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CORR Synthesis

CORR® Synthesis: What Is the Role of Reverse Shoulder Arthroplasty for the Treatment of Proximal Humerus Fractures in Patients Older Than 65 Years?

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In the Beginning

Proximal humerus fractures are the third most common fracture in people older than 65 years and are the second most common fracture in the upper extremity [10, 12, 15, 27]. Most of these fractures occur in patients older than 65 years after low-energy trauma, and osteoporosis is a known risk factor [15]. The incidence of these fractures in the United States is increasing and parallels the increasing average age of the population [15].

Historically, proximal humerus fractures were treated without surgery. Hemiarthroplasty was introduced by Charles Neer in the 1970s for a treatment of glenohumeral arthritis [19]. Before that, he used hemiarthroplasty exclusively for the treatment of proximal humerus fractures and their sequelae. At that time, hemiarthroplasty was the operative treatment of choice for comminuted proximal humerus fractures [10, 12, 19]. In the early 2000s, locking plates were developed, which led to more comminuted proximal humerus fractures being treated with open reduction internal fixation (ORIF) [10, 12, 15]. Despite these advances, the complication risk remained high in patients treated with both ORIF and hemiarthroplasty [9, 37].

There has been considerable evolution in the treatment of proximal humerus fractures over the past two decades. Although most proximal humerus fractures in patients older than 65 years of age can be treated without surgery, in certain scenarios, surgical treatment is indicated. Percutaneous or minimally invasive osteosynthesis, internal fixation with locked plates or intramedullary nails, hemiarthroplasty, and reverse total shoulder arthroplasty (RTSA) are the main surgical options [10, 12, 15, 19, 32]. RTSA has seen increased use to treat proximal humerus fractures in patients older than 65 years of age during the past decade [21]. However, some important gaps remain in our understanding of when to use this approach to give patients the best possible restoration of function and relief of pain, and how to minimize complications of the intervention.

Argument

The ideal treatment for displaced proximal humerus fractures in patients older than 65 years of age continues to be

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debated [18]. Perhaps most importantly, the decision-making process for the treatment of proximal humerus fractures in this patient population is not dictated solely by the radiographic classification of the fracture. The main goals of treatment include pain relief and regaining physiologic ROM and strength to allow for functional use of the arm.

RTSA is a constrained arthroplasty that, unlike hemiarthroplasty or total shoulder arthroplasty (TSA) does not rely on the rotator cuff for elevation in the forward plane. Reverse articulation with a medialized and distalized center of rotation recruits the deltoid muscle to function as an effective forward elevator and abductor of the shoulder. In patients with proximal humerus fracture, RTSA with tuberosity reconstruction provides predictable pain relief, restores forward elevation (in most patients, more than 90° is achieved [6, 25, 31]), and rotationally controls the arm in space [6, 9, 17, 25, 31]. However, RTSA carries a substantial risk of both short-term and long-term complications, which occur in patient between 5% and 40% of the time after these procedures [37], with complications being more likely to occur when performed in patients with rheumatoid arthritis, for acute proximal humerus fractures, and in those undergoing revision arthroplasty [37]. Prosthetic dislocation after RTSA for fractures is the most common complication [3, 12]. Acromial, glenoid, and periprosthetic humeral fractures can occur as well, especially given the frequent co-occurrence of osteoporosis in this patient population. Despite these risks, RTSA has certain advantages compared with other surgical options such as hemiarthroplasty and internal fixation, including the ability to obtain a good functional outcome irrespective of rotator cuff function and the ability to avoid dependance on fracture fixation into osteoporotic bone [4]. For these reasons, the use of RTSA is increasing in the treatment of patients with proximal humerus fractures [1, 6, 9, 16, 25, 31, 36].

Despite the success of locking plates compared with previous fracture fixation techniques, internal fixation of proximal humerus fractures, especially in osteoporotic bone, is still associated with a high complication risk (studies reporting complications in 20% to 30% of patients are not unusual), with complications including screw cut-out, varus collapse, and fixation failure being among the more common and serious ones observed [7, 11, 13]. Pain relief and postoperative ROM after ORIF also depends on the retention of the vascularity of the humeral head, which is considerably compromised in the setting of dislocation, displaced anatomic neck fractures, and head-splitting fractures [7, 13]. Because RTSA replaces the humeral head and functions independently of the rotator cuff, it is not susceptible to the same complications as ORIF, although, as mentioned, RTSA carries very real risks of the complications one would expect after complex arthroplasty in patients with osteopenia or osteoporosis.

