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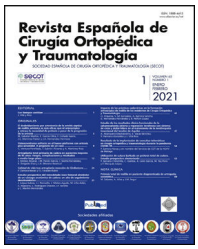

ORIGINAL PAPER

[Translated article] Influence of lateralized reverse shoulder prosthesis design on tuberosity union in proximal humerus fractures

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KEYWORDS
Proximal humerus fractures;
Reverse shoulder prosthesis;
Tuberosity;
Union;
Lateralized design

Abstract
Introduction: Proximal humerus fractures are the third most frequent type of fracture in elderly patients. Nowadays, surgical treatment is indicated one third of the time, being the reverse shoulder prosthesis an option especially in complex comminuted patterns. In this study we analyzed the effects of a lateralized reverse prosthesis in tuberosity union and its relationship with the functional results.
Material and methods: Retrospective case study of patients with proximal humerus fractures treated with a lateralized design reverse shoulder prosthesis with one-year minimum follow-up. Tuberosity nonunion was defined as a radiological concept: absence of tuberosity, distance >1 cm from the tuberosity fragment to the humeral shaft or tuberosity above the humeral tray. Subgroup analysis was performed, group 1 ($n = 16$) tuberosity union vs. group 2 ($n = 19$) tuberosity nonunion. Groups were compared with the following functional scores: Constant, American Shoulder and Elbow Surgeons and Subjective Shoulder Value.
Results: A total of 35 patients were included in this study with a median age of 72.65 years. Post-operative radiographic analysis at one year after surgery revealed a tuberosity nonunion rate of 54%. Subgroup analysis revealed no statistically significant differences in terms of range of motion or functional scores. However, there were differences regarding the Patte sign ($p = 0.03$) which was positive in a larger proportion of patients in the group with tuberosity nonunion.

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Conclusion: Even though there was a large percentage of tuberosity nonunion with the use of a lateralized prosthesis design, patients obtained good results in a similar manner to those found in the union group in terms of range of motion, scores, and patient satisfaction.

PALABRAS CLAVE
Fractura de húmero proximal;
Prótesis invertida;
Tuberosidades;
Consolidación;
Diseño lateralizado

Influencia de las prótesis inversas con diseño lateralizado en la consolidación de las tuberosidades en fracturas de húmero proximal

Resumen
Introducción: El objetivo del estudio es analizar la influencia del uso de un diseño lateralizado de prótesis invertida en la consolidación de las tuberosidades y su correlación con los resultados funcionales.
Material y métodos: Estudio retrospectivo de pacientes intervenidos de fractura de húmero proximal tratados con una prótesis invertida de diseño lateralizado con seguimiento mínimo de un año. Se categorizó como consolidación no anatómica cuando existía: no unión, malunión u osteólisis de las tuberosidades. Más específicamente, dentro del subgrupo se incluyeron: los pacientes con ausencia de tuberosidad, una separación >1 cm del fragmento a la diáfisis humeral, o que la tuberosidad se encontrase por encima de la bandeja humeral. Se realizó un análisis por subgrupos, grupo 1 (n = 16) consolidación anatómica vs. grupo 2 (n = 19) consolidación no anatómica de las tuberosidades, donde los resultados funcionales se analizaron utilizando la escala de Constant, la escala American Shoulder and Elbow Surgeons y el Subjective Shoulder Value.
Resultados: Un total de 35 pacientes se incluyeron en el estudio con una edad media de 72,65 años. En la radiografía postoperatoria al año, la tasa de consolidación no anatómica de tuberosidades fue del 54%. En el análisis por subgrupos no se encontraron diferencias estadísticamente significativas en cuanto a la movilidad y los scores funcionales; en cambio, sí que se encontraron diferencias estadísticamente significativas en cuanto el test de Patte (p = 0,03), siendo positivo en una mayor proporción en el grupo de no consolidación.
Conclusión: A pesar de la alta tasa de consolidación no anatómica de las tuberosidades (54%), los pacientes con consolidación no anatómica obtuvieron unos resultados satisfactorios y similares al grupo de comparación en cuanto a movilidad, *scores* y satisfacción subjetiva del paciente.

