Clin Orthop Relat Res (2022) 00:1-13
DOI 10.1097/CORR.0000000000002480

Clinical Orthopaedics and Related Research®
A Publication of The Association of Bone and Joint Surgeons®

Clinical Research

Reverse Total Shoulder Arthroplasty Demonstrates Better Outcomes Than Angular Stable Plate in the Treatment of Three-part and Four-part Proximal Humerus Fractures in Patients Older Than 70 Years

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Received: 15 April 2022 / Revised: 18 August 2022 / Accepted: 12 October 2022 / Published online: 15 November 2022

Abstract

Background Proximal humeral fractures are traditionally treated with open reduction and internal fixation (ORIF), but reverse total shoulder arthroplasty (RTSA) has emerged as an increasingly popular treatment option. Although ORIF with angular locking plates is a common treatment for proximal humerus fractures, prior reports suggest high failure and complication rates. Although RTSA has become an increasingly popular option for complex proximal humeral head fractures given its low complication rates, there are concerns it may lead to limited postoperative ROM. Thus, the optimal treatment for patients older than 70 years from a functional and radiographic perspective remains unclear.

Questions/purposes (1) In patients older than 70 years with three-part and four-part proximal humerus fractures, does RTSA result in better functional outcome scores (Constant, American Shoulder and Elbow Surgeons [ASES], and DASH scores) than ORIF with a locking plate? (2) Does RTSA result in greater ROM than ORIF? (3) Does RTSA result in a lower risk of complications than ORIF? (4) In patients with either procedure, what are the rates of negative radiographic outcomes in those treated with ORIF (such as malunion, bone resorption, malalignment, or avascular necrosis) or those with RTSA (such as resorption, notching, and loosening)? (5) At a minimum of 2 years of follow-up, does ORIF result in a greater number of revision procedures than RTSA?

Methods Between January 1, 2013, and June 30, 2018, we treated 235 patients for a proximal humeral fracture. We considered only patients without previous ipsilateral fracture or surgery, other fractures, or radial nerve injuries; age older than 70 years; and patients without neurologic disease or cognitive dysfunction as potentially eligible. Sixty-nine percent (162 patients) of the patients were eligible; a further 31% (73 patients) were excluded because 18% (13 of 73 patients) did not meet the inclusion criteria, 62% (45 patients) underwent nonoperative treatment, and 21% (15 patients) declined to participate. Patients were nonrandomly allocated

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All ICMJE Conflict of Interest Forms for authors and *Clinical Orthopaedics and Related Research®* editors and board members are on file with the publication and can be viewed on request.
Ethical approval for this study was obtained from the San Camillo Forlanini Hospital, Rome, Italy.
This work was performed at San Camillo Forlanini Hospital, Rome, Italy.

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to receive RTSA if they had supraspinatus Goutallier/Fuchs Grade 3 or 4 atrophy or ORIF if they had supraspinatus Goutallier/Fuchs Grade 1 or 2 atrophy. This left 81 patients who were treated with RTSA and another 81 patients who were treated with ORIF. Among the 81 patients treated with RTSA, 11% (nine patients) were lost to the minimum study follow-up of 2 years or had incomplete datasets, leaving 89% (72 patients) for analysis. Among the 81 patients treated with ORIF, 19% (15 patients) were lost before the minimal study follow-up of 2 years or had incomplete datasets, leaving 82% (66 patients) for analysis. The median follow-up for both groups was 53 months (range 24 to 72 months). The mean age was 76 ± 2.9 years in the RTSA group and 73 ± 2.9 years in the ORIF group. In the RTSA group, 27 patients had a three-part fracture and 45 patients had a four-part fracture. In the ORIF group, 24 patients had three-part fractures and 42 patients had four-part fractures (p = 0.48). Shoulder function was assessed using functional outcome questionnaires (ASES, DASH, and Constant) and active ROM measurements. A surgical complication was defined as any instance of dislocations, fractures, adhesive capsulitis, nerve injuries, or surgical site infections. Radiographic outcomes after ORIF (malunion, tuberosity resorption, or avascular necrosis) and RTSA (notching and osteolysis) were assessed. In calculating the revision rate, we considered unplanned revision procedures only.

Results Compared with patients treated with ORIF, patients treated with RTSA had superior improvements in Constant (85.0 ± 7.0 versus 53.0 ± 5.0; mean difference 32 [95% CI 30 to 34]; p < 0.01), ASES (46.3 ± 3.7 versus 30.0 ± 3.5; mean difference 16 [95% CI 15 to 18]; p < 0.01), and DASH scores (40.5 ± 4.2 versus 30.5 ± 2.6; mean difference 10 [95% CI 9 to 11]; p < 0.01). The mean elevation was 135° ± 7° for patients with RTSA and 100° ± 6° for patients with ORIF (mean difference 35° [95% CI 33 to 37]; p < 0.01). The mean abduction was 131° ± 7° for patients with RTSA and 104° ± 6° for those with ORIF (mean difference 27° [95% CI 25° to 29°]; p < 0.01). The mean external rotation was 85° ± 5° for patients with RTSA and 64° ± 5° for those with ORIF (mean difference 21° [95% CI 19° to 23°]; p < 0.01). The mean internal rotation was 45° ± 6° for patients with RTSA and 40° ± 6° for those with ORIF (mean difference 5° [95% CI 3° to 7°]; p < 0.01). The risk of complications was not different between patients with ORIF and those with RTSA (5% [three of 66] versus 1% [one of 72]; relative risk 3.3 [95% CI 0.3 to 30.7]; p = 0.30). Among patients with ORIF, 8% had varus malunions (five of 66), 6% had resorption of the greater tuberosity (four of 66), and 2% had avascular necrosis of the humeral head (one of 66). In the RTSA group, 24% (17 of 72 patients) demonstrated reabsorption of periprosthetic bone and 79% of patients (57 of 72) exhibited no notching. The risk of revision was not different between the RTSA and ORIF groups (0% [0 of 72] versus 9% [six of 66]; relative risk 0.07 [95% CI 0.0 to 1.2]; p = 0.07).