Before the advent of RTSA, hemiarthroplasty was more commonly used as a surgical solution in lieu of ORIF. However, postoperative pain relief, ROM, and achievement of satisfactory validated patient-reported outcome scores were unpredictable with hemiarthroplasty; in addition, tuberosity healing and rotator cuff integrity both were inconsistent (yet important in terms of achieving satisfactory results), which is not the case with RTSA [6, 10, 24, 25, 28]. Tuberosity malunion and resorption after hemiarthroplasty occurs in up to 43% of shoulders, and these patients have poor function postoperatively, usually with a limited ROM in all planes [6, 10, 24, 25, 28]. Hemiarthroplasty after a proximal humerus fracture also may be complicated by prosthetic instability, preexisting rotator cuff deficiency, and subacromial mechanical impingement from a high-riding (proud) prosthesis.

Despite its advantages over other surgical options, RTSA may not be the ideal way to treat every proximal humerus fracture. Therefore, we critically reviewed existing studies to determine the role of RTSA for treating proximal humerus fractures in patients older than 65 years. We limited this review to studies evaluating patients older than the age of 65 years.

Essential Elements

We systematically reviewed the PubMed, Embase, and Cochrane Central Register of Controlled Trials databases from inception to November 2020 based on the Preferred Reporting Items for Systematic Review and Meta-analyses guidelines [26]. Identified articles were uploaded and screened.

The terms used in the search were proximal humerus, proximal humerus fracture, proximal humeral fracture, fractures of the proximal humerus, reverse total shoulder arthroplasty, clinical, trial, and clinical trials. All search terms were grouped by "OR" and subsequently combined using "AND." Two reviewers (MAB and another who was not an author) screened the titles, abstracts, and full text of studies based on specific eligibility criteria. Studies were included based on the agreement of the two reviewers, with the senior author (MSV) consulted in the event of disagreement.

We included studies evaluating RTSA after acute proximal humeral fractures that reported on ROM, validated patient-reported outcome scores, or complications. We limited inclusion to Level I or Level II clinical studies comparing RTSA with an alternative treatment method, studies that enrolled skeletally mature patients, and articles that were published in peer-reviewed journals and were written in English. We excluded studies that did not evaluate RTSA after acute proximal humerus fractures, studies that focused on patients who were skeletally immature, animal studies, case reports, case series, reviews, and articles written in a language other than English.

Data were extracted into a Microsoft® Excel datasheet. The variables collected included the treatment, inclusion criteria, gender ratio per protocol, mean age, comorbidities, bone graft use, greater tuberosity repair, implants, and final or mean follow-up. The number of shoulders treated in per-protocol analyses were recorded for each study group.

We collected outcomes (as they were available) including the total American Shoulder and Elbow Surgeons shoulder score, Simple Shoulder Test score, Constant score, DASH score, University of California-Los Angeles score, VAS score, patient satisfaction score, forward elevation, abduction, external rotation, internal rotation, greater tuberosity healing, survival, secondary procedures, and complications. Since not all outcomes were reported in all studies, we did not make quantitative comparisons between or among studies.

We assessed the included studies' evidence using three different techniques: level of evidence, quality of evidence, and conflicts of interest. Criteria published by *The Journal of Bone and Joint Surgery, American Volume,* were used to assess the level of evidence [35]. The Newcastle-Ottawa scale was used to assess the quality of evidence [5]. Studies with 7 to 9 stars were classified as having very good quality of evidence, those with 5 to 6 stars were considered to have a good quality of evidence, studies with 4 stars were considered to have a satisfactory quality of evidence, and those with 0 to 3 stars were considered to have an unsatisfactory quality of evidence. All included studies were classified as having very good quality of evidence (Table 1).

We identified five Level I and Level II clinical comparative studies evaluating RTSA to treat acute proximal humerus fractures in patients aged older than 65 years (Fig. 1). Two studies compared proximal humerus hemiarthroplasty and RTSA [6, 25], one study compared nonoperative management with RTSA [17], one study compared ORIF with RTSA [9], and the final study reported on outcomes after patients' care decisions were directed by an algorithm, with possible treatments including nonoperative management, ORIF, hemiarthroplasty, and RTSA [31]. Each study focused only on patients older than 65 years of age, except for the algorithm-based study, which included all patients aged 18 years and older [31] (Table 1).

