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Reverse shoulder arthroplasty versus nonoperative treatment for 3- or 4-part proximal humeral fractures in elderly patients: a prospective randomized controlled trial



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Background: Proximal humeral fractures (PHFs) are among the most common fractures in elderly patients, but there is insufficient evidence from randomized controlled trials (RCTs) to determine which interventions are the most appropriate for their management. To date, no RCT has directly compared reverse shoulder arthroplasty (RSA) with nonoperative treatment for 3- or 4-part PHFs in elderly patients.

Methods: This was a prospective RCT. The primary objective was to compare pain and function 12 months after fracture using the Constant score in patients aged 80 years or older with 3- and 4-part PHFs, treated by either RSA or nonoperative treatment. Secondary outcome measures included Disabilities of the Arm, Shoulder and Hand, visual analog scale (VAS), Short Form 12 (SF-12), EuroQol 5 Dimensions, and EQ-VAS scores.

Results: We analyzed 30 nonoperative and 29 RSA patients with mean ages of 85 years and 82 years, respectively. No differences between the nonoperative and RSA groups were noted for any patient-reported outcomes at 12 months' follow-up except the VAS pain score. The Constant scores were 55.7 in the nonoperative group and 61.7 in the RSA group ($P = .071$); the Disabilities of the Arm, Shoulder and Hand scores were 29 and 21, respectively ($P = .075$); the VAS scores were 1.6 and 0.9, respectively ($P = .011$); the physical SF-12 scores were 36 and 37, respectively ($P = .709$); the mental SF-12 scores were 43 and 42, respectively ($P = .625$); the EuroQol 5 Dimensions scores were 0.89 and 0.92, respectively ($P = .319$); and the EQ-VAS scores were 65 and 67, respectively ($P = .604$).

The Ethics Committee for Clinical Research of Clínico San Carlos Hospital (Madrid, Spain) approved this study (no. 14/099-P_BS).

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Conclusions: This study yields important evidence for the treatment of complex PHFs in elderly patients suggesting minimal benefits of RSA over nonoperative treatment for displaced 3- and 4-part PHFs. At short-term follow-up, the main advantage of RSA appeared to be less pain perception.

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

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Keywords: Proximal humeral fracture; reverse shoulder arthroplasty; elderly; conservative treatment; patient-reported outcome measures; quality of life

Proximal humeral fractures (PHFs) currently account for 5% of all adult fractures and are the second-most-common upper-limb fracture; up to 53% of all the fractures occur around the shoulder girdle.³⁸ In our setting, they are the third-most-common osteoporotic fracture and up to three-fourths affect patients older than 60 years.⁷ They have an overall incidence of 40 in 100,000 patients, which is predicted to triple by 2030.⁴²

The ideal treatment for PHFs is controversial because there is insufficient scientific evidence to recommend 1 treatment over another.²⁴ Nevertheless, we are now witnessing the increasing use of reverse shoulder arthroplasty (RSA), especially in elderly patients.⁴³ These patients' poor bone quality owing to osteoporosis causes complex fracture patterns that render open reduction–internal fixation (ORIF) impossible to perform, and when they are performed, they often entail high complication rates, up to 50% depending on the series.^{52,53} These 2 factors (complexity of fracture pattern and failure of osteosynthesis because of poor bone quality) reduce the current therapeutic options practically down to 2: conservative treatment vs. shoulder arthroplasty. For many years, hemiarthroplasty alone was available to us, which traditionally offered good results in terms of pain relief but with very variable and unpredictable functional outcomes, dependent on healing of the tuberosities.¹

In 2004, RSA was approved for use in the United States, and it has emerged as a promising procedure because its functional outcomes appear to be more reproducible and less dependent on healing of the tuberosities,^{23,48} which is of particular interest for elderly patients. However, previous results regarding functional outcomes and quality of life obtained for geriatric patients³⁶ highlighted that these outcomes are influenced by age, with poorer results being obtained for those older than 80 years compared with those achieved in younger patients. Studies comparing conservative treatment with hemiarthroplasty have been performed,^{2,41,54} with outcomes that did not demonstrate either treatment to be superior to the other. However, to date, no randomized controlled trials (RCTs) have directly compared RSA with nonoperative treatment for 3- or 4-part PHFs in elderly patients.

The high frequency of PHFs, the growing epidemiologic pattern that they follow, and the absence of scientific evidence on their ideal treatment are the reasons

these types of studies are necessary. The purpose of this study was to perform a prospective evaluation of patient functional outcomes and quality of life comparing conservative treatment and RSA for the treatment of comminuted PHFs in elderly patients.

Materials and methods

Study design

This was a prospective RCT. Between May 2014 and January 2018, of 85 patients aged 80 years or older with displaced Neer 3- or 4-part PHFs, 23 were excluded because at least 1 of the exclusion criteria was present. Therefore, 62 patients were eventually randomized for treatment with either RSA or conservative treatment. Of the 30 patients assigned to treatment with RSA, 1 withdrew consent and was excluded from the study. Of the 32 patients assigned to conservative treatment, 1 withdrew consent and underwent conversion to RSA; in addition, 1 death unrelated to treatment occurred. Therefore, the nonoperative group finally comprised 30 patients and the RSA group comprised 29. All patients had a minimum follow-up period of 12 months. The study flowchart is provided in [Figure 1](#).

Inclusion and exclusion criteria and sample size

The inclusion criteria were patients aged 80 years or older with a 3- or 4-part displaced PHF available for follow-up for at least 12 months. The patients had to be able to understand the informed-consent process of the study.

