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Reverse total shoulder arthroplasty provides better shoulder function than hemiarthroplasty for displaced 3- and 4-part proximal humeral fractures in patients aged 70 years or older: a multicenter randomized controlled trial

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Background: The most appropriate treatment for displaced multiple-fragment proximal humeral fractures in elderly patients is currently unclear. Reverse total shoulder arthroplasty (rTSA) is a promising treatment option that is being used increasingly. The purpose of this study was to compare the outcome of rTSA vs. hemiarthroplasty (HA) for the treatment of displaced 3- and 4-part fractures in elderly patients.
Methods: This was a multicenter randomized controlled trial. We included patients aged ≥ 70 years with displaced 3- or 4-part proximal humeral fractures between September 2013 and May 2016. The minimum follow-up period was 2 years, with outcome measures including the Constant score (primary outcome), Western Ontario Osteoarthritis of the Shoulder index, EQ-5D (EuroQol 5 Dimensions) index, and range of motion, as well as pain and shoulder satisfaction assessed on a visual analog scale.
Results: We randomized 99 patients to rTSA (48 patients) or HA (51 patients). Fifteen patients were lost to follow-up, leaving 41 rTSA and 43 HA patients for analysis. The mean age was 79.5 years, and there were 76 women (90%). The rTSA group had a mean Constant score of 58.7 points compared with 47.7 points in the HA group, with a mean difference of 11.1 points (95% CI, 3.0-18.9 points; $P = .007$). Compared with HA patients, rTSA patients had greater mean satisfaction with the shoulder (79 mm vs. 63 mm, $P = .011$), flexion (125° vs. 90°, $P < .001$), and abduction (112° vs. 83°, $P < .001$), but there was no difference in Western Ontario Osteoarthritis of the Shoulder index, pain, or EQ-5D index scores. We identified 3 and 4 adverse events in the rTSA and HA groups, respectively. Among patients aged ≥ 80 years (n = 38), there was no difference between rTSA treatment and HA treatment in pain (17 mm vs. 9 mm, $P = .17$) or shoulder satisfaction (77 mm vs. 74 mm, $P = .73$).

This study was approved by the Swedish Ethical Review Authority (study no. 2013/1053-31/3).

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Conclusion: We found that rTSA provides better shoulder function than HA as measured with the Constant score, further emphasized by rTSA patients being more satisfied with their shoulder function. The difference appears to be mainly a result of better range of motion (abduction and flexion) in the rTSA group. The results also indicate that patients aged ≥ 80 years benefit less from rTSA than patients aged 70-79 years.

Level of evidence: Level I; Randomized Controlled Trial; Treatment Study

Keywords: Proximal humeral fracture; reverse total shoulder arthroplasty; shoulder hemiarthroplasty; randomized controlled trial; functional outcome; shoulder arthroplasty

Proximal humeral fractures are common injuries, accounting for 5%-6% of all fractures.[19] Most proximal humeral fractures have minimal or no displacement[6] and are treated nonoperatively with acceptable outcomes.[30] However, the choice of treatment for displaced proximal humeral fractures is controversial.[2] The most recent Cochrane analysis concluded that surgery does not result in a better outcome for patients with displaced fractures of the surgical neck compared with nonoperative treatment.[29] However, it is possible that specific subgroups of patients, not targeted by the Cochrane analysis, might still benefit from surgical intervention. One such group comprises elderly patients with displaced 3- and 4-part fractures, who often have disappointing functional outcomes following nonoperative treatment.[9,41,42] The incidence of proximal humeral fractures is highest in elderly patients, and displaced 3- and 4-part fractures account for 23% of all proximal humeral fractures.[6]

Hemiarthroplasty (HA) has generally been regarded as the preferred option for operative treatment of displaced 3- and 4-part fractures of the proximal humerus in elderly patients. Nevertheless, 2 randomized studies have failed to show a clear benefit of HA over nonoperative treatment.[9,42] Another type of prosthesis, reverse total shoulder arthroplasty (rTSA), has emerged as a treatment option for displaced 3- and 4-part fractures of the proximal humerus. The main theoretical advantage of rTSA is that shoulder function is thought to be less dependent on tuberosity healing as compared with HA. Since the publication of the first case series,[11,14] the use of rTSA for proximal humeral fractures has increased substantially, and rTSA is currently more commonly used than HA in some countries,[23,31,34,38] with some previous studies supporting the increasing use of rTSA[24,49] whereas others have not supported this.[37]

We conducted a multicenter, generic randomized controlled trial (RCT) to test the hypothesis that rTSA provides better shoulder function than HA, with the Constant score as the primary outcome measure, for displaced 3- and 4-part proximal humeral fractures in elderly patients. The secondary outcome measures were the Western Ontario Osteoarthritis of the Shoulder (WOOS) index score, EQ-5D (EuroQol 5 Dimensions) index score, pain, satisfaction, and range of motion.

Materials and methods

Trial design and eligibility criteria

This was a multicenter, prospective RCT. The inclusion criteria were a displaced 3- or 4-part proximal humeral fracture, age ≥ 70 years, independent living, and a low-energy injury mechanism. The exclusion criteria were a pre-existing shoulder condition and comorbidity or concurrent injury considerably affecting shoulder rehabilitation. Patients with severe cognitive impairment according to the Short Portable Mental Status Questionnaire[43] were not eligible for participation in the study.

Study settings

Eight hospitals in Sweden recruited patients for the study; these included 5 university hospitals (Danderyd University Hospital, Stockholm; Sahlgrenska University Hospital, Gothenburg; Skåne University Hospital, Malmö; Stockholm South General Hospital, Stockholm; and Linköping University Hospital, Linköping) and 3 county hospitals (Karlstad Central Hospital, Karlstad; Hallands Hospital Varberg, Varberg; and Ryhov Hospital, Jönköping). All patients provided written informed consent to participate in the study.

