Proximal and distal humeral fractures

Outcome of primary arthroplasty

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“Ég held ekkert um það sem ég veit”

Truck driver in the film *Children of Nature*
by *Friðrik Þór Friðriksson* from 1991

Abstract

This thesis deals with both proximal humeral fractures and elbow injuries, especially distal humeral fractures. The main focus is difficult fractures in the elderly. Few randomized controlled trials (RCTs) are available to guide treatment choices. If the joint surface is considerably affected (for example by comminution and displacement), arthroplasty is a treatment option. Comparing more recently introduced types of arthroplasty with established types lies at the center of this thesis.

In **Study I**, *reverse total shoulder arthroplasty* (rTSA) was compared with *hemiarthroplasty* (HA), which was the established type of arthroplasty for proximal humeral fractures for many years. The understanding that tuberosity healing has a positive effect on the outcome of HA following the treatment of proximal humeral fractures is widespread. The available evidence has not, however, previously been summarized in a meta-analysis, which was done in **Study II**.

In **Study III**, *elbow hemiarthroplasty* (EHA) was compared with *total elbow arthroplasty* (TEA), an established treatment for distal humeral fractures. *Patient-reported outcome measures* (PROMs), such as the *Oxford Elbow Score* (OES), are used increasingly to assess outcome. A short recall period may have advantages for PROMs. The effect of shortening the recall period for the *Oxford Elbow Score* was explored in **Study IV**.

Study I: In an RCT, of patients with 3- or 4-part proximal humeral fractures (≥ 70 years of age), the mean Constant score was higher for patients treated with rTSA (n = 41) than for patients treated with HA (n = 43, 58.7 vs. 47.7, 95% CI: 3.0–18.9) as was mean flexion (125° vs. 90°, 95% CI: 20–49) and abduction (112° vs. 83°, 95% CI: 15–43).

Study II: In a systematic review and meta-analysis, tuberosity healing (n = 317) was found to provide better function than failed tuberosity healing (n = 217) for patients treated with HA for proximal humeral fractures with better Constant scores (mean difference (MD) = 10.8 points, 55.4 vs. 44.6, 95% CI: 3.8–17.9) and flexion (MD = 34°, 107° vs. 73°, 95% CI: 23–46).

Study III: In an RCT, patients (≥60 years of age) with unreconstructable distal humeral fractures had similar function following treatment with EHA (n = 18) and TEA (n = 17) in terms of mean *Disabilities of the arm, shoulder and hand*

(DASH) scores (21.6 vs. 27.2, 95% CI: −7.5–18.6) and *Mayo elbow performance scores* (MEPS, 85.0 vs. 88.2, 95% CI: −8.9–15.4).

Study IV: When used with a 7-day recall period, the OES demonstrated good measurement properties based on an analysis of 75 patients, in terms of construct validity, responsiveness and reliability.

In conclusion, rTSA provides better shoulder function than HA for elderly patients with displaced 3- and 4-part proximal humeral fractures and is preferable to HA, at least in most elderly women. Moreover, tuberosity healing provides better shoulder function than failed tuberosity healing after treatment with HA for a proximal humeral fracture. For unreconstructable distal humeral fractures, EHA and TEA provide similar function, at least in elderly women. Other factors, such as activity level, should be considered when choosing between these treatment options. The results of **Study IV** further establish the *Oxford Elbow Score* as a well-validated, elbow-specific PROM and support the use of a 7-day recall period.

Sammanfattning

Denna avhandling handlar om frakturer på övre och nedre änden av överarmen samt även om utvärdering av armbågsfunktion. Huvudfokus ligger på svåra frakturer hos äldre vilket är beforskat endast i ett fåtal randomiserade studier. Protes är ett behandlingsalternativ om ledytan är avsevärt skadad (till exempel tunna och felställda bitar) och i två studier jämförs nyare proteskoncept med tidigare etablerade typer av protes.

I **Studie I** jämfördes behandling med omvänd axelprotes med halvprotes vilket under många år varit den etablerade behandlingen för icke reparerbara frakturer på övre änden av överarmen. Inläkning av tuberkulum majus anses ha en positiv effekt på resultatet efter behandling av frakturer på övre änden av överarmen med halvprotes. Studier av ämnet har dock inte sammanfattats i en litteraturöversikt vilket gjordes i **Studie II**.

I **Studie III** jämfördes halvprotes med helprotes som har varit den etablerade behandlingen för icke reparerbara frakturer på nedre änden av överarmen. Patientrapporterade utfallsmått som Oxford Elbow Score (OES) används alltmer. ”Recall period” är den tidsperiod patienter ombeds att utgå ifrån och värdera när frågor på patientrapporterade utfallsmått besvaras. Det kan ha fördelar att ha en kort ”recall period”. I **Studie IV** undersöktes effekten av att korta ”recall perioden” för OES från 28 till 7 dagar.

Studie I: En randomiserad studie där behandling med omvänd axelprotes (n = 41) eller halvprotes (n = 43) jämfördes för patienter (70 år och äldre) med frakturer på övre änden av överarmen (3- eller 4-delar). Patienter behandlade med omvänd axelprotes hade bättre axelfunktion i form av fler poäng i Constants score och bättre rörelseomfång (flexion och abduktion).

Studie II: En litteraturöversikt visade att patienter som hade inläkt tuberkulum majus efter behandling av en fraktur på övre änden av överarmen med halvprotes hade bättre axelfunktion än patienter där tuberkulum majus inte läkt fast eller läkt i felaktig position. Patienter med inläkt tuberkulum majus hade fler poäng i Constants score och bättre lyftförmåga (flexion).

Studie III: En randomiserad studie där behandling med halvprotes (n = 18) eller helprotes (n = 17) jämfördes för patienter (60 år och äldre) med fraktur på nedre änden av överarmen som ej var möjlig att reparera med plattor och skruvar.

Behandlingarna resulterade i likvärdig armbågsfunktion. Grupperna hade jämförbara resultat avseende poäng i *Disabilities of the arm, shoulder and hand* (DASH) score och *Mayo elbow performance score* (MEPS) och även jämförbara resultat avseende rörelseomfång (böjning och sträckning).

Studie IV: OES hade bra mätegenskaper när det användes med en 7-dagars ”recall period” i stället för den ursprungliga 28-dagars ”recall perioden”.

Sammanfattningsvis ger omvänd axelprotes bättre axelfunktion än halvprotes för behandlingen av frakturer på övre änden av överarmen (3- och 4-delar) hos äldre patienter, åtminstone för äldre kvinnor **(Studie I)**. För patienter behandlade med halvprotes är axelfunktionen bättre om tuberkulum majus är inläkt än om den ej är inläkt eller har läkt på fel plats **(Studie II)**. För frakturer på nedre delen av överarmen som ej går att laga med platta och skruvar på grund av för dåligt fäste ger behandling med halvprotes och helprotes jämförbar armbågsfunktion **(Studie III)**. Andra faktorer än funktion, så som aktivitetsnivå, kan beaktas vid val av behandling. Resultaten av **Studie IV** stödjer att en 7-dagars ”recall period” kan användas för Oxford Elbow Score (OES).

List of papers

Study I Eythor Ö. Jonsson, Carl Ekholm, Björn Salomonsson, Yilmaz Demir, Per Olerud, and Collaborators in the SAPF study group*

Reverse total shoulder arthroplasty versus hemiarthroplasty for displaced 3- and 4-part proximal humeral fractures in patients older than 70 years. A multicenter randomized controlled trial

Journal of Shoulder and Elbow Surgery. 2021; 30(5):994-1006.

*SAPF (Swedish Arthroplasty for Proximal humeral Fracture) study group: Mikael Etzner, MD, Robert Ihrman, MD, Anders Nordqvist, MD, PhD, Johan Scheer, MD, PhD, Fredrik Westman, MD

Study II Eythor Ö. Jonsson, Marléne Evaldsson, Fredrik Einarsson, Lars Adolfsson, Jón Karlsson

Tuberosity healing provides better function than failed tuberosity healing after hemiarthroplasty for proximal humeral fracture: systematic review and meta-analysis

Manuscript

Study III Eythor Ö. Jonsson, Carl Ekholm, Hanna Björnsson Hallgren, Jens Nestorson, Mikael Etzner, Lars Adolfsson

Elbow hemiarthroplasty and total elbow arthroplasty provide similar functional outcome for unreconstructable distal humeral fractures in patients aged 60 years or older: a multicenter randomized controlled trial

Manuscript

Study IV Eythor Ö. Jonsson, Johan Wänström, Hanna Björnsson Hallgren, Lars Adolfsson

The Oxford elbow score demonstrated good measurement properties when used with a shortened 7-day recall period

Submitted to JSES International

Abbreviations

AO	Arbeitsgemeinschaft für Osteosynthesefragen
ASES	American Shoulder and Elbow Surgeons
AVN	Avascular necrosis
COSMIN	COnsensus-based Standards for the selection of health status Measurement INstruments
DASH	Disabilities of the Arm, Shoulder and Hand
EHA	Elbow hemiarthroplasty
EQ-5D	An outcome instrument for assessing generic health-related quality of life, developed by the EuroQol group
FE	Fixed-effects
FTH	Failed tuberosity healing
HA	Hemiarthroplasty
HH	Head height
HR	Health-related
HTD	Head-tuberosity distance
HW	Head width
ICC	Intraclass correlation coefficient
IMN	Intramedullary nail
JRF	Joint reaction force
MD	Mean difference
MDC	Minimal detectable change
MEPS	Mayo Elbow Performance Score
MID	Minimal important difference
MINORS	Methodological index for non-randomized studies
NRS	Numerical rating scale
OES	Oxford Elbow Score
ORIF	Open reduction and internal fixation

OTA	Orthopaedic Trauma Association
PHILOS	Proximal Humeral Internal Locking System
PICO	Population, Intervention, Comparison and Outcomes
PRO	Patient-reported outcome
PROM	Patient-reported outcome measure
PROMIS	Patient-Reported Outcomes Measurement Information System
RCT	Randomized controlled trial
RE	Random-effects
ROB	Risk-of-bias
ROM	Range of motion
rTSA	reverse total shoulder arthroplasty
SANE	Single Assessment Numeric Evaluation
SDC	Smallest detectable change
SMD	Standardized mean difference
SPMSQ	Short Portable Mental Status Questionnaire
SST	Simple Shoulder Test
TA	Transcondylar axis
TEA	Total elbow arthroplasty
TH	Tuberosity healing
TSA	Total shoulder arthroplasty
UCLA	University of California, Los Angeles
VAS	Visual analogue scale
WOOS	Western Ontario Osteoarthritis of the Shoulder

Overall aims and research questions

This thesis deals with both proximal humeral fractures and elbow injuries, especially distal humeral fractures. The main focus is comparing more recently introduced types of arthroplasty with established types, for the treatment of severe fractures in elderly patients. In **Study I**, *reverse total shoulder arthroplasty* (rTSA) was compared with *hemiarthroplasty* (HA) for treating proximal humeral fractures. In **Study II**, the functional outcome of patients with tuberosity healing was compared with failed tuberosity healing, following the treatment of a proximal humeral fracture with HA. In **Study III**, *elbow hemiarthroplasty* (EHA) was compared with *total elbow arthroplasty* (TEA) for treating distal humeral fractures. In **Study IV**, the effect of using the Oxford Elbow Score with a shortened 7-day recall period on measurement properties was studied.

Study I Does reverse total shoulder arthroplasty (rTSA) provide better shoulder function than hemiarthroplasty (HA), using the Constant score as the primary outcome measure, for displaced 3- and 4-part proximal humeral fractures in elderly patients?

Study II Does tuberosity healing provide better functional outcome than failed tuberosity healing after treatment with hemiarthroplasty (HA) for a proximal humeral fracture?

Study III Does elbow hemiarthroplasty (EHA) provide better functional outcome than total elbow arthroplasty (TEA) for unreconstructable distal humeral fractures in elderly patients using the DASH score as primary outcome measure?

Study IV Does the Oxford Elbow Score (OES) have good measurement properties when used with a shortened 7-day recall period (OES-7d)?

Content

1.

Introduction

BACKGROUND

The treatment of fractures has changed a great deal since the middle of the 20th century and has become increasingly active. Nevertheless, for some types of fractures, it is still not possible to obtain acceptable treatment results with any consistency. Not surprisingly, the optimal treatment of these injuries is controversial. They include proximal humeral fractures that have multiple displaced fragments (comminuted fractures) affecting the shoulder joint and fractures of the distal humerus that lie very distally, severely affecting the elbow joint (Figure 1). These injuries are not only most common in elderly patients[85] but are also particularly problematic due to the poor bone quality (porous bone providing insufficient screw purchase) often encountered. None of the currently available treatment options (non-surgical treatment, open reduction and internal fixation and arthroplasty) restores function reliably. As non-surgical treatment can lead to considerable impairment,[2; 369] surgical methods have been introduced in an attempt to improve outcome. In the case of *open reduction and internal fixation* (ORIF, for example plate fixation), a commonly used surgical technique, fracture healing is dependent on the fixation being stable. Poor bone quality can jeopardize stability, leading in the worst-case scenario to failure of the fixation. With insufficient stability, mobilization can be painful, potentially resulting in stiffness. Although fracture healing is not as crucial for arthroplasty, it is still an issue. The healing of the tuberosities is generally believed to have a positive effect on the outcome of shoulder arthroplasty for proximal humeral fractures. Likewise, the healing of the epicondyles is important in order to obtain a stable joint after hemiarthroplasty for distal humeral fractures.

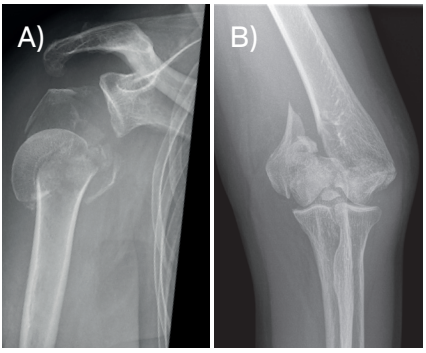

FIGURE 1 Radiographic appearance of displaced multifragment fractures of the proximal and distal humerus. **A)** Proximal humeral fracture. Both of the tuberosities (greater and lesser) and the humeral head are fractured and widely displaced. **B)** A fracture of the distal humerus resulting in multiple thin distal fragments. Medially the trochlea is broken distal to the inferior portion of the medial epicondyle and impacted up into the medial column.

The scientific basis for guiding treatment choices is limited in the case of proximal humeral fractures and even more so for distal humeral fractures. Randomized controlled trials (RCTs) are considered to be the most reliable type of study for comparing treatment methods, reflected by their placement at the highest level (Level I) in systems used to rate level of evidence.[290] RCTs of proximal humeral fractures are not abundant and those available are statistically fragile,[66] as most individual studies include only a modest number of patients. For distal humeral fractures, the evidence is even weaker, with only one study available that compares two fundamentally different treatment options.[250]

Summarizing the results of individual studies, randomized or non-randomized, can sometimes provide a clearer picture of a topic. This can, for example, be of help when individual studies are relatively underpowered. The available evidence is usually summarized through a structured review of the literature in a process termed "systematic review". In some cases, this can be the basis of a numerical summary, termed meta-analysis. Systematic reviews and meta-analyses have become established within the field of orthopedics during the past 15–20 years.

Subsequent to the shift towards more active fracture treatment, the need to assess the outcome in a structured way has become evident. A number of aspects are relevant when assessing the outcome of treatment, but the importance of capturing patients' perspectives (patient-reported outcome, PRO) has become increasingly recognized in orthopedics.[133] It is important that standardized questionnaires, known as *patient-reported outcome measures* (PROM), which are used increasingly to capture patient perspectives, have good validity, reliability and responsiveness. These three characteristics are referred to as measurement properties.[257] The *COnsensus-based Standards for the selection of health Measurement INstruments* (COSMIN) initiative has defined validity as "The degree to which an HR-PRO instrument measures the construct(s) it purports to measure"; reliability as: "The degree to which the measurement is free from measurement error "; and responsiveness as "The ability of an HR-PRO instrument to detect change over time in the construct to be measured".[257] Efforts to improve PROMs and their validity are continuously ongoing.

The main focus of this thesis is to compare new and promising types of treatment with more established treatment options. In **Study I**, *reverse total shoulder arthroplasty* (rTSA), a promising treatment option, is compared with *hemiarthroplasty* (HA) for displaced and comminuted proximal humeral fractures in elderly patients. In **Study II**, in order to summarize available knowledge comparing the outcome of patients with tuberosity healing and failed tuberosity healing following the treatment of a proximal humeral fracture

with hemiarthroplasty, a systematic review and meta-analysis was performed. In **Study III,** the focus was once again on comparing treatment options, where *elbow hemiarthroplasty* (EHA) was compared with the more established option of *total elbow arthroplasty* (TEA) for treating unreconstructable distal humeral fractures (e.g. not possible to repair with open reduction and internal fixation (ORIF)). Finally, in **Study IV**, the focus was to study the effect of shortening the recall period[383] of the *Oxford Elbow Score* (OES),[96] an established elbow-specific patient-reported outcome measure, in a cohort of patients with elbow injuries. The recall period of a PROM is the period of time patients are requested to consider when responding to items. As opposed to longer recall periods, shorter recall periods have potential advantages, such as being less affected by inaccurate memory in addition to being more suitable during a period of change in the constructs to be assessed.

PROXIMAL HUMERAL FRACTURES

Anatomy of the proximal humerus and shoulder joint

The integrity of the proximal end of the humerus and structures with which it is associated, such as the rotator cuff, are important for the optimal function of the glenohumeral joint.

The humerus is the largest and longest bone in the upper extremities.[360] The proximal end articulates with the scapula to form the shoulder joint and the distal end articulates with the bones of the forearm (radius and ulna) to form the elbow joint (Figure 2). The boundary between the shaft and the proximal end of the humerus can be seen as being at the lower end of the metaphyseal flare. A more formal definition is provided in the AO/OTA classification. The end segments of long bones, which correspond roughly to the metaphysis, are defined as the bone within the boundaries of a square of which the lengths of the sides correspond to the widest part of the metaphysis[252] (Figure 2).

Bony anatomy and the shoulder joint

The humeral head, which protrudes medially from the most proximal part of the humerus, corresponds to roughly 40% of a sphere[188; 303] (although actually slightly elliptical[173]) and is covered with cartilage. The humeral head forms the glenohumeral joint, together with the glenoid of the scapula. As the glenoid is only moderately concave, the glenohumeral joint has very limited bony constraints, allowing a high degree of mobility. This is, however, at the expense of inherent articular stability, with stability instead being heavily dependent on the soft tissues, such as the labrum, capsule and rotator cuff.

The circumference of bone immediately distal to the articular surface is known as the anatomical neck, which roughly corresponds to the insertion of the joint capsule (Figure 3). Just distal to the anatomical neck, there are two prominences, the greater and lesser tuberosities, which face laterally and anteriorly, respectively. They serve as the insertion points for the rotator cuff. The surgical neck is not as well defined anatomically, but consists of the metaphyseal bone connecting the tuberosities and humeral head to the shaft. Proximal humeral fractures are often located at the surgical neck. In a recent study by Hasan et al.,[160] 34 of 38 (81%) proximal humeral fractures analyzed with 3-dimensional computed tomography had a horizontal fracture component corresponding to the surgical neck as viewed from the anterior.

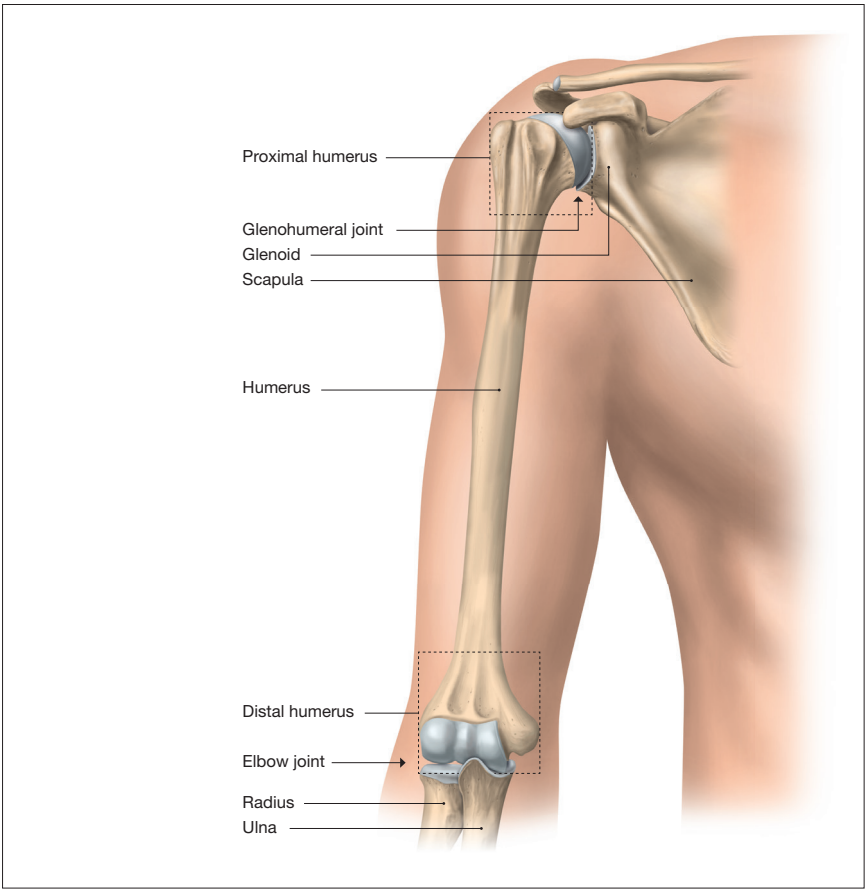

FIGURE 2 The humerus. The end segments, which can be understood as being the proximal and distal ends, are defined in the AO/OTA classification as the bone within the limits of a "square whose sides are the same length as the widest part of the epiphysis/metaphysis in question".[252] The boundaries of the proximal and distal end segments of the humerus are illustrated by squares with broken lines. The articular surface on the proximal end articulates with the glenoid on the scapula constituting the shoulder joint, or more specifically the glenohumeral joint. The articular surface on the distal end articulates with the proximal ulna and radius constituting the elbow joint, or more specifically the ulnohumeral and radiocapitellar joints, respectively.

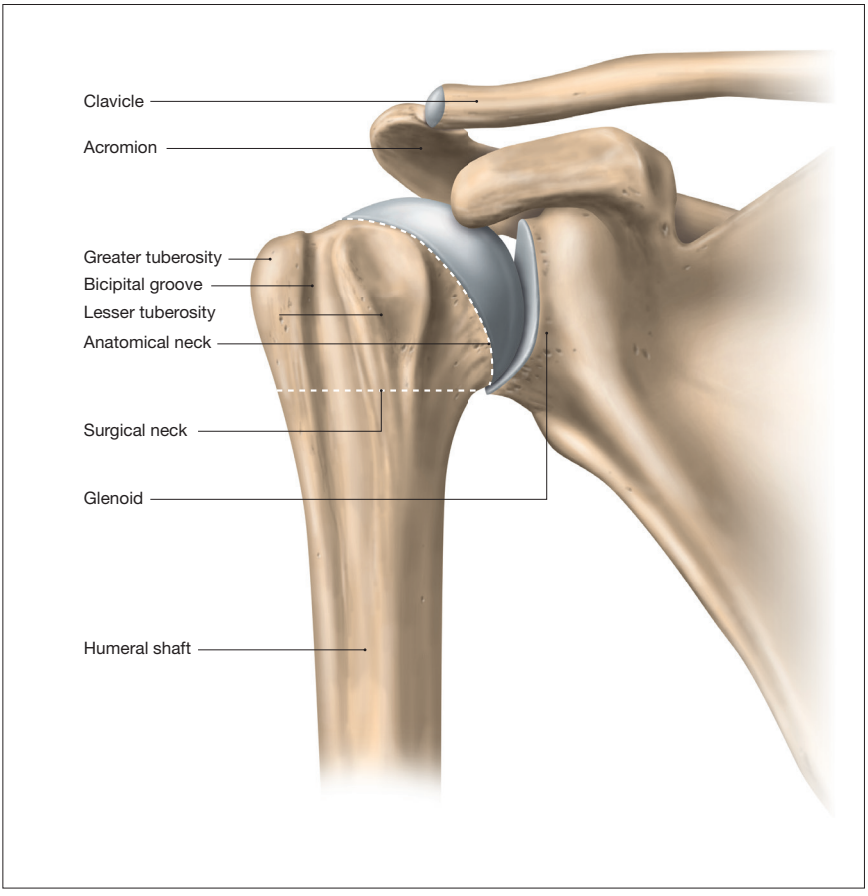

FIGURE 3 The bony anatomy of the proximal humerus, scapula and clavicle. The surgical and anatomical necks are depicted with broken white lines.

There are large variations in the dimensions of the proximal humerus (Figure 4).[47; 330] For instance, studies by Boileau et al. and Hertel et al. reported a mean width of the humeral head of 43 mm and 42–45 mm, respectively, while the combined range in these studies was 34–57 mm.[47; 164] Likewise the mean height of the humeral head has been reported to be 17–20 mm with a range of 13–24 mm.[164; 172; 303] As an anatomical position of the tuberosities is essential for the optimal biomechanical behavior of the rotator cuff and glenohumeral joint, malunion of the tuberosities is undesirable.[130] The head-tuberosity distance (HTD)[254] is a parameter used to characterize the position of the greater tuberosity in relation to

the humeral head (Figure 4) and it is commonly measured as described by Boileau et al.[45] Iannotti et al.[389] and Takase et al.[172] reported mean HTD values of 8 mm and 6.7 mm, respectively; the combined range in these studies was 2–20 mm. It is therefore clear that there is a wide variation in the dimensions of the proximal humerus which have been found to be dependent on the gender[389] and height of individuals.[137]

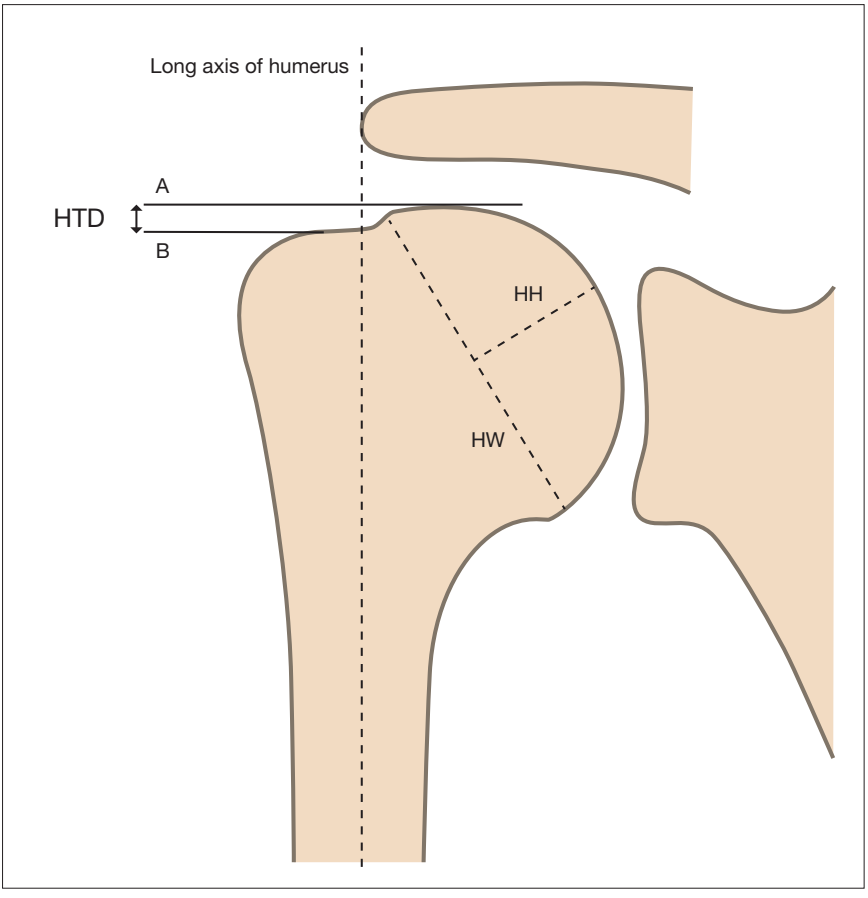

FIGURE 4 Measurement of the dimensions of the native humerus. A and B are lines that are both perpendicular to the long axis of the humerus (the humeral stem if applicable). Line A tangents the most proximal point of the humeral (or prosthetic) head. Line B tangents the most proximal point of the greater tuberosity. The difference between A and B constitutes the head-tuberosity distance (HTD). Most commonly positive numbers indicate that the tuberosity is distal to the most proximal point of the humeral head. HH, head height. HW, head width.

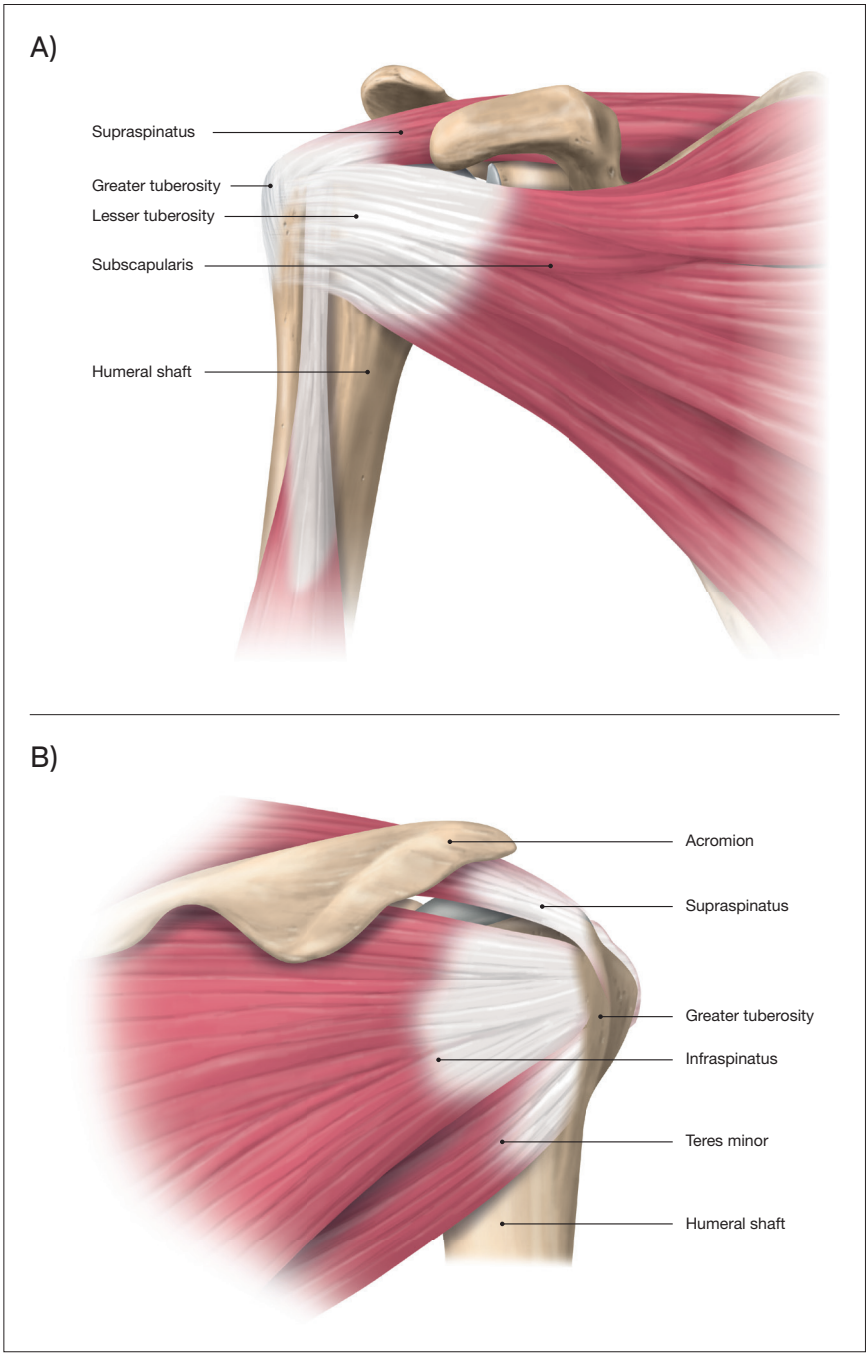

FIGURE 5 The rotator cuff. **A)** Anterior view illustrating the subscapularis and supraspinatus. **B)** Posterior view illustrating the supraspinatus and the external rotators: infraspinatus and teres minor.

The rotator cuff and motion of the shoulder

The rotator cuff, which performs a number of important functions, consists of four muscles: the supraspinatus, infraspinatus and teres minor muscles, all of which insert on the greater tuberosity, and the subscapularis, which inserts on the lesser tuberosity (Figure 5). The rotator cuff contributes to the direct movement of the glenohumeral joint: internal rotation (subscapularis), abduction (supraspinatus and infraspinatus) and external rotation (infraspinatus and teres minor). The rotator cuff also provides stability to the glenohumeral joint. Through a mechanism known as concavity compression,[231] the rotator cuff allows the deltoid muscle efficiently to provide power to elevate the shoulder without dislocating the joint. The deltoid is a large superficial muscle that originates on the scapular spine, acromion and lateral part of the clavicle and has a long (on average up to 70 mm) and broad insertion (on average up to 22 mm)[329] on the lateral side of the proximal third of the humerus.[329] The deltoid makes an important contribution to shoulder strength.[162] However, if acting in isolation (i.e. without a functioning rotator cuff), contraction of the deltoid results in only proximal translation of the humeral head. This leads to limited useful elevation but can cause painful impingement against the acromion (Figure 6A). When the deltoid acts in harmony with the rotator cuff, a strong and smooth elevation of the shoulder is ensured (Figure 6B).

