tissue releases, etc., cannot be repaired, and a salvage operation must be attempted. These patients have limited options for success, and their options are often somewhat

technically demanding and have unpredictable outcomes. It is important to understand the pros and cons of each procedure.

Available literature and quality of the evidence

The evidence supporting the answer to this question is poor with several level IV studies.[17–24]

Findings

Unfortunately, there are no studies that have directly compared SCR to tendon transfers. However, there are several studies that have reported results of both individually. Pennington et al. reported the one-year results of 86 patients who underwent SCR for massive, irreparable rotator cuff tears.[17] Significant improvements in Visual Analog Scale (VAS) and American Shoulder and Elbow Surgeons (ASES) scores, as well as strength and range of motion (ROM), were seen. Several other level IV studies have corroborated these results.[18–20] Complications following SCR include failure and/or resorption of the graft.

There are a few options for tendon transfers in patients with irreparable posterosuperior rotator cuff tears including the latissimus dorsi, lower trapezius, and teres major.[21,23,25,26] Boileau et al. reported the results of an isolated latissimus dorsi transfer to restore external rotation in massive, irreparable rotator cuff tears.[21] The authors found significant improvements in Constant and Simple Shoulder Value (SSV) scores as well as a significant increase in shoulder external rotation following latissimus transfer (there was a 26° increase in external rotation with the arm at the side and 18.5° increase in external rotation with the arm in 90° of abduction).

Similarly, Kanatli et al. reported the outcomes of 15 patients with irreparable rotator cuff tears and pseudoparalysis treated with latissimus dorsi transfer and found significant improvements in all clinical outcome scores as well as all shoulder ROM.[22] Elhassan et al. reported the results of lower trapezius transfers in 33 patients (average age 53) at an average of 47 months' follow-up.[23] The authors found significant improvements in pain and SSV scores, and significant improvements in ROM. Complications following tendon transfers include seroma formation, harvest site morbidity, neuropraxias, etc. Therefore, both SCR and tendon transfers are viable options when treating middle-aged, active, laborer patients with massive, irreparable rotator cuff tears. SCR may be slightly less technically demanding with fewer potential complications (harvest site issues, neuropraxias, etc.).

Resolution of clinical scenario

- Direct comparison between SCR and tendon transfers for treatment of massive irreparable rotator cuff tears cannot be made.
- Both SCR and tendon transfers help restore ROM and improve clinical outcome scores in this difficult patient population.

Summary of answers

- In massive rotator cuff tears, double row RCR results in lower re-tear rates and possibly improved outcome scores compared to single row RCR.
- Patch augmentation to RCR may decrease re-tear rates, but it has no effect on clinical outcome scores.

- Both SCR and tendon transfer (using a variety of tendons) are viable treatment options in the middle-aged patient with a massive, irreparable rotator cuff tear.

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125 Subacromial Pain Syndrome

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Clinical scenario

- A 48-year-old male presents to an orthopedic surgeon with shoulder complaints.
- He works in a hardware store and has had progressive pain in his right shoulder for five months. The pain is located anterolateral and radiates to the upper arm. There is no history of trauma, overhead activities are painful, and sleeping is disturbed.
- At examination there is a painful arc between 70 and 120°. The Neer sign and Hawkins–Kennedy test are positive.
- The orthopedic surgeon doubts whether he uses an magnetic resonance imaging (MRI) or ultrasound (US) to investigate the persistent complaints.
- A subacromial injection with local anesthetic and steroids gave relieve.

Top three questions

1. Does the Hawkins–Kennedy test predict subacromial pain syndrome (SAPS) better in patients with shoulder pain compared to other physical tests?
2. How sensitive is an MRI scan in comparison to US for diagnosing SAPS in patients with shoulder pain?

3. Does surgery lead to a better functional outcome compared to conservative treatment (physiotherapy, infiltrations) in patients with SAPS?

Question 1: Does the Hawkins–Kennedy test predict subacromial pain syndrome (SAPS) better in patients with shoulder pain compared to other physical tests?

Rationale

SAPS causes pain, impairment in daily activities and work, and a clear and unambiguous anatomical substrate is lacking.[1] It is a frequently encountered condition in daily practice of orthopedic surgeons; between 7 and 34% of adults have shoulder pain at times and the incidence of shoulder pain in is estimated to be 19 per 1000 person-years, and is highest in women over 45 years and lowest in young adults. In the general practice the incidence is 0.8–2.3%, with a lifetime prevalence of up to 66.7%.[2] A thorough physical examination is an essential diagnostic tool and can help to rule out other shoulder pathologies. Though often associated with rotator cuff tears, the discussion of SAPS in this chapter will not include cuff tears. Please see Chapters 123 and 124 for a full discussion of rotator cuff pathology.

Clinical comment

Many shoulder tests are available to test a variety of diagnoses of the shoulder. One commonly used test is the Hawkins–Kennedy test.[3] The patients is examined while sitting with their shoulder flexed to 90° and their elbow

flexed to 90°. The examiner grasps and supports proximal to the wrist and elbow to ensure maximal relaxation. The examiner and the patient then quickly rotate the arm internally. The test is considered positive when the pain is located below the acromioclavicular joint with internal rotation. It would be helpful to have a specific test for SAPS as it is a clinical diagnosis.

Available literature and quality of the evidence

A Cochrane review by Hanchard et al. from 2013 investigated all physical tests for subacromial pain syndrome.[4] They reviewed various tests for shoulder pain but five were selected specific for *impingement* with a total of 356 patients. Only two studies could answer the question with both level II evidence.[5,6]

Findings

The review included five studies for specific *impingement* tests. They showed a sensitivity of 0.92 (0. 72–0.99) with specificity from 0.26 (0.13–0.43) to 0.44 (0.32–0.58) but this raised to 0.96 (0.79–1.00) when the Hawkins–Kennedy test or the Neer sign (pain produced by maximal passive abduction in the scapula plane, with internal rotation whilst stabilizing the scapula by the examiner)[7] was positive with specificity 0.41 (0.29–0.54). This is also confirmed in another review which stated that one physical sign cannot sufficiently differentiate between the various shoulder disorders and so a combination of tests should be used.[8]

Resolution of clinical scenario

- Clinical examination is the hallmark for diagnosing SAPS.

- The Hawkins–Kennedy has a very high sensitivity for testing SAPS.
- The test should be combined with other tests to differentiate between different conditions.

Question 2: How sensitive is an MRI scan in comparison to US for diagnosing SAPS in patients with shoulder pain?

Rationale

SAPS is a clinical diagnosis and can be caused or accompanied with different traumatic or degenerative changes of the shoulder. Surgical intervention is, in these patients, not recommended in most cases. If a rotator cuff tear is of traumatic origin, if the patients is young, or very active, if there is an invalidating loss of function, then a rotator cuff repair should be considered.[9] To differentiate between a bursitis or tendinopathy, or to judge the size, retraction, atrophy, or fatty infiltration of a torn rotator cuff, different imaging techniques are available. MRI and US are widely used in investigating patients with complaints of their shoulder.

Clinical comment

In a number of patients with SAPS, complaints may be of a more serious character, as described above, A reparable lesion in the shoulder that can mimic impingement need to be ruled out as this may lead to a different line of treatment (e.g. surgery). As well, appropriate diagnostic tests need to be performed in order to accurately diagnose SAPS.

Available literature and quality of the evidence

Two systematic reviews and meta-analyses assess ultrasonographic performance in terms of diagnosing subacromial conditions. A review by Manzoor et al. (level IV) included 14 studies, three of which specifically looked at the use of US in diagnosing SAPS.[10] Another study, by Ottenheijm et al., included 23 studies, seven of which assess subacromial pathologies.[11] Two diagnostic studies (both level III) assessed the role of MRI in diagnosing SAPS.[12],[13]

Findings

In their systematic review and meta-analysis, Manzoor et al. identified three studies which looked at the diagnostic performance of US in terms of SAPS. There were a total of 177 patients included in the studies. They found that sensitivity for *subacromial impingement* ranged from 35.7 to 79%, whereas specificity ranged from 58.8 to 84.4%. No pooled analysis was performed due to significant heterogeneity, and no positive or negative predictive values were reported.[10] Ottenheijm et al. separated studies on the specific type of subacromial pathologies analyzed. They also did not pool data due to heterogeneity and small sample sizes; they found that in diagnosing subacromial bursitis, US had a sensitivity of 79–81% and a specificity of 94–98%. For tendinopathy, they found a sensitivity of 67–93% and a specificity of 88–100%; finally, for calcific tendonitis, they found a sensitivity of 100% and a specificity of 85–98%.[11]

Birtane et al. enrolled 125 patients in their study, with the subacromial injection test serving as a reference standard. All patients underwent MRI testing as well as functional evaluation. They found that, in diagnosing *subacromial impingement*, MRI had a sensitivity of 98.9% and a specificity of 36.8%, along with positive and negative

predictive values of 78.2 and 93.3%, respectively.[12] Iannotti et al. evaluated MRI performance in 91 patients and 15 asymptomatic volunteers. They found that, in diagnosing impingement syndrome, MRI had a sensitivity of 93% and a specificity of 87%. All shoulders were evaluated arthroscopically as a gold standard reference.[13]

Resolution of clinical scenario

- The diagnostic performance of US is somewhat variable, though it appears to be relatively specific and sensitive for most subacromial pathologies.
- MRI is highly sensitive for SAPS, though it may lack specificity in this regard.

Question 3: Does surgery lead to a better functional outcome compared to conservative treatment (physiotherapy, infiltrations) in patients with SAPS?

Rationale

Evidence is rising that surgery doesn't lead to better results in the treatment of SAPS in the absence of a rotator cuff tear. Patients may have the same results after conservative treatment.

Clinical comment

Subacromial decompression for SAPS is one of the most widely performed surgical procedures of the shoulder. Increasing evidence does not support this treatment for the majority of patients.

Available literature and quality of the evidence

A multicenter, pragmatic, parallel group, placebo-controlled, three-group, randomized surgical trial of level I evidence was recently published.[1] The investigators included 313 patients divided over three groups (arthroscopic subacromial decompression, investigational arthroscopy only, or no treatment). All patients had had at least six months of conservative treatment before inclusion. Surgical patients were blinded for intervention with the *arthroscopy only* as a placebo. Primary outcome was the Oxford Shoulder Score at six months and an intention to treat analysis was performed. A recent systematic review and meta-analysis of RCTs (level I) analyzed 13 RCTs (n = 1062).[14]

Findings

The RCT showed no difference in outcome, measured by the Oxford Shoulder Score, at six months between the arthroscopic subacromial decompression (ASAD) and arthroscopy only (sham) groups – ASAD mean 32.7 (standard deviation [SD] 11.6) vs SHAM mean 34.2 (SD 9.2); mean difference: −1.3 points (95% confidence interval [CI]: 3.8–1.3). In the no-treatment group only a single advice from a consultant was offered and a rehabilitation program was not followed.[15] Comparing the no-treatment to the ASAD and sham groups, no difference was seen in the same outcome at six months. No treatment group Oxford Shoulder Score 29.4 (SD: 11.9) mean differences: 2.8 (95% CI: 0.5 to −5.2) and 4.2 (95% CI: 1.8–6.6). This study failed to show any clinical important advantage of ASAD and questioned the value of surgery for SAPS. The effect of a rehabilitation program was not investigated. Finally, the meta-analysis by Khan et al. found no benefit to surgery in terms of pain relief (mean difference: −0.07;

95% CI: −0.40 to 0.26), or short-term functional outcomes (standardized mean difference: −0.09; 95% CI: −0.27 to 0.08).[14] In accordance with the above, a BMJ Clinical Practice Guideline advised against subacromial decompression surgery in patients with SAPS.[16]

Resolution of clinical scenario

- The patient was treated by conservative treatment with guided training with a physiotherapist, nonsteroidal anti-inflammatory drugs, and a subacromial injection with analgesics and steroids.
- After temporarily adjusting his daily work to desk tasks, he could resume his above-head work after six months and the pain was relieved.

Summary of answers

- The Hawkins–Kennedy test can be used for diagnosing SAPS because of its high sensitivity. It should be used combined with other shoulder tests because this will lead to rising sensitivity and specificity.
- An MRI scan of the shoulder can effectively detect other abnormalities (like RCTs). US can also be used, but only by experienced practitioners.
- Patients with SAPS, in the absence of a rotator cuff tear, should be treated with conservative treatment as it has equal results to surgery. Therefore, surgery should be reserved for patients with persistent complaints.

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126 Pathology of the Long Head of the Biceps

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Clinical scenario

- A 58-year-old self-employed electrician has right shoulder pain that started six months ago after he put together a swing set in his backyard.
- On examination, he is tender over the bicipital groove. He has positive Speed and Yergason tests (Box 126.1).
- There is no weakness of the rotator cuff to suggest a large rotator cuff defect.

Top three questions

1. What is the role of clinical examination and imaging in isolating biceps tendinopathy in patients with shoulder symptoms?
2. What is involved in the decision-making to perform a biceps tendon debridement versus tenodesis or tenotomy in patients with biceps tendinopathy?
3. In patients undergoing biceps tenodesis, are there any differences in the clinical outcome and complication rates among various techniques used for biceps tenodesis? Between arthroscopic biceps tenodesis versus open biceps tenodesis?

Question 1: What is the role of clinical examination and imaging in isolating biceps tendinopathy in patients with shoulder symptoms?

Rationale

It can be difficult to discern the precise anatomical source of shoulder pain.

Clinical comment

Many shoulder surgeons believe they can distinguish pain from the LHB from other types of shoulder pain, and that it is worthwhile to do so.

Available literature and quality of the evidence

- Level I: 3 prospective blinded studies of consecutive patients.[4–6]
- Level II: 1 randomized cohort study,[7] 1 prospective nonrandomized clinical trial,[8] 2 cohort studies,[9,10] and 6 independent, blinded comparisons with a reference standard among non-consecutive patients or confined to a narrow population of study patients.[7,11–15]
- Level IV: 1 diagnostic study with poor reference standard,[16] 1 independent, unblinded comparison with a reference standard,[17] independent, unblinded comparison with poor reference standard.[18]
- Level V: 3 expert opinions.[19–21]

Findings

For diagnosis of LHB tendinopathy, tenderness in the bicipital groove has a sensitivity of 53% and a specificity of 54%; Speed test has a sensitivity from 32 to 69% (with one outlier of 90%) and a specificity from 48 to 81% (with one outlier of 14); Yergason test has a sensitivity of 41% and a specificity of 79%. It is important to note that many of the studies listed below also utilized the same tests to evaluate and diagnose rotator cuff and/or labral pathology, which indicates that these exam maneuvers do not provide a reliable or accurate distinction between LHB pathology and other common causes of shoulder pain.

Ultrasound has a sensitivity between 53 and 100% and a specificity between 97 and 100% for diagnosis of discrete

Box 126.1 Description of physical examination tests

Tenderness of the long head of the biceps (LHB) as it exits the intra-articular space, through the intertubercular groove, and down to a point approximately 7 cm below the acromion.[1]

Speed test: The externally rotated (supinated) arm with an extended elbow is forward elevated. The examiner resists this forward elevation of the arm and checks for pain.[2]

Yergason test: The elbow is flexed to 90° and the patient is asked to supinate the forearm against resistance. The test is considered positive if this resistance produces pain referred to the bicipital groove.[3]

pathology of the LHB such as dislocation, subluxation, and rupture. In patients with near-normal body habitus, imaging is not required to diagnose LHB rupture, making all studies that include ruptures misleading and unhelpful. Tendinopathy of the LHB tendon is not detectable with ultrasound. Biceps tendon sheath effusions detected sonographically are not specific to LHB pathology.[19,20]

The oblique sagittal plane magnetic resonance imaging (MRI) gives the best image of the intra-articular portion of the biceps tendon in the rotator cuff interval, but there is still a discrepancy with other diagnostic methods such as direct visualization at arthroscopy. For instance, Dubrow and colleagues evaluated concordance rate (defined as both modalities achieving a diagnosis of the exact same pathological classification) between noncontrast MRI and arthroscopy in 66 patients with LHB pathology, with equivalent findings only 35% of the time.[22] Mohtadi et al. (level I) similarly found that MRI and arthroscopy were concordant in 38% of patients (n = 58).[5]

Urita et al. (level II) found that MRI imaging demonstrating a medial spur of the bicipital groove and presence of a subscapularis tear were significant predictors of higher-grade LHB pathology (utilizing the Lafosse classification of LHB tendon disorder).[15]

Resolution of clinical scenario

- Physical examination maneuvers have limited ability to distinguish pain from biceps pathology from other types of shoulder pathology (overall quality: moderate).
- Diagnostic imaging has limited and variable sensitivity and specificity for LHB tendon pathology, most of which is either obvious on examination (e.g. rupture) or associated with other, more pressing pathologies such

as subscapularis rupture (with LHB subluxation). Imaging is not adequately studied for its use in distinguishing LHB pain from rotator cuff pain in general or other sources of shoulder pain (overall quality: moderate).

Question 2: What is involved in the decision-making to perform a biceps tendon debridement versus tenodesis or tenotomy in patients with biceps tendinopathy?

Rationale

The role and type of surgical treatment for tendinopathy of the LHB is debated.

Clinical comment

Tenotomy or tenodesis are considered when there is tendinopathy, subluxation, or dislocation of the LHB. Tenotomy is a safer, more expedient, and less technically demanding option in patients who are comfortable with a prominent biceps. Tenodesis is considered based on the rationale that it provides better aesthetics and less postoperative discomfort.

Available literature and quality of the evidence

Level I: 1 systematic review, meta-analysis.[23]

Level III: 2 retrospective cohorts.[24],[25]

Level IV: 5 case series.[26]–[30]

Findings

A 2015 systematic review and meta-analysis of three randomized controlled trials among patients with various diagnoses (not just LHB tendinopathy) and four cohort studies found that the incidence of categorical *cramping pain* was slightly, but significantly, decreased in 192 patients undergoing tenodesis (6%) when compared to tenotomy (13%, n = 198). One wonders what this would look like on a more appropriate measure of pain on its continuum. Prominence of the biceps was noted in 5% of patients undergoing tenodesis (n = 314) and 31% of patients undergoing tenotomy (n = 308). Patients were equally satisfied.[23]

Data from three retrospective case series that assessed tenotomy were pooled together (n = 377), with 73% of the patients categorized as a good or excellent outcome and satisfaction in spite of prominence of the biceps in most.[26–28] In cohort studies comparing tenotomy and tenodesis, there were expected differences in biceps deformity that were not a concern for any patients.[24]

A case series by Delle Rose found that 17% of patients who underwent tenotomy experienced muscle cramping at a mean postoperative time of one month, whereas no patients who underwent tenodesis had muscle cramping. Thirty-seven percent of patients in the tenotomy cohort had a prominent biceps; 5% of patients in the tenodesis cohort experienced biceps deformity, but only due to failure of the tenodesis.[29] In one case series (level IV) 40 patients were treated with tenotomy had decreased elbow flexion and supination strength compared with age, sex, and dominance-matched controls, but 86 percent were satisfied.[30]

Another comparison (level III) noted that 16 of 80 patients (20%) had near normal strength after tenotomy compared to 51 of 80 (64%) patients who underwent tenodesis.[24]

Boileau et al. (level III) found no changes in preoperative and postoperative Constant score between tenotomy and tenodesis.[25]

Resolution of clinical scenario

- Patients that want a less prominent biceps and are willing to take additional risks and invest more money might consider tenodesis, but tenotomy is effective (overall quality: low).
- It's important to note that the role of any operative treatment specifically for the biceps is debatable.

Question 3: In patients undergoing biceps tenodesis, are there any differences in the clinical outcome and complication rates among various techniques used for biceps tenodesis? Between arthroscopic biceps tenodesis versus open biceps tenodesis?

Rationale

The optimal tenodesis approach is debated.

Clinical comment

The surgical approach is based on the physician's preferences and skills. There are advocates for subpectoral tenodesis.

Available literature and quality of the evidence

Level III: 7 retrospective cohorts.[31_37]

Level IV: 7 case series.[3138_40]

Findings

Case series of patients treated with arthroscopic tenodesis report an average of 88% categorically good results.[3138_40]

A (level III) retrospective cohort study comparing open (25 patients) and arthroscopic (20 patients) tenodesis found slightly better active forward elevation in those treated via open tenodesis when compared to arthroscopic tenodesis (171.3 ± 11.7° vs 177.8 ± 9.3°; p = 0.049). Otherwise, there were no other differences in motion or strength one year after treatment. The percentage of patients with persistent bicipital groove tenderness was 15.6%, with no significant difference in frequency between the open and arthroscopic tenodesis groups.[33] Other cohort studies drew similar conclusions.[34_36]

Several retrospective cohort studies (level III) compared different techniques for open tenodesis. One comparing open subpectoral biceps tenodesis with either interference screw fixation (34 patients) or suture anchor fixation (54 patients) an average of 13 months after surgery found that both techniques offered significant pain relief and functional improvement without significant difference in these outcomes between the two methods. Additionally, there were no failures of fixation or complications with either method of fixation.[32]

Another comparing tenodesis to the rotator cuff with suture with (11 patients) and without (11 patients) resection of the intra-articular tendon found no difference in the UCLA (University of California Los Angeles) scores.[31] A third study noted more repeat surgery without release of the transverse humeral ligament during the initial tenodesis

procedure, with 20.6% of patients (n = 68) requesting subsequent surgery when the biceps sheath was not initially released compared to 6.8% of patients (n = 59) in which the sheath was released.[37]

The case series above amount to technique articles and are not otherwise detailed.

Resolution of clinical scenario

- There are no clear benefits to arthroscopic over open tenodesis, or vice versa (overall quality: low).
- In the absence of evidence in favor of one tenodesis technique over another we recommend the simplest, safest, least costly technique and we recommend that efforts be directed not at technique but rather at whether surgery is better than simulated surgery (overall quality: low).

Summary of answers

- Physical examination and imaging cannot distinguish pain from LHB tendinopathy specifically from rotator cuff tendinopathy in general.
- There are no specific nonoperative treatments. Operative treatment may not be better than simulated operative treatment.
- Surgery for an LHB rupture is largely aesthetic.
- Diagnosis and treatment of LHB should be considered experimental until better and more applicable data are produced.
- If LHB tendon fraying or subluxation is encountered at the time of arthroscopy, either tenotomy or tenodesis (arthroscopic or open) is an acceptable treatment.

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127 Superior Labral Tears and Throwing Shoulder Injuries

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Clinical scenario

- A 25-year-old baseball pitcher has several months of atraumatic shoulder pain in his dominant arm.
- He has decreased throwing velocity and ability locating pitches. He also reports occasional “popping” and “clicking” in his shoulder while throwing.
- On examination, he has a positive O'Brien's, Biceps Load II and modified Dynamic Labral Shear test. Magnetic resonance arthrogram (MRA) demonstrates increased signal in the superior labrum.

Top three questions

1. In overhead throwing athletes, how reliable is the physical exam compared to imaging studies in the diagnosis of symptomatic superior labral tear anterior to posterior (SLAP) tears?
2. In overhead throwing athletes with symptomatic SLAP tears, does primary operative intervention result in

improved return to play (RTP) compared to nonoperative treatment?

3. Are overhead nonthrowing athletes better able to return to competition following surgical treatment of SLAP tears compared to overhead throwing athletes?

Question 1: In overhead throwing athletes, how reliable is the physical exam compared to imaging studies in the diagnosis of symptomatic superior labral tear anterior to posterior (SLAP) tears?

Rationale

The clinical presentation and evaluation of SLAP tears in overhead athletes can be highly variable. Physical examination and imaging studies may be inconsistent and unreliable for predictably diagnosing these injuries.

Clinical comment

Shoulder pain in the overhead throwing athlete may be difficult to isolate. Physical examination is important;[1,2] however, it has questionable utility in reliably diagnosing SLAP tears.[3–5] The role of advanced imaging may be limited by high false-positive rates reported in asymptomatic overhead athletes[6] and concomitant pathology frequently associated with SLAP tears.[7] Accurate diagnosis is paramount prior to directing any surgical or nonsurgical treatment.

Available literature and quality of the evidence

Imaging

- Level I: 1 study[8]
- Level II: 2 studies[9,10]
- Level III: 6 studies[11–16]
- Unassigned level of evidence: 1 study.[17]

Physical exam

- Level I: 1 study[18]
- Level II: 3 studies[19–21]
- Level III: 4 studies.[22–25]
- Unassigned level of evidence: 2 studies.[26,27]

Findings

We sought to evaluate the role of physical examination and advanced imaging in diagnosing SLAP tears in overhead athletes. Surprisingly, we were unable to identify a single study that exclusively evaluated solely symptomatic throwing athletes. Rather, all studies consisted of a heterogeneous population. The diagnosis of symptomatic SLAP tears in overhead athletes remains challenging given the striking inconsistency in evaluating and diagnosing SLAP tears coupled with the lack of literature evaluating exclusively overhead athletes.[1,2,28]

Among the available literature, the evidence evaluating the diagnosis of SLAP tears remains poor. Cook et al. concluded that neither a single exam in isolation nor a combination of exam findings provided any substantial value in diagnosing a SLAP tear.[18] Similar results were reported by Oh et al.[25] and Michener et al.[21] Several systematic reviews and meta-analyses have demonstrated

minimal clinical utility for physical exam findings in accurately diagnosing SLAP tears.[19,22–24,26,27]

For studies evaluating advanced imaging, several authors noted the superiority of MRA over conventional MRI for detecting SLAP tears.[9–12,15] A meta-analysis by Arirachakaran et al. evaluating over 2000 shoulders reported a sensitivity of 0.87 (95% confidence interval [CI]: 0.82–0.91), specificity of 0.92 (95% CI: 0.85–0.95) and a positive likelihood ratio of 10.28 (95% CI: 5.84–18.08) with MRA.[11] Other authors, such as Modi et al., have demonstrated improved diagnostic accuracy with abduction external rotation positioning of the arm during MRA.[14]

Resolution of clinical scenario

- Physical examination alone adds limited diagnostic value for detecting clinically relevant SLAP tears.
- Advanced imaging with MRA appears to be more reliable compared to noncontrast MRI for diagnosing SLAP tears. Positioning the arm in the abduction external rotation position may increase the diagnostic abilities of MRA.

Question 2: In overhead throwing athletes with symptomatic SLAP tears, does primary operative intervention result in improved return to play (RTP) compared to nonoperative treatment?

Rationale

Reported outcomes following operative treatment of SLAP tears are highly variable and include heterogeneous patient populations and treatment techniques.[29–31]

Clinical comment

SLAP tears can result in significant disability among overhead throwing athletes. Optimal treatment of SLAP tears in this patient population remains controversial.

Available literature and quality of the evidence

Operative

- Level III: 2 studies[32,33]
- Level IV: 5 studies.[34–38]

Nonoperative

- Level IV: 1 study.[35]

Findings

Overall, pooled RTP for an overhead athlete following operative treatment of SLAP tears was 56.5% (156/276, range 32–85%). Additionally, 7–64% of athletes were able to return to their prior performance (RTPP)/level of competition following operative intervention. Several authors evaluated RTP in baseball pitchers compared to position players.[35–37] Fedoriw et al. reported a RTP and RTPP of 48 and 7%, respectively, in professional pitchers compared to 85 and 54% respectively in position players.[35] Gilliam et al. similarly reported lower RTP in pitchers compared to position players (59% vs 83%),[36] whereas Chalmers et al. reported only 17% RTP in pitchers compared to 80% in position players.[37] Interestingly,

Gilliam et al. reported that only 41% of pitchers felt the same or better following surgical repair of their SLAP tear.[36]

Only Fedoriw et al. reported exclusively on throwers treated nonoperatively for SLAP tears.[35] Nonoperative management focused on addressing glenohumeral internal rotation deficit (GIRD) if present, scapular dyskinesis, posterior capsular contracture, and concomitant shoulder pathology. Overall, 40% of pitchers RTP and 22% RTPP with nonoperative management compared to 39% RTP and 26% RTPP in position players. Interestingly, 40% of athletes who previously failed nonoperative management were able to RTP with this specific treatment algorithm, of which 24% RTPP.

Resolution of clinical scenario

- Outcomes following operative treatment of SLAP tears in overhead throwing athletes are highly variable.
- Operative treatment of SLAP tears results in poor RTP/RTPP.
- Pitchers appear to have worse RTP/RTPP compared to position players.
- Nonoperative treatment addressing GIRD, scapular dyskinesis, and other concomitant shoulder pathology can result in similar RTP/RTPP, even among athletes that have previously failed nonoperative treatment.

Question 3: Are overhead nonthrowing athletes better able to return to competition following surgical treatment of SLAP tears compared to overhead throwing athletes?

Rationale

The demands on overhead athletes are often variable and unique to the nature of their sport. Previous reports on SLAP tears in overhead athletes often consist of a heterogeneous population, which limits interpretation for throwers and nonthrowers alike.

Clinical comment

In order to best counsel overhead athletes with SLAP tears, a better understanding of the ability to return to competition in throwers and nonthrowers is needed.

Available literature and quality of the evidence

Throwers

- Level III: 2 studies[32],[33]
- Level IV: 8 studies.[34]–[41]

Nonthrowers

- Level III: 2 studies[42],[43]
- Level IV: 5 studies.[39]–[41],[44],[45]

Findings

Overall, 57.7% (195/338) of overhead throwing athletes were able to RTP following operative treatment of SLAP tears compared to 68.5% (187/273) of overhead nonthrowing athletes. All studies of throwing athletes with the exception of two[33,35] characterized athletes as returning to the same/higher level of competition. One may argue that returning an athlete to the same preinjury level of competition is not sufficient enough, but rather assessing their ability to return to the same level of prior athletic performance may better assess the success of surgery. Smith et al. and Fedoriw et al. used specific criteria and previous seasons statistics to assess the RTPP.[33,35] The pooled RTPP from these studies is only 37.5% (24/64), compared to 62.4% (171/274) when looking at studies assessing return to the same/higher level.[32,34,36–41] Of note, all studies of nonthrowers assessed return to the same/higher level of competition without further qualitative analysis.[39–45]

Resolution of clinical scenario

- Overhead throwing athletes may have lower RTP compared to overhead nonthrowing athletes.
- Studies which quantitatively assess RTPP report significantly lower RTPP compared to those which only characterize athletes as returning to the same/higher level of competition.

Summary of answers

- Neither physical exams nor imaging studies alone are sufficient for diagnosing symptomatic SLAP tears in overhead throwing athletes.

- RTP following operative treatment of SLAP tears in overhead throwing athletes is highly variable, with pooled analysis demonstrating 56.5% RTP. There is limited data evaluating nonoperative treatment of SLAP tears in overhead throwing athletes.
- Overhead throwing athletes appear to have lower RTP compared to overhead nonthrowing athletes.
- More research is necessary to more accurately define outcome assessment in this unique patient population.

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128 Ulnar Collateral Ligament Injuries of the Elbow

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Clinical scenario

- A 23-year-old professional baseball pitcher presents with longstanding medial-sided pain in his right, dominant, elbow for six months.
- A “wrong” pitch two months ago has severely increased the pain, resulting in an inability to pitch.
- At physical examination an extension deficit of 10°, a positive moving valgus test and a positive milking test are found.

Top three questions

1. Is magnetic resonance arthrography (MRA) a more accurate test to diagnose ulnar collateral ligament (UCL) injury in adult athletes than conventional magnetic resonance imaging (MRI)?
2. Do UCL reconstructions performed with a docking technique result in a higher return-to-sport rate compared to the “classical” Jobe technique in athletes with UCL injury?

3. Is there any difference in pitching performance in athletes after UCL reconstruction compared to matched uninjured pitchers?

Question 1: Is magnetic resonance arthrography (MRA) a more accurate test to diagnose ulnar collateral ligament (UCL) injury in adult athletes than conventional magnetic resonance imaging (MRI)?

Rationale

It is important to distinguish complete UCL tears from partial tears and other medial elbow pathology to establish the right treatment. Recent studies suggest that MRI-based grading systems may provide diagnostic and prognostic information on the outcome of (non)operative management.[1]

Clinical comment

Athletes with UCL injury generally present with medial-sided elbow pain and valgus instability or apprehension on stress testing. However, the injury severity may vary from a simple sprain to a total rupture. Operative management is indicated in athletes with complete disruption of the UCL, but less severe types of injury may recover with conservative treatment.[1–3] Therefore, assessment of the severity of UCL injury is important in order to apply for the optimal treatment algorithm.

Recent studies suggest that MR-based classification systems for UCL injury provide information on outcome and, eventually, return-to-sports.[1] Thus, the importance of

MR may evolve from a diagnostic test toward a prognostic test. The addition of intra-articular contrast may provide additional information, but – as an invasive procedure – adds a (small) risk for complications. The question therefore is whether MRA substantially improves the diagnostic accuracy of MRI.

Available literature and quality of the evidence

- Level I: 0 randomized controlled trials (RCTs).
- Level II: 0prospective cohort studies.
- Level III: 5 retrospective cohort/case-control studies.

Findings

There are only a few comparative studies on MRI in UCL injuries in the current literature. Three studies compared MRI of UCL injury in athletes to surgical findings.[4–6] Furthermore, there were two cadaveric studies,[7,8] four studies compared MRI and arthrography,[4,5,7,8] and one study presented the results of MRA only.[6]

The aforementioned studies showed a sensitivity and specificity of MRI for UCL tears of 63–100 and 89–100%, respectively. In a study by Nakanishi et al., MRIs were interpreted as abnormal in all patients (10/10); however, the observers were not able to differentiate between a tear or scarring of the UCL.[4]

Sensitivity and specificity of MRA for UCL tears in the selected studies was 88–100 and 80–100%, respectively. Most authors concluded that conventional MRI is sufficient to detect pathology of the UCL. However, the addition of arthrography provides more information on injury severity, for example partial thickness tears of the UCL. An advantage of MRI in general, as compared to ultrasound or

computed tomography (CT) arthrography, is the ability to identify associated pathology, such as medial epicondylitis or osteochondral lesions.

Resolution of clinical scenario

- The sensitivity of MRA is superior to conventional MRI, but specificity is similar for both image modalities.
- To decrease the rate of false-negative findings with advanced imaging, MRA is recommended for the evaluation of athletes with suspicion for UCL injury. However, the addition of arthrography seems not to be necessary to prevent surgical intervention in athletes with a false-positive MR scan.

Question 2: Do UCL reconstructions performed with a docking technique result in a higher return-to-sport rate compared to the “classical” Jobe technique in athletes with UCL injury?

Rationale

Frank Jobe performed the first ulnar collateral ligament reconstruction (UCLR) in 1974, with his figure-of-eight technique.[9] Many other techniques have been described since then. The importance is to identify which frequently performed technique results in the best outcome for the athlete.

Clinical comment

For (professional) athletes, the most important outcome after UCL injury is return to previous level of play. The two

most frequently reported UCLR techniques are the Jobe technique and the docking technique (including modifications).[9],[10] Therefore, we will further evaluate the rate of return to previous level of sport for these two techniques.

Available literature and quality of the evidence

- Level I: 6 randomized controlled trials.
- Level II:0 prospective cohort studies.
- Level III:0 retrospective cohort/case-control studies.
- Level IV:16 case series.

Findings

Last three decades, numerous surgical techniques for reconstruction of the UCL have been described. The majority of studies are from the US, focusing on the surgical treatment of UCL injuries in baseball pitchers. The most commonly used graft is a palmaris longus or hamstring autograft. Some recent studies have described the use of cortical buttons and interference screws, but the two traditional UCLR techniques – the Jobe and docking technique – used bone tunnels and sutures for graft fixation.[9],[10] The original Jobe technique involved a figure-of-eight reconstruction in which the graft was passed through bone tunnels in the ulna and humerus and sutured to itself. Furthermore, Jobe detached the flexor pronator mass and performed an ulnar nerve transposition. Modifications of this technique include a flexor muscle splitting approach, alternative handling of the ulnar nerve, and the addition of elbow arthroscopy.

The original docking technique involved a triangular reconstruction in which the graft was passed through a bone tunnel in the ulna and humerus and then sutured over

a bony bridge on the posterior side of the humerus. The authors used a muscle splitting approach, routinely performed an elbow arthroscopy and transposed the ulnar nerve only when there were clinical symptoms. Modifications on the docking technique included the addition of elbow arthroscopy on indication (posteromedial impingement) and the use of triple-stranded grafts.

Three systematic reviews concluded that the outcomes of the docking technique were superior compared to the Jobe technique.[11–13] One original research article described the results of both the docking and (modified) Jobe technique,[14] seven articles described the outcome of the docking technique,[10,15–20] and eight articles focused on the outcomes of the (modified) Jobe technique.[9,21–27] Combined, a total of 278 patients underwent UCLR using a docking technique. After a mean of 35 months, 90% of patients returned to their previous level of sport, and 6% of patients endured a complication. The (modified) Jobe technique is described in a total of 1082 patients. On average, 82% of patients returned to their previous level of play after 42 months, and 18% of patients endured a complication.

The (modified) docking technique appears to result in superior outcomes compared to the (modified) Jobe technique. However, the results of the (modified) Jobe technique are based on more patients, with a slightly longer follow-up. Moreover, five out of eight articles on the (modified) docking technique were from the institution of the original developer of the technique (Dr. David Altchek). In conclusion, many articles have been published on UCLR, but there is a need for an RCT to adequately compare the different techniques and acquire a high level of evidence to answer this question.

Resolution of clinical scenario

- The return to previous level of play after UCLR according to the (modified) docking technique is 90% and therefore superior to the (modified) Jobe technique with 82%.
- More complications are seen after the (modified) Jobe technique (18%) compared to the (modified) docking technique (6%).
- A possible source of bias in current literature is the high number of studies performed by or at the institutions of the original inventors of the surgical techniques.

Question 3: Is there any difference in pitching performance in athletes after UCL reconstruction compared to matched uninjured pitchers?

Rationale

UCLR allows most overhead athletes to return to sports. However, the number of athletes who truly return to their preinjury level of performance is unclear.

Clinical comment

Over the past decade, the number of UCLRs has significantly increased, especially in adolescent overhead athletes.[28] The public perception of UCLR is positive, with up to 42% of athletes, 20% of coaches, and 35% of parents believing that UCLR leads to enhanced pitching performance beyond that of the preinjury level.[29] Traditionally, surgical outcomes in sports medicine are

measured in conventional terms, such as return to play or (semiquantitative) patient-reported assessments.

Most studies reported return to play rates >80% following UCLR.[30] However, there is no standard to determine whether an athlete has truly successfully returned to play. The abundance of performance metrics in baseball allows us to assess outcomes after UCLR independent of subjective symptoms or return-to-play rates. These metrics may better demonstrate the true number of athletes who returned to their previous level of play, especially when compared to preinjury levels or matched uninjured control athletes.

Available literature and quality of the evidence

- Level I: 0 randomized controlled trials.
- Level II: 0 prospective cohort studies.
- Level III: 8 retrospective cohort/case-control studies.
- Level IV: 2 case series.

Findings

In total, 10 studies evaluated pitching performance after UCLR.[31–40] One study in 178 Major League Baseball (MLB) pitchers reported improved performance postoperatively.[31] Both *earned run average* (ERA) and *walks plus hits per inning pitched* (WHIP) were lower than before UCLR and lower compared with matched controls. Five other studies found no significant differences in common performance metrics between pitchers after UCLR and controls.[32–36] As expected, the average number of innings pitched in the first season after reconstruction was significantly lower in the surgical group compared to the healthy controls, reflecting the long duration of rehabilitation after UCLR.[33]

However, the mean number of innings pitched was similar between the two groups in the second and third season after UCLR. In addition, other key performance measures, including ERA, WHIP, pitch selection, velocity, and accuracy, also returned to preinjury levels and were comparable to matched uninjured pitchers.[33–36] Fleisig et al. compared the biomechanics of 40 professional pitchers after UCLR with 40 matched uninjured pitchers.[32] They observed no significant differences in shoulder and elbow range of motion and no significant differences in pitching kinetics.

Four studies found a decline in pitching performance after UCLR,[37–40] although these declines were not statistically different from the decline in pitching performance observed in uninjured controls in two of the four studies.[37,40] In other words, postoperative performance was similar to that of pair-matched peers who did not undergo UCLR. More specific, one study found a small, but statistically significant, decrease in fastball velocity following UCLR (mean: −0.7 mph), but did not compare this to a healthy control group.[39] The clinical relevance of this observed decrease in fastball velocity is unclear. Pitch velocity for other pitch types did not change significantly after surgery. Keller et al. evaluated performance data of 168 MLB pitcher who had undergone UCLR (averaged over three years before and after surgery) and that of 178 age-matched uninjured MLB pitchers.[38] Compared to presurgical data, pitching performance after UCLR significantly declined in terms of innings pitched, WHIP, and ERA. The control pitchers had a significant higher winner percentage than the UCLR pitchers in the first and third after surgery. All other performance metrics after surgery were similar between the cohorts. Most performance metrics were significantly higher before surgery in the UCLR pitchers than in the controls. This

suggest that most pitchers who underwent UCLR make it back to acceptable levels (i.e. comparable to uninjured controls) but do not fully return to their preinjury level of performance. More recent, novel pitching performance measures, such as f*ielding independent pitching*, that are largely independent from teammate performance may further increase our ability to assess the true functioning of pitchers after UCLR.

Resolution of clinical scenario

- Contrary to popular belief, pitching performance does *not* increase after UCLR.
- Most (professional) pitchers return to performance levels similar to that of matched uninjured controls after UCLR.

Summary of answers

- The sensitivity of MRA is superior to conventional MRI, but specificity is similar for both image modalities.
- To decrease the rate of false-negative findings with advanced imaging, MRA is recommended for the evaluation of athletes with suspicion for UCL injury. However, the addition of arthrography seems not to be necessary to prevent surgical intervention in athletes with a false-positive MR scan.
- The return to previous level of play after UCLR according to the (modified) docking technique is 90% and therefore superior to the (modified) Jobe technique with 82%.
- More complications are seen after the (modified) Jobe technique (18%) compared to the (modified) docking technique (6%).

- A possible source of bias in current literature is the high number of studies performed by or at the institutions of the original inventors of the surgical techniques.
- Contrary to popular belief, pitching performance does *not* increase after UCLR
- Most (professional) pitchers return to performance levels similar to that of matched uninjured controls after UCLR.

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129 Lateral Epicondylitis (Tennis Elbow)

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Clinical scenario

- A 45-year-old right-hand-dominant woman who is a recreational tennis player can no longer play.
- She comes to your practice with complaints of pain at the lateral side of her right elbow. The pain has been present for three months, and is worse while hitting a backhand.
- At physical examination she has pain with pressure on the origin of the common extensor tendon of the wrist at the lateral epicondyle of the humerus. There is mild wrist extension weakness with the elbow in full extension.

Top three questions

1. In adult patients with lateral epicondylitis, does advanced imaging result in improved diagnosis compared with clinical exam with or without radiography?
2. In adult patients with lateral epicondylitis, does conservative management result in improved pain and function compared to therapy with injections?
3. In adult patients with lateral epicondylitis, does surgery result in improved pain and function compared to nonoperative treatments?

Question 1: In adult patients with lateral epicondylitis, does advanced imaging result in improved diagnosis compared with clinical exam with or without radiography?

Rationale

It is important to know if diagnostic imaging is necessary or worthwhile for patients with a clinical presentation consistent with lateral epicondylitis. If imaging is warranted, we need to know if ultrasound findings are comparable to MRI results. Furthermore, with the ease of use and cost-effectiveness of musculoskeletal ultrasound, we may be able to better diagnose the stage of epicondylitis initially which can influence clinical decision-making.

Clinical comment

Generally, radiography is often unnecessary for the initial diagnosis and treatment of lateral epicondylitis. However, it is reasonable to obtain a standard three-view plain radiograph if symptoms persist after initial management. This should include an axial view if there is posterior pain to evaluate for posterior osteophytes and calcifications within the tendon.[1]Advanced diagnostic imaging has typically been reserved for cases resistant to conservative treatment. Magnetic resonance imaging (MRI) and ultrasonography (US) have been used to evaluate the extent of disease, detect associated pathological processes, exclude other primary sources of elbow pain, and quantify the degree of tendon injury in lateral epicondylitis.[2–7]

Available literature and quality of the evidence

- Overall, there is little high-quality evidence regarding the role of imaging studies in management plans and detection of lateral epicondylitis. Advanced imaging for this problem is primarily limited to MRI and US. Apart from the reviews discussed below, there are a number of studies addressing MRI and ultrasound imaging for lateral epicondylitis with data quality ranging from level II to level VI.
- There are a multitude of systematic reviews regarding MRI of the elbow. However, none of these reviews is focused solely on MRI in the evaluation of lateral epicondylitis. MRI can be regarded as the gold standard of advanced imaging; however, due to cost and availability, MRI cannot be considered a screening tool for all patients with clinically suspected lateral epicondylitis.
- There are two systematic reviews addressing US and lateral epicondylitis. Both indicate that there is evidence to support the use of ultrasound in the detection of lateral epicondylitis.[8],[9] Latham and colleagues warn that its accuracy is highly dependent on numerous variables such as operator experience, quality of equipment, and extent of pathology. However, Dones et al. determined that US is recommended to objectively diagnose lateral epicondylitis.[9] Furthermore, ultrasound allows localization of pathology, which can assist in the design of treatment plans.

Findings

Magnetic resonance imaging

Qi et al. evaluated the MRI findings and clinical symptoms in 96 patients with lateral epicondylitis. They determined

that MRI is a valid tool in assessing the clinical severity of lateral epicondylitis with a significant positive correlation (Pearson's r = 0.920, p <0.01) between MRI results and clinical symptoms.[10]

Similarly, Jeon and colleagues compared MRI findings in 60 patients with lateral epicondylitis treated conservatively or with surgery. MRI-assessed common extensor tendon abnormalities, muscle edema, pain frequency, and pain intensity differed significantly between the two groups (p <0.05) with increased severity in operative group. Persistent pain (odds ratio [OR] = 12.2, p <0.01), common extensor tendon abnormality (OR = 7.5, p = 0.03 for grade 2; OR = 22.4, p <0.01 for grade 3), and muscle edema (OR = 6.7, p = 0.03) were major factors associated with operative treatment.[11] Therefore, MRI findings combined with clinical assessment could better facilitate appropriate operative management planning for patients with lateral epicondylitis as opposed to clinical exam alone.[11]

Conversely, although Walton et al. confirmed the findings of previous studies that the majority of patients with a clinical diagnosis of chronic lateral epicondylitis have signal changes on MRI, they found no statistically significant correlation between the grade of tendinosis and any clinical symptoms (QuickDASH, p 0.496; UEFS, p = 0.970; maximum pain, p = 0.491; grip strength, p = 0.465).[4,6,12–14] Therefore, they conclude that this is further evidence that the role of MRI is not to confirm a diagnosis of lateral epicondylitis, which can be accomplished by the gold standard of clinical examination.[14]

Ultrasound

Levin et al. reported that sensitivities of US in the detection of symptomatic lateral epicondylitis ranged from 72 to 88% and specificities from 36 to 48.5%. Odds ratios between

symptoms and US findings were statistically significant ($p < 0.05$) for calcification of common extensor tendon, tendon thickening, adjacent bone irregularity, focal hypoechoic regions, diffuse heterogeneity, and lateral epicondyle enthesophytes. These findings indicate that US has a high sensitivity but low specificity in the detection of symptomatic lateral epicondylitis and that the relationship between ultrasound findings and symptoms is significant.[15]

Similarly, Clarke and colleagues used ultrasound to evaluate 62 patients with a clinical diagnosis of lateral epicondylitis. A positive correlation was identified between the presence of a lateral collateral ligament tear ($p < 0001$) and the size of the largest intra-substance tear ($p < 0001$) and poor outcome. Patients with these findings were less likely to respond to conservative treatment. Therefore, the identification and size of intra-substance tears and presence of a lateral collateral ligament tear on ultrasound can be used to assess lateral elbow tendinopathy severity, indicate those who may not respond to conservative therapy, and potentially guide more invasive treatment.[16]

Regarding the use of power Doppler, du Toit et al. conducted a cross-sectional study to determine the diagnostic accuracy of ultrasound with power Doppler for tennis elbow. Thirty-two affected elbows and 56 unaffected elbows were evaluated. Power Doppler had a strong positive likelihood ratio of 45.39, whereas a combined negative finding in power Doppler and grayscale US resulted in a robust negative likelihood ratio of 0.05. These findings indicate significant diagnostic accuracy of power Doppler US for ruling in lateral epicondylitis, whereas the absence of tendon neovascularity and grayscale ultrasound changes should raise the question of an alternative cause for lateral elbow pain.[17]

In their review, Latham and colleagues[8] reported that the majority of the papers reviewed concluded that the use of ultrasound was beneficial to assist with the detection of lateral epicondylitis.[17–22] Amongst these, sensitivity ranged from 76.5 to 100% and specificity from 76.2 to 100%. However, the use of ultrasound in the detection of lateral epicondylitis is recommended with caution since its accuracy appears to be highly dependent on numerous variables, such as operator experience, quality of equipment, and extent of disease.[8]

In their review of 15 previous studies, Dones et al. concluded that the use of grayscale US is recommended in objectively diagnosing lateral epicondylitis. The presence of hypoechogenicity and bone changes indicates the presence of a stressed common extensor origin-lateral epicondyle complex. In addition to diagnosis, detection of these abnormal ultrasound findings allows localization of pathologies to the tendon or bone that would assist in designing an appropriate treatment suited to a patient's condition.[9]

Magnetic resonance imaging versus ultrasound

Bachta and colleagues found good sensitivity (64.52%), accuracy (72.73%), and very good specificity (85.19%) with US (vs MRI) in detecting common extensor tendon pathology. All patients with high-grade common extensor tendon tear on US had confirmed tear on MRI. No patient without common extensor tendon tear on US had high-grade common extensor tendon tear on MRI. Thus, high-grade tear on US can be considered a reliable equivalent of confirmed tear on MRI. On the other hand, lack of evident tear on US virtually excludes the presence of high-grade common extensor tendon tear.[23] These results are in agreement with several other previous studies showing US

as a reliable method to evaluate tendinoligamentous structures of the lateral elbow region and the results of an US assessment are comparable to those of MRI.[24–26] Determination of high-grade common extensor tendon pathology with imaging is important in predicting disease outcome and may be helpful in determining optimal treatment strategy, as Clarke et al. suggested a lower threshold for surgery in patients with high-grade tears.[16]

Resolution of clinical scenario

- Advanced imaging is often unnecessary for the initial diagnosis and treatment of lateral epicondylitis. Prior to advanced imaging, we may obtain a standard three-view elbow x-ray series, which should include an axial view to evaluate for posterior osteophytes and calcifications within the tendons. MRI and US have been used to evaluate the extent of disease, exclude other primary sources of elbow pain, and quantify the degree of tendon injury (overall quality: moderate).
- US is reliable in confirming the diagnosis of lateral epicondylitis. Lack of pathology on US in chronic cases can reliably exclude the presence of lateral epicondylitis. In experienced hands, ultrasound can identify abnormal tendon appearance and neovascularity when color flow Doppler is used. Current evidence emphasizes the advantages of the noninvasive, cheap, quick, and accessible nature of diagnostic ultrasound compared to MRI or arthroscopy. Nonetheless, ultrasound requires extensive skill and experience to operate effectively (overall quality: low).
- MRI is beneficial in recalcitrant cases to localize lesions, to confirm the diagnosis of lateral epicondylitis, or to particularly aid in surgical planning (overall quality: low).

- Identified pathology with ultrasound can be considered equivalent to pathology identified on MRI given an experienced ultrasound practitioner (overall quality: low).
- Data are mixed as to whether MRI or US findings correlate with clinical symptoms (overall quality: low).

Question 2: In adult patients with lateral epicondylitis, does conservative management result in improved pain and function compared to therapy with injections?

Rationale

Once diagnosed, it is important to know the best treatment strategy for the condition and what the effectiveness of a certain treatment will be compared to other treatments. Treatment strategy will vary for each patient, depending on prior therapies, degree of disability, and activity goals.

Clinical comment

Generally, initial treatment of lateral epicondylitis is conservative including activity modification, nonsteroidal anti-inflammatory drugs (NSAIDs), bracing, and physical therapy with eccentric exercises. However, many patients present seeking rapid improvement in symptoms, and clinicians are frequently asked about the use of injections, including glucocorticoid injections and treatments under study such as ultrasound-guided percutaneous tenotomy and platelet-rich plasma (PRP) injections.

Available literature and quality of the evidence

- When approaching lateral epicondylitis, there are a number of different treatment options. Several systematic reviews and meta-analyses (level II, therapeutic) have analyzed these different nonsurgical treatment options without any high-quality evidence to support a specific treatment strategy.[27,28]
- When assessing the efficacy of glucocorticoid injections, three systematic reviews (level II, therapeutic) reviewing glucocorticoid injections all came to the same conclusion, glucocorticoid injections are effective in the short term but may have diminishing or negative effects in the intermediate and long term.[29] Two of these reviews compared glucocorticoid injections to physical therapy and found that physical therapy was more effective at intermediate- and long-term follow-up.[30,31]
- There has been growing interest in the use of PRP for tendinopathy, although the lack of high-quality evidence has deemed its use controversial. There are systematic reviews that demonstrate efficacy with the use of PRP in lateral epicondylitis (level II, therapeutic),[32] while others have not demonstrated significant benefit (level II, therapeutic).[33] One of the largest randomized controlled trials (RCTs) (level II, therapeutic) of patients with lateral epicondylitis treated with PRP demonstrated significant differences in pain in the PRP group at 24 weeks.[34]
- Lastly, needle tenotomy has been suggested as a technique for recalcitrant lateral epicondylitis to augment or supersede PRP injections. There are no high-level studies, but observational uncontrolled data (level IV, therapeutic) demonstrate encouraging results.[35,36]

Findings

Nonsurgical treatment versus no treatment

A systematic review of 58 RCTs of patients with lateral epicondylitis treated with nonsurgical techniques demonstrated that best evidence synthesis found no conclusive evidence of one preferred treatment method.[28] Another meta-analysis of 22 RCTs containing 2280 patients reviewing any form of nonsurgical treatment with either observation only or placebo at follow-up for at least six months demonstrated no significant difference between nonsurgical treatment versus no treatment in regards to overall improvement (risk ratio [RR] = 1.05; 95% confidence interval [CI]: 0.96–1.15), need for escape treatment (RR = 1.50; 95% CI: 0.84–2.70), DASH (Disabilities of the Arm, Shoulder, and Hand) scores (mean difference [MD]: −2.69; 95% CI: −15.8 to 10.4), overall function using change-from-baseline data (standardized mean difference [SMD]: 0.11; 95% CI: −0.14 to 0.36), maximum grip strength using change-from-baseline data (SMD: 0.12; 95% CI: −0.11 to 0.35), and pain-free grip strength using change-from-baseline data (SMD: −0.20; 95% CI: −0.84 to 0.43).[27] While the aggregation of multiple nonsurgical treatments allowed the possibility of less effective treatments countering those that are more effective and the author cautioned that certain nonsurgical treatments may be more effective than others, this meta-analysis concluded that watchful waiting may be a practical alternative to nonsurgical treatments.

When evaluating individual treatment strategies, a meta-analysis of 12 RCTs in patients with lateral epicondylitis treated with physical therapy demonstrated that, compared with sham control groups, physical therapy resulted in a significant decrease in pain (SMD: −7.50; 95% CI: −14.94 to −0.07) and significant increase in handgrip strength

(SMD: 3.47; 95% CI: 0.17–6.76).[37] Another systematic review of 12 RCTs and one systematic review evaluated patients with lateral epicondylitis treated with physical therapy.[38] Best-evidence synthesis demonstrated evidence for short-term effectiveness of strengthening. Lastly, a systematic review of 12 studies (eight RCTs and four controlled clinical trials) of 616 participants with lateral epicondylitis treated with eccentric exercise performed best-evidence synthesis and determined that an eccentric exercise program resulted in decreased pain and improved function and grip strength in comparison to baseline measures.[39]

Glucocorticoid injection versus physiotherapy

A systematic review of 13 RCTs of patients with lateral epicondylitis treated with glucocorticoid injection has been reported.[29] All studies reported statistically significant short-term ($\leq$6 weeks) results in favor of glucocorticoid injections. None of the studies that performed intermediate (six weeks to six months) or long-term ($\geq$6 months) outcome assessments found statistically significant results in favor of corticosteroid injections.

A systematic review of 11 RCTs including 1161 patients with lateral epicondylitis comparing glucocorticoid injection versus nonelectrotherapeutic physiotherapy (stretching, mobilization, manipulation, massage, exercise, or home training) has been reported.[30] In short-term follow-up, glucocorticoid injection significantly reduced pain compared to NSAIDs or no intervention (SMD: −1.43; 95% CI: −1.64 to −1.23). At intermediate follow-up; however, glucocorticoid injections demonstrated increased pain (SMD: 0.32; 95% CI: 0.13–0.51), reduction in grip strength (SMD: −0.48; 95% CI: −0.73 to −0.24) and a negative effect on the overall improvement effect (RR =

0.66; 95% CI: 0.53–0.81). Manipulation and exercise versus no intervention demonstrated beneficial overall improvement at short-term follow-up (RR = 2.75; 95% CI: 1.30–5.82) but no significant improvement at intermediate- or long-term follow-up. Eccentric exercise and stretching demonstrated moderate evidence at short- and long-term follow-up.

A systematic review of five RCTs of patients with lateral epicondylitis treated with corticosteroid injection versus physiotherapeutic interventions demonstrated large effect sizes in favor of corticosteroids at short-term follow-up, but medium- to large-effect sizes in favor of physiotherapeutic interventions at intermediate- and long-term follow-up.[31]

Advanced treatment options: platelet-rich plasma and percutaneous needle tenotomy

When assessing all injections, one systematic review of 27 RCTs of patients with lateral epicondylitis treated with injection therapies found that most injection treatments showed a trend toward better effects than placebo.[40] The review could not recommend one injection over the other, though the article mentioned that the benefits of glucocorticoid injection were only short-term, thus the author would recommend other injections over glucocorticoid injections. Another systematic review of 17 RCTs of 1381 patients with lateral epicondylitis treated with injection therapies demonstrated that botulinum toxin, autologous blood, PRP, prolotherapy, and hyaluronic acid were all statistically superior to placebo.[41]

PRP continues to generate controversy. A systematic review of four RCTs of patients with lateral epicondylitis treated with PRP demonstrated improvements in pain and disability at 6 and 12 months in two of the four studies.[32] Another systematic review of six RCTs of patients with

lateral epicondylitis treated with PRP used best-evidence synthesis to determine that there is strong evidence that PRP injections are not efficacious in chronic lateral epicondylar tendinopathy.[33] However, these systematic reviews are limited by heterogeneity, and studies with small sample sizes and high risk of bias. One point of contention has been short duration of follow-up in many studies, as the effects of PRP may take up to six months to take effect. One of the largest RCTs,[34] a double-blind, prospective, multicenter RCT of 230 patients with lateral epicondylitis who had failed either a local steroid injection, physical therapy, or NSAIDs of PRP versus bupivacaine (control) demonstrated no significant differences between the PRP and control group at 12 weeks but significant differences in pain (29.1% in PRP group vs 54.0% in the control group, p = 0.009) and success rates (83.9% in PRP group vs 68.3% in the control group, p = 0.37) at 24 weeks.

Needle tenotomy has been suggested as a technique for recalcitrant lateral epicondylitis to augment or supersede PRP injections. There are no high-level studies, but an observational case series of 55 patients with recalcitrant lateral epicondylitis treated by percutaneous tenotomy reported that 80% of patients reported good to excellent outcomes at average follow-up of 28 months.[35] Another observational case series of 20 patients with lateral epicondylitis treated with percutaneous needle tenotomy demonstrated 100% patient satisfaction with sustained pain relief and functional improvement at three-year follow-up.[36]

Resolution of clinical scenario

- Initial treatment of lateral epicondylitis is conservative consisting of a combination of activity modification, NSAIDs, bracing, and physical therapy with eccentric exercises (overall quality: low).

- Patients who do not improve after initial conservative treatments can continue conservative treatment or be treated with more invasive nonsurgical treatments, including glucocorticoid injection, ultrasound-guided percutaneous tenotomy, and PRP injection (overall quality: low).
- Glucocorticoid injections may be effective at improving pain in the short term (<6 weeks) but have diminishing and possibly negative effects in the intermediate and long term (overall quality: low).
- Although treatment with ultrasound-guided percutaneous tenotomy and PRP injections is conflicting, multiple studies have demonstrated success with these interventions in patients with recalcitrant lateral epicondylitis (overall quality: very low).

Question 3: In adult patients with lateral epicondylitis, does surgery result in improved pain and function compared to nonoperative treatments?

Rationale

Patients with lateral epicondylitis can be frustrated by slow improvement or failure to respond to conservative treatments. It is important to know when, if ever, a surgical referral should be placed, and the effectiveness of surgical therapy compared to nonoperative treatments.

Clinical comment

The majority (90%) of patients with lateral epicondylitis can be managed with nonoperative treatments. However,

surgical referral may be considered for patients who do not respond to at least six months of nonoperative treatment with continued severe pain or dysfunction.

Available literature and quality of the evidence

- There are not many studies that address surgical management of lateral epicondylitis. A Cochrane systematic review (level II, therapeutic) deemed that there was insufficient evidence to support or refute the efficacy of surgery for lateral epicondylitis.[42] A recent systematic review (level II, therapeutic) concluded that surgery for lateral epicondylitis was no more effective than nonsurgical treatment.[43] Comparing newer treatment modalities to surgery, a retrospective review (level IV) of patients with lateral epicondylitis treated with either PRP or surgery demonstrated similar outcomes in pain and return to work.[44] An RCT (level II) of patients with chronic lateral epicondylitis who received arthroscopic release or PRP injection demonstrated effective short- and medium-term results in pain and function; however, patients in the arthroscopy group had better long-term outcomes in pain and grip strength.[45]
- Regarding the different types of surgical procedures, two systematic reviews compared open, arthroscopic and percutaneous surgical techniques for treating lateral epicondylitis.[46],[47] One of these systematic reviews (level IV) reported improved functional outcomes with open and arthroscopic surgery, but less pain with arthroscopic and percutaneous techniques.[46] The other (level II) reported no clinically significant differences between the three techniques.[47]

Findings

Surgical treatment versus nonoperative treatments

- A Cochrane systematic review analyzing five trials of 191 patients with lateral epicondylitis who failed conservative treatment and had persistent symptoms of at least five months' duration found insufficient evidence to support or refute the efficacy of surgery given the small number of studies and large heterogeneity across the trials.[42] A more recent systematic review of 12 RCTs of 490 patients with lateral epicondylitis treated with surgery performed a best-evidence analysis and determined that surgery for lateral epicondylitis was no more effective than nonsurgical treatment or sham interventions.[43]
- A retrospective review of 78 patients with lateral epicondylitis treated with either PRP (n = 28) or surgery (n = 50) demonstrated similar outcomes in pain and return to work.[44] One hundred percent of the PRP group and 98% of the surgical group tried conservative therapy prior to intervention. No statistical difference in measured outcomes was found in regards to pain improvement (89.3% vs 84%), numbness, paresthesias, and weakness with gripping ($p > 0.05$). No significant difference was found on tenderness to palpation or pain with wrist extension following intervention between the two groups ($p > 0.05$), or return to full activity (82% vs 82%, $p > 0.05$). An RCT of patients with chronic lateral epicondylitis who received arthroscopic release (n = 50) or ultrasound-guided PRP injection (n = 51) demonstrated similar improvements in pain and function scores between groups at short- and medium-term follow-up, but at week 104 the arthroscopy group had significant decrease in pain scores (2.1 vs 7.1, $p = 0.0021$),

improvements in grip strength (p <0.001), and functional evaluation (p = 0.0013) compared to PRP.[45]

- Three different types of surgical procedures have been described: open, arthroscopic, and percutaneous. One systematic review of 30 level III and IV studies of patients with lateral epicondylitis who underwent surgery evaluated patients who underwent open (n = 848), arthroscopic (n = 578), and percutaneous (n = 178) releases.[46] Functional outcomes measured with the mean DASH scores were better with open (19.9 vs 29, p <0.001) and arthroscopic techniques (21.3 vs 29, p<0.001) compared to percutaneous release. Less pain was reported in the arthroscopic (1.9 vs 1.3, p <0.0001) and percutaneous (1.4 vs 1.3, p <0.0001) groups compared to open. Another systematic review of six RCTs of patients with lateral epicondylitis compared patients who underwent open (n = 83), arthroscopic (n = 14), and percutaneous (n = 82) surgeries.[47] There were no significant differences between the three techniques in regards to functional outcome, pain intensity, and patient satisfaction at one-year follow-up.

Resolution of clinical scenario

- There is not enough high-level evidence to recommend for or against surgery for recalcitrant lateral epicondylitis; however, surgical referral may be considered for patients who do not respond to at least six months of nonoperative treatment with continued severe pain or dysfunction (overall quality: very low).
- When considering surgery, it is reasonable to consider PRP injection, as low-quality evidence demonstrates similar outcomes compared to surgery (overall quality: very low).

- If the decision is made to pursue surgery, there is not enough high-level evidence favoring one type of surgical technique, though low-quality evidence suggests possible improved functional outcomes with open and arthroscopic techniques (overall quality: very low).

Summary of answers

- Advanced imaging is often unnecessary for the initial diagnosis and treatment of lateral epicondylitis.
- Initial treatment of lateral epicondylitis is conservative consisting of a combination of activity modification, NSAIDs, bracing, and physical therapy with eccentric exercises.
- There is not enough high-level evidence to recommend for or against surgery for recalcitrant lateral epicondylitis.
- If the decision is made to pursue surgery, there is not enough high-level evidence favoring one type of surgical technique.

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130 Osteochondritis Dissecans Lesions of the Elbow

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Clinical scenario

- A 14-year-old with posterior lateral elbow pain for over one year.
- The pain is sharp during loading of the elbow with throwing, and with axial loading with the elbow in extension.
- Plain radiographs show radiolucency in the capitellum and magnetic resonance imaging (MRI) shows a 1 × 1.2 cm capitellar osteochondral defect.

Top three questions

1. In patients with osteochondritis dissecans (OCD) of the capitellum, are outcomes with nonoperative treatment better in patients with an open capitellar physis compared to patients with a closed capitellar physis?
2. In patients with a clinically and radiographically unstable capitellar OCD, are clinical outcomes better after surgical debridement in patients with small defects compared to patients with large defects?

3. In patients with a clinically and radiographically unstable capitellar OCD, does osteochondral autograft transfer result in superior outcomes compared to debridement for pain and return to sport?

Question 1: In patients with osteochondritis dissecans (OCD) of the capitellum, are outcomes with nonoperative treatment better in patients with an open capitellar physis compared to patients with a closed capitellar physis?

Rationale

Nonoperative management is considered the first step in the treatment of patients with a clinically and radiographically stable OCD lesion of the humeral capitellum; however, studies suggest differences in outcomes and healing related to skeletal maturity of the capitellum.

Clinical comment

Although nonoperative management is commonly the first step in the treatment of many osteochondral injuries, not all patients are appropriate candidates for nonoperative treatment. It is important to understand and identify which patients can be considered good candidates for nonsurgical management and which patients have a higher likelihood of needing surgical treatment.

Available literature and quality of the evidence

- The literature reviewed and summarized to address the clinical question above includes level III retrospective cohort studies and level IV case series studies.

Findings

Early studies on nonoperative management of elbow OCD lesions reported generally poor outcomes.[1–3] Takahara et al. reported 50% of patients had residual symptoms in their elbow with daily activity and displayed radiographic evidence of degenerative changes, and no patients returned to previous sport.[2] In subsequent studies, outcomes with nonoperative treatment have been stratified by radiographic and clinical findings at presentation.[4,5] Takahara et al. and Mihara et al. characterized a lesion as "stable" if patients had an open capitellar physis, flattening or radiolucency of the subchondral bone, and normal elbow range of motion.[4,5] A radiographically "early" defect was considered grade I (localized flattening or radiolucency without sclerosis) or grade II (nondisplaced fragment with sclerosis). A radiographically "advanced" defect showed grade III (displaced or detached fragment) changes.[4,5] Early stable lesions in skeletally immature patients often heal with nonoperative management;[4,5] therefore, a trial of nonoperative management was indicated in these patients. Nonoperative treatment typically included activity restriction, a brief period of immobilization, oral nonsteroidal anti-inflammatory drugs (NSAIDs), and physical therapy exercises.[4–6] Currently, no universal guidelines exist on duration of nonoperative treatment, but rather it is guided by symptoms. Generally, it involves six weeks of strict rest from activities that cause pain, with a gradual return to activity and sport over a three- to six-month period.[6,7]

While patients with early stable lesions often healed with rest alone, more advanced defects and defects in patients with a closed capitellar physis are at higher risk of failure with nonsurgical treatment.[4,5] In general, patients with a closed physis typically have more advanced OCD lesions at presentation.[5] Mihara et al. reported significantly higher healing rates after nonoperative management in patients with early-stage OCD lesions and an open physis when compared to patients with a more advanced OCD and a closed physis. They were unable to demonstrate a statistical difference in healing rates between early-stage OCD lesions between patients with open versus closed physes, but the number of patients was small.[5] In other reports, the healing rate with nonoperative management in patients with closed growth plates and unstable, advanced lesions has been low.[3,5,6,8,9] Therefore, patients with an open capitellar physis and stable OCD lesions have greater healing potential with nonoperative management than patients with advanced OCD lesions with a closed physis.

Resolution of clinical scenario

- Outcomes of nonoperative management in patients with capitellar OCD lesions depend on the combination of the skeletal maturity of the capitellar physis, the radiographic grading of the defect, and the clinical stability of the defect.
- Better outcomes after nonoperative management are seen in patients with early lesions with open capitellar growth plates, localized flattening or radiolucency of the subchondral bone, and good elbow range of motion.
- Poor outcomes after nonoperative management are seen in patients with unstable, radiographically advanced lesions, and a closed capitellar physis.

Question 2: In patients with a clinically and radiographically unstable capitellar OCD, are clinical outcomes better after surgical debridement in patients with small defects compared to patients with large defects?

Rationale

There have been several surgical treatments (i.e. fixation, debridement) described for unstable OCD lesions in the elbow. Debridement of the defect has shown good short-term results, but larger defects may not do as well with debridement.

Clinical comment

Studies suggest that lesion stability, size, and location are important factors to consider when selecting the most appropriate form of treatment. Debridement procedures are a commonly considered treatment in patients with small, unstable OCD lesions, and in patients with stable lesions who have failed a nonoperative therapy. With advances in arthroscopic technique, debridement has become a mainstay of treatment in patients with unstable lesions and those refractory to nonoperative management.

Available literature and quality of the evidence

- The literature reviewed and summarized to address the clinical question above includes level III retrospective cohort studies and level IV case series studies.

Findings

Takahara et al. classified OCD lesions as unstable if they were associated with closed growth plates, radiographic fragmentation, or restricted elbow range of motion ≥20° at the time of diagnosis.[4] Surgical intervention is generally recommended in patients with unstable lesions, in addition to those refractory to nonoperative treatment.[10],[11] Many different surgical techniques have been described for treatment of OCD lesions in the elbow. They include lesion debridement (open vs arthroscopic), bone marrow stimulation (drilling vs microfracture), fragment fixation, and removal of loose bodies. In general, arthroscopic debridement is the mainstay of surgical treatment in patients when fragment fixation is not possible.

Previous studies have reported outcomes in short- to medium-term follow-up after arthroscopic debridement, and the results have been good.[12–19] In a study by Mihara et al., 25 of 27 patients returned to baseball at near or full previous performance levels.[20] Similarly, Brownlow et al. reported all patients were able to perform activities of daily living, and nearly all reported good to excellent outcomes.[19] When OCD lesions are stratified according to size, results in patients with moderate to large sized OCD lesions have been worse. Takahara et al. reported all patients with large lesions (≥70% of capitellum surface), and 24% with moderate sized lesions (55–70% of capitellum surface) had poor outcomes.[2] Bauer et al. reported 43% of patients treated for large lesions had persistent mild symptoms, and 61% displayed radiographic evidence of osteoarthritis in the radiocapitellar joint.[9] Overall, outcomes after arthroscopic debridement are poor in patients with defects that involve >50% of the articular surface, are >1 cm in diameter, or violate the lateral edge of the capitellum.[2],[4],[20],[21] Therefore, patients with small

lesions (<1 cm) that involve <50% of the articular surface are generally good candidates for debridement procedures. Cartilage restoration procedures should be considered for large defects.

Resolution of clinical scenario

- Good outcomes are seen after debridement in patients with lesions <1 cm, involving <50% of the articular surface, and not involving the lateral edge of the capitellum.
- In patients returning to sport, such as baseball, debridement provided better relief in pain symptoms, increased range of motion, and higher rates of return to baseball at near or full previous performance levels.
- Long-term follow-up results revealed high rates of radiocapitellar osteoarthritis, and mild pain being common in nearly half of patients.

Question 3: In patients with a clinically and radiographically unstable capitellar OCD, does osteochondral autograft transfer result in superior outcomes compared to debridement for pain and return to sport?

Rationale

Few surgical treatments have been described for the treatment of large OCD lesions. However, recent studies have reported good outcomes in patients after

osteochondral autograft transfer due to its ability to restore articular surface and congruity of the radiocapitellar joint.

Clinical comment

Studies suggest that lesion stability, size, and location are important factors to consider when selecting the most appropriate form of treatment. The technique of osteochondral autograft transfer in the elbow has gained popularity due to high success rates seen after similar procedures in the knee and ankle.[22] It represents an effective treatment option in patients with larger OCD defects, OCD defects along the lateral capitellar rim, and in patients who have failed prior debridement.

Available literature and quality of the evidence

- The literature reviewed and summarized to address the clinical question above includes level III retrospective cohort studies and level IV case series studies.

Findings

Due to its increasingly proven success rates in the knee,[22] the operative technique of osteochondral autograft transfer has gained popularity for the treatment of OCD lesions in the elbow. Patients with large capitellar OCD defects (>1 cm) that involve a significant portion of the articular surface (>50%), extend into the lateral margins of the capitellum, or have radial head engagement have worse outcomes after debridement.[2],[4],[20] Although the indications for osteochondral autograft transfer are still evolving, these patients may benefit from osteochondral autograft transfer. The procedure includes the transfer of single or multiple bone and cartilage plugs to restore the capitellar articular surface.

In an early study, Takahara et al. reported that fragment fixation or bone graft or osteochondral autograft transfer provided significantly better results ($p < 0.05$) than fragment debridement alone in larger unstable defects of the articular surface.[4] Recently, several studies have evaluated the technique's efficacy and reported very encouraging clinical outcomes.[23–27] The majority of patients became pain-free, and were able to return to previous activity levels, while few experienced persistent mild occasional pain.[23–27] Donor-site morbidity after autologous osteochondral transplantation is an additional concern to take into consideration when performing these procedures. Autografts may be harvested from the femoral condyle of the knee or costal–osteochondral junction of the ribs. A recent systematic review analyzed differences in outcomes between the two donor sites, and there was no significant difference in donor-site morbidity seen between both harvest techniques.[28]

With regards to baseball, studies have reported that six of eight patients[23] and 17 of 19[29] patients returned to previous level of play, and furthermore 17 of 18[30] experienced no pain with throwing six months after surgery. Authors have also evaluated its impact on prevention of joint degeneration, and nearly all showed little to no degenerative changes at a mean follow-up of up to five years.[31] Overall, osteochondral autograft transfer has proven a reasonable treatment option with good clinical outcomes, and should be considered in patients with the appropriate indications.

Resolution of clinical scenario

- Osteochondral autograft transfer is indicated in large (>1 cm), unstable OCD lesions involving >50% of the

articular surface, or the lateral margins of the capitellum.

- Near complete resolution of pain symptoms, and return to previous activity level is commonly experienced by patients.
- Radiographic evidence of degenerative changes is rare at time of follow-up.

Summary of answers

- Nonoperative management provides good outcomes, and is indicated in patients with stable OCD lesions, open capitellar growth plates, localized flattening or radiolucency of the subchondral bone, and good elbow range of motion.
- Arthroscopic debridement is indicated in patients with unstable, small OCD lesions (<1 cm), involving <50% of the articular surface, and not involving the lateral edge of the capitellum. Patients often report good pain relief, improved range of motion, and return to activity or sport.
- Osteochondral autograft transfer is indicated in patients with unstable, large OCD lesions (>1 cm), involving >50% of the articular surface or the lateral margins of the capitellum. Patients often report good pain relief, and return to previous activity or sport.

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131 Labral Tears

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Clinical scenario

- An athletic 38-year-old woman presents with insidious onset, moderately severe, groin pain that is activity related, especially when she is walking or pivoting on the right leg.
- Pain is worse going from sitting to standing. She also has night pain.
- The patient's pain is reproduced when her hip is positioned in a flexed, adducted, and internally rotated (FADIR) position. X-rays are unremarkable.
- A magnetic resonance arthrogram (MAR) is performed of her right hip which reveals a labral tear.

Top three questions

1. In patients undergoing surgical treatment for a labral tear of the hip, do patients treated with labral repair have superior functional outcome scores to those treated with labral debridement?
2. In patients undergoing surgical treatment for an irreparable labral tear of the hip, do patients treated with labral reconstruction have superior functional

outcome scores to those treated with labral debridement or a match-controlled labral repair group?

3. In patients undergoing surgical treatment for a labral tear of the hip, do younger patients have superior functional outcome scores and lower rates of conversion to hip arthroplasty compared to older patients?

Question 1: In patients undergoing surgical treatment for a labral tear of the hip, do patients treated with labral repair have superior functional outcome scores to those treated with labral debridement?

Rationale

Compelling data on labral repair versus debridement will allow surgeons to perform the procedure which yields better results.

Clinical comment

The labrum of the hip has multiple functions, including increasing the surface area and volume of the acetabulum,[1] acts as a seal against synovial fluid flow in and out of the hip central compartment,[2] and may assume a load-sharing and stabilization role.[3] Therefore, when deciding how much labrum to debride and whether to repair the labrum, one should consider the function of the intact labrum and therefore the possible consequences of a partial or complete labrectomy.

Available literature and quality of the evidence

- Level I: 1 randomized controlled trial (RCT).
- Level III: 2 retrospective comparative cohort studies.

Findings

Krych et al. published an RCT comparing arthroscopic labral repair versus selective labral debridement in female patients with femoroacetabular impingement (FAI). At a mean 32 months' follow-up the repair group had significantly better Hip Outcome Scores (HOS) and subjective outcome scores.[4] Larson et al. had similar findings in their retrospective comparative cohort study comparing labral repair versus debridement.[5] The labral repair group was found to have improved Visual Analog Scale (VAS) scores and functional outcome scores at 3.5 year follow-up.

A retrospective comparative cohort study published by Chen et al. compared outcomes between a labral debridement group using narrow indications and a matched-pair labral repair group.[6] Patients were only eligible for labral debridement in this study if they had a stable labrum with minor damage, and minimal intrasubstance abnormalities. In this study there was no significant difference in a number of functional outcome scores and patient satisfaction between the two groups.

Resolution of clinical scenario

- Level I evidence suggests that patients treated with labral repair will in general have superior outcomes to those treated with labral debridement.
- Level III evidence suggests that labral debridement provides comparable outcomes to labral repair in patients with a stable labrum with minor damage, and minimal intrasubstance abnormalities.

Question 2: In patients undergoing surgical treatment for an irreparable labral tear of the hip, do patients treated with labral reconstruction have superior functional outcome scores to those treated with labral debridement or a match-controlled labral repair group?

Rationale

Identifying which surgical procedure produce superior outcomes for patients with irreparable labral tears will allow surgeons to provide the best treatment option.

Clinical comment

Arthroscopic labral repair has evolved over the years as an effective treatment for hip labral tears, with consistent results of high patient satisfaction, decreasing revision rates, and improved patient-reported outcome (PRO) scores.[5],[7],[8] Certain tear patterns or poor tissue quality are not always amenable to repair, in which case surgical options include labral reconstruction or labral debridement.[9] Labral reconstruction is a more costly and technically demanding procedure than labral debridement. Labral reconstruction aims to restore the natural biomechanics of the labrum while decreasing pain associated with resection of damaged labral tissue.[10] Determining whether labral reconstruction produces superior outcomes is important to determine its overall effectiveness in comparison to labral debridement.

Available literature and quality of the evidence

- Level III: 3 retrospective comparative cohort studies and 2 prospective comparative cohort studies.

Findings

A prospective comparative cohort study by Domb et al. matched 11 patients who underwent arthroscopic acetabular labral reconstruction to 22 patients who had segmental labral resection.[11] It found greater improvement in Non-Arthritic Hip Scores (NAHS) and HOS in the reconstruction group ($p = 0.046$ and 0.045, respectively).

Three cohort studies compare arthroscopic hip labral reconstruction to a match-controlled labral repair group. A comparative retrospective review of 54 patients was done by Matsuda et al. and included a nested case-control analysis within the review.[12] They reported that patients who underwent labral reconstruction with gracilis autograft and those who had labral repair both had significant increases in NAHS with no significant difference between groups. A nested match-paired retrospective cohort study by Domb et al. similarly found comparable survivorship and improvements in PROs between reconstruction and repair groups, except patients in the reconstruction group had lower satisfaction at five-year follow-up.[13] White et al. used patients as their own controls by identifying those who had primary labral repair in one hip and primary labral reconstruction with iliotibial band allograft in the other hip by a single surgeon. There was no significant difference in functional outcome scores between the labral repair and reconstruction groups.[14]

Scanaliato et al. reported in a prospective comparative cohort study of 99 labral repairs and 63 labral reconstructions that both procedures had a similar failure rate (5% for repair and 8% for reconstruction) and no statistical difference in PROs (modified Harris Hip Score,

International Hip Outcome Tool, VAS).[10] It is important to note that this study did not have a matched control analysis, and the patients in the labral reconstruction group had less favorable preoperative characteristics.

Resolution of clinical scenario

- Level III evidence suggests that both arthroscopic labral reconstruction and labral debridement for irreparable labral tears result in improvement in PROs, but greater improvement can be seen with reconstruction.
- Level III evidence suggests that arthroscopic hip labral reconstruction and labral repair have similar survivorship and PROs when comparing matched controls with similar baseline characteristics.

Question 3: In patients undergoing surgical treatment for a labral tear of the hip, do younger patients have superior functional outcome scores and lower rates of conversion to hip arthroplasty compared to older patients?

Rationale

Patient selection is key when determining who to offer surgery to for optimal results. If evidence suggested that patients over a particular age do not benefit from labral repair, surgeons could avoid performing unnecessary procedures on these patients.

Clinical comment

Labral repairs of the hip are most commonly performed through hip arthroscopy. Hip arthroscopy is generally thought of as being a procedure reserved for a young, athletic patient population.[15] Numerous studies have shown positive outcomes in athletes.[16] However, the literature on hip arthroscopy in the middle-aged population has been limited and several studies have advised caution when considering hip arthroscopy in older individuals, particularly in the presence of osteoarthritis (OA).[17]

Available literature and quality of the evidence

- Level III: multiple retrospective case-control studies.
- Level IV: 1 systematic review.

Findings

Horner et al. published a systematic review of 17 level III and IV studies in 2017 on the outcomes of hip arthroscopy in patients aged 40 or older.[18] The systematic review found that patients over 40 who had a labral repair had significant improvement in their postoperative functional outcome scores. However, the rate of conversion to total hip arthroplasty (THA) was significantly higher in patients over 40 than in patients under 40. The presence of OA was found to be a more significant predictor of a poor outcome after hip arthroscopy than increased age.

A retrospective case control published by McCormick et al. in 2012 found that patients <40 and those without osteoarthritic changes were significantly more likely to have a *good* or *excellent* outcome after hip arthroscopy for the treatment of a labral repair.[19]

A study by Domb et al. in 2015 compared patients over the age of 50 with those under 30 undergoing hip arthroscopy. They found that at a mean follow-up of 32 months the under 30 group had a 98.1% survivorship rate, whereas the over 50 group had only an 82.7% survivorship rate. However, there was no significant difference in PROs between the survivors in the two groups.[20]

Honda et al. found that patients aged 50–60 and 60–70 were significantly more likely to have progression of OA after hip arthroscopy than patients under age 50.[21] The presence of preoperative mild OA changes and/or severe cartilage damage on the acetabulum further increased the risk of OA progression.

Resolution of clinical scenario

Older patients may still benefit from labral repair; however, they should be counselled about their increased risk of conversion to THA compared to younger patients. Furthermore, older patients with OA are less likely to have a positive outcome after hip arthroscopy and more likely to have progression of their OA than patients without preoperative osteoarthritic changes. It should be noted that much of the literature on this topic combines all patients undergoing hip arthroscopy regardless of indication, and is in many cases not specific to labral tears.

Summary of answers

- Patients with hip labral tears who undergo labral repair generally have superior functional outcome scores than those treated with labral debridement, except in patients with minimally damaged stable labrums, for whom outcomes of both treatments are comparable.

- For patients with irreparable labral tears, level III evidence suggests that arthroscopic hip labral reconstruction results in greater improvements in PROs than labral debridement. However, both still result in significant improvements overall.
- When comparing matched controls of patients receiving labral reconstruction and labral repair for labral tears, similar survivorship and PROs are seen, according to level III evidence
- Patients over the age of 40 see improvements in outcome scores with hip arthroscopy but experience a higher conversion rate to THA than patients under 40.
- Patients with osteoarthritic changes of the hip are less likely to have a positive outcome after hip arthroscopy for many indications, including labral repair. OA is a greater predictor of outcome than age.

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132 Femoroacetabular Impingement

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Clinical scenario

- A 25-year-old male hockey goalie complains about right hip pain.
- The pain is intermittent, is aggravated with activity, and peaks when he obtains the butterfly stance during hockey. Prolonged sitting also reproduces his hip pain.
- He has tried conservative management (physical therapy, oral analgesics, activity modification) with no resolution of symptoms.

Introduction

Femoroacetabular impingement (FAI) is a common source of hip pain in patients who participate in sports.[1] FAI results from an abnormal biomechanical relationship between the proximal femur and the acetabulum which leads to bony impingement and is associated with soft tissue injury and chondral damage.[2],[3] Certain sport activities, including hockey, predispose the hip joint to the development of FAI due to overuse injury.[4] Such sports include repetitive hip flexion and rotational movements which generate conflict between the femur and the acetabulum.[5]

Cam and pincer impingement are the two main types of FAI. *Pincer impingement* refers to the acetabular component and it is less understood than the *cam FAI*, which refers to the femoral component.[6] Studies have shown the association between the cam lesion and labral or chondral damage in the hip.[2,3,6] Untreated FAI has been associated with hip labral tears and early osteoarthritis, and therefore early diagnosis and prompt therapy are necessary to avoid this complication in young, active individuals.[3,7,8] Hip arthroscopy is an expanding procedure which treats FAI and the associated lesions with minimal intervention.[9] Hip arthroscopy has been reported to result in superior general health-related quality of life (HRQoL) in the Short Form 12 (SF-12) physical health component compared to open FAI surgery, although the hip-specific outcomes were not different based on a recent study.[10]

Top three questions

1. In young adults with hip pain, which physical examination maneuvers are most accurate in the diagnosis of FAI, compared to others?
2. In patients with cartilage defects of the hip, do some treatment options, compared to others, result in better outcomes?
3. In young patients who have undergone treatment for FAI, what are the timelines for return to sport?

Question 1: In young adults with hip pain, which physical examination maneuvers are most accurate in the diagnosis of FAI, compared to others?

Rationale

The young hockey player had a positive anterior impingement sign and he had an increased flexion, abduction, and external rotation (FABER) distance test on the painful hip. Before prescribing advanced imaging, exam results should provide a strong suspicion of FAI.

Clinical comment

A thorough physical exam is critical in order to determine the source of the patient's symptoms. Physical exam findings should guide the clinician in the ordering of further diagnostic investigations.

Available literature and quality of the evidence

- Level of evidence I or II: 3 systematic reviews.
- Most other studies are descriptive or have limited analysis of the accuracy of the physical exam tests.

Findings

Several studies have investigated the physical exam for diagnosis of hip pain.[11–16] One systematic review on physical examination test for FAI found that the accuracy of exam tests are limited due to the heterogenicity of studies.[11] They found that the FABER test had sensitivity of greater than 0.8 and the anterior impingement test had specificity and positive predictive value (PPV) of 1.0.[11] Another systematic review with meta-analysis found the sensitivity of flexion–adduction–internal rotation, which can be compared with the anterior impingement test, equal to 0.99 and a PPV of 0.90.[12] This study also concluded that the current research did not support exam tests for diagnosis.[12]

The other systematic review looked at diagnosis in the skeletally immature patient.[13] Of the six articles included on hip arthroscopy, five reported the physical exam. All five reported using the impingement test for diagnosis. The study made no conclusions on the best physical exam test.[13] The FABER test has been modified to the FABER distance test. One study showed that the FABER distance test was associated with higher alpha angle, which is a common radiographic measurement associated with FAI.[14]

The use of ultrasound has become more popular for diagnosis; however, the literature is limited on its diagnostic capability for FAI.[15] In addition, new three-dimensional models may assist with accurate diagnosis and preoperative planning.[16] While the anterior impingement test is very examiner specific, it has been shown to have good diagnostic characteristics. The FABER distance can provide a measurement to compare both hips with greater interobserver reliability. When used in combination, these tests (anterior impingement and FABER distance test) can be helpful in identifying patients who are at high risk for chondrolabral dysfunction due to FAI and may need addition imaging.

Resolution of clinical scenario

- A thorough clinical exam is necessary as there is no evidence to support the use of specific tests for the diagnosis of FAI.
- It is our experience that the FABER distance test and the anterior impingement test are relatively specific for the diagnosis of FAI.

Question 2: In patients with cartilage defects of the hip, do some treatment options, compared to others, result in better outcomes?

Rationale

There is insufficient evidence to support the effectiveness of currently available cartilage restoration techniques in the hip. Only short- and medium-term outcomes have been published and the superiority of one technique over the other has not been showed. In athletes, only microfractures have been reported to result in improved outcomes and high return to sport rate.

Clinical comment

Anterosuperior labral tears are associated with adjacent acetabular cartilage delamination in patients with FAI. The cam lesion, which is common finding in young hockey players, has been associated with hip cartilage defects. An Outerbridge grade IV cartilage defect was present on the acetabulum and a grade II defect was present on the femoral head. Acetabular microfractures were performed, whereas the femoral defect was treated with chondroplasty.

Available literature and quality of the evidence

- There is not enough literature to propose the ultimate cartilage repair technique to restore the cartilage defects in the hip.
- Level IV: 2 studies.
- Level III: 3 studies.

- Systematic review of Level III and IV studies: 1 study.

Findings

A recent systematic review reported more than 10 cartilage repair techniques in the hip, but the authors concluded that more research is necessary to support one technique over another.[17] The most recent studies have focused on intra-articular bone marrow mesenchymal stem cells injection and the Autologous Matrix-Induced Chondrogenesis (AMIC) procedure with satisfactory two- to five-year outcomes.[18–20] None of the recent studies has focused exclusively on athletes, except from McDonald et al. in 2013 who had reported that elite athletes who underwent hip arthroscopy for FAI with microfractures had a similarly high return to sport rate with a control group of elite athletes who did not have microfractures.[8] In the last study, the return to sport rate was 77 and 84% in the microfracture group and the control group, respectively. McDonald et al. reported an 82% return to sport rate in professional hockey players who underwent hip arthroscopy for FAI, labral repair and microfractures.[21]

Resolution of clinical scenario

- Performance of hip microfractures in athletes with severe chondral defects results in improved outcomes and a high return to sport rate.
- Severe chondral defects can be treated with microfractures or newer cartilage repair techniques.

Question 3: In young patients who have undergone treatment for FAI, what are the timelines for return to sport?

Rationale

In the sports medicine population, return to activity is what the patients expect following surgery. Many patients do not have surgery due to the severity of symptoms but due to their inability to participate in their sport. The last is especially true for professional athletes. Hip arthroscopy has been reported to result in a high return to sport rate in athletic individuals, but this has been supported by only level IV evidence data in the literature.

Clinical comment

After eight weeks of postoperative rehabilitation, this patient passed the hip sport test and could return to full activity. The patient returned to the ice at eight weeks and completed full training sessions at nine weeks. It is important to establish evidence-based, return-to-play protocols for athletes undergoing hip arthroscopy to reduce the re-injury rate and prolong the athlete's career.

Available literature and quality of the evidence

- Not many studies have reported successful outcomes following hip arthroscopy in hockey players.
- Level IV: 3 studies.
- Systematic review of level IV studies that include hockey players: 1 study.
- Case reports: 2 studies.

Findings

The most recent systematic review (1296 patients, 1442 hips) reported the return to sport rate following hip arthroscopy to be 84.6% at a mean follow-up of 25.8 months.[22] Philippon et al. reported that the time to return to play following hip arthroscopy and labral repair in professional hockey players was 3.4 months on average.[4] McDonald et al. reported a high return to sport rate and no difference in games played and number of seasons in the league following hip arthroscopy with or without microfractures, in professional hockey players.[21] In addition, the authors did not find a significant difference between number of seasons in the league between the microfracture and the nonmicrofracture group. In a group of 60 professional hockey players, Menge et al. reported that 5.9 years following hip arthroscopy for FAI, 67% (40/60 athletes) of the athletes were still playing.[23] Case reports have showed that hockey players who undergo hip arthroscopy with proper rehabilitation can safely return to sport and continue their career.[24],[25]

Resolution of clinical scenario

- Hockey players with FAI, labral tears, and/or cartilage defects have a high chance to return to sport following hip arthroscopy with or without microfractures.
- Postoperative rehabilitation is critical to optimize the surgical outcome and allows for an early return to sport.

Summary of answers

- Diagnosis of FAI begins with the physical exam; however, the literature does not support specific exams

as part of a diagnostic algorithm.

- The anterior impingement test and the FABER distance test are commonly used for the preliminary diagnosis of FAI.
- Performance of hip microfractures in athletes with severe chondral defects results in improved outcomes and a high return to sport rate.
- Severe chondral defects can be treated with microfractures or newer cartilage regeneration techniques.
- Hockey players with FAI, labral tears, and/or cartilage defects have a high chance to return to sport following hip arthroscopy with or without microfractures.
- Postoperative rehabilitation is critical to optimize the surgical outcome and allows for an early return to sport.

Conclusion

FAI and the commonly associated labral or hip cartilage lesions are common diagnostic findings in young athletes. Early diagnosis and treatment of the hip structural lesions in symptomatic athletes are necessary to reduce the prevalence of early degenerative joint disease and prolong their participation in sports.

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133 Initial Management of the Sports Injured Knee

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Clinical scenario

- A 27-year-old female presents at the Emergency Department after she twists her knee during a basketball game.
- The patient reports pain and acute functional limitation.
- At the time she is evaluated, an effusion can be detected.

Top three questions

1. In patients with an acutely injured knee, does magnetic resonance imaging (MRI) performed acutely provide greater diagnostic ability compared to delayed MRI?
2. In patients with an acutely injured knee, does MRI, compared to diagnostic arthroscopy, provide sufficient diagnostic capability?
3. In acute post-traumatic hemarthrosis, does aspiration, compared to no aspiration, play a diagnostic or therapeutic role?

Question 1: In patients with an acutely injured knee, does magnetic resonance imaging (MRI) performed acutely provide greater diagnostic ability compared to delayed MRI?

Rationale

The role of MRI in acute trauma has classically been controversial; this section aims to resolve these doubts by shedding light with the help of currently published literature.

Clinical comment

Knee injury secondary to sports is a common reason for presentation to the Emergency Department. The majority of injuries are often due to extra-articular soft tissue injury. Despite this, sometimes we find severe knee effusion which suggests hemarthrosis, and may involve injury to intra-articular structures.

A large intra-articular effusion after trauma often points directly to a diagnosis of hemarthrosis through physical examination. Physical examination has great sensitivity to detect knee injuries, although the specificity is very low because it is difficult to perform specific maneuvers given that the patient often has significant pain and guarding. This is accentuated more at an early age, due to fear, guarding, or difficulty in expressing current symptoms.

Traditionally, a delayed MRI was the gold standard treatment due to concerns about missed intra-articular injuries in an early MRI. However, new studies have demonstrated that perhaps there is a role for early MRI.

Available literature and quality of the evidence

There is a wide spectrum of articles that discuss timing of MRI following injury, though most are level III–IV studies. At the moment, no randomized clinical trials have been published.

Findings

One of the characteristics that should matter most about a diagnostic test is the ability to detect injuries and the ability to distinguish between them, that is a test that minimizes false-negatives and false-positives. Munshi et al. published a prospective double-blind study performing MRI on a 1.5 T magnet and comparing the results to knee arthroscopy.[1] They reported sensitivity and specificity for early MRI of 90 and 67%, respectively, for detecting any anterior cruciate ligament (ACL) injury, 50 and 86% for detecting medial meniscal tears, and 88 and 73% for detecting lateral meniscal tears. The overall detection of injury requiring surgical intervention yielded a sensitivity of 100% and a specificity of 71%.

As previously mentioned, there are injuries that can may go unnoticed in the Emergency Department. Askenberger et al. conducted a prospective study in a pediatric hospital with children aged between 9 and 14 years;[2] they observed that, even though 77% of children who visited the Emergency Department with knee trauma had serious intra-articular injuries, 56% of these patients had no apparent lesion on plain radiography. Therefore, if there is a suspicion of serious injury, an MRI is recommended even in the context of normal X-rays.

Phelan et al. published a systematic review of the articles that correlated the initial MRI findings with findings during knee arthroscopy.[3] They found that a positive finding on

MRI doubled the probability of an ACL tear from 35.7 to 85.8%. They found several confounding factors: (i) the magnetic field strength of the MRI, (ii) the year of publication of the article, since MRI techniques have evolved, (iii) the ability to differentiate between complete and partial ACL tear, (iv) the radiologist's experience, and (v) the blinding of the arthroscopist. A similar study conducted by Monaco et al. compared MRI findings with intraoperative anterolateral exploration in the acute ACL-injured knee.[4] They concluded that MRI evaluation demonstrated high sensitivity, specificity, and accuracy for the detection of abnormalities of the anterolateral ligament complex. For other parameters, the sensitivity and specificity were not as high, such as whether there was a complete tear or not.

Abbasi et al. conducted a prospective study that aimed to describe the MRI findings in adolescents with traumatic knee effusions and to compare injuries based on age, sex, and physeal maturity.[5] They found that severe intra-articular knee injuries occur in young patients with ACL tears and patellar dislocations accounting for the majority of injuries. Injury patterns were affected by age with significantly more ACL tears occurring in the 15- to 18-year-old age group (40% vs 22%, $p < 0.05$).

Resolution of clinical scenario

As has been observed, the MRI diagnosis has an acceptable sensitivity and specificity detecting intra-articular knee injuries in the acute setting. In contrast to traditional texts, it seems the rate of missed occult injuries may be as low as 5%.

- MRI is necessary when a knee with severe swelling occurs after sports trauma.

- The false-negative rate is low with the techniques and knowledge of the current MRI.
- MRI acceptably identifies potentially surgical lesions.

Question 2: In patients with an acutely injured knee, does MRI, compared to diagnostic arthroscopy, provide sufficient diagnostic capability?

Rationale

The patient is concerned regarding the potential for intra-articular injury but is reluctant to proceed with surgical intervention. She wants to be sure that surgery is necessary and asks for further diagnostic testing.

Clinical comment

Diagnostic arthroscopy was a very popular procedure a few decades ago because of the immediacy of the diagnosis and its therapeutic possibilities;[6] however, it is still an invasive procedure not free of possible adverse effects. As with many other procedures, the accuracy of diagnostic arthroscopy, particularly in the context of acute injury and hemarthrosis, depends on the surgeon's skill level. Varying blind areas arise depending upon the arthroscopic approach such as peripheral and posterior parts of the menisci, although the experienced arthroscopist may overcome this problem by using a hook for palpation of the intra-articular structures. The role of diagnostic arthroscopy is losing popularity with a more common tendency to perform MRI studies.[7],[8]

Available literature and quality of the evidence

- Level II: 2 systematic reviews.

Findings

Rappeport et al. performed a systematic review[9] and a prospective study,[10] which concluded that MRI is in many respects equal or even preferable to diagnostic arthroscopy. It has a high ability to detect lesions of the major and most commonly affected structures of the knee joint. Furthermore, information is obtained about other structures like the collateral ligaments and the patellar ligament that are not visualized at arthroscopy. They advocated its use as a first-line investigation after clinical examination.

Crawford et al. performed a systematic review of largely level II evidence (47 prospective studies and a total of 59 articles) to assess the difference between MRI and arthroscopy in the diagnosis of knee pathology.[11] The findings indicated that MRI was highly accurate in diagnosing ligament and meniscal pathology. Furthermore, performing an early MRI prior to diagnostic arthroscopy has been reported to avoid unnecessary surgical intervention in 22–51% of cases.[12] Avoid unnecessary arthroscopic procedures is crucial to minimize the possibility of adverse effects or other complications, as well as to ensure appropriate use of limited healthcare uses.

Resolution of clinical scenario

- In a large proportion of patients management can be planned on the basis of MRI findings with arthroscopy deferred in the presence of a normal examination.

- Routine MRI avoids unnecessary diagnostic arthroscopy in more than 20% of cases.

Question 3: In acute post-traumatic hemarthrosis, does aspiration, compared to no aspiration, play a diagnostic or therapeutic role?

Rationale

The patient is suffering from significant pain and limited active range of motion (ROM). She desires to know whether an aspiration would reduce her symptoms without taking any further risks.

Clinical comment

Joint aspiration of acute injury hemarthrosis has always been seen as an easy and helpful technique, but it is uncertain if it may alleviate the initial pain and increase function of the knee. Furthermore, its role in diagnosis is becoming less necessary with the previously discussed improvements in MRI. The related risks of iatrogenic infection and recurrence effusion should also be taken into account.

Available literature and quality of the evidence

- Level I: 1 randomized trial.
- Level III: 1 retrospective cohort study.

Findings

A randomized trial conducted by Paschos et al. analyzed 167 patients with a knee effusion (95 traumatic) and

divided them into two groups: aspiration versus nonaspiration.[13] In the traumatic group, aspiration showed a temporary improvement in pain relief ($p < 0.05$), ROM, and reduction in swelling ($p < 0.05$ for all) compared with nonaspiration. However, the improvement lasted less than one week regarding pain and approximately three days regarding edema and function. Moreover, trauma effusions recorded higher rates of re-accumulation (37% of patients reoccurred within the first week) compared with nontraumatic effusions. Concerning the analgesic intake and required time to return to normal activities, no differences were observed. Two patients showed signs and symptoms of infection and were treated with antibiotics, but it was not specified if they were traumatic or nontraumatic effusions.

On the other hand, Wang et al. published a retrospective cohort study of 60 patients that underwent ACL reconstruction.[14] All participants were divided into two groups based on the presence or absence of joint aspiration in the Emergency Department. It should be emphasized that there was not strict selection criteria for aspiration. In fact, the aspiration group showed a higher mean pain score on Visual Analog Scale (VAS) and effusion and a reduced ROM at the initial examination. It was observed that the aspiration group had a significantly greater decrease in VAS at follow-up than the nonaspiration group (2.8 ± 1.9 vs 1.0 ± 2.5, $p < 0.05$). ROM was re-established in the aspiration group by $28.2 \pm 23.1°$ versus $3.5 \pm 38.3°$ in the nonaspiration group ($p < 0.05$). Additionally, it was showed a higher sensitivity of Lachman and Pivot Shift tests at the second visit: 76.5% (13/18) of positive Lachman test in the aspiration group versus 47.6% (20/42) in the nonaspiration group ($p = 0.047$) and 76.5% (13/18) of positive Pivot Shift test versus 31% (13/42) ($p = 0.001$). The incidence of iatrogenic infection was not mentioned.

Overall, there is a shortage of literature to define the benefit of the arthrocentesis in the acutely injured knee with hemarthrosis and its inherent risks.

Resolution of clinical scenario

- Post-traumatic knee joint aspiration may be effective in reducing the immediate pain and edema but a prompt re-accumulation of the effusion seems frequent.
- The aspiration of acute hemarthrosis remains of questionable value.

Summary of answers

- In a large proportion of patients management can be planned on the basis of MRI findings with arthroscopy deferred in the presence of a normal examination.
- Routine MRI avoids unnecessary diagnostic arthroscopy in more than 20% of cases.
- Post-traumatic knee joint aspiration may be effective in reducing the immediate pain and edema but a prompt re-accumulation of the effusion seems frequent.
- The aspiration of acute hemarthrosis remains of questionable value.

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134 Meniscal Tears

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Clinical scenario

- A 28-year-old soccer player comes to the Emergency Department with right knee pain after sustaining direct trauma during a match. Clinical examination reveals an effusion, locking, tenderness, and painful flexion/extension of the knee, suggesting a meniscal lesion. Magnetic resonance imaging (MRI) is proposed as the primary tool for the tear detection, but the primary care physician suggests ultrasound (US) for a quick examination.
- After the imaging confirmation of meniscal tear, meniscal repair is proposed as the most suitable surgical technique.
- After a failed meniscal repair, the patient undergoes an arthroscopic partial meniscectomy, and asks about the best way to recover knee function and muscle strength in the operated leg.

Table 134.1 Correlation between MRI, arthroscopy, and ultrasonography.

Reference	Level of evidence	Total no. of patients studied	Age of patients mean (SD)	Affected meniscus	Sensitivity	Specificity	PPV	NPV
Akatsu et al.[6]	II	70	33.5 (-)	M	0.95 (0.87–0.100)	0.82 (0.69–0.94)	0.85	0.93
				L	0.79 (0.66–0.93)	0.89 (0.77–0.100)	0.85	0.84
				M+L	0.88 (0.80–0.96)	0.85 (0.77–0.94)	0.85	0.88
Cook et al.[7]	II	71	37.2 (-)	M+L	0.91	0.84	0.95	0.76
Mahdy et al.[8]	II	15	30.4 (-)	M+L (overall)	0.88 (overall)	—	—	—
Mostafa et al.[9]	II	50	37.65 (10.24)	M+L	0.89	0.77	—	—
Alizadeh et al.[10]	II	74	33.5 (7.15)	M+L	0.83 (0.65–0.94)	0.71 (0.29–0.96)	0.92 (0.76–0.99)	0.50 (0.19–0.81)
Unlu et al.[11]	II	35	—	M+L	0.91	0.64	—	—

SD: standard deviation; PPV: positive predictive value; NPV: negative predictive value; M: medial; L: lateral; M+L medial and lateral.

Top three questions

1. In patients with suspected meniscal lesions, is US preferable for tear detection compared to arthroscopy and MRI?
2. In patients with meniscal lesions, does a specific repair technique result in better surgical outcomes compared to others?
3. In patients with meniscal lesions, does a specific rehabilitation protocol result in better clinical outcomes compared to others?

Question 1: In patients with suspected meniscal lesions, is US preferable for tear detection compared to arthroscopy and MRI?

Rationale

MRI is the gold standard for the diagnosis of meniscal tears. USs are a suitable noninvasive and safe alternative tool to establish a diagnosis of meniscal tear.

Clinical comment

Current opinion suggests that MRI is preferable to diagnostic arthroscopy in most patients because it avoids the surgical risks of arthroscopy with high accuracy in diagnosing meniscal and anterior cruciate ligament (ACL) tears.[1] US has been proposed in case of contraindications for MRI, such as the presence of indwelling cardiac pacemakers, metal implants, patient intolerance due to claustrophobia, and delay in treatment due to long wait periods.[2]

Available literature and quality of the evidence

A number of different studies have evaluated the role of US for meniscal tear diagnosis, both alone or in comparison with MRI and/or arthroscopy. Three systematic review and meta-analyses evaluated the diagnostic accuracy of US for meniscal tears.[3–5] One trial (n = 70 patients) provided the correlation between arthroscopy and US,[6] stating that US may be used for screening for meniscal tears (Table 134.1). Three trials (n = 71, n = 15, and n = 50 patients, respectively) determined the clinical usefulness of US for diagnosis of meniscal injuries and compared its diagnostic accuracy to MRI (Table 134.1).[7–9] Two trials (n = 74 and n = 35 patients, respectively) provided the correlation between MRI, US, and arthroscopy for meniscal tears diagnosis (Table 134.1).[10,11]

Findings

Dai et al. and Xia et al. found that US has high specificity (0.90; 95% confidence interval [CI]: 0.86–0.93 and 0.838; 95% CI: 0.818–0.857, respectively) and moderate sensitivity (0.88; 95% CI: 0.84–0.91 and 0.775; 95% CI: 0.747–0.801, respectively),[3,4] while Dong et al. found that two-dimensional US has higher sensitivity (0.888; 95% CI: 82.83–92.87) than specificity (0.846; 95% CI: 75.89–90.64).[5] All three studies agreed that the diagnostic accuracy of US for meniscal injury was acceptable, and that US could be routinely used to diagnose meniscal tears.

Cook et al. stated that US is a useful tool for diagnosis of meniscal pathology with potential advantages over MRI.[7] Mahdy et al. and Mostafa et al. pointed out that US (especially high resolution US) examination may be suitable for screening for meniscal

tears, but detection of the morphology of meniscal tears seems insufficient, with MRI being more sensitive in detection and determination of tear type.[8,9]

Alizadeh et al. stated that US could be effective as an initial investigation for tears of medial meniscus for patients aged 30 or less,[10] while Unlu et al. concluded out that US is not a suitable alternative for MRI in the routine diagnostic evaluation of meniscal tears, and that only in selected cases, such as young patients, traumatic cases, and cases with a contraindication for MRI, US may find a role as a quick exam to stratify patients for further evaluation.[11]

Overall, there is consensus about the usefulness of US for meniscal tears detection. Level I evidence suggests that US could be used as a reliable tool, with a good diagnostic accuracy.[3,10] However, level I evidence also suggests that US cannot completely replace MRI for meniscal tear diagnosis, particularly for classifying tear type.[11]

Resolution of clinical scenario

- Level I evidence demonstrates that US could be useful screening tool for the detection of meniscal tears, especially if high-resolution US is used. Since the available data about US sensitivity and specificity are discordant, US cannot replace MRI, which remains the mainstay for the diagnosis of meniscal pathologies.

Question 2: In patients with meniscal lesions, does a specific repair technique result in better surgical outcomes compared to others?

Rationale

MRI shows an extended vertical longitudinal meniscal tear. Meniscal repair could represent an option for this patient.

Current comment

Several techniques have been proposed to optimize the healing of a repairable meniscal tear. Meniscectomy is one of the most popular orthopedic procedures, but long-term results are not entirely satisfactory and the concept of meniscal preservation has therefore progressed over the years because of its functional importance to the knee and risk of long-term osteoarthritis associated with meniscectomy.[12,13] Arthroscopic meniscal repair surgery includes inside-out, outside-in, and all-inside techniques. All-inside meniscal repair devices are an attractive option owing to cosmesis, surgical time, and decreased risk of injury to neurovascular structures.

Available literature and quality of the evidence

The inside-out technique is considered the gold standard for meniscal repair, although all-inside techniques continue to evolve.[14] Studies available to answer this question include a meta-analysis,[15] a laboratory study,[16] a randomized controlled trial (RCT),[17] and a systematic review.[18]

Findings

A meta-analysis by Mutsaerts et al. found that the only surgical treatments compared in homogeneous fashion across more than one study were the arrow and inside-out technique, which showed no difference in terms of re-tear or complication rate.[15]

A controlled laboratory study investigated the biomechanical response to cyclic loading (up to 100 000 cycles) of all-inside meniscal repairs compared with inside-out suture controls, and showed comparable biomechanical properties, even after 100 000 cycles.[16] In this study, 72 porcine menisci were repaired using the Omnispan and Fast-Fix 360 (all-inside devices) and Orthocord 2-0 and Ultrabraid 2-0 sutures (inside-out sutures). Initial displacement and displacement after cyclic loading were not different between the groups, but the Omnispan repair demonstrated significantly higher load-to-failure force compared with all the other constructs, and the Orthocord vertical inside-out mattress repair was significantly stronger than the FAST-FIX 360 repair.

An RCT by Kise et al. compared an all-inside suture device to meniscal arrows.[17] They treated 46 patients either by Biofix (n = 21, 45.7%) or FAST-FIX (n = 25, 54.3%) with two-year follow-up. Their results indicate that FAST-FIX suture is superior to Biofix arrows with significantly lower failure; the risk of reoperation was 3.6 times higher for the Biofix (95% CI: 1.1–11.5). It should be noted, however, that patients in the Biofix group had higher activity scores preoperatively and at three-month follow-up, and thus activity level may also influence risk of reoperation.