Randomization

For treatment allocation, sequentially numbered, sealed opaque envelopes were used. Randomization was performed in blocks of 10. The blocks were generated by an online computer program (Sealed Envelope, London, UK).[48]

Interventions

Patients received prophylactic antibiotics perioperatively according to local routine. Seventeen surgeons, all experienced in shoulder replacement, performed the procedures. With the patient in the beach-chair position, the deltopectoral approach was used in all but 2 rTSA procedures, in which an anterosuperior approach was used. The choice of prosthesis brand was at the discretion of the treating surgeon, generally based on local routine.

Reverse total shoulder arthroplasty

For rTSA, the stem was typically inserted with retroversion of 20° or slightly less. The supraspinatus tendon was excised, and the tuberosities were reduced as anatomically as possible and

reattached with nonabsorbable sutures (Nos. 2 and 5). The general strategy for placement of fixating sutures was as described by Boileau et al[7] but adapted to the particular type of prosthesis and fracture pattern.

Following rTSA, a sling was typically worn for 2-4 weeks. Rehabilitation was individualized but generally started with passive and active-assisted motion, progressing to active exercises at approximately 4-6 weeks postoperatively. External rotation and internal rotation behind the back were avoided during the first 6 postoperative weeks. Strengthening exercises with light loads were typically initiated at 8-12 weeks postoperatively.

Hemiarthroplasty

For HA, the stem was typically implanted in 20°-30° of retroversion and the humeral head size was chosen to best replicate the patient's anatomy. The tuberosities were reduced and fixed as previously outlined for rTSA, with the exception of the Global Fx (DePuy Synthes, Warsaw, IN, USA) and Global Unite (DePuy Synthes) prostheses, in which the tuberosities were fixed as described in the surgical technique of the manufacturer. Ruptures of the rotator cuff encountered intraoperatively were repaired in a standard fashion.

Rehabilitation after HA was similar to that after rTSA, although progressing more cautiously, including deferring active exercises until around 6 weeks postoperatively.

Clinical outcome

The final follow-up assessment was performed at a minimum of 2 years postoperatively. In addition, patients were followed up at 1 year postoperatively. Follow-up included completion of the Constant score,[18] the WOOS index,[33,36] and the 3-level EQ-5D instrument.[22] Pain and shoulder satisfaction were recorded. A clinical examination, including range of motion and measurement of strength, was performed by an independent physiotherapist. Radiographs were taken and adverse events recorded.

The primary outcome measure was the Constant score[18] at the final follow-up. Strength was assessed with the shoulder in 90° of abduction. Patients who were unable to achieve 90° of abduction were assigned 0 points for strength, as suggested by Constant et al.[17] The WOOS index is a shoulder-specific, self-administered, patient-reported outcome measure used for evaluation by the Swedish Shoulder Arthroplasty Register.[36] The result is summarized as a percentage of normal shoulder function ranging from 0 to 100, with higher values representing better shoulder function. WOOS questionnaires were excluded if half or more of the items in a particular domain were missing or if >3 items in total were missing. For questionnaires with ≤3 missing items, values were imputed based on the average of the available responses for the particular domain. The EQ-5D index score was calculated using model 4 described in a publication by Burström et al.[12]

Pain was assessed by requesting the patient to respond to the following question on a 100-mm visual analog scale (VAS): How much shoulder pain do you have on average? Satisfaction with the shoulder (hereafter termed "shoulder satisfaction") was assessed in response to the following question, also on a 100-mm VAS: How satisfied are you with your shoulder?

Abduction, forward flexion, and external rotation were assessed with a handheld goniometer. External rotation was assessed in 0° of abduction. Internal rotation was analyzed as recorded by the Constant score.

Radiographic assessment

Radiographs were assessed by a surgeon (E.J.) with experience in shoulder replacement who was not involved in the treatment of any of the patients. On the basis of preoperative radiographs, injuries were categorized as either 3- or 4-part fractures[40] and the occurrence of associated anterior or posterior shoulder dislocation was recorded. Radiographs at the final follow-up were compared with the first postoperative radiographs and assessed for signs of stem loosening such as subsidence or tilt. The width of any radiolucent lines was recorded after calibration based on measurements of known dimensions of the implant. Stems with associated radiolucent lines >2 mm in width in ≥3 zones were considered at risk of clinical loosening.[47]

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 nonunions. Tuberosities not visible in any projection were regarded as resorbed.

HAs were assessed for erosion of the glenoid according to Antuna et al.[1] Notching of the rTSA was graded according to Sirveaux et al,[51] and the glenoid component was assessed for signs of loosening.[55]

Adverse events

Information on 4 predetermined adverse events was collected at the final follow-up: infection, joint dislocation, reoperation, and neurologic complications. Patients were asked to provide information about any other potential adverse events. Medical records were subsequently reviewed as appropriate.

Sample size

The minimal clinically important difference (MCID) of the Constant score was assumed to be 10 points. On the basis of previous studies, a standard deviation (SD) of 15 points was deemed reasonable.[32,42] A group size of ≥48 patients in each group was considered adequate for detecting a minimum difference of 10 points with 85% power and a 2-sided 5% significance level, considering a 15% potential loss to follow-up.