When the anatomy and function of the shoulder are discussed, much of the focus is frequently directed towards the glenohumeral joint. Nevertheless, a considerable contribution to the elevation of the arm is made by the thoracoscapular joint, together with the sternoclavicular and acromioclaviclar joints. This contribution is estimated to be approximately 50°.[247] The significance of the thoracoscapular motion is well exemplified by the considerable mean flexion (72°) and abduction (59°) obtained by 18 patients treated with glenohumeral arthrodesis in a study by Dimmen and Madsen.[107]

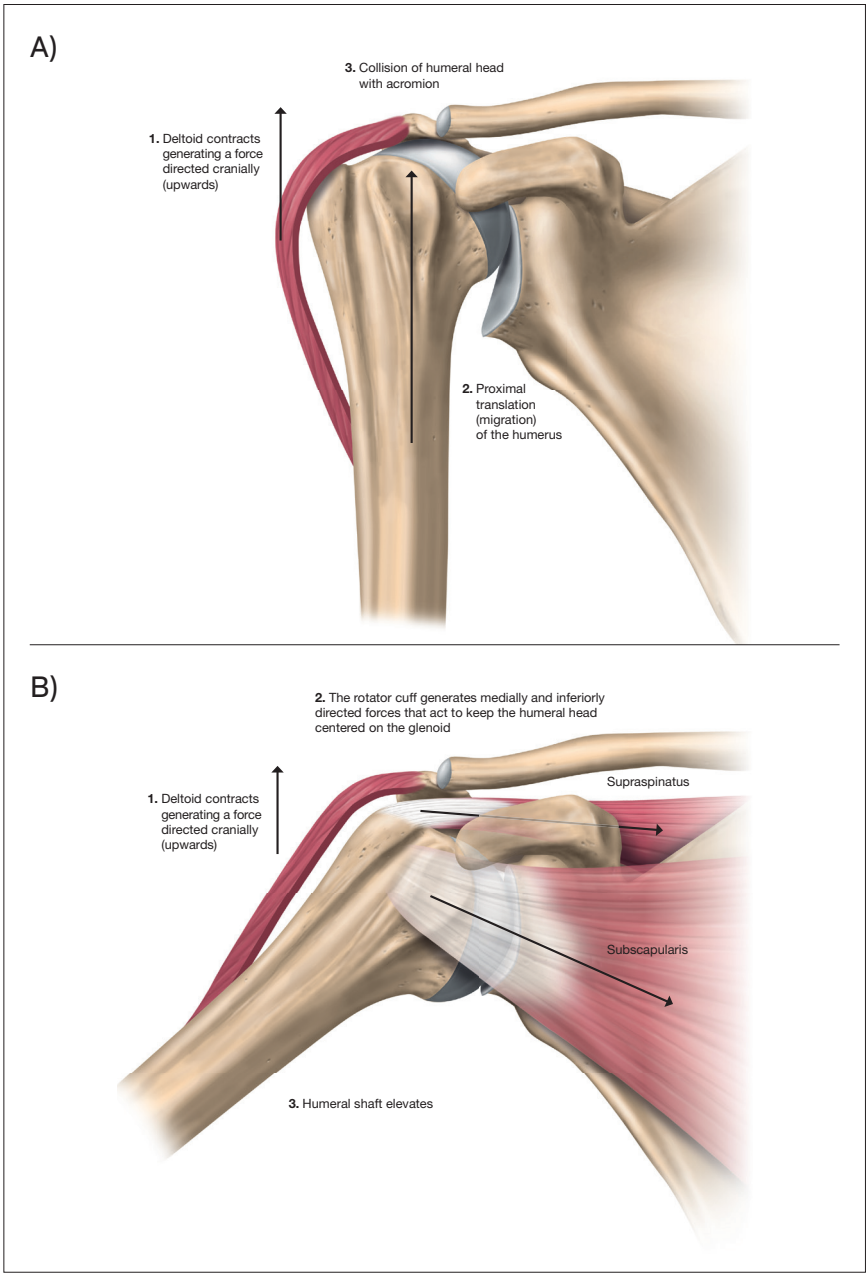

FIGURE 6 Coordinated action of the deltoid and the rotator cuff muscles ensures smooth, and strong shoulder movements. **A)** Acting in isolation, the contraction of the deltoid results in a proximally directed force that can lead to proximal migration (translation) of the humeral head relative to the glenoid, painful collision of the humeral head with the acromion but limited elevation. **B)** When the deltoid and rotator cuff work in harmony, the contraction of the deltoid ensures that shoulder elevation is strong but no translation occurs due to medially and inferiorly directed forces generated by the rotator cuff.

Classification of proximal humeral fractures

The appearance of proximal humeral fractures is commonly described based on the number of fragments present and their degree of displacement. This holds true both for formal classification and in everyday communication between healthcare professionals. As early as in 1934, Codman[80] stated that, for proximal humeral fractures, fracture lines commonly occur along the lines of epiphyseal union located between the former positions of the ossification centers: the humeral head, greater tuberosity, lesser tuberosity and humeral shaft (Figure 7A). This can potentially lead to four fragments (parts). These fragments can all occur simultaneously, in isolation or in various combinations. Codman's idea still forms the basis for describing the appearance of proximal humeral fractures. Muscle forces acting on the fragments can potentially lead to their displacement (Figures 7, B and C). Charles Neer refined these ideas and, in 1970, he published a new classification[275] that took displacement into consideration (Figure 8). If fragments were displaced over 1 cm or angulated over 45°, they were arbitrarily[277] defined as being displaced. Otherwise, fractures were considered minimally displaced (termed 1-part fracture), irrespective of the number of fracture lines. Two-part fractures are named according to the fracture line involved. Although 3-part fractures can theoretically be of multiple different types, Neer recognized that those involving the surgical neck and either greater or lesser tuberosity were most relevant and they were incorporated into the classification and named by the involved tuberosity. Other factors that are considered in the Neer classification include the occurrence of dislocation and involvement of the articular surface (head split).

In three recent studies, the occurrence of 1-part fractures was in the range of 13–24%, while 4-part fractures were consistently least prevalent (7–22%).[20; 174; 216] Bahrs et al.[20] and Launonen et al.[216] found that 2-part fractures were the most prevalent. Still today, the Neer classification dominates the literature and has heavily influenced many later classification systems, including the AO/OTA classification.[252]

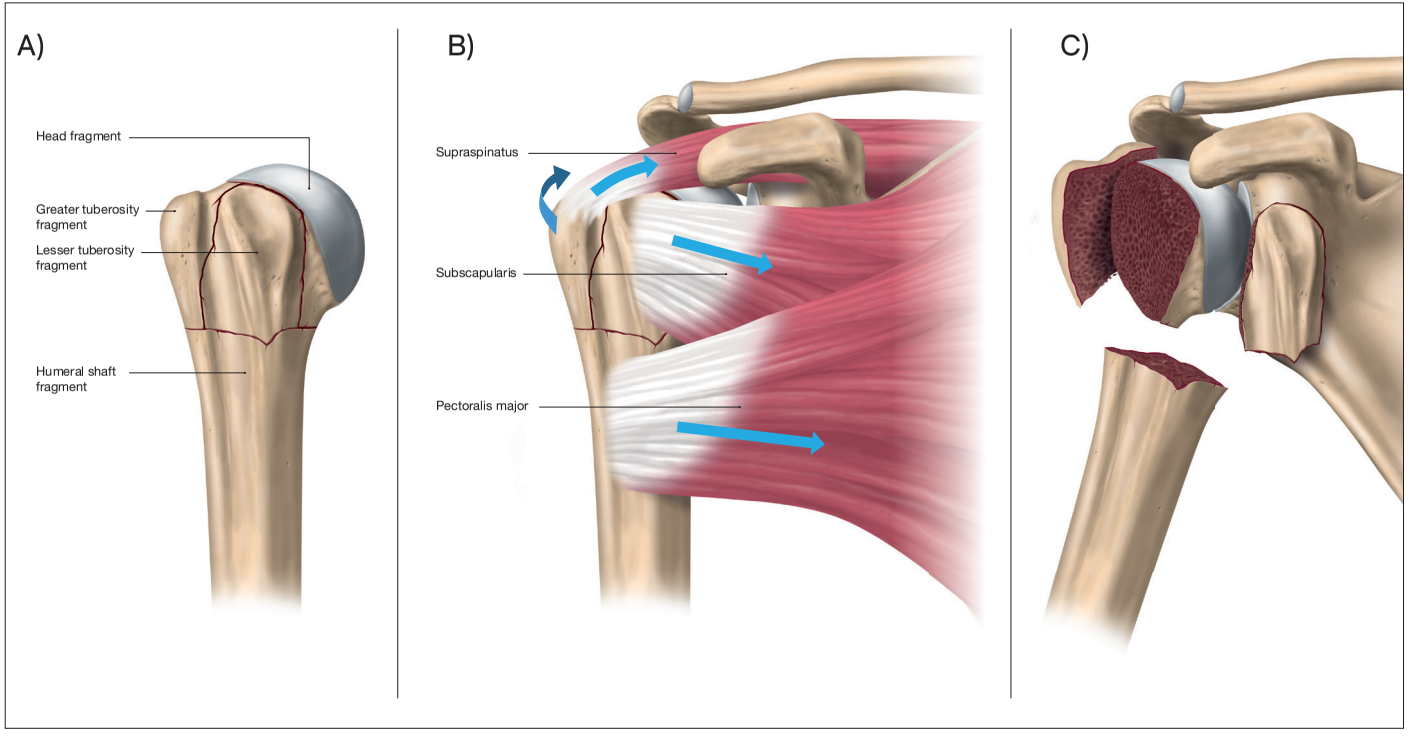

FIGURE 7 Commonly occurring patterns of fracture lines for proximal humeral fractures and direction of potential displacement. **A)** The fractures lines can occur in different combinations but, if all occur at the same time this results in the following fragments: humeral shaft, greater tuberosity, lesser tuberosity and humeral head. **B)** Muscle forces acting on the fragments can potentially lead to displacement. The pectoralis major exerts an antero-medially directed force on the humeral shaft. The subscapularis exerts a medially directed and internally rotating force on the lesser tuberosity. The supraspinatus pulls the greater tuberosity superiorly (and medially), while the infraspinatus and teres minor exert an externally rotating force on the greater tuberosity in addition to a medially directed force. **C)** Directions of typical fragment displacement.

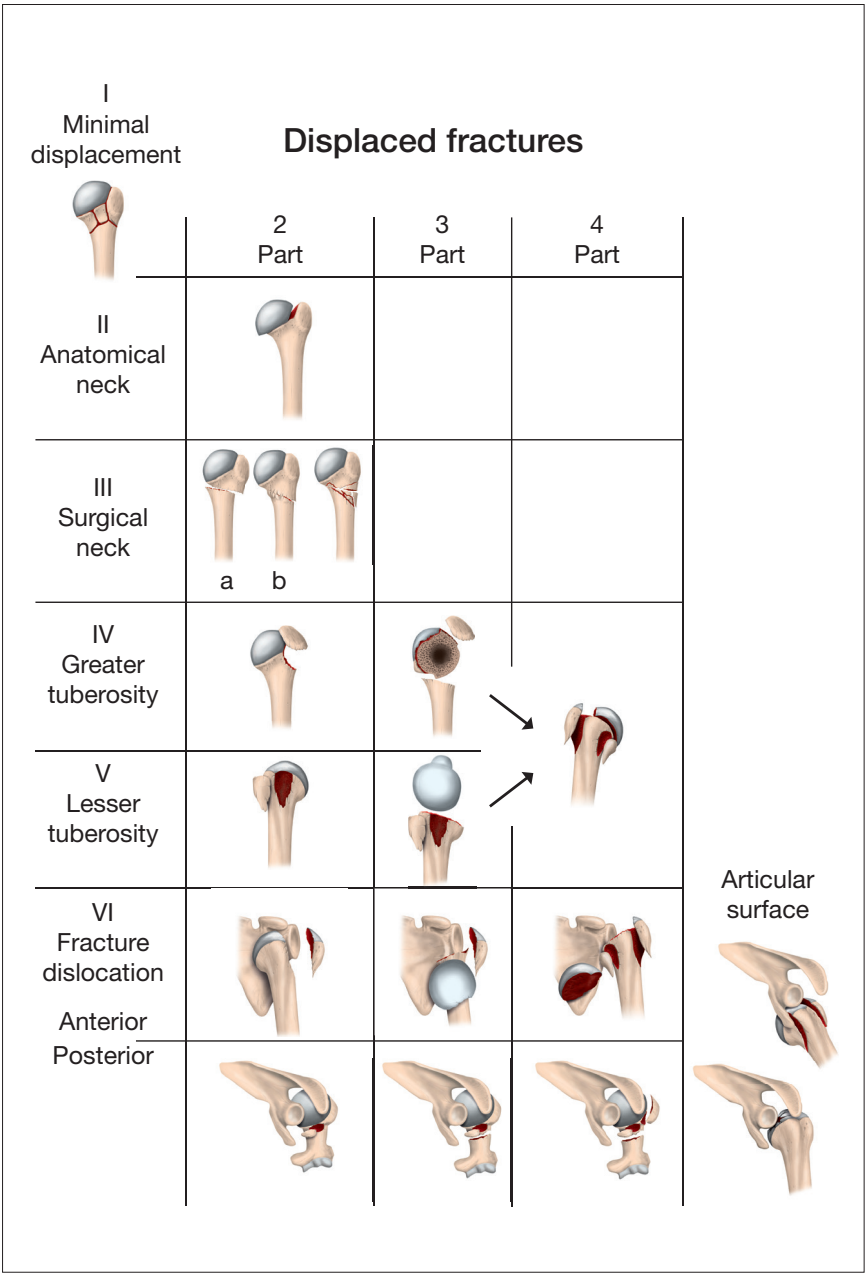

FIGURE 8 Neer's classification of proximal humeral fractures. In order to be considered a fragment (or segment using Neer's terminology), a displacement of over 1 cm or angulation of over 45° is required. Fractures with less displacement are considered minimally displaced (1-part), irrespective of the number of fracture lines. Fractures are classified according to the number of fragments into: 2-part, 3-part and 4-part fractures (top line). Other characteristics that are considered are the location of the fracture and the presence of displacement.

Epidemiology of proximal humeral fractures

Proximal humeral fractures are common. In a recent study, they were the fourth most common type of fracture (8.2%), trailing behind only fractures of the distal radius (16.4%), proximal femur (14.7%) and ankle (10.3%).[39] Estimates of incidence that take account of patients treated in both the in- and outpatient setting are scarce, but they have ranged from 60 to 120 proximal humeral fractures per 100,000 population.[36; 174; 385] The risk of sustaining a proximal humeral fracture (incidence) has increased in recent years[84; 226; 385] Combined with the predicted increase in the number of elderly individuals in the population,[400] it appears that the absolute number of proximal humeral fractures is bound to increase in the coming years. This will impose an increasing burden on both individuals and healthcare systems. With respect to age, the incidence of proximal humeral fractures is low before 50 years of age, whereafter it increases continuously.[36; 216; 385]

Not only does the risk of incurring a proximal humeral fracture increase with age, but the proportion of more severe fracture types does too. The occurrence of multi-fragment displaced proximal humeral fractures in elderly patients is of particular interest, as these are the patients most commonly considered for treatment with arthroplasty. In their studies, both Roux et al.[337] and Court-Brown et al.[85] found that 3- and 4-part fractures were uncommon in patients younger than 40 years, but, in patients older than 70 years of age, their frequency was 19% and approximately 15% respectively. According to data available to registered users, the combined frequency of head-split fractures, fractures of the anatomical neck and displaced 3- and 4-part fractures (including fracture dislocations) in patients over 70 years of age was 24% of all proximal humeral fractures in the Swedish Fracture Register[259] for 2020.[387] This corresponded to 14% of all proximal humeral fractures across all adult age groups.

Assessing outcome of proximal humeral fractures

A recent review found that the following outcome measures have been used in RCTs and comparative cohort studies of proximal humeral fractures; results of outcome instruments and the occurrence of complications and hardware problems.[286] Considering other study types as well, a number of other outcome measures emerge, such as mortality,[37] risk of surgical revision,[38] radiographic parameters (e.g. rate of healing)[50] and economic analysis.[287] Using the terminology presented by Poolman et al.,[315] most outcome instruments used in orthopedics are of two main types: patient-reported outcome measures (PROM) and *mixed clinician-based and functional outcome instruments,* hereinafter referred to as *mixed clinician-based* instruments. PROMs are instruments designed to assess

patient-reported outcome, the latter having been defined as: "…any report of the status of a patient's health condition that comes directly from the patient, without interpretation of the patient's response by a clinician or anyone else".[399] It follows that outcome instruments, which are administered by healthcare professionals (clinician based) or include results of clinical measurements (e.g. range of motion), such as the Constant score, are not PROMs.

Although the term *functional outcome* is ubiquitous in the literature relating to proximal humeral fractures, as well as orthopedics in general, the term is seldom defined. Some understanding of this term, as well as of other types of outcome measures, can be acquired from the five-level model of patient outcomes first suggested by Wilson and Carrey[417] in 1995 and revised by Ferrans et al.[120] in 2005. Biological function constitutes level one (e.g. healing according to radiographs), symptom status level two (e.g. pain which can be assessed on a visual analogue scale), functional status level three, general health perceptions level four and overall quality of life level five. The model does not suggest a hierarchy but emphasizes that all the levels can be influenced by the characteristics of the individual and environment. This influence increases at higher levels, leading to greater complexity and measurement difficulties. Moreover, it is assumed that a relationship exists between the levels, in particular that the lower levels affect the higher levels, e.g. that symptoms affect function which can in turn affect quality of life. Level three is discussed in the following paragraph. Level four is a general health perception, a concept closely related to health-related quality of life, which can be assessed with so-called generic PROMs. Assessing level five, which refers to quality of life in broad terms, including non-medical factors, is not deemed necessary in studies considering specific medical conditions.[315]

The concept of functional status deserves further attention. It was defined by Wilson and Carrey[417] as the ability of the individual to perform defined tasks. In their revised version of the model, Ferrans et al. emphasized the dimensions of functional status described by Leidy,[224] of which the first two have the most practical implications: functional capacity (maximum potential) and functional performance. The latter refers to everyday activities in broad terms, including physical, psychological, social, occupational and spiritual activities carried out on a day-to-day basis to meet basic needs, fulfil usual roles and ensure well-being. Using range of motion as an example, functional capacity would be assessed as the maximum achievable motion measured with a goniometer. Functional performance could be assessed with PROM items that enquire about functional performance relating to the particular joint (joint-specific PROMs) or disorder (disease-specific PROMs).

There is no universally accepted definition of the term "functional outcome". Both range of motion and PROMs are commonly referred to as assessing functional outcome, which appears reasonable considering the aforementioned theoretical framework. Considering range of motion (ROM) as a component of functional outcome is further supported by the results of Slobogean et al.,[364] who found that ROM explains a considerable proportion (0.38–0.70) of the variation in the results of PROMs completed by patients who have suffered a proximal humeral fracture.

In the following sections, aspects relating to the use of ROM and outcome instruments to assess the outcome in patients with proximal humeral fractures are discussed. This is of particular relevance to **Studies I and II**.

Range of motion

In clinical studies, range of motion is generally assessed with a goniometer. To interpret the results, information on normative values, the range of motion necessary for performing essential activities of daily life (including functional arc of motion) and the minimal detectable change (MDC) can be useful. In a study based on 2,404 adults (age 20 to 91 years of age) without a history of shoulder pain or stiffness, Gill et al.[141] found that the mean degrees of flexion were approximately 160°, abduction 150° and external rotation between 55–60°. In an interesting study, Namdari et al.[272] had 20 volunteers perform tasks enquired about in the American Shoulder and Elbow Surgeons (ASES) score,[325] the University of Pennsylvania Shoulder Score[222] and the Simple Shoulder Test (SST).[335] They defined functional range of shoulder motion as the mean flexion and abduction necessary to complete these tasks, 121° and 128°, respectively. Oosterwijk et al.[294] have provided a useful literature summary of the range of motion necessary for performing different activities of daily life. The minimal detectable change (MDC), also known as the smallest detectable change (SDC), is a useful parameter when interpreting the results of measurements. The MDC has been defined as the smallest change that can be detected beyond measurement error.[99] The MDC for elevation in the scapular plane has been estimated to be 8–10°,[206] values which appear reasonable to apply to the measurement of abduction and flexion. MDC estimates for external rotation using a goniometer and generated with sufficient methodology[99] are scarce.

Outcome instruments

In a systematic review of studies of proximal humeral fractures published between 2008 and 2018, Richard et al.[324] found that the most commonly used outcome instruments were (proportion of all studies) the Constant score (65%), DASH score

(31%), pain on visual analogue scale (27%) and ASES score (18%). In a systematic review of the outcome instruments used in shoulder arthroplasty literature, Hijji et al. also found that the Constant score was the most commonly used instrument (50%).[166] The DASH will be discussed further in the section on distal humeral fractures. Most of the outcome instruments used in shoulder surgery are of one of three main types: mixed clinician-based, joint- or disease-specific PROMs or generic PROMS. In the following section one outcome instrument representative of these three main types, and of relevance to **Studies I and II,** is discussed further.

Mixed clinician based: the Constant score

The Constant score is a shoulder-specific score first published in 1987.[83] The aim is not defined explicitly, but it is stated that the method provides an overall clinical functional assessment. Scores range between 0–100, with higher scores indicating better shoulder function. Three questions are aimed at patients but are probably most frequently posed by the clinician. One relates to pain (maximum 15 points) and the other two are related to activities of daily living (maximum 20 points). The remaining points are allocated depending on range of motion (flexion, lateral elevation, internal and external rotation; maximum 40 points) and strength (maximum 25 points, Figure 9). The general structure resembles that of the criteria for the evaluation of results published by Neer in 1970,[275] which was also scored from 0–100 and pain, function and range of motion were assessed in a similar way. In the Constant score, an assessment of strength replaced the assessment of anatomy in the Neer criteria.

FIGURE 9 Measurement of abduction strength for the Constant score. A number of different methods have been described. Constant et al.[82] recommended measuring with the shoulder in 90°of abduction in the scapular plane, with the forearm in pronation and the strap of the measuring device around the wrist.

The use of the Constant score has been questioned.[407] Modern outcome instruments are expected to be developed following a rigorously structured multi-step process that includes involving patient perspectives

in the selection of items and excluding items that perform poorly in statistical analysis (field testing).[100] In addition, instruments are expected to have sufficient measurement properties (validity, reliability and responsiveness)[257] that are assessed with proper methodology.[256] The Constant score was constructed before these ideas became widespread and some did not exist at all. It is therefore not reasonable to expect that the Constant score or other older outcome instruments (e.g. EQ-5D and the Mayo Elbow Performance Score, MEPS) will live up to modern requirements for the development of outcome instruments. Nevertheless, it is reasonable to expect that outcome instruments used in contemporary research will show sufficient measurement properties. The Constant score has been found to have adequate construct validity and responsiveness.[338] Issues with reliability have, however, been identified. Insufficient internal consistency has been indicated,[407] although this is of questionable relevance. Unidimensionality is a prerequisite for an analysis of internal consistency,[256] but it appears improbable that the Constant score is unidimensional.[311] Issues have been raised in relation to inter-rater reliability.[334] This is likely, at least in part, to be due to the limited instructions provided in the original publication on how to obtain the Constant score, in particular with respect to assessment of strength. In addition, it appears likely that many of the different language versions that are currently available were created before structured translational processes[31] became commonplace, possibly introducing local nuances. Indeed, Roucourt et al.[334] reviewed Constant score protocols from seven institutions in five European countries and found that they varied widely. This is obviously unfortunate.

The minimal important difference (MID), as well as the smallest detectable change mentioned previously, are concepts that can aid in the interpretation of differences in the results of outcome instruments. The concept of the MID as such was initially defined in 1989 by Jaersecke et al. as: "the smallest difference in score in the domain of interest which patients perceive as beneficial and which would mandate, in the absence of troublesome side-effects and excessive costs, a change in the patient's management".[180] Various methods have been used to estimate the MID, but the mean change method is most commonly used.[270] Estimates of the MID are likely to be dependent on the population under study and context,[355] being affected by factors such as diagnosis. There is only one MID estimate available for the Constant score for proximal humeral fractures specifically. Van de Water et al.[403] reported an MID value of 11.6, but, although 20 patients were included in the study, this value was derived on the basis of responses from only 5 patients. Available MID estimates, irrespective of diagnosis, range from at least 4.6 to 36.[150; 397] This wide range is possibly due to differences in context (e.g. diagnosis) but unfortunately probably also at least in part to the use of methodology not true to the original MID concept of determining the smallest difference perceived as

beneficial by patients. Gowd et al.[149] and Simovitch et al.[361] reported MID values of 5.1 and 5.7, respectively for shoulder arthroplasties and these might be the available estimates that are most relevant for interpreting the results of **Studies I and II**.

Disease-specific: WOOS index

There is only one outcome instrument available that has been specifically developed (disease-specific) for proximal humeral fractures.[285] This instrument, the Shoulder Function Index (SFInx), is a performance-based functional test which implies that a clinician rates the degree to which patients are able to perform a set of thirteen predetermined activities.[402] The SFInx was introduced in 2015, but it has not been used extensively. There is no PROM available that has been developed specifically to assess the outcome of patients with proximal humeral fractures.

One example of a PROM that was developed for a particular diagnosis (disease-specific) is the Western Ontario Osteoarthritis of the Shoulder (WOOS) index[232] that was used as a secondary outcome measure in **Study I**. The WOOS was developed in a structured manner that is well documented in the original publication. The process included input from patients at the item generation stage, item reduction as well as scaling and weighting. Moreover, the measurement properties were found to be good. The WOOS has not been validated specifically for fractures but was chosen as a secondary outcome parameter both because it is regarded as a well-developed and validated PROM and because it is used in the Swedish Shoulder Arthroplasty Register. The WOOS has been used in other studies of proximal humeral fractures.[8; 169] In one of these, Mannberg et al.[242] evaluated patients who had suffered a proximal humeral fracture 6 weeks earlier using the Patient Specific Functional Scale (PSFS) and the WOOS. Sixty-two percent of the items patients listed on the PSFS as being difficult to perform were found in the WOOS, which lends some support to its use in fracture patients.

Generic PROM: EQ-5D

The EQ-5D is a generic PROM that has been used extensively, in particular in Europe where it was developed. The Euroqol group that went on to develop the EQ-5D was established in 1987 with the aim "to test the feasibility of jointly developing a standardized non-disease-specific instrument for describing and valuing health-related quality of life".[116] The EQ-5D consists of five dimensions, each represented by one question assessing: mobility, daily activity and self-care, psychological functioning, social and role performance and pain and other health problems.[106] There were three response levels (3L) for each item, until a five-level

(5L) version was introduced in 2011.[163] The responses to the individual items can be summarized by calculating an index, for which values closer to 1 represent better health and values closer to 0 represent poorer health. Evidence relating to measurement properties such as responsiveness and reliability for the 3L version has been accumulated over time, while the 5L version was directly subjected to rigorous validation, the results of which have been favorable.[119]

A recent review of the use of the EQ-5D for patients with orthopedic upper extremity disorders by Grobet et al.[155] concluded that the available literature indicated good reliability, validity and moderate responsiveness. Olerud et al. [293] found that the EQ-5D had good responsiveness in a study specifically addressing proximal humeral fractures. A recent review summarizing available information on the measurement properties of PROMs for assessing the outcome of proximal humeral fractures recommended the use of the EQ-5D as a generic PROM, although the available evidence was somewhat limited.[285]

Treatment options for 3- and 4-part proximal humeral fractures in elderly patients

The choice of treatment for proximal humeral fractures stands between three main alternatives: non-surgical treatment, internal fixation or arthroplasty. Overall, most proximal humeral fractures are treated non-surgically. In a recent study from Sweden, 79% of proximal humeral fractures were treated non-surgically in 2016–2017.[38] This number is comparable to recent studies from some other countries: Finland (81%),[226] USA (82%)[302] and Spain (80%).[174] While there is general consensus that most minimally and non-displaced fractures can be treated non-surgically, the treatment of displaced fracture is all the more controversial.[14; 59]

The controversy regarding the surgical treatment of displaced proximal humeral fractures is largely based on evidence indicating that surgical treatment does not lead to a better outcome than non-surgical treatment. In fact, the latest Cochrane review[159] from 2015 found no clinically important differences in patient-reported outcomes between patients treated surgically or non-surgically for displaced proximal humeral fractures involving the surgical neck.[159] This does not, however, mean that no patients with proximal humeral fracture can benefit from surgical treatment. First of all, it should be noted that the conclusion relates to surgical neck fractures. This is due to the heterogeneity of the injuries included in the analysis. Although information on fracture type is difficult to discern, it is clear that 3- and 4-part fractures constituted 73% of the included fractures, with the remaining

27% presumably being mostly 2-part fractures, although a couple of 1-part fractures were included in the PROximal Fracture of the Humerus: Evaluation by Randomisation (ProFHER) study.[320] This raises the issue of how diverse the injuries referred to as proximal humeral fractures are. It can be convenient to refer to these injuries collectively in some situations. In other situations, such as when choosing treatment, it is important to recognize that these injuries border on being different diagnoses with different potential consequences. For instance, the potential consequences of a slightly displaced surgical neck fracture (e.g. risk of nonunion[147]) are very different from those of widely displaced 4-fragment fractures (e.g. poor rotator cuff function, deformity of the joint, in addition to nonunion). The data included in the Cochrane analysis are also heterogenous with respect to age (range: 31 to 92 years) and the type of surgical treatment (hemiarthroplasty, plate and tension band osteosynthesis of different types). It should also be noted that some of the included studies excluded patients with certain characteristics such as off-ended fractures,[217; 291; 292] less than 50% bone contact at the surgical neck[122] and fracture dislocations.[217; 320] To summarize, the Cochrane review tells us that for fractures of the surgical neck (with or without the involvement of the tuberosities) in adults of all ages, attempting to reconstruct the proximal humerus using an unspecified surgical method will not provide better shoulder function than non-surgical treatment. Although this is a very important conclusion that should be borne in mind when selecting treatment, it is non-specific. As a result, the characteristics of the individual patients and injury patterns need to be considered when choosing between non-surgical treatment and a specific type of surgical treatment. One large subgroup of patients not specifically accounted for in the Cochrane analysis are elderly patients with displaced 3- and 4- part fractures (14% of all proximal humeral fractures) who frequently experience disappointing function after non-surgical treatment.[339] These patients might benefit from a specific type of treatment, such as reverse total shoulder arthroplasty. The results of randomized studies comparing nonoperative and surgical treatment using contemporary methods are summarized in Table 1.

TABLE 1 Overview of randomized controlled trials comparing non-surgical treatment with surgical treatment using contemporary surgical techniques

			Type of fracture	Women	Age	Analyzed, n		Main results		
Type of operation	**Author**	**Year**		**%**	**Mean**	**Surgery**	**Non- surgical**	**Primary outcome measure***	**Flexion**	**Abduction**
Plate	Olerud	2011	3-part	81	74	27	26	CS, no difference†	No difference	No difference
Plate	Fjalestad	2012	B2 and C2*	88	73	23	25	CS, no difference		
Plate	Launonen	2019	2- part surgical neck	91	73	33	39	DASH, no difference		
HA	Olerud	2011	4-part	86	77	24	25	CS, no difference†	No difference	No difference
HA	Boons	2012	4-part	94	78	24	23	CS, no difference	No difference	No difference
rTSA	Lopiz	2019	3- and 4-part	86	84	29	30	CS, no difference		
Multiple‡	Rangan§	2015	1 to 4-part	77	66	114	117	OSS, no difference		

HA, hemiarthroplasty; ORIF, open reduction and internal fixation; rTSA, reverse total shoulder arthroplasty

* according to the AO/OTA classification

† EQ-5D was the primary outcome measure

‡ Locking plate, hemiarthroplasty, intramedullary nail and other

§ Proximal Fracture of the Humerus Evaluation by Randomization (ProFHER) study

Non-surgical treatment

Overall, non-surgical treatment leads to a good outcome for proximal humeral fractures for optimally selected patients.[178] The arm is typically immobilized with a simple or Velepeau sling (Figure 10). The period of immobilization should ideally be short enough to avoid stiffness, while not causing problems such as secondary displacement, typically lasting a couple of weeks.[336] Some earlier studies have found that function, range of motion and pain were more favorable in the short term, when mobilization was initiated after 1 week or less as compared with after three weeks.[167; 168; 221] However, a recent meta-analysis found that the benefit of early mobilization was limited (5 points on the Constant score) and concluded that the clinical relevance was questionable. In an RCT published in 2021, Martínez et al.[244] found no difference in outcome between commencing mobilization at 1 week or 3 weeks at any follow-up point up to 2 years and no difference in the occurrence of adverse events. Most of the patients in these studies had fractures of minimal displacement or displaced 2-part fractures.

