



Early outcomes of locked noncemented stems for the management of proximal humeral fractures: a comparative study



Alberto Jorge-Mora, MD, PhD^{a,b,*}, Samer Amhaz-Escanlar, MD^b,
Sabela Fernández-Pose, MD^b, Cristina Lope-del-Teso, MD^b,
Jesús Pino-Mínguez, MD, PhD^b, José Ramón Caeiro-Rey, MD, PhD^b,
Juan Pretell-Mazzini, MD^c, Rodolfo Gómez, MD, PhD^a

^aMusculoskeletal Pathology Group, Institute IDIS, Santiago University Clinical Hospital, Santiago de Compostela, Spain

^bDivision of Traumatology, Santiago University Clinical Hospital, Santiago de Compostela, Spain

^cMusculoskeletal Oncology Division, Department of Orthopedics, Miller School of Medicine, University of Miami, Miami, FL, USA

Background: Proximal humeral fractures are common and a major concern in public health resources utilization. There is an increase in the use of reverse total shoulder arthroplasty (RTSA) as an option for complex fractures in the elderly. The complexity of the technique in RTSA is increased because of the fracture. To find an advantage of locking stems in RTSA for the treatment of proximal humeral fractures, we designed a comparative study between fracture-dedicated locking stems vs. cemented stems.

Materials and methods: We retrospectively studied 58 patients treated with an RTSA after a fracture. We compared how the implant design and the tuberosity consolidation affects patient outcome through measuring range of motion and the Constant score.

Results: The groups were similar in age, sex, time to surgery, and Constant score in the uninjured side. Patients treated with a dedicated locking noncemented stem performed better, with an increased Constant score ($P > .05$) and reached more mobility with no statistical significance. We found that 13 of the 24 fractures (54%) treated with a cemented stem consolidated, and 26 of 34 tuberosities (76%) healed in the noncemented locked stems. Patients with tuberosity consolidation acquired better range of motion and Constant scores ($P < .05$).

Conclusions: A dedicated stem improves tuberosity healing and increases outcomes seen in Constant scores. Tuberosity consolidation is a main goal when treating proximal humeral fractures with RTSA.

Level of evidence: Level III; Retrospective Cohort Design; Treatment Study

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*Reprint requests: Alberto Jorge-Mora, MD, PhD, Musculoskeletal Pathology Group, Institute IDIS, Santiago University Clinical Hospital, Avda. Choupana s/n, 15706 Santiago de Compostela, Spain.

E-mail address: aljmora@gmail.com (A. Jorge-Mora).

Proximal humeral fractures are one of the most common fractures in adults, with an incidence of 5.7% of all fractures.¹⁰ Most of these fractures are closed.⁹ A progressive increase in the incidence of these fractures has been described, particularly in older patients,⁸ with an incidence exceeding 10%

in patients between 50 and 90 years of age.¹¹ Even in those patients with acceptable radiologic and functional outcomes, perceived quality of life is diminished in these patients 2 years after the injury.²⁹ The burden of proximal humeral fractures for the health system is elevated, with costs estimated in the French National hospital database as high as €34 million for initial management and €52 million for rehospitalization.²⁶

Use of reverse total shoulder arthroplasty (RTSA) for the treatment of proximal humeral fractures has increased in recent years, with dedicated designed stems for fractures.^{25,35} Recent studies postulate that the management of these fractures using an acute RTSA replacement is a cost-effective solution²⁷ for some patients. Outcomes obtained with proximal humeral fractures treated with RTSA differ from those obtained for primary replacement, mainly because the situations are different. We can expect from elective procedures a low complication rate with more than a 90% prosthesis survival in 10 years,¹² but complications increase when we search for RTSA in fracture management, with series describing displacement of tuberosities in more than 50% of the patients, glenoid loosening in more than 60%, heterotopic calcifications in nearly all patients, and tuberosity nonunions reported in 38%.^{6,7,18} A recent review by Boileau¹ focused on the study of complications and reinterventions in RTSA described a 10% postoperative complication rate in their patients compared with a 20% complication rate described in the literature. These different complications can negatively affect the outcomes of the RTSA.⁶

To perform an RTSA for a proximal humeral fracture, several complications should thus be taken into account to optimize the final outcome.^{1,37} Instability is considered the main postoperative complication cause of reinterventions after an RTSA,¹ but there are also several complications associated with fracture management, including soft tissue injury, nonunion or malunion of the tuberosities, poor bone stock in the glenoid, and metaphyseal bone defect, among others.