A recent systematic review by Fillingham et al. pointed out that the quality of the evidence comparing inside-out and all-inside meniscal repair is low, and that there were no significant differences in terms of anatomical and clinical failure rates, functional outcome scores, and complication rates.[18]

Given the paucity of RCTs, no definite conclusions could be drawn regarding the difference in clinical outcomes of various meniscal repair devices. For this reason, more evidence is needed to reduce the numbers of ineffective interventions and support potentially beneficial surgery.[19]

Overall, there is consensus about the absence of a specific repair technique which results in better surgical outcomes for meniscal tears. Level I studies suggest that there is a lack of evidence to guide the surgical management of meniscal tears, with no significant differences between the repair techniques in terms of clinical or surgical outcomes.[15,18,19] For these reasons, the choice of a particular repair technique is unlikely to improve outcomes.[1]

Resolution of clinical scenario

- Level I evidence demonstrates that there are no reasons to believe that the choice of a particular repair technique would improve outcomes following meniscal repair.

Question 3: In patients with meniscal lesions, does a specific rehabilitation protocol result in better clinical outcomes compared to others?

Rationale

After a failed meniscal repair and subsequent arthroscopic partial meniscectomy, an appropriate rehabilitation program is a key point for the overall success of surgery.

Clinical comment

Type of lesion, type of surgery, timing of biological healing, and the patient's symptoms determine the appropriate rehabilitation program for a full recovery.[20] After partial meniscectomy, the rehabilitation protocol can be aggressive, because the knee joint anatomical structure does not need to be protected.[20]

Available literature and quality of the evidence

A large meta-analysis,[21] a laboratory study,[22] and two RCTs[23],[24] exist to answer this question.

Findings

A meta-analysis by Dias et al. evaluated 18 RCTs and six meta-analyses of patients treated with arthroscopic meniscectomy, and pointed out that outpatient physical therapy plus a home exercise program improves function and knee flexion range of motion when compared to a home program alone.[21] Moreover, inpatient physical therapy alone compared to inpatient plus outpatient physical therapy reduced the likelihood of effusion.

A descriptive laboratory study by Hsu et al. compared single-leg hop performance (distance and landing mechanics) between limbs to examine the association of single-leg hop performance with quadriceps strength and psychosocial factors in patients with meniscectomy.[22] A total of 22 subjects who underwent meniscectomy for traumatic meniscal tears received either standard rehabilitation alone or with additional quadriceps strengthening. Greater quadriceps strength was associated with greater single-leg hop distance and better landing mechanics at both postrehabilitation and one-year postsurgery.

An RCT by Zhang et al. aimed to determine an effective knee function rehabilitation program for athletes undergoing partial medial meniscectomy.[23] Participants were randomly assigned to neuromuscular training (NT) or strength training (ST) and subjected to functional assessments before surgery and again at four and eight weeks *postoperation*. Functional knee assessment, such as Lysholm knee scoring scale, Star Excursion Balance Test, and BTE PrimusRS isokinetic performance tests were evaluated in each group. All postoperational symptoms were significantly improved after four and eight weeks of NT and ST. Both NT and ST programs showed effective knee function recovery seen as an increase in muscular strength and endurance. However, the NT program showed the most significant functional improvement of dynamic balance and coordination.

A recent RCT by Vidmar et al. compared the effects of conventional (constant load) eccentric training and isokinetic eccentric training on quadriceps muscle mass, strength, and functionality of recreational athletes following partial meniscectomy.[24] Thirty-two recreational male athletes who underwent partial meniscectomy and performed a six-week quadriceps ST program were divided into a conventional group (CG) or an isokinetic group (IG). Both groups had enhanced muscle mass, strength, and functional outcomes. The IG patients had significantly higher increases for muscle mass, strength, and Lysholm knee scoring system. These results suggested that, after partial meniscectomy, isokinetic eccentric training is more effective than conventional eccentric training to restore quadriceps muscle mass, strength, and functional capacity.

Overall, many different types of rehabilitation protocols reported good outcomes. Level I evidence suggests that physical therapy plus a home exercise program in outpatients treated with arthroscopic meniscectomy improves function and knee flexion, and that neuromuscular, strength, and isokinetic programs ensure the best results in terms of clinical improvement.[21],[23],[24] Level IV evidence suggests that greater quadriceps strength was associated with greater single-leg hop distance and better landing mechanics compared with rehabilitation alone.[22]

Resolution of clinical scenario

- Level I evidence demonstrates that muscle strengthening is an integral part of rehabilitation programs after meniscectomy, resulting in a better landing mechanism.

NT showed better results in dynamic balance and coordination.

- Level I evidence demonstrates that isokinetic eccentric training is more effective than conventional eccentric training to restore quadriceps muscle mass, strength, and functional capacity.

Summary of answers

- US is a useful screening tool for the detection of meniscal tears, especially if high-resolution US is used. Since the available data about US sensitivity and specificity are discordant, US cannot replace MRI, which remains the mainstay for the diagnosis of meniscal pathologies.
- There are no reasons to believe that the choice of a particular repair technique would improve the outcomes following meniscal repair.
- Muscle strengthening is an integral part of rehabilitation programs after meniscectomy, resulting in better landing mechanics. NT improves dynamic balance and coordination.
- Isokinetic eccentric training is more effective than conventional eccentric training to restore quadriceps muscle mass, strength, and functional capacity.

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135 Anterior Cruciate Ligament Injuries

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Clinical scenario

- An 18-year-old varsity football player presents to clinic complaining of right knee pain and instability after sustaining an injury in practice one month ago. The patient describes that he planted his foot on the turf and sustained a twisting injury.
- Physical exam demonstrates a grade 3 Lachman's test and a 2+ Pivot Shift test.
- MRI demonstrates an acute, full thickness anterior cruciate ligament (ACL) tear.

Top three questions

1. In patients undergoing ACL reconstruction, does autograft result in improved outcomes compared to allograft?
2. In patients undergoing ACL reconstruction, does hamstring or quadriceps tendon autograft result in differences in outcomes compared to conventional bone patellar tendon bone (BPTB) autograft?

3. In patients undergoing ACL reconstruction, does early surgical intervention improve outcomes compared to delayed reconstruction in both skeletally mature and immature patients?

Question 1: In patients undergoing ACL reconstruction, does autograft result in improved outcomes compared to allograft?

Rationale

The choice of graft can have important implications for outcome and function after ACL reconstruction. Both allograft and autograft have their respective advantages and disadvantages, which need to be discussed with the patient.

Clinical comment

ACL ruptures are devastating injuries and can lead to recurrent instability, degenerative changes, and chronic pain.[1–4] Although is consensus that arthroscopic reconstruction is the treatment of choice in active individuals, there is still debate as to whether autograft or allograft should be used.[5–8]

Autograft options consist of bone patellar tendon bone (BPTB), hamstring tendon (HT) and less commonly, quadriceps tendon (QT).[9] Allograft is generally acquired from cadaveric BPTB, anterior tibial tendon, or Achilles tendon.[9] Autografts have been found to have faster graft incorporation and are free of the potential for disease transmission.[10] However, this comes at a cost of donor site morbidity depending on the site of harvest. Allografts avoid

donor site morbidity, but come with the risk of delayed incorporation, altered biomechanics secondary to sterilization processes, risk of disease transmission, as well as increased cost.[9],[10]

Available literature and quality of the evidence

Multiple randomized controlled trials (RCTs) have compared the efficacy of various autografts compared to both irradiated and nonirradiated allografts in different populations.[11]–[14] Gorschewsky et al. (level II) randomized 268 patients to autograft BPTB or irradiated allograft BPTB.[12] They found significantly higher re-rupture rates in the allograft group compared to the autograft group (20.6% vs 4.8%). Subgroup analysis demonstrated even higher re-rupture rates in the allograft group when evaluating young, active patients. More recently, Sun et al. (level II) randomized 208 patients to hamstring autograft versus nonirradiated fresh-frozen HT allograft.[13] They found no significant differences in outcomes at an average of 7.8 years of follow-up.

A meta-analysis by Zeng et al. (level IV) evaluated the results of nine RCTs comparing allograft and autograft for ACL reconstruction.[15] They demonstrated that autograft was favored over allograft with regards to clinical failure rates (risk ratio [RR] = 0.47; p = 0.0007), the Lachman test (RR = 1.18; p = 0.03), the instrumented laxity test (weighted mean difference: −0.88; p = 0.004). However, when a subgroup analysis was performed comparing autograft with nonirradiated allograft no significant differences were found. Wei et al. (level II) performed a meta-analysis of 12 RCTs comparing nonirradiated allograft with autograft and found no significant differences in postoperative knee stability, function, or side effects.[16]

Given that younger, active patients have a significantly higher re-rupture rate, there has been an interest in determining differences in graft success rates in this specific population. Bottoni et al. (level I) randomized 100 active-duty military personnel with ACL-deficient knees to hamstring autograft or nonirradiated tibialis posterior allograft.[17] At a minimum of 10-year follow-up, they found there was a significantly increased number of failures (26.5% vs 8.3%, $p = 0.03$) in the allograft group when compared to autograft. Wasserstein et al. (level III) performed a meta-analysis on seven studies comparing autograft to allograft in young or active populations.[18] Pooled results of 788 patients treated with autograft tissue and 228 with various allografts demonstrated a significantly higher failure rate in the allograft group (25% vs 9.6%, $p < 0.00001$).

Findings

Overall, level II–IV evidence suggests that autograft has low failure rates when compared to irradiated allografts.[12],[15] There are significant limitations in the literature including low patient numbers, varying graft substances, and differences in follow-up length. There is level I–III evidence that demonstrates higher failure rates in allograft when compared to autograft in young, active patients.[17],[18] This is a particularly important subgroup that has historical seen higher failure rates and may benefit from autograft for primary ACL reconstruction.[19]

Resolution of clinical scenario

- Level II evidence suggests that autograft has lower failure rate when compared to irradiated allograft.[12]

- Level II evidence suggests that there is no differences in clinical outcomes when autograft is compared to nonirradiated allograft.[16]
- Level I evidence suggests that in young, active patients, autograft has significantly lower failure rates when compared to allograft.[17]

Question 2: In patients undergoing ACL reconstruction, does hamstring or quadriceps tendon autograft result in differences in outcomes compared to conventional bone patellar tendon bone (BPTB) autograft?

Rationale

Autograft remains the most common choice for ACL reconstruction.[20] There remains controversy over the most favorable graft selection with the most commonly utilized autografts being BPTB and four-strand HT.[20] Recently, there has been renewed interest in quadriceps tendon autograft. There are advantages and disadvantages of each graft choice, which should be discussed with the patient preoperatively.

Clinical comment

Some experts favor BPTB because of faster graft incorporation, potential for lower risk of graft rupture, and postoperative hamstring weakness.[21] However, BPTB is generally considered to have higher donor site morbidity.[9] Experts favoring HT autograft cite lower donor site

morbidity, particularly reduced incidence of anterior knee pain, osteoarthritis, and extensor mechanism weakness.[9]

The quadriceps tendon is the least investigated and used autograft for primary anterior cruciate ligament reconstruction (ACLR).[20] However, there has been increased interest due to the potential for larger cross-sectional area, less extensor mechanism disruption, and overall lower donor-site morbidity.[22,23]

Available literature and quality of the evidence

A meta-analysis by Samuelsen et al. (level III) analyzed 14 RCTs, 10 prospective comparative studies, and one high-quality national data study with a total of 47 613 patients undergoing either BPTB or HT reconstruction.[21] They found a small but statistically significant higher failure rate in HT when compared to BPTB (2.84% vs 2.80%; odds ratio [OR] = 0.83; 95% confidence interval [CI]: 0.72–0.96; p = 0.01).

A recent RCT with excellent follow-up performed by Mohtadi et al. (level I) compared the results of 315 patients undergoing ACL reconstruction with BPTB, double-stranded HT, or single-bundle quadruple-stranded HT.[24] They reported significantly higher traumatic re-tear rates in both HT groups when compared to BPTB (4% vs 10%, p = 0.01). However, they also reported a significantly greater proportion of patients undergoing BPTB reconstruction reporting moderate to severe kneeling pain at five years (p = 0.029).

Literature surrounding the young, active population has demonstrated differences in re-rupture rates between BPTB and HT. Kaeding et al. (level II) prospectively followed 839 young (aged 14–22) active patients undergoing ACLR and found at six-year follow-up there was

a significant increase of re-rupture rate in HT versus BPTB (OR = 2.1; 95% CI: 1.3–3.5; p = 0.004).[25] Similarly, Salem et al. (level II) prospectively followed 256 young female athletes and found an increased re-rupture rate in HT versus BPTB in younger patients (15–20 years old, 6.4% vs 17.5%, p = 0.02) but not in older patients (20–25).[26]

The utilization of quadriceps tendon in primary ACLR has gained traction recently. Lund et al. (level I) randomized 51 patients to either BPTB or QT and found no differences in rupture rates or laxity at two-year follow-up.[27] They demonstrated significantly lower prevalence of anterior kneeling pain in QT versus BPTB (7% vs 34%). Cavaignac et al. (level III) reviewed 86 patients undergoing QT versus HT ACLR and reported improved functional outcomes with the QT with no differences in re-operation.[28] Mouarbes et al. (level II) performed a meta-analysis comparing failure rates and functional outcomes of QT versus BPTB and QT versus HT.[29] They demonstrated no difference in failure rates of QT when compared to BPTB or HT. They found that QT showed significantly less harvest site pain when compared to BPTB (RR for QT vs BPTB groups, 0.25; 95% CI: 0.18–0.36; p = 0.00001). They also demonstrated improved functional outcome scores when comparing QT to HT (mean difference between QT and HT groups, 3.81; 95% CI: 0.45–7.17; p = 0.03).

When utilizing HT autograft, smaller graft size has been associated with increased failure rates in ACLR.[30] This has prompted investigation into combined autograft–allograft hybrid HT to increase graft diameter, increasing strength, and potentially reducing failure rates.[31],[32] The only RCT published to date, by Li et al. (level I), to compare HT autograft with a hybrid autograft–allograft HT demonstrated no significant differences between the two groups at five-year follow-up.[33] Similarly, a meta-analysis

by Abouljoud et al. (level III) demonstrated no evidence of differences in graft failure between HT autograft and hybrid graft despite a significantly larger graft diameter in the hybrid group.[34]

Findings

Overall, there is level I–II evidence demonstrating lower failure rates when comparing BPTB to HT autografts in ACLR.[21,24] However, both appear to have high success rates and are acceptable options. In young, active populations there is level II evidence demonstrating significantly higher re-rupture rates in HT versus BPTB.[25,26] There is level I evidence demonstrating higher prevalence of anterior knee pain in BPTB versus HT autografts.[24,35] There is level II evidence suggesting that QT is a viable autograft alternative when compared to HT and BPTB autografts when comparing re-tear rates. QT has lower donor site morbidity compared to BPTB and higher functional outcome scores when compared to HT autograft.[27–29] There is level I evidence demonstrating that hybrid graft does not affect graft failure rates when compared to HT autograft.[33]

Resolution of clinical scenario

- Level I–II evidence suggests slightly higher rupture rates in HT when compared to BPTB.[21,24] Level II evidence exists suggesting higher re-rupture rates with HT when compared to BPTB in a young, active population.
- Level I evidence demonstrates higher prevalence of anterior knee pain in BPTB versus HT autograft.[24]
- Level II evidence suggests that QT is a viable alternative to both BPTB and HT and has low re-tear

rates and a more favorable donor site morbidity profile.[27,29]

- Level I evidence demonstrating no difference in graft failure when comparing hybrid graft with HT autograft.[33]

Question 3: In patients undergoing ACL reconstruction, does early surgical intervention improve outcomes compared to delayed reconstruction in both skeletally mature and immature patients?

Rationale

There is still considerable debate regarding the optimal timing of ACL reconstruction in both the skeletally mature and immature populations.

Clinical comment

In the skeletally mature population, proponents of delayed reconstruction cite the risk of arthrofibrosis, subsequent postoperative stiffness and loss of terminal extension which is associated with poor outcomes.[36,37] In contrast, some experts advocate for early reconstruction to reduce the risk of further meniscal or cartilage damage second to instability.[38,39] There is considerable heterogeneity in the literature regarding the definition of early versus delayed reconstruction.[40–43]

In skeletally immature patients, some experts advocate for delayed reconstruction to avoid iatrogenic disturbances to the growth plate as well as the ability to comply with

postoperative rehabilitation.[44],[45] Those in favor of early reconstruction cite the concern of secondary meniscal and chondral damage as a result of ongoing instability.[46]–[49]

Available literature and quality of the evidence

Bottoni et al. (level I) randomized 69 patients to either acute (<3 weeks) or delayed (>6 weeks) ACLR and found no significant differences in postoperative range of motion, articular cartilage damage meniscal between the two groups at an average of one-year follow-up.[41] Lee et al. (level II) performed a meta-analysis on six level I RCTs and one level II cohort study comparing early (nine days to five months) and delayed (10 weeks ≥24 months, mean of 10 weeks).[40] Pooled analysis of included level I studies demonstrated no difference in postoperative clinical outcomes or stability. Differences in chondral or meniscal damage was not assessed.

Granan et al. (level II) performed a cohort study using registry data to assess the relationship between timing of repair and risk of meniscal tears or cartilage damage.[39] A total of 3475 patients were evaluated and they determined that in the adult population (>16) the odds of a cartilage lesion increased by 1.006 (95% CI: 1.003–1.010) for each month that elapsed from injury to surgery. Church and Keating (level III) retrospectively reviewed the incidence of meniscal tears and degenerative changes in patients undergoing ACL reconstruction within 12 months of the injury compared to beyond 12 months.[50] They found a significant increase in both meniscal tears (71.2% vs 41.7%; $p < 0.001$) and degenerative changes (31.3% vs 10.7%; $p < 0.001$) in the delayed group.

There are currently no modern RCTs evaluating the effects of timing of reconstruction in the skeletally immature population. Dumont et al. (level III) retrospectively

reviewed 370 skeletally immature patients undergoing early (<150 days) versus delayed (>150 days) treatment and compared rate of meniscal and chondral injuries.[47] They found a significant increase in medial meniscal tears in the delayed group compared to early reconstruction (53.5% vs 37.8%, p = 0.014; OR = 1.8; 95% CI: 1.12–2.83). The presence of chondral injuries was significantly associated with the presence of meniscal tear in the same compartment. A meta-analysis by Kay et al. (level IV) pooled the results of nine level III–IV studies of 1353 children and adolescents undergoing early or delayed ACLR.[49] There was a significant reduction in medial meniscal tears in early compared to delayed reconstruction (26% vs 47%, pooled RR = 0.49; 95% CI 0.36–0.65, p <0.00001). There was a significant reduction in chondral lesions in the early reconstruction group compared to the delayed group.

Findings

Overall, in the adult population, there appears to be no difference in postoperative functional outcomes or stability in early versus delayed reconstruction. There is level I evidence that there is no difference in chondral or meniscal damage when reconstruction takes place at three versus six weeks postinjury. There are registry data indicating that there is increased risk of chondral and meniscal damage when reconstruction is delayed in the adult population. In the pediatric population, the evidence suggests that early reconstruction is associated with reduced meniscal and chondral injuries.

Resolution of clinical scenario

- Level I–II evidence demonstrates that there is no differences in postoperative functional outcomes or

stability in early versus delayed ACL reconstruction in the adult population.[40],[41] There is considerable heterogeneity in the definition of delayed or early reconstruction.

- Level II–III evidence demonstrates that delayed reconstruction is associated with higher rates of meniscal and chondral damage in skeletally mature patients.[39],[50]
- Level III–IV demonstrates that in the pediatric and adolescent population there is increased risk of meniscal and chondral damage with delayed reconstruction.[47],[49]

Summary of answers

- Autografts may have a lower failure rate when compared to allografts, especially in the young, active population. However, autografts have higher donor site morbidity.
- BPTB have a slightly lower re-rupture rate when compared to HT. QT has comparable re-rupture rates when compared to BPTB and HT with lower donor site morbidity.
- BPTB autografts have a higher prevalence of long-term anterior knee pain when compared to allografts, HT autograft, and QT autograft.
- Delaying reconstruction does not seem to affect postoperative functional outcomes in an adult population. There may be a reduction in concomitant medial meniscal tears with early reconstruction.
- In a pediatric and adolescent population, early reconstruction is favored and has been shown to reduce

the prevalence of meniscal tears and chondral damage.

- Concomitant anterolateral ligament reconstruction or lateral extra-articular tenodesis reduces postoperative instability and re-rupture rates in young patients at a high risk of graft failure.

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136 Posterior Cruciate Ligament Injuries

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Clinical scenario

- A 19-year-old male soccer goalkeeper hit on left anterior shin while jumping with knees flexed trying to catch a ball.
- Sudden onset pain in left knee joint and inability to play the rest of the game.
- On assessment, patient has an effusion in the left knee joint, lack of full extension, and 9 mm of anterior posterior laxity.
- No fractures on plain film radiographs.

Top three questions

1. In patients with a posterior cruciate ligament (PCL) injury, how accurate is the clinical examination in the diagnosis of PCL injury compared to magnetic resonance imaging (MRI)?
2. In patients with isolated PCL injury, does reconstruction surgery result in improved patient-

centered outcomes compared to nonoperative management?

3. In patients with isolated PCL injury, does a double-bundle (DB) reconstruction technique result in improved patient-centered outcomes compared to a single-bundle (SB) reconstruction technique?

Question 1: In patients with a posterior cruciate ligament (PCL) injury, how accurate is the clinical examination in the diagnosis of PCL injury compared to magnetic resonance imaging (MRI)?

Rationale

The ability to accurately diagnose a PCL tear in both the acute and the chronic setting is essential in guiding treatment by an orthopedic surgeon.

Clinical comment

PCL injury is often overlooked by both patients and clinicians, and for this reason it is important that sensitive and specific tools are used in the diagnostic process.[1] There is large variability in the reported rate of injury to the PCL with numbers ranging between 1 and 44% of all acute knee injuries depending on the population studied.[2–4] The sensitivity, specificity, and accuracy of MRI have been found to approach 100% in the diagnosis of PCL injuries.[5] However, accurate diagnosis via clinical exam would increase the ease and cost-effectiveness of diagnosis and could facilitate the earlier detection and treatment of PCL injuries.

Available literature and quality of the evidence

- Level I: 1 retrospective cohort examining accuracy of MRI[5] and 1 randomized controlled trial (RCT) examining physical exam versus MRI.[6]
- Level III: 1 systematic review examining physical exam versus reference standard: arthrotomy, arthroscopy, or MRI.[7]
- Level IV: 3 case series examining accuracy of MRI.[8–10]

Findings

The last double-blinded, RCT examining clinical tests for PCL insufficiency was performed in 1994 by Rubinstein et al.[6] Using direct comparison to MRI, the study found that there was a 96% overall clinical examination accuracy in diagnosing chronic PCL injuries amongst sports medicine fellowship-trained orthopedic surgeons, with a 90% sensitivity and 99% specificity in detecting a PCL tear. However, interobserver disagreement about the grade of injury existed in 19% of cases. The posterior drawer test was found to be the most sensitive and specific clinical test; however, for grade 1 laxity it was found to only have a sensitivity of 70%. A systematic review of level II and III studies by Kopkow et al. concluded that the diagnostic accuracy of physical exam tests for PCL injury was largely unknown due to poor quality evidence with high risk of bias.[7] Multiple level III[5] and IV[8,9] studies have suggested that the accuracy of MRI for the diagnosis of acute PCL injury approaches 100%. Its accuracy for chronic PCL injuries, on the other hand, has been shown to be as low as 57% in a level IV case series by Servant et al.[10]

Another method of diagnosis to consider for PCL injuries not included in the studies above is posterior stress

radiography, which can be superior to arthrometric evaluation in quantifying posterior tibial translation.[11] Its efficacy and comparison to MRI need to be studied further.

Resolution of clinical scenario

- One level I study suggests that the overall clinical examination accuracy in diagnosing chronic PCL injuries is excellent (96%).
- The majority of studies examining diagnostic accuracy of physical exam for PCL injury are old and contain high risk of bias.
- Level III and IV studies suggest the accuracy, specificity, and sensitivity of MRI in detecting acute PCL injury approaches 100% but is much less accurate for chronic PCL injury.
- Return to case: for the male goalkeeper with a mechanism of injury concerning for PCL injury, MRI would be helpful in the acute setting for diagnosis. Clinical examination is nearly as accurate as MRI if assessed in the chronic setting. However, MRI may still be helpful to rule out associated pathology, such as posterolateral corner (PLC) injury, or for preoperative planning.

Question 2: In patients with isolated PCL injury, does reconstruction surgery result in improved patient-centered outcomes compared to nonoperative management?

Rationale

All surgical procedures pose a risk to the patient. The orthopedic surgeon needs relevant evidence-based data on long-term outcomes and risks in order to determine whether the benefit of surgical reconstruction is greater than conservative treatment and whether the risk/benefit ratio is justifiable.

Clinical comment

PCL injuries can be classified based on grade. A grade 1 PCL injury has 1–5 mm of posterior translation of the tibia on the femur on posterior drawer test as compared to the contralateral knee, grade 2 has 6–10 mm of translation, and grade 3 has >10 mm.[12] Typically, nonsurgical management has been advocated for patients with isolated grade 1 or 2 PCL injuries or for those who have grade 3 injuries with mild symptoms or low activity demands.[13] Nonoperative treatment involves use of a dynamic anterior drawer brace and focused rehabilitation.

Available literature and quality of the evidence

- Level III: 2 retrospective cohort studies.[14],[15]
- Level IV: 3 case series on outcomes of nonoperative management of isolated PCL injury.[12],[16],[17]
- Level IV: 1 systematic review of level III and IV studies comparing long-term outcomes after operative and nonoperative management of isolated PCL injuries.[18]

Findings

In a retrospective comparative cohort study of 4169 patients, Wang et al. evaluated long-term results of PCL deficiency and found that patients with PCL reconstruction had a decreased cumulative incidence of meniscus tear (0.41%), osteoarthritis (OA) (2.30%), and subsequent total

knee replacement (TKR) (0.48%) compared with patients who were treated nonoperatively (2.44%, 3.46%, 1.69%; all $p < 0.05$).[14] After adjusting for covariates, PCL-injured patients who underwent reconstruction within one year after PCL injury showed a significantly lower risk of these aforementioned sequelae than those who never underwent reconstruction (within one month: adjusted hazard ratio [HR] = 0.390; 95% confidence interval [CI] = 0.284–0.535; one month to one year: adjusted HR = 0.546; 95% CI = 0.398–0.748). The study did not specify the initial grade of PCL injury. Another retrospective cohort, by Patel et al., followed 57 patients (58 knees) with isolated grade 1 or 2 PCL injuries treated nonoperatively with rehabilitation programs over a mean 6.9 years.[15] At latest follow-up, 66% of patients had no knee pain and 10% had moderate knee pain on exertion. Lysholm-II knee scores were excellent in 23 knees (40%), good in 30 knees (52%), fair in two knees (3%), and poor in three knees (5%). No statistically significant correlation ($p = 0.097$) was seen between the grade of PCL laxity and Lysholm-II knee score. Shelbourne et al. also found no correlation between knee laxity and subjective knee scores or radiographic changes in a 10-year follow-up case series of 68 patients who underwent nonsurgical treatment of acute, isolated grade 1 or 2 PCL injuries.[16] On the other hand, a case series by Keller et al. of patients with PCL tears treated nonoperatively reported that those with greater ligamentous laxity had more subjective complaints, lower overall knee scores, and were less likely to return to their preinjury activity level.[12] However, unlike the aforementioned studies, Keller et al. also included patients with grade 3 initial knee laxity. Jacobi et al. found the use of dynamic PCL bracing for four months after isolated acute PCL injury significantly reduced initial posterior sag from 7.1 mm to 2.3 mm at 12

months and restored continuity of PCL on MRI in 95% of patients at six months.[17]

Although no level I comparative studies between operative and nonoperative management for PCL injuries have been done, a systematic review of 12 level III and IV studies by Shelbourne et al. in 2017 reported that Tegner scores, International Knee Documentation Committee (IKDC) scores, and Lysholm scores were comparable between operative (n = 6) and non-operative (n = 66) studies (Table 136.1).[18] The authors concluded that, outside of laxity, nonoperative management of isolated PCL tears compared favorably with the long-term results of operative management.

Table 136.1 Summary of outcomes from a systematic review by Shelbourne et al.[18]

Outcomes at final follow-up	Nonoperative studies	Operative studies
Final follow-up times (years)	6.2–15	6.3–12
Tegner scores	6.6–7.7	5.7–7.4
IKDC scores	73.4, 82.7, 84	65, 87
Lysholm scores	85.2	81–92.1
Rates of osteoarthritis	17–88%	13.3–63.6%

Resolution of clinical scenario

- Level III evidence suggests PCL reconstruction may decrease the cumulative incidence of meniscal tears, OA, and subsequent TKR in the long term; however, grade of initial injury was not specified.
- Level III and IV evidence suggests that nonoperative management of grade 1 or 2 PCL tears results in

comparable functional outcome scores as operative management in the long term. It should be noted that these studies did not include bony avulsions of the PCL, for which surgical management is typically advocated.[13]

- Level III evidence suggests that treating grade 1 or 2 PCL injuries with bracing significantly reduces initial posterior sag and restores continuity of PCL on MRI in the majority of patients.
- Return to case: the goalkeeper is found to have an isolated PCL injury with 9 mm of anterior posterior laxity (grade 2). He is treated nonoperatively with a dynamic anterior drawer brace and sent for functional rehabilitation.

Question 3: In patients with isolated PCL injury, does a double-bundle (DB) reconstruction technique result in improved patient-centered outcomes compared to a single-bundle (SB) reconstruction technique?

Rationale

A number of different surgical techniques exist to reconstruct the PCL. Understanding the patient-important outcomes associated with these techniques and whether one is superior can help orthopedic surgeons choose the best operative technique.

Clinical comment

Surgical management of isolated PCL injuries is typically reserved for patients with symptomatic grade 3 injuries who continue to have pain or clinical instability despite nonoperative management.[13] One of the main controversies regarding surgical technique for posterior cruciate ligament reconstruction (PCLR) include use of an SB or DB technique. An SB technique reconstructs only the anterolateral bundle (ALB) of the PCL, while a DB technique aims to restore normal anatomy and native knee kinematics by reconstructing both the ALB and the posteromedial bundle (PMB).[19] These can be further modified by utilizing a transtibial technique or tibial inlay technique. Transtibial technique involves centering the femoral and tibial tunnels on the ALB footprint, for which concern has been reported regarding the sharp angle that the PCL graft forms at the proximal aperture of the tibial tunnel. Thus, the tibial inlay technique was developed, which involves securing a bone plug with a cannulated screw in a bone trough created in the tibial PCL attachment site.[20]

Available literature and quality of the evidence

- Level III: 1 systematic review and meta-analysis comparing SB PCLR to DB technique,[21] 1 systematic review,[22] 3 prospective RCTs, 8 case-control studies, 7 retrospective cohort studies.

Findings

A systematic review and meta-analysis of level II and III studies (n = 441 patients) by Chahla et al. compared SB and DB PCLR techniques at minimum two-year follow-up. The authors found significantly improved objective posterior tibial stability and objective IKDC scores in the DB cohort, but no significant differences in postoperative

Lysholm or Tegner scores.[21] Focusing on the randomized trials, Wang et al. found no difference in functional assessment, posterior tibial translation, knee scores, or radiographic changes between SB and DB PCLR.[23] However, both Yoon et al. and Li et al. reported significant decreases in posterior tibial translation with DB technique compared to SB.[24],[25] Whether this difference in posterior translation is clinically significant is unknown.

A limitation when comparing SB to DB PCLR in the aforementioned studies is the variation in use of transtibial and tibial inlay techniques. However, whether utilizing these different techniques will influence clinical outcomes is unclear. A systematic review of seven retrospective studies (n = 149 patients transtibial, 148 patients tibial inlay) found no clinically important differences between transtibial and tibial inlay techniques, including Tegner or Lysholm scores or residual laxity.[22]

Resolution of clinical scenario

- Currently, the literature is lacking any level I clinical studies to definitively determine the superiority of a specific PCLR technique, including SB versus DB and transtibial versus tibial inlay techniques.
- Level III evidence suggests the DB technique improves objective posterior tibial stability relative to SB technique, but the clinical relevance of this remains unclear. There is no significant difference found in Lysholm or Tegner scores.
- Return to case: after four months of intensive physiotherapy and bracing, the patient has not been able to fully return to sport at his previous level and returns to the clinic. Posterior laxity is now approximately 11 mm (grade 3) and a reconstruction is

planned. The surgeon decides to do an arthroscopic SB transtibial PCLR, as this is the surgeon's preferred technique and no one technique has been shown to be superior in the literature.

Summary of answers

- The overall clinical knee examination has a 96% accuracy in diagnosing chronic PCL injuries.
- Low-quality evidence suggests the accuracy, specificity, and sensitivity of MRI for diagnosis of acute PCL injuries approaches 100%, but is less accurate for chronic injuries.
- Grade 1 and 2 PCL injuries treated nonoperatively have comparable long-term knee function scores as those treated operatively.
- Low-quality evidence suggests PCL reconstruction could decrease the cumulative incidence of meniscal tears, OA, and subsequent TKR in the long term.
- DB PCLR may improve objective posterior tibial stability relative to SB PCLR, but there is no clinical difference in Lysholm or Tegner scores.
- Future high-quality studies are needed to determine the superiority of one PCLR technique over the others.

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137 Combined Anterior Cruciate Ligament and Medial Collateral Ligament Injuries

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Clinical scenario

- A 27-year-old woman presents to the outpatient clinic with pain and giving way in her left knee. The patient mentions having fallen while skiing two months before. At the time of the injury, she heard a “pop” followed by about four days of knee pain and swelling, forcing her to remain immobile.
- On examination, abnormal anterior laxity was detected in the injured left knee. In addition, there is a grade III positive valgus stress test.
- Two weeks after the trauma, feeling well, the patient resumed playing sports. While playing basketball, she experienced the first episode of her knee giving way.
- Magnetic resonance imaging (MRI) confirms the diagnosis of a combined anterior cruciate ligament and medial collateral ligament (ACL+MCL) injury.
- The patient undergoes surgical treatment with an arthroscopic reconstruction of the ACL, and open repair of the MCL.

Top three questions

1. In patients with ACL+MCL tears, are some clinical examination maneuvers more accurate in terms of diagnostic ability compared to others?
2. Are there any specific risk factors that predispose individuals to combined ACL+MCL injuries?
3. In patients with ACL+MCL tears, does a specific treatment result in better clinical outcomes compared to others?

Question 1: In patients with ACL+MCL tears, are some clinical examination maneuvers more accurate in terms of diagnostic ability compared to others?

Rationale

It is important to know how to accurately diagnose a combined ACL+MCL injury, since clinical examination plays a crucial role in the diagnosis. Advanced imaging (i.e. MRI) is appropriate, but should not replace a thorough history and physical examination.[1]

Clinical comment

Many clinical diagnostic tests are available to diagnose ligamentous injuries, and they require a thorough understanding of the anatomy and the biomechanics of the joint. The most commonly used are the valgus stress test (Table 137.1), Lachman test, and the anterior drawer test.

Table 137.1 Classical method of grading MCL injuries using the valgus stress test. Source: Adapted from Reider[2] and Bollier and Smith.[3]

Grade I	MCL is tender and swollen but exhibits no increased laxity; it signifies a partial injury to some fibers without elongation of ligament
Grade II	MCL is elongated but not completely disrupted; there is increased tenderness and laxity to the valgus stress test but with a firm endpoint
Grade III	MCL has lost all structural integrity so there is laxity without endpoint and instability • 1+ (3–5 mm) • 2+ (6–10 mm) • 3+ (>10 mm)

Available literature and quality of the evidence

Levels I–V evidence exists to answer this question.

Findings

A case series study by Kastelein et al. evaluated the reliability of pain valgus stress test (PVST) and laxity valgus stress test (LVST) comparing

them with MRI data.[4] The sensitivity and specificity were 0.78 (0.64–0.92) and 0.67 (0.57–0.76), respectively, for PVST and 0.91 (0.81–1.00) and 0.49 (0.39–0.59), respectively, for the LVST.

The valgus stress test is the best way to assess the competency of the MCL complex (superficial and deep MCL fibers). Pain or laxity with valgus stress applied through the knee indicates an MCL injury, and it allows the clinician to establish the degree of the lesion.[2]

The Lachman test and the anterior drawer tests are the most common tests for diagnosing anterior instability of the knee. A systematic review and meta-analysis by Huang et al. showed good reliability of these tests in diagnosing ACL injuries.[5] The Lachman test sensitivity ranges from 0.84 to 0.9 and the specificity from 0.89 to 0.93. The sensitivity of the anterior drawer test ranges from 0.69 to 0.76 and the specificity from 0.91 to 0.94.

The pivot shift test is a dynamic test that demonstrates the subluxation occurring when the ACL is nonfunctional.[3] The sensitivity of the pivot shift test ranges from 0.43 to 0.55, and the specificity from 0.95 to 0.99.[4]

Overall, many clinical diagnostic tests are available to diagnose ligamentous injuries. Level IV[4] and V[2] evidence suggests that PVSTs and LVSTs have a high sensitivity in detecting ACL+MCL tears, and can establish the degree of the lesion. Level I evidence suggests that the Lachman test have high sensitivity and specificity, while the anterior drawer test shows good sensitivity and high specificity.[5] Level I evidence also suggests that the pivot shift test shows a low sensitivity and a high specificity.[5]

Resolution of clinical scenario

- Level IV and V evidence demonstrates that suspected MCL lesions should be assessed by the valgus stress test for the MCL.
- Level I evidence demonstrates that suspected ACL lesions should be assessed by the Lachman test, the anterior drawer test, and the pivot shift test.

Question 2: Are there any specific risk factors that predispose individuals to combined ACL+MCL injuries?

Rationale

Sport is an important risk factor for ACL+MCL injuries, but many recent studies showed that sex and anatomical features can also predispose patients to ligament rupture.

Clinical comment

ACL tear is a multifactorial injury involving biomechanical, neuromuscular, hormonal, anatomical, and genetic mechanisms.[6] Risk factors can lead to poor control and high mechanical loads on both ACL and MCL during athletic movements like landing, cutting, pivoting, and twisting.[7] In particular, females, with maturity, experience worsening of their neuromuscular joint control.[8]

Available literature and quality of the evidence

Level I–V evidence exists to answer this question.

Findings

The ACL injury rate for female athletes is often reported as being 2–8 times higher than the rate for male athletes in the same sport at the same level of competition.[9–11]

Recent controlled laboratory studies focused on the influence of loading on the ACL and MCL,[12–15] and demonstrated that both ligaments experience strains during multiplanar simulated jump landing, with the ACL being loaded more and expressing larger peak strains than the MCL during physiologic athletic tasks.

Schilaty et al. performed two controlled laboratory studies on cadaveric specimens which confirmed that females experience a greater strain on the ACL when compared to males during simulated jump landing tasks, but that there were no differences in MCL loading between sexes, with only a minimal increase of MCL loading during the impact forces.[16,17]

Some studies have demonstrated that narrow intercondylar notch dimensions are associated with the risk of ACL injury, and that lower intercondylar notch width index (NWI) and intercondylar notch width (NW) stenosis predispose to ACL injury.[18,19]

Overall, level II evidence suggests that female athletes have the highest risk of ACL injury.[7,11]

Level V evidence suggests that both ACL and MCL experience strains during multiplanar simulated jump landing,[12–15] and that females experience a greater strain on the ACL when compared to males during simulated jump landing tasks, with no differences in MCL loading between sexes.[16,17] Level I[18] and level III[19] evidences suggest that

narrow intercondylar notch dimensions are associated with the risk of ACL injury.

Resolution of clinical scenario

- Level II, III, and V evidence demonstrates that a combined ACL–MCL lesion should be suspected in athletes (especially if female) with well-recognized risk factors playing sports that have a high risk for ligament injuries.
- Level I and III evidence demonstrates that a combined ACL–MCL lesion should be suspected in patients with a narrow femoral intercondylar notch or in whom diagnostic tools such as MRI show a smaller NWI.

Question 3: In patients with ACL+MCL tears, does a specific treatment result in better clinical outcomes compared to others?

Rationale

It is important to know the treatment options for combined ACL+MCL tears; the options vary depending on the grades of lesion in each ligament.

Clinical comment

Currently, the described options are as follows: full conservative MCL–ACL treatment, full surgical MCL–ACL treatment, combined surgical MCL and conservative ACL treatment, and combined conservative MCL and surgical ACL treatment. Table 137.2 summarizes the available literature.

Table 137.2 Relevant data of each study on ACL+MCL combined tears.

Author	n	MCL Grade diagnosis		Treatment MCL injury	ACL injury	Outcome
Blanke et al.[21]	**5**	**II**	**MVST and IKDC grading**	**Surgery**	**Surgery**	At final follow-up all patients had no problems in activities of daily living with normal ROM. All patients reached full range of motion in flexion and extension equivalent to grade A according to IKDC score
Dong et al.[24]	**69**	**III**	**MVST, radiographic stress-position imaging, and IKDC grading**	**Surgery**	**Surgery**	At follow-up, 89% of patients group had returned to a normal or nearly normal level of sports participation. Most patients showed no signs of trouble during their daily routine, with normal or nearly normal ROM

Author	n	MCL Grade diagnosis		Treatment MCL injury	ACL injury	Outcome
Ateschrang et al.[27]	**16**	**II–III**	**MVST at 0° and 30°, and valgus stress radiograph at 0° and 20°**	**Surgery**	**Surgery**	ROM improved gradually after 6 and 12 weeks postoperatively, resulting in good function after one year. Knee range of motion was reduced slightly after three months postoperatively and nearly normal at one-year follow-up
Blanke et al.[22]	**67**	**I–III**	**MVST at 0° and 30° and IKDC grading**	**Combined**	**Surgery**	At the final follow-up, all patients had no problems in activities of daily life with normal or nearly normal ROM. All the patients had returned to performing at a normal or nearly normal level of sports

Author	n	MCL Grade diagnosis		Treatment MCL injury	ACL injury	Outcome
Piątkowski et al.[30]	**27**	**III**	**MVST at 0° and flexion, and MRI**	**Surgery**	**Surgery**	Good and very good functional outcomes in the Lysholm scale were seen in 74% of the sample. Good and excellent outcomes were achieved by 63% of the patients in the IKDC scale. There were three cases of major ROM limitation

Author	n	MCL Grade diagnosis		Treatment MCL injury	ACL injury	Outcome
Zhang et al.[23]	**21**	**II–III**	**Valgus stress radiograph at 20°, MRI, and IKDC grading**	**Surgery**	**Surgery**	At follow-up, no patient exhibited anteromedial rotatory instability (AMRI), and 95% of patients had full ROM of the affected knee. The 90% of patients returned to their preinjury activity level postoperatively, whereas two patients were still participating at a lower activity level and complained of pain in the knee

Author	n	MCL Grade diagnosis		Treatment MCL injury	ACL injury	Outcome
Koga et al.[25]	**17**	**III**	**MVST at 0° and 30°**	**Surgery**	**Surgery**	Almost all patients recovered sufficient valgus stability in valgus stress radiograph, and the median Lysholm score was 91. Valgus laxity with concurrent residual laxity of reconstructed cruciate ligaments progressed in two patients postoperatively

Author	n	MCL Grade	diagnosis	Treatment MCL injury	ACL injury	Outcome
Liu et al.[26]	**7**	**—**	**Valgus stress radiograph at 20°, IKDC grading**	**Surgery**	**Surgery**	At the final follow-up, almost all patients had improved in terms of valgus laxity, and both the IKDC subjective scores and Lysholm scores significantly improved postoperatively. None of the patients had limitations of knee extension, and the patients did not complain of subjective functional knee problems

Author	n	MCL Grade diagnosis		Treatment MCL injury	ACL injury	Outcome
Kitamura et al.[32]	**16**	**III**	**Valgus stress radiograph at 20°, arthroscopy, and IKDC grading**	**Surgery**	**Surgery**	At the final follow-up, one patient showed a loss of knee extension of more than three. Lysholm scores averaged 94.8 points. In the IKDC evaluation, most patients were graded as A or B. The clinical outcome with a minimum two-year follow-up was favorable with satisfactory stability

Author	n	MCL Grade diagnosis		Treatment MCL injury	ACL injury	Outcome
Marx and Hetsroni[29]	**13**	**III**	**MVST, arthroscopy**	**Surgery**	**Surgery**	Knee motion was maintained in nearly all cases. Grade 0–1+ valgus stability was obtained in all cases. In cases of MCL with primary ACL reconstruction, IKDC subjective, Lysholm, and KOOS sports scores were 91 ± 6, 92 ± 6, and 93 ± 12, respectively, and return to preinjury activity levels was achieved

Author	n	MCL Grade diagnosis		Treatment MCL injury	ACL injury	Outcome
Dong et al.[28]	**29**	**—**	**MVST, radiographic stress-position imaging, and IKDC grading**	**Surgery**	**Surgery**	Most patients had normal or nearly normal range of motion of the knee joint. In 83.9% of patients the symptoms were graded as normal or nearly normal according to IKDC symptom scores. The 91.1% of patients had returned to performing at a normal or nearly normal level of sports

Author	n	MCL Grade diagnosis		Treatment MCL injury	ACL injury	Outcome
Westermann et al.[31]	**27**	**III**	**KOOS, IKDC, and Marx activity scores**	**Combined**	**Surgery**	At the baseline, lower KOOS and IKDC scores were seen in patients who underwent operative MCL treatment. At two years the nonoperative MCL cohort maintained significantly better KOOS Sports Rec (88.2 vs 74.4), KOOS QOL (81.3 vs 68.4), and IKDC (87.6 vs 76.0) scores compared to the MCL surgery group. Marx activity scores were equal between groups at the time of study enrollment; however, patients who underwent operative MCL management had lower activity scores at two years (6.5 vs 10.7)

IKDC, International Knee Documentation Committee score; MVST, manual valgus stress test; ROM, range of motion; KOOS, Knee injury and Osteoarthritis Outcome Score.

Available literature and quality of the evidence

Level I–IV evidence exists to answer this question.

Findings

Grade I MCL lesions

While surgical treatment of an ACL rupture is well established to allow individuals to return to demanding activities, the treatment of concomitant MCL lesions is controversial. Conservative treatment of concomitant grade I MCL injuries is generally advised, given the good healing potential of this ligament.[20–26]

Grade II MCL lesions

The optimal treatment regimen of concomitant grade II MCL lesions remains unclear, with a tendency toward surgical intervention.[20,21] However, a standard surgical technique for grade II MCL lesions does not exist. Blanke et al. suggested a surgical technique for grade II concomitant MCL lesions that improved both valgus and anterior stability, and led to excellent short-term results at final follow-up.[21]

One year later, Blanke et al. proposed a new treatment concept for concomitant lesions of the MCL and ACL: for grade II MCL lesion, they suggested conservative treatment in the absence of AMRI.[21] Surgical management was proposed in the presence of AMRI. The outcomes, at the final follow-up, were optimal for both nonoperative and operative procedures, with the former being more satisfactory. AMRI seems to be a crucial factor for the decision between the surgical and nonsurgical treatment of concomitant MCL lesions, and should be considered in the treatment decision, especially in grade II MCL lesions. The possibility of conservative treatment should be taken into account depending on patient preferences, since spontaneous healing and downgrading of the MCL lesion is possible.

Ateschrang et al. presented the first clinical results grade II and III MCL reconstruction by a novel minimally invasive ligament bracing technique in combination with a single-bundle ACL reconstruction within 14 days of injury.[27] They reported good clinical results and objectively restored knee stability without cases of knee stiffness or arthrofibrosis.

Grade III MCL lesions

In 2012, Dong et al. presented a novel triangular shape, double-bundle allograft technique with a reconstruction of chronic MCL injury in patients with medial instability of the knee, and investigated its clinical

outcomes and with a follow-up of 33 months on average.[28] They reported improved valgus and rotational stability in the short term, with patients being able to return to a normal or nearly normal levels of sports. The authors of that study also cautioned against using this technique in acute cases due to risk of scarring and stiffness.

Koga et al. treated acute cases of medial knee injury (MCL and posterior oblique ligament) combined with cruciate ligament injuries initially conservatively, followed by subsequent operative treatment for residual grade III valgus instability combined with ACL reconstructions.[25] The clinical outcomes of their surgical management strategy were reasonable in terms of restoring medial knee stability, although valgus laxity with concurrent residual laxity of reconstructed cruciate ligaments progressed in some patients.

Marx and Hetsroni evaluated 12 patients who had ACL and MCL reconstructions, with the latter being performed using Achilles allograft, small incisions, and anatomic insertions to reconstruct the MCL.[29] Patients were first treated nonoperatively for 10 weeks using braces, then underwent surgery in case of increased valgus laxity. With this combined procedure, return to preinjury activity level in recreational athletes was achieved.

The treatment approach suggested by Zhang et al. for patients with chronic combined ACL-grade III MCL tears was nonoperative treatment for the MCL and late ACL reconstruction, using bracing for six weeks to allow the MCL to heal.[23] If nonoperative treatment of the MCL failed after appropriate nonoperative management, they performed simultaneous reconstruction of both the ACL and MCL. The outcomes were improved anterior, valgus, and rotatory stability of the knee, along with good functional result at a minimum follow-up of two years.

While all the previous studies advocated nonoperative treatment as the first choice for acute MCL injury, Piątkowski et al. and Dong et al. performed their surgical treatment in the acute setting.[24],[30] They performed a two-stage operative treatment (MCL repair first, and delayed ACL repair) in patients with acute anteromedial instability of the knee. Good or very good clinical outcomes were achieved according to the International Knee Documentation Committee (IKDC) scale and the Lysholm scale. Unsatisfactory functional outcomes and risk of complications were seen more often in older patients, suggesting that this technique is currently recommended in younger individuals.

Dong et al. compared the clinical results of two techniques – the triangular ligament reconstruction (TLR, described above[28]) and the anatomic ligament repair (ALR) – in the treatment of acute grade III MCL

injury combined with an ACL tear.[24] Clinical outcomes showed no major difference in the ALR and TLR groups based on IKDC scores and medial opening evaluations in the short-term. However, TLR offered better rotatory stability than ALR at final follow-up.

Finally, Westermann et al. showed that both operative and nonoperative management of MCL tears demonstrated clinical improvements between study enrollment and two-year follow-up, but that MCL surgery during ACL reconstruction was associated with more frequent stiffness, worse patient-reported outcomes and lower activity at two years, with a higher reoperation rate for arthrofibrosis after operative repair of the MCL (19%) versus nonoperative treatment (9%).[31]

Overall, the management of combined ACL+MCL injuries is widely debated and should be tailored based on injury grade and individual goals for each patient. In combined ACL grade I MCL tears, level I[24] and level IV evidence[20–23,25,26] suggests that while the ACL is treated surgically the MCL can be treated conservatively.

In combined ACL grade II MCL tears, level II[23] and IV[19–21] evidence suggests that a clearly preferred option for grade II MCL lesions does not exist, and that the MCL can be treated both surgically or conservatively, with a recent tendency toward surgical intervention.

In combined ACL grade III MCL tears, level II[24,31] and IV[23,25,28–30] evidence suggests that grade III MCL tears can be treated nonoperatively at first (with surgery being performed later in case of failed conservative management) or surgically in the acute setting.

Given the lack of standardization in the selection process of patients, timing of surgery, surgical technique (combined or two-stage), outcome criteria, and outcome assessment, this question still remains largely unanswered.

Resolution of clinical scenario

- Level I and IV evidence demonstrates that in patients with suspected ACL–MCL injury, isolated partial and grade I injuries of the MCL can be managed nonoperatively.
- Level II and IV evidence demonstrates that there are no differences in outcomes when an ACL injury associated with grade II MCL injury is addressed by surgical reconstruction of ACL and conservative measures or surgical repair of MCL.
- Level II and IV evidence demonstrates that surgical repair for combined ACL grade III MCL injury is advocated. Early versus late ACL reconstruction is still controversial.

Summary of answers

- Suspected MCL lesions should be examined by the valgus stress test.
- Suspected ACL lesions should be examined by the Lachman test, the anterior drawer test, and the pivot shift test.
- An ACL+MCL lesion should be suspected in patients (especially if female) playing sports that have a high risk for ligament injuries, and in patients with a previous diagnosis of narrow femoral intercondylar notch or in whom diagnostic tools such as MRI show a smaller NWI.
- Isolated partial and grade I MCL injuries can be managed nonoperatively.
- There are no differences in outcomes when an ACL injury associated with grade II valgus laxity is addressed by surgical reconstruction of ACL and conservative measures or surgical repair of MCL.
- Surgical repair for combined ACL grade III MCL injury is advocated. Early versus late ACL reconstruction is still controversial.

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138 Multiligamentous Knee Injuries

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Clinical scenario

- A 32-year-old male construction worker is involved in a motor vehicle collision on the way home from work. He sustains a right femur fracture and is noted to have mild swelling around the right knee as well.
- After intramedullary nailing of the femur the next day, it is noted that the patient has gross knee instability in all directions.
- He has a normal vascular exam with 2+ pulses bilaterally for both the dorsalis pedis and posterior tibial arteries.

Top three questions

1. In patients undergoing surgical treatment for knee dislocation, does collateral ligament reconstruction result in better clinical outcome compared to repair?
2. In patients diagnosed with knee dislocation, does acute reconstruction within three weeks after the injury result in improved results compared to delayed reconstruction?
3. In patients undergoing knee surgery, does restricted blood flow therapy yield better clinical outcomes, muscle strength, and size compared to conventional rehabilitation?

Question 1: In patients undergoing surgical treatment for knee dislocation, does collateral ligament reconstruction result in better clinical outcome compared to repair?

Rationale

Traditional instruction has been that medial and lateral corners should be repaired if good quality tissue is present and the repair is accomplished within three weeks. However, the current opinion is that the failure rate is lower for both the posteromedial corners (PMCs) and posterolateral corners (PLCs) with reconstruction of the ligaments when compared with repair. Thus, it is important to understand if, and by how much, reconstruction improves clinical outcomes.

Clinical comment

Dislocation of the knee refers to a multiligamentous knee injury that frequently includes a bi-cruciate injury.[1] Commonly, knee dislocation results in disruption of at least three of the four major ligaments of the knee and leads to significant functional instability. Vascular and neurologic damage, as well as associated fractures, can complicate the treatment of the multiligament-injured knee.[2]

Early versus delayed surgery, repair versus reconstruction, and autograft versus allograft tissue for reconstruction remain topics of debate. High-quality research efforts to investigate these controversies are hampered by the heterogeneous nature of the injuries themselves, the relatively infrequent occurrence of knee dislocations, and the many treatment strategies available.[3]

Available literature and quality of the evidence

Posteromedial corner (PMC)

Stannard et al. reported a significant difference between the failure rate of PMC repairs and PMC reconstructions treated within four weeks of the injury. This study compared the outcomes in knee dislocation patients whose injury included a torn PMC. A total of 71 knee dislocation patients with 73 PMC tears qualified for the study and were followed for a mean of 43 months. A total of 25 patients had a repair, with five failures (20%), compared with 48 patients who had a reconstruction (with auto- or allograft) with only two failures (4%). Reconstruction of the PMC using a technique that re-establishes the critical triangle of the medial collateral ligament, the posterior oblique ligament, and the semitendinosus yielded better stability than repair in patients with a knee dislocation that included PMC instability.[4]

Posterolateral corner (PLC)

In direct comparisons of repair versus reconstruction, there are two publications regarding high-grade lateral/posterolateral injuries. Stannard et al. reported a significant difference in favor of reconstruction when evaluating stability and return to sport.[5] They did not detect a statistically significant difference in Lysholm, International Knee Documentation Committee (IKDC) scores, or return to work rates between the two groups of 57 knees. Levy et al. initially repaired lateral injuries before reconstruction. The 40% (4 of 10) failure rate in the repair group was reduced to a 6% (1 of 18) failure rate in the reconstruction group.[6] Due to the higher failure rate of repair compared to reconstruction (40% vs 6% in one cohort and 37% vs 9% in another cohort), repair is not currently recommended.[2],[6] However, avulsed ligaments,

particularly off the fibular head (lateral collateral ligament, LCL; popliteofibular ligament PFL, and the biceps tendon) should be repaired. Additionally, it is recommended that capsular tissue and the lateral meniscocapsular ligaments should be reattached to the bone.[7]

- Level II: 3[1],[4],[5]
- Level III: 3[2],[3],[6]
- Level V: 1.[7]

Findings

Level II evidence indicated a significant difference in objective stability with reconstruction but did not indicate a significant difference in Lysholm, IKDC scores, or return to work rates.

Resolution of clinical scenario

- Reconstruction of the PMC and PLC is recommended to avoid treatment failure.

Question 2: In patients diagnosed with knee dislocation, does acute reconstruction within three weeks after the injury result in improved results compared to delayed reconstruction?

Rationale

The timing of surgical reconstruction remains controversial. Reconstruction during the acute phase after the injury allows patients to recover from fractures and

knee reconstruction simultaneously. However, the risk of skin breakdown and arthrofibrosis may be higher during the acute inflammatory phase immediately following the injury. Early surgical reconstruction has been reported to yield better functional and clinical outcomes, and reduction of the risk of additional chondral and meniscal injuries as a result of instability.[8]

Clinical comment

Some authors have reported that early surgery resulted in arthrofibrosis, and a low rate of return to work. In contrast, delayed surgery has been reported to show restoration of preoperative knee range of motion (ROM) and reduced wound complications after resolution of swelling postoperatively.[9]

Available literature and quality of the evidence

The heterogeneous nature of knee dislocations involving more than two ligament injury combinations makes it difficult to generalize the findings of surgical outcome studies and to design and conduct prospective randomized treatment studies.

Harner et al. reported 33 patients on subjective and objective outcomes with use of four different knee rating scales at a minimum of 24 months after the operation including 19 patients treated within three weeks after injury and 12 patients treated three weeks after injury. Patients group treated within three weeks had a higher mean Knee Outcome Survey Sports Activity Score (89 vs 69, $p = 0.04$) less positive Lachman test (2+) (3 vs 6, $p = 0.04$). The mean Lysholm score (91 vs 80, $p = 0.07$) was also better in the acutely treated group. Final knee ROM was similar although four patients in the acute group

required manipulation under anesthesia for arthrofibrosis (21%).[10]

A study by Tzurbakis et al. reported statistically better clinical outcomes in terms of IKDC knee form subjective (86% vs 44%, p = 0.008) and symptom (85% vs 56%, p = 0.04) subgroups in the acute treatment group (within three weeks of injury, 35 patients) compared with the chronic group (>3 weeks following injury, nine patients) with a minimum of 24 months' follow-up. However, overall IKDC normal or near-normal rating (77% vs 55%), mean Lysholm score (88 vs 82), and final knee ROM were not significantly different.[11]

In a systematic review of 24 retrospective studies involving 396 knees, Mook et al. suggested that delayed reconstructions of severe multiligament knee injuries have equivalent outcomes in terms of stability when compared with acute surgery. However, acute surgery was associated with flexion deficits (odds ratio = 5.18; 95% confidence interval [CI]: 1.5–17.5; p = 0.004). Additional treatment for joint stiffness was significantly more likely in association with acute treatment (17%; 95% CI: 13.0–22.4%; p <0.001) when compared with chronic treatment (0% [0 of 71]; 95% CI 0.0–5.1%).[12]

- Level II: 3[8],[10],[11]
- Level III: 1[12]
- Level IV: 1.[9]

Findings

Overall, in comparative studies that have directly compared acute to chronic management of knee dislocations, there were mixed results in Lysholm, Meyers, IKDC, and Knee Outcome Survey scores.

In a systematic review, a higher portion of patients in the acutely treated group showed more flexion deficits that required additional treatment for joint stiffness.

Resolution of clinical scenario

- It is recommended that knee reconstruction should be started acutely if the patient's condition allows.

Question 3: In patients undergoing knee surgery, does restricted blood flow therapy yield better clinical outcomes, muscle strength, and size compared to conventional rehabilitation?

Rationale

Blood flow restriction (BFR) with low resistance loads is becoming popular in musculoskeletal rehabilitation, especially in the postoperative setting, in order to mitigate disuse atrophy and to promote hypertrophy following immobilization for earlier return to activities. Thus, it is clinically important to understand the application of BFR to multiligament injury of the knee that generally requires a longer time for rehabilitation.

Clinical comment

Postoperative rehabilitation of the multiligament reconstructed/repaired knee begins with restoration of motion and is followed by a gradual, progressive strengthening program.[2]

Since these patients cannot tolerate high-intensity exercise postoperatively, low-intensity exercise with BFR should be adopted while protecting reconstructed structures in an earlier phase of healing.

A low-intensity resistive load (20–50% of one-repetition maximum) with hypoxic metabolic stress induced by externally applied tourniquet around the proximal portion of the exercising limb promotes muscle hypertrophy by various physiological synergistic pathways.

Available literature and quality of the evidence

There is a lack of direct, comparative analysis in regard to the effectiveness of BFR in terms of preserving muscle mass and strength.

However, there are two level I randomized controlled trials (RCT) and one level II controlled trial that analyzed BFR rehabilitation following ACL reconstruction using hamstring tendons.

In 2000, Takarada et al. reported diminished disuse atrophy of quadriceps muscle after ACL reconstruction in cross-sectional images on magnetic resonance imaging (MRI) on postoperative day 3 and day 14. They compared two matched groups, five minutes of occlusive stimuli using a pneumatic cuff that was given to one group twice a day from day 3 to 14.[13] These stimuli were applied without the addition of a load.

Ohta et al. compared two randomized groups of ACL reconstruction patients. Occlusion stimuli were applied to one group of patients with pneumatic tourniquets and both groups followed the same training protocol. They found a statistically significant difference in quadriceps cross-sectional area on MRI scans after 16 weeks.[14]

In contrast, in 2016, Iversen et al. compared two randomized groups of athletes who underwent ACL reconstruction. Occlusive stimuli with pneumatic cuff twice a day and low-load resistance quadriceps exercises were performed from postoperative day 2 to 14. They did not find a difference regarding the reduction of quadriceps atrophy measured by MRI.[15]

In 2019, Hughes et al. compared two groups of hamstring autograft ACL reconstruction patients pre- and postoperatively during an eight-week rehabilitation program. In this randomized trial, significant and comparable increases in muscle thickness (5.8 ± 0.2% and 6.7 ± 0.3%) and pennation angle (4.1 ± 0.3% and 3.4 ± 0.1%) were observed with no difference in the BFR group (n = 14, 30% of one repetition maximum) and high load resistance exercise group. However, significantly greater increases in several measures of self-reported function (50–218 ± 48% vs 35–152 ± 56%), Y-balance performance (18–59 ± 22% vs 18–33 ± 19%), ROM (78 ± 22% vs 48 ± 13%), and reductions in knee joint pain (67 ± 15% vs 39 ± 12%) and effusion (6 ± 2% vs 2 ± 2%) were observed in the BFR group compared to high load resistance exercise group. From these observations, they suggested blood flow restricted resistance training BFR-RT may be more appropriate for early rehabilitation in ACL reconstruction patients due to the similar effect on skeletal muscle hypertrophy and strength and favorable effect on knee joint pain and effusion.[16]

A meta-analysis of 20 studies performed by Hughes et al. included an analysis of ACL reconstruction (n = 3), knee osteoarthritis (n = 3), older adults at risk of sarcopenia (n = 13), and sporadic inclusion body myositis (n = 1). Analysis of pooled data indicated low-load BFR training had a moderate effect on increasing strength (Hedges' g = 0.523; 95% CI 0.263–0.784, p <0.001), but was less

effective than heavy-load training (Hedges' g = 0.674; 95% CI: 0.296–1.052, p <0.001).[17]

- Level I: 3[13],[14],[16]
- Level II: 1[15]
- Level III: 2.[2],[17]

Findings

Overall, the literature shows that BFR with low load training rehabilitation can be effective in reducing muscle atrophy following knee surgery. And it can be hypothesized that accelerated rehabilitation with BFR can result in effective clinical outcome in the short-term follow-up. However, long-term results have yet to be published. In addition, further research is needed to establish specific protocols for postoperative rehabilitation using BFR technique including its frequency, duration, and intensity.

Resolution of clinical scenario

- Level I RCTs suggest that BFR can reduce disuse hypotrophy of quadriceps after ACL reconstruction.
- Level I RCTs suggest that BFR can be beneficial for early rehabilitation considering its favorable effect on pain and effusion.

Summary of answers

- Reconstruction of PMC and PLC is recommended to avoid treatment failure, but it does not show significantly better results in Lysholm, IKDC scores, or return to work rates.

- It is recommended that knee reconstruction should be started acutely if the patient's condition allows, but the quality of the data is low. There is a current multicenter trial that seeks to answer this question.
- BFR can be considered a promising rehabilitation method in order to preserve quadriceps muscle mass after knee surgery.

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139 Posterolateral Corner Injuries

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Clinical scenario

- A 32-year-old hockey player injured his knee after suffering a pivoting injury playing hockey one month ago.
- He now complains of posterolateral knee pain and is unable to play hockey. His knee hyperextends when going up and down stairs and gives way with twisting and pivoting activities.
- His physical exam reveals 10 mm of lateral opening on varus stress with no endpoint, a positive posterolateral drawer test, and a positive dial test at 30° of flexion.
- The patient's magnetic resonance imaging (MRI) shows complete tears of the lateral collateral ligament (LCL), popliteus tendon (PLT), and popliteofibular ligament (PFL).

Top three questions

1. In patients undergoing surgical treatment for an isolated posterolateral corner (PLC) injury, does PLC reconstruction result in superior functional outcome

scores and reduced re-rupture rates compared to PLC repair?

2. How do the functional outcomes and rupture rates in patients with isolated PLC injuries compare between surgical management and nonoperative management?
3. In patients undergoing surgical treatment for a PLC injury, do anatomic PLC reconstructions improve functional outcomes and rupture rates compared to other reconstruction techniques?

Question 1: In patients undergoing surgical treatment for an isolated posterolateral corner (PLC) injury, does PLC reconstruction result in superior functional outcome scores and reduced re-rupture rates compared to PLC repair?

Rationale

There are compelling data on acute repair versus reconstruction that will help surgeons perform procedures which yield better results.

Clinical comment

There has been much debate in the literature regarding the decision to repair or reconstruct the PLC in patients with high-grade injuries. In general, repair of the PLC involves repair of the LCL and other anatomic structures of the PLC to their anatomic locations. Multiple reconstruction techniques have been described using autogenous or allograft tendons to reconstruct the PLC.[1],[2] It should be

noted that repair of the PLC may not always be possible if surgery is performed in a delayed fashion or if the patient presents with a chronic PLC injury. Furthermore, some authors have advocated for augmenting acute repairs with reconstruction techniques.[3]

Available literature and quality of the evidence

- Level II: 1 prospective comparative cohort study.[4]
- Level III: 1 retrospective comparative cohort study.[5]

Findings

In 2005, Stannard et al. reported their prospective cohort study in which there were 57 cases of PLC injury. Of the 35 patients treated with acute (<3 weeks) repair and 22 patients treated with primary reconstruction, there were 13 (37%) and 2 (9%) failures, respectively. There was no significant difference in Lysholm scores between the two groups after revision reconstruction of the failures. However, 44 of these patients had sustained high-energy trauma resulting in multiligament knee injury. A total of 13 patients had an isolated PLC injury. Of these 13 patients, seven underwent acute repair within three weeks of injury; the remaining six underwent reconstruction. None of the six reconstructions failed, but two of the seven repairs failed.[4]

Levy et al., in 2010, reported their results on patients with multiligament knee injuries who underwent either repair (n = 10) or reconstruction (n = 18) of the posterolateral structures.[5] There were four failures in the repair group and only one failure in the reconstruction group. The difference in failure rates was found to be significant (p = 0.04). After revision reconstruction for failures there was no statistical difference found between the two groups in

terms of International Knee Documentation Committee (IKDC) or Lysholm scores. Multivariate regression analysis found that patient demographics, time to surgery, interval between stages (for the repair group), number of ligaments involved, and location of LCL/PLC tears did not affect final outcome.

Resolution of clinical scenario

- Level II and III evidence suggests that repair of the PLC results in a higher failure rate than reconstruction.
- Level II and III evidence suggests that there is no difference in functional outcomes between repair and reconstruction after revision reconstruction of failures.
- Current best evidence is limited by sample sizes and the fact that isolated high-grade PLC injuries are rare and often treated in conjunction with other knee injuries.

Question 2: How do the functional outcomes and rupture rates in patients with isolated PLC injuries compare between surgical management and nonoperative management?

Rationale

If comparable outcomes can be achieved between surgical and nonoperative management for patients with PLC injury then avoiding the risks associated with surgery would be beneficial for patients.

Clinical comment

PLC injuries are generally classified as grade I+ through 3+.[6] A grade I+ injury has 0–5 mm opening on varus stress with a definitive endpoint, grade II+ injuries have 5–10 mm opening on varus stress with a definitive endpoint, and grade III+ injuries have >10 mm opening on varus stress with no or a soft endpoint. Although surgical management of high-grade PLC injuries has generally been reported to have good outcomes, nonsurgical management may be a good option in patients with low-grade injuries or who are not suitable for surgery. Nonoperative management of PLC injuries includes extension bracing and physiotherapy.

Available literature and quality of the evidence

- Level IV: 2 retrospective case series.

Findings

Kannus reported nonoperative management for 11 grade II and 12 grade III injuries of the PLC.[7] Patients were immobilized for a variable period of time (grade II, 2–5 weeks, grade III, 2–7 weeks), followed by early rehabilitation which continued for at least six months. At follow-up (average 8.3 years) the grade II patients had generally good Lysholm scores; however, residual laxity was common (Table 139.1). Patients with grade III injuries fared more poorly and at follow-up had high rates of gross lateral laxity, post-traumatic osteoarthritis (OA), and less favorable Lysholm scores. However, it should be noted that there may have been confounding factors contributing to the poor outcomes in the patients with grade III injuries, as these patients are more likely to have concomitant injuries to other ligaments, the articular cartilage, and the meniscus.

Table 139.1 Results reported by Kannus after nonoperative management of PLC injuries. Source: Adapted from Kannus.[7]

Injury grade	Lysholm score	Return to preinjury activity	Post-traumatic OA
Grade II (n = 11)	88 (good)	9 (82%)	0 (0%)
Grade III (n = 12)	65 (fair)	2 (17%)	6 (50%)

Krukhaug et al. reported on the nonoperative management of seven patients with primary lateral instability of 1+.[8] Six patients were managed with early range of motion and one with a cylinder cast for six weeks. At follow-up (average 7.5 years), six patients had a completely stable knee on varus stressing, and one patient treated in a cylinder cast had residual laxity of 1+. Median Lysholm score for the stable patients was excellent, at 95.

Resolution of clinical scenario

- Level IV evidence suggests that grade I+ and II+ isolated PLC injuries can be treated nonoperatively.
- Level IV evidence suggests that grade III+ PLC injuries treated nonoperatively will have high rates of post-traumatic OA and gross lateral laxity and therefore operative management should be strongly considered in most patients.
- There is currently insufficient literature comparing nonoperative management to operative management of isolated grade I+ and II+ PLC injuries to make any conclusions about the superiority of one management strategy.

Question 3: In patients undergoing surgical treatment for a PLC injury, do anatomic PLC reconstructions improve functional outcomes and rupture rates compared to other reconstruction techniques?

Rationale

Strong evidence to establish the optimal technique for reconstruction of PLC injuries will allow for improved outcomes for patients.

Clinical comment

Many anatomic and nonanatomic PLC reconstruction techniques are described in the literature. Biomechanical studies have shown the LCL, the PFL, and the PLT to represent the most important structures to the stability of the PLC.[9] Anatomic posterolateral reconstructions reproduce all three of these key structures, whereas nonanatomic PLC reconstructions only aim to reproduce one or two of these structures.[10]

Available literature and quality of the evidence

- Level IV: multiple case series.
- Level III: 3 retrospective comparative cohort studies.

Findings

Various case series exist showing significant improvement in postoperative functional outcome scores using a variety of different anatomic and nonanatomic reconstruction techniques.[11–14] In all studies the number of patients was

small and the injuries sustained were varied in terms of the other associated ligamentous injuries.

Three studies have retrospectively compared clinical outcomes for different types of reconstruction techniques. Jung and coworkers reported a retrospective cohort study of patients with PCL and grade II PLC injuries.[15] In this study 19 patients underwent PLC reconstruction via a transtibial sling procedure and 20 patients via a transfibular sling procedure. The fibular head tunnel technique led to a significantly better improvement in rotational stability ($p = 0.007$), although no significant difference was found for varus stability and clinical outcome scores. Yoon et al. retrospectively compared anatomic reconstruction (n = 21) with a PLC sling procedure (n = 25).[16] They found a significantly better improvement in external rotation laxity and varus laxity with anatomic reconstruction ($p < 0.05$). The Lysholm Knee Score improved significantly in both groups ($p < 0.05$) and no significant difference was found between the two groups. Another retrospective comparative cohort compared treatment of grade III PLC injuries with either LCL and PFL reconstruction (n = 5) versus an anatomic LCL, PFL, and PLT reconstruction (n = 17). The anatomic reconstruction resulted in significantly improved side-to-side difference in lateral joint opening ($p < 0.001$); however, there was no significant difference in IKDC forms.

Resolution of clinical scenario

- Level IV evidence suggests that a number of different anatomic and nonanatomic reconstruction techniques result in significantly improved functional outcome scores and posterolateral stability postoperatively.
- Level III evidence has shown no significant difference in functional outcomes between reconstruction

techniques.

Summary of answers

- Early evidence suggests that acute (<3 weeks) PLC repair may have higher rates of failure than reconstruction; however, the same evidence suggests there is no difference in functional outcome scores after revision reconstruction of failures.
- Low-quality evidence suggests that patients have good functional outcomes and low rates of post-traumatic OA after nonoperative management of grade I+ and II+ PLC injuries.
- Grade III+ PLC injuries should generally be treated operatively as those treated nonoperatively have high rates of gross laxity and post-traumatic OA.
- There are many reconstruction techniques that have been described in the literature that result in good outcomes for the treatment of high-grade PLC injuries. There is no literature to suggest the clear superiority of one PLC reconstruction technique.
- The PLC literature as a whole is made up of low-level evidence. Interpreting the PLC literature is further complicated by the fact that isolated high-grade PLC injuries are rare and often occur in conjunction with other ligamentous knee injuries. For this reason, there is both high intra- and interstudy heterogeneity in terms of the associated injuries in patients treated for PLC injuries.

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140 Lateral Extra-Articular Tenodesis Procedures and the Anterolateral Ligament

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Clinical scenario

- A 15-year-old woman comes to your office for pain and effusion in her right knee after sustaining an injury while playing basketball (landing from a jump) four days ago.
- History and physical reveals a Lachman 2+, grade II/III pivot shift, knee hyperextension, and joint effusion. MRI confirms rupture of the ACL at the level of its femoral insertion. There is no associated meniscal injury.
- The patient is a passionate basketball player (semiprofessional) and wants to continue practicing this sport.

Top three questions

1. In patients undergoing anterior cruciate ligament reconstruction (ACLR), does the addition of lateral extra-articular tenodesis (LET), compared to ACLR alone, improve function, and return to sport results while diminishing failure rate?
2. In patients undergoing ACLR, does the addition of LET, compared to ACLR alone, reduce rotational laxity, thus

preventing osteoarthritis (OA) and meniscal lesions?

3. In patients undergoing ACLR, is there a surgical technique of LET, as an augmentation to ACLR, that has proven to have superior biomechanical and clinical results compared to other techniques?

Question 1: In patients undergoing anterior cruciate ligament reconstruction (ACLR), does the addition of lateral extra-articular tenodesis (LET), compared to ACLR alone, improve function, and return to sport results while diminishing failure rate?

Rationale

Intra-articular reconstruction has become the technique of choice to address ACL deficiency. However, intra-articular reconstruction does not restore normal knee kinematics and failure rate also remains a factor to consider in many cases, especially in high-demand young athletes.[1],[2] In the past two decades, many surgeons have recommended extra-articular reconstruction in conjunction with an intra-articular technique in order to address normal kinematics and reduce failure rate.

Clinical comment

It is our impression that the use of additional extra-articular procedures is increasing in number, especially in challenging primary cases and revisions. By attempting to control rotation laterally, further away from the pivot point

of the knee, extra-articular reconstruction may be better suited to control rotational motion by having a better lever arm.[3] A simple intra-articular procedure combined with an extra-articular augmentation may achieve better clinical results, while also diminishing failure rates.

Available literature and quality of the evidence

The quality of literature addressing results of lateral extra-articular procedures associated with ACLR is highly variable, with levels I–IV evidence. Studies lack standardization of protocols and outcomes. The majority of the outcome papers are case series or cohort studies. There are seven randomized controlled trials (RCTs),[4–10] five recent systematic reviews,[11–15] and one large trial currently underway.[16]

Findings

Randomized controlled trials

A growing number of RCTs examine the effect of extra-articular augmentation. The trials differ in the type of LET and intra-articular reconstruction, outcome measures, and definitions of failure. Drawing firm and reliable conclusions is difficult based on this current highly heterogeneous data set. In total, seven RCTs were found.[4–10] Only one study demonstrated improved patient-reported outcomes for patients undergoing ACLR associated with LET over controls(6).[6] In this study, 75 patients were randomized evenly to three treatment groups. These consisted of: (i) the Marcacci technique (ACLR+LET), (ii) a four-strand, single-bundle hamstring ACLR, or (iii) a bone–patella–bone ACLR. At five-year follow-up the LET group had higher subjective International Knee Documentation Committee (IKDC) scores and also a quicker return to sport. Later on,

some of the same authors in a different study found that, when compared to a double-bundle group, the Marcacci technique performed worse in terms of IKDC scoring and pivot shift grading.[8] Higher return to sport rates were seen in the double-bundle group, with the Marcacci cohort returning to sport more quickly.

Current trials

The Standard ACL Reconstruction versus ACL and Lateral Extra-Articular Tenodesis (STAbiLiTY) study is a recently-completed RCT of 600 divided in two groups (ACLR + modified Lemaire LET vs ACLR), focusing on high-risk patients, coordinated by the University of Western Ontario.[16] The trial includes patients 14 to 25 years old with an ACL deficient knee who play competitive pivoting sports, and have a grade 2 pivot shift or generalized ligamentous laxity. Participants are randomized to hamstring ACLR or ACLR with an iliotibial band-based LET (modified Lemaire). The primary outcome measure is graft failure at two years, with secondary outcomes being patient-reported outcome scores, objective functional outcomes, biomechanical assessment, imaging, return to activity, adverse events, and cost outcomes. Preliminary results of the trial have been presente,[17] and while the interim results should be interpreted with caution, they appear favorable for LET. Failure rates and the rate of asymmetric pivot shift are significantly lower in favor of the LET procedure. However, this appears to come at the cost of increased early morbidity, with increased pain and reduced lower limb function at three months.[17]

Resolution of clinical scenario

- Extra-articular anterolateral procedures have undergone a renaissance in combination with ACLR in

selected cases.

- Preliminary results from an ongoing clinical trials are supportive for LET when used as an augmented intra-articular ACL reconstruction in a targeted group of high-risk patients.
- Based on these findings, one can only hypothesize some potential indications for high-risk patients (professional athletes, revision cases, etc.).

Question 2: In patients undergoing ACLR, does the addition of LET, compared to ACLR alone, reduce rotational laxity, thus preventing osteoarthritis (OA) and meniscal lesions?

Rationale

Rotational stability may not be restored by intra-articular reconstruction alone. Subjectively measured as a positive pivot shift, this instability may be negatively associated with subjective and objective outcomes.[18],[19] Renewed interest in LET is based on its important role in biomechanical stability. Nevertheless, over-constraint has also been linked to OA.

Clinical comment

Despite the reported risk of joint over-constraint, consideration should be given to reconstructing the anterolateral structures and the ACL concurrently to maximally restore both anterior tibial translation and rotatory stability. However, the role of LET in improving

rotational knee stability remains a controversial subject.[12] To reduce rotational laxity might mean reducing residual pivot shift, and increasing patient satisfaction and functional stability, though it may also risk over-constraint.

Available literature and quality of the evidence

Most of the studies discussed in Question 1 also report on rotational laxity and OA, with level I–IV evidence. The same seven RCTs are available,[4–10] one meta-analysis,[14] as well as the STAbiLiTY trial.[16] Level IV evidence has been found in relation to meniscal lesions.[13,20]

Findings

Randomized controlled trials

The same seven RCT mentioned above also look into biomechanics.[4–10] Only one of those studies found statistically significant results. Vadalà et al. prospectively evaluated the role of Coker–Arnold's extra-articular procedure in reducing the incidence of a residual postoperative rotational knee laxity in female patients with ACL deficient knees who had a preoperative grade 2 or 3+ pivot shift.[9] They randomized 60 patients to four-strand hamstring ACLR with or without an extra-articular Coker–Arnold procedure. At mean follow-up of 44.4 months, a residual positive pivot shift was found in 57.1% of patients with an isolated ACLR and in 18.6% of patients with a combined ACLR and LET, thus significantly reducing the rotational instability of the knee.[9]

Meta-analysis

A meta-analysis published by Devitt et al. investigated the effect of LET augmentation in early (≤12 months) and delayed ACLR.[14] Interestingly, LET augmentation was not

effective in reducing residual pivot shift in the early ACLR group; however, there was statistically significant reduction in residual pivot shift in delayed ACLR.

Current trials

The STAbiLiTY study discussed above, includes radiographic markers of OA as a secondary outcome.[16] Preliminary results report significantly lower rates of pivot shift in favor of the LET procedure.[17] No meniscal lesions or OA markers have yet shown preliminary significant results.

Resolution of clinical scenario

- Biomechanical studies suggest that traditional lateral tenodeses are most efficient in restoring native knee kinematics in combined ACL and anterolateral injured knees.
- Reduction in pivot shift favors LET augmentation.
- In one study, ACLR + LET was not associated with an increased rate of OA of the knee in the first 11 years, but the authors found rates increased thereafter.[13]

Question 3: In patients undergoing ACLR, is there a surgical technique of LET, as an augmentation to ACLR, that has proven to have superior biomechanical and clinical results compared to other techniques?

Rationale

At least 12 procedures have been described in order to address the rotational instability that is left when performing an ACL reconstruction. Therefore, if LET as an augmentation process can be recommended in certain cases, there should also be an *ideal* LET technique. Choosing and becoming proficient in one procedure would simplify and refine a surgeon's learning curve.

Clinical comment

LET techniques have evolved by mainly altering graft choice and tibiofemoral positioning. Despite that, a significant degree of uniformity can be observed, with the extra-articular graft generally attaching distally at the Gerdy's tubercle and traveling proximally and posterolaterally toward the lateral femoral condyle.[21–31] A recent article consulting global experts on the field saw agreement that LET procedures do have a place in current ACL surgery. Lemaire tenodesis was reported as being the most used technique.[32]

Available literature and quality of the evidence

One systematic review has been done comparing biomechanical outcomes of various LET procedures.[20] Most of the evidence recorded in this review was level III–IV. No level I–II study has been done in order to compare clinical results among different LET techniques.

Findings

Among LET procedures there is no single best *evidence-based* approach, and most surgeons regularly undertake extra-articular reconstructions following a technique that is most familiar to them.[32]

Anatomical and biomechanical studies documenting LET procedures recommend fixing the graft with the tibia maintained in an externally rotated position.[21–30] However, non-neutral positioning of the tibia interferes with the *screw home* mechanism because the externally fixed graft effectively inhibits physiological rotation of the tibia about its central axis.[33] A common theme among the aforementioned studies was the nonanatomic nature of their graft placement.

Slette et al. performed a systematic review of the various LET techniques.[20] From the eight studies that analyzed rotatory movement, seven showed joint over-constraint, indicated by a significant reduction in internal rotatory movement relative to that of the native knee joint.[33–39] After a period of initial stability, LET reconstructions have often shown a tendency to elongate, with return of anterolateral rotatory instability in the ACL-deficient knee. This could theoretically be avoided by isometric placement of graft. Sidles et al. asserted that an entirely isometric LET procedure does not exist.[40] It has been reported that an increase in separation distance between the insertion points of a ligament reconstruction of 6% could lead to permanent graft elongation; therefore, appropriate graft positioning and tensioning of LET procedures are paramount in order to at least minimize its risk of elongation.[41] In a recent study, Kittl et al. reported that any tibiofemoral reconstruction combination that inserted proximal to the lateral epicondyle and coursed deep to the lateral collateral ligament was nearly isometric between 0 and 90. As the knee extended, only a slight increase in length was shown, implying an ability to inhibit anterior subluxation of the lateral tibial plateau. Among the LET procedures analyzed, the MacIntosh procedure was

reported to display the most isometric pattern from 0 to 90 of flexion.[42]

Resolution of clinical scenario

- No one technique appears to be superior from the others.
- The MacIntosh procedure was reported to display the most isometric pattern.
- Investigation on the anatomy and biomechanics might prove to be extremely helpful in the future guiding possible new procedures.

Summary of answers

- RCT evidence supports the use of LET to augment ACL reconstruction in high-risk patients (e.g. high-level athletes, revision cases, etc.).
- Biomechanical studies suggest LET augmentation leads to a reduction in positive pivot shift tests, and is not associated with increased rates of osteoarthritis.
- No one LET technique has been definitively shown to be superior to others.

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141 Cartilage Lesions of the Knee

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Clinical scenario

- A 25-year-old patient presents following a low-energy torsional trauma sustained to his left knee while playing recreational sports.
- He has persistent pain, occasional catching, and locking preventing him from returning to his preinjury sports participation.
- On physical exam, a mild left knee effusion is present. Ligaments are intact; however, provocative tests indicate medial meniscus pathology, and clinically, coincident articular cartilage injury is suspected.

Top three questions

1. In patients with suspected chondral knee injury, how accurate is magnetic resonance imaging (MRI) compared to subsequent arthroscopic findings in the diagnosis of focal cartilage lesions of the knee?
2. In patients with full-thickness cartilage lesions undergoing knee preservation surgery, what is the difference in clinical outcomes between common surgical options for treating focal cartilage pathology?

3. For patients undergoing articular cartilage surgery, do certain patient-specific, prognostic factors predict improved or inferior clinical outcomes following surgical intervention compared to others?

Question 1: In patients with suspected chondral knee injury, how accurate is magnetic resonance imaging (MRI) compared to subsequent arthroscopic findings in the diagnosis of focal cartilage lesions of the knee?

Rationale

The prevalence of trauma-related cartilage lesions ranges from 23 to 54%, with meniscal tears often accompanied by focal chondral pathology.[1] Most lesions are not detected at the time of initial evaluation and place patients at risk to develop early-onset osteoarthritis with subsequent, accompanying decreases in quality of life as well as high associated medical costs.

Clinical comment

Evaluation of cartilage pathology on MRI is important to inform both the patient and the surgeon regarding potential treatment and management approaches to focal traumatic defects in the absence of generalized degenerative changes. The clinical suspicion of an articular cartilage defect and related surgical strategy is mainly based on clinical examination and MRI.

Available literature and quality of the evidence

Level I evidence consisting of three validating cohort studies with a good reference standard (arthroscopy) is available.[2–4] All included studies were prospective and compared a pre-arthroscopic MRI to findings during arthroscopy, considering Outerbridge grade 0–I changes as disease-negative status and grade II–IV changes as disease positive status.

Table 141.1 Treatment options for focal articular cartilage lesions.

Microfracture (MF): a 12 mm diameter awl is used to penetrate the subchondral plate, creating access to the bone marrow, filling the cartilage lesion with a clot populated with bone-marrow-derived stem cells, growth factors, and platelets and generating a fibrocartilage scar.[5]
Autologous chondrocyte implantation/matrix-induced chondrocyte implantation (ACI/MACI): Chondrocytes are taken by biopsy, expanded in vitro, and reinjected under a periosteal flap that covers the defect.[6] Newer generations of ACI use collagen covers (second generation), characterize the chondrogenic potential of the product (CCI), or seed chondrocytes onto matrices (MACI).[7] Resulting repair tissue is hyaline-like cartilage.
Osteochondral autologous transplantation (OATs): osteochondral autografts are harvested from less-weight bearing areas of the knee and transferred to the defect, providing a hyaline cartilage surface.[8]

Findings

Overall, MRI sensitivity ranged from 57 to 91%, specificity from 71 to 95%, negative predictive value from 74 to 95%, and positive predictive value from 59 to 87%.[2–4] In a sub-analysis provided by von Engelhardt et al., sensitivity and

specificity improved with increasing lesion grade, with 29% sensitivity and 95 % specificity for subtle grade I structural changes and 74% sensitivity and 95% specificity for full-thickness grade IV changes.[3]

In summary, MRI shows a moderate detection of clinically relevant (grade II–IV) articular cartilage defects (sensitivity: 57–91%) (overall quality: moderate). MRI is the best available noninvasive diagnostic tool to detect high-grade focal articular cartilage lesions.

Resolution of clinical scenario

- We recommend routine MRI in the workup of patients with suspected cartilage pathology to inform management including surgical plan and approach.

Question 2: In patients with full-thickness cartilage lesions undergoing knee preservation surgery, what is the difference in clinical outcomes between common surgical options for treating focal cartilage pathology?

Case clarification

The MRI showed a 4 cm^2 grade IV articular cartilage lesion of the medial femoral condyle (MFC).

Rationale

Advances in cartilage preservation and restoration procedures have led to an increasing number of therapies available to the treating physician. The nature of

regenerated tissue and the theoretical basis of different cartilage surgeries vary.

Clinical comment

Adequate treatment is important for young patients presenting with focal cartilage lesions of the knee to prevent progression to early osteoarthritis. Surgical success relies on selecting the optimal treatment to address the corresponding pathology (Table 141.1).

Available literature and quality of the evidence

Multiple level I systematic reviews of randomized controlled trials (RCTs)[9,10] as well as 15 clinically relevant level I randomized trials[11–25] are available in comparing and contrasting outcomes for treatment options for focal articular cartilage lesions. All included studies were of high quality with Coleman scores ranging from 68 to 94.[9,10] The average defect size ranged from 2.4 to 6.1 cm^2 and all but two defects were graded ≥III. A pooled analysis of clinical outcomes was not possible due to the heterogeneity of clinical outcome measures.

Findings

After one-year follow-up, MF demonstrated inferior clinical outcomes compared to OATs in both Hospital for Special Surgery ($p < 0.05$) and International Cartilage Repair Society (ICRS) scores ($p < 0.03$).[12] Following 2–3 years of follow-up, MF demonstrated inferior clinical results when compared to ACI ($p = 0.048$), MACI ($p = 0.001$), and OATs ($p < 0.001$).[12,16,18] MF outcomes remained inferior to OATs when follow-up was extended to 10 years, with significantly decreased ICRS and Tegner activity scores ($p < 0.005$).[21] Lesions >4 cm^2 or >2 cm^2 performed clinically worse ($p < 0.05$) after MF treatment, while the influence of lesion

size on clinical outcome was not present after ACI or OATs.[12,15,21] An increase in clinical outcome after ACI or a decrease in MF was generally observed after 12 years of follow-up, suggesting MF generates a less stable regenerative product.[12,16] However, a randomized study of chronic articular cartilage lesions did not show any difference in clinical outcome between ACI and MF at five-year follow-up and later at 15 years.[13–15]

In terms of comparisons between advanced regenerative techniques, at one year OATs and MACI did not differ in terms of Cincinnati score ($p = 0.32$) and after 19 months of follow-up, OAT and ACI did not differ ($p = 0.227$) on the same scale; however, failure rates and clinical outcomes were superior in the ACI group as compared to OATs at 10-year follow-up.[11,19,25] In summary, treatment of focal articular cartilage lesions by ACI/MACI or OATs provides better medium-term clinical results compared to MF (overall quality: high). ACI/MACI and OAT are both good treatment options for grade III and IV focal articular cartilage lesions with similar clinical results.

Resolution of clinical scenario

We recommend addressing the patient's defect with ACI/MACI or OATs preferentially over MF given his young age and the desirability of durable preservation outcomes.

Question 3: For patients undergoing articular cartilage surgery, do certain patient-specific, prognostic factors predict improved or inferior clinical outcomes following surgical intervention compared to others?

Rationale

Identification of prognostic factors for clinical outcomes following joint preservation surgery will lead to optimal patient selection and subsequent benefit from cartilage surgery.

Clinical comment

The overall benefit from cartilage surgery is 70–95%. Cartilage preservation success hinges on selecting patients with prognostic factors favorable for regenerative therapies.

Available literature and quality of the evidence

Multiple level I randomized trials are available which have demonstrated data linking age,[18,19,21,25] symptom duration,[23,25] and defect location[19,21] to patient outcomes.

Findings

Patient age

Studies showed a statistically significant influence ($p < 0.05$) of patient age on MF, ACI, and OATs treatment outcome, where increasing age is associated with inferior clinical results out to 10-year follow-up.[18,19,21,25]

Duration of symptoms

Treatment of focal cartilage defects in patients with symptom duration shorter than three years in CCI and shorter than one year as well as 50 months in ACI and MACI were clinically more successful ($p < 0.05$) than patients undergoing treatment for prolonged symptomatology.[23,25]

Defect location

Initial reports on ACI safety and efficacy suggested inferior outcomes when used in the patella, with two of seven patients reporting good to excellent results.[6] However, at the time, patellar maltracking and instability were not well recognized and not addressed intraoperatively. In modern series, clinically and statistically similar results have been reported for OATs and MF for medial and lateral femoral condyle (LFC) defects at up to 10-year follow-up.[21] Similarly, at 10-year minimum follow-up, Bentley et al. reported no difference in failure rate between LFC, MFC, and patellar lesion location for ACI or MF.[19] However, level I RCTs investigating the safety and efficacy of regenerative therapies for focal cartilage injuries were not powered for a primary outcome of detecting differences in outcomes between anatomic locations.

Resolution of clinical scenario

- The patient's young age and short duration of symptoms are positive prognostic factors, favoring the efficacy of cartilage preservation surgery in this scenario.
- The nonpatellar location of his defect may also be of positive prognostic value; however, results regarding lesion location are conflicting.

Summary of answers

- The increasing number of young patients presenting with knee trauma and related cartilage injury requires detailed evaluation of articular cartilage damage followed by customized treatment plans to prevent the development of early osteoarthritis.

- MRI is the best available noninvasive diagnostic tool to detect high-grade focal articular cartilage lesions, providing moderate detection of clinically relevant (grade II–IV) articular cartilage defects.
- Several surgical treatment options for focal cartilage lesions are available.
- Medium-term clinical outcomes favor cell-therapy and transplantation-based procedures (ACI/MACI, OATs) over other treatment strategies.
- The location of cartilage defects may influence clinical outcomes, but more recent results demonstrate equally good outcomes in the patellofemoral joint when underlying maltracking and instability are addressed at the time of surgery.
- Increasing age negatively influences clinical outcomes after cartilage surgery, while a shorter duration of symptoms is favorable for prognosis.

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142 Patellofemoral Pain Syndrome (Runner's Knee)

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The term *patellofemoral pain* is the preferred term, and is a synonym for other terms including: *PFP syndrome*, *chondromalacia patellae*, *anterior knee pain* and/or *syndrome*, and *runner's knee*.[1]

Clinical scenario

- An overweight 25-year-old female patient presents with bilateral anterior knee pain which is exacerbated by running.
- The pain started three months ago, and there is no medical history of trauma, infection, or surgery.
- Pain is predominantly anterior, and activities such as going up and down stairs exacerbate her pain. Radiographs and magnetic resonance imaging (MRI) show no abnormality.

Top four questions

1. In patients with a diagnosis of runner's knee, are there specific imaging findings that are different compared with patients without runner's knee?

2. In patients with a diagnosis of runner's knee, does neuromuscular electrical stimulation (NMES) associated with conservative treatment result in better patient-reported outcome measures (PROMs), compared with conservative treatment without NMES?
3. In patients with a diagnosis of runner's knee, are combined hip and knee exercises associated with better clinical outcomes, compared with knee exercises alone?
4. In patients with a diagnosis of runner's knee, does being overweight predict worse PROMs, compared with being normal weight?

Question 1: In patients with a diagnosis of runner's knee, are there specific imaging findings that are different compared with patients without runner's knee?

Rationale

Diagnostic imaging tools represent an important cost for the healthcare system and/or patients. Given the high prevalence and clear clinical presentation of this condition, it is reasonable to analyze if imaging is necessary in the diagnosis and treatment process of these patients. In addition, potential association between this disorder and patellofemoral osteoarthritis has been reported.

Clinical comment

Runner's knee, also known as *patellofemoral pain* (PFP) is a common syndrome. Usually, when patients decide to pursue medical attention, they expect to be referred for diagnostic imaging tests. Nevertheless, these tests

represent an economic burden to patients and/or the healthcare system, without necessarily changing treatment or prognosis. In addition, some studies had shown an association between PFP and patellofemoral osteoarthritis, which have increased the awareness of this condition.[2]

Available literature and quality of the evidence

This search produced the following level I studies: one systematic review and meta-analysis[3] and three randomized controlled trials (RCTs). Whenever possible, these level I studies will be used to answer the question. Lower level of evidence studies will be used to address the role of other imaging modalities that lack high-quality evidence.

Findings

Diagnostic modalities findings in runner's knee patients compared to the normal population

Magnetic resonance imaging (MRI)

Drew et al. found that an increased MRI bisect offset at 0° flexion angle under load was associated with PFP, and that there was a large standardized mean difference (SMD = 0.99; 95% confidence interval [CI]: 0.49–1.49) as determined from moderate level evidence.[3] MRI bisect offset has been shown as the most significant feature related to patellofemoral joint (PFJ) space narrowing in adults between 70 and 79 years with knee pain.[4] There is also a moderate SMD for the association between PFP, patellar tilt (0.63; 95% CI: 0.37–0.90) and patellofemoral contact area (−0.53; 95% CI: −1.01 to −0.06).

Computed tomography (CT)

CT-derived congruence angles at 15° flexion angle, with and without load, have shown a large SMD from moderate evidence level (1.40; 95% CI: 0.04–2.76) and (1.24; 95% CI: 0.37–2.12), respectively. There is limited evidence to support a difference between PFP patients and the normal population regarding tibial tubercle rotation angle at 0° without load[5,6] and trochlear depth at 15° without load.[7] In addition, there is controversial evidence for patellar tilt at 15° under load.[8,9]

Ultrasound (US)

Different studies comparing US findings between patients with PFP and healthy individuals have been conducted. Limited evidence supports a difference between PFP patients and healthy controls in terms of: vastus medialis oblique (VMO) fiber angle, VMO insertion, and volume;[10] VMO contraction ratio and capacity reduction;[11] and an increase in VMO electrical mechanical delay and vastus lateralis delay.[12] In addition, evidence suggests that the atrophy is not specific for VMO, but for the quadriceps as a whole muscular group.[13]

X-rays

There is controversial evidence regarding a difference in congruence angle, support sulcus angle, and Insall–Salvati index at 30° without load, between patients with PFP and healthy individuals. Limited evidence support a difference in congruence angle at 45° with load,[14,15] but not at 35°.[16] Similarly, limited evidence supports sulcus angle difference at 45° without load,[14,15] but no evidence shows a difference at 35°[16] or 30°.[17]

Changes observed during intervention through imaging modalities

Two studies have revealed that, after quadriceps strengthening exercises, there was a significant increase in PFJ contact area which might reduce mechanical stress, improving PFJ function. These studies also exhibited that the patellofemoral bisect offset and patellar tilt changed with bracing.[18],[19]

Resolution of clinical scenario

The patient's imaging did not show any specific abnormalities, which is the case in the majority of cases of PFP. Eventually, some dynamic imaging exam measurements can be performed to identify certain features associated with PFP, but this will probably not change the patient's initial management (overall quality: moderate).

Question 2: In patients with a diagnosis of runner's knee, does neuromuscular electrical stimulation (NMES) associated with conservative treatment result in better patient-reported outcome measures (PROMs), compared with conservative treatment without NMES?

Rationale

- Even when NMES is widely used as a therapeutic tool in patients with PFP, there is controversy concerning its utility as concurrent treatment with other nonsurgical interventions.

Clinical comment

Patients with PFP are frequently sent to physiotherapy. NMES has been extensively used during physiotherapy sessions despite the lack of consensus in its benefit.

Available literature and quality of the evidence

This search produced the following level I studies: one systematic review[20] and eight RCTs. Whenever possible, these level I studies were used to answer the question.

Findings

NMES

A recent systematic review included eight RCTs (n = 345) where PFP patients were treated with different NMES protocols and associated co-interventions.[20] Four trials compared NMES plus exercise versus exercise alone. Different NMES protocols were used as well as co-interventions associated with exercise (one study added patellar taping[21] and another added patellar taping and ice in both groups).[22] On average, studies showed pain reduction with a mean difference in Visual Analog Scale (VAS) score of −1.63 (95% CI: −2.23 to −1.02). However, this difference may not be relevant given that the minimal clinically important difference (MCID) in VAS has been determined to be between 1.5 to 2.0 points[23] and lies within the CI range.

Two RCTs compared NMES protocols.[24],[25] They did not find any differences at six weeks between the protocols in overall knee pain, knee function, or quadriceps fatigue.

A recent RCT, not included in the systematic review, showed knee extensors strengthening, muscle hypertrophic response, and increased fascicle length with an eccentric

training program, but no difference when NMES was added.[26]

Resolution of clinical scenario

Current evidence demonstrates no benefit of adding NMES as an intervention in patients with PFP. Physicians and physiotherapists should encourage patients to focus on other conservative measures while working at rehabilitation sessions (overall quality: low).

Question 3: In patients with a diagnosis of runner's knee, are combined hip and knee exercises associated with better clinical outcomes, compared with knee exercises alone?

Rationale

- Controversy exists for the utility of hip training to treat patients with PFP and its effectiveness compared to knee strengthening alone.
- Physiotherapy is probably the most commonly used therapeutic tool in PFP patients, but there is a lack of standardized rehabilitation protocols. Therefore, most patients are treated with different rehabilitation methods depending on physiotherapists' preferences.

Clinical comment

Patients with PFP are frequently sent to physiotherapy. The high diversity of rehabilitation protocols can lead to

unpredictable results. Reviewing the evidence could help clinicians to make better decisions in patients with PFP.

Available literature and quality of the evidence

This search produced the following level I studies: two systematic reviews addressing this research question were included. Whenever possible, these level I studies were used to answer the question.

Findings

Hip plus knee exercises versus knee exercises

A recent systematic review and meta-analysis included six studies (n = 359) comparing the effect of hip and knee strengthening with a knee-only strengthening program on strength, and found no differences (SMD = 0.2; 95% CI: −0.1 to 0.4).[27] Nevertheless, this study found that hip and knee strengthening significantly reduced pain by 1.5 points (95% CI: −2.3 to −0.8) out of 10 points, compared with knee strengthening alone, during the intervention (10 trials, n = 517). This reduction was held beyond the intervention for 12.0 ± 5.7 weeks with a decrease in intensity of 1.9 points (95% CI: −3.1 to −0.7) out of 10. In addition, the effect of both intervention programs on self-reported activity levels was examined (eight trials, n = 471) showing a significantly improved activity level with an effect size of 0.7 (95% CI: 0.2–1.3) for the hip and knee strengthening group. This was also held beyond the intervention (five trials, n = 188) with an effect size of 1.2 (95% CI: 0.4–2.0) at 12.0 ± 5.7 weeks.[27]

A meta-analysis evaluating exercise as a treatment for PFP pooled data from three studies (n = 104) which assessed pain during activity in the short-term (≤3 months).[28] Hip

and knee exercises were associated with better results than knee exercises alone (SMD = −2.02; 95% CI: −3.8 to −0.6).

Similar results, with data gathered from two studies (n = 46), were observed favoring hip plus knee exercises for usual pain at short-term (SMD = −1.77; 95% CI: −2.78 to −0.76). Moreover, one study including 49 participants exhibited a clinically important reduction in pain during activity at long-term (≥3 months) for the hip plus knee exercise group (SMD = −3.9; 95% CI: −4.46 to −3.34).[29]

Resolution of clinical scenario

Adding hip exercises to knee exercises helps patients with PFP in diminishing both their short- and long-term pain at rest and during activity. Therefore, adding hip exercises to knee exercises for patients with PFP should be routine (overall quality: high).

Question 4: In patients with a diagnosis of runner's knee, does being overweight predict worse PROMs, compared with being normal weight?

Rationale

- An increasing proportion of the population is overweight and obese, with an estimated 39% of adults being at least overweight based on body mass index (BMI).
- Many patients with PFP are overweight and are actively attempting to lose weight through exercise, thus

appropriate recommendations regarding BMI and safe exercises are necessary.

Clinical comment

PROMs used to compare clinical results are increasing in popularity because they incorporate patients views on clinical outcomes. Treating physicians frequently advise overweight PFP patients to lose weight as part of their treatment, but frequently do so without considering evidence to support this recommendation.

Available literature and quality of the evidence

This search produced the following level I studies: one systematic review concerning BMI and PFP[30] and one systematic review about PROMs in PFP.[31] We could not find specific evidence concerning overweight patients and PROMs compared to healthy individuals in PFP.

Findings

Overweight patients with runner's knee syndrome

Hart et al. assessed whether BMI was a risk factor for PFP development, whether BMI was higher in individuals with PFP, and whether there was any link between BMI and intervention outcomes.[30] Data from 33 studies provided moderate evidence of higher BMI in patients with PFP compared to healthy individuals (equivalent to mean difference 0.84; 95% CI: 0.43–1.26). There was not a significant relationship between BMI and interventions outcomes. On the other hand, a clinical trial in adolescents revealed that BMI did not increase the risk of developing PFP (−0.66; 95% CI: −1.98 to 0.66).[32]

PFP PROMs

Green et al. evaluated PFP disease-specific PROMs, finding moderate level evidence supporting the use of the following six measures:[31]

- Flandry Questionnaire
- AKPS (Kujala Anterior Knee Pain Scale)
- MFIQ (Modified Functional Index Questionnaire)
- EPQ (Eng and Pierrynowski Questionnaire)
- VAS-U (Visual Analog Pain Scale: usual pain)
- VAS-W (Visual Analog Pain Scale: worst pain).

Resolution of clinical scenario

It is challenging to give recommendations regarding BMI and its influence on knee pain due to PFP. Best current evidence suggests that being overweight is associated with an increased prevalence of PFP, but it is not clear whether losing weight will improve outcomes. Nevertheless, even when healthcare professionals cannot guarantee that losing weight will improve symptoms in these patients, increased physical activity is likely to help patients in many other health domains (overall quality: moderate).

Summary of answers

- Diagnostic imaging is rarely specific for PFP. Only a few characteristics, like an increased MRI bisect offset at 0° knee flexion under load and a CT-derived congruence angle at 15° with and without load, were associated with PFP.
- Adding NMES to traditional nonsurgical treatment does not seem to confer any additional benefit in patients with PFP.

- Physiotherapy for PFP patients should include not only knee exercises but also hip strengthening exercises, to help patients reduce their short- and long-term pain at rest and during activity.
- An elevated BMI is associated with increased prevalence of PFP in adults, but it is not clear that losing weight will improve symptoms.

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143 Osteotomy and Lower Extremity Realignment Procedures

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Clinical scenario

- A 49-year-old male runner with a history of bilateral partial medial meniscectomies (six years prior), and worsening medial-sided right knee pain of several months' duration, refractory to cortisone injection, and conservative treatment.
- Body mass index (BMI) 27.3. Bilateral varus alignment, normal range of motion (ROM) (0–130), right knee medial joint line tenderness and pain with McMurray maneuvers.
- Radiographs demonstrate medial joint space narrowing and moderate Fairbank's changes. Long cassette radiograph reveals bilateral varus (8°).

Top three questions

1. In middle-aged patients with varus malalignment and medial osteoarthritis (OA), does high tibial osteotomy (HTO) result in superior outcomes (i.e. survivorship, function, complications) compared to unicompartmental knee arthroplasty (UKA)?
2. In middle-aged patients with lower limb varus malalignment, concomitant meniscal deficiency, and OA, does medial open-wedge high tibial osteotomy (OWHTO) result in improved outcomes (i.e. limb length alignment, function, time-dependent improvement) compared to lateral closed-wedge high tibial osteotomy (CWHTO)?
3. In middle-aged patients undergoing HTO, does bone graft supplementation improve bone healing and patient outcomes compared to no bone graft supplementation?

Question 1: In middle-aged patients with varus malalignment and medial osteoarthritis (OA), does high tibial osteotomy (HTO) result in superior outcomes (i.e. survivorship, function, complications) compared to unicompartmental knee arthroplasty (UKA)?

Rationale

HTO and UKA are both indicated for the active, middle-aged patient suffering medial-sided knee OA. However, the superiority of one technique over the other with regards to function, survivorship, and complication profiles is

controversial. Currently, a paucity of high-level evidence exists to suggest a clear benefit of one procedure over the other.

Clinical comment

It is unclear whether HTO or UKA is superior for treatment of varus-associated medial knee OA.

Available literature and quality of the evidence

To date, only three prospective, randomized controlled trials (RCTs),[1–3] performed in 1991, 2001, and 2004, have compared risks and benefits of HTO versus UKA – all specifically using CWHTO. Two nonrandomized prospective studies,[4,5] one utilizing CWHTO and one OWHTO, were published in 1989 and 2008, respectively. More recently, numerous retrospective analyses have also been included for systematic review.[6]

Findings

The highest-quality evidence comparing HTO and UKA for medial-sided OA rests with three RCTs, all using CWHTO, and published many years ago.[1–3] There was no statistical significance in 10-year survival for patients with a mean age of 67 years (77% UKA; 60% HTO).[3] Both groups had similar mean knee scores, functional Knee Society Scores, and British Orthopaedic Association scores at one, five,[2] and seven, 10 years.[3] Range of motion did not differ significantly between cohorts.[1,2] In terms of muscle torque, maximal gait velocity, and duration of single support, UKA patients demonstrated superior results at six months postoperatively compared to HTO patients at 12 months.[1] However, while UKA patients showed significantly greater free walking speed, step frequency, and step length at three months postoperatively, these differences

disappeared at one and five years.[2] Lastly, only one of three studies investigated intraoperative and postoperative complication rates, revealing higher complication rates in HTO (28.1%) versus UKA (7.1%), including deep vein thrombosis, superficial wound infection, pseudarthrosis, hardware failure, and fracture in the HTO cohort versus arthrofibrosis with UKA.[3] In summary, comparable outcomes with regard to survivorship, patient-reported outcomes, ROM, and gait were found, with possible increased complication rates in HTO over UKA.[1–3] From these studies alone, however, superiority cannot be established. Furthermore, with increasing prevalence of OWHTO versus CWHTO, RCTs comparing OWHTO and UKA are required.

A systematic review and meta-analysis of pooled results was conducted on studies of all levels of evidence: nine retrospective, three prospective randomized, and two prospective non-RCTs (total 1041 knees undergoing HTO and 5497 knees undergoing UKA). The meta-analysis demonstrated superior ROM following HTO, but less pain, higher rates of self-perceived outcome as *excellent/good*, and fewer perioperative complications after UKA. However, the procedural indications and patient characteristics vary among studies. Indeed, both procedures yield satisfactory outcomes, though it appears that valgus HTO may be more appropriate for younger active patients and UKA more appropriate for older patients.[6]

Resolution of clinical scenario

- HTO and UKA are reasonable options for this middle-aged, active individual.
- Older, high-quality trials show similar results between CWHTO and UKA.

- With the advent of OWHTO and improved technology, consideration may be given to recent, lower-level studies.
- Pooled meta-analyses showed HTO patients had better ROM, but UKA patients reported less pain, better patient scores, and fewer perioperative complications.
- As this patient is young, nonobese, and possesses full ROM, and a desire to return to activity, a joint preserving procedure may be more appropriate.

Question 2: In middle-aged patients with lower limb varus malalignment, concomitant meniscal deficiency, and OA, does medial open-wedge high tibial osteotomy (OWHTO) result in improved outcomes (i.e. limb length alignment, function, time-dependent improvement) compared to lateral closed-wedge high tibial osteotomy (CWHTO)?

Rationale

HTO is a well-established procedure for the treatment of patients with varus malalignment and OA of the medial knee. The most commonly performed techniques of HTO are lateral CWHTO and the medial OWHTO. Both techniques have their advantages and disadvantages. Still, no consensus has been reached in the literature regarding the optimal approach.

Clinical comment

As lateral-closing and medial-opening HTO are both frequently performed procedures in this aforementioned patient population, elucidating the optimal technique is critical for a more individualized and appropriate treatment plan.

Available literature and quality of the evidence

To date, several RCTs have been published comparing lateral-closing wedge and medial-opening wedge HTOs. Additionally, prospective and retrospective cohort studies have been performed.