The exclusion criteria were as follows: patients with mental disorders including cognitive impairment measured using the Mini-Mental State Examination,⁵⁶ open fracture, pathologic fracture, fracture-dislocation or head-splitting fracture according to Neer,³⁷ neurologic disorder, associated ipsilateral or contralateral upper- or lower-limb fracture, prior surgery on the shoulder, or associated comorbidity contraindicating surgery, as well as patients who were not autonomous prior to the fracture as determined using the Katz index.²⁹

Patients who met all the inclusion criteria and none of the exclusion criteria comprised the study group. After their written informed consent was received, the patients were randomly allocated to either nonoperative treatment or RSA. Randomization was performed during the outpatient consultation the first week after the patient had incurred the fracture and was based on

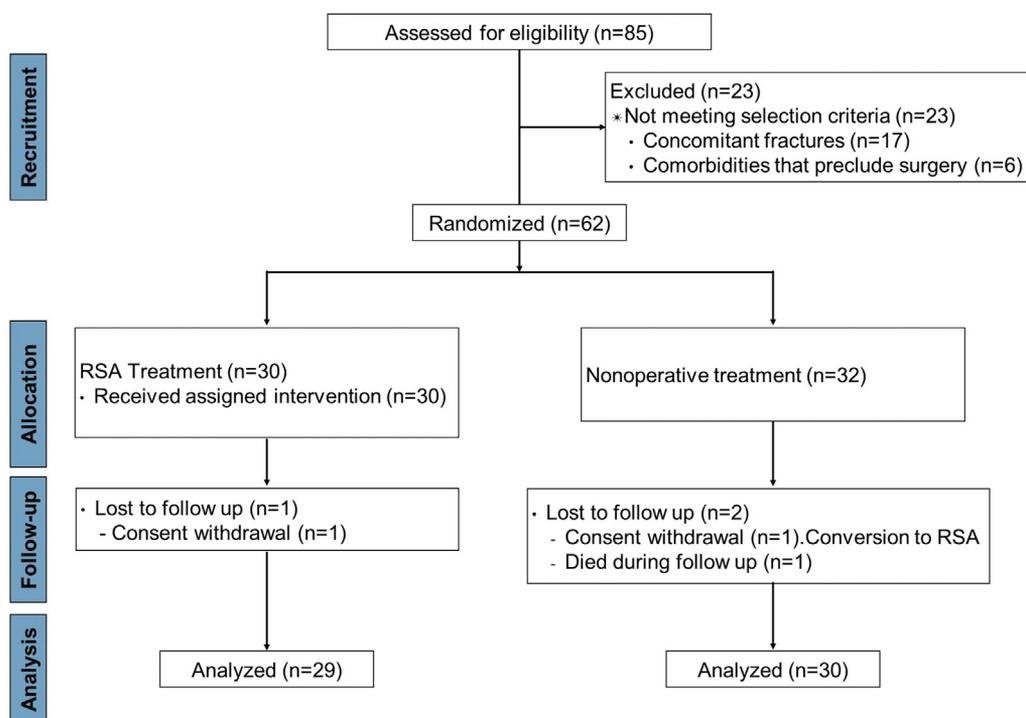


Figure 1 Study flowchart. RSA, reverse shoulder arthroplasty.

sequentially numbered, opaque, sealed envelopes. The surgeons were not involved in the randomization process.

The sample size calculation was based on the postoperative minimal clinically important difference of 8 points for the Constant score in a previously published comparative study.⁵⁹ To detect such a relevant difference between groups, considering the Constant score in nonoperative studies,²² at least 56 patients needed to be enrolled in the study, assuming a dropout rate of 20%.

Interventions

In the patients who were allocated to RSA, surgery was performed around 7 days after the trauma by at least 2 of the 3 senior shoulder surgeons (F.M., C.G.-F., and Y.L.). All of the patients were operated on under general anesthesia using an interscalene block, in the beach-chair position, with a deltopectoral approach. Patients received the Delta XTEND Reverse Shoulder System prosthesis (DePuy, Warsaw, IN, USA) or SMR Modular Shoulder System (Systema Multiplana Randelli; Lima-LTO, San Daniele del Friuli, Italy). The tuberosities were reattached using 2 horizontal and 2 vertical suture configurations (Ethibond; Johnson & Johnson, New Brunswick, NJ, USA). A cerclage suture was placed circumferentially around the greater tuberosity and through the supraspinatus insertion at the tendon-bone junction, medial to the prosthesis, and through the subscapularis insertion at the tendon-bone junction. Prior to suture tying, spaces between the prosthesis, shaft, and tuberosities were packed with cancellous bone graft from the resected humeral head. Then, the lateral portion of the rotator interval was closed with a No. 2 nonabsorbable suture and the arm in 30° of external rotation. Postoperatively, the arm was immobilized in a sling for 3 weeks, allowing elbow, wrist, hand, and pendulum shoulder movements

from the first day after surgery. From the second week, passive-assisted Codman movements with neutral rotation and less than 90° of anteversion were allowed. Active range of motion (ROM) started at 6 weeks and gradually progressed until counter-resistance was felt after 12 weeks to strengthen the musculature. Patients randomized to conservative treatment were immobilized in a sling until the third week after their fracture before starting the same rehabilitation program as the operatively treated patients. The patients were reassessed by a different independent physician monthly to ensure their improvement with physical therapy. When the patients had reached the point at which no further improvements were noted between 2 visits, formal physiotherapy in the hospital was discontinued.

Clinical and radiologic evaluation

Clinical and radiographic evaluations were carried out preoperatively and postoperatively at 1 week, 1 month, 3 months, 6 months, and 1 year. Functional evaluation was performed by 2 independent examiners (B.A.-D. and M.G.-O.) who were not involved in the surgical procedure and did not know the treatment undergone by the patients. The Constant score—absolute and adjusted for age and sex—was the primary outcome.¹² Abduction strength was objectively quantified at 45° of abduction for 4 seconds with a Lafayette MMT (Manual Muscle Tester; Lafayette Instrument, Lafayette, IN, USA) recording the average maximum strength of 3 measures. The Disabilities of the Arm, Shoulder and Hand questionnaire,²⁵ the Short Form 12 (SF-12) adapted for the Spanish population⁶¹ and the visual analog scale (VAS) were used as secondary outcomes measures. Health-related quality of life (HRQoL) was measured with the EuroQol 5 Dimensions (EQ-5D) and the EQ-VAS, a visual analog scale included in the EQ5D by which respondents can report their perceived health status with a

grade ranging from 0 (the worst possible health status, to 100 (the best possible health status).^{4,55} The Charlson Comorbidity Index (CCI) was used to compare the medical situation of both groups of patients in terms of comorbidities. The functional results were also stratified between patients aged 85 years or younger and those older than 85 years. Patients older than 85 years (“oldest-old patients”) are given particular consideration by other medical specialties such as cardiology or geriatrics when deciding on any specific medical action.²⁸ Finally, to determine satisfaction with the treatment, the patients were asked the following dichotomous question: “Based on the results you have achieved, would you undergo the same treatment again?” The only possible answers were yes and no.