Introduction

Proximal humerus fractures are the third most common fracture in elderly patients. Surgical treatment is currently indicated for one third of these fractures, and this figure is increasing.[1,2]

Of the therapeutic alternatives, the reverse shoulder prosthesis as treatment for proximal humerus fractures in elderly patients was relegated to complex patterns. However, in recent years its use has been considerably extended.[3–7] In addition, there has been a progressive shift towards the use of reverse shoulder prostheses with lateralised designs versus the original medialised Grammont design, as they provide lower rates of notching, and an increase in external rotation without increased complications.[8,9]

The main objective of this study was to evaluate tuberosity union when a lateralised reverse shoulder prosthesis is used in the treatment of proximal humerus fractures. A secondary objective was to analyse the influence of tuberosity union vs. nonunion on final function.

Our working hypothesis is that lateralised reverse shoulder prostheses with a large diameter tray (44 mm) impede correct tuberosity closure, causing excessive tension, which will influence union, leading to a lower rate of union than described in the literature and, therefore, a worse functional outcome.

Material and methods

A retrospective study of patients undergoing surgery between 2019 and 2020 for proximal humerus fractures treated with a lateralised design reverse shoulder prosthesis (Comprehensive® Reverse Shoulder System, Zimmer Biomet, Warsaw, Indiana, USA) with a mean follow-up of 14 months. The inclusion criteria were patients with proximal humerus fractures displaced in 3–4 parts diagnosed by radiography in 2 projections (true AP and axial shoulder) and CT, not suitable for reconstruction by osteosynthesis. The exclusion criteria were patients who underwent surgery with a follow-up of less than one year, infection after surgery, or who required revision surgery, intraoperative fractures, and/or

the presence of neurological injury. We performed a preoperative CT scan systematically in all patients whose X-ray showed a proximal humerus fracture and in patients who were candidates for surgical treatment. We established the Neer classification of the fracture,[10] glenoid morphology according to Walch,[11] and measured the degree of glenoid retroversion on the CT scan.

The operations were performed by 2 senior surgeons after an interscalene block, under general anaesthesia, in the beach chair position. A deltopectoral approach was used, placing 4 high-strength sutures (PremiCron®, B. Braun Surgical, Barcelona, Spain), 2 in the greater tuberosity (referencing supraspinatus and infraspinatus), and 2 in the lesser tuberosity (subscapularis). The glenoid was then exposed through a 360° capsular release, placing the glenoid component in the lower third of the glenoid surface with 10° of inferior tilt with the guide provided by the prosthetic company. Three holes were drilled in the humeral diaphysis at the posterior, anterolateral, and anteromedial levels, passing 2 high-strength sutures (PremiCron®, Braun) through the holes. The 135° cementless stem was inserted into the humeral canal through the humeral suture loop. In all cases, a 44 mm onlay-type tray and a polyethylene with a 12° tilt of a variable height according to each case were placed until optimal soft tissue tension was obtained. Optimal tension was defined intraoperatively by palpating the joint tendon (presence of resistance to digital counter-pressure) and the impossibility of dislocation of the polyethylene-glenosphere joint by checking all ranges of motion: anterior flexion, external rotation, internal rotation, and extension, using the smallest thickness of polyethylene available. Finally, both tuberosities were knotted to the humeral diaphysis and then to each other. Specifically, the reference sutures of the supraspinatus/infraspinatus and subscapularis were used to form an ''X'' knot (cross) with the diaphysis (2 supra/infraspinatus ends with the anterolateral end of the humerus, 2 subscapularis ends with the anterolateral end of the humerus, 2 subscapularis ends with the anterolateral end of the humerus and 2 subscapularis ends with the anterolateral end of the humerus), 2 subscapularis ends with an anteromedial end of the humerus, 2 supra/infra ends with posterior end of the humerus, 2 subscapularis ends with an anteromedial end of the humerus), and then loose suture to knot the tuberosities together. The post-surgical protocol is immobilisation with a simple sling for 4 weeks, which can be removed when sitting to mobilise the hand, wrist, and elbow. From the fourth week post-surgery, the patient is referred to the rehabilitation service to begin a protocol of progressive active and passive motion and strengthening of the anterior deltoid.