Conclusion In patients older than 70 years with three-part and four-part proximal humerus fractures, primary RTSA resulted in better patient-reported outcome scores and better ROM than ORIF with an angular stable locking plate. Our findings might help surgeons decide between internal fixation and arthroplasty to surgically treat these injuries in older patients. Although RTSA seems to be a preferable treatment modality in view of these findings, longer follow-up is required to evaluate its longevity compared with ORIF with an angular locking plate. Dissimilar to ORIF, which is generally stable once healed, arthroplasties are at a continued risk for loosening and infection even after healing is complete.

Level of Evidence Level II, therapeutic study.

Introduction

Proximal humeral fractures are common in people older than 65 years, representing approximately 6% of all fractures in adults [4]. Three-part and four-part fractures are the most severe injuries in the proximal humerus, resulting in substantial impairment in a patient's function and quality of life when managed nonsurgically [5, 28]. Thus, these injuries are often treated surgically, often with percutaneous pinning, intramedullary locking nails, open reduction and internal fixation (ORIF) plates, hemiarthroplasty, and reverse total shoulder arthroplasty (RTSA) [31, 36, 42, 43]. ORIF is typically performed in younger patients (< 60 years) because it has a higher rate of unplanned reoperations and revision surgery in older patients [21, 26, 27]. However, considering the major advancements in arthroplasty techniques and the constantly expanding number of reconstructive options, RTSA has emerged as a viable treatment modality for independent older patients with nonreconstructible fractures and/or associated rotator cuff deficiencies [32].

Currently, no clear guidelines exist to make management decisions in patients presenting with complex fracture patterns of the proximal humerus. Many older patients may not have commonly associated medical comorbidities that affect their bone quality and can maintain a high degree of physical activity. In such patients, the decision between humeral head preservation or replacement can be far more nuanced [16]. Although ORIF with angular locking plates is one of the most common treatments for proximal humerus fracture [47], prior reports suggest failure rates as high as 37% and complication rates up to 49% [40, 45]. Consequently, many of these patients will undergo additional procedures, with up to 20% undergoing revision [23, 26], sometimes involving a secondary hemiarthroplasty or total shoulder arthroplasty [12, 13]. Because there is a higher incidence of rotator cuff injury and dysfunction in the aging population and those with complex proximal humerus fractures, RTSA remains a viable option because it provides a fulcrum and increases deltoid tension, thereby counteracting superior migration of the humerus in a patient with rotator cuff deficiency [22]. However, RTSA may lead to limited postoperative ROM, particularly in internal and external rotation, which might restrict a patient's quality of life [39]. Although some studies in a systematic review indirectly compared management strategies for proximal humerus fractures [11], prospective investigations engaging in direct, head-to-head comparisons are scarce [9, 13]. Consequently, prospective studies are required to guide evidence-based surgical decision-making for proximal humerus fractures.

Therefore, we sought to answer the following research questions: (1) In patients older than 70 years with three-part and four-part proximal humerus fractures, does RTSA result in better functional outcome scores (Constant, American Shoulder and Elbow Surgeons [ASES], and DASH scores) than ORIF with a locking plate? (2) Does RTSA result in greater ROM than ORIF? (3) Does RTSA result in a lower risk of complications than ORIF? (4) In patients with either procedure, what are the rates of negative radiographic outcomes in those treated with ORIF (such as malunion, bone resorption, malalignment, or avascular necrosis) or those with RTSA (such as resorption, notching, and loosening)? (5) At a minimum of 2 years of follow-up, does ORIF result in a greater number of revision procedures than RTSA?

Patients and Methods

Study Design and Setting

All patients older than 70 years who were treated surgically for a proximal humeral fracture at an urban trauma hospital between January 1, 2013, and June 30, 2018, were considered for eligibility. At our center, approximately 80% of orthopaedic care is focused on treating patients with trauma.

Patients

Between January 1, 2013, and June 30, 2018, approximately 235 patients were identified as having a three-part or four-part proximal humeral fractures using the 16-point Neer Classification system [33]. Patients were excluded if they had previous ipsilateral shoulder fracture or surgery, endured polytrauma, had concomitant fractures or radial nerve injuries, contracted local or general infective disease within 30 days of the fracture, had pre-existing shoulder conditions considerably affecting shoulder rehabilitation, had neurologic disease or cognitive dysfunction that impaired their ability to complete patient-reported outcome questionnaires, or were unwilling or unable to participate in postoperative follow-up.

Between 2013 and 2018, we treated 235 patients for a proximal humeral fracture (Fig. 1). We considered only patients without previous ipsilateral fracture or surgery, other fractures, or radial nerve injuries; age older than 70 years; and patients without neurologic disease or cognitive dysfunction as potentially eligible. A total of 69% (162 patients) were eligible; a further 31% (73 patients) were excluded because 18% (13 of 73 patients) did not meet the inclusion criteria, 62% (45 patients) underwent nonoperative treatment, and 21% (15 patients) declined to participate. This left 81 patients who were treated with RTSA and another 81 patients who were treated with ORIF. Among the 81 patients treated with RTSA, 11% (nine patients) were lost to the minimum study follow-up of 2 years or had incomplete datasets, leaving 89% (72 patients) for analysis. Among the 81 patients treated with ORIF, 19% (15 patients) were lost before the minimal study follow-up of 2 years or had incomplete datasets, leaving 82% (66 patients) for analysis. The median follow-up for both groups was 53 months (range 24 to 72 months).