Three senior shoulder surgeons (F.M., C.G.-F., and Y.L.) performed the radiographic assessment independently to reduce known interobserver variability. The fracture was diagnosed from an anteroposterior view, a lateral shoulder view in the scapular plane, and computed tomography for fracture classification according to the Neer criteria.³²

Postoperative radiographs were obtained at each follow-up and analyzed for the presence or absence of baseplate loosening (radiolucency around the screws or central peg, classified as grade 0 when no radiolucent lines were present, grade 1 when a line <1 mm wide and incomplete was present, grade 2 when a line 1 mm wide and complete was present, grade 3 when a line 1.5 mm wide and incomplete was present, grade 4 when a line 1.5 mm wide and complete was present, or grade 5 when a line 2 mm wide and complete was present)¹⁴; scapular notching classified according to the system described by Sirveaux et al⁵⁰; and any evidence of hardware failure, humeral stem loosening, and nonanatomic healing of the tuberosities (nonunion, resorption, or migration). For the nonoperative treatment, nonunion, malunion, avascular necrosis, and osteoarthritis were assessed. A schedule of events is shown in Table I.

Statistical analysis

Statistical analysis was performed by a statistician from the investigation support unit of our hospital’s research foundation using IBM SPSS software (version 22; IBM, Armonk, NY, USA).

For comparisons between groups, we used the Student *t* test for parametric continuous data, the Wilcoxon (Mann-Whitney) *U* test for nonparametric continuous data, and the χ^2 test for categorical data. For comparisons between preoperative and postoperative data within a group, the paired *t* test or Wilcoxon signed rank test was used. The significance level was set at $P < .05$.

Results

Epidemiologic results

The mechanism of injury in all patients was a fall on the upper extremity. The mean age was 83.5 years for the entire group and 85 years (standard deviation, 4.8 years) for the nonoperative group vs. 82 years (standard deviation, 3.2 years) for the RSA group ($P = .007$). Of all the patients, 86.4% were women (86.7% in the conservative treatment group and 86.2% in the RSA group, $P = .959$). According to the CCI, the conservative treatment group had an average CCI of 6.1 and the RSA group, 5.7 ($P = .117$). Neither lateral nor dominant limb involvement was statistically different between the groups. Of the fractures in the nonoperative group, 17% were 3-part fractures and 83% were 4-part fractures, and of the fractures in the RSA group, 13% were 3-part fractures and 87% were 4-part fractures. Therefore, both groups were comparable regarding the epidemiologic results except for age, where the conservative treatment group was an average of 3 years older than the RSA group. Epidemiologic data are summarized in Table II.

Functional results

The main functional results are provided in Table III. No differences in the mean Constant score were found between the 2 groups at the 3-, 6-, and 12-month follow-up assessments (Fig. 2). At 12 months, the Constant score was 55.7

Table I Schedule of follow-up measurements

	Study period							
	Preoperatively	Surgery	Postop and at discharge	1 week	1 mo	3 mo	6 mo	12 mo
Eligibility screen	x							
Informed consent	x							
Randomization	x							
CT	x							
Radiography	x		x	x	x	x	x	x
Epidemiologic data	x				x	x	x	x
DASH score	x			x	x	x	x	x
VAS pain score	x			x	x	x	x	x
EQ-5D score	x				x	x	x	x
SF-12 score	x				x	x	x	x
Constant score					x	x	x	x
Adverse events		x	x	x	x	x	x	x

Postop, postoperative; *CT*, computed tomography; *DASH*, Disabilities of the Arm, Shoulder and Hand; *VAS*, visual analog scale; *EQ-5D*, EuroQol 5 Dimensions; *SF-12*, Short Form 12.

Table II General epidemiologic characteristics of nonoperative and RSA groups

	Nonoperative	RSA	<i>P</i> value
Patients	30	29	
Age, mean \pm SD, yr	85 \pm 4.8	82 \pm 3.4	.007*
Sex, male/female	4 (13)/26 (87)	4 (14)/25 (86)	.959
Dominant/nondominant	20 (67)/10 (33)	13 (45)/16 (55)	.091
CCI, mean \pm SD	6.1 \pm 1.2	5.7 \pm 1.1	.117
Fracture type, 3 part/4 part	5 (17)/25 (83)	4 (13)/25 (87)	.7306

RSA, reverse shoulder arthroplasty; SD, standard deviation; CCI, Charlson Comorbidity Index.

Data are presented as number of patients (percentage) unless otherwise indicated.

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

± 12.4 in the nonoperative group vs. 61.7 ± 12.1 in the RSA group ($P = .071$).

When the 4 variables of the Constant score were analyzed at 12 months, the main difference between the 2 groups was in ROM, with a mean score of 20.5 points in the nonoperative treatment group vs. 24.2 in the RSA group, although this result was not statistically significant ($P = .059$) (Fig. 3). Ranges of movements for each treatment at last follow-up for forward elevation, external rotation, and

Table III Postoperative functional and quality-of-life outcomes

	Postoperative outcomes at 12 mo		
	Nonoperative (n = 30)	RSA (n = 29)	<i>P</i> value
Normalized Constant score	79.6	81.2	.253
Constant score	55.7 \pm 12.4	61.7 \pm 12.1	.071
Pain	13.5 \pm 2.8	14.6 \pm 1.2	.068
Activities of daily living	14.9 \pm 3.2	15.8 \pm 2.9	.269
Range of motion	20.5 \pm 6.9	24.2 \pm 7.8	.059
Strength	6.9 \pm 4.6	7.1 \pm 5.8	.851
DASH score	28.8 \pm 19.6	20.7 \pm 13.9	.075
VAS pain score	1.6 \pm 2.2	0.9 \pm 0.9	.011*
SF-12 score			
Physical	36.4 \pm 8.2	37.1 \pm 6.3	.709
Mental	42.9 \pm 9.8	41.6 \pm 9.8	.625
EQ-5D score	0.89 \pm 0.14	0.92 \pm 0.13	.319
EQ-VAS score	64.8 \pm 18.3	67.1 \pm 14.2	.604

RSA, reverse shoulder arthroplasty; DASH, Disabilities of the Arm, Shoulder and Hand; VAS, visual analog scale; SF-12, Short Form 12; EQ-5D, EuroQol 5 Dimensions.

Data are presented as mean \pm standard deviation, with the exception of the normalized Constant score.