Data management and statistics

The data were computerized with FileMaker Pro (version 15; Claris International, Santa Clara, CA, USA). Analyses were performed with SAS software (version 9.4; SAS Institute, Cary, NC, USA). Data are presented as mean (SD) for continuous variables but as number (percentage) for categorical variables. The results of statistical tests were considered significant at $P < .05$. For comparisons between groups, we used the Fisher exact test for dichotomous variables, the χ^2 exact test for non-ordered categorical variables, and the Fisher nonparametric permutation test for continuous variables. For comparisons over time, we used the Wilcoxon signed rank test for continuous variables and the sign test for categorical variables.

Results

Between September 2013 and May 2016, 99 patients were included in the study: 48 were randomized to rTSA, and 51, to HA. Figure 1 shows the flow of patients through the study. Fifteen patients did not complete the final follow-up, including 10 patients who died: 4 in the rTSA group and 6 in the HA group. One patient in the rTSA group died of pneumonia 8 days after surgery while still in the hospital. The other deaths occurred between 0.2 and 3.0 years after surgery and were not related to the proximal humeral fracture or its treatment. As a result, 84 patients completed the final follow-up and were analyzed. The last follow-up occurred in February 2019. The mean length of time between surgery and the final follow-up was 2.4 years in both treatment groups (SD, 0.56 years in rTSA group and 0.55 years in HA group). For the analyzed patients, there were no differences in demographic and clinical characteristics between the 41 patients in the rTSA group and the 43 patients in the HA group (Table I). Compared with the analyzed patients, the patients lost to follow-up were older at baseline (82.4 years [SD, 5.8 years] vs. 79.5 years [SD, 4.7 years]; $P = .04$) and had a lower preinjury EQ-5D index score (0.80 [SD, 0.18] vs. 0.91 [SD, 0.10]; $P = .004$). Otherwise, there were no differences between the analyzed and unanalyzed patients in the demographic and clinical characteristics included in Table I. Three patients in the HA group had an rTSA at the time of the final follow-up and were analyzed on an intention-to-treat basis. One of these patients was treated with an rTSA at the time of primary surgery because of a chronic retracted rupture of the supraspinatus tendon that was discovered intraoperatively. The other 2 patients underwent revision to an rTSA during the follow-up period, one for painful rotator cuff dysfunction and the other for stem loosening after a periprosthetic fracture.

Four different brands of prosthesis were used in the rTSA group: Aequalis Reversed FX (Wright, Memphis, TN, USA) (n = 2), Comprehensive (Zimmer Biomet, Warsaw, IN, USA) (n = 6), Delta Xtend (DePuy Synthes) (n = 26), and SMR Reverse (Lima, Villanova di San Daniele del Friuli, Udine, Italy) (n = 7). All rTSA stems were fixed with cement, whereas all glenoid components were uncemented. Eight different brands of prosthesis were used in the HA group: Aequalis FX (Wright) (n = 4), Bigliani/Flatow (Zimmer Biomet) (n = 5), Comprehensive (Zimmer Biomet) (n = 10), Equinoxe (Exatech, Gainesville, Florida, USA) (n = 2), Global Fx (Depuy Synthes) (n = 4), Global Unite (Depuy Synthes) (n = 6), SMR Trauma (Lima) (n = 11), and SMR Reverse (Lima) (n = 1). The stem was fixed with cement in 32 patients. A rupture of the supraspinatus tendon occurred in 5 patients in the HA group; of these, 4 were treated with HA and suture repair of the supraspinatus tendon whereas 1 received an rTSA.

Outcome

The rTSA group had a significantly higher mean Constant score than the HA group (58.7 points vs. 47.7 points, $P = .007$). A Constant score < 40 points was noted in 7 patients in the rTSA group (17%) as opposed to 17 patients in the HA group (40%, $P = .040$). Clinical data from the final follow-up are shown in Table II, and the distribution of the Constant score is presented in Figure 2. There were no differences in the WOOS or EQ-5D index scores between the treatment groups. The majority of patients in both treatment groups had a WOOS score between 80 and 100: 22 patients in the rTSA group (55%) and 22 as well in the HA group (54%). There were 6 rTSA patients (15%) and 7 HA patients (17%) with a WOOS score ≥ 97.

Mean shoulder satisfaction, as assessed in millimeters on a VAS, was higher for rTSA patients than for HA patients (79 mm vs. 63 mm, $P = .011$). There was no difference in pain, as assessed on a VAS, between the groups. The mean degrees of flexion (Fig. 3) and abduction were significantly higher in the rTSA group, whereas the HA group had better external rotation. Regarding flexion, 26 patients in the rTSA group (63%) and 8 in the HA group (19%) had ≥120° of flexion ($P < .001$), whereas 14 patients in the rTSA group (34%) and 6 in the HA group (14%) had ≥130° of abduction ($P = .054$).

Within both treatment groups, the EQ-5D index score was lower at the final follow-up compared with the preinjury state. In the rTSA group (n = 39), the mean EQ-5D index score was 0.93 (SD, 0.06) in the preinjury state compared with 0.84 (SD, 0.14) at the final follow-up ($P < .001$); the corresponding values in the HA group (n = 41) were 0.90 (SD, 0.10) compared with 0.83 (SD, 0.13) ($P = .002$).

Outcome at final follow-up according to age

When the results were stratified into 2 groups according to age—patients aged 70-79 years and patients aged ≥ 80 years—the same pattern as that observed for the primary analysis largely remained (Table III). It is noteworthy that the differences in shoulder satisfaction and pain between the treatment groups in the younger age group were 26 mm ($P < .005$) and −18 mm ($P = .024$), respectively, in favor of rTSA, but for patients aged ≥ 80 years, these differences were small and not statistically significant.