Findings

Several differences have been reported between OWHTO and CWHTO. For example, OWHTO has been shown to lead to greater incidences of patella baja,[7,8] the effects of which may alter knee kinematics, decrease ROM, increase patellofemoral contact pressures, and lead to anterior knee pain.[7] Conflicting and variable data exists regarding accuracy of correction between the two approaches.[8–10] Higher complication rates after OWHTO have been described,[9,11] with reported six-year complication rates 38% (9% after CWHTO).[11] Conversely, in a one-year follow-up study, a greater number of complications and longer surgery times were reported following CWHTO.[8] Interestingly, more patients undergoing CWHTO required early conversion to total knee arthroplasty (TKA).[11] Additional conflicting data exists regarding limb length changes following surgery. At one-year follow-up, OWHTO significantly increased lower limb length (mean 7.6 mm), while CWHTO did not have a significant effect.[12] Additionally, radiologic outcomes at six months reported an increase in limb length after OWHTO (3.1 mm), but

observed a mean leg length decrease after CWHTO (5.7 mm).[13] Cruciate ligament stability is critical for choosing between CWHTO and OWHTO, as the technique can be employed to additionally alter tibial slope, and confer stability in the ligament-deficient state.[7,14–17] Perhaps most importantly, many studies reliably show comparable improvements in clinical outcomes between techniques regarding reduced pain and improved function comparably at one-year,[11] two-year,[18] and six-year follow-up.[11]

Resolution of clinical scenario

- CWHTO and OWHTO are both appropriate options for this selected patient, given the lack of concomitant cruciate deficiency.
- Despite conflicting data, both techniques reliably achieve alignment correction and improve clinical outcomes.
- Differences in complication rates between techniques is controversial.
- OWHTO can lead to patella baja and altered limb length.
- Earlier conversion to TKA may be expected in patients undergoing CWHTO.

Question 3: In middle-aged patients undergoing HTO, does bone graft supplementation improve bone healing and patient outcomes compared to no bone graft supplementation?

Rationale

Healing of the osteotomy site is influenced by a multitude of factors, including patient co-morbidities, surgical technique, implant stability, and biologic factors. To enhance the success of HTO procedures, there is increasing interest in developing and applying a variety of biologic and complementary therapies to accelerate new bone formation and maturation at the osteotomy site. Currently, several potential augmentation techniques exist, and efforts to define their application, efficacy, and safety are ongoing.

Clinical comment

It is unclear whether healing at the osteotomy site post-HTO can be influenced by factors (i.e. biologics, low-intensity pulsed ultrasound [LIPUS]) outside of surgical technique, implant stability, and patient characteristics.

Available literature and quality of the evidence

To date, several randomized studies exist; however, they are limited by small sample sizes, short follow-up periods, and biases from their individual randomization techniques, allocation of concealment (or lack thereof), blinding, losses to follow-up, and application of intention-to-treat analyses.

Findings

The effectiveness of mesenchymal stem cell (MSC) augmentation for improved healing in HTO patients has yet to be determined. In a prospective study comparing platelet-rich plasma (PRP) and MSC augmentation of HTO, though improved cartilage healing and acceptable improvements in Knee injury and Osteoarthritis Outcome Score (KOOS), Lysholm, and Visual Analog Scale (VAS) scores were observed in both techniques, there was no

indication of either technique contributing to enhanced healing at the osteotomy site.[19] The same holds true in another prospective RCT examining intra-articular administration of autologous bone-marrow-derived MSCs.[20]

Data regarding the effectiveness of PRP for osteotomy site healing are conflicting. Computed tomography (CT) evaluation of bone healing at the osteotomy site yielded no significant differences six weeks postoperatively when bone chips were supplemented with or without PRP.[21] In fact, marked, statistically significant reductions in bone density below the wedge were observed in PRP-supplemented patients, suggesting no benefit and even potential harm with PRP supplementation.[21] This finding contrasts the beneficial effects reported in a study comparing rates of and time for bone healing in patients with PRP and bone marrow aspirate versus patients in whom autologous iliac crest graft was used.[22] Bone-healing rates were achieved in 100% of patients grafted with autologous iliac crest, and in 91% of patients with PRP supplementation – with no difference in time required for bone healing.[22] This latter study is further supported by an RCT, which compared three groups of osteotomy site fillings: (i) osteotomy site filled with lyophilized bone chips with platelet gel (PG), (ii) lyophilized bone chips with PG and bone marrow stromal cells, and (iii) lyophilized bone chips in isolation.[23] Histology of CT-guided biopsies of the osteotomy site, and serial clinical and radiographic assessments, demonstrated complete clinical and functional healing one year postoperatively in all three groups, though both noncontrol groups demonstrated more enhanced osteointegration.[23] In an RCT of patients undergoing HTO for genu varum, comparing lyophilized bone chips with PG to those without PG, CT-guided biopsies, clinical data, and radiographic evidence demonstrated new vessel formation and

deposition of new bone 45 days postoperatively after PG supplementation, suggesting accelerated healing.[24]

Bone substitute materials have been investigated to enhance post-HTO healing. Supplementation of heterologous bone graft (HBG) with nonhydroxyapatite (NHA) been shown to improve osteointegration one year postoperatively.[25],[26] Use of hydroxyapatite or lyophilized bone chips demonstrated comparable efficacy at one year.[27] Lastly, both cadaveric and clinical studies demonstrate improved stability, complete gap healing, and no issues with wound healing, loss of correction, infection, or complications from injectable calcium phosphate into the osteotomy void.[28–30]

Lastly, of increasing interest is the application of LIPUS. Though extensively studied in the fracture population, data are sparse concerning HTO.[31] The addition of LIPUS in patients undergoing OWHTO demonstrated accelerated radiographic bone healing over the short term.[32] The clinical significance of this, however, remains unknown, and is likely influenced by the phase of bone healing that the technology is applied, as well as its duration at individual applications.[33]

Resolution of clinical scenario

- Optimizing patient characteristics and surgical technique remains the mainstay to ensuring optimal osteotomy site healing.
- There is a paucity of data surrounding the use of PRP, MSCs, hyaluronic acid, or LIPUS in the HTO population; larger studies with longer-term follow-up are needed to assess efficacy and complication profile.

Summary of answers

- High-quality evidence demonstrates similar patient-reported outcomes, gait measurements, and ROM when comparing CWHTO and UKA. A recent meta-analysis, which incorporates studies utilizing both CWHTO and OWHTO, however, demonstrates superior ROM following HTO, but less pain, better patient scores, and fewer perioperative complications after UKA. There is a paucity of high-level clinical evidence comparing OWHTO and UKA.
- In varus OA, CWHTO and OWHTO are appropriate with concomitant ACL and PCL deficiency, respectively. Controversy exists regarding the accuracy of alignment correction and complication profiles between techniques. Many studies reliably show comparable improvements in clinical outcomes between techniques regarding reduced pain and improved function comparably at one-,[11] two-,[18] and six-year follow-up.[11]
- Augmentation of osteotomy site healing with biologics or LIPUS has shown promise in short-term studies; however, larger studies with longer-term follow-up are needed to assess efficacy and complication profile.

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144 Ankle Ligament Injuries

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Clinical scenario

- During a soccer match, a 23-year-old male athlete suffers an inversion injury during a cutting movement while trying to pass an opponent. The ankle immediately feels swollen and painful. He has limited ability to bear weight, and is transferred to the Emergency Department.
- According to standard protocol, the Ottawa Ankle Rules (OAR) are applied and are found positive due to pain over the lateral malleolus, and an x-ray is taken, which is negative for a fracture.
- Apart from visible swelling of the lateral ankle and pain on palpation, no further physical tests can be tolerated by the patient.

Relevant anatomy

Of all ankle sprains, 85% involve the lateral ankle ligaments.[1] This ligament complex consists of three ligaments: the anterior talofibular ligament (ATFL), the calcaneofibular ligament (CFL), and the posterior talofibular ligament (PTFL).[2] The most common mechanism leading to lateral ligament damage is an inversion–plantarflexion–internal rotation injury of the foot. Ligament damage occurs when tension on any of the three ligaments in the ankle exceeds the extensile strength in the tissue. The maximal load to failure is lowest for the ATFL followed by the CFL. The PTFL has the highest load to failure.[3] The deltoid is the primary ligament on the medial side of the ankle. Damage on the medial side of the ankle occurs less frequently and is often associated with ankle fractures. The focus of this chapter is on the lateral ankle sprains (LAS), and deltoid damage will therefore not be further discussed in this chapter.

Overall, the term *ankle sprain* is used to describe a variety of pathologies of the ligaments of the ankle. To classify the severity of damage to the ankle ligaments, a grading system has been developed (Table 144.1).[4] As the microscopic ligament severity often does not completely capture a patient's overall pathology, a system based on clinical symptoms only has also been introduced.[5]

Table 144.1 Classification system for ankle sprains and injury to lateral ligaments. Source: Adapted from Konradsen et al.[4]

	Injury severity[4]	**Clinical symptoms[5]**
Grade I	Microscopic injury without stretching of the ligament on macroscopic level	Little swelling and tenderness, minimal or no functional loss, and no mechanical joint instability
Grade II	Macroscopic stretching, but the ligament remains intact	Moderate pain, swelling, and tenderness, some joint motion loss, and mild to moderate joint instability
Grade III	Complete rupture of the ligament	Complete ligament rupture with marked swelling, hemorrhage, and tenderness, function loss, and joint motion and instability are markedly abnormal

Top three questions

1. In patients with acute lateral ankle injuries, does advanced imaging result in better diagnosis compared to radiographs only?
2. In patients with lateral ankle ligament injuries, does functional support result in better outcomes compared to cast immobilization?
3. In patients with acute injury of the lateral ligament complex, does surgical treatment lead to better outcomes compared to conservative treatment?

Question 1: In patients with acute lateral ankle injuries, does advanced imaging result in better diagnosis compared to radiographs only?

Rationale

Many patients who present to the Emergency Department after sustaining an LAS mainly suffer from pain and are unable to bear weight on the affected ankle. This in combination with pain of the lateral ankle usually leads to positive OAR, and thus x-rays are typically performed. For most patients, a fracture is then excluded. Are these rules reliable enough and are there other types of imaging that may provide more accurate diagnosis, especially in those who suffer from so much pain that it prevents full physical examination?

Clinical comment

In many patients, the pain is so severe that a thorough initial physical assessment is impossible. Reliable initial imaging techniques may help diagnose the injured tissue and decide whether early treatment is required to enable quick return to play.

Available literature and quality of the evidence

The best available evidence for this research question was mainly extracted from cohort studies and systematic reviews based on cohort studies (level II). Only two included studies had a randomized controlled trial (RCT) design (level I).

Findings

The OAR are widely used to diagnose fractures in patients who have suffered from acute ankle trauma. However, a large proportion of the radiographs are negative in patients who sustained an LAS. This raises the question whether the OAR are sufficient in patients with LAS. To compensate for the low reported specificity, the use of OAR only by an experienced nurse or physician has been proposed.[6] Other clinical decision rules, such as the Bernese decision rules, have also been suggested.[7] The sensitivity of these clinical decision rules, however, was too low to promote clinical use.[6] Ultrasound (sensitivity 92%; specificity 64%)[8],[9] in the acute setting may actually do a better job of determining which patients require a radiograph,[6] as it may both diagnose small foot and ankle fractures and ligament and other soft tissue injury (level III).[10],[11]

Additional diagnostics that may provide further insights include magnetic resonance imaging (MRI) and computed tomography (CT). Despite the role of MRI in patients who require further treatment, it is costlier than other imaging modalities, its availability is limited in the acute setting,[12] and it does not have an additional role in those who can be discharged without further follow-up.[13] Therefore, just as with CT scans, MRIs do not have any additional value in the acute setting (level II).[7]

Resolution of clinical scenario

- If a fracture is suspected, other clinical decision rules may be used in addition to the OAR to increase specificity.
- If available, ultrasonography can be used to provide a more reliable assessment of the extent of the injury and may be used to determine who requires a radiograph.

- MRI and CT imaging, especially in the acute setting, are generally not indicated.

Question 2: In patients with lateral ankle ligament injuries, does functional support result in better outcomes compared to cast immobilization?

Rationale

Patients that present to the Emergency Department are often unable to bear weight on their affected ankle. To provide some stability, immobilization by means of a cast may be chosen as an acute treatment method. However, this prevents early exercise, whereas taping and braces may be applied and removed by patients as needed.

Clinical comment

Lateral ankle ligament injury can be treated with plaster cast immobilization or functional supports, such as tape, elastic bandage, or brace. All options are widely used in clinical practice, which suggests either a lack of available evidence or a lack of familiarity with the evidence.

Available literature and quality of the evidence

A total of 10 RCTs have compared functional support with plaster cast immobilization in patients who sustained lateral ankle ligament injuries (level I).[14–23]

Findings

Functional support by means of tape, elastic bandage, or brace is widely used in the treatment of LAS. This type of

treatment provides support without immobilizing the ankle joint. Patients who were treated with a lower leg plaster cast for at least four weeks experienced more pain at short-, intermediate-, and long-term follow-up compared to patients who were treated with functional support (risk ratio [RR] = 1.50; 95% confidence interval [CI]: 1.14–1.91) (level III).[14–23] At follow-up, patients who received a plaster cast also experienced more swelling compared to patients who received functional support (RR = 1.75; 95% CI: 1.21–2.43) (level III).[14,15,17,18,21,24,25] For subjective stability, no difference was found between the different types of treatment (RR = 1.10; 95% CI: 0.81–1.45) (level III).[14–18,21,26,27]

Resolution of clinical scenario

- In case of lateral ankle ligament injury, functional support is superior to immobilization in terms of pain and swelling.
- The athlete from the clinical scenario should primarily be treated by means of functional support of choice.

Question 3: In patients with acute injury of the lateral ligament complex, does surgical treatment lead to better outcomes compared to conservative treatment?

Rationale

In patients that suffer from a severe lateral ligament injury, only elite athletes generally qualify for surgical treatment to enable quick recovery. Direct comparisons, however, are required to define the superiority of one treatment over

another and to define which patients require which type of treatment.

Clinical comment

To minimize costs and optimize decision-making, treatment modalities (e.g. conservative and surgical) need to be compared and indications need to be well defined.

Available literature and quality of the evidence

A total of 20 RCTs were found that included some form of comparison between conservative treatment and surgery in patients with lateral ligament damage after sustaining an ankle sprain (level I). Table 144.2 summarizes recommendations from available RCTs, and prospective and retrospective cohort studies (level III).

Table 144.2 Treatment per grade of severity of the ankle sprain. Source: Adapted from Lynch and Renstrom.[28]

Grade	Treatment
Grade I	"Non-operative management: functional treatment including RICE, short period of immobilization if indicated, functional support, early ROM exercises; weight-bearing, neuromuscular training exercises including proprioceptive training."[28]
Grade II	
Grade III	Early functional treatment provides the fastest recovery. Secondary surgical repair provides results comparable results to primary repair, even years after the initial injury. However, for individuals with chronic instability not responding to conservative treatment, surgery may be required.

*RICE: rest ice compression elevation; ROM: range of motion

Findings

The selected treatment may depend on the severity of the initial injury and the timing of treatment (Table 144.2). Initially, conservative treatment may be preferred as it is less invasive and provides good early functional outcomes and reasonable return to work and sport timelines. Additionally, in contrast to surgical treatment, conservative treatment is without any direct complications (other than perhaps stiffness). If surgery is found to be indicated in the subacute or chronic setting, secondary repair still provides outcomes equal to primary repair. Unfortunately, after both conservative and surgical treatment, 10–30% of patients may still suffer from chronic symptoms (level II).[28]

In terms of pain, there is a significant difference in favor of surgery only while weightbearing (RR = 0.67; 95% CI: 0.54–0.82), whereas there was no difference for pain at rest or on palpation (level II).[18,19,29–38] This effect diminishes at long-term follow-up. For swelling, no difference has been demonstrated (RR = 0.84; 95% CI: 0.64–1.10) (level II).[18,19,29–38] ROM was evidently better in the conservative treatment group (RR = 1.95; 95% CI: 1.16–3.28) (grade III).[18,27,32,34,37–39] Subjective instability is less frequent in surgical treatment patients compared to the conservative treatment patients (RR = 0.69; 95% CI: 0.57–0.83) (level II).[18,19,29–38] More patients returned to their pre-injury sports levels after surgical treatment (RR = 0.75; 95% CI: 0.39–0.83) (grade III).[27,34,37–39] Of these, there was no difference in number of patients that quit their sporting activities (RR = 0.68; 95% CI: 0.35–1.35).[34,37–39] Despite an initial reduction in level of sporting activity among patients that underwent surgical treatment, more patients returned to a higher level of activity compared to the conservative treatment group (RR = 0.53; 95% CI: 0.33–0.86) (level III).[27,34,37–39] Concerning reinjury, surgery only showed a minimal advantage (RR = 0.80; 95% CI: 0.65–

0.98) (level II).[18,27,29,31,32,34–37,40] Finally, complications reported for surgery included deep venous thrombosis (DVT), tenderness of the scar, sensory loss, wound infection, and/or necrosis, atrophy, and arthrosis, of which DVT and arthrosis were also reported for conservative treatment.[18,27,32,34,37–39]

Resolution of clinical scenario

- Both conservative treatment and surgery provide quick recovery in the acute setting, but conservative treatment provides superior results concerning joint; range of motion ROM.
- For this athlete, conservative treatment should be first-line, with secondary surgical stabilization as an option in case of failure.
- If complaints persist, and at delayed physical examination the injury is diagnosed as a grade III injury or becomes chronic, surgery should be considered.
- In individual cases of professional athletes and in cases of concomitant injuries, surgical treatment can be considered.

Summary of answers

- Imaging is of value after LAS, especially if a fracture is suspected. If available, ultrasonography should also be considered to assess who requires further assessment.
- In case of lateral ankle ligament injury, functional support is preferred over immobilization because of superior results regarding pain and swelling.
- In the less severe cases, conservative treatment is preferred.

- Secondary surgery provides similar long-term results as primary surgery, thus in case of uncertainty, a surgeon may choose to await normal recovery based on conservative treatment.
- In individual cases of professional athletes and in cases of concomitant injuries, acute surgical treatment can be considered.

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145 Achilles Tendinopathy

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Clinical scenario

- A 41-year-old male runner presents with swelling 2.5 cm in diameter, 4 cm proximal to the insertion of the Achilles tendon. For three months, he has felt pain at the beginning and at the end of training sessions, with diminished discomfort in between.
- There is tenderness of the Achilles tendon. He has no neurovascular deficits. The physician makes a diagnosis of Achilles tendinopathy (AT).
- Eccentric exercise is presented as an option for this patient. However, the patient would like to apply a wait-and-see policy or undertake a program of concentric exercises.
- After failed management with eccentric exercises alone, the physician proposes to the patient that he should undertake extracorporeal shockwave therapy (ESWT).
- After searching the internet, the patient asks the doctor to give him information about platelet-rich plasma

(PRP) injections.

Top three questions

1. In patients with AT, does a program of eccentric exercises result in better clinical outcomes compared to control?
2. In patients with AT, does a program of eccentric exercises result in better clinical outcomes compared to shockwave therapy?
3. In patients with AT, does a program of eccentric exercises result in better clinical outcomes compared to PRP injections plus eccentric exercises?

Question 1: In patients with AT, does a program of eccentric exercises result in better clinical outcomes compared to control?

Rationale

Current opinion suggests that the majority of health professionals consider eccentric exercises as an appropriate management tool for AT. Eccentric exercises have been proposed to promote collagen fiber cross-link formation within the tendon, thereby facilitating tendon remodelling.[1]

Clinical comment

Several management options have been proposed to allow recovery of patients with AT. However, outcomes with long-term follow-up of the different options are not well defined.

Available literature and quality of the evidence

A range of randomized controlled trials (RCTs) and case control studies are available to answer this question.

Findings

Comparison of eccentric exercise versus wait-and-see strategy

Horstmann et al. conducted an RCT comparing the effectiveness of whole-body vibration versus eccentric training or a wait-and-see approach for chronic AT.[2] After a 12-week intervention phase, pain improvements at the midsection of the tendon were greater in the vibration and eccentric training groups than in the wait-and-see group, but only the eccentric training intervention reduced pain at the musculotendinous junction. Improvements in sonographic parameters and changes in muscle strength were similar for the vibration training and the eccentric training groups.

Comparison of eccentric exercises versus concentric exercises

Rowe et al. performed a systematic review on the conservative management of midportion AT.[3] They pointed out that eccentric loading exercises have the strongest supporting evidence of all the conservative treatment modalities. There is moderate evidence to suggest that concentric calf muscle training is not as effective as an eccentric training regimen. Two studies randomized participants to either eccentric or concentric calf muscle training for 12 weeks.[4,5] The results from both studies showed significantly greater reductions in pain for the eccentric training group compared with the concentric training group. However, in both studies, patients reported

some improvement with concentric exercises and, in practice, combined concentric/eccentric exercises were frequently prescribed initially where eccentric exercises were intolerable because of pain or because the patient was too weak to start with eccentric exercises right away.

In a case control study, Yu et al. assessed the effect of eccentric strengthening on pain, muscle strength, endurance, and functional fitness factors in male patients with AT.[6] Eccentric strengthening, in comparison with concentric strengthening, showed significant improvement in pain, ankle dorsiflexion endurance, total balance index, and agility after the intervention.

One year later, in a single-blind, cross-sectional study, Yu et al. aimed to identify changes in muscle activation by comparing muscle activities of the affected side (AS) and nonaffected side (NAS) during eccentric and concentric exercise in runners with unilateral AT.[7] Concentric exercise induces higher maximum muscle activation in every muscle studied, except the medial gastrocnemius of the AS, where eccentric exercise induced higher maximum muscle activation when compared with concentric exercise. Relatively high levels of statistical significance were found for the rectus femoris, tibialis anterior, peroneus longus, and lateral gastrocnemius.

Beyer et al., in an RCT comprising 58 recreational athletes, evaluated the effectiveness of eccentric training (ECC) and heavy slow resistance (HSR) training among patients with midportion AT.[8] HSR training three times per week was equally effective in reducing symptoms compared to ECC performed seven days per week in patients with AT, with the former being associated with greater patient satisfaction at short-term follow-up.

Overall, there is a consensus about the positive effects of eccentric exercises protocols for patients with AT. Level I

evidence suggests that eccentric exercises are better than wait-and-see treatment in terms of pain reduction at both tendon midsection and musculotendinous junction.[2]

Regarding the comparison between eccentric and concentric exercises, in level I studies the eccentric exercises were found to be superior to concentric exercises in reducing symptoms.[3–5,8]

Level III studies have demonstrated that eccentric exercises demonstrate significant improvements in pain, ankle dorsiflexion endurance, total balance index, and agility after the intervention, and that concentric exercises are useful for muscle activation on the AS, with the exception of the medial gastrocnemius, where eccentric exercises were found to be superior.[6,7]

The available evidence provides little support for the superiority of eccentric exercises used as the only management modality; therefore, future work should compare isolated eccentric and concentric action under equal load at various exercise dosages in individuals with tendinopathy.

Resolution of clinical scenario

- Level I evidence demonstrates that eccentric exercises are superior to wait-and-see treatment.
- Level III evidence demonstrates that both eccentric and concentric exercises could be considered as equally good for patients with AT.

Question 2: In patients with AT, does a program of eccentric exercises result in better clinical outcomes compared to shockwave therapy?

Rationale

Unfortunately, not all patients with AT respond well to a program of eccentric exercises, and often other management modalities are required.

Clinical comment

ESWT may be a good option in these patients, and offers a potential alternative to other more invasive management modalities.

Available literature and quality of the evidence

Two systematic reviews[9],[10] and one current concepts review[11] are available to answer this question.

Findings

Conservative treatment with ESWT is proving successful, and moderate evidence indicates that ESWT is more effective than eccentric loading for insertional AT[12] and equal to eccentric loading for midportion AT in the short term. Additionally, there is moderate evidence that combining ESWT and eccentric loading in midportion AT may produce superior outcomes to eccentric loading alone, as reported by Rompe et al.[13]

Overall, level I evidence suggests that, even if ESWT is proving successful for AT, it is not more effective than eccentric exercises, and both ESWT and eccentric

exercises can be used together in a more efficient rehabilitative protocol for patients with AT.[9–11]

Resolution of clinical scenario

- Level I evidence demonstrates comparable results with eccentric loading or low-energy ESWT.
- Level I evidence demonstrates that eccentric loading alone is less effective when compared with a combination of eccentric loading and repetitive low-energy ESWT.

Question 3: In patients with AT, does a program of eccentric exercises result in better clinical outcomes compared to PRP injections plus eccentric exercises?

Rationale

The rationale for the use of PRP to promote tendon healing is the high content of cytokines and cells in hyperphysiologic doses of PRP.

Clinical comment

PRP is a bioactive component of whole blood, which is now being widely used in different fields of medicine for its perceived effect of aiding the regeneration of tissues with poor healing potential.[14]

Available literature and quality of the evidence

Maffulli et al.[15] evaluated the role of PRP injections for AT through the outcomes of several studies.[16–18]

Findings

De Jonge et al. did not find superiority of PRP injections over a placebo (saline) injection combined with the typical eccentric loading exercise program in terms of clinical outcomes and healing of the tendon, with no significant intergroup differences over a one-year follow-up.[16] In agreement with these findings, a follow-up study to this RCT confirmed that injection therapy using PRP does not produce a significant improvement in patients with AT compared with saline.[17] Patients were randomized to eccentric exercises with either a PRP injection or saline injection; the Victorian Institute of Sports Assessment-Achilles (VISA-A) scores over 24 weeks follow-up showed no significant differences between the two groups.

Kearney et al. published a pilot study for a larger RCT to evaluate the feasibility of conducting a larger trial to evaluate the difference in VISA-A scores at six months between patients with AT treated with a PRP injection compared with an eccentric loading programme.[18] They explicitly noted that, as a pilot study, the study was underpowered to detect clinical differences, and, in 20 patients, they failed to find a statistically significant difference between the outcome scores (VISA-A) recorded for both groups at final follow-up. The results of the definitive trial will be of great interest.

Overall, level I studies suggest that PRP injections are not superior to both placebo treatments and eccentric exercises for patients with AT.[15–18] Currently, there is no evidence that PRP injections provide statistically significant relief versus placebo in multiple randomized trials. Therefore, routine use for midsubstance AT cannot be recommended at this time.[19]

Resolution of clinical scenario

- Level I evidence demonstrates that there is no evidence to justify a PRP injection in patients with AT even when associated with appropriate physical therapy.

Summary of answers

- Eccentric exercises are superior to wait-and-see treatment, and both eccentric and concentric exercises could be considered as equally good for patients with AT.
- Comparable results can be obtained with eccentric loading or low-energy ESWT.
- Eccentric loading alone or low-energy ESWT are each less effective than a combination of eccentric loading and repetitive low-energy ESWT.
- There is no evidence to justify a PRP injection in patients with AT, even when associated with appropriate physical therapy.

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VII Wrist

146 Distal Radius Malunions

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Clinical scenario

- A 59-year-old healthy woman injures her dominant wrist after a fall at home. Her wrist radiographs show a displaced extra-articular distal radius fracture with a dorsal angulation of 15° (from 0°) and an ulnar variance of 3 mm.
- The treating surgeon has a discussion with the patient about surgical and nonsurgical treatment options and the expected outcomes in case the fracture heals with malunion or in a near anatomical position. They also discuss which treatment method would be most effective in restoring near normal anatomy.
- The patient asks, in case of symptomatic malunion, whether future surgical treatment would improve her symptoms.

Top three questions

1. In patients with distal radius fracture, does malunion increase the risk of greater patient-reported disability

and poor functional outcomes compared to those that heal in a near anatomical position?

2. In patients with displaced distal radius fracture, does treatment with open reduction and volar locking-plate fixation reduce the incidence of malunion compared to closed reduction and cast or percutaneous pin fixation?
3. In patients with a malunited distal radius fracture, is corrective osteotomy effective in improving patient-reported disability and function?

Question 1: In patients with distal radius fracture, does malunion increase the risk of greater patient-reported disability and poor functional outcomes compared to those that heal in a near anatomical position?

Rationale

Displaced distal radius fractures, if not reduced and the reduction effectively maintained by some type of fixation, heal with malunion. There is controversy regarding whether, and to what extent, distal radius fracture malunion increases the risk of disability and poor functional outcomes such as weak grip strength and limited wrist and forearm range of motion. This issue is important because it directly impacts the choice of treatment.

Clinical comment

If there is evidence that patients with malunited distal radius fracture are more likely to have worse patient-

reported outcomes and functional outcomes than those without malunion, the goal of treatment should be to ensure fracture healing in a near anatomical position. Consequently, treatment methods that have a higher likelihood of achieving this goal should be used (provided that the complication rate does not outweigh the treatment benefit). There are no established criteria for the definition of malunion but dorsal angulation of 10° or greater and positive ulnar variance of 3 mm or greater have been commonly used.[1–3]

Available literature and quality of the evidence

With regard to patient-reported disability our search identified two prognostic studies that directly address the question (one level I study and one level II study) and one therapeutic randomized controlled trial (RCT) (level I) that indirectly relates to the question. Only the level I prognostic study reported longitudinal outcomes (including baseline disability). Both prognostic studies reported relative risks (RRs). With regard to functional outcomes, our search identified three therapeutic RCTs (level I) that have addressed these outcomes in relation to malunion, but the analyses of this relationship were cross-sectional and no odds ratios or RRs were reported, decreasing their level of evidence.

Findings

In a level I prognostic longitudinal study Brogren et al. reported one-year outcomes in adult patients with displaced extra-articular or intra-articular distal radius fractures, treated with closed reduction and cast or external or percutaneous pin fixation.[4] The study found that malunion (defined as dorsal tilt >10° and/or ulnar variance ≥1 mm) is associated with higher disability, measured with the Disabilities of the Arm, Shoulder, and Hand (DASH)

questionnaire, regardless of patient age. The RR for persistent disability at one year (defined as a DASH score of ≥15) was 2.5 (95% confidence interval [CI]: 1.1–5.8) in malunion involving either dorsal tilt or ulnar variance and 3.7 (95% CI: 1.5–9.1) in malunion involving both dorsal tilt and ulnar variance. The number needed to harm (NNH) was 2.5 (95% CI: 1.8–5.4). In a longer follow-up of the cohort, Brogren et al. reported that arm-related disability, measured with the DASH, is more likely to persist at least two years in patients with fractures that healed with malunion than in patients without malunion.[5] In a level II study Grewal and MacDermid estimated that RR for persistent disability (defined as DASH score >20 or Patient-rated Wrist Evaluation [PRWE] score >20) associated with malunion (defined as dorsal angulation >10°, radial inclination <15°, or ulnar variance ≥ 3 mm) one year after distal radius fracture was 5.8 in patients of <65 years and 1.5 in older patients (DASH) and 2.9 and 1.6, respectively (PRWE); the authors concluded that patients at all ages have a higher risk of a poor outcome with malalignment of the distal radius when compared with those with acceptable alignment, but the risk is mitigated in patients over the age of 65 years.[1] In a therapeutic RCT among patients aged >65 years with distal radius fracture Arora et al. reported that in the group treated with closed reduction and cast, all patients who attended one-year follow-up (80% of those randomized) had malunion (defined as dorsal tilt ≥10°, radial shortening >2 mm, and articular incongruity ≥2 mm), but still had mean DASH and the PRWE scores indicating no or low disability.[6] The study, however, did not analyze whether the outcomes differed according to severity of malunion.

With regard to functional outcomes, Wakefield and McQueen reported that malunion, defined as dorsal angulation of ≥10° or radial shortening of ≥3 mm, was a

predictor of poor outcome.[7] Sanchez-Sotelo et al. reported that at one-year follow-up volar angle, radial angle, and ulnar variance showed a significant relationship with grip strength and range of movement.[8] McQueen et al. reported that at one-year follow-up, carpal malalignment had significant correlation with diminished grip strength and range of rotation and radial shortening had significant correlation with diminished grip strength (only p values reported, not the actual correlation coefficients).[9]

Resolution of clinical scenario

There is evidence that patients with malunion of distal radius fractures are more likely to have higher patient-reported disability and worse functional outcomes than patients without malunion.

Question 2: In patients with displaced distal radius fracture, does treatment with open reduction and volar locking-plate fixation reduce the incidence of malunion compared to closed reduction and cast or percutaneous pin fixation?

Rationale

Treatment of displaced distal radius fractures has shifted toward increasing use of open reduction and fixation with volar locking-plate. This has been based (besides the advantage of allowing early wrist motion) on the assumption that volar locking-plate fixation is more effective than closed reduction and cast or percutaneous pin fixation (common treatment methods) in restoring

normal anatomy. However, treatment with open reduction and volar plate fixation is associated with greater costs and complications.

Clinical comment

If treatment of distal radius fracture with open reduction and volar locking-plate fixation reduces the incidence of malunion, and if there is evidence that malunion is associated with a higher risk of worse patient-reported disability and functional outcomes, then the use of this treatment method is justified (provided that the complication rate does not outweigh this benefit).

Available literature and quality of the evidence

We identified six RCTs (level I therapeutic) that reported adequate radiological outcomes data comparing open reduction and fixation with volar locking-plate with closed reduction and cast or percutaneous pin fixation (with none or only a minor proportion of the patients receiving other supplemental treatment, such as external fixation).

Findings

Arora et al. compared volar locking-plate fixation with closed reduction and cast in 73 patients aged ≥65 years and reported that at one-year mean standard deviation (SD) palmar tilt was 3° (7), radial inclination 21° (3), and ulnar variance 0.7 (1.8) mm in the plate group versus −10° (19), 16° (9), and 3.2 (2.9) mm, respectively, in the cast group (all between-group differences were statistically significant).[6] Costa et al. conducted a multicenter trial with 461 adult patients and found that at one-year mean (SD) dorsal angulation was −5° (8) and ulnar variance 1.3 (2.0) mm in the plate group versus −0.5° (12) and 2.4 (2.3) mm, respectively, in the Kirschner wire (K-wire) fixation group;

adjusted mean differences (95% CI) −4.6 (−6.8 to −2.5) and −1.1 (−1.5 to −0.6), respectively.[10] Bartl et al. compared volar locking-plate fixation with closed reduction and cast in 155 patients aged ≥65 years and reported that at three months mean (SD) palmar tilt was 5° (7), radial inclination 20° (5), and ulnar variance 0.4 (1.6) mm in the plate group versus −4° (13), 18° (6), and 1.6 (2.3) mm in the cast group; mean difference (95% CI) 8.8 (5.5–12.1), 2.6 (0.9–4.3), and −1.2 (−1.8 to −0.6), respectively.[11] Marcheix et al. compared volar locking-plate with mixed pinning in 103 patients aged >50 years and reported that at six months mean (SD) palmar tilt was 1° (7), radial inclination 22° (4), and ulnar variance 2 (2) mm in the plate group versus 4° (11), 23° (5), and 2 (2) mm, respectively, in the pinning group (no statistically significant between-group differences).[12] Rozental et al. compared volar locking-plate fixation with percutaneous pin fixation in 45 patients aged 19–79 years and found that at one-year mean (SD) volar tilt was 5° (5), radial inclination 21° (4), and radial height 11 (2) mm in the plate group versus 3° (4), 21° (3), and 11 (2) mm, respectively, in the pin-fixation group (no statistically significant between-group differences); 9% of the pin-fixation group had supplemental external fixation.[13] Karantana et al. compared volar locking-plate with percutaneous pin fixation in 130 patients aged 18–73 years and found that at one-year mean (SD) volar tilt was 8° (6), radial inclination 24° (4), and radial height 11 (2) mm in the plate group, versus 2° (10), 23° (4), and 9 (3) mm, respectively, in the pin-fixation group (between-group difference in volar tilt was statistically significant); 17% of the pin-fixation group had supplemental external fixation.[14]

Resolution of clinical scenario

Treatment of displaced distal radius fracture with volar locking-plate fixation reduces the incidence of malunion compared to closed reduction and cast or percutaneous pin fixation. This benefit would need to be judged in relation to evidence regarding complications associated with these treatment methods.

Question 3: In patients with a malunited distal radius fracture, is corrective osteotomy effective in improving patient-reported disability and function?

Rationale

Patients with distal radius fracture malunion presenting with persistent disability and pain, hand weakness, and reduced wrist and/or forearm range of movement are often treated surgically with osteotomy. Distal radius osteotomy (sometimes combined with ulnar osteotomy) is a major surgical procedure that requires substantial postoperative rehabilitation.

Clinical comment

Patients with malunion of distal radius fracture often consult surgeons about the benefits of reconstructive surgery. Therefore, it is important to determine the evidence supporting the efficacy of corrective osteotomy of the malunited distal radius fracture in reducing disability and pain and improving function.

Available literature and quality of the evidence

The most appropriate study design to answer this research question would be an RCT, but no RCTs could be found. The search found three level II therapeutic studies reporting preoperative and postoperative data, enabling calculation of effect size (ES), as well as several level III studies.

Findings

Abramo et al. studied 25 patients (age 25–74, mean 52 years) with mean (SD) dorsal angulation 17° (10), radial inclination 20° (10), and ulnar variance 4.0 (2.2) mm.[15] The authors reported that at one year after osteotomy mean DASH score had improved from 36 to 23 (ES 0.81), Visual Analog Scale (VAS) pain score from 6.3 to 3.8 (ES 1.2), grip strength from 62 to 82% of uninjured side (ES 1.05), forearm rotation from 137° to 156° (ES 0.58), and flexion/extension from 102° to 120° (ES 0.85). Tarallo et al. studied 20 patients (age 17–64, mean 40 years) with mean (SD) dorsal angulation 23° (7), radial inclination 29° (7), and ulnar variance 3.6 (0.3) mm.[16] The authors reported that at 1.7–6 (mean 4) years after osteotomy, mean DASH score improved from 54 to 25 (ES 2.1), VAS pain score from 1.1 to 0.3 (ES 0.62), grip strength from 11 to 27 (ES 5.5), forearm supination from 16° to 80° (ES 8.5), forearm pronation from 75° to 84° (ES 0.62), wrist flexion from 45° to 60° (ES 0.9), and wrist extension from 39° to 70° (ES 2.8). Kiliç et al. studied 17 patients (age 18–67, mean 41 years) with mean (SD) dorsal angulation 27° (10), radial inclination 18° (6), and ulnar variance 12.1 (3.8) mm.[17] The authors reported that at 1–3.2 (mean 1.7) years after osteotomy mean Quick-DASH score improved from 27 to 6 (ES 2.3), grip strength from 18 to 24 (ES 1.0), wrist flexion from 42° to 51° (ES 0.75), forearm supination from 58° to 78° (ES 1.9), and forearm pronation from 61° to 79° (ES 5.1), whereas mean extension decreased from 59° to 56°.

The complications reported in these three studies were transient nerve lesions (radial sensory nerve in six and median nerve in two), one re-operation because of plate breakage and one flexor pollicis longus tendinitis; seven patients underwent implant removal.

The majority of the level III studies reported results in the same direction as the level II studies but the complications also included nonunions and complex regional pain syndrome.

Resolution of clinical scenario

Based on level II evidence (no RCTs) corrective osteotomy of the malunited distal radius improves patient-reported disability and pain, range of motion, and grip strength.

Summary of answers

- Patients with malunion after distal radius fracture are more likely than patients without malunion to have worse patient-reported outcomes and functional outcomes.
- Distal radius fractures are less likely to heal with malunion if treated with open reduction and fixation with volar locking-plate than with closed reduction and cast or percutaneous pin fixation.
- In patients with distal radius malunion corrective osteotomy is effective in improving patient-reported disability and pain, grip strength, and range of motion.

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147 Distal Radial–Ulnar Joint

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Clinical scenario

- A 70-year-old female complains of persistent ulnar-sided right wrist pain with pain and clunking particularly with wrist supination and pronation.
- She has tried activity modification, bracing, and nonsteroidal anti-inflammatories with no relief of symptoms.
- She has no medical co-morbidities but she does have a remote history of a right distal radius fracture with an ulnar styloid base fracture that was treated with locked volar plating of the distal radius.

Top three questions

1. Should patients with concomitant ulnar styloid base fracture be treated with open reduction and internal fixation (ORIF) or conservatively at the time of distal radius locked plating to preserve distal radial–ulnar joint (DRUJ) stability and wrist function?
2. In patients with DRUJ instability, how successful are anatomical reconstructions of the volar and dorsal radioulnar ligaments in restoring DRUJ stability and improving clinical symptoms?

3. In patients with DRUJ instability that lead to DRUJ arthritis, does semi-constrained total DRUJ arthroplasty provide greater function, pain relief, and implant longevity compared to total ulnar head replacement?

Question 1: Should patients with concomitant ulnar styloid base fracture be treated with open reduction and internal fixation (ORIF) or conservatively at the time of distal radius locked plating to preserve distal radial–ulnar joint (DRUJ) stability and wrist function?

Rationale

Distal radius fractures are one of the most common injuries of the upper extremity and ulnar styloid fractures can be present in nearly 60% of cases.[1,2] However, the impact of an ulnar styloid fracture on DRUJ instability and wrist function in the setting of a concomitant distal radius fracture is as yet unclear and there remains contradictory evidence reported in the literature.[2–4] In particular, the impact of the location of ulnar styloid fracture, base versus nonbase, is important to understand: the attachment of the superficial limb of the triangular fibrocartilage complex (TFCC) gives the theoretical risk of increased DRUJ instability with ulnar styloid base fractures. DRUJ instability is an independent risk factor for poorer clinical outcomes and so must be avoided at all costs.[5]

Clinical comment

Understanding the radiographic parameters associated with DRUJ instability after locked volar plating will help guide clinicians to predict those injury patterns requiring early intervention.

Available literature and quality of the evidence

Literature remains sparse on this topic, and although prospective studies have been reported in the literature, none was randomized.[2,4,6,7] The majority of studies are retrospective case series.[8]

Findings

The majority of clinical studies found that the presence and/or nonunion of an ulnar styloid fracture did not affect DRUJ stability,[2,4,6–8] wrist range of motion (ROM),[2,9] grip strength,[2] and clinical outcome measures such as the Modified Mayo Wrist Score (MMWS),[2,9] Michigan Hand Outcomes Questionnaire (MHQ),[7] and/or the Disabilities of the Arm, Shoulder, and Hand Questionnaire (DASH).[2,9] Moreover, in those patients who received volar locked plating, Souer et al. found that untreated ulnar styloid base fractures that were initially displaced $\geq$2 mm did not demonstrate negative sequelae with respect to function or outcome.[6] Furthermore, although untreated ulnar styloid fractures trended toward decreased grip strength, flexion, and ulnar deviation in their patient cohort, the insignificance of ulnar styloid fracture location and displacement on DRUJ instability was confirmed by Kim et al.[2] These findings were also consistent with Lindau et al.'s study that reported no negative outcomes associated with ulnar styloid fractures despite an association between complete peripheral TFCC tears and DRUJ instability.[10] Potential bias may be present in the literature, however, as Kazemian et al. and Sammer et al. excluded patients that

were identified with ulnar styloid fractures and intraoperative DRUJ instability after volar plating of the distal radius.[4,7]

Contrary studies include a biomechanical study that found ulnar styloid fractures into the fovea caused DRUJ instability and reported only partial recovery of stability with anatomic fixation.[11] Additionally, in a mixed cohort of conservatively and operatively managed distal radius fractures, Kramer et al., May et al., and Stoffelen et al. found higher pain scores, DRUJ instability, and decreased ROM with ulnar styloid fractures.[1,12,13]

Resolution of clinical scenario

- The radiographic presence of an ulnar styloid fracture irrespective of size and displacement is not necessarily associated with DRUJ instability or worsened clinical outcomes in the setting of a distal radius fracture that has undergone open reduction internal fixation.[2,4,6–9]
- Intraoperative assessment of the DRUJ after distal radius volar plating should be undertaken to assess for residual DRUJ instability and, if present, instability should be addressed at that time.[4,7]

Question 2: In patients with DRUJ instability, how successful are anatomical reconstructions of the volar and dorsal radioulnar ligaments in restoring DRUJ stability and improving clinical symptoms?

Rationale

The DRUJ requires strong soft tissue support for stability as the bony architecture confers minimal inherent structural support.[14] The TFCC is the primary soft tissue support agreed upon in the literature and is composed of various components of which the volar and dorsal radioulnar ligaments are of particular importance.[15] Persistent DRUJ instability leads to incongruent contact on the cartilaginous surfaces and subsequently post-traumatic arthritic wear may ensue causing pain, weakness, and decreased ROM. Although other nonarticular DRUJ reconstructions are reported in the literature, they have been limited by their poor biomechanical restoration of DRUJ kinematics and stability.[16] Consequently, reconstruction of both the volar and dorsal radioulnar ligaments is favored to restore the primary restraints and kinematics of the DRUJ.

Clinical comment

Understanding the effectiveness of reconstructing both volar and dorsal radioulnar ligaments in restoring DRUJ stability and symptom relief will help guide patients to make an informed decision about postoperative surgical expectations.

Available literature and quality of the evidence

Literature remains sparse on outcomes from anatomical volar and dorsal radioulnar ligament repairs, and all reported studies are retrospective case series with varied outcome measures and inconsistent follow-up.[17–23] The largest series reported 48 patients,[20] while the longest follow-up averaged approximately nine years.[21] Although the original reconstruction proposed by Adams and Berger was the basis for most volar and dorsal radioulnar ligament reconstructions,[17] modifications were performed by many authors making true procedural comparisons

difficult.[19,20,22] In addition, some patients required concurrent procedures, making delineation of the effect of the ligamentous reconstruction alone difficult.[17,23]

Findings

All studies reported that the vast majority of patients improved DRUJ stability after the procedure with greater than 78% of patients having objective clinical resolution of DRUJ instability (range: 55–100%).[18,21,23] Mayo Wrist Scores also improved,[19,21,22] as did DASH[18,19] and Patient-Rated Wrist Evaluation (PRWE) scores.[19,23] Pain typically decreased[17,22] allowing the majority of patients to return to pre-injury work or recreational activities.[18]

Recovery of postoperative motion was less predictable with some authors reporting loss of the pronation–supination arc,[17,20,21] no change,[18,19] or an improvement.[22] Grip strength recovery was also variable with some authors reporting no significant change,[18,20] while others reported an improvement.[19,22,23] The most common postoperative complications were residual instability,[17,19–23] residual pain,[17,23] and irritation from the graft knot.[19,22] Otherwise, the procedure was not associated with complications causing significant morbidity. Lastly, no radiographic arthritic changes were noted at long-term follow-up (mean follow-up: 85.53 months).[22]

Arthroscopic-assisted TFCC ligament reconstruction is reported by some authors in the literature due to the theoretical advantage of soft tissue preservation while allowing greater exposure to debride the TFCC prior to reconstruction.[19,22] Based on the published reports in the literature, no conclusive superiority of arthroscopic versus open methods can be recommended yet.

Resolution of clinical scenario

- Reconstruction of the volar and dorsal radioulnar ligaments for irreparable TFCC tears can be recommended to provide symptom relief, improved patient satisfaction scores, increased grip strength, and equivocal pronation–supination ROM recovery with minimal complications.[17,23]
- Further investigation is required to assess whether arthroscopic methods are superior to open methods. Consequently, in the interim, the surgeon should choose the approach they are most proficient in executing.[17,19,22]

Question 3: In patients with DRUJ instability that lead to DRUJ arthritis, does semi-constrained total DRUJ arthroplasty provide greater function, pain relief, and implant longevity compared to total ulnar head replacement?

Rationale

DRUJ arthritis results in diminished wrist ROM as well as grip strength. Traditional reconstructive options for an arthritic DRUJ include partial or total distal ulna resections. However, complications such as residual stump instability and/or radioulnar convergence have compelled clinicians to seek out solutions that recreate more normal DRUJ kinematics.[24] As a result, partial or complete DRUJ arthroplasties have increasingly been utilized to provide

pain-free, stable wrists for patients; however, the evidence for clinical superiority remains unclear.

Clinical comment

Understanding the clinical outcome differences between partial versus total DRUJ arthroplasties may help guide clinicians attempting to decide between different prostheses for symptomatic DRUJ arthritis.

Available literature and quality of the evidence

The literature remains sparse with the majority of studies being retrospective, nonstandardized case series with variable long-term follow-up and inconsistent clinical outcome reporting.[25–52] The patient population investigated was also heterogeneous with variable indications for surgery, and no randomized controlled study comparing implants has yet been published.[25–52]

Findings

The two major ulnar head replacements reported in the literature are the Herbert-type prosthesis (KLS Martin, Tuttlingen, Germany)[25–33] and the Avanta Uhead (Small Bones Innovations, Morrisville, PA, USA).[30,34–37] Lesser-known implants such as the First Choice ulnar head replacement (Ascension Orthopedics Inc, Austin, TX, USA) also exist. Data interpretation is difficult as multiple implants are pooled for data comparison.[32,33] A biomechanical study comparing the Herbert and Avanta ulnar implants found them comparable in maintaining near-normal DRUJ kinematics as compared to the significantly abnormal kinematics found with distal ulna resection.[38]

For all studies related to ulnar head replacements, reported postoperative pain scores were improved[25,26,29–

[32],[36],[37],[39] and the postoperative supination to pronation arc ranged from 107° to 164°[25],[28] Furthermore, implant longevity was 99% for the Herbert-type prosthesis at a mean follow-up of 6.5 years and 90% for the Uhead at a mean follow-up of four years.[40]

Nearly all studies related to total DRUJ arthroplasty reported on the Aptis implant (Aptis Medical, Glenview, KY, USA) with the majority of published clinical outcomes originating from the institution of the original surgeon developer.[41–52] However, all studies reported postoperative pain relief with good patient satisfaction and the reported postoperative supination to pronation arc was 115° to 167°.[41–52] Implant longevity was also reported to be 98% at a mean of five years.[40]

Resolution of clinical scenario

- Implant arthroplasty would be reasonable to consider for DRUJ osteoarthritis (OA) to maintain normal DRUJ kinematics and to provide improved ROM and pain relief to patients.
- No significant difference in pain relief, ROM recovery, or implant longevity is observed between ulnar head replacement versus total DRUJ replacement; however, no comparative studies have been performed.
- Further prospective, randomized controlled, long-term trials are required to delineate implant longevity and the extent of postoperative motion recovery for partial and total DRUJ replacements.

Summary of answers

- The radiographic presence of an ulnar styloid fracture irrespective of size and displacement is not associated

with DRUJ instability or worsened clinical outcomes in the setting of a distal radius fracture that has undergone ORIF.[2,4,6–9]

- Intraoperative assessment of the DRUJ after distal radius volar plating should be undertaken to assess for residual DRUJ instability and, if present, instability should be addressed at that time.[4,7]
- Reconstruction of the volar and dorsal radioulnar ligaments for irreparable TFCC tears can be recommended to provide symptom relief, improved patient satisfaction scores, increased grip strength, and equivocal pronation–supination ROM recovery with minimal complications.[17–23]
- Further investigation is required to assess whether arthroscopic methods are superior to open methods. Consequently, in the interim, the surgeon should choose the approach they are most proficient in executing.[17,19–22]
- Implant arthroplasty would be reasonable to consider for DRUJ OA to maintain normal DRUJ kinematics and to provide improved ROM and pain relief to patients.
- No significant difference in pain relief, ROM recovery, or implant longevity is observed between ulnar head replacement versus total DRUJ replacement; however, no comparative studies have been performed.
- Further prospective, randomized controlled, long-term trials are required to delineate implant longevity and the extent of postoperative motion recovery for partial and total DRUJ replacements.

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148 Wrist Osteoarthritis

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Clinical scenario

- A 50-year-old accountant complains of right wrist and left thumb pain. He recalls a wrist sprain occurring over 10 years ago. Over the past two years, his pain has been gradually worsening. He describes a dull, aching pain worse with activity in the right wrist. In addition, he complains of insidious onset of left thumb pain, worse with pinching and gripping activities.
- Radiographs show evidence of radioscaphoid arthritis and scapholunate advanced collapse (SLAC) wrist on the right and scaphotrapeziotrapezoidal (STT) arthritis on the left.

Top three questions

1. In patients with wrist osteoarthritis with involvement of the radiocarpal and midcarpal joint, is arthroplasty more appropriate than total wrist fusion?
2. In patients with radioscaphoid arthritis, and preservation of the radiolunate joint, does proximal row carpectomy (PRC) result in better wrist motion than four-corner arthrodesis (4CA)?
3. In patients with STT joint arthritis is excisional arthroplasty (either distal scaphoid excision or

trapeziectomy with ligament reconstruction) more effective than STT joint arthrodesis?

Question 1: In patients with wrist osteoarthritis with involvement of the radiocarpal and midcarpal joint, is arthroplasty more appropriate than total wrist fusion?

Rationale

Total wrist arthroplasty (TWA) is a newer treatment option for the management of wrist osteoarthritis in low-demand individuals. Earlier ball-and-socket designs were associated with high loosening and dislocation rates. Current implants are better designed to be more stable with lesser range of motion (ROM) and better bony fixation.

Clinical comments

Wrist arthroplasty is indicated when other options such as PRC and partial fusion are not viable and the patient desires to retain wrist mobility. Examples of this situation would be bilateral wrist arthritis or occupation-specific situations, such as in musicians.

Available literature and quality of the evidence

Most of the literature available currently comprises case series and retrospective analyses. There is only one level III retrospective review which compares the outcomes of arthroplasty and arthrodesis of the wrist. Additionally, other literature on TWA is focused on patients with rheumatoid arthritis, which is outside the scope of this chapter.

Findings

Nydick and colleagues' study compared patient outcomes between two groups patients of whom 15 underwent wrist arthrodesis and seven had arthroplasty.[1] Mean Disabilities of the Arm, Shoulder, and Hand (DASH) Visual Analog Scale (VAS) scores were not statistically different between groups. However, mean Patient-Rated Wrist Evaluation (PRWE) was statistically significant: 31 versus 73 for TWA and arthrodesis, respectively. These questions from the PRWE were statistically significant and supportive of TWA: cut meat using a knife, fasten buttons, pushing up from a chair, personal care activities, and household work ($p = 0.01$). There was one complication of fixed wrist contracture in the arthroplasty group, two patients in the arthrodesis group had delayed union, and one required symptomatic screw removal.

In a retrospective review of 56 patients with a mean age of 52 years, who had undergone uncemented Motec wrist arthroplasty, Reigstad and colleagues found that the patients had greater ROM and grip strength at a mean of eight years following surgery.[2] Compared to preoperative values grip strength had increased by 3 kg ($p < 0.05$) and ROM had increased from 97 to 126° ($p < 0.05$). At final follow-up, 27 of 56 patients were working. The 10-year Kaplan–Meier survival of the implants was 86%.

In retrospective review of 23 wrists in 22 patients with the Maestro TWA, Nydick et al. noted that patients had a statistically significant reduction in pain from 8 to 2 ($p < 0.05$) at mean follow-up of 28 months.[3] Complications occurred in seven of the 23 patients: four wrist contractures, one implant failure, one deep infection, and one instability.

In a multicenter registry of the Remotion TWA implant, Boeckstyns reported a significant reduction in pain scores by 42 points at a mean two-year follow-up ($p < 0.01$).[4] The revision rate in this series was 3.7% with an estimated survival rate of 90% at four years.

Total wrist fusion (TWF) of the wrist has been used effectively for pain relief in the past. Weiss et al. reported being able to achieve pain relief in all of their 28 patients who underwent TWF for post-traumatic arthritis and enabled 13 of patients to return to full-time work, without restriction.[5] Four patients required re-operation due to discomfort of the extensor tendons following the surgery. In another study of 23 patients with TWF by Weiss and colleagues, 15 were able to return to full-time work at the average follow-up of 54 months.[6]

Results are not universally favorable. De Smet et al. found that many patients continued to have ongoing pain following fusions. Only six of 36 patients were pain free with activity at the time of follow-up of four years.[7] Many complications were seen in this study; 21 patients required re-operation following TWF where 18 required removal of metalwork and three required revision.

Resolution of clinical scenario

In this patient with post-traumatic wrist osteoarthritis, with pan-carpal changes, either arthroplasty or total fusion may be considered. The procedure selected will be dependent on the patient's activity level and desire to retain wrist mobility and their understanding of the limitations imposed by TWA and possibility of conversion of arthroplasty to fusion in the long term.

Question 2: In patients with radioscaphoid arthritis, and preservation of the radiolunate joint, does proximal row carpectomy (PRC) result in better wrist motion than four-corner arthrodesis (4CA)?

Rationale

Early stages of wrist arthritis with isolated involvement of the radioscaphoid joint are amenable to either PRC or 4CA. If the radiolunate and midcarpal joints are preserved, both procedures can provide pain relief while preserving wrist motion, but have different recovery periods and complications.

Clinical comment

Two usual patterns of wrist osteoarthritis include SLAC and scaphoid nonunion advanced collapse (SNAC). As long as the degenerative changes are confined to the radioscaphoid joint, both procedures (PRC and 4CA) can be offered to patients for pain relief and preservation of motion. However, once the arthritis has progressed to involve the midcarpal joint and the capitate articular surface, PRC becomes less viable and surgeons generally prefer 4CA.

Available literature and quality of the evidence

Authors have compared the outcomes of 4CA versus PRC with randomized controlled trials, and others have reported on case series. Clinical outcomes measured include: grip strength, wrist motion, rates of complication, and re-operations.

Findings

Both procedures have yielded good results with regard to pain relief. In a prospective randomized study Bisneto et al. reported on 23 patients with SLAC wrist not involving the midcarpal joint who underwent either PRC or 4CA performed by a single surgeon.[8] Pain reduction in the PRC group was significantly higher at 41% compared to preoperative scores ($p \leq 0.05$). The 4CA group experienced a 33% reduction in pain, but this was not statistically significant. Comparative postoperative pain scores between the two groups were not statistically significant. When measured 12 months postoperatively, ROM was significantly reduced in the operated wrists compared to preoperative values ($p \leq 0.05$). The average arc of flexion/extension was reduced by 25 and 17% in the 4CA and PRC groups, respectively. The average radial deviation was 0.3 and 10% less in the 4CA and PRC groups, respectively. Both procedures resulted in improved DASH scores when compared to preoperative values; the 4CA group saw a 30% reduction, while the PRC group saw a similar reduction of 28%.

Complications, particularly relating to hardware and union of the arthrodesis, are exclusive to 4CA. Traditional fixation involved stabilization of the construct with multiple Kirschner wires. Infection and discomfort from the wires prompted the use of specialized plates and similar implants. The use of circular plate fixations has been associated with delayed or non-union and dorsal impingement of the plate.[9] In this series, complications of the implant resulted in worsened grip strength, motion and a patient dissatisfaction rate of 40%. Furthermore, DASH scores were significantly different between the two groups: plate fixation scored 27, while traditional methods scored 8 ($p < 0.01$).[9]

Clinical improvement following PRC appears to be sustained in the long term. At an average of 24 years' follow-up, Wall and co-workers reported that 65% of patients were still satisfied with the outcome of the surgery.[10] Other authors have reported sustained improvement in grip and maintenance of satisfactory movement after more than a decade.[10],[11]

In a retrospective review by DiDonna and co-workers, where 21 patients treated with PRC, four patients required wrist fusion for painful radiocapitate arthritis. All these patients were below 35 years of age ($p = 0.03$), and this finding was presumably due to their higher activity levels and demands placed on the wrist.[12]

Resolution of clinical scenario

In our patient with wrist osteoarthritis involving the radioscaphoid joint following a chronic scapholunate disruption, it is appropriate to consider either 4CA or PRC. The reported higher complication rates of nonunion with 4CA and relatively similar outcomes with PRC, favor undertaking a PRC in patients over the age of 35.

Question 3: In patients with STT joint arthritis is excisional arthroplasty (either distal scaphoid excision or trapeziectomy with ligament reconstruction) more effective than STT joint arthrodesis?

Rationale

Scaphotrapeziotrapezoidal (STT) joint arthritis can be managed operatively by arthrodesis or arthroplasty using

an implant or interposed tendon. Arthroplasty has the advantage of retaining movement and avoids the risk of nonunion associated with arthrodesis.

Clinical comment

Degeneration of the STT joint is a natural part of aging. Arthritis in the STT joint can be disabling due to involvement of the wrist and the thumb. Once conservative management fails, operative treatment can be considered in the form of arthrodesis or excision arthroplasty of the STT articulation.

Available literature and quality of the evidence

While there is no study comparing outcomes of excision arthroplasty versus fusion, there are several case series of each treatment option that can help guide management. Among the options for excision arthroplasty, there are no studies comparing trapeziectomy with distal scaphoid excision for the management of isolated STT osteoarthritis.

Findings

When considering distal scaphoid excision arthroplasty or arthrodesis for this patient, it is important to consider the requirements of the patient. Garcia-Elias et al. reviewed 21 patients who were treated with a partial distal scaphoid excision, with or without tendon interposition.[13] The authors found that grip and pinch strength had increased by 26% and 40%, respectively, when compared to their preoperative measurements ($p = 0.001$). Nine patients had insertion of a flexor carpi radialis (FCR) *anchovy* or a capsular flap following resection. Patients with soft tissue interposition had significantly reduced motion at 113° compared to no interposition at 127° ($p = 0.04$) and there

was no difference in the grip strength between the two groups.

Pyrocarbon interposition arthroplasty for STT arthritis is generally considered for patients with dorsal intercalated segment instability (DISI) collapse of the wrist where excision is contraindicated. Scaphotrapezium pyrocarbon implants were employed for interpositional arthroplasty in a series of nine patients by Low and Edmunds.[14] Patients experienced pain relief following the procedure with VAS pain scores decreasing at rest and heavy activity by 4.9 and 6.7, respectively. In addition, wrist flexion and extension on average was above 90%, while grip and pinch strength were above 80% when compared to the contralateral side. The mean DASH score was 21 postoperatively and there were no complications at the mean follow-up time of 16.4 months. Pegoli and colleagues examined ten patients at an average of 19 months after pyrocarbon arthroplasty.[15] All patients returned to their daily activities three months postoperatively and pain scores reduced by four at both rest and activity. Additionally, both grip and pinch strength improved postoperatively by 25 and 29%, respectively. The authors had two (20%) dislocations requiring re-operation in their study.

In patients who have isolated STT arthritis, a trapeziectomy and excision of the proximal 2 mm of the trapezoid with ligamental reconstruction and tendon interposition has been recommended as an alternative treatment option.[16,17]

Andrachuk and Yang in 2012 examined cases of isolated STT arthritis in 12 wrists in 10 patients with an average age of 59 years and mean follow up 18 months.[18] The authors performed a complete excision of trapezium and resected approximately one-quarter of the proximal trapezoid. The authors noted a significant postoperative increase in the mean wrist flexion and extension from 48°

and 53° to 52° and 55°, respectively ($p < 0.05$). While these results are statistically significant, they are not, however, clinically relevant. Mean grip and pinch strengths improved from 15.6 to 19.2 kg and from 3.5 to 4.5 kg, respectively. Postoperative pain scores improved from 8.5 to 1.8 ($p < 0.001$). The Modified Mayo Wrist Score graded six patients as excellent, three as good, and a single patient as fair.

Reporting similar clinical outcome, Lagenhan and associates have recommended trapeziectomy with soft tissue reconstruction without partial trapezoid resection for the treatment of isolated STT arthritis.[19] In their series of 14 consecutive patients with a mean age of 65 and mean follow-up of 54 months, the authors reported a mean VAS score of 0, average grip strength of 24 kg, pinch strength 5 kg, DASH score of 16, and Modified Mayo Wrist Score of 84. The authors noted two patients complained of wrist pain at the time of final follow-up.

Watson et al. found that arthrodesis of the scaphotrapezial joint for arthritis provides pain relief and satisfactory wrist motion with 86% of patients, reporting improved function following operation. After an average of 14.7 weeks, 88% of patients returned to work.[16] Furthermore, the authors noted a low complication rate of 4%. However, other authors have had higher failure rates following STT fusion. Five of 19 patients had nonunion of STT fusion in the series reported by Frykman and coworkers.[17]

Resolution of clinical scenario

In this patient is appropriate to offer a distal scaphoid excision arthroplasty for treatment of his painful wrist; however, the existence of a DISI deformity must be excluded preoperatively. Alternatively, this patient may be offered a trapeziectomy with ligament reconstruction and

tendon interposition (LRTI), with similar clinical outcomes. Excision of the proximal part of the trapezoid does not seem to be imperative.

Summary of answers

- Wrist arthroplasty provides higher satisfaction rates than wrist arthrodesis. TWA does place restrictions on patients' activity level, and careful patient selection is necessary.
- For early stages of SLAC wrist, PRC provides outcomes similar to 4CA with a lower complication rate.
- When treating symptomatic isolated STT arthritis in the absence of wrist instability, excision arthroplasty, either of the distal scaphoid or the trapezium, is a more favorable option as it avoids the risk of nonunion while providing pain relief and maintaining mobility. There is no evidence that the interposition of soft tissue or implants provides any additional benefit.

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149 Rheumatoid Wrist Reconstruction

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Clinical scenario

- A 55-year-old woman with a history of rheumatoid arthritis (RA) is seen with progressive deformity in her wrists and hands.
- Radiographs demonstrate distal radioulnar joint (DRUJ) incongruity with dorsal prominence of her distal ulna, flexion of the scaphoid, radiocarpal degenerative changes, and ulnar deviation of her fingers.

Top three questions

1. In RA patients with DRUJ arthritis, does prosthetic arthroplasty provide better outcomes and stability compared to distal ulnar resection arthroplasty (Darrach)?
2. In RA patients with radiocarpal deformities (arthritis or carpal subluxation), does limited arthrodesis provide acceptable long-term results compared to total wrist arthrodesis?
3. In RA patients with advanced radiocarpal and midcarpal arthritis, do total wrist arthroplasty outcomes justify the expense when compared to wrist arthrodesis?

Question 1: In RA patients with DRUJ arthritis, does prosthetic arthroplasty provide better outcomes and stability compared to distal ulnar resection arthroplasty (Darrach)?

Rationale

The distal ulna is commonly dorsally prominent in RA due to incompetent ligamentous stabilizers of the DRUJ and volar extensor carpi ulnaris (ECU) subluxation, causing carpal supination and a caput ulna deformity. This deformity can cause attritional ruptures of extensor tendons, pain, and limitation in forearm pronation and supination.[1] Surgical treatment initially focused upon resection arthroplasty, as described by Darrach;[2] however, this treatment can lead to painful complications and newer surgical treatments have been developed, including a semi-constrained total DRUJ arthroplasty.[1],[3]

Clinical comment

Treatment of DRUJ pathology with resection arthroplasty relies upon local tissue stabilization to prevent symptomatic radioulnar impingement. Semi-constrained prostheses, which include an ulnar stem and link to the radius at the sigmoid notch, as described by Scheker,[3] do not rely upon soft tissue stabilization in patients that have demonstrated incompetent tissue quality, and may help prevent complications in the RA patient.

Available literature and quality of the evidence

No studies have directly compared prosthetic arthroplasty to resection arthroplasty. Level IV studies have evaluated

patient outcomes both with total DRUJ arthroplasty and distal ulna resection arthroplasty in RA patients.

Findings

With regards to distal ulna resection, Fraser et al. in 1999 evaluated the outcomes in RA patients and in post-traumatic patients and found that RA patients had improved pain, with 34 of 37 wrists pain free, and an increase in grip strength (average of 0.8 kg).[4] Additionally, Rana and Taylor evaluated 86 wrists in 70 RA patients treated with distal ulnar resection, reporting 95% pain-free wrists after surgery, improvement in forearm pronation and supination in all, and improvement in grip strength in 88%.[5] Within these case series, the authors did not find substantial pain or functional limitations from the previously described complications of distal ulna resection, including ulnar drift of the carpus, radioulnar impingement and ulnar instability. They reported ulnar clicking, without significant pain, and progressive ulnar drift of the carpus, without an influence on the patient's overall result.[4],[5]

When evaluating the semi-constrained DRUJ arthroplasty, Galvis and colleagues in 2014 evaluated a case series of RA patients who underwent 19 total DRUJ arthroplasties. At an average of 39-month follow-up, these patients demonstrated decreased pain from Visual Analog Scale (VAS) of 7.4 to 2.2, improvement in pronation from 56° to 78°, and improved supination of from 56° to 72°. No progression of ulnar carpal drift or tendon ruptures occurred; however, tendon irritation was seen in one patient.[6] Additional studies have evaluated patient outcomes after DRUJ arthroplasty; however, these studies were not specific to RA patients.

Resolution of clinical scenario

- There is incomplete evidence to conclusively support DRUJ arthroplasty over resection arthroplasty.
- Technical rationale including decreased reliance on incompetent soft tissue structures and decreased risk of radioulnar impingement support DRUJ arthroplasty as a reasonable alternative to DRUJ resection arthroplasty, specifically in the younger and less debilitated RA patient.
- Additionally, total DRUJ arthroplasty could be considered as a salvage option for a symptomatic resection arthroplasty if adequate ulnar length is maintained.
- Longer follow-up studies will be helpful in supporting DRUJ arthroplasty as a primary procedure for DRUJ deformity in RA.

Question 2: In RA patients with radiocarpal deformities (arthritis or carpal subluxation), does limited arthrodesis provide acceptable long-term results compared to total wrist arthrodesis?

Rationale

As commonly seen in RA patients, limited arthrodesis at the radiolunate or radioscapholunate joints allows for maintenance of wrist motion at the capitolunate articulation, or in the dart-throwing motion plane,[7] in patients with advanced degenerative changes of the radiocarpal articulation or carpal subluxation and preservation of the midcarpal joint.

Clinical comment

Degenerative changes within the midcarpal joint are commonly delayed in RA patients, as synovitis occurs later in the midcarpal joint as a result of the sparse ligamentous attachments.[1] In patients with subluxation of the carpus or advanced radiocarpal arthritis without degenerative changes to the midcarpal joint, partial wrist fusions allow for maintenance of some wrist motion. However, it is unclear whether partial wrist fusions demonstrate acceptable long-term outcomes versus total wrist arthrodesis in RA patients.

Available literature and quality of the evidence

No studies have directly compared limited versus total wrist arthrodesis. Level IV studies have evaluated patient outcomes with partial wrist arthrodesis.

Findings

Raven et al. performed the most recent long-term follow-up of RA patients after partial wrist arthrodeses and demonstrated improved wrist range of motion (ROM) and less pain, in spite of radiographic progression of midcarpal arthritis over time.[8] The authors reviewed studies on a total of 395 partial wrist arthrodeses and demonstrated consistent improvement in pain, patient satisfaction, wrist ROM, and grip strength.[8] Honkanen et al. showed maintenance of fusion in a mixed group of radioscapholunate and radiolunate arthrodesis RA patients who demonstrated a functional arc of wrist motion and improved grip strength. Two wrists progressed to midcarpal arthritis and underwent total wrist arthrodesis within the group of 23 wrists.[9] Ishikawa and colleagues evaluated long-term results in 25 patients who underwent partial wrist arthrodeses, demonstrating decreased pain,

improved forearm rotation, and increased grip strength at 10-year follow-up. They noted progression of carpal collapse in many of the patients over the follow-up period; however, all but one wrist remained stable.[10] The primary limitation of these studies is the lack of a control group, as all are case series.

Cavaliere and Chung's systematic review comparing arthrodesis and arthroplasty reported improved pain and patient satisfaction with consistent surgical outcomes after wrist arthrodesis.[11] Overall, total wrist arthrodesis does provide consistent outcomes but with loss of all wrist motion compared to a partial wrist arthrodesis.

Resolution of clinical scenario

- In the RA patient with radiocarpal deformity, without advanced degenerative changes in the midcarpal joint, a partial wrist arthrodesis provides a reliable rate of union, pain relief, and patient satisfaction.
- Even with progression of midcarpal arthritis after limited arthrodesis, the majority of patients demonstrate acceptable long-term outcomes to recommend partial wrist arthrodesis.

Question 3: In RA patients with advanced radiocarpal and midcarpal arthritis, do total wrist arthroplasty outcomes justify the expense when compared to wrist arthrodesis?

Rationale

In patients with RA at both the radiocarpal and midcarpal joints, total wrist arthrodesis and wrist arthroplasty are viable surgical options to alleviate pain.[1] While total wrist arthroplasty theoretically maintains wrist ROM, it is unclear whether patient outcomes after arthroplasty are sufficiently improved to justify the increased cost of arthroplasty when compared to arthrodesis.

Clinical comment

When wrist arthritis involves the midcarpal joint and there is loss of wrist motion, both wrist arthroplasty and total wrist arthroplasty provide reliable outcomes in the RA patient population.

Available literature and quality of the evidence

Systematic reviews of case series and cohort studies comparing the outcomes of arthroplasty and arthrodesis are present within the literature. A single level III prospective cohort study comparing patients is identified. A decision analysis level II study is also present to assist in answering this clinical question.

Findings

Murphy et al. evaluated arthroplasty and arthrodesis in 51 RA wrists in a prospective cohort study. Patients had similar outcomes, but improved ability for personal hygiene and buttoning in the arthroplasty group.[12] Cavaliere and Chung have contributed several studies to the management of advanced wrist arthritis in the RA patient. In 2008, they performed a systematic review on 18 arthroplasty and 20 arthrodesis studies. They concluded that arthrodesis provides more reliable outcomes and improved pain relief when compared to arthroplasty. Both groups demonstrated high patient satisfaction with increased complication and

revision rates following arthroplasty. While a theoretical benefit of arthroplasty is maintenance of motion, only three of the 14 studies demonstrated a functional ROM after arthroplasty.[11] In 2015, Yeoh and Tourret performed a systematic review of total wrist arthroplasty studies in the preceding five years and reported complication rates. Similarly, complications following wrist arthroplasty were higher than for arthrodesis and the preserved ROM did not always reach the full functional range. Additionally, survival rates vary between prosthetic design, and the authors recommend being selective in patients receiving this procedure.[13]

A survey of the American Society for Surgery of the Hand members and RA patients in 2010[14] reported that arthroplasty was preferred over nonsurgical treatment. An incremental cost of $2328/QALY gained for arthroplasty over arthrodesis was well below the $50 000 benchmark used to set the preferred treatment. This decision analysis study demonstrates that, despite the risk of revision surgery and increased costs of arthroplasty, RA patients may prefer this option and it should be considered a viable alternative.[15]

Resolution of clinical scenario

- Total wrist arthroplasty appears to be a cost-effective surgical option if the patient desires wrist motion, understands that functional wrist ROM cannot be guaranteed, and accepts the increased risks of revision and complications.
- If a patient with a contralateral wrist arthrodesis presents with advanced wrist arthritis, wrist arthroplasty should be considered to optimize function and the patient's ability to perform activities of daily living.

Summary of answers

- No comparative studies exist between prosthetic or resection arthroplasty of the DRUJ. In younger patients primary semi-constrained prosthetic DRUJ arthroplasty may decrease potential complications; however, resection of the distal ulna in lower demand patients may provide good outcomes.
- In patients without midcarpal arthritis, partial wrist arthrodesis provides reliable long-term outcomes with improved pain and patient satisfaction while maintaining wrist ROM and improving grip strength.
- Outcomes and cost analysis of wrist arthroplasty demonstrate that it is a reasonable surgical option for patients; however, preoperative patient counseling about the unpredictable outcomes and increased risk of revisions is critical to patient expectations.

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150 Acute Scaphoid Fractures

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Clinical scenario

- A 26-year-old man presents after a fall onto outstretched hand with pain on the radial side of the wrist.
- He has five radiographic views of the wrist which demonstrate a clear bicortical fracture of the waist of the scaphoid.

Background

One in every 50 fractures is a scaphoid fracture,[1] and it occurs in young men, especially aged between 15 and 24.[2] Only 12% of scaphoid fractures occur in women, and the highest incidence is in girls between 10 and 14 years of age. The waist of the scaphoid is fractured in 77%, the tuberosity in 18%, and the proximal pole in around 5%. No scaphoid fracture classification clearly predicts union or indicates treatment but classifications help describe reported cases.[3–6]

Once a clear bicortical fracture is identified, the treatment objective is to get the fracture to unite and restore function without pain. The clinician needs to decide how to immobilize the fracture so that it unites without (i) disabling the patient for long periods or (ii) exposing patients to significant risks with lifelong disability.

Top three questions

1. In adult patients with a scaphoid fracture, do some imaging modalities provide better ability to determine union compared to other modalities?
2. In adult patients with a clear bicortical fracture of the scaphoid, does cast immobilization or screw fixation result in higher union rates and faster time to union?
3. In adults with clear bicortical fractures, are there certain fracture characteristics that influence union rates or the decision to treat operatively versus nonoperatively?

Question 1: In adult patients with a scaphoid fracture, do some imaging modalities provide better ability to determine union compared to other modalities?

Rationale

Union is the common endpoint used to define outcomes in scaphoid fractures. Clear definitions of union, time to union, partial union, and nonunion are needed.

Clinical comment

Union and time to union can be difficult to define and authors use different methods (i.e. x-ray vs computerized tomography) to diagnose union.

Available literature and quality of the evidence

The clinically relevant outcome for a scaphoid fracture is *union* of the fracture as determined by imaging. The imaging attributes which suggest that the fracture is uniting are:[7]

- Trabeculae crossing the fracture line on *all* imaging projections.
- Sclerosis at the fracture line on *all* imaging projections.
- Absence of a clear gap across the full width of the fracture line on *any* imaging projection.

For radiographs these attributes are difficult to assess confidently, and the assessment of union,[8] especially at early timepoints, is unreliable.[7] Computed tomography (CT) CT scan has been proposed as an alternative and some methods of assessing union and especially partial union have been suggested and tested but have not yet been established.[9–11] At present there is no clarity of definition and classification of union on imaging, although a framework for this has been suggested.[12]

Findings

Union

Union is established on imaging. Radiographic views of the scaphoid are usually taken to confirm the absence of adverse radiological features such as a gap at the fracture site or displacement. Very rarely, if an implant has been used, lucency or implant movement will suggest failure of union.[12] Radiographs taken 12 weeks after a scaphoid fracture do not provide reliable and reproducible evidence of healing.[7] The usual advice is that radiological union is only considered to have occurred when *bridging trabeculae* are seen across the whole cross-section of the scaphoid on

radiographs or a CT scan.[13] This is difficult to confirm, so it is sensible to identify failure rather than assume that *no gap* means the bone has united.

Time to union

Time to union is difficult to calculate as it depends on the interval of the imaging and how union was assessed. It is usually provided as a *mean* but reflects the first clinical timepoint where imaging obtained is judged to suggest fracture union.[14] "Measuring 'time to union' presupposes that the state of union has been clearly defined, that it can be reliably assessed using current techniques and that this state is measured continuously rather than at the usual intervals after intervention. Although the time to union is documented in a number of studies, this is based on the first visit after intervention when the surgeon has felt able to diagnose 'union.'"[12]

Partial union

Partial union is defined as the presence of a visible gap across part of the fracture site associated with probable *trabecular bridging* in other areas identified on radiographs but quantified on CT scan.[15] Partial union is common, being reported in up to 42% of patients. With trabeculae bridging across more than 25% of the cross-section of the scaphoid, it typically progresses to complete union without the need for further immobilization, although the wrist may need protection in a splint for heavy activity for a further four- to six-week period.[15]

Nonunion

Nonunion is the absence of radiographic signs of healing at 12 weeks with a clear gap on radiographs on any view and confirmed on a CT scan.[9],[11],[13] A high-quality CT scan (fine

cut, bone window) will help establish a diagnosis of nonunion, define the anatomy, and help with preoperative planning. Patients with an established scaphoid nonunion (whether they are symptomatic or not) who decide to be treated nonoperatively should be advised that osteoarthritis is a likely, and avoidable, eventuality.[16]

Resolution of clinical scenario

In our clinical practice, CT scans are only indicated to identify nonunion and quantify significant partial union. We do not routinely use CT scans to confirm union, owing to cost, capacity, and availability. We recognize, however, that many surgeons use CT scans to define union rather than relying on plain radiography.

Question 2: In adult patients with a clear bicortical fracture of the scaphoid, does cast immobilization or screw fixation result in higher union rates and faster time to union?

Rationale

The decision to treat undisplaced or minimally displaced scaphoid fractures with cast immobilization or with surgical fixation is one of the most controversial areas in the treatment of scaphoid fractures. Multiple studies have attempted to address this issue, but the answer is still unclear.

Clinical comment

When using a cast to immobilize the broken scaphoid, surgeons must decide on the type of cast used and the

duration of immobilization. An undisplaced or minimally displaced scaphoid fracture can be immobilized in a below-elbow plaster cast with the thumb free for as little as four weeks to achieve union.[17] The alternative is to operate and fix the broken scaphoid. The intervention must be explained, and the patient should understand the risks, benefits, and alternatives to surgery. Many patients assume that surgical fixation will allow immediate resumption of activity, regardless of its demands on the wrist, as if the fracture has “healed.” Patients must be made aware that fixation is only an internal splint holding the alignment of the scaphoid as the physiological processes of healing occurs.

Available literature and quality of the evidence

There are at least seven reported trials[14,18–23] comparing cast versus fixation and one multicenter cohort study[24] for the treatment of acute scaphoid fractures. There are numerous systematic reviews of these papers.[25–32]

Findings

About 50% of units in the UK (including the author's) use a below-elbow cast,[33] which leaves the thumb free and, by permitting pinch, retains function from the outset.[34] Others continue to use a so-called traditional scaphoid plaster cast, which immobilizes the thumb. With the thumb immobilized, the additional restriction of movement at the fracture site is very small. The thumb can be immobilized in two positions. A functional position permits opposition of the thumb allowing pulp-pinch and tripod-pinch. A thumb immobilized in extension renders pinch difficult, limiting prehension and activities of daily living. In summary, hand function is *good* in a below-elbow cast with the thumb left free, *adequate* in a scaphoid cast in functional position,

restricted in a scaphoid cast in a dysfunctional position, and *hugely compromised* in an above-elbow cast.

Surgical screw fixation is an alternative treatment option. The risks of surgery include infection (1%),[30] the need for additional surgery (7.7%),[30] chronic regional pain syndrome (2%),[30] and osteoarthritis, if the approach damages joint cartilage (40%).[35] Delayed union and nonunion (3–7%)[35,36] after internal fixation can occur if there is a loss of rigid fixation caused by screw malpositioning, fixation maintaining a gap, inadequate reduction, avascular necrosis (AVN) of the proximal pole,[37] or implant loosening. Chondrolysis and implant-related problems can also occur, especially if the hold is poor or the implant was long and protruding into a joint.

The literature has not been able to establish a significant difference between the two treatment methods for the rate of union: patient-reported outcome measures (PROMs) or re-operation/surgery for nonunion rate after acute fractures. A few have suggested that *time to union* and recovery of function is quicker after surgery. The studies included are small, with different timepoints and some reviews,[32] and meta-analyses have also included case series.[38–40]

Resolution of clinical scenario

We formulate an intervention plan with our patient having considered that:

- There is no difference in union rates between cast immobilization and fixation (overall quality: moderate).
- There is no difference in PROMs between these two alternatives (overall quality: very low).

- There are slightly more patients requiring re-operation than requiring early fixation for a nonunion (overall quality: low).
- And there is a higher complication rate in patients having immediate fixation (overall quality: low).

Our patients usually choose the nonoperative pathway and are prepared for fixation of a nonunion if required.

Question 3: In adults with clear bicortical fractures, are there certain fracture characteristics that influence union rates or the decision to treat operatively versus nonoperatively?

Rationale

Two factors that can modify a treatment pathway are fracture location and fracture displacement as these can change the natural history of this injury.

Clinical comment

Proximal pole fractures and displaced fractures have a higher likelihood of developing into a nonunion. In cases such as these, where it is considered unlikely that the fracture will heal with conservative measures, surgery could be considered from the outset.

Available literature and quality of the evidence

There is little literature reporting specifically on the outcomes of proximal pole fractures. Eight papers were identified which reported outcomes of proximal pole fractures separately.[34–41–47] Two of the papers were RCTs

with identified flaws in method so were regarded as providing level II evidence,[34,42] the remaining six papers were retrospective case series accounting for level IV evidence.

At present, there is no RCT comparing healing rates of displaced versus undisplaced scaphoid fractures. A meta-analysis[48] identified eight papers[4,34,46,49–53] reporting outcomes after cast immobilization in 232 displaced and 1303 undisplaced fractures. Two of these papers were RCTs with some flaws in method and so were considered to provide level II evidence,[34,49] six were case series of which one was prospective but all were considered as providing level IV evidence. One paper[52] was excluded and the pooled relative risk of nonunion for displaced fractures versus undisplaced fractures of the scaphoid treated in a plaster cast was 4.4. Review of case series of displaced fractures operated suggests a very low rate of failure of union (2 of 157 cases).[36,54–57]

Findings

Proximal pole fractures are uncommon and account for around 5% of all scaphoid fractures. They behave differently than waist or distal pole fractures.[58] This may reflect the intra-articular location and the precarious circulation of this region of the scaphoid.

Extracting information on proximal pole fractures is difficult as studies use different definitions of proximal fractures so the fractures so classified may not be only those located in the proximal 20%.[58] Eight papers were identified[34,41–47] reporting on 1147 scaphoid waist fracture, of which 1021 united, and 67 proximal pole fractures, of which 44 united. The relative risk of nonunion in proximal pole scaphoid fractures compared to fractures of the waist of the scaphoid is 6.3, although 69% of these

fractures will still unite if immobilized in a cast. There is no good evidence at present to suggest that early fixation of proximal pole fractures improves the union rate. The few that report surgery in 40 patients with a *proximal* fracture (and which may have included waist fractures) report union in 38.[59–61]

The second fracture attribute which may alter the pathway chosen is displacement of the fracture fragment. A scaphoid fracture is considered displaced if the fracture fragments have a step or gap ≥1 mm between the corresponding cortices on any radiological view, although the fragments may also angle or rotate. A step or gap ≥ 2mm is considered significantly displaced. Fracture displacement is better assessed on CT or magnetic resonance imaging (MRI) than on scaphoid series radiographs.[33] Angulation is more reproducibly measured using the height to length ratio[62] and the mean normal ratio is 0.61.[63] This needs to be >0.69 to consider it as a significant angular malposition. However, this method too is not fully robust.[63] A high-quality CT scan with multiplanar reconstructions in the axis of the scaphoid and using a bone window may provide better definition of fracture displacement.

The clinical impression is that fractures involving the proximal 20% and/or displaced fractures, with a 3 mm or more gap, do not unite as readily and as quickly as waist fractures so the case to consider surgical fixation is stronger. Although immobilization in a cast for six weeks will result in union of 80–85% of displaced fractures of the scaphoid,[34] the consequence of the fracture healing in a displaced position is malunion, but we do not clearly know what to tell our patients about symptoms they will experience if the scaphoid heals in a nonanatomical position. At present we know that there is a higher risk of

nonunion for displaced scaphoid fractures compared with nondisplaced fractures if treated in a cast. There is some weak evidence that fixation reduces the rate of nonunion. But we do not know if fixation reduces the rate of malunion or arthritis. This should be explained to patients.

Resolution of clinical scenario

We check if the fracture affects the proximal 20% and our counseling reflects the current evidence (overall quality: low). We then measure displacement as <1 mm, 1 to <2 mm and ≥2 mm step or gap and again modify our discussion with the patient based on the current evidence (overall quality: low).

Summary of answers

- In our clinical practice, CT scans are only indicated to identify nonunion and quantify significant partial union. We do not routinely use CT scans to confirm union, owing to cost, capacity, and availability.
- We formulate an intervention plan with our patient having considered that:

    There is no difference in union rates between cast immobilization and fixation (overall quality: moderate).

    There is no difference in PROMs between these two alternatives (overall quality: very low).

    There are slightly more patients requiring re-operation than requiring early fixation for a nonunion (overall quality: low).

    And there is a higher complication rate in patients having immediate fixation (overall quality: low).

Our patients usually choose the nonoperative pathway and are prepared for fixation of a nonunion if required.

- We check if the fracture affects the proximal 20% and our counseling reflects the current evidence (overall quality: low). We then measure displacement as <1 mm, 1 to <2 mm and ≥2 mm step or gap and again modify our discussion with the patient based on the current evidence (overall quality: low).

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151 Scaphoid Nonunions

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Clinical scenario

- A 39-year-old male presents with progressive wrist pain, possibly following a wrist sprain sustained 1.5 years ago, for which he did not seek medical attention.
- Physical examination reveals tenderness in the anatomic snuff box and a reduced range of motion.
- Computed tomography (CT) imaging confirms a nonunion of the scaphoid (Figure 151.1)

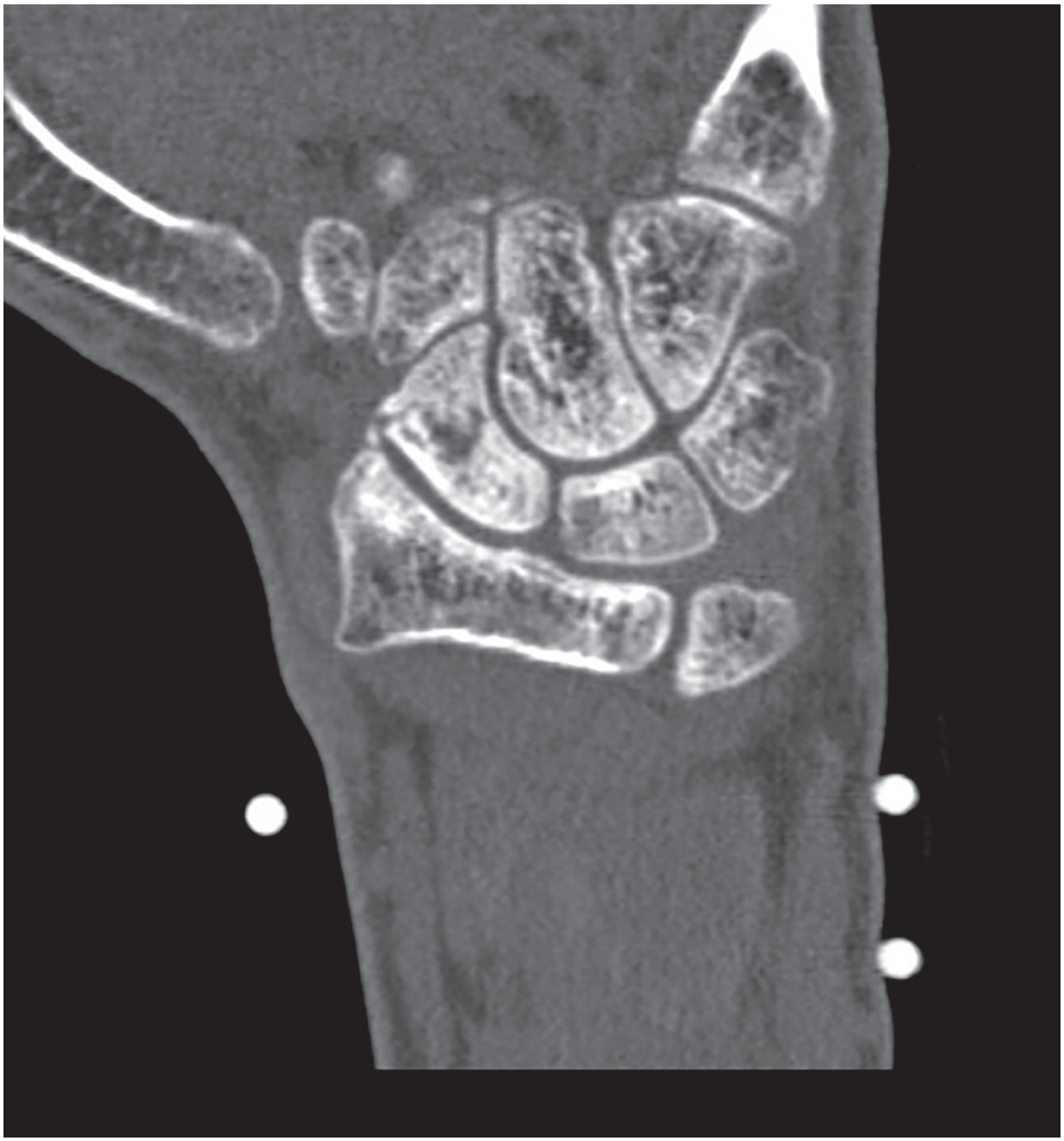

Figure 151.1 Coronal CT image of the wrist displaying a nonacute fracture of the scaphoid waist extending to the distal pole, with a wide fracture cleft and sclerosis of the fracture surface, confirming scaphoid nonunion.

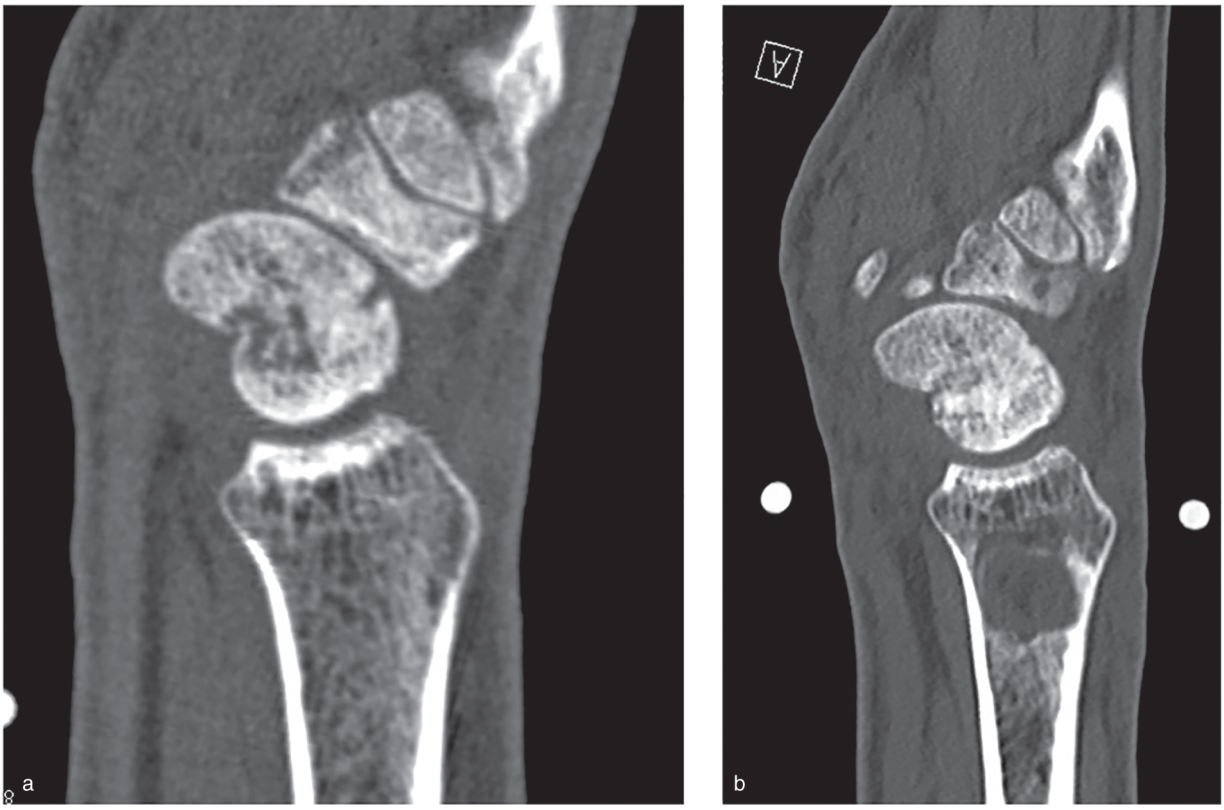

Figure 151.2 Resolution of clinical scenario: scaphoid reconstruction with a corticocancellous bone graft. (A) Preoperative sagittal CT image of the wrist shows a tendency toward a humpback deformity. (B) The patient is treated with a nonvascularized corticocancellous graft of the distal radius. The postoperative CT, three months after surgery, demonstrates improvement in scaphoid height and near complete consolidation.

Top three questions

1. In patients with a scaphoid fracture, which risk factors are associated with scaphoid nonunion?
2. In patients with a scaphoid nonunion, which management options, compared to others, yield the best outcomes?

3. In patients with scaphoid nonunion advanced collapse (SNAC), which treatment options, compared to others, yield the best outcomes?

Question 1: In patients with a scaphoid fracture, which risk factors are associated with scaphoid nonunion?

Rationale

Identification of risk factors associated with scaphoid nonunion contributes to the prevention, diagnosis, and tailored treatment in at risk patients.

Clinical comment

Although the majority of scaphoid fractures heal when treated conservatively, nonunion rates of up to 34% are reported in the literature.[1,2] The relatively high rates of nonunion can be attributed to the scaphoid's tenuous vascular supply and the poor diagnostic reliability of radiographs to diagnose acute scaphoid fractures. Identifying risk factors for nonunion may optimize treatment strategies. Assuming that surgical intervention increases rates of union in specific cases, these patients may be offered early surgical intervention.

Available literature and quality of the evidence

- Level I: 1 large inception cohort study.[3]
- Level II: 1 retrospective case control study.[4]
- Level III: 1 retrospective cohort study[5] and 3 systematic reviews with methodological limitations.[1,2,6]

- Level IV: 9 retrospective case series and reviews with methodological limitations.

Findings

Fracture location and displacement are considered important determinants for fracture union. Proximal pole fractures are at the highest risk for nonunion (10–34%)[1,7] compared to waist (0–33%)[8,9] and distal (0–2%)[10] pole fractures. The increased risk of nonunion in proximal pole fractures is typically attributed to the decreased arterial blood supply and associated risk of avascular necrosis (AVN).[1] In displaced fractures, generally defined as fractures with a gap of 1 mm or greater between fragments, nonunion rates of up to 55% have been reported.[11] CT is the recommended diagnostic test to identify fracture displacement and bony configuration of scaphoid fractures.[4] An exponential relationship exists between the amount of fracture diastasis on CT and the risk of nonunion.[4]

Delayed treatment, resulting from both patient delay and missed diagnosis, increases the risk of nonunion. Nonunion rates are higher in fractures diagnosed and immobilized after four weeks (40%) compared to those treated within four weeks (3%).[12] In a quantitative meta-analysis of 1827 patients with established scaphoid nonunion, Merrell et al. described union rates of 90 versus 80% when fractures were treated surgically within, or after, 12 months, respectively ($p < 0.0001$).[2]

A large inception cohort study by Zura et al. including 7149 scaphoid fractures, identified several risk factors for nonunion, including male sex, use of nonsteroidal anti-inflammatory drugs (NSAIDs) or opioids, and osteoarthritis.[3] Other studies reported higher success rates

in nonsmokers undergoing corrective nonunion surgery than smokers.[5,6]

Resolution of clinical scenario

- The risk of nonunion is increased in proximal pole fractures, displaced fractures, and fractures with signs of AVN (overall quality: moderate).
- Adequate diagnosis and early treatment reduce the risk of nonunion (overall quality: moderate).
- Smoking decreases the chance of successful scaphoid reconstruction (overall quality: low).
- Excessive use of NSAIDs or opioids should be avoided where possible (overall quality: low).

Question 2: In patients with a scaphoid nonunion, which management options, compared to others, yield the best outcomes?

Rationale

The aim of treating scaphoid nonunion includes union, the relief of symptoms, as well as the limitation of degenerative wrist arthritis, known as the SNAC wrist.[13]

Clinical comment

Persistence of unstable scaphoid nonunion leads to degenerative changes in the scaphoid, radial styloid, and ultimately pancarpal arthritis of the scaphocapitate and capitolunate joints.[13] A 97% incidence rate of degenerative changes in untreated symptomatic nonunions older than five years has been described.[14] However, the actual

correlation between symptoms and disease is poorly reported. It is not clear whether surgery significantly alters disease progression, even if union is attained.[15]

Available literature and quality of the evidence

- Level II: 3 randomized controlled trials (RCTs) with methodological limitations.[16–18]
- Level III: 1 RCT of limited methodological quality, 4 retrospective comparative studies with methodological limitations,[19–21] and 7 systematic reviews of uncontrolled comparative studies and case series.[2,6,22–26]
- Level IV: 159 retrospective case series.

Findings

Operative treatment

The prevailing treatment of scaphoid nonunion constitutes the use of a bone graft and internal fixation.[25] Bone grafts may be vascularized (VBGs) or nonvascularized (NVBGs). VBGs include pedicled grafts from the distal radius or free vascularized grafts from the iliac crest and the medial femoral condyle (MFC). NVBGs include various types of (cortico-) cancellous grafts, typically harvested from the iliac crest or distal radius.[15]

In a meta-analysis of 1602 patients, Pinder et al. reported comparable rates of union in VBGs (88%) and NVBGs (92%) with similar union rates.[25] However, the vascular status as well as the bony configuration should be taken into consideration when planning scaphoid reconstruction, using preoperative magnetic resonance imaging (MRI) or CT, respectively.[4,27]

In case of unstable nonunions with a humpback deformity and dorsal intercalated segment instability (DISI), structural corticocancellous grafts allow for the restoration of scaphoid height and carpal alignment.[26] In a systematic review by Sayegh and Strauch, union rates of corticocancellous grafts were comparable to nonstructural cancellous grafts (92% vs 95%, respectively, p = 0.26), while functional outcomes were significantly higher.[26]

Regarding the scaphoid's vascular status, proximal pole viability should be assessed preoperatively. Gadolinium-enhanced MRI has proven the most sensitive and specific diagnostic modality to assess the presence of AVN.[27] However, its correlation with rates of union after bone grafting remains inconclusive.[28] In the absence of AVN, NVBGs appear equivalent to VBGs in terms of union rate and functional outcome.[25,29] In case of AVN, VBGs are associated with higher rates of union than NVBGs.[2,23,25] Merrell et al. demonstrated VBGs to yield significantly higher rates in patients with AVN (88% vs NVBGs 47%, p <0.01) and in patients who had previous surgery (94% vs 81%, p >0.05).[2] There is no consistent high-quality evidence supporting the superiority of free VBGs versus pedicled VBGs.[6,30]

Regarding donor site morbidity, grafts from the distal radius (vascularized and nonvascularized) and free MFC are associated with the least donor site morbidity.[22,25]

Adjunctive treatment

Treatment modalities such as pulsed electromagnetic field (PEMF) therapy,[31] low-intensity pulsed ultrasound (LIPUS),[32] and the use of recombinant human bone morphogenetic proteins (rhBMP)[33] have been investigated as adjunctive therapy to increase union rates. Most studies

reporting on the use of such modalities are subject to important methodological limitations affecting outcome reliability and should be interpreted with caution. Overall, there is insufficient evidence supporting the use of these adjunctive treatment modalities.

Resolution of clinical scenario

- In the absence of proximal pole AVN, NVBGs and VBGs yield equivalent union rates and functional outcomes (overall quality: moderate).
- In nonunions with DISI deformity, structural corticocancellous grafts can provide a better restoration of carpal geometry (overall quality: moderate).
- In case of AVN, or following unsuccessful surgery, VBGs are associated with higher rates of union (overall quality: low to moderate).
- There is no consistent evidence supporting the superiority of free VBGs to pedicled VBGs in case of AVN (overall quality: low).
- There is insufficient evidence for the use of adjunctive treatments such as LIPUS, PEMF, or rhBMP (overall quality: low).

See Figure 151.2 for the resolution of the clinical scenario.

Question 3: In patients with scaphoid nonunion advanced collapse (SNAC), which treatment options, compared to others, yield the best outcomes?

Rationale

Proximal row carpectomy (PRC) and four-corner arthrodesis (4CA) are salvage procedures for stage II–III SNAC wrists. It is important to identify the relative advantages in terms of postoperative function, pain, and the risk of osteoarthritis associated with each procedure.

Clinical comment

In stage II and III SNAC wrists, or in the event of unsuccessful nonunion surgery, salvage procedures aim to alleviate pain and preserve wrist function.[15] Options include partial or complete wrist arthrodesis, PRC, radial denervation, radial styloidectomy, excision of the distal ununited scaphoid fragment, or excision of the proximal pole and replacement with a pyrocarbon implant.[34,35] Management will largely be dictated by the stage of degenerative arthritis, as classified by Vender et al.[13] In stage II–III wrists PRC and scaphoid excision with 4CA are the most commonly described interventions.

Available literature and quality of the evidence

- Level II: 1 RCT with methodological limitations.[36]
- Level III: 1 systematic review of comparative studies,[37] 1 systematic review of noncomparative retrospective case series,[38] and 13 retrospective cohort studies.[37,39]
- Level IV: 78 retrospective case series.

Findings

PRC and 4CA have proven equally effective in alleviating pain and comparable in terms of postoperative function.[37] A systematic review by Saltzman et al. reported no significant differences in the proportional change in grip strength (+17% 4CA, +19% PRC, $p = 0.8$), wrist extension (<+1% 4CA, PRC), flexion (−13% 4CA, −14% PRC, p =

0.88), and ulnar deviation (+1% 4CA, −4.8% PRC, p = 0.28).[37] The change in radial deviation was significantly greater following 4CA (+55% vs −30%, p = 0.02).[37] Studies report patient-rated wrist function to be better following PRC or similar following both procedures.[37,39] Brinkhorst et al. demonstrated patients in the PRC group to perform tasks significantly faster, except for activities requiring torque strength.[39] Importantly, Saltzman et al. reported the cumulative incidence of complications to be significantly higher in 4CA groups (29%, including 6.1% nonunion) than PRC (14%, p = 0.01).[37] Long-term follow-up studies establishing the incidence of osteoarthritis are scarce. Some studies report a higher incidence of osteoarthritis in PRC groups, but without correlation to clinical symptoms.[38] In a 17-year follow-up by Berkhout et al., no differences in radiographic osteoarthritis or correlation with pain were described between PRC and 4CA.[40]

Resolution of clinical scenario

- PRC and 4CA effectively alleviate pain and yield comparable results in terms of change in range of motion (overall quality: low).
- Patient-reported wrist function following PRC and 4CA is similar or better following PRC (overall quality: low).
- 4CA is associated with a higher overall complication rate (overall quality: low).
- There is inconsistent evidence on the incidence of osteoarthritis following PRC and 4CA (overall quality: low).

See Figure 151.3 for the resolution of the clinical scenario.

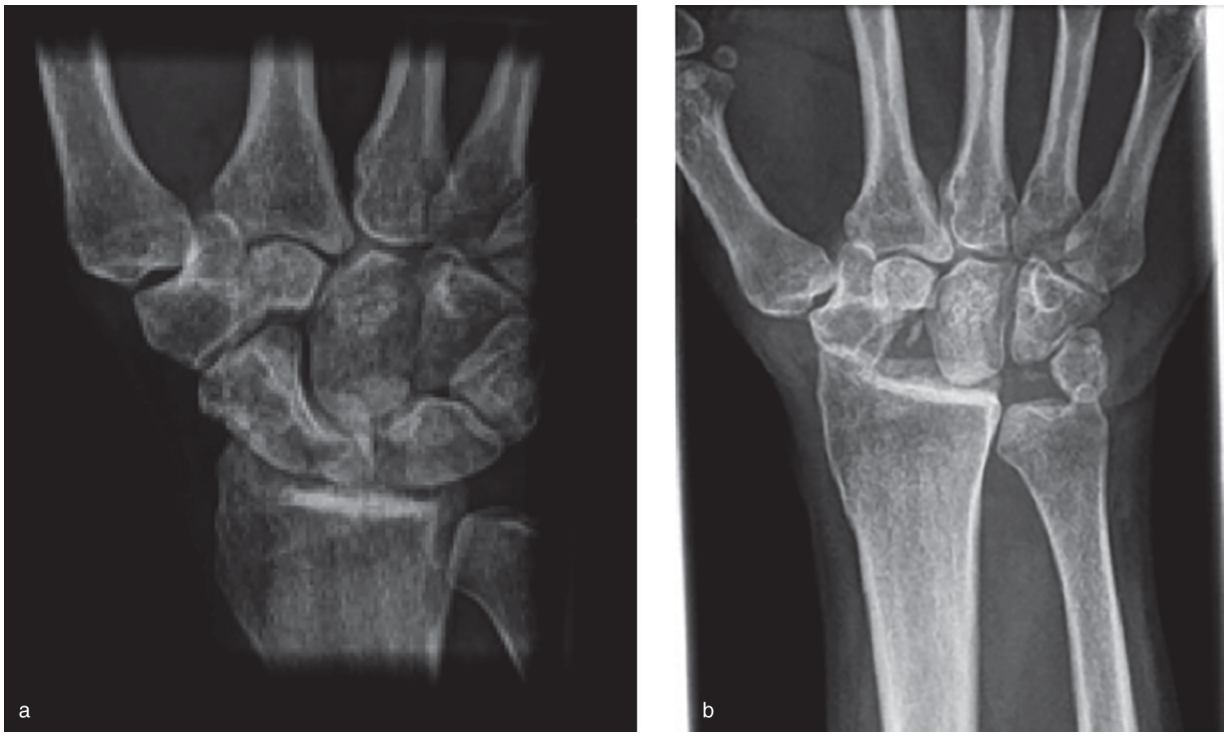

Figure 151.3 (A) Preoperative plain radiograph illustrative of a patient with a SNAC stage III, demonstrating degenerative changes of the proximal scaphoid (in this case following a proximal pole fracture), the radial scaphoid fossa and scaphocapitate and lunocapitate joint. (B) Postoperative plain radiograph following a PRC.

Summary of answers

- The risk of nonunion is increased in proximal pole fractures, fractures with AVN, and displaced fractures.
- Delayed treatment, use of opioids or NSAIDs, and smoking increase chances of nonunion and reduce chances of successful nonunion surgery.
- In the absence of AVN, scaphoid reconstructions with VBGs and NVBGs are equivalent in terms of union rates and functional outcome. Considering the technical difficulty of VBGs, NVBGs may be preferred.

- Structural bone grafts enable better restoration of carpal geometry in unstable scaphoid nonunions with DISI.
- In the context of AVN, VBGs yield superior union rates. There is no consistent evidence supporting the superiority of free VBGs compared to pedicled grafts.
- In SNAC stage II–III wrists, PRC and 4CA offer comparable results in terms of pain relief and range of motion.
- No evidence-based recommendations can be made with regards to the risk of osteoarthritis following PRC or 4CA.

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152 Carpal Instability

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Clinical scenario

- A 32-year-old, right-hand-dominant female presents eight weeks after falling onto her right wrist while playing rugby.
- She presents with persistent wrist pain despite nonsteroidal anti-inflammatory medications and bracing.
- The patient has findings on exam concerning for carpal instability; however, x-rays obtained in the office are negative for fracture, joint space widening, and carpal malalignment. A carpal ligament injury is suspected.

Top three questions

1. In patients with wrist pain, what is the role of arthroscopy in diagnosing and treating ligamentous injuries of the wrist?
2. In a young, healthy patient with subacute scapholunate ligament tear and no radiographic arthritic changes, what is the best treatment option to ensure optimal outcomes?

3. What are the best treatment options to ensure optimal outcomes for a patient with an isolated lunotriquetral injury and no radiographic arthritis?

Question 1: In patients with wrist pain, what is the role of arthroscopy in diagnosing and treating ligamentous injuries of the wrist?

Rationale

Carpal instability is difficult to diagnose. Physical examination is practitioner-dependent and there are few, if any, objective measurements of wrist stability. Radiographs may appear normal after a ligament tear because secondary ligamentous stabilizers delay static carpal changes, prompting a need for advanced imaging or direct visualization.

Clinical comment

Static and dynamic radiographs and advanced imaging studies such as arthrograms, ultrasound, computed tomography (CT), and magnetic resonance imaging (MRI) can fail to visualize ligament tears in the wrist. Arthroscopic evaluation remains the gold standard as it allows the ligaments to be directly visualized. The tears can then be described with a reproducible classification system (grade I–IV) defined by Geissler.[1] The role of arthroscopy is to determine whether a ligament is partially or completely torn and how this likely affects wrist kinematics.

Available literature and quality of the evidence

The use of arthroscopy in diagnosis of carpal ligament tears has been investigated for almost 30 years, mostly for

scapholunate and lunotriquetral ligament injuries. Most recently it has been compared to advances in MRI and CT modalities, including 3.0 Tesla (3T) MRI, and still found to be superior. Arthroscopic repair techniques are described in mostly level IV and V evidence, but do provide the added benefit of combining diagnostic and treatment modalities.

Findings

Radiography is noninvasive and can demonstrate static, chronic scapholunate instability.[2] Stress radiographs may demonstrate abnormalities not visualized on static films; however, “normal” films do not rule out pathology and may be technician-dependent.

Advances with 3T MRI systems allow for 3D sequences and multiplanar reconstructive options to visualize thin intercarpal ligaments during their oblique or curved courses.[3,4] In comparison to arthroscopy for the diagnosis of ligamentous injury, Ochman et al. found the sensitivity and specificity were 75 and 100%, respectively, for pathology seen on MRI and confirmed with arthroscopy.[5] Hafezi-Nejad reported magnetic resonance arthrogram (MRA) had the highest sensitivity and specificity for the diagnosis of scapholunate interosseous ligament (SLIL) tears (82.1 and 92.8%) when compared to 3T MRI and 1.5T MRI.[4] MRA is an expensive and time-consuming test. Lee et al. compared CT arthrography, conventional MRI, and MRA, and found that CT arthrography was the most sensitive, specific, and accurate (100% for all) of the three methods for diagnosing SLIL tears. Multidetector computed tomography (MDCT) Arthrography has sensitivity of 100%, specificity from 86–100%, and a sensitivity of 94% for detecting partial injuries.[6–8]

In Lindau's 2015 review, the role of arthroscopy in carpal instability was determined to be the most valuable

diagnostic tool despite the lack of any level I evidence on the topic. Arthroscopy allows for direct visualization of the ligaments, assessment of the type of injury, and the severity of the injury. It is highly sensitive and specific.[9] Disadvantages include that it is user-dependent, requires an invasive procedure with associated risks, the surgeon must determine whether findings are truly the pathology causing the patient's symptoms, and it is more expensive than imaging.