For 3- and 4-part proximal humeral fractures, the data on both how to perform non-surgical treatment and its outcome are limited. In a systematic review, Soler-Peiro et al.[369] were only able to identify 55 patients with 3-part fractures and 78 with 4-part fractures who had been treated non-surgically. Patients with 3-part fractures had fair functional outcome, with mean Constant scores of 65 points, while patients with 4-part fractures fared less well, with a mean Constant score of 55 points. The natural history of these injuries is therefore poorly defined and is unfortunately likely to remain so in the future. Moreover, the available data are unfortunately likely to be affected by a selection bias to some degree, as active patients with greater displacement are likely to have been chosen for surgical treatment. The evidence guiding the choice of length of time for immobilization for 3- and 4-part fractures is scarce, but in clinical practice it is often extended to between 3–4 weeks.

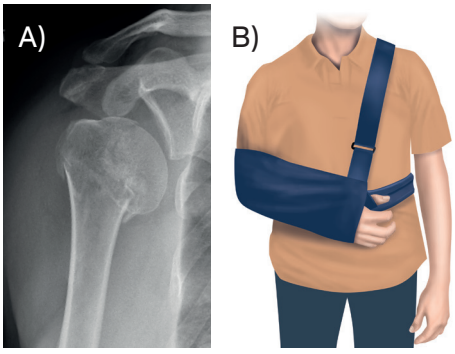

FIGURE 10 Non-surgical treatment of proximal humeral fractures. **A)** A 4-part proximal humeral fracture with limited displacement for which non-surgical treatment can be an option, depending on patient factors. **B)** For non-surgical treatment, a sling is typically worn for a couple of days or weeks before gradually increasing range of motion and activity level.

Internal fixation

Although many different types of internal fixation are available, locking plate fixation (with angular stable screws) and intramedullary nails (IMNs) are the options that dominate in contemporary literature. Based on available randomized studies, neither of these treatments provides a clearly superior functional outcome or more favorable profile in terms of complications. Three earlier randomized studies did not find any difference in shoulder function between these treatment options.[151; 313; 423] These studies included predominantly 2- and 3-part fractures. In a recent RCT, Boyer et al.[54] included only 3-part (mainly) and 4-part fractures but no 2-part fractures. In this study, IMNs were found to provide better shoulder function than plate fixation. It should, however, be noted that the plate used in this study has considerably fewer holes intended for fixation of the humeral head (3 holes) compared with plates of standard design including the *Proximal Humeral Internal Locking System* (PHILOS, see next paragraph) which has 9 holes. It therefore remains unclear if there are any differences in the outcome for patients treated with locking plates of standard design and IMNs.

The recent history of plating is very interesting. Fixation with conventional plates with non-locking screws was fraught with problems, such as a high rate of fixation failure.[165] Plate fixation was revolutionized with the advent of precontoured locking plates at the turn of the millennium (Figure 11). The first to come into widespread use was the PHILOS.[409] Biomechanical studies found that these devices performed well in osteoporotic bone[230] and were stiffer constructs than conventional plates. The short-term clinical results in some of the first publications were promising and optimism was high. Locking plates were recommended as a treatment in osteoporotic bone that allowed early mobilization.[42; 208] This enthusiasm was reflected by a rapid increase in the use of plates during the first decade of the 21st century.[385] As experience accumulated, it became clear that the occurrence of

complications was considerable. A review by Thanasas et al.[392] from 2009 reported a rate of 7.9% for avascular necrosis (AVN) and 11.6% for screw cut-out. AVN and loss of reduction are probably the main causes of secondary screw perforation which accounts for a considerable proportion of all complications.[299] Two RCTs, including elderly patients with mainly 3-part fractures, published at the beginning of the second decade of the 21st century, did not find any functional benefit from ORIF compared with non-surgical treatment.[123; 291] Enthusiasm declined, as evident from the decrease in the use of locking plates in the following years.[38] Even in recent publications, the rate of complications (44%) and failures (34%) remains high for elderly patients treated with locking plates.[24]

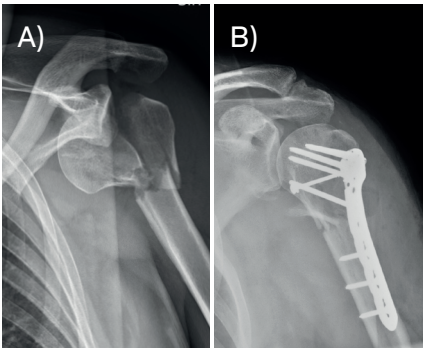

FIGURE 11 A) A 3- part fracture dislocation of the proximal humerus, **B)** treated with open reduction and internal fixation with a precontoured plate with locking screws.

Shoulder arthroplasty – practical aspects

The two main types of arthroplasty used for treating proximal humeral fractures are hemiarthroplasty (HA) and reverse total shoulder arthroplasty (rTSA) (Figure 12). Both are typically inserted using a deltopectoral approach although other approaches such as the anterosuperior approach have been used as well.[138] The humeral head is removed. After the prosthesis has been inserted the tuberosities are fixed in a position that allows anatomical healing to the shaft. None of the numerous methods[30] that have been described for tuberosity fixation has been shown to be superior in terms of healing rate. In practice, the characteristics of the particular brand of prosthesis used influences the way the tuberosities can be fixed. A method described by Boileau et al.[48] in 2000, or a variation thereof, is commonly used (Figure 13). In hemiarthroplasty, the entire rotator cuff is preserved, while the supraspinatus is typically removed during rTSA.

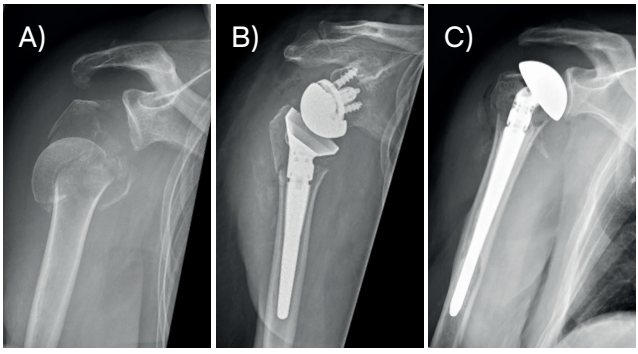

FIGURE 12 Radiographic appearance of proximal humeral fractures treated with arthroplasty.

A) A widely displaced 4-part fracture of the proximal humerus.

B) The injury depicted in A was treated with reverse total shoulder arthroplasty.

C) Hemiarthroplasty can also be used for treating proximal humeral fractures.

Only limited evidence is available to guide rehabilitation; length of immobilization period and timepoint of commencing passive and active range of motion. The general idea is to restrict movement long enough to allow the tuberosities to heal but without causing undue stiffness. However, considerable forces act on the glenohumeral joint, even in simple activities of daily life.[203] It is unclear how effective limitations in range of motion are at preventing the failure of tuberosity healing. In a cohort of 39 patients treated with HA, Amirfeyz et al.[6] found that, despite a relatively long immobilization of 4 weeks, the failure of tuberosity healing nevertheless occurred in 5 patients. Moreover, biomechanical studies have found that the failure of fixation occurs even with loads that can be expected in the initial postoperative period.[53; 124] Meanwhile, Macfarlane et al.[238] applied an accelerated rehabilitation regimen (passive ROM from day 1, active ROM from the second week and strengthening exercises from 4 weeks) in 23 patients treated with HA, where only one patient had failure of tuberosity healing. Much larger studies would be necessary to draw firm conclusions. In practice, flexion and external rotation are typically restricted for the first few weeks following surgery, with active range of motion starting after approximately 6 weeks.[60; 63]

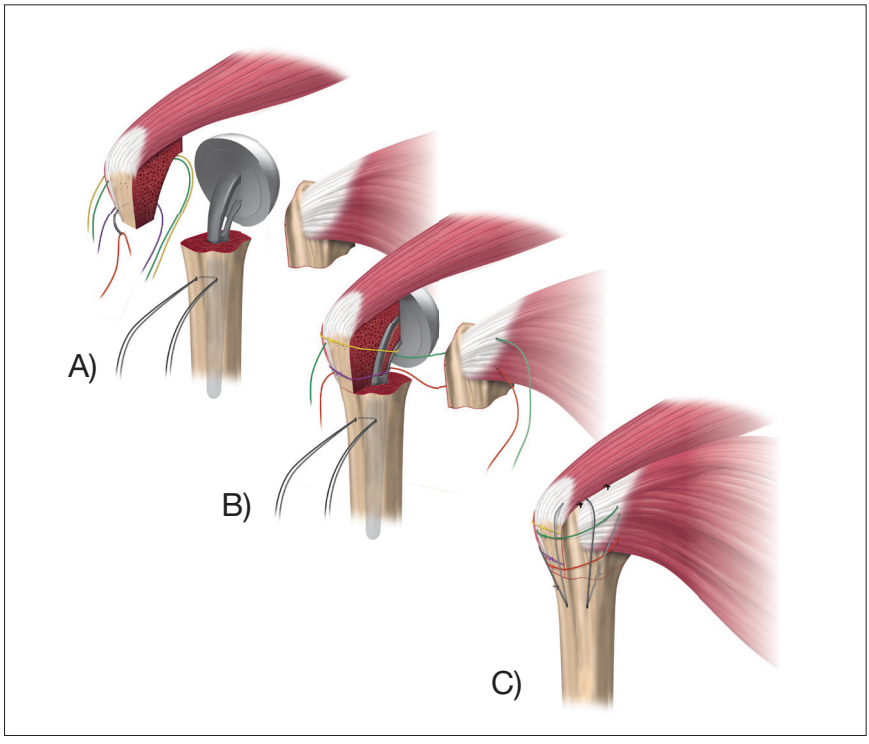

FIGURE 13 The basics of a commonly used strategy for fixing the tuberosities in association with arthroplasty for proximal humeral fracture using sutures.[48] Demonstrated here for hemiarthroplasty, but can be performed in a similar manner for reverse total shoulder arthroplasty. In tendons, sutures are placed at the insertion. **A)** Sutures are inserted through the external rotators (infraspinatus and teres minor) and also through bone tunnels in the humeral shaft. **B)** The greater tuberosity is reduced and with horizontally oriented sutures fixed by either placement around the prosthesis or to the prosthesis, for example through holes. Sutures are placed through the lesser tuberosity. **C)** The lesser tuberosity is reduced in a similar fashion. Typically, one or two sutures are placed circumferentially, embracing both tuberosities and the prosthesis. The sutures anchored in the shaft are placed in the rotator cuff, hindering vertical displacement and medialization.

Arthroplasty – historical perspective

Charles Neer. Observations on fracture dislocations

The beginnings of modern shoulder arthroplasty cannot be pinpointed to one single event or person. It is, however, clear that Charles Neer was an important pioneer in shoulder surgery. Moreover, some observations made early in his career spurred his interest in shoulder arthroplasty. He did his residency in orthopedic surgery at the New York Orthopaedic Hospital and Columbian Presbyterian Medical Center under William Darrach in the 1940s. A publication from 1912[91] by Dr. Darrach

popularized a procedure that is still in use, commonly referred to as the Darrach procedure, which involves the resection of the distal ulna for disorders of the distal radioulnar joint. In the 1940s, some proximal humeral fracture dislocations were also treated with resection – of the humeral head. Dr. Neer, who observed that these patients often experienced poor outcomes, was encouraged by Dr. Darrach to "do something about it",[333] which resulted in a publication in 1953 in which 20 patients with fractures of the anatomical neck associated with dislocation of the glenohumeral joint were presented. Sixteen of these patients had been treated with resection of the humeral head and were observed to have pain and limited range of motion on follow-up.[278]

First results and further important observations

The first publication in which Dr Neer presented results of shoulder hemiarthroplasty is from 1955.[274] There were 13 patients who had no pain as opposed to the marked pain that had been observed in patients treated with resection arthroplasty. Range of motion was variable with HA, while it had been determined to be poor in the group treated with resection arthroplasty. A number of points raised in this publication, at this early stage, are still valid. Dr. Neer emphasized the importance of reconstructing the tuberosities, an idea that still has implications today (**Study II**). The fact that tuberosity healing and a well-functioning rotator cuff are presumably necessary for the successful outcome of hemiarthroplasty can be appreciated, based on the role the rotator cuff plays in keeping the head centered in the glenoid, as explained previously (Figure 6). Dr. Neer emphasized the importance of tuberosity reconstruction in contrast to some contemporary authors who recommended tuberosity resection.[323] On this point, Dr. Neer might have been inspired by the recent successful use of a hemiarthroplasty by one of his New York colleagues. Fredrik Krueger had treated a young patient with AVN with a custom-made hemiarthroplasty.[211] The patient experienced a relatively good outcome after the procedure, which involved the preservation of the rotator cuff. In his 1955 publication, Dr. Neer also emphasized the limited indications for hemiarthroplasty for trauma: anterior fracture dislocation with a humeral head devoid of soft-tissue attachments, posterior dislocations with large defects of the head and head-splitting fractures defined as the articular surface being in several unattached pieces. Finally, it should be observed that the main conclusion that hemiarthroplasty improved the outcome for patients with fracture dislocations was made with reference to the treatment of this diagnosis with resection of the humeral head.

Neer's seminal 1970 publications

In 1970, Dr. Neer published two papers that proved to be very influential.[275; 276] The latter of these described the outcome of the treatment of 3- and 4-part proximal humeral fractures.[276] This study included 43 patients treated with hemiarthroplasty, where 33 had fracture dislocations. Based on the Neer criteria, 27 patients were determined to have a satisfactory outcome and the mean score was 82. Subsequent literature has at times been suspicious of these results, as they were difficult to replicate. It is, however, difficult to discern which outcome the patients really had. In accordance with common practice at the time, the data presented are limited and statistical analysis is absent. The score of the Neer criteria ranges from 0 to 100 and was categorized as follows: failure < 70, unsatisfactory (70 to 79), satisfactory (80 to 89) and excellent (≥ 90). As 35 points are allocated to a pain-free shoulder and hemiarthroplasties would be expected to collect at least some of the 10 morphological (radiographic) points, only 55 points are actually assigned to describe function. Information on range of motion, or any other outcome measure, was not provided separately. It is likely that one of the main conclusions of the study, that the results were satisfactory, was drawn with reference to the treatment of fracture dislocation with humeral head resection (33 of 43 patients), although this is not stated specifically. Another, perhaps, less well-founded conclusion was the recommendation to treat 4-part fractures with hemiarthroplasty. A conclusion that proved to be influential.

Increasing use of hemiarthroplasty

Interest in using hemiarthroplasty for proximal fractures grew continuously over the coming decades, at least in terms of the number of publications. Hemiarthroplasty went from being a treatment reserved for selected cases of fracture dislocations to being the preferred treatment option for the surgical treatment of all displaced, unreconstructable proximal humeral fractures.[382] While the results of some of the early reports from other centers were promising,[374] the tone in others was less enthusiastic.[210; 413] A systematic review from 2008 including 810 hemiarthroplasties confirmed what Neer had already observed in 1955, namely that pain was not a general problem (over 90% had no or only mild pain), but function was unpredictable and limited.[207] Another systematic review by Nijs et al.[282] from 2009 found that studies providing information on tuberosity healing most often reported healing rates of approximately 50% or less. In the only two randomized studies on the topic, Olerud et al.[292] (2011) and Boons et al.[52] (2012) found no clear benefit in shoulder function when treating 4-part fractures with hemiarthroplasty as compared with non-surgical treatment. At the beginning of the second decade of the 21st century, the future of hemiarthroplasty as the gold standard treatment for unreconstructable proximal humeral fractures

was uncertain – in particular considering the promising results of reverse total shoulder arthroplasty.

Reverse total shoulder arthroplasty

The development of shoulder arthroplasty continued during the 1970s with the introduction of total shoulder arthroplasty (TSA) consisting of polyethylene glenoid components used with metallic humeral heads.[179] This made it possible to treat degenerative disease of the shoulder (e.g. osteoarthritis), but treating rotator cuff-deficient shoulders remained a problem for reasons that are understandable based on the biomechanical importance of the rotator cuff. In an attempt to counteract proximal translation of the humeral head by the deltoid in rotator cuff-deficient shoulders, a number of different reversed designs were developed. Most of these performed poorly, because the center of rotation was lateral to the scapula, resulting in poor range of motion and the loosening of the glenoid component due to unfavorable torque.[46] The Grammont reverse prosthesis presented in a publication from 1987[153] introduced important innovations[28; 46; 49] that proved to be a breakthrough in the treatment of shoulders with degenerative changes and deficient rotator cuffs (Figure 14). The glenoid component consisted of a sphere (glenosphere) that was placed on the glenoid surface, resulting in a medialized center of rotation (COR). This minimized the effect of proximally directed shear forces from the humerus on the glenoid component, caused by the contraction of the deltoid. Moreover, the medialized COR resulted in a more favorable lever arm for the deltoid to elevate the humerus, making it more capable of compensating for the absence of the rotator cuff. The large size of the glenosphere and relatively small cup on the humerus allowed a large range of motion before impingement occurred between the components. Finally, the design led to the distalization of the humerus, improving deltoid tension and its ability to elevate the arm. The clinical results summarized by Boileau et al. in 2005 were promising.[49]

In the light of the promising results in cuff-deficient shoulders, it would have appeared reasonable to use rTSA for another situation in which unpredictable rotator cuff function can be a problem, namely displaced multi-fragment fractures in elderly patients. It is therefore not surprising that Paul Grammont himself used rTSA for proximal humeral fractures back in the late 1980s.[362] It is clear that others had started to use rTSA for proximal humeral fractures in the 1990s, at least in France[67] and Sweden.[113] Nevertheless, it was not until after the turn of the millennium that the first case series were published.[61; 67] There was an optimistic tone in some of the early literature reviews,[375] while other authors were less optimistic.[365] The first review comparing HA and rTSA did not find any clear difference in functional outcome between the treatments.[271]

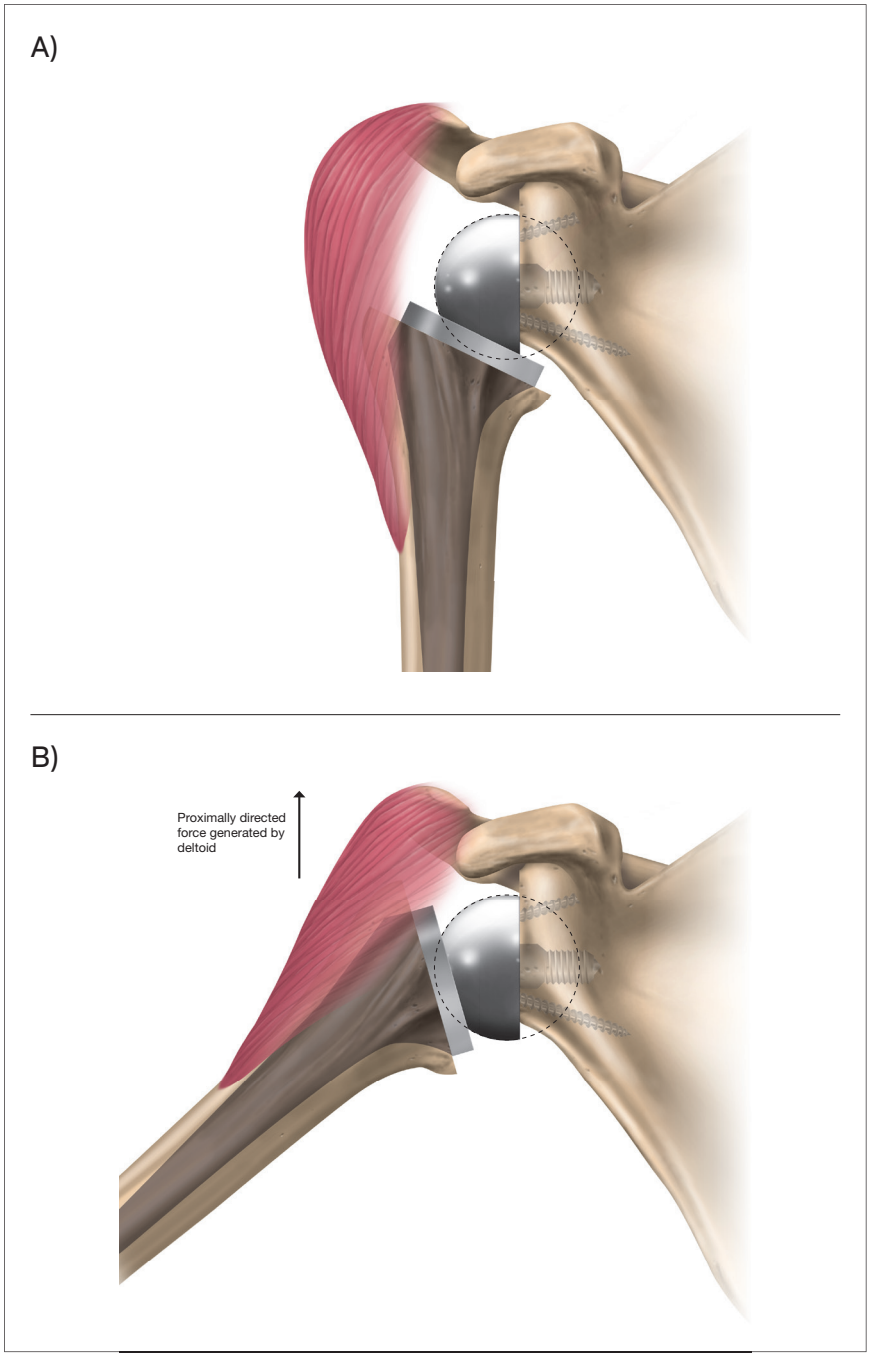

FIGURE 14 A) Basic design of reverse total shoulder arthroplasty. **B)** The glenosphere acts as a fulcrum, translating the force generated by contraction of the deltoideus muscle into elevation of the humerus.

DISTAL HUMERAL FRACTURES

Anatomy of the elbow

The articular surface of the distal humerus has two distinct parts: the trochlea and the capitellum (Figure 15). The capitellum is best described as an ellipsoid, as the radius of curvature is larger from medial to lateral than in the sagittal plane.[340] The trochlea has the shape of a hyperboloid, with two main joint surfaces facing each other, separated by a distinct groove. There are three joints within the capsule of the elbow joint. The distal articular surface of the humerus contributes to two of these. The trochlea articulates with the greater sigmoid notch on the ulna to form the ulnohumeral joint, while the capitellum articulates with the radial head to form the radiohumeral joint. The third articulation of the elbow, the proximal radioulnar joint is between the radial head and lesser sigmoid notch on the ulna, thus not involving the humerus.

The articular block (trochlea and capitellum) is connected to the humeral shaft by two diaphysis-like struts, the medial and lateral columns. The bone between the columns is thin due to indentations on the anterior and posterior sides, which are important for terminal flexion and extension, respectively. In flexion, the radial head and coronoid process are accommodated by the radial and coronoid fossae, respectively and, in extension, the olecranon fossa gives room to the olecranon. The importance of this mechanism was illustrated in a cadaver study by Willing et al.,[415] with simulated osteophytes obstructing the coronoid and olecranon fossae. Bony impingement already occurred at 119° of flexion and 38° of extension. At the lower end of each column, there are bony prominences, the lateral and medial epicondyle, where the latter is a larger, more distinct structure. The medial and lateral epicondyles and nearby bone serve as the origins of the extensor and flexor/pronator muscles of the forearm, as well as the collateral ligaments.

The medial ulnar collateral ligament (MUCL) has three distinct parts: the anterior bundle, posterior bundle and transverse bundle (Figure 16). Of these, the anterior bundle is generally considered to be of greatest functional importance. The anterior bundle originates on the antero-inferior portion of the medial epicondyle, approximately 8 mm from its apex.[129] The insertion is centered on the sublime tubercule on the ulna but stretches distally up to 3 cm along the ulnar ridge.[77] The lateral collateral ligament complex has three parts: the annular ligament, radial collateral ligament (RCL) and lateral ulnar collateral ligament (LUCL). Of these, the last is thought to be of particular functional importance for elbow joint stability. The annular ligament encircles the lateral margin of the radial head and attaches to the ulna at the anterior and posterior margins of the lesser sigmoid notch. The RCL and LUCL originate antero-distally to the lateral

epicondyle, approximately 1 cm from its apex and 7–8 mm from the joint surface of the capitellum.[65] Distally, the RCL blends with the annular ligament, while the LUCL inserts on the supinator crest of the ulna.

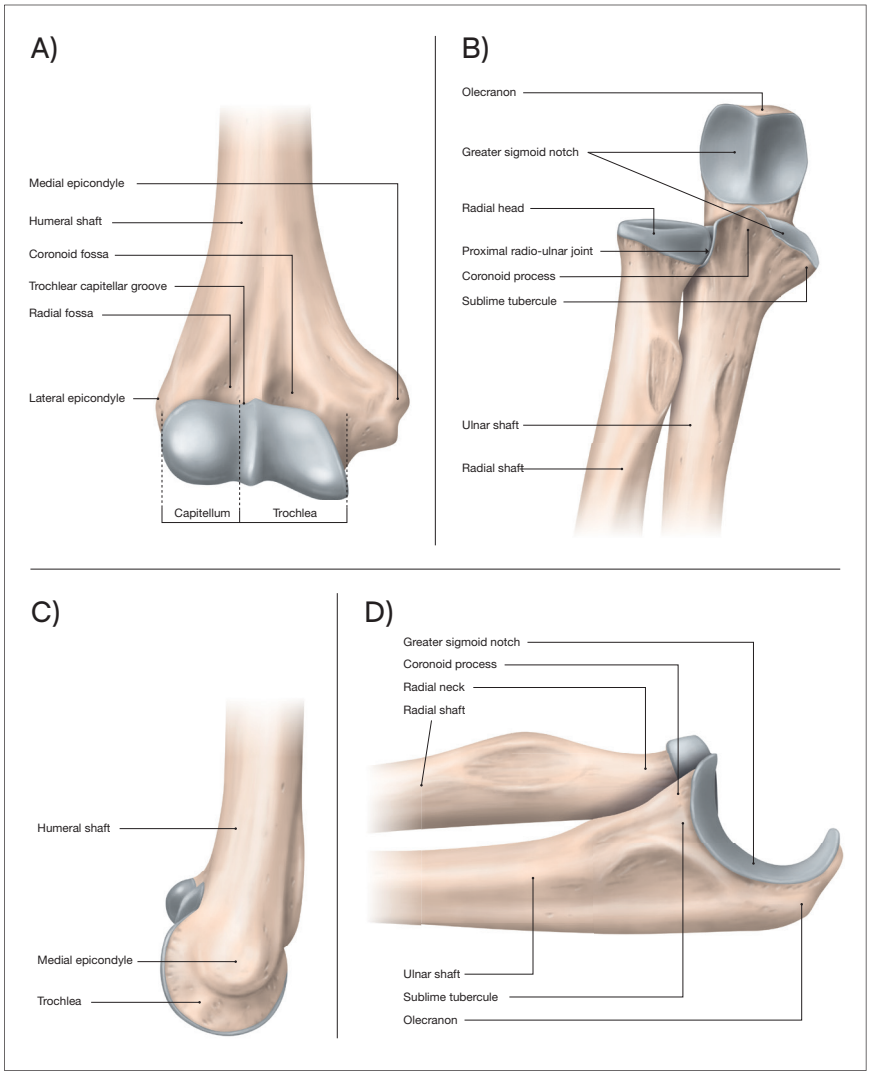

FIGURE 15 Bony anatomy of the elbow. **A)** Anterior view of the distal humerus. **B)** Anterior view of the proximal forearm. **C)** Side view of the distal humerus. The joint surface is angled approximately 30° anteriorly with reference to the long axis of the humerus. **D)** Side view of the proximal forearm.

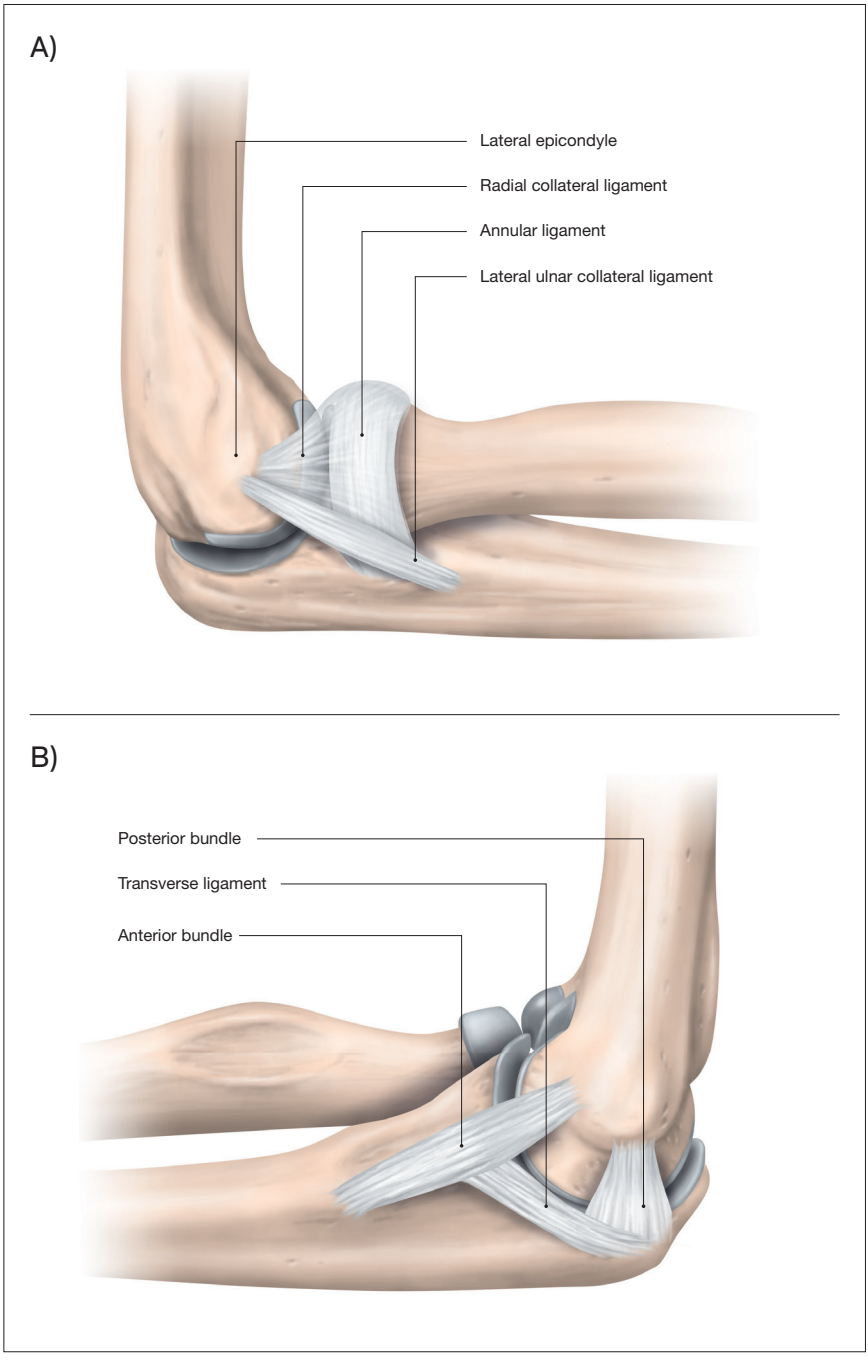

FIGURE 16 The collateral ligaments of the elbow. **A)** The lateral collateral ligament complex consists of the annular ligament, radial collateral ligament and lateral ulnar collateral ligament. **B)** The medial ulnar collateral ligament consists of the anterior bundle, posterior bundle and transverse ligament.

Biomechanics of the elbow

An understanding of the basic biomechanical attributes of the elbow is useful in order to understand elbow disorders and their treatment. The biomechanical characteristics of the elbow are complicated, with different properties being displayed depending on factors such as the exact position of the joint and the application of external loads. In addition, the biomechanical properties of one structure are affected by the status of others. In the following paragraphs, general biomechanical principles that are of particular relevance to the treatment of distal humeral fractures are presented.

The position of the biomechanical axis of the elbow shifts slightly with different degrees of flexion,[114] but it passes approximately through the center of the capitellum and trochlea.[416] On the medial side, it lies close to the inferior portion of the medial epicondyle, in proximity to the origin of the medial collateral ligament.[152] Knowledge of the position of the biomechanical axis of the elbow has implications for how to both design and insert an elbow prosthesis. Although possibly giving the impression of being a rigid hinge, the elbow actually displays up to 5° of both varus and valgus movements under normal circumstances,[200] an observation with considerable implications for the design of elbow prostheses.

The forces acting on the elbow are of considerable magnitude, despite the fact that the elbow is not a weight-bearing joint. One key issue is that external loads, such as those caused by an object held in the hand, result in disproportional loads at the elbow. The reason for this is that external loads (e.g. at the level of the hand) act on the elbow through long lever arms, extenuated in some situations by the muscles working through very short lever arms. Moreover, forces act on the elbow in different planes: varus-valgus, rotational and in the sagittal plane. The last of these have been best defined and are often used to explain loading of the elbow joint (Figure 17).