Outcome at 1-year follow-up compared with final follow-up

At the 1-year follow-up (n = 69), the mean Constant score was significantly higher in the rTSA group (54.8 points; SD, 16.2 points) than in the HA group (45.1 points; SD, 19.1 points) ($P = .028$), whereas there was no difference in

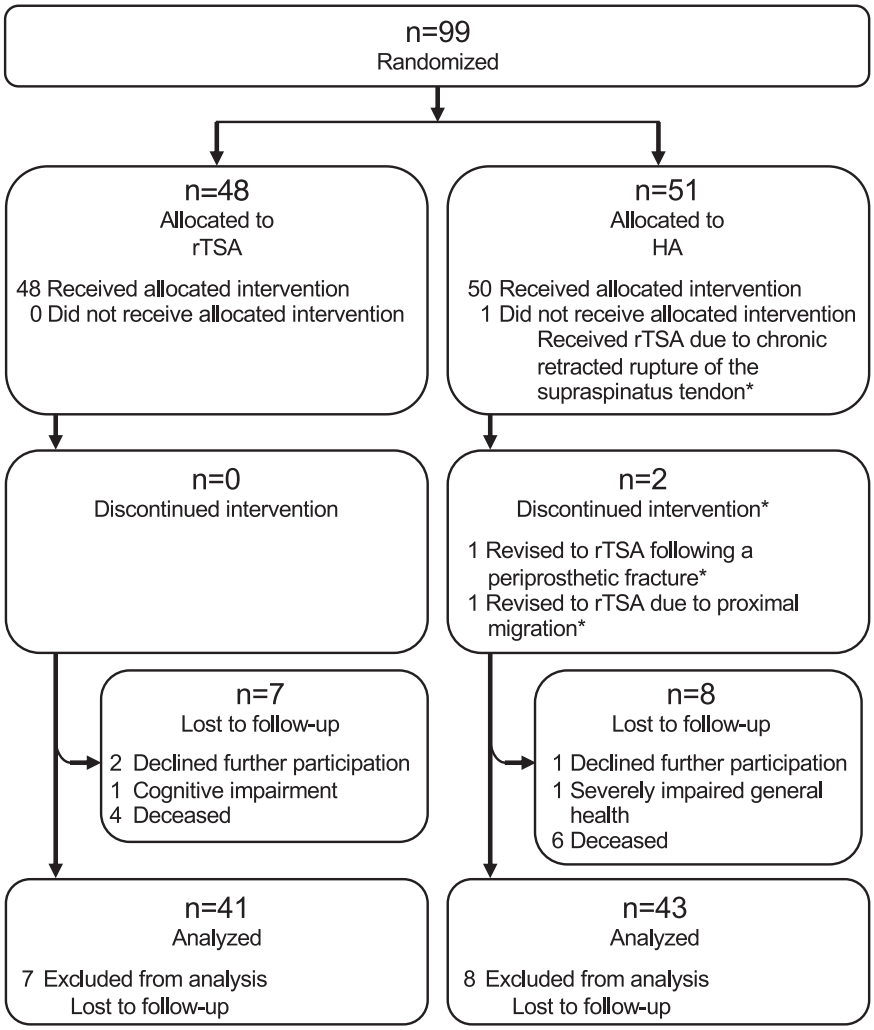

Figure 1 Flow of patients with displaced 3- and 4-part proximal humeral fractures through study comparing reverse total shoulder arthroplasty *(rTSA)* and hemiarthroplasty (*HA*). *Patients who did not receive the allocated intervention or discontinued the allocated intervention are included in the analysis on an intention-to-treat basis.

the mean WOOS, EQ-5D index, pain, or shoulder satisfaction score.

In the rTSA group, statistically significant improvements in the Constant score ($P = .004$), degrees of flexion ($P = .017$), and internal rotation ($P = .003$) were noted between the 1-year follow-up and the final follow-up (Table IV). The data in the HA group were stationary between these time points, except for a deterioration in the EQ-5D index score from 0.86 to 0.82 ($P = .017$).

Radiographic parameters

Radiographs from the final follow-up were available for 36 rTSA patients and for 34 of the 40 HA patients who did not have an rTSA in place at the time of the final follow-up. None of the stems in either treatment group had subsided or tilted. One patient in the rTSA group had radiolucent lines wider than 2 mm in ≥3 zones, although there were no clinical signs or symptoms of loosening at the most recent follow-up.

The greater tuberosity was united with the shaft on the AP view in 24 patients in the rTSA group (67%) and 24 in the HA group (71%). The difference in the Constant score between patients with a united greater tuberosity and those with failed union was not statistically significant in either the rTSA group (60.7 points and 57.1 points, respectively; $P = .52$) or the HA group (47.9 points and 41.5 points, respectively; $P = .37$).

Notching of the rTSA was assessed according to Sirveaux et al[51] as none (n = 28), grade 1 (n = 6), or grade 2 (n = 2). None of the glenoid components showed signs of loosening (tilting, medialization, or radiolucent lines). Glenoid erosion of the HA was assessed according to Antuna et al[1] as none (n = 14), mild (n = 12), moderate (n = 7), or severe (n = 1).