Treatment Allocation

The senior surgeon (MS) decided what type of treatment to use, primarily based on the degree of fatty atrophy via imaging and preoperative ROM deficits. The strongest factor affecting treatment allocation was evidence of trophism and adipose infiltration on CT images, based on the classification of Goutallier et al. [17] and Fuchs et al. [14]. Any patient with Grade 3 or 4 fatty atrophy was allocated to the RTSA group. Further, even before experiencing a fracture, patients with severely limited preoperative ROM or those with nocturnal pain that awoke them from sleep were treated with RTSA. The fracture pattern did not affect the treatment decision-making process. After detailed counseling regarding the risks and benefits of nonoperative or surgical treatment, each patient made an informed decision regarding their management strategy. Informed consent was obtained before surgical intervention.

Participants' Baseline Data

In total, 72 patients who underwent RTSA (44% men [32] and 56% women [40], mean age 76 ± 2.9 years) and 66

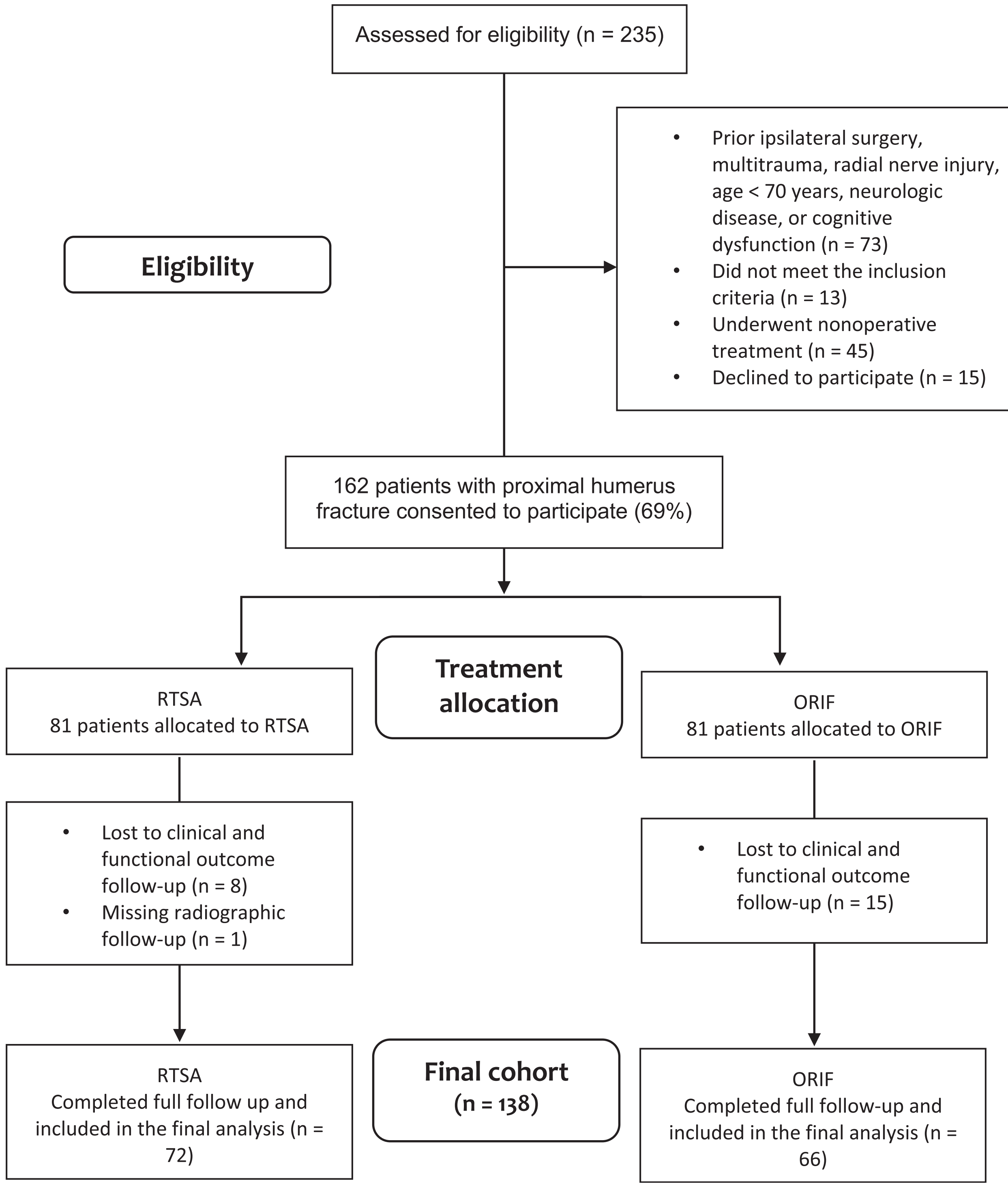

Fig. 1 This STROBE flow diagram demonstrates eligible patients who were included in this study.

who underwent ORIF (56% men [37] and 44% women [29], mean age 73 ± 2.9 years) were available for analysis at a mean follow-up of 53 months (maximum follow-up: range 24 to 72 months) (Table 1). All fractures were three-part (Type 8 or 9 according to the Neer classification) or four-part (Type 12). In the RTSA group, overall, 38% (27 of 72 patients) had a three-part fracture pattern; among these, 74% (20 of 27 patients) had Type 8 and

Table 1. Postoperative functional outcome questionnaire scores for patients undergoing reverse shoulder arthroplasty and those undergoing open reduction and internal fixation with plate

Variable	RTSA (n = 72)	ORIF (n = 66)
Age in years, mean ± SD	76 ± 2.9	73 ± 2.9
Gender, % (n) women	56 (40)	44 (29)
Diabetes, % (n)	17 (12)	15 (10)
Hypertension, % (n)	40 (29)	38 (25)
Chronic obstructive pulmonary disease, % (n)	7 (5)	8 (5)
Neer classification of fracture, % (n)		
Three-part: Type 8	28 (20)	32 (21)
Three-part: Type 9	10 (7)	4 (3)
Four-part	62 (45)	64 (42)
AO classification of fracture, % (n)[a]		
11B1	25 (18)	21 (14)
11B2	12 (9)	15 (10)
11C1	24 (17)	35 (23)
11C2	39 (28)	29 (19)
Surgical time in hours, mean ± SD	1.5 ± 0.3	1.0 ± 0.3

[a]AO classifications were extrapolated from the original radiographic analysis, which was done using the Neer classification. These are not primary data and should be used for contextualizing the baseline cohort characteristics only.