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

abduction are provided in Figure 4. The Constant scores achieved in each group (nonoperative and RSA) for the ROM item at 12 months' follow-up were as follows: 5.7 ± 1.9 and 6.9 ± 2.3 , respectively, for forward flexion ($P = .028$); 5.6 ± 2 and 6.6 ± 2.2 , respectively, for abduction ($P = .064$); 4.4 ± 2.5 and 5.2 ± 2.9 , respectively, for external rotation ($P = .293$); and 4.8 ± 2.0 and 5.5 ± 2.2 , respectively, for internal rotation ($P = .211$).

No differences in the Disabilities of the Arm, Shoulder and Hand (DASH) score at 3, 6, and 12 months' follow-up were found between the 2 groups. At 12 months, the final score was 28.8 ± 19.6 in the nonoperative group vs. 20.7 ± 13.9 in the RSA group ($P = .075$). After dividing patients by age and comparing the mean total Constant and DASH scores, we found they were 10 and 26.7 points higher, respectively, for the patients aged 85 or younger than for those older than 85 years. However, comparison of the conservative and RSA patients within each age group showed that the differences were only about 6 points for the Constant score and 4 points for the DASH score in favor of RSA treatment. At 1, 3, and 6 months, no significant differences in the VAS score were found between the 2 groups (RSA vs. nonoperative), but at 12 months' follow-up, the RSA group had significantly less pain (0.9 ± 0.9) than the nonoperative group (1.6 ± 2.2 , $P = .011$). The scores obtained for the 2 dimensions of the SF-12, that is, physical and mental, at 12 months were 36.4 ± 8.2 and 42.9 ± 9.8 , respectively, in the nonoperative group and 37.1 ± 6.3 and 41.6 ± 9.8 , respectively, in the RSA group ($P = .709$ and $P = .625$, respectively). The results obtained throughout follow-up using the Constant, DASH, VAS, and SF-12 scores are presented in Figure 3.

HRQoL results

Analysis of covariance confirmed no statistically significant differences at 12 months between the nonoperative and RSA groups in the EQ-5D score (0.89 ± 0.14 vs. 0.92 ± 0.13 , $P = .319$) or EQ-VAS score (64.8 ± 18.3 vs. 67.1 ± 14.2 , $P = .604$) (Fig. 5). When we compared each dimension of the

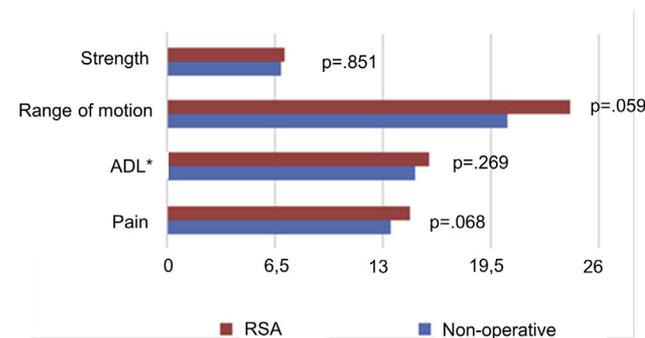


Figure 2 Scores for the 4 variables of the Constant score in the nonoperative group and reverse shoulder arthroplasty (RSA) group. ADL*, activities of daily living.