Table I Demographic, injury-related, and treatment-related data for analyzed patients (N = 84) by treatment group: rTSA versus HA

	rTSA (n = 41)	HA (n = 43)	Difference, mean (95% CI)	*P* value*
Age, mean (SD), yr	80.4 (4.5)	78.6 (4.8)	1.8 (−0.2 to 3.9)	.078
Sex, n (%)				.3
Female	39 (95)	37 (86)		
Male	2 (5)	6 (14)		
Right side dominant, n (%)	41 (100)	40 (93)		.26
Dominant side injured, n (%)	21 (51)	24 (56)		.84
Preinjury EQ-5D index score,† mean (SD)	0.92 (0.10)	0.90 (0.10)	0.02 (−0.03 to 0.05)	.6
Injury type, n (%)				.18
3-Part fracture	20 (49)	20 (47)		
4-Part fracture	19 (46)	16 (37)		
Fracture-dislocation				
Anterior dislocation, 3 part		4 (9)		
Anterior dislocation, 4 part	1 (2)	3 (7)		
Posterior dislocation, 4 part	1 (2)			
Time from injury to surgery, mean (SD), d	5.6 (3.5)	6.5 (4.0)	−0.9 (−2.6 to 0.7)	.3
Duration of surgery,‡ mean (SD), min	114 (26)	104 (33)	10 (−3 to 23)	.13
Study center, n (%)				.79
Danderyd University Hospital	12 (29)	7 (16)		
Hallands Hospital Varberg	2 (5)	2 (5)		
Karlstad Central Hospital	2 (5)	3 (7)		
Linköping University Hospital	3 (7)	4 (9)		
Ryhov Hospital	6 (15)	10 (23)		
Sahlgrenska University Hospital	4 (10)	7 (16)		
Skåne University Hospital	4 (10)	2 (5)		
Stockholm South General Hospital	8 (20)	8 (19)		

rTSA, reverse total shoulder arthroplasty; *HA*, hemiarthroplasty; *CI*, confidence interval; *SD*, standard deviation; *EQ-5D*, EuroQol 5 Dimensions.
Data are presented as mean (SD) for continuous variables but as number (percentage) for categorical variables.
* For comparisons between groups, we used the Fisher exact test for dichotomous variables, the χ^2 exact test for non-ordered categorical variables, and the Fisher nonparametric permutation test for continuous variables.
† The preinjury EQ-5D index score was missing for 2 patients in the HA group and 1 patient in the rTSA group.
‡ The duration of surgery was missing for 1 patient in the rTSA group.

Adverse events

There were few adverse events in overall terms and without any clear difference in pattern between the treatment groups (Table V). Two patients in the HA group underwent surgical revision. There were 4 periprosthetic humeral fractures, all sustained after a simple fall: 1 in the rTSA group and 3 in the HA group.

Discussion

In this multicenter RCT, we analyzed 84 patients, aged ≥ 70 years, with displaced 3- or 4-part fractures of the proximal humerus and found that rTSA led to better shoulder function than HA, using the Constant score as the primary outcome parameter. The mean Constant score was 58.7 points in the rTSA group and 47.7 points in the HA group ($P = .007$). Moreover, mean shoulder satisfaction (79 mm vs. 63 mm), abduction (112° vs. 83°), and flexion (125° vs. 90°) were significantly better in the rTSA group, whereas there was no clear difference in the occurrence of adverse events.

The results of this study are in line with the findings of previous literature comparing rTSA and HA. In 2014, after the initiation of our study, Sebastiá-Forcada et al[49] published the only previous RCT comparing rTSA and HA in 61 patients aged ≥ 70 years, with a minimum follow-up period of 2 years. In their single-center trial, rTSA gave a significantly higher mean Constant score compared with HA (56.1 points vs. 40.0 points), as well as significantly higher flexion (120° vs. 80°) and abduction (113° vs. 79°). There were fewer revisions due to rotator cuff failure in our study as compared with that of Sebastiá-Forcada et al (1 of 43 patients vs. 6 of 30 patients), possibly owing to our patients being about 5 years older and less willing to undergo further surgery. The results of our study are also consistent with the findings of a meta-analysis of studies comparing rTSA and HA by Austin et al.[3] This meta-analysis included 913 patients and was based mainly on retrospective cohort studies,[5,8,15,25,26,44,54,61] although some

Table II Outcome at final follow-up (minimum of 2 years) by treatment group (rTSA and HA): clinical rating systems, pain, shoulder satisfaction, and range of motion

	rTSA (n = 41)	HA (n = 43)	Difference, mean (95% CI)	*P* value*
Constant score, mean (SD), points	58.7 (16.3)	47.7 (20.0)	11.1 (3.0 to 18.9)	.007†
Pain	11.6 (3.8)	11.4 (4.8)	0.2 (−1.7 to 2.1)	.93
Daily activities	16.0 (4.3)	13.9 (5.5)	2.1 (0 to 4.2)	.055
Range of motion	25.4 (7.6)	19.5 (9.5)	5.9 (2.2 to 9.6)	.003†
Strength	6.6 (3.5)	4.6 (4.1)	2.0 (0.07 to 3.9)	.042†
WOOS index score,‡ mean (SD)	77.3 (21.0)	74.5 (23.5)	2.8 (−7.0 to 12.7)	.57
Physical symptoms	83.2 (17.7)	81.2 (18.5)	2.0 (−6.0 to 10.0)	.62
Sports, recreation, and work	71.7 (24.7)	67.4 (27.3)	4.3 (−7.0 to 15.8)	.45
Lifestyle	72.7 (25.0)	69.1 (29.5)	3.6 (−8.4 to 15.6)	.55
Emotions	82.1 (23.4)	81.5 (23.1)	0.6 (−9.6 to 11.0)	.9
EQ-5D index score,§ mean (SD)	0.84 (0.13)	0.83 (0.13)	0.01 (−0.05 to 0.07)	.72
Pain score on VAS, mean (SD), mm	15 (20)	22 (26)	−7 (−17 to 3)	.17
Shoulder satisfaction score on VAS, mean (SD), mm	79 (22)	63 (33)	16 (4 to 28)	.011†
Range of motion				
Abduction, mean (SD), °	112 (29)	83 (38)	29 (15 to 43)	<.001†
Flexion, mean (SD), °	125 (28)	90 (39)	35 (20 to 49)	<.001†
External rotation, mean (SD), °	18 (18)	27 (19)	−9 (−17 to −1)	.026†
Internal rotation, n (%)				
None	0 (0)	2 (5)		.47
Buttocks	9 (22)	5 (12)		
Sacroiliac joint	8 (20)	6 (14)		
Waist level	14 (34)	15 (35)		
Twelfth thoracic vertebra	8 (20)	13 (30)		
Interscapular level	2 (5)	2 (5)		

rTSA, reverse total shoulder arthroplasty; *HA*, hemiarthroplasty; *CI*, confidence interval; *SD*, standard deviation; *WOOS*, Western Ontario Osteoarthritis of the Shoulder; *EQ-5D*, EuroQol 5 Dimensions; *VAS*, visual analog scale.