26% (seven of 27 patients) had Type 9 according to the Neer classification. A total of 63% (45 of 72 patients) of patients who underwent RTSA had a four-part fracture. According to the AO classification, 25% of patients with RTSA had a Type 11B1 fracture (18 of 72), 13% had a Type 11B2 fracture (nine of 72), 24% had a Type 11C1 fracture (17 of 72), and 39% had a Type 11C2 fracture (28 of 72).

In the ORIF group, overall, 36% (24 of 66 patients) had three-part fractures; among them, 88% (21 of 24 patients) were Neer Type 8 and 12% (three of 24 patients) were Neer Type 9. A total of 64% (42 of 66 patients) of patients in the ORIF group had four-part fractures. According to the AO classification, 21% of patients with ORIF had a Type 11B1 fracture (14 of 66), 15% had a Type 11B2 fracture (10 of 66), 35% had a Type 11C1 fracture (23 of 66), and 29% had a Type 11C2 fracture (19 of 66). No patients in either group had a humeral head split. The mean surgical time was 1.5 hours ± 0.3 hours for RTSA and 1.0 hours ± 0.3 hours for ORIF.

Radiographic Assessment and Preoperative Planning

Preoperatively, all patients underwent trauma-series radiography and CT (Toshiba Aquilion 16-slice CT scanner) of the affected shoulder. The scanning parameters were 120 kilovoltage peak, 125 milliamps, field of view of 250 mm, and a detector pitch of 15. A soft tissue filter and raster artifact suppression tool were used, producing a 512 matrix of 1-mm-thick slices (slice overlap: 0.5 mm). Preoperative images were obtained to plan and characterize the fracture pattern using the Neer classification system [33]. The Neer classification system demonstrates good interobserver reliability (kappa 0.51 to 0.80) and intraobserver reliability (kappa 0.63 to 0.88) when fractures are assessed on plain radiographs and 3D CT images [6]. Preoperative radiographs and CT images were used to categorize injuries as either three-part or four-part fractures, and the presence of anterior or posterior shoulder dislocation was recorded (Fig. 2).

Surgical Technique

Two senior authors (RML, MS) performed all procedures, which were performed within 1 week of injury. ORIF was performed using the PHILOS angular stable plate (Phelps Synthesis). The lateral approach, in which the axillary nerve was carefully addressed, was used to obtain fixation of posterior fragments and adequately reduce tuberosities with nonabsorbable wires. RTSA was performed using the SMR reverse shoulder system (LIMA Corporate). The senior authors (RML, MS) performed a deltopectoral approach during glenoid baseplate implantation for better visualization and control of baseplate inclination, while also minimizing the risk of axillary nerve injury. Importantly, this approach also did not use a deltoid detachment, but rather passage through the muscle fibers.

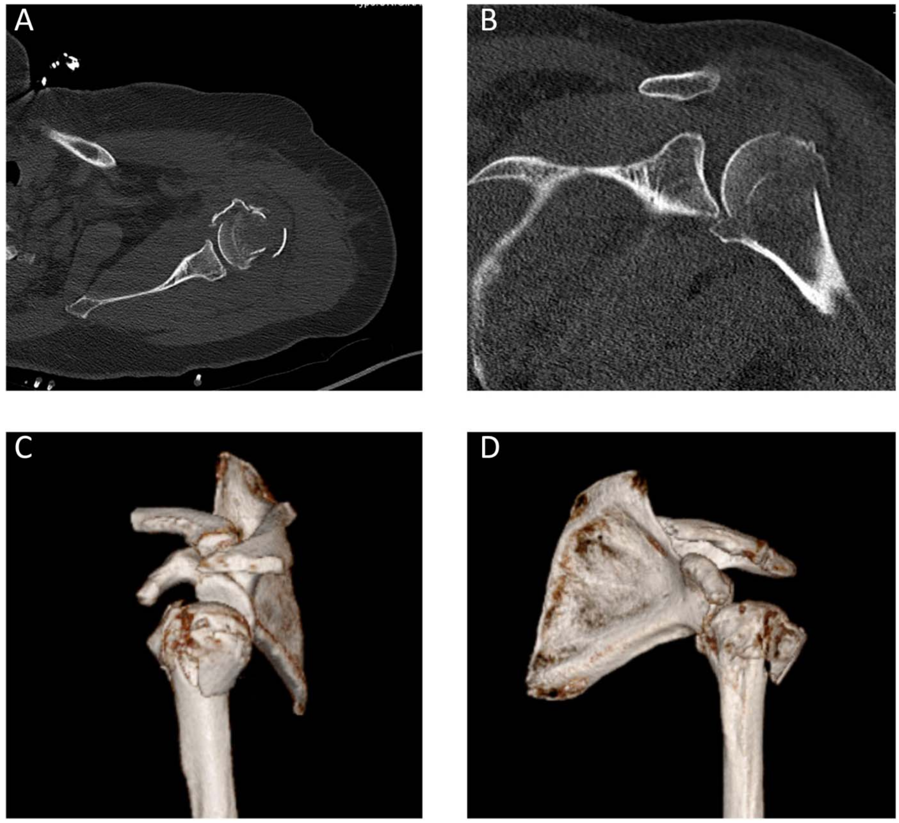

Fig. 2 Representative preoperative images were used to assess treatment allocation. Two-dimensional CT (**A**) axial and (**B**) coronal views of two patients who were included in this study are shown. Three-dimensional CT (**C**) sagittal and (**D**) coronal reconstructions of two other included patients are shown.