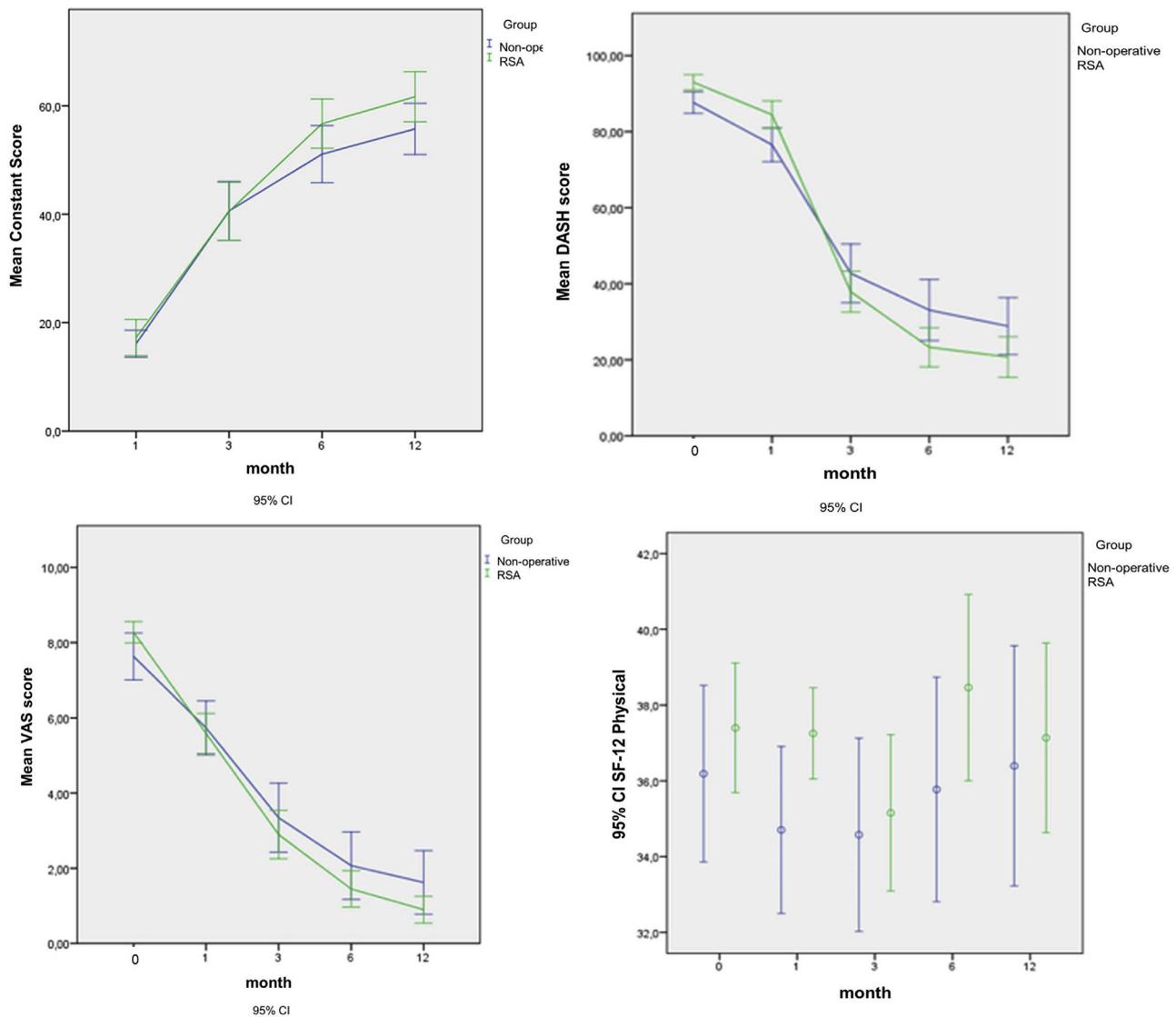


Figure 3 Results obtained throughout follow-up for the Constant score; Disabilities of the Arm, Shoulder and Hand (*DASH*) score; visual analog scale (*VAS*) score; and Short Form 12 (*SF-12*) physical dimension score. *RSA*, reverse shoulder arthroplasty; *CI*, confidence interval.

EQ-5D (mobility, self-care, usual activity, pain/discomfort, and anxiety) between the treatment groups, we also found no statistically significant differences.

Patient satisfaction

At 12 months' follow-up, in response to the dichotomous question "Based on the results you have achieved, would you undergo the same treatment again?," all the patients in the RSA said yes compared with 93% in the nonoperative treatment group. No statistically significant difference was found between the 2 treatment groups ($P = .2373$).

Radiologic results

The radiographic results are summarized in [Table IV](#). Nonanatomic healing or resorption of the tuberosities was

not associated with poor Constant and *DASH* scores, except for the Constant score at 6 months' follow-up (61.8 ± 11.4 vs. 52.0 ± 10.8 , $P = .024$). The functional results after RSA with anatomic tuberosity healing, RSA with nonanatomic tuberosity healing, and nonoperative treatment are provided at 1, 3, 6, and 12 months' follow-up in [Table V](#).

The presence of osteonecrosis was not associated with poor *DASH* and Constant scores: 28.9 ± 21.8 and 53.6 ± 13.8 , respectively, vs. 28.8 ± 17.1 and 58.7 ± 9.9 , respectively, in the patients with no osteonecrosis ($P = .993$ and $P = .285$, respectively).

Complications

At 12 months' follow-up, in the RSA group, no additional surgical procedures were performed, and no other complications such as prosthesis dislocation, periprosthetic

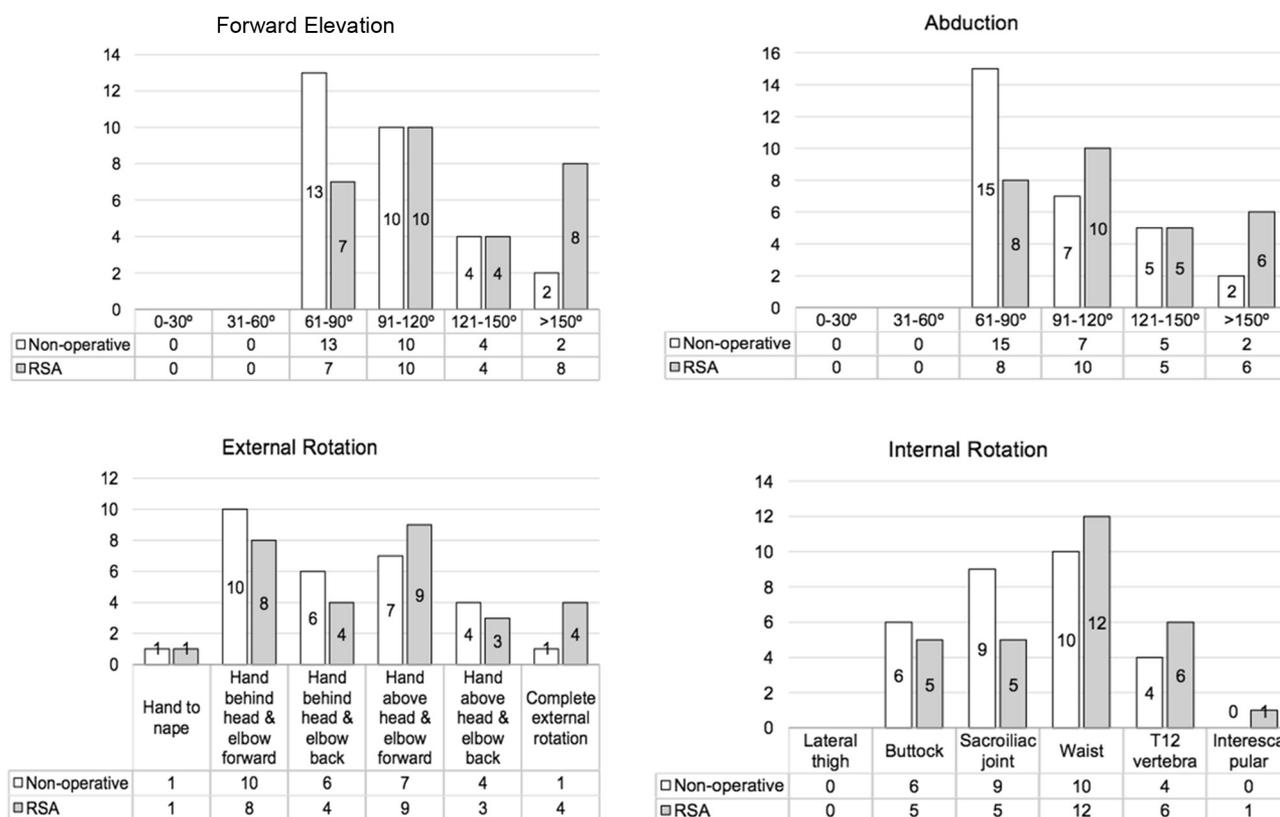


Figure 4 Range of motion in nonoperative treatment and reverse shoulder arthroplasty (RSA) groups.

fracture, acromial stress fracture, or infection were found. However, there were 2 cases of suprascapular nerve injury confirmed by electromyographic study. These 2 cases were patients with poorer pain control.