Recent publications have highlighted the importance of tuberosity healing when an RTSA is used for the management of proximal humeral fractures^{16,22} and how the addition of small gestures, such as tuberosity grafting and proper suture technique, improve patient outcomes.²² Moreover, the consolidation and position of the tuberosities is essential to achieve good function and to minimize the presence of complications.^{2,14,15,20,33} In fact, in hemiarthroplasties for proximal humeral fractures, malposition of the tuberosity increases fat infiltration in rotator cuff muscles, leading to a diminished function.^{19,20} In line with this, tuberosity management is the key step to obtain a favorable outcome in proximal humeral fractures treated with joint replacement.^{2,14,15,20,33}

Previous studies^{19,20} have also revealed that proximal humeral fractures with proximal bone defects have worse outcomes than those with proper bone stock. Recent publications have established that tuberosity management is the key to obtaining a favorable outcome in proximal humeral fractures treated with arthroplasty and that the consolidation and position of them is essential to achieving good function and minimizing complications.^{2,14,15,20,33}

Most of the recent designs for elective RTSA favor metaphyseal fixation, and we can see an increasing trend in the use of short, noncemented stem implants with similar outcomes.^{23,28} Achieving metaphyseal support for 3- and 4-part humeral fractures is almost impossible, and we have to choose another fixation strategy. Early designs selected poly-(methyl methacrylate) for the fixation of the implant; however, it can interfere with tuberosity healing if a proper technique is not applied,^{17,33} and noncemented fracture stems and modular stems are now available.

Evidence supporting a benefit of one option over others is lacking,³⁶ and we cannot find an increased risk of long-term periprosthetic fracture associated with noncemented stems.³⁴ The use of locked stems is a reasonable option to maintain fixation until metaphyseal integration in a fracture situation.⁵ It prevents the interposition of poly(methyl methacrylate) between the prosthesis and the tuberosities and allows surgeons to modify the definitive position of the implant in case of a complication.²⁸ This would improve implant height and version to obtain the best stem position, confirmed by direct vision and x-ray imaging.

In our institution, since 2015, we have moved from a standard cemented stem to a fracture-dedicated locked stem for the management of proximal humeral fractures treated with RTSA. We currently use a fracture-dedicated locked stem with metaphyseal plasma hydroxyapatite coating and a titanium cage to increase tuberosity offset and graft fixation and optimize tuberosity healing and patient function.

To demonstrate the advantage of the new implant, we performed a retrospective comparative study of the complication rate and outcomes of both replacement methods in our institution to find out whether fracture-dedicated locking stems improve the management of proximal humeral fractures compared with fracture-nondedicated cemented stems and how tuberosity healing affects the outcome.

Materials and methods

Patients

The study included all patients operated on between January 2012 and January 2017 in the orthopedic division who were treated with an RTSA for an isolated proximal humeral fracture. These patients were divided in 2 groups: the cemented group received a cemented stem (Arrow Shoulder Fracture & Anatomic Shoulder Reconstruction; FH Ortho, Chicago, IL, USA), and the noncemented group received a noncemented locked stem (Humelock II; Fx Solutions, Viriat, France). The study excluded patients with concomitant injuries, and the functional study excluded patients who died within the first 6 months (we accepted this point as a primary functional stability control) and patients with a follow-up of less than 6 months.

Surgical procedure

Patients were operated on in the beach chair position using a radiolucent table and treated with standard prophylactic antibiotics

(cefazolin, 2 g 30 minutes before the incision, and 3 doses every 8 hours over the next 24 hours). To diminish septic complications, the skin was systematically cleaned with a chlorhexidine scrub, and the anatomic area was draped. Afterwards, the skin was prepared with alcohol-chlorhexidine 2%. After it dried, the skin was treated again to minimize septic complications. This exhaustive protocol was used to prevent infection in patients immobilized in our ward for more than 24 hours. Then we complete the surgical field before surgical incision.