All RTSA procedures used a 40-mm or 44-mm glenosphere with the humerus oriented in 20° of retroversion. Prostheses were secured by press-fit fixation; no patient in this study who underwent RTSA had a cemented construct. The greater tuberosity was repaired in every patient, and the subscapularis tendon was sutured with Number 2 nonabsorbable wires.

Postoperative Rehabilitation Protocol

The rehabilitation course was generally similar between patients treated with ORIF and those treated with RTSA. Individuals who underwent ORIF wore a sling for 3 weeks, and physical therapy was initiated on postoperative day 1 with gentle, gravity-assisted pendulum exercises. Active assisted ROM exercises began after 6 weeks, and active ROM exercises with rotation strengthening began at 7 weeks. Patients who underwent RTSA wore a shoulder immobilizer in 15° of abduction for 4 weeks, while also starting physical therapy on postoperative day 1 with gentle, gravity-assisted pendulum exercises. These patients avoided external rotation for 6 weeks. Patients performed passive ROM exercises for 4 weeks and active assisted and active ROM exercises for 6 weeks until the start of independent home exercises.

Clinical and Functional Outcomes Questionnaires

Patients were requested to return for a final follow-up visit at a minimum of 2 years after their index surgery. At this visit, an orthopaedic surgeon (EG), who was not involved in the treatment of these patients, assessed active ROM using a goniometer, including elevation, abduction, external rotation in the neutral position, and internal rotation in the neutral position. The same surgeon assisted in completing several functional outcome questionnaires, including the Constant, ASES, and DASH scores.

Complications

We assessed rates of surgical complications including dislocations, fractures, adhesive capsulitis, nerve injuries,

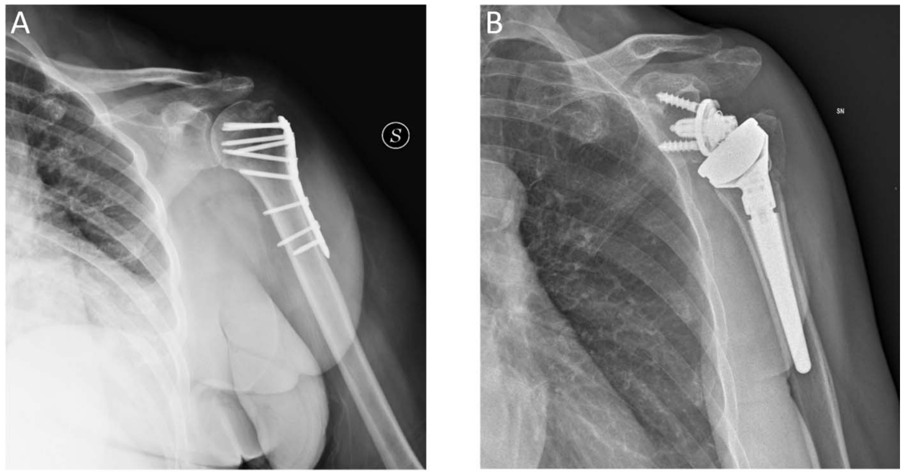

Fig. 3 Representative postoperative radiographs were taken in (**A**) a patient with ORIF and (**B**) a patient with RTSA.

or surgical site infections. Additionally, the rates of reoperation and revision procedures are reported. Medical complications such as urinary tract infection or acute kidney injury were not compared because these complications are typically thought to be related to surgical time, anesthesia concerns, and immobilization rather than the choice of surgical approach or implants. This is consistent with the complications reported in a recent Level I study comparing these treatments [13].

Radiographic Measures

All study participants were prospectively assessed using true AP and axillary views (Fig. 3). Radiographs were assessed by one surgeon (EG), who was not involved in the treatment of any of the patients. This surgeon also possesses extensive experience in shoulder arthroplasty. Postoperative AP radiographs were obtained immediately postoperatively and at the final follow-up interval to assess the location and grade of humeral bone resorption. The location of bone resorption was divided into seven zones based on the methods proposed by Inoue et al. [18]: Zone 1, greater tuberosity; Zone 2, lateral diaphysis; Zone 3, lateral diaphysis beyond the deltoid tuberosity; Zone 4, tip of the stem; Zone 5, medial diaphysis beyond the deltoid tuberosity; Zone 6, medial diaphysis; and Zone 7, calcar region. The degree of bone resorption was classified from Grades 0 to 4: Grade 0, no bone resorption; Grade 1, decrease in cortical bone density; Grade 2, thinning of the cortical bone comprising less than one-half of the original thickness; Grade 3, thinning of the cortical bone comprising more than one-half of the original thickness; and Grade 4, complete disappearance of the cortical bone.

Notching was assessed via the methods of Sirveaux et al. [38]. In this system, the degree of inferior glenoid impingement is graded based on the size of the scapular notch defect. Grade 1 is a defect confined to the pillar, Grade 2 is a defect in contact with the lower screw, Grade 3 is a defect over the lower screw, and Grade 4 is a defect extending beneath the baseplate.

Radiographs taken at the final follow-up visit were also compared with those from the first visit, and we assessed for signs of stem or plate loosening, such as subsidence or tilt. The width of any radiolucent lines was recorded after calibration based on measurements of the implant's known dimensions. Stems with radiolucent lines wider than 2 mm involving three or more zones were considered at risk of clinical loosening.