Postoperative follow-up was at 1 month, 3 months, 6 months, and 1 year. Correct tuberosity union was initially assessed by two independent surgeons and then corroborated by a senior surgeon in the 2 radiographic projections (true AP and axial) in all patients who chose to participate and had been followed up for at least one year. Non-anatomical union (group 2) was categorised as tuberosity nonunion, malunion, or osteolysis. More specifically, the subgroup included patients with an absent tuberosity, a separation >1 cm from the fragment to the humeral diaphysis, or the tuberosity was above the humeral tray (Figs. 1 and 2). The study was approved by the research ethics committee.

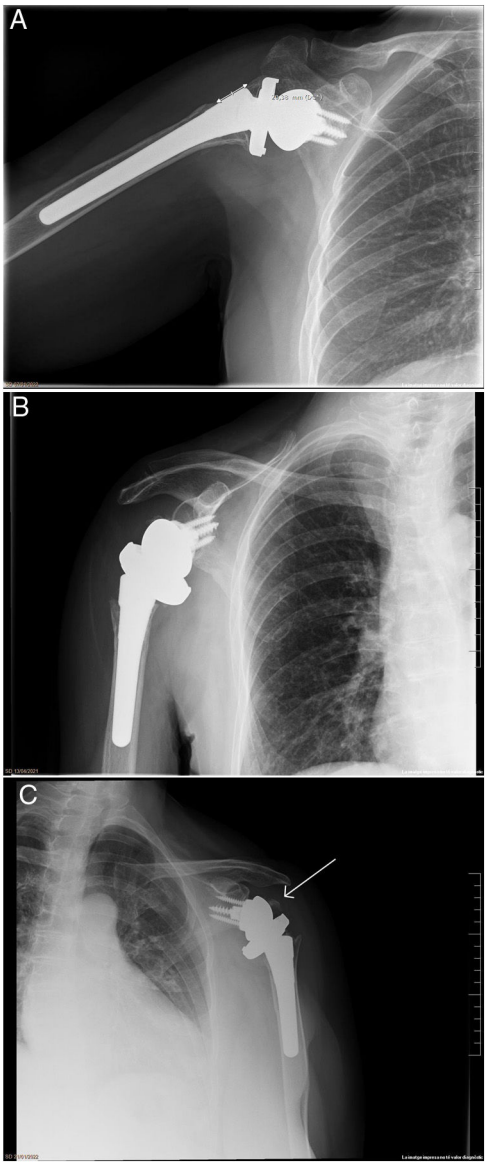

Figure 1 (a) Separation >1 cm from the humeral diaphysis. (b) Absence of tuberosities. (c) Tuberosity above the tray (malunion).

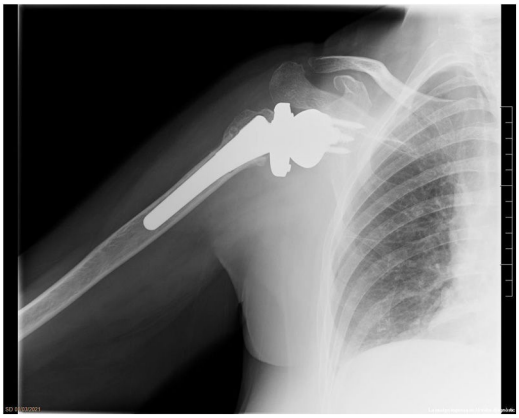

Figure 2 Correct tuberosity union.