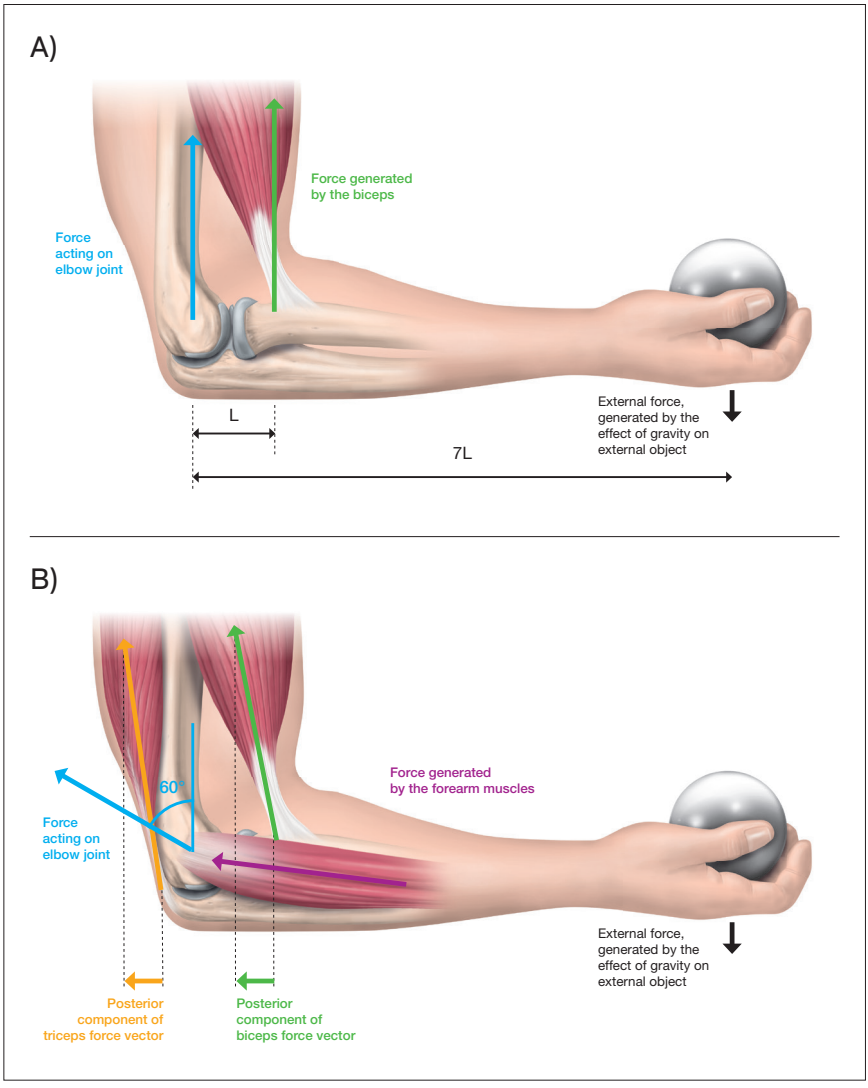

FIGURE 17 Forces acting on the elbow joint with 90° of flexion maintained. **A)** A free body diagram illustrating the force that acts on the elbow joint resulting from an external load at the hand that is resisted by contraction of the biceps. To maintain a steady state, the biceps needs to generate a force sufficiently large so that when it is multiplied by the distance from the elbow joint to the radial tuberosity (L), this equals the product of the external force at the hand and the distance from the elbow to the hand (7L). This is according to the law of moments. The distance from the elbow to the hand is typically assumed to be larger than L by a factor of 7.[7] The force acting on the elbow joint equals the biceps force minus the external force. **B)** When the action of other muscles than the biceps is considered, the total force vector acting on the elbow at 90° of flexion is directed 60° posterior to the long axis of the humerus. This is partly explained by the biceps and triceps force vectors being directed slightly posteriorly (orange and green arrows), but also by the action of the forearm muscles when they grip an object in the hand. The forearm muscles run across the elbow joint and when they contract, this results in a posteriorly directed force on the elbow.

The forces acting on the elbow in the sagittal plane are typically explained by a free body diagram akin to Figure 17. Although models of this sort are obviously an oversimplification of reality, they provide a useful insight into the forces acting on the elbow. In a review from 2013, Kincaid and An[200] summarized the results of available studies assessing elbow joint reaction forces (JRF), with the following findings applying to the sagittal plane. For light activities of daily life, the forces acting on the elbow are estimated to be 0.5 of body weight, but they are approximately two times body weight with more strenuous activities such as manual labor with a tool. For flexion, the JRF is greatest at around 0° and 30° (15 per unit of weight in hand), due to the very short effective lever arm of the flexors in this position, but it decreases with higher degrees of flexion. The JRF is directed anteriorly in the initial phases of flexion (from full extension) but becomes posteriorly oriented before reaching 30°. With higher degrees of flexion, the JRF maintains an overall posterior direction, but the exact angle of the force vector relative to the long axis of the humerus varies with the degree of flexion. The typical number of flexion-extension cycles per day has been hypothesized to be 1,400.[200] It is therefore clear that, in the sagittal plane, the elbow must withstand considerable forces that are continuously shifting in direction and magnitude, in addition to forces working in other planes. This has important implications for the treatment of distal humeral fractures, potentially nudging fractures and prostheses out of place, resulting in nonunion or prosthesis loosening.

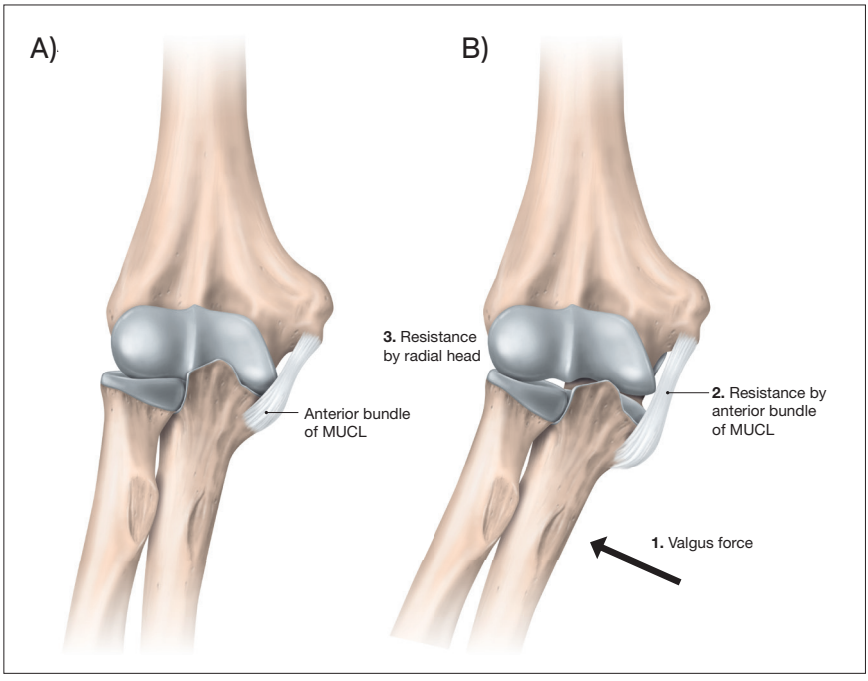

FIGURE 18 Elbow stability is provided by the bony configuration of the joint, ligaments and soft tissues (e.g. muscles and joint capsule), here demonstrated by resistance to valgus. **A)** Anterior view of a congruent elbow joint. **B)** A valgus force acts on the forearm (1). The anterior bundle of the medial ulnar collateral ligament is the primary stabilizer of the elbow joint for valgus forces (2), with the radial head acting as a secondary stabilizer (3).

A number of structures are important in order to counteract the forces acting on the elbow. In the sagittal plane, where posteriorly directed forces prevail, the coronoid process has been pointed out as the most important stabilizer.[263] The contraction of muscles crossing from the upper arm to the forearm also contributes to stability by pressing the joint surfaces against each other. With respect to valgus loads, the anterior bundle of the MUCL is regarded as the most important stabilizing structure, with the radial head being termed a secondary stabilizer (Figure 18).[267] The lateral ulnar collateral ligament[34] and the anteromedial facet of the coronoid[186] are both important in resisting varus forces. Muscles also contribute to resisting varus (extensor carpi ulnaris, extensor carpi radialis longus and brevis and anconeus) and valgus (flexor carpi ulnaris and flexor digitorum superficialis) forces.[416] The anterior[341] and posterior bundle[143] of the MUCL play an important role in resisting internal rotation of the forearm relative to the humerus (Figure 19). Likewise, the LUCL resists external rotation of the forearm relative to the humerus.[289]

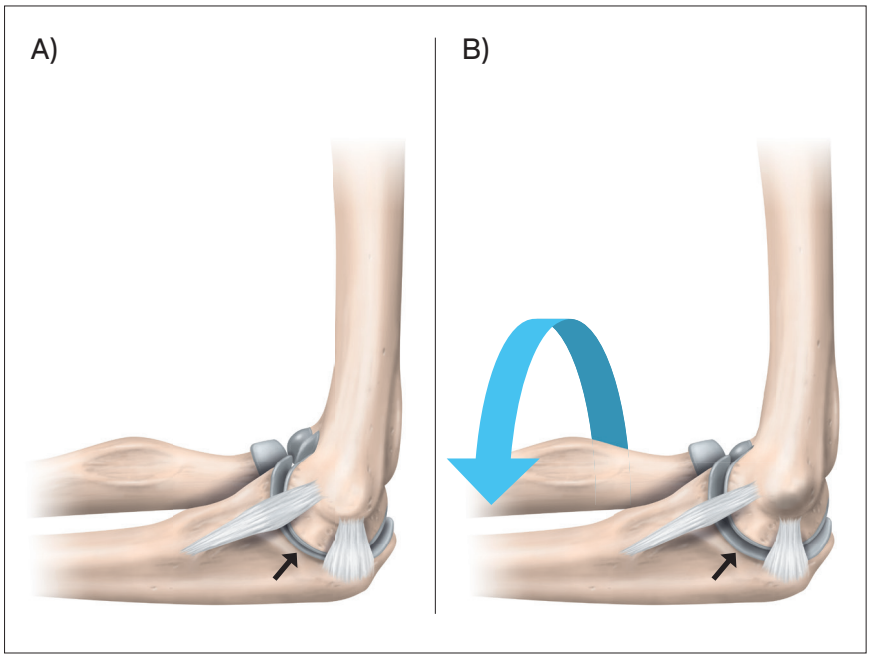

FIGURE 19 The collateral ligaments of the elbow provide stability in relation to rotational forces.
A) Medial view of a congruent elbow joint. The joint surfaces (trochlea on the humerus and greater sigmoid notch on the ulna) are in tight apposition to each other and the joint line is narrow (black arrow).
B) An internal rotatory force acts on the forearm. A slight rotation of the forearm relative to the humerus occurs, manifesting as widening of the joint (black arrow). Further widening is hindered by the anterior bundle of the medial ulnar collateral ligament, ensuring joint stability.

Classification of distal humeral fractures

The AO Foundation/Orthopaedic Trauma Association (AO/OTA) fracture classification system [252] is commonly used for distal humeral fractures. In a recent review by Piggot et al.[310] of elbow hemiarthroplasty for acute distal humeral fractures, 12 of 13 included studies used the AO/OTA classification. Likewise, 9 of 10 studies in a review by Kholinne et al.[199] of total elbow arthroplasty used the AO/OTA classification. In the AO/OTA classification, there are three types of distal humeral fractures: type A, which are extraarticular, B, which are partially articular and C, which are articular fractures with the complete separation of all articular fragments from the diaphysis (Figure 20).

Other classification systems for distal humeral fractures are available. Some of them are meant to be comprehensive, i.e. they cover all (or at least most) possible fracture patterns. Examples are the classification systems of Mehne and Jupiter[193] and Davies and Stanley.[93] A number of classification systems have also been

devised for specific types of fractures, primarily coronal shear fractures.[109; 328; 412] Of these, the classification of Dubberly et al.[109] has perhaps had the greatest impact. Fractures involving the capitellum are classified as type I, fractures involving the capitellum and trochlea as one-piece type II and those in which the capitellum and trochlea are fractured as separate fragments as type III. Emphasis is placed on the effect on choice of treatment of comminution of the posterior aspect of the most distal part of the lateral column. The letter B designates comminution, while A indicates its absence.

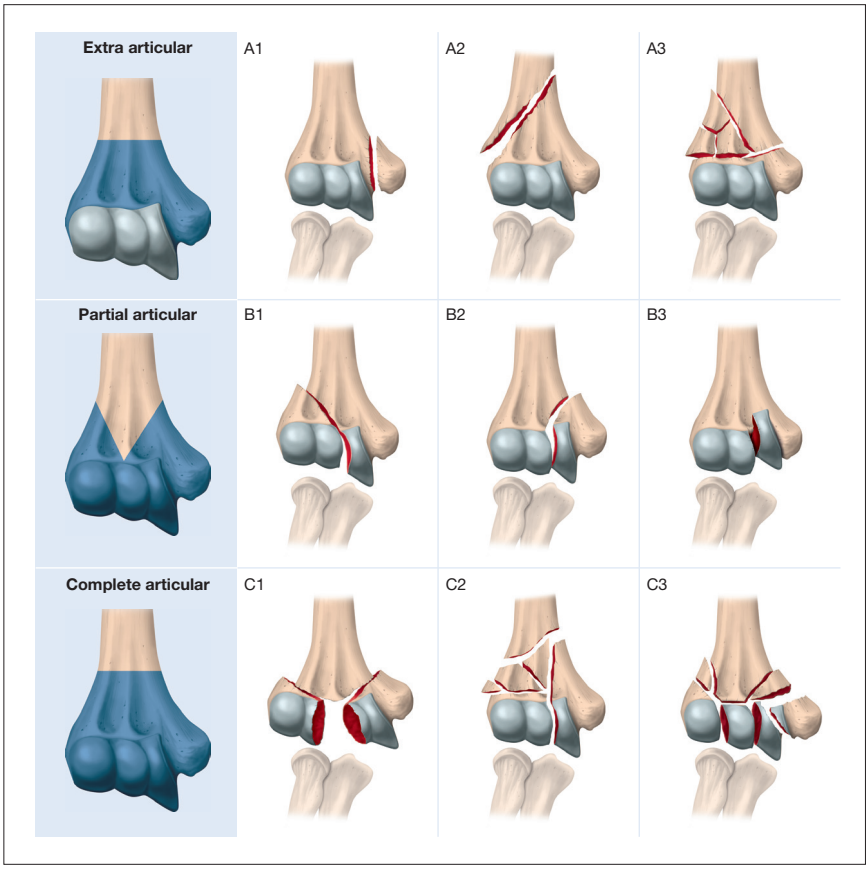

FIGURE 20 AO/OTA classification of distal humeral fractures. There are three types of fractures, each is represented in one of the lines: Type A which are extraarticular (top line), Type B which are partial articular fractures (middle line) and Type C which are complete articular fractures (bottom line). Partial articular implies that a part of the joint surface is still connected to the shaft. Complete articular implies that no part of the articular surface is connected to the shaft. Each fracture type is divided into three groups numbered from 1 to 3. Type A has the following groups: A1, Avulsion fracture; A2, Simple fracture and A3, Wedge or multifragmentary fracture. Type B has the following groups: B1, Lateral sagittal fracture; B2, Medial sagittal fracture and B3, Frontal/coronal plane fracture. Type C has the following groups: C1, Simple articular, simple metaphyseal; C2, Simple articular, wedge or multifragmentary metaphyseal fracture and C3, Multifragmentary articular fracture, wedge or multifragmentary metaphyseal fracture.

Epidemiology of distal humeral fractures

Distal humeral fractures are not particularly common in adults. A recent study by Bergh et al.[39] based on data from the Swedish Fracture Register found that distal humeral fractures constituted 0.9% of all fractures (≥ 16 years of age) in Gothenburg, Sweden, in 2015–2018. Considering fractures in order of occurrence, distal humeral fractures shared places 20 and 21 (of the 27), together with calcaneus fractures.

Studies of the incidence of elbow fractures are scarce, in particular those including both in- and outpatients. In one such study by Robinson et al.[332] from Edinburgh, Scotland, the annual incidence was 5.7 per 100,000 population (≥ 12 years of age) in 1988–1997. In a more recent study from Gothenburg, Bergdahl et al.[36] reported an incidence of 8.3 per 100,000 in 2011–2013. The incidence, which can be understood as the risk of suffering a distal humeral fracture, is relatively low before the age of 50, after which there is a continuous increase.[36; 332]

Data on temporal changes in the incidence of distal humeral fractures are both limited and contradictory. According to a series of studies from Finland,[197] the incidence of distal humeral fractures in women aged 60 years and older increased between 1970 and 1998, but it then declined up to 2014. It should, however, be noted that these studies are only based on hospitalized patients. Although surgical treatment is considered the most suitable treatment for most distal humeral fractures, not including outpatients will affect estimates of incidence. In contrast to the results from Finland, a study from Edinburgh, which included both in- and outpatients, found an increase in the incidence of distal humeral fracture between 2000 and 2010/2011.[84] The increase was statistically significant for males (5.2 to 14.2 per 100,000; $p = 0.04$) but not for females (22.3 to 35.9). Two recent studies from Gothenburg have indicated a possible increase in incidence. As mentioned previously, Bergdahl et al.[36] reported an incidence of 8.3 per 100,000 in 2011–2013, while Bergh et al.[39] reported an incidence of 11.3 per 100,000 for 2015–2018. Both these studies included in- and outpatients.

It would be useful to obtain an insight into how many patients with distal humeral fractures are potential candidates for treatment with arthroplasty. It is, however, difficult efficiently to identify unreconstructable distal humeral fractures using the AO/OTA classification. What is clear is that extraarticular fractures (Type A) and fractures involving the lateral and medial columns are reconstructable in the vast majority of cases. These fractures represented approximately 55% of all distal humeral fractures in the studies by Robinson et al.[332] and Bergdahl et al.[36] The remaining fractures are coronal plane fractures (B3) and complete intraarticular fractures (Type C). Only some of these fractures

are unreconstructable. Another approach is to consider age, as arthroplasty is mainly considered in elderly patients. According to data available to registered users in the Swedish Arthroplasty Register,[259] of all distal humeral fractures registered in 2018 to 2020 (approximately 1,750 fractures), the proportion of patients over the age of 60 years with B3 and C fractures was 25%.[387] However, only approximately one-third were treated with elbow arthroplasty, indicating that characteristics other than those captured by the AO/OTA classification also affect the decision to perform arthroplasty.

Assessing outcome of distal humeral fractures

Several outcome measures have been used to assess the outcome of the treatment of distal humeral fractures. In a review of studies of distal humeral fractures published between 2006–2016, Zarezadeh et al.[422] found that the most used outcome instruments were the (proportion of all studies): MEPS (75%), DASH (28%) and *Quick*DASH (11%). In the following section, the assessment of elbow range of motion is reviewed, after which the basic attributes of these outcome instruments are discussed.

Range of motion

In clinical studies, elbow range of motion is typically measured using a goniometer, although information regarding the placement of the goniometer is seldom provided. It appears probable, and there is some evidence to support this,[405] that the standardized use of anatomic landmarks to guide goniometer placement improves reliability. Some of the studies included in a recent review of the reliability and validity of goniometric elbow measurements provided information on the use of anatomic landmarks. In these studies, the axis of the goniometer was consistently placed on the lateral epicondyle. The long axis was commonly placed along the long axis of the humerus[13; 145; 305] while the mobile end was often directed towards the styloid of the radius.[13; 145; 424] It appears that measurements are commonly performed with the forearm in supination, which can be problematic in patients with limited forearm motion. Measuring routinely in neutral rotation might be a suitable option, as patients with limitations in rotation are most often able to achieve this position. Descriptions of how to place the goniometer for measuring rotation are even more heterogeneous. Zwerus et al.[424] placed the mobile arm on the distal forearm and aligned the fixed arm with the longitudinal axis of the humerus. Placing the fixed arm perpendicular to the floor has been suggested,[13] but this is illogical, as the humerus is not necessarily perpendicular to the floor, due to habitus, for example. The hand has been used as a reference for the mobile arm,[76] but this introduces variability, if the assessment

of forearm rotation is of primary interest. Standardizing measurements of elbow range of motion is therefore desirable.

In a recent study using sound methodology, Zwerus et al.[424] determined that the smallest detectable difference (analogous to the minimal detectable change mentioned previously) between raters (inter-rater) was 7° for flexion, 6° for extension and 8° for both supination and pronation, information which is very useful for interpreting differences in range of motion.

Many activities of daily life can be completed without having a completely normal range of motion. In the previously mentioned study by Zwerus et al.,[424] the mean active motion was determined in a cohort of 352 individuals to be 146° of flexion, −2° of extension, 80° of pronation and 87° supination. In a classic paper from 1981, Bernhard Morrey et al.[265] assessed the range of motion necessary for completing arbitrarily selected sedentary tasks of daily life such as eating, using a telephone and rising from a chair. The conclusion was drawn that an arc of elbow flexion of 100° (30°–130°) was sufficient to perform most of the studied tasks. These results have been cited extensively and are now commonly referred to as a functional arc of flexion and extension[268] (Figure 21). As might be excepted, later studies have found that, for some activities of daily life, a greater range of motion is required.[342] While it may bother some people not to have a range of motion in excess of the functional arc, it is clear that very few people are satisfied with a range of motion that is less than 30°–130°. This is understandable, as at least 130° of flexion is required for several essential tasks such as eating.[294]

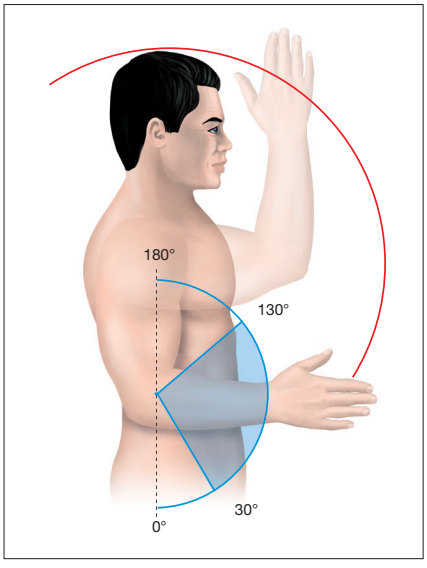

FIGURE 21 Elbow flexion and extension. A functional arc of flexion-extension, allowing most activities of daily life to be performed, is commonly considered to be between 30° and 130° of flexion (blue area within blue semicircle). Limited flexion is particularly troublesome, as many activities such as eating and washing the head and neck are impossible to perform. The motion of other joints such as the shoulder does not compensate (red semicircle).

Mayo elbow performance score (MEPS)

The MEPS is used extensively. It is the most commonly used rating system in studies of distal humeral fractures,[422] elbow trauma in general,[117] degenerative conditions[235] and, in fact,

for elbow disorders overall.[117] The MEPS was constructed by Bernhard Morrey at the Mayo Clinic.[264] A study by Morrey and Adams published in 1992[261] was one of the earliest, if not the first, to use the MEPS. In this publication, it is stated that the MEPS is a rating system that was recently developed, citing a book chapter from 1991.[260] The system is described as being used to: "document, subjective, objective, and functional characteristics". Three of four subscales consist of one item: Pain (maximum 45 points), Motion (maximum 20 points) and Stability (maximum 10 points). The Function subscale (maximum 25 points) has five items, each enquiring about the ability to complete a particular activity of daily life. The Pain and Function subscales require input from the patient, while the Motion and Stability subscales are scored according to clinical findings. The MEPS is thus not a PROM but a *mixed clinician-based* instrument. The MEPS is scored from 0 to 100, with higher scores representing better results.

Although not evaluated initially, some later studies have assessed the measurement properties of the MEPS. In a review from 2013, The et al.[393] assessed the methods that had been used to evaluate the measurement properties of available elbow-specific instruments. They found only four studies assessing the measurement properties of the MEPS and the methods used were rated as poor or fair. Since 2013, some further evidence relating to the measurement properties of the MEPS has emerged. In terms of construct validity, correlations with other outcome instruments have been: approximately –0.6 with the DASH in three studies,[68; 139; 312] 0.83 with the ASES score in one study[89] and 0.67 with the Subjective Elbow Value in one study[348] and approximately 0.5–0.8 with the domains of the OES.[96; 97; 177; 297; 312] The correlations are moderate to high, lending some support to the construct validity of the MEPS. One explanation for correlations not being higher is that some of these instruments include items on psychological and social aspects, while no such items are included in the MEPS. Celik[97] reported an intra-class correlation of 0.89 based on a test-retest analysis, concluding that the MEPS had good reliability. It should be noted that no assessment of the quality of the methods used in these later studies has been performed.

Based on an analysis of 265 patients treated with arthrolysis, Sun et al.[386] estimated that the minimal important difference (MID) of the MEPS was 12. Moreover, these authors estimated that the smallest detectable change (SDC) was 7.6, while Celik[68] reported a value of 11.3.

Taken together, the MEPS may have reasonable measurement properties, but the data are limited, considering how extensively it is used.

DASH

The Disabilities of the Arm, Shoulder and Hand (DASH) score is a PROM that was developed as a joint initiative by the *Institute of Work and Health* in Canada and the *American Academy of Orthopaedic Surgeons* (AAOS). Certain aspects of its development were described in publications from 1996 and 1999,[94; 171; 245] before it was introduced in 1999.[248] The DASH consists of 30 questions, with total scores ranging between 0 and 100. Most outcome measures used in orthopedics aim to assess function and it therefore makes sense that higher scores generally indicate better function. The scoring of the DASH is reversed, with higher scores indicating poorer function. This is, however, understandable, considering the aim of the DASH, as stated in a publication by Marx et al. from 1999:[245] "to evaluate symptoms (such as pain, numbness and tingling), as well as physical, social and psychological disability for patients with upper-extremity disorders". Based on this definition, it is clear that the DASH is neither joint- nor disease-specific, but it is more appropriately described as region-specific. The measurement properties of the DASH were favorable in the initial studies,[32; 202; 237] based on cohorts with shoulder and hand diagnoses, but, notably, no elbow disorders were included. Some later studies have evaluated the measurement properties of the DASH in cohorts including patients with shoulder, elbow and hand pathology, consistent with the aim of being a region-specific, upper-extremity outcome measure. [9; 298] The measurement properties have also been favorable in these studies.

There are also some studies that have validated the DASH specifically for elbow conditions.[117] The magnitude of correlation of DASH scores with those of the domains of the Oxford Elbow Score (OES) has been in the range 0.6–0.8, lending some support to the construct validity of the DASH specifically for elbow conditions,[96; 112; 312] although the DASH was actually the comparator in these studies. Dawson et al.[95] found a correlation of 0.5–0.6 between DASH and OES change scores, indicating only moderate responsiveness for elbow conditions.

Estimates of the MID for the DASH, based on calculating the mean change scores for patients with small or slight improvements, have been in the range of 7–12 points.[95; 128; 240; 404] Dawson et al.[95] estimated that the MID of the DASH was 9–10 points in the only one of these studies that includes only patients with elbow disorders. Estimates of the smallest detectable change (SDC) are scarce for elbow disorders specifically. Two studies based on cohorts with mixed upper-extremity disorders, including patients with elbow pathology, reported SDC estimates of 11[128] and 13 points,[347] respectively.

QuickDASH

The *Quick*DASH is a shortened version of the DASH score, consisting of 11 items.[33] The use of the *Quick*DASH is probably increasing, at least for degenerative disease. In a review by Evans et al.,[117] the *Quick*DASH was used in 9% of studies of elbow arthroplasty in 2010–2016, while it was used in 23% of studies of degenerative elbow diseases in 2010–2020, according to a review by Lu et al.[235] The *Quick*DASH is an attractive alternative to the DASH, as it requires less effort by the patients. Some studies have suggested that higher scores are seen with the *Quick*DASH than with the full-length DASH,[158; 236] but the differences have been small. In a study by Angst et al.,[9] the mean score of the *Quick*DASH was in fact slightly lower (difference of 1 point) than of the DASH in 79 patients with elbow pathology. The observed differences between the total scores of the DASH and *Quick*DASH are therefore small. The *Quick*DASH has been found to have construct validity that is very similar to the full-length DASH in terms of correlations with joint-specific scores.[9; 236; 398] Responsiveness[158] and reliability (test-retest)[33; 158] have also been found to be very similar between the two instruments. For elbow trauma, estimates of the MID of the *Quick*DASH have been in the range of 5–12 points, while two studies have reported SDC values of 11[411] and 12 points.[177]

Treatment options for distal humeral fractures

Very limited evidence is available to guide treatment choices for distal humeral fractures. Several RCTs are available, but most of them compare different ways to perform plating rather than comparing fundamentally different treatment options. Three studies have compared the parallel and perpendicular placement of plates, but none of them found any clear differences in outcome.[148; 220; 359] Crönlein et al.[87] found no difference between two different types of polyaxial locking plates (VA-LCP vs. Aptus), while Galal et al.[134] found no difference in locking and nonlocking plating for extraarticular fractures. Dehghan et al.[103] found similar outcomes between leaving the ulnar nerve in situ or performing an anterior transposition at the completion of plate fixation.

In the only available RCT comparing fundamentally different treatment strategies, McKee et al.[250] compared total elbow arthroplasty (TEA) with plate fixation for complex distal humeral fractures in elderly patients not amenable to stable fixation, concluding that TEA was preferable to plate fixation.

Most distal humeral fractures are treated with surgery. In a study by Robinson et al.,[332] 85% of all distal humeral fractures were treated with surgery, although it should be noted that this number reflects practice during the period 1988–1997.

Of all distal humeral fractures registered (patients aged 16 years and older) in the Swedish Fracture Register[259] in 2018–2020, approximately 60% were treated with surgery.[387] This is according to data available to registered users. The relatively high rate of surgical treatment reflects the generally accepted view that surgical treatment produces improved function and a lower rate of complications than non-surgical treatment, even for most patients with fractures of limited displacement.[15] This appears reasonable considering the large forces acting on the elbow, as described previously. In addition, surgical treatment appears reasonable to enable early mobility in order to avoid stiffness. Although historical evidence and experience suggest that non-surgical treatment results in greater impairment than surgical treatment, evidence based on direct comparisons is limited. In the previously mentioned series by Robinson et al.,[332] the risk of nonunion was approximately five times higher for non-surgically treated (n = 47) as compared with surgically treated fractures (n = 273). In a review from 2011 that was otherwise narrative, Nauth et al.[273] pooled the results of two available studies comparing surgical and non-surgical treatment. Non-surgical treatment had an approximately three times higher risk of unacceptable results, a finding that is frequently cited. One of these studies, by Zagorski et al.,[421] reported the results for 42 patients with comminuted intraarticular distal humeral fractures. Of the 29 patients treated with ORIF, 22 (76%) had satisfactory (good or excellent according to Bickel and Perry) results. Non-ORIF treatment (skeletal traction, n = 6; excision arthroplasty, n = 2; collar'n cuff, n = 2; closed reduction and plaster, n = 3) was selected based on physician or patient preference and resulted in satisfactory results for only one patient (8%). The non-ORIF treatments were thus not purely non-surgical. The other study by Srinivasan et al.[373] included 28 patients (29 fractures) aged 75 years or older with AO/OTA type A, B and C fractures, of which 21 were treated with screws and/or plates (non-locking and not precontoured). Eight patients who refused or were unfit to undergo surgery were treated with a plaster for 3 weeks. Twelve (57%) of the surgically treated fractures had acceptable (excellent or good) results, according to the Orthopaedic Trauma Association grading, while this applied to only two fractures (25%) in the non-surgically treated group, ($p = 0.003$). Modern surgical techniques, such as precontoured plates, would be expected to produce even better results than those used in these studies, but the fact remains that the methodological quality of these studies is low. Taken together, choosing surgical over non-surgical treatment for most fit and independently living patients with distal humeral fractures appears to be prudent, but the evidence is weak.

Non-surgical treatment of distal humeral fractures

In recent years, non-surgical treatment has been revisited in a few studies.[2; 27; 105; 309; 394] Although the results give an idea of what non-surgical treatment can encompass, the insights are limited by selection bias. The majority of the included patients were chosen for non-surgical treatment as they were frail and probably to some extent based on having injuries that were not entirely unsuitable for non-surgical treatment. A recent review by Sudah et al. summarized the outcome of non-surgical treatment in 143 patients from 5 studies.[384] The fragility of the included patients is illustrated by the high mean age (74–87) and relatively high mortality rate observed. Aitkens et al. reported a mortality rate of 40% at five years in their non-surgically treated cohort.[2] Likewise, in the study by Battens et al.[27] in which the mean follow-up was 55 months, 55% of the non-surgically treated patients had died.

There appear to be two different schools of thought with regard to the length of immobilization: short (2 weeks or less)[2; 27] and long (5–7 weeks), (Figure 22).[105; 309; 394] Even with longer immobilization mean flexion has been reported to be 110–128° and extension 22–29°. The rate of union in the studies by Pidhorz et al.[309] and Desloges et al.[105] was 95% and 81%, respectively. Arthritis developed in a large proportion of patients (25–48%[105; 309]), even with a mean follow-up of only approximately 2 years. This might be of negligible importance for frail elderly patients, but it suggests that surgical treatment is reasonable in order to avoid osteoarthritis in the younger and more active patients.