Ethical Approval

This study was reviewed and approved by our institutional review board and was conducted in accordance with the principles of the Declaration of Helsinki.

Statistical Analysis

All data are described as percentages and numbers. Normality of the data was confirmed via the skewness and kurtosis tests. The mean and standard deviation or number and proportion are reported, where appropriate. Differences between groups were calculated using Fisher exact or t-tests. Our sample size of 162 patients provided us with greater than 80% power to detect a 15% difference in complication rates between groups, assuming a loss to

Table 2. Postoperative functional outcome questionnaire scores for patients undergoing RTSA and those undergoing ORIF

Variable	RTSA	ORIF	Mean difference (95% CI)	p value
Constant score	85 ± 7	53 ± 5	32 (30 to 34)	< 0.01
ASES score	46 ± 4	30 ± 4	16 (15 to 18)	< 0.01
DASH Score	41 ± 4	31 ± 3	10 (9 to 11)	< 0.01

follow-up rate of 20% (5% per year). Alpha was set to 0.05. All analyses were performed in Stata, version 13.

Results

Functional Outcomes Questionnaire Scores

Patients who received RTSA had higher Constant, ASES, and DASH scores at 2 to 6 years than patients with ORIF did (Table 2). The Constant score was 85 ± 7 in the RTSA group versus 53 ± 5 in the ORIF group (mean difference 32 [95% CI 30 to 34]; p < 0.01), the mean ASES score was 46 ± 4 for RTSA versus 30 ± 4 for ORIF (mean difference 16 [95% CI 15 to 18]; p < 0.01), and the mean DASH score was 41 ± 4 for RTSA versus 31 ± 3 for ORIF (mean difference 10 [95% CI 9 to 11]; p < 0.01).

Postoperative ROM

At the final follow-up interval, patients who underwent RTSA had greater elevation, abduction, external rotation, and internal rotation than patients with ORIF did (Table 3). The mean elevation was 135° ± 7° for patients with RTSA and 100° ± 6° for patients with ORIF (mean difference 35° [95% CI 33° to 37°]; p < 0.01). The mean abduction was 131° ± 7° for patients with RTSA and 104° ± 6° for those with ORIF (mean difference 27° [95% CI 25° to 29°]; p < 0.01). The mean external rotation was 85° ± 5° for patients with RTSA and 64° ± 5° for those with ORIF (mean difference 21° [95% CI 19° to 23°]; p < 0.01). The mean internal rotation was 45° ± 6° for patients with RTSA and 40° ± 6° for those with ORIF (mean difference 5° [95% CI 3° to 7°]; p < 0.01).

Surgical Complications

The risk of complications was not different between patients with ORIF and those with RTSA (5% [three of 66] versus 1% [one of 72], relative risk 3.3 [95% CI 0.3 to 30.7]; p = 0.30). Among the 72 patients with RTSA, one patient experienced postoperative shoulder dislocation and was subsequently treated with closed reduction and immobilization for 4 weeks. Of the 66 patients in the ORIF group, 3% (two patients) had adhesive capsulitis and 2% (one patient) experienced avascular necrosis of the humeral head. Periprosthetic joint infection, periprosthetic fracture, acromion fracture, and axillary nerve palsy were not reported in either group.

Radiographic Measures

Among the 66 patients with ORIF, 8% had varus malunions (five of 66), 6% had resorption of the greater tuberosity (four of 66), and 2% had avascular necrosis of the humeral head (one of 66). Of the five patients with varus malunions, four went on to receive RTSA and one opted for nonoperative treatment. In the RTSA group, 24% (17 of 72 patients) demonstrated reabsorption of periprosthetic bone. According to the methods of Inoue et al. [18], Grade 1 resorption was present in 0% (0 of 17 patients), Grade 2 occurred in 41% (seven patients), Grade 3 was present in 35% (six patients), and Grade 4 occurred in 24% (four patients). Bone resorption was in Zone 1 in 78% (56 of 72 patients), Zone 2 in 44% (32 patients), Zone 3 in 3% (two patients), Zone 4 in 0% (0 patients), Zone 5 in 3% (two patients), Zone 6 in 28% (20 patients), and Zone 7 in 64% (46 patients) (Fig. 4). Grade 4 bone resorption did not occur in Zones 3 and 5. Notching of RTSA was assessed using the methods of Sirveaux et al. [38]: none in 79% of patients (57 of 72), Grade 1 in 17% of patients (12 patients), and

Table 3. Postoperative active ROM for patients undergoing RTSA and those undergoing ORIF

Variable	RTSA	ORIF	Mean difference (95% CI)	p value
Elevation in degrees	135 ± 7	100 ± 6	35 (33 to 37)	< 0.01
Abduction in degrees	131 ± 7	104 ± 6	27 (25 to 29)	< 0.01
External rotation in neutral in degrees	85 ± 5	64 ± 5	21 (19 to 23)	< 0.01
Internal rotation in neutral in degrees	45 ± 6	40 ± 6	5 (3 to 7)	< 0.01

Grade 2 in 4% of patients (three patients). None of the glenoid components showed evidence of loosening (such as tilting, medialization, or radiolucent lines) on postoperative radiographs.

Revisions

The risk of revision was comparable between the ORIF and RTSA groups (9% [six of 66] versus 0% [0 of 72], relative risk 0.07 [95% CI 0.0 to 1.2]; p = 0.07). The six patients in the ORIF group with a revision underwent conversion to RTSA because their posttraumatic osteoarthritis and pain were not compatible with their quality of life. Four of these patients had varus malunions, one had avascular necrosis of the humeral head, and one had resorption of the greater tuberosity.