Discussion

There remains no clear consensus or guidelines on the best treatment for PHFs, specifically in elderly patients, because of various problems with the study designs in terms of selection bias, unreliable classification of the fracture, interobserver differences in the assessment of the Constant score, and the absence of stratification of patients according to age or treatment.³³ However, despite the lack of scientific evidence,²⁴ there is a growing trend toward treating these fractures surgically, which has increased since RSA became available. In recent years, we have seen an increased number of level I research studies attempting to shed light on this problem. The latest of these is the PROFHER (Proximal Fracture of the Humerus: Evaluation by Randomization) study,⁴⁴ which is a multicenter randomized clinical study undertaken in the United Kingdom that has shown no difference between surgical and conservative treatment of PHFs.²⁷ However, this study had major biases. It included a heterogeneous, nonconsecutive group of

patients with no clear inclusion criteria and very different ages (16-66 years) and did not cover how the surgical procedure was performed (type of surgeon and implant), and the effects of the fracture types in terms of displacement are not known.

Sabharwal et al,⁴⁷ after an analysis of 7 randomized clinical studies,^{2,17,40,41,44,54,64} demonstrated that differences in outcomes were detected when subgroup and sensitivity analyses were performed based on the type of fracture, as well as the type of surgical intervention performed. This highlights that comparing groups that are so heterogeneous in clinical research has major disadvantages and can act as a confusion factor leading to erroneous conclusions. When we performed a literature review of the results of performing RSA or conservative treatment in elderly patients, we realized that the main problem was the definition of an “elderly patient.” Although there are authors who regard patients aged 65 years as elderly, there are others who only include patients older than 80 years^{36,58} (Table VI). Although the concept of the elderly patient is very broad and does not encompass age alone but also implies associated comorbidities, we need to define what we consider “elderly” to be able to compare results, given that the demands of life, life expectancy, and improved perceived quality of life after our interventions are very

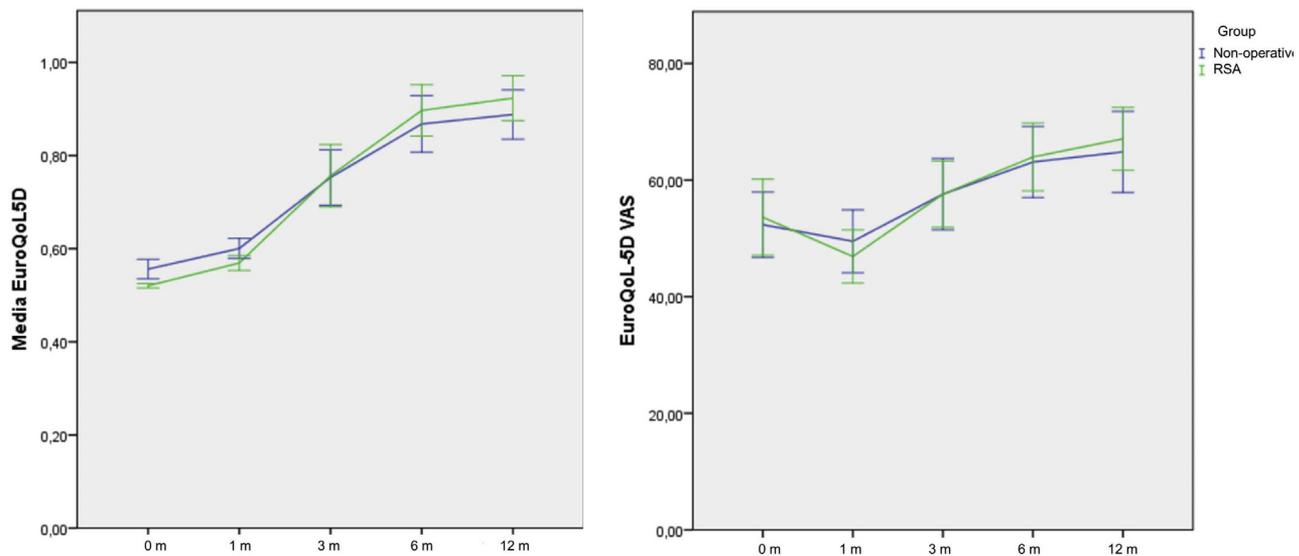


Figure 5 Health-related quality of life. The results were obtained throughout follow-up using the EuroQol 5 Dimensions (5D) and EQ-VAS. *m*, months.

different for a patient aged 65 years vs. a patient aged 80 years.⁵⁸

Du et al,¹⁵ in a meta-analysis that examined possible treatments for 3- or 4-part fractures in elderly patients, identified 7 randomized studies with mean ages older than 70 years in which these treatments were compared: conservative vs. ORIF,^{17,40,64} conservative vs. hemiarthroplasty,^{2,41} ORIF vs. hemiarthroplasty,⁶ and hemiarthroplasty vs. RSA.⁴⁸ They concluded that RSA has become a beneficial choice to treat displaced 3- or 4-part fractures in elderly patients, with better clinical results and lower reoperation rates than the other methods performed for the same indication.

However, no studies have directly prospectively compared nonoperative management with RSA for the treatment of 3- and 4-part PHFs in elderly patients. The present study is the first RCT to assess the treatment of 3- or 4-part PHFs in geriatric patients. Although multiple studies have reported results after RSA or nonoperative treatment of PHFs separately, only 2 retrospective studies have compared both treatments^{10,46} (Table V). The study by Roberson et al⁴⁶ that compared the results of conservative treatment with RSA, apart from being a retrospective study, has a major selection bias in that all the patients were offered treatment with a reverse prosthesis but only those who refused it became part of the conservative treatment group. The study compared 19 nonoperative and 20 RSA patients with mean follow-up periods of 29 and 53 months, respectively, and a mean age of 71 years in both groups, 12.5 years younger than our mean age. Roberson et al concluded that there are no benefits of RSA over nonoperative treatment for 3- and 4-part PHFs in the older adult regarding ROM and patient-reported outcomes. Chivot et al¹⁰ recently published a multicenter retrospective and

comparative study between RSA and nonoperative treatment in patients older than 70 years. They found no significant differences in the mean scores for the short version of the DASH (QuickDASH), activities of daily living, and VAS for pain in either group at the last assessment, and they found a relatively small clinical difference in the Constant score (56.5 points vs. 50.5 points, $P = .03$). They concluded that RSA must be proposed only to patients with significant functional demands.