Fractures were treated by surgeons specialized in upper limb trauma. Deltpectoral or superolateral approaches (extended deltoid-splitting) were used depending on surgeon preferences. Next, the humeral head was taken out, the tuberosities were marked with a suture, and the glenoid was prepared. We systematically performed a biceps release and tenodesis if the tendon was attached to its origin.

The manufacturer's protocol for glenoid component fixation was followed for both designs (Arrow Shoulder Fracture & Anatomic Shoulder Reconstruction and Humelock II). When the metaglene was fixed, the definitive glenosphere was implanted. We continued with the preparation of the humeral stem following the manufacturer's recommendations for stem fixation. Before definitive fixation, the tuberosity osteosuture was prepared. We used the technique described by Boileau et al³ to fix the tuberosities after definitive reduction. In cemented stems, we were aware to prevent cement from reaching the fracture area, and we added autologous graft from the humeral head under the tuberosities. In noncemented locked stems, a titanium cage screwed to the stem was used to fix the graft obtained and to increase tuberosity offset to its anatomic position.

The cinematics and stability of the prosthesis was confirmed with fluoroscopy. In those patients with an intact rotator cuff, part of the supraspinous was resected to prevent impingement. Drains were not used routinely. Patients usually were discharged within the next 48 hours.

Follow-up

Patients started passive full range of motion (ROM) from the very beginning, depending on pain. The surgical site was reviewed after 2 weeks, and stitches were removed. Then, passive assisted ROM was started under the control of a physiotherapist.

Follow-up evaluations in our outpatient clinic were made at 6 and 12 weeks and at 4, 6, and 12 months with x-ray controls at every assessment (Figs. 1 and 2).

ROM and complications were registered. The Constant score in the affected and in the uninjured limb were measured.

Design and statistical analysis

Data collected from our prospective register were age, sex, time to surgery, approach, fracture classification, ROM, tuberosity consolidation, and Constant score. Complications recorded included infection (defined as any need for antibiotic use, except prophylactic, due to arthroplasty complication), instability (defined as any episode of luxation), and tuberosity consolidation (defined as the consolidation seen in x-ray images with continuity with the shaft). Two of the authors (A.J-M. and S.A-E.) reviewed the x-ray images to confirm consolidation, and only in the case of agreement was the tuberosity considered consolidated (Fig. 2).

We defined the primary objective as the difference in tuberosity consolidation between groups. Secondary objectives were differences in functional outcomes and complications between groups. We also performed a comparison between patients with and without tuberosity consolidation.

To prevent bias due to the learning curve, we compared the first half of cemented and noncemented prosthesis with the second half. The statistical analysis was performed with GraphPad Prism 6 software (GraphPad Software, La Jolla, CA, USA). We completed a descriptive analysis. To confirm that the groups were comparable, we performed an unpaired Mann-Whitney test with the Welch modification or a χ^2 test, depending on the variable. Different variables were compared in the nonaffected side between groups: age, sex, time to surgery, and Constant score. Differences in the consolidation rate between groups were calculated with a χ^2 test, and odds ratios were calculated. We compared the ROM and Constant scores between groups by applying an unpaired Mann-Whitney test. A *P* value of <.05 was considered significant.

Results

Patients

Among all of the patients who underwent an RTSA surgical procedure in the orthopedic division, 61 patients met the inclusion criteria. However, 3 patients were excluded from the

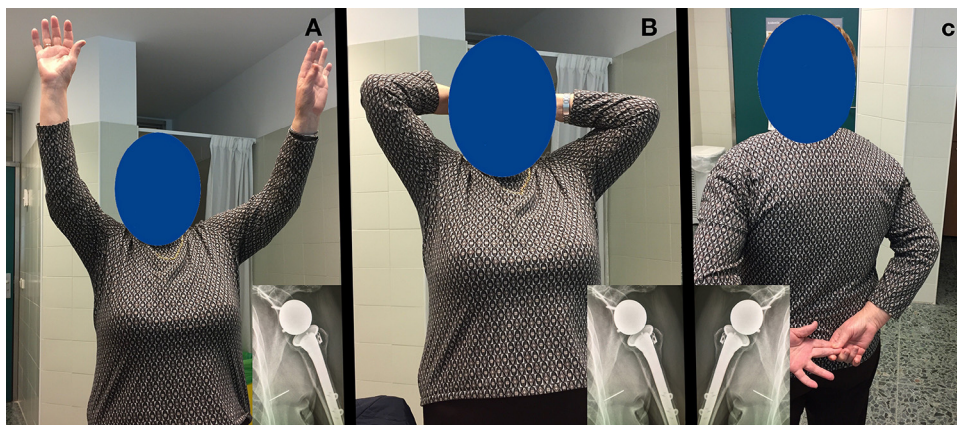


Figure 1 Function is shown in a patient with a proximal humeral fracture treated with reverse total shoulder arthroplasty. The postoperative anteroposterior radiograph is shown in the inferior corner of each image.