Data are presented as mean (SD) for continuous variables but as number (percentage) for categorical variables.

* For comparisons between groups, the χ^2 test was used to test for non-ordered categorical variables and the Fisher nonparametric permutation test was used for continuous variables.

† Statistically significant ($P < .05$).

‡ The WOOS score was missing for 1 patient in the rTSA group and was excluded for 2 patients in the HA group because of >3 missing items. Values were imputed for 2 patients in the rTSA group and 1 patient in the HA group.

§ The EQ-5D index score was missing for 1 patient in the rTSA group.

studies with other types of designs were included as well: the previously mentioned RCT by Sebastiá-Forcada et al, nonrandomized prospective studies,[10,20] and a registry-based study.[59] Patients treated with rTSA had higher functional outcome scores overall, but in particular, the difference with respect to the Constant score was 12.7 points, which is not far from the 11.1-point difference in our study. Patients treated with rTSA had better flexion and abduction by 24° and 26°, respectively.

The mean difference in the Constant score between the treatment groups (11.1 points) is likely to be not only statistically significant ($P < .007$) but also clinically significant. Van de Water et al[58] reported an MCID of 11.6 points in the only previous study specifically addressing proximal humeral fractures, although it was based on only 20 patients, of whom 16 were treated nonoperatively. In a study that is currently the largest study estimating the MCID for patients treated with shoulder arthroplasty, including 466 patients with degenerative disease, Simovitch et al[50] found an MCID of 5.7 points. Moreover, Simovitch et al found

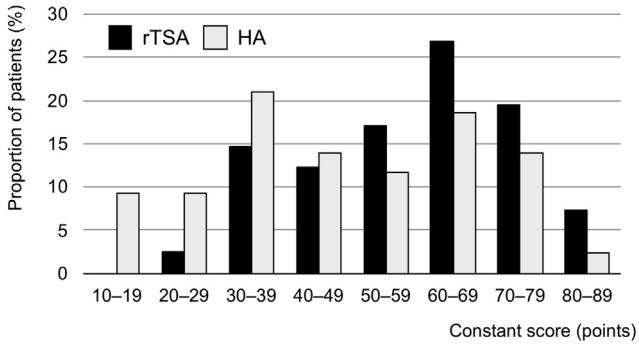

Figure 2 Distribution of Constant score at final follow-up by treatment group. *rTSA*, reverse total shoulder arthroplasty; *HA*, hemiarthroplasty.

that the MCID was lower in women than in men and in patients aged > 70 years than in patients aged < 70 years. Both of these observations are relevant to the interpretation of the results of our study, dominated by elderly women. In addition to a significant difference in the mean Constant

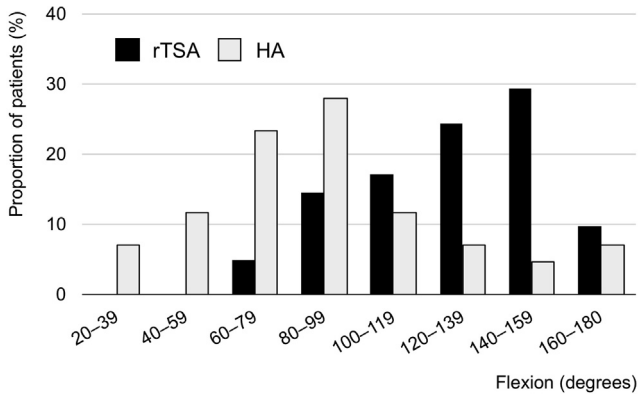

Figure 3 Distribution of degrees of flexion at final follow-up by treatment group. *rTSA*, reverse total shoulder arthroplasty; *HA*, hemiarthroplasty.

score between the treatment groups, there were significantly fewer patients in the rTSA group with a Constant score < 40 points as compared with the HA group, with the distribution tending to be bimodal rather than normal. Reverse total shoulder arthroplasty thus appears to have the advantage of avoiding a poor outcome to a greater extent than HA.

By simply asking about satisfaction with the shoulder, we found that patients in the rTSA group were more satisfied. The absence of complications and the presence of low pain levels and better range of motion have been identified as independent predictors of satisfaction following shoulder arthroplasty.[4,16] The greater satisfaction of the rTSA patients is probably mainly because of better range of motion, as there were no clear differences in pain levels or complications between the treatment groups. Although rTSA did not restore normal abduction or flexion, estimated to be around 160° for patients aged 70-80 years,[21,60] a significantly higher proportion of rTSA patients than HA patients obtained 120° of flexion (63% vs. 19%), as well as 130° of abduction (34% vs. 14%), described by Namdari et al[39] as being required to complete tasks of daily living. The difference in flexion is noteworthy, and an interesting observation is that previous studies have suggested that flexion ability is associated with outcome. In a study of 31 patients with proximal humeral fractures, Slobogean et al[52] investigated the discriminatory ability of physical examination maneuvers to identify normally functioning shoulders, defined as a Disabilities of the Arm, Shoulder and Hand score of <15 points. Forward flexion had the best discriminatory ability, with a threshold of 120° correctly classifying 90% of the shoulders. In terms of shoulder arthroplasty, flexion has been found to correlate with the Constant score[45,46] and the patient-reported portion of the American Shoulder and Elbow Surgeons score.[27]

Greater shoulder satisfaction in the rTSA group did not translate into a significant difference in the mean WOOS score between the treatment groups (77.3 vs. 74.5). However, the WOOS index may not be the optimal instrument to detect perceived functional differences in this group of patients, as ≥15% of the patients reached the maximum score (>97) in both treatment groups, suggesting a ceiling effect[57] that might compromise the ability to detect differences between the groups (sensitivity).