What We (Think) We Know

In a randomized controlled trial, Lopiz et al. [17] compared the 1-year outcomes of nonsurgical treatment with RTSA for acute three-part or four-part proximal humerus fractures in patients 80 years and older (Table 2). Internal fixation was not considered in the surgical treatment group because of known challenges with internal fixation in osteoporotic bone, as well as the higher complication risk in patients older than 65 years of age. Patients with fracture dislocations and head-splitting fractures were excluded from that study. The study authors found no clinically important differences between the RTSA group and the nonsurgical treatment group with respect to VAS pain score (0.9 versus 1.6) and Constant score (56.7 versus 61.7; $p = 0.70$). Furthermore, at the final follow-up, the authors found no difference between the two study groups in terms of the quality-of-life outcome score and ROM measurements (abduction, external rotation, or internal rotation). The only reported adverse event was suprascapular nerve injury in the RTSA group. In summary, this study did not show any short-term clinically important benefits of treatment with RTSA in three-part and four-part proximal humerus facturs without dislocation and head-splitting fractures in patients 80 years and older.

In another randomized controlled study, Fraser et al. [9] compared RTSA with ORIF for severely displaced acute proximal humerus fractures (AO Type B2 or C2) in patients 65 to 85 years old (Table 2). The authors excluded head-splitting fractures, fracture dislocations, and higher-energy proximal humerus fractures from the study. At the final follow-up at 2 years, RTSA outperformed internal fixation with respect to the primary outcome measure, the total Constant score (68 versus 54.6; $p < 0.001$) [9] (Table 2). The better Constant score was because the RTSA group had better ROM compared with the internal fixation group (flexion Constant score: 7 versus 5.2; abduction Constant score: 6.7 versus 4.7; external rotation Constant score: 7 versus 4.4; $p < 0.001$). There were seven adverse events in the RTSA group and 12 in the ORIF group. As expected, the most common adverse event in the ORIF group was screw penetration (nine patients), which resulted in implant removal (in three patients) or RTSA (in four). The adverse events in the RTSA group included deep wound infection (in two patients), transient nerve injury (two patients), and intraoperative or postoperative fracture (three patients). Eight patients in the ORIF group and four patients in the RTSA group underwent secondary procedures. Although this study did not have a nonsurgical treatment group, it was well designed (with a quality of evidence score of 8 of 9) and included patients who were likely to benefit from surgical treatment. Furthermore, it highlighted the specific surgical risks and common secondary procedures expected with RTSA versus ORIF for displaced proximal humerus fractures.

Several studies have demonstrated the superiority of RTSA over hemiarthroplasty to treat acute three-part or four-part proximal humerus fractures in patients aged 70

Table 1. Summary of study and patient characteristics

Study	Level of evidence	Quality of evidence	Potential COI	Treatment	Inclusion criteria	Number
Cuff and Pupello [6]	2	9	Yes	HA; RTSA	Four-part fracture, three-part fracture with greater tuberosity comminution, articular split of the humeral head	26; 27
Sebastiá-Forcada et al. [25]	1	9	No	HA; RTSA	Four-part fracture, fracture-dislocations with three-part fracture, head-splitting fracture with more than 40% articular surface involvement	31; 31
Lopiz et al. [17]	1	9	No	Nonoperative management; RTSA	Three-part fracture, four-part fracture	32; 30
Spross et al. [31]	2	8	No	Nonoperative management; ORIF; HA; RTSA	All proximal humerus fractures	132; 36; 4; 20
Fraser et al. [9]	1	8	Yes	ORIF; RTSA	Severely displaced Type B2 or C2 fractures	60; 64