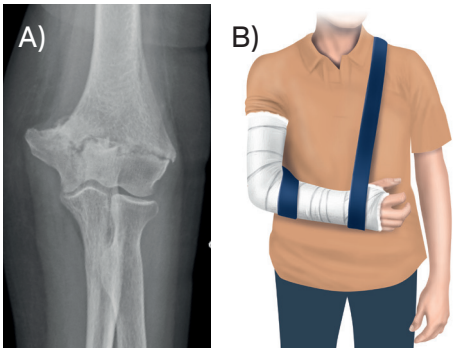

FIGURE 22 Non-surgical treatment of a distal humeral fracture **A)** An extraarticular distal humeral fracture. An injury that can be suitable for non-surgical treatment in frail, low demand, elderly patients. **B)** There is a considerable variation in how non-surgical treatment is performed, but typically a cast is worn for a couple of weeks.

Internal fixation of distal humeral fractures

Internal fixation – historical perspective

Plate fixation is the most commonly used treatment for distal humeral fractures[71; 332] and this could be expected, as ORIF is currently the preferred type of treatment for most patients,[15] although this has not always been the case. Distal humeral fractures were treated with open reduction and internal fixation as early as in 1914[209] and the following decades saw sporadic attempts at internal fixation with techniques that were as diverse as the results. Opposition and doubts relating to surgical treatment were strong during this period, only beginning to decline in the 1970s but even lasting into the 1980s.[23] It was increasingly recognized during this period that anatomic reduction and rigid internal fixation are essential to obtain a successful outcome, by Johansson and Olerud[189] in 1971 and Lansinger and Måre[214] in 1982, amongst others. This development was undoubtedly affected by the techniques and principles developed by the AO group, founded in 1958.[246]

The pioneering work done by Martin Allgöwer and his colleagues at the Kantonspitale, Basel, Switzerland, in developing and applying the AO principles in the treatment of distal humeral fractures deserves particular attention. Their work resulted in a milestone publication, by Scharplatz and Allgöwer, in 1975.[343] The results were promising, with ten of 15 patients with comminuted distal humeral fractures treated with plate fixation having satisfactory results. There were only two complications (1 infection and 1 nonunion). A second study based on the experience from Basel, authored by Jessie Jupiter, was published in 1985.[194] In this influential study, AO principles were applied in the treatment of 34 patients, of which 27 had a good or excellent outcome. Whether due to this study or not, the internal fixation of distal humeral fractures started to take off in the late 1980s.

Meanwhile, it became clear that there was a need for more stable implants. The shape of plates that are to be placed on the distal humerus needs to conform to the complex three-dimensional anatomy. At this time, 1/3 and 1/2 tubular plates were bent intraoperatively to accomplish this. Not unexpectedly, these pliable implants turned out to be prone to failure.[379] However, a major new innovation was already in the making – stiffer precontoured plates. Until this point of time, plates had been placed primarily in a perpendicular configuration (on the ridge of the medial column and posteriorly on the lateral column). Precontoured plates designed for placement on the ridge of the lateral column facilitate a parallel configuration, which allows long screws to be inserted into the articular

block from both the medial and lateral sides, maximizing the grip in the distal fragment. Precontoured lateral plates were in use as early as in 1988[408] and a biomechanical study from 1994 found that the parallel configuration provided superior rigidity.[344] However, it was not until around 2004, when O'Driscoll tied these and other concepts together into a coherent treatment strategy,[288] that the use of precontoured plates took off – revolutionizing the internal fixation of distal humeral fractures. Locking plates for distal humeral fractures were introduced at about the same time.[154]

Internal fixation – practical aspects

Plate fixation is generally performed using a posterior skin incision. A number of different strategies exist when it comes to exposing the distal humerus, but they can be broadly divided into various triceps-on approaches and approaches detaching the triceps, including olecranon osteotomy. The last mentioned offers a good view of the joint surface, but at the expense of an additional fracture requiring osteosynthesis, increasing the potential for complications. Plates can be placed in a perpendicular or parallel configuration as mentioned previously (Figure 23). A recent systematic review of biomechanical properties found that a parallel configuration was superior,[358] while another review found that the risk of nonunion was lower with parallel configuration as compared with perpendicular.[418] Postoperative treatment varies from immediate free range of motion, if stable fixation has been achieved, to a plaster for a couple of weeks in the event of insufficient stability or compromised soft tissues.

Outcome of plate fixation

Treatment with plate fixation generally results in acceptable functional outcome although completely normal function cannot be expected. In a couple of large recent cohorts, the mean extension deficit has been reported to be approximately 15–25°, flexion 120–130°, MEPS 85 points and DASH scores 20–25 points.[43; 125; 346; 370] In a recent review, Yetter et al.[418] found that complications occurred at a rate of 53% and reoperations at a rate of 21%. The authors acknowledged that the rate of complications might have been overestimated as their total number was considered, with some patients probably experiencing more than one complication. Another important point is that studies dating as far back as the mid-1980s were included. This may have inflated the rate of complications, as enormous changes have occurred in treatment (e.g. surgical technique, implants and rehabilitation). Yet another notable consideration is that the results of subgroups, elderly patients, for instance, are likely to deviate from those of the overall group.

Internal fixation in elderly patients

Some of the first series reporting specifically on the outcome of plating in elderly patients are from the 1990s.[190] A recent meta-analysis comparing TEA and ORIF for distal humeral fractures in elderly patients found that the pooled rate of complications was 34% for ORIF.[192] The included studies predominantly used older surgical techniques. In the past few years, series including elderly patients with predominantly AO type C fractures treated with locking precontoured plates have become available.[41; 110; 132; 196; 356] In order to reduce these difficult fractures, an osteotomy was necessary in most cases. The functional outcome has generally been reported to be good. The mean range of motion in these series has been approximately 20° for extension and approximately 120–130° of flexion. MEPS scores have had a mean of 85–90 points and DASH scores a mean of 20–30 points, which is reasonable with respect to age. The results have, however, differed with respect to complications, with two studies reporting rates of over 30%,[41; 110] while others have reported considerably lower rates.[132; 196; 356]

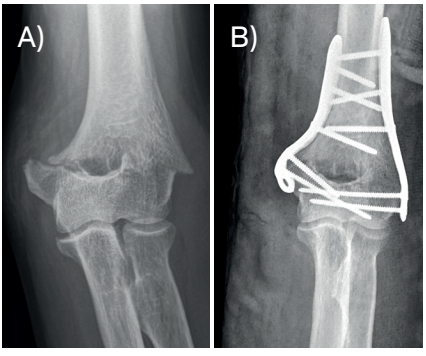

FIGURE 23 Plate fixation of a distal humeral fracture with precontoured plates in a parallel configuration. Anterior views.
A) An extraarticular distal humeral fracture.
B) Fixation with parallel plating.

Elbow arthroplasty – historical perspective

It appears reasonable to suggest that the modern era of elbow arthroplasty started in the 1970s. Sporadic attempts were made in the preceding decades[317] but the outcomes were insufficient for elbow arthroplasty to gain acceptance. It is noteworthy that, in the early 1950s, MacAusland and Veneble reported one case each of hemiarthroplasty for acute fractures.[308] It would take over half a century until a serious interest in hemiarthroplasty was seen. In the meantime, total elbow arthroplasty continued to develop.

Three main innovations contributed to moving total elbow arthroplasty forward in the 1970s: the use of cement for component fixation, the use of polyethylene in the bearings and the development of semi-constrained designs. In the 1960s,[73] John Charnley's pioneering work resulted in the successful low-friction hip arthroplasty that involved the use of poly(methyl methacrylate) (PMMA), also known simply as bone cement, and ultra high molecular weight polyethylene (UHMWP) in the bearings. This laid the foundations for the introduction of bone cement for elbow arthroplasty in the early 1970s. As Charnley was working in Wrightington, England, it is not surprising that one of the earliest reports on the experience of using cement for elbow arthroplasty came from Dee in London.[101] Despite promising early results, the rate of loosening turned out to be 27.5% after only 2–5 years.[218]

An understanding developed that the rigid hinges used in early designs were a likely culprit. Morrey and Bryan estimated that the rate of loosening of hinged designs was 26% after only 3.3 years.[266] A rigid hinge results in the large forces acting on the elbow joint being transferred directly from the forearm to the cement mantle in the humerus. This applies to forces acting in the sagittal plane, as explained in Figure 17, but also to forces in other planes. Varus and internal rotation forces are of particular interest, as they occur with abduction of the shoulder, which is required for many activities, such as eating, taking care of hygiene of the head and neck, reaching for objects on shelves and housekeeping chores, to mention just a few examples. In analogy with forces acting in the sagittal plane, these forces acting on the elbow are disproportionate in the event of external loads. With a rigid hinge design, varus forces can result in loosening (Figure 24A and B).

The understanding that the human elbow is not a rigid hinge was of key importance in enabling the development of total elbow arthroplasty to move forward. Biomechanical studies have found that 5° degrees of varus and valgus motion occur in the ulnohumeral joint with activities of daily life.[200] It was known back in the 1950s that the human ulnohumeral joint displayed these characteristics,[7] but it appears that the relevance of this knowledge relating to total elbow arthroplasty was not fully understood until the 1970s. In response, the development of total elbow arthroplasty diverged along two main conceptual paths: semi-constrained and unlinked designs. The latter has a limited bearing on fracture treatment and will not be discussed further. The idea behind semi-constrained total elbow arthroplasty is that, by allowing some motion (e.g. varus-valgus and rotational) between the components, the soft tissues are allowed to counteract some of the forces acting on the elbow, thereby reducing the forces transferred to the cement mantle (Figure 24C and D). This idea was clearly described in a paper by Schlein

in 1977.[345] Some of the earliest designs to embrace this idea were the Prichard and the Triaxial, which were already in use in the mid-1970s.[175] In 1978, two prostheses that would become widely used were changed to semi-constrained designs: the *Gschwend, Scheier, Baehler* (GSB)[156] and Coonrad prostheses, the latter subsequently referred to as Coonrad II. An anterior flange was added to the Coonrad prosthesis in 1981 to further diminish torque and forces in the sagittal plane.[4] Most contemporary semiconstrained elbow prostheses have an anterior flange, although it is unclear whether it provides a biomechanical advantage, at least with regard to the Latitude prosthesis studied by Quenneville et al.[319]

Semi-constrained total elbow arthroplasty for distal humeral fractures

Currently, both semi-constrained total elbow arthroplasty and hemiarthroplasty are regarded as treatment options for unreconstructable distal humeral fractures (Figure 25). During the 1980s and 1990s, total arthroplasty was mainly used for treating rheumatoid arthritis, with occasional case series on the treatment of fracture sequelae.[121; 262] In 1997, Cobb and Morrey published the first case series on total elbow arthroplasty as a treatment for distal humeral fractures.[79] Twenty-one fractures were treated. The mean age of the patients was 72 years and the mean length of follow-up was 3 years. The mean MEPS score was 95 points and the mean range of motion was 25° of extension and 130° flexion. Seven patients experienced local adverse events, one of them was revised. Cobb and Morrey emphasized that TEA was only indicated for severely comminuted distal humeral fractures in elderly patients. The use of TEA for fractures has increased since 2000, while it has decreased for rheumatoid arthritis on the other hand.[239] Due to the risk of loosening and the plausible role of disproportionately large forces caused by external loads, it remains common practice to recommend patients treated with total elbow arthroplasty to limit loading for the rest of their lives (typically to loads smaller than 5 kg).[25]

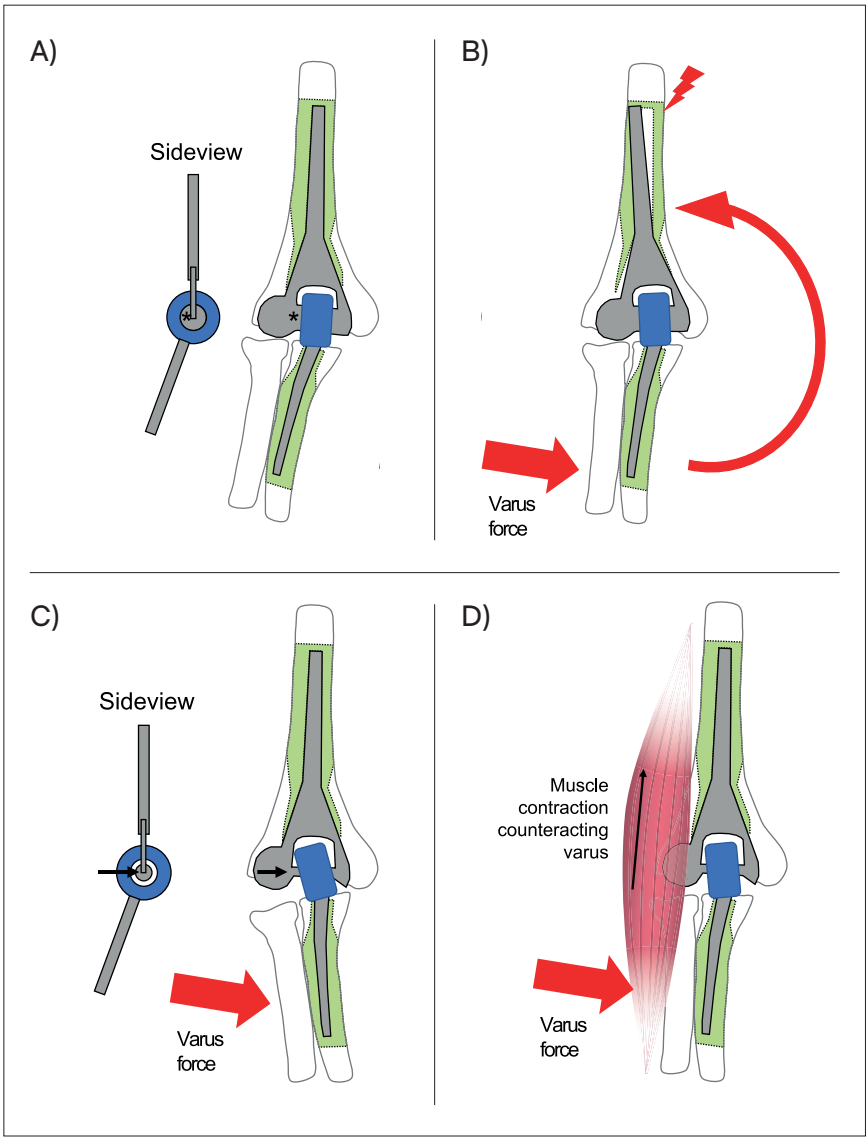

FIGURE 24 Potential effects of varus forces on total elbow replacement. Anterior view unless otherwise indicated. The cement mantle is represented by a green color. **A)** A theoretical rigid linked design. The pin on the humeral side fills the opening of the ring on the ulnar side (*). As a result, no motion is possible between the components (ulnar and humeral) at the coupling. **B)** With this design, external forces are transferred to a large degree to the cement mantle. This is demonstrated here by a varus force resulting in load transfer to the humeral cement-prosthesis interface due to the forearm and components (ulnar and humeral) rotating together. Repetitive forces of this type can lead to loosening. **C)** A linked but semi-constrained design implies that the some motion is possible between the components at the coupling, here demonstrated with a pin on the humeral side that is undersized relative to the ring on the ulnar side (black arrows). A varus force now leads to angulation of the components relative to each other at the coupling and a lower load is transferred to the cement mantle. **D)** Ideally, loading of the coupling is limited or abolished by the soft tissues counteracting the external forces.

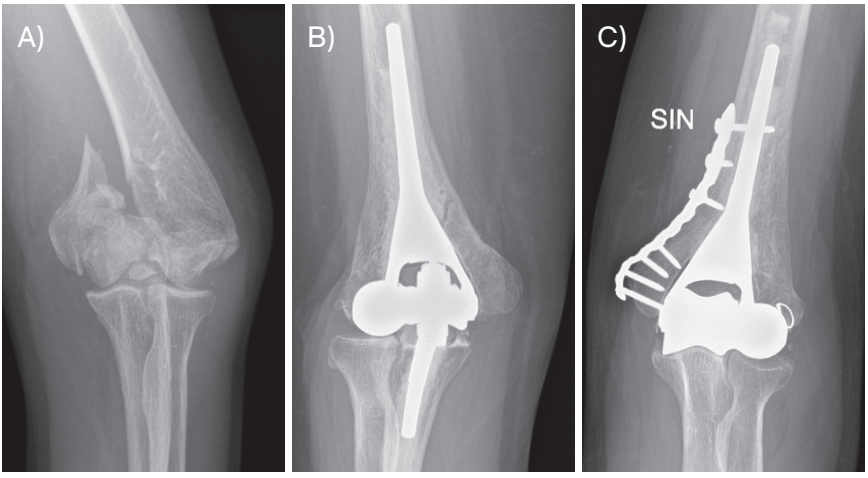

FIGURE 25 Radiographic appearance of distal humeral fractures treated with arthroplasty.
A) A comminuted fracture of the distal humerus with thin distal fragments. **B)** An injury equivalent to A), treated with total elbow arthroplasty. Image from follow-up demonstrating healing of the medial column initially fixed with K-wires that were removed a couple of months from the primary operation. **C)** An injury equivalent to A) treated with hemiarthroplasty and plate fixation of the medial column. Image from follow-up demonstrating healing of the medial column.

Hemiarthroplasty for distal humeral fractures

The first case series on the use of hemiarthroplasty for distal humeral fractures were published by Parsons et al.[301] in 2005 and Adolfsson and Hammer[1] in 2006. Neither of the implants used in these studies (Sorbie-Quester and Kudo) was designed specifically as a distal humeral replacement, but they are humeral components intended for total elbow arthroplasty. By 2005, the Latitude Anatomic, which is specifically designed as a distal humeral replacement, had come into use.[368] The Latitude Anatomic is part of the Latitude elbow arthroplasty platform, which also includes a convertible total elbow arthroplasty (Figure 26). In the mid-2000s, TEA had begun to gain acceptance as a treatment for selected distal humeral fractures,[135; 136; 219] but with the disadvantage of lifelong limitations in loading of the elbow. Hemiarthroplasty offers the opportunity to replicate the biomechanics of the native elbow (articular configuration and ligamentous stability), which means that load limitations should be avoidable. The results of the initial case series using the Latitude Anatomic, published in 2011[62] and 2012,[12] were promising.

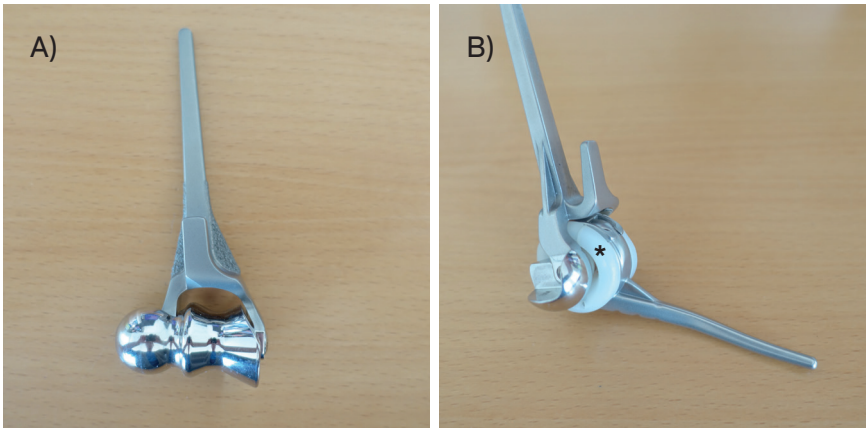

FIGURE 26 Latitude elbow arthroplasty system. **A)** An anterior view of a hemiprosthesis. The metal spool distally is designed to articulate with and conform to the shape of the greater sigmoid notch and radial head. **B)** An anterolateral view of a Latitude total elbow prosthesis. The design of the stem is the same as for the hemiprosthesis, but the part of the spool corresponding to the trochlea is much more narrow. The ulna component is linked to the humeral component by a ring that has a polyethylene surface (*) that articulates with the narrow part of the spool. The articulation is designed to allow some movements of the components relative to each other in order to lower load transfer to the cement mantle.

TEA and EHA for distal humeral fractures are typically performed using a posterior skin incision and the prosthesis is implanted without detaching the triceps (triceps-on approach). Some designs of TEA allow the reconstruction of the columns and epicondyles, but resection has also been advocated.[249] For EHA, restoring the continuity of the ligaments is essential to obtain joint stability (Figure 27). Elbow mobility is typically limited for a couple of weeks following EHA to allow ligament healing, while, for TEA, range of motion as tolerated is typically allowed within a few days.

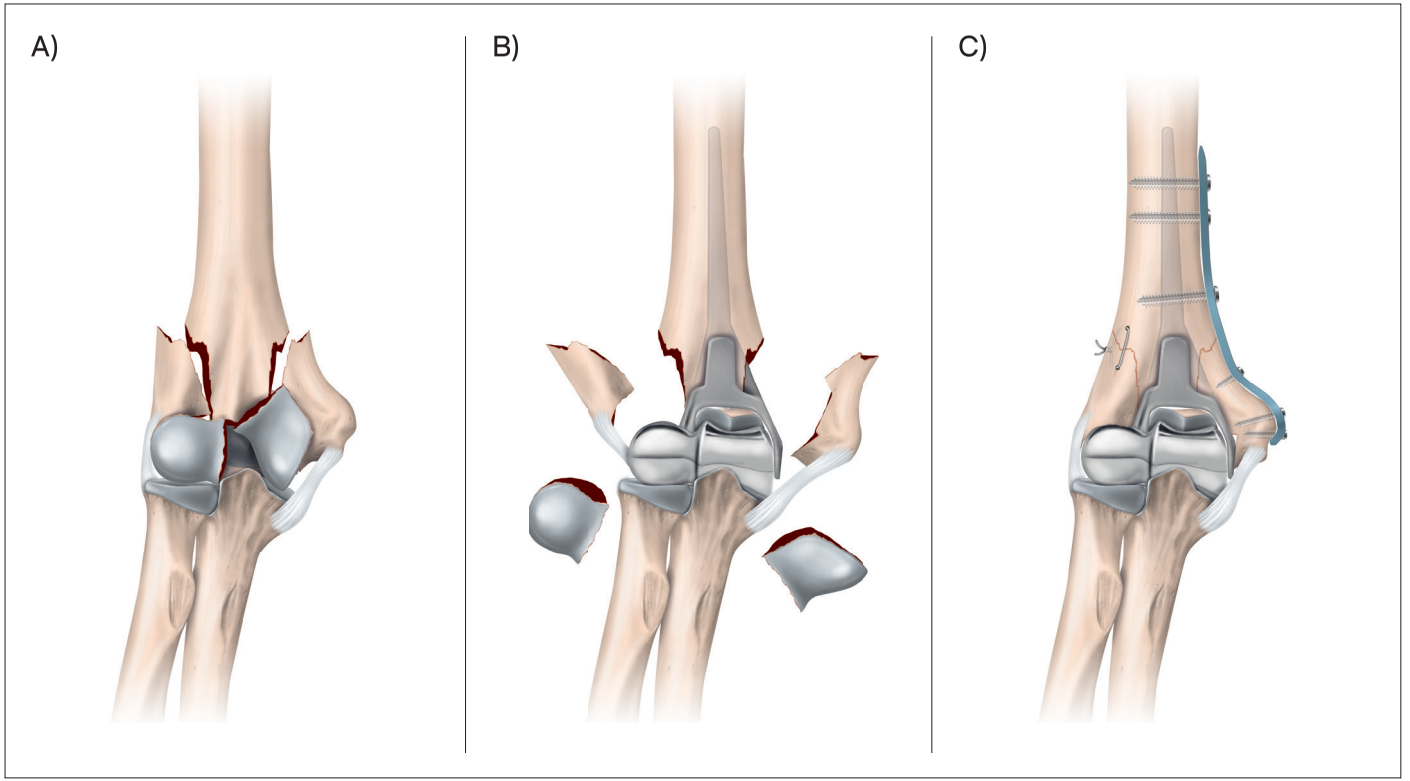

FIGURE 27 Management of epicondyles and columns in hemiarthroplasty for distal humeral fracture, view from anterior. **A)** A distal humeral fracture with very thin distal fragments. Both the lateral and medial column are fractured. The collateral ligaments are intact. The lateral ulnar collateral ligament lies behind the radial head, extending to its insertion on the ulna. **B)** The thin articular fragments are removed. The prosthesis is inserted and the joint reduced. **C)** The epicondyle/column fragments are reduced. A number of methods have been described for fixation, including plate fixation (medial side) and cerclage with wire or sutures (lateral side).

The Oxford Elbow Score and recall period

The Oxford Elbow Score (OES) is an elbow-specific outcome instrument developed with the aim of "assessing patient-reported outcome after surgery of the elbow".[96] The development of the OES followed a structured path that included multiple steps, such as including patient input at the item generation stage. Moreover, items were excluded if they performed poorly on statistical testing and aspects related to scoring were considered carefully. The assessment of construct validity and reliability was described in one publication,[96] while responsiveness was described in another.[95] In a review by The et al.[393] from 2013, the COSMIN checklist was used to evaluate the quality of methods used for assessing the measurement properties of available elbow-specific outcome instruments. They found that the OES was the only instrument that had been assessed with good quality standards. Although not assessed specifically in this review, the results of assessments of the measurement properties of the OES have been favorable.

The OES is an elbow-generic instrument, as it is not specific for any particular diagnosis. The analysis of measurement properties in the original publication by Dawson et al. was based on a group of patients with heterogeneous chronic conditions.[96] The high methodological quality applied in the original studies has set a high standard for the use of the OES. For instance, the multiple translations of the OES that have been made have followed appropriate guidelines.[31] Renewed validation of PROMs is considered appropriate if any changes are made to the instrument, such as in language or population.[321; 399] The measurement properties of new language versions of the OES have been favorable, reinforcing the belief that the OES has good measurement properties. Moreover, these studies have indicated good measurement properties for some specific diagnoses based on analyses of cohorts where most of the patients had: epicondylitis[112; 281; 420], elbow dislocation[97; 98; 177] and traumatic injuries[297]. To date, however, the measurement properties of the OES have not been assessed in a cohort of patients with mixed elbow injuries.

Iordens et al.[177] estimated that the MID of the total score of the OES was 8 points. Meanwhile, Dawson et al.[95] estimated that the MID for the Pain and Social-Psychological domains was approximately 18 points, whereas it was 10 points for the Function domain. The SDC of the total score has been reported to be 12 points.[177]

The recall period for the OES is 4 weeks. In a publication by Reeve et al. recall period was defined as "the period of time of reference (e.g. currently, past 24 h, past 7 days, past 4 weeks) for patients to describe their experiences with the

measured PRO".[321] A recall period of 4 weeks is relatively long compared with many outcome instruments used in orthopedics, where recall periods of 1 week are common.[171 232] There is no gold standard for the length of a recall period for a PROM. It needs to be sufficiently long so that it is likely that the patient has experienced the phenomena enquired about during the period. This, however, needs to be balanced against the potential problems that longer recall periods can entail. The United States Food and Drug Administration (FDA) recommends the use of short recall periods due to longer recall periods potentially being more affected by inaccurate recollection.[399] Systematic or temporal changes in symptoms pose another problem. Systematic (temporal) changes over the course of a recall period have been found to threaten the accuracy of results of PROMs,[349] with longer recall periods being likely to be disproportionately affected. Assessing elbow function while patients are still improving following surgery or injury can therefore be problematic, with a 4-week recall period, particularly in the initial phases.

2.

Material and methods

STUDY I

Study design, eligibility and settings

Study I is a multicenter, randomized controlled trial (RCT). Patients were eligible if they had a displaced 3- or 4-part fracture of the proximal humerus, were over 70 years of age, lived independently and had an injury caused by a low-energy mechanism. Patients were excluded if they had a concurrent injury that was likely to affect rehabilitation considerably, had a pre-existing shoulder condition, or had more than 7 errors on the *short portable mental status questionnaire* (SPMSQ),[306] corresponding to *severe cognitive impairment.* Patients were included and underwent surgery at one of the following hospitals: Danderyd University Hospital, Stockholm; Sahlgrenska University Hospital, Gothenburg; Skåne University Hospital, Malmö; Stockholm South General Hospital, Stockholm; and Linköping University Hospital, Linköping; Karlstad Central Hospital, Karlstad; Hallands Hospital Varberg, Varberg; and Ryhov Hospital, Jönköping (the last 3 are county hospitals).

Randomization

Randomization blocks of ten were generated using an online computer program.[353] Information about treatment allocation was written on pieces of paper, which were placed in sealed, opaque envelopes. These were opened according to the predetermined order for randomizing individual patients to the treatment groups.

Interventions

Patients were randomized to the type of arthroplasty: HA or rTSA. The delivery of interventions was partly pragmatic,[127] as normal practice at the treating hospital determined which specific brand of prosthesis was used. The procedures were performed by orthopedic surgeons with extensive experience of shoulder arthroplasty for proximal humeral fractures. Overall, the rehabilitation was similar for both treatment groups. Further details on the interventions are provided in the methods section of **Study I**.

Assessment of outcome

Patients were followed up at both 1 year and after at least 2 years from surgery (final follow-up). The primary outcome measure was the Constant score[83] at final follow-up. Secondary outcome measures were range of motion (flexion, abduction, external rotation and internal rotation) assessed in degrees with a goniometer, pain on a VAS, the *Western Ontario Osteoarthritis of the Shoulder* (WOOS) index[232] and the EQ-5D index.[106] Patients were assessed by an independent physiotherapist. Patients were asked about the occurrence of adverse events at follow-ups. In addition, medical records were reviewed, noting any adverse events.

Radiographic assessment

Fractures were classified as 3- or 4-part fractures based on radiographs and CT images when available. The occurrence of fracture dislocation was noted. Radiographs taken postoperatively and, in association with the final follow-up were calibrated by measuring the width of parts of the prosthesis with known dimensions and assessed with respect to signs of loosening, as well as the healing of the greater tuberosity according to a predetermined algorithm stated in the methods section of **Study I**:

Greater tuberosities in bony continuity with the shaft on anteroposterior (AP) radiographs were regarded as united. Tuberosities that were not visible on the AP view, but were detectable on the lateral view were considered horizontally malunited if in continuity with the shaft. Tuberosities visible on either of the views but not in continuity with the shaft were regarded as non-unions. Tuberosities not visible in any projection were regarded as resorbed.[191]

Registration at ClinicalTrials.gov

Study I was registered at ClinicalTrials.gov, identifier (NCT number): NCT03383991, available at https://clinicaltrials.gov/ct2/show/NCT03383991

Sample size calculation

To detect a difference of 10 points on the Constant score with 85% power and statistical significance set at 0.05, a group size of ≥ 48 patients was considered adequate, assuming a standard deviation of 10 points and allowing for a dropout rate of 15%.

Statistical methods

Patients were analyzed on an intention-to-treat basis. Comparisons were made between the treatment groups using Fisher's non-parametric permutation test for continuous variables, Fisher's exact test for comparing dichotomous variables and the chi-square exact test for non-ordered categorical variables. The Wilcoxon signed rank test was used to compare continuous variables over time and the sign test was used for categorical variables.

STUDY II

Study design, eligibility criteria and search strategy

Study II is a systematic review and meta-analysis. Studies were eligible if the outcome of patients with tuberosity healing (TH) and failed tuberosity healing (FTH) was compared after treatment with primary hemiarthroplasty for a proximal humeral fracture. Studies that specifically stated including the lesser tuberosity in the definition of healing were excluded, as it is difficult reliably to identify the lesser tuberosity on radiographs. In addition, a method for assessing and reporting lesser tuberosity healing is lacking. Information on the complete exclusion criteria is provided in the material and methods section of the manuscript and a PICO table is presented in Supplementary Appendix S1 in the manuscript. The following databases were searched from January 1, 1987 to January 24, 2022: MEDLINE, EMBASE, The Cochrane Library and CINAHL. The search strategies had the following basic structure: hemiarthroplasty AND (shoulder fracture OR proximal humeral fracture OR upper arm fracture).

Screening, assessment of eligibility and data extraction

Each of these steps was performed independently by two authors followed by a consensus discussion together with a third author. Titles and abstracts were screened and studies were excluded, unless they fulfilled the following requirements: reported at least one outcome measure for a group of patients ($n > 5$) treated with primary HA for proximal humeral fractures, and the tuberosities were mentioned. Full-text versions of the remaining publications were reviewed and included if they fulfilled the complete eligibility criteria. Data were extracted using a predetermined and piloted extraction form. Information on the variables extracted is provided in the material and methods section of the manuscript.

Assessment of methodological quality and risk-of-bias

The methodological quality of included non-randomized studies was evaluated using the *methodological index for non-randomized studies* (MINORS).[363] Randomized studies were evaluated using version 2 of the Cochrane risk-of-bias tool (ROB 2).[378]

Data synthesis

As opposed to fixed-effects (FE) models, random-effects (RE) models allow effect estimates of individual studies to differ, but they are assumed to originate from a common distribution,[283] with a normal distribution being a conventional choice for RE models.[102] In **Study II**, the meta-analyses were planned to be performed with an RE model, as potentially available studies were expected to have some degree of clinical and methodological heterogeneity, likely to be manifested at least to some degree in statistical heterogeneity. For analyses of standardized mean differences (SMD), if studies reported the results of more than one clinical rating system, the one reported most commonly in the literature on proximal humeral fractures was chosen according to a predetermined hierarchy.[324]

STUDY III

Study design, eligibility and settings

Study III is a multi-center, randomized controlled trial. Patients were eligible if they had an unreconstructable distal humeral fracture, were more than 60 years of age and lived independently. Joint stability following EHA is dependent on both bony and ligamentous stabilizers. Patients were therefore excluded if there were injuries not compatible with the reconstruction of bony (e.g. unreconstructable radial head fracture) and ligamentous (e.g. unreconstructable column or epicondyle) stability. Further exclusion criteria were pre-existing upper extremity conditions and/or concurrent injury considerably affecting function and an inability to participate in follow-ups (due, for example, to cognitive impairment or insufficient understanding of the Swedish language). Patients were included and underwent surgery at one of the following hospitals in Sweden: Sahlgrenska University Hospital, Gothenburg; Linköping University Hospital, Linköping or Hallands Hospital Varberg, Varberg (a county hospital). Surgery was performed by orthopedic surgeons with extensive experience of performing elbow arthroplasty.