Table III Outcome at final follow-up by age (70-79 years vs. ≥80 years): Constant score, pain, shoulder satisfaction, and range of motion

	Age 70-79 yr (n = 46)				Age ≥ 80 yr (n = 38)			
	rTSA (n = 20)	HA (n = 26)	Difference, mean (95% CI)	*P* value*	rTSA (n = 21)	HA (n = 17)	Difference, mean (95% CI)	*P* value*
Constant score, points	56.2 (17.7)	44.7 (22.6)	11.5 (−0.8 to 24.0)	.068	61.1 (14.9)	52.2 (14.7)	8.9 (−0.9 to 18.8)	.074
Pain score on VAS, mm	13 (20)	31 (29)	−18 (−33 to −3)	.024†	17 (21)	9 (13)	8 (−3 to 20)	.17
Shoulder satisfaction score on VAS, mm	82 (19)	56 (34)	26 (9 to 43)	.005†	77 (25)	74 (28)	3 (−14 to 20)	.73
Range of motion, °								
Abduction	109 (29)	82 (40)	26 (5 to 47)	.017†	116 (28)	85 (36)	31 (10 to 52)	.006†
Flexion	121 (29)	90 (41)	31 (9 to 53)	.007†	129 (27)	90 (37)	39 (18 to 60)	<.001†
External rotation	20 (17)	28 (18)	−8 (−18 to 3)	.14	17 (20)	27 (21)	−10 (−23 to 4)	.15

rTSA, reverse total shoulder arthroplasty; *HA*, hemiarthroplasty; *CI*, confidence interval; *SD*, standard deviation; *VAS*, visual analog scale.
Data are presented as mean (SD) for continuous variables.
* For comparisons between groups, the χ^2 test was used to test for non-ordered categorical variables and the Fisher nonparametric permutation test was used for continuous variables.
† Statistically significant ($P < .05$).

Table IV Comparison of outcome at 1-year follow-up and at final follow-up: clinical rating systems, pain, shoulder satisfaction, and range of motion

	rTSA					HA				
	n	1-year follow-up	Final follow-up	Difference, mean (95% CI)	*P* value*	n	1-year follow-up	Final follow-up	Difference, mean (95% CI)	*P* value*
Constant score,† mean (SD), points	35	54.8 (16.2)	59.6 (17.1)	4.8 (1.1 to 8.5)	.004‡	32	45.1 (19.1)	47.2 (19.9)	2.1 (−1.1 to 5.3)	.21
WOOS index score,§ mean (SD)	35	74.9 (20.2)	77.0 (21.7)	2.1 (−3.1 to 7.3)	.13	30	72.4 (18.7)	73.4 (24.2)	1.0 (−4.2 to 6.2)	.24
EQ-5D index score,‖ mean (SD)	35	0.87 (0.10)	0.84 (0.14)	−0.03 (−0.07 to 0.01)	.27	31	0.86 (0.09)	0.82 (0.13)	−0.04 (−0.07 to −0.01)	.017‡
Pain score on VAS,¶ mean (SD), mm	36	18 (19)	15 (21)	– 3 (–9 to 4)	.51	31	24 (25)	26 (29)	2 (–5 to 10)	.9
Shoulder satisfaction score on VAS,# mean (SD), mm	36	73 (24)	80 (22)	7 (−1 to 15)	.085	32	69 (26)	60 (34)	−9 (−20 to 2)	.094
Range of motion#										
Abduction, mean (SD), °	36	107 (30)	113 (28)	7 (−2 to 15)	.12	32	85 (36)	86 (37)	1 (−6 to 8)	.53
Flexion, mean (SD), °	36	119 (25)	127 (27)	9 (2 to 15)	.017‡	32	97 (36)	94 (38)	−3 (−12 to 5)	.95
External rotation, mean (SD), °	36	17 (16)	19 (18)	2 (−3 to 7)	.86	32	29 (20)	29 (20)	0 (−5 to 5)	.72
Internal rotation,† n (%)	35				.003‡	32				.39
None		4 (11)	0 (0)				0 (0)	2 (6)		
Buttocks		10 (29)	7 (20)				6 (19)	3 (9)		
Sacroiliac joint		8 (23)	6 (17)				7 (22)	5 (16)		
Waist level		7 (20)	12 (34)				8 (25)	10 (31)		
Twelfth thoracic vertebra		6 (17)	8 (23)				11 (34)	10 (31)		
Interscapular level		0	2 (6)				0 (0)	2 (6)		

rTSA, reverse total shoulder arthroplasty; *HA*, hemiarthroplasty; *CI*, confidence interval; *SD*, standard deviation; *WOOS*, Western Ontario Osteoarthritis of the Shoulder; *EQ-5D*, EuroQol 5 Dimensions; *VAS*, visual analog scale.

Data are presented as mean (SD) for continuous variables but as number (percentage) for categorical variables.