Study	Gender ratio per protocol, men:women	Mean age in years	Comorbidities	Bone graft use	Greater tuberosity repair	Implants	Final/mean follow-up in months (range)
Cuff and Pupello [6]	9:14; 10:14	74.1; 74.8	7 (HA) and 9 (RTSA) with diabetes	Morselized autograft (HA and RTSA)	Suture repair (HA and RTSA)	Aequalis fracture stem or Foundation fracture system; DJO Reverse Shoulder Prosthesis	30 (24-48)
Sebastiá-Forcada et al. [25]	5:25; 4:27	73.3; 74.7	NR	NR	Suture repair (HA and RTSA)	SMR Trauma prosthesis; SMR modular shoulder replacement system	27.7 (24-49); 29.4 (24-44)
Lopiz et al. [17]	4:26; 4:25	85; 82	Mean CCI 6.1; 5.7	Morselized autograft (RTSA)	Suture repair (RTSA)	Delta XTEND Reverse Shoulder System prosthesis or SMR Modular Shoulder System (RTSA)	12
Spross et al. [31]	58: 134 (total)	58.4 (men): 69.1 (women)	NR	NR	NR	NR	12
Fraser et al. [9]	8:52; 5:59	74.7; 75.7	1 (ORIF) and 8 (RTSA) with diabetes	NR	NR	PHILOS angular stable plate; Delta Xtend Reverse Total Shoulder Arthroplasty or Promos Reverse Prosthesis	24

All columns are organized respective to the treatment column unless otherwise specified. Implants: Aequalis fracture stem (Wright Medical), Foundation fracture system (DJO Surgical), DJO Reverse Shoulder Prosthesis (DJO), SMR Trauma prosthesis (System Multiplana Randelli, LIMA-LTO), SMR modular shoulder replacement system (System Multiplana Randelli, LIMA-LTO), Delta XTEND Reverse Shoulder System prosthesis (DePuy Synthes), SMR Modular Shoulder System (System Multiplana Randelli, LIMA-LTO), Delta Xtend Reverse Total Shoulder Arthroplasty (DePuy Synthes), Promos Reverse Prosthesis (Smith and Nephew), PHILOS angular stable plate (DePuy Synthes); COI = conflicts of interest; HA = hemiarthroplasty; NR = not recorded; CCI = Charlson comorbidity index; ORIF = open reduction and internal fixation.

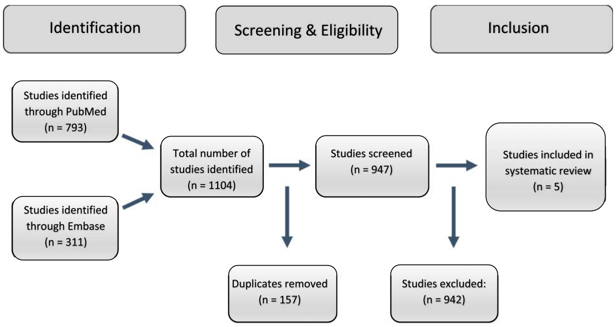

Fig. 1. This flowchart shows the studies that were included in this systematic review.

years or older [6, 25, 31] (Table 2). Patients with RTSA consistently have had higher American Shoulder and Elbow Surgeons scores, Simple Shoulder Test scores, Constant scores, University of California-Los Angeles scores, and DASH scores than those undergoing hemiarthroplasty (Table 2) [25]. Of these scores, the improvement in the American Shoulder and Elbow Surgeons, Simple Shoulder Test, and Constant scores was considered clinically important [29, 33]. Forward elevation was also consistently higher, at 139° versus 100° ($p = 0.0002$), 120.3° versus 79.8° ($p = 0.001$), and 134.4° versus 70° in the three studies evaluating RTSA and hemiarthroplasty [6, 25, 31]. In one study, abduction was higher after RTSA (112.9°) than after hemiarthroplasty (78.7°; $p = 0.001$) [25]. The improvements in forward flexion and abduction with RTSA reported in these studies were considered clinically important [29].

Because of a lack of high-quality evidence, the determination of which patients should be treated surgically continues to be a topic of ongoing debate [6, 9, 25, 31]. RTSA seems to have more compelling advantages in patients with proximal humerus fractures who have the most severe fracture patterns, such as displaced head-splitting fractures and fracture dislocations; this is especially true in patients whose preinjury activity levels were higher [12]. By contrast, RTSA for other displaced three-part and four-part fractures, particularly in patients whose activity levels are lower, is less likely to offer any advantage over nonsurgical treatment [12].

Knowledge Gaps and Unsupported Practices

Current decision-making algorithms for proximal humerus fractures are largely based on radiographic findings [12, 17, 31]. Other important considerations that can affect outcomes and patient satisfaction include the patient's pain level, baseline activity level and ambulatory status (with or without walking aids), living status (independent versus in a facility), demand on the extremity, handedness (dominant versus nondominant arm), desired postoperative function, skeletal mineral density, and the presence of serious medical comorbidities. These factors are not always well considered, and we need studies that can guide us as to how best to factor them into our clinical decisions, specifically large, randomized controlled trials looking at these specific patient variables. Unfortunately, two patients with the same fracture displacement pattern may differ with respect to pain scores, functional status, treatment expectations, and demands on the involved extremity, and treating these patients with one over-arching treatment (surgical versus nonsurgical) may not always succeed.