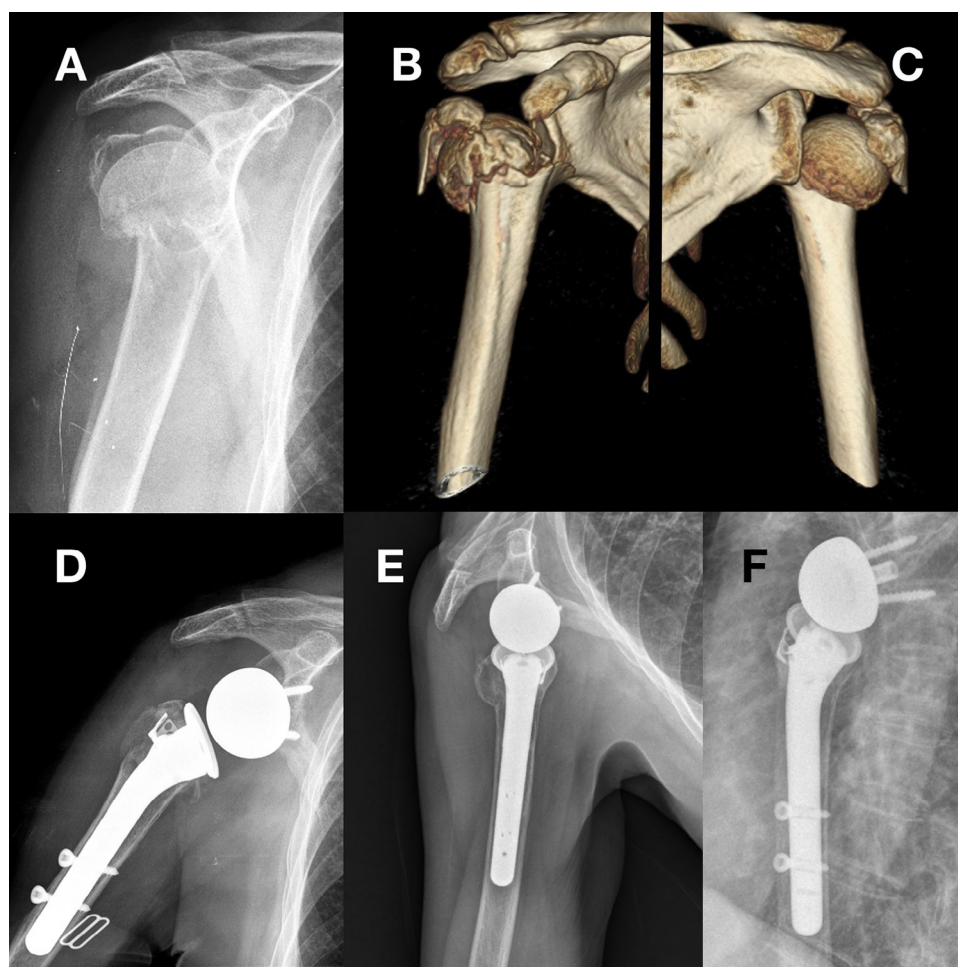


Figure 2 A valgus 4-part impacted fracture in is seen in (A) x-ray and (B and C) 3-dimensional computed tomography images. (D, E, and F) The reconstruction with healed tuberosities is shown in anteroposterior, axillar, and lateral x-ray projections, respectively.