Table 1 Baseline characteristics.

	Total ($n = 35$)	Anatomical tuberosity union Group 1 ($n = 16$)	No anatomical tuberosity union Group 2 ($n = 19$)	p
Mean age in years ± SD	72.7 ± 6.2	72.7 ± 6.4	72.6 ± 6.2	.96
Mean time to surgery in days ± SD	7.9 ± 4	10 ± 4	6 ± 4	.01
Laterality				.20
Right	15	5	10	
Left	20	11	9	
Neer fracture type				.49
I	0	0	0	
II	2	1	1	
III	9	5	4	
III + split	3	0	3	
IV	18	8	10	
IV + split	3	2	1	
Walch				.74
A1	18	8	10	
A2	1	1	0	
B1	5	2	3	
B2	11	5	6	
C	0	0	0	
Friedman mean in degrees ± SD	−3.8 ± 5.7	−5.49 ± 5.6	−2.38 ± 5.4	.11
Glenosphere offset				.07
A (.5 mm)	0	0	0	
B (1.5 mm)	31	12	19	
C (2.5 mm)	1	1	0	
D (3.5 mm)	3	3	0	
E (4.5 mm)	0	0	0	
Glenosphere size (mm)				.90
36	33	15	18	
41	2	1	1	
Stem				.76
Standard (length 122 mm)	21	10	11	
Fracture (length 122 mm)	5	3	2	
Mini (length 83 mm)	9	4	5	
Tuberosity suture				.50
Greater tuberosity	3	2	1	
Greater tuberosity + lesser tuberosity	31	14	17	
Lesser tuberosity	1	0	1	

SD: standard deviation.

The initial sample was 52 patients, of which 17 were excluded (2 with postoperative infection requiring 2-stage replacement, one for preoperative nerve injury in the context of brachial plexus injury due to pulling, 10 for loss to follow-up, and 4 for using another prosthetic design). Finally, 35 patients with a mean age of 72.7 years were included. The mean time to surgery was 7.9 days.

The functional outcomes recorded for the analysis were assessed by 2 surgeons independent of the service (without the presence of the main surgeon). On the one hand, Constant,[12] American Shoulder and Elbow Surgeons (ASES),[13] and the Subjective Shoulder Value (SSV)[14] scores were recorded. On the other, range of motion (in degrees), the presence of Patte sign and lag sign were recorded. The Patte test is performed based on an abduction of 90° in the scapular plane with 90° of elbow flexion. The patient is asked to perform a counter-resisted external rotation. The test is considered positive with a force of less than 4 according to the Medical Research Council classification. The lag test is performed with the elbow flexed at 90° and the shoulder elevated 20° in the scapular plane, the arm is brought into maximum external rotation. The patient is asked to hold the position while the examiner releases the wrist. A positive test is defined as an internal rotation greater than 10°.[15]

Strength was assessed with a manual dynamometer, in 5 consecutive shots, measuring in kilograms, as the only parameter, the anterior flexion of the shoulder with the elbow in extension. The arithmetic mean of the 5 results was then calculated for analysis and conversion to Constant.

The minimum necessary sample calculated by Stata 16.0 is 16 patients per group, accepting an alpha risk of .05 and a beta risk of less than .2 to find a difference equal to or greater than 5 units in the Constant score. A common standard deviation (SD) of 5 is assumed. Data are presented as median and interquartile range. Categorical variables are represented by their frequency. Differences in continuous variables between patient categories were analysed using the Mann–Whitney *U*-test. Fisher's test was used to analyse differences in proportions. Stata 16.0 was used for all tests, setting a p value <.05 as statistically significant.

Results

Demographics

A total of 35 patients were included in the study. The mean age was 72.7 years (SD ± 6.2), mean time to intervention was 7.9 days (SD ± 4), 57% had left-sided involvement. Sixty per cent of the fractures were classified into 4 parts according to Neer's classification (Table 1).