* The results at 1-year follow-up and final follow-up are compared between the treatment groups with the Wilcoxon signed rank test for continuous variables and the sign test for categorical variables.

† The Constant score was missing for 2 patients in the rTSA group at 1-year follow-up.

‡ Statistically significant ($P < .05$).

§ The WOOS score was unavailable for analysis for 2 patients in each treatment group because of missing or excluded data.

‖ The EQ-5D index score was unavailable for analysis for 2 patients in the rTSA group and 1 in the HA group because of missing items.

¶ The VAS pain score was missing at 1-year follow-up for 1 patient in the rTSA group and 1 in the HA group.

\# The shoulder satisfaction score and range of motion were missing at 1-year follow-up for 1 patient in the rTSA group.

Table V Adverse events by treatment group: time point of adverse event, treatment, and outcome

	rTSA (n = 3)	HA (n = 4)	Time point*	Treatment	Outcome	Constant score, points†
Death in early postoperative period						
Pneumonia	1		8 d	Intensive care	Death	
Periprosthetic fracture						
Distal humeral fracture	1		11 mo	ORIF	Fracture union	31
Humeral shaft fracture‡		1	2 mo	Revision to rTSA	No complications	36
Humeral shaft fracture		1	4 mo	Nonoperative	Fracture union; persisting radial nerve palsy	10
Humeral shaft fracture‡		1	1 mo	Nonoperative	Fracture union	63
CRPS	1		2 mo	Nonoperative	Persisting symptoms	32
Proximal migration of HA head		1	10 mo	Revision to rTSA	No complications	76

rTSA, reverse total shoulder arthroplasty; *HA*, hemiarthroplasty; *ORIF*, open reduction and internal fixation; *CRPS*, complex regional pain syndrome.
* Duration from surgery to adverse event.
† Constant score at final follow-up.
‡ Uncemented stem.

Although rTSA appears to lead to better shoulder function than HA, treatment with rTSA did not prevent the EQ-5D index score from deteriorating significantly from 0.93 prior to injury to 0.84 at the final follow-up. A similar development occurred in the HA group. These results are in line with previous work concluding that the EQ-5D score does not generally return to the preinjury level following a proximal humeral fracture.[28,41,42]

There are 2 recent RCTs on proximal humeral fractures comparing rTSA with treatments other than HA.[24,37] In one of these studies, Fraser et al[24] found that rTSA was superior to plate osteosynthesis. They analyzed 104 patients aged between 65 and 85 years and found a mean difference in the Constant score of 13.4 points in favor of rTSA at 2 years. This difference is compatible with the finding in our study, showing a difference of 11.1 points, particularly as some previous studies have suggested that HA produces similar or slightly better shoulder function compared with plate osteosynthesis in elderly patients.[13,56]

In the other recent study, by Lopiz et al[37] in 2019, rTSA was compared with nonoperative treatment in 59 patients, all aged $\geq$ 80 years. Only a minimal benefit of rTSA was found compared with nonoperative treatment in this age group. The Constant score was higher in the rTSA group (61.7 points vs. 55.7 points), but the difference was not statistically significant ($P = .071$). In fact, the results of our study suggest that the benefit of treatment with rTSA as compared with HA might decrease with increasing age. Although we found no difference in shoulder satisfaction or pain between rTSA and HA in patients aged $\geq$ 80 years, the differences were considerable in those aged between 70 and 79 years: 26 mm and –18 mm, respectively. Today's studies of ''elderly'' patients include a heterogeneous group of individuals with respect to age (from age 65 years and older),[37] with a large variation in activity level. The results of our study and the study by Lopiz et al thus highlight the potential importance of age in terms of outcome, even within the loosely defined group of elderly patients. To improve our understanding of the effect of factors such as age, activity level, and comorbidity on outcome, future RCTs will hopefully be of sufficient size to allow for the careful stratification of these factors, with some studies already underway.[35,53]

The results of this study suggest that shoulder function continues to improve between follow-up at 1 year and follow-up at a minimum of 2 years, without any additional complications being observed. There are limited data from previous studies on the rate of improvement in shoulder function beyond 1 year after rTSA for proximal humeral fractures. Lopiz et al[37] followed up patients for 1 year to illustrate the short-term results in their patient cohort with high comorbidity and a short life expectancy. The potential for improvement beyond 1 year needs to be considered when comparing studies with different lengths of follow-up.

We found no difference in shoulder function between patients with greater tuberosities that had healed and patients in whom they had failed to heal in either of the treatment groups. However, the healing of tuberosities is difficult to judge and grade and is, in any case, only a proxy for rotator cuff function.

This study has both strengths and limitations. In this multicenter study, several different implants were used, and the results, therefore, are based not on specific design features but instead on the generic concepts: rTSA compared with HA. Patients were followed up for 2 years, which contributed to the 15% loss to follow-up, similar to

the previously mentioned study by Fraser et al,[24] highlighting the problems encountered when conducting research in elderly patients. Long-term shoulder function is still unclear.

Conclusion

In this multicenter study, shoulder function after treatment with rTSA and HA for 3- and 4-part proximal humeral fractures in elderly patients (aged $\geq$ 70 years) was compared. We found that rTSA provides better shoulder function as measured with the Constant score, and this is further emphasized by the fact that patients treated with rTSA were more satisfied with their shoulder function than patients treated with HA. The difference appears to be mainly a result of better range of motion (abduction and flexion) in the rTSA group. The occurrence of complications did not differ between the treatment groups, but poor functional outcomes were more common in the HA group. The results indicate that patients aged $\geq$ 80 years benefit less from rTSA than patients aged 70-79 years.

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