Most RTSAs are performed by surgeons who are performing fewer than five RTSAs per year; some research suggests that very-low-volume surgeons may be at increased risk for serious complications after this operation [34]. Referring patients to a shoulder specialist interested in caring for these fractures using RTSA is one strategy that may help to minimize this concern. However, this is not feasible or in the patient's interest everywhere, especially in rural areas, where it may be impractical or impossible. Other strategies include improved surgeon training in and use of alternate treatment options (such as hemiarthroplasty) for surgeons who are not comfortable with RTSA. Even though hemiarthroplasty is technically easier to perform in general compared with RTSA, it is considered by many experts to be technically more difficult to achieve good postoperative ROM and high patient-reported outcomes scores [6, 25, 31].

Many different designs of RTSA (traditional Grammont-style versus lateralized) and humeral stem options (short stem, standard stem, fracture stem) are now available. It is unclear whether there is an ideal implant design to treat proximal humerus fractures. Uncemented humeral stems have been shown to be reliable in shoulder arthroplasty for arthritic indications, but their use in osteoporotic bone, as seen in proximal humerus fractures, is debatable, and long-term data on this practice are unavailable [14, 20].

Finally, there is no universally accepted technique for repairing the tuberosities, and the best tuberosity management technique continues to be debated. Nonetheless, multiple Level III and IV studies have shown that repairing the tuberosities in RTSA leads to improved external rotation and patient satisfaction [2, 4, 8, 23, 30]. Future studies should focus on comparing specific implant designs and surgical techniques in RTSA for proximal humerus fractures to better define the most favorable treatment method.

The long-term outcomes of RTSA for proximal humerus fractures are not yet known. There are unique challenges when treating patients who have a proximal humerus fracture with RTSA, and these may have important implications over time. For example, we do not yet know to what degree complications like RTSA dislocation and periprosthetic fractures will increase over longer-term

Table 2. Summary of outcomes

		Clinical scores						
Study	Treatment	Total ASES score	SST score	Constant score	DASH score	UCLA score	VAS pain score	Patient satisfaction (%)
Cuff and Pupello [6]	HA; RTSA	62; 77	5.8; 7.4	NR	NR	NR	NR	61; 91
Sebastiá-Forcada et al. [25]	HA; RTSA	NR	NR	40; 56.1	24.4; 17.5	21.1; 29.1	NR	NR
Lopiz et al. [17]	Nonoperative treatment; RTSA	NR	NR	55.7; 61.7	28.8; 20.7	NR	1.6; 0.9	93; 100
Spross et al. [31]	Nonoperative management; ORIF; HA; RTSA	NR	NR	76; 63; 44; 69	NR	NR	NR	NR
Fraser et al. [9]	ORIF; RTSA	NR	NR	54.6; 68	NR	NR	NR	NR

	ROM							
Study	Forward elevation in degrees	Abduction in degrees	External rotation in degrees	Internal rotation in degrees	Greater tuberosity healed, %	Survival (revision or clinical failure)	Secondary procedures, % of patients	Complications
Cuff and Pupello [6]	100; 139	NR	25; 24	30; 46	61; 83	NR	13; 0	HA: 1 hematoma, 1 apical pneumothorax; RTSA: 1 operative transient ulnar nerve paresthesia, 1 periprosthetic fracture at 8 months
Sebastiá-Forcada et al. [25]	79.8; 120.3	78.7; 112.9	3.3; 4.7	2.6; 2.7	56.7; 64.5	40 months: 43.3 (95% CI 25.6-65.1); 71 (95% CI 55.1-86.9)	23; 3	HA: 1 intraoperative humerus fracture, 1 superficial infection, 1 MUA for stiffness, 6 revisions to RTSA RTSA: 1 hematoma, 1 deep wound infection resulting in revision
Lopiz et al. [17]	5.7; 6.9[a]	5.6; 6.6[a]	4.4; 5.2[a]	4.8; 5.5[a]	0; 52[b]	NR	None	Nonoperative management: none RTSA: 2 suprascapular nerve injuries