Resolution of clinical scenario

- With normal radiographs and suspicion of a ligamentous injury, advanced diagnostic techniques are required.
- MRI, MRA, and CT arthrography all provide advanced options for imaging, although all of these techniques still might miss ligament injuries. CT Arthrography is currently the best option, where available.
- Arthroscopy may be the appropriate next step instead of advanced imaging, as it provides high sensitivity and specific for diagnosing SLIL and lunotriquetral interosseous ligament (LTIL) injuries, and if injury is identified the surgeon may convert to reconstruction (open or arthroscopic) in the same operative session.
- If index of suspicion is low, advanced imaging provides a lower cost and lower risk option before a procedure is performed.

Question 2: In a young, healthy patient with subacute scapholunate ligament tear and no radiographic arthritic changes, what is the best treatment option to ensure optimal outcomes?

Rationale

Injury to the SLIL can lead to the development of deformity and arthritis about the wrist if not properly identified and treated early. Although management with direct ligament repair in the acute phase is generally the best option, the successful reconstruction of subacute injuries remains a challenge.

Clinical comment

SLIL injury results in dissociation of the scaphoid and the lunate, causing abnormal movement in the proximal carpal row and leading to cartilage wear and eventual arthritis. Recapitulating this relationship and preventing the aberrant biomechanics is the best way to avoid accelerated wrist degeneration; however, many of the techniques described and used have inadequate outcomes (stiffness, persistent pain, recurrent SL relationship changes, etc.).

Available literature and quality of the evidence

The majority of available evidence pertaining to the treatment of acute and chronic scapholunate injuries is limited to level IV and V studies; however, there are a few level III studies addressed here. Additionally, multiple narrative and literature reviews have attempted to address this issue.

Findings

The treatment options for symptomatic SLIL tears are based upon the chronicity of the injury, the degree of instability, and the presence or absence of wrist arthritis. Urgency is needed in diagnosing and treating SLIL injury because treatment within six weeks of injury has the best results, as demonstrated by Rohman et al. Treatment options include direct repair (open or arthroscopic), soft tissue stabilization (tenodesis, capsulodesis, bone-ligament-bone reconstruction, reduction and association of the scapholunate ligament [RASL]), or arthrodesis.[10]

Proponents of arthroscopic SL debridement and/or reconstruction have proposed specific indications for these techniques, including partial tears, patients wishing to avoid open surgery,[11] pediatric patients,[12] and injuries to the extrinsic ligaments of the wrist,[13],[14] but the efficacy of these procedures is still based on limited quality evidence. Arthroscopic thermal capsular shrinkage was reported by Mason and Hargreaves to achieve improvement or resolution of midcarpal instability. Hargreaves reported follow-up data and at four years, average loss of motion was 15% due to stiffness and no patients required reoperation, though several noted recurrences of instability.[15],[16] Using a similar concept for scapholunate (SL) injuries, in 2005 Darlis proposed debridement and thermal shrinkage for partial SL injuries.[17] A subsequent study by Lee in 2012 reported on 16 wrists with partial SL injuries treated with thermal shrinkage, all with good or excellent outcomes at an average of 53-month follow-up.[18]

Acute complete tears are treated with direct repair if there is sufficient ligament remnant, the scaphoid and lunate are reducible, and there is no evidence of wrist arthritis. For subacute tears where the ligament remnants are often no longer adequate, other techniques are required.[19_22]

Capsulodesis can provide short-term relief, but it does not entirely eliminate pain or significantly improve grip strength, and the repair attenuates over time. Megerle retrospectively evaluated 59 capsulodesis patients after an average of eight years. Eight of the patients required salvage procedure, Disabilities of the Arm, Shoulder, and Hand (DASH) scores were 28 on average, Modified Mayo Wrist Score was 61 on average, the mean carpal height decreased significantly, and 40 patients had evidence of degenerative arthritis.[23]

The majority of the higher-level evidence pertains to the other reported soft tissue stabilization techniques. Sousa et al. reviewed 22 patients who were treated with the modified Brunelli tenodesis with an average follow-up of five years. Patients had an average Visual Analog Scale (VAS) pain score of 2, a DASH score of 16, reduced range of motion and grip as compared to the contralateral side, and diastasis from 1.9 to 3.1 mm of the scapholunate interval.[24] Three-ligament tenodesis was reviewed in Garcia-Elias's 2006 paper that included 38 patients, 28 of whom had complete pain relief, eight had mild discomfort, and two had pain in most activities of daily life. Twenty-nine had resumed their job at two-year follow-up. Grip strength was reported at 65% of the contralateral, healthy, side.[25] Links et al. compared 23 patients treated with the four-bone Almquist tendon weave against 21 patients treated with the modified Brunelli technique, all performed by one surgeon. All patients had decreased scapholunate angles, though the modified Brunelli patients had superior outcomes in pain, DASH scores, range of motion, and grip strength at 2.5 years follow-up.[22]

Due to the success of bone–ligament–bone reconstruction in the knee, the same principle has been applied to reconstructing the SLIL with variable success. Nakamura

harvested the proximal half of the capitohamate ligament and inserted it into troughs made on the scaphoid and lunate. They reported eight excellent, five good, and two fair results using the Modified Mayo Wrist Score with two-years of follow-up.[26] The first dorsal compartment has been studied as a potential donor site in recent biomechanical studies with indications that it has comparable tensile properties to the SLIL.[27] This has yet to be evaluated in clinical practice.

After noting superior outcomes in patients with pseudarthrosis of the SL joint, RASL was developed using a Herbert screw to achieve union. In 33 cases, 22 patients reported good results and 11 reported poor results. Five of the poor results saw loss of fixation with the Herbert screw due to its rigidity. The scapholunate intercarpal (SLIC) screw (Acumed, Hillsboro, OR, USA) was developed to address this issue by allowing for *anatomic toggling* of 15–20° between the scaphoid and lunate.[28] Geissler et al. reported good outcomes in athletic patients with return to play at 1–2 weeks with a protective splint.[29]

Chronic tears that are not amenable to reconstruction are managed with scaphotrapezial–trapezoid or scaphocapitate fusions. Scapholunate fusions have also been attempted but largely have been abandoned due to issues with nonunions. Although arthrodesis stabilizes the scaphoid with respect to the other carpal bones and the radius, it alters wrist kinematics and has demonstrated eventual progression to wrist arthritis. These and other salvage options are reviewed in other chapters.

Resolution of clinical scenario

- For patients with an acute tear, direct repair is recommended.

- Tenodesis is demonstrated to have superior outcomes over capsulodesis or bone–ligament–bone reconstruction.
- Arthrodesis is a salvage procedure for chronic SLIL injuries or failed SLIL reconstruction.

Question 3: What are the best treatment options to ensure optimal outcomes for a patient with an isolated lunotriquetral injury and no radiographic arthritis?

Rationale

LTIL tears are less common than SLIL injuries and are more difficult to diagnose than SLIL. Recognizing the pathology and determining the correct treatment approach has limited available evidence.

Clinical comment

Patients with LTIL tears often present with vague, ulnar sided wrist pain, with or without signs of instability. Due to the difficulty in diagnosing these injuries, the majority of LTIL tears encountered will be chronic. Due to the biomechanics of the joint, surgical interventions for the LTIL focus on reconstructing the palmar component.

Available literature and quality of the evidence

Only level IV and V studies are available. Similar to SLIL injury, multiple review articles are available.

Findings

Unlike SLIL injuries, the literature on treatment of LTIL injuries is not centered around intervention timing, as the majority of LTIL pathology is identified late. Treatment options include soft tissue repair with tenodesis, ligament reconstruction, arthrodesis, and ulnar shortening osteotomy.

Tenodesis for LTIL reconstruction is described using a portion of extensor carpi ulnaris (ECU) (while maintaining the distal portion), passing it through two drillholes in the triquetrum, and securing it to itself after appropriate tensioning. Shahane reviewed 46 patients who had tenodesis for tenderness to palpation and positive ballottement test on examination, with step and gap in the LT joint seen arthroscopically. Using the Mayo Wrist Score, 40 of the 46 patients had satisfactory to excellent outcomes.[30]

Shin et al. compared ligament reconstruction, ligament repair, and arthrodesis. There was no difference in mean DASH scores for the three groups, with an average of 9.5-year follow-up. The nonunion rate in the arthrodesis group was 41%. Additional surgery including revision arthrodesis, ulnar recession, and hardware removal was required within five years for two of eight patients treated with lunotriquetral (LT) ligament reconstruction, 6 of 22 patients treated with LT ligament repair, and 14 of 22 patients treated with arthrodesis.[31]

LT arthrodesis is reported to have normal range of motion in 59–85% of patients, patient satisfaction varying from 0 to 93%, and 27–56% of patients still experiencing some pain. Nonunion rates are reported up to 57%. This procedure has overall poor postoperative outcomes.[32],[33]

Ulnar shortening osteotomy is an alternative to intracarpal surgery that increases strain in the ulnolunate and ulnotriquetral ligaments, thereby reducing motion at the

lunotriquetral joint. Mirza et al. reported on 53 post-traumatic cases and determined that 83% had good outcomes on the Gartland–Werley score, grip strength increased 41%, and all patients had clinical and radiographic union by 10 months. This study only followed patients for one year.[34]

Resolution of clinical scenario

- Patients who undergo ligamentous repair or reconstruction for LTIL injuries have superior outcomes to those who undergo arthrodesis.
- Ulnar shortening osteotomy is an extracarpal surgical alternative.

Summary of answers

- With normal radiographs and suspicion of a ligamentous injury, CT arthrography is currently the best diagnostic modality for ligamentous injuries of the wrist.
- Arthroscopy may be the appropriate next step instead of advanced imaging, as it provides high sensitivity and specific for diagnosing SLIL and LTIL injuries.
- Tenodesis is demonstrated to have superior outcomes over capsulodesis or bone–ligament–bone reconstruction. Arthrodesis is a salvage procedure for chronic SLIL injuries or failed SLIL reconstruction.
- Patients who undergo ligamentous repair or reconstruction for LTIL injuries have superior outcomes to those who undergo arthrodesis. Ulnar shortening osteotomy is an extracarpal surgical alternative with overall good outcomes in early reports.

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153 Kienböck's Disease

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Introductory statement/disclaimer

Kienböck's disease is a rare condition. Literature on the topic therefore is limited and lacks quality studies with a high level of evidence. All evidence, therefore, is based on retrospective cohort studies, case series, and expert opinion. There are no high-quality comparative studies or randomized trials dictating the best treatment option.

There are a number of highly debated topics in Kienböck's disease. For example: “What is the natural history of the disease?” and “Which treatment is best?” These questions, although pertinent, remain unanswered.

The evidence provided in this chapter therefore represents a review of the literature, conclusions based on basic science studies, and concepts developed by the senior author.

Clinical scenario

- A 17-year-old boy presents with a two-year history of pain, swelling, and stiffness in his wrist.
- He has tried wrist splints and his GP injected his wrist last year with no benefit. He has tenderness over the carpus, and decreased grip strength.
- You arrange a number of investigations. An x-ray shows a sclerotic lunate. A computed tomography (CT) scan

shows a coronal lunate fracture. The remaining joint surfaces look normal. A gadolinium-enhanced magnetic resonance imaging (MRI) scan shows generalized signal loss in the lunate.

- He has failed nonoperative treatment for over a year and wants to know whether there is any other treatment available for him.

Top three questions

1. Do patients under 20 years of age have good outcomes with nonoperative treatment in Kienböck's disease?
2. What is the role of radial shortening osteotomy in improving outcomes in patients with Kienböck's disease?
3. Is arthroscopy warranted as an assessment and treatment tool in patients with Kienböck's disease?

Question 1: Do patients under 20 years of age have good outcomes with nonoperative treatment in Kienböck's disease?

Rationale

There are a number of treatment options well described in adults with Kienböck's disease. The disease is known to occur in younger patients as well. The best treatment option in this group is highly controversial.

Clinical comment

The condition can be highly disabling at a time of life when the patient is highly active. The natural history in this age group is unclear. The ideal treatment would allow the patient to rapidly return to functional activity.

Available literature and quality of the evidence

- Level IV: 2 case series, 3 case reports.

Findings

Irisarri's series reports his experience in 13 cases.[1] Four patients had *infantile lunatomalacia* (up to and including 12 years of age). All patients resolved with nonoperative management, with immobilization alone. All patients resolved symptomatically, although one patient had only partial remodeling of the lunate. Nine patients were treated with *juvenile lunatomalacia* (age 13 until skeletal maturity). After periods of immobilization, three patients remained symptomatic and were treated with radial shortening osteotomy. At a mean follow-up of five years, clinical and radiological outcome was good in this subgroup.

Iwasaki reported his experience with radial osteotomies in 11 patients between the ages of 11 and 19 who had failed nonoperative treatment for Kienböck's disease.[2] There were three patients with Lichtman stage II disease, two with stage IIIA disease, and six with stage IIIB disease. Nine patients with negative ulnar variance had radial shortening osteotomies, and two with zero or positive ulnar variance had lateral closing wedge osteotomies. Ten out of 11 patients had excellent clinical outcomes. Eight patients had radiographic improvement showing lunate revascularization. One patient had persistent wrist pain following surgery.

In other case reports, radial shortening or temporary scaphotrapeziotrapezoidal (STT) joint pinning for four weeks has been shown to lead to improvement in pain, function, and lunate revascularization.[3],[4] In two cases of patients with cerebral palsy and Kienböck's disease, temporary immobilization resulted in functional and radiographic resolution.[5]

Resolution of clinical scenario

The vast majority of patients with pediatric Kienböck's disease will resolve with a variable period of immobilization in a splint or cast. This usually leads to improvement both radiologically and clinically. In the older child or teenager with *juvenile osteomalacia*, recalcitrant cases do occur. *Ulnar-negative patients* may benefit from a radial shortening osteotomy. *Ulnar-neutral* or *ulnar-negative* patients may benefit from radial closing wedge osteotomy or temporary STT joint pinning.

Question 2: What is the role of radial shortening osteotomy in improving outcomes in patients with Kienböck's disease?

Rationale

Radial shortening osteotomy has been described as a means of correcting negative ulnar variance – which is thought to be a morphological risk factor for the development of Kienböck's disease.

Clinical comment

There are numerous surgical options described for the treatment of Kienböck's disease. There is debate as to which patients may benefit from radial shortening osteotomy. The long-term success of the procedure and its ability to slow or reverse the progression of the disease is controversial.

Available literature and quality of the evidence

- Level III: 1 retrospective cohort study.
- Level IV: 6 case series.

Findings

Several series reported good to excellent functional outcomes in adults at a minimum of two years' follow-up. Significant improvements have been shown for Disabilities of the Arm, Shoulder, and Hand (DASH) score, Mayo Score, Visual Analog Score (VAS), range of motion, and grip strength. Results have been shown to be maintained for up to 10 years.[6] Results have been shown to be comparable with radial closing wedge and capitate shortening osteotomies in comparative studies.[6–11]

Most series contain patients at Lichtman grades IIIa, IIIb, and IV. Despite the advanced stage of the disease in these patients, most studies report clinical improvement in symptoms. Lichtman grade has not been shown to improve after radial shortening osteotomies, and either remains static or slowly progresses.[12]

One study showed that the risk of development of ulnar-sided wrist pain increases with shortening of the radius more than 4 mm, and functional outcomes may be worse in patients >30 years old. Although initially indicated for patients with negative ulnar variance, to bring their ulnar to *neutral*, clinical results may be similar regardless of

preoperative ulnar variance.[12] In all studies there is a low reported rate of salvage procedures.

Resolution of clinical scenario

Evidence suggests that radial shortening osteotomy is an effective treatment for Kienböck's disease, even in patients with advanced Lichtman grade. There is no evidence in adults, however, that the disease stage regresses following this procedure.

Question 3: Is arthroscopy warranted as an assessment and treatment tool in patients with Kienböck's disease?

Rationale

Arthroscopy is regarded as the gold standard for assessment of the articular surfaces as it allows direct visualization and probing. It also allows assessment of the surrounding structures, including synovium, ligaments, and adjacent joints. Arthroscopic treatment is a minimally invasive method of treating Kienböck's disease and may have advantages such as accelerated rehabilitation and avoidance of extra-articular adhesions.

Clinical comment

Decision-making in the operative treatment of Kienböck's disease is challenging. Imaging helps to assess the osseous and vascular components of the disease. Arthroscopy gives the best assessment of the chondral component of the disease and helps dictate operative management – either arthroscopic or open.

Available literature and quality of the evidence

- Level IV: 3 case series.
- Level V: 4 expert opinion.

Findings

A case series reported arthroscopic assessment and debridement of seven patients with Kienböck's disease.[13] All seven patients had partial or complete tears of their perilunate ligaments. Five patients had synovitis. A full arthroscopic assessment followed by debridement of the chondral surfaces and ligaments was performed in all patients. At a 19-month follow-up, six reported good or excellent outcomes on the Modified Mayo Wrist Score, grip strength, and range of motion. There was further disease progression in three patients, but no cases of carpal collapse.

Excellent results have been shown for arthroscopic- and arthroscopic-assisted partial carpal fusions in Kienböck's disease.[14] In Ho's series, 12 patients had arthroscopic assessment and one of the following procedures: STT fusion, four-corner fusion and scaphoidectomy, radioscapholunate fusion, radiolunate fusion, and lunotriquetral fusion. Average follow-up period was 70 months. Full union was obtained in 9/12 patients. All patients had improvement in pain and a functional range of motion.

Rajfer described a technique of arthroscopic insertion of cancellous bone graft and BMP-2 into the lunate.[15] Graft from the distal radius or iliac crest was used. The lunate was enucleated of necrotic bone, and graft and BMP-2 (with collagen seal) tamped into the defect. All patients reported improvement in pain and DASH scores. Carpal height was maintained at follow-up.

Resolution of clinical scenario

The Bain and Begg classification was introduced in 2006 as a tool for assessing articular cartilage and planning treatment in Kienböck's disease.[16],[17] An articular-based algorithm has been developed by the senior author as a framework to help guide the treating surgeon.[18–21] Arthroscopy is an effective method of assessing the articular cartilage and surrounding structures in Kienböck's disease.

Summary of answers

- The majority of patients in this age group get excellent results with nonoperative treatment. In *juvenile* cases (over the age of 12 years) – some may fail to respond to conservative treatment. In these cases, radial shortening, radial lateral closing wedge osteotomy, and temporary STT pinning have been proven to be effective treatment options in small series.
- Radial shortening osteotomy has been shown to be an effective treatment for all Lichtman grades for pain, function, and range of motion. Patients under 30 years may have better results. The osteotomy does not reverse the disease process, however; carpal collapse may occur later and further salvage procedures may be warranted.
- Arthroscopy is the gold standard for assessment of the articular surfaces in Kienböck's disease. Further treatment can then be planned. Simple arthroscopic synovectomy or debridement has proven to be an effective treatment option, as has arthroscopic lunate forage and bone grafting. In small series, arthroscopic partial carpal fusions have shown high union rates and good functional outcomes.

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154 Trapeziometacarpal Osteoarthritis

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Clinical scenario

- A 61-year-old, right-hand-dominant female presents with three years of progressive right base of thumb pain unrelated to any injury. She reports her pain is provoked by activities such as opening jars.
- On exam, she is tender over the trapeziometacarpal (TM) joint and pain is elicited with axial loading and extension of the joint.
- Her radiographs show narrowing of the TM joint with cystic changes and subchondral sclerosis, and small loose bodies.

Top three questions

1. In a patient who presents with symptomatic TM arthritis, what nonoperative intervention is most effective in relieving symptoms compared to placebo?
2. In a patient with TM osteoarthritis, which arthroplasty procedures have been shown to result in improved patient outcomes with the fewest complications?

3. In a patient who presents with symptomatic TM osteoarthritis, does implant arthroplasty or arthrodesis offer any advantages over trapeziectomy with or without ligament reconstruction and tendon interposition (LRTI)?

Question 1: In a patient who presents with symptomatic TM arthritis, what nonoperative intervention is most effective in relieving symptoms compared to placebo?

Rationale

There are many nonoperative treatments for TM arthritis. Treating physicians optimally want an effective intervention to relieve symptoms and maximize function for one of the most common joints affected by osteoarthritis.

Clinical comment

Conservative treatment of TM arthritis includes: therapy, orthoses (splinting), and corticosteroid injections. Hyaluronate injections have been described but are less commonly used. These treatments can be used in combination. It is essential to determine which conservative interventions provide patients with the best outcomes in order to guide treatment and manage symptoms long term.

Available literature and quality of the evidence

- Level I: 9 studies.
- Level II: 1 meta-analysis and 2 systematic reviews.

Findings

Corticosteroid and hyaluronate injections

A randomized controlled trial (RCT) comparing functional outcomes after intra-articular hyaluronic acid (HA) injections of the TM joint in 29 patients to saline placebo in 29 patients. The authors reported HA reduced pain Visual Analog Scale (VAS) scores and improved function (Dreiser's Functional Index) from baseline values, but did not reach a significant difference compared with controls at six months.[1] A meta-analysis compared HA injections in 169 patients and an unspecified placebo in 74 patients. The authors reported HA marginally improved functional capacity (standardized response means [SRM] −1.14; 95% confidence interval [CI]: −1.59 to −0.60) at 12 weeks, but provided no difference in unspecified pain scores.[2] The meta-analysis also compared corticosteroids injections in 147 patients and unspecified placebo injections in 74 patients. The authors reported no difference in pain scores at 24 weeks (SRM −1.20; 95% CI: −3.69 to 1.29). A RCT of 40 patients comparing hyaluronate and corticosteroids injections found corticosteroids was superior in reducing pain (4.9 mm ± 2.0 vs 5.7 mm ± 2.2) and improving hand function (Duruoz Hand Index [DHI]: 12.0 pts ± 8.7 vs 22.1 pts ± 12.5) for up to six months, but other studies have failed to replicate corticosteroid's superiority.[3] Two RCTs found no difference in pain and functional outcome scores up to six months after treatment between hyaluronate or steroid injections.[4,5] In a cohort of 80 patients, Heyworth et al. compared the two types of injections with saline placebo and reported no difference in VAS or Disabilities of the Arm, Shoulder, and Hand (DASH) scores between the three groups.[4] Stahl et al. found no difference in 50 patients treated with hyaluronate or corticosteroids but reported a significant reduction between baseline and six-month pain

VAS for both groups at rest (−2.2 mm ± 2.0, −2.2 mm ± 2.1) and after activity (−2.7 mm ± 2.2, 2.2 mm ± 1.9).[5] Two review articles concluded there was no difference in various pain or functional outcomes scores between hyaluronic and steroid injections.[6,7] A meta-analysis comparing HA and corticosteroids reported corticosteroid was superior in reducing pain measurements compared to HA (SRM 1.44; 95% CI: 0.14–2.74) but was heavily influenced by one RCT.[2]

Orthoses

An RCT compared custom neoprene orthoses (n = 57) with standard care at the discretion of their physician (n = 55), and reported a reduction in pain VAS with orthoses for up to 12 months (−22.2 mm ± 3.2 vs −7.9 mm ± 3.5).[8] Several RCTs compared types of orthoses in patients with TM OA.[8–12] Two studies compared prefabricated orthoses to custom orthoses. Weiss et al. found patients with prefabricated splints had better VAS pain (2.29, standard error of the mean [SEM]: 0.44 vs 3.59, SEM: 0.33) and satisfaction scores (7.5, SEM: 0.45 vs 4.9, SEM: 0.43) in a randomized, cross-over study of 25 patients.[10] Another randomized, crossover study of 63 patients demonstrated no difference in pain, but the Push Ortho Thumb Brace had higher satisfaction on the D-QUEST questionnaire (30.6, standard deviation [SD]: 3.9) versus a custom brace likely due to less interference with key grip (26.9, SD 4.9).[9] Spaans et al. reviewed 10 RCTs utilizing various orthoses and reported evidence for improved pain control but no improvement regarding function or strength.[7]

Hand therapy

Spaans et al. reviewed six RCTs comparing various hand therapy techniques with nontherapeutic ultrasound as a

control and reported all four techniques provided some reduction in pain without any notable improvement in function.[7] Unfortunately, all six studies had limited follow-up, ranging from two weeks to three months. One RCT (n = 40) comparing splinting to exercise therapy reported no significant differences between groups in VAS pain or Sollerman Test of Hand Function scores at six weeks.[13]

Resolution of clinical scenario

- Multiple RCTs have reported that corticosteroids and HA injections reduce patient's TM pain compared with baseline values; however, neither steroid nor hyaluronate showed superiority in pain relief or functional outcomes when compared with placebo for either intervention.
- There is growing evidence supporting bracing with custom or prefabricated splints as a method of providing long-term pain relief.
- There is no strong evidence supporting any specific orthosis as superior in terms of pain relief. However, some studies have suggested higher patient satisfaction with smaller, less bulky splints.
- There is no strong evidence that hand therapy provides long-term pain relief for symptomatic TM arthritis and only low-quality evidence therapy provides short-term pain relief.

Question 2: In a patient with TM osteoarthritis, which arthroplasty procedures have been shown to result in improved patient outcomes with the fewest complications?

Rationale

Multiple arthroplasty techniques are currently employed to treat TM osteoarthritis, and understanding the possible risks and benefits of different procedures will help guide surgical decisions.

Clinical comment

The current opinion regarding surgical treatment of TM osteoarthritis varies widely among surgeons. A simple trapeziectomy would likely provide relief of pain, but many surgeons advocate for tendon interposition (TI) and/or ligament reconstruction (LR) to fill the trapezial void and prevent subluxation of the metacarpal. Surgical procedures have evolved to produce varying techniques for ligament reconstruction and tendon interposition (LRTI).

Available literature and quality of the evidence

- Level I: 7 studies.
- Level II: 3 studies were identified including 1 meta-analysis.

Findings

One systemic review comparing trapeziectomy versus trapeziectomy with TI,[14–17] trapeziectomy with LR,[18,19] and trapeziectomy with LRTI,[16,20,21] failed to find any

additional benefit of TI, LR, or LRTI over a simple trapeziectomy in terms of pain, strength, satisfaction, and DASH scores.[22] Three RCTs reported LRTI was associated with an increased complication rate over simple trapeziectomy, but the studies only had a one-year mean follow-up.[16,17,21] Vermeulen et al. was unable to pool data for statistical analysis due to heterogeneity of patient population, surgical technique, and outcome measures.[22]

A Cochrane review comparing trapeziectomy and trapeziectomy with LRTI included five RCTs or quasi-RCTs with 376 participants[14,17,20,23,24] and revealed LRTI provided no addition benefit in terms of pain on a 0–100 mm scale (mean difference [MD]: −2.8 mm, 95% CI: −9.82 to 4.21) and function on a similar scale (0.03 points, 95% CI: −0.83 to 0.88%).[25] In addition, the meta-analysis reported no significant difference in mean adverse events with a rate of 10 and 19% (p = 0.07) in the trapeziectomy and trapeziectomy with LRTI cohort, respectively, but the data demonstrate a trend toward an elevated rate in the LRTI cohort (risk ratio [RR] = 1.89; 95% CI: 0.96–3.73). Gangopadhyay et al. included trapeziectomy with TI in their RCT evaluating 174 thumbs and demonstrated no difference in pain or strength in comparison to trapeziectomy at five-year follow-up.[23] Two studies compared trapeziectomy with LRTI (n = 25) and trapeziectomy with LR (n = 26),[18,19] and there was no difference in pain (RR = 2.8; 95% CI: 0.33–24.16), function scores (RR = 0.82; 95% CI: 0.63–1.06), and adverse events (RR = 1.41; 95% CI: −1.90 to 0.50) between the two groups.

Resolution of clinical scenario

- Current evidence has not revealed any additional benefit regarding LR, TI, or LRTI over simple

trapeziectomy in terms of pain relief or improved function.

- There appears to be a trend toward an increase in adverse events with the addition of LRTI when compared with trapeziectomy alone.

In a patient who presents with symptomatic TM osteoarthritis, does implant arthroplasty or arthrodesis offer any advantages over trapeziectomy with or without ligament reconstruction and tendon interposition (LRTI)?

Rationale

There is growing interest in alternative surgical techniques to treat thumb TM arthritis and improve patient outcomes following surgery.

Clinical comment

Trapeziectomy with LRTI is the most common surgical procedure for TM arthritis. However, many have expressed concern for shortening of the thumb, decreased thumb strength, and subluxation of the thumb metacarpal. Trapeziometacarpal arthrodesis (TMA) and arthroplasty have been explored as possible alternative to treat these concerns.

Available literature and quality of the evidence

- Level I: 2 studies.

- Level II: 4 studies and 1 meta-analysis.
- Level IV: 1 systematic review and 1 retrospective study were included in reviewing arthrodesis and implant arthroplasty procedures for TM arthritis.

Findings

Arthrodesis

A Cochrane review identified studies comparing trapeziectomy with LRTI versus TMA but was unable to draw any conclusions due to including only one study with incomplete statistical analysis.[25] Since then, Vermeulen et al. randomized 43 patients to LRTI or TMA utilizing a plate but prematurely terminated the study due to a significantly higher complication rate in the arthrodesis group (71% vs 29%, $p = 0.016$), especially regarding delayed union, nonunion requiring revision, neuromas, and complex regional pain syndrome.[26] Hippensteel et al.'s prospective study comparing LRTI and TMA with a locked plate reported no significant differences in QuickDASH scores, pinch or grip strength, and VAS pain scores.[27] Seven out of 25 (26%) TMA patients had radiographic nonunion and five (19%) required revision surgery compared to none in the LRTI cohort; however, the LRTI group had more superficial branch of the radial nerve paresthesias which eventually resolved (32% vs 0%, $p < 0.05$).

Implant arthroplasty

A Cochrane review identified two RCTs[28],[29] comparing trapeziectomy with TI ($n = 42$) versus the Artelon joint resurfacing implant ($n = 82$) and reported decreased pain in the TI cohort with tripod pinch (MD: −14 mm; 95% CI: −23.06 to −4.94), no difference in lateral pinch strength (MD: −1.09 kg; 95% CI: −2.4 to 0.22), and no difference in

treatment failure due to pain.[25] Tägil et al. randomized 13 patients each to trapeziectomy with TI and to a Swanson silicone implant and reported no difference in pain relief (MD: 5.0 mm; 95% CI: 7.41–17.41), lateral pinch strength (MD: 0.01 kp/cm^2; 95% CI: −0.09 to 0.11), or adverse events (RR = 0.20; 95% CI: 0.01–3.80).[30]

Overall, the studies comparing implant arthroplasty with trapeziectomy are of low quality and provide no strong conclusions regarding any benefit of arthroplasty over trapeziectomy. Huang et al. performed a systematic review of TM joint replacements and reported only two prospective controlled studies, five prospective cohort studies, and 26 retrospective studies.[31] The authors concluded there was no strong evidence implant arthroplasty provides better clinical results than trapeziectomy and some implants may have high failure rates. A retrospective review of the Norwegian Arthroplasty Register yielded 479 cases, including four different implants (Swanson Silastic, Swanson Titanium, Elektra, and Motec).[32] The authors reported pain and dislocation were the major reasons for revision and a cumulative five- and 10-year implant survivorship of 91 and 90%, respectively, with no significant difference between the four implants.

Resolution of clinical scenario

- Low-quality evidence has not revealed any advantages of arthrodesis over trapeziectomy with LRTI, and arthrodesis likely has an increased risk of adverse events.
- There is insufficient evidence to draw any conclusions comparing implant arthroplasty and trapeziectomy with LRTI.

Summary of answers

- Splinting patients with symptomatic TM arthritis can relieve pain for up to 12 months.
- There is no difference in pain relief among various TM splints.
- There is no strong evidence corticosteroids or HA improve TM osteoarthritis symptoms.
- Hand therapy may provide some short-term pain relief for patients with TM arthritis.
- LR, TI, or LRTI do not provide any advantages over trapeziectomy alone; however, the additional procedures may increase the risk of adverse events.
- TMA is not superior to trapeziectomy with LRTI and may have increased risks related to nonunion/malunion.
- There is insufficient evidence comparing implant arthroplasty with trapeziectomy and LRTI.

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VIII Hand

155 Carpal Tunnel Syndrome: Nonoperative Management

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Clinical scenario

- A 52-year-old man works in an automotive plant, with repetitive tasks, presents with a six-month history of increasing nocturnal numbness, paresthesiae, in a median nerve distribution. His hands awaken him most nights. He has a tendency to drop screws if using his thumb and index finger without vision support. He is concerned that his occupation is causing the problem.
- Clinically, he has a positive Durkan's test, a positive Phalen's test, and a decrease in sensation in the median nerve territory that splits the ring finger. There is no thenar atrophy, and no focal abductor pollicis brevis (APB) weakness.
- NCS (nerve conduction studies) reveal focal slowing of the median nerve at the level of wrist with sensory comparison studies, and a cumulative sensory index >1.8 ms with no motor axonal loss, and normal electromyography (EMG) (needle EMG) of the thenar APB.
- He would like to understand his treatment options.

Top three questions

1. In patients with symptoms suggestive of carpal tunnel syndrome (CTS), how helpful is the clinical exam in the diagnosis of CTS?
2. In patients with symptoms suggestive of CTS, are electrodiagnostic studies (EMG/NCS) required in assessing and treating CTS?
3. In patients with mild to moderate CTS, what are, and how effective are, the nonoperative treatment options in mild to moderate CTS?

Question 1: In patients with symptoms suggestive of carpal tunnel syndrome (CTS), how helpful is the clinical exam in the diagnosis of CTS?

Rationale

CTS is the most common entrapment neuropathy presenting to physicians. The classic history is often diagnostic. It is characterized by sensory symptoms particularly nocturnal with frequent awakening or when talking on the phone or driving a car. Paresthesiae are confined to the hand, but often the pain and discomfort can be felt not only in the hand and wrist but also proximally in the arm, shoulder, or scapular area. The shaking or flicking of the hand has been reported to be highly suggestive of the diagnosis of CTS,[1] although other authors have shown it to be neither sensitive nor specific.[2]

Clinical comment

The sensory and motor exam are the basis for every good clinician's assessment of nerve pathology. Sensory testing is normal in 20–50% of patients depending on degree, thoroughness of examiner, and patient understanding. Light touch and pinprick are more useful than two-point discrimination.[3] Restricted sensory findings can be found if carefully examined and are due to the fascicular anatomy of the median nerve at the wrist.[4] Positive motor examination, weakness, and atrophy of thenar muscles (APB) are late findings.

Available literature and quality of the evidence

As with all clinical and laboratory testing, sensitivity (true positives) and specificity (true negatives) require a gold standard. There is no gold standard, and this remains controversial as will be highlighted in the second question, and most studies have either used clinical criteria or electrodiagnosis or a combination as the gold standard. In the majority of cases a careful history and physical are sufficient to make a diagnosis and initiate treatment decisions. However, many patients present with multiple problems and/or their presentations are atypical. This then requires electrodiagnostic testing to confirm the clinical impression of CTS.[5–9]

Findings

The American Academy of Orthopedic Surgeons (AAOS) Evidence based Clinical practice guidelines (AAOS) and the treatment and Management of CTS have produced 2 consensus guidelines from experts.[6,10]

A few conclusions are outlined:

- Strong evidence supports that thenar atrophy is strongly associated with ruling in CTS but poorly

associated with ruling out CTS.

- Strong evidence supports not using Phalen's test or Tinel sign as independent physical examination maneuvers to diagnose CTS, because when used alone each has a poor or weak association with ruling in or ruling out CTS.
- Moderate evidence supports not using carpal compression test, Phalen's test, two-point discrimination, or scratch collapse as independent physical examination maneuvers to diagnose CTS because alone each has poor or weak association in ruling in or ruling out CTS.[6]

Phalen's test results ranged in sensitivity (0.46–0.80) and in specificity (0.51–0.91); Tinel's sign from 0.28–0.73 in sensitivity and specificity of 0.44–0.95. The median nerve compression test ranged from 0.04 to 0.79 and specificity of 0.25 to 0.96. Many of the studies had poor study design, inconsistent data, and small data sets, and no single test has been identified as a gold standard.[11]

There is no consensus on combining diagnostic tests and which combination should be used, but most reviews suggest that this is prudent, common, and clinically relevant practice.[5,7,8,12–14]

The association of CTS to work and ergonomic factors remains an important topic given the costs of workmen's compensation. A meta-analysis of all studies between 1980 and 2009 using a case definition of CTS that included NCS abnormality, with signs and or symptoms, found the following risk factors to be significantly associated with an increased risk of CTS among workers: (i) vibration, (ii) hand force, and (iii) repetition (level I evidence). The results of this review also concluded no association to computer typing which agreed with other reviews.[15,16] The

challenge in ascribing etiology is the difficulty in evaluating CTS in the presence of concurrent non-neurologic and musculoskeletal factors such as age, obesity, cold, diabetes, and psychosocial factors complicating the presentations.

Resolution of clinical scenario

- While the literature varies, a combination of clinical symptoms and signs has been shown to diagnose CTS and its outcome, thus the reason it is referred to as a *syndrome*.
- In clinical practice the combination of signs, symptoms, and NCS (electrodiagnostic testing) are most commonly used to diagnosis and treat CTS.
- High force, vibration, and repetition can be associated with an increased incidence of CTS.

Question 2: In patients with symptoms suggestive of CTS, are electrodiagnostic studies (EMG/NCS) required in assessing and treating CTS?

Rationale

Electrodiagnostic studies are sometimes normal in patients who meet the clinical criteria of CTS (a possible false negative), and some authors have argued that NCS are unnecessary when the clinical examination is *classic*. Estimates vary between 5 and 25% and have led to more detailed and more sensitive comparison studies being recommended.[5,17] Conversely, NCS may also be abnormal in a person with a normal clinical examination (possible

false positive).[7,8,18] This has led to controversy in the literature in regard to the benefit of electrodiagnostic testing in patients with CTS.[6,19,20]

Clinical comment

A pragmatic recommendation is to think of the electrodiagnostic test as an extension of the clinical exam and allow the physician to correlate their clinical diagnosis with a physiological test of nerve function. Given the thousands of published papers on CTS, it remains surprising why this controversy is so entrenched and likely relates to posturing by specialty groups instead of a patient-centered approach.[6,13,20]

Available literature and quality of the evidence

The quantity of evidence to date is overwhelming for such a "simple" disorder. A literature search with the terms *carpal tunnel syndrome* and *electrodiagnosis* yielded over 1500 papers. The guidelines of both European and American experts are important starting points and are included as references for the reader.[5,6,21]

Findings

Robinson and colleagues suggested the sum of three comparison tests improve reliability, sensitivity, and specificity of NCS to diagnose CTS (thumb differential + ring differential +palm differential). An abnormal response is defined as 0.9 ms with sensitivity and specificity of 83 and 95%, respectively.[22,23] However, it is important to remember that multiple comparisons increase the risk of a type I error (false-positive result), and alternatively, finding more than one abnormality when assessing the median nerve across the wrist will lower the possibility of a type I error.[8]

Correlating clinical severity with neurophysiological studies remains a challenge in predicting outcome and can be divided into two main camps: a three-scale (the lumper) camp (mild, moderate, severe)[7] and a six-scale (splitter) camp of the UK and Italian groups.[24],[25]

Padua's group in Italy assessed 500 hands in a prospective study of CTS in 379 patients and developed a neurophysiological classification based on a six-point scale: Extreme (absent motor sensory), Severe (absence sensory, abnormal distal motor latency [DML]), Moderate (abnormal sensory CV, abnormal motor latency DML), Mild, Minimal (abnormal segmental/comparative test only), and Negative (normal tests). This improved sensitivity by 20% and correlated with outcomes.[25] In a later study, they showed that the scale correlated with clinical patient-rated outcomes in 100 consecutive patients with CTS.[26]

Using a large group of 8501 patients, Bland developed a similar six-point scale based on NCS and demonstrated a significant linear relationship between neurophysiological grading and clinical history.[24] The grade is normal (grade 0), very mild (grade 1), mild (grade 2), moderate (grade 3), severe (grade 4), very severe (grade 5), and extremely severe (grade 6).

The same group recently reviewed 3382 operations to develop prognostic models in CTS and the above neurophysiological scale. They found patients with moderately severe nerve conduction abnormalities, night wakening, a family history of CTS, and a good response to corticosteroid injection, and women had better outcomes.[21]

A study by De Kleermaeker looked at patients with clinically defined CTS and normal electrodiagnostic test results, and whether these patients benefitted from surgery for CTS. Of the 57 patients, 39 had surgery and 18 had

nonsurgical treatment.[27] Outcome was based on the Boston Carpal Tunnel Questionnaire at six-month follow-up.[27] Seventy percent of the surgically treated group were significantly improved and 39.6% reported full recovery. The Functional Scale and Symptom Scale improved in the surgical group.[27]

Resolution of clinical scenario

Based on the cumulative evidence shown above, for this patient we recommend the following:

- NCS severity can be used to assist choice of initial treatment, but should not dictate treatment. Patient factors such as social, employment, and degree of discomfort are important considerations.
- This patient has CTS, and given the fact that we lack a gold standard for diagnosis, clinicians should use all reasonable diagnostic measures including symptoms/signs and NCS to increase accuracy. NCS can document the state of neural dysfunction before treatment and allow for postintervention comparison when required.
- Before considering surgical intervention for peripheral nerve problems, a number of authors have suggested the use of a four-legged table analogy. Each leg consists of corroborative findings, and for the diagnosis to rest on the table you must have at least three legs. The legs are (i) symptoms, (ii) signs, (iii) neurophysiological findings, and (iv) imaging.[28]

Question 3: In patients with mild to moderate CTS, what are, and how effective are, the nonoperative treatment options in mild to moderate CTS?

Rationale

The nonoperative treatment of mild to moderate CTS can be divided into the following main categories: (i) activity modification, (ii) splinting, (iii) oral medications, (iv) physiotherapy and modalities, and (v) corticosteroid injection.

Clinical comment

The majority of studies and clinical practice guidelines suggest the following regimen: (i) activity modification and education, (ii) resting night splints for nocturnal numbness, (iii) a trial of corticosteroid injection, and (iv) if no improvement, or worsening of signs and symptoms, operative intervention and decompression should be considered.

Available literature and quality of the evidence

The Cochrane collaborations have issued a number of summary statements. Their review of splinting looked at 19 studies and approximately 1200 patients.[29] They concluded that there was limited evidence that a splint worn at night was more effective than no splint in the short term but more research is needed.[29] Their review on the usefulness of exercise and mobilization concluded limited evidence of benefit.[30] Conversely, there is good evidence (level I) supporting treatment with corticosteroid injection.[31–33]

Findings

The Cochrane review by Marshall et al. in 2007 looked at 12 studies and over 671 patients and supports at least over the short to medium term improvement with corticosteroid injection.[33] Subsequent studies and an open label UK study in over 240 patients randomized to steroid versus splinting found, in the short term, corticosteroid to be more effective than splinting for symptom relief at six-week follow-up.[32] They noted that the optimum dose and frequency of injection has not been established. Another study demonstrated the benefit/effectiveness of a second steroid injection (on relapse after primary injection) in a cohort of 230 patients.[31]

The AAOS reviews by Keith and Graham concluded that there is strong evidence to support treatment with immobilization (brace/splint/orthosis), and steroid injections whereas magnet therapy is of no benefit.[6],[11] They also concluded that there is moderate evidence to suggest that oral treatments (diuretic, Vitamin B6, gabapentin, astaxanthin, nonsteroidal anti-inflammatory drugs) are of no benefit compared with placebo. Finally, they concluded that oral steroids, and ketoprofen phonophoresis, could improve patient-reported outcomes compared to placebo (moderate evidence) and that there was limited evidence that therapeutic ultrasound and laser therapy is effective.[6]

Resolution of clinical scenario

Based on the cumulative evidence shown above, for this patient we recommend the following:

- Education and wrist splints nocturnally are effective with little possibility of negative effects.

- There is good evidence to support corticosteroid injection as a low-risk and effective treatment for CTS over the short term.

Summary of answers

- CTS can often be diagnosed on the basis of a combination of clinical symptoms and signs alone.
- In clinical practice, the combination of signs, symptoms, and NCS are most commonly used to diagnose and treat CTS.
- Occupational exposure to high force, vibration, and repetition may be associated with an increased incidence of CTS.
- Electrodiagnostic testing can be a useful adjunct in diagnosing CTS, and while severity findings on NCS may be used to assist choice of initial treatment they should not dictate treatment.
- Education and nocturnal wrist splints are effective initial treatments for many patients.
- There is good evidence to support corticosteroid injection as a low-risk and effective treatment for CTS over the short term.

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156 Carpal Tunnel Syndrome: Operative Management

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Clinical scenario

- A 57-year-old woman presents to her family physician with a six-month history of numbness and tingling in her thumb, index, and long fingers. This frequently awakens her at night.
- She works as an administrative assistant and spends much of her workday using a keyboard.

Top three questions

1. In patients with carpal tunnel syndrome (CTS), is electrodiagnostic testing necessary prior to carpal tunnel release (CTR)?
2. In patients undergoing CTR, is endoscopic carpal tunnel release (ECTR) advantageous relative to open carpal tunnel release (OCTR)?
3. In patients undergoing CTR, what type of anesthesia is best for CTR?

Question 1: In patients with carpal tunnel syndrome (CTS), is electrodiagnostic testing necessary prior to carpal tunnel release (CTR)?

Rationale

In order to decide upon the best surgical treatment of CTS, it is important to know when nonoperative treatment is unlikely to be successful and therefore surgery is indicated.

Clinical comment

In patients with severe CTS in which there is clear wasting of the thenar muscles (specifically abductor pollicis brevis) and objective sensory changes such as a decrease in two-point discrimination, the diagnosis of CTS is typically clear on the basis of clinical examination alone. However, many, and in fact the majority of, patients do not exhibit these clinical features.

Available literature and quality of the evidence

In a highly rigorous process, the American Academy of Orthopaedic Surgeons (AAOS) published an evidence-based set of guidelines for CTS (level IV evidence).[1]

Findings

The AAOS concluded that there was strong evidence that thenar atrophy “is strongly associated with ruling-in carpal tunnel syndrome”; they also concluded that common clinical signs such as Phalen's sign – when used in isolation – “has a poor or weak association with ruling-in or ruling-out carpal tunnel syndrome.” Conversely, they concluded that “limited evidence supports that a hand-held nerve

conduction study (NCS) device" be used to diagnose CTS. It is understood that a "hand-held NCS device" meant an office-based device used by surgeons who were not using American Association of Electrodiagnostic Medicine (AAEM) criteria for the diagnosis of CTS versus formal electrodiagnostic testing. In the body of the AAOS review,[1] the authors articulated this, and in an AAOS review on the diagnosis of CTS they recommended formal NCS be performed before surgical intervention (level II).[2]

The AAEM performed a meta-analysis of prospective studies which compared independently gathered clinical data with rigorously performed electrodiagnostic testing.[3] They concluded that "median sensory and motor NCS are valid and reproducible clinical laboratory studies that confirm a clinical diagnosis of CTS with a high degree of sensitivity and specificity." Although this level I evidence suggests that NCS is useful for *diagnosing* CTS, it does not address whether NCS is *necessary* for patients prior to carpal tunnel surgery.

Another way to examine this question is to ask whether NCS can predict outcomes after CTR and particularly whether patients with normal NCS benefit from CTR. The evidence in this question is of relatively low quality and contradictory. Longstaff et al. as well as Glowacki et al. found that clinical outcomes after CTR did not correlate with preoperative NCS,[4],[5] whereas Bland reviewed a large (n = 1268) group of patients and found that patients with either normal or severe findings on NCS had a higher rate of surgical failure (all level IV).[6]

The evidence to support preoperative NCS prior to carpal tunnel surgery is contradictory. There is good evidence to support the ability of NCS to *diagnose* CTS, but it is unclear whether the addition of NCS to clinical examination is necessary in all circumstances. Interestingly, when

presented with scenarios of patients with a low or medium probability of CTS (on clinical testing tools such as the CTS-6), participants in the AAOS appropriate use guidelines development supported the use of NCS to further investigate patients as *appropriate*.[7]

Resolution of clinical scenario

- NCS are sensitive and specific for the diagnosis of CTS.
- NCS are likely unnecessary in patients with advanced findings of CTS, such as thenar wasting or objective sensory deficits, but can differentiate other neurological pathologies, and assist in postoperative management when outcomes are poor or unexpected.
- NCS are likely useful in patients with mild clinical findings or atypical presentations.

Question 2: In patients undergoing CTR, is endoscopic carpal tunnel release (ECTR) advantageous relative to open carpal tunnel release (OCTR)?

Rationale

ECTR has been championed as a less invasive method of releasing the transverse carpal ligament which allows for an earlier return to work and normal activities of daily living (ADLs) relative to OCTR. Conversely, opponents of ECTR feel that complications may be more common.

Clinical comment

The debate as to whether ECTR provides benefits relative to OCTR has been a somewhat emotional one amongst

hand surgeons since ECTR was introduced in the 1990s. The early studies of Chow and Agee et al. suggested that the procedure could be done safely and with earlier return to ADLs and work (especially in Workman's Compensation patients).[8,9] Subsequent studies failed to confirm these findings. In addition, there were a significant number of case reports documenting major complications such as median or ulnar nerve injuries after ECTR.

Available literature and quality of the evidence

There have been a large number of studies comparing ECTR and OCTR including several prospective randomized trials.[10,11]

Findings

A Cochrane review in 2014 by Vasiliadis et al. reviewed 28 papers comparing ECTR and OCTR. They found a lower rate of minor complications and an earlier return to work (eight days on average) after ECTR. However, they concluded that "[the results] of this review are limited by the high risk of bias, statistical imprecision and inconsistency in the included studies."[12] A meta-analysis by Zuo et al. in 2015 examined 13 randomized trials and reached somewhat different conclusions, including no differences in return to work, overall complications, or patient satisfaction.[13] They did find a lower rate of hand pain at 12 weeks postsurgery after ECTR but a higher risk of nerve injury (risk ratio [RR] = 2.38).

Devana et al. utilized large databases to examine complications and costs of ECTR versus OCTR.[14] They were able to compare 72 116 patients who underwent ECTR with 495 164 patients who underwent OCTR in both a private and public insurance system in the United States. They found a significantly higher rate of wound complications

such as infection and dehiscence in the OCTR group. They also found a higher rate of median nerve injury in the OCTR group, although they did not comment on whether the difference was statistically significant. The costs associated with ECTR were significantly higher and in the case of the private insurance setting were more than 1.5× that of OCTR. This is similar to the findings of Thoma et al., who found the cost utility of ECTR was poor when comparing ECTR completed in a main operating room setting versus OCTR in a minor procedure room setting.[15]

Overall, the quality of the evidence comparing ECTR and OCTR is quite high. Although the conclusions are somewhat different in various studies, it appears that minor complications are slightly higher in OCTR and that the incidence of major complications such as nerve injury are not different between the two techniques.

There is likely little difference in outcomes whether the carpal tunnel is released endoscopically or by using an open technique. Relief of sensory symptoms is high in both techniques.

Resolution of clinical scenario

- Efficacy rates are largely equivalent for ECTR and OCTR.
- Minor complications are higher with OCTR relative to ECTR.
- The incidence of major nerve injury is likely no different between the two techniques.

Question 3: In patients undergoing CTR, what type of anesthesia is best for CTR?

Rationale

Hand surgery in general, and carpal tunnel surgery specifically, is increasingly being done using local anesthesia in a minor procedure room setting.[16]

Clinical comment

Since the end of the last century, surgery for CTS has evolved from a procedure that was done in an inpatient setting under general anesthesia to one done with regional anesthesia and sedation being completed as an outpatient. Both of these techniques typically employ a main operating setting with the presence of an anesthetist. More recently, CTR under purely local anesthesia and no sedation in a minor procedure setting has been advocated.[17] The latter has been termed *wide awake, local anesthesia* (WALA) hand surgery. Purported benefits of WALA include lower costs, improved patient safety, shorter wait times in a single payer system, and a smaller environmental impact.[18]

Available literature and quality of the evidence

Although there are an increasing number of reports of the use of WALA and CTR,[16],[17] there are relatively few papers comparing WALA to traditional anesthesia techniques.

Findings

Tulipan et al. reported on 230 patients undergoing OCTR and randomized to either WALA or monitored regional anesthesia.[19] Complications, outcomes using validated tools such as the Disabilities of the Arm, Shoulder, and Hand (DASH), as well as custom Likert scales, were no different between groups.

Nabhan et al. reported on a small group of 44 patients undergoing ECTR who were randomized to either WALA or

regional anesthesia.[20] They found no differences in complications or clinical outcomes but a shorter operating room time and tourniquet time using WALA. They concluded WALA was well tolerated and effective.

Foster et al. utilized a large database to examine the comparative costs of WALA versus regional or general anesthesia.[16] They identified 86 687 patients who had undergone CTR over a five-year period and found that just over 80% of procedures had been done under general or regional anesthesia. They found that WALA saved an average of $654/procedure and that if all CTR were done under local anesthesia the direct cost savings to the US healthcare system would be $2.3 billion over the next decade.

Overall, there is little literature directly comparing the use of WALA and general/regional anesthesia for carpal tunnel surgery. Multiple small case series have documented the safety and efficacy of WALA for CTR.

Local anesthesia is becoming increasingly used for carpal tunnel surgery. It appears that there are clear cost savings associated with WALA, and therefore it is particularly attractive in cost-constrained healthcare systems.

Resolution of clinical scenario

- Carpal tunnel surgery done under local anesthesia is safe and effective.
- WALA is associated with cost savings.
- At present, there is no high-quality evidence to suggest clinical outcomes are different depending on the type of anesthesia used for CTR.

Summary of answers

- NCS are unnecessary in all patients undergoing surgery (CTR) with clinical findings of CTS but are helpful in patients with mild clinical findings or atypical presentations, and are correlated with outcomes.
- Efficacy rates are largely equivalent for ECTR and OCTR, although minor complications are higher with OCTR relative to ECTR.
- The incidence of major nerve injury is likely no different between ECTR and OCTR.
- Carpal tunnel surgery done under local anesthesia is safe and effective, and has associated cost savings.

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157 Carpal Tunnel Release: Minor Procedure Room or Operating Room?

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Clinical scenario

- A 56-year-old woman presents with complaints of right-hand weakness and numbness that awakens her at night.
- On examination, she has wasting of the thenar eminence and positive Tinel's sign at the wrist.
- Electrodiagnostic studies show prolonged median motor latency and decreased sensory conduction across the wrist.
- You decide to offer an open carpal tunnel release (CTR).

Background

CTR is one of the most common hand surgeries.[1,2] Historically, the procedure has been performed primarily in the main operating room (OR).[3] With the use of local anesthetic, however, the procedure is now routinely performed in the minor procedure setting across North America.[1,2] We reviewed the evidence examining the benefits and possible risks of performing CTR in the minor procedure setting and discuss possible indications for release in the main OR.

Top three questions

1. For patients with carpal tunnel syndrome (CTS), does performing CTR in the minor procedure room, compared to the OR, result in lower costs and improved efficiency?
2. For patients with CTS, are there differences in patient outcomes and complication rates for CTR performed in the minor procedure setting compared to the main OR?
3. For patients with CTS, are there (relative or absolute) contraindications to performing CTR under local anesthetic in the minor procedure setting?

Question 1: For patients with carpal tunnel syndrome (CTS), does performing CTR in the minor procedure room, compared to the OR, result in lower costs and improved efficiency?

Rationale

Performing CTR in minor procedure setting, such as an office or ambulatory care clinic, has the potential to have a large impact on decreasing costs and improving efficiency.

Clinical comment

Several studies have demonstrated cost savings and an improvement in efficiency when performing CTR in the minor procedure setting as compared to the main OR.[14_6]

Available literature and quality of the evidence

Evidence available to address the question was primarily level II[1,6] and III[4,5] (prospective and retrospective cohort studies).

Findings

The high costs in the main OR are due to costs of full sterility, anesthesia, and nursing staff, and longer turnover times.[1] CTR in the minor procedure room eliminates the cost for an anesthesiologist as the local anesthetic is administered by the surgeon.[4] This translates to both cost savings and increased efficiency.

Leblanc et al. analyzed the costs and efficiency of performing CTR in the main OR versus the ambulatory setting in Canada.[1] They looked at costs of carpal tunnel surgeries in private office, clinic, and main OR which were all in the same hospital, performed using a wide awake approach with pure local anesthesia (no sedation, no tourniquet, and no anesthesia provider). They performed cost analysis including nonphysician salaries of each person directly or indirectly involved and cost of material for CTR by the same surgeon in all three venues. They reported that the cost for supplies and labor for CTR in the ambulatory setting was $36/case as compared to $137/case in the main OR in the same hospital. For the three different venues (office, clinic, and main OR), an efficiency analysis was performed for a standard three-hour surgical block for CTR. In a three-hour surgical block, surgeons were able to perform nine CTRs in the ambulatory setting versus four in the main OR.[1]

Cheung et al. performed a prospective cost-effectiveness analysis to compare open CTR at a center in Canada and one in the United States.[6] CTR was performed in the minor procedure and main OR setting at the Canadian and US center, respectively. Mean total costs from a societal

perspective were significantly less in the Canadian minor procedure room setting ($1581 vs $2179, respectively).

Chatterjee et al. calculated a total cost comparison, profit analysis, and assessment of efficiency of open and endoscopic carpal tunnel surgery in the United States in both the clinic and the main OR.[4] For open CTR, the main OR was more than four times as expensive as the clinic ($3469 vs $670). Clinic cases had a profit margin of $1186 per case, and procedures in the main OR incurred a loss of $650 per case after considering the cost of the procedure and the revenue earned. The most significant direct cost in the main OR setting was the presence of an anesthesiologist. For efficiency analysis, the researchers calculated that twice as many surgeries could be done in a clinic setting.[4]

Without the use of full sterility and the supplies of procedures needed in the main OR, there is also a hypothesized environmental impact due to a decrease in medical waste. Leblanc et al. estimated that the amount of garbage generated by the main OR setting is at least 10 times that of minor procedure field sterility.[7]

Resolution of clinical scenario

- There are significant cost savings and increased efficiency when open CTR is performed in the minor procedure setting in comparison to the main OR, where full sterility, higher turnover times, and the services of an anesthesiologist and additional nursing staff are required.
- Although the evidence is derived from a lower level of evidence study design (II and III), the conclusion of all these studies is the same, thus providing a strong

recommendation to perform CTR in the minor procedure room.

Question 2: For patients with CTS, are there differences in patient outcomes and complication rates for CTR performed in the minor procedure setting compared to the main OR?

Rationale

With an increasing number of hand surgeons in North America performing CTR surgery under local anesthetic in the minor procedure setting,[1],[2],[8] it is important to ensure that outcomes and the patient experience are not compromised. Some centers continue to use the main OR preferentially. Are complication rates and patient-reported outcomes comparable in the two settings?

Clinical comment

Surveys have shown that hand surgeons in UK and America continue to use general anesthetic for CTR because of the belief that local anesthetic is poorly tolerated by patients.[9] General anesthesia may impact associated medical conditions such as diabetes, cardiac disease and lung problems. In addition, postoperative side effects such as nausea and vomiting[8] are common. The use of local anesthesia alone avoids these issues and can be administered without the need of an anesthetist.[8] In deciding whether to perform carpal tunnel surgery in the minor procedure room versus the main OR, it is important to understand if there are any differences in outcomes, complications, and patient experience.

Available literature and quality of the evidence

Evidence to address the question was primarily level II[6–8,10] and III (prospective and retrospective cohort studies).

Findings

In a prospective cohort study of 1504 CTR procedures in five Canadian training centers, Leblanc et al. demonstrated a low incidence of infection and general safety of CTR in minor procedure setting.[7] They report six superficial infections (0.4%), and no deep postoperative infections requiring admission, incision and drainage, or intravenous antibiotics. Nosrati et al. investigated differences between the main OR and clinic setting with respect to complications and patient satisfaction and found no differences in rates of infection or nerve injury.[5]

In the prospective, cost-effectiveness analysis of patients undergoing open CTR, Cheung et al. demonstrated similar postoperative improvements in health-related quality of life regardless if surgery was performed in a minor procedure setting under wrist block or main OR setting under Bier block.[6] Clinically significant improvements were observed in both the Michigan Hand Questionnaire and EuroQol five-dimensional questionnaire (EQ5D).

Several studies have demonstrated that most patients prefer CTR under local anesthetic without sedation if offered in a positive manner.[10,11] Derkash et al. reported on 20 patients undergoing CTR in the office with wrist block anesthesia and wrist tourniquet that all were pleased with the office surgical procedure. One patient reported mild discomfort from the wrist tourniquet.[8] Barros et al. had patients complete a questionnaire following their surgery regarding their anesthetic experience, including the number of times they felt pain during the anesthesia

and the intensity of that pain.[11] Seventy-five percent of patients reported that the technique was the same or better than venous puncture and 81% reported that it was better than a dental procedure.

Davison et al. performed a prospective cohort study to examine the patient's perspective on CTR related to two types of anesthesia.[10] The first group of 100 patients had open CTR with only lidocaine and epinephrine in Saint John, New Brunswick, and the second cohort of 100 patients underwent endoscopic CTR with local anesthesia, IV sedation, and use of tourniquet in Davenport, Iowa. They used questionnaires completed by patients at their first postoperative visit to gather information on patient perspectives on the anesthesia experience. Interestingly, they found that patients generally liked whichever form of anesthesia that was provided and that wide-awake carpal tunnel surgery was well tolerated. Similarly, Baguneid et al. performed a prospective study to assess effectiveness, safety, and patient tolerance of CTR using local anesthetic and upper arm tourniquet.[9] Patients reported no discomfort or only slight discomfort for all aspects of the operation in 94% of cases. All patients preferred local anesthesia over general anesthetic.

Despite previous beliefs,[7] current evidence demonstrates that CTR performed in an ambulatory setting with local anesthetic is well tolerated by the majority of patients with low complication rates and high patient satisfaction.[6–8,10]

Resolution of clinical scenario

- CTR in the minor procedure setting under local anesthetic is well tolerated by most patients.
- Complication rates and patient-reported outcomes were comparable to CTR performed in the main OR.

Question 3: For patients with CTS, are there (relative or absolute) contraindications to performing CTR under local anesthetic in the minor procedure setting?

Rationale

There is evidence for cost savings, increased efficiency, comparable outcomes, and patient preferences for undergoing CTR in the minor procedure setting under local anesthetic. While this is an appropriate setting for most patients, it is important to identify any relative or absolute contraindications to performing CTR in the minor procedure setting.

Clinical comment

The minor procedure setting is an appropriate environment for most patients undergoing CTR, but there may be some situations where the main OR is indicated.

Available literature and quality of the evidence

Evidence available to address the question was primarily level II, III, and V, including prospective and retrospective studies, as well as literature reviews and expert opinion.

Findings

There are few absolute contraindications for CTR in the minor procedure setting. In fact, contraindications to general anesthesia, such as medical co-morbidity or pregnancy, may be an indication to consider local anesthetic. Grekin and Auletta discussed local anesthetic, its uses, and its contraindications.[12] Although it is rare to

have a true allergy to local anesthesia, this would be an indication for CTR to be performed in the main OR under general anesthetic.[11,13]

Presumed relative contraindications for CTR in the minor procedure setting may not be evidence based. While some surgeons will bring patients who are on antiplatelets or anticoagulants to the main OR for elective hand surgery, there is a lack evidence to support doing this. Several studies report no difference in bleeding complications if anticoagulation or antiplatelet therapy are continued for elective hand surgery.[14–16] Smit and Hooper reviewed a group of patients who had surgical treatment for CTS or Dupuytren's disease while anticoagulated on warfarin.[14] Surgery was carried out without stopping the warfarin, provided the INR was 3 or less. Open CTR was performed under local anesthetic with pneumatic tourniquet; there were no perioperative or postoperative bleeding complications.

Despite a lack of evidence, we hypothesize that other relative contraindications to CTR in the minor procedure setting include the inability to lie flat or still, such as Parkinson's disease or cognitive impairment. Patients undergoing other procedures under general anesthetic may wish to have concomitant CTR performed during the same anesthetic. Patient anxiety and preference may also be a relative contraindication, although there is evidence that when CTR under local anesthetic is presented to patients in positive manner it is generally well tolerated.[6–8,10]

Resolution of clinical scenario

- There are few relative and absolute contraindications to carpal tunnel surgery in the minor procedure setting.

Summary of answers

- There are significant cost savings and increased efficiency of CTR when performed in the minor procedure setting compared to the main OR.
- CTR in the minor procedure room setting is well tolerated by most patients.
- There is no increased risk of complications when CTR is performed in the minor procedure setting compared to the main OR.
- There are few relative and absolute contraindications to performing carpal tunnel surgery in the minor procedure setting.

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158 Thumb Carpometacarpal Osteoarthritis

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Clinical scenario

- A 59-year-old right-hand-dominant woman who works as an administrator complains of pain at the base of her thumb, radiating along her thenar eminence and radial forearm.
- The pain has been present for a few years and has gradually worsened.
- She has difficulty opening jars and chopping vegetables due to this pain.

Top three questions

1. In patients with primary thumb carpometacarpal osteoarthritis (CMC OA), does intra-articular corticosteroid injection result in greater pain relief than placebo or hyaluronic acid?
2. In patients with primary thumb CMC OA, does an orthosis improve pain and function?

3. In patients with primary thumb CMC OA, does trapeziectomy plus ligament reconstruction and tendon interposition (LRTI) result in greater pain relief than trapeziectomy alone?

Question 1: In patients with primary thumb carpometacarpal osteoarthritis (CMC OA), does intra-articular corticosteroid injection result in greater pain relief than placebo or hyaluronic acid?

Rationale

Initial nonsurgical treatment of patients with thumb CMC OA typically involves joint injections and splinting. Intra-articular injections are a common presurgical intervention aimed mainly at pain relief. It is unclear which conservative measures, if any, are most effective.

Clinical comment

Intra-articular corticosteroid injections are thought to decrease pain and inflammation associated with osteoarthritis. Alternatively, intra-articular hyaluronic acid injections aim to supplement and increase the viscoelasticity of synovial fluid.

Available literature and quality of the evidence

The best evidence to answer this question comes from a recent systematic review that included meta-analyses of six randomized controlled trials (RCTs).[1–7] The majority of the studies were not of high methodological quality and many

sources of heterogeneity were present. This is level II evidence.

Findings

Pooled meta-analysis was performed on three sets of data: corticosteroid injection versus placebo, hyaluronic acid injection versus placebo, and corticosteroid versus hyaluronic acid. Analysis of corticosteroid injection versus placebo showed that individual study findings were mixed. Pooled analysis, with 82 patients in each arm, showed no difference between corticosteroid injection and placebo at 24 weeks post injection (Standardized response means [SRM]: −1.20; 95% confidence interval [CI]: −3.69 to 1.29). Earlier time points were unable to be pooled for analysis. Pooled analysis of hyaluronic acid versus placebo, with 74 patients in each arm, showed improvement in functional capacity in the hyaluronic acid group (SRM: −1.14 [−1.69 to −0.60]) at 12 weeks, but no difference in pain (SRM: −0.95 [−3.87 to 1.97]). Results at 24 weeks were unable to be pooled. Pooled analysis between corticosteroid and hyaluronic acid did not yield significant results at four and 12 weeks; however, differences were apparent at 24 weeks. Hyaluronic acid appeared superior on pulp pinch force (SRM: −1.66 [−0.75 to −2.57]), and corticosteroid superior for pain (SRM 1.44 [0.17–2.74]); however, the authors commented that the results at 24 weeks were almost entirely driven by one strongly positive study, while the other studies showed no effect.

Resolution of clinical scenario

- In patients with thumb CMC OA, there is weak evidence to support the use of corticosteroid and hyaluronic acid injections for relief of pain and improvement in function.

- Studies comparing the two forms of injection suggest that corticosteroid may be better for pain relief, whereas hyaluronic acid may be more useful for increasing functional capacity.

Question 2: In patients with primary thumb CMC OA, does an orthosis improve pain and function?

Rationale

Use of an orthosis is a common nonoperative treatment prescribed by family physicians, sports medicine physicians, and hand and wrist surgeons. Orthoses vary in their size, rigidity, and method of manufacture. Despite widespread use, optimal type and duration of use of splinting is unclear.

Clinical comment

Orthoses are prescribed to immobilize the first CMC joint in order to decrease pain and perhaps improve function.

Available literature and quality of the evidence

The current best evidence comes from a systematic review of 10 RCTs studying the effects of orthoses in patients with symptomatic thumb CMC OA.[8] This is level I evidence.

Findings

Ten RCTs were reviewed and the results of each study were synthesized to make conclusions; however, pooled meta-analysis were not performed. Two RCTs compared prefabricated versus custom orthoses.[9],[10] Both studies found that pain improved in both groups; however, custom-

made orthoses provided significantly better pain reduction in both studies. One of these studies also found an improvement in pinch strength and Disabilities of the Arm, Shoulder, and Hand (DASH) scores in both groups.[10] Weiss et al. compared short and long prefabricated orthoses and found that pain was improved in both groups.[11] They found that short orthoses were favored by most patients. Another RCT compared soft orthoses to rigid and semi-rigid orthoses and found no significant difference in pain scores between the two treatment arms.[12] Most patients preferred the use of the flexible orthosis, and most patients preferred to wear the orthosis for the entire day. One study compared two groups consisting of the use of an orthosis plus an exercise protocol and found that both groups improved in terms of pain, strength, and function.[13] No difference between the groups was found.

Resolution of clinical scenario

- In patients with thumb CMC OA, there is evidence to support the use of an orthosis for the reduction of pain.
- While custom-made orthoses appear to be superior in terms of pain reduction, there does not appear to be an effect of orthosis length or rigidity.
- Orthoses do not appear to alter overall function, strength, or dexterity.
- Most patients preferred to wear the splint for the entire day.

Question 3: In patients with primary thumb CMC OA, does trapeziectomy plus ligament reconstruction and tendon interposition (LRTI) result in greater pain relief than trapeziectomy alone?

Rationale

In patients with primary thumb carpometacarpal osteoarthritis, does trapeziectomy plus LRTI result in greater pain relief than trapeziectomy alone?

Clinical comment

Amongst surgeons who perform thumb CMC procedures, there is a continued trend toward utilization of trapeziectomy plus LRTI. In a recent study, 95% of surgeons utilize only one type of surgical procedure, and of these 93% exclusively perform trapeziectomy plus LRTI.[14]

Available literature and quality of the evidence

The best evidence available to address this question comes from a systematic review of 11 RCTs, quasi-randomized, and controlled studies,[15] in which meta-analysis was performed on data pooled from the included studies. Five of these studies compared trapeziectomy alone to trapeziectomy plus LRTI.[16–21] This is level II evidence; the authors of the paper concluded that the quality of available and included studies was low.

Findings

Meta-analysis of three studies which compared pain on a 100 mm Visual Analog Scale (VAS) found no difference on pain relief between trapeziectomy plus and trapeziectomy alone.[16,18–20] The mean reduction in pain with trapeziectomy plus LRTI was 2.8 mm (95% CI: −9.82 mm to 4.21 mm). Meta-analysis of two studies comparing the number of participants with resting pain found no difference between trapeziectomy plus LRTI and trapeziectomy alone (risk ratio [RR] = 1.18; 95% CI: 0.31–4.54).[17,21]

Furthermore, meta-analysis revealed that there was no difference between the two groups for physical function, as measured by the DASH score (SMD: 0.01 out of 100 points; 95% CI: −0.30 to 0.32). Meta-analysis of complication rates revealed that 19 out of 100 people who underwent trapeziectomy plus LRTI had an adverse event, and 10 out of 100 people who had trapeziectomy alone had an adverse event (RR = 1.89; 95% CI: 0.96–3.73). Adverse events included tendon rupture or adhesion, scar tenderness, recurrent pain, sensory changes, cut palmar cutaneous branch of the median nerve, neuroma, instability, de Quervain's syndrome, and complex regional pain syndrome.

Resolution of clinical scenario

- In patients with thumb CMC OA, trapeziectomy plus LRTI does not improve pain or function compared to trapeziectomy alone.
- Trapeziectomy plus LRTI may have a higher risk of complications.
- Despite the presence of level I and III evidence showing equivalent outcomes and a higher risk of complication in trapeziectomy with LRTI, there continues to be a trend toward its use in basal thumb osteoarthritis.

- There is evidence that trapeziectomy with LRTI has substantially more cost compared to the simpler trapeziectomy ($2576 vs $1268, respectively).[22]

Summary of answers

- In the nonsurgical management of thumb CMC OA, evidence supports the use of intra-articular injections for relieving pain and improving function. Corticosteroid injections may be better for pain relief, and hyaluronic acid may be more helpful for improving functional capacity.
- There is evidence to support the use of an orthosis to reduce pain in thumb CMC OA. While custom-made orthoses appear to be superior in terms of pain reduction compared to prefabricated splints, the type of orthosis (long, short, rigid, or flexible) does not appear to make a difference.
- In the surgical treatment of thumb CMC OA, trapeziectomy alone has equivalent outcomes in terms of pain relief and function when compared to trapeziectomy and LRTI. LRTI has a higher complication risk as well as healthcare cost.

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159 Flexor Tendon Injuries: Surgical Management

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Clinical scenario

- A 35-year-old woman presents with inability to flex her index finger after sustaining a laceration while cutting a bagel yesterday.
- She has a 1 cm transverse laceration over the palmar proximal phalanx and increased extension posture.
- She can't flex her proximal or distal interphalangeal joints. Her sensory exam is normal.

Top three questions

1. In patients with acute zone II flexor tendon lacerations, does multistrand core-suture repair result in fewer re-ruptures and better range of motion (ROM) compared to two-strand repairs?
2. In patients undergoing zone II flexor tendon repair, does release of the A2 or A4 pulley result in poorer outcome or bowstringing compared to preservation of these annular pulleys?
3. In cooperative patients with zone II flexor tendon lacerations, does wide awake, local anesthesia, no tourniquet (WALANT) flexor tendon repair improve

ROM and function compared to repairs done under regional or general anesthesia?

Question 1: In patients with acute zone II flexor tendon lacerations, does multistrand core-suture repair result in fewer re-ruptures and better range of motion (ROM) compared to two-strand repairs?

Rationale

Biomechanical studies have shown the strength of the repair increases with the number of suture strands crossing the repair site. However, suture techniques using more strands across the repair site are technically demanding and require increased manipulation of the tendon ends. Multistrand repairs are also bulkier, which may compromise tendon gliding under the pulleys.

Clinical comment

A tendon repair must be strong enough to allow for early ROM without creating too much bulk to impair tendon gliding within zone II.

Available literature and quality of the evidence

There is one randomized controlled trial (RCT),[1] one retrospective comparative study,[2] two level III meta-analyses,[3],[4] and one level IV systemic review comparing two-strand repair to multistrand repair.[5]

Findings

Overall, rupture rates for flexor tendon repairs using all methods average approximately 4%.[6,7] Although in vitro studies have confirmed increasing the number of core sutures across the repair site increases the strength of tendon repair in vitro,[8–14] the clinical benefits of increasing the number of core sutures have not been proven.

Several papers have tried to determine whether there is a benefit of multistrand repair over two-strand core suture repair. Navali and Rouhani published an RCT comparing flexor tendon repairs in zone II performed with a two-strand or four-strand core-suture repair.[1] They followed a passive ROM protocol after surgery which may have negated the principal advantage of multistrand repairs (early *active* motion). There was no statistical difference in clinical outcome between the two groups. There were two tendon ruptures in the two-strand repair group and none in the four-strand repair group. This difference was not statistically significant.

Hoffman et al. compared the clinical outcomes of 46 patients (51 digits) undergoing a six-strand Lim/Tsai repair to 25 patients (26 digits) treated with a two-strand modified Kessler stitch in zone II flexor tendon repairs.[2] The complication rate was lower in the six-strand group (4%) than in the two-strand group (23%). The rupture rate was also lower in the six-strand group (2% vs 11% in the other group), but this was not statistically significant. The two groups followed different rehabilitation protocols, confounding the results.

A systematic review of two-strand versus multistrand core suture techniques for flexor tendon repair found no difference in functional outcome.[4] There was a trend toward lower rupture rates in the multistrand repair group, but this difference was not clinically significant. Other meta-analyses evaluating flexor tendon repairs in all zones

have also failed to find a statistically significant difference in outcomes or rupture rates between two-strand and multistrand repairs.[3,5] One study found that a modified Kessler technique decreased the risk of adhesions by 134%.[6]

Resolution of the clinical scenario

- For zone II flexor tendon lacerations, we cannot recommend a multistrand repair over a two-strand repair.
- The benefit of adding increased strength with more core strands must be weighed against the risk of causing more bulk and adhesions to the repair.

Question 2: In patients undergoing zone II flexor tendon repair, does release of the A2 or A4 pulley result in poorer outcome or bowstringing compared to preservation of these annular pulleys?

Rationale

Traditionally, the A2 and A4 pulley have been preserved, repaired, or reconstructed during zone II flexor tendon repair to prevent bowstringing.

Clinical comment

Release or venting of these essential pulleys during zone II flexor tendon repair can facilitate repair, may improve tendon excursion, and decrease work of flexion.[15–22] The

practice of venting essential pulleys during flexor tendon repair is gaining wide clinical acceptance.

Available literature and quality of the evidence

There are two level IV studies describing outcomes after complete release of the A4 pulley during flexor tendon repair.[23–25] There is one small retrospective case series reporting the results of flexor tendon repair after complete release of the A2 pulley.[24] Tang and colleagues published a large prospective study describing results after zone II flexor tendon repairs involving release of various portions (including the A2 and A4 pulley) of the flexor sheath.[26]

Findings

Partial release or venting of the A2 and A4 pulley have been described to aid in tendon repair and allow for smooth gliding of the swollen and edematous tendon repair. Complete release of the A2 and A4 pulley was discouraged because of concern for bowstringing. In contrast, Kwai and colleagues reported the frequency and degree of venting of the A2 and A4 pulleys necessary either to perform a flexor tendon repair or to allow the repairs to run freely without snagging on the pulleys is greater in clinical practice than the earlier literature would suggest.[27] In addition, recent biomechanical and clinical research have challenged the need to preserve these “critical” pulleys.[18,19,22]

Several papers have described partial and even complete release of the A4 pulley during flexor tendon repair.[23,27,28] Moriya and colleagues reported on 15 patients, with 22 fingers, who had complete release of the A4, C2, and in some patients A3 pulley during zone II flexor tendon repair.[25] Good to excellent results were noted in 91% according to Strickland or Tang criteria. Two small fingers required tenolysis. Al-Qattan and Al-Turaiki published a

prospective study showing good to excellent results in patients requiring complete release of the A4 pulley or portions of the A2 pulley during zone II flexor tendon repair.[23] The authors attributed a decrease in rupture rate and PIP flexion contracture to generous venting of pulleys, including the critical A4 and A2 pulley.

With regard to the A2 pulley, biomechanical research suggests release of the A2 pulley may actually improve tendon excursion and decrease work of flexion.[29] Moriya and colleagues reported their results on seven fingers with zone II flexor tendon injuries requiring complete release of the A2 pulley.[24] Two patients required additional release of the C1 pulley. They had six (86%) good to excellent results according to Strickland and Tang criteria with no bowstringing. These results were compared to 33 patients who only underwent partial A2 pulley release, who had 73% good to excellent results. Two patients (29%) required tenolysis in the complete A2 pulley release group compared to only one finger (3%) in the partial release group. There were two clinical failures according to the Tang criteria in the partial release group but none in the complete release group.

Tang and colleagues reported intern results of 300 flexor tendon repairs in which up to 2 cm of tendon sheath was released to allow for unimpeded motion of the tendon.[26] Venting was performed in different portions of the sheath depending on location of the tendon injury. Good to excellent results were found in over 83% of repairs with only one rupture in the entire series. They did not find any clinically significant bowstringing even in cases were complete release of the A2 or A4 pulley was required.

A systemic review of venting of the pulley system with early active mobilization (114 digits) compared with no venting and passive flexion active extension mobilization (335

digits) showed a trend toward an improvement in the incidence of excellent outcomes but not to statistical significance.[4] However, this study did not specify which pulleys were released or the extent of release and involved different postoperative mobilization programs.

Resolution of the clinical scenario

- Partial release of “critical” pulleys is acceptable to aid tendon repair and allow for smooth gliding of the repaired tendon.
- Early clinical evidence suggests complete A4 release during flexor tendon repair does not adversely affect outcome after surgery.
- There is still insufficient clinical data to support complete release of the A2 pulley during flexor tendon repair.

Question 3: In cooperative patients with zone II flexor tendon lacerations, does wide awake, local anesthesia, no tourniquet (WALANT) flexor tendon repair improve ROM and function compared to repairs done under regional or general anesthesia?

Rationale

In recent years, there has been increasing interest in performing hand surgery under WALANT. The use of WALANT in hand surgery has been shown to be safe and well-tolerated by patients.[29],[30] Flexor tendon repair under WALANT is gaining attention.

Clinical comment

By having the patient actively flex their finger after flexor tendon repair, the surgeon is able to test the integrity of the repair and ensure the repair is gliding smoothly in the tendon sheath.

Available literature and quality of the evidence

Lalonde first described his method for wide awake flexor tendon repair in 2009.[31] Since then, Higgins and his colleagues have published one level IV retrospective chart review on patients undergoing wide awake flexor tendon repair.[32]

Findings

Lidocaine with epinephrine allows for anesthesia and a bloodless field without tourniquet. The patient can then actively flex their finger before skin closure to ensure there is no gapping or triggering at the repair site and smooth gliding of the repaired tendon under the pulleys.[33] Higgins and colleagues reported the results of 68 patients, undergoing two 122 wide awake flexor tendon repairs: three patients had re-rupture (4.4%) or four tendons of 122 repairs (3.3%).[32] Results included patients undergoing two- and four-strand core repairs with epitendinous suture in zone I–IV, 25 flexor pollicis longus repairs, and six cases where the zone was not documented. Final ROM was not presented.

Despite the potential advantages of WALANT for flexor tendon surgery, a recent survey of 410 members of the ASSH, revealed only 20% of surgeons reported using WALANT for flexor tendon repairs.[34] The authors speculated WALANT for flexor tendon surgery has not been widely adopted by hand surgeons in the United States

because of the invasiveness of the procedure and lack of evidence showing an improvement in outcome.

Resolution of the clinical scenario

- WALANT may help improve the quality of flexor tendon repair; however, evidence showing a clear advantage or improvement in outcomes compared to regional and general anesthesia is lacking.
- The surgeon should continue to perform flexor tendon repair in the manner which they feel most comfortable.
- The surgeon should continue to perform flexor tendon repair in the manner in which they feel most comfortable.

Summary of answers

- For zone II flexor tendon lacerations, there is insufficient clinical evidence to recommend a multistrand repair over a two-strand repair.
- Early clinical evidence suggests complete release of the A4 pulley during zone II flexor tendon repair can safely aid flexor tendon repair and does not lead to bowstringing.
- There is still insufficient evidence to recommend complete release of the A2 pulley during flexor tendon repair.
- WALANT anesthesia is safe for flexor tendon repair surgery but has not been shown to improve clinical outcomes in flexor tendon surgery

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160 Flexor Tendon Injuries: Rehabilitation

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Clinical scenario

- A 40-year-old male lacerates both flexor digitorum profundus (FDP) and flexor digitorum superficialis (FDS) of the long finger over the proximal phalanx while using a knife to cut food.
- This is repaired using four core strands with a 4-0 braided polyester suture, a 6-0 monofilament epitendinous repair of the FDP, and a two-strand figure-of-eight repair of both slips of FDS with 4-0 braided polyester suture.
- The referral from the surgeon asks for a splint and range of motion (ROM) exercises.

Top three questions

1. In adults with zone II flexor tendon injuries, would an early active ROM rehabilitation protocol result in better finger ROM than early controlled passive ROM?
2. In adults with zone II flexor tendon injury, does immediate initiation of motion result in better total finger ROM than those initiated in a delayed fashion?
3. In adults with zone II flexor tendon injury, after surgical repair does splinting in a neutral wrist position

result in better total finger ROM than with the wrist held in flexion?

Question 1: In adults with zone II flexor tendon injuries, would an early active ROM rehabilitation protocol result in better finger ROM than early controlled passive ROM?

Rationale

Early motion protocols have greatly improved outcomes after flexor tendon surgery. There has been considerable debate on the optimal postoperative rehabilitation strategy for zone II flexor tendon repairs. Medical professionals remain divided on protocols that employ only passive flexion or a combination of passive and active flexion.[1–3]

Clinical comment

Zone II flexor tendon injuries are associated with poorer outcomes than injuries in other parts of the flexor tendon system. Following repair, there is a competing demand on the tendon for gliding through the sheath to prevent adhesions and minimizing excessive forces on the repair to prevent rupture. Although, intuitively, early active motion will decrease adhesions and improve outcomes, this is not necessarily supported in the literature.

Available literature and quality of the evidence

- Level Ib: randomized controlled trial (RCT).[4]
- Level IIb: RCT.[5]
- Level V: expert opinion.[6]

Findings

Trumble et al. compared a group of patients using early passive ROM using a passive flexion and active extension protocol with a group using a combined passive and active flexion rehabilitation protocol employing place and hold.[4] The total finger ROM was significantly better ($p < 0.05$) in the combined passive and active place and hold group ($\mu 156° \pm \sigma 25°$) compared to the early passive ROM only group ($\mu 128° \pm \sigma 22°$). Rupture rates appeared to be equivalent between early passive ROM only and early active with place and hold groups.

A second RCT by Farzad compared early active motion with a place and hold and early passive motion only. This study showed a significant increase in total active motion ($p = 0.001$) eight weeks after surgery in the early active motion group ($\mu 146° \pm \sigma 29°$) than the early passive motion group ($\mu 114° \pm \sigma 38°$). There were no ruptures reported among the 54 patients. This trial represents level II evidence due to underpowering of the control and study groups.[5]

A review by Tang highlighted the challenges in comparing outcomes even amongst what appeared to be similar therapy protocols. These authors compiled flexor tendon repair therapy protocols of 10 of the world's leading hand surgery centers and showed great variability in the protocols used as well as variability in the method of passive and/or active ROM utilized by each center. Synergistic wrist movement in passive motion protocols and midrange finger active motion are two examples of state-of-the-art strategies that could improve tendon excursion while minimizing force applied to a healing tendon.[6]

Resolution of clinical scenario

- Patients with isolated flexor tendon lacerations in zone II likely benefit from an early active ROM protocol that combines elements of early passive motion and early active motion with place and hold, which will result in the greatest total arc of motion for the repaired fingers.
- There is no increase in rupture rates of the repaired tendon(s) compared to passive ROM protocols with active extension.
- There are a large variety of postoperative flexor tendon protocols that vary by center. There is a trend toward a combination of early passive with early active ROM in leading hand surgery centers.

Question 2: In adults with zone II flexor tendon injury, does immediate initiation of motion result in better total finger ROM than those initiated in a delayed fashion?

Rationale

Early motion postflexor tendon repair has resulted in dramatically improved composite motion of the fingers compared to immobilization. The decision of when to commence early motion therapy after surgery varies by center.

Clinical comment

Early motion protocols can be considered those that begin motion within seven days of repair.[7] *Work of flexion* reflects the resistance against which a repaired tendon must pull to permit gliding within the sheath.[8] The goal is to minimize the forces that prevent active motion via the repaired flexor

tendon. The foremost postoperative factor that can increase work of flexion in the first week after surgery is finger edema, while adhesions and joint stiffness introduce a further component resisting motion beyond seven days. Proponents of immediate *passive* motion suggest that immediate motion after surgery can help reduce edema and prevent tendon adhesion.[9] Others suggest that a short period of rest (3–5 days) to the hand following surgery allows clots to stabilize and edema to improve, making motion more comfortable and effective.[8],[10]

Available literature and quality of the evidence

- Level III: 1 retrospective cohort.[11]
- Level V: 1 biomechanical study[12] and 3 expert opinions.[8],[9],[13]

Since the level of evidence available in this area is level III–V, key results should be considered cautiously.

Findings

Immediate *passive* motion, as early as postoperative day one, is employed at many hand surgery centers, including the two RCTs performed comparing early active and early passive ROM. Advantages for early ROM would be prevention of stiffness and edema and early evaluation and monitoring for early signs of infection.[4],[5]

Arguments against postoperative day one passive movement include patient discomfort and the possibility of causing fresh bleeding around the tendon that could cause worsened adhesion formation.[8] Biomechanical studies in animal models recommend against waiting more than seven days for motion, while also suggesting that postoperative day one *active* motion may be detrimental.

Immediate postoperative *active* movement in a chicken model of flexor tendon repair showed an increased work of flexion in the immediate postoperative period of the first three days due to edema. By 7–9 days, the force required to actively move the tendon again increased due to adhesion formation.[12]

In a canine model of active motion after flexor tendon repair of a lacerated tendon, work of flexion remained high at three days, dropped at day five and then increased by day seven following the procedure. It was hypothesized that the force increased at day seven due to adhesion formation, resisting the gliding tendon. It was hypothesized that the decreased work of flexion at day five was due to decreased extrinsic forces on the tendon, such as edema resolution in surrounding tissue.[13]

A study in Taiwan looked at patients with any tendon injury of the hand. Those that started rehabilitation with motion at under one week required fewer therapy visits, were in therapy for a shorter time, and required fewer revision surgeries than those who initiated therapy at over one week. This resulted in both better clinical results and cost savings.[11]

Resolution of clinical scenario

With the goal of maximizing finger ROM after zone II flexor tendon repair:

- This patient should begin early motion within seven days after zone II flexor tendon repair.
- Passive motion can commence as early as postoperative day one. Evidence is contradictory on whether a short period of immobilization of 3–5 days is beneficial.

- Active motion should be delayed until 3–5 days after surgical repair.

Question 3: In adults with zone II flexor tendon injury, after surgical repair does splinting in a neutral wrist position result in better total finger ROM than with the wrist held in flexion?

Rationale

Traditionally, the wrist is held in a position of slight flexion after flexor tendon repair to reduce force exerted on the healing tendon repair and to permit passive ROM. Early active motion protocols often have the wrist held in neutral or slight extension.

Clinical comment

The flexor tendon repair must be protected after surgery as unrestrained movement or accidental forced flexion can overpower the repair resulting in gapping and possible tendon rupture. The position of the wrist during the rehabilitation period has been said to influence the force that the tendon is subjected to in passive and active ROM.

Available literature and quality of the evidence

- Level V: 3 animal studies,[14–16] 1 biomechanical study,[17] and 2 expert opinions.[18,19]

As the level of evidence available is level V, key results and recommendations should be considered cautiously.

Findings

Flexion of the wrist does reduce the maximum force (deliberate or inadvertent) that can be generated through a flexor tendon. Burssens et al. tested uninjured human hands and showed that the maximum grip force increased progressively by changing the wrist from a position of flexion to one of extension. The maximum force that can be generated by the muscles in the forearm via the flexor tendon decreases with wrist flexion.[18]

In a canine model of passive and active motion measuring force through the tendon, peak tendon force was 2–3 times greater with the canine wrist in extension than in flexion. Passive tension on the tendon decreased substantially from extension to flexion. With stimulation of the muscle simulating active motion, a significant decrease in force was measured in the tendon when the wrist was flexed instead of extended.[16]

In a canine model of flexor tendon repair with passive ROM, extension of the wrist allowed for greater excursion of the tendon than fixed flexion of the wrist. Fixed flexion of the wrist may limit passive tendon excursion, particularly in a flexor tendon sheath that has been subjected to the trauma of tendon repair.[14]

In a biomechanical model in uninjured human fingers, the force required to actively flex the fingers is deemed to be lowest with the wrist in 45° extension and metacarpophalangeal MCP joints flexed and interphalangeal IP joints straight. This is compared to the wrist in a neutral or flexed position, where the resting tension of the intrinsic/extensor tendons impose a greater extension force that counters flexion.[17]

In a study that used buckle force transducers on uninjured flexor tendons in the carpal tunnel, with active motion, the

force on the FDS tendon increased with wrist flexion while the force generated through the FDP did not change between flexed or neutral positioning of the wrist. They advise the wrist to be held in neutral for early active ROM to reduce force on the FDS tendon.[19]

A study in human cadavers highlighted the merits of synergistic wrist extension in reducing the tension of the finger flexors during active finger flexion.[15] Additionally, international leaders in flexor tendon repair advocate a neutral, hinged splint or slight extension of the wrist for initiation of early active ROM protocols after flexor tendon repair.[6]

Resolution of clinical scenario

There is limited evidence supporting one position of the wrist over another depending on the goal of rehabilitation.

- Slight flexion of the wrist limits the active force possible through the repaired tendon and may be ideal prior to initiating an active motion protocol, to prevent inadvertent use and to protect a weak repair.
- Passive motion flexor tendon excursion may be augmented with wrist extension.
- For early active ROM of the fingers, the wrist should not be flexed but rather in neutral or slight extension to reduce the force required for active motion via the repaired tendon.

Summary of answers

- Early active ROM with place and hold results in greater finger ROM than passive flexion only.
- Motion should commence within seven days of repair.

- Rehabilitation with active motion should be initiated 3–5 days postoperatively. Passive motion may commence as early as day one.
- Wrist flexion reduces the force that can be generated through a flexor tendon; however, wrist flexion also limits passive tendon excursion and increases the force required through the flexor tendon for active flexion.

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161 Extensor Tendon Injuries

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Clinical scenario

- A 35-year-old self-employed male contractor cutting dry wall with a knife.
- The blade slipped causing a 4 cm laceration to the dorsum of his nondominant hand.
- The patient severed the extensor tendons to the four fingers between the metacarpophalangeal (MP) joints and the wrist; he is unable to extend his fingers.

Top three questions

1. In patients with fully lacerated extensor tendons, does a multistrand core suture technique result in better functional outcomes when compared to other techniques?
2. In patients with fully lacerated extensor tendons, does an early active range of motion (ROM) rehabilitation protocol result in better outcomes when compared to immobilization?
3. In patients with fully lacerated extensor tendons, what preoperative factors contribute to better functional outcomes?

Question 1: In patients with fully lacerated extensor tendons, does a multistrand core suture technique result in better functional outcomes when compared to other techniques?

Rationale

The strength of an extensor tendon repair dictates which postoperative rehabilitation protocol may be implemented. The repair needs to be strong enough to withstand an early ROM protocol and prevent rupture or tendon gaping.

Clinical comment

The goal of extensor tendon repair is to create sufficient repair strength to prevent rupture, safely engage in postrepair therapy, and allow the patient to return to work and activities of daily living as soon as possible. There is less controversy about the technique of repairing extensor tendons compared to flexor tendons. Most experts would agree that a strong repair that will withstand tension during early ROM protocols is advisable. A bulky repair that can be detrimental in flexor tendon repairs within the fibro-osseous tunnel is less problematic in extensor tendon repairs.

Available literature and quality of the evidence

- Level IV: 2 case series.
- Level V: 6 cadaver studies.

Compared to the literature concerning flexor tendon repair techniques, there are few studies on extensor tendons. Most of the research is on in vitro cadaveric models, with only two clinical studies with a low level of evidence.

Findings

The studies investigated different suture techniques and their biomechanical performances in tendon shortening, stiffness, and final load to failure as measures of ultimate strength. In 1992, Newport and William showed that for zone VI lacerations the Kleinert-modified Bunnell repair was strongest compared to mattress, figure-of-eight, and modified Kessler techniques.[1] Three years later, a second study concluded that the modified Bunnell and modified Kessler techniques were the strongest for zone IV and were suitable for dynamic or active ROM in short arcs.[2]

In 1997, Howard et al. showed that the augmented Massachusetts General Hospital (MGH) Becker technique had the highest strength when repairing zone VI tendon lacerations compared to the modified Bunnell and modified Krackow–Thomas methods.[3] Similarly, Woo et al. found that the augmented Becker repair had the greatest ultimate strength and significant greater resistance to gaping compared to double figure-of-eight, double modified Kessler, and six-strand double-loop.[4] Chung et al. showed that using the modified Becker with one cross-stitch provided superior mechanical properties compared with two or three cross-stitches.[5]

The running-interlocking horizontal mattress (RIHM) repair in zone VI was shown by Lee et al. to be significantly stiffer, results in less shortening and faster to perform as compared to the augmented MGH Becker and modified Bunnell.[6] The results were further augmented by a retrospective clinical study by Altobelli et al. illustrating the RIHM technique to be strong for immediate controlled active motion.[7]

In the only prospective clinical study, Namazi et al. showed that a roll stitch technique when used in zone V repairs had a superior outcome compared to the modified Kessler core suture technique.[8]

Resolution of clinical scenario

- A multistrand interlocking extensor tendon repair such as a modified Bunnell, augmented Becker, or RIHM is stronger than other suture techniques and is recommended.
- A roll stitch technique may produce less extension lag when compared to a modified Kessler core suture technique.
- Overall quality: low.

Question 2: In patients with fully lacerated extensor tendons, does an early active range of motion (ROM) rehabilitation protocol result in better outcomes when compared to immobilization?

Rationale

There continues to be debate in the literature and clinical community about the most effective postoperative management of primary extensor tendon repair in zones V–VII. Traditional programs statically splint the injury for up to four weeks and then start to mobilize.[9] This can result in joint capsule tightness, adhesions, and/or extensor lag.[10–15]

Rehabilitation protocols for extensor tendon repair have evolved from passive mobilization allowing active flexion and assisted extension to early active motion protocols. Variable study designs with differing results exist, making the ideal protocol controversial.

Clinical comment

In this particular patient, an injury in zone VI significantly increases the risk for adhesions due to the anatomy of the dorsum of the hand. Since the patient is self-employed, the rehabilitation protocol selected that allows for rapid return to normal activities could be a priority for him. That being said, given the multiple tendon involvement and his work requiring complex hand coordination, a protocol that maximizes overall outcome would also be a consideration in protocol choice. A protocol that would allow him to work with assured repair protection with the least demanding home exercise program would likely be preferable to the patient as well.

Available literature and quality of the evidence

The available evidence evaluating different treatment protocols for extensor tendon repairs in multiple zones is summarized in Table 161.1.[11–35] The quality of the studies is varied, ranging from level IV to I evidence, and uses different outcomes measures. There are four meta-analyses that have attempted to synthesize the research to date to provide clarity in clinical decision-making.

Table 161.1 Available evidence evaluating different treatment protocols for extensor tendon repairs in multiple zones.

Reference	Meta-Analysis Inclusion				Study Design	Surgical Technique	Therapy Program	Outcome Measured	R
	1	2	3	4					
Kerr et al.[16]		√			Retrospective case series **Exclusion:** associated bone and joint injury	Zones VI–VII Not reported	**Dynamic splint:** 13 d postop dynamic splint without block Unrestricted active flex no active ext or passive flex 200–1000 reps/d Splinted for 26 d	ROM	4 r p A u p f 1 T c d
Browne and Ribik[17]		√			Prospective case series	Zones IV–VII Not reported	**Dynamic splint** ext assist with wrist and digits in full ext Unrestricted motion to full fist 10 reps/h Added resistance at 5 wk and dynamic splint discontinued 4 wk of splint at night	Complications ROM, grip	5 w n 7 fl 4 c o w R 8
O'Dwyer and Quinton[18]		√			Case series	Zones III–IV If >50% of the slip lacerated was repaired with braided suture	**Dynamic splint** PIP spring splint actively assisting ext introduced after 10–14 d Finger only splinted due to zone of injury	ROM, return to work	9 p f A e g 7 a p A g e 1 p

Reference	Meta-Analysis Inclusion				Study Design	Surgical Technique	Therapy Program	Outcome Measured	R
	1	2	3	4					
Newport et al.[19]		√			Retrospective review: 36 patients were fully evaluated at time of chart audit 26 chart data were used No exclusions	Zones I–VIII not reported	**Immobilization static splint** worn for 3–4 wk Position not specified AROM started then PROM 2 wk later	ROM, grip	6 w ir a o h N s d b c a u ir T p w a ir g e f u c f c
Hung et al.[20]		√			Prospective trial **Exclusion:** complex injuries, mallet injuries	Zones II–VII Not reported	**Dynamic splint** 3 d postop Dynamic splint applied proximal to MCP splinted in full ext with traction to MCP and distal to MCP (II–IV) MCP in 70° flex and PIP active flex increased weekly by 30° for 4 wk Dynamic component removed at 4 wk 5 wk no splint	Grip, ROM	3 w 7 p A t 8

Reference	Meta-Analysis Inclusion				Study Design	Surgical Technique	Therapy Program	Outcome Measured	R
	1	2	3	4					
Slater and Bynum[21]		√			Retrospective case review **Exclusion:** complex injuries	Zones II–VII Multiple surgical techniques	**Early active motion** static splint either volar or dorsal Wrist 30° ext, MCP flex 20–30° flex, IPs free Flex IPs several times/h	Extensor lag	2 s 1 fu re in W c E p lo m la
Sylaidis et al.[22]		√			Inclusion all tendons zone IV–VII simple and complex injuries	Zones IV–VII Modified Kessler zone VI horizontal mattress	**Early active motion** splinted in wrist 45° ext, MC rested in 50° flex and IPs extended Exercise, intrinsic plus to full ext and intrinsic minus No composite flex: 4 cycles, 4 sessions for 4 wk Week 5 progressive work on flex and strengthening Extended splint use if a lag develops	Extensor lag, return to work time and complication rate	2 lo In te 1 re 2 In te 9 re 2 R si c

Reference	Meta-Analysis Inclusion				Study Design	Surgical Technique	Therapy Program	Outcome Measured	R
	1	2	3	4					
Ip and Chow[23]		√			Prospective study 1990–1994 **Inclusion:** zones IV–VIII for fingers and I–IV for thumbs **Exclusion:** no young children, no partial lacerations	Zones IV–VII 2 horizontal mattress sutures	**Dynamic therapy** immobilized for 2 d with wrist in 30° and digits in full ext Dynamic splint applied MCP and IP passive ext active flex of MCP 30° and full IP flex 10 times/h Day 7: 45° flex, day 14: 60° flex, day 21: full flex, day 35: splint d/c free active flex/ext, gentle passive flex, strong passive ext, wrist AROM Week 8: strengthening	ROM; strength grip; and pinch, swelling, pain, function – no detail	1 w ir w p 1 ir D tl e r r T E g F e g 2 R T la g g
Chow et al.[13]		√		√	One hospital had dynamic protocol and at another had static protocol **Exclusions:** fractures, skin loss, joint injuries **Inclusions:** zones IV–VII	Zones IV–VII Horizontal mattress in zones IV–V modified Kessler in zones VI and VII	**Dynamic vs immobilization:** **Group A:** dynamic splint wrist 30° MCP in full ext increased amount of flex at MCP 30° week 1, 45° week 2, 60° week 3, full week 4 and 5 active flex 10 reps/h no restriction on flex of IPs 5 wk d/c splint AROM vs Group B Static immobilized for 3 wk wrist in ext and MCP mild flex	ROM grip	G te e ir g s g o p G 4 3 fa m r te r fi d G

Reference	Meta-Analysis Inclusion				Study Design	Surgical Technique	Therapy Program	Outcome Measured	R
	1	2	3	4					
Crosby and Wehbe[24]		√			Prospective descriptive study **Exclusions:** wrist extensor tendons and fractures	Zones III–VIII Modified Kessler or figure of 8 or mattress	**Dynamic splinting:** immobilized 1–5 d postop Zones V–VII: dorsal forearm dynamic splint, wrist 20° ext, full fisting but MCP blocked as needed based on repair Zones III and IV: hand based dynamic splint, active therapy 2–5 times/wk tendon mobilization holding other joints in maximal ext while passively moving the joint Exercise fisting 10 reps/h, weaned off splint 4 wk	Grip, ROM	5 3 N b fc d ir m re p 4 fu a 9 sl la A re A 9 g ir n tl 3
Purcell et al.[25]		√			Prospective static protocol **Inclusions:** all complete tendon lacerations all zones **Exclusions:** crush, mental health issues, previous hand injuries	Zone V–VIII Tubular tendon Kessler repair and flat tendons mattress suture	**Immobilization:** splinted all zones included 1 and 2, hyperextended DIP, 8 wk, 3 and 4 gutter splint 0–3 wk, increasing flex of POP to full range 3–8 wk night splinting 5–8 splint wrist 30° ext, MCP 30° flex, IP straight, week 4–8 night ext splint for MCP full ext, full ROM week 8 resistance	ROM	2 w d 2 re g (2 A w th e (5 (3 (2

Reference	Meta-Analysis Inclusion				Study Design	Surgical Technique	Therapy Program	Outcome Measured	R
	1	2	3	4					
Chester et al.[14]		√	√	√	RCT early active vs dynamic Passive protocol patients 1996–2000 **Inclusions:** simple tendon injuries	Zone IV–VII modified Kessler horizontal mattress	**Dynamic vs early active:** randomized to two treatment groups: Group (A) early active program in static splint with MCP in 30° flex and wrist in 30° ext and removed to do exercises intrinsic plus and minus 5 times/h for 2 wk Then AROM of wrist, 3 wk concurrent fisting, 4 wk splint only at night light ADL, vs 4–6 wk gentle PROM, 6–8 wk grip strengthening Group (B) day 5–7 dynamic outrigger wrist 30, MCP 30° flex and night splint, same exercises 2 wk wrist AROM, and progress in the same way	TROM	1 G 2 te w d d s m d th e G e re G e re N si d b g

Reference	Meta-Analysis Inclusion				Study Design	Surgical Technique	Therapy Program	Outcome Measured	R
	1	2	3	4					
Russell et al.[26]	√	√		√	Retrospective study design Dynamic vs static **Inclusion:** 1995–2000, zones V–VIII	Zone V–VII standard mattress repair or modified Kessler repair	**Dynamic vs immobilization** 34 dynamic splinting protocol, 2–3 wk in plaster followed by 4 wk dynamic splinting 31 static splinting protocol, 8 wk splinted at 4 wk gentle ext exercises	TAM, return to work, low complication rate	1 t n T 2 2 2 d p N R 9 S g f d h c n w u d n
Bruner et al.[11]		√			Retrospective study design Dynamic protocol **Inclusion:** 1995–1999, nonsevere injuries, zones V–VII	Zone V–VII Kirchmayr–Kessler suture or horizontal mattress	**Dynamic vs immobilization** 2nd postop day wrist 30° ext MCP 10° hyperext Active flex MCP 15° or 30° determined by surgeon Increased incrementally until at 90° at week 5 AROM of distal joints at week 4 splint d/c week 5 then compared to a historical group of static protocol patients	ROM, grip strength, patient graded outcomes	5 h d d (u h w h g 9 u n 0 g o e g

Reference	Meta-Analysis Inclusion				Study Design	Surgical Technique	Therapy Program	Outcome Measured	R
	1	2	3	4					
Bulstrode et al.[12]		√	√	√	Prospective randomized comparison Immobilized vs immobilized with IPs free vs early active **Inclusion:** zone V and VI, noncomplex injuries	Surgical technique: mattress technique with epitendinous sutures	**Immobilization vs reduced splinting vs early active** Randomized to one of three groups, 1 immobilized in wrist 30° ext, MCP and IP extended for 4 wk, 2 immobilized as above in splint with IPs free to move hourly, flex and ext no function 3 splint wrist 45°, MCP 50° flex and IP straight for 4 wk every 4 h extend digits off the pan and hook Splint at night or high-risk activities until 8 wk No passive flex or resistive flex until 8 wk	Blinded therapist evaluation, standardized assessment protocol, time spent with therapists	4 r r 3 r 1 8 f d D e N g b 3 s d g w N d ti tl

Reference	Meta-Analysis Inclusion				Study Design	Surgical Technique	Therapy Program	Outcome Measured	R
	1	2	3	4					
Mowlavi et al.[15]		√	√	√	Prospective RCT Dynamic vs Static **Inclusion:** simple V and VI repairs	Zone V–VI Figure 8 and mattress stitches	**Immobilization vs dynamic:** group A dynamic splinting 30° at MCP full IP then at 2 wk increased to 45°, then 4 wk AROM d/c splint only static at night, 6 wk no splinting and PROM started ext splinting continued if 15° ext lag evident vs Group B static splint wrist 30° ext, MCP 15–20° flex IP straight same as other protocol	TROM, grip strength	1 e w d d a s t 6 n a s h n h f 1

Reference	Meta-Analysis Inclusion				Study Design	Surgical Technique	Therapy Program	Outcome Measured	R
	1	2	3	4					
Howell et al.[27]				√	Prospective controlled active protocol **Inclusion:** 1984–1994, zone IV–VII EDC, EDI, EDM single tendon repair no crush injury, no delay, etc.	Not reported	**Early active relative motion splint: Exclusion:** yoke splint to digits and wrist splint wrist at 20° and injured digit in 20–25° hyperext from other digits Week 0–3: continuous wear full AROM of all finger digits encouraged within limits of ICAM splint (immediate controlled active motion) Week 3–5: yoke worn at all times unless pt doing resistive tasks then wrist splint to be worn as well, AROM of wrist with fingers relaxed Week 5: wrist d/c completely, finger yoke, or buddy strap worn during activity Week 6: yoke off full AROM digits	ROM, grip strength, return to work, and therapy visits	7 p c p e la (5 (1 (3 e lo g lo (2 p G u re m p tl 8
Carl et al.[28]		√			Prospective static protocol	Zone I–VI Double loop technique of repair	**Immobilization:** static splint for 6 wk, intense therapy until no improvement for 2 wk f/u 13 ± 7 mo	Not reported	1 2 re e re 2 g 1 re 3

Reference	Meta-Analysis Inclusion				Study Design	Surgical Technique	Therapy Program	Outcome Measured	R
	1	2	3	4					
Zubovic et al.[29]		√			Prospective static study **Exclusion:** no children,no partial repairs, no mental health history, no history of previous injuries	Augmented Becker technique	**Immobilization:** splinted wrist in 30 MCP in 60 and IPs straight, splint d/cd after 3 wk, seen weekly for 6 wk no details about the therapy provision	ROM	1 te 3 3
Khandwala et al.[30]		√		√	Prospective randomized trial 46 patients excluded with no description of criteria	Zones V–VI Kirchmayr–Kessler or horizontal mattress, simple epitendinous suture	**Dynamic vs early active motion:** Group 1 dynamic protocol as in Chow's study or Group 2 an early active protocol where the IP joints are free and the MCP joints are blocked from flexing beyond 45° and the wrist is held in 30° of ext Exercises exactly the same, intrinsic plus, intrinsic minus, full composite Group 2 full composite blocked at MCP and in Group 1 active assist for ext, 10 reps/h Week 3: splint is modified to allow 70° of MCP flex, ongoing therapy was provided based on needs of patients so not standardized	ROM	G fi G fi N d b tv

Reference	Meta-Analysis Inclusion				Study Design	Surgical Technique	Therapy Program	Outcome Measured	R
	1	2	3	4					
Hall et al.[31]			√	√	Pilot prospective randomized comparative trial static vs dynamic/passive vs active **Exclusion:** associated pathology, limited ability to comply with protocol or only one tendon repair in index or little fingers	Not reported	**Immobilization vs dynamic vs early active:** random allocation to 3 treatment groups: Immobilization (IM) group splinted, wrist 30–45°, MCP 0–30° for 3 wk Early passive motion (EPM) dorsal dynamic ext splint, wrist 40–45°, MCP resting at 0 with palmar block at 30–40° flex 20/h, week 3 ROM not blocked, d/c splint week 6 Early active motion (EAM) wrist 30° MCP 45° IP free Exercises Active MCP flex/ext in splint with IP straight, 70° flex of MCPs allowed at 3 wk to week 6	ROM, complication rate	2 s s c s r i W c E p l m l

Reference	Meta-Analysis Inclusion				Study Design	Surgical Technique	Therapy Program	Outcome Measured	R
	1	2	3	4					
Hirth et al.[32]				√	Retrospective comparison: patients assigned to treatment group based on treatment onset I**nclusion:** single finger injuries, zone V and VI Isolated EI, EDM, EDC and/or associated capsular repair **Exclusion:** >1 digit, associated fractures and <age 17	Not reported	**Early active relative motion splint:** modified relative active motion splint (MRMS) group started with yoke splint with injured finger positioned in 19–20° of hyperext relative to other digits No wrist support worn 8–10 wk with exercises and active use Asked not to combine wrist and finger flex Mobilization splint worn for 4 wk then progressive ROM	ROM, return to work	1 i g t g S s b m (e c i (m s s e t
Kitis et al.[33]				√	Prospective RCT static vs dynamic **Inclusion:** adults, zone V and VII noncomplex injuries **Exclusion:** other trauma, thumb	Modified Kessler two-strand core with circumferential running suture	**Immobilization vs dynamic** randomized to two groups (1) immobilized in wrist 30° ext, MCP 45° flex and IPs free, week 4 active ext, wrist gravity eliminated, 6 wk light ADL, 8 wk strengthening (2) dynamic splint MCP 30° flex IPs straight, 4 wk active ext, 5 wk wrist ROM, 8 wk strengthening	ROM, DASH, Grip	5 l c 1 e g a 2 e g S s d D 2 G 3 s s

Reference	Meta-Analysis Inclusion				Study Design	Surgical Technique	Therapy Program	Outcome Measured	R
	1	2	3	4					
Svens et al.[34]				√	Pilot nonrandomized prospective trial **Inclusion:** adults, simple tendon laceration, zones IV, V, or VI **Exclusion:** language issues, laceration of all 4 tendons, complex injuries	Different repairs from 4-strand, 2-strand, figure of 8, mattress, epitendinous sutures	**Early active two relative motion splint protocols** IRAM: 3 wk wrist orthoses with yoke splint, active composite flex, ext 5–10 reps/h, 35 d wean wrist splint yoke at all times, wrist AROM Wrist splint d/c day 36 yoke as needed, mIRAM same for zones IV, V for zones IV proximal to juncturae tendinum EDM repairs, just yoke splint until day 36 no splint no restriction	ROM, grip strength and functional questionnaire, return to work	6 m Il r c

Reference	Meta-Analysis Inclusion				Study Design	Surgical Technique	Therapy Program	Outcome Measured	R
	1	2	3	4					
Patil and Koul[35]					Prospective RCT Exclusions and complex associated traumas and index and little fingers only injuries	Surgical technique: modified Kessler with continuous over and over epitendinous suture	**Immobilization vs early active** IM group splint wrist 40 ext and MCPs straight Week 4: block removed to allow 0–45° flex Week 6: 0–90° Week 7–9 splint at night, exercises 4 times/day EAM resting splint same as IM only for injured fingers but AROM starts 3rd day 0–30° 4 times/d Week 2: 45–50° block Week 3: 70° flex block and PIP flex with MCP extended Week 4: 90° block Week 5–6: no splint except at night	ROM, pain, swelling, grip, return to work	4 p t g 6 E C g s s b R b m o r s P s l g c E G E r w b s s

h: hour; d: day, wk: week; mo: month, flex: flexion; ext: extension; hyperext: hyperextension; postop: postoperatively

EDC: extensor digitorum communis, EDI: extensor digitorum indices, EDM: extensor digiti minimi, EI: extensor indices, IPs: interphalangeals

PIP: proximal interphalangeal, AROM: active range of motion, PROM: passive range of motion, flex: flexion, ext: extension, MC: metacarpal, MCP: metacarpophalangeal, d/c: discontinue, DIP: distal interphalangeal, ICAM: immediate controlled active motion

t: patient, mIRAM: modified immediate relative active motion

ROM: range of motion, TROM: total range of motion, TAM: total active motion, DASH: Disabilities of the Arm, Shoulder, and Hand

TAM: total active motion, EAM: early active motion, IM: immobilization, VAS: Visual Analog Scale, mRMS: modified relative motion splint, mIRAM: modified Immediate relative active motion, IRAM: immediate relative active motion

RCT: randomized controlled trial

Findings

Talsma et al. performed a meta-analysis integrating early findings from four randomized controlled trials (RCTs) and one cohort study design.[36] They found that early outcomes (four weeks) after immobilization were significantly worse compared to those of either

passive or active early mobilization protocols. While findings suggested that protocols of early passive motion had greater benefit than those with early active motion, there was no significant difference found between the two protocols at three months postoperatively. They concluded that there was no superiority of any of the protocols researched.