Our study suggests that there are no benefits of RSA over nonoperative treatment for 3- and 4-part PHFs in elderly patients regarding functional outcomes and HRQoL. The Constant score was a mean of 6 points higher in the RSA group (as previously reported by Chivot et al¹⁰), but this difference was not statistically significant. Although not statistically significant, it could be clinically relevant as the minimal clinically important difference for the Constant score in RSA patients has been set at between 5.7 and 10 points.^{49,58} However, this result does not translate to perceived HRQoL (EQ-5D and EQ-VAS).

The repercussions of tuberosity fixation on functional outcomes after RSA in fractures are still controversial. The absence of well-designed prospective, randomized clinical trials in relation to tuberosity fixation makes this procedure still to be clarified.²⁶ Several studies have shown satisfactory clinical outcomes regardless of tuberosity healing. Cuff and Pupello¹³ did not find significant differences in outcomes except for ROM in external rotation between a tuberosity-healed group and a resorption group. Gallinet et al¹⁹ also compared patients with tuberosity repair and without tuberosity repair, concluding that shoulder rotational ability was improved when anatomic repair of the tuberosities was achieved and concluding that when nonunion or malunion of the tuberosities was present, it did

Table IV Radiologic results

Outcome at 12 mo follow-up	Nonoperative (n = 30), n (%)	RSA (n = 29), n (%)
Osteonecrosis	17 (58.6)	—
Malunion	30 (100)	—
Nonunion	1 (3.4)	—
GT anatomic healing	—	15 (52)
GT nonanatomic healing or resorption	—	14 (48)
Scapular notching	—	0
Lucent lines	—	0

RSA, reverse shoulder arthroplasty; GT, greater tuberosity.

not lead to a functional disaster. Chun et al¹¹ found that patients with healed tuberosities and patients with unhealed tuberosities showed no significant differences in functional outcomes or ROM except external rotation. Sebastián-Forcada et al⁴⁸ reported better scores with no statistically significant difference between the 2 groups, and Torrens et al⁵⁷ showed no difference between the 2 groups. In this study, we did not find significant differences between patients with anatomic tuberosity healing and those with nonhealing tuberosities, although the Constant score was always higher in the tuberosity healing group (57.5 vs. 66.1 at 12 months' follow-up). Other authors have theorized that the healed tuberosities are more important for achieving implant stability than for improving ROM.¹¹

The rate of tuberosity healing in our study was 52%. In a recent meta-analysis, the weighted mean tuberosity healing rate was 70.58% (range, 47%-100%).²⁶ The lower healing rate in our study can be related to 3 points. The first factor is the humeral component. Although the Delta III (DePuy Orthopedics, Inc., Warsaw, IN, USA) RSA system has been used in previous studies,^{5,9,19} the absence of a porous coating surface in the proximal portion of the stem may be related to a low rate of tuberosity healing. Previous studies have focused on the optimal humeral component design for fracture arthroplasty.³¹ Some of these studies, however, reported higher anatomic tuberosity healing rates, reaching

66% for the greater tuberosity and 100% for the lesser tuberosity. That is why we believe that another important factor is the high mean age in our series (82 ± 3.4 years). These patients usually have higher rates of severe osteoporosis (although preoperative bone mineral density was not evaluated in this study), and this second factor could also play an important role in the healing failure rate. Finally, another possible reason for the higher rate of tuberosity failure reported in this study is the fact that we considered only tuberosities that healed in anatomic position as achieving "tuberosity healing" and we did not include those patients with tuberosities that healed in a high or low position.

Similarly to Chivot et al,¹⁰ we did not find differences in the DASH and SF-12 scores at 12 months' follow-up; however, we observed a favorable VAS pain score in the RSA group. In contrast to other authors who compared hemiarthroplasty with nonoperative treatment, finding a favorable VAS pain score at 3 months that disappeared at 12 months' follow-up,⁴¹ we found no difference between the 2 treatments at 3 months' follow-up but did find a difference at 12 months. The development of degenerative joint changes probably plays a role in this; however, this higher VAS pain score does not translate to perceived HRQoL either, probably because, although statistically relevant, the difference of 0.7 points is not clinically relevant in these patients.

Surgical treatment of PHFs gives a relatively wide range of results depending on the population selected and the treatment applied. This study analyzed a homogeneous population, not only in fracture type and age but also in associated comorbidities measured using the CCI. This index, apart from enabling us to quantify the comorbidities of patients, informs us on the life expectancy of the study population. The mean CCI for the entire group was 5.9. This is a severe CCI, which translates to a 2.25% likelihood that each patient will still be alive in 10 years. The follow-up period in this study was 1 year, a period that could be criticized as being too short to provide reliable results. However, as we explained earlier, in light of the CCI for this elderly population and the patients' survival, it is a priority to determine their functional situation and short-term quality of life rather than long-term complications

Table V Functional results (Constant scores) in patients with nonoperative treatment, RSA with anatomic TH, and RSA with NTH

	Constant score			P value for NTH vs. TH
	Nonoperative (n = 30)	NTH (n = 15)	TH (n = 14)	
1 mo	16.0 ± 6.8	17.9 ± 8.0	18.0 ± 9.1	.975
3 mo	40.6 ± 14.3	39.5 ± 12.0	41.6 ± 16.4	.689
6 mo	51.1 ± 13.8	52.0 ± 10.8	61.8 ± 11.4	.024
12 mo	55.7 ± 12.4	57.5 ± 12.6	66.1 ± 10.2	.054

RSA, reverse shoulder arthroplasty; TH, tuberosity healing; NTH, non-tuberosity healing.

Table VI Results of conservative and surgical treatment with RSA in elderly patients in literature