Radiological and clinical assessment

The comparison groups were similar in baseline characteristics; differences were only found in time to surgery, which was slightly longer in group 1. The most frequent glenoid type according to the preoperative CT scan was Walch type A1, at 51% of cases. The mean retroversion was −3.8° (SD ± 5.66). With regard to the characteristics of the prostheses implanted, a type B offset (lower offset +1.5 mm) was used in 88% of cases, and the chosen size was 36 mm diameter 91% of the time; the standard lateralised design stem (122 mm) was the most commonly used in 60% of patients. Intraoperatively, the tuberosities were sutured in 88% of cases according to the surgical notes, with only 4 cases remaining without complete closure of the 2 tuberosities due to excessive tension (impossibility of reducing the tuberosity below the humeral tray). In 3 only the greater tuberosity could be sutured and in one the lesser tuberosity to the humeral diaphysis. The mean Constant score was 56.5 (SD ± 13.3), the mean ASES was 71.2 (SD ± 23.5) and the SSV was 8.2 (SD ± 1.6). The mean range of mobility was 121.1° (SD ± 32.4) of anterior flexion, 96.6° (SD ± 20.3) of abduction, 19.7° (SD ± 14.7) of external rotation and an internal rotation up to T12 in 31% of cases. A negative lag sign was observed in 83% of patients and a negative Patte test in 77%. At one year follow-up, 54% of patients had no anatomical union (Table 2). More specifically, 5/19 (26%) were cases of nonunion, 5/19 (26%) were cases of malunion, and 9/19 (47%) were cases of osteolysis.

Table 2 Global functional results.

Mean Constant ± SD	56.5 ± 13.3
Mean ASES ± SD	71.2 ± 23.5
Mean SSV ± SD	8.2 ± 1.6
Mean anterior flexion (°)	121.1 ± 32.4
Mean abduction (°)	96.6 ± 20.3
IR	
SI	9
Waist	3
Scapula	1
Thigh	1
Buttock	10
T12	11
Mean ER (°)	19.9 ± 14.7
Lag sign ER (%)	
Yes	6
No	29
Patte ER (%)	
Yes	8
No	27

ASES: American Shoulder and Elbow Surgeons; ER: external rotation; IR: internal rotation; SD: standard deviation; SI: sacroiliac; SSV: Subjective Shoulder Value.

Analysis by subgroup

A subgroup analysis was performed comparing patients with reverse shoulder prosthesis with tuberosity union (group 1, $n = 16$) versus patients without anatomical union (group 2, $n = 19$) and correlated with the results of the different scores, range of motion (anterior flexion, abduction, external rotation) and the presence of lag and Patte signs.

As shown in Table 3, no statistically significant differences were found for scores and range of motion. However, statistically significant differences were found between the groups in terms of the Patte test, where in group 1 no patient had a positive Patte sign compared to 7 in group 2 ($p = .03$). In the union group, 2 patients had a positive lag sign versus 4 in the group without anatomical union ($p = .5$).

Discussion

In this study, we obtained a low rate of tuberosity union (54%), slightly lower than that described in the literature (64%–84%)[16–23]; only Chun et al.[24] report a lower union rate (34%).[24] This difference, according to our initial hypothesis, may be because of the prosthetic design used: lateralised design with a large diameter tray, the smallest size available being 44 mm. This large diameter may make it difficult to close the tuberosities, leaving them with excessive tension and thus compromising union when compared to other prosthetic designs (Fig. 3). This difference in tray size is remarkable considering the increase in surface area involved. For example, the difference in surface area (cm^2) between the 32 mm Humelock Reversed® tray (surface area 8 cm^2), from Fx Shoulder Solutions, and the 44 mm tray

Table 3 Comparison of functional outcomes in patients undergoing reverse shoulder prosthesis surgery with vs. without anatomical tuberosity union.