Randomization

Information on randomization, which was performed in blocks of ten, was stored in sequentially numbered, sealed opaque envelopes that were opened to allocate patients to treatment groups, according to a predetermined order.

Interventions

A posterior approach was used for both treatment groups. The final decision to perform an arthroplasty was made intraoperatively if reliable fixation was deemed impossible (unreconstructable). The ulnar nerve was decompressed, protected and then left in situ at the end of the procedure whenever possible, but it was transposed if deemed necessary, for example, if flexion led to undue tension on the nerve. All components were fixed with cement. The Latitude Anatomic (Wright Medical, a subsidiary of Stryker, Kalamazoo, Michigan, USA) was used for EHA. After inserting the prosthesis, bony and ligamentous structures were repaired as necessary to obtain joint stability. The primary choice of implant for TEA was Latitude Total Elbow Arthroplasty (Wright Medical, a subsidiary of Stryker, Kalamazoo, Michigan, USA).

The postoperative management of EHA included immobilization using a plaster for 2–7 days. Excessive extension was then limited using a brace or thermoplastic splint until active extension exercises were initiated after approximately 4 weeks. Unrestricted use of the elbow joint was typically allowed after 3 months from surgery. The postoperative management of TEA consisted of immobilization with a plaster in 45° of flexion for 1–2 days. Range of motion was then allowed as tolerated. Patients treated with TEA were recommended to limit weight-bearing to less than 5 kg for the rest of their lives.

Assessment of outcome

The primary outcome measure was the DASH score[171] at follow-up after a minimum of 2 years from surgery. Secondary outcome measures were the MEPS,[201] the EQ-5D index,[106] grip strength measured with an hydraulic dynamometer in kg and range of motion (flexion, extension, supination and pronation) measured in degrees with a universal goniometer. Adverse events were identified by specifically asking about their occurrence at all follow-ups but also by reviewing medical records.

Radiographic assessment

Based on radiographs and computed tomography images, fractures were classified based on the level of their most distal transverse component, beginning with coronal shear fractures, which were described using Dubberly's classification[109] (Figure 28). Fractures below the transcondylar axis (TA) were then considered and this was followed by those through the transcondylar axis. In the AO/OTA classification, these two fracture types are classified into one common group, 13C1.3.[252] In **Study III**, these fractures were further defined based on level as described previously (below or through the transcondylar axis) but also based on the presence of intraarticular fracture lines and comminution (≥ 3 articular fragments). Lastly, fractures above the transcondylar axis were classified according to the AO/OTA classification.[252]

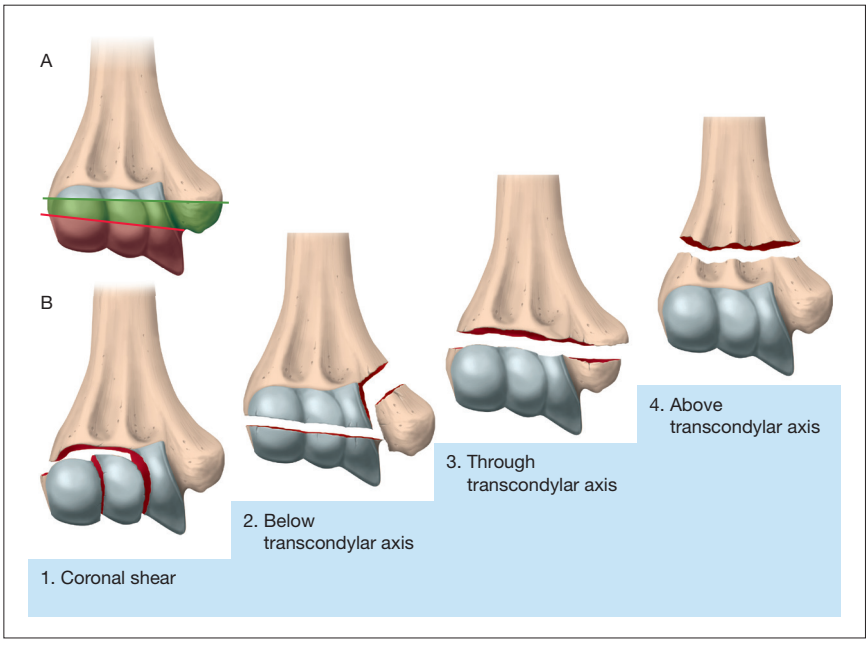

FIGURE 28 In **Study III**, distal humeral fractures were classified in a stepwise manner based on the level of the most distal fracture component, irrespective of any more proximal components (e.g. involvement of the columns) except as described below. **A)** Transcondylar axis (green line). Fractures through transcondylar axis (green shade). Fractures distal to the transcondylar axis (red shade) were those with either a fracture of the trochlea at or below the level of the inferior portion of the medial epicondyle or a coronal shear type component on the lateral side (or both). **B1)** Fractures distal to the transcondylar axis, but not involving the medial epicondyle (coronal shear fractures) were considered first and classified according to Dubberly.[109] **B2)** Next, fractures below the transcondylar axis (TA) which involved the medial epicondyle or column (with or without involvement of the lateral column) were considered, **B3)** followed by fractures through the TA. For the last two mentioned fracture types, any intraarticular involvement was noted. Intraarticular comminution was defined as ≥ 3 fragments. **B4)** Finally, fractures above the TA axis were classified according the AO/OTA classification.[252]

Registration at ClinicalTrials.gov

Study III was registered at ClinicalTrials.gov, identifier (NCT number): NCT03596736, available at https://clinicaltrials.gov/ct2/show/NCT03596736.

Sample size calculation

To detect a difference of 10 points on the DASH score with 80% power and statistical significance set at 0.05, a group size of 20 patients was considered adequate assuming a standard deviation of 10 points and allowing for a dropout rate of 20%.

Statistical methods

Patients were analyzed on an intention-to-treat basis. The primary comparison of continuous variables between groups was performed with the independent samples t-test, but an analysis using the non-parametric Mann-Whitney U test was also performed. Differences in categorical variables were compared between groups using Fisher's exact test. Statistical significance was set at 0.05.

STUDY IV

Study IV is a prospective cohort study that was designed to assess the measurement properties of the Oxford Elbow Score (OES) when used with a shortened 7-day recall period.

Eligibility criteria and settings

Patients were eligible if they had suffered a fracture, tendon rupture or dislocation affecting the elbow. Patients were excluded if they had other concurrent upper extremity injuries, a pre-existing impairment in upper extremity function (> 10 points on the *Quick*DASH assessing pre-injury function by recall), cognitive impairment or an inability to communicate in Swedish. Patients were included at one of the following hospitals in Sweden: Helsingborg Hospital, Helsingborg; Linköping University Hospital, Linköping or Sahlgrenska University Hospital, Gothenburg.

Outcome measures

Patients responded to three patient-reported outcome measures at three different

timepoints. Firstly, the Oxford Elbow Score (OES), which was developed to assess the outcome after surgery on the elbow.[96] The OES was originally described for use with a 4-week recall period, but in this study a shortened 7-day recall period was used (OES-7d). Secondly, the *Quick* Disabilities of the Arm, Shoulder and Hand (*Quick*DASH) score.[33] Finally, the Single Assessment Numeric Evaluation (SANE),[414] which was modified in this study by incorporating the term "function" in the question: *How would you rate your current elbow function compared with a completely normal elbow?* and consequently termed SANE-F. Patients responded to the SANE-F on an 11-point numerical rating scale (NRS).[19; 396]

Patients responded to the OES-7d, *Quick*DASH and SANE-F for three different periods of time (timepoints relative to injury): last week before (termed T1), first week after (termed T2) and a period of one week after 3–5 months (termed T3).

Statistical methods

Assessments of measurement properties were made in accordance with the *COnsensus-based Standards for the selection of health Measurement Instruments* (COSMIN) checklist[258] and the COSMIN terminology[257] was used. The following measurement properties were assessed: construct validity, responsiveness and internal consistency in addition to intra-rater reliability, which was assessed in a separate cohort, as described in the following section. Correlations were assessed with Spearman's rho (r_s). Construct validity was assessed by correlating the scores from T3 of the OES-7d with those of the *Quick*DASH and SANE-F. Responsiveness was assessed using change scores. Changes in scores between T2 and T3 (T3 minus T2) were termed T2/T3 change scores. Changes in scores between T1 and T2 (T2 minus T1) were termed T1/T2 change scores. Correlations between T2/T3 changes scores were expected to illustrate responsiveness to improvement while those between T1/T2 changes scores were expected to illustrate responsiveness to deterioration. Calculations of Cronbach's alpha, based on results at T3, were used to assess the internal consistency of the domains of the OES.

Intra-rater reliability

Intra-rater reliability was assessed in a separate group of patients who had injured their elbow 1–2 years previously but had not since suffered any new upper extremity issues (surgery, debut of a new condition or exacerbation of a pre-existing condition). These patients responded to the OES-7d, *Quick*DASH and SANE-F twice, with at least 1 week but at most 3 weeks between the occasions. Based on these data, intraclass correlation coefficients (ICCs) were calculated using a single-measurement, absolute agreement, 2-way mixed-effects model.[318]

ETHICS

Studies I, III and IV were approved by the Swedish Ethical Review Authority, the reference numbers of the approvals are 2013/1053-31/3 for **Study I**, 2010/342-31 for **Study III**, and 2020-00749 and 2020-04709 for **Study IV**. All patients included in these studies provided written informed consent to participate.

3.

Results

STUDY I

Flow of patients and baseline data

Ninety-nine patients were included between September 2013 and May 2016, with 48 randomized to rTSA and 51 to HA. Overall, 15 patients were lost to follow-up, leaving 41 rTSAs and 43 HAs available for analysis (Figure 29). The overall mean age was 79.5 years and there were 76 women (90%). There were no differences between the treatment groups in terms of age, gender, pre-injury EQ-5D index or type of injury (3-part fracture, 4-part fracture or fracture dislocation).

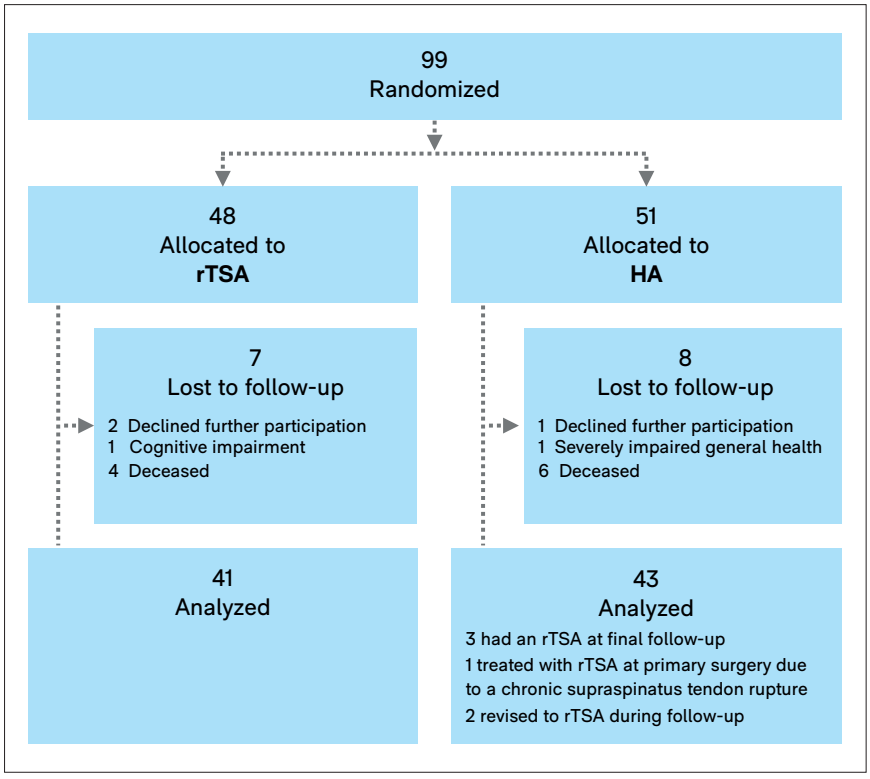

FIGURE 29 Flow of participants through **Study I**. The 3 patients allocated to HA who had an rTSA at the time of final follow-up were analyzed on an intention-to-treat basis. rTSA, reverse Total Shoulder Arthroplasty; HA, Hemiarthroplasty

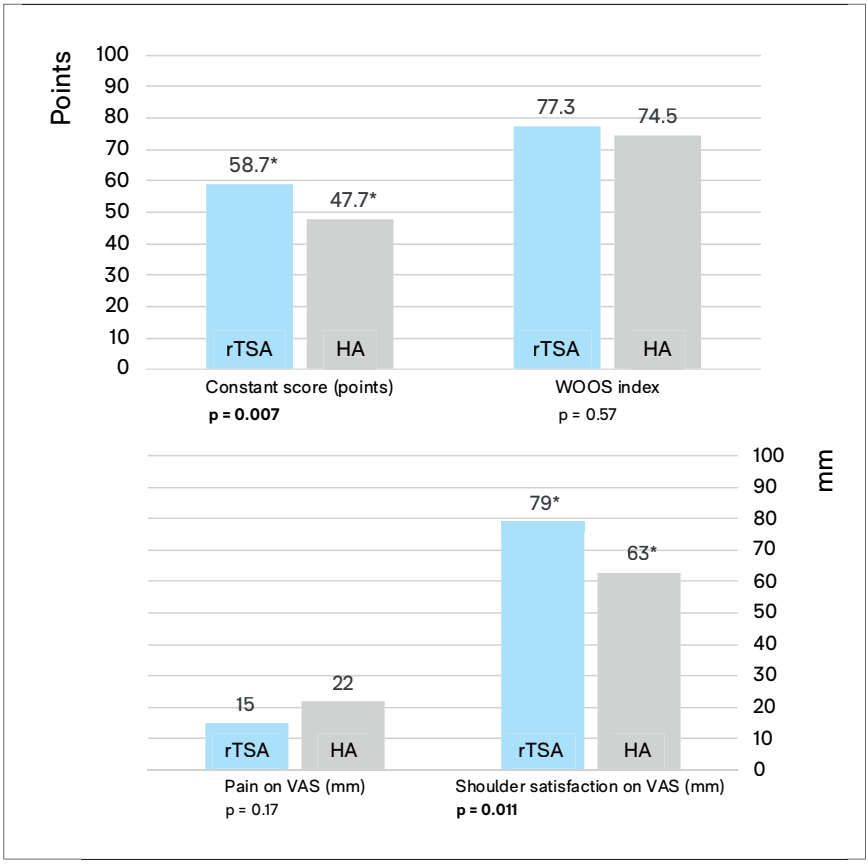

FIGURE 30 Result of clinical rating systems reflecting shoulder function, used in **Study I**. Comparison between treatment with rTSA (blue) and HA (grey) for mean values of the Constant score (points), WOOS index (points), pain on VAS (mm) and shoulder satisfaction on VAS (mm). Mean values are displayed above the columns and marked with * when differences between treatment groups are statistically significant ($p < 0.05$). rTSA, reverse Total Shoulder Arthroplasty; HA, Hemiarthroplasty; WOOS, Western Ontario Osteoarthritis of the Shoulder; VAS, Visual Analogue Scale.

Outcome

Patients treated with rTSA had significantly higher mean Constant scores (58.7 points, (SD: 16.3)), the primary outcome measure, compared with patients treated with HA (47.7 (20.0)), $p = 0.007$), (Figure 30 and Table 2). Moreover, compared with patients treated with HA, patients treated with rTSA had significantly higher mean degrees of flexion (125° (28) vs. 90° (39), $p < 0.001$) and abduction (112° (29) vs. 83° (38), $p < 0.001$), (Figure 31). Moreover, satisfaction with shoulder function was higher in the rTSA group compared with the HA group, 79 mm vs. 63 mm, $p = 0.011$. There were no statistically significant differences in the results for the WOOS index, EQ-5D index or pain on VAS between the treatment groups.

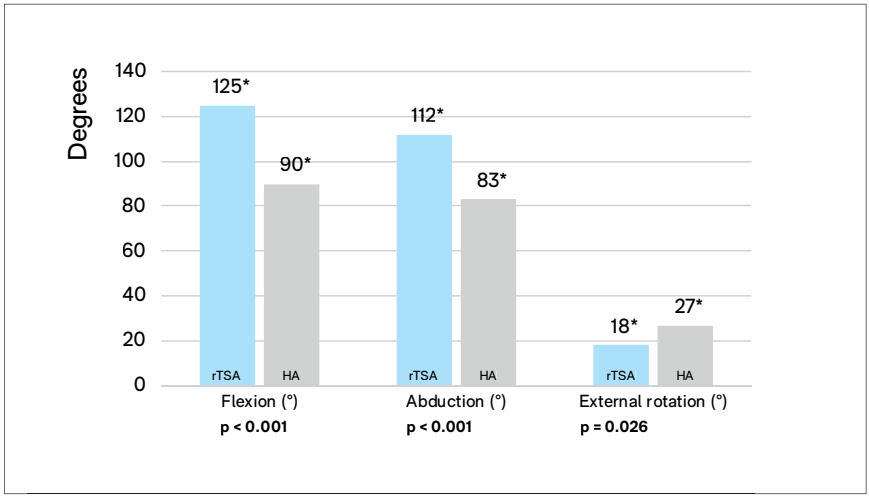

FIGURE 31 Result of range of motion in **Study I**. Comparisons between treatment with rTSA (blue) and HA (grey) for mean degrees of flexion, abduction and external rotation. Mean values are displayed above the columns and marked with * when differences between treatment groups are statistically significant ($p < 0.05$). rTSA, reverse Total Shoulder Arthroplasty; HA, Hemiarthroplasty

There were 26 patients in the rTSA group (63%) who obtained ≥ 120° flexion compared with 8 in the HA group (19%), $p < 0.001$. Fourteen patients (34%) in the rTSA group obtained ≥ 130° of abduction compared with 6 patients (14%) in the HA group, $p = 0.054$.

TABLE 2 Main results of clinical rating systems and range of motion for the rTSA and HA randomization groups

	rTSA (n = 41)		HA (n = 43)				
	Mean	(SD)	Mean	(SD)	Mean difference	(95% CI)	p-value
Constant score, points	58.7	(16.3)	47.7	(20.0)	11.1	(3.0 to 18.9)	0.007
WOOS index, points	77.3	(21.0)	74.5	(23.5)	2.8	(−7.0 to 12.7)	0.57
EQ-5D index	0.84	(0.13)	0.83	(0.13)	0.01	(−0.05 to 0.07)	0.72
Pain on VAS, mm	15	(20)	22	(26)	−7	(−17 to 3)	0.17
Shoulder satisfaction on VAS, mm	79	(22)	63	(33)	16	(4 to 28)	0.011
Range of motion, degrees							
Flexion	125	(28)	90	(39)	35	(20 to 49)	<0.001
Abduction	112	(29)	83	(38)	29	(15 to 43)	<0.001
External rotation	18	(18)	27	(19)	−9	(−17 to −1)	0.026

rTSA, reverse Total Shoulder Arthroplasty; HA, Hemiarthroplasty; CI, Confidence interval; WOOS, Western Ontario Osteoarthritis of the Shoulder; VAS, visual analogue scale

Patients treated with rTSA improved between the 1-year follow-up and final follow-up (≥ 2 years) in terms of the mean Constant score (n = 35, 54.8 (16.2) vs. 59.6 (17.1) points, p = 0.004), flexion (n = 36, 119° (25) vs. 127° (27), p = 0.017) and internal rotation (p = 0.003). Meanwhile, patients treated with HA were stationary between these two timepoints, not showing any statistically significant improvement in any of the outcome parameters.

Radiographic analysis

On radiographs taken in association with the final follow-up (rTSA = 36 and HA = 34), none of the patients had any component with subsidence, angulation, fractured cement mantle or a circumferential zone of radiolucency (clear signs of loosening). There were 24 patients with healing of the greater tuberosity in each of the treatment groups resulting in healing rates of 24/36 (67%) and 24/34 (71%) for rTSA and HA, respectively. Considering all radiographs taken both postoperatively and at the final follow-up, the magnification was 12% on average (range: 0.4 to 36%).

Adverse events

There were 3 adverse events in the rTSA group, including 1 humeral shaft fracture that healed after treatment with ORIF, 1 patient with complex regional pain syndrome (CRPS) and 1 patient who died of pneumonia 8 days after surgery. In the HA group, there were 4 adverse events, including 1 humeral shaft fracture treated with revision rTSA, 2 humeral shaft fractures that both united with non-surgical treatment and 1 patient who was revised to rTSA due to symptoms related to proximal migration of the prosthetic head. One of the patients treated non-surgically for a humeral shaft fracture had persistent radial nerve palsy.

STUDY II

Study selection

A total of 1,364 records were identified in the database searches and 7 by a reference review. The flow of records through the review process, leading to the inclusion of 10 studies in a quantitative analysis, is illustrated in Figure 32.

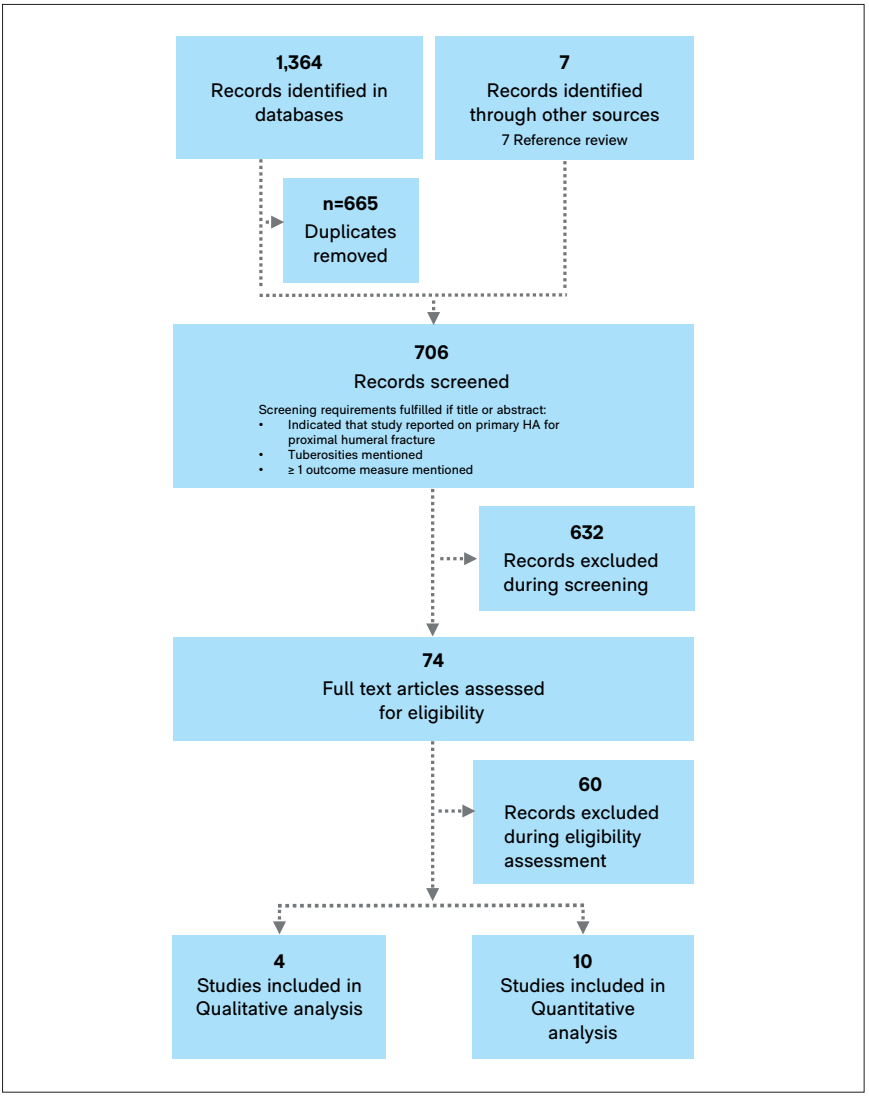

FIGURE 32 The flow of publications through **Study II** leading to inclusion in the analysis.

Characteristics of included studies

The 10 studies included in the quantitative analysis comprised a total of 559 proximal humeral fractures (557 patients) treated with HA. The basic characteristics of the included studies are summarized in Table 3. Of the nine non-randomized studies, the methodological quality was low for two,[11; 142] moderate for six[50; 51; 55; 169; 322; 401] and high for one,[228] according to assessments with MINORS. The only included RCT was judged to have a low risk of bias.[191] The overall mean age, weighted according to study size, was 68.7 years and 369 (66%) of the patients were women. In eight studies,[11; 50; 51; 55; 142; 169; 191; 228] tuberosity healing was defined as the healing of the greater tuberosity. Two studies[322; 401] did not define healing specifically, but in neither of them was there anything to indicate that the lesser tuberosity had been included in the definition of tuberosity healing.

Table 3 Basic study characteristics of studies included in the quantitative analysis

			Women		Age, years		Follow-up, years	
First author	**Year**	**Patients, n**	**n**	**(%)**	**Mean**	**(Range)**	**Mean**	**(Range)**
Antuna	2006	57	88	86	66	(23–89)	10.3	(5–22)
Reuther	2010	102	38	63	72		2.3	(1.0–4.6)
Boileau	2013	60	47	70	67	(39–86)	5.3	(2–12.5)
Brandao	2013	67	22	81	65	(44–88)	3.2	(1–5.2)
Giovale	2014	27	45	66	72	(48–88)	7.2	(5–9.8)
Li	2014	68	23	68	64		4.6	(3–6.6)
Bonnevialle	2016	57	39	68	67	(38–87)	3.3	(1.7–5.3)
Hoel	2016	34	23	67	71	(47–88)	3.2	(1.9–5.6)
Valenti	2017	51	39	77	71	(32–91)	1.5	(1–5)
Jonsson	2021	34	28	82	79		2.4	(2–3.9)

Main findings

The overall rate of tuberosity healing was 317/534 (59.4%). The results from individual studies, for the clinical rating system used for the SMD analysis, are shown in Table 4.[11; 50; 51; 55; 142; 169; 191; 228; 322; 401] The SMD was 0.89 (95% CI: 0.53–1.25, $p < 0.001$), indicating better shoulder function for patients with TH as compared with FTH (Figure 33.) Meta-analyses revealed that the mean Constant scores, degrees of flexion and external rotation were significantly better for TH than for FTH (Table 5).

TABLE 4 Main results of individual studies, tuberosity healing and results of the clinical rating system used in analysis of standardized mean difference (SMD)

			Clinical rating system in SMD analysis				
	Tuberosity healing			Tuberosity healing		Failed tuberosity healing	
First author	n	(%)	Name	Mean	n	Mean	n
Antuna	22	(63)					
Reuther	36	(35)	Abs Constant score	53	36	40.1	66
Boileau	40	(66)	Abs Constant score	69	40	54	21
Brandao	33	(49)	UCLA	29.5	33	22.7	34
Giovale	15	(63)	Abs Constant score	68.1	15	25.6	9
Li	57	(84)	ASES score	80	57	57.6	11
Bonnevialle	41	(72)	Adj Constant score	80	41	54	16
Hoel	11	(31)	Abs Constant score	50.3	11	39.8	24
Valenti	38	(75)	Abs Constant score	49.3	38	52.3	13
Jonsson	24	(71)	Abs Constant score	47.9	24	41.5	10

Adjusted Constant score indicates that the results have been adjusted with reference to normative values for age and gender

Abs, Absolute; UCLA, University of California, Los Angeles; ASES, American Shoulder and Elbow Surgeons; Adj, Adjusted

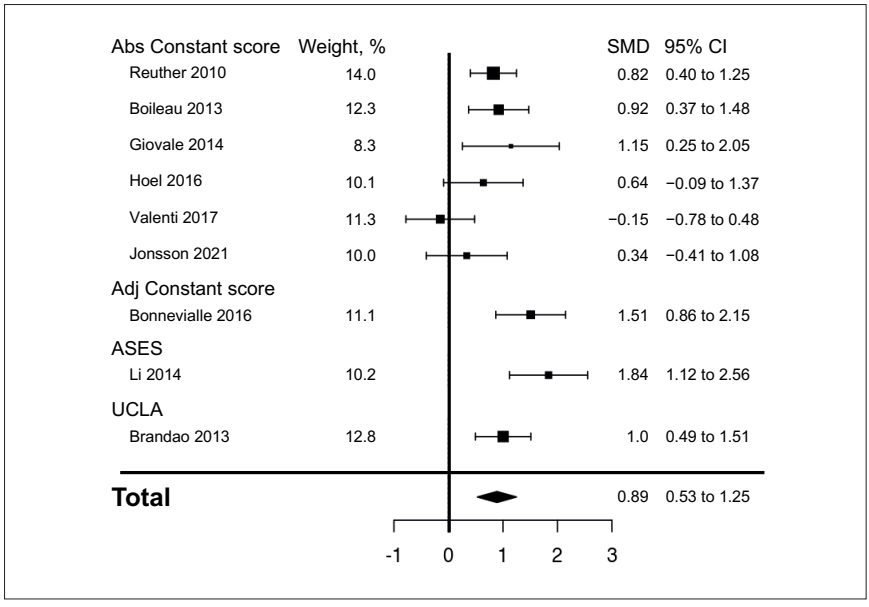

FIGURE 33 Forest plot illustrating the standardized mean differences of clinical rating systems between tuberosity healing and failed tuberosity healing following treatment with hemiarthroplasty for a proximal humeral fracture. The position of the boxes reflects the magnitude of the effect estimate and their size the weight assigned by the random-effects model. Boxes positioned to the right of 0 indicate that tuberosity healing provides favorable results while boxes position to the left of zero indicate that failed tuberosity healing provides favorable results. Adj, adjusted; SMD, standardized mean difference; CI, Confidence interval; abs, absolute; ASES, American Shoulder and Elbow Surgeon; UCLA, University California, Los Angeles.

TABLE 5 Main results of meta-analyses comparing outcome of patients with tuberosity healing and failed tuberosity healing with respect to mean Constant score, flexion and external rotation

	Tuberosity healing		Failed tuberosity healing					
	Mean	n	Mean	n	Mean difference	95% CI	p-value	I^2, %
Constant score, points	55.4	164	44.6	143	10.8	3.8 to 17.9	0.003	53
Flexion, degrees	107	214	73	167	34	23 to 46	<0.001	58
External rotation, degrees	31	156	20	56	12	6 to 17	<0.001	0

CI, Confidence interval

STUDY III

Flow of patients and baseline data

Forty patients were included between January 2011 and November 2019, of which 20 were randomized to each treatment group: elbow hemiarthroplasty (EHA) and total elbow arthroplasty (TEA). Eighteen EHA patients were available for analysis, while 17 were available in the TEA group, as five patients passed away prior to the final follow-up (Figure 34). Overall, there were 31 women (89%). In the EHA group, the mean age was 74.0 years (8.5), while it was 76.9 years (7.6) in the TEA group (p = 0.30). There was no statistically significant difference in the distribution of fracture classification between the treatment groups (p = 0.18). Overall, there were 13 coronal shear fractures (12 were of Dubberly type 3), 19 of below transcondylar axis (TA) type (18 intraarticular), 2 were through the TA and one was above the TA (AO 13C3.1).

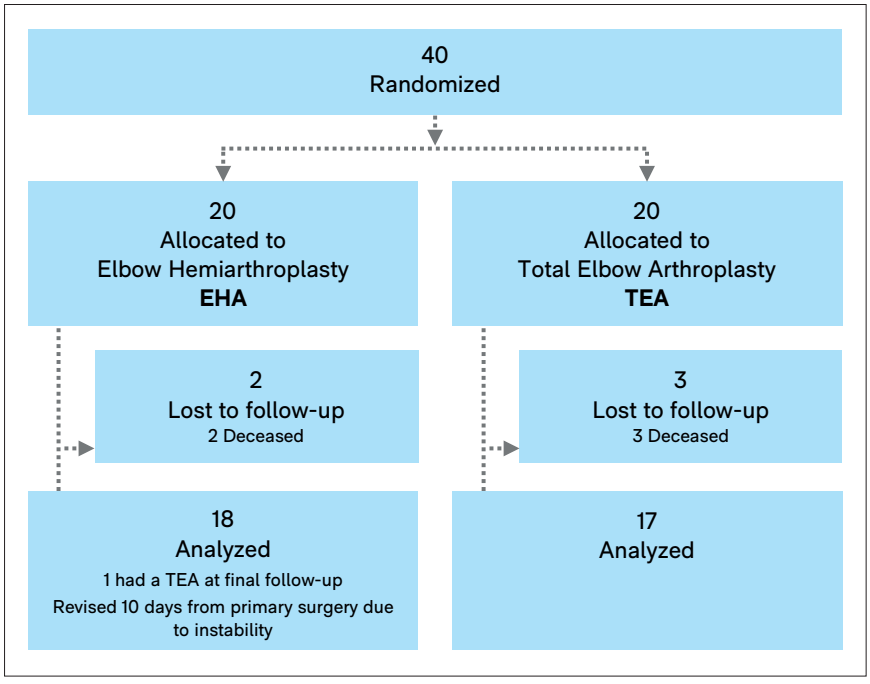

FIGURE 34 Flow of participants through **Study III**. The patient allocated to EHA who was revised to TEA was analyzed on an intention-to-treat basis.