Study	Treatment	Age, yr	n	Follow-up, mo	Constant score [adjusted]	HRQoL or DLA
Zyto et al ⁶⁴ (1997)	Nonoperative	75	15	50	65 ± 15	
Sirveaux et al ⁵¹ (2006)	RSA	78	15	24	55	
Bufquin et al ⁵ (2007)	RSA	78	41	22	44 [66]	ASES: 9 DASH: 44
Klein et al ³⁰ (2008)	RSA	74.85	20	33.29	67.85	ASES: 68 DASH: 46.85
Gallinet et al ²⁰ (2009)	RSA	74	16	12.4	53	DASH: 37.4
Cazeneuve and Cristofari ⁸ (2010)	RSA	75	35	86	53 [68]	
Young et al ⁶² (2010)	RSA	77.2	10	22	—	ASES: 65 OSS: 28.7
Fjalestad et al ¹⁸ (2010)	Nonoperative	73.1	25	12	65 ± 15	15D: 0.819
Yüksel et al ⁶³ (2011)	Nonoperative	68.2	8/10*	39.1	63/50.6*	
Reitman and Kerzhner ⁴⁵ (2011)	RSA	70	13	33.3	67	
Torrens et al ⁵⁸ (2011)	Nonoperative	72.1	70	—	73.58/59.41 [†] ; 70.83/54.63 [‡]	
Olerud et al ⁴⁰ (2011)	Nonoperative	74.9	29	12/24 [§]	56.8/58.4 [§]	DASH: 35.1/35 [§] EQ-5D: 0.65/0.59 [§]
Olerud et al ⁴¹ (2011)	Nonoperative	77.5	28	12/24	47.7/49.6	DASH: 35/36.9 EQ-5D: 0.66/0.65
Lenarz et al ³⁴ (2011)	RSA	77	30	23	—	ASES: 78 VAS: 1
Valenti et al ⁶⁰ (2012)	RSA	78	30	22.5	54.9	
Garrigues et al ²¹ (2012)	RSA	80.5	10	42	81.5 (Penn)	ASES: 81 EQ-5D: 86.6
Boons et al ² (2012)	Nonoperative	79.9	25	12	60 ± 17.6	SST: 23 VAS pain (100): 25
Gallinet et al ¹⁹ (2013)	RSA	76.9	41	24	60.1/51.7 [¶]	DASH: 31.5/39.8 [¶]
Boyle et al ³ (2013)	RSA	79.6	55	—	—	OSS: 41.5
Grassi and Zorzolo ²² (2014)	RSA	75	15	22	45.7 [58.5]	SPADI: 39 ± 22.1
Sebastiá-Forcada et al ⁴⁸ (2014)	RSA	74.7	31	28.5	56.1	DASH: 17.5 UCLA: 29.1
Obert et al ³⁹ (2016)	RSA	78/79 [#]	41/32 [#]	39/11 [#]	57/50 [#]	DASH: 28/40 [#] SSV: 75/69 [#]
Lopiz et al ³⁶ (2016)	RSA	82	42	32.6	47 [68]	EQ-5D: 69.6 DASH: 29.5 ± 9.2
Longo et al ³⁵ (2016)	RSA	75.5	265 ^{**}	27.8	56.7 ± 7.6 ^{**}	DASH: 39.9 ± 6 ASES: 70.3 OSS: 28.7 ^{**}
Roberson et al ⁴⁶ (2017)	Nonoperative/RSA	71/71	19/20	29/53	—	ASES: 72/72 VAS pain: 1.1/1.5 SF-12: 87/85
Chivot et al ¹⁰ (2019)	Nonoperative/RSA	79.2/77	32/28	32.1/31.8	50.5/56.5 [76.8/82.1]	QuickDASH: 31.2/38.6 SSV: 67/73
Current study	Nonoperative/RSA	85/82	30/29	12	55.7/61.7 [79.6/81.2]	EQ-5D: 0.89/0.92 DASH: 28.8/20.7 VAS pain: 1.6/0.9 EQ-VAS: 64.8/67.1 SF-12, physical; mental: 36.4; 42.9/37.1; 41.6

RSA, reverse shoulder arthroplasty; HRQoL, health-related quality of life; DLA, daily living activities; ASES, American Shoulder and Elbow Surgeons; DASH, Disabilities of the Arm, Shoulder and Hand; OSS, Oxford Shoulder Score; EQ-5D, EuroQol 5 Dimensions; VAS, visual analog scale; SST, Simple Shoulder Test; SPADI, Shoulder Pain and Disability Index; UCLA, University of California, Los Angeles; SSV, Subjective Shoulder Value; SF-12, Short Form 12; QuickDASH, short version of Disabilities of the Arm, Shoulder and Hand.

* Three-part fracture/four-part fracture.

† Nondisplaced/displaced.

‡ Less than 75 years/greater than 75 years.

§ Proximal humeral fracture with 3 fragments at 12 months/24 months.

|| Proximal humeral fracture with 4 fragments at 12 months/24 months.

¶ With/without tuberosity suture.

Retrospective/prospective.

** Meta-analysis of RSA in fractures.

such as implant loosening or scapular notching. This is why we consider 12 months' follow-up sufficient for this objective for this particular population. Regarding the clinical situation, various studies have highlighted that for fractures treated conservatively and those treated with RSA, there is not usually any functional improvement at 1 year following the fractures,^{36,46} and long-term complications related to nonoperative treatment, such as osteonecrosis, have been indicated as rare and well tolerated by other authors.^{2,16} Our main finding in the nonoperative group was that the majority of 4-part fractures, even severely displaced fractures, showed union (97%), although they healed with malpositioning of the humeral head and greater tuberosity.

Study limitations

Our study has some limitations. The standard minimum follow-up period for arthroplasty research is 24 months, and we cannot exclude the fact that a longer follow-up period could detect possible differences in the complication rates of RSA and in the development of future complications including osteonecrosis and post-traumatic arthritis. However, the fact that arthroplasty for a fracture is a very different entity (important observations can be made at 12 months), as well as the advanced age of the patients in this study, means that medical action was directed at achieving the best possible short- and medium-term results. This study sample had a high comorbidity index, which might have resulted in fewer differences in the results of perceived quality of life between the therapeutic options. This means that applying these options could be limited for patients who, although aged 80 years or older, have a better quality of life.

The strength of our study is the prospective randomized design in a well-defined study population in terms of age and fracture, with appropriate procedures to prevent observer bias (blinding) both in the randomization process and in the evaluation of results. In addition, all the surgical procedures were performed by orthopedic surgeons experienced in shoulder surgery.

Conclusion

This is the first study to prospectively compare nonoperative management vs. RSA in the treatment of displaced 3- and 4-part PHFs in this specific population of elderly patients (aged 80 years or older). This study suggests that at short-term follow-up, there are no clinical and HRQoL benefits of RSA over nonoperative treatment except regarding pain perception. The high comorbidity index of our population could limit the extrapolation of these results to patients with significant functional demands.

Disclaimer

This work was supported by a scientific grant for research projects from Mutua Madrileña Foundation (no. 153192014).

The authors, their immediate families, and any research foundations with which they are affiliated have not received any financial payments or other benefits from any commercial entity related to the subject of this article.

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