	Reverse shoulder prosthesis with anatomical tuberosity union ($n = 16$)	Reverse shoulder prosthesis without anatomical tuberosity union ($n = 19$)	p
Median Constant ± SD	57.5 ± 11.5	55.7 ± 15	.70
Mean ASES ± SD	70.4 ± 25.1	71.8 ± 22.8	.87
Mean SSV ± SD	8 ± 1.4	8.4 ± 1.7	.50
Mean anterior flexion (°)	126.6 ± 31.6	116.6 ± 33.1	.37
Mean abduction (°)	101.3 ± 25.6	92.6 ± 14	.22
IR			.70
SI	5	4	
Waist	2	1	
Scapula	0	1	
Thigh	0	1	
Buttock	5	5	
T12	4	7	
Mean ER (°)	18.8 ± 15.1	20.8 ± 14.7	.69
Lag sign RE			.50
Yes	2	4	
No	14	15	
Patte ER			.03
Yes	1	7	
No	15	12	

ASES: American Shoulder and Elbow Surgeons; ER: external rotation; IR: internal rotation; SD: standard deviation; SI: sacroiliac; SSV: Subjective Shoulder Value.

Table 4 Dimensions of the trays of different prosthesis models.

Manufacturer	Model	Tray diameter (mm)	Surface (cm^2)
Arthrex	Univers Revers™ Modular Glenoid System	36/39/42	5.3/11.9/13.8
DePuy Synthes	Delta Xtend™	38/42	11.3/13.8
Exatech	Equinoxe®	38/42	11.3/13.8
Fx Shoulder Solutions	Humelock Reversed®	32/36/40	8.0/11.9/12.6
Lima Corporate	SMR Reverse	40/44	12.6/15.2
Stryker	Tornier Ascend Flex®	40	12.6
Zimmer Biomet	Comprehesive® Reverse Shoulder System	44	15.2

Measurements obtained from the technical data sheet of each product.

(surface area 15.2 cm^2) Comprehensive® Reverse Shoulder System model, from Zimmer Biomet, corresponds to a 90% increase (Table 4).

Another cause of nonunion could be the type of knotting used and not routinely using humeral head graft. The type of knotting described in the material and methods is simple and reproducible, but it is not that described by other authors with a higher rate of union. Boileau et al. describe a specific knotting technique[25] using humeral head graft with a union rate of up to 84%. Similarly, Cuff and Pupello[19] and Garofalo et al.[22] used bone graft and reported a union rate of 83% and 75%, respectively. However, another aspect to consider is that we used cementless stems in 32/35 (91%) of the cases. It has been reported in the literature that the proportion of osteolysis of the tuberosities is more frequent when cementless stems are used.[26,27] However, the level of evidence in the studies is low and our sample size prevents us from concluding causality.

Another reason for the lower union rate in the study may be the criteria used. Torrens et al.[16] described 3 requirements for tuberosity union to be considered when: (1) the greater tuberosity visible in the anterior–posterior view with the arm in neutral position; (2) the top of the greater tuberosity at the level of the polyethylene of the humeral

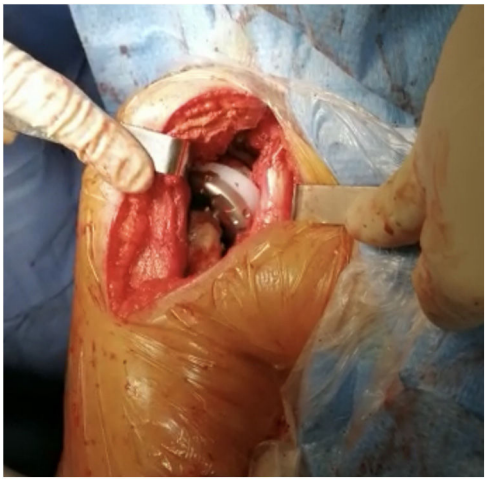

Figure 3 Impingement of the humeral tray (44 mm) with the conjoined tendon.

component, and (3) the top of the greater tuberosity at the level of the epiphyseal part of the prosthesis. We were more restrictive, also considering that the separation between the tuberosities and the humeral diaphysis could not be greater than 1 cm. We believe that this restriction may have contributed to finding a lower union rate than the one described, because a situation can occur in which there is a tuberosity in the epiphysis of the prosthesis, but without contact with the diaphysis.