Since 2000, a focus on more protocols and those that include early active motion has enhanced the available evidence for review. Hammond et al. completed a meta-analysis including 19 articles with varying levels of evidence from case series to RCTs.[37] They showed that early active motion programs had the lowest complication rate. Immobilization required more tenolyses, and loss of ROM, while dynamic splinting protocols demonstrated potential extensor lag. The variability of protocols, research design, and statistical reporting methods precluded them from comparing treatment outcomes.

Wong et al. completed a systemic review for repairs of zones IV–VIII attempting to more closely examine the orthotic factors affecting treatment protocol and outcomes.[38] Eleven studies were reviewed showing that early active motion protocol is superior to other protocols. However, similar to Hammond et al.,[37] the extensive research variability limited conclusions that could be made as to which protocol and splint was superior.

Ng et al.[39] completed a systemic review of controlled trials of rehabilitation protocols for acute extensor tendon repairs excluding mallet fingers or thumbs. All prospective RCTs or quasi-RCTs comparing rehabilitation programs were included. Five studies were analyzed representing static immobilization, dynamic splinting, and early active mobilization. The results showed that total ROM outcomes for both dynamic mobilization and early active mobilization were essentially the same but were significantly better compared to immobilization. Recovery was also faster in both mobilization protocols resulting in faster recovery. There was no greater utilization of therapy services for any of the protocols and there was only a 3% tendon rupture rate (two in early active mobilization and one in dynamic protocols). The authors identified that, since the outcomes were statistically the same, the rationale to choose one protocol over another would be related to implementation or patient-related factors. They concluded that using early active motion is superior since it is less technical and complicated, making it easier for the therapist and the patient.

Resolution of clinical scenario

- The available meta-analyses suggest that an early active mobilization program is superior to both passive and full immobilization. The combined data support faster recovery time and decreased complication rates.
- The Immediate Relative Active Motion protocol has a number of beneficial factors, as outlined in Svens et al.[34] The yoke splint design has a low profile and allows the patient to work with adequate protection and is referred to as the standard protocol for injuries affecting one or two digits. Specific to this case, the patient has injured all the tendons in zone IV negating the use of this protocol.
- An active protocol, such as in Patil and Koul[35] or Bulstrode et al.,[12] where a simple static splint is used which can be readily worn to protect the nondominant hand at work and a simple block that can be removed to do exercises, may be the solution in this case.

Question 3: In patients with fully lacerated extensor tendons, what preoperative factors contribute to better functional outcomes?

Rationale

Understanding the extent and severity of the injury could help predict the functional outcome of the patient's hand. This can further assist the patient, surgeon, therapist, and employer in directing care, rehabilitation, and return to work.

Clinical comment

The goal of management should be to allow the patient to return to the preinjury state whenever possible. Being able to predict what factors are important for recovery may allow us to better inform patients as well as change any modifiable factors to enhance final outcomes.

Available literature and quality of the evidence

- Level IV: 3 case series, 1 retrospective, and 2 prospective studies.

The search did not yield true outcome studies from prospective trials; however, there were some individual case series.

Findings

In 1990, Newport et al. retrospectively studied 62 patients and showed that 64% of patients with extensor tendon lacerations without associated injuries (fracture, dislocation, joint capsule, or flexor tendon damage) achieved good or excellent results, whereas only 45% of patients with associated injuries did. Injury of tendons in distal zones (I–IV) had significantly poorer results when compared to more proximal zones (V–VIII) with evidence of increased total extensor lag and loss of flexion.[19]

In contrast, in 2007, Carl et al. performed a prospective study of 203 tendon repairs and showed that injuries in zones I, II, IV, and V obtained good or excellent results in the majority of patients, whereas the outcome was significantly worse after tendon repair in zones III and VI.[28] However, they noted a higher frequency of complex injuries with concomitant soft tissue and bony injuries when zones III and VI lacerations were present. Similar to Newport et al., they concluded that recovery of finger function after primary extensor tendon repair depends on the complexity of trauma and the anatomical zone of tendon injury.[19]

Mehdinasab et al. conducted a prospective case series of 72 extensor tendons repaired and found that the best results were obtained in zones III and V, and the worst were in zones I, II, and IV.[40]

Resolution of clinical scenario

- Patients undergoing repair of extensor tendons achieve better functional outcomes when compared to those with associated injuries (e.g. soft tissue or bone fractures).
- The anatomical zone of tendon laceration affects the ultimate functional outcome; however, there are inconsistencies in the literature as to which zones recover best.

Summary of answers

- A multistrand interlocking extensor tendon repair such as a modified Bunnell, augmented Becker or running interlocking horizontal mattress is stronger than other techniques.

- A roll stitch technique may produce a decreased extensor lag when compared to a modified Kessler core suture technique.
- An early active mobilization protocol produces better outcomes provided the repair supports active forces and the specific protocol is matched to the patient's abilities and functional needs.
- Functional outcomes of patients with repaired extensor tendon lacerations are worse when there are other associated complex injuries.
- The anatomical zone of tendon laceration affects the ultimate functional outcome, though inconsistencies exist in the literature as to which zones recover best.

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162 Dupuytren's Disease

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Clinical scenario

- A 65-year-old man is referred to you complaining of progressive curling of his ring and little fingers, and inability to straighten his fingers.
- His father had a similar problem, and so does his older brother. He does not report pain, but the contracted fingers make it difficult for him to put on gloves in the wintertime, and to perform many tasks of daily living.
- Examination demonstrates pre-tendinous cords extending from the proximal palm to the middle phalanx of these digits, with inability to passively extend the metacarpophalangeal (MCP) and proximal interphalangeal (PIP) joints. He is able to flex the digits to the palm.

Top three questions

1. In patients with Dupuytren's disease (DD), is collagenase injection superior to open partial palmar fasciectomy in correcting extension deficits?

2. In patients with DD, which treatment – limited palmar fasciectomy or collagenase injection – offers the patient better prognosis in terms of (i) fewer and less severe postprocedural complications and (ii) lower rates of disease recurrence?
3. In patients with DD, which of the following common treatment options results in the lowest disease recurrence rate: collagenase, open fasciectomy, or percutaneous needle fasciotomy (PNF)?

Question 1: In patients with Dupuytren's disease (DD), is collagenase injection superior to open partial palmar fasciectomy in correcting extension deficits?

Rationale

There is no consensus on the most effective treatment for DD. Currently, the two most common treatments for DD are partial palmar fasciectomy and collagenase injection.[1] Fasciectomy involves the surgical excision of the diseased cords, while injections with collagenase from *Clostridium histolyticum* degrade collagen within the cords, allowing them to be subsequently broken by forced digital extension.[2]

Clinical comment

Fasciectomy procedures are more invasive, historically requiring operating room access under general anesthesia, use of a tourniquet, and a more prolonged rehabilitation period. In contrast, collagenase injection has a faster patient recovery time and can be easily performed in an

office or clinic setting without sedation, and requires fewer follow-up appointments. This reduces healthcare costs and improves patient access to treatment.[3,4]

Available literature and quality of the evidence

The highest level of evidence comparing palmar fasciectomy with collagenase is available from four retrospective cohort studies (level III).[4–7]

Findings

Two retrospective cohort studies comparing these treatment modalities found that treatment with limited fasciectomy (LF) is superior in correcting extension deficits.[5,6] In the study by Muppavarapu et al., the researchers analyzed results from 117 patients who underwent treatment with either LF or collagenase injection.[5] After a mean follow-up duration of 14.2 months for the collagenase group, and 16.3 months for the LF group, significantly more joints treated with LF met the primary outcome measure of contracture reduction to 0–5° ($p = 0.0001$). The mean residual contracture for all joints was 28.4° in the collagenase group and 11.8° in the LF group ($p = 0.001$), although the MCP joints generally responded better to both treatments than PIP joints.[5] Similarly, in a retrospective analysis of 37 patients, Wei et al. found greater contracture corrections in patients treated with LF, compared to collagenase.[6] The mean passive extension deficit achieved in joints treated with LF and collagenase was 3.9° and 6.5°, respectively, in MCP joints ($p = 0.02$), and 6.5° and 40.6°, respectively, in PIP joints ($p = 0.0001$).[6]

In contrast, Zhou et al. used a propensity-matched score to compare 66 patients treated with collagenase to 66 patients treated with fasciectomy between 6 and 12 weeks

postoperatively.[7] They found no difference in correction of MCP joint contractures; however, LF was superior in correcting PIP joint contractures (25° vs 15° contracture correction, p = 0.01).[7] In a much smaller study, Naam compared 25 patients treated with collagenase to 21 fasciectomy patients and found post-treatment range of motion (ROM) at the MCP joint was greater for collagenase-treated patients.[4] However, when the researchers compared the mean increase in ROM from baseline, no significant difference was found between the two groups. Overall, the study found no significant differences in post-treatment contractures between the two groups.[4]

Resolution of clinical scenario

- Currently, available evidence suggests that LF is equal, or superior, to collagenase in correcting extension deficits.
- LF is superior to collagenase in correcting PIP joint deformities.
- Therefore, your patient should be advised that LF may be better than collagenase to correct their extension deficits, especially at the PIP joint.

Question 2: In patients with DD, which treatment – limited palmar fasciectomy or collagenase injection – offers the patient better prognosis in terms of (i) fewer and less severe postprocedural complications and (ii) lower rates of disease recurrence?

Rationale

Safety is paramount when deciding upon an appropriate treatment, particularly when a variety of treatment modalities exist. When deciding between comparably efficacious treatments, the physician should aim to choose the intervention that is safest. In DD patients, disease recurrence is a common post-treatment event, and is to be expected as currently available treatments do not definitively cure the condition. The surgeon should consider the intervention that will reduce disease recurrence, or prolong the time to re-contracture. Comprehensive knowledge backed by high-quality evidence is essential when counseling patients.

Clinical comment

Complications range from relatively minor and easily treated, such as skin splitting and local infection, to more severe and difficult to treat, such as tendon rupture, digital nerve injuries, and joint stiffness. Reported recurrence rates also range substantially from 12 to 100%, and vary depending on the treatment, length of follow-up, and the authors' definition of recurrence.[8] Ideally, the treatment of choice should be both safe, and minimize the need for repeat treatment.

Available literature and quality of the evidence

The highest-quality evidence comparing adverse events in LF and collagenase includes four retrospective cohort studies (level III).[4–7] Additional evidence on safety of collagenase includes a recent randomized controlled trial (RCT) (level I), and review of prospective trials (level II).[9,10] The highest-quality evidence assessing recurrence in both LF and collagenase comes from a retrospective cohort study (level III).[4] Additionally, two randomized,

placebo-controlled trials[11],[12] (level I) and one high-quality prospective cohort study[13] (level II) assess recurrence in collagenase-treated patients.

Findings

Safety

Complications following treatment with collagenase injection are common, but are usually less severe than those following LF. In a retrospective cohort study by Zhou et al., serious adverse events were found to be much more common after LF compared to collagenase injection ($p = 0.042$).[7] Serious complications such as nerve injury and tenosynovitis were found in patients treated with LF, and no such events were reported in the collagenase group. Additionally, Muppavarapu et al. reported one case of digital neurovascular injury and two cases of deep wound infection in LF-treated patients, but no such serious complications following collagenase treatment.[5] In the studies by Naam and Wei et al. severe complications were absent in both treatment groups.[4],[6]

The relative incidence of mild complications between the two treatments in unclear based on currently available literature.[4]–[7] Wei et al. reported similar minor complications rates of 45 and 42% in the collagenase and LF treatment groups, respectively;[6] however, Muppavarapu et al. found that over 70% of collagenase-treated patients experienced a mild adverse event.[5] Common minor complications of collagenase treatment include peripheral edema, mild contusion, extremity pain, hematoma, and skin tears. Minor complications following LF include paresthesia, wound dehiscence, neurapraxia, and hematoma.[4]–[7]

The safety profile of collagenase has also been assessed in several prospective RCTs. Badalamente et al. analyzed the four major clinical trials for collagenase injection (CORD I and II and JOINT I and II) and found serious adverse events in 0.5% of cases, including two cases of tendon rupture.[10] The most common complications encountered in these studies included peripheral edema (58%) and contusion (38%). One RCT found that the most common adverse events associated with collagenase injections were contusions, extremity pain, and localized swelling, with contusions and swelling being dose-dependent.[9] There were no serious adverse events reported in this trial.

Recurrence

Limited evidence is available comparing recurrence rates of collagenase injections and fasciectomy. Naam et al. found no instances of disease recurrence (defined as an increase of ≥20° from the point of correction) in either group, after two years.[4] However, smaller re-contractures were reported in 10 patients. A recurrence in contracture of 15° from the point of correction was reported in one fasciectomy patient, and recurrences of 10° were found in five collagenase patients and four fasciectomy patients.[4]

In placebo-controlled RCTs evaluating collagenase injections, patients who had a successful correction of contracture to within 0 to 5° of full extension had no disease recurrence (defined as ≥20° extension deficit) at 90 days and one year following treatment.[11],[12] However, in an observational study with a five-year follow-up, 47% of successfully treated joints had recurrence (39% occurred in MCP joints and 66% in PIP joints).[13]

Resolution of clinical scenario

- Collagenase injections are safe, and complications appear to be primarily nonsevere.
- The patient should be counseled that risk of serious adverse events is lower after treatment with collagenase injection.
- There is currently insufficient evidence to conclude which of the two approaches (collagenase or fasciectomy) is associated with the lower rates of disease recurrence.
- The patient should be counseled that the disease is most likely to recur at their PIP joint.

During a discussion with your patient, he reveals that he is most concerned about *recurrence* of his DD. If possible, he asks to receive the intervention that will most successfully prevent recurrence. In light of the patient's priorities, and lack of clear evidence about relative recurrence rates between collagenase and fasciectomy, you decide to additionally consider PNF to determine which intervention offers the lowest recurrence rate. PNF is another commonly performed treatment for DD, and involves division of the diseased cords with a hypodermic needle.[1]

Question 3: In patients with DD, which of the following common treatment options results in the lowest disease recurrence rate: collagenase, open fasciectomy, or percutaneous needle fasciotomy (PNF)?

Rationale

The concerns of your patient are not unusual. In one study, patients reported recurrence rate to be the most important factor they considered when choosing a treatment for their DD.[14]

Clinical comment

Many researchers theorize that surgical excision of Dupuytren's cords is most effective at reducing disease recurrence. This is because surgical intervention removes the diseased tissue from the hand, while the cords remain in the hand after less invasive treatments such as PNF and collagenase injections.[15]

Available literature and quality of the evidence

The highest level of evidence includes studies of varying methodological quality comparing open fasciectomy, PNF, and collagenase. One long-term follow-up of patients from a previous RCT compares fasciectomy and PNF (level II).[16] Another high-quality RCT compares fasciectomy to a modified PNF technique (level I).[17] Collagenase and PNF are compared in two RCTs (level I).[18],[19] The highest level of evidence comparing recurrence rates in collagenase and fasciectomy is a retrospective cohort study (level III).[4]

Findings

Long-term data from an RCT comparing LF and PNF reported significantly higher recurrence after five years in the PNF group (20.9% recurrence following LF vs 84.9% with PNF, $p < 0.001$; 95% confidence interval [CI]: 1.597–2.628).[16] In both groups, recurrence rates were significantly lower in older patients ($p = 0.005$). Kan et al. used a modification of the PNF technique by adding autologous fat graft and compared this to LF in an RCT.[17] Recurrence rate in patients treated with this technique was

not significantly different from those treated with LF (p = 0.107), although subjects were only followed for one year.

Recurrence rates of collagenase injections and PNF were not found to be significantly different in two level I RCTs. In the RCT comparing PNF and collagenase in DD affecting the MCP joint, only one patient in each group developed recurrence after one year.[19] In PIP joints, recurrence rate was 83% (95% CI: 68–99) in the collagenase group, and 68% (95% CI: 46–91) in the PNF group after two years (p = 0.25).[18] In a study comparing recurrence rates in patients undergoing fasciectomy or collagenase injection, no instances of recurrence were reported in either group two years after treatment.[4]

Resolution of clinical scenario

- The patient should be counseled that treatment with fasciectomy has a lower recurrence rate than PNF. If they prefer a less invasive treatment, there is no significant difference in recurrence rates between PNF and collagenase injection.
- Although early data show a combined PNF and lipofilling treatment has a disease recurrence rate similar to fasciectomy, long-term recurrence rates are unknown.

Summary of answers

- Based on available evidence: LF is superior to PNF and collagenase in improving contractures in DD and has the lowest rate of recurrence.
- Patients can return to normal activities more quickly with less-invasive procedures, such as PNF or collagenase.

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163 Rheumatoid Hand Reconstruction

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Clinical scenario

- A 58-year-old Caucasian woman reports a several-month history of generalized fatigue and “stiffness” of both hands that lasts through the morning.
- She notices painful swelling of the joints in her fingers.
- She describes throbbing pain that she rates as an 8 on a Visual Analog Scale (VAS) of 0 to 10.

Top three questions

1. In rheumatoid arthritis (RA) patients, does small joint synovectomy improve pain and joint swelling compared to nonsurgical management?
2. In RA patients, does flexor tenosynovectomy improve extensor lag and pain compared to nonsurgical management?
3. In RA patients, does metacarpophalangeal (MCP) joint arthroplasty improve hand function compared to nonsurgical management?

Question 1: In rheumatoid arthritis (RA) patients, does small joint synovectomy improve pain and joint swelling compared to nonsurgical management?

Rationale

Synovial proliferation in the small joints of the hand causes joint tenderness, swelling, and limited range of motion, and to a considerable degree the synovitis also propagates progressive joint destruction. Hand surgeons use open and arthroscopic techniques to remove the infiltrative synovium to ameliorate symptoms, improve function, and halt destructive synovitis.

Clinical comment

Swelling of a patient's joints could be an indication of proliferative synovitis. Small joint synovectomy can have a role in managing patients with persistent pain after six months of medical therapy, provided they show no joint cartilage and bone destruction.

Available literature and quality of the evidence

Level I: 2 randomized controlled trials (RCTs).

Findings

In a study conducted by the Arthritis and Rheumatism Council and British Orthopaedic Association, patients were randomized to synovectomy (n = 13 patients, 41 MCP joints) or to nonsurgical management (n = 9 patients, 28 MCP joints).[1] The patients were examined after three years. There were no significant differences between the

groups in terms of pain (p = 0.32), range of motion (p = 0.13), swelling (p = 0.40), tenderness (p = 0.33), or grip strength (p = 0.88). All of the patients who underwent synovectomy said that they would agree to the surgery again.

Thompson et al. randomized RA patients affected by synovitis into two groups: MCP synovectomy or a nonsurgical splinted group.[2] At the two-year follow-up, there were 45 patients in the surgical group and 42 patients in the nonsurgical group. Results demonstrated significantly improved grip, palmar pinch, and joint tenderness in the surgical group compared to the nonsurgical group (p values not provided). There was no significant difference between the groups in joint swelling. Subjective assessment by the patient in terms of pain, functional ability, grip strength, and appearance were higher in the surgical group. In terms of radiographs, the authors stated that “all groups deteriorated to an approximately equal degree in respect of the MCP joints.”

Resolution of clinical scenario

- Performing small joint synovectomy, when there is persistent pain and functional limitation in the absence of joint destruction, may provide symptomatic relief of limited duration.

Question 2: In RA patients, does flexor tenosynovectomy improve extensor lag and pain compared to nonsurgical management?

Rationale

The prevalence of flexor tenosynovitis in rheumatoid disease has been reported to be between 42 and 55%.[3,4] Current thought is that patients can achieve considerable improvement in functional ability with flexor tenosynovectomy.

Clinical comment

When a patient with RA has difficulty with active digital flexion, it is important to determine whether the problem is in the flexor tendons or in the joints. If the problem lies in the flexor tendons, the patient will have full passive flexion of the joint, but the active flexion is limited because swelling in the flexor tendons restricts tendon excursion. If the problem is isolated to the joints, the patient will have limited joint motion, both in passive and active motion. Hypertrophic synovial infiltration within the flexor tendon sheath presents with bulges along the tendon sheath, and these bulges often occur at the weaker, stretched cruciform pulleys.[5] A plain radiograph should be obtained to rule out concomitant proximal interphalangeal (PIP) joint disease.

Available literature and quality of the evidence

Level IV: 3 retrospective case reviews.

Findings

Jackson and Paton performed flexor tenosynovectomy in 21 patients (36 fingers) over a period of four years and assessed their results 6 to 37 months postoperatively.[6] They developed a motion scoring system that incorporated the ability to flex combined with residual fixed flexion deformities at the MP and PIP joints. It ranged from excellent (full movement with no extensor lag) to good (extensor lag at the MP and PIP joints <30°, vertical distance from fingertip to palm <2 cm) to fair (extensor lag

at the MP and PIP joints <30°, vertical distance from fingertip to palm 2–4 cm) to poor (extensor lag at the MP and PIP joints >30° or vertical distance from fingertip to palm >4 cm). Using this scale, 44% had excellent results, 31% good, 11% fair, and 14% poor.

In a retrospective case study by Tolat et al., 43 RA patients (49 hands, 424 flexor tendons) were assessed at a mean of five years and seven months after tenosynovectomy and tenolysis.[7] All patients improved in pain score from a mean preoperative score of 7.5 (fair) to a mean postoperative score of 0.9 (excellent), assessed via VAS of 0 to 10. The mean postoperative satisfaction score was 2.2 (excellent), also assessed via VAS of 0 to 10. Using the Jackson and Paton scoring system, 31% of patients had excellent flexion, 14% had good, 22% had fair and 33% had poor flexion. There was a complication rate of 18% (nine hands) including three minor infections and six categorized as major complications (four cases of recurrence with formation of further adhesion, one postoperative tendon rupture, and one intraoperative fracture of the proximal phalanx).

Wheen et al. reviewed the results of 15 patients (18 hands, 61 fingers) who underwent digital flexor tenosynovectomy at a mean of four years prior.[8] Using slightly modified Jackson and Paton criteria, they found that 31% had excellent flexion, 36% good, 21% fair, and 11% poor. The active flexion deficit, measured in centimeters, improved significantly from 4.3 (3.8–4.7) preoperatively to 2.1 (1.8–2.6) at final assessment ($p < 0.01$). Four patients (22%) reported that their function was completely restored, 13 (72%) that it was improved, and one (6%) that there was no change. Nineteen fingers (31%) showed signs of recurrence or underwent re-operation.

Resolution of clinical scenario

- Flexor tenosynovectomy can provide functional benefit for patients with impairment of active flexion caused by synovitis.
- Patients should be counseled regarding the possibility of recurrence, which has been shown to occur at a rate of 10–31% approximately five years after surgery.

Question 3: In RA patients, does metacarpophalangeal (MCP) joint arthroplasty improve hand function compared to nonsurgical management?

Rationale

Owing to the progressive nature of RA, joint destruction can reach a stage in which a surgical salvage procedure such as MCP joint arthroplasty is necessary.

Clinical comment

The MCP joint is most commonly affected in RA. End-stage destruction of these joints can render patients functionally impaired with unappealing appearance of their hands. The course of MCP joint disease in RA is caused by synovial infiltration and subsequent attenuation of joint support structures. Radial and ulnar sagittal bands that stabilize the extensor tendon over the MCP joint are stretched by synovitis. The radial band is further weakened by the gripping motion involved in daily activities that causes progressive ulnar displacement of extensor tendons characteristic of rheumatoid hands. As a result, ulnar lateral bands contract to further accentuate the drift of the extensor tendons. Furthermore, the proximal phalanx itself

may become volarly subluxed. These structural changes adversely affect the functional ability of the hand and cause cosmetic concerns for patients. This degree of joint destruction is a clear indication for joint replacement.

Available literature and quality of the evidence

- Level I: 1 RCT.
- Level II: 1 prospective cohort study.

Findings

A clinical trial assessed 33 patients (40 hands) who were randomized to receive Swanson MCP joint implants (n = 20 hands) or NeuFlex MCP joint implants (n = 20 hands).[9] The NeuFlex implant is preflexed to 30° to enhance joint flexion and diminish peak stresses.[10] Patients were assessed preoperatively and 12 months postoperatively. Preoperative active range of motion did not differ between the groups. At 12 months, active flexion was significantly better in the NeuFlex group for all four digits (all $p < 0.01$), but there was no difference in active extension. Both groups significantly improved from their preoperative values in terms of extension, flexion, arc of motion, and ulnar deviation (all $p < 0.001$). Patients were also assessed with the Michigan Hand Questionnaire (MHQ), which is a hand-specific, patient-reported questionnaire that measures function, activities of daily living, work, pain, aesthetics, and satisfaction.[11],[12] Patients in both groups showed significant improvement in all domains from preoperative values. Patients in the Swanson groups scored significantly better postoperatively in the Function domain ($p = 0.03$) and the Aesthetics domain ($p = 0.03$) compared to the NeuFlex group. There were no complications in either group. The authors concluded that both groups obtained satisfactory clinical improvement and the greater flexion in

the NeuFlex group was not accompanied by greater function as reported by patients via the MHQ.

In a prospective, multicenter cohort study by Chung et al., RA patients with severe MCP joint deformity elected to participate in a surgical group that underwent silicone metacarpophalangeal joint arthroplasty (SMPA) using the Swanson implant or in a nonsurgical group that was managed medically (non-SMPA).[13] Follow-up was performed at three, five, and seven years and included 23 SMPA and 52 non-SMPA patients at the final follow-up. The main outcome measure was the MHQ. Over the seven years of follow-up, although the SMPA group scored worse on the MHQ than the non-SMPA group, the SMPA group showed large improvements from their preoperative scores that were maintained over time. Grip strength did not improve postoperatively in the SMPA group. Ulnar drift, extensor lag, and MCP joint arc of motion were all worse in the SMPA groups at baseline ($p < 0.001$ for extensor lag and arc of motion) compared to the non-SMPA group, but consistently showed better results for the SMPA group at each follow-up. There was one mild adverse event (Kirschner wire infection) and three moderate implant-specific adverse events that all required re-operation (one due to ulnar deviation, one due to implant dislocation, and one due to MCP joint sepsis). The majority of implants did not show signs of fracture when assessed via radiographs.

Resolution of clinical scenario

- MCP joint arthroplasty can deliver improved hand function, appearance, and ability to perform activities of daily living.
- Functional and aesthetic improvements from MCP joint arthroplasty are maintained over time, with low rates of implant fracture.

Summary of answers

- In patients with persistent pain and functional limitation from small joint synovitis, synovectomy can provide short-term symptomatic relief.
- Flexor tenosynovectomy can effectively improve flexion hampered by synovial proliferation along the tendon sheath. Due to the progressive nature of RA, re-operation may be required.
- MCP joint arthroplasty provides long-term improvement in subjective outcomes and should be considered in end-stage destruction of MCP joints.

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164 Replantation

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Clinical scenario

- You are paged to the Emergency Department to see a 20-year-old male carpenter with a traumatic amputation of the index and long digits of his dominant hand in a table saw accident. The injury occurred at the level of the proximal phalanx.
- The injury occurred three hours prior to Emergency Department presentation. The amputated digits were placed on ice following the injury. Hemostasis was achieved through direct pressure to the area of injury.
- Radiographs of the stump and amputated digits show clean amputations.

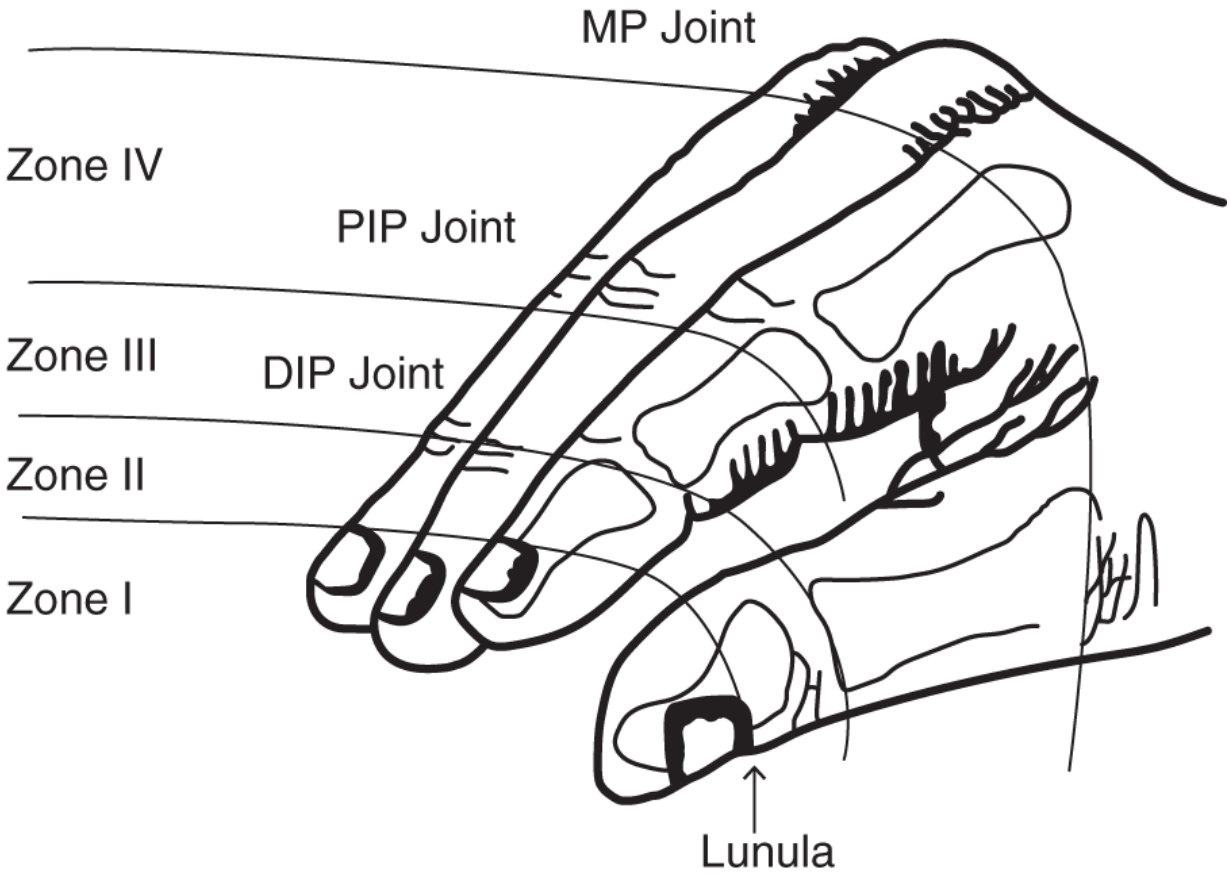

Figure 164.1 Tamai classification of zones in digital amputation: zone I (distal to lunula), zone II (proximal to lunula, distal to DIP joint), zone III (proximal to DIP joint, distal to insertion of FDS tendon), and zone IV (proximal to FDS tendon insertion, distal to MP joint). DIP, distal interphalangeal; PIP, proximal interphalangeal; MP, metacarpophalangeal. Source: Lee et al.[4]

Top three questions

1. In patients requiring replantation, how many veins should be anastomosed when performing digital replantation to achieve optimal outcomes?
2. In patients undergoing replantation, does prophylactic anticoagulation and/or do antithrombotic agents

ordered postoperatively prevent thrombosis compared to placebo or control?

3. In patients who have undergone replantation, does early range of motion (ROM), compared to delayed ROM, restore total ROM more effectively?

Question 1: In patients requiring replantation, how many veins should be anastomosed when performing digital replantation to achieve optimal outcomes?

Rationale

In 1978, Tamai et al. reported that two veins should be anastomosed for each artery repaired during digital replantation.[1] In contemporary practice, there exists little consensus among microsurgeons regarding the optimal number of veins that must be repaired when performing digital replantation surgery (Table 164.1).[2]

Clinical comment

Though bone, tendon, and nerve repair correlates with long-term functional outcomes, venous outflow remains the most important factor influencing replantation success in the immediate postoperative period.[2],[3] While a surgeon may not have a choice on the matter if only one or multiple veins are not present, the question is: what if multiple veins exist? How many should one repair per digit? While it is considered to be favorable to anastomose as many veins as possible, a balance must be achieved between ischemia time, survival rate, and overall operation time.[4]

Available literature and quality of the evidence

At present, the highest-quality evidence for venous anastomosis in the setting of digital replantation consists of retrospective cohort trials. Seven retrospective cohort studies were identified consisting of 1317 replanted digits (level III evidence).[2,4–9]

Findings

A retrospective cohort study by Ryu et al. assessed the relationship between the number of venous anastomoses and replantation survival in 143 cases.[5] No significant correlation was identified between the number of veins anastomosed and replantation survival (p = 0.689).

Efanov et al. reviewed 101 digital replantations and concluded that single vein repair corresponded to an increase in replantation failure when compared to two vein anastomoses (p = 0.032; risk ratio [RR] = 1.27; 95% confidence interval [CI]: 0.991–1.343).[2] A significant increase in replantation failure was also demonstrated in cases of no vein repair versus two vein anastomoses (p = 0.008; RR, 1.49; 95% CI: 1.026–1.735). However, no significant difference was identified between one vein versus no vein anastomosis (p = 0.502; RR = 1.179; 95% CI: 0.834–2.102].

Huang and Yeong (n = 31) as well as Neto et al. (n = 50) failed to reach statistical significance when comparing one vein versus no vein anastomosis (p >0.05) and one vein versus multiple vein anastomosis (p = 0.105), respectively.[6,7]

Lee et al. and Matsuda et al. (n = 847 total digital replantations) provided recommendations for optimal venous anastomosis at each Tamai amputation zone (Figure 164.1).[4,8]

Zone 1

- Lee et al. (n = 162) recommended the repair of at least one vein. The authors demonstrated statistically significant survival in digits with one repaired vein versus no vein repair (p = 0.008).[4]
- Matsuda et al. (n = 21) showed no difference in survival with no vein versus one vein repair at this level.[8]

Zone 2

- Lee et al. (n = 203) recommended the repair of at least as many veins as arteries and demonstrated that vein anastomosis versus no vein repair resulted in a significant increase in replant survival (p = 0.001).[4]
- Matsuda et al. (n = 46) recommended the repair of at least one vein and demonstrated a significant difference in survival between no vein versus one vein repair.[8]

Zone 3

- Lee et al. (n = 182) recommended that at least two veins be anastomosed, and demonstrated statistical significance when they compared venous anastomosis versus no anastomosis (p = 0.025).[4]
- Matsuda et al. (n = 63) demonstrated statistical significance between one vein versus two vein anastomoses and therefore recommended that at least two veins be repaired at this level.[8]
- A study by Chaivanichsiri and Rattanasrithong (n = 61) reported a statistically significant benefit by repairing at least one vein at Tamai zone 3, but reported no

significance when more than one vein was anastomosed.[9]

Zone 4

- Lee at al. (n = 84) demonstrated a significant replantation survival benefit with venous repair (p = 0.001) and recommended an equal ratio of artery to vein anastomosis.[4]
- Matsuda et al. (n = 86) reported a significant increase in survival when two or more veins were repaired versus no repair; however, there was no significant difference between one vein anastomosis versus two or more veins. Thus, Matsuda et al. recommended that only one vein be repaired at this level.[8]

Table 164.1 Number of anastomosed veins and associated survival rates (%). Source: Modified from Efanov et al.[2], Lee et al.[4], Ryu et al.[5], Matsuda et al.[8], Chaivanichsiri and Rattanasrithong[9]

No. of veins repaired	None	One	Two or more
Zone I			
Lee et al.[4]	73.2% (104/142)	90.0% (18/20)	N/A
Matsuda et al.[8]	85.7% (12/14)	66.7% (4/6)	100.0% (1/1)
Efanov et al.[2]	100.0% (5/5)	87.5% (7/8)	100.0% (1/1)
Ryu et al.[5]	94.2% (65/69)	93.0% (40/43)	96.8% (30/31)
Zone II			
Lee et al.[4]	49.0% (25/51)	80.8% (101/125)	92.6% (25/27)
Matsuda et al.[8]	38.5% (5/13)	81.0% (17/21)	83.3% (10/12)
Efanov et al.[2]	N/A	75.0% (3/4)	100.0% (3/3)
Zone III			
Lee et al.[4]	47.6% (10/21)	76.5% (78/102)	88.1% (52/59)
Matsuda et al.[8]	0.0% (0/1)	59.1% (13/22)	87.5% (35/40)
Efanov et al.[2]	N/A	100.0% (7/7)	100.0% (8/8)

No. of veins repaired	None	One	Two or more
Chaivanichsiri and Rattanasrithong[9]	40.0% (2/5)	84.4% (27/32)	91.7% (22/24)
Zone IV			
Lee et al.[4]	N/A	74.5% (35/47)	100.0% (37/37)
Matsuda et al.[8]	33.3% (1/3)	84.2% (16/19)	89.1% (57/64)
Efanov et al.[2]	28.6% (2/7)	67.5% 27/40	90.9% (10/11)

( ), number of replanted digits

Resolution of clinical scenario

Based on the cumulative evidence shown above, for this patient we recommend the following:

- While literature reports vary, a greater number of venous anastomoses tend to confer a higher survival rate in cases of digital replantation.
- Recommendations regarding the optimal number of vessel anastomoses vary at each Tamai amputation level.
- As this likely represents a zone IV amputation, we would attempt to repair at least two or more veins for each digital artery.

Question 2: In patients undergoing replantation, does prophylactic anticoagulation and/or do antithrombotic agents ordered postoperatively prevent thrombosis compared to placebo or control?

Rationale

Survival of amputated digits following replantation has been reported at 70–90%, with arterial and venous thrombosis considered the leading causes of failure.[10] At present, there is a lack of consensus regarding the effectiveness and duration of postoperative anticoagulation/antithrombotic therapy with substantial variability in surgeon practice.[11]

Clinical comment

Theoretically, anticoagulant/antithrombotic therapy has the potential to improve outcomes following digital replantation by inhibiting thrombus formation.[10]

Available literature and quality of the evidence

There is a paucity of evidence addressing the topic of anticoagulation following digital replantation. The highest level of evidence evaluating outcomes of antithrombotic therapy following digital replantation includes one prospective cohort study (level II)[10] and two retrospective cohort studies (level III).[12],[13] Further evidence comparing the effectiveness of low-molecular-weight heparin (LMWH) versus unfractionated heparin (UFH) consists of one Cochrane systematic review of randomized controlled trials (RCTs) (level I).[14]

Findings

A prospective cohort study (n = 477) assessed the role of antithrombotic therapy (dextran with LMWH versus dextran with prostaglandin E1, vs no antithrombotic therapy) in the setting of papaverine administration. Dextran with LMWH (odds ratio [OR] = 0.93; 95% CI: 0.4–2.2; p = 0.85) and dextran with prostaglandin E1 (OR = 1.09; 95% CI: 0.5–2.6; p = 0.83) demonstrated no advantage when compared to no antithrombotic therapy.[10]

In a retrospective cohort study, Nikolis et al. (n = 281) concluded that routine use or no use of intravenous (IV) heparin therapy with acetylsalicylic acid (ASA) following digital replantation did not significantly impact the final outcome of replantation success in two patient cohorts (cohort 1, n = 175, p = 0.275; cohort 2, n = 106, p = 0.440].[12]

In another retrospective cohort study, Lee et al. (n = 61) examined the success rate of artery-only distal digital replantation (Tamai zone I and II) with controlled continuous heparinization (CCH) when compared to intermittent bolus heparinization (IBH).[13] They concluded that the CCH group had a statistically significant higher replantation success rate when compared to IBH (91.17% vs 59.25%, p = 0.032).[13]

A Cochrane systematic review of RCTs by Chen et al. assessed whether subcutaneous LMWH improved salvage rates following digital replantation secondary to traumatic amputation.[14] The review identified two RCTs involving 122 replanted digits, both comparing the efficacy and safety of LMWH versus UFH; no RCTs were found to compare LMWH to placebo or other forms of anticoagulation. Replantation success did not differ between the LMWH and UFH groups (Trial 1: RR = 1.00; 95% CI: 0.89–1.13; Trial 2:

RR = 1.03; 95% CI: 0.87–1.22). The reported incidence of postoperative arterial thrombosis and venous insufficiency was not significantly different between groups (LMWH: RR = 1.08; 95% CI: 0.16–7.10; UFH: RR = 0.81; 95% CI: 0.20–3.27).[14] The study authors concluded that there was no difference in the success of replantation with LMWH versus UFH; an increased bleeding tendency was noted with UFH, although this was not deemed statistically significant.

Resolution of clinical scenario

Based on the cumulative evidence shown above, for this patient we recommend the following:

- There is limited evidence to demonstrate the effectiveness of postoperative prophylactic antithrombotic therapy following digital replantation.
- Heparinization is recommended as confidence intervals seem to have more weight on the beneficial side despite nonstatistically significant p values.
- In cases where postoperative heparinization is used, higher replantation success has been shown when CCH is used compared to IBH in distal digit amputation.
- Replantation success does not differ between subcutaneous LMWH and UFH.
- Based on the above evidence we should implement CCH postoperatively.

Question 3: In patients who have undergone replantation, does early range of motion (ROM), compared to delayed ROM, restore total ROM more effectively?

Rationale

For patients, finger amputation is associated with emotional, social, and physical trauma. The primary goal for patients following successful digit replantation is to regain use of function and return to regular activities.[15]

Clinical comment

Extensor and flexor tendon ROM requirements in replantation can be conflicting. Despite this rehabilitation following digital replantation has been associated with satisfactory long-term functional outcomes. At present, therapists and surgeons recommend early mobilization to improve function in the postoperative period.[15],[16]

Available literature and quality of the evidence

The highest level of evidence to address this topic is of variable methodological quality. Two retrospective cohort studies assessed functional outcomes of rehabilitation following successful replantation (level III).[15],[16] Three studies presented rehabilitation protocols and described the biomechanical implications of early active motion in cases of digital replantation (level V).[17]–[19]

Findings

A retrospective observational study by Ross et al. assessed total active movement (TAM) outcomes in 103 digital

replantations.[16] Patients that commenced therapy prior to day 14 of injury had a statistically significant improvement in TAM when compared to patients whose therapy commenced after day 14 ($p = 0.0001$); this corresponded to TAM values of 165 versus 121° at 25 months' follow-up, respectively.

A retrospective cohort study by Ugurlar et al. assessed the functional results of rehabilitation following digital replantation in 160 amputated digits.[15] In all cases, rehabilitation was started in the fourth to eighth postoperative week and continued until the 24th week. According to Tamai criteria outcomes were excellent in 36 (26.7%) patients, good in 54 (40%) patients, average in 27 (20%) patients, and poor in 18 (13.3%) patients.[20] The authors concluded that postoperative rehabilitation should be initiated as soon as possible after surgery.

Chan and LaStayo, Scheker and Hodges, and Silverman and Gordon presented mechanism-based reasoning for early protective motion (EPM) programs following digital replantation.[17],[18],[20] EPM is initiated at postinjury day five and attempts to reintegrate the patient into their work environment at 3–6 months.

Resolution of clinical scenario

Based on the cumulative evidence shown above, for this patient we recommend the following:

- Postoperative rehabilitation should be started for this patient within 14 days of injury as it is associated with a statistically significant improvement in TAM.
- The goal of rehabilitation will be to reintegrate this patient to their work environment at 3–6 months postoperatively.

Summary of answers

- A greater number of venous anastomoses confer a higher survival rate in cases of digital replantation, and this is more important as the level of amputation becomes more proximal.
- There is limited evidence supporting the use of prophylactic antithrombotic therapy following digital replantation.
- In cases of distal digital amputation, CCH has a higher replantation success rate than IBH.
- Postoperative rehabilitation started within 14 days of injury is associated with a statistically significant increase in TAM.

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165 Ulnar Neuropathy

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Clinical scenario

- A 53-year-old man presents with an eight-month history of progressive numbness in the ulnar nerve distribution and weakness with fine motor tasks.
- Examination demonstrates abnormal sensation in the small and half the ring fingers; as well as the dorsal sensory branch. Ulnar innervated intrinsic function is weak, graded Medical Research Council (MRC) 3 out of 5 and evidence of muscle wasting.
- Nerve conduction study and electromyographic (EMG) findings show isolated compressive neuropathy at the elbow with evidence of axonal loss and denervation to the first dorsal interossei and abductor digiti quinti.

Top three questions

1. In patients with ulnar neuropathy, what are the indications for surgical management versus nonoperative management?

2. In patients with ulnar nerve distribution symptoms, what is the most effective surgical technique for managing compressive ulnar neuropathy at the elbow?
3. In patients with severe ulnar neuropathy, are there adjunct procedures to augment intrinsic muscle dysfunction?

Question 1: In patients with ulnar neuropathy, what are the indications for surgical management versus nonoperative management?

Rationale

The decision to manage cubital tunnel syndrome nonoperatively versus surgically is based on clinical and electrodiagnostic characteristics. The distance between site of compression at the elbow and motor targets can result in variable recovery of musculature after surgical release given the time it takes for axons to recover down the length of the nerve.[1] In some circumstances, attempting nonoperative treatment may delay nerve recovery and it is prudent to recognize when prompt release is required.

Clinical comment

McGowan grade 3 ulnar neuropathy presents the difficult challenge of improving patient sensory symptoms and reinnervating the ulnar-innervated intrinsic musculature. Neuromuscular junction atrophy is an important consideration as the nerve recovers after release. Given the distance from the elbow to the hand, and the rate at which axons recover after release, the recovery of intrinsic function can be variable resulting in modest patient

outcomes.[1],[2] Failure to intervene surgically may result in delay of recovery of intrinsic musculature and permanent dysfunction.

Available literature and quality of the evidence

Nonoperative management of cubital tunnel syndrome includes nerve gliding exercises, splinting the elbow in an extended position, padding over the cubital tunnel, and avoidance of pressure over the nerve and elbow flexion. Currently, there are no randomized controlled trials (RCTs) comparing conservative versus surgical management.[3] One RCT exists comparing two forms of conservative treatment demonstrating reasonable effectiveness for mild to moderate disease.[4] Patients in this study with muscle dysfunction (McGowan 3) showed no improvement in muscle strength with conservative measures. This study is level I evidence; however, it only compares two forms of conservative management instead of conservative versus surgical management.

In a prospective study by Dellon et al., 128 patients with various degrees of cubital tunnel syndrome were followed nonoperatively with an average follow-up of 58 months.[5] A requirement for surgical intervention defined failure of conservative management. In general, patients with mild symptoms required surgical management less often versus moderate to severe disease. In patients experiencing symptoms only with no objective findings, nonoperative measures were successful 89% of the time. Those with abnormal sensorimotor thresholds were successful 67% and only 38% with abnormal sensorimotor density. This is level IV evidence.

Dellon et al. also published a review of the literature analyzing all work evaluating conservative and surgical management prior to 1988, which included more than 2000

patients.[6] They concluded that, in mild disease, conservative management produced excellent sensory results in an estimated 50% of patients compared to 90% using operative techniques. In moderate to severe disease, Dellon et al. concluded that nonoperative measures were “completely unsuccessful” and that surgical management is indicated.[6] This is level IV evidence.

Eisen and Danon also produced level IV evidence following 30 patients over 22 months. This study supports nonoperative measures in patients with mild disease.[7] They defined electrodiagnostic parameters suggesting operative management is required in those with motor conduction velocity less than 41 m/s across the elbow and a motor latency from above elbow greater than 10.2 ms.

Overall, quality of evidence is weak with one RCT and none comparing conservative to surgical management. Two level IV studies exist examining indications for conservative versus operative management.

Findings

Conservative measures have been shown to be effective in patients with mild and possibly moderate disease (McGowan grade 1 or 2) with no evidence of intrinsic muscle abnormality. Failure to improve symptoms in mild to moderate disease is an indication for surgical management. Surgical management should be considered in severe disease – McGowan grade 3. Electrodiagnostic studies with motor conduction velocity less than 41 m/s and motor latency greater than 10.2 ms is also an indication for surgical management. The decision to offer surgical management should also consider overall patient factors and may differ on a case-to-case basis.

Resolution of clinical scenario

- Nonoperative management is primarily recommended for mild disease with symptoms only.
- In this case, there are objective findings of motor dysfunction and severe compression; therefore, surgical management is suggested.

Question 2: In patients with ulnar nerve distribution symptoms, what is the most effective surgical technique for managing compressive ulnar neuropathy at the elbow?

Rationale

Surgical management of cubital tunnel syndrome is among the most debated topics in peripheral nerve surgery as multiple options exist.[8] In general, the most common contemporary techniques are simple decompression versus anterior transposition of the ulnar nerve.[9]

Clinical comment

With multiple techniques available for surgical management of cubital tunnel syndrome, selecting a technique that is supported by the best available evidence is important. In managing a patient surgically, the goal is to ensure the ulnar nerve is free from further compression and to maximize symptom resolution with sensory and motor recovery.

Available literature and quality of the evidence

The highest-level evidence to address this question analyzes the efficacy of various decompression or transposition techniques. There is relatively strong

evidence with multiple level I RCTs and meta-analyses.[3,10–17]

Bartels et al. performed a prospective RCT comparing simple decompression versus subcutaneous transposition of the ulnar nerve in patients who had varying degrees of severity.[10] This study is graded as level I evidence. Clinical outcomes at one year were assessed in 152 patients, with 75 patients randomized to simple decompression and 77 to subcutaneous transposition. At all follow-up visits, there was no significant difference in clinical outcomes between groups, although there was a trend toward favoring subcutaneous transposition at one year (risk ratio [RR] = 0.8; 95% confidence interval [CI]: 0.6–1.1). Sixty-five percent of patients and 70% with subcutaneous transposition achieved good to excellent results, respectively. There was a higher complication rate in the subcutaneous transposition group, with scar hypersensitivity being the most common.[10]

In a second publication with this cohort, a cost analysis was performed, which reviewed professional fees, opportunity cost from sick leave, operating time, and resource costs.[11] Simple decompression was associated with overall less cost per patient (mean €1124 vs €2730) and less operating time.[11]

Nabhan et al. also performed a prospective RCT comparing simple decompression versus subcutaneous transposition in 66 patients with 9-month follow-up.[12] This is graded level I evidence. Thirty-two patients underwent nerve decompression and 34 subcutaneous transposition. At three- and nine-month postoperative evaluation, both groups showed improvement with respect to pain, sensory, and motor findings. There was no statistically significant difference between the two groups.[12]

In another prospective RCT, Gervasio et al. analyzed simple decompression versus anterior submuscular transposition in patients with severe cubital tunnel syndrome.[13] This study is graded as level I evidence. Severe cubital tunnel syndrome was defined according to the Dellon classification – grade 3.[5] Seventy patients met inclusion criteria with 35 randomized to decompression and 35 to transposition. Mean follow-up was 47 months for each group. Clinical results were graded with a Bishop score. Fifty-four percent of patients in the simple decompression group achieved excellent results and 51% in the transposition group achieved the same score. No statistical difference was noted for clinical outcome between groups. Both groups showed overall improvement of electrophysiology for motor and sensory response in approximately 50% of cases, with no significant statistical difference. No major complications were noted, with more scar hypersensitivity in the simple decompression group versus the transposition.[13]

Zhong et al. performed an RCT of 278 patients who underwent either subcutaneous transposition or submuscular transposition with z-lengthening.[14] This study is graded as level I evidence. Patients had varying degrees of severity (McGowan grade 1–3). Electrophysiology outcomes alone were followed for up to two years postoperatively. All patients demonstrated significant improvement in sensory and motor conduction velocity from pre to postop. McGowan grade 1 patients were found to have no difference between subcutaneous and submuscular transposition. In those with McGowan grade 2 and 3, patients with submuscular transposition had significantly better electrophysiology outcomes at two years. There were no clinical outcomes assessed.[14]

Zarezadeh et al. performed a prospective RCT comparing anterior subcutaneous transposition versus submuscular.[15] This is level I evidence; however, there may have been some biases with blinded assessments in this study. Forty-eight patients were divided evenly and followed over 12 months postoperatively. The two groups were comparable with respect to sensation, muscle strength, and muscle atrophy. Pain was improved in the submuscular group.[15]

There are also meta-analysis reviewing this subject. A Cochrane review article (2016) was published by Caliandro et al., who originally reviewed this topic in 2010 and updated it in 2012.[3] With respect to surgical management of compressive ulnar neuropathy at the elbow, their meta-analysis included four updated RCTs. Their analysis revealed no significant difference in clinical outcomes comparing simple decompression versus transposition (RR = 0.93; CI: 0.80–1.08). The same result was found when analyzing neurophysiological outcomes, with mean difference in conduction velocity of 1.47 m/s (CI: −0.94 to 3.87). Lastly, there was a significant increase in wound infections with the transposition group.[3]

In their meta-analysis, McAdam et al. examined literature comparing anterior transposition versus simple decompression.[8] Studies included in the meta-analysis were either RCTs or cohort analysis. This is level II evidence. Ten studies were included for analysis. With respect to anterior transpositions, studies included either subcutaneous or submuscular transposition. There was no significant difference between those patients undergoing transposition versus simple decompression with an odds ratio of 0.75 (CI: 0.54–1.04). A sub-analysis was performed comparing subcutaneous transposition or submuscular versus simple decompression. There was no difference

between subcutaneous transposition or submuscular transposition in comparison to simple decompression.[8]

Another meta-analysis on this topic was published by Chen et al. in 2014.[16] Thirteen studies were included for analysis. Studies comprised of prospective randomized and cohort analysis as well as retrospective cohort analysis. This is level II evidence. The odds ratio between anterior transposition and simple decompression was 0.91 (CI: 0.67–1.23). There was a significantly decreased risk of complications in the simple decompression group with an odds ratio of 0.32 (CI: 0.17–0.60).[16]

In a similar fashion, Liu et al. specifically compared anterior subcutaneous versus submuscular transposition in a meta-analysis.[17] Two RCTs and one quasi-randomized trial met criteria for analysis. This is level II evidence. Risk ratio of clinical improvement between these techniques was 1.05 (CI: 0.86–1.25).[17]

Findings

Overall, reasonably good evidence exists examining various surgical techniques for addressing cubital tunnel syndrome. Level of evidence presented here is I–II.

Of the RCTs, there has been no study that demonstrates a significant difference between simple decompression, subcutaneous transposition, or submuscular transposition. The most commonly debated techniques are simple decompression versus subcutaneous transposition. Bartels et al. showed a risk ratio 0.8 (CI: 0.6–1.1) between these methods demonstrating their equivalence.[10] Similarly, in their sub-analysis, McAdam et al. demonstrated an odds ratio of 0.836 (CI: 0.562–1.242) between these techniques.[8] Caliandro et al. revealed a risk ratio of 0.93 (CI: 0.80–1.08).[3]

There is less quality evidence in comparing submuscular versus subcutaneous transposition. McAdam et al. had an odds ratio of 0.836 (CI: 0.562–1.242) for subcutaneous transposition versus 0.596 (CI: 0.341–1.044) for submuscular transposition when comparing to simple decompression.[8] Liu et al. demonstrated a risk ratio of 1.05 (CI: 0.86–1.25) comparing subcutaneous to submuscular transposition directly.[17]

In some studies, complications were noted to be lower in the simple decompression group (RR = 0.32, CI: 0.17–0.60;[17] RR = 0.32, CI: 0.14–0.69).[10] Whereas, there was no difference in complications in the majority of other studies.

Resolution of clinical scenario

- High-quality evidence supports no significant difference in clinical and neurophysiological outcomes between simple decompression and anterior subcutaneous transposition.
- Some studies demonstrate a reduced complication rate with simple decompression.
- There is no difference in clinical outcomes between subcutaneous and submuscular transposition.

Question 3: In patients with severe ulnar neuropathy, are there adjunct procedures to augment intrinsic muscle dysfunction?

Rationale

As described previously, severe ulnar neuropathy resulting in intrinsic muscle dysfunction muscle recovery is variable

following simple decompression or anterior transposition. A distal nerve transfer would be helpful to maximize intrinsic muscle recovery.

Clinical comment

In this clinical setting, the patient has an eight-month history of ulnar innervated intrinsic muscle dysfunction with evidence of wasting. EMG findings demonstrate axonal loss with denervation. Rennervating affected musculature is of utmost importance.

Available literature and quality of the evidence

There is very limited literature on this topic. The level of evidence is III or V, primarily composed of one cohort study and case series or case reports.

The original description of a distal nerve transfer that may be applied to severe cubital tunnel syndrome is an extension of the anterior interosseous nerve (AIN) to ulnar end-to-end transfer, by Isaacs et al.[18] In this nerve transfer, the AIN is divided distally and coapted to the side ulnar motor fascicle proximal to the wrist. The main advantage to this technique is the ulnar motor fascicle is preserved as opposed to an end-to-end coaptation where the motor fascicle is divided and therefore completely downgraded. The reverse end-to-side transfer allows for recovering axons from the elbow to still reach the hand intrinsic musculature while augmenting the motor fascicles distally. The term *reverse end-to-side transfer* is used by Isaacs et al. to distinguish it from the historically used term *end-to-side transfer*, where the recipient nerve is cut and coapted into the side of the donor nerve, which remains in continuity.

Baltzer et al. present a retrospective matched cohort study. This is level III evidence. Thirteen patients with high ulnar

nerve injury or compression were matched in age, mechanism of injury, and level of injury with those who did not receive the transfer. Patients had at least one-year follow-up. Eleven patients demonstrated ulnar intrinsic recovery versus five in the nontransfer group, which was statistically significant.[19]

Kale et al. present one case report using this nerve transfer. Quality of evidence is level V. Follow-up was one year demonstrating recovery of ulnar intrinsic function.[20]

Our group has presented a case series of 30 patients with McGowan grade 3 cubital tunnel syndrome and a mean follow-up of 16 months (work yet published).[21] To our knowledge, this represents the largest cohort of patients presented to date. This is level V evidence. The technique involves anterior ulnar nerve transposition and concurrent AIN to ulnar reverse end-to-side transfer. Patients demonstrated a significant improvement in mean MRC intrinsic muscle strength, from 1.85 preoperatively to 3.02 postoperatively ($p = 0.001$). To demonstrate the effectiveness of this transfer, we compared the McGowan grade 3 cubital tunnel cohort with a group of patients with complete nerve transection at or above the elbow, in other words a total downgrade of ulnar nerve function. At final follow-up, there was no significant difference in mean MRC between these groups: 3.02 versus 3.11, respectively.

Findings

There is little evidence assessing the addition of a distal nerve transfer to augment axonal recovery distally in the setting of McGowan grade 3 ulnar neuropathy. The existing literature is graded level III or V evidence. Case series demonstrate a better-than-expected recovery of intrinsic recovery with the addition of an AIN to ulnar reverse end-

to-side transfer. Future work with higher-quality evidence is required.

Resolution of clinical scenario

- A distal nerve transfer has been described to augment ulnar-innervated intrinsic muscle recovery.
- There is little literature to support its use, and future work is required.

Summary of answers

- Nonoperative management is recommended for patients with mild, symptomatic ulnar neuropathy.
- In cases with objective findings of motor dysfunction and severe compression, surgical management is recommended.
- There is no significant difference in clinical and neurophysiological outcomes between simple decompression and transposition.
- A distal nerve transfer has been described to augment ulnar-innervated intrinsic muscle recovery, but limited evidence exists to support this.

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166 Finger Fractures

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Clinical scenario

- A 31-year-old woman presents to the Emergency Department after being struck on the right small finger while playing field hockey.
- Physical examination reveals a diffusely swollen and tender small finger but with no deformity.

Top three questions

1. How long should patients with extra-articular small finger metacarpal (aka *boxer's*) fractures be immobilized to achieve optimal outcomes?
2. Should open reduction and internal fixation (ORIF) or a dynamic external device be used for the management of patients with unstable proximal interphalangeal (PIP) joint fracture/dislocations to optimize outcomes?
3. Which is a better treatment for achieving optimal outcomes in patients with extra-articular metacarpal and phalanx fractures: pinning or ORIF?

Question 1: How long should patients with extra-articular small finger metacarpal (aka boxer's) fractures be immobilized to achieve optimal outcomes?

Rationale

Extra-articular small finger metacarpal fractures are extremely common and treatment methods vary widely from no immobilization to casting for up to six weeks.

Clinical comment

These fractures are generally treated nonoperatively but often occur in patients who may be poorly compliant with removable splints and early motion regimens.

Available literature and quality of the evidence

There are several high-quality studies which examine this question including multiple level I studies.[1–5]

Findings

Statius Muller et al. randomized 40 patients with boxer's fractures to either cast immobilization for three weeks versus one week of soft bandaging followed by mobilization.[1] Angulation up to 70° was accepted without reduction. At three months postinjury, there was no statistical differences with respect to range of motion (ROM), satisfaction, pain perception, return to work and hobby, and need for physiotherapy. Kuokkanen et al. randomized 29 patients to either closed reduction and rigid immobilization or immediate mobilization.[3] Patients treated without immobilization regained grip strength and ROM

slightly earlier, but by three months the two groups were equivalent. They concluded that reduction and immobilization were not necessary.

Braakman et al. prospectively randomized 50 patients to either ulnar gutter casting or functional taping for four weeks.[4] The functional taping group showed significantly earlier return of ROM and strength, but by six months there was no difference between the groups. There was no difference in increased fracture angulation between the groups. Similarly, van Aaken et al. compared buddy taping with early mobilization to closed reduction and casting for the treatment of small finger metacarpal neck fractures.[5] The authors found no significant difference in functional outcomes, patient satisfaction, or metacarpophalangeal (MCP) joint motion between the two groups at four months.

Two trials compared cast immobilization and a custom functional fracture brace (level II evidence).[6],[7] Konradsen et al. found significantly better wrist, MCP, and PIP motion after three and four weeks, respectively, in the brace group, but no differences after three months.[6] Sørensen et al. noted that only 42% of the brace group completed treatment, pointing to the challenges with compliance in this patient group.[7] However, in those who completed treatment, there was no difference in ROM.

Sletten et al. randomized 85 patients with small finger metacarpal neck fractures with >30° palmar angulation found that patients who were treated with a week of splint immobilization followed by buddy taping had similar functional outcomes and satisfaction scores as patients who underwent operative treatment with closed reduction and bouquet pinning (level I).[8]

In a systematic review of studies of the treatment of small finger metacarpal neck fractures, Dunn et al. found that

reduction and cast immobilization did not provide superior ROM, grip strength, or healing compared to treatment with a soft wrap without any reduction attempt.[9] In a Cochrane review, Poolman et al. criticized the lack of consistent, validated outcome tools in all studies but concluded: “No single non-operative treatment regimen for fracture of the neck of the fifth metacarpal can be recommended as superior to another” (level V).[10]

Although multiple different treatments are utilized by hand surgeons, there is good evidence that cast immobilization is unnecessary in the treatment of small finger metacarpal neck fractures. Level I evidence suggests an earlier improvement in ROM and grip strength will occur in patients treated with functional bracing or even taping. However, at medium-term follow-up, there is no significant difference in outcomes such as pain and ROM.

Resolution of clinical scenario

- Early mobilization with either functional bracing or taping does not affect the final outcome of closed metacarpal fractures and appears to be associated with an earlier return of finger motion and grip strength.
- Immobilization is also effective with good long-term outcomes and can be utilized at the discretion of patient and surgeon.

Question 2: Should open reduction and internal fixation (ORIF) or a dynamic external device be used for the management of patients with unstable proximal interphalangeal (PIP) joint fracture/dislocations to optimize outcomes?

Rationale

Unstable PIP fracture/dislocations are amongst the most challenging injuries faced by hand surgeons.

Clinical comment

PIP fracture/dislocations are often associated with suboptimal outcomes. Fracture fragments are typically small and comminuted which does not allow for rigid fixation. In addition, the PIP joint is intolerant and becomes stiff after even minor trauma. Trying to choose the “best” treatment for an individual patient is difficult for the hand surgeon.

Available literature and quality of the evidence

A randomized controlled trial (RCT) and three retrospective case series exist on this topic.

Findings

Aladin et al. prospectively randomized 19 patients to closed reduction and trans-articular Kirschner wires (K-wires) or ORIF (lag screws or cerclage wire).[11] The authors reported the ORIF group as two separate subgroups with cerclage wiring associated with a 30° fixed flexion deformity (FFD)

and an arc of motion of 48°. By comparison, K-wire and lag screw fixation had FFDs of 0° and 4°, respectively, and arcs of motion of 75° and 73°. There was no statistical comparison of treatment groups, but the authors concluded that K-wire fixation was technically simpler with similar outcomes.

Three retrospective case series reported on internal screw fixation (level IV).[12–14] Seven retrospective case series reported on various types of dynamic traction/external fixation (level IV).[15–21] The average arc of PIP joint motion was 88.7° with a range from 70° to 165°. Complication rates ranged from 8 to 63%. There was no clear advantage of one approach over another.

There is minimal level I evidence to support one treatment paradigm over the other. Multiple case series document similar ranges of motion at final follow-up. Because of the heterogeneity of fracture patterns, a large clinical trial to account for different types of fracture patterns is required to resolve this question.

Resolution of clinical scenario

- There is no high-level evidence to support one type of treatment as being superior to another.
- Data from one RCT suggest that less invasive treatment has the advantage of technical simplicity while producing similar outcomes.

Question 3: Which is a better treatment for achieving optimal outcomes in patients with extra-articular metacarpal and phalanx fractures: pinning or ORIF?

Rationale

ORIF with plates and screws provides excellent stability which allows early motion; however, it causes additional soft tissue trauma, which may lead to extensor and/or flexor tendon adhesions potentially limiting ultimate ROM. Closed reduction and K-wire pinning is less expensive, simpler, and may limit soft tissue trauma; however, the lack of rigid fixation may not allow for early motion therapy protocols.

Clinical comment

The ideal treatment of extra-articular finger fractures remains controversial. Despite the conceptual advantages of ORIF in providing stability and alignment, pinning frequently offers a good alternative. Individual fractures (metacarpal, proximal phalanx, distal phalanx) and fracture patterns (oblique, transverse, comminuted vs simple) make comparison of specific treatment techniques challenging.

Available literature and quality of the evidence

An RCT, as well as a systematic review of RCTs along with expert opinion, exists on this topic.

Findings

Horton et al. prospectively randomized 40 patients with long oblique proximal phalanx fractures to either

percutaneous K-wire fixation versus open reduction and lag screw fixation (level I).[22] At a mean follow-up of 40 months, the authors found no differences in pain, malunion, ROM, or grip strength.

A systematic review by Yammine et al. (level V) of RCTs or quasi-RCTs comparing antegrade intramedullary nailing (AIMN) with other fixation techniques for fifth metacarpal neck fractures found patients treated with AIMN to have better grip strength, pain scores and ROM when compared to fixation with plates or transverse pins.[23] Conversely, Ozer et al. compared retrospective cohorts of patients with metacarpal fractures treated with intramedullary nail fixation of extra-articular fractures with plate and screw fixation and found no significant differences in total active motion or Disabilities of the Hand, Arm, and Shoulder (DASH) scores regardless of fracture location (level III).[24]

Most literature consists of expert opinion such as the articles by Henry and Kozin et al.[25],[26] Their recommendations are based on their considerable experience and are specific to individual fractures (level V). A single prospective RCT addressed a very particular fracture pattern which lends itself to screw fixation.[22] It is likely that the results of that study are not generalizable to other types of fractures.

Resolution of clinical scenario

- There are insufficient data to recommend one fixation technique over another.
- At present, the choice of treatment depends on the individual fracture characteristics and surgeon/patient preference.

Summary of answers

- Early mobilization with functional bracing or taping is associated with earlier return of motion and grip strength.
- There is no good evidence to support the use of any specific surgical technique over another.
- The choice of treatment should be guided by fracture characteristics and surgeon/patient preference.

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IX Oncology

167 Radiation Therapy in Soft Tissue Sarcoma

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Clinical scenario

- A 50-year-old woman presents with a growing mass in the medial thigh. On examination there is a firm 15 cm mass in the adductor compartment. Magnetic resonance imaging (MRI) confirms a tumor with heterogeneous signal characteristics. The neurovascular bundle is displaced but not encased. A biopsy performed at the regional tumor center is consistent with a high-grade undifferentiated pleomorphic sarcoma. Systemic staging is negative for metastasis.
- Will the patient receive radiation therapy (XRT) as part of her management?
- The patient asks if she will receive XRT before or after surgery.
- Apart from local recurrence, short- and long-term treatment morbidity remain important considerations for patients undergoing treatment with surgery and XRT.

Importance of the problem

Radiation-induced cell death is brought about by direct DNA damage and the production of free radicals. Tumors with varying DNA concentrations and local oxygen tensions respond differently to identical doses of radiation. The presence of prior surgery also affects tumor cell sensitivity.[1] The exact timing, sequence, and dose of XRT remain controversial. A recent population-based review of over 8000 soft tissue tumors documented the distribution of soft tissue sarcomas (STS) to be the lower extremity (32%), upper limb (13%), and axial (55%).[2]

Top three questions

1. Is there evidence to use XRT in the management of STS?
2. What are the relative advantages and disadvantages of pre- versus postoperative XRT?
3. What are the short- and long-term complications of XRT?

Question 1: Is there evidence to use XRT in the management of STS?

In patients undergoing wide resection for soft tissue sarcoma, does the use of XRT result in better local control and overall survival compared to surgical resection alone?

Rationale

STS constitute 1% of all cancer diagnoses and the incidence is estimated at 1 per 30 000. The mainstay of treatment is wide surgical excision. XRT is used in the management of STS, with the goal of extending the *virtual margin* to the surrounding tissues.[3]

Clinical comment

Limb-sparing surgery plus XRT is as effective as amputation for the local control of STS.

Available literature and quality of the evidence

STS are rare and there is a paucity of level I evidence upon which to base treatment decisions.

Findings

There is agreement that local control is important, and some authors have correlated local recurrence with diminished overall survival. Most studies are retrospective with small (average 182, range 41–517) numbers of patients. There are two systematic reviews that included 4579 patients, and there is significant overlap between these reviews. There are three randomized controlled trials (RCTs) that evaluated 298 patients. A systematic review concluded that XRT in addition to limb-sparing surgery improves local control for extremity STS over surgery alone, but does not affect overall survival.[4] A review of RCTs in extremity STS found that limb-sparing surgery plus XRT is equivalent to amputation for local control.[5] Furthermore, adding XRT to surgical resection significantly improves local control over surgery alone but does not improve overall survival. The first RCT compared limb-sparing surgery plus postoperative XRT to amputation in 43 patients.[6] At the time of this study, amputation was the standard of care for local control of STS. The authors found no significant differences in local recurrence ($p = 0.06$; odds ratio [OR] = 6.32; 95% confidence interval [CI]: 0.32–125.52) or overall survival ($p = 0.99$; OR = 0.86; 95% CI: 0.13–5.89) at five years. They concluded that limb-sparing surgery plus XRT is a reasonable alternative to amputation. The next two RCTs compared limb-sparing surgery alone to

limb-sparing surgery plus postoperative RT. Pisters et al. (n = 164 patients) reported a significant improvement (p = 0.002; OR = 0.23; 95% CI: 0.08–0.66) in local control with surgery plus brachytherapy compared with the surgery alone in patients with high-grade tumors.[7] Brachytherapy did not provide an advantage in patients with low-grade tumors. There were no differences between the two treatment groups in terms of metastatic disease (p = 0.60; OR = 0.74; 95% CI: 0.35–1.56) or five-year survival (p = 0.65; OR = 0.8; 95% CI: 0.35–1.81). Yang et al. stratified 141 patients into high- and low-grade tumors.[8] All patients had surgery and were randomized to receive external beam XRT or not. XRT significantly improved local control in both high-grade (p = 0.003; OR = 0.05; 95% CI: 0.00–0.81) and low-grade (p = 0.02; OR = 0.08; 95% CI: 0.01–0.70) tumors. However, there were no differences in overall survival at 10 years (p = 0.71; OR = 0.93; 95% CI: 0.40–2.15). An outcomes study involving 8249 patients using the Florida Cancer Registry demonstrated that surgical resection (p <0.001) and XRT (p <0.001) were the only treatment variables to improve survival.[9] The findings of earlier studies from the 1980s and 1990s are in line with the newer RCTs and systematic reviews.[10–17]

Resolution of clinical scenario

- XRT plus limb-sparing surgery is as effective as amputation for the local control of extremity STS (overall quality: high).
- XRT plus limb-sparing surgery is superior to surgery alone for the local control of high-grade extremity STS (overall quality: high).
- XRT does not impact overall survival (overall quality: high).

Question 2: What are the relative advantages and disadvantages of pre- versus postoperative XRT?

In patients receiving XRT for management of their soft-tissue sarcoma, does preoperative XRT result in better survival outcomes compared to postoperative XRT?

Rationale

Sarcomas are best treated by multidisciplinary teams and individualized treatment plans. The relative advantages and disadvantages of pre- versus postoperative XRT must be related to each patient.

Clinical comment

There are potential advantages and disadvantages to both pre- and postoperative XRT. Both strategies are successfully used to treat patients. Preoperative XRT is associated with a higher rate of wound complications but better long-term functional outcomes.

Available literature and quality of the evidence

High-quality evidence exists to answer this question.

Findings

Advantages and disadvantages

Potential advantages of preoperative XRT include smaller radiation dose and treatment volume, greater sensitivity of the tumor to radiation, no delay in the initiation of XRT, less long-term tissue toxicity (joint contracture, fibrosis, edema, and fracture), and the ability to administer a postoperative radiation boost if desired. Reported advantages of postoperative XRT include immediate

surgery, better-quality tissue for pathologic evaluation, and fewer wound complications.

Level I, III, and IV data report statistically smaller treatment doses and fields with preoperative XRT: preoperative XRT is typically ~50 Gy, whereas postoperative treatment is typically 66 Gy.

Recurrence and survival

No studies have shown a significant difference in local recurrence or metastatic disease with either pre- or postoperative XRT. A Canadian RCT comparing pre- and postoperative XRT reported a slight survival advantage of preoperative XRT at three years ($p = 0.05$; OR = 0.47; 95% CI: 0.23–0.97) which did not persist with longer-term follow-up.[18,19]

Al-Absi et al. performed a meta-analysis comparing pre- and postoperative XRT for local recurrence and overall survival.[20] Of 1098 patients, 526 had preoperative XRT. Although there were fewer local recurrences in the preoperative group, this finding was dependent on whether a random- or fixed-effect statistical model was used. The authors stressed that these findings should be interpreted cautiously due to heterogeneity within the meta-analysis (heterogeneity $p = 0.26$, variability = 25%). They concluded that the timing of XRT is unlikely to affect survival. The decision to use preoperative or postoperative XRT is based on the expected advantages of one treatment strategy versus the other. Preoperative XRT might be chosen if the tumor is in close proximity to critical structures (e.g. femoral artery) and smaller radiation doses/volumes are required. Complex soft tissue reconstructions could make preoperative XRT desirable. Alternatively, patients unable to tolerate a wound complication might benefit from postoperative XRT.

Resolution of clinical scenario

- Preoperative XRT utilizes smaller treatment volumes and lower overall radiation dosages than postoperative XRT (overall quality: high).
- Pre- and postoperative XRT have equivalent efficacy in terms of local control and overall survival (overall quality: high).

Question 3: What are the short- and long-term complications of XRT?

In patients receiving XRT for the management of their soft-tissue sarcoma, does preoperative XRT result in better functional outcomes compared to postoperative XRT?

Rationale

Pre- and postoperative XRT cause distinct complications. Immediately following preoperative XRT, wound complications are the most common problem, particularly in the management of lower limb lesions. The longer-term effects of postoperative XRT on normal tissues increase the probability of developing limb and joint stiffness, fibrosis, edema, and long bone fracture.

Clinical comment

Multiple studies have demonstrated that preoperative XRT increases the probability of wound complications compared with postoperative XRT, which can cause adverse long-term functional consequences. Wound complications are challenging but manageable problems. In contradistinction, once the long-term effects of XRT have established themselves in the limb, they are difficult to manage.

Available literature and quality of the evidence

Moderate- to high-quality literature exists on this topic.

Findings

Short-term complications

Even without adjuvant treatment, wound complications are to be expected following STS excision. In a consecutive series of 98 patients managed with STS excision without adjuvant treatment, the wound complication rate was 40%.[21]

A Canadian RCT demonstrated 35% (31 of 88 patients) versus 17% (16 of 94 patients) wound complication rate in the pre- versus postoperative XRT groups, respectively ($p = 0.01$; OR = 2.65; 95% CI: 1.33–5.30) with the predominant effect almost entirely confined to the lower limb.[18]

The retrospective data of Cheng et al., Pollack et al., and Cannon et al. independently reported that preoperative radiation leads to increased rates of wound complications in the lower limb compared to postoperative XRT.[22–24] Specifically, Cheng et al. reported wound complications in 15 of 48 (31%) preoperative XRT patients compared with 5 of 64 (8%) postoperative XRT patients ($p = 0.001$; OR = 5.36; 95% CI: 1.79–16.08).[22] Pollack et al. reported wound complications in 32 of 128 (25%) preoperative XRT patients compared with 10 of 165 (6%) postoperative XRT patients ($p < 0.001$; OR = 5.17; 95% CI: 2.43–10.99).[23] Finally, Cannon et al. reported complications in 90 of 269 (34%) preoperative XRT patients and 23 of 143 (16%) postoperative XRT patients ($p < 0.001$; OR = 2.63; CI: 1.57–4.38).[24]

Long-term complications

Rimner et al. retrospectively reviewed 225 thigh tumors.[25] Overall complication rates at five years were edema (13%), joint stiffness (12%), wound reoperation (10%), nerve damage (8%), and bone fractures (7%). In this study 69% of these patients were treated with brachytherapy, while 31% received external beam XRT. Cannon et al. reported on 412 patients at 20 years following external beam XRT and found that chronic radiation related complications were higher in patients with a tumor located in the groin or thigh.[24]

Davis et al. analyzed 129 patients for late radiation morbidity in an RCT.[19] At two years, there was a trend toward greater fibrosis following postoperative XRT ($p = 0.07$; OR = 0.49; 95% CI: 0.24–1.02). Moderate degrees of fibrosis and stiffness correlated with significantly worse patient reported outcomes (Toronto Extremity Salvage Score [TESS] scores) as well as objective assessments (Musculoskeletal Tumor Society [MSTS] scores). There was also increased edema (23% vs 15%; $p = 0.26$; OR = 0.59; 95% CI: 0.24–1.43), and joint stiffness (23% vs 18%; $p = 0.51$; OR = 0.72; 95% CI: 0.30–1.70) in the post- versus preoperative XRT groups. Large field size is typically associated with postoperative XRT and was predictive of increased fibrosis ($p = 0.002$), joint stiffness ($p = 0.006$), and edema ($p = 0.06$) in logistic regression analysis. The Musculoskeletal Tumor Society (MSTS) score and Toronto Extremity Salvage Score (TESS) were not significantly different between both treatment arms but were adversely affected by radiation morbidity.

Stinson et al. retrospectively reviewed acute and chronic postradiation effects in 145 patients and identified tissue induration (57%), decreased range of motion (32%), decreased muscle power (20%), edema (19%), pain (7%), use of walking aids (7%), and fracture (6%).[26] Examining

radiation-associated fractures, Holt et al. noted that patients undergoing thigh STS resection were more likely to sustain a fracture if they received either high-dose postoperative XRT or high-dose combined preoperative XRT and a postoperative boost (60 or 66 Gy) compared to low-dose (50 Gy) preoperative treatment.[27] In this study 24 of 27 fractures occurred in patients who had received high-dose XRT ($p = 0.007$; OR = 0.12; 95% CI: 0.04–0.42).

Resolution of clinical scenario

- Preoperative XRT leads to an increased rate of wound complications relative to postoperative XRT in lower limb tumors (overall quality: high).
- Larger tumors treated with XRT have an increased risk of developing complications (overall quality: high).
- A moderate degree of fibrosis and stiffness leads to significantly poorer patient-reported outcomes (overall quality: high).
- Postoperative XRT leads to diminished long-term functional outcomes, when measured with MSTS and TESS scores, than preoperative XRT (overall quality: moderate).

Summary of answers

- XRT plus limb-sparing surgery is as effective as amputation for the local control of extremity STS.
- XRT plus limb-sparing surgery is superior to surgery alone for the local control of high-grade extremity STS.
- XRT does not impact overall survival.
- Preoperative XRT utilizes smaller treatment volumes and lower overall radiation dosages than postoperative

XRT.

- Pre- and postoperative XRT have equivalent efficacy in terms of overall survival.
- Preoperative XRT leads to an increased rate of wound complications relative to postoperative XRT in lower limb tumors.
- Larger tumors treated with XRT have an increased risk of developing complications.
- A moderate degree of fibrosis and stiffness leads to significantly poorer patient-reported outcomes.
- Postoperative XRT leads to diminished long-term functional outcomes, when measured with MSTS and TESS scores, than preoperative XRT.

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168 Chemotherapy in Soft Tissue Sarcoma

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Note: in this chapter, the odds ratio (OR) reported in italics has been calculated by the authors and is not reported as part of the manuscripts referenced. Table 168.1A provides an overall review of studies cited and includes either the reported or calculated hazard ratio (HR) or OR for overall survival as related to chemotherapy administration.

Introduction

The two staging systems used to describe soft tissue sarcoma (STS) are the American Joint Committee on Cancer (AJCC) and the Enneking System (Surgical Staging System of the Musculoskeletal Tumor Society). The AJCC is based upon the tumor–node–metastasis (TNM) system, but also includes histologic grade as a measure. The Enneking system is based upon histopathologic grade, anatomic site and extent, and presence or absence of metastases.

Doxorubicin (Adriamycin) is an anthracycline antibiotic used as a chemotherapeutic agent. It works by intercalating DNA. Toxicities can include nausea, vomiting, and heart arrhythmias. Cumulative doses can lead to cardiotoxicity including congestive heart failure and dilated cardiomyopathy.

Ifosfamide (Ifex) is an alkylating agent whose mechanism of action includes the formation of covalent bonds with DNA, RNA, and proteins thereby impairing cell function. Dosing is limited by genitourinary and neurologic toxicity and is usually administered in conjunction with mesna to reduce the genitourinary toxicity.

Synovial sarcoma comprises 10–15% of adult STSs. Synovial sarcomas contain a characteristic translocation (X;18; p11;q11) representing the fusion of SYT (18q11) with either SSX1 or SSX2 (both at Xp11) resulting in the fusion genes SYT-SSX1 or SYT-SSX2.

Clinical scenario

- A 38-year-old vending machine repairman presents for evaluation of left groin pain. Physical examination reveals asymmetric thigh girth (left 67 cm vs right 55 cm).
- Imaging studies demonstrates a 12.5 × 15 × 20 cm mass within the adductor compartment of the left thigh.
- There is no evidence of lung parenchymal disease.
- Open biopsy of the mass is performed.

- Final pathology is reported as pleomorphic high-grade sarcoma (Figure 168.1).

Table 168.1A Efficacy of neoadjuvant chemotherapy in the treatment of STS.

Literature Reference	Study Design Quality of evidence	No. of Patients	Results	Conclusions	Statistical Significance: Overall Survival Related to Intervention
Gronchi et al.[3]	RCT	328	3 cycles NeoCT not inferior to 3 cycles NeoCT plus 2 adjuvant cycles	No control arm of no chemo to compare chemo arms with Study could not evaluate NeoCT compared to no chemo	N/A – cannot compare NeoCT to no chemo control
Gronchi et al.[4]	RCT	287	3 cycles of standard NeoCT compared to 3 cycles of histology-specific chemo regimens for high-grade myxoid liposarcoma, leiomyosarcoma, synovial sarcoma, malignant peripheral nerve sheath tumor, undifferentiated pleomorphic sarcoma	At 1-year follow-up the histologic-specific chemo group had statistically worse OS (38% vs 62% in standard NeoCT group, p = 0.006) so the study was halted early	Histology-specific chemo regimens for high-grade myxoid liposarcoma, leiomyosarcoma, synovial sarcoma, malignant peripheral nerve sheath tumor, and undifferentiated pleomorphic sarcoma are worse than standard NeoCT regimen (epirubicin, IF)

Literature Reference	Study Design Quality of evidence	No. of Patients	Results	Conclusions	Statistical Significance: Overall Survival Related to Intervention
Issels et al.[5]	RCT	329	Regional hyperthermia and NeoCT compared to NeoCT alone had better OS (p = 0.04) and better LRFS (p = 0.002)	No control arm of no chemo to compare NeoCT arm and Neo CT plus hyperthermia arms to Study could not evaluate NeoCT compared to no chemo	N/A – cannot compare NeoCT to no chemo control
Pennington et al.[6]	Retrospective Low	116	IF-based NeoCT and radiotherapy for extremity STS Median follow-up 5.9 years	No control group of no chemo to compare to	OS at 3/6 years was 82/67% Age over 60 years (p = 0.03; HR = 2.34; 95% CI: 1.10–4.98) and tumor size over 10 cm compared with tumor size ≤5 cm (p = 0.03; HR = 3.32; 95% CI: 1.15–9.61) were associated with worse OS

Literature Reference	Study Design Quality of evidence	No. of Patients	Results	Conclusions	Statistical Significance: Overall Survival Related to Intervention
Mullen et al.[7]	Retrospective Low	73	48 extremity STS patients treated with NeoCT and radiotherapy followed by three cycles of adjuvant chemo and 16 Gy postoperative radiotherapy was compared to a historical matched-control 25 patient population at a single center Median follow-up was 9.3 years in NeoCT group, 13.2 years in control group	NeoCT plus adjuvant chemo and pre- and postoperative radiotherapy conferred significant survival benefits	7-year DSS and OS rates were 81 and 50% (p = 0.004) and 79 and 45% (p = 0.003) for the NeoCT and control groups, respectively

Literature Reference	Study Design Quality of evidence	No. of Patients	Results	Conclusions	Statistical Significance: Overall Survival Related to Intervention
Meric et al.[12]	Retrospective Low	65	Reviewed records of patients treated with NeoCT to determine radiographic response: 34% partial, 9% minor, 31% stable, 26% progressive In 13%, NeoCT *downstaged* the operation, 78% had no change, and 9% progressed However, radiographic response was the most significant predictor of overall survival	Although only a few NeoCT patients had smaller surgery, radiographic response did correlate to improved survival	N/A – correlates radiographic response to survival
Eilber et al.[8]	Retrospective Low	496	The percentage of patients who achieved ≥95% necrosis increased from 13% to 48% with the addition of IF to doxorubicin. 5-year survival in patients with >95% necrosis = 80% vs 62% in patients with <95% necrosis	In patients who received neoadjuvant therapy and had evidence of treatment induced necrosis, patients with >95% necrosis demonstrated improved OS and LRFS	N/A – correlates % necrosis to overall survival

Literature Reference	Study Design Quality of evidence	No. of Patients	Results	Conclusions	Statistical Significance: Overall Survival Related to Intervention
Menendez et al.[9]	Retrospective Low	82	The overall five year survivorship for patients with <95% or >95% necrosis were 20 and 33%, respectively	Tissue necrosis from NeoCT did not seem to predict outcome	N/A – correlates % necrosis to overall survival
Gortzak et al.[10]	RCT	134	Chemotherapy did not interfere with planned surgery and did not affect postoperative wound healing Trial closed after phase II because of poor patient accrual Median follow-up of 7.3 years, five-year disease-free survival was 52% for no neoadjuvant chemo and 56% for neoadjuvant chemo groups, and 64 and 65%, respectively, for overall survival	Although chemotherapy did not compromise surgical intervention, there was not a major survival benefit observed with administration of neoadjuvant chemotherapy	*Calculated OR overall survival at mean of 7.3 years: OR = 0.68; 95%CI: 0.34–1.38; p = 0.29*

Literature Reference	Study Design Quality of evidence	No. of Patients	Results	Conclusions	Statistical Significance: Overall Survival Related to Intervention
Pisters et al.[11]	Retrospective Low	76	Responding patients had rates of LRFS, DMFS, DFS, OS similar to nonresponders	NeoCT associated with response, DFS, OS rates similar to reported adjuvant chemotherapy Responding patients had rates of LRFS, DMFS, DFS, OS similar to nonresponders	N/A – correlates radiographic response to survival
Italiano et al.[24]	Retrospective Low	237 (SS)	Median follow-up 58 months Neither neoadjuvant or adjuvant chemotherapy (IF-containing regimen) had significant impact on DSS, LRFS, DRFS	Wide surgical excision of SS with adjuvant radiotherapy are accepted treatments Chemotherapy shows no statistically significant benefit	Reported: HR = 0.91; 95% CI: 0.56–1.49; p = 0.725

IF: ifosfamide, DSS: disease-specific survival, DFS: disease free survival, DRFS: distant recurrence free survival, LRFS: local recurrence free survival, OR: odds ratio, SS: synovial sarcoma, OS: overall survival, NeoCT: neoadjuvant chemotherapy, Reported: authors reported OR/CI in published manuscripts, Calculated: authors of this review calculated OR/CI to improve statistical validity of analysis, N/A – did not address overall survival reported between control (no chemo) and experimental (chemo group), DMFS: distant metastasis-free survival

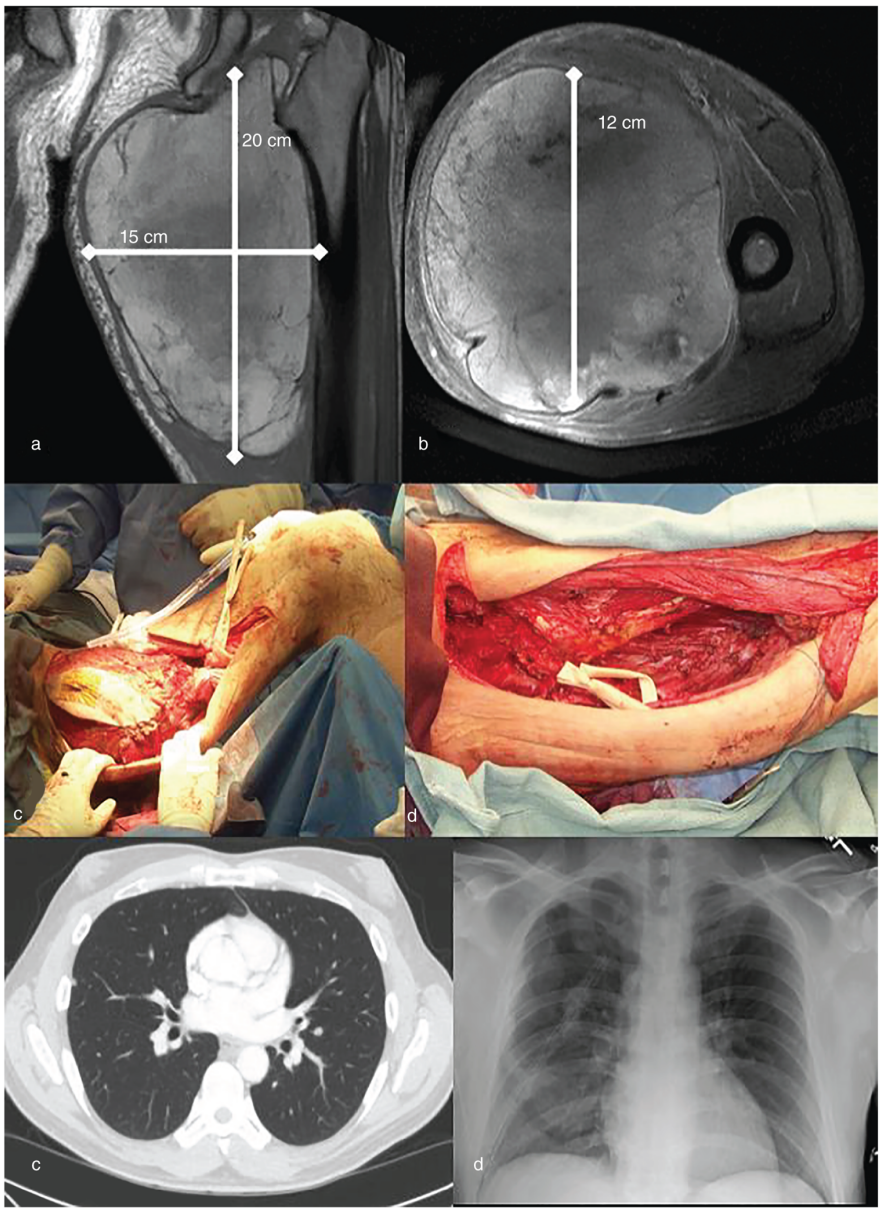

Figure 168.1 Clinical images of patient presented embody the inherent difficulty in treatment of high-risk STS. Pretreatment MRI scans revealed a large 20 × 15 × 12 cm mass in the left medial thigh (A, B). Following neoadjuvant radiation therapy, the patient is taken to the operating room for a wide excision of the tumor (C). Post resection, the sciatic nerve is skeletonized, tagged with a vessi-loop (D). Despite negative margins, no prior evidence of lung involvement on staging studies, and no evidence of local recurrence, the patient developed radiographically detectable lung metastases on CT scan nine months following definitive resection (E). Following treatment with adjuvant chemotherapy (adriamycin and ifosfamide/mesna), the patient underwent pulmonary metastatectomies (F). Source: Robert J. Wilson, Jennifer L. Halpern, Jill Gilbert, Ginger E. Holt, Vicki L. Keedy, Herbert S. Schwartz.

Table 168.1B Efficacy of adjuvant chemotherapy in the treatment of STS.

Literature Reference	Study Design Quality of evidence	No. of Patients	Results	Conclusions	Statistical Significance: Overall Survival Related to Intervention
Sarcoma Meta-analysis Group[16]	Meta-analysis High	1568	HRs of 0.73 for LRFS, 0.70 for DRFS, 0.75 for DFS correspond to absolute benefits from adjuvant chemotherapy of 6, 10, and 10%, respectively at 10 years For OS, the hazard ratio of 0.89 was not significant	Adjuvant doxorubicin-based chemotherapy (statistically) significantly improves time to local and distant recurrence and overall recurrence-free survival	Reported: HR = 0.89; 95% CI: 0.76–1.03; p = 0.12
Frustaci et al.[17]	RCT High	104	Median follow-up of 59 months Median DFS 48 months in treatment group and 16 months in control group DSS was 75 months for treated group and 46 months for control Absolute benefit in OS was 13% at two years and 19% at four years	Intensified adjuvant chemotherapy had a positive impact on DFS and OS in patients with high-risk extremity STS	*Calculated OR overall survival to four years: OR = 0.54; 95% CI: 0.25–1.18; p = 0.12*

Literature Reference	Study Design Quality of evidence	No. of Patients	Results	Conclusions	Statistical Significance: Overall Survival Related to Intervention
Frustaci et al.[18]	RCT High	104	Further follow-up of prior experimental group showed that DFS and OS differences in treatment arm vs control group no longer statistically different	The previously observed overall survival benefit loses statistical significance at later time points Therefore, time to recurrence may be lengthened, but overall survival at further follow up is the same	*Calculated OR overall survival to 89.6 months: OR = 0.538; 95% CI: 0.25–1.17; p = 0.12*
Cormier et al.[19]	Retrospective Low	674	Median follow-up 6.1 years Use of chemotherapy is associated with time-varying clinical effects	Clinical benefits associated with doxorubicin-based chemotherapy are not sustained beyond 1 year	Reported HR DSS at 12 months: HR = 0.37; 95% CI: 0.20–0.69; p = 0.002 Reported HR after 12 months: HR = 1.36; 95% CI: 1.02– 1.81; p = 0.04

Literature Reference	Study Design Quality of evidence	No. of Patients	Results	Conclusions	Statistical Significance: Overall Survival Related to Intervention
Pervaiz et al.[20]	Meta-analysis High	1953	OR for local recurrence was 0.73 in favor of chemotherapy For distant and overall recurrence, OR 0.67 in favor of chemotherapy Regarding survival, OR for doxorubicin with IF was 0.56 in favor of chemotherapy	Analysis confirms marginal efficacy of chemotherapy with respect to LRFS, DRFS, and DSS	Reported: OS doxo-alone based therapies: OR = 0.84; 95% CI: 0.68–1.03; p = 0.09 OS doxo+ifos based therapies: OR = 0.56; 95% CI: 0.36–0.85; p = 0.01
Cochrane Gynaecological Cancer Group[15]	Cochrane Systematic Review High	1568□	LRFS R with chemo was 0.73. DRFS was 0.70 Overall survival was 0.75 Those correspond to significant absolute benefits of 6–10% at 10 years For OS, HR of 0.89 not statistically significant but does potentially represent absolute benefit of 4%	Doxorubicin-based chemo appears to significantly improve LRFS, DRFS, DFS, and trends toward improved OS	Reported HR = 0.89; 95% CI: 0.76–1.03; p = 0.12

Literature Reference	Study Design Quality of evidence	No. of Patients	Results	Conclusions	Statistical Significance: Overall Survival Related to Intervention
Eilber et al.[23]	Prospective Observation Low	101	4-year DSS of IF treated patients was 88% compared to 67% in no treatment group Treatment with IF associated with improved DRFS but not LRFS	IF-based chemotherapy associated with an improved DSS in adult patients with high-risk extremity synovial sarcoma	*Calculated OR overall survival to 48 months: OR 0.26; 95% CI: 0.10–0.67; p = 0.005*
Italiano et al.[24]	Retrospective Low	237 (SS)	Median follow-up 58 months Neither neoadjuvant or adjuvant chemotherapy (IF-containing regimen) had significant impact on DSS, LRFS, DRFS	Wide surgical excision of SS with adjuvant radiotherapy are accepted treatments Chemotherapy showed no statistically significant benefit	Reported HR = 1.62; 95% CI: 0.91–2.87; p = 0.099

Literature Reference	Study Design Quality of evidence	No. of Patients	Results	Conclusions	Statistical Significance: Overall Survival Related to Intervention
Woll et al.[21]	RCT	351	Adjuvant doxorubicin, IF vs no chemo, equal numbers received radiotherapy Median follow-up 7.99 years	Adjuvant chemotherapy with doxorubicin, IF in resected STS showed no benefit in relapse-free survival or OS	OS did not differ significantly between groups (HR = 0.94; 95% CI: 0.68–1.31; p = 0.72) nor did relapse-free survival (HR = 0.91; 95% CI: 0.67–1.22; p = 0.51) 5-year OS was 66.5% in the chemotherapy group and 67.8% in the control group
Le Cesne et al.[22]	Pooled analysis of 2 RCTs	819	Adjuvant chemotherapy vs no chemo Median follow-up 8.2 years	“Adjuvant chemotherapy for STS remains an investigational procedure and is not a routine standard of care”	Adjuvant chemotherapy did not improve OS but improved DFS, HR = 0.74; 95% CI: 0.60–0.92; p = 0.0056

Literature Reference	Study Design Quality of evidence	No. of Patients	Results	Conclusions	Statistical Significance: Overall Survival Related to Intervention
Vining et al.[25]	National Database Review	544 (SS)	131 patients (24% of cohort) received adjuvant chemotherapy in the National Cancer Data Base Median follow-up was 4.1 years OS was the primary endpoint	Adjuvant chemotherapy prolonged OS only for stage III SS patients	Chemotherapy, overall cohort: 0.95; 95% CI: 0.63–1.44; p = 0.811 Stage I: 4.80 (95% CI: 0.91–25.3) p = 0.065 Stage IIA: 1.32 (95% CI: 0.54–3.20) p = 0.541 Stage IIB: 0.36 (95% CI: 0.07–1.76) p = 0.205 Stage III: 0.56 (95% CI: 0.33–0.93) p = 0.028

IF: ifosfamide, DSS: disease-specific survival, DFS: disease free survival, DRFS: distant recurrence free survival, LRFS: local recurrence free survival, OR: odds ratio, SS: synovial sarcoma, OS: overall survival, NeoCT: neoadjuvant chemotherapy, □1568: number of patients pooled from 14 trials, Reported: authors report OR/CI in published manuscripts, Calculated: authors of this review have calculated OR/CI to improve statistical validity of analysis, N/A – did not address overall survival reported between control (no chemo) and experimental (chemo group)

Top two questions

1. In patients with STS, is there a role for neoadjuvant chemotherapy in the treatment of the disease?
2. In patients with STS, is there a role for adjuvant chemotherapy in the treatment of the disease?

Question 1: In patients with STS, is there a role for neoadjuvant chemotherapy in the treatment of the disease?

Rationale

A multimodal approach utilizing radiation and surgery achieves excellent local control. Using successful osteosarcoma treatment regimens as a model, the question raised was whether pretreatment of STS with chemotherapy would result in significant

tumor necrosis thereby facilitating wide resection, and would also decrease the incidence of distant disease.[1,2]

Clinical comment

Current opinion suggests that administration of neoadjuvant chemotherapy does not improve overall survival, except in specific subtypes of STS known to be chemo-sensitive.

Available literature and quality of the evidence

- Level I: 3 randomized controlled trials (RCTs).
- Level IV: 0 prospective case series and 1 retrospective review.

In general, level I evidence still does not exist to justify administration of neoadjuvant chemotherapy in the setting of localized, high-risk STS. Since the prior edition, three RCTs have been performed involving neoadjuvant chemotherapy. Gronchi et al. looked at three cycles of epirubicin and ifosfamide (EI) neoadjuvant chemo compared to three cycles of neoadjuvant chemo followed by two cycles of adjuvant chemo. The three neoadjuvant cycles alone were not inferior to the five cycles. However, a control arm of no chemotherapy was not used to establish baseline survival.[3] The question of the efficacy of histologic subtype-specific chemo regimens was investigated in an RCT as well. Patients were randomized to either standard neoadjuvant EI chemo or histology-specific regimens for the following five subtypes: high-grade myxoid liposarcoma, leiomyosarcoma, synovial sarcoma, malignant peripheral nerve sheath tumor, and undifferentiated pleomorphic sarcoma. Unfortunately, the trial was stopped early due to significantly worse results ($p < 0.006$) in the histology-specific regimen group.[4] This trial did not have a control arm of no chemotherapy either to establish baseline survival. In a study by Issels et al. patients were randomly assigned to either neoadjuvant chemotherapy consisting of doxorubicin, ifosfamide, and etoposide alone, or combined with regional hyperthermia. Mean follow-up was 11.3 years. Regional hyperthermia plus neoadjuvant chemotherapy had statistically significant prolongation of survival ($p = 0.04$) and local progression-free survival ($p = 0.002$). Unfortunately, again, this study lacked a control arm of no chemotherapy to establish baseline survival.[5]

Pennington et al. reported long-term retrospective results of neoadjuvant chemoradiotherapy for 116 extremity STS patients with a median follow-up of 5.9 years at a single center. Local control was deemed *acceptable* in this study, but the overall survival was unfortunately found to be similar to randomized studies treating STS with surgery and radiotherapy only.[6]

A retrospective review of 48 extremity STS patients treated with neoadjuvant mesna, doxorubicin, ifosfamide, and dacarbazine (MAID) and radiotherapy followed by three cycles of adjuvant MAID and 16 Gy postoperative radiotherapy was compared to a historical matched-control patient population at a single center. Median follow-up was 9.3 years. Disease-specific and overall survival were significantly better in the intensive chemotherapy group.[7]

Eilber et al., in small group of patients, demonstrated that complete response to chemo (≥95% necrosis), translated clinically into an improved 10-year local recurrence free rate of 11% versus 23% and 10-year overall survival of 71 versus 55%.[8]

However, most prior studies reported no difference in oncologic outcome in patients treated with neoadjuvant chemotherapy. This may or may not be because these studies were underpowered. Menendez et al. showed no statistical significance in recurrence free or overall survival in patients who received 3–4 cycles of neoadjuvant doxorubicin, ifosfamide, and cisplatin.[9] However, power analysis indicated that the necessary sample size to show an improvement in recurrence-free or overall survival would be 532 patients, and that study reviewed only 82 patients after exclusion criteria were considered. The European Organization for Research and Treatment of Cancer (EORTC) organized an RCT comparing neoadjuvant doxorubicin and ifosfamide in high-risk adult STS. No difference in overall or disease-free survival was noted and the study was closed early due to poor patient accrual.[10] Pisters et al. reported a retrospective review of 76 patients with stage IIIB STS, treated with neoadjuvant chemo with doxorubicin regimens.[11] They found that there was no statistically significant difference in local recurrence-free survival, distant metastases-free survival, disease-free survival, or overall survival between responders and nonresponders (characterized radiographically). The implication was that even the purported advantage of neoadjuvant chemotherapy administration (decrease in tumor size and increase tumor kill) did not correlate to improved oncologic outcomes.

The value of neoadjuvant chemotherapy to aid in margin-negative resection has been further investigated. Previously, Meric et al. showed that out of 105 patients treated with neoadjuvant chemotherapy, only 12% responded enough to simplify their surgical procedure, and in addition 9% required a larger surgery because the tumor progressed while the patient was on chemotherapy.[12] Despite that result, in the group that did demonstrate radiographic response, there were an increased number of margin-negative resections, fewer local failures, and improved overall survival when compared to patients with no radiographic response.

O'Donnell et al. analyzed 28 high-grade extremity STS sarcomas larger than 5 cm that were treated with neoadjuvant chemotherapy and surgery compared to 47 matched controls treated with surgery alone. Histologic evaluation of the pseudocapsules of the tumors were performed and compared between the groups. The neoadjuvant chemotherapy treated tumors more frequently had well-defined pseudocapsules that were more frequently continuous and thicker than the surgery alone group. The neoadjuvant chemotherapy treated tumors also had less malignant cells identified within and beyond the pseudocapsule. No clinical comparisons looking at local recurrence rates or survival were performed between the two groups.[13] An additional study with similar methodology had similar results with the combination of neoadjuvant chemotherapy and radiotherapy having the highest capsular integrity and the thickest capsule. However, no clinical comparison looking at local recurrence rates or survival was performed between the two groups in this study either.[14]

Ultimately, the evidence still does not support a definitive survival benefit in patients treated with neoadjuvant chemotherapy. As shown in Table 168.1A, reported and calculated ORs show no statistical significance in a correlation between neoadjuvant chemotherapy administration and overall survival.[3–12] In addition, it remains unclear whether there is even a survival benefit difference observed between chemotherapy responders and nonresponders.

Resolution of clinical scenario

- Administration of neoadjuvant chemotherapy is not beneficial in the treatment of localized high-risk STS, as there is no difference in overall survival or disease-free

survival, and surgical resectability has not been definitively improved by its administration (overall quality: very low).

Question 2: In patients with STS, is there a role for adjuvant chemotherapy in the treatment of the disease?

Case clarification

Another treatment option for the patient presented would be to initiate treatment with a combination of radiation and wide surgical resection, and then refer for adjuvant chemotherapy. The theoretic benefit of adjuvant chemotherapy would be to improve disease-free survival rates by eliminating micro-metastases.

Clinical elevance

A multimodal approach utilizing radiation and surgery achieves excellent local control. However, despite local control, distant metastases are not controlled. Adjuvant chemotherapy potentially could address unrecognized micro-metastases in high-risk patients.

Clinical comment

Current opinion suggests that administration of adjuvant chemotherapy has marginal efficacy, and its benefits may be outweighed by the significant associated toxicities.

Available literature and quality of the evidence

- Level I: 1 systematic reviews/meta-analyses/database analysis and 2 RCTs.

Findings

The best prior evidence, summarized in the Cochrane review from 2000, suggested that doxorubicin-based adjuvant chemotherapy improves time to local and distant recurrence and overall recurrence-free survival in adults with resectable sarcoma. A trend toward overall improved survival was also observed.[15]

The Sarcoma Meta-analysis Collaboration (SMAC) formed and reported in 1997 on 1568 with localized, resectable disease treated in a series of 14 doxorubicin-based trials. With a median follow-up of 9.4 years, they reported statistically significant treatment effects including decreased risk of local recurrence (27% decrease, absolute benefit of 6%), decreased risk of distant disease (30% reduction in risk, absolute benefit of 10%) at 10 years. There was a trend toward improved overall survival which was not statistically significant (HR = 0.89; 95% confidence interval [CI]: 0.76–1.03; p = 0.12). However, in a specific subgroup (high grade, large, extremity sarcomas) there was a clear survival advantage (7% at 10 years).[16]

Based on that meta-analysis, an RCT designed to assess the clinical efficacy of combined doxorubicin and high-dose ifosfamide therapy was initiated by the Italian Sarcoma Group.[17] Initial results comparing outcomes of patients with extremity and pelvic sarcomas treated either with resection and adjuvant radiation, or with resection, radiation and adjuvant 4'-epidoxorubicin and ifosfamide demonstrated a statistically significant difference between the treatment and control groups. There were observed improvements in median disease-free survival (48 months vs 16

months), median survival (75 months vs 46 months), and an absolute survival benefit of 13% at two years and 19% at four years *(calculated OR overall survival to four years: OR = 0.539; 95% CI: 0.247–1.177; p = 0.12)*. The study was stopped, based on the conclusion that chemotherapy afforded improved oncologic outcomes. However, the same 140 patients were subsequently evaluated in 2003.[18] Now with longer follow-up (89.6 months), the previously observed survival benefit was no longer statistically significant (*calculated OR overall survival to 89.6 months: OR = 0.538; 95% CI: 0.247–1.172; p = 0.11)*.