Outcome

Patients treated with EHA had similar (p = 0.39) DASH scores (21.6 (16.6) points), the primary outcome measure, compared with patients treated with TEA (27.7 (21.2) points), (Table 6 and Figure 35).

TABLE 6 Main results of clinical rating systems and range of motion for the EHA and TEA randomization groups

	EHA (n = 18)		TEA (n = 17)		Mean		
	Mean	(SD)	Mean	(SD)	difference	(95% CI)	p-value
DASH score, points	21.6	(16.6)	27.2	(21.1)	5.6	(−7.5 to 18.6)	0.39
MEPS, points	85.0	(17.6)	88.2	(17.7)	3.2	(−8.9 to 15.4)	0.59
EQ-5D index	0.92	(0.08)	0.86	(0.14)	−0.06	(−0.14 to 0.02)	0.13
Range of motion, degrees							
Extension deficit	29	(12.2)	29	(18.0)	0	(−11 to 11)	0.98
Flexion	126	(15.0)	136	(11.1)	9	(0 to 19)	0.05
Supination	81	(9.2)	75	(13.7)	−6	(−15 to 2)	0.13
Pronation	78	(4.8)	74	(10.5)	−4	(−10 to −2)	0.16

CI, Confidence interval; EHA, Elbow Hemiarthroplasty; TEA, Total Elbow Arthroplasty; DASH, Disabilities of the Arm, Shoulder and Hand; MEPS, Mayo Elbow Performance Score

Moreover, the results for secondary outcomes measures were similar between treatment with EHA and TEA, including the mean values for the MEPS (85.0 (17.6) vs. 88.2, (17.7), p = 0.59), extension deficit (29° (12.2) vs. 29° (18.0), p = 0.98) and flexion (126° (15.0) vs. 136° (11.1), p = 0.05), (Table 6).

Six patients in the EHA group (33%) obtained a functional elbow flexion-extension arc (30°–130°) compared with 10 in the TEA group (59%) but the difference in proportions was not statistically significant (p = 0.17).

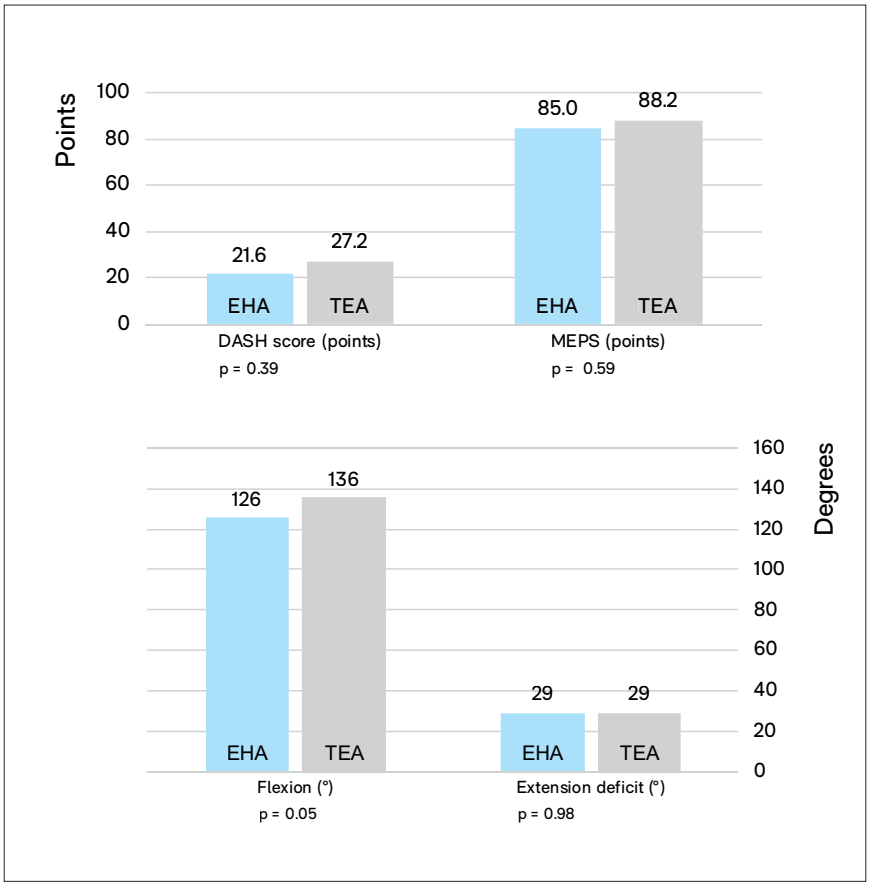

FIGURE 35 Result of clinical rating systems and range of motion in **Study III**. Comparison between treatment with EHA (blue) and TEA (grey) of mean values of the DASH score (points), MEPS (points), flexion (°) and extension deficit (°). Mean values are displayed above the columns and marked with * when differences between treatment groups are statistically significant (p < 0.05). EHA, Elbow Hemiarthroplasty; TEA, Total Elbow Arthroplasty; DASH, Disabilities of the Arm, Shoulder and Hand; MEPS, Mayo Elbow Performance Score

Adverse events

There were six adverse events in each treatment group. In the EHA group, one patient was revised to TEA 10 days after the primary surgery due to joint instability related to the failure of plate fixation of a fracture of the medial column. Two patients in the EHA group underwent arthrolysis due to stiffness (at 6 and 9 months from primary surgery), one patient had a prominent K-wire removed from the medial epicondyle, one patient had an olecranon fracture treated with plate fixation and one patient had a fracture of the humeral shaft that united after treatment with a brace. In the TEA group, there were two periprosthetic joint infections that were eradicated with *debridement, antibiotics and implant retention*, two patients had prominent K-wires which were removed, one patient had arthrolysis and transposition of the ulnar nerve and one patient was treated non-surgically for an olecranon fracture.

STUDY IV

Baseline characteristics and overall development between T1, T2 and T3

Between May 2020 and July 2021, a total of 75 patients with a mean age of 51.7 years were included (45 women). The most common diagnoses were radial head fracture (n = 32), terrible triad injury (n = 10), distal humerus fracture (n = 7) and Monteggia fracture (n = 6). Fifty-four patients were treated with surgery. The results for all three PROMs deteriorated ($p < 0.001$) between T1 (last week before injury) and T2 (first week after injury) but improved between T2 and T3 (3–5 months after injury), $p < 0.001$, (Figure 36).

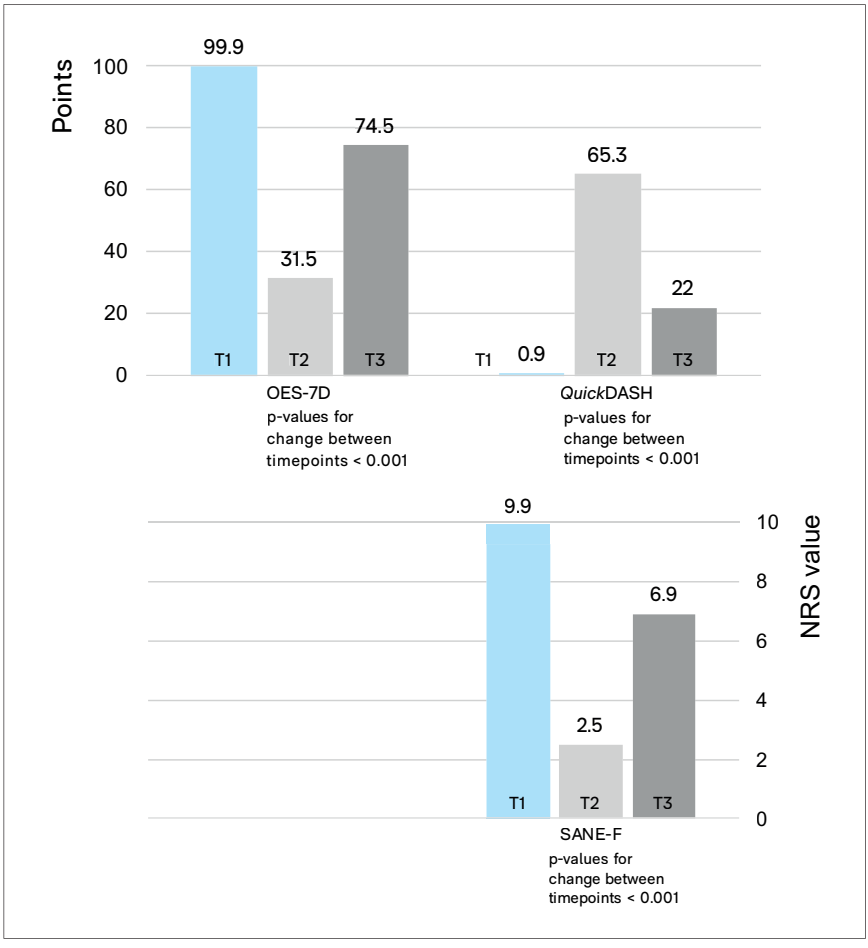

FIGURE 36 Result of clinical rating systems for the three different periods of time assessed in **Study IV**: T1 (last week before injury), T2 (first week after injury), T3 (period of 1 week, 3–5 months after injury). Mean values are displayed above the columns. OES, Oxford Elbow Score; DASH, Disabilities of the Arm, Shoulder and Hand; SANE-F, NRS, Numerical Rating Scale; Single Assessment Numeric Evaluation- Function

Construct validity At T3, the correlation between the results for the OES total scores and the *Quick*DASH scores was −0.91 (Spearman's rho, r_s). Meanwhile, the correlation between the OES total scores and SANE-F values was 0.76.

Responsiveness The results of the correlation of changes scores of the OES with those of both the *Quick*DASH and SANE-F are given in Table 7 for both T1/T2 and T2/T3. The results for T1/T2 (T2 minus T1) pertain to deterioration, while those for T2/T3 (T3 minus T2) pertain to improvement.

TABLE 7 Responsiveness assessed by correlation of change scores for T1/T2 (T2 minus T1) and T2/T3 (T3 minus T2)

			T1/T2	T2/T3
			(T2 minus T1)	(T3 minus T2)
*Quick*DASH	vs.	OES-7d	−0.88	−0.85
SANE-F	vs.	OES-7d	0.38	0.52

OES, Oxford Elbow Score; DASH, Disabilities of the Arm, Shoulder and Hand; SANE-F, Single Assessment Numeric Evaluation-Function

Reliability was assessed in terms of both internal consistency and intra-rater reliability. In an analysis based on data from T3 the internal consistency of the domains of the OES was found to be (Cronbach's alpha): elbow function (0.83), pain (0.91), social-psychological (0.90).

Intra-rater reliability was assessed in a separate group of patients (n = 56) who had incurred an elbow injury on average 1.2 years prior (range: 1–1.8) to completing the three PROMs (OES-7d, *Quick*DASH and SANE-F) on two occasions, 1–3 weeks apart. The intraclass correlation coefficient for the OES total score was 0.96 and for the (domains): 0.91 (elbow function), 0.89 (pain) and 0.94 (social-psychological).

4.

Discussion

The results of the studies included in this thesis have implications for the treatment of displaced, multi-fragment fractures of the proximal and distal humerus, especially in elderly patients. The results also have implications for the assessment of elbow function. The results of **Studies I–IV** are only small pieces in a larger, as of yet incomplete puzzle, but may contribute to make the overall picture somewhat clearer. In the following sections, the results of **Studies I–IV** will be put into context and the overall picture interpreted. Some of the imperfections of the literature as a whole will be illustrated and future perspectives mentioned. The results are divided into three main themes:

❶ Choosing treatment for elderly patients with displaced multi-fragment proximal humeral fractures

❷ Choosing treatment for elderly patients with distal humeral fractures

❸ The Oxford Elbow Score (OES) and recall period

1 CHOOSING TREATMENT FOR ELDERLY PATIENTS WITH DISPLACED MULTI-FRAGMENT PROXIMAL HUMERAL FRACTURES

RCTs and functional outcome

The results of **Study I** indicate that rTSA provides better shoulder function than HA for displaced 3- and 4-part proximal humeral fractures in elderly patients, at least for women. This is consistent with other studies.

When **Study I** was initiated, no RCTs comparing these two treatments were available. However, two other RCTs on the topic are available now. In 2014, a study by Sebastiá-Forcada et al.[354] was published. A study by Laas et al.[212] was published at approximately the same time as **Study I** in 2021. All three studies have similar overall characteristics, as they include mainly elderly (mean age of 74–80 years) women (58–90%) with displaced 3- and 4-part fractures (Table 8).

Although it is presumably only a question of time, the results of these studies have not yet been summarized in a formal meta-analysis. With respect to the direction and magnitude of the treatment effect, the main results of all three studies are consistently in favor of rTSA. An analysis of pooled data with a random-effects model reveals that patients treated with rTSA had higher Constant scores compared with patients treated with HA (mean difference (MD) = 13.7 points, 95% CI: 8.1–19.4, $p < 0.001$), (Figure 37). Moreover, compared with patients treated with HA, patients treated with rTSA had greater mean flexion (MD = 30°, 95% CI: 19–42°, $p < 0.001$) and abduction (MD = 24°, 95% CI: 12–36°, $p < 0.001$). **Study I** and the study by Sebastiá-Forcada et al. supplement each other very well. In general, based on their characteristics, RCTs can be seen as being a spectrum, from explanatory to pragmatic.[331] Most clinical studies in the field of orthopedics are in the pragmatic end. The study by Sebastiá-Forcada et al. is more towards the explanatory end of the spectrum than **Study I**, in that all the patients were operated on using the same implants by two surgeons at a single institution. This methodology is good for testing the hypothesis but can be considered to be at the expense of external validity. **Study I**, on the other hand, was multicenter and several different brands of implants were used. Finding a difference between the treatments despite this heterogeneity strengthens the conclusion that rTSA provides better function than HA. The use of different implant brands by several surgeons at different institutions carries good external validity. The study by Laas et al. is significantly smaller in size and has a shorter follow-up, with 18 patients completing the follow-up after one year. In addition, the results of these three RCTs are in line with a meta-analysis including non-randomized comparative studies,[18] further strengthening the conclusion that rTSA provides a better functional outcome than HA.

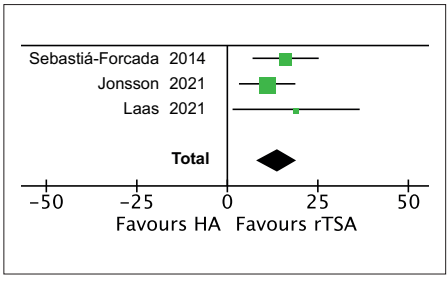

FIGURE 37 A random-effects model summarizing the results of the Constant score in the three available randomized controlled trials comparing rTSA and HA for treating proximal humeral fractures in elderly patients. The position of the solid squares represents the mean of each study, while their dimensions reflect the weight assigned to the study in the model. The lines associated with the squares depict the 95% confidence interval. The position of the diamond represents the total mean difference and its ends the 95% confidence interval. $I^2 = 0\%$.

Failure of the greater tuberosity to heal is likely to be one important reason why HA provides inferior function to rTSA, at least at the group level. That a good functional outcome following HA is dependent on the healing of the greater tuberosity has been regarded as orthopedic common sense, because it is a prerequisite for rotator cuff function. When statements of this kind are made in publications, different studies with varying methodological quality are cited and sometimes no citation is provided at all. The idea to perform **Study II** came quite naturally. When writing the introduction to **Study I**, I set out to look for a systematic review and meta-analysis of the effect of tuberosity healing on functional outcome following HA, but it emerged that no such study was available. Nijs and Broos[282] made a fruitless attempt in 2009, but they described their experience as frustrating, due to the low methodological quality of available studies. It is, however, well known that the publication of scientific results often lags behind clinical practice.

Charnley performed the first low-friction arthroplasty in 1962, but it would take 10 years before the results were formally published.[72] In the case of HA for proximal humeral fractures, there has been a delay in publication. Although the use of HA has decreased[187; 204; 251] since Nijs and Broos[282] made their review attempt in 2009, some of the best studies on the topic have been published since then. The results of these studies are summarized in **Study II**, which resulted in two main findings. First, patients with tuberosity healing had a better functional outcome than patients with failed tuberosity healing. Second, the rate of failed tuberosity healing was substantial (approximately 40%), despite the majority of the patients being treated with modern implants. The effect of tuberosity healing on the outcome of HA is still commonly mentioned in contemporary publications and **Study II** is a suitable reference for these statements. Although the use of HA has decreased dramatically, it is still a relevant treatment for some patients (e.g. younger patients). Moreover, tuberosity healing is still a relevant topic in the context of shoulder arthroplasty for proximal humeral fractures, as it has been found to have an impact on the outcome of rTSA as well.[181] Lastly, even for treatments for which use has diminished or been discontinued altogether, it is worthwhile to summarize knowledge and experience that has accumulated. Such knowledge is valuable and can for instance be useful for moving other treatments forward.

It appears fairly convincing that rTSA provides a better functional outcome than HA, but we would like to know how rTSA compares with other available treatments, in particular non-surgical treatment. For RCTs, it is, however, important that proposed treatments are accepted by care providers. The rate of discontinuation of surgical RCTs has been reported to be up to 43%, with slow recruitment being one of the main causes. Poor motivation among caregivers (recruiters) has been identified as a risk factor for discontinuation.[56]

When **Study I** was initiated in 2013, HA was still an accepted treatment for displaced multi-fragment fractures in elderly patients in Sweden and was more commonly used than rTSA.[38; 388] Nevertheless, some centers declined to participate in the study, as rTSA was already in routine use. In fact, rTSA already superseded HA as the most commonly used type of arthroplasty for this indication in some other countries in 2014.[204; 251] This did not happen in Sweden until 2018,[388] possibly due to a degree of stamina in Sweden towards introducing new treatments on a large-scale until relevant evidence is available, in line with the idea of a stepwise introduction of new surgical procedures.[241] It would probably have had a detrimental effect on the recruitment rate if the study had started much later than 2013, possibly leading to discontinuation. This was unfortunately the fate of the study by Laas et al.[212] It would have been interesting to compare rTSA with non-surgical treatment in **Study I**, but this would have entailed a significant risk of discontinuation, due to limited acceptance of non-surgical treatment among caregivers for this indication.

Comparisons of the functional outcome of rTSA and HA are part of a broader question; what is the most appropriate treatment for displaced 3- and 4-part proximal humeral fractures in elderly patients? Obviously, this depends on the exact circumstances, including appearance of the fracture, the patient's general health, functional level and social situation. Some general conclusions can, however, be drawn based on the available RCTs on the topic, many of which have been published after **Study I** was initiated (Table 8). This can be done in a systematic manner with network meta-analysis, as Davey et al.[92] recently did. rTSA was the only treatment modality to provide better shoulder function than nonsurgical treatment in terms of Constant scores. Unfortunately, the results of one study were included twice in their analysis, as Olerud et al.[291] and as Leighton et al.[225] The latter is a commentary in the Journal of Bone and Joint Surgery on the study by Olerud et al. It is, however, unlikely that this has affected the main results of Davey et al., which are in line with a previous network meta-analysis by Du et al.[108] from 2017. In three of the studies included by Davey et al. (Gracitelli et al.,[151] Launonen et al.,[217] Zhu et al.[423]), 2-part fractures dominate, a type of fracture not relevant to the broader question under discussion here. In addition, **Study I** and the study by Laas et al.[212] were not included, so a narrative review of available RCTs with relevance to the treatment of 3- and 4-part proximal humeral fractures in elderly patients appears to be appropriate (Table 8).[52; 64; 122; 131; 191; 212; 234; 291; 292; 313; 354]

TABLE 8 Overview of randomized controlled trials comparing treatments for proximal humeral fractures, using contemporary surgical treatments.

								Main results, mean		
Type of operation	**Author**	**Year**	**Type of fracture**	**Women, %**	**Age, mean**	**Analyzed, n**		**Constant score**	**Flexion**	**Abduction**
Non-surgical treatment vs:						**Surgery**	**Non-surgical**			
Locking plate	Olerud	2011	3-part	81	74	27	26	No difference	No difference	No difference
Locking plate	Fjalestad	2012	B2 or C2*	88	73	23	25	No difference		
HA	Olerud	2011	4-part	86	77	24	25	No difference	No difference	No difference
HA	Boons	2012	4-part	94	78	24	23	No difference	No difference	No difference
rTSA	Lopiz	2019	3- and 4-part	86	84	29	30	No difference		
rTSA vs. HA						**rTSA**	**HA**			
	Sebastiá-Forcada	2014	3- and 4-part	85	74	31	30	Higher for rTSA (56 vs. 40, p=0.001)	Higher for rTSA (120° vs. 80°, p=0.001)	Higher for rTSA (112° vs. 79°, p=0.001)
	Jonsson	2021	3- and 4-part	90	80	41	43	Higher for rTSA (59 vs. 48, p=0.007)	Higher for rTSA (125° vs. 90°, p<0.001)	Higher for rTSA (112° vs. 83°, p<0.001)
	Laas	2021	3- and 4-part	58	75	17	14	Borderline (51 vs. 32, p=0.05)	Higher for rTSA (110° vs. 90°, p=0.02)	Higher for rTSA (90° vs. 75°, p=0.01)
rTSA vs. locking plate						**rTSA**	**Plate**			
	Fraser	2020	B2 or C2*	90	75	64	60	Higher for rTSA (68 vs. 55, p<0.001)		
HA vs. locking plate						**HA**	**Plate**			
	Cai	2012	4-part	87	72	15	12	Higher for HA (73 vs. 61, p=0.017)	No difference (129° vs. 117°, p=0.27)	No difference (123° vs. 111°, p=0.41)
Locking plate vs. IMN						**Plate**	**IMN**			
	Plath	2019	2- (13%), 3-, and 4-part	75	76	27	28	No difference (64† vs. 67†, p=0.66)	No difference (83° vs. 88°, p=0.36)	No difference (77° vs. 84°, p=0.23)

HA, hemiarthroplasty; ORIF, open reduction and internal fixation; rTSA, reverse total shoulder arthroplasty; IMN, intramedullary nail

* according to the AO/OTA classficiation, roughly corresponding to 3- and 4-part fractures

† median values

Based on two available RCTs by Olerud et al.[291] and Fjalestad et al.,[122] it appears that open reduction and internal fixation with locking plates provides a functional outcome similar to non-surgical treatment for 3- and 4-part fractures. Likewise, hemiarthroplasty appears to provide a functional outcome similar to non-surgical treatment for 4-part fractures based on the two available RCTs on the topic.[52; 292] Four RCTs comparing rTSA with either HA[191; 212; 354] (three previously mentioned studies) or locking plates (Fraser et al.,[131] Table 8) have found that rTSA provides superior shoulder function. This indirectly suggests that rTSA provides a better functional outcome than non-surgical treatment. An important study by Lopiz et al.[234] does not fit perfectly into this pattern. This is the first study comparing rTSA (n = 29) and non-surgical treatment (n = 30). In that study, there was no statistically significant difference between the treatment groups in terms of the Constant score. A couple of points need to be considered when interpreting the results. The patients in the rTSA group actually had a higher Constant score by 6 points, with a p-value of 0.071, but unfortunately no confidence interval was provided. The possibility of a type II error exists. It can be argued that the difference is small, but it is nevertheless larger than estimates of the MID for the Constant score in the context of arthroplasty of 5.1[149] and 5.7.[361] Moreover, the patients were followed up for 1 year as opposed to 2 years in most RCTs of proximal humeral fractures. This might have affected the result, as **Study I** indicated that patients treated with rTSA improved beyond 1 year after the procedure. Most importantly, only patients aged 80 years or older were included. It is possible that older elderly patients simply benefit less from rTSA than younger elderly patients. There were some indications, albeit weak, of an effect of this kind in **Study I**. Further trials comparing rTSA and non-surgical treatment are therefore needed.

Currently, at least two randomized trials comparing rTSA and non-surgical treatment are ongoing.[215; 366] Completing trials of this type is no easy task, as both treatments need to have the acceptance of caregivers as mentioned previously, for example. This can be an issue with non-surgical treatment in particular. Acceptance among patients is also important in order to avoid a high degree of cross-over. However, even when published, interpreting the results of studies comparing non-surgical and surgical treatment may prove difficult. Surgical treatment, in particular arthroplasty, leads to a relatively standardized situation, although the way a procedure is executed is most likely of great significance for the outcome. For instance, a poorly executed reduction and fixation of the tuberosities is likely to result in an undue risk of failure of tuberosity healing. Failure of tuberosity healing has been found to affect the outcome of rTSA negatively,[181] as well as for HA, as shown in **Study II**.

For some diagnoses, indicators describing the quality of the surgical procedure are available. For instance, the tip-apex distance[29] is a parameter that is widely used to assess how well implants used to treat hip fractures have been placed in the femoral head. In randomized studies of proximal humeral fractures, the quality of the surgical treatment is seldom illustrated and few if any well-founded indicators exist. The situation is considerably less standardized for displaced multi-fragment proximal humeral fractures that are left to heal with non-surgical treatment. For instance, an increasing degree of displacement at the surgical neck involves a greater risk of nonunion,[147] while displacement of the greater tuberosity is likely to affect the rotator cuff negatively even if healed. Understanding exactly which types of fractures have been included can be difficult, as discussed further in the next section.

What available RCTs do not tell us

There are a number of aspects that are relevant to any comparison of the outcome of treatments for displaced multi-fragment fractures of the proximal humerus in elderly patients into which the previously mentioned randomized trials give only limited or no insights. The discussion in the preceding paragraphs has focused on functional outcome, as that is what these RCTs were designed to compare. There are, however, other aspects to the use of rTSA that these RCTs do not elucidate, such as the risk of adverse events and long-term function.

rTSA – adverse events

Determining the occurrence of adverse events is important when assessing the feasibility of a surgical procedure. Most RCTs in orthopedics report the occurrence of adverse events,[144] but detecting differences between treatments requires a much larger number of patients than are typically included in RCTs.[229] Other types of study design, such as large cohort studies, registry studies or literature reviews, are more useful in defining the occurrence of adverse events.

In a systematic review from 2021, Kennedy et al.[198] found that, following rTSA for a proximal humeral fracture the overall rate of complications was 11% at a follow-up of approximately 3 years. The distribution of complications was (%) instability (1.7), periprosthetic fracture (0.8), glenoid loosening (1.8) and infection (1.2). Notably, there were no patients with fracture of the spine of the scapula. The occurrence of complications after rTSA for proximal humeral fractures was higher than for primary osteoarthritis and rotator cuff tear arthropathy, but lower than for massive irreparable rotator cuff tears, rheumatoid arthritis and revision surgery.

Interpreting the rate of adverse events presented in studies and making comparisons between studies is difficult. The main problem is that there is no universally accepted definition of what constitutes an adverse event[326] and many other similar terms are in fact used, such as complications,[326] side-effects and harm.[176] A review by Alispahic et al.[5] of the reporting of local complications for proximal humeral fractures in 2010 to 2017 revealed that 667 different terms were used. Moreover, few studies provided a definition of the individual types of complication. Recently, Audigé et al.[16] have conducted an international Delphi process that resulted in a core event set (CES) for proximal humeral fractures. The same group has developed a CES for shoulder arthroplasty.[17] This is an important initiative that will hopefully lead to more standardized reporting and in turn ease the interpretation of results. However, some of the included items do not necessarily affect patient outcome. This applies, for example to the occurrence of radiolucent lines and bone formation. Another approach to adverse events is evaluating the rate of secondary procedures (reoperation or revision), events that do not pass unnoticed.

Using data from the Nordic Arthroplasty Register Association, Lehtimäki et al.[223] found that the overall risk of revision following rTSA for proximal humeral fractures was 3% at 5 years, based on 1,523 procedures performed in 2004–2016.[223] The most common causes of revision were instability (0.7%), periprosthetic fracture (0.4%) and infection (0.3%). Similar results were prestented in a publication based on data from the Australian Orthopaedic Association National Joint Replacement Registry.[86] This analysis was based on 3,049 patients. The overall risk of revision was 7% at 9 years. The frequencies (%) of the indications for revision were: instability (1.7), infection (0.6), periprosthetic fracture (0.6) and loosening (0.4). Although risk of revision is a clear-cut endpoint, the disadvantage of this parameter is that problems affecting patients but not resulting in revision are unaccounted for.

Taken together, adverse events still occur, but at a rate that can be regarded as acceptable. The rate has declined,[88] probably due at least in part to improved surgical technique related to greater experience among surgeons.

rTSA – long-term outcome

Concerns have been raised that there is a drop in function after treatment with rTSA starting after approximately 5–10 years, due to fatigue of the deltoid.[118; 157 26] Recent studies have, however, not confirmed an effect of this kind. In a systematic review including 365 patients from 8 studies, Ernstbrunner et al.[115] found no significant decline in shoulder function between 5 and 20 years after rTSA for

rotator cuff dysfunction. In a recent study, Schoch et al.[351] followed 165 patients treated with rTSA (indications: cuff tear arthropathy, osteoarthritis and irreparable rotator cuff tear) longitudinally over a period of 5 years which revealed a steady mean annual decline in both abduction and flexion of 0.8°. This corresponds with the loss of range of motion that has been seen with aging. In a large community-based study by Gill et al.,[141] the mean flexion for women was approximately 165° at 25–29 years of age but 145° at 70–74 years of age. The annual decline in degrees of abduction per year has been reported to be 0.7° for women after the age of 63 years and 0.8° for men after the age of 71 years.[376] The previously anticipated drop in function following rTSA might in fact be due to normal aging.

In addition to a decrease in range of motion, there is also a decrease in strength with increasing age.[21] Unsurprisingly, the results of PROMs also decline with age.[78] The results for the Constant score have been estimated to decline at a rate of 0.3 points a year after 50 years of age.[410] The mean Constant score for women 71–80 years of age has been reported to be around 80 points, as compared with approximately 85 points for women 21–30 years of age.[419] When interpreting the results for the Constant score, it is useful to remember the decline in shoulder function that occurs with age but also to note that, despite the Constant score ranging up to 100 points, this level is not reached on average, even by young, healthy individuals.

External validity – to which patients can the results of RCTs be applied

In the CONSORT statement, external validity is defined as being "the extent to which the results of a study can be generalised to other circumstances".[255] Moreover, the population we wish to include in an RCT and subsequently draw conclusions about has been defined as the *target population*, while the patients actually included in studies can be referred to as the *study population*.[104] Most RCTs (including **Study I**) of proximal humeral fractures in the elderly do not provide a thorough analysis of the patients in the target population that presented during the study period but were not included. An exemplary exception from this is a recent analysis of the external validity of the so-called DelPhi trial, with the main results of the trial published in one study[131] and the analysis of external validity in a separate study.[390] As might be expected, the patients that were not included were older, had comorbidities (heart disease) and were less independent. Caution needs to be exercised when applying the results of the DelPhi trial to patients with these characteristics and, although speculative, it is likely that similar terms apply to other RCTs on the topic as well.

Males deserve special attention with respect to external validity. The target population of the RCTs in question is elderly patients, without specifying gender. However, the majority of the included patients are women, constituting 85 to 90% of patients in most of the studies presented in Table 8, which is to be expected, as females are affected much more often than males.[36] Data on the functional outcome for males specifically are scarce and comparative data are absent. Koeppe et al.[205] found that males run a higher risk of complication than females following treatment with rTSA for proximal humeral fractures.[205] In a registry study from Australia by Critchley et al.,[86] the overall risk of revision following the treatment of a proximal humeral fracture with rTSA was 7.0% after 9 years as compared with 11.7% for HA. In a multivariate analysis, this benefit was found to be specific to women. The risk of revision was 3 times higher for males than females. These authors concluded that treatment options other than rTSA may be indicated for males. With respect to HA, the risk of revision was significantly lower for males than for women. In a publication from 2013, Boileau et al.[50] reported that shoulder function was better for males treated with HA than for women, indicated by higher mean Constant scores, 71 and 58, respectively ($p = 0.0005$).[50] These results might be due in part to males having a much higher likelihood of tuberosity healing than females (11-fold),[322] as tuberosity healing has a positive effect on functional outcome (**Study II**). Further studies of the treatment of proximal humeral fractures in males are warranted.

Age is relevant when it comes to external validity as well. The studies that indicate that rTSA has a favorable functional outcome include patients 65 years or older[131; 212] or 70 years or older.[191; 354] There is, however, reason to believe that rTSA is being used increasingly in slightly younger patients. In patients 60 years or younger, it appears reasonable to reduce and fix displaced fractures, if this is at all possible, perhaps using augmentation techniques such as bone grafting if necessary.[40] For unreconstructable fractures, arthroplasty is indicated, but no comparative data are available to guide the choice between HA and rTSA.