It remains a matter of controversy whether final functionality depends on the tuberosity union. Regarding range of motion, Gallinet et al.[28] and Garofalo et al.[22] found statistically significant differences between the two groups, in favour of the union group. Chun et al.[24] found differences only in abduction and external rotation in the two groups, being greater in the tuberosity union group. In our study, although it appears that the union group has a better range of motion, statistical significance was not reached. We only found statistically significant differences between the two groups in terms of Patte test positivity. This finding is important, because patients with reverse shoulder prostheses with no strength or ability to maintain the arm in external rotation find it more difficult to perform basic activities such as combing their hair (also reflected in the ASES questionnaire).

As for the functional scales, the Constant was slightly higher in the anatomical union group, but not statistically significant, as in the studies by Sebastiá-Forcada et al.,[20] Chun et al.,[24] and Torrens et al.[16] In terms of ASES score, we found no statistically significant differences when comparing the 2 groups, nor did Cuff and Pupello[19] or Chun et al.[24]

An important aspect of our study is that we assessed a single lateralised prosthetic design, unlike other studies that evaluate different prosthetic designs in the same evaluation group.[28] Despite having a low rate of anatomical tuberosity union, the final functional results were satisfactory. Excessive lateralisation at both the glenoid and humeral levels gives us an acceptable union rate and functional results similar to other prosthetic designs with less lateralisation, therefore it does not appear to be a determining factor for final function. There is currently a trend towards combined designs with lateralised glenoid and medialised inlay or flushlay humeral component (Tornier Perform Humeral System™, Stryker, Kalamazoo, Michigan, USA). Because our study compared a fully lateralised design with similar results to those published with medialised designs, this trend is questioned as it appears that the functional outcome may be dependent on other components, such as soft tissue tension and deltoid moment, rather than on the prosthetic design.

This study has several limitations. The first is the retrospective nature and the sample size. It is similar to studies published in the literature and has the strength of a homogeneous sample in terms of the prosthetic model. Another limitation is that there is no clear consensus on the definition of anatomical tuberosity union; we attempted to minimise this limitation by incorporating more restrictive radiological parameters. Another limitation is that 4 patients were included in the radiological evaluation at 1 year of union in whom one of the 2 tuberosities could not be repaired intraoperatively. This may result in a selection bias, since only one of the 2 tuberosities can be assessed for union on radiographic analysis. Finally, radiographic assessment of tuberosity union in 2 projections has its limitations (especially the interpretation of union of the lesser tuberosity); nevertheless, in cases where there was no consensus among the investigators, a CT was performed to minimise this potential bias.

Conclusions

In this study we observed a high rate of non-anatomical tuberosity union (54%: 26% cases of nonunion, 26% cases of malunion, and 47% cases of osteolysis) when using a lateralised reverse shoulder prosthesis design (135) with a large tray size (44 mm). Differences were found in terms of Patte test, with a worse result in the nonunion group; nevertheless, similar results were obtained to the comparison group in terms of motion, scores, and subjective patient satisfaction.

Level of evidence

Level of evidence IV.

Funding

No funding was received for this work.

Conflict of interests

The authors have no conflict of interests to declare.

Right to privacy and informed consent

The authors have obtained informed consent from the patients and/or subjects referred to in the article. This document is held by the corresponding author.

Ethics committee approval

Research approved by Hospital Universitari Sant Joan de Reus.

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