Additional studies also failed to find a treatment benefit. A retrospective review of 674 patients out of Sloan Kettering and MD Anderson reported that positive treatment effects from adjuvant doxorubicin were not sustained for greater than one year (reported HR disease-specific survival (DSS) at 12 months: HR = 0.37; 95% CI: 0.20–0.69; p = 0.002. Reported HR after 12 months: HR = 1.36; 95% CI: 1.02–1.81; p = 0.04).[19]

However, a systemic meta-analysis of RCTs in 2008 identified a total of 18 trials (1953 patients).[20] That meta-analysis revealed a marginal efficacy with regards to local recurrence, distant recurrence, overall recurrence, and overall survival (OR = 0.8; 95% CI: 0.68–1.03; p = 0.09) that is slightly enhanced with combination doxorubicin and ifosfamide therapy. This is considered strong evidence supporting the efficacy of ifosfamide, but the marginal improvement must be weighed against potential toxicity.

The 2000 Cochrane review determined that adjuvant chemotherapy slightly improved the time to local and distant recurrence, and overall recurrence-free survival in adults with localized, resectable STS, with a trend toward improved overall survival (14 trials including 1568 patients: reported HR = 0.89; 95% CI: 0.76–1.03; p = 0.12).[15]

Since 2000, the evidence supporting adjuvant chemotherapy remains poor. Two RCTs have been published since 2000. The EORTC 62931 trial randomized 351 patients to either five cycles of doxorubicin, ifosfamide, or lenograstim, or no chemotherapy. Equal numbers of patients in each group received radiotherapy. Overall survival, relapse-free survival, and five-year overall survival rate were not statistically different between the groups. The authors concluded adjuvant chemotherapy provided no benefit.[21] A pooled analysis of two phase III trials (Soft Tissue and Bone Sarcoma Group [STBSG], EORTC) was performed which analyzed 819 patients with a median follow-up of 8.2 years receiving doxorubicin-based chemotherapy (CT) found no benefit in overall survival and stated “adjuvant CT for STS remains an investigational procedure and is not a routine standard of care.”[22]

The above analysis primarily focuses on adult STS without further delineating subtypes. Within the heading of STS, there are specific tumors that have characteristic genetic translocations which potentiate more accurate classification. Improved classification translates into better evidence because of more homogeneous study populations. One example is synovial sarcoma.

In the case of synovial sarcoma, there is some evidence to suggest that adjuvant chemotherapy might improve oncologic outcomes, and therefore chemotherapy may be a reasonable intervention in those patients. In a recent prospective study of 101 patients, ifosfamide-based therapy was associated with an improved DSS in adult patients with high-risk, primary, extremity synovial sarcomas.[23] In that study, 67 patients were treated with IF and 33% received no therapy (NoC). The four-year DSS of the IF-treated patients was 88% compared with 67% for the NoC patients (p = 0.01) (*calculated OR overall survival to 48 months: OR = 0.262; 95% CI: 0.102–0.674;*

p = 0.005). Smaller size (HR = 0.3 per 5 cm decrease; p <0.0001) and treatment with IF (HR = 0.3 compared with NoC; *p* = 0.007) were independently associated with an improved DSS. Treatment with IF was independently associated with an improved distant recurrence-free survival (HR = 0.4; *p* = 0.03) but not associated with an improved local recurrence-free survival (*p* = 0.39). However, even with synovial sarcoma there is conflicting evidence. A retrospective analysis of 237 patients with a median follow-up of 58 months, neither neoadjuvant nor adjuvant chemotherapy has a significant impact on overall survival, local recurrence-free survival, or distant recurrence free survival.[24]

A 2017 review of the National Cancer Data Base identified 544 patients with Synovial Sarcoma of which 131 received adjuvant chemotherapy. After stratification of patients by sarcoma stage, prolonged overall survival was found in stage III patients only (p = 0.033).[25]

Therefore, synovial sarcoma in adults is often treated like other STSs, and chemotherapy is reserved for high-risk tumors or metastatic disease at presentation. If adjuvant chemotherapy is offered, combination doxorubicin and ifosfamide is prescribed in appropriate patients.

Resolution of clinical scenario

- Administration of adjuvant chemotherapy in the setting of high-grade, large extremity sarcomas may result in a longer time intervals until local or distant recurrences. There is a trend, and perhaps statistically significant marginal improvement, in survival in those patients, and therefore in patients who can tolerate chemotherapy side effects, chemotherapy could be offered as an adjuvant (overall quality: high).
- There is not overwhelming evidence of a significant oncologic benefit in treating synovial sarcoma with adjuvant chemotherapy. There is evidence of increased tumor sensitivity to ifosfamide, and therefore synovial sarcoma should be treated with meticulous surgical resection and neoadjuvant or adjuvant radiation. Chemotherapy, utilizing doxorubicin and ifosfamide, may be indicated in the treatment of high-risk patients or patients with metastatic disease at presentation (overall quality: low.)

Summary of answers

- Administration of neoadjuvant chemotherapy is not beneficial in the treatment of localized high-risk STS, as there is no difference in overall survival or disease-free survival, and surgical respectability is not definitively improved by its administration (overall quality: very low).
- Administration of adjuvant chemotherapy in the setting of high-grade, large extremity sarcomas may result in a longer time interval until local or distant recurrences. There is a trend, and perhaps statistically significant marginal improvement, in survival in those patients, and therefore in patients who can tolerate chemotherapy side effects, chemotherapy could be offered as an adjuvant (overall quality: high).
- There is not overwhelming evidence of a significant oncologic benefit in treating synovial sarcoma with adjuvant chemotherapy. There is evidence of increased tumor sensitivity to ifosfamide, and therefore synovial sarcoma should be treated

with meticulous surgical resection and neoadjuvant or adjuvant radiation. Chemotherapy, utilizing doxorubicin and ifosfamide, may be indicated in the treatment of high-risk patients or patients with metastatic disease at presentation (overall quality: low).

Conclusion

Despite excellent strategies in STS local control, adjuvant chemotherapy offers only marginal efficacy in the treatment of STS. The evidence supporting this marginal efficacy is considered to be high quality (Table 168.1A). Chemotherapy administered in the neoadjuvant setting does not definitively result in easier resections, but the pseudocapsule of the tumor is likely better defined and thicker when chemotherapy is given. The addition of neoadjuvant regional hyperthermia may improve STS outcomes. Adjuvant chemotherapy may result in improved survival in patients with large, high-grade isolated extremity sarcomas. The inherent difficulty in achieving adequate statistical power in this patient population has resulted in studies that are poorly powered to determine the presence of true statistical significance.

Possible advances in systemic treatment for STS are ongoing with several trials looking at new medicines, which hopefully can offer more effective treatment with less toxicity than doxorubicin-based regimens. New treatment modalities such as immunotherapy have shown benefit in metastatic sarcoma in phase II trials,[26,27] but are outside the scope of this chapter. A current phase II trial of immunotherapy in histologic subsets of localized STS is actively recruiting.[28] Unfortunately, at this time, no systemic therapy regimen currently has shown superior efficacy to doxorubicin-based chemotherapy regimens

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169 Surgical Margins in Soft Tissue Sarcoma

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Clinical scenario

- A 48-year-old woman has had a 6 cm mass in the anterior compartment of the leg for about three months (Figure 169.1). She requests that it be removed during the same anesthetic as an elective abdominal procedure. The leg tumor is removed with positive margins. The diagnosis is benign angiomyxoma.
- Sixteen months later there is progressive enlargement of a mass in the same area. Surgical excision is performed, removing 15 cm of fascia and tissue, with an intended clinical margin of 2 cm.
- Pathology shows that the tumor was a 5 cm recurrent high-grade myxofibrosarcoma (MFS). The margins are focally positive. Re-excision is done. No tumor is found on final pathology review. Systemic staging is negative for metastases. Chemotherapy is declined by the patient. Adjuvant 50 Gy radiotherapy is given. Follow-up shows no local or systemic recurrence.

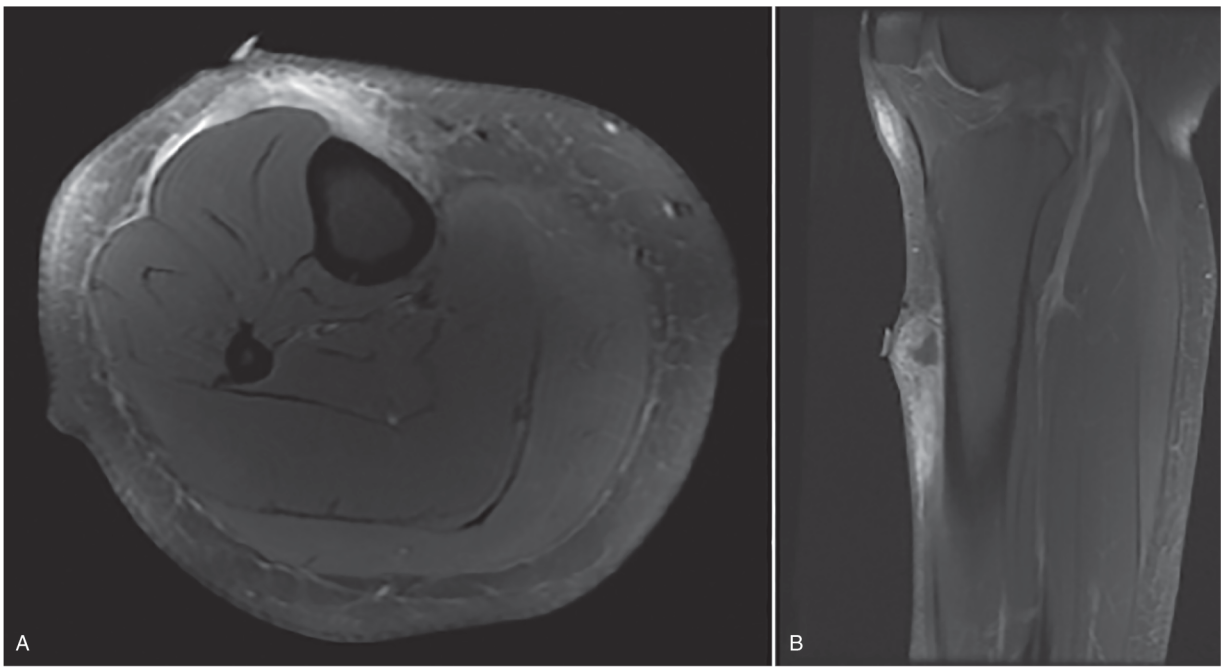

Figure 169.1 T2 weighted images in axial (A) and sagittal (B) view. A hyperintense enhancing signal is extending over 11 cm in the muscle, subcutaneous tissue, along the fascia, and over the tibial periosteum. Source: Eugenia Schwarzkopf, Tomohiro Fujiwara, John H. Healey.

Top three questions

1. Is surgical tumor excision with narrow margins associated with a higher rate of local recurrence than wide margins in patients with localized soft tissue sarcomas (STS)?
2. Does the use of pre- or postoperative radiation therapy (XRT) alter the impact of surgical margins on local recurrence in patients with localized STS?
3. How does the histological subtype affect the relationship between surgical margins and local recurrence among patients with localized STS?

Question 1: Is surgical tumor excision with narrow margins associated with a higher rate of local recurrence than wide margins in patients with localized soft tissue sarcomas (STS)?

Rationale

A balance between adequate surgical margins and preservation of important anatomical structures is required for optimal patient outcomes.

Clinical comment

Oncologically sufficient surgical excision of STS remains indispensable for the cure of patients.

Available literature and quality of the evidence

Level IV studies are available to answer this question.

Findings

Local management of STS requires a surgical margin including a cuff of normal tissue to minimize the risk of local recurrence. The impact of margin status on rate of local recurrence in extremity STS patients is the objective of several studies, but the findings differ.

In a retrospective analysis of prospectively collected data, Potter et al. evaluated the impact of margin status and local recurrence on survival in 363 patients who underwent resection of localized primary extremity STS. Positive margins (hazard ratio [HR] = 1.99; 95% confidence interval [CI]: 1.15–3.45) were significantly associated with worse overall survival on multivariate analysis. For disease-specific survival, positive margins (HR = 1.95; 95% CI:

1.05–3.63) were independent adverse prognostic factors. However, margin width was not discussed.[1] Bonvalot et al. evaluated margin adequacy in the local treatment of extremity STS and assessed the relationship between local control and overall survival. The authors reviewed 531 patients who underwent surgery with or without (neo)adjuvant treatment. In a multivariate analysis, specific subtypes such as epithelioid sarcoma and MFS and surgical margin size <1 mm were correlated with a higher rate of local recurrence. However, neither margin status nor local recurrence affected overall survival in this study.[2] In a retrospective review of 997 patients, Gronchi et al. obtained different results. Ten-year mortality estimates (95% CI) were 0.19 in R0 cases and 0.38 in R1 cases (p = 0.0003). Size, grade, depth, and histologic subtype were also significant predictors of mortality. Furthermore, surgical margins independently predicted local control and survival.[3] In a retrospective multicenter study, Willeumier et al. investigated the effect of surgical margins and radiotherapy on survival in 687 patients with primary high-grade STS of the extremities. Wide surgical margins decreased local recurrence risk but had little effect on survival.[4] Ahmad et al. analyzed the significance of resection margin status and quantitative margin width on outcomes of 382 patients with localized extremity or truncal STS who underwent limb-sparing surgery and XRT. A total of 235 patients had reported quantitative negative margin widths of ≤1 mm (n = 128), >1 mm and ≤5 mm (n = 79), and >5 mm (n = 28). There were no differences in rates of local or distant recurrence nor of any survival outcome based on negative surgical margin width. However, these conclusions must not be applied to patients who undergo surgery alone.[5] In a large retrospective study, Harati et al. assessed the relationship between local recurrence-free, disease-specific, and metastasis-free

survival and potential prognostic factors in 643 patients. Microscopically negative margins (R0) were associated with better local recurrence-free, disease-specific, and metastasis-free survival regardless of whether adjuvant radiation was administered. Within the R0 subgroup, univariate and multivariate analyses of categorized (≤1 mm vs 1–5 mm vs >5 mm) and noncategorized margin widths revealed that close and wide negative margins led to similar outcomes.[6]

To summarize, surgical margins were associated with local recurrence-free survival in localized STS of the extremity. However, the impact of the specific width of the surgical margin has not been sufficiently investigated.

Resolution of clinical scenario

This case exemplifies the so-called whoops procedure, where a lesion is removed in a nononcologic way, often with positive surgical margins. A re-resection was necessary to achieve negative margins and reduce the risk of tumor recurrence and distant metastasis.

Question 2: Does the use of pre- or postoperative radiation therapy (XRT) alter the impact of surgical margin on local recurrence in patients with localized STS?

Rationale

XRT is used to facilitate local control in multidisciplinary treatment of STS.

Clinical comment

XRT can be administered pre- or postoperatively. The relevance of the timing of administration remains open to debate.

Available literature and quality of the evidence

Level I studies and level IV studies are available to answer this question.

Findings

Local management of extremity STS consists of surgery combined with adjuvant treatment modalities in a multidisciplinary setting. The aim of this strategy is to have maximum local control while preserving function. However, the timing of XRT remains open to debate.

In a randomized prospective study, Yang et al. assessed the impact of postoperative external-beam XRT on local recurrence and overall survival. Ninety-one patients with high-grade sarcomas and 50 patients with low-grade lesions were randomized for postoperative XRT or surgery alone. A highly significant decrease in the probability of local recurrence was seen in patients with high- and low-grade lesions who received radiation ($p = 0.0028$ and $p = 0.016$, respectively), but no difference in overall survival was shown.[7] However, this study should be interpreted with caution since preoperative XRT was not included. Another randomized controlled trial was done by O'Sullivan et al. The authors randomized 190 patients for pre- or postoperative XRT. In this study, the rates of local recurrence ($p = 0.7119$), regional/distant recurrence ($p = 0.7911$), and progression-free survival ($p = 0.8349$) did not differ significantly between the two groups. Overall survival was slightly better in patients who had preoperative XRT ($p = 0.0481$).[8]

However, several studies have obtained different results. In a multi-institutional analysis of 821 patients, Sampath et al. evaluated 821 STS patients. Preoperative XRT was associated with significantly improved overall and disease-specific survival compared with postoperative XRT. Furthermore, preoperative radiation was associated with a reduced risk for local and distant relapse compared with postoperative administration.[9] A National Cancer Database (USA) analysis by Gingrich et al. compared the impact of XRT on rates of R0 resection and overall survival in extremity STS patients undergoing surgery; patients who received preoperative, postoperative, and no XRT were included in this study. The rates of R0 resection were 90.1% for the preoperative, 74.9% for the postoperative, and 79.9% for the no-XRT cohort ($p < 0.001$). Preoperative XRT independently predicted higher rates of R0 resection (odds ratio [OR] = 1.83; 95% CI: 1.61–2.07). Both R0 resection and pre-/postoperative XRT were associated with improved overall survival. However, the impact of XRT on local recurrence was not reported.[10] Al Yami et al. retrospectively reviewed extremity STS patients with a positive surgical margin after preoperative XRT. Fifty-two patients were treated with preoperative XRT alone (50 Gy), whereas 41 received preoperative XRT plus a postoperative boost (80% received 16 Gy postoperatively for a total of 66 Gy). The authors found that including the postoperative radiation boost after preoperative radiation and a margin-positive excision did not provide an advantage in preventing local recurrence. Five-year estimated local recurrence-free survival with and without postoperative radiation boost was 73.8% and 90.4%, respectively ($p = 0.13$).[11] Müller et al. performed a large retrospective study and analyzed 769 patients with high-grade STS of the extremities, who underwent a limb-sparing surgery. Eighty-nine patients were treated with neoadjuvant XRT, 315

patients with adjuvant irradiation, and 365 patients with surgery alone. Neoadjuvant XRT provided the best local recurrence-free rate for five years (90.0%), whereas after 10 years (78.3%) adjuvant irradiation showed better local control. The metastatic-free rate was independent from achieved surgical margins ($p = 0.179$).[12] Regarding the timing of administration of XRT, another relevant factor must be considered: wound healing complications, which occur twice as often after preoperative XRT. They are particularly common in the lower extremities of older patients, perhaps due to poorer vascularity in those locations.[13]

In conclusion, there are insufficient data to establish that preoperative XRT is favorable compared to postoperative XRT for local control and overall survival in extremity STS patients.

Resolution of clinical scenario

New technology is needed to identify residual cancer cells in the tumor bed so they can be removed at the time of surgery and not depend on adjuvant therapy. However, (neo)adjuvant XRT can be a useful tool to eradicate residual sarcoma and give the highest chance for achieving a negative surgical margin, as discussed in our clinical scenario.

Question 3: How does the histological subtype affect the relationship between surgical margins and local recurrence among patients with localized STS?

Rationale

The impact of surgical margin on outcome varies depending on the histological subtype of the STS.

Clinical comment

To reduce the risk of local recurrence, surgeons should take into consideration the histological subtypes and their biological features.

Available literature and quality of the evidence

Level IV studies are available to answer this question.

Findings

STS are a heterogeneous group of more than 50 different histological subtypes with a variety of biological behaviors.[14] Decision-making about adequate margins should incorporate any available data on whether the specific histological subtype is infiltrative in nature.

MFS and undifferentiated pleomorphic sarcoma (UPS) frequently exhibit an infiltrative growth pattern, which has been associated with inadequate/positive margin rates of 29–67% and local recurrence rates of 20–62%.[15–18] The infiltrative growth pattern in malignant fibrous histiocytoma (MFH) was first reported in 1999 by Fanburg-Smith et al., who observed pathological infiltration in 83% of patients with superficial MFH and in 24% of deep MFH.[15] Since then, this growth pattern has been documented on magnetic resonance imaging (MRI), and correlation between radiological and pathological infiltration ranges from 87 to 100%.[15,17] In a retrospective review of 89 patients diagnosed with MFS or UPS, Iwata et al. observed an infiltrative growth pattern in 36% of MFS and 22% of UPS on preoperative MRI, which was described as a tail-like extensive lesion along the normal fascial plane.[16] Although their surgical protocol was to excise 2–3

cm from the edge of the tumor extension on imaging studies, the surgical margin was positive in 48% (n = 43/89) and five-year local recurrence-free survival was 81%. These outcomes collectively underscore the difficulty of achieving wide margins for infiltrative subtypes. In a recent retrospective review of 18 patients with superficial MFS and UPS who were treated with preoperative XRT and surgery, Imanishi et al. reported that 60% of UPS (n = 6/10), but no MFS patients were classified as nearly complete-response (≥95% nonviable area) with the nonviable proportion of the remaining 12 cases ranging from 0 to 90%.[18] Tail sign was pathologically confirmed in 13 patients, eight (62%) of which remained viable. They observed that these patients with viable residual tumor cells in the tail were associated with a relatively high ratio of positive margins (25%, n = 2/8) and local recurrence (38%, n = 3/8), concluding that wider surgical margins, safely including the tail sign based on preoperative MRI before XRT if combined, should be chosen. Gronchi et al. described that wide surgical margins with 2–4 cm beyond the clinical boundaries of the palpable mass should be the goal of surgery for these subtypes.[19] The rationale could be supported by the observations of Imanishi et al.; there was no major differences in the tail length between on the glass slides and on the T1 postcontrast (mean 23.6 mm; range 5–36 mm) and fat-saturated MRI (mean 26.0 mm; range 7–79 mm).[18]

In contrast, atypical lipomatous tumor (ALT)/well-differentiated liposarcoma (WDLS) is a relatively common subgroup of liposarcomas and marginal margin for this subtype is allowed by several guidelines.[20],[21] However, Mussi et al. described that simple resection, which consists of a *shell-out* procedure without inclusion of a muscle/soft tissue cuff around the mass, should be avoided, because this procedure was associated with a higher risk of

intraoperative tumor rupture, which was an independent prognostic factor for local recurrence (HR = 4.37; 95% CI: 1.23–15.56).[22]

In conclusion, surgeons should be mindful of the histological subtype and associated biological behavior in surgical planning. Although the ideal margin of excision remains debatable, a wider margin is advisable, especially for infiltrative STS, and the use of intraoperative frozen sections may be helpful as an additional guide for the extent of tissue excision.

Resolution of clinical scenario

Margin assessment of different types of sarcoma is difficult to evaluate. Hyperintense signal commonly spreads along the fascia, creating so-called tails. These may or may not contain cancer cells or be just inflammatory reactive tissue. The best oncologic treatment is to resect the questionable tissue to give the lowest risk of local recurrence and distant metastasis.

Summary of answers

- Positive surgical margins were associated with worse local recurrence-free survival in localized STS of the extremities.
- There are insufficient data to establish that preoperative XRT is favorable compared to postoperative XRT for local control and overall survival in extremity STS patients.
- A wider margin (>4 cm) is advised for histologic subtypes of STS with infiltrative growth.

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170 Allograft versus Megaprosthesis

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Clinical scenario (proximal humerus)

- A 13-year-old female presents with a three-month history of left shoulder pain that awakens her at night.
- Open biopsy is consistent with Ewing's sarcoma. Resection and reconstruction are planned.

Clinical scenario (proximal tibia)

- A 45-year-old female presents with a six-week history of knee pain.
- Open biopsy is consistent with high-grade dedifferentiated chondrosarcoma. Resection and reconstruction are planned.

Rationale

An estimated 3600 new primary bone cancers will be diagnosed in the United States in 2020, causing 1720

deaths.[1] With advances in chemotherapy and imaging, it is now possible to provide limb salvage surgery in 90–95% of patients.[2–5] With longer patient survival, it is important that a durable reconstruction follows tumor resection.

Clinical comment

Three common means of reconstruction have been used after periarticular tumor resection: osteoarticular allograft, allograft-prosthetic composite (APC), and endoprosthesis. An osteoarticular allograft reconstruction utilizes a matched cadaver bone that is affixed to host bone via plate/screw construct or intramedullary nail fixation. APCs combine an osteoarticular allograft that is skewered with a joint replacing prosthesis. Endoprostheses replace resected bone with a metal implant cemented or press fit into remaining host bone.

There are many advantages and disadvantages of each method of reconstruction. An important advantage of an osteoarticular allograft is the ability to repair host soft tissue to donor tendon/ligament attachments. Disadvantages of osteoarticular allografts include allograft fracture, host-allograft nonunion, infection, and secondary osteoarthritis. Advantages of endoprostheses include immediate use, modularity, and ease of reconstruction while disadvantages consist of aseptic loosening and wear. APCs provide donor soft tissue attachments for repair and prevent late osteoarthritis by resurfacing the joint, but carry the risk of allograft fracture and nonunion, infection, and the technical challenge of the reconstruction.

Although any anatomic location may be subject to tumor invasion requiring reconstruction, currently the most controversial sites of reconstruction are the proximal humerus and proximal tibia as choices of reconstruction are largely based on individual surgeon experience and

preference without universal agreement on optimal care. Thus, this chapter will focus on these two anatomic locations. The following questions will be addressed in each section.

Available literature and quality of the evidence

Literature review found nine articles meeting the criteria for osteoarticular allografts in the proximal humerus, seven articles for APCs, and 16 articles for endoprostheses.[6–32]

Literature review found seven articles meeting the criteria for osteoarticular allografts in the proximal tibia, four articles for APC, and 17 articles for endoprostheses.[6,8,9,33–54]

Top three questions

1. In patients receiving allograft megaprosthesis, what is the comparative risk of postoperative complications between osteoarticular allografts, APCs, and endoprostheses?
2. In patients receiving allograft megaprosthesis, what are the comparative functional outcomes between osteoarticular allografts, APCs, and endoprostheses via Musculoskeletal Tumor Society (MSTS) score or range of motion, if applicable?
3. In patients receiving allograft megaprosthesis, what is the comparative success of limb salvage and implant survival at 5, 10, and 20 years between osteoarticular allografts, APCs, and endoprostheses?

Question 1: In patients receiving allograft megaprosthesis, what is the comparative risk of postoperative complications between osteoarticular allografts, APCs, and endoprostheses?

Proximal humerus

Pooled data showed 1.3% deep infection in proximal humerus endoprostheses, 6.7% in osteoarticular allografts, and 6% in APCs. The rate of deep infection is significantly lower in endoprostheses when compared to osteoarticular allografts (relative risk [RR] = 0.19; 95% confidence interval [CI]: 0.07–0.47, p <0.001) and APCs (RR = 0.21; 95% CI: 0.08–0.58, p = 0.001).

Local recurrence occurred in 7.3% of endoprostheses, 10% of osteoarticular allografts, and 6% of APCs. These differences were not statistically significant.

Aseptic loosening occurred in 5.5% of endoprostheses and in 4.7% of APCs. These differences were not statistically significant.

Implant fractures occurred in 1.0% of endoprostheses. Periprosthetic fractures occurred in 0.2% of endoprostheses, 1.8% of osteoarticular allograft studies, and in 0% of APCs. Allograft fracture occurred in 30.8% of osteoarticular allografts and only 6.7% of APCs, reaching statistical significance (RR = 0.22; 95% CI: 0.1–0.48, p <0.001).

Nonunion occurred in 10.5% of osteoarticular allografts, as well as 14.3% of APCs. These differences were not statistically significant.

Dislocation occurred in 5.7% of endoprostheses, 20.8% of osteoarticular allografts, and 10.3% of APCs. Thus, endoprostheses had a significantly lower rate of dislocation than osteoarticular allografts (RR = 0.27; 95% CI: 0.17–0.44, p <0.001). Endoprostheses had a lower rate of dislocation than APCs that was close to statistical significance (RR = 0.55; 95% CI: 0.29–1.03, p = 0.06). APCs had a significantly lower rate of dislocation than osteoarticular allografts as well (RR = 0.5; 95% CI: 0.26–0.94, p = 0.03).

Proximal tibia

Pooled data showed a deep infection rate of 15.0% in proximal tibia endoprostheses, 22.3% in osteoarticular allografts, and 16.5% in APCs. Endoprostheses had a significantly lower rate of infection compared to osteoarticular allografts (RR = 0.67; 95% CI: 0.49–0.91, p = 0.01). The differences in infection rate between endoprostheses and APCs and APCs and osteoarticular allografts were not statistically significant.

Local recurrence occurred in 5.4% of endoprostheses, 7.4% of osteoarticular allografts, and 5.9% of APCs. These differences were not statistically significant.

Aseptic loosening was similar between endoprostheses and APCs, occurring in 7.8% of endoprostheses and 9% of APCs, a difference without statistical significance. Within the endoprosthesis group, independent analysis of fixed versus rotating hinge designs was unable to be performed as studies including rotating hinges did not report separate aseptic loosening rates in this subgroup of their analysis. When comparing cemented versus uncemented prostheses, there was a significantly higher rate of aseptic loosening in cemented prostheses (RR = 8.53; 95% CI: 1.16–62.7, p = 0.035). Eleven percent of cemented endoprostheses had

aseptic loosening (five studies, 19 of 168 patients) versus 1.2% of uncemented endoprostheses (three studies, 1 of 83 patients).

Bushing failures requiring re-operation occurred in 7.1% of endoprostheses when recorded.

Implant fractures occurred in 2.7% of endoprostheses and 0% of APCs. Periprosthetic fractures occurred in 2.8% of endoprostheses. No periprosthetic fractures were reported in APCs. Allograft fractures occurred in 30.9% of osteoarticular allografts and in 10.9% of APCs which was statistically significant in favor of APCs (RR = 0.35; 95% CI: 0.2–0.62, p <0.001).

One of the unique challenges of reconstruction after resection of proximal tibia tumors is reconstruction of the extensor mechanism. Of the papers that reported on extensor mechanism failures, they were reported in 6.6% of endoprostheses and in 13.4% of APCs and 0% in osteoarticular allografts (0/97 patients). Osteoarticular allografts were significantly less likely to have extensor mechanism failure than endoprostheses (RR = 0.93; 95% CI: 0.9–0.97, p = 0.01) or APCs (RR = 0.87; 95% CI: 0.81–0.93, p <0.001). Endoprosthesis also had a statistically significantly decreased failure rate compared to APCs (RR = 0.49; 95% CI: 0.25–0.96, p = 0.03).

Three studies on endoprostheses looked at mean extensor lag, with means of 6, 18, and 30° reported. Thirty percent of patients with endoprostheses had an extensor lag >5° (24 of 79 patients, two studies, range 25–37%) as compared with 26% patients with APCs (10 of 38 patients, two studies, range 25–27%). Unfortunately, the articles on osteoarticular allografts did not comment on extensor mechanism failure or extensor lags.

Question 2: In patients receiving allograft megaprosthesis, what are the comparative functional outcomes between osteoarticular allografts, APCs, and endoprostheses via Musculoskeletal Tumor Society (MSTS) score or range of motion, if applicable?

Proximal humerus

The mean 1993 revised MSTS score was 73.6% (22 out of 30) in the endoprosthesis group, 72% in the osteoarticular allograft group, and 77% in the APC group.

Range of motion was infrequently reported. Endoprostheses had an overall mean of 40° abduction and 47° forward flexion Mean range of motion in osteoarticular allografts was abduction of 59° and forward flexion 47°. In APCs, a mean abduction of 55° and a mean forward flexion of 48° was reported.

Proximal tibia

The mean 1993 revised MSTS score was 76% (23.8 out of 30) in the endoprosthesis group, 77% in APCs, and 90% in osteoarticular allografts.

Question 3: In patients receiving allograft megaprosthesis, what is the comparative success of limb salvage and implant survival at 5, 10, and 20 years between osteoarticular allografts, APCs, and endoprostheses?

Proximal humerus

Amputation for any reason was required in 5.1% of patients with endoprostheses, in 10% of patients with osteoarticular allografts, and in 1.7% of APCs. These differences were not statistically significant.

Five-year survival based on Kaplan–Meier survival analysis in endoprostheses showed a range of 83–100%. The range in osteoarticular allografts was 56–78%, and was 90–91% in APCs. Mean 10-year survival rate in endoprostheses was a range of 42–93%. It was not reported in osteoarticular allografts, and was 88% in APCs based on one paper. Only the endoprosthesis group had a 20-year survival rate reported as 66.7–70%.

Mean revision rate for any reason for the endoprosthesis group was 12.8%, 37.2% for osteoarticular allografts, and 10% for APCs. Endoprostheses and APCs had a significantly lower rate of revision than osteoarticular allografts (RR = 0.34; 95% CI: 0.23–0.52, $p < 0.001$; RR = 0.27; 95% CI: 0.14–0.53, $p < 0.001$). There was no significant difference between endoprostheses and APCs. Re-operation rates were infrequently tabulated in the included studies and thus was not analyzed specifically.

The overall five-year survival appears similar between endoprostheses and APCs, both of which have a trend toward improved survival when compared to osteoarticular allografts. Follow-up studies are needed to better predict the 10- and 20-year survival rates of these reconstructions.

Osteoarticular allograft reconstructions have a statistically significant higher rate of revision operations when compared to endoprostheses and APCs.

The rate of deep infection is significantly lower in endoprostheses when compared to osteoarticular allografts and APCs.

Allograft fracture occurred in a high percentage of osteoarticular allografts (30.8%). This, along with the higher rate of deep infections, may account for the significantly higher rate of revision operations.

Interestingly, despite the common belief that osteoarticular allografts offer improved stability due to the ability to repair donor tendon/ligament attachments back to what remains of host soft tissue, osteoarticular allografts had a significantly higher rate of dislocation without any apparent improvement in range of motion or MSTS score. Endoprostheses had the lowest dislocation rate (6%) and APCs fell in between with 10.3%. Range of motion was similar in all groups and overall poor, with no reconstruction obtaining a mean abduction greater than 60° or forward flexion greater than 50°.

Proximal tibia

Amputation for any reason was required in 15.1% of patients with endoprostheses, in 7.5% of patients with APCs, and in 12.7% of patients with osteoarticular allografts. Amputations in the endoprosthesis group were

higher than APCs and it almost reached statistical significance (RR = 2.0; 95% CI: 0.97–4.15, p = 0.05).

The range of five-year survival rate based on Kaplan–Meier survival analysis was 54–84.5% in the endoprosthesis group. It was 45–78% in osteoarticular allografts and 68–73% in APCs. The 10-year survival rate range was 30–63%, 20–68% in osteoarticular allografts, and 33% in APCs. Only the endoprosthesis group had 20-year survival rates reported as 20.7 and 27% in two papers.

Mean revision rate for any reason for the endoprosthesis group was 35.7%, 36% in the osteoarticular allograft group, and 35.1% in the APC group. These differences were not statistically significant. Re-operation rates were infrequently tabulated in the included studies and thus were not analyzed specifically.

Resolution of clinical scenario

Proximal humerus

Though it is difficult to make strong recommendations as to the type of reconstruction that should be performed in the proximal humerus, it should be noted that osteoarticular allografts performed the worst in every outcome examined, with the exception of mean abduction. Endoprostheses and APCs performed quite similarly, with each appearing to be a viable reconstruction option.

Proximal tibia

Overall, proximal tibia reconstructions have the highest rates of amputation, the highest revision rates, and the shortest overall survival when compared to reconstructions in any other part of the body.

Five-year survival rates and revision rates were similar between the three methods of reconstruction; however,

more data are needed to compare the long-term survival of these reconstructions.

Using the data obtained, endoprostheses had a lower infection rate than osteoarticular allografts. APCs trended toward a significantly lower rate of amputation than endoprostheses. Extensor mechanism failure was significantly higher in both APCs and endoprostheses compared to osteoarticular allografts. APCs also had significantly more extensor mechanism failures than endoprostheses. There was no statistical difference between the groups in regards to local recurrence.

Aseptic loosening is similar between endoprostheses and APCs (7.8 and 9%, respectively). Allograft fracture is common, being seen in 30.9% of osteoarticular allografts, and 10.9% of APCs, significantly favoring APCs.

Based on the data points analyzed, it is not possible to definitively recommend one type of reconstruction over the other in the proximal tibia. However, it is important to note the differential risks between the three groups for fractures, deep infection, and extensor mechanism failure. There is a higher risk for fracture in osteoarticular allografts compared to peri-prosthetic fractures for APCs and endoprostheses. We also found a higher risk of deep infection in osteoarticular allografts compared to endoprostheses, and a higher risk of extensor mechanism failure in APCs and endoprostheses compared to osteoarticular allografts. APCs nearly had a statistically significant lower risk of amputation than endoprostheses. Uncemented endoprostheses appear to have a lower rate of aseptic loosening than cemented stems, albeit with small numbers. Certainly, inconsistent reporting of complications and the overall sample size is small, so differences between each reconstruction type may be over- or underestimated due to statistical power.

Summary of answers

- Osteoarticular allografts and endoprostheses perform well in the proximal humerus.
- In the proximal tibia, there is a higher risk of fracture and deep infection in those treated with osteoarticular allografts, while there is a lower risk of extensor mechanism failure in these patients.

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171 Biopsy of Soft Tissue Masses

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Clinical scenario

- A 70-year-old woman has an enlarging mass in the right axilla. Her primary care physician orders a needle biopsy to be done by a radiologist who carries out a fine needle aspiration (FNA) from 15 different sites around the 4 cm mass in order to obtain adequate tissue. The result is nondiagnostic but suggestive of malignancy, possibly carcinoma with necrosis. The patient is referred to a breast oncologic surgeon, who performs an extensive lymph node dissection and open biopsy of the axillary mass. The entire brachial plexus is carefully exposed and protected during the lymph node dissection. The pathologist finds that the lymph nodes are normal, but the axillary mass is diagnosed as a high-grade sarcoma. The woman is then referred to an orthopedic oncologist, who discusses forequarter amputation for adequate local control.
- The initial needle biopsy contaminated a large area of soft tissue around the sarcoma and was nondiagnostic. The next biopsy was definitive in making the diagnosis, but contaminated further tissue by exposing the brachial plexus at the time of the sarcoma biopsy. A carefully placed biopsy with adequate tissue for diagnosis could have allowed this woman a limb-sparing resection with an excellent chance of local control and probable cure.

Top three questions

1. In patients requiring diagnostic biopsies, does percutaneous biopsy result in different diagnostic accuracy and complication rates compared to surgical biopsy?
2. In patients undergoing biopsy of a soft tissue mass, what are the evidence-based biopsy principles that reduce potential complications and improve outcomes?
3. In patients with soft tissue masses, does biopsy by a specialist at a sarcoma center, compared to a community surgeon in a nonspecialized center, reduce biopsy-related complications and improve survival?

Question 1: In patients requiring diagnostic biopsies, does percutaneous biopsy result in different diagnostic accuracy and complication rates compared to surgical biopsy?

Rationale

There are various methods of biopsy that are available to clinicians when a histologic analysis is required for a patient presenting with a soft tissue mass. The three most common options available are incisional biopsies (IBs), core needle biopsies (CNBs), and FNAs. It is important to understand the advantages and disadvantages of each technique.

Clinical comment

Historically, open biopsies have been considered the gold standard for biopsies of soft tissue masses as provide large volumes of tissue sample which facilitates high diagnostic accuracy. increased morbidity. Percutaneous options, including FNAs and CNBs, have been introduced in attempts to reduce complications and cost while maintaining diagnostic accuracy.

Available literature and quality of the evidence

Level I–III evidence exists to answer this question.

Findings

Kasraeian et al. (level I) prospectively studied 57 patients with palpable soft tissue masses, performing first an FNA, followed by CNB, followed by open biopsy of the same mass.[1] They reported 100% accuracy with regards to the surgical biopsy compared to 80.7 and 75.4% accuracy of the CNB and FNA, respectively. Yang and Damron (level II) compared FNAs to CNBs in the same 50 consecutive patients.[2] CNB was found to have a higher diagnostic accuracy than FNA with respect to nature of the lesion, specific diagnosis, as well as histologic grading and typing. Traina et al. (level IV) performed a systematic review analyzing the accuracy rates of the various biopsy methods.[3] IB has a documented accuracy of 94–100%, CNB a reported accuracy of 72.7–100%, and FNA a wide accuracy range of 21.9–98%.

With regards to complication rates, there is a lack of high level evidence reporting on the differences between open and percutaneous biopsies. Mankin et al. (level III) obtained records from 25 orthopedic oncologists to determine the rates of complications associated with surgical biopsies. Out of 507 patients undergoing for a bone or soft tissue tumor, 15.9% of patients had a

complication associated with the biopsy.[4] Barrientos-Ruiz et al. (level III) retrospectively assessed the number of biopsy tracts that were contaminated with tumor cells at the time of definitive resection in 221 patients with bone and soft tissue sarcomas (STS).[5] They found that significantly more IBs had contamination when compared to percutaneous CNB (odds ratio [OR] = 56; 95% confidence interval [CI]: 7–428; p <0.001). The local recurrence-free survival was shorter with patients who had biopsy tract seeding (mean 11 months; 95% CI: 1–20 months; p <0.001). Adams et al. (level II) reviewed 252 CNBs of bone and soft tissue neoplasms performed in an outpatient setting. They recorded zero biopsy-related complications and a diagnostic accuracy of 91%.[6]

With advancements in interventional radiology and image guided biopsies, there has been an interest in image guided percutaneous biopsies. Narvani et al. (level II) compared nonimage guided CNB with image guided (computed tomography [CT] or ultrasound) CNB in 140 patients with suspected STS.[7] They demonstrated that the diagnostic accuracy of image guided CNB was significantly higher when compared to nonimage guided CNB (95% vs 78%, p <0.025) despite the image guided group having smaller and deeper tumors. However, excellent accuracy results have been published for unassisted CNB in the diagnosis of soft tissue masses. The two methods are difficult to compare as there is likely a bias toward more superficial and larger masses when nonimage guided biopsies are performed.

Overall, level I evidence suggests that incisional surgical biopsies have higher diagnostic accuracy when compared to CNB and FNA. However, IB have significantly higher morbidity than both CNB and FNB.

Resolution of clinical scenario

- Level I evidence suggests that IB has higher diagnostic accuracy when compared to CNB and FNA.
- Level II–IV evidence suggests that open biopsy has higher morbidity than both CNB and FNA.
- Level II–IV evidence suggests that CNB provides higher diagnostic accuracy when compared to FNA.
- Level I evidence that both image guided and nonimage guided CNB can produce acceptable diagnostic accuracy levels; however, for deeper and smaller masses, image guided biopsy is recommended.
- Given the relatively high diagnostic accuracy and low complication rates, CNBs are favored as the first line tool for biopsies of soft tissue masses.

Question 2: In patients undergoing biopsy of a soft tissue mass, what are the evidence-based biopsy principles that reduce potential complications and improve outcomes?

Rationale

Biopsies are a critical step in the timely diagnosis and treatment of soft tissue masses. Inappropriately performed biopsies can result in tumor spread, compromising reconstructive options, and sometimes lead to amputations in order to gain local control.

Clinical comment

Historically, there are several biopsy principles that have been utilized in order to minimize biopsy-related principles. With changes in how biopsies are performed, it is important to revisit these principles to determine if they are the safest options for patients requiring a diagnostic soft tissue biopsy.

Available literature and quality of the evidence

Level III–V evidence exists to answer this question.

Findings

Much of our early understanding regarding the complications of biopsies are gleaned from the landmark study by Mankin et al. (level III) in which data from 25 surgeons on 597 patients with malignant soft tissue or bone tumors were analyzed.[4] 16.6% of patients with soft tissue tumors had their outcomes negatively altered due to errors or complication in biopsies.

All lesions should be treated as malignant until a biopsy proves otherwise. There is expert consensus that meticulous hemostasis must be obtained to prevent postoperative hematoma (level V).[3,8] Postbiopsy hematoma must be considered contaminated by tumor cells, and large hematomas have the potential to contaminate the entire extremity leaving amputation as the only curative option.[8]

The surgeon performing the definitive surgery should be consulted prior to biopsy to determine appropriate placement of the biopsy tract.[8] Historically, the soft tissue tract that the biopsy was performed through was considered contaminated and was excised at the time of definitive surgery.

The literature has supported these concerns in the case of open biopsies. If IB is indicated, the incision should be

performed longitudinally in line with the proposed surgical approach to minimize the amount of soft tissue resection required at the time of definitive surgery.[4] Barrientos-Ruiz et al. (level III) determined that a significant percentage of IB had biopsy tract contamination which was associated with a reduced local recurrence-free survival.[5]

However, in the case of percutaneous biopsies, recent literature and expert opinion have found that excision of the biopsy tract may not affect outcomes.[5],[9],[10] Siddiqi et al. (level III) evaluated 36 patients with STS that did not have biopsy excisions and matched with 36 patients who had resection of the biopsy tract.[11] All patients underwent percutaneous needle biopsy and there was no difference in local recurrence or five-year survival, suggesting excision of the biopsy tract may be less critical after percutaneous biopsy. Barrientos-Ruiz et al. (level III) also examined percutaneous biopsy tracts for contamination and found that only 0.8% of CNBs had evidence of cell seeding.[5]

Historically, expert opinion has also recommended that biopsies occur within one muscular compartment and avoid critical structures including joints and neurovascular structures in attempts to reduce the risk of tumor spill.[12] However, UyBico et al. (level III) retrospectively reviewed percutaneous needle biopsies performed in 363 patients with musculoskeletal tumors.[13] They found 3.6% of biopsies violated the anatomic compartment and 11.6% of biopsies violated critical structures. No cases of recurrences were attributed to seeding along the needle tract.

There is level III evidence that among patients who require IB, there are high rates of biopsy tract seeding.[5] There is level III evidence that, in patients who undergo CNB, resection of the biopsy tract does not alter recurrence or survival rate.[11] There is level III evidence that patients who undergo CNB that violates historically critical structures do

not have higher recurrence rates.[13] There is expert opinion (level V) that meticulous hemostasis is required to reduce the risk of tumor spread secondary to postoperative biopsy.[3]

Resolution of clinical scenario

- There is level III evidence that IB tracts have a significant rate of tumor seeding and thus should be excised at the time of definitive surgery.
- There is level V evidence that meticulous hemostasis is required to prevent tumor spill and postoperative hematomas.
- There is level III evidence that CNB tracts do not need to be excised in the definitive resection.
- There is level III evidence that violation of previously considered critical structures does not increase recurrence in patients who undergo CNB.

Question 3: In patients with soft tissue masses, does biopsy by a specialist at a sarcoma center, compared to a community surgeon in a nonspecialized center, reduce biopsy-related complications and improve survival?

Rationale

Some debate exists on the safety and outcomes of soft tissue biopsies performed in a nonspecialized community setting compared to those performed by experienced

personnel in a specialized sarcoma center. Errors and complications related to the biopsy may influence the clinical course and have a profound impact on survival, quality of life, and cost of care.

Clinical comment

Biopsy is one of the first crucial steps in the diagnosis and management of musculoskeletal lesions. The importance of an accurate and safe biopsy cannot be overstated, as it provides a presumptive diagnosis that will determine management and impact the rest of the clinical course. Delayed or misdiagnosed lesions may lead to inappropriate treatments, greater complications, and decreased survival. There may also be a difference in biopsy-related complications between biopsies performed by community surgeons in a nonspecialized institution compared to those performed by experienced personnel in a specialized sarcoma center.

Available literature and quality of the evidence

Level III–IV evidence exists to answer this question.

Findings

The setting in which soft tissue biopsies take place has been reported to have a direct impact on outcomes in patients with STS. In this context, most of the current literature favors soft tissue biopsy carried out by experts in a specialized sarcoma center over those done by community surgeons in a nonspecialized referring institution.[4,14–18]

The aforementioned paper by Mankin et al. (level III) remains one of the most well-known articles that advocate for soft tissue biopsies to be undertaken at specialized centres.[4] Based on a retrospective evaluation of 597

patients from 25 surgeons across 21 institutions, patients who had a biopsy performed at a nonspecialized institution were more often inaccurately diagnosed (27.4% vs 12.3%), underwent technically poor procedures more frequently (13.9% vs 3.5%), had a greater number of treatment plan alterations (36.3% vs 4.1%), and had a change of clinical course more often as a result of the biopsy (17.4% vs 3.5%) compared to patients who were biopsied in specialized sarcoma centers. The authors suggest that the inherent difficulty level of the biopsy procedures coupled with the inexperience of community practitioners may put the patient at greater risk of complications and change the course of the disease.[4]

The European Cancer Organization (ECCO) published a review detailing updated practice recommendations among European oncology practitioners (level V).[15] Most notably, the ECCO framework discouraged biopsies performed in the community setting and reported that biopsies performed by nonexperts may lead to missed diagnoses, more complications, ineffective subsequent treatments, and possible tumor spread. In line with these recommendations, Bedi et al. (level III) retrospectively reviewed 92 patients with STS who had undergone percutaneous biopsy at either a tertiary sarcoma center or a community hospital.[19] They found that patients undergoing CNBs in the community had significantly higher wound complications after their definitive surgery.

The ECCO framework also highlights the importance of having radiology experts involved in image-guided CNBs as the preferred first method for tissue sampling. This recommendation is reaffirmed in Kubo et al.'s (level IV) systematic review and meta-analysis involving 32 studies and 7209 musculoskeletal lesions.[17] They found that diagnostic accuracy was slightly improved if the CNB

operator was a radiologist compared to if they were a surgeon, likely due to their expertise in interventional radiology techniques.[17]

Care based in specialized sarcoma centers also benefits from improved accuracy in histologic diagnoses from specialized pathologists. Ray-Coquard et al. (level II) performed a population based study in which histologic samples of 1463 sarcoma patients were reviewed by expert pathologists.[18] More than 40% of histological diagnosis made by community pathologists were modified at second reading by a specialized pathologist.

Resolution of clinical scenario

- Level III evidence suggests that patients with STS who undergo biopsy by an expert with multidisciplinary support at a specialized sarcoma center have fewer biopsy-related complications, greater diagnostic accuracy, and more timely treatment.
- There is level IV evidence that CNBs performed by radiologists have higher diagnostic accuracy than those performed by orthopedic surgeons.
- Level II evidence demonstrates that sarcoma-trained pathologists' histologic diagnoses differ significantly from nonspecialized pathologists' diagnoses.

Summary of answers

- CNB is the preferred first-line biopsy in patients with soft tissue masses given their acceptable diagnostic accuracy rates and low morbidity. If nondiagnostic, open biopsy should be considered.
- In the case of IB, the biopsy tract should be made in line with the planned incision and should be excised at

the time of definitive surgery. There is a lack of evidence suggesting CNB tracts require excision.

- Biopsies should be performed by subspecialized personnel, radiologists, or fellowship trained orthopedic oncologists, and should be interpreted by specialized pathologists.
- Care coordinated through a specialized sarcoma center improves outcomes.

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172 Denosumab in Giant Cell Tumors of Bone

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Introduction

Giant cell tumor of bone (GCTB) is a primary, intermediate grade tumor with an aggressive local behavior and a rare tendency to metastasize (Ref). The tumor has a preponderance for the meta-epiphyses of long bones, particularly in patients in the third to fifth decade, though it can arise in difficult sites for management, such as the spine and pelvis. Histologically, GCTBs are composed of large, multinucleated giant cells, which resemble osteoclasts in both form and function, and stromal cells which comprise macrophage-like, non-neoplastic cells, and mononuclear spindle cell shaped fibro-osteoblastic-like stromal cells. These neoplastic stromal cells express receptor activators of nuclear factor kappa-B ligand (RANKL), which promote and activate the giant cells, which express RANK, resulting in the characteristic bone resorption seen in GCTB.

Conventional treatment for GCTB comprises surgical removal, either through intralesional curettage, or by en bloc excision or, in extreme cases, amputation. Recurrence following intralesional excision varies but ranges from 12 to 67%. There is no convincing evidence that adjuvants reduce the rate of recurrence following detailed curettage, although a variety are widely used including phenol, liquid nitrogen, cement, etc. The high risk of recurrence and the need for multiple surgical procedures may be associated with a high degree of morbidity. This has prompted the

drive for novel agents to improve local control and maintain function at an acceptable level of morbidity.

Denosumab is a fully human monoclonal antibody that binds with high affinity and specificity to the soluble and cell-membrane forms of human RANKL. Its effect is to effectively switch off osteoclastic activity and, when used for the treatment of GCTB, to stop the lytic effect, pushing bone turnover toward bone formation.

Top three questions

1. In patients with truly inoperable GCTB, is denosumab a safe treatment in the long term?
2. For patients with extensive GCTB, does denosumab allow salvage of the joint where previously the joint would have been sacrificed?
3. How would patients on denosumab benefit from further research?

Question 1: In patients with truly inoperable GCTB, is denosumab a safe treatment in the long term?

Rationale

While denosumab has found a role in the neoadjuvant management of GCTB, it is increasingly being used for tumors where resection presents a significant challenge or risk of mortality, or where the morbidity associated with resection is unacceptable. Such sites include the base of skull or large tumors of the spine and sacrum. In such sites, denosumab is increasingly being used as a definitive treatment option, often with good effect.

Clinical comment

The long-term effects of such prolonged treatment remain unknown or as yet undiscovered. Given the age group most commonly affected by GCTB, many of the acceptable side effects of denosumab applicable to the more conventional use of the drug for the treatment of metastatic bone disease do not apply, and indeed many new side effects have become apparent in the drug's novel application to GCTB. The rate of relapse while on treatment remains uncertain and the risk of relapse after treatment is stopped (for whatever reason) is also not yet known

Available literature and quality of the evidence

Acute side effects of denosumab treatment include bone pain, fatigue, headache, nausea, hypocalcemia, hypophosphatemia, and osteonecrosis of the jaw.[1–3] While the long-term effects of bisphosphonates when used in children and adolescents have been documented,[4,5] the same cannot be said for denosumab. Only 10 adolescent patients were included in the original safety study for denosumab in GCTB,[1] as denosumab is contraindicated in the skeletally immature. The safety of long-term denosumab in the treatment of osteogenesis imperfecta has been shown.[6] However, it should be noted that four juvenile patients developed severe rebound hypercalcemia following cessation of denosumab,[7] a phenomenon reproduced in other applications of denosumab, including GCTB.[8,9] This rebound hypercalcemia has also been reported in the adult population following cessation of denosumab after prolonged treatment for GCTB.[10] Therefore, great caution and hypervigilance for this potentially fatal phenomenon should be exercised after cessation of denosumab.

The effect of denosumab on the human fetus remains unknown. Denosumab was seen to result in increased stillbirths, decreased body weight gain, and decreased growth and development in cynomolgus monkeys,[11] though no case reports exist in the literature to assess the effect on human fetal development. In the absence of such evidence, it is mandatory that female patients avoid pregnancy while undergoing denosumab treatment. This raises a treatment challenge for females of childbearing age with an inoperable GCTB, and patients must be counselled accordingly.

In a multicenter retrospective study on the efficacy of denosumab in unresectable GCTB, Palmerini et al. were able to monitor the long-term effects of prolonged denosumab treatment.[12] The study comprised 97 patients, though 43 went on to have surgical resection after a median time of 12 months. The remaining 54 patients were on denosumab on continuous treatment for the treatment of unresectable GCTB or metastatic GCTB. Twenty patients stopped denosumab treatment for a variety of reasons, and of these 20 patients, further information was available on only 10. Of these 10 patients, four developed recurrent disease after a median of eight months. The incidence of osteonecrosis of the jaw (ONJ) on those on prolonged treatment was 9% with a five-year ONJ-free survival of 92%. Other side effects included mild peripheral neuropathy (11%), skin rash (9%), hypophosphatemia (4%), and atypical femoral fractures (4%). The study supports the long-term use of denosumab in unresectable GCTB with an acceptable safety profile, supporting the findings of others.[1,2] The authors have demonstrated an effective cure following cessation of denosumab in six patients on whom data were available, though it should be noted that only two of these patients have follow-up beyond 12 months.

Rutkowski et al. reported a control rate of 92.3% at almost four years in 48 patients with inoperable disease.[13]

How long and at what dose to continue denosumab remains an area of debate. It would seem logical that, in patients in whom a steady state has been achieved (usually 9 12 months of treatment) and in whom surgery is not possible, reducing the frequency of dosing may reduce the side effect profile. While published data outside of individual case reports are lacking,[14] several reports have been presented demonstrating effective local control at a reduced dose frequency. These findings contradict the findings of Lipton et al., who found that a three-monthly dosing regimen was insufficient to maintain local control in metastatic bone disease, when compared to monthly dosing.[15] However, these findings were in patients who had not yet achieved a steady state of the drug through prolonged monthly dosing.

Concern has been raised around the possibility of malignant transformation of GCTB, which some have speculated relates to the use of denosumab. In an initial safety study on the application of denosumab for GCTB, Thomas et al. report two cases of sarcoma developing while on denosumab.[2] In one case, the patient developed a high-grade sarcoma in the upper limb, and the second developed lung metastases following malignant transformation of a GCTB eight months following discontinuing denosumab. Chawla et al. reported two cases of malignant transformation while undergoing denosumab treatment.[1] However, in one, this was thought to be a misdiagnosis of GCTB, while in the second this was considered malignant transformation of a GCTB. Rutkowski et al. reported 4/222 patients undergoing denosumab developed malignant transformation.[3] However, in two of these cases, this transformation was within the field of previous

radiotherapy, while in the latter two cases the diagnosis of malignant GCTB had not been made due to a sampling error at presentation. Further case series have reported on individuals who have developed malignant GCTB while undergoing denosumab treatment for histologically confirmed GCTB.[16],[17] In all three cases, the malignant transformation occurred in recurrent GCTB having initially undergone a number of previous procedures, in one case en bloc resection.

Evidence is at best level III but in the majority of available literature, it is level IV or V.

Findings

It would appear that the risks of long-term denosumab are offset by the almost universal response of GCTB to denosumab.

Resolution of clinical scenario

It remains to be seen if the risks of recurrence and serious side effects can be reduced by decreased frequency of dosage once control of the primary tumor has been achieved.

Question 2: For patients with extensive GCTB, does denosumab allow salvage of the joint where previously the joint would have been sacrificed?

Rationale

A second application of denosumab in the treatment of GCTB is in the setting of advanced local disease where

extensive bone destruction has rendered the salvage of bone or joint unfeasible either due to pathological fracture or due to extensive infiltration or soft tissue extension.

Clinical comment

Higher-stage lesions (those with extensive bone destruction and soft tissue involvement) are associated with a higher rate of local recurrence following intralesional curettage when compared to Campanacci 1 or 2 lesions.[18] In such situations, sacrifice of the joint may be the only option to achieve an acceptable rate of local recurrence. And the addition of denosumab may allow effective downstaging of the tumor and facilitate joint preserving surgery with an improved rate of local recurrence.

Available literature and quality of the evidence

Denosumab results in the formation of a rim of new bone around the tumor essentially downstaging a Campanacci 3 lesion to a lower grade.[3],[19] An early report by Gaston et al. demonstrated the effective treatment of a Campanacci 3 lesion of the proximal femur with neoadjuvant denosumab, curettage, and autologous fibula grafting that, without denosumab, would have required joint sacrificing surgery.[20] An interim analysis of the phase II study on the efficacy of denosumab in the treatment of GCTB identified patients in whom neoadjuvant denosumab was given in an attempt to downstage tumors and therefore allow less aggressive surgical management.[1],[3] In their study, the authors prospectively recorded the intention to treat at the point of diagnosis. The study population comprised 222 patients, of whom 148 (66.7%) were undergoing treatment for a primary GCTB. High morbidity procedures (e.g. amputation, hemipelvectomy) were avoided in 80%, while 80% of patients in whom an en bloc excision and 37% of

patients in whom an en bloc resection was planned managed to avoid an operation. The native joint preservation rate was 96%. Therefore, in summary, assuming that all 222 patients were intended to have a surgical intervention at the outset in the absence of denosumab, the addition of denosumab has delayed the need for surgery in 48% and a further 38% have undergone a lesser surgery than was planned without the addition of denosumab.

While this is the largest series aimed at answering the question of whether denosumab can downstage GCTB and reduce the morbidity of surgical treatment, it is not without flaws. This was a multicenter study from a number of different countries. The treatment decision at diagnosis was at the discretion of the treating physician and not based on standardized criteria or by peer review. What was deemed only treatable by excision in one institution may have been regarded as treatable by curettage in another. In addition, no details are given of the specific relapse rate for those who underwent a lesser morbid surgery. While the authors state a local recurrence rate of 15% for those who underwent surgery (17/116) at a median time of 13 months (interquartile range [IQR]: 8.5–17.9), the exact details of these recurrences are not given. The question remains, therefore, in the case of those whose disease was downstaged allowing less morbid surgery: was this at the expense of an increase in local recurrence?

Traub et al. reported on 20 patients with GCTB classified as Campanacci 2 (7/20) or Campanacci 3 (13/20), in whom joint preservation at presentation was felt not to be possible or at high risk of failure treated with neoadjuvant denosumab and subsequent intralesional curettage.[21] All underwent intralesional curettage with preservation of the joint in 18/20. At a median follow-up of 20 months (range 20–45), three patients (15%) after curettage.

While providing a detailed analysis of the success in downstaging disease in a group of *high risk* GCTB, the identification of patients deemed unresectable must again be questioned. Discrepancy exists between specialist opinions as to what constitutes a *high risk* tumor, and the potential efficacy of curettage for particular lesions. While the authors felt that the tumors included were likely to recur or go on to jeopardize nearby joints, other experts in the field may disagree with this decision and proceed directly to curettage without denosumab. The success of denosumab in downstaging the GCTB therefore must be questioned as there is the possibility that in other centers these lesions would have been treated with curettage without denosumab with a comparable potential for cure.

In a retrospective assessment of a cohort of patients with GCTB, Rutkowski et al. analyzed the effect of denosumab on local control in 138 patients, a subset of whom (23/138, 17%) were deemed as unresectable.[13] Of the remaining 115 patients, 89 went on to have surgical treatment after neoadjuvant denosumab, with a median duration of six months of treatment. Fifty patients (56%) were treated by curettage, while 39 (44%) underwent excision including prosthetic replacement in 17. The rate of relapse was 21% after surgical treatment, 32% after intralesional curettage, and 7.7% after excision (no patients who underwent prosthetic replacement relapsed).

It is difficult to extrapolate these findings to the GCTB population as a whole in that, again, it is difficult to comment on whether denosumab downstaged tumors and allowed less aggressive treatment. The authors did not state the intention to treat prior to commencing denosumab. Even if these details had been included, it would have been difficult to state categorically that patients had undergone less intrusive surgery as a result of denosumab. However, the authors stated that “all these

tumours were very advanced locally with large soft tissue mass," and if one were to assume that all those treated with neoadjuvant denosumab would likely have required excision, including sacrifice of the joint, then denosumab does offer an attractive alternative.[13]

There is concern that the neo-ossification seen after denosumab treatment may reduce the likelihood of cure following curettage. This rim of new bone may harbor neoplastic stromal cells which are insufficiently removed at the time of curettage and which reactivate the GCTB following cessation of denosumab. Where curettage is planned for local control and denosumab is being used as an adjunct, a shortened course should be considered. While some speculate a reasonable period to be three months,[13] the exact balance between effective consolidation and unacceptable rates of local recurrence remains unclear. Surgeons using denosumab prior to intralesional curettage must be cognizant of the need for a more detailed and rigorous curettage than would be expected for GCTB without prior denosumab. This may account for the increased risk of local recurrence following curettage following denosumab observed by some.[22] The role of adjuvants in this situation to extend the *biological margin* of curettage is again unclear, as it is for primary GCTB.

Evidence is at best level III, but in the majority of available literature it is level IV or V.

Findings

There is increasing, evolving evidence to support the use of denosumab in downstaging GCTB allowing less morbid surgical treatment. Questions still remain about the duration of denosumab prior to curettage allowing an acceptable rate of local recurrence. Surgeons must be cognizant of the effect of denosumab on GCTB when

undertaking intralesional procedures due to the potential for neoplastic cells to remain in the corticated margin of the GCTB and therefore significantly increase the risk for LR.

Resolution of clinical scenario

A clinical trial comparing primary curettage with a group of patients pretreated with denosumab may well be the only way this question can be answered. The use of adjuvants could be another arm of that trial, as could the duration of pretreatment.

Question 3: How would patients on denosumab benefit from further research?

Rationale

While the benefits of denosumab in the treatment of GCTB are immediately apparent, this is clearly an evolving field that requires close scrutiny and further research. The question therefore that follows is in what areas should this research be focused. With our understanding of denosumab evolving with time, it is imperative that we focus our attention on key areas that will benefit patients.

Clinical comment

Questions remain as to the efficacy and application of denosumab for patients with GCTB. These areas of future research should focus on:

- Can denosumab still achieve local disease control at a reduced dose or reduced dose frequency in inoperable cases?

- Is denosumab the best option for local disease control for GCTB?
- Is there an effective way to monitor the response of GCTB to denosumab to try to more accurately predict the risk of recurrence?
- What is the optimum duration of denosumab treatment prior to curettage for operable GCTB?
- Is there a benefit to using adjuvants along with curettage in patients with operable GCTB?

Available literature and quality of the evidence

Conventional treatment algorithms for denosumab when applied to GCTB utilize a dose and frequency of administration based on experience with the drug's application to metastatic bone disease. However, this regimen may well be at an inappropriate dose and frequency for its application to GCTB. Instead, a reduced dose or a reduced frequency may still be effective at achieving local disease control with the added benefit of a reduction in drug-related side effects. While no published evidence exists in this area, small series have been presented at a number of society meetings reporting acceptable rates of disease control using denosumab at a less frequent dose administration than is conventional. This will be the focus of a recently opened multicenter study conducted by the European Organization for Research and Treatment of Cancer (EORTC).

While denosumab is clearly effective at controlling the osteoclastic effect of giant cells, it does not have an effect on the neoplastic stromal cells responsible for giant cell activation. This explains the reactivation of GCTB following cessation of denosumab. Zoledronic acid, a nitrogen-containing bisphosphonate, induces osteoclast apoptosis

through interference with the activation of RAS-related protein, and has demonstrated efficacy in the treatment of benign and malignant lesions of bone.[23] Comparative studies using denosumab or zoledronic acid in the treatment of metastatic bone disease support the use of both agents though with a beneficial effect of denosumab both in terms of efficacy and serious adverse events.[24] In vitro studies on the effect of both agents on osteoclast and differentiation, survival, and cell growth have demonstrated superiority of zoledronic acid over denosumab in terms of osteoclast survival, osteoclast differentiation, and dose-dependent inhibition of neoplastic cell growth. In a comparative study administering neoadjuvant zoledronic acid prior to curettage of GCTB compared to curettage without zoledronic acid, a higher rate of recurrence was seen in those not receiving zoledronic acid (Kundu et al. 2018).[25] However, the potential beneficial effects of zoledronic acid do not appear to have been borne out by clinical studies. In a multicenter study on the effects of adjuvant zoledronic acid, Gouin et al. reported a recurrence rate of 15% which was not affected by zoledronic acid and compares to the local recurrence rate seen following curettage for comparable lesions treated without zoledronic acid.[26]

Treatment of GCTB with denosumab clearly has an effect on the histological appearance when compared to GCTB not conditioned by denosumab. GCTBs treated with denosumab consistently demonstrate ossification, fibrosis, depletion of giant cells, and proliferation of mononuclear cells.[27] While there is often a variable response in terms of viability of giant cells, a consistent feature is one of a reduction in the number of viable giant cells, though of course this will have no reflection on the likelihood of recurrence of the GCTB as this implies a reflection of the inhibition of RANKL activation. Further research should

focus on pathological assessment to the response of GCTB to denosumab treatment prior to resection or curettage to more accurately predict the likelihood of relapse and to guide surveillance.

Findings

While great advances in the understanding and application of denosumab and other anti-osteoclastic agents in the treatment of GCTB have been made, greater focus is still required to assess the response to these agents, to explore the role of alternative agents, and to guide treatment algorithms.

Resolution of clinical scenario

There appears little doubt that the treatment of GCTB has evolved dramatically with the introduction of denosumab. However, as this is an evolving novel application of an existing drug treatment, great efforts are required to more accurately assess its application in the treatment of GCTB. We can expect not only further understanding of this application, but also further awareness of the complications related to the use of denosumab in the neo-adjuvant treatment and definitive treatment of GCTB.

Summary of answers

- It remains to be seen whether risks of recurrence and serious side effects can be reduced by decreased frequency of dosage once tumor control is achieved.
- It is unclear whether pretreatment with denosumab can help promote limb salvage in patients with extensive GCTB.

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X Pediatrics

173 Outcomes in Pediatric Orthopedics

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Measuring outcomes that matter in pediatric orthopedics

The mandate of *Evidence-Based Orthopedics* is to promote evidence-based practice and to identify areas of clinical uncertainty that would benefit from quality research. The quality of evidence is underpinned by the tenets of *evidence-based medicine* (EBM), a term first introduced by Gordon Guyatt,[1] based on the principles of critical appraisal developed by David Sackett, one of the pioneers of EBM.[2] For each clinical question tackled in this book, authors have used the *PICO framework* to guide their appraisal of the evidence pertinent to that question.[3] The *O* in PICO stands for the *outcome* that should be used to evaluate the effectiveness of the *intervention (I)* of interest relative to the *comparison intervention or control (C)* applied to a specific *patient population or problem (P)*. Fundamental to the practice of EBM is how we choose to define effectiveness, or the *O*. Sacket himself defined EBM "as the conscientious, explicit, and judicious use of current best evidence in making decisions about the *care of individual patients*."[4] The pillars of EBM include (i) using the best available external clinical evidence from

systematic research integrated with (ii) individual clinical expertise. Often overlooked is the third pillar of EBM, which is (iii) the “compassionate use of individual patients' predicaments, rights, and preferences in making clinical decisions about their care.” The emphasis on *patient values and preferences* in evidence based decision-making[5] evolved concurrently with the evolution of the outcomes research movement which set out “to sort out what works in medicine and to learn how to make clinical decisions that reflect more truly *the needs and wants of the individual patient*.”[6] The imperative for patient-centered care as a critical aspect of high-quality healthcare is enshrined in the Institute of Medicine Report in 2001.[7] The outcomes we measure should be meaningful to patients and consistent with their priorities and preferences.

This chapter reviews current concepts of outcome measurement, highlighting frameworks for the conceptualization of outcomes, with an emphasis on patient-reported outcomes (PROs) and the challenges pertinent to measuring these in children. The example of a child with ambulatory cerebral palsy (CP) will be used to demonstrate some of the advances and limitations of outcome measures for pediatric orthopedic patients.

Clinical scenario

- Consider a 10-year-old boy with bilateral spastic CP. He walks on tip toe, legs and feet turned in, and his knees flexed. He finds it difficult to keep up with his friends, trips frequently, tires easily, experiences knee pain, and is relying more on a walker even for shorter distances.
- He undergoes multilevel surgery to improve his gait. Six months after surgery and extensive physiotherapy,

he walks with his heels down and his feet pointing straight ahead. His knees come to full extension during stance.

- He is using a walker at home and at school and a wheelchair in the community. His knee pain has resolved. He experiences some hypersensitivity in his feet and uses ankle foot orthoses (AFOs) for support. His walking speed and endurance declined in the first few months after surgery but has recently improved, but not exceeded, his preoperative level.
- Has the intervention made him better?

What are outcomes?

Outcomes are the consequences of an intervention to treat a condition or what happens over time (natural history) if the condition is untreated.[8] An effective intervention is one which alters the natural history of that condition favorably and achieves the *goal(s)* for which that treatment was intended. The goals of an intervention can be *reactive*, to address a symptom or problem (e.g. eliminate knee pain, tripping, increase walking speed) or *preventative or prophylactic* to prevent some future problem associated with the natural history (e.g. preserves walking, prevents osteoarthritis in adulthood). Some outcomes occur early (e.g. improved gait pattern), while others occur later (e.g. improved walking speed and endurance several months after surgery). An intervention can be associated with many outcomes, some *desirable* (benefits) and others *undesirable* (harms). An undesirable outcome can be *expected* (e.g. postoperative pain, muscle weakness) or *unexpected – complications or adverse events* (e.g. dysesthesias in the feet following nerve stretch injury), which can be transient or permanent.

How does one judge the overall effectiveness of an intervention for an individual patient or a group of patients with a given condition?

Frameworks of health and disease and the evaluation of outcomes

Pediatric orthopedics has a relatively short history of recognizing the importance of measuring outcomes. In 1991, Michael Goldberg proposed a framework of outcomes assessment in which he made the distinction between the more immediate *technical* outcomes of an intervention (e.g. correcting excessive femoral anteversion, normalizing the migration percentage of a displaced hip, reducing the Cobb angle in scoliosis) from *functional* outcomes which were the reasons for which the operation was being done (e.g. decreased tripping, pain relief, improved appearance).[9] He also recommended measurement of patient *satisfaction* to gauge patients' perception of the intervention's success and *cost effectiveness* to measure whether the intervention was worth the costs involved. This framework served the field well with the development of generic and condition-specific patient-reported outcome measures (PROMs) pertinent to pediatric orthopedics.

More recently, the International Classification of Functioning, Disability and Health, or ICF model, introduced by the World Health Organization (WHO),[10] and its pediatric equivalent, the ICF for Children and Youth (ICF-CY),[11],[12] provide a unified language to classify health and health-related domains and a framework to measure health outcomes associated with any health condition.[11]

In the ICF framework, *body structures* refer to the anatomic parts affected by the health condition of interest (e.g. periventricular leukomalacia in CP; spastic muscle;

bone deformity), and *body functions* refer to physiological functions of body systems (e.g. decreased range of motion, lever arm dysfunction). Body functions and structures allow functional *activities* or specific tasks or actions (e.g. sitting, walking, running), which facilitate *participation* or doing the things that one wants to do to engage in life roles (e.g. being independent, going to school, playing sports). Implicit is the assumption that participation contributes to one's quality of life (QOL). The impact of a health condition on the body functions and structures are the biophysical impairments that might lead to activity *limitations* (e.g. inability to run), which might result in participation *restrictions* (e.g. inability to keep up with friends or play sports). The ICF framework incorporates the influence of *environmental factors* (e.g. home/school/community, socioeconomic status, access to health care) and *personal factors* (e.g. demographic characteristics, culture, lifestyle preferences, motivation, personality).[13] These contextual factors can explain the gap between what one *can* do (capacity) and what one actually *does* do in daily life (performance).[14]

Interventions act at the level of body functions and structures. In the management of ambulatory CP, the technical objective of multilevel surgery is to address the impairments such as muscle contractures and bony deformities. Correction of these impairments (technical outcome) is assumed to lead to (functional) outcomes that patients and parents want, which is to achieve activities and participation with fewer restrictions.[15] A technically successful outcome may not necessarily result in a functionally successful outcome. Also, a positive impact on activities and participation can be achieved without an intervention to correct impairments. For example, the use of powered mobility (wheelchair) might provide an

alternative means of efficient locomotion, which may increase participation by allowing an individual to be independent and able to move around faster and with less effort. These gains in participation might be accompanied by a negative impact at the level of body function and structure such as decreased cardiovascular fitness or increased knee flexion contractures. Ultimately, to make meaningful judgments about effectiveness, it is necessary to base these on specific goals that are aligned with the patient's or parents' priorities.

The Priority Framework for Outcomes Evaluation (Figure 173.1)

Patient *priorities* are the concerns, needs, desires, and expectations associated with living with a health condition. Patient and parent *goals* are the product of these priorities and informed by input from clinicians. Understanding priorities and goals is crucial for making decisions about *interventions* that will best address these. There may be multiple perspectives (e.g. the child's or the parent's) which may not be completely concordant.

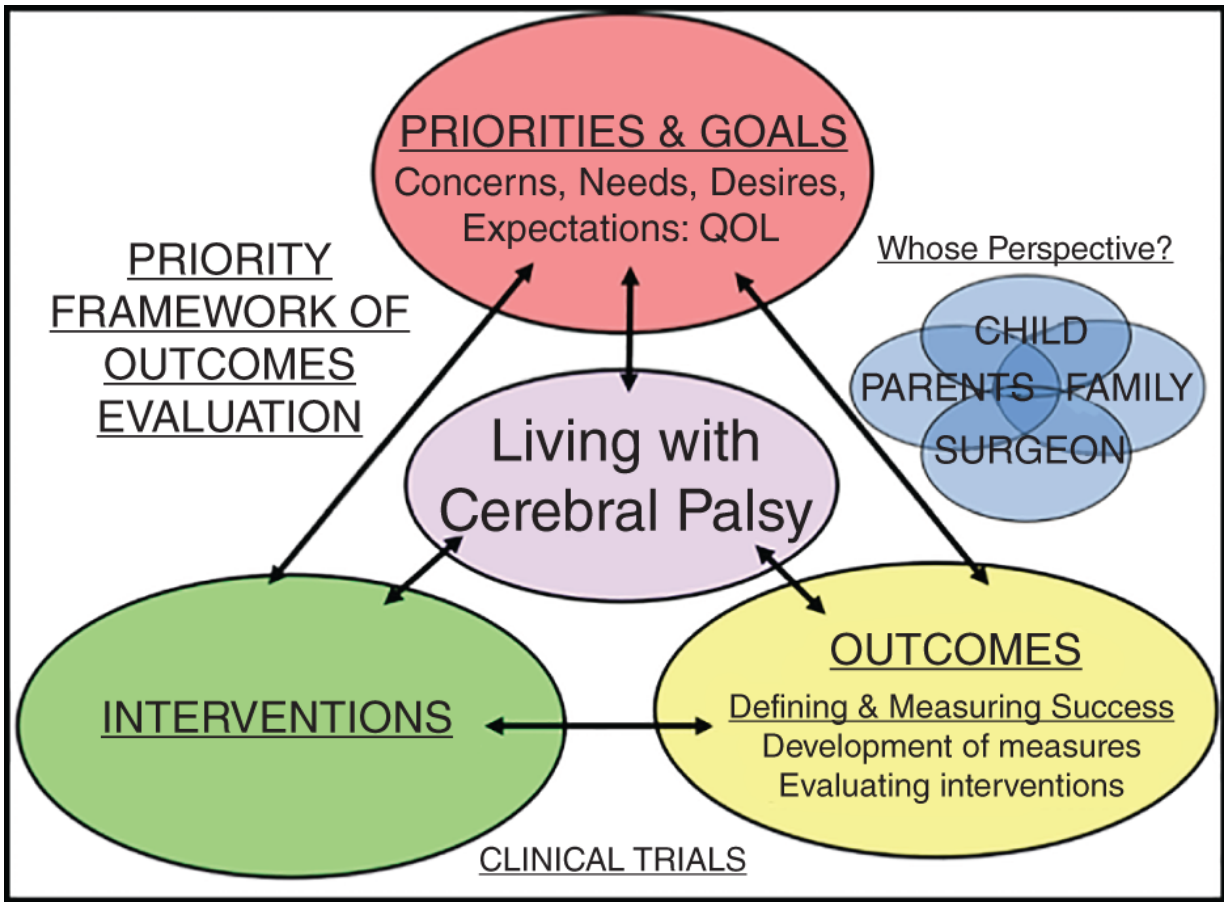

Figure 173.1 The Priority Framework for Outcomes Assessment. Source: Modified from Narayanan.[16]

Outcomes are most meaningful when they are aligned with patient priorities and goals. If our interventions are intended to address these priorities and goals, their effectiveness must be evaluated using *outcome* measures which specifically incorporate the goals and priorities of the patient population.[16]

Outcome measures in pediatric orthopedics: general considerations

Patient-reported outcome measures (PROMs) are the gold standard to evaluate the effectiveness of interventions. The content of PROMs should have been derived from patients

themselves, and in the case of children, parents and caregivers as well. When the perspectives of patients are not accessible because they are very young or cognitively unable, one has to rely on the report of the child's parent(s). The views of older children can and must be taken into consideration, but their perspectives might differ from those of their parents. The level of agreement between parents and children is usually better for domains reflecting physical activity, functioning, and symptoms, but poorer for domains which reflect more social or emotional issues.[17] Whenever possible, both perspectives should be considered during decision-making, and for measuring outcomes as well.

Generic versus condition-specific measures

Generic PROMs evaluate the impact of physical, mental, and social function; health status; and wellbeing across different health conditions. These are useful to policymakers as they can be used to compare outcomes across different clinical conditions and interventions to understand the relative value of some types of interventions over others for purposes of healthcare utilization, planning, and resource allocation. However, generic measures are less sensitive to change than *condition-specific* measures, which focus on issues directly relevant to the condition.

Mortality, health, and quality of life

When the primary goal of an intervention is to save or extend life, measuring *mortality* (survival) must be the primary outcome. However, adding years of life alone is insufficient if the life saved is not worth living. *Quality of*

life (QOL) is defined as “individuals' perceptions of their position in life in the context of the culture and value systems in which they live, and in relation to their goals, expectations, standards and concerns.”[18] *Health-related quality of life (HRQoL)* refers to the health-related factors that contribute to the goodness and meaning of life, where *health* is “a state of complete physical, mental and social well-being, and not merely the absence of disease or infirmity.”[19] HRQoL is multidimensional, encompassing physical, mental, and social domains and their relation to as role attainment, daily functioning, and participation in community life.[20],[21]

Psychometric properties of an outcome measure (See also in Chapter 5)

Reliability is a fundamental requirement and is the property of the measure to produce the same result when no change has occurred.[22] *Internal consistency* refers to a special type of reliability which assesses how well items within a scale correlate with each other to measure a single construct (e.g. physical function).[23]

An outcome measure is valid when it measures the phenomenon it was designed to measure. An outcome measure has face validity when its items appear to be measuring what they are supposed to.[23] Content validity examines the extent to which all relevant and important content or domains pertinent to the attribute of interest are adequately addressed by the items in the measure. Face and content validity represent the sensibility of the measure,[24] and are established by using qualitative research with patients (and their parents) and experts who work with these patients to develop the outcome to ensure it adequately captures what's important to patients and parents. *Criterion validity* is the correlation of an outcome measure with another measure that is regarded as a more accurate measure (gold standard) of the criterion. When such a gold standard measure does not exist, particularly for subjective attributes, *construct validity* requires a process of hypothesis testing to examine the logical relationship that should exist between a measure and characteristics of patients and patient groups.[22] For instance, one can test the hypothesis that the outcome measure should generate different scores when tested on two groups, known to be different in severity of that condition (*known groups* or *extreme groups validity*).

Convergent validity is a type of construct validity demonstrated when the scales of a measure correlate with the related scales of another measure, but not to unrelated scales (*divergent validity*).

A *discriminative* outcome measure is sufficiently sensitive to detect small (but meaningful) differences between patients and is free from *ceiling effects* (i.e. many subjects rate the highest possible score on the measure because it is unable to distinguish higher functioning subjects from each other) and *floor effects* (i.e. less discriminative of lower functioning subjects who are rated at the lower end of the scale). Finally, an outcome instrument that is intended to measure effectiveness is an *evaluative measure*, which must be *responsive* or *sensitive to change* that occurs following an intervention.[25,26]

Outcome measures for ambulatory cerebral palsy

The presenting history of deterioration in gait in a 10-year-old boy with CP is consistent with the functional decline and symptoms that many ambulatory children experience in adolescence. Multilevel surgery is recommended to improve gait or preserve function and a number of outcome measures have been used to evaluate whether these interventions have been effective.

- *Gait Analysis & Gait Analysis Derived Gait Indices:* the (technical) objectives of multilevel surgery are to address the body function and structure impairments (e.g. contractures of the gastrocnemius and medial hamstrings, the lever arm dysfunction and internal rotation gait from increased femoral anteversion). After surgery the range of motion and femoral anteversion

are important to measure but of little direct relevance to the patient. The impact of these impairments on gait can be quantified objectively using three-dimensional (3D) gait analysis to generate temporospatial measures of gait velocity and step length, kinematic and kinetic data, electromyography, and energy consumption. A number of summary indices derived from 3D gait analysis that quantify the overall magnitude of gait deviation from normal, such as the *Gillette Gait (Normalcy) Index (GGI)*[27,28] or the *Gait Deviation Index (GDI)*.[29] The *Gait Profile Score (GPS)* is another index measure that summarizes the overall deviation of kinematic gait data from the norm.[30] The GPS can be decomposed to provide *Gait Variable Scores (GVS)* of nine key component kinematic gait variables, which are presented as a *Movement Analysis Profile (MAP)*.[31] These are valid measures of impairment at the ICF level of activity but may not necessarily correlate with the functional goals at the level of participation that patients want.[32] They may be good summary measures of the overall appearance of gait, in so far as walking on level ground for a few meters in a motion lab is representative of overall gait function in the real world. For that we must rely on functional outcome measures that span the domains of activities and participation.

- *Gross Motor Function Measure (GMFM-66)* is a well-validated, condition-specific measure of gross motor function in children with CP,[33–35] and is evaluated by a trained physiotherapist. The GMFM-66 has been used in numerous trials and has been shown to be sensitive to change following surgery for ambulatory CP.[36] However, the GMFM-66 is a measure of *capacity or capability* (observed under ideal circumstances) rather than *performance* (what one actually does), and does

not necessarily represent the child's activities and participation.

- *Pediatric Outcomes Data Collection Instrument (PODCI)* is a generic measure of musculoskeletal functional health outcomes in children and adolescents, addressing upper extremity function, transfers and mobility, physical function and sports, comfort (pain), happiness and satisfaction, and expectations of treatment.[37] It is reliable and valid for children with CP,[38] but has shown only modest sensitivity to change following surgery for these children.[36]
- *Gillette Functional Assessment Questionnaire (FAQ)* is a reliable, condition-specific functional scale developed for children with CP.[39] It is composed of a 10-level ordinal rating scale of parent report of walking abilities, in addition to the degree of difficulty of 22 higher-level skills. It has been used to evaluate effectiveness of surgery in ambulatory children with CP.[40],[41]
- *Functional Mobility Scale (FMS)* measures the level of walking aid support used for each of three distances: 5 m, 50 m and 500 m, corresponding to walking distances encountered in the home, school and the community, respectively.[42] However, it is limited to six levels of walking aid required for the different distances and does not measure any of the other gait-related domains that are important to patients and their parents.

What were the goals of our patient and to what extent were his goals met? His parents wanted him to walk without any walking aids and to preserve his independence and walking abilities. The patient wanted to trip less, get rid of his knee pain, and feel less tired so that he could keep up with his friends. He wanted to look less different from others. He

wanted to stand up taller and walk with his feet flat on the ground without the use of braces. He wanted his feet and legs to point straight ahead. Six months after surgery he has achieved some of his desired goals. However, many of these goals are not captured by any of the outcome measures that have been used for this population, because the content of all these measures were not derived by asking patients or parents what their priorities and goals are. Consequently, many important domains or items are missing, which might account for the modest improvements demonstrated in clinical trials potentially underestimating the outcomes of multilevel surgery. At the same time, some goals that were realized came at the expense of others. He is disappointed that he remains reliant on a walker, even for shorter distances, and that he is still unable to keep up with his peers. He is also unhappy about the sensitivity in his feet and the fact that he still needs his AFOs for support. This speaks to the need for multidimensional outcome measures that can capture both positive and negative outcomes, when considering overall effectiveness.

Gait Outcomes Assessment List (GOAL) questionnaire

To address these limitations, the *Gait Outcomes Assessment List (GOAL) questionnaire* was developed,[43] with items derived directly from qualitative interviews of patients with ambulatory CP and their parents to capture their gait-related priorities and goals. This newly validated measure is the only goal-based, gait-related PROM. The GOAL has 49 items across seven domains: (i) Independence and Activities of Daily Living; (ii) Gait Function; (iii) Comfort and Endurance; (iv) Sports and Recreation; (v) Gait Appearance; (vi) Use of Mobility Aids and Braces; and (vii) Body Image and Self-Esteem. The GOAL generates a

total and seven domain scores, each from 0 to 100. Unique to this measure is the feature that allows the respondent to indicate for each item whether making an improvement on that item is an important goal for them. This allows patients' and parents' goals to be identified that can inform shared decision-making about the choice of interventions, while serving as a more meaningful goal-based measure of outcomes for gait-related interventions. The GOAL has been shown to have construct and convergent validity with strong correlations between the GOAL scores and the GPS, FMS, and FAQ.[43] It is currently undergoing longitudinal assessment for its responsiveness, following which it has the potential to be a more meaningful and comprehensive functional outcome measure that spans the patient-centered domains of the ICF, including activities, participation, and environmental and personal contextual factors aligned with the priorities and goals of this population, while the technical outcomes at the level of the body's function and structure are best measured by gait analysis. From the patient and parent perspective, the GOAL questionnaire would suggest that the multilevel surgery has made our patient better in some domains but not (perhaps yet) as much in others.[44]

Generic patient-reported outcomes measures of pediatric musculoskeletal function

The *Pediatric Outcomes Data Collection Instrument (PODCI)*[37] has been shown to have good reliability, construct validity, and sensitivity to change when tested in a large sample of children (and parents) over a range of ages (2 to 18 years) and diagnoses and has been used to evaluate pediatric fracture management.[45],[46]

The *Activities Scale for Kids (ASK)* is a reliable and valid, self-reported measure of physical function in children, from 5 to 15 years old.[47,48] The ASK comprises 30 items spanning the dimensions of: locomotion, standing skills, transfers, play, personal care, dressing, and other skills. There is a capability version (ASK Capability) that asks kids what they *could have* done, and a performance version (ASK Performance) that ask kids about what they *did*, in the past week. It has been used in studies of fractures of the upper and lower extremity in children.[49–52]

The *Disabilities of the Arm, Shoulder, and Hand (DASH)* outcome measure (30 items) and its shorter version, the *QuickDASH* (11 items), is a reliable, valid, and responsive self-reported measure of physical function and symptoms arising from musculoskeletal disorders of the upper extremity.[53] Although developed for adults, it has been used for pediatric conditions, including fractures of the upper limb.[54,55]

Generic patient-reported outcome measures of health-related quality of life

The *Child Health Questionnaire (CHQ)* is a generic measure of the physical and psychosocial wellbeing of children. It has been extensively validated in a variety of conditions such as asthma, epilepsy, and attention deficit disorder, and musculoskeletal disorders such as juvenile rheumatoid arthritis and pediatric injury.[56–58] The CHQ has an 87-item child self-reported version (CHQ-CF87) and two parental versions (CHQ-PF50 and CHQ-PF28) comprising 50 and 28 items, respectively, which span 14 unique physical and psychosocial constructs, which can generate a summary score for overall physical and overall psychosocial

health, respectively. Normative values of the parent-reported versions are available for the United States.

The *Pediatric Quality of Life Inventory (PedsQL)* is a generic, multidimensional measure of health-related quality of life of children and adolescents.[59] The 23 items cover the core dimensions of physical, social, and emotional functioning, as well as role (school) functioning. The PedsQL generates a total score, as well as a summary score for physical health and psychosocial health. The PedsQL includes three self-reported children's versions for age groups 5–7 years, 8–12 years and 13–18 years, and separate parent proxy reports for age groups 2–4 years, 5–7 years, 8–2 years, and 13–18 years.[59] The developers of the PedsQL have also developed condition-specific modules for many pediatric health conditions.

Patient Reported Outcome Measurement Information System (PROMIS) is an initiative of the National Institutes of Health to establish a system of reliable, valid, flexible, precise, and responsive PROMs.[60],[61] PROMIS measures cover global health, physical function, fatigue, pain, sleep/wake function, emotional distress, and social health. A number of child or proxy item banks are available for pediatric health domains.[62]–[64] The PROMIS Pediatric Mobility item bank assesses activities of physical mobility. The PROMIS Pain Intensity item pool assesses how much a person hurts. The PROMIS Pain Interference item bank assesses the impact of pain on social, cognitive, emotional, physical, and recreational activities as well as sleep and enjoyment in life. The PROMIS Pediatric Upper Extremity item bank assesses activities that require use of the upper extremity including shoulder, arm, and hand activities. The Peer Relationships item bank assesses the quality of relationships with friends and other acquaintances.

Many of these PROs were developed using *item response theory (IRT)*.[65] Large item banks are created to evaluate the full spectrum of a particular domain or aspect of health. These items are calibrated on a scale using IRT methodology (e.g. Rasch scaling). Statistical models based on IRT allows *computer adaptive testing (CAT)*. The item bank provides a common metric, but each respondent only completes a minimum set of items based on responses to a prior question, which will precisely place them along the continuum of that domain.[22] This increases efficiency and reduces respondent burden. However, CATs only work for unidimensional and hierarchical constructs. Multidimensional constructs, like HRQoL, where individual preferences are important, do not lend themselves to CATs.

Condition-specific patient-reported outcome measures

The *Scoliosis Research Society (SRS) Questionnaire* is an extensively validated patient-reported outcome measure for adolescent idiopathic scoliosis.[66] Since its introduction, various versions of the SRS instrument (SRS-22, SRS-23, SRS-24, SRS-30) have been used to evaluate the effectiveness of nonoperative (bracing) and surgical treatments of idiopathic scoliosis. Although it is psychometrically sound and widely translated worldwide, the major limitation of this instrument is that its content is not directly derived from evaluation of patients' priorities, making it possible that important domains and items relevant to this population are missing or inadequately addressed.

The *Oxford Ankle Foot Questionnaire for Children (OxAFQ-C)* is a child- and/or parent-reported measure of wellbeing for children (aged 5–16) affected by foot and ankle

conditions.[67] In contrast to the SRS questionnaire, the content of the OxAFQ was derived from children to ensure that it covers the issues that are important to them.[67] It has 15 items, 14 of which are used to calculate scores for physical, school and play, and emotional domains. A final item addresses a common concern of many children with respect to their ability to wear footwear of their choice. It is reliable, valid, and responsive, and increasingly becoming the PROM of choice to assess the effectiveness of interventions for pediatric foot and ankle conditions.[68],[69]

Challenges of measuring meaningful outcomes in pediatric orthopedics

Despite advances in our understanding of outcomes assessment, much of the literature on pediatric orthopedic conditions continues to focus on physical examination findings and radiographic measurements (such as range of motion, alignment, length, Cobb angles, migration percentages). These might be sufficient for the assessment of technical objectives of our interventions, but are a far cry from the outcomes that matter to patients. There are many challenges to evaluating meaningful outcomes in pediatric orthopedic conditions, some of which were illustrated in the preceding discussion about ambulatory CP.

- For many pediatric musculoskeletal conditions, PROs are poorly defined and the PROMs to measure them don't exist.
- Some outcome measures might be patient- (or parent-) reported but that does not necessarily mean the content is representative of patients' or parents'

priorities, if their content was not derived from patients' priorities.

- When working with children, whose goals should prevail, those of the child's or of their parents? It is important to measure both whenever possible. For a chronic condition, the perspective of the child, when cognitively able, is important because he or she knows best about their own lived experience. The parents' perspectives are also important as they are often primary decision-makers. When children are young or cognitively impaired, we must rely on the priorities of their parents or the primary caregivers who know the child best.
- Some PROMs have not been adequately validated for use for specific pediatric orthopedic conditions.
- Very few PROMs have been tested for their responsiveness or sensitivity to change. Consequently, it is a challenge to interpret whether the lack of a difference following an intervention is indicative of the ineffectiveness of the treatment or the unresponsiveness of the outcome measure, or both.
- For many pediatric orthopedics conditions our interventions are prophylactic and intended to prevent some problem in the future. A prophylactic intervention will not be associated with a change or improvement in a PROM. In some conditions, patients might be asymptomatic or symptomatic at baseline (e.g. hip displacement in nonambulatory CP, scoliosis in nonambulatory CP). If both these types of patients are analyzed together, the lack of response in the asymptomatic group might dilute any improvements noted in the symptomatic group. This could lead to an underestimation of the true effect unless the asymptomatic and symptomatic groups are identified

and stratified at baseline so that they can be analyzed separately.

- For many pediatric orthopedic conditions, the outcomes of interest are years into the future or much later in adulthood (e.g. treatment of developmental hip dysplasia in infancy to prevent osteoarthritis in adulthood). These are difficult to ascertain, necessitating the use of proxy measures whose association with future good or bad outcomes must be validated with some certainty to justify their use.
- The clinician remains responsible for communicating to parents what is known about the natural history of their child's condition and the evidence based on which an informed decision might be made about whether to intervene (because an intervention has been proven to alter the natural history favorably) or which intervention to choose, if more than one option exists. In some instances, there is strong evidence that one specific treatment is clearly superior. However, for many conditions, there may be more than one treatment strategy that could be expected to accomplish the intended goal, but each strategy has its pros and cons that different patients or parents might weigh differently in making a choice that they believe is right for them. For instance, a closed reduction and immediate application of a spica cast of a femur fracture in a five-year-old might be expected to have just as good an outcome as elastic stable intramedullary nailing (ESIN) of the same fracture. ESIN is minimally invasive and avoids the inconvenience of external immobilization, which can interfere with the care and transportation of the child but does require a second operation under general anesthetic for removal of the nails at a later date. The inconvenience of the spica cast might be outweighed by

the benefits of a single intervention with no scars or retained hardware. Either intervention might be a legitimate choice, and different parents might choose differently based on their circumstances and preferences.[44] Facilitating shared decision-making under such circumstance would only be possible, if they were provided that choice and informed about the relative advantages and disadvantages of each approach.

- In the absence of a meaningful PROM, a clinical trial to measure comparative effectiveness might be premature.

Summary

Pediatric orthopedics encompasses a broad spectrum of musculoskeletal conditions involving a variety of pathologies in different anatomic regions of the axial and appendicular skeleton. There is a wide array of existing and emerging treatments for many of these conditions, the effectiveness of which will need to be established. As the number, diversity, complexity, and costs of treatment options grow, the imperative to evaluate outcomes becomes ever more compelling. This evidence must be generated from high-quality research, clinical trials, and prospective comparative cohort studies. However, these trials will be of little value without the appropriate means to measure effectiveness. Much work remains to improve the status of outcome measurement in our field. This chapter has provided an overview of the principles of outcomes development and measurement, and a framework to define more meaningfully what “works” for patients.[70]

Table of instrument measures

- ICF – International Classification of Functioning, Disability and Health[10]
- QOL – Quality of life[18]
- HRQoL – Health related quality of life[19]
- GGI – Gillette Gait (Normalcy) Index[27,28]
- GDI – Gait Deviation Index[29]
- GPS – Gait Profile Score[30]
- GVS – Gait Variable Scores
- MAP – Movement Analysis Profile[31]
- GMFM-66 – Gross Motor Function Measure[33–35]
- PODCI – Pediatric Outcomes Data Collection Instrument[36–38]
- FAQ – Gillette Functional Assessment Questionnaire[39]
- FMS – Functional Mobility Scale[42]
- GOAL – Gait Outcomes Assessment List[43]
- ASK – Activities Scale for Kids[47,48]
- DASH – Disabilities of the Arm, Shoulder, and Hand[53–55]
- QuickDASH – Quick Disabilities of the Arm, Shoulder and Hand[53–55]
- CHQ – Child Health Questionnaire[56–58]
- PedsQL – Pediatric Quality of Life Inventory[59]
- PROs – Patient-Reported Outcomes
- PROMs – Patient-Reported Outcome Measures
- PROMIS – Patient Reported Outcome Measure Information System

- CAT – Computer Adaptive Testing[22]
- IRT – item response theory[65]
- SRS – Scoliosis Research Society[66]
- OxAFQ-C – Oxford Ankle Foot Questionnaire for Children[67]

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Clinical scenario

- Twin siblings with bilateral spastic cerebral palsy (CP) secondary to prematurity, present at age 7. Twin A walks with ankle foot orthoses (AFOs) and the support of a walker – a Gross Motor Function Classification System (GMFCS, level III evidence). His parents report one year of increasing fatigue with walking, problems with balance and tripping, and decreasing tolerance of his AFOs. He walks with a jump gait pattern, up on his tip toes, with his feet and knees rotated internally, and flexed at his knees. His physical examination reveals bilateral equinus contractures involving the gastrocnemius (but not soleus), medial hamstring contractures, and increased femoral anteversion.
- His brother, Twin B, uses a power wheelchair and is able to stand with assistance for transfers (GMFCS, level IV). His parents note decreased hip abduction over the past few years but this does not interfere with care, and he has no hip pain with sitting, standing, or transfers. An anteroposterior (AP) radiograph of the pelvis demonstrates a hip migration percentage (MP) of 35% bilaterally.

Top three questions

1. Does multilevel orthopedic surgery (MLS) improve gait outcomes for children with ambulatory CP?
2. Is three-dimensional gait analysis (3DGA) essential for surgical decision-making for children with ambulatory CP?
3. Does surveillance for hip displacement result in improved outcomes for nonambulatory children with CP?

Question 1: Does multilevel orthopedic surgery (MLS) improve gait outcomes for children with ambulatory CP?

Rationale

Ambulatory children with CP have gait abnormalities due to tendon contractures, bony torsional malalignments, joint instability, muscle weakness, and abnormal muscle activation patterns, which can limit their independence and participation in activities. The musculoskeletal consequences of CP get worse over time. Left untreated, children with bilateral CP experience deterioration of gait and function as they approach puberty and adolescence.[1–3] This can manifest as a decrease in walking endurance (decreased walking distance and fatigue), poor stability, increasing reliance on walking aids, pain, and reduced physical or recreational activity. The previously common practice of multiple episodes of orthopedic surgery addressing abnormalities at a single level at a time over successive years, has been replaced by simultaneously performed MLS that addresses abnormalities at multiple levels of both lower limbs under a single anesthetic and

episode of hospitalization, followed by an intensive course of rehabilitation.

Clinical comment

The objective of MLS is to optimize lower limb biomechanics – restore muscle length and balance, and bony alignment, in order to preserve or improve gait-related function and appearance and to promote independence and increased participation. Additional surgery may be required in the future as a child grows.[4] The effectiveness of such resource-intensive interventions deserves clarification.

Available literature and quality of the evidence

- Level II: 1 randomized controlled trial (RCT)[5] and1 prospective cohort.[4]
- Level III: 1 retrospective cohort.[6]

Findings

In a small RCT by Thomason et al., patients were allocated to either MLS (n = 11) or progressive resistance strength training (n = 8).[5] At 12 months, the MLS group had a 35% improvement in the Gait Profile Score (GPS), an improvement over 4 times the minimally clinically important difference (MCID) of 1.6°. The patients in the MLS group were followed to 24 months, showing a clinically significant improvement of 4.9% in their Gross Motor Function Measure-66 (GMFM-66) score. The five-year outcomes of the same MLS cohort showed improvements from baseline of 64% in GPS and 3.29% in GMFM-66. The Functional Mobility Scale (FMS) improved in nearly half the children at 50 m and 500 m, and no child had an FMS rated worse than before surgery.[4]

In 2018, Dreher et al. reported the outcomes of a retrospective cohort of 231 patients with bilateral CP who underwent MLS at three high-volume centers that utilized 3DGA for decision-making and outcome assessment.[6] At one year, GPS improved by an average of 5° which was maintained at a mean of nine years after surgery. Seventy-seven percent of children maintained their improvement in the long-term. Up to 40% of children required additional but smaller interventions at a later date.

The outcome measures used in these studies are primarily measurements of gait impairment derived from 3DGA (GPS), and physiotherapist observed functional measures (GMFM-66). The FMS measures the type of walking aid used for different walking distances (5 m, 50 m, and 500 m). Although studies do not adequately evaluate patient-reported outcomes (PROMs) that are aligned with the goals of patients and parents, a recent study has shown a strong correlation between the GPS and the GOAL questionnaire, which is a goal-based PROM derived from the priorities of children with ambulatory CP and their parents.

Resolution of clinical scenario

Evidence from one small RCT and one large multicenter retrospective cohort (without controls) study of prospectively collected data over the long term suggests that Twin A would benefit from appropriately selected MLS, particularly if performed at a high-volume center utilizing 3D gait analysis with access to experienced rehabilitation personnel. The functional outcomes he and his parents seek are likely to be achieved in the short term and maintained in the long term. However, he might require additional surgery before the end of growth.

Question 2: Is three-dimensional gait analysis (3DGA) essential for surgical decision-making for children with ambulatory CP?

Rationale

Although MLS might be beneficial, the question remains whether 3DGA is necessary to inform which operations to include for MLS, and whether this leads to improved outcomes over MLS performed without 3DGA to guide decisions. 3DGA has the potential for such a benefit, since gait deviations in CP are often multiplanar and complex interactions of pathologic and compensatory patterns that are difficult to interpret and quantify with observational gait analysis (OGA) alone. 3DGA in a motion lab is the best technology available to objectively quantify gait deviations and has greatly improved our understanding of the biomechanics of pathological gait patterns in children with CP.

Clinical comment

Surgical decision-making in ambulatory CP involves integrating information from the history of a patient's gait problems, physical examination, including observation of gait, patient goals, and expectations, lower extremity imaging, in addition to 3DGA.[7] In order for 3DGA to be deemed essential for surgical decision-making, the data from 3DGA should be reliable, should alter surgical decision-making at least some of the time, and should lead to improved patient outcomes. This is crucial to establish because there are many centers that perform MLS without access to, or use of, 3DGA.

Available literature and quality of the evidence

3DGA reliability

- Level II: 2 prospective diagnostic studies.[8,9] Level III: 6 retrospective diagnostic studies.[10–15]

3DGA alters decision making

- Level II: 1 RCT.[16]
- Level IV: 1 retrospective cohort.[17]

3DGA improves outcome

- Level I: 1 RCT.[18]

Findings

3DGA reliability

Concerns were raised in 2003 by Noonan et al. about the variability of data generated by different motion labs testing the same 11 patients.[8] Some of this variability can arise from patients themselves and some can be explained by a lack of standardization across different labs. Gorton et al. evaluated the sources and magnitude of kinematic variability of one subject at 12 motion analysis laboratories and found the standard deviation (SD) of mean joint angles of the lower extremity varied from 1.2° to 7.3°.[9] The major source of variability was marker placement by the laboratory staff, and a standardized marker placement protocol improved the SD by 22% in seven of nine kinematic measurements. Pinzone et al. compared the normative data of 81 patients at two well-established pediatric motion analysis centers and found the difference between institutions to be small, with mean SD of

kinematic measurements between 2.2° and 9.7° and mean SD of moments and powers between 0 and 0.3.[10] Several studies in children with CP suggest that 3DGA is reliable when tested at the same institution,[11–13] but summary gait deviation scores can vary substantially between institutions if gait laboratory hardware, processing, and model application are not standardized.[14] OGA using the Edinburgh Visual Gait Score (EVGS) offers an alternative to 3DGA but has high variability and inconsistent reliability. One study found a kappa value for intraobserver reliability of 0.54 (moderate) or below in 11 of 17 scoring items. When compared with 3DGA, complete agreement with EVGS was obtained only 61% of the time.[15]

3DGA alters decision-making

Several case series have shown that the addition of 3DGA does alter decisions first made by OGA. When 3DGA was analyzed, Cook et al. found that 11% of 102 patients did not need the surgery that was proposed by OGA alone.[17] 3DGA concurred with 161 proposed procedures, disagreed with 54 proposed procedures, and added 52 additional procedures. However, are the altered decisions better? Wren et al. randomized patients who were candidates for MLS into two groups, a gait report group where the surgeon received a 3DGA report prior to surgery, and a control group where the surgeon did not receive the 3DGA report.[16] The participating surgeons in this trial did not consistently follow the recommendations of the 3DGA, and more often than not followed their original decisions based on their OGA. When 3DGA recommendation reinforced the surgeon's planned procedures based on OGA, the recommendation was accepted more often in the gait report group (91% vs 71%, relative acceptance = 1.30). When the 3DGA recommended against a planned procedure based on OGA, it was abandoned more

frequently in the gait report group (48% vs 27%, relative acceptance = 1.78). However, when the 3DGA suggested an additional procedure that was not part of the surgeon's plan based on OGA, it was seldom added in either group (12% gait report vs 7% control, relative acceptance = 1.88).

3DGA improves outcome

Wren et al. reported the results of this RCT to examine whether outcomes were better in the patients who were allocated to the gait report group.[18] Unfortunately, this study could not satisfactorily answer the question because of the low concordance between the 3DGA recommendations and the actual surgery that was done (42% gait report, 35% control). They did find that, when concordance between surgery done and gait analysis recommendation was more than 50%, Functional Assessment Questionnaire (FAQ) was more likely to improve (43% vs 23%) and the change in Gait Deviation Index (GDI) was greater (7.5 vs 4.5).

Resolution of clinical scenario

For Twin A there is evidence that the use of 3DGA prior to MLS can influence decision-making by altering decisions made by OGA alone. There is moderate evidence that 3DGA is more reliable that OGA. Although it is believed that 3DGA contributes to better decisions and is widely recommended prior to MLS, there is less evidence that decision-making for MLS by 3DGA directly contributes to improved surgical outcomes.

Question 3: Does surveillance for hip displacement result in improved outcomes for nonambulatory children with CP?

Rationale

Population-based studies in countries with universal healthcare have established that hip displacement occurs in one-third of children with CP, with nonambulatory (GMFCS, level IV and V) children affected in 75–90% of cases.[19] Progressive hip displacement (subluxation to dislocation) can be associated with contractures that interfere with care, including dressing and hygiene, pain, difficulty with seating and mobility, fractures, and a negative impact on the quality of life. Hip displacement can be silent, leading to late presentation. More severe hip displacement might be associated with worse health-related quality of life (HRQoL) and less amenable to effective treatment. Hip surveillance achieved by a schedule of regular physical examinations and radiographs throughout childhood can identify hip displacement before it becomes symptomatic, allowing for earlier or timelier, less invasive, and presumably more effective interventions.

Clinical comment

Twin B is nonambulant and at high risk for progressive hip displacement. He currently has no hip-related symptoms, but radiographs have revealed that he has mild subluxation of both hips with an MP of 35%. The status of his hips would not be known without radiographs. Radiographic measurement of MP is the cornerstone of all hip surveillance programs. Both timing and type of surgical intervention is influenced by MP and other radiographic

findings. Surgery to treat hip displacement can involve (i) soft tissue surgery (lengthening/releases primarily of the adductors iliopsoas, and proximal or distal hamstrings); these are preventive operations which are less invasive but often associated with high rates of recurrence requiring additional future surgery; (ii) reconstructive surgery includes soft tissue releases along with bone operations (femoral varus osteotomy and pelvic osteotomies); these are more invasive and might be associated with higher rates of complications if done for more severe displacement; (iii) salvage surgery, which is less effective, is reserved for when degenerative changes preclude reconstruction (proximal femoral resection, valgus osteotomy, arthroplasty). What is the evidence that a hip surveillance program results in improved hip outcomes for nonambulatory children with CP?

Available literature and quality of the evidence

Hip displacement is associated with poorer HRQoL

- Level III: 3 retrospective cohort studies.[20–22]

Hip surveillance improves clinical outcomes

- Level II: 2 prospective cohort studies.[23,24]
- Level III: 1 retrospective cohort study.[25]

Hip reconstructive surgery improves HRQoL

- Level IV: 1 case series.[26]

Findings

Hip displacement is associated with poorer health related quality of life

Increased hip displacement is associated with poorer HRQoL as measured by the Caregiver Priorities and Child Health Index of Life with Disabilities (CPCHILD) questionnaire, a caregiver-reported measure of HRQoL for children with nonambulatory CP.[27] Jung et al. studied 34 patients with CP and found a decrease in total CPCHILD score with incremental increase in MP (Pearson's r = −0.382).[20] Ramstad et al. found that MP >40% was associated with lower CPCHILD domain scores in Comfort and Emotions and Health in a cohort of 67 patients.[21] In a separate study of 77 patients, Ramstad et al. found that pain as measured on the Child Health Questionnaire (CHQ) occurred in 60% of hips with an MP >50% compared with 14% in an MP <50%. MP >50% was an independent risk factor for pain in multivariate analyses.[22]

Hip surveillance improves clinical outcomes

A 10-year prospective population-based cohort study reported by Hagglund et al. showed that the implementation of a population-based hip surveillance program with prompt referral, treatment, and continued follow-up care essentially eliminated hip dislocation in children with CP in southern Sweden.[23] Hagglund et al. subsequently published the 20-year results of the Swedish hip surveillance program, showing that the population prevalence of hip dislocation had decreased from 8% prior to the implementation of surveillance to 0%, and any need for salvage surgery was eliminated.[25] Every child with a dislocation in their historical cohort had severe hip pain. GMFCS was the strongest predictor of need for preventative surgery (odds ratio [OR] = 12.72 for GMFCS, level III, 18.16 for GMFCS, level IV, and 41.04 for GMFCS, level V), and children with spastic bilateral CP had twice the risk of undergoing surgery compared with those with dyskinetic CP when adjusted for GMFCS (OR = 1.98).

The long-term outcomes of preventative surgeries (i.e. soft tissue releases) as part of the Australian hip surveillance program was evaluated by Shore et al. in a level II prospective cohort trial.[24] GMFCS level and initial MP were the most important predictors of the need for subsequent reconstructive surgery. Overall success was only 32%, with GMFCS levels IV and V having the highest recurrence rates of 73% and 86%, respectively.

Hip reconstructive surgery improves HRQoL

A level IV prospective cohort study by DiFazio et al. of 38 patients found that hip reconstructive surgery increased CPCHILD score from 49.6 points to 58.9 points at 24 months.[26]

Resolution of clinical scenario

There is good evidence that the implementation of hip surveillance enables the early detection of hip subluxation, and if combined with a program of intervention can eliminate hip dislocations and need for salvage surgery. Twin B will benefit from ongoing surveillance to track the progression of his hip displacement and allow timely intervention well before the hip is dislocated. There is less evidence that early preventive surgery (less invasive but high rates of recurrence and repeat surgery) is superior to later reconstructive surgery (more invasive, but less likely to recur) which has been shown to have a positive impact on HRQoL. However, both approach require hip surveillance of the MP to pick the optimal time to intervene and to avoid less effective salvage surgery.