Table I Description analysis for both groups

Group	No.	Age (yr)	<i>P</i> value	Sex, No.		<i>P</i> value	Time to surgery (d)	<i>P</i> value	Constant	<i>P</i> value	Approach		<i>P</i> value
				M	F						D	SL	
Cemented	24	77.6	.39	0	24	.24	8.7	.24	74	.09	22	2	.5
Noncemented	34	76.5		3	31		7.8		76		32	2	
Consolidation													
Yes	39	76.5	.26	2	37	.46	8.3	.43	75,9	.35	36	3	.43
No	19	77.9		1	18		7.9		74,4		18	1	

M, male; *F*, female; *D*, deltopectoral; *SL*, superolateral.

analysis because 2 died in the first 6 months and another patient was lost to follow-up in the first month. Finally, 58 patients were included in the study, 24 in the cemented group and 34 in the noncemented group with locked stems. All patients had a 3- or 4-part fracture or a split of the humeral head. The mean follow-up was 26 months (range, 6-56 months).

The characteristics of each group are described in Table I. Statistical analyses revealed that the groups were similar ($P > .05$) in age, sex, days to surgery, and selected ap-

proach. Constant scores in the nonaffected limb were also comparable, at 76 points for noncemented vs. 74 points for cemented stems ($P > .05$).

Cemented vs. noncemented stems

Consolidation occurred in 13 of the 24 fractures (54%) treated with a cemented stem and in 26 of the 34 fractures

Table II Summary of the Constant score and range of motion in the patient groups

Group	CS*	Difference CS	ABD	FLX	IN ROT	EX ROT
Cemented	53 (12)	16 (10)	92 (35)	92 (32)	35 (6)	17 (12)
Noncemented	60 (12)	20 (9)	104 (32)	106 (34)	36 (11)	23 (13)
	CS*	Difference CS*	ABD*	FLX*	IN ROT*	EX ROT*
Consolidation						
Yes	63 (10)	9 (6)	115 (22)	115 (22)	38 (6)	28 (8)
No	45 (8)	24 (7)	68 (32)	69 (31)	31 (12)	5 (7)

CS, Constant score; ABD, abduction; FLX, forward flexion; IN ROT, internal rotation; EX ROT, external rotation.

Data are shown as mean (standard deviation).

* $P < .05$ between groups.

(76%) treated with an noncemented locked stem. Although the percentage of consolidation in the noncemented group was greater than in the cemented group, the increase was not statistically significant (odds ratio, 0.36; 95% confidence interval, 0.12-1.12). Similar results were obtained using χ^2 analysis ($P = .07$). Nonetheless, the evaluation of articular function and range of movement (Table II) revealed that cemented and noncemented groups were significantly different, with the noncemented group exhibiting better Constant scores. In the locking-stems group, we also found better, but not statistically significant, outcomes in abduction ($P = .21$), flexion ($P = .15$), and external rotation ($P = .06$).

RTSA is a complex technique. As a result, we decided to test whether the surgeon's learning curve could affect the articular function and, therefore, the differences between the groups. Thus, we compared the outcomes in each group obtained in the first half of the operations (through the difference in the Constant score between the injured and uninjured arm) with the second half of the operations. The results obtained showed no difference between first and second half of the operations in the cemented ($P = .36$) and noncemented groups ($P = .054$).

Tuberosity consolidation and surgery outcomes

Consolidation and position of the tuberosities is believed to be essential to achieve good function and to minimize the presence of complications in the treatment of proximal humeral fractures with an RTSA.^{2,14,15,20,33} Accordingly, we compared the outcomes of the operations where patients had tuberosity consolidation with those with nonunion or full resorption. The Constant scores and the evaluation of all the studied movements were significantly better in the operations with consolidated tuberosities, as summarized in Table II. Moreover, the differences in the Constant scores between the injured and noninjured arms were significantly lower in the patients with healed tuberosity than in those with unhealed tuberosities (Table II).

Complications

During the study period, luxation of the prosthesis occurred in 1 patient in the noncemented group after a low-energy trauma. This patient had a fracture with metaphyseal extension, and tuberosity reconstruction was not possible because of bone comminution and resorption. This patient underwent 2 more operations, first to change components and then to perform a latissimus dorsi transfer, but the subluxation was not resolved. In the last follow-up, this patient had a pseudoparalysis with no pain, and he declined more interventions.