Discussion

Complex proximal humerus fractures are challenging to treat. These injuries typically affect patients > 65 years old with osteoporosis and other comorbidities affecting the potential for bony healing [22]. Historically, ORIF with plate fixation has been the treatment of choice, with revision rates of 10% to 20% at 3 to 10 years of follow-up [23, 37]; however, according to a systematic review, prior reports have found rates of implant-related complications ranging from 9% to 26% [22]. After an early case series demonstrated adequate pain relief, ROM, and functional outcomes in older patients undergoing primary RTSA [8, 29], RTSA became an increasingly popular choice to treat complex proximal humerus fractures. This current study prospectively compared the minimum 2-year results of RTSA and ORIF, with treatment allocation nonrandomly decided based on a preoperative clinical and radiographic assessment of the integrity of the rotator cuff. Patients with RTSA had superior functional scores and active ROM, with comparable complication and revision rates. These superior findings advocate for initial treatment with RTSA over ORIF, especially in patients with Goutallier/Fuchs Grade 3 or 4 fatty atrophy of the supraspinatus.

Limitations

This study was not randomized and thus may be subject to selection bias related to imbalance in treatment allocation, which may serve as important confounders to the measured endpoints. Patients with Goutallier/Fuchs Grade 3 or 4 fatty atrophy of the rotator cuff were allocated to the RTSA group to maximize postoperative motion. Therefore, we would expect these patients to have a lower likelihood of regaining motion and functionality; however, the opposite findings were observed. Often, patients with better results are less likely to return for follow-up. Therefore, this attrition bias may have artificially suppressed the results of the groups, although given the lack of a difference in loss to follow-up, we would expect this bias to affect both groups equally. All patients underwent surgery via the same approach with the same types of implants, limiting the generalizability of our results to other surgical techniques. Second, our hospital uses the Neer classification system to describe proximal humerus fractures; however, this classification system demonstrated variable intraobserver (kappa 0.51 to 0.80) and interobserver (kappa 0.63 to 0.88) agreement in a diagnostic study [6]. Although AO classifications of fracture patterns are provided, these are extrapolated from secondary data and not the original radiographs. Finally, we did not conduct a by-gender analysis because there were equivalent proportions of patients identifying as men and women in each group. Especially given the known effects of estrogen on bone remodeling, readers should not assume the results of these treatments will apply equally based on sexual characteristics or gender presentation [3].

Functional Outcome Questionnaire Scores

Patients treated with RTSA had higher Constant, ASES, and DASH scores at the latest follow-up than patients who underwent ORIF. The minimum clinically important differences for the ASES, Constant, and DASH in RTSA vary

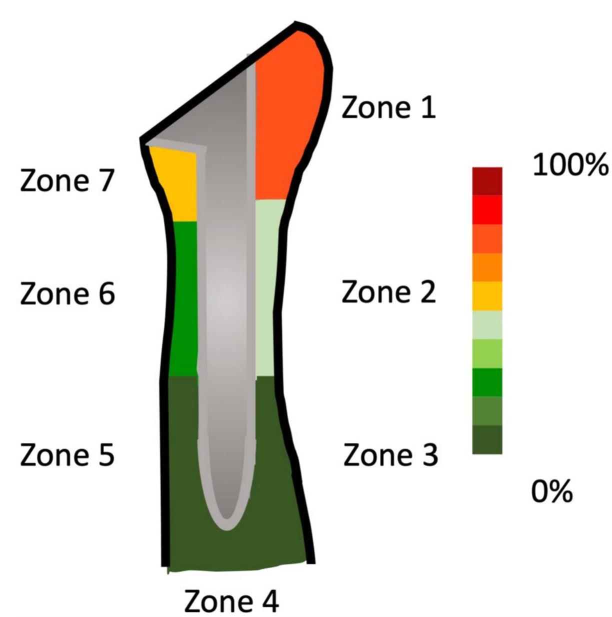

Fig. 4 This heat map represents periprosthetic bone resorption in the RTSA arm per the methods of Inuoe et al. [18].

depending on the calculation method and population included, with a mean minimum clinically important difference of 14, 7, and 11, respectively [25]. The lower range of the 95% CI for the mean difference of each score supersedes the minimum clinically important difference for all three scores. In a retrospective study, RTSA demonstrated positive effects on quality of life after proximal humerus fractures, with more than 90% of patients returning to their previous level of independence [46]. A recent randomized controlled trial of RTSA versus ORIF for proximal humerus fractures similarly compared these two treatments in patients aged 65 to 85 years who had OTA/AO Type B2 and C2 fractures [13]. Patients with RTSA had a superior Constant score at 2 years of follow-up, especially those with a Type C2 fracture. By contrast, a retrospective matched-pair analysis by Klug et al. [23] of ORIF and RTSA in patients > 65 years old found no difference in Constant and ASES scores between groups, but a superior DASH score that was equal to the minimum clinically important difference. However, Klug et al.'s study contained more humeral head split fractures in the RTSA group, which are known to have poorer results than fracture patterns that do not involve the articular surface [35]. Therefore, our current results contribute to a growing body of evidence suggesting equivalent or better functional scores for RTSA than for ORIF for complex proximal humerus fractures in patients > 70 years old.