Summary of answers

- MLS improves gait indices and functional outcomes when performed at high-volume centers that use 3D gait analysis for surgical decision-making in collaboration with experienced rehabilitation personnel.
- Use of 3DGA does alter surgical decisions about the specific types of MLS, which has the potential to lead to better outcomes if followed.
- Hip displacement in nonambulatory children with CP is associated with increased pain and poorer HRQoL.
- Population-based hip surveillance programs coupled with timely access to surgical intervention can dramatically reduce the prevalence of painful hip dislocations.
- Reconstructive surgery for hip displacement in nonambulatory children likely improves HRQoL outcomes.

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175 Pediatric Osteoarticular Infections

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Clinical scenario

- A 3-year-old child presents with malaise, low-grade fever (38°), and a limp.
- Physical exam reveals pain with hip motion, limited internal rotation.
- X-rays are negative. Ultrasound shows a moderate hip effusion. Erythrocyte sedimentation rate (ESR) and C-reactive protein (CRP) are mildly elevated.
- There is clinical concern for septic hip and/or osteomyelitis of the proximal femur/pelvis, versus transient synovitis/inflammatory arthritis.

Top three questions

1. In children aged less than four years with suspected osteoarticular infection, is oropharyngeal *Kingella kingae* carriage status a viable indirect diagnostic alternative to synovial fluid/bone sample cultures?
2. In children with acute osteomyelitis, is outpatient oral antibiotic therapy equivalent to inpatient treatment

with intravenous (IV) antibiotics?

3. In children with a chronic benign bone lesion, what is the best method to differentiate chronic nonbacterial osteomyelitis (CNO)/chronic recurrent multifocal osteomyelitis (CRMO) from bacterial osteomyelitis (BOM)?

Questions 1: In children aged less than four years with suspected osteoarticular infection, is oropharyngeal Kingella kingae carriage status a viable indirect diagnostic alternative to synovial fluid/bone sample cultures?

Rationale

Osteoarticular infections (OAI) in young children are frequently caused by organisms carried asymptomatically in the respiratory tract, such as *Staphylococcus aureus*, *Streptococcus pneumoniae*, *Streptococcus pyogenes, Haemophilus influenzae* type b, or *K. kingae*,[1],[2] with *K. kingae* currently being the most common pathogen causing osteoarticular infection in children <4 years of age in many regions.[3],[4] Septic arthritis (SA) due to *K. kingae* may be particularly difficult to clinically differentiate from transient synovitis, as *K. kingae* infections are typically characterized by relatively mild symptoms, low-grade fever, and minimally elevated inflammatory markers.[5],[6]

Clinical comment

Standard practice for diagnosis of SA includes arthrocentesis with cell count and culture. Due to inherent difficulties in obtaining positive cultures for *K. kingae*, real-time quantitative polymerase chain reaction (qPCR) assays on synovial fluid, targeting *K. kingae*, are recommended in children <4 years.[7] As acquiring synovial fluid from the affected joint typically necessitates administration of anesthetic and an invasive procedure (arthrocentesis or arthrotomy), the ability to diagnose *K. kingae* SA by alternative noninvasive measures would be highly desirable. The sensitivity/specificity of oropharyngeal *K. kingae* carriage status as indirect evidence of *K. kingae* SA is essential to determining the utility of this potential indirect test.

Available literature and quality of the evidence

- Level II: 2 prospective diagnostic studies.[5],[7]
- Level III: 2 retrospective diagnostic studies.[8],[9]
- Level IV: 3 case series.[3],[4],[10]

Findings

In Switzerland and France, *K. kingae* causes up to 90% of osteoarticular infection in children <4 years of age.[1],[4] *K. kingae* is notoriously difficult to culture on standard culture media, with a false-negative rate of almost 100%.[5],[11] Culturing in liquid medium/blood culture vials improves detection, yet the false-negative rate is still high.[12],[13] Given high rates of false negative cultures, a definitive diagnosis cannot be made in many cases, and it can be difficult to determine appropriate treatment, including whether antibiotics are required, and which antibiotic should be selected. The false-negative culture rate ranges from 24 to 68% for acute hematogenous osteomyelitis (AHO) and 21–

80% for SA.[14–17] It is theorized that *K. kingae* must first colonize the oropharynx in order to subsequently travel by hematogenous spread to a distant osteoarticular location.[18] Obtaining oropharyngeal samples is minimally invasive. Real-time PCR can be performed on these samples, providing results in less than 24 hours. Multilocus sequence typing (MLST; a technique for identifying multiple loci of microbial species using the DNA sequences of internal fragments of multiple housekeeping genes) allows for genotyping of oropharyngeal *K. kingae*, and this has demonstrated that strains carried in the oropharynx of sick children matched with the most frequently invasive strains of *K. kingae* causing OAI, namely ST-6 and ST-25.[8]

A number of studies have investigated the use of oropharyngeal carrier status in the diagnosis of *K. kingae* OAI. A prospective study demonstrated that detection of *K. kingae* in the oropharynx of children aged between 6 and 48 months with suspected OAI had a positive predictive value of 90.5% in diagnosing *K. kingae* osteoarticular infection.[7] A prospective case control study of 77 children admitted for suspected osteoarticular infection and 286 age-matched controls in Switzerland and Canada investigated whether oropharyngeal swab polymerase chain reaction (PCR) could predict OAI due to *K. kingae* in young children with osteoarticular symptoms.[9] The sensitivity and specificity of the oropharyngeal swab PCR assay for *K. kingae* were 100% and 90.5%, respectively. Oropharyngeal testing has also been used to diagnose *K. kingae* in epidemics that occurred in France and Israel.[8,10]

Although detection of K. kingae in oropharyngeal swabs does not mean always that a child has a *K. kingae* OAI, negative oropharyngeal results may exclude *K. kingae* as the cause of their osteoarticular symptoms. Indirect testing has some limitations: it is possible that there could be

multiple organisms causing an infection of which *K. kingae* is only one, or *K. kingae* could be present in the oropharynx but a different bacteria or a nonbacterial process could be responsible for joint inflammation. The technique is also limited by mild discomfort in obtaining oropharyngeal specimens and requires optimal extraction of bacterial DNA. Subsequent investigations focusing on colonization rates of the respiratory tract and test contamination rates may permit more confidence in this indirect diagnostic strategy. PCR assay on oropharyngeal swabs should be added to the standard OAI workup, but at this time synovial analysis is still necessary.

Resolution of clinical scenario

Given 100% sensitivity and 90.5% specificity for nasopharyngeal swab PCR for *K. kingae* in predicting *K. kingae* as the causative organism in a presumed septic joint, this is a reasonable adjunct test in facilities where real-time PCR for *K. kingae* is available.[7] Until further testing confirms sensitivity and specificity, rates of test contamination and rates of respiratory tract colonization, synovial analysis of the involved joint for cell count culture, and PCR are recommended.

Questions 2: In children with acute osteomyelitis, is outpatient oral antibiotic therapy equivalent to inpatient treatment with intravenous (IV) antibiotics?

Rationale and clinical comment

Acute osteomyelitis may occur through hematogenous spread, by contiguous extension of neighboring infection, or through penetration into the bone with direct inoculation.[19] Acute osteomyelitis is typically treated medically not surgically.[19],[20] Patients are admitted and hospitalized, bony/joint biopsy is obtained, and IV broad spectrum empiric antibiotics are initiated, targeted to cover the most likely causative organisms for that region/population. Culture/sensitivity results guide changes to the antibiotic regimen. In cases of suspected bacterial infection with presumed false-negative cultures, empiric antibiotics are continued and are based on regional data on the most common causative organisms and rates of community-associated methicillin-resistant *S. aureus* (MRSA). Historically, patients with acute osteomyelitis would be admitted and receive weeks of IV antibiotics. Over the past decade the length of hospital stay and parenteral treatment has decreased in favor of a less restrictive oral treatment, reducing both the management cost (fewer hospitalization days, less expensive medications) and complications related to IV or peripherally inserted central catheter (PICC) line.[21]

Available literature and quality of the evidence

- Level I: 1 RCT.[21]
- Level II: 1 prospective cohort.[22]
- Level III: 1 retrospective cohort study and 1 case control study.[20],[23]
- Level IV: 3 case series.[4],[22],[24]

Findings

Recent evidence suggests shorter courses of antibiotics (3–4 weeks) and early conversion (day 2–4) from IV to oral administration is safe and effective in acute noncomplicated osteomyelitis that is responding to treatment.[21] Even with prolonged clinical symptoms prior to diagnosis and positive blood cultures, this regimen was successful.[21] Such protocols can even be considered in regions with relatively high rates of MRSA, such as the United States.[22] Large oral doses of well-absorbed antibiotics (such as first-generation cephalosporin or clindamycin), administrated three or four times daily (depending of half-life of the medication), are required to efficiently eradicate noncomplicated cases of osteomyelitis while reducing cost and allowing earlier discharge.[21]

Guidelines for transition to oral antibiotics include: (i) confirmed diagnosis of uncomplicated hematogenous osteomyelitis, (ii) clinical improvement of signs and symptoms, (iii) afebrile at least 48 hours, (iv) CRP decreased from 50% of initial CRP, and (v) received at least 72 hours of IV antibiotics.[20]

The emergence of *K. kingae* in children aged <4 years and the frequent paucity of symptoms have led some authors to question the need for initial IV therapy in Europe.[25] Since early transition to oral therapy has also proved to be a safe option in patients with *S. aureus* OAI (both osteomyelitis and SA), including those due to MRSA, ambulatory treatment might also be considered elsewhere.[22]

To date, only two clinical studies have investigated outcomes following completely ambulatory treatment in pediatric OAI. Roul-Levy et al. treated uncomplicated osteomyelitis in healthy children, with a six-week oral antibiotic regimen and retrospectively reviewed their outcomes.[23] The contraindications for oral treatment at the Emergency Department were (i) patients with severe signs

of infection including CRP rate >50 mg/L, (ii) fever >38.5° or signs of septic shock (hypothermia, hyperthermia, tachycardia, hypotension), (iii) subperiosteal abscesses suspected or diagnosed at admission, (iv) multiple sites of infection, (v) severe immunosuppression or underlying conditions such as sickle cells disease.[23] Since the incidence of clindamycin- and erythromycin-resistant *S. aureus* is increasing, and the necessity to take cephalosporin four times daily, the authors recommended oral amoxicillin + clavulanic acid, despite low bone diffusion. Outcomes were satisfactory at six months follow-up, with only one treatment failure (5%), while three failures were observed in the control group who received initial doses of IV antibiotics before transitioning to oral therapy.

Alcobendas et al. reported a prospective study evaluating a three-week oral treatment in 25 young (mean age 25 months) healthy children with OAI (osteomyelitis, arthritis, and spondylodiscitis), who were compared to 228 hospitalized ones.[25] Patients with a suspicion of OAI and no severe clinical symptoms (no evidence sepsis/shock) were sent home with either cephalosporin, clindamycin, or amoxicillin + clavulanic acid, and received a follow-up appointment within 48 hours. More than half (52%) of the patients treated orally showed fever at some point during the disease course, but all of them had full recovery without sequelae at most recent follow-up. Arthrocentesis and articular lavage were performed in the seven cases of arthritis, but none of them required conversion to open arthrotomy. Of note, MRSA was not found in any patient treated orally. MRSA and a CRP >100 mg/L at presentation were found to be risk factors for complications and sequelae in both groups.

The results of oral only regimens versus traditional IV followed by oral regimens for acute osteomyelitis is limited and evolving. The outcomes of this treatment have not been sufficiently studied to recommend sole oral antibiotic regimens at this time, given the potential severity of OAI and the risk of severe complications in young patients.[24]

Resolution of clinical scenario

In this patient with mild clinical, radiological and biological signs of infection, MRI can diagnose the presence of acute osteomyelitis, and aspiration of the hip can determine whether the effusion is septic. Provided the patient has acute osteomyelitis only, empiric ambulatory antibiotics such as first-generation cephalosporin and/or amoxicillin + clavulanic acid could be considered, but is not standard care. Duration of ambulatory treatment should be at least three weeks. If synovial cell count and clinical signs are suspicious for SA, the patient must undergo irrigation and debridement of the hip with hospitalization, and this same oral antibiotic regimen could still be considered.

Questions 3: In children with a chronic benign bone lesion, what is the best method to differentiate chronic nonbacterial osteomyelitis (CNO)/chronic recurrent multifocal osteomyelitis (CRMO) from bacterial osteomyelitis (BOM)?

Rationale and clinical comment

CNO/CRMO is an idiopathic, auto-inflammatory disorder characterized by multifocal osseous lesions that may mimic

BOM. No diagnostic criteria or biomarkers exist for CNO, and it remains a diagnosis of exclusion. Differentiating between CNO and BOM is paramount, as delayed diagnoses of BOM may result in complications.

Clinical forms of CNO vary from unifocal and time-limited courses to prolonged, chronic and/or recurrent and multifocal forms with severe courses, known as CRMO.[26]

BOM can be classified into three groups (acute, subacute, and chronic) depending on the duration of symptoms. At first presentation, distinguishing a unifocal CNO from a subacute or chronic BOM can be challenging, and requires treatment regimens differ significantly.

Available literature and quality of the evidence

Findings

- Comparison between chronic nonbacterial and bacterial osteomyelitis in children:

  Level III: 1 retrospective cohort.[27]

- Chronic nonbacterial osteomyelitis:

  Level II: 2 prospective cohorts.[26],[28]

  Level III: 2 retrospective cohorts.[29],[30]

  Level IV: 2 literature reviews.[31],[32]

Epidemiology and pathophysiology of CNO

The epidemiology of CNO is not well described. However, it is described as the most common auto-inflammatory bone disorder in central Europe,[31] with an incidence rate estimated at 0.4 per 100 000 children/year in Germany.[27] Although CNO is considered a rare disorder, its incidence is likely underestimated: Schnabel and al. reported CNO

incidence comparable to BOM incidence (4.7 new cases of CNO per year vs 5.4 cases of BOM per year).[27] The exact pathophysiology of CNO remains unknown. Immune dysregulation has been hypothesized as the cause of chronic bone inflammation, bone erosions, and hyperostosis with 38% patients with elevated antinuclear antibodies in one study,[26] and bone biopsies showing chronic bone inflammation and lymphoplasmacytoid infiltrates in another.[27]

Additional inflammatory extra-osteo-articular manifestations have been described in 10 to 25%.[27],[29],[32] The skin (18% acne, psoriasis, palmoplantar pustulosis), and the gastrointestinal systems (5%) (Crohn disease, ulcerative colitis) are most commonly affected.[26]

Existence of extra-osteo-articular manifestations may help to differentiate CNO from BOM.[27]

Demographic data and clinical characteristics

- Sex: no difference in distribution has been reported.[27]
- Age: CNO affects children and adolescent with peak age reported between 7 and 12 years.[26],[27],[31] It rarely occurs in children <3 years old,[27] whereas BOM can affect children at any age.
- Clinical characteristics: clinical presentation of CNO is variable (unifocal or multifocal). Schnabel et al. reported that it is not possible to differentiate CNO from BOM based on clinical findings.[27] Clinical manifestations of CNO include: clinical signs of osteomyelitis (elevated temperature), swelling, pain (92%), redness, and arthralgia (65%).[26] In CNO, noninfectious arthritis is described in 30%.[31],[32]

- Location: children with CNO more commonly suffered from multifocal bone pain.[27] Multifocal lesions have been reported in 78% of patients in the Eurofever (European registry of autoinflammatory diseases) cohort.[27] Both CNO and BOM typically affect the lower limbs (50%)[27],[29] in the metaphyseal part of the long bone.[26]
- Spinal, pelvic, clavicular, and mandibular lesions (especially hyperostosis lesions) are commonly seen in CNO.[26–30],[32]

Radiology

X-rays cannot differentiate CNO from BOM: in both cases, x-rays can initially be normal, or show osteitis or lytic lesions with marginal sclerosis.[26]

Magnetic resonance imaging (MRI) can identify bone edema in the early stages of both CNO and BMO. Other typical findings include cortical thickening, and/or lytic lesions with sclerotic edges.[32] Hyperostotic lesions are more often described in CNO.[27] Abscesses, cutaneous fistulas, and sequestrations are exclusively seen in BOM.[27]

Whole-body MRI is a useful tool to diagnose asymptomatic multifocal lesions in the early stages of the disease in CNO,[28] and thus differentiate CNO and BOM: Schnabel et al. reported unifocal lesion more commonly in the setting of BMO (unifocal lesion: 20% in CNO, 80% in BMO).[27]

Biomarkers

At present, no specific biomarkers exist for the diagnosis of CNO. In CNO, inflammatory markers are typically elevated (67%):[29] mildly elevated CRP (mean 23.6 mg/L) in 50%,[26],[29] mildly elevated ESR (mean 37.7 mm/h) in 86%.[27] Blood cell count is typically normal (77%).[29] Schnabel et al.

reported no differences between CNO and BMO in the inflammatory markers, just a trend to higher CRP in BOM.[27] Biomarkers including antinuclear antibodies and rheumatoid factor and HLA B27 genotyping do not differ between CNO patients and healthy patients.[28]

Jansson score[30]

This score was described to facilitate the diagnosis of CNO and is based on seven criteria:

- Normal blood cell (odds ratio [OR] = 81.5) (13 points).
- Symmetric bone lesions (affecting both sides) (OR = 30.0) (10 points).
- Lesions with marginal sclerosis (OR = 26.8) (10 points).
- Normal body temperature (OR = 20.3) (9 points).
- Vertebral, clavicular, or sternal lesions (OR = 13.9)(8 points).
- Radiologically proven lesions >1 (OR = 10.9) (7 points).
- CRP ≥10 mg/L (OR = 6.9) (6 points).

A score ≥39 had a positive predictive value of 97% and a sensitivity of 68% for CNO.

Bone biopsy

Bone biopsy is an invasive procedure but remains an essential diagnostic tool especially to rule out malignant lesions. Both in CNO and BOM, bone biopsy shows signs of inflammation: Schnabel et al. described differences in the composition of cellular infiltrates with a predominance of neutrophils in BOM and lymphocytes plasma cells in CNO.[27]

Bacteriological cultures or PCR are always negative in CNO,[32] and may be helpful in BOM to identify the causative agent. Nevertheless, identification of the causative agent may be absent in up to 40% of cases of BOM.[16],[27]

Resolution of clinical scenario

In our clinical scenario, in case of culture and PCR-negative results, the differential diagnosis could still include culture negative (false-negative) osteomyelitis with neighboring SA, or inflammatory arthritis, or CNO with inflammatory arthritis. MRI should be used to assess the lesion and scan for potential multifocal lesions.

Conclusion

In case of unifocal lesion, age at diagnosis, clinical and biological findings, nonmusculoskeletal manifestations, x-rays and MRI can help to differentiate subacute or chronic BOM from unifocal CNO (which represent 20% of the CNO), but none is definitively diagnostic. Whole-body MRI is recommended to characterize lesions and may identify asymptomatic multifocal lesions. The Jansson score may help to guide diagnostic and therapeutic decisions:

- if ≤28 points, biopsy and cultures are recommended.
- if ≥39 points, CNO is strongly suspected.
- If 29–38 patients could be clinically monitored and need for biopsy re-evaluated.

Summary of answers

- Indirect diagnosis of *K. kingae* OAI through oropharyngeal culture and DNA detection has high sensitivity and specificity, but has not been fully

validated and is not yet standard of care. Standard work up including serology for CBC, ESR, CRP blood cultures, and synovial fluid analysis including cell count, culture with PCR for detection of *K. kingae* DNA in children aged <4 is still recommended.

- Outpatient antibiotics without an initial IV antibiotic regimen can be considered in patients with acute osteomyelitis, provided they have mild clinical and biological signs without complications. Bone biopsy/arthrocentesis is recommended before starting any antibiotic therapy for any suspected OAI.
- Tumor or CNO can mimic BOM. Localized MRI and biopsy followed by whole-body MRI in culture negative lesions can help to differentiate between these diagnoses.

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176 Simple Bone Cysts

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Clinical scenario

- A five-year-old boy is limping and complaining of thigh pain. He does not have any other symptoms.
- There is no clinical or laboratory evidence of infection. Ultrasound of the hip shows no effusion.
- He has mild tenderness in his inguinal region and slightly decreased hip range of motion (ROM). Radiographs show a lucent lesion at the femoral neck.
- A simple bone cyst (SBC) is suspected.

Top three questions

1. In children with an isolated lucent lesion in a long bone, are radiographs and clinical presentation sufficient to make the diagnosis of SBC?

2. In children with an SBC, which features should prompt treatment of the lesion?
3. In children with an SBC, which treatment yields the most successful results at maturity, considering cyst healing and (re)fracture rate?

Question 1: In children with an isolated lucent lesion in a long bone, are radiographs and clinical presentation sufficient to make the diagnosis of SBC?

Rationale

SBCs are benign fluid-filled lesions of bone, with unknown prevalence, as many are asymptomatic. They are estimated to account for 3% of all bone tumors, with males being three times more commonly affected than females. Bone cysts may be unicameral or contain one or more septations. Although SBCs can affect any bone, the proximal humerus and proximal femur account for 90% of all locations.[1,2] Patients with SBC usually present with a pathologic fracture or pain, although some SBCs are discovered incidentally when x-rays or other imaging is obtained for unrelated reasons. Differentiating between a benign lesion and a neoplastic process is of paramount importance.

Clinical comment

The majority of patients presenting with SBC are children, and as such may have difficulty being still for axial imaging such as computed tomography (CT) or magnetic resonance imaging (MRI). Thus, the question arises: are x-rays sufficient to make the diagnosis?

Available literature and quality of the evidence

- Level IV: 1 study
- Level V:1 study.

Findings

In most cases, plain radiographs and clinical presentation are sufficient to establish the diagnosis of SBC. MRI is indicated in the presence of atypical features: periosteal reaction, eccentric or other atypical location, extension to the articular surface, or soft tissue involvement.[3–6] Cases of pseudocystic osteosarcoma or low-grade central osteosarcoma that were mistaken for SBC have been reported.[3]

When present in a lucent lesion, the fallen fragment sign is pathognomonic of SBC. The fallen fragment is caused by fracture of the cyst wall and dislodgement of fragments into the cyst cavity. Its presence establishes that the cystic contents are not solid, thus distinguishing the unicameral bone cyst from fibrous lesions of bone, which have a solid center.[5] This is particularly helpful in cases where breaches in the cortex secondary to fracture may appear consistent with an intramedullary malignancy with cortical erosion.[3]

In a case series including 51 cases of SBC with 39 cases in patients 17 years old or younger, Struhl et al. identified 10 cases with a fallen fragment sign. All cysts were seen in patients with open growth plates and associated with pathologic fracture through the cyst.[5] Farr et al. surveyed pediatric orthopedic surgeons, members of the European Paediatric Orthopaedic Society, and the Pediatric Orthopaedic Society of North America and found that the preferred diagnostic modalities to confirm the diagnosis of a unicameral bone cyst (UBC) in the humerus were radiographs (88%), MRI in cases of questionable diagnosis

(58%), or CT scan (8%).[6] Only 10% of respondents preferred obtaining an MRI in every single SBC case. In painless, incidental SBCs, advanced imaging (MRI/CT) was never (50%), sometimes (43%), or always (7%) preferred. This rate, however, increased in painful cases to 9, 58, and 33%, respectively, and in fractured UBCs to 36, 54, and 10%, respectively. Bone biopsy was mainly preferred in cases of unclear diagnosis/imaging (64%) or pathologic fracture (3%); 8% of respondents reported they always performed a biopsy. Most common reasons for biopsy were: radiographs unclear (73%), pain (13%), need to establish differential diagnosis (9%), unusual location (9%), and physeal proximity (9%).

Resolution of clinical scenario

In this child with a lucent lesion of the femoral neck, without constitutional symptoms and no clinical or radiological signs of infection or malignancy, plain radiographs alone are typical, yet there is low evidence to guide clinical management at this time.

Question 2: In children with an SBC, which features should prompt treatment of the lesion?

Rationale

Although SBCs are benign lesions, their treatment course may be prolonged and have a significant impact on the patient and family's quality of life, due to relatively high recurrence rates, risk of pathologic fractures,[7] relatively poor efficacy of traditional treatment methods, necessitating activity restrictions to avoid pathologic fractures; evolution to complete healing is rare.[8] Growth

disturbance affects up to 10% of patients, leading to angular deformity or limb length discrepancy.[9–11] Children with SBCs are at risk for continued pain, activity restriction, and anxiety.[12]

Clinical comment

Identifying patients and/or cyst features that predict the risk of fracture in SBCs would help surgeons to select the appropriate treatment for each patient and lesion.

Observation may be a choice for an asymptomatic humeral SBC with minimal cortical thinning. However, for cysts that are large or progressively increasing in size, expansile with progressive thinning of the cortex, and particularly those in lower extremity weight bearing bones, operative treatment may be warranted to minimize the risk of pathologic fracture.

Available literature and quality of the evidence

- Level IV: 1 study[7]
- Level III: 1 study.[13]

Findings

Larger cysts typically have more cortical thinning; the bone is weaker and there is increased risk of fracture.[6] To quantify the strength of the remaining cortex, which is related to the size of the cyst and the size of the involved bone, Kaelin at al. devised the cyst index (cyst index = area of the cyst/diaphysis diameter × diaphysis diameter)[7] to help predict the risk of a pathologic fracture. The authors recommended observation for humeral cysts with an index <4 and for femoral cysts with an index of less than 3.5.[7]

However, others have questioned the usefulness of the cyst index.[13]

Leong et al. investigated the use of CT structural analysis to predict fractures in children with a benign appendicular skeletal lesion.[14] The resistance of the affected bone to compressive, bending, and torsional loads was calculated. Structural rigidity is the product of a material property (modulus of elasticity, or shear modulus) and a cross-sectional geometric property (area, moment of inertia, or polar moment of inertia). For each trans-axial CT image, the axial rigidity (EA), bending rigidity (EI), and torsional rigidity (GJ) were calculated. The ratio of the structural rigidities of the affected bone relative to the normal, contralateral bone was determined at matching cross-sectional levels. Pathologic fracture was predicted if the ratio for EA, EI, or GJ was 65% or less. Both structural analysis with quantitative CT and radiographic analysis were performed. According to the criteria based on the plain radiographs, a skeletal lesion was considered at increased risk of fracture if the defect length was ≥3.3 cm, width ≥2.5 cm, or there was involvement of ≥50% of the cortex as measured on anteroposterior or lateral views.

Of 41 included patients, 34 completed activity questionnaire at least two years after the quantitative CT rigidity analysis. No patient for whom no increased fracture risk was predicted sustained a fracture. Thirty-five patients were predicted to be at risk for a fracture on the basis of the plain radiographs but not on the basis of the quantitative CT rigidity analysis, and the converse was true for one patient. Overall, the specificity of the quantitative CT-based rigidity analysis was 97%, correctly predicting that a bone containing a lytic lesion would not fracture when the patient engaged in activities of daily living, compared with a specificity of 12% for criteria based on plain radiographs. This CT-based analysis has some

limitations: it exposes the patient to relatively large doses of radiation, CT scans are not as readily available as standard radiographs, the application of the algorithm requires sophisticated knowledge of image analysis software to properly align virtual images of right and left bone pairs, and the interpretation of the results requires a background in structural mechanics.

Resolution of clinical scenario

Not all cysts require surgical management or restriction from athletic activities. Although CT structural rigidity analysis has demonstrated success in predicting which cysts are unlikely to fracture, the technique involves significant radiation to the patient and advanced skills and software, making this technique difficult to assimilate into clinical practice. Lucent lesions with a length ≥3.3 cm, width ≥2.5 cm, or involvement of ≥50% of the cortex as measured on anteroposterior or lateral views may be at increased risk of fracture, but these absolute cutoffs may not apply to smaller children. Other radiographic features that should warrant concern for impending pathologic fracture include increasing size, expansion, and progressive thinning of the cortex. In this patient, although not strictly based on evidence, this proximal femoral cyst should be treated to avoid the high morbidity of a pathologic fracture in this region.

Question 3: In children with an SBC, which treatment yields the most successful results at maturity, considering cyst healing and (re)fracture rate?

Rationale

SBCs may be treated nonoperatively (observation, activity restriction, immobilization when a pathological fracture occurs). Conversely, many procedures and surgical interventions have been described: curettage only,[15] curettage and grafting,[16] subtotal resection with and without grafting,[17] percutaneous corticosteroid injection,[18] percutaneous bone marrow injection,[1] drilling holes and continued decompression with a cannulated screw,[19] drilling holes and lavage of the cyst cavity with saline,[20] filling of the cyst cavity with calcium sulphate or calcium phosphate or both,[21],[22] filling of the cyst cavity with demineralized bone matrix,[23] internal fixation and continued decompression with Kirschner wire,[24] internal fixation and continued decompression with elastic stable intramedullary nailing,[25] or a combination of these options.

Clinical comment

Goals of treatment include minimizing the risk of pathological fracture, cyst healing, and pain resolution. Numerous treatment methods have been described for SBCs in children; there is no consensus on the optimal treatment method for SBCs.[26] An RCT historically provided support for injection with steroid, yet this treatment has fallen out of favor due to prolonged cyst resolution time and poor cure rates <50%. Do recent studies provide a potential better solution?

Available literature and quality of the evidence

- Level I: 1 meta-analysis and Cochrane review[26] and 1 randomized controlled trial (RCT).[27]
- Level III: 3 studies.[28–30]

- Level IV: 3 studies.[31–33]

Findings

Wright et al. reported their RCT of 90 patients randomly allocated to treatment with injection of either bone marrow or methylprednisolone with the primary outcome being radiographic evidence of healing. Forty-two percent of those treated with methylprednisolone acetate healed, and 23% of those treated with bone marrow healed ($p = 0.01$). There was no significant difference between the treatment groups ($p > 0.09$) concerning function, pain, number of injections, additional fractures, or complications. However, while superior to simple injection of bone marrow, methylprednisolone still had a very low healing rate (42%) and patients required multiple injections to obtain this result (1.7 ± 1.0 injections under general anesthesia).[27]

Two retrospective studies from the 1980s compared steroid injection with curettage and grafting. Oppenheim and Galleno compared 37 patients with SBC treated operatively (curettage with or without grafting, using autologous or allograft bone) to 20 patients treated with steroid injection with a minimum follow-up of two years.[28] In the operative group the recurrence rate was 40%, rising to 88% in patients under the age of 10 years with active cysts (less than 1 cm from the physis). Major complications occurred in 15% and included infection, refracture, coxa vara, extremity shortening, and physeal damage. In the steroid injected group, the overall response rate to the first injection was 40%, with 50% requiring more than one injection. The injections were done at intervals from 3 to 17 months when no progressive healing was observed in sequential radiographs. Both demonstrated low rates of healing. Due to the simplicity of the procedure and lower morbidity associated with the steroid technique, this was

favored by the authors. Bovill and Skinner reviewed a retrospective cohort of 32 patients with SBC treated in three different ways: 15 patients were treated surgically with diverse procedures, 12 were given steroid injections, and five were treated nonoperatively.[29] The average age at presentation was 8.9 years and average follow-up was 5.6 years. They concluded that steroid injections were as effective as surgical intervention while having lower morbidity. This evidence demonstrating no difference between techniques must be taken in context; the studies were small and likely underpowered, and the surgical procedures were not well documented or standardized, without mention of modern techniques that typically include complete cyst lining excision, breaking through the cyst wall into the medullary canal, and grafting with a material that is slow to resorb.[34]

Roposch et al. reported their results of flexible intramedullary nailing for the treatment of humeral femoral and radial SBCs in 32 patients with mean follow-up of 54 months.[31] Healing ranged from 3 to 105 months. Fourteen cysts healed completely, and 16 healed with residual radiolucent areas visible on radiographs. There was recurrence of two cysts that had healed with residual radiolucency. A change of nails was necessary in nine patients, as the nails had become too short after bone growth. No major complications were observed. They concluded that flexible intramedullary nailing provides early stability, which allows early mobilization and thus obviates the need for a plaster cast, decreases the prevalence of pathological fracture, and also allows for an early return to normal activity.

Wilke et al. completed a multicenter retrospective cohort study to determine whether internal fixation reduces the risk of further procedures for the treatment of SBC and if

radiographic healing is faster with internal fixation.[30] The study included 36 patients treated for SBC of the proximal femur between 1974 and 2014. SBCs were located in the femoral neck (n = 13), intertrochanteric (n = 16), and subtrochanteric (n = 7) regions. Initial treatment included steroid injection (n = 2), curettage and bone grafting (n = 9), and internal fixation with curettage and bone grafting (n = 25). Mean time was to radiographic healing was nine months and time to return to full activity was 15 months. A significant reduction in additional procedures was observed when patients had been treated with internal fixation. There was no difference in time to radiographic healing, but time to return to normal activities was reduced if patients had received internal fixation.

Jamshidi et al. described their experience with surgical reconstruction of pediatric SBCs of the proximal femur using a proximal locking plate and fibular strut allograft, in 14 patients.[32] Complete healing was seen in 10 cysts, while four other cysts healed with residual radiolucent areas. Mean time to healing was 14.1 ± 5.1 (9–24) months. One patient had superficial infection, one heterotopic ossification, and one mild coxa vara, and mean Musculoskeletal Tumor Society (MSTS) score was 99.5%.

Zhang et al. retrospectively evaluated 30 children who underwent curettage and bone grafting combined with elastic intramedullary nailing (EIN) and 32 patients who underwent curettage and bone grafting alone.[33] No statistically significant differences in sex, age, location, activity, pathological fracture, cyst volume, operative time, and intraoperative blood loss were found between the two groups. In the EIN group, 17 cases fully healed, 10 cases were partially healed, and three cases demonstrated persistent cyst. The authors reported an effective rate of 90.0% (effective rate = [cured + partially cured] / total

number of people). In the curettage and bone grafting alone group, 10 cases fully healed, 12 cases were partially healed, and 10 cases were not healed. The effective rate was 68.8%. There was a significant difference in curative effects between the two groups ($p = 0.013$). The authors concluded that, compared to simple curettage and bone grafting, curettage and bone grafting combined with EIN treatment can significantly improve the prognosis of children with bone cysts.

Resolution of clinical scenario

There is still little evidence to guide the management of SBCs in pediatric patients. Historically, steroid injection was favored due to its simplicity and low morbidity, but due to healing rates <50% this technique has been increasingly abandoned in favor of cyst curettage with complete removal of the cyst wall, grafting with synthetic or allogeneic graft, and internal fixation for long bones. The evidence to guide treatment of SBCs is low; recent studies do support treatment of proximal femoral SBCs with curettage, grafting, and internal fixation.

Summary of answers

- In children with an isolated geographical lucent lesion in the proximal metaphysis of the femur or humerus, who have no constitutional symptoms or clinical or radiological signs of infection or malignancy, plain radiographs may suffice (recommendation weak given low evidence).
- In the presence of presumed SBC, MRI is indicated in the presence of periosteal reaction, eccentric location, extension to the articular surface, or soft tissue involvement.

- Lucent lesions with length ≥3.3 cm, ≥2.5 cm, or involvement of ≥50% of the cortex as measured on anteroposterior or lateral views may be at increased risk of fracture and should be considered for potential surgical management.
- There is no role for injection of bone marrow aspirate.
- Historically, steroid injection was favored over curettage and bone grafting, as the technique was simpler and healing was equivalent. However, multiple anesthetics/injections were required, and the overall healing rate was unsatisfactory, <50%.
- Recent series have demonstrated 80–90% cyst healing rates when curettage and grafting is used in combination with internal fixation, and this is currently the favored approach for proximal femoral bone cysts, although the recommendation is weak (evidence is low).

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177 Pediatric Clavicle Fractures

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Clinical scenario

- A 14-year-old right-hand-dominant football wide receiver sustains a mid-diaphyseal clavicle fracture secondary to a direct shoulder blow during football practice.
- Radiographs in the Emergency Department demonstrate 100% translation with bayonet apposition, with 20 mm shortening.
- The patient is placed in a sling and seeks treatment recommendations in the orthopedic clinic several days later.

Top three questions

1. Does primary surgical fixation of displaced clavicle fractures in the pediatric and adolescent population improve patient function or patient outcomes, compared with nonoperative treatment?
2. What risks are associated with surgical fixation of clavicle fractures in the pediatric and adolescent

population, including risk of secondary surgery, such as removal of implants?

3. Does the amount of shortening influence outcomes in displaced clavicle fractures in pediatric and adolescent patients?

Question 1: Does primary surgical fixation of displaced clavicle fractures in the pediatric and adolescent population improve patient function or patient outcomes, compared with nonoperative treatment?

Rationale

While historical treatment of closed clavicle fractures in the twentieth century consisted almost exclusively of nonoperative measures, management with slings or figure-of-eight braces, studies in the early 2000s suggested that clavicle fracture nonunion[1–3] and symptomatic malunion[4,5] were more common and more functionally debilitating sequalae of nonoperative treatment in adults than previously suspected. Moreover, several studies, including randomized controlled trials (RCTs), suggested superior functional outcomes following operative treatment in adult populations, when compared to nonoperative treatment. A clear trend toward clavicle fracture fixation in adults emerged, with caregivers of adolescent and pediatric patients also following suit[6,7] and increasing the frequency of operative treatment, despite a dearth of comparative studies investigating this concept in young patients.[8]

Clinical comment

The nonunion rate following nonoperative treatment of displaced midshaft clavicle fractures in *adults* is approximately 15%, and the symptomatic malunion rates in *adults* is approximately 9%.[9] The degree to which the clavicle studies of adult populations are applicable to pediatric and adolescent populations remains unclear.

Do children or adolescents have clinically significant rates of nonunion or symptomatic malunion, similar to adults? Is primary open reduction and internal fixation (ORIF) associated with significantly lower rates of nonunion and malunion? Does ORIF in a child or adolescent improve shoulder function, in terms of strength, range of motion (ROM), or scapular kinematics? Does ORIF lead to a faster return to activities of daily life or athletic activities?

Available literature and quality of the evidence

- Level I: 5 RCTs and 1 meta-analysis.
- Level II: 2 systematic reviews and 1 meta-analysis.
- Level III: 3 clinical series.
- Level IV: 6 clinical series and 1 review.

Findings

Several RCTs have emerged comparing operative to nonoperative treatment of displaced diaphyseal clavicle fractures in adult populations. In a landmark RCT conducted by the Canadian Orthopedic Trauma Society,[10] the authors reported a 14% nonunion and 18% symptomatic malunion rate in the nonoperative cohort, with significantly faster time to union, superior appearance scores, and superior patient-reported functional outcome scores in the operative cohort at all time points, including 6, 12, 24, and 52 weeks. In four subsequent similarly

designed RCTs performed in Finland,[11] the United Kingdom,[12] the Netherlands,[13] and Brazil,[14] respectively, nonunion rates ranged from 14 to 24% following nonoperative treatment, but similar functional outcome measure scores between treatment arms were reported at most or all time points in each study, leading the authors of all four studies to conclude that nonoperative treatment was the preferred primary treatment in adults.

Meta-analyses and systematic reviews of multiple level I or II studies have emerged, with varying conclusions. By pooling six level I studies, McKee et al. showed a nonunion rate of 14.5% and symptomatic malunion rate of 8.5% with nonoperative treatment, both significantly higher than those with operative treatment.[9] However, based on pooled outcomes scores that were *not* significantly different, the authors concluded there was little evidence to support a difference in long-term functional outcome between treatments. Xu et al. performed a meta-analysis including eight RCTs and demonstrated superior Disabilities of the Arm, Shoulder, and Hand (DASH) and Constant scores with surgery than nonoperative treatment.[15] In a systematic review, Virtanen et al. demonstrated that superior function associated with operative fixation is present only prior to six months postinjury/surgery.[16] A separate systematic review by Smeeing et al. demonstrated higher nonunion and malunion rates in nonoperatively treated fractures and faster return to work in surgical patients, but in the conclusions cited similar functional outcomes between cohorts.[17]

No RCTs or prospective cohort studies investigating clavicle fracture treatment in pediatric or adolescent patients have been published. Parry et al. retrospectively compared eight operatively treated to eight nonoperatively treated adolescents (mean age 14 years, range 10–16), and

found no difference in functional outcome measures, strength, ROM, or shoulder fatigue between the two groups.[18] Vander Have et al. reported on treatment of 43 clavicle fractures in adolescents (mean age 15.4 years), with no nonunions seen in 17 operatively and 25 nonoperatively treated patients. Symptomatic malunion was reported in 20% of nonoperatively treated patients, with 16% undergoing osteotomy surgery to resolve symptoms, compared with 18% of operative patients undergoing secondary hardware removal surgery. While reported as a level III retrospective study, the comparability of the two cohorts was not assessed, and no functional outcome measures were reported.[19] However, a number of level IV studies have assessed the outcome measures of pediatric and adolescent patients. Namdari et al. reported on 14 adolescents with ORIF and a mean QuickDASH score of 7 at a minimum of 24 months postoperatively, though four patients had undergone plate removal for hardware-related irritation or pain.[20] Randsborg et al. retrospectively analyzed 122 adolescents (mean age 14.4 years) treated nonoperatively with essentially normal functional shoulder scores, one nonunion (0.8%) successfully treated with delayed ORIF, and no cases of symptomatic malunion (0%) requiring surgery.[21] O'Neill et al. reported on 190 pediatric clavicle fractures, 65% of which were completely displaced, and reported no cases of nonunion and no cases of symptomatic malunion requiring intervention.[22] Hagstrom et al. retrospectively compared a series of 46 operatively treated patients (mean age 13.6 years, range 8–18) to 32 nonoperatively treated patients (mean age 10.3, range 10 months to 18 years), finding no difference in time to healing or DASH score, although three operative patients underwent peri-implant fracture and two operative patients underwent secondary hardware removal. No nonunions or

symptomatic malunions were reported.[23] Pennock et al. investigated 25 nonunions treated at nine pediatric hospitals over an 11-year period, underscoring the extreme rarity of this complication, surgical treatment was effective in all cases.[24] Hughes performed a similar study in the form of a systematic review, identifying all 21 previous cases of pediatric clavicle nonunion in the literature (prior to the Pennock study), 16 of which underwent surgery with satisfactory functional outcomes.[25]

Resolution of clinical scenario

While nonunion and symptomatic malunion are relatively common (5–25%) following nonoperative treatment of displaced midshaft clavicle fractures in adults, the most recent evidence suggests no difference in functional outcomes following operative versus nonoperative treatment, and most authors now recommend primary nonoperative treatment for displaced midshaft clavicle fractures in adults.

High-quality evidence to guide the treatment of this 14-year-old's displaced midshaft clavicle fracture is lacking. To date, there are no prospective comparative studies published comparing operative to nonoperative treatment in adolescents and children. Retrospective comparative studies and case series exist, and from these there is no evidence to support improved outcomes with surgical intervention in this population. With pediatric/adolescent nonunion and symptomatic malunions each estimated at <2%,[21] the theoretical benefit of surgical intervention in this population is minimal.

Question 2: What risks are associated with surgical fixation of clavicle fractures in the pediatric and adolescent population, including risk of secondary surgery, such as removal of implants?

Rationale

An increase in the primary surgical treatment of pediatric and adolescent clavicle fractures has emerged,[6,7] despite the absence of evidence supporting this practice.[8] Survey studies have shown that this trend relates to the influence of studies of adult populations on pediatric caregivers. If this trend toward surgeries continues on a national scale, an understanding of the potential risks to which children and adolescents are being exposed, beyond the inherent medical and anesthesia risks of surgery, is critical to insuring patient safety.

Clinical comment

While the risks of nonsurgical treatment in adults sustaining completely displaced clavicle fractures has been elucidated in a body of level I and II studies, nonunions, and symptomatic malunions are extremely rare in children and adolescents, with only one case of each in the largest series of 65 displaced midshaft clavicle fractures followed by Randsborg et al.[21] The risks of surgery for adults with completely displaced fractures includes, in descending order of frequency: painful or irritating hardware, with or without subsequent surgery for hardware removal (19%),[26] neuropraxia or chest wall numbness, wound infection,

implant failure and refracture/peri-implant fracture, nonunion,[9] pneumothorax,[27] and neurovascular injury.

To what degree do the risks of clavicle surgery affect pediatric and adolescent patients? Are they similar to those that affect adults? How common is secondary surgery? Are there unique risks for this younger population?

Available literature and quality of the evidence

- Level I: 1 meta-analysis.
- Level II: 1 meta-analysis.
- Level III: 2 clinical series.
- Level IV: 5 clinical series.

Findings

Higher-level studies investigating complications after clavicle fracture treatment have more frequently been published in the adult literature than the pediatric and adolescent literature. Two meta-analyses effectively report on the breadth of complications that have been reported in high-level adult studies.[9,15] McKee et al. investigated studies accounting for 212 operative patients, 62 (29%) of whom sustained reported complications, most common of which was painful, irritating, or protruding hardware (13%), most of which underwent subsequent surgery for hardware removal. Five cases of delayed union and three nonunions were reported, suggesting this as a rare occurrence, and five cases of nerve injury or neuropraxia. Xu et al. focused on five major complications – symptomatic malunion, delayed union, refracture/implant failure, infection, and secondary surgery – and found no difference in the complication rates between surgical and nonoperative treatment. Leroux et al. performed a population-based study on the administrative database for

the entire province of Ontario, Canada. Surprisingly, 24.6% of patients underwent at least one clavicle re-operation within two years, the most common of which was implant removal (18.8%), but reasons for re-operation also included nonunion (2.6%), deep infection (2.6%), and malunion (1.1%). Pneumothorax (1.2%) and brachial plexus and subclavian vessel injuries rarely occurred (<1%).[26]

In pediatric populations, no cases of subclavian vessel or brachial plexus injury have been reported, but secondary hardware removal is common, with various authors reporting relatively high rates: Vander Have et al. (18%),[19] Namdari et al. (29%),[20] Mehlman et al. (100%).[28] Li et al. reported an overall complication rate of 86% following operative treatment, including 42% implant removal surgery, anterior chest wall numbness (15%), superficial wound dehiscence or infection (5%), peri-implant fracture adjacent to the plate (3%), and refracture following plate removal (3%).[27] Hagstrom et al. also reported on peri-implant fracture in three of the 46 operative patients (7%).[23]

Resolution of clinical scenario

Complications following operative treatment of clavicle fractures are relatively common, based on studies of both adult and pediatric populations. While the most common reported complication is hardware-related pain (approximately 15–20%), frequently requiring secondary surgery for hardware removal, the athletic participation and activity level of the adolescent population may put patients at higher risk for complications that relate to the hardware, either before (peri-implant fracture) or after simple hardware removal surgery (re-fracture through screw holes).

With surgical fixation of his clavicle fracture, this patient has a small risk of potentially life/limb-threatening complications such as pneumothorax or neurovascular injury. Risk of refracture about the plate and infection are estimated at <10%. Eighteen to 100% of patients undergo implant removal, and following implant removal there is a small risk of refracture. Given the considerable risk of minor and major complications associated with surgical treatment of clavicle fractures, the evidence supports primary nonoperative treatment of displaced midshaft clavicle fractures in children and adolescents.

Question 3: Does the amount of shortening influence outcomes in displaced clavicle fractures in pediatric and adolescent patients?

Rationale

Several studies of adult patient populations have suggested that the degree of *shortening* associated with completely displaced clavicle fractures is a critical determinant of patient outcomes.[3–5,29–32] Greater shortening has been linked to higher rates of nonunion and symptomatic malunion, which may relate to altered shoulder kinematics. Shortening has therefore been utilized by surgeons as a threshold in the indications for surgery, or at least a factor in the decision-making process for surgical versus nonsurgical treatment. Specifically, fractures with shortening ≥20 mm are frequently cited as meeting relative indications for fixation. These same thresholds are frequently applied to the pediatric and adolescent populations; younger patients are undergoing more surgical treatment than in decades past.[6–8]

Clinical comment

As the last bone in the human skeleton to complete its ossification process – as late as 25 years old in most people – the clavicle may have enhanced remodeling capacity, compared with many long bones. Therefore, adolescents may be able to accommodate for changes in clavicle morphology following completely displaced fractures, including those with even severe shortening, on both the short- and long-term postinjury periods. To what degree does shortening influence outcomes after adolescent clavicle fractures? How well does the pediatric skeleton recover from a nonoperatively treated, shortened fracture?

Available literature and quality of the evidence

- Level III: 2 clinical series.
- Level IV: 3 clinical series.

Findings

Vander Have et al. reported on 5 of 25 (20%) adolescent clavicle fracture patients who developed symptomatic malunions after nonoperative treatment.[19] The symptomatic malunion diagnosis was made at a mean of 14.6 month postinjury, and four of these five patients (16% overall) elected to undergo osteotomy and plate fixation of the clavicle, which addressed their symptoms in all four cases. Given that the mean fracture shortening in this subset was 26.6 mm, the authors concluded that malunions may be more common in adolescents than previously thought, and cited the 20 mm threshold often referred to in the adult literature, stating that operative fixation restores clavicle length with low complication rates. Randsborg et al. reported on one patient (out of 56 older children and adolescents, ages 10–18) whose completely displaced

fracture with 15 mm of shortening developed a symptomatic nonunion requiring fixation 5.3 months postinjury.[21] While three other patients were reported to have a symptomatic malunion, none required surgery. The authors separately reported a small, but statistically significant adverse effect of shortening on overall functional, cosmetic, and satisfaction scores. However, the authors concluded that conservative treatment should remain the mainstay of management for fractures of the clavicle in this age group. Parry et al. compared eight operative to eight nonoperative patients with ≥15 mm of shortening, citing no cases of symptomatic malunion in the nonoperative group and no clinically significant differences in ROM, strength, or shoulder fatigue between cohorts.[18] Bae et al. similarly investigated two-year results of 16 adolescents with >20 mm shortening in midshaft fractures, reporting outcome scores and pain scores comparable to normative values, and only one of whom developed symptoms requiring osteotomy.[33] Schulz et al. investigated 16 adolescents with completely displaced fractures and a mean shortening of 14 mm (range 11–21 mm). Fifteen patients were satisfied with their treatment, and one was dissatisfied with their clavicle prominence.[34] The authors found no significant difference in the strength, pain, ROM, and outcome scores between the injured and uninjured shoulders in this cohort.

Resolution of clinical scenario

There is no high-quality evidence to guide surgical indications as it relates to clavicular shortening in children and adolescents. The range of 15–20 mm of shortening has been used as a convention in this population, but comparative studies have not demonstrated differences in clinical outcomes at these cutoffs in this age group. Unlike authors of adult clavicle fractures, most authors of

pediatric and adolescent studies have concluded that symptomatic malunion represents an extremely rare event, with minimal to no adverse effects on shoulder strength, ROM, overall function, and patient-reported outcomes, even in the setting of severe shortening. Despite 20 mm of shortening and 100% fracture translation in this 14-year-old football player, there is no clear indication for surgical intervention.

Summary of answers

- Although nonunion and symptomatic malunion are not uncommon in adults, they are rare in children and adolescents (<2%).
- No prospective comparative studies exist between the operative and nonoperative treatment of displaced clavicle fractures in children and adolescents. Results of retrospective comparative studies and case series in this population suggest no functional or patient-reported benefit with surgical treatment.
- Following surgical treatment of clavicle fractures, there is a small risk of limb/life-threatening complications such as pneumothorax or neurovascular injury. Fracture around the plate, or following plate removal may occur 3–7% of the time. Plate removal is common, with some series reporting 100% plate removal.
- There is no magnitude of shortening to constitute a definitive cutoff for indicating surgery in this young population. There is no consistent evidence demonstrating worse outcomes with shortening >15–20 mm in this population. There is no defined threshold of shortening beyond which surgery should be indicated.

- Prospective comparative studies with sufficient sample size are warranted to more clearly elucidate the relative risks and benefits of the operative versus nonoperative treatment of this common injury in children/adolescents.

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178 Supracondylar Humerus Fractures

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Clinical scenario

- A five-year-old girl sustains a left supracondylar humerus fracture after a fall from the monkey bars.
- In the Emergency Department, she is cooperative with exam and has no neurologic deficits.
- She has no skin puckering and the injury is closed. Her hand is warm and well-perfused with brisk capillary refill.
- A radial pulse is not palpable.

Top three questions

1. In children with a supracondylar humerus fracture, when should an open reduction be performed instead of a closed reduction to ensure optimal outcomes?
2. In a child whose supracondylar humerus fracture needs an open reduction, which surgical approach is best to optimize outcomes?
3. In a child who presents with a supracondylar humerus fracture without a palpable pulse, when should a

vascular, open exploration be performed to optimize outcomes?

Question 1: In children with a supracondylar humerus fracture, when should an open reduction be performed instead of a closed reduction to ensure optimal outcomes?

Rationale

The gold standard in the treatment of displaced pediatric supracondylar humerus fractures is closed reduction with percutaneous pinning. However, there are supracondylar humerus fractures that necessitate an open reduction.

Clinical comment

An open reduction is indicated in the following situations:

- Unable to obtain an acceptable alignment of the fracture fragments using closed reduction.
- Open fracture.
- Compartment syndrome.
- Vascular injury

  Hand is poorly perfused following reduction and fixation.
- Change in neurologic exam or vascular exam (for the worse) following closed reduction of a supracondylar fracture.

Findings

According to Holt et al., nationally 24% of children with supracondylar humerus fractures undergo surgery in the US. Among surgically treated supracondylar humerus fractures, there is a 12.7% rate of open reduction. They also found that, as displaced supracondylar fractures are more often being transferred to tertiary care facilities and being treated by fellowship-trained pediatric orthopedic surgeons, the rates of performing open reductions are trending down.[1] In another study of pediatric closed type III supracondylar humerus fractures, there was a 9.4% rate of conversion following an attempted closed reduction to an open reduction,[2],[3] Novais et al. in their retrospective review found that the incidence of conversion from closed to open reduction was 7%. Among those treated with ORIF, the indication in the majority (93%) of cases to convert to open treatment was secondary to irreducibility of fracture fragments – 40% due to fracture instability, 36% secondary to brachialis interposition, 16% due to periosteal interposition, and 8% secondary to triceps interposition. In those children where the indication to convert to open reduction was secondary to change in vascular status after attempted closed reduction, neurovascular structures were entrapped at the fracture site.[4]

In a retrospective review of 236 surgically treated type III supracondylar fractures at a single institution, Pesenti et al. noted that the low-volume surgeons (treating less than five type III supracondylar fractures/year) had a higher frequency of performing open reduction and had worse postoperative radiographic alignment than those fractures treated by higher volume surgeons. This same study also demonstrated that there is a learning curve of approximately 20 patients with supracondylar humerus fractures treated surgically (close or open reduction) to

positively impact operative time and radiographic outcomes.[5]

The flexion type supracondylar humerus fracture is less common than extension type, approximately 5% of supracondylar humerus fractures. The ulnar nerve can be entrapped in the fracture site – causing nerve compromise and blocking reduction. Open reduction should be undertaken if there is a persistent gap at the fracture side or when the fracture gap closes down, but then springs back open: the *rubbery* reduction.[6]

A retrospective study done by Flynn et al. found that a flexion-type injury had a 15.4-fold increase in the odds of open reduction. They also found that if a flexion-type supracondylar fracture presented with an ulnar nerve injury, there also was a 6.7-fold additional higher risk of open reduction. This study brought to light the need to counsel patients and families preoperatively regarding the increased rate of performing an open reduction in these specific situations and to prepare the operating room appropriately.[7]

Based on the available evidence, the need for open versus closed reduction techniques is not a predictor of clinical outcome.[2] Studies have failed to demonstrate clinically significant differences in outcome when comparing open reduction to closed reduction of displaced supracondylar humerus fractures. Clinical outcome is most often assessed using Flynn's criteria[8] and are comparable in final radiographic alignment and range of motion.[9],[10] The only differences between the two approaches was a longer surgical time and a larger scar in those who underwent open reduction.[9]

Question 2: In a child whose supracondylar humerus fracture needs an open reduction, which surgical approach is best to optimize outcomes?

Rationale

The “best” approach is controversial. For closed fractures, there is literature to support the use of anterior, medial, lateral, and posterior approaches.

Clinical comment

Open fractures, which account for 1% of supracondylar humerus fractures, obviate the decision of the preferred surgical approach.[2],[11] The zone of injury allows for direct visualization and decompression of the fracture, often utilizing an extension of the traumatic wound.

Findings

A principle to keep in mind is that the incision for open reduction of supracondylar humerus fractures is dictated by the location of the distal metaphyseal spike of the proximal fragment. Make a direct approach that is centered over the prominent metaphyseal spike as this is where the overlying periosteum or muscle (most often brachialis) is most likely entrapped and blocking the reduction[6],[10] By choosing the incision based on the location of the metaphyseal spike, one avoids disruption of the remaining intact periosteum, which acts as a periosteal hinge. Otherwise, one risks further destabilization of the fracture fragment or interruption of blood supply to the distal fragment.[10],[12] We believe that this surgical approach is

logical when the indication for an open reduction is an inability to obtain an acceptable close reduction.

In general, the anterior approach (of Henry) is the best used in cases of possible vascular injury since it allows for exploration of the brachial artery. The fracture site can be exposed with a transverse incision in the cubital fossa along the flexion crease of the elbow. The incision can then be extended to a *boat race* incision with the medial limb extending proximally to follow the median nerve and brachial artery. If an anterior approach is used primarily due to inability to achieve an acceptable closed reduction in an extension type injury, one can often make a very small incision directly over the anterior spike, in order to use a finger to sweep out an entrapped brachialis muscle.

After removal of any interposed tissue from the fracture site, place a thumb on the anterior metaphyseal spike and index finger on the olecranon posteriorly to obtain a reduction. The anterior incision allows for palpation of both, the lateral and medial epicondyles to evaluate for any malrotation at the fracture site.[13] It is the authors' experience that an anterior incision is rarely needed secondary to irreducibility if a *milking maneuver* is performed.[14],[15]

A medial approach to the elbow allows for direct visualization of the medial column of the distal humerus, as an aid for restoration of rotation and alignment at the fracture site. It also facilitates placement of a medial Kirschner wire (K-wire), if necessary, minimizing the risk for iatrogenic injury to the ulnar nerve. A medial approach is most often used in a flexion-type injury. The advantages of this approach are direct visualization of the ulnar nerve, and a cosmetic incision.

The lateral approach often affords a more familiar approach to most surgeons, and is similar to the one used

for the open reduction and percutaneous pinning of lateral condyle fractures. The disadvantage of this approach is a very visible scar.

A direct posterior approach can also be performed with a triceps-splitting technique versus triceps tendon transection and proximal reflection. Both approaches allow adequate visualization of the medial and lateral columns. However, the triceps transection technique has been associated with a significant decrease in triceps strength. Some studies also demonstrate that posterior approaches lead to restriction in range of motion, specifically extension. Transection of the triceps tendon has not been found to benefit fracture reduction.[16]

With the posterior approach to a supracondylar humerus fracture, there is also an increased risk of avascular necrosis secondary to disruption of the posterior blood supply to the trochlea. Avascular necrosis of the trochlea remains a known risk for the lateral approach as well.[17] These authors recommend against a posterior approach due to the risk of avascular necrosis (AVN). In an immature elbow subperiosteal dissection should be avoided posteriorly over the capitellum and trochlea.

Question 3: In a child who presents with a supracondylar humerus fracture without a palpable pulse, when should a vascular, open exploration be performed to optimize outcomes?

Rationale

If a child with a supracondylar humerus fracture has a pulseless, poorly perfused hand, undoubtedly the child should undergo emergent reduction and fixation. Hand perfusion may be assessed by arterial capillary refill, warmth, and color of the hand.[18]

Patients presenting with a pulseless and poorly perfused hand (sluggish capillary refill, cool, and pale) are at highest risk for compartment syndrome and needing vascular repair.[19] Preoperative ischemia is the primary factor that has been shown to significantly increase the need for vascular surgery.[20]

If, after closed reduction, there is no pulse and the hand is still poorly perfused (hand is cool and white), one should open the fracture anteriorly and explore the brachial artery. The artery may have been caught at the fracture site and need to be untethered from the fracture site. There also may be a thrombus or an arterial laceration. A surgeon trained in vascular repair should be consulted for thrombolysis or repair of the injured artery.[21],[22] We recommend consulting vascular surgery when a child presents with a pulseless, cold, white hand and having them on standby if vascular status is not improved with reduction and fixation.

Clinical comment

The area of controversy is the warm, well-perfused hand without a pulse. Debate exists as to whether *pulseless* refers to simply not palpable or not palpable and not Dopplerable radial pulse. Still, the presence of a pulse either by palpation or Doppler should be established and documented preoperatively, intraoperatively, and postoperatively. To access a pulse postoperatively for close monitoring, one can place the patient in a posterior splint.

This will also allow the surgeon to assess for compartment syndrome.

Another layer of the controversy is also the optimal postoperative management for the pulseless, well-perfused supracondylar humerus fractures after operative reduction and fixation.

Findings

If a pulse is not palpable, but there is a Dopplerable signal, there is no evidence to support delaying treatment.[23] In other words, these authors recommend urgent treatment of the pulseless supracondylar humerus fracture, whether a pulse signal is dopplerable or not.[18] There is also no indication for prereduction angiography in a pulseless limb.[23–25] Angiography often unnecessarily delays definitive treatment. If the brachial artery is injured, the injury is almost always at the fracture site, in the absence of some highly unusual conditions such as a concomitant proximal humerus fracture,[26] Duplex ultrasound can also be used to map the arterial flow in the arm, determining if there is a defect in the course of the artery and if there is sufficient flow distally, with or without collateral circulation.

A pulse oximeter on the affected limb can be used as another objective assessment tool for distal perfusion. After operative stabilization of the supracondylar fracture, the presence of waveform on the pulse oximeter is highly sensitive (95.6%) in determining vascular perfusion. Soh et al. used the presence and quality of waveform using a pulse oximeter to support or reject the decision for surgical exploration. In their study, four patients with type III supracondylar humerus fractures did not have pulse oximeter waveforms postoperatively. These four patients

underwent exploration of the brachial artery with significant findings.[27]

After fixation of a supracondylar humerus fracture in a well-perfused pulseless hand, if there is return of a pulse (palpable or Dopplerable), we observe the patient for at least 24 hours before discharge. Additionally, if after fixation there is no pulse but the hand is warm and well perfused, the child should be observed closely for at least 48 hours, with regular clinical checks, staying vigilant for an evolving compartment syndrome.[18,19]

If there is a decrease in limb perfusion postoperatively, the child should be taken back to the operating room for emergent vascular exploration.[18–20] In these cases, the majority of the time the artery itself may not trapped be in the fracture site, but tissue surrounding the artery is trapped in the fracture site, tethering the artery at an acute angle. When this tissue is released, the pulse and perfusion usually return.

Even with interruption of the brachial artery at the level of the fracture there can still be distal flow secondary to rich collateral circulation. This can manifest with a well-perfused hand without a palpable or consistently Dopplerable pulse. At that point, whether the artery should be explored should be a discussion between the orthopedic surgeon and the vascular surgeon. Color flow Doppler ultrasound, which is noninvasive and often readily available, may help surgeons better determine the adequacy of distal flow.[26] Still, the question of how much arterial flow distally is sufficient is not well documented in the literature and is a judgment based on physical exam and shared clinical experience.

Surgeons need to have a heightened suspicion of brachial artery injury in a supracondylar humerus fracture with a median nerve deficit. These two structures travel together

in the cubital fossa. The artery can be lacerated or kinked by the metaphyseal spike of an extension type III supracondylar humerus fracture.[18,28] Additionally, median nerve injury can mask the typical clinical signs of compartment syndrome.

To summarize, for a patient who presents with a pulseless supracondylar humerus fracture with poor perfusion, the first-line treatment is an urgent attempt at fracture reduction under general anesthesia. Surgeons, however, should have a low threshold for open exploration and possible vascular repair if perfusion is not improved following fracture reduction or an adequate reduction cannot be obtained by closed means.[19] Anticipation of open reduction and/or vascular repair should be heightened if the patient presents with a pulseless, ischemic hand or has a pulseless hand with a median nerve deficit (Figure 178.1).

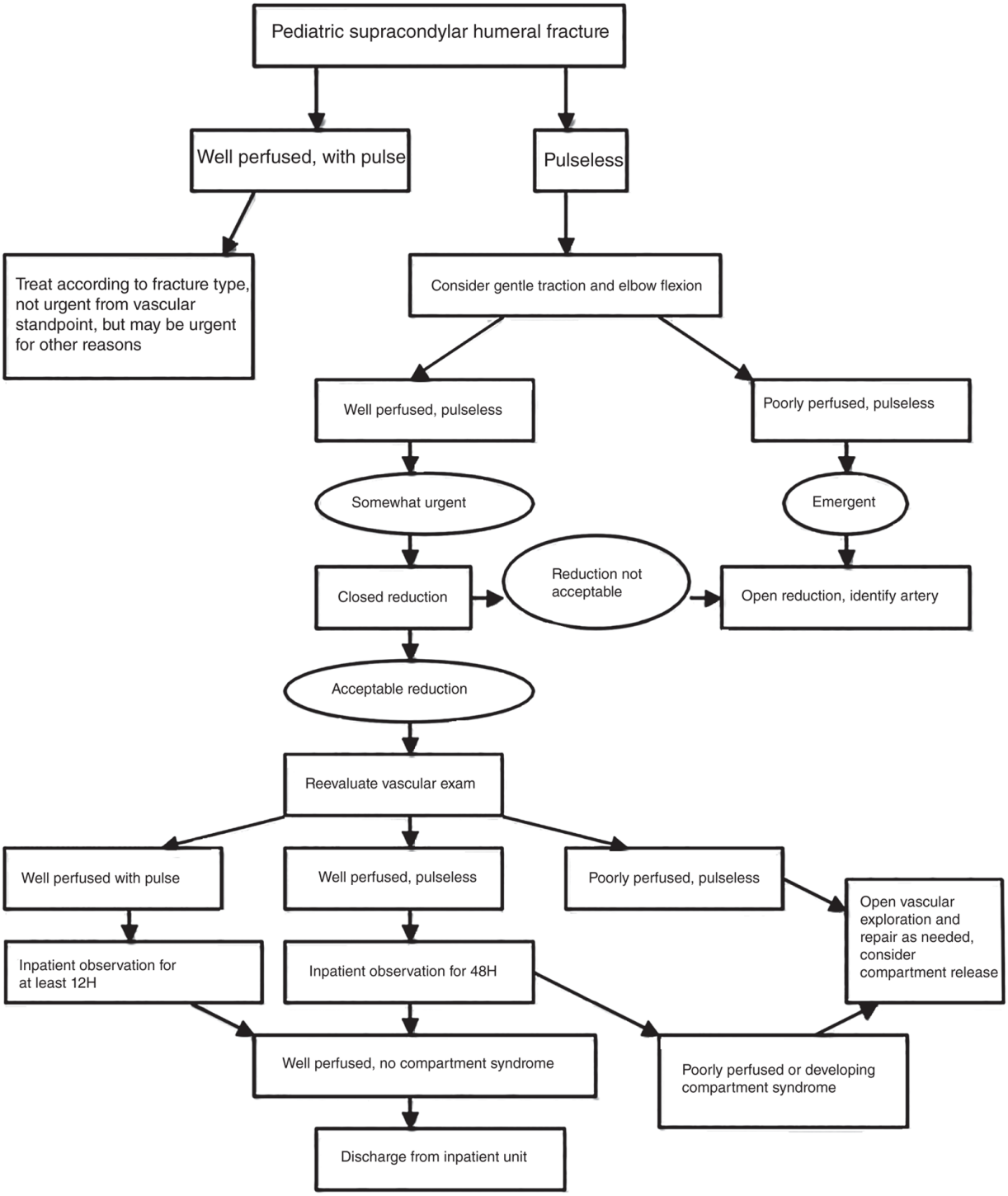

Figure 178.1 Supracondylar humeral fracture treatment algorithm. Source: Badkoobehi et al.[18]

Summary of answers

- The gold standard for operative treatment of supracondylar humerus fractures is closed reduction with percutaneous fixation. However, some supracondylar humerus fractures cannot be treated with closed reduction secondary to irreducibility and soft tissue interposition.
- There is a higher likelihood of open reduction in the flexion type supracondylar humerus fracture.
- According to the available literature, there is no difference in clinical outcomes between children with supracondylar humerus fractures who underwent closed reduction versus open reduction.
- There is no single best surgical approach for an open reduction of a supracondylar humerus fracture. Still, the authors caution against a posterior approach and advocate an anterior approach in a supracondylar humerus fracture that may need vascular exploration.
- The first line of treatment for a pulseless supracondylar humerus fracture with poor perfusion is urgent fracture reduction. There should be a low threshold for performing an open exploration with possible vascular repair if the fracture cannot be reduced or the perfusion does not substantially improve with fracture reduction.
- A median nerve deficit can mask compartment syndrome. Since the median nerve runs is in anatomic proximity to the brachial artery, a median nerve deficit should prompt more suspicion for vascular injury and the need for open exploration in a pulseless supracondylar humerus fracture.

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179 Adolescent Spondylolisthesis

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Clinical scenario

- A 12-year-old female presents with recurrent low back pain despite six weeks of rest from gymnastics.
- The pain is reproduced with hyperextension of the lumbosacral spine.
- Her popliteal angle measured 30° on the right and 30° on the left. Motor and sensory exam are normal.
- The patient would like to compete in the regional gymnastic competition in four weeks' time. Radiographs are performed at an outside office but are not available for review at the time of the visit.

Top three questions

1. In adolescent patients with acute low back pain, what is the ideal diagnostic imaging to assess for spondylolysis?
2. In adolescent patients with a radiographic diagnosis of acute lumbar spondylolysis, what is the natural history of this condition?

3. In adolescent patients, what is the ideal treatment for low-grade versus high-grade spondylolisthesis?

Question 1: In adolescent patients with acute low back pain, what is the ideal diagnostic imaging to assess for spondylolysis?

Rationale

Diagnostic imaging is essential for establishing a distinct diagnosis for back pain with hyperextension. Patients who present with classic history and physical examination consistent with spondylolysis may be treated with a presumptive diagnosis for six weeks. However, if pain persists then diagnostic imaging should be performed. The ideal imaging modality providing the best accuracy with the least radiation exposure to assess for spondylolysis in adolescent patients is unclear.

Clinical comment

Diagnosis of spondylolysis in adolescent patients with persistent low back is challenging. Imaging is needed, but the ideal imaging modality must be accurate and minimize ionizing radiation exposure in the assessment, diagnosis, and treatment of this condition.

Available literature and quality of the evidence

Systematic reviews and retrospective cohort studies exist to answer this question.

Findings

The difficulty in the assessment of pediatric spondylolysis lies in the desire to choose an imaging study with the best diagnostic accuracy while limiting radiation exposure to the patient. Plain radiographs are readily available and relatively low radiation, but controversy exists as to whether two (anteroposterior [AP] and lateral) versus four views (AP, lateral, and obliques) are needed for optimal diagnostic accuracy. Beck and colleagues investigated this issue with a retrospective cohort study looking at the diagnostic value of these two types of radiographic imaging studies. They found no significant difference in either imaging technique in regards to the test characteristics. Two view radiographs had an accuracy of 0.81, sensitivity of 0.59, a specificity of 0.96, and positive and negative predicative values of 0.91 and 0.78. Four view radiographs demonstrated comparative values of 0.78, 0.53, 0.94, 0.85, and 0.76, respectively.[1]

While computed tomography (CT) scanning is thought to be more accurate then magnetic resonance imaging (MRI) in the assessment of pediatric spondylolysis, Campbell and colleagues assessed the diagnostic accuracy of CT and single-photon emission computerized tomography (SPECT) imaging to that of MRI in 72 pediatric patients with acute low back pain. These authors found MRI was able to diagnose pars abnormalities in 98% (39/40) of pars defects found on CT/SPECT. Concordant defect grading between MRI and CT/SPECT was seen in 73% (29/40) of cases.[2] While both normal anatomy and complete pars fractures were readily identified on both CT/SPECT and MRI, incomplete fracture identification remained challenging with MRI. Similar findings were found by Masci and colleagues in their investigation of 71 subjects with acute low back pain. They found 80% of the pars abnormalities identified by bone scan to be seen on MRI and 95% of pars fractures identified on CT to be seen on MRI.[3]

Two recent systematic reviews of the literature investigating imaging for pediatric spondylolysis have been performed.[4],[5] Both studies indicate that it is difficult to reach any conclusions based on review of the literature because of the lack of high level evidence and variation in outcomes reporting in the studies reviewed. Despite this, both studies recommend screening for pediatric spondylolysis should start with a two-view plan radiograph. Advanced imaging in cases of indeterminate radiographs or persistent symptoms can be done with either CT or MRI scan. While CT scan is associated with more radiation exposure, this modality may be more accurate in detecting incomplete pars fractures.

Resolution of clinical scenario

- Despite a reported low sensitively with plain radiographs, due to the availability of this imaging and the relatively low radiation exposure, screening for spondylolysis in this patient with persistent low back pain is best done with two-view lumbar radiographs.
- Advanced imaging for detection of lumbar spondylolysis can be performed by CT or MRI scan when back pain persists and radiographs are negative or indeterminate. While both modalities are comparable, CT may be considered in longer courses of symptoms when incomplete fractures are more prevalent, whereas MRI should be considered in shorter-duration cases when pars stress reaction is more likely. If the plain radiographs are normal, an MRI should be ordered to assess for pars injury in this patient.
- Use of SPECT bone scan in the diagnosis of extension-induced back pain in the adolescent athlete does not seem to be supported by any evidence in light of the high radiation dose of this imaging modality.

Question 2: In adolescent patients with a radiographic diagnosis of acute lumbar spondylolysis, what is the natural history of this condition?

Rationale

Following diagnosis of acute lumbar spondylolysis in pediatric patients, questions exist as to the natural history of this condition. Understanding the effects of lumbar spondylolysis found in childhood in regards to the healing of the underlying pars fracture, expected symptoms in the future, and progression of the defect to spondylolisthesis significantly impacts informed decisions on appropriate treatment and follow-up.

Clinical comment

A clear understanding of the natural history of acute lumbar spondylolysis, in regards to defect healing, long-term symptoms, and progression of the defect to spondylolisthesis is critical to determine appropriate treatment in pediatric patients presenting with this condition.

Available literature and quality of the evidence

Systematic reviews, as well as prospective and retrospective cohorts, exist to answer this question.

Findings

The expectation of healing of pediatric spondylolysis appears to depend on the morphology of the pars defect. Two studies investigating the long-term natural history of pediatric spondylolysis have demonstrated healing in only

unilateral defects.[6,7] Despite this, other studies have demonstrated healing of some bilateral defects, depending on the presences of specific prognostic findings. Fujii and colleagues evaluated 134 patients with pediatric lumbar spondylolysis at a mean follow up of 3.4 years and found the following factors to be predictive of defect healing: vertebral level of the defect, degree of lumbar lordosis, slipping of the affected vertebral body, location of the defect, and condition of the contralateral pars.[8] Sairyo and colleagues developed a grading system of lumbar spondylolytic defects on CT scan and found this was predictive of eventual defect healing.[9]

Less information is available in regards to the natural history of symptoms in patients with acute lumbar spondylolysis diagnosed in childhood. Beutler published a follow-up study on the natural history of a cohort of 30 patients at 45 years following diagnosis of this condition. They found no statistical differences in the reported function and pain domains of the Short Form 36 (SF-36) survey in these patients with spondylolysis as compared to age-matched norms.[6] Similarly, Miller and colleagues reported on 32 patients with a mean follow-up of nine years following diagnosis of spondylolysis. They reported 91% of patients had good or excellent scores on the Low Back Outcome Score (LBOS) survey.[7]

Finally, progression of a spondylolytic defect in pediatric patients to spondylolisthesis seems to be associated with laterality of the defect and maturity of the patient. In numerous studies, authors have found only bilateral spondylolysis are at risk of progressive deformity. Additionally, Sairyo and colleagues showed progression is dependent on the skeletal maturity of the patient, with those patients presenting with less maturity having a higher risk of progressive deformities.[10]

Resolution of clinical scenario

- The natural history of pediatric spondylolysis appears to be most related to the morphology of the pars defect and skeletal maturity of the patient.
- Healing of a spondylolytic defect and progressive deformity are inversely related, with bilateral defects and less mature patients being more likely to have persistent defects and progressive deformities.
- Despite the low incidence of pars defect healing, long-term symptoms of pain and disability appear to be rare as compared to age-matched norms.

Question 3: In adolescent patients, what is the ideal treatment for low-grade versus high-grade spondylolisthesis?

Rationale

Low back pain, restricted range of motion, and performance anxiety are symptoms that drive patients to seek medical care. The high prevalence rate of 6% of spondylolysis/listhesis in the asymptomatic adolescent population requires clinicians to establish a causative relationship between the clinical presentation and the imaging. Restoration of function and reduction of pain are the goals in treatment of low-grade spondylolisthesis. High-grade patients have proven instability of the vertebral column with risk for nerve root injury.

Clinical comment

Adolescent patients with spondylolytic defects and their parents often are anxious to return to their activities as quickly as possible. However, they need to be informed about the potential for recurrent injury limiting their immediate athletic participation as well as potential long-term effects that will extend into adulthood. Therefore, often the “ideal” treatment plan is a shared decision to balance the short- and long-term goals of the patient and their parents.

Available literature and quality of the evidence

Systematic reviews and diagnostic studies exist to answer this question.

Findings

The systematic structured reviews of the literature were unable to find any level I or II studies of comparative treatment for spondylolisthesis.[11,12]

Nonsurgical treatment of spondylolysis has included restricted activity, nonsteroidal medications, physical therapy, and bracing. A systematic review of the treatment of pediatric spondylolysis did not find any comparative studies of natural history to nonoperative treatments. Both natural history and various nonoperative treatments report return to activity of 80–85% of patients. There was insufficient evidence to favor a specific treatment modality.[11,12]

Operative repair of spondylolysis and low-grade spondylolisthesis has been performed by several methods. A meta-analysis of 46 studies reported on 900 patients from retrospective observational studies with the majority of the patients in their second decade of life. The best fusion rates (90.21 and 83.53%) and lowest complication rates (12.8

and 13.41%) were found in the pedicle screw and Buck screw groups, respectively.[13]

Comparative studies on the surgical results of high-grade spondylolisthesis have mixed results possibly due to poor preoperative classification systems. Pathologic posture of the lumbosacral junction can be distinguished from compensatory stance based on radiographic measurements. A radiologic classification based on standing sagittal images of the total spine and pelvis (C7 to femoral heads) was validated by Mac-Thiong et al. Outcomes measures of surgical treatment based on the severity scale have not yet been published.[14]

Systematic reviews which focus on treatment of high-grade spondylolisthesis by in situ fusion versus reduction and fusion have identified eight retrospective comparative series (level III).[15],[16] No comparative series of operative or nonoperative treatment of high-grade spondylolisthesis were identified. The mean reduction in anterior translation of L5 on S1 was 27.8% ± 13.2%. Slip angle mean reduction 20.9° ± 1.7° (four studies). Pseudarthrosis rate was 5.5% in the 165 patients in the reduction groups, while the 101 patients in the fusion in situ groups had a rate of 17.8% ($p = 0.004$). The standardized risk ratio for a pseudarthrosis in the pooled reduction group was 0.4 (95% confidence interval: 0.19–0.81) compared to the patients with in situ fusion.

Neurologic deficits, a concern with surgical treatment, were found in 13 (7.9%) of the 165 in the reduction group patients in the reduction group and in nine (8.9%) of the 101 patients in the arthrodesis in situ group ($p = 0.8$). Instrumentation failure leading to revision surgery was reported in eight (4.8%) of the 165 patients in the reduction group and none in the in situ group. The analysis concluded that reduction and fusion of high-grade

spondylolisthesis lowered the risk of nonunion and there was no difference in rate of neurological injury between the surgical groups.[15,16]

Resolution of clinical scenario

The patients radiograph showed Meyerding grade I spondylolisthesis with lumbosacral angle of 95° (normal 110°). A discussion of the treatment options of observation, nonoperative treatment, or surgical treatment was had with the patient and her family. The patient and family agreed on a treatment plan to initially withdraw from sports activity for six weeks, the use of lumbosacral orthosis, and undertaking a physical therapy program. This plan gave her an 85% chance to return to her sport after three months of consistent brace wear. She would progress out of the brace and back to gymnastics based on her clinical improvement as imaging studies would most likely not change over this period.

Summary of answers

- Initial imaging should be performed using two-view lumbar radiographs. If symptoms persist following a course of nonoperative treatment in the setting of normal radiographs, an MRI or CT scan should be performed (modality dependent on the length of symptoms) to assess for pars defect.
- Healing and progression of spondylolysis are related to the skeletal maturity of the patient and pars defect morphology with unilateral pars injury and more mature patients being more likely to heal the defect and have less progression. Long-term symptoms of pain and disability in this condition are rare.

- Treatment of low-grade spondylolisthesis is similar to the plan for spondylolysis. Restricting activity has rates of success equivalent to lumbosacral orthosis use. The evidence supports the reduction of high-grade spondylolisthesis to reduce the rate of pseudarthrosis. Neurological injury rate attributed to surgery was not different between surgical techniques.

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180 Early Onset Scoliosis

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Clinical scenario

- An otherwise healthy two-year-old boy with syndromic scoliosis presents with a 45° right thoracic scoliosis and 40° kyphosis.
- At the age of 2.5 years, his scoliosis has progressed to 55° and he is treated with Mehta casting.
- Despite initial success with casting, at the age of six years his curve progresses to 65° and he is treated with magnetically controlled growing rods.

Top three questions

1. In patients with nonidiopathic early onset scoliosis (EOS), does serial casting control curve progression as compared to idiopathic EOS?
2. In patients with EOS, do magnetically controlled growing rods (MCGRs) result in fewer complications as compared to traditional growing rods (TGRs)?

3. In patients with EOS, does treatment with traditional spinal growing rods result in greater spine growth compared to rib-based distraction?

Question 1: In patients with nonidiopathic early onset scoliosis (EOS), does serial casting control curve progression as compared to idiopathic EOS?

Rationale

The resurgence of serial casting as a viable treatment option for EOS is one of the greatest changes in the past decade for the management of early onset spinal deformity. The work by Mehta and Sanders et al. showed serial elongation de-rotation flexion casting could result in complete curve correction in infantile idiopathic scoliosis.[1–3] The idea that serial casting can be utilized to delay growing instrumentation in EOS of all etiologies is appealing.

Clinical comment

Management of EOS remains a challenging problem for the pediatric orthopedic surgeon. Progressive curves during early life can negatively impact the development of the lungs, spine, and chest wall and are potentially fatal. Managing these with growing instrumentation allows delay of formal fusion until around 10 years of age due to the detrimental effects of pulmonary function when fusion is performed earlier.[4] However, growing instrumentation is not without complications and limitations. Compelling findings such as a 13% decrease in the likelihood of

experiencing complications for each year of increase in age at initial implantation of TGRs,[5] unintended auto-fusion,[6,7] and diminishing returns after repeat lengthening of growing instrumentation[8,9] make delaying growing instrumentation appealing as long as progression of deformity can be controlled. Thus, use of serial casting has expanded to include multiple etiologies of EOS with even larger curves. Whether serially casting for early onset nonidiopathic scoliosis can control curve progression, delay surgical intervention, and allow for growth of the spine without increased complication is not well delineated.

Available literature and quality of the evidence

No level I or II evidence was identified pertaining to serial casting outcomes, control of curve progression, or delay of growing instrumentation. The majority of the evidence comes from case series and retrospective studies. To compare outcomes, results were summarized from recent studies that included heterogeneous populations as well as single etiology EOS patients (Table 180.1).

Table 180.1 Level of evidence (LOE) of included articles.

Serial casting articles	LOE
Sanders et al.[3]	IV
Fletcher et al.[12]	IV
Baulesh et al.[13]	III
Waldron et al.[14]	IV
Johnston et al.[16]	III
Gussous et al.[15]	IV
Demirkiran et al.[11]	IV
Cao et al.[10]	IV
Iorio et al.[17]	IV
Hassanzadeh et al.[18]	IV

Findings

There were two papers dedicated to investigating casting in congenital patients,[10,11] with others including mixed etiologies,[3,12–16] or only idiopathic patients.[17,18] Overall, the majority of patients were idiopathic (Table 180.2). In regard to controlling curve progression, although idiopathic patients were the only cases of resolution, as would be expected, nonidiopathic curves were also controlled with casting. Notably a wide range of curve sizes were casted in both idiopathic and nonidiopathic groups. Although spine growth in nonidiopathic cases appears less than in idiopathic groups, there were still cases with comparatively normal growth.

Table 180.2 Number of EOS patients included by etiology.

Etiology	Papers	Patients (N)	Patients (%)	Follow-up (months)
Idiopathic	9	209	61.3	12–91
Nonidiopathic total	8	132	38.7	12–91
Congenital	3*	20	5.9	13–91
Neuromuscular	4*	17	5	12–91
Syndromic	4*	45	13.2	12–91

*Two studies did not sub-classify nonidiopathic diagnoses.

Sanders et al. and Johnston et al. investigated outcomes of serially casting in heterogeneous EOS populations.[3,16] However, the authors did not separate the population by etiology for comparison. Importantly, Sanders's early work echoed that of Mehta's, demonstrating good correction of deformity if treatment was started prior to 13.2 months of age, and full correction was rare in those starting treatment who were greater than 18 months of age. However, the majority of the population (68%) were patients with idiopathic EOS, and 75% of those patients with resolution of the curve were idiopathic.[3] Johnston et al. investigated TGRs versus serially casting in a retrospective matched study including pairs with neuromuscular, syndromic, and idiopathic EOS. They found that overall the curve magnitude was controlled over a mean casting course of 2.4 years, with surgery delayed by a mean of 1.7 years subsequent to that.[16] While more nonidiopathic patients in this review required surgery over the follow-up period than idiopathic patients, studies reported delays in surgery for all etiologies of EOS, up to a mean 52.8-month delay to surgical intervention in idiopathic patients,[17] mean 26.3-month delay in congenital

patients,[11] and up to mean a 39-month delay in mixed etiologies.[12]

While the level of evidence is low, these results suggest that casting may be an initial option for all etiologies of progressive EOS, even congenital cases, without increased complications compared to idiopathic cases. Minor complications were more common including skin irritation, which was reported in all but one study.[17] Respiratory complications that were temporary were reported in four studies,[10],[11],[13],[18] and nausea/vomiting postcasting in three studies.[10],[12],[18] Nonspecific cast intolerance in two patients in one study,[14] intolerance secondary to increase increased seizure activity in one patient,[12] and noncompliance with casting one idiopathic patient were reported.[18] Major complications including subclavian vein thrombosis, cardiac arrest, and one death were reported in a single study;[15] cardiac arrest occurred in an idiopathic patient on induction of anesthesia with negative further cardiac workup, subclavian thrombosis, and the death from presumed asthma attack, six and three weeks after cast application, respectively, in syndromic patients. Importantly, few respiratory complications were noted and all resolved, with only one instance where cast removal was required,[11] and one case where the cast was bivalved;[10] this indicates that serial casting did not pose increased respiratory risk for patients with larger curves or nonidiopathic curves where respiratory function may be more concerning.

The longest reported follow-up in this review was 7.6 years, with most reporting a minimum follow-up of 1–2 years. With the resurgence of serial casting and expanded indications, longer-term follow-up will soon be available that may augment the current evidence, and with the increased use of casting there are opportunities for

prospective investigation. The most recent literature on serial casting has also expanded the indications to include congenital patients. These patients were not included in the initial serial casting literature, although the largest population investigated remains early onset idiopathic patients.

Resolution of clinical scenario

- Serial casting has become common for progressive EOS with recent evidence from relatively short follow-up and largely case series.
- Infantile idiopathic patients remain the EOS population with the largest numbers in the literature, with evidence of resolution of scoliosis for some patients with serial casting, and control of curve progression for up to several years possible with a wide range of curve magnitudes.
- While more nonidiopathic progressive curves will likely undergo surgery, these curves may be temporarily controlled with serial casting without increase in complications compared to idiopathic patients. The delay to surgical intervention may be shorter than for idiopathic patients.

Question 2: In patients with EOS, do magnetically controlled growing rods (MCGRs) result in fewer complications as compared to traditional growing rods (TGRs)?

Rationale

MCGRs have revolutionized the management of EOS, as they provide noninvasive spine lengthening, allowing for more frequent and smaller distractions to better mimic normal physiological growth. However, whether this surgery actually reduces the number of complications as observed with TGRs is unknown.

Clinical comment

TGRs have previously been the gold standard for the treatment of EOS with abundant evidence supporting their use in preventing curve progression and allowing physiological spine growth.[19–21] However, there is increased risk of anesthetic and wound complications due to manual distractions of the rods every six months under general anesthesia.[22] With MCGRs, distractions can be performed in the outpatient clinic with the patient awake. Hence, patients can undergo safe distractions under constant neurological monitoring and avoid the risks with repeated surgery for surgical lengthening. The MCGR has been shown to be effective in controlling curve progression and promoting spine growth.[23–26] It is also useful as a temporary measure for gradual correction of severe deformities.[27] Although frequent distractions require regular imaging for monitoring length gains, the ultrasound has been shown to provide equal accuracy as radiographs but with reduced radiation exposure.[28–30] Despite these improvements, whether MCGRs result in fewer complications and less re-operation risk overall is unknown and requires attention.

Available literature and quality of the evidence

Limited evidence exists comparing the complication rates between TGR and MCGR. There are no randomized controlled trials (RCTs) or comparative cohorts. Most of the

available evidence are based on case series. A total of six TGR studies[5,8,23,31–35] and nine MCGR studies[23,33,36–42] are included in the analysis.

Findings

The main complications to be highlighted include infection/wound complications, implant dislodgement, rod fracture, proximal junctional kyphosis (PJK), law of diminishing returns and medical complications, and MCGR-specific distraction-related complications (distraction failure or rod slippage).

The main TGR article that is the benchmark for comparison was reported by Bess et al.[5] This study reported, from the largest TGR patient population, a breakdown for each complication. Along with several other key articles on TGR complication data, the overall complication rate was 132.6%, suggesting that more than one complication on average will occur in every TGR-treated patient. Of these, implant dislodgement is most common (55.8%), followed by infection/wound complications (27.0%) and rod fractures (17.5%). It should be noted that Bess et al. did not evaluate for risk of PJK.[5] Despite better distraction gains with dual rods, implant and rod fracture complications occur both in single and dual rods. Implant-related complications in MCGR treatment are similarly the most prevalent (19.5%) but MCGR has dramatically reduced infection/wound complications (5.3%). Rod fractures are still common (8.4%) but less so in more recent reports. The overall rate of PJK may be skewed due to limited reporting and follow-up in the MCGR studies. Nevertheless, overall reporting is low as the simple presence of PJK may not warrant revision surgery. Those subjects with proximal junction failure such as proximal implant dislodgement are included in the implant dislodgement complication group for analysis.

There are increasing concerns regarding distraction problems such as failure of distraction and rod slippage, which both affect the degree of length gains. However, it appears that the law of diminishing returns does not occur or at significantly reduced rates as compared to TGR. This may be due to reduced rates of auto-fusion with smaller degrees of distraction and higher distraction frequencies.[36],[37]

Due to the relatively recent introduction of the MCGR, the overall patient population reviewed was much smaller than the TGR and with shorter follow-up duration. Despite having fewer reported complications in general for the MCGR group, our findings will need to be revisited when longer-term follow-up studies are available. In addition, fewer complications may not equate to fewer re-operations, as Kwan et al. reported that up to 46.7% of patients require unplanned re-operations up to a two-year postoperative follow-up.[43] What occurs in MCGR graduates is of interest, as outcomes and complications are variable at skeletal maturity and beyond final fusion surgery.[44],[45] There is a specific concern with regards to the law of diminishing returns as the current available evidence on MCGR is based only on a monthly distraction methodology. Whether the absence of this phenomenon is also present in longer distraction intervals is unknown. It is also important to note that these studies all report unexpected returns to the operating theater. The overall rate of surgery may not be as low for the MCGR if the expected returns for rod exchanges are taken into consideration as the current maximum allowable distractible length of the rod is only 4.8 cm. Moreover, some specific MCGR complications, like actuator pin fracture, have been identified but may be underreported.[46],[47] In addition, distraction-related complications require further examination in future work. The significance of these events on length gain and

correction is currently unknown and requires attention. Preliminary reports suggest that the effectiveness of distractions reduces with use and may result in early rod exchanges.[36,37] This has implications on the overall re-operation rate and has significant cost concerns.

Resolution of clinical scenario

- The overall evidence for MCGR is based on a relatively smaller patient population and shorter follow-up as compared to TGR.
- Based on the available early follow-up, MCGRs may have an overall reduced complication rate as compared to TGRs.
- MCGRs have a significantly lower relative percentage of infection or wound complications.
- Not all complications are comparable as there are specific complications that exist which only concern MCGR, such as distraction failure and rod slippage.
- MCGR appears to avoid the law of diminishing returns due to more frequent distractions and at smaller amounts.
- Distraction failure and rod slippage are major concerns in MCGR as they have been shown to reduce length gains and may require rod exchange. This has implications on clinical effectiveness and costs.

Question 3: In patients with EOS, does treatment with traditional spinal growing rods result in greater spine growth compared to rib-based distraction?

Rationale

As growth-friendly surgery is utilized to promote spine growth for children with EOS, it is important to know whether normal spine growth is achieved utilizing these techniques.

Clinical comment

Fusion has been the gold standard for treatment of progressive scoliosis. For children diagnosed with scoliosis under the age of 10 years (EOS), the spine, thorax, and lungs have significant growth remaining.[48,49] As surgical fusion has been found to halt growth of these structures,[4] it is now common to treat EOS with techniques *that* allow for growth of the spine.[50–52] Only recently has literature been available to assess the effects of these techniques on spine growth.

Available literature and quality of the evidence

Limited reference data exist for normal spine growth. These data are based on two-dimensional (2D) coronal plane radiographs and do not take into account the three-dimensional (3D) nature of spine growth.[53,54] As this is currently the best available literature, it has been used as a reference for assessing spine growth for growth friendly surgeries. There are no RCTs currently published. The available evidence is based on prospective and retrospective case series.

Findings

The landmark paper describing a *law of diminishing returns* for spinal growth during treatment with TGRs was published in 2011.[8] The conclusion of this paper was that total spine height (T1–S1) did not change appreciably after

the seventh lengthening procedure; however, after mean follow-up of 3.3 years, T1–S1 height increased from 24.9 to 33.1 cm. This represented an 8.2 cm, or 33%, increase in spine height. Of note, 3.2 cm of the increase occurred during the implantation procedure and 5.0 cm of the increase occurred during the distraction phase. Although this widely quoted study asserts that growth-friendly surgery is ineffective over time, it is important to recognize that this population achieved significant growth during the study period.

A similar study on spine growth, which focused on rib-based distraction rather than TGR, demonstrated improvement in T1–S1 height from 19.9 cm preoperatively to 22.1 cm postimplantation, to 28.0 cm at minimum five-year follow-up.[55] This 8.1 cm gain in height represented a 41% increase over the study period. This study also evaluated the sagittal plane and determined that kyphosis increased from 40° to 65°. This prompted the authors to evaluate *out of plane* spinal growth that may explain the law of diminishing returns.[56],[57] Since posterior distraction-based surgery may be kyphogenic, lengthening of growth friendly implants may increase spinal length when measured in the sagittal plane (sagittal spine length, or SSL). These increases may not be evident when evaluating spine height purely on a coronal plane radiograph. While some authors are now questioning the accuracy of Dimeglio's original coronal plane spine growth data,[58] Dimeglio and his group continue their significant efforts to define spine growth by now evaluating 3D spine and chest growth.[59]

In 2007, the Children's Spine Study Group embarked upon a prospective, multicenter study on the use of rib-based distraction in children with scoliosis that do not have associated fused ribs.[60] That study demonstrated that

preoperative coronal spine height for T1–T12 (15.7 ± 3 cm) and T1–S1 (25 ± 6 cm) increased significantly after implantation surgery (17.7 ± 4 cm and 28.6 ± 6 cm, respectively) and at two years postoperatively (18.4 ± 4 cm and 29.1 ± 5 cm, respectively). Ninety-four percent of patients were found to have an increase in spine height over the study period. In addition, this study also recognized that SSL and instrumented spine length also increased significantly.

A combined Children's Spine Study Group and Growing Study Group retrospective comparative review compared TGRs to rib-based distraction in patients with idiopathic EOS. With a minimum five-year follow-up, they determined that TGR patients gained a greater percentage of thoracic height (24%) as compared to the rib-based group (12%) during the distraction phase of treatment.[61]

Resolution of clinical scenario

- The overall evidence for spine growth is based on relatively small patient numbers with minimum two- to five-year follow-up.
- Level II evidence is available with only short-term follow-up results. Rib-based distraction significantly increases spine height and length at minimum two-year follow-up.
- Level III evidence is available with longer follow-up time intervals. At minimum five-year follow-up, TGRs were found to achieve greater gains in spine height than rib-based distraction techniques.
- Level IV evidence is also available with a minimum five-year follow-up. Spine height and length for rib-based distraction increases significantly without evidence of diminishing returns.

- Despite higher levels of evidence, a level IV study with only two-year follow-up has been widely quoted and has popularized a law of diminishing returns for TGRs.
- Level II and Level III studies have *not* demonstrated a law of diminishing returns for rib-based distraction or for TGRs.
- Based on the best available evidence, there is no evidence to support a law of diminishing returns for growth-friendly treatment.
- Traditional spinal growing rods may result in slightly greater spine growth compared to rib-based distraction.

Summary of answers

- While more nonidiopathic progressive curves will likely undergo surgery, these curves may be temporarily controlled with serial casting without increase in complications compared to idiopathic patients. The delay to surgical intervention may be shorter than for idiopathic patients.
- Based on the available early follow-up, MCGRs may have an overall reduced complication rate as compared to TGRs.
- Based on the best available evidence, there is no evidence to support a law of diminishing returns for growth-friendly treatment. TGRs may result in slightly greater spine growth compared to rib-based distraction.

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181 Developmental Dysplasia of the Hip

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Clinical scenario

- A two-day-old female infant receives her newborn clinical hip assessment examination by a pediatrician in the newborn nursery.
- She is first-born and presented breech at birth; there is no known family history of developmental dysplasia of the hip (DDH).
- Barlow and Ortolani maneuvers are both negative and there is no evidence of hip instability upon examination.

Top three questions

1. In newborn infants, what is the evidence to support universal compared to selective ultrasound (US) imaging in conjunction with clinical examination for screening for DDH?
2. For infants with risk factors for DDH, to what extent is clinical and radiologic follow-up required after a normal screening US to ensure optimal outcomes?

3. For infants treated successfully by harness/brace treatment for DDH, what extent of clinical and radiologic follow-up is required to ensure optimal outcomes?

Question 1: In newborn infants, what is the evidence to support universal compared to selective ultrasound (US) imaging in conjunction with clinical examination for screening for DDH?

Rationale

The early diagnosis and treatment of DDH is widely accepted to improve long-term radiographic and functional outcomes for the patient, while decreasing the need for more complex, operative treatment approaches and their potential complications. There is much controversy, however, as to which screening programs best optimize the balance between early detection and potential overdiagnosis or overtreatment. Clinical newborn examination for hip instability remains the universal minimum standard for DDH screening. However, the utility of additional ultrasound (US) imaging in DDH screening is an issue of continuing debate. Some centers or countries employ universal US screening in conjunction with newborn clinical examination, while others employ selective US screening based on the presence of defined DDH risk factors.[1]

Clinical comment

DDH is a spectrum of hip joint abnormalities ranging in severity from mild dysplasia of a reduced and stable hip to an irreducible hip dislocation. The Barlow and Ortolani maneuvers are the standard clinical tests performed on newborns to detect the presence of a dislocated or dislocatable hip. However, these tests for clinical instability cannot detect the presence of stable acetabular dysplasia.[1] US is the primary imaging modality of choice to detect dysplasia in infants under 4–6 months of age, as bony ossification has not yet developed to the extent to allow plain radiographs to be useful. Some natural history studies have shown that up to 70% of cases of neonatal hip instability and 90% of cases of acetabular dysplasia resolve spontaneously as the hip joint matures in the developing infant.[2]

Available literature and quality of the evidence

- Level I: 1 systematic review/meta-analysis.[3]
- Level II: 2 prospective studies.[4],[5]
- Level III: 4 retrospective cohort studies.[6]–[9]

Findings

Shorter and colleagues sought to evaluate and compare screening programs for DDH in order to assess the effectiveness of clinical and US-based screening procedures at preventing late presentation.[3] With strict inclusion criteria of randomized, quasi-randomized controlled trials (RCTs), and cluster randomized trials comparing different types of screening programs, only five studies were ultimately included for analysis. Meta-analysis of two studies comparing clinical examination with universal US to clinical examination with targeted US in unselected infants revealed no significant difference in late-

diagnosed DDH between the two programs with a pooled relative risk (RR) ratio of 0.49 (95% confidence interval [CI]: 0.19–1.26). There was also no significant difference in surgery (pooled RR = 0.36; 0.04–3.48) or incidence of avascular necrosis or osteoarthritis (pooled RR = 0.33; 0.01–8.02). Meta-analysis of two studies comparing treatment guided by US surveillance and treatment guided based on clinical assessment alone for infants with unstable hips likewise revealed no significant difference in late-diagnosed DDH (RR = 1.05; 0.6–1.85). Given the small number of studies included and lack of power within individual studies to detect rare events, Shorter and colleagues concluded that neither US strategy proved more effective at improving clinical outcomes.

Laborie et al. performed a prospective survey of their center's selective US screening program for all infants born in a 15-year period with defined DDH risk factors of clinical hip instability, breech presentation, congenital foot deformities, or a family history.[4] During the study period, 11 539/81 564 infants were identified as at-risk infants, and subsequently received a US scan at 1–3 days of age. In total, 2433 infants received abduction treatment as a result of early screening (21.7% of at-risk infants, 3.0% of entire cohort). Of the 152 infants diagnosed with late-presenting DDH requiring treatment, only three (0.004%) were from the at-risk group. The authors concluded that their screening program resulted in acceptable rates of early treatment and low rates of late-detected DDH.

Choudry and Paton undertook a similar prospective assessment of their neonatal hip instability screening program.[5] Rather than employ selective US screening for risk factors, this program only performed US scans on infants with positive clinical exam findings of hip instability. The primary goal was to assess the positive predictive value (PPV) of the initial screening – a positive

Barlow or Ortolani maneuver performed by a nonexpert – compared with an expert in screening detecting clinical instability or sonographic dysplasia. During the study period, 124 newborns with findings of clinical instability were referred to the authors' institution for clinical and sonographic screening from a birth cohort of 28 241. Overall, they reported a PPV of 4% for the Barlow/Ortolani tests (5/124 hips) and 16.1% for sonographic assessment (20 Graf type IV/124 hips). The authors concluded that referral volume for hip instability appeared to be increasing in conjunction with a decreasing PPV, and thus advocated for limiting DDH screening to a small group of experienced examiners.

Sahin et al. retrospectively reviewed hospital records of 5798 infants who were examined regularly until walking age at their institution over a seven-year period.[6] While 111 infants were found to have DDH risk factors, and 606 infants had physical examination findings suggestive of DDH, 10 infants were ultimately diagnosed with DDH. The authors concluded that the combined sensitivity of risk factors and physical exam findings is high enough to merit acceptance as a screening tool.

Schams et al. investigated the association of risk and protective factors with DDH in a cohort of 11 820 infants receiving universal US screening.[7] While the authors did identify female gender: odds ratio (OR) = 4.07 (3.01–5.51); breech presentation: OR = 4.98 (3.71–6.71); and family history: OR = 5.05 (3.49–7.31), as independent predictive risk factors, they concluded that the strength of these predictive factors to inform selective US screening was limited, and therefore advocate for early universal US screening.

Westacott et al. performed a retrospective comparative study examining a universal US screening cohort of 10 015

infants and a selectively screened cohort of 18 053 infants.[8] Rates of delayed presentation were comparable between the two cohorts (0.5/1000 universal vs 0.28/1000 selective). Treatment rate was higher in the universally screened cohort (0.79% vs 0.23%); however, surgical treatment was found to be higher in the selectively screened cohort (26% vs 12% of those treated in each cohort).

Olsen et al. examined the impact of adding universal US screening to a single-examiner clinical screening clinic at a single institution in Norway over an eight-year period.[9] A total of 4245 infants receiving both clinical and US assessment were compared to a historical cohort of 3594 infants receiving clinical examination alone. The treatment rate increased from 1 to 2.1% in the universally screened cohort, while the number of late-detected cases was halved from 1.0 to 0.5/1000.

Resolution of clinical scenario

While many retrospective studies have been performed, little strong evidence exists to suggest universal US screening provides significant benefit over clinical examination and selective US screening based on particular risk factors for DDH. This infant should be referred for selective US screening between four and six weeks of age based upon the presence of the risk factor breech presentation.

Question 2: For infants with risk factors for DDH, to what extent is clinical and radiologic follow-up required after a normal screening US to ensure optimal outcomes?

Rationale

Late-presenting or late-diagnosed DDH (dislocation, instability, or dysplasia) can lead to the need for more complex corrective procedures, increased potential for complication, and result in long-term debilitation that impacts quality of life. Consequently, US screening for infants with risk factors (breech presentation, positive family history, or history of clinical hip instability) is routinely employed at 4–6 weeks of age. However, dysplasia may still develop later in infancy after initial screening tests and little is known about the extent of follow-up necessary in those infants with risk factors who receive a normal initial screening US examination in order to prevent this occurrence of late dysplasia.

Clinical comment

A great degree of practice variability exists among orthopedic surgeons on the extent to which they follow-up with infants with risk factors after an initially normal screening US. This follow-up may range from immediate discharge after US, to a single radiograph at 4–6 months of age, to serial radiographs at six months, one year, and two years.

Available literature and quality of the evidence

- Level II: 1 prospective study.[10]

- Level III: 2 retrospective studies.[11],[12]

Findings

In a prospective randomized study, Morris et al. sought to identify the rate of late dysplasia after normal screening in a breech infant cohort while also examining the impact of a prophylactic abduction diaper.[10] Infants were prospectively randomized into observational or prophylactic treatment arms following referral for breech presentation and a normal clinical examination and screening US. Routine clinical and US follow-ups were performed, ending with a pelvic radiograph at approximately 13 months. The authors reported a 7.4% overall rate of radiographic dysplasia in the 90 patient cohort (8.3% in the observational arm and 5% in the prophylactic abduction arm), thus they suggested follow-up beyond a normal screening US was recommended for the risk factor of breech presentation.

Imrie et al. retrospectively reviewed the incidence of DDH in breech infants on six-month radiograph after receiving a normal screening US.[11] Out of the cohort of 193 infants with normal USs at six weeks, 131 returned for a four- to six-month radiograph. From those, 38 (29%) infants had abnormal findings that resulted in treatment for DDH.

Similar to Imrie et al., Brusalis et al. performed a retrospective analysis of 94 hips in 47 breech infants with normal screening tests to determine the rate of subsequent acetabular dysplasia at six months.[12] Applying a traditionally used threshold for defining dysplasia (acetabular index [AI] ≥30°), 10/94 hips (10.6%) met diagnostic criteria. Applying a normative AI value stratified by gender and laterality, 4/94 hips (4.3%) were deemed significantly dysplastic. Despite discrepancies in diagnostic definitions, their findings supported a role for observation of breech infants beyond six weeks of age.

Resolution of clinical scenario

Very few studies have been done, prospectively or retrospectively, to determine the appropriate amount and length of follow-up required for infants with DDH to balance detection of late-presenting DDH and radiation exposure. Although high-level evidence is lacking and incidence rates are variable, the existing studies suggest some degree of follow-up is recommended, at least for infants born breech following a normal screening US at six weeks of age. This infant should be followed until at least six months of age with a pelvic radiograph, even if her screening US due to a breech risk factor referral is normal.

Question 3: For infants treated successfully by harness/brace treatment for DDH, what extent of clinical and radiologic follow-up is required to ensure optimal outcomes?

Rationale

When detected early, and/or in mild cases of DDH, a harness or brace can be an effective approach to treatment that avoids complex or invasive operative procedures while still providing excellent long-term outcomes for the patient. Numerous long-term studies have mentioned late sequelae relating to acetabular dysplasia or femoral head deformities and therefore recommend follow-up to skeletal maturity. Follow-up is resource- and time-intensive for both the family and hospital/healthcare system; therefore, understanding the extent of follow-up required to ensure normalization of hip development is important.

Clinical comment

Follow-up to skeletal maturity is often recommended, even for cases in which successful reduction and stabilization of the hip is achieved through early brace treatment in order to detect late acetabular dysplasia. Practice variability does exist, however, and discharge following a normal two-year pelvic radiograph is not uncommon among orthopedic surgeons.

Available literature and quality of the evidence

- Level II: 1 prospective study.[13]
- Level III: 4 retrospective studies.[14–17]

Findings

Cashman et al. performed a prospective longitudinal follow-up study of 332 infants (546 dysplastic hips) treated by Pavlik harness over a mean period of 6.5 years.[13] While the Pavlik harness failed to reduce 18 hips in 16 infants, no significant difference was found from the normal values of AI for successfully treated hips beyond 18 months of age. Persistent significant late dysplasia was seen in 2.4% of successfully treated hips, all cases of which were identified no later than five years of age by an abnormal center edge angle. The authors therefore recommend radiological surveillance until this age for harness-treated patients.

Allington retrospectively reviewed 109 hips in 83 infants who had been successfully treated for DDH by Pavlik harness and had a normal pelvic radiograph at two years of age.[14] At a mean follow-up of 10.2 years, all hips had a normal clinical examination and a normal pelvic radiograph with no signs of avascular necrosis. Thus, the authors suggested long-term follow-up is not required provided

normal clinical and radiographic findings at two years of age.

Bin et al. retrospectively reviewed the evolution of acetabular dysplasia after hip stabilization by Pavlik harness in a series of 42 hips in 30 patients with a mean follow-up of 6.7 years.[15] Mean acetabular angle and Wiberg's lateral center-edge angle were within normal range for all hips, with one report of recurrent dislocation occurring at five months of age following Pavlik harness treatment. The authors suggested that early, brief treatment by Pavlik harness was sufficient to promote self-correction of acetabular dysplasia, but recommended radiological follow-up at four months, 18 months, and five years.

Fujioka et al. retrospectively reported on 158 hips with >20-year follow-up from an original cohort of 574 hips treated by Pavlik harness in infancy.[16] At final follow-up, mean Sharp angle was significantly larger and mean center-edge angle was significantly smaller than the normal value, and 19% of hips were Severin class III (dysplastic). Although the patient sample is likely enriched for poor outcomes (27.5% follow-up), this is one of the few studies to report radiographic and clinical outcomes on Pavlik-treated hips in the third decade of life, and findings suggest outcomes are not always satisfactory despite early success.

Sarkissian et al. assessed the importance of importance of continued radiographic monitoring following a normalized US in a retrospective series of 115 infants diagnosed with DDH, 79 of whom were treated by Pavlik harness.[17] All included patients had achieved a normal US and clinical examination by 3.1 months of age; however, 17% had radiographic signs of acetabular dysplasia on pelvic radiograph at 6.6 months, and 33% had dysplasia at 12.5 months. Consequently, radiographic follow-up at six and 12

months is recommended to detect residual dysplasia. This study could not comment on longer-term outcomes as follow-up was limited to 12 months.

Resolution of clinical scenario

While few high-level studies with long-term radiographic and clinical follow-up exist, most have reported at least some instances of acetabular dysplasia after successful Pavlik harness treatment. Comprehensive prospective studies will be required to strengthen the evidence in this regard; however, radiographic follow-up in these patients until at least two years of age is recommended to monitor for residual dysplasia.

Summary of answers

- Little strong evidence exists to suggest universal US screening provides benefit over clinical examination.
- Some degree of follow-up is recommended, at least for infants born breech following normal screening.
- There are at least some instances of acetabular dysplasia after successful Pavlik harness treatment.

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182 Legg–Calvé–Perthes Disease

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Clinical scenario

- A nine-year-old boy presents with pain in the left hip and a limp for the duration of one month.
- Radiographs of the pelvis reveal features of Legg–Calvé–Perthes disease in the late stage of avascular necrosis (Stage Ib: Modified Waldenström classification) with sclerosis and minimal loss of height of the capital femoral epiphysis.[1]
- A perfusion magnetic resonance imaging (MRI) scan confirms that over 50% of the epiphysis is avascular.[2]

Top three questions

1. In children with Legg–Calvé–Perthes disease, are the chances of preserving the spherical shape of the femoral head (i.e. preventing the femoral head from getting deformed) greater following surgical or nonsurgical containment than following symptomatic treatment?