Limitations and problems common to available RCTs

Some limitations and problems are common to available RCTs on the treatment of displaced multi-fragment proximal humeral fractures in elderly patients. One such issue is; which fractures should be included in RCTs? This is not as straightforward as it might appear, but it is an important topic, as it directly affects the interpretation and external validity of results. Another important issue is; what is the most appropriate way to assess outcome?

Inclusion criteria – fracture appearance

Understanding exactly which fracture types have been included in RCTs is not straightforward and it affects the external validity. This is particularly important with respect to non-surgical treatment, as leaving the shoulder with a displaced fracture is a much less standardized situation than arthroplasty, for instance. Most available RCTs use the terminology of Neer when stating the inclusion criteria, including patients with either 3- or 4-part fractures. However, it is important to consider the exclusion criteria as well, and some studies have excluded patients with a certain degree of displacement, such as less than 50% bone contact[122] at the surgical neck or those that have no contact between the shaft and head (off-ended).[291; 292] Most studies do not mention the eligibility of fracture dislocations, which are presumably excluded. The collective interpretation of the literature can therefore not be applied directly to patients with these injuries. However, even after considering eligibility criteria, some uncertainty as to the morphology of included fractures remains. Some studies specifically state that fractures have to be displaced 1 cm or angulated 45° to be regarded as displaced, while most others only mention using the Neer criteria. In the ProFHER trial,[320] it was simply stated that it was the surgeon's perception of the need for surgery that formed the basis of inclusion and that Neer's criteria were not followed. It is unclear whether Neer's criteria for displacement have been followed stringently for all patients included in other studies; they are, after all, completely arbitrary.[277] Moreover, the dimensions of the proximal humerus vary considerably in the population, as described in the introduction, and are affected by factors such as height[137] and gender.[389] As a result, the implications of a 1 cm displacement may be affected by the size of the proximal humerus. In addition, measurements are affected by magnification on radiographs (**Study I**) and presumably also by the degree of rotation and the position of the fracture at the exact time point at which the radiographs are taken. In the end, in RCTs with a non-surgical arm, the surgeon needs to be a least fairly comfortable about randomizing the patient to both treatments.

The above is partly speculative, but it is not entirely without basis, albeit first and foremost reflecting that the natural history of these injuries is poorly defined, as is the prognostic value of fracture appearance. We do not know exactly which fracture appearances should be included in RCTs. Based on a large group of non-surgically treated patients, Goudie et al.[147] developed a model predicting the risk of nonunion of the surgical neck, which considers head-shaft translation, head angulation and smoking status. In order to predict outcome, this is probably a more useful approach than working with traditional radiological classification systems. To predict functional outcome accurately, a number of other factors will have to be considered. In fact, the same group found that outcomes in terms of PROMs

were more influenced by pre-existing patient-related psychosocial factors than fracture-related factors.[146] A number of other factors are likely to be important. For example, a recent study found that rotator cuff ruptures occur in association with proximal humeral fractures in one-third of patients. The presence of a rotator cuff rupture led to significantly inferior shoulder function, as compared with patients with isolated fractures without rotator cuff injury.[295]

Constructing a model that accurately predicts outcome is no easy task. The significance of different aspects of radiographic appearance on outcome and their interrelatedness would need to be untangled. Perhaps artificial intelligence (AI), which has already been used to classify proximal humeral fracture with some success,[75] could come to the rescue. In addition, very large groups of preferably non-surgically treated patients with a wide assortment of fracture characteristics would be needed. In addition, accurate data on both baseline characteristics and outcome would be needed. Perhaps in the future, it will be possible to more accurately identify which patients should be included in RCTs, thereby enabling more accurate conclusions to be drawn.

Assessing functional outcome

All the RCTs in Table 8 use the Constant score, but there is otherwise noticeable heterogeneity in reporting. Some studies provide information on range of motion and pain based only on the categories of the Constant score.[122; 131; 234] The categories of the Constant score are too wide to adequately reflect these characteristics. Range of motion has been found to contribute to explaining a considerable proportion of the variation in the results of PROMs,[364] supporting the hypothesis that range of motion is a relevant parameter. Providing results of measurements with a goniometer as a continuous variable is preferable to categorical reporting. Mean pain levels are generally low, irrespective of the treatment modality that is chosen (e.g. non-surgical treatment, ORIF, HA or rTSA) for displaced multi-fragment proximal humeral fractures.[191; 291; 292] However, patients who have higher pain levels are not satisfied and deserve to be identified and adequately accounted for. Using an instrument designated for assessing pain, such as the visual analogue scale (VAS) or numerical rating scale (NRS), is justified. The use of a generic health-related quality of life instrument is recommended.[161]

Another problem is that different versions of the Constant score are in use. This is probably one of the reasons for the variation seen in Constant scores between studies including patients that appear to be largely comparable. One example of this are the results of rTSAs presented in Table 8 and those of a recent review of rTSA and HA by Austin et al.[18] (Supplemental Digital Content 6). The

standardization of the original version[83] with regard to content, scoring and how to perform examinations was suboptimal, which has led to nuances in protocols between centers.[334] To add to the variability, there are now two official versions of the score in use. In 2008, the original developer, Christopher Constant, suggested that pain and two items relating to activities of daily life should be recorded on a visual analogue scale.[82] In the same publication, clarifications were made in terms of the measurement and scoring of strength. However, Hollman et al.[170] recently found that there were considerable differences in total scores when categorical and VAS scales were used. To add to the confusion, further modifications have been made, including at least two different self-administered versions.[74; 227] With respect to the collective interpretation of RCTs, the heterogeneity in absolute scores can be avoided by focusing on differences between groups.

In **Study I**, the Constant score discriminated shoulder function effectively between patients, as opposed to the WOOS, which displayed a ceiling effect. Response shift can be one explanation for ceiling effects in PROMs. Response shift was defined by Schwartz and Spranger[372] in a publication from 1999 as follows.

> *The working definition of response shift, adopted in this paper, refers to a change in the meaning of one's self-evaluation of a target construct as a result of: (a) a change in the respondent's internal standards of measurement (scale recalibration, in psychometric terms); (b) a change in the respondent's values (i.e. the importance of component domains constituting the target construct); or (c) a redefinition of the target construct (i.e. reconceptualization)*

For the use of PROMs, it is generally assumed that patient values remain constant over time, which is not necessarily the case. Most physicians treating elderly patients with proximal humeral fractures have met individuals with limited range of motion that are nevertheless satisfied with their function. To prove their point, some of these patients demonstrate that they are able to reach their head – by tilting their head. The patient has adapted and a response shift has occurred. However, not all patients are happy with a limited range of motion and this difference in reaction can be understood based on the model of Wilson and Cleary[417] presented in the introduction which emphasized the important influence of the characteristics of the individual and environment on outcome. The Constant score is probably less influenced by response shift than PROMs as items assessing the objective function of the shoulder are included.

The difference in Constant score between rTSA and HA in **Study I** was driven largely by differences in range of motion, with smaller contributions from the strength and activities of daily life subscales. All the subscales included

in the Constant score are relevant when it comes to assessing the outcome of shoulder disorders. However, summarizing these aspects into one single score is questionable. The scoring of the Constant score is arbitrary and it is not known whether the points weigh equally between the subscales, which is in fact unlikely. One way forward would be to redevelop the Constant score. Being able to report and interpret outcome in terms of a single number is convenient. The focus on power calculations, which are important as such, may have contributed to the notion that functional outcome can be accounted for by a single number. Instead of redeveloping the Constant score or adding yet another outcome instrument to the arsenal, it might be easier simply to accept that, to assess outcome, an evaluation of the overall picture and several different parameters is necessary. Consensus on the parameters that should be assessed and how to report them would, however, be helpful.

Conclusion – displaced multi-fragment proximal humeral fractures in elderly patients

In conclusion, rTSA appears to provide a better functional outcome than other available treatment options for elderly patients with displaced multi-fragment proximal humeral fractures. Further direct comparisons between rTSAs and non-surgical treatment are needed. The external validity of available RCTs needs to be considered when choosing treatment. The results can, for example, not be applied directly to males, patients with considerable comorbidities and those who have fractures with major displacement at the surgical neck.

Suffering from a displaced multi-fragment proximal humeral fracture is a life-changing event for elderly patients, as none of the currently available treatment options reliably restores function. Hopefully, the future will bring advances in treatment that will improve outcome. The outcome of rTSA is good, but imperfect. Changes in implant design and surgical techniques might bring improved outcome, by promoting tuberosity healing, for instance. For some cases, non-surgical treatment might simply be the best alternative, but, choosing non-surgical treatment is not always easy. As physicians, we want to do everything we can to help the individual patient as much as possible. If in doubt, it is in many ways easier to choose surgery. In fact, Mauner et al.[253] found that orthopedic surgeons were more likely to choose non-surgical treatment with increasing experience. The outcome of delayed rTSA for a proximal humeral fracture may be the equivalent of acute rTSA,[395] but the evidence is so far limited and conflicting.[296] For some borderline fractures, it may be reasonable to choose non-surgical treatment initially, at least if the greater tuberosity is not markedly displaced, with the possibility of performing delayed rTSA if needed.

2 CHOOSING TREATMENT FOR ELDERLY PATIENTS WITH DISTAL HUMERAL FRACTURES

In **Study III**, elbow hemiarthroplasty (EHA) and total elbow arthroplasty (TEA) were found to provide similar function following the treatment of unreconstructable distal humeral fractures in elderly patients. No previous comparative studies to put these results into context are available. The results can, however, be put into context with the treatment of distal humeral fractures in elderly patients in general.

Non-surgical treatment

Non-surgical treatment can be considered for some fractures with no or only limited displacement, but these injuries are not particularly common. Extraarticular fractures (type A in the AO/OTA classification) occasionally have no or only limited displacement, but this is uncommon for type B and type C fractures. In their series, Robinson et al.[332] found that 10 of 77 type B fractures and 2 of 119 type C fractures were non-displaced (< 5 mm). For the remaining patients, plate fixation is the preferred treatment, with the exception of some injuries in frail elderly patients for whom non-surgical treatment is an option. For exactly which patients this treatment choice is most suitable is unknown. With regard to fracture characteristics, Desloges et al.[105] made several reasonable suggestions. In their experience, a favorable outcome was generally associated with at least partial contact of the articular surfaces on the medial side of the ulnohumeral joint and the lateral side of the elbow (lateral ulnohumeral joint or radiocapitellar joint). Elderly lower-demand patients were offered surgical treatment in the event of gross displacement of the columns, if anesthesia was not contraindicated.

Secondary displacement of non-surgically treated distal humeral fractures can be troublesome and can in the worst-case scenario led to skin penetration. If non-surgical treatment is chosen, it is necessary to perform regular radiographs during the first weeks following injury, in order to detect secondary displacement.

Plating or arthroplasty?

For the majority of elderly patients, fixation with plates is the primary choice of treatment. In recent series where precontoured plates have been used, the functional outcome has been shown to be acceptable, [41; 110; 132; 196; 356] with a mean range of motion of approximately 20° of extension and 120–130° of flexion. Moreover, mean MEPS scores have been 85–90 points and mean DASH scores

20–30 points. However, in some studies, the rate of complications has been above 30%.[41; 110] In one of these studies, Biz et al.[41] found that patients with AO/OTA C3 fractures had poorer MEPS and *Quick*DASH scores, as compared with patients with less severe fracture types (B1, B2, C1 and C2). In addition, nonunion occurred in 5 of 12 patients with type C3 fractures, but in only 1 of 24 patients with less severe fracture types. For some distal humeral fractures in elderly patients, the distal fragments might simply be too thin, small and osteoporotic to allow stable internal fixation with plates and screws – that is, they are unreconstructable.

Total elbow arthroplasty is recognized as a treatment option for unreconstructable distal humeral fractures.[269] However, the question of which fractures are unreconstructable is highly subjective and there are very limited data to rely on. The study by Biz et al.[41] has been mentioned previously, but some of the most important results in this respect come from Robinson et al.[332] They found that "low" fractures (fracture line at or below the level of the condyles) ran a 7.5-times higher risk of union complications (delayed or nonunion) than "higher"(more proximal) fractures. Interestingly, in this study, the AO/OTA classification did not predict the occurrence of union complications.

The AO/OTA classification is not particularly helpful in identifying fractures for which it is likely to be difficult to achieve reliable internal fixation.[15] There are 28 different subgroups of distal humeral fractures in the most recent version of the AO/OTA classification.[252] Interest focuses heavily on accounting for the appearance of the metaphysis. There might be historical reasons for this. Back in 1936, Reich[193] described distal humeral fractures as having a T or Y form, pertaining to the metaphysis. In the classification of Jupiter and Mehne from 1992,[193] there is still considerable emphasis on describing different forms of fracture patterns in the metaphysis. While these different patterns of metaphyseal involvement were probably highly relevant when using the more rudimentary surgical and fixation techniques of the 1980s, many of these different fracture groups can now simply be reduced to those fractures that are fixable with modern implants and techniques.

It might be optimistic to strive for fracture classification systems to predict outcome reliably. However, aiming to describe fracture appearance effectively, based preferably on characteristics that have a bearing on the choice of treatment, is perhaps more reasonable. Two of the most important fracture characteristics to discern, with regard to clinical decision-making, are as follows; is the fracture too displaced to allow non-surgical treatment and, if so, is it possible to achieve a stable internal fixation? The most important factor when it comes to determining whether stable fixation can be achieved is probably how thin the most distal of the articular fragments is. Even without comminution in the metaphysis or intraarticular

fractures, a transverse fracture can for example be very difficult to fix if it is located so distally that the articular segment is very thin. This is illustrated by a few AO/OTA type A fractures being included in some of the case series of TEA for distal humeral fractures that are presented in Table 10. In **Study III**, the appearance of fractures was described based on how distally they were located (Figure 28).

One way of thinking about the indications for arthroplasty in the context of distal humeral fractures is in terms of type C fractures according to the AO/OTA system.[391] This is, however, problematic for two reasons. First of all, for most C1 and C2 fractures, it should be possible to obtain a stable internal fixation, even in elderly patients. The different subgroups of C1 and C2 fractures focus on describing different types of metaphyseal involvement, which is seldom a problem using modern plating techniques, even in elderly patients. Moreover, there are also other fractures than those of type C that are relevant for treatment with arthroplasty, such as different variations of coronal shear injuries (type B3 in the AO/OTA classification). Using the AO/OTA classification system as a basis for discussing the use of arthroplasty in the context of distal humeral fractures is probably not very helpful. It appears reasonable to use internal fixation with plates as the first line of treatment, reserving arthroplasty only for those fractures that are unreconstructable – irrespective of which AO/OTA groups might come closest to describing their appearance.

The experience of the orthopedic surgeon is undoubtably a pivotal factor in defining an unreconstructable distal humeral fracture. The relative degree of technical expertise with plating and arthroplasty is likely to affect which of these treatments is chosen for difficult distal humeral fractures, at least to some extent. From this perspective, centralizing the treatment of these difficult injuries appears to be logical. Moreover, the risk of revision and complications might be lower for patients treated by high-volume surgeons[183] and at high-volume institutions,[314] at least for elbow arthroplasty. The threshold for performing arthroplasty might in part depend on the technical skills of the surgeon with plating. In two recent series of the internal fixation of distal humeral fractures in elderly patients using precontoured plates, the authors acknowledged that arthroplasty was indicated for unreconstructable fractures, yet no such procedures were performed during the study periods.[132; 356] For difficult distal humeral fractures associated with severe osteoporosis, the approach adopted by the senior author of the study by Frachette et al.[132] is staged treatment with prolonged immobilization after ORIF (6 weeks for one patient in the study), followed by planned arthrolysis. These promising results of ORIF for comminuted distal humeral fractures in elderly patients obtained by surgeons with a very high level of expertise support the notion that centralization of treatment is prudent. Whether the results can be applied to practice in general

is unclear. The increasing use of elbow arthroplasty for distal humeral fractures indicates that some distal humeral fractures are perceived as unreconstructable.[239] For more difficult humeral fractures, there is some evidence to suggest that arthroplasty might be preferable to ORIF.

Based on the results of their RCT, McKee et al.[250] concluded that TEA was the preferred treatment for elderly patients with unreconstructable distal humeral fractures. This trial is notable for being the only previously available RCT comparing two fundamentally different treatment options for distal humeral fracture, with **Study III** being only the second. McKee et al. randomized 42 patients to either TEA or ORIF (5 of these patients were treated with TEA). After 2 years, elbow function was better in the TEA group, as compared with the ORIF group (86 vs. 73 points on the MEPS, $p = 0.02$). These results are in line with a recent meta-analysis by Jordan et al.[192] which found that TEA produced higher mean MEPS and DASH scores and a lower risk of complications as compared with ORIF.

Arthroplasty for distal humeral fractures

One disadvantage of TEA is the lifelong limitation relating to loading of the elbow which is imposed upon patients in order to minimize the risk of aseptic loosening. The rate of aseptic loosening has decreased since the early pioneering efforts of the 1970s, when it was 26%. According to recent registry studies the overall 10-year survival rate of TEA is 80–90%, with aseptic loosening as the leading cause of revision.[406] In a review from 2021, Parker et al.[300] found that the rate of revision for aseptic loosening was approximately 6% for contemporary prosthesis designs. In other words; aseptic loosening continues to be a problem and limiting loading still appears to be justified. One of the main advantages of elbow hemiarthroplasty (EHA) is that limitations in loading should be avoidable.

In **Study III**, the functional outcomes of EHA and TEA for the treatment of unreconstructable distal humeral fractures in elderly patients were found to be similar. The study is relatively small, but, although the risk of a type II error exists, the differences in the results of the DASH score, MEPS, extension and flexion were of small magnitude. None of these differences were of statistical significance and they were all below the estimates of the minimal important difference (MID) and smallest detectable change (SDC). There are no previous studies comparing these two treatments, randomized or otherwise. The results are, however, comparable to available cohort studies of each of the treatments.

The results of cases series of EHA and TEA have been summarized separately in several reviews. With regard to EHA, most of the reviews have included cases

series including patients with fracture sequelae in addition to acute fractures. Recently Piggot et al.[310] conducted a review focusing exclusively on the treatment of acute fractures. Although the Latitude Anatomic implant had been used for the majority of the included patients, some patients had been treated with humeral components not designed specifically for the replacement of the distal humerus (nonanatomic).[367; 368; 377] The first case series of which I am aware that reports on the use of a prosthesis designed specifically to replace the distal humerus, to treat acute fractures, is from 2012.[12] A sufficient number of case series that use an implant designed specifically to replace the distal humerus are now available and it therefore appears appropriate to use them as a reference (Table 9) for the results of **Study III**. The results of the patients in studies by Celli et al.[70] and Schultzel et al.[352] have been reported previously, but the study with the longest follow-up was included in Table 9.[3; 12; 182; 279; 307; 327]

The results of case series of the use of TEA for distal humeral fractures have also been summarized in reviews, recently by Kholinne et al.[199] Two studies have become available since the publication of this review.[69; 381] They are both included in Table 10 which summarizes the results of studies of the treatment of distal humeral fractures with TEA over the same period (2012–2022) as Table 9.[10; 22; 69; 111; 140; 213; 243; 316; 371; 381]

The results of the studies in Tables 9 and 10, which include the necessary data available were pooled. The mean MEPS was 85.1 points (95% CI: 81.1–89.1) for EHA and 88.4 points for TEA (95% CI 83.0–93.9). The mean DASH score was 26.0 points for EHA (15.2–36.7). The *Quick*DASH figured more frequently in studies on TEA and was therefore analyzed, revealing a mean score of 26.0 points (95% CI: 18.7–33.3). Mean extension was 22° (95% CI: 14–30°) for EHA and 21° (95% CI: 16–27°) for TEA. Mean flexion was 121° (95% CI: 114–128°) for EHA and 126° (95% CI: 121–131°) for TEA. Taken together, based on case series of EHA and TEA for the treatment of acute distal humeral fractures, the functional outcomes of both treatments appear to be similar. The results of **Study III** are thus in line with these findings.

EHA is a promising alternative to TEA, but there is reason for caution. The available data are limited to a relatively small number of patients treated by surgeons with a high level of expertise. Information on long-term outcome is also limited. The studies with the longest follow-up are by Schultzel et al.[352] and Celli et al.[70] Schultzel et al. concluded that the functional outcome was maintained between 6 and 9 year follow-ups, but the results were based on only 5 patients. At a mean follow-up of over 7 years, the 24 patients treated for acute distal humeral fractures in the study by Celli et al.[70] had reasonable elbow function.

TABLE 9 Overview of case series of patients treated for acute distal humeral fractures with hemiarthroplasty using implants designed specifically to replace the distal humerus, publications from 2012–2022

			AO/OTA fracture type					Main results, mean			
Author	**Year**	**Patients, n**	**B**	**C**	**Women, %**	**Age, mean**	**Years of follow-up, mean**	**MEPS, points**	**DASH*, points**	**Extension, °**	**Flexion, °**
Argintar	2012	10		C2 or C3	90	72	1	77	35	22	121
Nestorson	2015	42	B (n=23)	C3 (n=19)	93	72	2.9	90	20	24	127
Phadnis	2015	16	B3 (n=1)	C2 (n=2), C3 (n=13)	81	79	2.9	90	11*	15	131
Al-Hamdani	2019	24		C2 or C3	88	65	1.7	83			
Ricón-Recarey	2021	5		C3.1 (n=5)	100	75	5	82		8	109
Celli	2022	24	B3.3 (n=20)	C2 (n=1), C3 (n=3)	75	64	7.6	89	13	25	121
Jenkins	2022	37		C3 (n=37)	70	75	5.1		15*	17	125
Schultzel	2022	10		All C2 or C3		72	9.6	88	37	36	126

AO, Arbeitsgemeinschaft für Osteosynthesefragen; OTA, Orthopaedic Trauma Association; MEPS, Mayo elbow performance score; DASH, disabilities of the arm, shoulder and hand

* Or *Quick*DASH, marked with *

TABLE 10 Overview of case series including patients treated with total elbow arthroplasty (TEA) for an acute distal humeral fracture, publications from 2012–2022

			AO/OTA fracture type						Main results, mean			
Author	**Year**	**Patients, n**	**A**	**B**	**C**	**Women, %**	**Age, mean**	**Years of follow-up, mean**	**MEPS, points**	**DASH*, points**	**Extension, °**	**Flexion, °**
Antuna	2012	16		B3 (n=2)	C2 (n=2), C3 (n=12)	94	76	4.8	73	52	28	117
Ducrot	2013	20	A2 (n=2)	B2 (n=1), B3 (n=1)	C1 (n=1), C2 (n=5), C3 (n=9)	90	80	3.6	83		33	130
Mansat	2013	87	A (n=9)	B (n=8)	C1 (n=16), C2 (n=17), C3 (n=37)	92	79	3.1	86	24*	29	125
Giannicola	2014	10			C2 (n=2), C3 (n=8)		78	2.8	100	17*	15	138
Sorensen	2014	20	A2 (n=2)	B2 (n=1)	C3 (n=17)	90	77	1.8	94			
Prasad	2016	19	A3 (n=4)	B1 (n=2), B3 (n=3)	C1 (n=4), C3 (n=6)	63	68	13	90†		34	118
Barco	2017	44				75	71	>10	91		24	123
Lami	2017	21	A3 (n=2)		C1 (n=7), C2 (n=4), C3 (n=8)	95	81	3.2	84	32*	22	125
Celli	2021	13			C2 (n=3), C3 (n=10)	85	64	13	88		15	126
Strelzow	2021	40				88	79	4†	90	31*	16	127

The Coonrad-Morrey was the implant that was used except in studies by Strelzow et al. (Latitude) and Giannicola et al. (Discovery). In the study by Mansat et al., one elbow was replaced with a Discovery and another with a Latitude.

AO, Arbeitsgemeinschaft für Osteosynthesefragen; OTA, Orthopaedic Trauma Association; MEPS, Mayo elbow performance score; DASH, disabilities of the arm, shoulder and hand

* Or *Quick*DASH, marked with *

† median values

The potential for wear of the greater sigmoid notch and radial head is a major concern following treatment with elbow hemiarthroplasty. In the study by Celli et al.,[70] 6 out of 24 patients had signs of articular wear. Smith et al.[368] found that patients with severe wear had higher scores for pain and lower scores for satisfaction on the American Shoulder and Elbow Surgeons (ASES) score, as compared with patients with no or only mild wear. Moreover, there was a considerable correlation between the length of follow-up and the presence of wear. This emphasizes the need for long-term follow-up in large groups of patients. Data from joint replacement registries can be useful for detecting the risk of revision in large groups of patients. Nestorson et al.[280] identified 4 revisions for the 78 Latitude Anatomic implants that were registered in the Swedish Elbow Arthroplasty Register until 2014, but the follow-up time was only 4 years. Further data from arthroplasty registries are therefore awaited.

Conclusion – distal humeral fractures in elderly patients

In **Study III**, elbow hemiarthroplasty (EHA) was found to provide function similar to that of total elbow arthroplasty (TEA) after the treatment of unreconstructable distal humeral fractures in elderly patients. These results are in line with the limited previous literature available. The long-term outcome of elbow hemiarthroplasty is poorly defined. Moreover, arthroplasty is associated with a risk of troublesome adverse events, such as periprosthetic joint infection and fracture, as well as prosthetic loosening. Open reduction and internal fixation with plates should therfore remain the first line of treatment. Although the data are limited, total elbow arthroplasty following failed internal fixation might result in an outcome similar to that of primary TEA.[233] Using EHA for fracture sequelae is, however, likely more difficult than for acute fractures, but comparisons of outcome are still limited.

Acute elbow arthroplasty should be reserved for cases that are unreconstructable. For some of these patients, EHA may be a more favorable option than TEA. The risk of prosthetic loosening should be lower after EHA and loading of the elbow is therefore not limited after EHA, as opposed to after TEA. Future studies will reveal the long-term risk of loosening with EHA and the risk of other potential problems such as articular wear.

3 THE OXFORD ELBOW SCORE (OES) AND RECALL PERIOD

Several outcome instruments are available for assessing elbow function and their use has increased.[117] Of the available elbow-specific instruments, the Oxford Elbow Score (OES) stands out as the only one for which measurement properties have been assessed with modern psychometric methods of good quality.[393] The idea to perform **Study IV** arose in relation to discussions about conducting a study to assess the minimal important difference (MID) of the OES during the first months following elbow trauma. To assess function at, for example, 6–8 weeks and after 12 weeks, a recall period of 4 weeks, as originally described for the OES, would mean that it is very likely that considerable change would occur over the course of the recall period. It was anticipated that changes in function over the course of the recall period could potentially affect the results of the OES.

The reason for choosing a 4 week recall period for the OES was not explained in the original publication describing the instrument.[96] The OES was developed and evaluated based on a group of patients with different chronic elbow conditions.[95; 96] A recall period of 4 weeks is perhaps less of a problem in such a population than it is when assessing function while patients are recovering from injury or surgery. However, even for patients with chronic musculoskeletal problems, the course of the disease typically fluctuates and a period of 4 weeks leaves room for changes to occur. No data on the effect of variation in elbow function specifically on the results of outcome instruments are available. There are, however, some data on the effect of variations in other types of symptoms on how they are reported by recall.

Effect of variation in symptoms on recall

There is concern that rating symptoms by recall can led to inaccurate results. In fact, a number of studies indicate that patients overestimate their symptoms when accounted for by recall, as compared with repeated momentary ratings over the same period.[44; 58; 90] This effect is more pronounced with longer recall periods.[57] One possible explanation for these observations is the so-called "peak-and-end effect". The idea is that maximum symptoms (peak) and the symptoms experienced at the end of a recall period disproportionately affect pain ratings by recall. The idea of a "peak-and-end effect" traces its origins to laboratory experiments where subjects were exposed to two different set-ups for immersing their hand in cold water.[195] Subjects were more willing to repeat a set-up that involved a longer period of time in cold water (and pain) but warmer water towards the end (and less pain). This somewhat illogical finding was interpreted as indicating that symptoms

(less pain) experienced at the end of the period disproportionately affected the recall of the overall experience of pain. The idea was subsequently tested in a clinical setting. Patients undergoing colonoscopy were randomized to having the colonoscope left in the rectum for three minutes at the end of the procedure after deflation of the rectum (intervention) or to routine colonoscopy which involved removing the colonoscope directly at the end of the procedure. Patients in the intervention group rated their experience as significantly less unpleasant than those in the standard care group, again indicating an end effect. In patients with rheumatological diagnoses[350] and undergoing surgery,[184] recalled pain has been found to be unduly affected by peak pain experienced during the recall period. Moreover, the lowest pain level has also been found to be a good predictor of average pain by recall.[185] These observations might be best explained by a possible effect of symptom variation on assessment by recall. In fact, variations in pain,[380] symptoms from the lower urinary tract[126] and symptoms of diabetes[35] have been associated with a deviation in recalled symptoms from momentary ratings.

How about a systematic increase or decrease in symptoms over the recall period (temporal change)? The results of an interesting study by Schneider et al.[349] indicate that temporal changes over the course of a recall period can have an unfavorable effect on the accuracy of symptoms assessed by recall. They found that the correlation between menstrual symptoms (pain assessed on a numeric rating scale and symptoms of anger, fatigue and depression assessed using the *Patient Reported Outcome Measurement Information System*, PROMIS), assessed by recall and daily over 1 week, was lower if symptoms had increased or decreased over the period compared with no change in symptoms. Moreover, as compared with women with no change in symptoms over 7 days, those with an increase or decrease in symptoms had higher discrepancy scores (summarized momentary ratings subtracted from recalled ratings). These results possibly reflect that people find it difficult to summarize their experiences when symptoms have changed over the course of the recall period. Different strategies, such as basing response on average, highest or lowest intensity, most recent or earliest symptoms, are likely to result in variations in ratings by recall.

Longer recall periods could be expected to be disproportionately affected by variations in symptoms over the course of a recall period. The results reported by Perrot et al. indicate that this might be the case, as the assessment of pain by recall over a period of 4 weeks had a lower correlation with momentary pain ratings than a recall period of 1 week in a group of patients with hip and knee arthritis.[304]

An interesting study by Shapiro et al.[357] provides an insight into the effect of memory and perceived ability on the assessment of function with the DASH. One hundred and twelve patients with upper extremity disorders responded to the DASH before and after completing a set of tasks enquired about in the DASH. The mean score decreased by 14 points (less disability), suggesting that enquiring about recent experiences (short recall) is preferable.

Is a 7-day recall period better for the OES?

The OES displayed favorable measurement properties when used with a 7-day recall period. The measurement properties were at least as good as those reported in studies using the OES with the original 4-week recall period.[95; 96; 177; 297] It is difficult to prove that a certain recall period is better than another. It would be possible to randomize patients to different recall periods, but it is unclear which methods should be used to compare them and how the results should be interpreted. For instance, Condon et al.[81] randomized 2,400 people to responding to the PROMIS physical function with no recall period, a 24-hour recall period and a 7-day recall period. Items were assessed for potential differential item functioning (DIF) by recall period. Meanwhile, Boesen et al.[44] compared different lengths of recall periods for the *Thyroid-related patient-reported outcome measure* based on comparisons with momentary ratings.

There is no single correct length of recall period for all PROMS.[284] The most suitable length of recall period varies based on context. Factors that can be of importance include the variability, frequency and intensity of symptoms, the concept the PRO aims to measure, the ability of the patient reliably to recall relevant information and finally the design and length of the study.[284] The most suitable length of a recall period can even be different for the same instrument, depending on the context, for example, the diagnosis under study. In the end, determining the most suitable recall period for a PROM is a question of judgement. One of the most important aspects is that the recall period needs to be sufficiently long for it to be likely that the patients have experienced the phenomena about which the items enquire. This needs to be balanced against the risk of inaccurate recollection. For patients with most elbow disorders, acute or chronic, it is reasonable to assume that they experience the phenomena enquired about on the OES over the course of one week. Stull et al.[383] presented a heuristic for length of recall period, based on a literature review. The heuristic indicates that, for assessing pain, psychological state and activities of daily living, a recall period of approximately one week would be appropriate. These factors correspond roughly to the three domains of the OES.

Conclusion – Oxford Elbow Score (OES) and recall period

The results of **Study IV** further reinforce the view that the OES has good measurement properties. Moreover, the results support using the OES with a shortened 7-day recall period. The OES is not, however, perfect. For example, it can as other PROMs be affected by response shift mentioned in the section on the assessment of the outcome of proximal humeral fractures. When assessing the outcome of elbow disorders, the OES can provide valuable information. However, taking other factors into account is necessary in order to obtain an overall picture, including assessments of range of motion, pain, adverse events and so on.

5.

General Conclusions

Reverse total shoulder arthroplasty (rTSA) provides better shoulder function than hemiarthroplasty (HA) for elderly patients with displaced 3- and 4-part proximal humeral fractures and is preferable to HA, at least in most elderly women. Moreover, tuberosity healing provides better shoulder function than failed tuberosity healing after treatment with HA for a proximal humeral fracture. For unreconstructable distal humeral fractures, elbow hemiarthroplasty (EHA) and total elbow arthroplasty (TEA) provide similar function, at least in elderly women. Other factors, such as activity level, should be considered when choosing between these treatment options. The results of **Study IV** further establish the *Oxford Elbow Score* as a well-validated, elbow-specific PROM and support the use of a 7-day recall period.

6.

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7.

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