Postoperative ROM

Patients treated with RTSA demonstrated greater active ROM at the most recent follow-up interval than patients who underwent ORIF did. The goal of RTSA is to lower and medialize the center of rotation of the shoulder, thus allowing the deltoid to become the main driver of shoulder motion. Although RTSA might be preferred in patients with proximal humerus fractures [7], many surgeons could be concerned that RTSA limits a patient's ROM, and thus might caution against the intervention in individuals with physically demanding jobs or a desire to attain high activity levels. The current study and the Delphi trial [10] demonstrated the opposite finding, suggesting that patients with RTSA had greater postoperative ROM than those with ORIF did, except in internal rotation, which showed no difference. Comparable shoulder mobility after both interventions suggests the initial injury to the rotator cuff and greater tubercle may underlie the loss of motion, rather than the surgery type. In a large meta-analysis, tuberosity healing was consistently associated with improved ROM and functionality after RTSA for proximal humeral fractures [20]. There have been numerous advances in RTSA fracture-specific implants to better encourage tuberosity healing. These include metaphyseal "fins" that resist rotational stress, improved suture fixation to the stem, larger surfaces for tuberosity healing with voids for bone grafting, and trabecular metal prostheses for improved osseointegration [20]. In contrast, there have been fewer advances in the locking plate design to improve tuberosity fixation and healing, with translational studies still pending [1, 44]. Notably, all patients had reduced ROM, irrespective of the surgery type, highlighting the importance of patient counseling in managing realistic expectations for any procedure to treat a proximal humerus fracture.

Surgical Complications

Patients treated with RTSA experienced fewer surgical complications than those treated with ORIF did. By contrast, complication rates after RTSA range from 9% to 27.9%, with a decreasing prevalence over time [22]. In accordance with these studies, the current analysis found a 3% complication rate at a minimum of 2 years of follow-up, thus demonstrating continuously decreasing complication rates. In the Delphi trial of RTSA versus ORIF, there was no difference in complication rates (RTSA: 11%, ORIF: 20%) [13]. However, prior studies are limited by inconsistent definitions of surgical and medical complications versus adverse radiographic outcomes. We think these should be considered separately to better understand how patients may tolerate the surgery from a medical perspective versus how radiographic measurements suggest impending implant failure resulting in revision.

Radiographic Measures

It is difficult to compare radiographic measures between these different surgeries; therefore, we can only broadly compare the rate of radiographic adverse results between groups and their clinical importance. For ORIF, 16% of patients had malunion, greater tuberosity resorption, or avascular necrosis of the humeral head. Studies have found high rates of adverse radiographic findings after ORIF, particularly in older patients and those with osteoporosis [24, 41]. This is particularly concerning because functionality after ORIF appears to be contingent on anatomic healing of the tuberosities [37]. Patients with poorer bone quality appear to possess an increased risk of nonunion and implant migration that may damage the glenoid. A multicenter prospective study of ORIF using a locking plate system found that 35% of patients experienced implant-related radiographic complications, including primary or secondary screw perforation into the glenohumeral joint, as well as humeral head necrosis [7]. Nearly one of four patients with RTSA demonstrated notching. This is consistent with rates of notching in prior studies of RTSA to treat proximal humerus fractures, ranging from 32% to 52% at a mean follow-up of 28 months, which is consistently higher than for RTSA for other indications [19, 30]. One of five patients with RTSA demonstrated osteolysis, which also aligns with previously reported radiographic findings. In our study, among the patients with malunion, greater tuberosity resorption, or avascular necrosis of the humeral head after ORIF, 9% underwent revision. However, among patients with notching and patients with osteolysis, none exhibited aseptic loosening or impingement resulting in surgical intervention. These results suggest that in the short term, patients with proximal humerus fractures may have a greater chance of experiencing clinically major issues with callus formation or bony ingrowth after ORIF.

Revisions

At a minimum of 2 years of follow-up, there were fewer revision procedures in the RTSA group than in the ORIF group. The long-term survivability of implants is important to consider in patients older than 70 years, given they have a higher risk of medical comorbidities that limit their ability to tolerate multiple procedures. Thus, it is important to have a careful therapeutic plan that minimizes the likelihood of reoperation. A recent study of newer locking plates reported a 11% revision rate [2]. The 6% revision rate reported in the current study is consistent with these prior findings. In the Delphi trial, 6% of patients with RTSA and 12% of patients with ORIF had a revision procedure at a minimum of 2 years of follow-up [13]. Although the results of that trial and those of the current study seem to advocate for RTSA over ORIF because of a lower likelihood of reoperation, it is possible that the difference lies in the timing of revision procedures. Patients with ORIF may be prone to early revision but exhibit stability after 2 to 5 years, whereas patients with RTSA may demonstrate initially positive results with a greater rate of revisions at midterm or long-term follow-up. Therefore, a common criticism of the Delphi trial that is applicable to the current study is insufficient follow-up to assess the long-term survivability of these procedures, although a 5-year follow-up study is planned [10]. Although revision rates may ultimately appear similar between RTSA and ORIF during long-term follow-up, comparing early revision rates is important when considering whether a patient should initially undergo treatment with ORIF or RTSA, which is a more invasive procedure. A recent retrospective study suggested that patients with primary RTSA and patients who underwent conversion from ORIF to RTSA have similar functionality at 2 years postoperatively [34]. Subsequently, a surgeon might consider ORIF first, with a plan to conduct RTSA if ORIF does not work. However, other data suggest that patients older than 70 years undergoing revision RTSA experience more complications and poorer functionality than those who have primary RTSA [15, 34]. The results of the current study may advocate for proceeding with RTSA first to avoid complications and maximize patient satisfaction.

Conclusion

In patients older than 70 years with three-part and four-part proximal humerus fractures, primary RTSA resulted in better patient-reported outcome scores and improved active ROM than ORIF with an angular stable locking plate. Our findings might help surgeons decide between internal fixation and arthroplasty to surgically treat these injuries in an older cohort. Although RTSA may seem like a preferable treatment modality in view of these findings, longer follow-up is required to evaluate its longevity in relation to ORIF with an angular locking plate. Dissimilar to ORIF, which is generally stable once healed, arthroplasties are at a continued risk of loosening and infection, even after healing is complete.

Acknowledgments We thank Brian Forsythe MD for his mentorship of authors EG, EJP, and HHP in their clinical research education.

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