2. In children with Legg–Calvé–Perthes disease, are the chances of preventing femoral head deformation greater if containment is achieved early in the course of the disease (by Modified Waldenström Stage IIa) than if containment is achieved later in the evolution of the disease?
3. In children with Legg–Calvé–Perthes disease, which of these methods of containment offers the best chance of preventing femoral deformation: bracing, proximal femoral osteotomy, innominate osteotomy, shelf acetabuloplasty, or combined femoral and innominate osteotomy?

Question 1: In children with Legg–Calvé–Perthes disease, are the chances of preserving the spherical shape of the femoral head (i.e. preventing the femoral head from getting deformed) greater following surgical or nonsurgical containment than following symptomatic treatment?

Rationale

The aim of treatment of children with Legg–Calvé–Perthes disease is to prevent the femoral head from getting deformed.[3] Extrusion of the femoral head predisposes to femoral head deformation and, consequently, prevention or reversal of extrusion (i.e. by containment) should, potentially, minimize the risk of femoral head deformation.[1]

Clinical comment

There are two strategies for achieving containment (ensuring that the anterolateral part of the femoral capital epiphysis is well within the acetabular margin). The first involves keeping the hip abducted and internally rotated or abducted and flexed by bracing or a proximal femoral varus de-rotation (or varus extension) osteotomy. The second entails improving acetabular coverage of the anterolateral part of the femoral epiphysis by an innominate osteotomy (e.g. Salter osteotomy) or a shelf acetabuloplasty.

Available literature and quality of the evidence

- Level II: 3 prospective studies.[4–6]
- Level III: 1 meta-analysis[7] and 3 retrospective cohort studies.[8–10]
- Level IV: 1 retrospective cohort study.[11]

Findings

Saran and colleagues analyzed 14 level II and III studies and reported a pooled odds ratio (OR) of 1.29 (95% confidence interval [CI]: 1.05–1.60; p = 0.02) for a spherical head at skeletal maturity in children who had surgical containment either with a femoral varus osteotomy or a Salter innominate osteotomy when compared with children who were not operated on. Surgical containment did not influence femoral head sphericity in children under six years at onset of the disease (OR = 1.02; 95% CI: 0.45–2.36).[7] Children older than six years at the onset of disease were more likely to have spherical femoral heads at skeletal maturity if they had surgical containment rather than nonoperative treatment (OR = 2.05; 95% CI: 1.28–3.26).

Wiig and colleagues undertook a prospective study of 152 children with Legg–Calvé–Perthes disease.[4] The children were treated by physiotherapy (n = 55), Scottish Rite abduction orthosis (n = 26), or femoral varus osteotomy (n = 71). Sphericity of the femoral head was preserved more frequently following femoral varus osteotomy than following physiotherapy ($p < 0.001$).

Terjesen et al. treated 70 children who were between 6 and 10 years of age at onset of the disease with a femoral varus osteotomy and compared their outcomes with 61 children who received physiotherapy only.[5] Femoral head sphericity was retained in 86% of children who underwent an osteotomy compared to 25% who were treated with physiotherapy.

Herring et al. in a multicenter prospective study evaluated the shape of the femoral heads at skeletal maturity of 345 hips in 337 children and noted that 61% of hips treated by surgical containment had spherical femoral heads as opposed to 46% of hips that were not surgically contained ($p = 0.02$).[6]

Joseph et al. analyzed the outcome, after femoral varus osteotomy, of 48 children between 7 and 12 years of age at onset of symptoms in Stage I or II of the disease and compared them with the outcome in 30 historical controls treated symptomatically.[8] At the time of healing, 62.5% of the operated group had spherical femoral heads compared with 20% of those treated nonoperatively ($p < 0.001$).

Nguyen et al. did a meta-analysis of 23 reports of treatment of Legg–Calvé–Perthes disease which included 1232 children.[11] They observed that among children younger than six years the outcomes of operative and nonoperative treatments were comparable (OR = 1.071; 95% CI: 0.58–1.968; p: 0.828). In children older than six years, operative

treatment was almost twice as likely to result in a spherical femoral head (OR = 1.754; 95% CI: 1.299–2.370; p <0.0001).

Carsi et al., in a retrospective cohort study, noted that the shape of the femoral head at healing was spherical or ovoid in 84% of 44 children who had been treated with a shelf acetabuloplasty performed either during Modified Waldenström Stage I or Stage IIb of the disease.[9]

Rich and Schoenecker in a retrospective cohort study of 213 children, treated by a protocol of restoring and maintaining satisfactory hip abduction with an adductor tenotomy and abduction cast, followed by daily range of motion (ROM) exercises and an A-frame orthosis to facilitate femoral head containment, reported that 79% of hips were spherical at skeletal maturity.[10]

Resolution of clinical scenario

Despite the paucity of high-quality studies related to the treatment of Legg–Calvé–Perthes disease, there is some evidence to suggest that nonsurgical or surgical containment can improve the chances of retaining the spherical shape of the femoral head. In the light of this, the boy should be offered containment.

Question 2: In children with Legg–Calvé–Perthes disease, are the chances of preventing femoral head deformation greater if containment is achieved early in the course of the disease (by Modified Waldenström Stage IIa) than if containment is achieved later in the evolution of the disease?

Rationale

There is some evidence to suggest that if irreversible deformation of the femoral head occurs during the evolution of Legg–Calvé–Perthes disease, it occurs either in the late stage of fragmentation or shortly thereafter (in Stage IIb or IIIa of the Modified Waldenström classification).[1] Consequently, any intervention aimed at preventing the femoral head from getting deformed should be instituted before Stage IIb if it is to be effective.

Clinical comment

In the past, indications for considering containment were dictated, by the recognition of poor prognostic factors on radiographs (collapse of the lateral pillar, head-at-risk signs, and epiphyseal infarction exceeding half or more of the epiphysis).[12],[13] Most, if not all, of these signs become manifest in Stage IIb of the disease; consequently, intervention had to be deferred till then. Recently, there has been a trend to intervene earlier in the course of the disease.[14]

In children over the age of seven years at onset of Legg–Calvé–Perthes disease femoral head extrusion develops almost invariably as the disease evolves,[1,15] and this has led surgeons to consider pre-emptive containment even before extrusion develops in these older children.

Available literature and quality of the evidence

- Level I: 1 meta-analysis.[7]
- Level III: 1 meta-analysis[16] and 1 retrospective cohort study.[17]

Findings

Saran et al. noted, from meta-analysis of data of level II and IIIa studies, that surgery appears to be more likely to be associated with a spherical femoral head if treatment is instituted during or before the fragmentation stage (OR = 1.46; p = 0.02; 95% CI: 1.06–2.01).[7]

Kadhim et al. did a meta-analysis of 11 studies of children who underwent shelf acetabuloplasty either early in the course of the disease (in modified Waldenström Stage Ia, Ib, IIa, or IIb) or late in the course of the disease (in modified Waldenström Stage IIIa, IIIb, or IV).[16] They noted that among those operated on early good results (Stulberg Class I, II, or III) were seen in 85.6% (95% CI: 77.4–93.9; p <0.05) while good results were noted only in 69.9% (95% CI: 55.3–85.5; p <0.05) among those operated late in the disease.

Joseph et al. reported a multivariate logistic regression analysis of 97 children who underwent a femoral varus osteotomy.[17] They compared the outcome of treatment of children operated early (in modified Waldenström Stage Ia, Ib, or IIa) and those treated late (Stage IIb or later) and found that if containment was achieved late in the disease

the OR for a deformed, aspherical femoral head was 16.58 (p <0.01; 95% CI: 2.6–103.13).

Resolution of clinical scenario

There is no high-quality evidence that can resolve the question of whether the outcome of containment treatment is likely to be better if instituted by Stage IIa of the disease. Nevertheless, the OR for a poor outcome following treatment later in the disease noted in the study of Joseph et al. is so high that containment should be offered by Stage IIa.[17] Since extrusion invariably develops in children who are older than seven years of age at the disease onset, pre-emptive containment may be offered straight away in this child who is nine years old with Stage Ib disease involving more than half the femoral epiphysis.

Questions 3: In children with Legg–Calvé–Perthes disease, which of these methods of containment offers the best chance of preventing femoral deformation: bracing, proximal femoral osteotomy, innominate osteotomy, shelf acetabuloplasty, or combined femoral and innominate osteotomy?

Rationale

Improving the coverage of the anterolateral part of the capital femoral epiphysis is the basis of containment treatment for Legg–Calvé–Perthes disease, and this can be achieved by bracing or surgery on the proximal femur, on

the acetabulum, or on both the femur and the acetabulum. The choice of the method of achieving containment has largely been governed by personal preferences without sound scientific evidence. It would, therefore, be desirable to know which one of these methods is most effective in preserving the spherical shape of the femoral head.

Available literature and quality of the evidence

- Level II: 2 prospective studies.[4],[6]
- Level III: 7 retrospective cohort studies[10],[11],[16],[18_21]

Findings

Results of the multicenter prospective study of Herring et al. indicated that the likelihood of preserving the sphericity of the femoral head was higher if surgical containment was performed as compared to nonoperative treatment.[6] Within the nonoperative group, there were no significant differences in outcomes of children who received no active treatment, children treated by bracing, and children treated by ROM exercises ($p = 0.13$). Similarly, within the surgical containment group there was no difference in the outcome between children treated with a femoral or innominate osteotomy ($p = 0.65$). However, among children older than eight years, a higher proportion of children (62%) who had femoral osteotomy had spherical femoral heads as compared to children who had an innominate osteotomy (41%).

Wiig et al. in a prospective study reported that results following proximal femoral osteotomy were superior to those bracing ($p < 0.001$).[4]

Kamegaya et al. in a retrospective study noted that the frequency of spherical femoral heads at final follow-up was greater among children who had combined femoral and

acetabular osteotomies as compared to children who had only a femoral osteotomy (65.6% vs 38.3%; p = 0.031).[18]

Mosow et al. in a retrospective cohort study of children who had undergone combined femoral and pelvic osteotomies observed that the results (spherical femoral heads at skeletal maturity in 51% of patients) were not superior to results reported in the literature of isolated femoral or innominate osteotomies.[19]

Nguyen et al. in a meta-analysis noted that in children under six years the frequency of a spherical femoral head at follow-up was five times higher following a pelvic rather than a femoral osteotomy (p = 0.034; unadjusted OR = 5.20; 95% CI: 1.021–26.471) and in children older than six there was no difference in outcome following the two procedures (p = 0.174; unadjusted OR = 1.329; 95% CI: 0.881–2.004).[11]

Several retrospective studies of children treated by different methods of containment (without a control group of an alternate method for comparison) claim that the respective method is efficacious in preserving the sphericity of the femoral head in a high proportion of children treated. The treatment modalities include weight bearing brace (93% spherical femoral heads),[10] nonweight bearing brace (63% spherical femoral heads),[20] shelf acetabuloplasty (85.6% spherical femoral heads),[16] innominate osteotomy (43% spherical femoral heads),[22] and femoral osteotomy (56% spherical femoral heads).[21]

Resolution of clinical scenario

There is no high-quality evidence to suggest that any one method of containment is superior to others and hence the choice of the method of containment may be based on the surgeon's preference.

Summary of answers

- Containment of the femoral head in children with Legg–Calvé–Perthes disease either by nonsurgical or surgical means can improve the chances of retaining the spherical shape of the femoral head.
- Containment is likely to be more effective in preserving the spherical shape of the femoral head if achieved early in the course of Legg–Calvé–Perthes disease (i.e. by Stage IIa).
- There is no evidence to suggest that any one method of containment is more effective than other methods of containment in preserving the spherical shape of the femoral head in children with Legg–Calvé–Perthes disease.
- None of these answers is based on high-quality studies, because of the paucity of such studies. This highlights the need for level I studies to resolve these issues.

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183 Slipped Capital Femoral Epiphysis

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Clinical scenario

- A 12-year-old boy has sustained an unstable, completely displaced slipped capital femoral epiphysis (SCFE) following a minor fall while leaving the car in the garage.
- He has had prodromal hip pain for the past six months associated with mild limp after running.

Top three questions

1. In adolescent patients with completely displaced unstable SCFE, does an open procedure result in a lower proportion of osteonecrosis compared to in situ fixation?
2. In patients with unilateral SCFE, does prophylactic fixation of the contralateral hip safely reduce the risk of subsequent slip in the initially unaffected hip?
3. In patients with chronic stable moderate and severe SCFE, does subcapital realignment yield improved results as compared to in situ fixation and intertrochanteric realignment?

Question 1: In adolescent patients with completely displaced unstable SCFE, does an open procedure result in a lower proportion of osteonecrosis compared to in situ fixation?

Rationale

Recent studies have reported the importance of hip capsular decompression with gentle repositioning/inadvertent reduction and/or open reduction; however, the ideal treatment to reduce the risk of osteonecrosis after unstable SCFE remains controversial.

Clinical comment

Osteonecrosis of the femoral head is the most common complication associated with unstable SCFE. The outcomes of unstable SCFE are severely compromised by the occurrence of osteonecrosis as there is no definitive treatment for osteonecrosis and typically the hip will deteriorate to osteoarthritis. Osteonecrosis is the most common reasons why patients with a history of SCFE undergo a total hip arthroplasty (THA) in adult life.

Available literature and quality of the evidence

- Level III: 5 therapeutic studies.[1–5]
- Level IV: 3 therapeutic studies.[6–8]

Findings

SCFE is defined as unstable if the child has such severe pain that walking is not possible even with crutches, regardless of the duration of the symptoms.[5] Osteonecrosis

of the femoral head is the most feared complication following treatment of unstable SCFE. According to Loder et al. 47% of unstable SCFEs treated with fixation following reduction developed osteonecrosis of the femoral head.[5] Since Loder and colleagues proposed their classification, there has been persistent controversy about the ideal management of unstable SCFE.[5] Given that closed reduction with subsequent fixation results in a high proportion of osteonecrosis, several studies of open reduction have been reported.

Ziebarth et al. reported the results of the modified Dunn procedure for patients with moderate and severe SCFE.[7] In their series, no patients developed osteonecrosis of the femoral head. However, only four patients were found to have unstable SCFE. However, a multicenter North American series reported a 26% prevalence (seven out of 27 hips) of osteonecrosis after the modified Dunn procedure for unstable SCFE. Parsch et al. reported on 64 consecutive cases of unstable SCFE using a Watson-Jones approach to expose the hip joint and to perform a capsulotomy that allows for the surgeon to place the fingertip in the gap between the metaphysis and the epiphysis while gentle traction is achieved.[6] They reported 4.7% (three out of 64 hips) occurrence of osteonecrosis.

There are very few comparative studies in the literature. In a small series, Alves et al. compared six patients treated with closed reduction and percutaneous fixation versus six patients treated with open reduction using the modified Dunn procedure.[1] They noted osteonecrosis in four (66.7 %) patients after a modified Dunn procedure, while two (33.3 %) patients had osteonecrosis after closed reduction. Similarly, in a small series, Souder et al. reported that three of seven hips stabilized with a percutaneous screw developed osteonecrosis (43%) compared to two of the

seven unstable SCFE treated by the modified Dunn procedure developed avascular necrosis (AVN) (29%).[4]

Two larger comparative studies have also been reported. Walton et al. compared 16 hips that underwent intracapsular cuneiform osteotomy and 30 that underwent fixation after varying degrees of serendipitous reduction.[3] Osteonecrosis developed in four hips (25%) following osteotomy and in 11 (42%) following fixation after serendipitous reduction. The proportion of osteonecrosis was significantly higher following fixation with complete reduction than that following intracapsular osteotomy. Novais et al. evaluated 45 patients with unstable SCFE treated using the modified Dunn procedure (n = 27) or percutaneous pinning after inadvertent reduction (n = 18). Of the 27 patients treated by a modified Dunn procedure, seven (26%) developed osteonecrosis compared to 28% (5/18) patients treated by percutaneous pinning (p >0.999).[2]

Resolution of clinical scenario

In the treatment of unstable SCFE, there is low-quality evidence suggesting that open reduction using the modified Dunn yields better clinical and radiographic results but does not reduce the proportion of osteonecrosis when compared to in situ pinning after inadvertent reduction. Open reduction through an anterolateral approach seems to be a promising technique, but further comparative studies are required.

Question 2: In patients with unilateral SCFE, does prophylactic fixation of the contralateral hip safely reduce the risk of subsequent slip in the initially unaffected hip?

Rationale

The uninvolved contralateral hip in patients presenting with unilateral SCFE is at risk of slip. Prophylactic fixation would avoid a subsequent slip; however, it is controversial whether the risk outweighs the benefits.

Clinical comment

SCFE presents with unilateral involvement in 77–91% of patients.[9–11] However, between 18 and 41% of patients will develop a contralateral slip,[10–15] typically during the first 18 months after the initial diagnosis.[11]

Available literature and quality of the evidence

- Level III: 2 therapeutic studies.[16,17]
- Level IV: 1 case report[18] and 3 therapeutic studies.[19–21]

Findings

Bhattacharjee et al. compared 44 patients who underwent prophylactic fixation to 36 patients managed by observation and observed a higher incidence of sequential SCFE of initially unaffected hips in the observation group compared to those with prophylactic fixation without any cases of osteonecrosis or chondrolysis.[16]

Clement et al. compared the outcomes and cost of 36 patients who underwent prophylactic fixation with 50 who did not.[17] The proportion of a subsequent slip without prophylactic fixation was 46%. Patients in the nonfixation group were more likely to develop a subsequent slip and had inferior functional outcome as assessed by the Short Form 12 (SF-12) physical and mental patient outcome report. Femoroacetabular impingement (FAI) cam morphology was only observed in patients who did not undergo prophylactic fixation. Moreover, prophylactic fixation was found to be a cost-effective procedure.

Kroin et al. reported on two cases of osteonecrosis of the femoral head after prophylactic fixation of the asymptomatic contralateral noninvolved hip.[18]

Sankar et al. investigated 99 patients (mean age 11 years; range 8–15 years) who underwent prophylactic pinning of the contralateral hip after treatment of a unilateral SCFE.[19] They reported two cases of osteonecrosis (2%) but no cases of chondrolysis (0%). Two patients (2%) had femoral fractures around the implant. Three patients (3%) had symptomatic hardware with further surgery for implant removal performed in two of the three. However, no patients developed a subsequent slip on the side of the prophylactic pinning.

Woelfle et al. reviewed 66 patients with unilateral SCFE who underwent prophylactic fixation of the unaffected hip.[20] They did not observe major complications. However, there were minor complications including wound revision (4.6%; three of 65) and loss of fixation with need for repeat fixation (6.2%, 4/65). The authors concluded that prophylactic fixation in SCFE is a safe procedure with no major complications and an acceptable rate of minor complications.

Kumm et al. studied 34 patients who underwent prophylactic dynamic screw fixation with a contralateral SCFE and found no cases of perioperative complication.[21] Further, there was no osteonecrosis or chondrolysis, and no growth disturbance including greater trochanteric overgrowth was noted.

Resolution of clinical scenario

Prophylactic fixation of the initially uninvolved hip in patients presenting with unilateral SCFE prevents the development of further contralateral SCFE. Prophylactic fixation may be rarely associated with complications including osteonecrosis of the femoral head, subsequent growth with *outgrowth* of the screw, and peri-implant fracture. Although further prospective, comparative studies will be important to clarify the risks and safety of prophylactic fixation and to define the best implant, the available literature (level III and IV) favors prophylactic fixation in comparison to observation in those patients at higher risk of further contralateral SCFE.

Question 3: In patients with chronic stable moderate and severe SCFE, does subcapital realignment yield improved results as compared to in situ fixation and intertrochanteric realignment?

Rationale

Severe and moderate stable SCFE are associated with a deformity of the proximal femur that leads to FAI and acetabular cartilage damage. In situ fixation does not allow

for complete restoration of the deformity, and subcapital realignment using a modified Dunn technique has been proposed as an alternative to in situ pinning.[22]

Clinical comment

In situ fixation is a universally available technique that achieves the goal of stabilization of the SCFE with a low rate of complications, while the modified Dunn technique is technically difficult and may result in major complications. Osteonecrosis of the femoral head is a potential complication after the modified Dunn procedure.

Available literature and quality of the evidence

- Level III: 4 therapeutic studies.[22–25]
- Level IV: 1 therapeutic study[7] and 3 case series.[26–28]

Findings

Ziebarth et al. described the modified Dunn procedure for patients with moderate and severe SCFE and reported no cases of osteonecrosis or chondrolysis.[7] Most patients had moderate deformity.

Souder et al. compared an in situ fixation group to that of subcapital realignment with the modified. Dunn procedure: two of 10 patients developed osteonecrosis after the modified Dunn procedure for the treatment of stable SCFE, while no patients developed osteonecrosis after in situ fixation.[22]

Novais et al. compared 15 patients with severe stable SCFE treated with the modified Dunn procedure to 15 patients treated with in situ fixation and demonstrated better deformity correction with the modified Dunn procedure compared with in situ pinning.[23] The odds of good or

excellent clinic results in the modified Dunn group was higher than in the in situ group. There were no differences in the numbers of complications in each group, but there were more reoperations in the in situ pinning group. One patient (7%) developed osteonecrosis of the femoral head after a modified Dunn procedure.

Sikora-Klak et al. compared 12 patients with moderate and severe stable SCFE treated with a proximal femoral intertrochanteric osteotomy with 14 patients treated with the modified Dunn procedure.[24] Postoperative radiographic parameters were similar between the groups except the neck shaft angle, which was better improved in the modified Dunn group. The modified Dunn group had a 29% AVN rate, while no cases of osteonecrosis were observed in the intertrochanteric osteotomy group ($p = 0.1$). However, the overall proportion of complications rate was similar between the groups (33% after intertrochanteric osteotomy and 36% after a modified Dunn procedure; $p = 1.0$).

Abu Amara et al. reported a French multicenter retrospective study of 182 patients (186 hips) with severe SCFE; 94 hips (50.5%) were stable SCFEs and 92 (49.5%) unstable SCFEs. In the stable group, there were six cases of osteonecrosis (6.4%), all of which occurred after reduction by osteotomy.[25]

Aprato et al. reported a case series of hip instability after the modified Dunn procedure and described three potential causes of instability: (i) those directly related to SCFE (acetabular labral damage, severe abrasion of the acetabular cartilage, flattening of the acetabular roof, and a bell-shaped deformity of the epiphysis); (ii) those not related to the SCFE (acetabular orientation and poor quality of the soft tissues); and (iii) those directly related to the surgery (capsulotomy, division of the ligamentum teres, shortening of the femoral neck, trochanteric-pelvic

impingement, previous proximal femoral osteotomy and postoperative positioning of the leg).[26]

Upasani et al. reported that 17 of 406 (4%) patients treated with a modified Dunn procedure developed postoperative hip instability.[27] Fourteen of the 17 patients (82%) with hip instability developed osteonecrosis of the femoral head.

Abdelazeem et al. reported improvement in patient-reported outcomes and radiographic parameters of femoral alignment in 31 patients (32 hips) with moderate and severe SCFE after a modified Dunn procedure with only one case (3%) of osteonecrosis.[28]

Davis et al. compared the results of the modified Dunn procedure for 31 consecutive hips (29 patients) acute, unstable, to 17 chronic, stable SCFEs (15 patients).[29] Two patients (6%) developed AVN in the unstable group, with five patients (29.4%) in the stable group ($p = 0.027$).

Resolution of clinical scenario

Subcapital realignment using a modified Dunn procedure allows for radiographic correction of the deformity after moderate and severe SCFE compared to in situ fixation. However, the proportion of patients developing osteonecrosis remains a concern and to this date there is no high (level I). The potential for iatrogenic instability is also a concern after the modified Dunn procedure.

Summary of answers

- Low-quality evidence suggests that open reduction in the treatment of unstable SCFE yields better clinical and radiographic results but does not reduce the rates of osteonecrosis.

- Prophylactic fixation of the uninvolved hip prevents the development of contralateral SCFE, although it may be associated with some rare complications.
- Subcapital realignment allows for radiographic correction of moderate and severe SCFE; however, the proportion of patients developing osteonecrosis remains a concern.

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184 Pediatric Femoral Shaft Fractures

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Clinical scenario

- A pediatric patient sustains a diaphyseal femur fracture after a mechanical fall.

Top three questions

1. In children younger than four years of age with a femoral shaft fracture who are treated with a hip spica cast, does a single-leg cast portend improved clinical and radiographic outcomes when compared with double-leg casting?
2. In children between 4 and 11 years of age with a femoral shaft fracture, what is the ideal management of fracture fixation to optimize outcomes?
3. In children older than 11 years of age with a femoral shaft fracture, what is the ideal management of fracture fixation to optimize outcomes?

Question 1: In children younger than four years of age with a femoral shaft fracture who are treated with a hip spica cast, does a single-leg cast portend improved clinical and radiographic outcomes when compared with double-leg casting?

Rationale

Femur fractures are among the commonest fractures treated by the pediatric orthopedic surgeon, and over 70% of these involve the femoral shaft.[1],[2] Historical treatment included skeletal traction with or without casting, which was complicated by prolonged immobilization, traction injuries to nerves, and skin breakdown. Over the past 20 years, however, the standard of care has evolved to a systematic approach to the evaluation and treatment of pediatric femoral shaft fractures, with consideration given to both patient and injury characteristics, age, and fracture pattern.[2]

Clinical comment

In the young pediatric patient, tremendous remodeling potential exists and treatment modalities that are less invasive are generally preferred and have excellent outcomes.[1]

Available literature and quality of the evidence

- Level I: 1 prospective, randomized controlled trial (RCT).[3]
- Level II: 1 prospective, randomized cohort study.[4]

- Level III: 1 prospective observational cohort study,[5] 1 systematic review,[6] and 4 retrospective cohort studies.[7–10]
- Level V: 2 consensus guidelines.[1,2]

Findings

In a prospective case series of 14 patients with 16 femur fractures, Stannard et al. were the first to demonstrate the use of the Pavlik harness, demonstrating excellent outcomes.[5] Treatment was initiated at <6 months of age, and all fractures united within five weeks without adverse events. Morris et al. later compared the efficacy of the Pavlik harness with traction and traditional spica casting in birth-associated femoral fractures, studying eight femoral fractures retrospectively in 55 296 live births; all went on to heal without limb length discrepancy or angular deformity.[7] A retrospective study in children <1 year of age with a femoral shaft fracture comparing 24 patients treated with Pavlik harness and 16 patients with traditional spica casting found similar results, with no differences in radiographic outcomes between the two groups.[8] However, 38% of the patients treated with hip spica casting were noted to have skin complications from the casting. Despite excellent and equivalent fracture outcomes among these treatment modalities, potential advantages of the utilization of Pavlik harnesses in infants <6 months of age included ease of application without general anesthesia, ease of nursing care and hygiene, and ease of adjustment if the reduction was lost.[5]

Spica casting has generally been advocated for patients between six months and four years of age. Fracture patterns in this age group that are amenable to treatment with immediate spica casting include low-energy mechanism fractures with up to 2 cm of shortening. Flynn

et al. compared the efficacy of a *walking* spica cast (single leg spica with a hip band)[11] with traditional hip spica casting (bilateral leg spica).[4] In this prospective cohort trial in 45 children 1–4.8 years old with low-energy femoral shaft fractures, similar times to initial callus formation (traditional 2.4 weeks, 95% confidence interval [CI]: 2.1–2.7 weeks, vs walking 2.3 weeks, 95% CI: 1.7–2.8 weeks, p = 0.74) and mean time to fracture union (traditional 6.3 weeks, 95% CI: 5.9–6.6 weeks, vs spica 6.0 weeks, 95% CI: 5.7–6.3 weeks, p = 0.37) were observed. Two patients treated with traditional hip spica casts returned to the operating room for loss of fracture reduction, compared with one in the walking spica group (p = 1.0). Traditional hip spica casting was noted to place significantly more burden on family care, as assessed with Impact on Family Scale surveys (traditional 43.3, 95% CI: 38.5–48.0 vs walking 35.6, 95% CI: 28.7–42.4, p = 0.04) and a significant increase in the need for ambulance transportation (traditional 42% vs walking 0%, p = 0.001), costing an estimated $505 per trip with an additional $5 per mile at the time. Additionally, more patients with walking spica casts required wedge adjustments of the cast in clinic (traditional 4% vs walking 26%, p = 0.04). Both groups had similar malunion rates (traditional 8% vs walking 0%, p = 0.38).

Loss of reduction typically occurs in the first three weeks of care, secondary to decrease in swelling of the extremity, which can be corrected in the outpatient clinic setting with cast wedging. It has been recommended that patients with <2 cm of shortening have close surveillance during these first three weeks.[2]

Clinicians can use either single- or double-leg hip spica casting. A prospective RCT of 52 patients between two and six years of age comparing immediate single- and double-

leg hip spica casting found similar clinical outcomes;[3] however, patients with single-leg hip spica casts were more likely to fit into their previous car seat (71% single vs 35% double, p = 0.01), were more comfortable sitting in a chair (as assessed by Visual Analog Scale; single 4.38 vs double 6.26, p = 0.032), and required the caregiver to take fewer days off of work (single 10.38 days vs double 19.00 days, p = 0.049); this study notably suffers from short follow-up time and retrospective recall bias from survey instruments. Jaafar et al. in their retrospective chart review of 59 patients who underwent single-leg hip spica casting and 35 patients who underwent double-leg hip spica casting found that single-leg casting resulted in shorter time to cast removal (4.1 weeks vs 5.3 weeks, p <0.0001), lower rates of clinically significant limb length discrepancies (1.7% vs 20%, p = 0.004), and lower rates of skin complications (10.2% vs 31.4%, p = 0.013).[9] A systematic review corroborated these results.[6]

Some institutions have attempted to compare spica casting with other popular methods of fixation. Heffernan et al. performed a retrospective, multicenter chart review of 141 patients ages 2–6 years old treated with immediate spica casting and 74 treated with titanium elastic nails (TEN) and found that patients treated with TEN were more likely to have higher energy mechanisms of injury (26% vs 8%, p = 0.001), shorter time to unassisted ambulation (29 days vs 51 days, p <0.001), and similar times to radiographic union (45.1 days vs 44.1 days, p = 0.652); however, patients with hip spica casting were younger in this cohort (spica 3.2 years vs TEN 4.5 years, p <0.001),[10] and would have fallen into the present treatment algorithm of spica casting.

Finally, a subset of patients <5 years of age with initial shortening up to 3 cm and a negative telescope test can be

placed in a nonwalking/standard spica cast, with close, weekly follow-up and cast adjustments as necessary.[2]

Resolution of clinical scenario

- Despite excellent and equivalent fracture outcomes with casting, Pavlik harnesses are recommended in infants <6 months of age due to ease of application without general anesthesia, ease of nursing care and hygiene, and ease of adjustment if the reduction is lost.
- In patients between six months and four years of age, given the lower costs, lesser family burden, decreased return to the operating room, and equivalent fracture outcomes, immediate walking spica casting offers a reliable clinical solution.
- Cast wedging may need to be performed during the first several weeks after casting.
- In patients with shortening up to 3 cm with a negative telescope test, a standard/nonwalking spica cast can be used.

Question 2: In children between 4 and 11 years of age with a femoral shaft fracture, what is the ideal management of fracture fixation to optimize outcomes?

Rationale

The pediatric patient between 4 and 11 years of age presents a difficult choice in fracture fixation; a wide variety of patient characteristics and fracture patterns exist. Moreover, the orthopedic surgeon has an array of

options in the treatment toolbox, including titanium elastic nailing, external fixator placement, and submuscular plating. Regional implant use and surgeon comfort with specific implants also direct treatment considerations in this population.[12] Early application of hip spica casts to this group of patients led to inferior outcomes. A multicenter, RCT of external fixation versus early application of spica casts for pediatric patients 4 to 10 years of age with femoral shaft fractures and minimum two-year follow-up demonstrated higher rates of malunion in the hip spica group (45% vs 16%; 95% CI: 12–46%, p = 0.002).[13] No differences were appreciated in RAND physical function child health questionnaire scores (0.34 vs 0.45; 95% CI: −0.57 to 0.34, p = 0.61), parent satisfaction (4.3 vs 4.2; 95% CI: −0.3 to 0.6, p = 0.5), and child satisfaction scores (6.9 vs 7.7; 95% CI: −2.2 to 0.5, p = 0.21).

Clinical comment

The patient presenting in this scenario is seven years of age, under 45 kg in weight, and suffers a low-energy mechanism fracture. What treatment modalities exist for this patient?

Available literature and quality of the evidence

- Level I: 1 RCT.[14]
- Level II: 1 prospective clinical cohort study.[1]
- Level III: 1 systematic review[15] and 1 retrospective cohort study.[16]

Findings

Current treatment philosophy in this broad age range and patient characteristics take into consideration fracture pattern, patient weight, and mechanism of injury.

Generally, low-energy mechanism injuries with length stable fracture patterns (AO class 32D/4.1) in patients under 45 kg are amenable to titanium elastic nailing or submuscular plating. Patients at the lower end of the age spectrum in this category with unstable fractures (AO 32D/4.2, 32D/5.1, or 32D/5.2) can also be treated with titanium elastic nailing.[17] Older pediatric patients with higher body mass indices (BMI) are treated with locked trochanteric entry nails or plating, which is discussed later.

Baldwin et al. performed a systematic review comprising 1128 pediatric femoral shaft fractures treated with TEN.[15] Nearly all patients went on to union (99.5% union rate). Complications included infection (2%, ranging from superficial to deep requiring surgical debridement), hardware irritation (23.4%; noted to be as high as 60% in one series), and a 0.9% rate of refracture following hardware removal. Notably, the rate of malalignment was noted to be >15%; however, the authors noted that there was little consensus on malalignment criteria among the studies included in the systematic review and these results cannot be interpreted properly. Importantly, when compared with traction and casting, titanium elastic nailing was less expensive, had lower rates of complications (18.9% vs 34.3%, $p = 0.047$), but had only a trend toward decreased malunion (10.0% vs 18.0%, $p = 0.236$). Finally, in terms of patient satisfaction and quality of life, children treated with TEN were able to return to independent ambulation and school sooner than children treated with traction and casting, and 96% of patients with TEN would choose that treatment option again, whereas only 6% of patients treated with traction and casting would prefer to undergo the same. The main limitation of the systematic review stems from the inclusion of studies with lower levels of evidence.

Allen et al. recently performed a retrospective comparison of TEN, submuscular plating, and open reduction and internal fixation (ORIF) with plating in pediatric patients between the ages of 5 and 11 years.[16] No differences were seen in patient outcomes or perioperative variables in the plating groups and were combined for analysis. Patients undergoing titanium elastic nailing had significantly reduced operative time (1.6 hours vs 2.5 hours, p = 0.007) compared with both plating modalities; no differences were seen in estimated blood loss (EBL), fluoroscopy time, length of stay, pain scores, or postoperative narcotic requirements. The lack of differences among index procedures did not extend into those patients who underwent elective hardware removal; patients undergoing TEN removal had significantly decreased operative time and EBL than plate removal. Interestingly, the cost of TEN was lower than plating in terms of anesthesia time billed (due to the increased operative time) but not implant cost. This significant difference extended to elective removal of hardware procedures.

Flynn et al. performed a prospective cohort study of TEN versus traction and spica casting in children aged 6–16 years.[18] Of the 35 children treated with skeletal traction and spica casting, three had unacceptable angulation or leg length discrepancy at the time of fracture union, compared with 0 out of the 48 children treated with TEN. The studied recovery milestones were universally significantly difference among patients who underwent TEN: length of stay (5 days vs 24 days, p <0.0001); time to ambulation (14 days vs 70 days, p <0.0001); time to independent ambulation (67 days vs 106 days, p <0.0001); and return to school (48 days vs 103 days, p <0.0001). Total surgical charges for TEN implants were more expensive ($18 990.00 vs $13,338.49, p <0.0001), but these were offset by the increased cost due to increased length of stay in the

traction arm ($12 942.61 traction patients vs $5005.15 TEN patients, p <0.001); overall costs were not statistically significant between the two groups. Finally, 34% of patients undergoing traction sustained a complication, compared with 21% of TEN patients. Another randomized, prospective trial in 46 children aged 6–12 years comparing skeletal traction and hip spica casting and TEN fixation corroborated these results.[14]

Though beyond the scope of this clinical stem, the patient with higher-energy injuries and length-unstable patterns is generally treated with plating or external fixation; elastic nails typically result in higher loss of fixation rates in these groups.[19],[20] One study comparing TEN and external fixation in children between 5 and 11 years of age suggested that TEN fixation may be associated with lower complication rates and faster return to school in both stable and unstable fracture patterns, although the numbers of patients in this study were limited.[21]

Resolution of clinical scenario

- In the length-stable pediatric patient aged between 4 and 11 years and weighing under 45 kg, TEN offer lower rates of complications, acceptable clinical outcomes, and higher patient satisfaction.

Question 3: In children older than 11 years of age with a femoral shaft fracture, what is the ideal management of fracture fixation to optimize outcomes?

Rationale

In older children, the orthopedic surgeon should be aware of limitations of flexible nails: patients over 45 kg have been shown to have inferior outcomes with flexible nailing, and the largest flexible nails have less ability to fill the femoral canal to offer a viable load-sharing construct. Reamed, locked intramedullary nails are the standard for adult femoral shaft fractures; however, in the skeletally immature patient, with improper position of the entry reamer, the blood supply of the femoral head is at risk.[2] Additionally, the literature has raised concern for proximal femoral growth disturbance and abductor dysfunction because of disruption of the greater trochanteric apophysis.[22–24]

Clinical comment

If the patient were 12 years of age, obese, and suffered a high-energy mechanism injury, what treatment options exist for fixation?

Available literature and quality of the evidence

- Level III: 5 retrospective cohort studies[25–29] and 1 systematic review.[30]
- Level IV: 1 retrospective case series.[31]

Findings

Historically, physicians have avoided the utilization of reamed, locked, intramedullary devices in the skeletally immature patient due to concerns over disruption of the blood supply to the femoral head, leading to avascular necrosis (AVN), which can have devastating consequences. With proper placement of the entry reamer, so as to avoid a piriformis starting point, patients can experience excellent outcomes. A systematic review of locked intramedullary

nails in the skeletally immature patient identified a 2% rate of AVN when performed through the piriformis fossa, 1.4% rate of AVN for the tip of the greater trochanter entry site, and 0% rate of AVN using the lateral aspect of the greater trochanter as the entry site;[32] however, the ages of the patients included in the systematic review were not elaborated upon except to identify that all cases of AVN were in children >10 years of age. Similarly, a retrospective cohort study of 20 skeletally immature patients aged 11–16 years treated with closed, reamed, intramedullary nails using the tip of the greater trochanter as the starting point did not observe any AVN with 100% union rates.[25]

General indications for rigid nailing are in patients >11 years of age, or in select younger patients >45 kg in weight, due to studies that showed up to fivefold increased rate of complications in heavier pediatric patients treated with TEN fixation.[19,26] Quality studies are lacking in this arena; one retrospective cohort study of 78 patients with 80 fractures treated with rigid locked nails demonstrated excellent clinical outcomes with no nonunions, delayed unions, or malunions.[27] Similarly, Crosby et al. described their 20-year retrospective data of 241 patients with 246 fractures in patients aged 8–17 years.[31] The complication rate was 9.8% overall, with a 99% union rate, and a 2.2% incidence of proximal femoral growth disturbance; all patients with proximal femoral changes were asymptomatic.

In comparison with TEN, similar outcomes have been shown; however, the data are limited to retrospective studies. One small, retrospective weight-matched cohort study evaluated patients treated with TEN and rigid locked nailing, but no appreciable difference in fracture outcome metrics was found.[28] Additionally, these patients were

older (15.4 years rigid nail vs 13.5 years TEN, p = 0.005). A similar retrospective chart review corroborated these results, but the study was not weight-matched.[29]

It is the consensus that external fixation in this pediatric population can be used in unstable fracture patterns, with significant bone or soft tissue loss, and of course following a damage-control orthopedics philosophy in those patients with physiologic derangement which may preclude definitive fixation with a rigid locked nail at the index procedure.[30] Damage control external fixation is used and exchanged after physiologic resolution, typically between weeks one and two. Submuscular or open plating may also be used in cases where reamed nailing is undesirable, such as in the younger, heavier child with a more severe injury.

Resolution of clinical scenario

- Current evidence, although limited, points to lateral-entry rigid locked nailing in this patient.
- If the patient has physiologic derangements on presentation and after proper resuscitation, external fixation can be performed either definitively or as a temporizing measure until definitive rigid nailing can be performed.
- Pediatric patients >45 kg have inferior outcomes with titanium elastic nailing.

Summary of answers

- Despite excellent and equivalent fracture outcomes with casting, Pavlik harnesses are recommended in infants <6 months of age due to ease of application without general anesthesia, ease of nursing care and hygiene, and ease of adjustment if the reduction is lost.

- In patients between six months and four years of age, given the lower costs, lesser family burden, decreased return to the operating room, and equivalent fracture outcomes, immediate walking spica casting offers a reliable clinical solution.
- Cast wedging may need to be performed during the first several weeks after casting.
- In patients with shortening up to 3 cm with a negative telescope test, a standard/nonwalking spica cast can be used.
- In the length-stable pediatric patient aged between 4 and 11 years, weighing <45 kg, TEN offer lower rates of complications, acceptable clinical outcomes, and higher patient satisfaction.
- Rigid, locked lateral-entry nailing is acceptable for pediatric patients aged >11 years and weighing >45 kg.
- If the patient has physiologic derangements on presentation and after proper resuscitation, external fixation can be performed either definitively or as a temporizing measure until definitive rigid nailing can be performed.
- Pediatric patients >45 kg have inferior outcomes with titanium elastic nailing.

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185 Infantile Blount Disease

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Clinical scenario

- A 30-month-old boy is brought in for evaluation by his parents for progressive bowing of the child's left leg. He had a normal birth and developmental history and began walking at 11 months of age.
- He is at the 70th percentile for height, at the >95th percentile for weight, and his BMI is 24.
- On physical exam, the child is obese[1] with a varus alignment of the left knee and mild valgus alignment of the right. He walks with mild varus thrust of the left leg. His thigh–foot angle is 25° internal on the left in contrast to 5° external on the right.
- He does not have any ligamentous laxity of the knee in flexion or extension and the remainder of his physical exam is within normal limits. Standing full-length x-ray exam of both lower extremities demonstrates varus alignment on the left with a medial mechanical axis deviation and irregularity of the medial proximal tibial physis with medial beaking of the metaphysis consistent with Langenskiold stage II.
- The anatomic tibiofemoral angle is 23° of varus and his proximal tibial and distal femoral metaphyseal diaphyseal angles (FMDAs) are 14° and 8°, respectively. On the right, the tibiofemoral angle is 10°

valgus and the proximal tibial and distal FMDAs are −3° and −6°, respectively.[2–6]

Top three questions

1. Will all children who present with radiographic evidence of infantile Blount disease develop a progressive varus deformity?
2. Is bracing an effective treatment to prevent progression of deformity in patients with infantile Blount disease?
3. Is guided growth an effective treatment for correcting deformity in patients with infantile Blount disease?

Question 1: Will all children who present with radiographic evidence of infantile Blount disease develop a progressive varus deformity?

Rationale

Bowing of one or both legs in children aged 2–4 years is a common concern that prompts parents to seek orthopedic care. In 1975, Salenius and Vannka studied the natural history of the tibiofemoral angle in 979 children admitted to hospital for various reasons.[7] They noted that the tibiofemoral angle in newborn children was pronounced varus that slowly corrected until 18–24 months, when the angle changed to a valgus position between ages two and three years. In a few patients the varus alignment of the knees does not correct, but increases or persists beyond the third year of life and sometimes requires surgical intervention.[8] Below the age of two years, it can be difficult

to differentiate between patients with physiologic varus alignment, which is expected to correct spontaneously, from those who will develop infantile Blount disease, a radiographic diagnosis based on specific changes to the medial proximal tibia characterized by Langenskiold stages, which are expected to develop a progressive deformity and require treatment. Prior to the onset of these radiographic changes, certain physical and other radiographic criteria may be helpful in predicting those patients who can be safely observed versus those who are likely to develop true Blount disease who might warrant early intervention.

Clinical comment

Having noted improved patient outcomes (less chance of recurrent deformity) with surgical correction prior to age four years, some authors have emphasized early surgical realignment of children with infantile Blount disease.[8–10] This has typically been a valgus producing osteotomy to unload the medial physis to give it the best chance to recover. However, an osteotomy is an invasive surgical procedure with substantial risks such as neurovascular injury and compartment syndrome. The efficacy of bracing for Blount disease has been questioned by some authors and is discussed in greater detail in the next section.[11,12] It is still not well established as to which radiographic and physical characteristics in these young children are associated with a progressive deformity and those which will spontaneously correct. Understanding these characteristics can help determine which patients warrant early intervention versus continued observation and may help avoid unnecessary surgery in patients whose deformity could correct spontaneously.

Available literature and quality of the evidence

- Level III: 5 retrospective cohort studies and 1 prognostic study.
- Level IV: 3 case series.

Findings

The radiographic analysis of a patient with bowlegs should begin with a standing, full-length anteroposterior radiograph of both lower extremities with the patellae facing forward to help assess whether the deformity is primarily in the proximal tibia or if there is contribution from the distal femur as well.[8,13,14] Historically, the severity of a bowleg deformity was determined by comparing the anatomic tibiofemoral angle of affected patients with the normal angle for their age,[1] and examining for the classic radiographic changes of infantile Blount disease as described by Langenskiold.[15] In 1982, Levine and Drennan measured an angle between the transverse plane of the proximal tibial metaphysis and a line perpendicular to the long axis of the tibial shaft, named the *metaphyseal diaphyseal angle* (MDA), to determine its usefulness in differentiating physiologic bowing from infantile Blount disease.[2] They compared the MDA patients with infantile Blount disease to those with physiologic bowing and found that only 3 of 58 extremities with an MDA <11° developed progressive deformity compared to 29 of 30 with MDA >11° ($p < 0.001$).[2] Feldman and Schoenecker further analyzed the MDA and found that an MDA ≥11° resulted in a false-positive rate of 33% and an MDA of <11° had a false-negative rate of 9%.[3] They determined that an MDA ≤9° had a false-negative of <5% and an MDA ≥16° had a false-positive rate of <5%. They recommended observation for those with MDA ≤9° and early intervention for those with MDA ≥16°. Patients with

an MDA between 10° and 15° are in a gray area which requires close observation for progression.

Another study done in 1982 by O'Neill and MacEwen measured both the FMDA and tibial metaphyseal diaphyseal angle (TMDA),[4] and determined that patients whose TMDA was greater than their FMDA were at increased risk for disease progression. McCarthy et al. compared the FMDA to TMDA ratio, or femoral/tibial ratio (FTR), to the tibial MDA in determining which patients would develop progressive deformity.[5] The authors found that a TMDA >13° or an FTR <1° was prognostic for developing infantile Blount disease; however, the false-negative and false-positive rates were lower for the FTR. They also found that the FTR was affected less by rotation of the x-ray than the MDA. The authors concluded that the FTR was more accurate than the MDA in detecting which deformities would progress. Similarly, in 2002, Bowen et al. examined 98 patients with bowlegs and calculated the total limb varus (LV) by measuring the mechanical axes of the femur and tibia as well as the femoral varus (FV) and tibial varus (TV) by measuring a horizontal line through the joint line with the femoral and tibial mechanical axes, respectively.[6] They then calculated the percent deformity in the tibia (%DT) by dividing TV by LV. They found that a %DT >50% had a 100% sensitivity and 96% specificity as a predictor of future progression, compared to 64% sensitivity and 93% specificity for MDA ≥16°. They concluded that the %DT was more accurate than the MDA in predicting future progression but emphasized that the only true way to know was to follow a patient with serial radiographs until a trend toward progression or resolution became clear.

In 2000, Mukai et al. used MRI to try to differentiate physiologic bowing from infantile Blount disease.[16] They

found that all patients with bowlegs had a high-intensity area in the medial epiphyseal cartilage on T2 weighted imaging compared to normal tibiae, but that certain patients also exhibited an abnormality in metaphysis, and hypothesized that these patients were at higher risk to progress. At final follow-up, 5 of 11 patients with metaphyseal signal changes went on to develop the characteristic findings of infantile Blount such as medial metaphyseal beaking and fragmentation, while none of the 14 tibiae that lacked metaphyseal changes went on to progress. While magnetic resonance imaging (MRI) can be helpful, the increased cost of the study and need for sedation in a young child make it difficult to obtain such advanced imaging routinely.[8]

Scott et al. investigated the role of body mass index (BMI) in addition to radiographic findings to help determine which patients would progress.[17] They stated that the role of BMI in clinical decision-making is especially important in those patients whose MDA falls in the gray zone of 10–15°. The authors found that a TMDA ≥10° and a BMI ≥22 together had a 95% sensitivity and 100% specificity in predicting disease progression and recommended early treatment for these patients. The BMI of 22 corresponds to >99th percentile for children aged 2–4 years.

However, several other studies investigating the natural history of infantile Blount disease have questioned the predictive utility of the MDA and other radiographic parameters. Hagglund et al. followed 13 unoperated children with infantile Blount disease and found that their MDA averaged 15° at presentation but decreased to an average of 7° prior to skeletal maturity.[18] They noted that sometimes a bowing deformity with an MDA >20° could spontaneously correct. They cautioned against making treatment decisions based on a single measurement of the

MDA and recommended following such patients clinically until a trend toward progression or resolution was clearer. Shinohara et al. investigated 46 patients with an MDA ≥11° and Langenskiold stage I–III changes on initial radiographs and found that 100% of those with Langenskiold stage I and 75% of those with Langenskiold stage II–III changes resolved spontaneously.[11] They noted that all six patients that required surgical intervention showed persistent increase in the FTA and MDA at ages three and four, whereas those who went on to spontaneous resolution showed improvements by age four. The authors concluded that the only way to determine which deformities would progress was by performing serial examinations at six-month intervals until a clear trend was established. Laville et al. examined 26 patients with bowlegs and Langenskiold stage I radiographic changes and determined there was no difference in the FTA or MDA between patients that developed a progressive deformity and those who spontaneously corrected at presentation, but at subsequent visits a clear trend was detectable.[12] With increasing age, those tibiae which would spontaneously correct showed improvement in the FTA and MDA, whereas those with progressive deformity worsened, further emphasizing the need for clinical surveillance prior to making treatment decisions.

Resolution of clinical scenario

Our patient from the clinical scenario has several risk factors for disease progression. His MDA is 14°, which lies in the gray area of 10–15°; however, his FTR is <1 and %DT is >50%, indicating a high likelihood his deformity will progress. Furthermore, his BMI of 24 puts him at even higher risk for progression. Despite this, he is still less than three years old with Langenskiold stage II radiographic changes, so it is plausible that his condition could improve

with time. As such, the patient can be followed closely with serial radiographs to determine if his deformity will normalize over time or if he will progress and require treatment. If his deformity continues to progress over the next six months then surgery should not be delayed since realignment prior to age four is associated with better long-term outcomes.[8–10]

Question 2: Is bracing an effective treatment to prevent progression of deformity in patients with infantile Blount disease?

Rationale

The concept of bracing consists of producing a valgus force at the knee through various straps and hinges around the thigh and lower leg. Several different types of braces have been investigated with the most common being a knee–ankle–foot orthosis (KAFO) with a medial upright and drop lock hinges to unload the medial compartment.[8,19–22] The potential benefit of bracing over surgical correction is that it avoids all the inherent risks of an invasive surgical procedure. Some parents and surgeons may find bracing more appealing as an initial treatment, with the caveat that surgery can still be performed later if bracing is not effective. Despite this, significant challenges arise in trying to implement a strict bracing regimen in a young obese child, and the efficacy and utility of bracing for infantile Blount disease have been questioned.[8,23]

Clinical comment

Once progression of a bowleg deformity has occurred and a diagnosis of infantile Blount disease has been established,

emphasis is placed on early treatment and long-term follow-up. The classic treatment for a child with progressive deformity is a valgus producing high tibial osteotomy. Some authors advocate operating prior to age four for an optimal outcome with less chance of a recurrent deformity.[8–10] An osteotomy is an invasive procedure with associated risks such as deep infection and compartment syndrome and often requires adherence to strict postoperative weight bearing restrictions. Other authors believe that, if initiated early, brace treatment can help prevent progressive deformity of the leg and obviate the need for an invasive surgical procedure.[19–22]

Available literature and quality of the evidence

- Level III: 1 retrospective cohort study.
- Level IV: 6 case series.

Findings

Published series on bracing for infantile Blount disease primarily focus on patients with mild deformities, or Langenskiold stage I–III.[15] Schoenecker et al. initiated brace treatment on six extremities with an average MDA of 15°.[10] At two-year follow-up, they reported successful outcomes in five of six extremities (83%). The one poor outcome was in a patient with bilateral disease who had successful brace treatment on their contralateral extremity. They recommended brace treatment for any patient >2 years of age with stage I–II Langenskiold changes and a TFA <15°. Loder and Johnston initiated brace treatment for 23 patients with Langenskiold stage I–II changes and found that 11/23 patients failed brace treatment and eventually needed an osteotomy.[9] The authors recommended starting brace treatment early, at 1.5–2.5 years of age, and cautioned that despite bracing approximately half of

patients would still progress and require surgical correction.

Other authors have had similar success rates after bracing. Richards et al. reported successful outcomes in 24 of 37 extremities (64%) with infantile Blount disease treated with bracing.[19] Interestingly, the authors noted successful outcomes in 16 of 17 patients with unilateral disease (94%) compared to 3 of 10 patients with bilateral disease (8 of 20 extremities, 40%), $p < 0.001$.[19] Zionts and Shean used bracing to treat 42 extremities in 24 patients who presented before the age of three with Langenskiold stage I–III radiographic changes.[20] They reported good outcomes in 29 of 42 extremities (67%). Of these 42 extremities, two had radiographic changes consistent with Langenskiold stage III and both of these extremities had a poor outcome. They concluded that bracing may be effective in patients <3 years with Langenskiold stage I–II changes, but it is not effective for patients with stage III changes. Raney et al. implemented bracing for 60 extremities with MDA ≥16° or those with an MDA >9° and at least one risk factor for progression (ligamentous instability, weight >90th percentile, asymmetric radiographic appearance of the proximal tibial metaphysis, female gender, or black or Hispanic ethnicity[3,9,21]).[21] They obtained successful outcomes in 90% of patients. They found ligamentous instability, weight greater than 90th percentile, and late initiation of bracing (after age three) were associated with failure of bracing.[21] In 2013, Alsancak et al. used a KAFO for 22 patients and achieved improvement in the MDA of all patients and noted complete correction in 20 of 22 patients.[22] They recommended bracing for patients up to 38 months of age with Langenskiold stage I–III deformities. Despite the promising results with bracing, the published studies are subject to multiple limitations, including a retrospective study design without a control group; a lack

of long-term follow-up, including multiple variables; use of multiple different styles of braces, inconsistency among bracing regimens; a lack of specific details regarding time spent in the brace; and the difficulty differentiating infantile Blount disease from physiologic varus.[8,19–23] Furthermore, many of the recommendations for bracing were based on the Langenskiold staging system which itself has poor interobserver reliability, especially for the intermediate stages.[24] Collectively among the various published series on bracing, the most common reasons for failure were weight >90th percentile, bilateral disease, varus thrust on ambulation, age >3 at the start of treatment, and advanced deformity (Langenskiold stage ≥III).[8,19–23]

Other authors have studied the natural history of infantile Blount disease and noted a high rate of spontaneous correction among patients with less advanced deformity, leading them to question the utility of bracing. Shinohara et al. followed 40 patients with Langenskiold stage I and II radiographic changes and noted resolution in 100% of patients with stage I changes and 75% of patients with stage II.[11] Their 75% rate of spontaneous resolution in patients with stage II changes is comparable to the success rate after bracing reported by Richards et al.[19] and Zionts and Shean.[20] When analyzed using the criteria for bracing proposed by Raney et al.,[21] 27 patients would have met the criteria for bracing and 24 of these patients achieved spontaneous correction (89%), which corresponds to the 90% success rate achieved with bracing in Raney et al.'s series. The authors questioned the role of bracing, even in patients with MDA >11° and Langenskiold stage II–III radiographic changes.[11]

Resolution of clinical scenario

The child from the aforementioned clinical scenario fits into the criteria for bracing proposed by the previous authors.[19–22] However, authors have also reported a high rate of spontaneous resolution in children with such deformities.[11] While the concept of bracing is based on sound physiologic reasoning, there are currently no high-quality studies that demonstrate an improvement in correction compared to the natural history of the disease. Therefore, there is insufficient evidence to recommend use of bracing for infantile Blount disease.[8,23]

Question 3: Is guided growth an effective treatment for correcting deformity in patients with infantile Blount disease?

Rationale

Guided growth has been an effective strategy to treat angular deformities of the lower extremities of various etiologies in children. However, in patients with an abnormal physis, such as in Blount disease, the results are less predictable because the success of the technique requires growth of the medial side.[25] While there are some reports of guided growth using staples or the Phemister technique for adolescent Blount disease,[26,27] there has been an increase in the use of guided growth since the introduction of extraperiosteal tension-band plates.[28–30] Despite this, there are only a few reports on guided growth for patients with the infantile form of Blount disease.[31,32]

Clinical comment

Growth modulation through physeal stapling was first presented by Blount and Clarke in 1949 and became a popular alternative to acute correction with an osteotomy.[25] In 2007, Stevens presented the concept of guided growth with tension-band plating for patients with angular deformities, including adolescent Blount disease.[33] Some authors have reported similar outcomes between those treated with staples and tension-band plates.[34,35] Options include either permanent ablation of the lateral proximal tibial physis or a temporary growth arrest using extraperiosteal implants with the potential for growth resumption after implant removal following deformity (over)correction.[31] The appeal of the procedure is that correction of the deformity can be achieved while minimizing some of the risks associated with a high tibial osteotomy (compartment syndrome, neurovascular injury, deep infection) and allowing faster mobilization with immediate weight bearing postoperatively.[8,23,25]

Available literature and quality of the evidence

- Level IV: 3 case series.

Findings

Many of the initial series on guided growth for angular deformity correction involved a heterogeneous group of patients of varying ages and multiple diagnoses.[25,27,28,33] The patients with Blount disease included in these studies were typically either the adolescent form or no distinction between the two forms was made. Westberry et al. were one of the earliest to include results on both patients with infantile and adolescent Blount disease.[27] They reported improvement of the deformity in 55% of patients treated by hemiepiphysiodesis and an additional 33% which did not

progress after surgery, although they did not contrast outcomes between patients with the two forms of Blount.

In 2012, Scott presented results of guided growth on a series of 12 patients (18 extremities) with infantile Blount disease.[32] All patients had Langenskiold stage II–III radiographic changes, and the mean age at surgery was 4.8 years. Of these 18 extremities, 16 achieved full mechanical axis normalization (89%), one limb had residual varus deformity but improved from the preoperative mechanical axis, and one limb had persistent deformity and required an osteotomy. Follow-up ranged from 0 to 37 months after plate removal. Of eight extremities with >1 year follow-up after plate removal, the authors noted recurrent varus of >5° in three of eight extremities, highlighting the high rate of recurrence of this condition and the need for surveillance until skeletal maturity.[8],[23],[31],[36] The authors noted that while spontaneous correction of the internal tibial torsion occurred after correction of the angular deformity in most patients, 3 of the 12 patients had residual torsional deformity as determined by an internal foot progression angle.[32] Heflin et al. recently published results of a series of patients with Blount disease treated by guided growth including seven patients with the infantile form.[26] They obtained complete correction in all seven patients with infantile Blount and observed only one case of recurrent deformity at a mean of 33-month follow-up (range 14–70 months). They also noted spontaneous correction of the internal tibial torsion deformity in all patients.

The most common reported complication following guided growth is implant failure, which almost always occurs at the metaphyseal screw head–shaft junction in obese children.[8][29]–[31] Although not clinically validated, the risk of screw breakage may be lessened by using noncannulated

stainless-steel screws instead of cannulated titanium screws and using two plates instead of one or a plate with four instead of two screw holes.[37] Scott also implied that cannulated screws predispose to hematoma formation and subsequent wound dehiscence, potentially increasing the infection rate.[32] Given the unpredictable growth of the abnormal physis in Blount disease, even after deformity correction, recurrence of the varus malalignment remains a problem. Based on a recent report, children with infantile Blount disease often have advanced bone age, with an average of 26 months ahead of their chronologic age. This must be taken into consideration when performing guided growth as premature physeal closure can lead to undercorrection of the deformity.[38] Overcorrection into slight valgus (zone 2) is often performed with the anticipation of *rebound* varus growth after implant removal.[8],[23],[31] Unlike bracing, for which there are questions about efficacy (success might just be a consequence of natural history), there is better evidence that guided growth can facilitate correction in infantile Blount disease. However, in choosing who to operate on, the same considerations about the natural history of spontaneous resolution apply.

Resolution of clinical scenario

The child from the case scenario is the appropriate age with a moderate deformity and Langenskiold stage II radiographic changes which should respond to guided growth. However, he is still <3 years old with radiographic features associated with a high rate of spontaneous resolution reported in the literature.[11] As such, the patient can be followed closely with serial radiographs and observed if the deformity is shown to be decreasing over time. Surgical treatment should be offered immediately in the face of demonstrable increased deformity. If the

deformity persists (but does not increase), surgery should be offered by the age of four years. Solid stainless-steel screws are stronger than cannulated titanium screws and may minimize the risk of screw breakage. Some overcorrection into valgus is prudent prior to removal, because some recurrence or rebound is common, unless the patient has such advanced skeletal age that rebound growth is unlikely.[38] The patient should continue to have regular follow-up until skeletal maturity.

Summary of answers

- Prior to the onset of typical radiographic features of Blount disease, other radiographic criteria can be helpful in determining which patients are at higher risk for developing radiographic Blount disease. An MDA ≤9° has a false-negative of <5% and an MDA ≥16° has a false-positive rate of <5%.
- For patients with an MDA in the gray area of 10–15°, a BMI >22 is highly predictive of deformity progression.
- An FTR <1 and/or a %DT >50 is also predictive of deformity progression.
- Despite radiographic and clinical parameters, there remains a high rate of spontaneous resolution of early stages of Blount disease (Langenskiold stage I–II), so performing serial physical exams with follow-up radiographs may be the best way to determine which deformities will progress (and need treatment), and which will normalize.
- Although several small uncontrolled case series have reported promising results with the use of braces, there is no clear evidence that these results are any different from the natural history of the disease. Additionally,

there are many different types of braces and little consistency among bracing regimens, which limits the generalizability of these studies.

- Guided growth can be a safe and effective method for treating infantile Blount disease. Correction may not be permanent. The data are scarce and current reports using extraperiosteal nonlocking plates lack long-term follow-up until skeletal maturity.
- Breakage of the metaphyseal screw after guided growth and recurrence of varus deformity are common problems associated with guided growth.

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186 Pediatric Anterior Cruciate Ligament Injuries

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Clinical scenario

- A 12-year-old boy presents in clinic with an acute anterior cruciate ligament (ACL) tear that occurred during a soccer game.
- The patient reports twisting his knee awkwardly and feeling something pop.
- Magnetic resonance imaging (MRI) confirms a complete intrasubstance ACL tear without meniscal tear.
- Bone age imaging confirms his skeletal age matches his chronological age and therefore he has approximately four years of growth remaining.

Top three questions

1. In a child or teenager with acute ACL tear, what are the effects on cartilage and meniscus with delayed reconstruction compared to acute reconstruction?
2. In children/adolescents with acute ACL tear, is one surgical technique superior to others with respect to ACL re-rupture rates, pain, or return to sport (RTS)?

3. In children/adolescents with an acute ACL tear, what is the risk of re-injury to the same and contralateral side, and what can be done to prevent re-injury?

Question 1: In a child or teenager with acute ACL tear, what are the effects on cartilage and meniscus with delayed reconstruction compared to acute reconstruction?

Rationale

Children and adolescents with ACL tears are indicated for anterior cruciate ligament reconstruction (ACLR) shortly after initial presentation. Historically, these patients were definitively prescribed activity restriction, bracing, and physical therapy. However, these patients showed early, severe meniscal degeneration and cartilage defects that eventually required surgical intervention.[1]

Clinical comment

Pediatric ACLR techniques have advanced significantly in recent years. There are multiple physical sparing techniques and advanced rehabilitation protocols to prevent arthrofibrosis. What is the ideal timing for pediatric ACLR? Is this patient at risk for developing arthrofibrosis if ACLR is preformed too soon?

Available literature and quality of the evidence

- Level I: 2 meta-analyses.[2],[3]
- Level III: 1 cross-sectional study[4] and 6 retrospective cohorts.[5]–[10]

- Level IV: 1 systematic review.[1]

Findings

Current literature consistently agrees that indefinite delay to surgical intervention when treating ACL injuries in pediatric patients will result in further meniscal damage.[1–3] In a group of 370 pediatric patients with ACL tears, those with surgical treatment ≥150 days after injury had a significantly higher incidence of meniscus tears compared to those treated surgically ≤150 days postinjury.[4] Furthermore, multiple meta-analyses have demonstrated that nonoperative management equates to a 12-fold greater risk of developing a meniscal tear.[2,3] There is an increased meniscal injury prevalence of 6% for every month that surgery is delayed.[5] If surgery is delayed for over three months, patients are 3.5–4.8 times more likely to present with an additional or more severe medial meniscal tear.[6]

Guenther et al. reviewed 112 patients (mean age: 15.4 years) in which 51% of those who underwent surgery >1 year postinjury presented with a new or higher-grade medial meniscal tear versus only 20% of those who had surgery <1 year postinjury.[7] Comparing a group who underwent ACLR at a mean interval of 11.5 months to a group who underwent ACLR at a mean interval of 30.3 months, findings revealed that the group with a longer time to surgery presented with a significantly higher medial meniscal tear rate.[8]

Some authors have also hypothesized the risk of arthrofibrosis as a function of time interval from ACL injury to surgery, making this another relevant concern in surgical planning. In an attempt to understand this potential risk in the pediatric population, Nwachukwu et al. retrospectively reviewed 933 ACL reconstructions with an average follow-up of 6.3 years. Arthrofibrosis was defined

as loss of 5° or more extension that required a follow-up procedure, or a loss of 15° or more extension that required a follow-up procedure. The prevalence of arthrofibrosis was 8.3%.[9] Prior knee surgery and ACL reconstruction within one month of injury were not significantly associated with postoperative arthrofibrosis. Females, patients aged ≥16, patellar tendon autograft, and concomitant meniscal repair were associated with a higher incidence of arthrofibrosis.[9]

Some practitioners advocate for the use of postoperative continuous passive motion (CPM) machine protocols to reduce the risk of arthrofibrosis. A recent retrospective review compared the postoperative rates of MUA for arthrofibrosis among pediatric ACLR patients treated with or without postoperative CPM protocol. The no-CPM cohort has a 7.4% rate of MUA for arthrofibrosis while no patients in the CPM cohort required MUA. Future work may better define the clinical utility and cost effectiveness of CPM in rehabilitation.[10]

Resolution of clinical scenario

ACLR is recommended for the current clinical scenario at the patient's and family's earliest convenience. Current research does not suggest an increased risk of arthrofibrosis with early ACLR. However, if ACLR is delayed, the patient is at high risk of further internal derangement of the knee, and should adhere to activity restrictions.

Question 2: In children/adolescents with acute ACL tear, is one surgical technique superior to others with respect to ACL re-rupture rates, pain, or return to sport (RTS)?

Rationale

A variety of surgical techniques for ACLR have been developed to restore knee stability while minimizing the risk of physeal injury in young patients. These techniques include the all-epiphyseal (AE) reconstruction, the pediatric extra-articular ACLR with iliotibial band (ITB) autograft, and the complete transphyseal (CT) reconstruction with soft tissue graft. Of note, the bone tendon bone (BTB) autograft is an adult-type reconstruction for school- and college-aged patients at or near skeletal maturity due to its risk to physeal injury. As the focus of this chapter is the pediatric ACLR; BTB autograft will not be discussed further.

Clinical comment

The elected procedure should minimize the risk of postoperative growth arrest and/or angular deformity while maximizing the opportunity to RTS and daily activities. Of the three available techniques for ACLR in skeletally immature patients, is there one that has been shown to be superior to the others? Are there specific indications for each procedure that produce the best outcomes?

Available literature and quality of the evidence

- Level II: 9 prospective cohort studies.[12–20]

- Level III: 6 retrospective cohort studies[21–26] and 1 meta-analysis.[11]
- Level IV: 3 systematic reviews.[27–29]
- Level V: 1 technique article.[30]

Findings

The surgical technique is generally based upon the patient's skeletal age, predicted growth remaining, and surgeon preference. The pediatric extra-articular ACLR with ITB autograft and AE reconstructions are generally reserved for patients with approximately 3–6 years of growth remaining, while the transphyseal reconstruction is for young adolescents with approximately 2–3 years of growth remaining.[11,12,14–17,19,20,27–29]

The pediatric extra-articular ACLR with ITB autograft

Micheli et al. reported on a series of eight patients (mean age: 11 years) who underwent this modified intra- and extra-articular extraphyseal reconstruction originally described by MacIntosh and Darby.[18] The technique was performed with ITB autograft and the patients were followed for an average of 5.5 years after surgery. At latest follow-up, none of the patients experienced any complications or required revision surgery, and they were able to return to activities with a mean Lysholm score of 97.4.[18] Further studies similarly found satisfactory results with this procedure. Out of 237 patients (mean age: 11.2 years), Kocher et al. found at mean follow-up 25.8 months, 96.8 and 98.9% of patients were grade A on the Lachman and pivot-shift test, respectively. At an average 33.5 months postoperatively, graft rupture occurred in nine (6.6%) of 137 knees. For patients who did not sustain a graft rupture, the mean Pedi-IKDC score was 93.3, the

mean Lysholm score was 93.4, and the mean score on the Tegner Activity Scale was 7.8. No cases of limb-length discrepancy or angular deformity were observed.[23]

All-epiphyseal (AE)

Anderson described a transepiphyseal ACLR for pediatric patients that mitigates the risk of iatrogenic growth disturbance by avoiding graft fixation that violates the tibial or femoral physis.[24] In a preliminary report of 12 patients (mean age: 13.3 years), Anderson reported no instances of growth disturbance.[25] Although this technique intends to minimize the risk of complications, the chance for growth disturbance remains. Out of 12 patients (mean age: 12 years) who were clinically followed for an average of 4.5 years by Koch et al., six (50%) presented with leg length discrepancy (LLD).[25] Two patients had LLD >10 mm and four others had an overgrowth of the affected leg between 5 and 10 mm; however, none of these patients required surgical intervention to correct their growth deformities.

Modifications have been made to Anderson's technique that vary by surgeon and institution, but all are *all-epiphyseal* with fixation in the distal femoral and proximal tibial epiphysis, decreasing the possibility of soft tissue tethering to the growth plate.?30? Nawabi et al. prospectively studied 23 patients (mean skeletal age: 13.2 years) with 18.5-month mean follow-up to quantify physeal violation using MRI.[13] Results showed that 10 out of 15 patients in the AE group had minimal tibial physeal violation.[13] The authors concluded that the AE reconstruction is a safe technique in which the area of physeal compromise is significantly lower than published thresholds for growth arrest.

The reported RTS rate after AE ACLR is reported at over 90%.[28] Cordasco et al. found 100% of patients (n = 49) who underwent AE ACLR were able to RTS and only 6% required revision ACL surgery.[20] In addition, Tuca et al. reported 100% RTS without re-injury at an average of 30.7 months in 16 patients who underwent AE ACLR.[26] In studies where Pedi-IKDC/IKDC was administered, patients were highly satisfied with scores in the mid-90s postoperatively. [12],[14]

Complete transphyseal (CT)

The CT technique involves femoral fixation proximal to the femoral physis and tibial fixation distal to the tibial physis. In a meta-analysis in which 60% of the reconstructions performed used the CT technique, it was noted that 10 out of the 18 knees that presented with an angular deformity postoperatively had undergone a transphyseal reconstruction.[11] Other studies have shown some instances of growth disturbance postoperatively, yet patients continue to return to their activities at a high rate and report good to excellent satisfaction scores.[15–17],[19] Calvo et al. reported a 10-year follow-up study on 27 patients who underwent CT ACLR. The results showed 100% RTS.[17] However, three patients experienced graft rupture during contact sports and one patient developed progressive instability and required graft revision.

One systematic review conducted by Pierce et al. found no significant differences between CT and physeal-sparing reconstructions when comparing LLD, angular deformities, and graft rupture.[29] In another systematic review, Collins et al. reported growth abnormalities in 39 patients from 21 published studies on ACLR complications in skeletally immature patients.[27] Eleven of these patients had postoperative limb shortening by an average of 17 mm,

seven (64%) of which underwent a transphyseal technique. Sixteen cases had an angular malformation, eight (50%) of which were transphyseal on the femur. The clinical implications of these deformities were not presented, nor details on treatments undertaken.

Resolution of clinical scenario

In the current clinical scenario, this 12-year-old boy has approximately four years of growth remaining. Therefore, CT is not recommended due to the risk of physeal injury and growth arrest. The extra-articular ACLR and the AE reconstruction are both viable options for the younger age groups with significant growth remaining. There is currently no significant evidence suggesting the superiority of one technique over the other; therefore, both options can be considered and surgical technique can be selected by surgeon preference.

Question 3: In children/adolescents with an acute ACL tear, what is the risk of re-injury to the same and contralateral side, and what can be done to prevent re-injury?

Rationale

Although surgical reconstructions in the pediatric and adolescent populations have demonstrated favorable outcomes in terms of patient satisfaction and RTS, this cohort is at high risk for re-injury on both the ipsilateral and contralateral sides. Graft failure rates vary from 0% in smaller cohorts to as high as 21%, and contralateral ACL tear rates have been reported in 8–14% of patients.[20,31,32]

Clinical comment

Children and adolescents are likely to be symptom free and RTS after ACL reconstruction. Risk to the reconstructed ACL may be due to muscular deconditioning, incomplete rehabilitation, poor compliance with activity restrictions, and/or increased participation in at risk sports. Risk to the contralateral ACL may be due to patient anatomy and muscular deconditioning in the postoperative period, and increased participation in at-risk sports.

What is the annual risk of re-rupture? What is the risk of ACL injury to the other leg? Should RTS be delayed until a specific time postoperatively?

Available literature and quality of the evidence

- Level I: 1 meta-analysis[31] and 2 prospective studies.[33],[34]
- Level III: 7 retrospective cohorts[32][35]–[40] and 1 therapeutic study.[41]

Findings

When stratified by specific technique the transphyseal, AE, and the pediatric extra-articular ACLRs have overlapping rates of graft failure: 14–15%,[17],[37] 4.3–15%,[12],[14] and 4.5–14%,[21],[24],[38] respectively. In addition to graft failure is the risk for a contralateral ACL injury. In a review of 561 ACLR cases, Ho et al. found that 8% of patients went on to tear their contralateral ACL.[36]

Patients under the age of 20 are at greater risk for secondary ACL injury in comparison to older cohorts, with high rates of revision ACLR in the first two years after returning to activities.[41] Webster et al. saw that 74% of ACL graft ruptures in a group of 316 patients (mean age:

17.2 years) occurred during the first two years postoperatively.[34] While younger patients recover more quickly and are eager to return to their activities, they may have remaining functional deficits and altered motor patterns that could place them in danger of another injury. Dekker et al. found that a prolonged period before RTS may act as a protective factor against secondary ACL injury while prolonged periods of physical therapy may not.[39] This supports the idea that there may be an important biological recovery period that is not influenced by the patient's rehabilitation protocol. When comparing ACLR postoperative MRIs of pediatric patients who subsequently suffered a re-tear versus those who did not, Pauvert et al. found no significant different differences between the two groups. The MRI appearance of the graft at six months postoperatively was not predictive of risk of re-tear.[42]

The quality of movement analysis (QMA) is another tool that focuses on a combination of qualitative and quantitative criteria to determine RTS readiness. Rather than centering rehabilitation around demarcated timepoints, the QMA reveals the strength and functional deficits that the patient must improve upon before being cleared for unrestricted activity. After achieving satisfactory results on the QMA, Graziano et al. reported 35 of 42 skeletally immature athletes were able to return to play at an average of 12 months without re-injury. The remaining seven suffered a second injury (four ipsilateral and two contralateral ACL tears, one meniscus injury).[33] Of note, three of the subsequent ACL tears were injured in sports that the patient was not cleared to play.

Cordasco et al. recently published the RTS and re-operation rates after primary ACLR in 324 adolescent athletes.[20] The patients who underwent CT ACLR had a 20% rate of revision ACLR, compared to 6% in both the AE and BTB

groups. The authors discussed the possibility that the age and grade level of the patients undergoing CT ACLR are especially relevant to the higher risk of revision ACLR. These eighth and ninth graders are returning to a skeletally mature group of high school athletes who had not lost nearly a year of competition and associated developmental physical and sport specific growth.[20] This group of adolescent athletes is at particularly high risk for ACL graft rupture. It is especially important to ensure these patients adhere to physical therapy regimens, pass QMA testing, and maintain strength and cardiovascular health before returning to high risk sports.

Resolution of clinical scenario

There is no widely accepted time point for RTS after ACLR. The previously reported average was 12 months. However, rather than setting a particular time point, surgeons should assess the patient's commitment to physical therapy and QMA results. The patient should not RTS that involve contact play, cutting, and pivoting until they are able to pass their QMA. Another important aspect is setting expectations and goals with patients and their families as to which sport and what season the patient is working toward, with particular focus on the skills required to return successfully.

Rather than setting a particular time point for RTS, surgeons should assess a patient's commitment to physical therapy and periodical QMAs. In particular, the patient should not RTS that involve contact play, cutting, and pivoting until they are able to pass their QMA.

Summary of answers

- Because there is an estimated increased meniscal injury prevalence of 6% for every month that surgery is delayed, ACLR is recommended for young, otherwise healthy, athletic patients within a month postinjury. If ACLR is delayed, the patient must adhere to activity restrictions to prevent additional damage.
- The optimal ACLR technique depends on the child's skeletal age and functional requirements. However, because of the successful outcomes reported for all techniques, the specific technique should be selected by patient factors and surgeon comfort/preference.
- There are biomechanical, biologic, and cognitive aspects to rehabilitation. Appropriate attention to all areas is recommended to prevent re-injury. Specifically, the patient's specific adherence to physical therapy, and results of the QMA, should be used when clearing patients to RTS.

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187 Clubfoot

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Clinical scenario

- The parents of a newborn boy seek treatment for his clubfeet.
- On both sides, hindfoot is in equinus and varus with a deep posterior ankle crease; there is a medial foot crease with cavus; the lateral border is convex with the forefoot adducted.
- Deformities are isolated to the feet and not passively correctable, consistent with idiopathic congenital talipes equinovarus (CTEV).
- The parents have heard about the Ponseti method but are concerned about the prolonged period of bracing required. They want information about the success rates of serial casting and the potential for recurrence compared with early surgical correction of idiopathic clubfeet.

Top three questions

1. What are the success rates and recurrence rates following primary Ponseti treatment of infants with idiopathic clubfeet compared to other casting methods or surgical release?

2. What is the optimal application, duration, and length of use of foot abduction orthoses following Ponseti treatment to optimize outcomes in patients with idiopathic clubfoot?
3. How effective is the Ponseti method in correcting (untreated) idiopathic clubfeet in older children?

Question 1: What are the success rates and recurrence rates following primary Ponseti treatment of infants with idiopathic clubfeet compared to other casting methods or surgical release?

Rationale

CTEV is among the most common orthopedic conditions of the newborn, occurring in an estimated 1 in 1000 live births. Left untreated, it leads to significant morbidity and social stigma. The clubfoot deformity persists and becomes more fixed, preventing use of regular footwear. Walking is possible but weight bearing occurs over the dorsolateral or even dorsum of the foot. The goals of treatment are to achieve a plantigrade foot that is flexible, pain-free, and allows for use of regular footwear and unrestricted physical activity. Historically, treatment started with some form of manipulative serial casting followed by surgical releases which were commonplace as recently as 20 years ago. The Ponseti method of casting comprises a weekly series of above-knee casts applied after foot manipulation, following a sequence of correction of the cavus, forefoot adductus and hindfoot varus.[1] Once these components are fully corrected, a percutaneous Achilles tenotomy is performed

to address any residual hindfoot equinus.[2] The corrected foot/feet is/are left in a cast for three more weeks followed by a foot abduction orthosis (FAO) full time for three months, reduced to night-time use for up to four years. Ponseti reported a 98% initial success rate for correction of the deformity, which was superior to other casting techniques. Cooper and Dietz showed that the majority of patients had excellent outcomes at an average of a 34-year follow-up.[3] Dobbs et al. subsequently showed that almost 50% of patients had poor outcomes 25 years following extensive soft tissue release mainly as a result of stiffness.[4]

Clinical comment

In the presenting case, the patient has no evidence of any neuromuscular or syndromic etiology to explain his isolated foot deformities. Around the world, the Ponseti method has largely replaced other methods of casting, such as those described by Kite, and intra-articular surgical releases as the treatment of choice of idiopathic clubfeet.[1] What is the evidence that justifies this dramatic change in practice? How often is correction achieved by the Ponseti method maintained? What are the recurrence rates compared with other methods?

Available literature and quality of the evidence

- Level II: 5 studies[5–9]
- Level III: 5 studies[10–14]
- Level IV: 4 studies.[15–18]

Findings

Reviewing the literature for CTEV reveals several important limitations. There is little consensus amongst clinicians about how to categorize and quantify the severity

of CTEV. Treatment algorithms and casting and/or surgical techniques differ between providers and even evolve for a single provider. There is little clarity about what constitutes *residual* (partially treated) or *recurrent* (relapsed) deformity, and the indications for and timing of further intervention, and how we define a *good* outcome. Therefore, most studies have mixed cohorts of patients, loosely defined criteria for a relapse, and variable indications for additional surgical procedures, and a lack of validated patient/parent-reported outcomes.

How does the Ponseti method of casting compare with the Kite and other methods?

The two randomized controlled trials (RCTs) comparing the Ponseti method to the Kite method showed significantly faster rates of correction of deformity.[8],[9] Sud et al. reported correction in 33 of 36 feet (91.7%) in the Ponseti group with seven (21%) relapses,[9] while the Kite method achieved correction in 21 of 31 feet (67.7%) with 10 patients (32.2%) of feet requiring conventional surgery. In a prospective cohort study reported by Halanski et al.,[10] 40 clubfeet (26 children) treated by the Ponseti method group were compared with 46 feet (29 children) treated with below-knee casting. The Ponseti group required an average of six casts compared with 11 in the below-knee group. At an average of a 3.8-year follow-up, 12/26 patients in the Ponseti group needed more than a percutaneous tenotomy compared with 27/29 patients in the below-knee casting group. However, major posterior or posteromedial releases (PMRs) were only required in 4/40 feet in the Ponseti group compared with 43/46 in the below-knee group. Herzenberg et al. showed only one of 34 feet (3%) required a PMR in the Ponseti group versus 34 feet (94%) in the traditional casting method group.[14] Derzsi et al. showed a

failure rate of 30.3% in the Kite group and of 8.5% in the Ponseti group.[13]

Steinman et al. compared the results of the French method of manipulation and taping by daily physical therapy in 80 children (119 feet) with the Ponseti method for 176 patients (267 feet) at an average of a 4.3-year follow-up.[11] The initial correction rates and relapse rates were 94.4 and 37% for the Ponseti method and 95 and 29% for the French functional method. Two-thirds of the relapsed feet in the Ponseti group and all of the relapses in the French method group required operative intervention. At the time of the latest follow-up, the outcomes for the feet treated with the Ponseti method were good for 72%, fair for 12%, and poor for 16%. The outcomes for the feet treated with the French functional method were good for 67%, fair for 17%, and poor for 16%. When offered both treatments, parents preferred the Ponseti method to the French method at a ratio of 2 : 1.

How do the outcomes of the Ponseti method (casting and percutaneous tendo Achilles tenotomy) compare with surgical releases of idiopathic clubfeet?

The meta-analysis (mostly of cases series) by Lykissas et al. reviewed 12 studies from 1950 to 2011 that included 835 idiopathic clubfeet in 516 patients treated with either Ponseti method or surgical release with outcomes measured by the Laaveg-Ponseti Function Rating System (L-P FRS) score, and at least three radiographic outcome measures.[5] Average follow-up was 15.7 ± 10.8 years (range 1–42 years). Patients managed with the Ponseti method had a higher rate of excellent or good outcomes over those with open surgery. Zwick et al. randomized 19 infants with 28 CTEV to the Ponseti method and 10 infants with 16 CTEV to a surgical method that included limited pre- and postoperative casting.[6] The L-P FRS and PODCI scores at

an average of 3.3-year follow-up revealed good to excellent results for both groups, but parental satisfaction and passive mobility were better in the Ponseti method group. In a prospective case series, Smythe et al. reported excellent initial correction with 337 feet in 218 children showing that 85% of feet reached a Pirani score of 1 or less at the end of the correction phase.[18]

With respect to motor functional outcomes, Aulie et al. in a retrospective cohort study, compared the motor function of 89 children treated with primary surgery, 93 children treated with the Ponseti method, and 45 age-matched normative peers, using the Motor Assessment Battery for Children (MABC-2).[12] There was no difference between the Ponseti and surgical groups. However, in the clubfoot groups, only 76% had normal abilities compared with 96% of children without clubfeet.

What are the rates of recurrence following the Ponseti method?

In a systematic review by Thomas et al. looking at relapses, the studies included were all case series and showed a wide range of recurrence rates from 3.7 to 67.3%.[15] This might be explained by the variable lengths of follow-up and definitions of a relapse: reappearance of appearance of CTEV, and reliance on a surgeon's determination of need for further treatment with additional casting and/or surgery. There was a strong correlation between the rates of recurrence reported and the rates of joint-sparing surgical procedures to address these, and the duration of follow-up, with relapses reported as late as 10 years of age. Zionts et al. reported the results of 101 children treated in a single institution at a mean follow-up of 81.1 ± 17.1 months. Thirty-seven percent were adherent bracing by self-report, 68% of patients had one or more relapses, and 38% underwent a tendon transfer to address the relapse.[17]

Using the Dallas criteria, 62% had outcomes rated good, 38% had outcomes rated fair, and no patient had an outcome rated poor.

Resolution of clinical scenario

The Ponseti method provides the most effective method of achieving full correction with serial casting and minimal surgery (percutaneous tendo Achilles tenotomy). It involves fewer casts and a low likelihood of requiring major surgical releases compared with any other form of casting. It is preferred by parents to the French method. Compared with surgery, the long-term results of the Ponseti method appear superior particularly with respect to flexibility, although motor functional outcomes are not significantly different. Rates of recurrence after initial correction are similarly high over time, but recurrences following the Ponseti method require far fewer major surgical interventions compared with recurrences following early surgical releases.

Question 2: What is the optimal application, duration, and length of use of foot abduction orthoses following Ponseti treatment to optimize outcomes in patients with idiopathic clubfoot?

Rationale

Although there is an excellent rate of correction following serial casting by the Ponseti method followed by the Achilles tenotomy, there remains a high rate of recurrence thereafter. To maintain the correction, the Ponseti method

includes the use of an FAO for 23 hours/day for three months after correction, continued thereafter at night and nap time until 4–5 years of age. Use of the brace does not eliminate recurrences, and there is uncertainty regarding the duration of bracing necessary.

Clinical comment

For many families, bracing is a considerable hardship to maintain. The FAO includes both feet linked with a bar, which many young children don't tolerate. Recurrences are often attributed to failure of *compliance* with the bracing. It is conceivable that a recurrence might cause the brace to be less tolerated. Once a deformity recurs, bracing alone is no longer effective and the recurrence is treated with serial casting with or without additional surgery.

Available literature and quality of the evidence

- Level II: 3 studies[19–21]
- Level III: 2 studies[22,23]
- Level IV: 4 studies.[24–27]

Findings

The definition of recurrent deformity varies between studies. Early recurrence rates after the Ponseti method range from 26 to 48%.[19–21,25,26] The studies that recorded FAO use by self-report show a significantly higher risk of early recurrence in the nonadherent groups. Avilucea et al. defined early recurrence as the need for subsequent cast treatment or surgical treatment, and compliance as strict adherence to the FAO protocol described by Ponseti.[19] Abandonment of the brace protocol was associated with a 33.3-fold increase in the likelihood of early recurrence in the urban patients closer to the treating institution (95%

confidence interval [CI]: 5.2–212.2, p <0.001) and 120 times more likely among rural patients (95% CI: 18.8–765.1, p <0.0001).

Abdelgawad et al. demonstrated statistically significant better Dimeglio and Pirani scores in compliant versus noncompliant groups.[24] Eighty-four percent of patients in the compliant group required no additional treatment after two-year follow-up versus 24% in the noncompliant group. Haft et al. found that failures resulted in a fivefold greater risk of recurrence.[20] Zionts et al. found that patients were 2–3 times more likely to have a relapse if the family did not use the FAO as prescribed.[21] Dobbs et al. reported that poor compliance of the FAO is the main risk factor for recurrence with an odds ratio (OR) of 183 (95% CI: 9.5–3519),[25] and Ramirez et al. found that poor compliance with the FAO has a ninefold greater risk of recurrence (95% CI for the OR = 2.2–38.5).[26] The association found between reduced brace wear and increased recurrence rates does not conclusively demonstrate cause and effect, and the risk of bias of labeling someone as noncompliant when they are noted to have a recurrence is very high. In contrast to all the previous studies, the study by Kuzma et al. used objective measurement of brace wear with a sensor embedded within the FAO.[23] In their cohort of 42 patients, 64 affected feet, five-year follow-up, and a recurrence rate of 40%, there was no statistically significant relationship between recurrence and compliance with the FAO. They showed a statistically significant correlation with increased difficulty of CTEV correction (greater than nine casts) during initial treatment.

With respect to the type of bracing, Janicki et al. demonstrated the importance of using a FAO (Denis Browne Boots and bar) as recommended by Ponseti instead of an ankle foot orthosis (AFO).[22] In a retrospective cohort

study of 45 infants (69 feet) who achieved full correction with the Ponseti method, recurrence occurred in 83% (25/30) of clubfeet in the group treated with AFOs during the maintenance phase compared with 31% (12/39) in the FAO group. The use of an AFO for maintenance of correction was 10.6 times higher compared with use of an FAO ($p < 001$).

Resolution of clinical scenario

Given the high rates of recurrence after initial correction, the need for bracing to maintain correction achieved by the Ponseti method is well supported in the literature. AFOs are ineffective form of bracing. The FAOs recommended by Ponseti are superior to AFOs but do not eliminate recurrence. Nonadherence with brace wear is associated with higher recurrence rates. Although a clear cause and effect is difficult to infer from these studies, the evidence is largely supportive of the use of FAO to decrease recurrence after successful initial correction with Ponseti method. However, the specific duration (hours/day) of brace wear and the age at which braces may be stopped remain poorly studied.

Question 3: How effective is the Ponseti method in correcting (untreated) idiopathic clubfeet in older children?

Rationale

The Ponseti technique was developed for the treatment of infantile CTEV; however, the upper age limit of achieving correction becomes relevant as the technique has become

increasingly available in areas where many children with clubfeet may not have had access to care as infants.

Clinical comment

After recent studies demonstrating that neglected clubfoot can be corrected with serial casting, there are new questions regarding goals of deformity correction and the need for immediate versus delayed associated surgical procedures to achieve the best result.

Available literature and quality of the evidence

- Level II: 6 prospective cohort studies.[28–33]
- Level III: 1 retrospective cohort study.[34]
- Level IV: 5 studies.[35–39]

Findings

There is a growing body of evidence that untreated CTEV in older, walking children can be successfully treated with the Ponseti method. There are six level II prospective cohort studies,[28–33] one level III retrospective cohort,[34] and six level IV studies[35–39] that demonstrate a 67–100% rate of correction to a painless plantigrade foot. Nearly all cohorts included minor extra-articular surgical procedures as part of the Ponseti treatment and report some degree of persistent deformity despite being plantigrade. The average age at initial treatment for each study ranged from 1.7 to 11.2 years, and the time in cast ranged from 7 weeks to 3.9 months. Surprisingly, the case series with the oldest average patient age also had one of the highest success rates of 94.4%.[37] Khan and Kumar reported a 24% recurrence rate with a follow-up at 4.7 years,[28] and Ayana and Klungsøyr reported a 12.5% recurrence rate with a mean follow-up of 3.0 years. Banskota et al. reported rates

of recurrence as low as 16% (aged 5–10 years) with mean 2.6-year follow-up.[31]

The case series by Adegbehingbe et al. is the largest to date with 328 feet.[38] A mean of 6.8 (3–20) casts achieved a painless plantigrade foot in 78% of feet without any additional procedures. Banskota et al. reported 95% of feet achieved a pain-free plantigrade foot; 86% were completely satisfied, with 96% having improved self-confidence and 99% having improvements in activities of daily living.[39]

Resolution of clinical scenario

The current evidence supports the use of the Ponseti method in older children with untreated clubfeet with success reported at least until early adolescence. The upper age limit for success remains unknown.

Summary of answers

- The Ponseti method has the highest and most consistent success rates of over 90% for initial correction of CTEV.
- The use of the FAO following initial correction is associated with lower rates of recurrence, but the current recommendations for the duration and length of time in FAOs are not based on objective evidence.
- The Ponseti method has excellent results, even when treatment is initiated in older children well after the onset of walking.

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188 Tarsal Coalitions

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Clinical scenario

- A 13-year-old girl has activity-related pain below the medial malleolus, and on occasion in the medial arch of foot and in the sinus tarsi.
- Clinically, she has a flat arch, valgus hindfoot alignment, forefoot abduction, and no subtalar motion.
- X-rays are suggestive of a tarsal coalition with flatfoot deformity including 16° of hindfoot valgus. There are no degenerative changes of the posterior facet.
- She is an avid soccer player and wishes to return to sport pain-free.

Top three questions

1. In children with subtalar tarsal coalition and flatfoot deformity, what are the indications for coalition resection alone, flatfoot reconstruction alone, versus combined resection and concomitant flatfoot reconstruction?
2. In children with calcaneonavicular (CN) tarsal coalition and flatfoot deformity, what are the indications for coalition resection alone, flatfoot reconstruction alone,

versus combined resection and concomitant flatfoot reconstruction?

3. In children with tarsal coalition and flatfoot deformity, when is arthrodesis of the subtalar joint indicated?

Question 1: In children with subtalar tarsal coalition and flatfoot deformity, what are the indications for coalition resection alone, flatfoot reconstruction alone, versus combined resection and concomitant flatfoot reconstruction?

Relevance

A flatfoot deformity due to tarsal coalition is characterized by a flat medial arch that will not improve on toe standing, and rigid hindfoot valgus with restricted subtalar motion.[1],[2] Concomitant flatfoot deformity is commonly seen with talocalcaneal (TC) coalitions and can cause pain and disability.[3] TC coalitions typically involve the middle facet, but can occur at any location in the subtalar joint. Symptomatic TC coalitions are commonly treated with resection and interposition of fat or bone wax. Poor results have been reported for TC coalition resection when hindfoot valgus is >16°.[4] There are no reported predictors of outcome or consensus guidelines for treatment of rigid flatfeet with tarsal coalitions.

Clinical comment

Based on the commonly used criteria established by Wilde et al., TC coalitions are deemed resectable with good outcomes if the surface area of the coalition is <50% of the surface area of the calcaneal posterior facet on coronal computed tomography (CT) images, hindfoot valgus is <16°, and there is no narrowing of the posterior facet of the subtalar joint or impingement of the lateral talar process on the calcaneus.[4]

Is this patient a candidate for coalition resection? Should her flatfoot deformity be reconstructed? If so, should it be performed simultaneously with coalition resection or staged in a second surgery?

Available literature and quality of the evidence

- Level III: 1 case control.[5]
- Level IV: 6 retrospective case series.[6–11]

Findings

Excellent functional outcomes have been reported following coalition excision in both mid- and long-term follow-up with minimal functional limitations.[6,7] In some studies, these results were independent of coalition type and size.[6,7] Postoperative subtalar range of motion was significantly decreased for TC coalitions,[6] but this restricted motion did not affect functional outcome.[7] Increased medial midfoot pressure during running has been demonstrated after TC coalition resection from the resulting altered subtalar mechanics.[5] Patient-reported functional outcomes were not obtained in this biomechanical study.

Several small series have evaluated coalition resection with simultaneous or staged flatfoot reconstruction. Reconstruction techniques and indications vary. Kernbach et al. included six adolescent feet with TC coalitions that underwent resection with naviculocuneiform fusion, Evans calcaneal lengthening osteotomy, and medializing calcaneal osteotomies.[8] They demonstrated significant improvement in radiographic alignment as measured by calcaneal inclination, Meary's, and anteroposterior talar-first metatarsal angles. All had excellent postoperative American Orthopaedic Foot and Ankle Society (AOFAS) hindfoot scores.

Mosca and Bevan found similar radiographic and clinical improvement with calcaneal lengthening osteotomy combined with plication of the posterior tibialis tendon and talonavicular joint capsule, and Achilles lengthening or gastrocnemius recession in eight adolescent patients with flatfeet and tarsal coalitions with an average follow-up of 3.7 years.[9] Five of these patients underwent osteotomy alone as the coalitions were deemed unresectable by the Wilde criteria, one patient underwent simultaneous resection and osteotomy, and two patients underwent osteotomy following prior resection. Their suggested algorithm is to resect the coalition if the posterior subtalar joint is healthy and to correct flatfoot deformity if present. In the case of a large osseous coalition, they recommend leaving the coalition in situ. Their postoperative protocol consists of a short leg cast for eight weeks, with pin removal and change to weight bearing cast at six weeks. Postoperative AOFAS scores improved in all patients and did not correlate to timing of reconstruction (staged versus simultaneous).

Gantsoudes et al. prefer to first resect the coalition, regain mobility of the joint, and realign the foot in a second surgery.[10] In their series of adolescents with coalitions treated with resection and fat interposition, 8 of 49 feet that had flatfoot deformities underwent staged resection with subsequent deformity correction with calcaneal, cuboid, and medial cuneiform osteotomies. The decision to include flatfoot reconstruction was based on preoperative hindfoot valgus. Radiographic and clinical improvement after resection was similar regardless of concomitant flatfoot deformity (average AOFAS score 88 with versus 90 without flatfoot correction).

Masquijo et al. reported similar outcomes to Mosca and Bevan in 14 feet.[9],[11] Eight were treated with flatfoot

reconstruction and coalition resection and six were by reconstruction alone. The coalitions were resected if the coalition surface area was <50% of the calcaneus posterior facet. Hindfoot valgus was >16° in all patients. Reconstruction techniques included sliding posterior calcaneal osteotomy, calcaneal lengthening osteotomy, medial cuneiform osteotomy, and Achilles tendon lengthening. Both groups showed restoration of radiographic parameters to normal range and improvement in AOFAS scores with a minimum 12-month follow-up.

To date, no studies have been published directly comparing results of resection alone to resection and reconstruction, or outcomes of coalitions treated in childhood to those treated in adulthood.

Resolution of clinical scenario

- There is level III and IV evidence that this girl's coalition can be resected successfully; studies report good results with resection and reconstruction in flatfeet with tarsal coalitions whether staged or simultaneous. There is, however, no evidence directly comparing staged versus simultaneous resection and reconstruction to establish superiority of either approach.
- Based on the available literature, she would benefit from both resection and reconstruction. To minimize the number of surgeries, she could have the procedures simultaneously.

Question 2: In children with calcaneonavicular (CN) tarsal coalition and flatfoot deformity, what are the indications for coalition resection alone, flatfoot reconstruction alone, versus combined resection and concomitant flatfoot reconstruction?

Relevance

CN is the most common type of tarsal coalition, representing 54% of all coalitions.[12] Although deformity is more common in TC coalitions, CN coalitions can also present with flatfoot deformity causing pain and disability. Unlike TC coalitions, CN coalitions do not involve a joint. They act as an extra-articular tether, limiting movement through otherwise healthy cartilage.

Clinical comment

The presentation of planovalgus deformity with TC or CN coalition is similar. Some feet may have more than one coalition present.[13] It is important to obtain CT or magnetic resonance imaging (MRI) to delineate the type and location of coalition(s) as they are not always easily visualized on x-ray. Symptoms typically develop at a younger age in CN coalitions (aged 8–12 years) compared to TC coalitions at age 12–16 years.[14]

CT confirms CN coalition and standing x-rays demonstrated flatfoot deformity. Are this patient's symptoms more from the coalition or from flatfoot deformity? Should both be treated surgically?

Available literature and quality of the evidence

- Level III: 1 retrospective case control.[13]
- Level IV: 3 retrospective case series.[6],[7],[14]

Findings

Wilde et al. comment that outcomes of CN coalition resection and graft interposition are generally better than TC coalitions.[4] Newer literature calls this into question. Khoshbin et al. followed 24 patients for an average of 14.4 years following coalition resection and graft interposition (19 CN, 13 TN).[7] They found no significant difference in clinical outcomes at any point between the coalition types. They reported on two patients, one with CN and the other with TC coalition, who underwent additional procedures for planovalgus deformity correction. Given the good to excellent clinical outcome scores and low rate of subsequent surgery for deformity correction, they advocated resection and graft interposition alone for both coalition types.

Mahan et al. likewise followed a group of both TC and CN coalitions for an average of 4.6 years after resection and graft interposition.[6] Both coalition types demonstrated significant and maintained improvement in clinical function as assessed by AOFAS scores and UCLA activity scores. They, like Khoshbin et al., did not find a significant difference between the coalition types. Average ankle valgus preoperatively was also the same between CN and TC coalitions.

To further evaluate resection and interposition of CN coalitions, Masquijo et al. retrospectively reviewed 56 patients' clinical outcomes using different interposition materials: fat, bone wax, and extensor digitorum brevis

muscle.[15] They found that all groups had significant improvement in AOFAS scores and pain VAS scores. However, the fat graft and bone wax patients had significantly better postoperative pain and AOFAS scores. Coalitions radiographically recurred in eight patients and of these, five patients, all in the EDB group, were surgically revised due to pain at the coalition. The authors conclude that resection and graft interposition results in significant clinical improvement despite graft type, but fat and bone wax are superior to EDB for interposition material.

Only study to date examines flatfeet with CN coalitions. Quinn et al. report improved radiographic outcomes in seven patients treated with simultaneous CN coalition resection and flatfoot reconstruction compared to 20 patients treated with resection alone.[16] Clinical outcome scores were not measured. Surgical techniques included gastrocnemius and soleus fascia release, calcaneal osteotomy, and/or midfoot osteotomy to achieve correction of the flatfoot deformity.

Resolution of clinical scenario

- If CT/MRI imaging confirmed an isolated CN coalition in this young patient, excision and interposition could be expected to result in improved functional outcomes.
- Excellent mid and long-term clinical outcomes have been demonstrated with resection and graft interposition with various materials, with recent superiority shown for fat graft and bone wax over EDB.
- Improved radiographic outcomes can be achieved with flatfoot deformity correction at the time of resection, but to date no study has compared outcomes of flatfoot reconstruction performed at the time of CN coalition resection versus staged after resection.

Question 3: In children with tarsal coalition and flatfoot deformity, when is arthrodesis of the subtalar joint indicated?

Rationale

Subtalar or triple arthrodesis is traditionally the treatment for large TC coalitions deemed unresectable by the Wilde et al. criteria.[4],[17],[18] Reported indications include secondary degenerative arthrosis, particularly in adults, and persistent pain with or without concomitant deformity.[4],[18],[19] No study has examined the long-term effects of arthrodesis for coalition, but known long-term sequelae of subtalar and triple arthrodesis in adults include adjacent joint arthritis, difficulty ambulating on uneven surfaces, and limitations in activity.[20],[21]

Clinical comment

This patient's coalition is resectable per the Wilde criteria, though her hindfoot deformity is at the upper acceptable limit at 16°. She has normal cartilage thickness in the posterior facet (Figure 188.1).

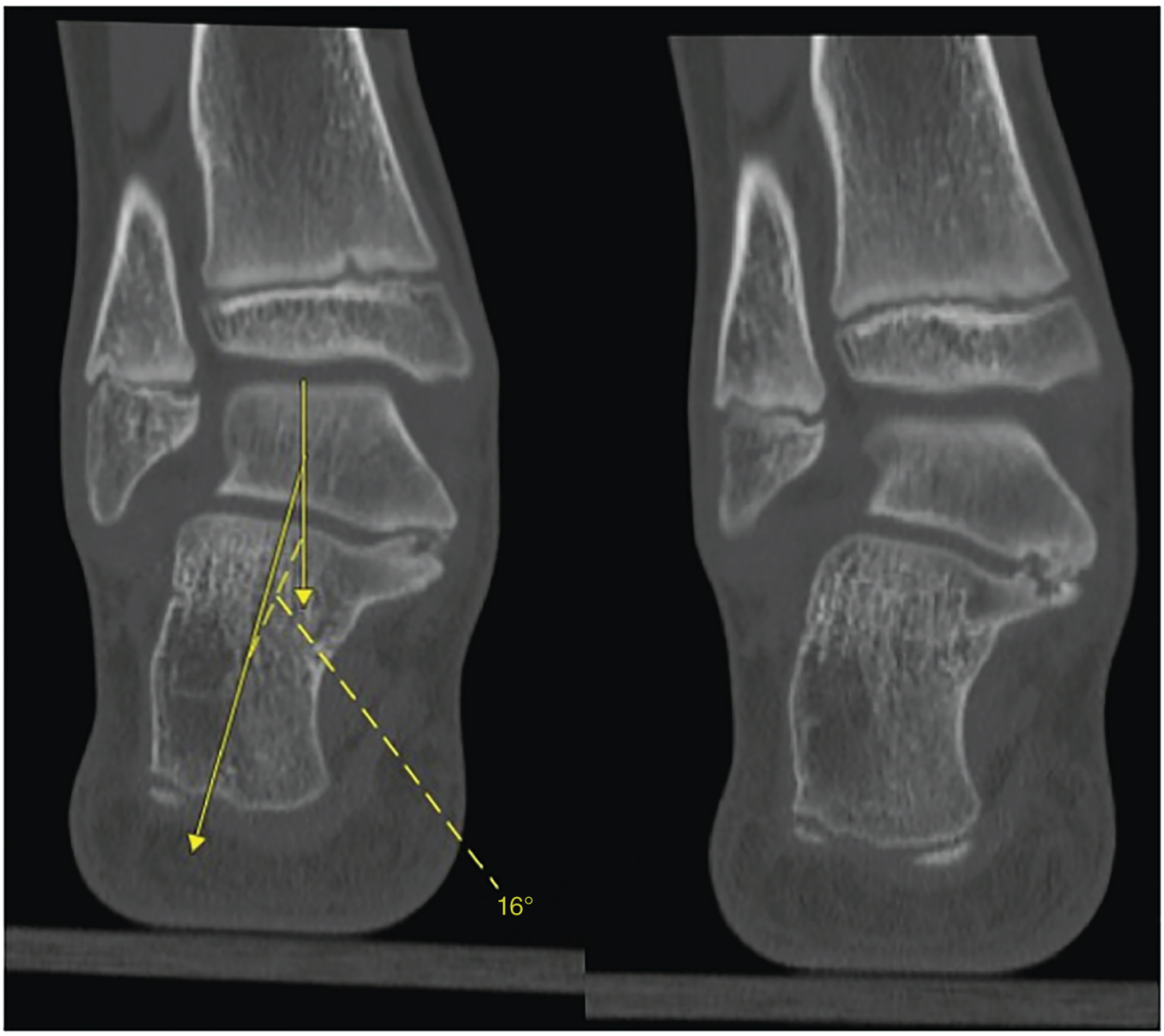

Figure 188.1 Preoperative CT scan demonstrating an osseofibrous middle facet TC coalition with a surface area measuring 30%. Hindfoot valgus measures 16°. The posterior facet is maintained, although is thin relative to the ankle joint. Source: Joseph Fox, Maryse Bouchard.

Would subtalar arthrodesis be a good solution to achieve deformity correction and prevent the possibility of deformity progression if the coalition were resected? Are the Wilde criteria predictive of need for arthrodesis?

Available literature and quality of the evidence

- Level III: 1 retrospective cohort study.[22]
- Level IV: 1 Retrospective case series,[4,17–19,23–25] and 2 biomechanical analyses.[20,21]

Findings

Wilde et al. noted poor outcome with resection of a coalition if the surface area is >50% of the calcaneal posterior facet, hindfoot valgus is >16°, there is narrowing of the posterior facet of the subtalar joint, or impingement of the lateral talar process on the calcaneus.[4] Luhmann et al. reported poor outcomes when valgus exceeded 21°.[19] Both studies advocate for arthrodesis in the setting of an *unresectable* subtalar coalition. Some studies have since called these criteria into question.

Khoshbin et al. followed 32 tarsal coalitions (19 CN and 13 TC) for an average of 13 years and found favorable clinical outcomes with resection irrespective of coalition size and hindfoot valgus.[7] Mahan et al. showed no difference in outcome scores or activity limiting foot pain between those with and without hindfoot valgus >16° and coalition surface area greater or less than 50% treated with resection alone at medium-term follow-up.[6]

Although many studies employ the Wilde criteria to determine resectability of the coalition, the only consistently described indication for arthrodesis was the presence of degenerative changes of the subtalar joint posterior facet.[8–11]

Long-term results of hindfoot and triple arthrodesis in adults without neuromuscular conditions demonstrate >50% of patients develop adjacent ankle arthrosis, difficulty with uneven ground, and pain with mild to moderate activity.[20,21] Cadaveric studies showed altered ankle biomechanics with increased peak pressure in the

ankle joint following subtalar and triple arthrodesis.[23,24] Despite this, most patients reported satisfaction with the treatment.[20,21]

The only long-term studies evaluating clinical results of triple arthrodesis in children are in patients with neuromuscular conditions.[22,25] In Saltzman et al.'s study with over 40-year follow-up, progressive ankle arthritis was observed in 100% of patients with 69% reporting overall function as *fair*.[22] These patients predominantly suffered from poliomyelitis. In the cerebral palsy population, Trehan et al. reported low rates of ankle arthritis (11.5%), high overall satisfaction (95%), and pain-free ambulation (62%) at 10 years.[25] These patients have different underlying pathology, deformity, and treatment goals than otherwise healthy children with coalitions, and therefore these results may not apply.

Khoshbin et al. reported on reoperation rates after resection of TC and CN coalitions in 304 young adults with an average age of 24.2 years.[26] Concomitant arthrodesis (typically subtalar) at the time of resection was found to be an independent risk factor for subsequent adjacent-joint arthrodesis with a hazard ratio of 9.7 and an overall rate of 5.3%.

Schwartz et al. described subtalar joint distraction arthrodesis (the technique of fusion with addition of a bone block in the joint to restore alignment) in eight pediatric patients with TC coalitions and hindfoot valgus.[27] Postoperative AOFAS scores were an average of 90.1/94 with a 25-month mean follow-up. They report good deformity correction but do not describe preoperative valgus or health of the posterior facet.

There are no studies directly comparing arthrodesis to deformity correction in flatfeet with coalitions.

Resolution of clinical scenario

- The only consistently reported indication for primary arthrodesis for tarsal coalitions is the presence of degenerative changes of the subtalar posterior facet. Size of the coalition as a criterion for fusion has been refuted in subsequent studies, suggesting the Wilde criteria are not predictive of the need for arthrodesis.
- Long-term level IV evidence demonstrates a high risk of adjacent joint degeneration following subtalar joint arthrodesis for TC coalitions. Several large, long-term studies of subtalar joint and triple arthrodesis in neuromuscular patients show high rates of ankle arthritis, with fair to good clinical function, but these studies are not directly applicable to healthy active patients.
- No long-term studies exist reporting functional outcomes or activity level of subtalar fusion in an average, active pediatric population.
- If CT/MRI imaging confirmed a TC coalition <50% the width of the posterior facet, this patient's coalition would be deemed resectable by Wilde criteria, and with the posterior subtalar joint cartilage being healthy, she would not meet criteria for arthrodesis (Figure 188.1).

Summary of answers

- In flatfeet with symptomatic tarsal coalitions, correction of the deformity is recommended in addition to resection to prevent worsening of the deformity and to address all sources of pain.
- Simultaneous flatfoot reconstruction and coalition resection is preferred to obviate the need of a second surgery.

- There is no evidence to support a particular technique of flatfoot correction, but we recommend calcaneal lengthening osteotomy with its associated procedures as it provides a powerful correction and does not rely on movement within the subtalar joint.
- We recommend resecting the coalition if it is painful at the site of the coalition and the posterior facet joint is healthy. If there is hindfoot valgus and a flatfoot, deformity correction should be performed simultaneously to prevent possible worsening of deformity and pain.
- CN coalition resection and graft interposition results in excellent long-term clinical outcomes.
- Fat and bone wax interposition shows superior outcomes in a level III study.
- Limited evidence is available regarding concomitant flatfoot reconstruction with CN resection.
- Primary arthrodesis for tarsal coalitions leads to adjacent joint arthritis and should be avoided unless posterior facet subtalar cartilage already demonstrates degenerative changes.

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