Table 2. continued

	ROM							
Study	Forward elevation in degrees	Abduction in degrees	External rotation in degrees	Internal rotation in degrees	Greater tuberosity healed, %	Survival (revision or clinical failure)	Secondary procedures, % of patients	Complications
Spross et al. [31]	144; 122; 70; 134.4	NR	NR	NR	NR	NR	2; 44; 50; 0	Nonoperative management: 3 greater tuberosity displacements treated with surgery ORIF: 8 plate removals, 3 with arthroscopic arthrolysis for stiffness, 3 with early loss of reduction, 1 avascular necrosis, 1 secondary cut out HA: 1 arthroscopic arthrolysis, 1 removal of hardware for infection RTSA: none
Fraser et al. [9]	5.2; 7[a]	4.7;6.7[a]	4.4; 7[a]	5.7; 5.9[a]	NR	NR	12; 6	ORIF: 9 screw penetrations, 1 fracture distal to plate, 1 nonunion, 1 rotator cuff rupture RTSA: 2 transient nerve injuries, 2 deep wound infections, 2 periprosthetic fractures, 1 perioperative glenoid fracture

All columns are organized respective to the treatment column unless otherwise specified.

[a]Constant scores.

[b]Refers to anatomic healing as specified in the reference (compared with malunion); ASES = American Shoulder and Elbow Surgeons; SST = simple shoulder test; UCLA = University of California-Los Angeles; HA = hemiarthroplasty; ORIF = open reduction and internal fixation; NR = not recorded; MUA = manipulation under anesthesia.

follow-up. Continued follow-up on the currently available clinical studies should be pursued.

One of the less commonly discussed advantages of RTSA over internal fixation is that delayed surgical treatment with RTSA (2 to 3 months after injury) still may provide good pain relief and postoperative ROM in patients with displaced proximal humerus fractures. Comparative studies have shown that patients who had malunion and resorption of the tuberosities and were treated with RTSA were able to maintain good function compared with those treated with hemiarthroplasty [6, 25]. We have used this to our advantage in decision-making for patients older than 65 years of age with displaced three-part and four-part proximal humerus fractures who have intractable pain and poor function at the initial presentation, but who are not certain whether they should have surgery. Nonsurgical treatment in the initial 2 to 3 months allows patients to experience the effect of limitations incurred by the fracture, and they then can decide whether they want to proceed with prosthetic replacement. This allows us to further refine and select patients who feel they would benefit from surgery (RTSA) in this setting. Although this has been beneficial to us and has worked well in our hands, it is largely unsupported by currently available evidence, and the true benefit over continued nonoperative treatment in these patients is not known.

Barriers and How to Overcome Them

Indications for surgical treatment, including RTSA, continue to be an ongoing debate for the treatment of proximal humerus fractures in people older than 65 years of age. The results of one well-conducted randomized controlled clinical trial demonstrated no clear advantage of surgical treatment over nonsurgical treatment in proximal humerus fractures involving the surgical neck [22]. However, clinical scenarios such as proximal humeral fracture/dislocation and displaced head-splitting fractures were not studied in this clinical trial, undermining the clinical utility of RTSA in patients older than 65 years of age [22]. Although these fracture patterns are not common, and randomized studies evaluating these indications are difficult to conduct for ethical reasons, we believe that RTSA outperforms hemiarthroplasty and internal fixation in these scenarios. Future well-designed clinical studies should focus on several patient variables, such as preoperative pain level, demand of the extremity, desired postoperative activities, and perhaps others, to help refine the indications for RTSA in patients with proximal humeral fractures. Finally, there are currently no clinical practice guidelines for the treatment of proximal humerus fractures of which we are aware, and the development of such guidelines certainly would be beneficial as new research becomes available.

5-year Forecast

RTSA is seeing increased use for displaced three-part and four-part proximal humerus fractures and fracture dislocation in patients older than 65 years because of its ability to provide predictable improvements in pain and shoulder function. If the current trend of the increasingly aging population continues, the use of RTSA is also expected to increase [10]. As surgical techniques and RTSA components continue to improve, patient outcomes and implant longevity may also improve. Even as the indications for the treatment of proximal humerus fractures continue to evolve, radiographic classification-based treatment of proximal humerus fractures will likely be replaced by an algorithm-based individualized treatment approach that incorporates other important patient-related factors (such as functional age, functional demands on the extremity, comorbidities, and pain scores) that could impact treatment decision-making.

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