Other complications in the noncemented group included 1 early infection by *Staphylococcus aureus*. The patient was treated with débridement, change of mobile components, and antibiotics. There were no signs of infection at 1 year after the last intervention, and values for C-reactive protein and the erythrocyte sedimentation rate were within normal reference ranges. Another patient sustained a proximal periprosthetic fracture in the metaphyseal-diaphyseal junction that was treated with the locking stem with 1 cerclage. The fracture healed uneventfully. These complications did not reach significance between the groups.

From the 61 patients operated during the study period, 2 died within the first 6 months, 1 in the second year after the prosthesis was implanted, and another after 4 years, with no relation to the operation or complications of it.

Discussion

In an effort to improve the outcome of proximal humeral fractures treated with an RTSA, we have evolved the treatment of these fractures in our institution and have added together different concepts (Fig. 3): First, we emulated the technique from Boileau et al³ for tuberosity reconstruction to improve consolidation; second, we tried to put aside cement in primary stabilization to prevent fibroblastic response and nonunion.³² We also used a titanium cage fixed to the stem to prevent graft motion and migration, while we increased the tuberosity offset to improve deltoid function through an increase in the wrapping angle.^{1,28} We also chose a diaphyseal

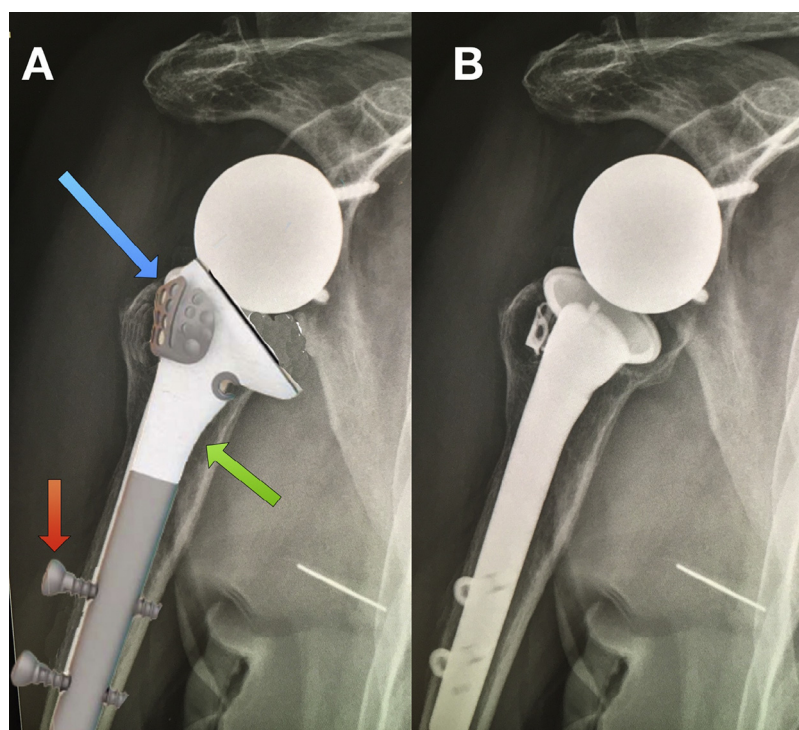


Figure 3 (A) A reconstruction demonstrates our standard methodology to increase tuberosity healing. The *blue arrow* shows the titanium cage used to increase tuberosity offset and graft fixation. The *green arrow* points to the hydroxyapatite coating in the metaphyseal area. The *red arrow* points to the screws used for primary fixation of the stem. (B) X-ray of anteroposterior view of a consolidated fracture treated with a reverse total shoulder arthroplasty. All structures described in part (A) (the cage, metaphyseal area, and locking screws) are easily identified. (For interpretation of the references to color in this figure legend, the reader is referred to the web version of this article.)

locking stem to increase initial micromotion^{13,30,31} in the first weeks to facilitate healing and protect fixation until metaphyseal integration through the hydroxyapatite-coated metaphysis. We believe that with this maneuver, long-term tuberosity resorption due to diaphyseal fixation is avoided.¹ The locking stem also provides the chance to modify the stem without difficulty if there is any problem during surgery, and the use of 2 locking screws maximizes stability in wide diaphysis and is the rule in older patients.

By combining these techniques, we have reached a consolidation rate of 76%, and this increase in the consolidation rate increased significantly the Constant score of our patients. Obert et al²⁸ demonstrated the security and utility of the same locked stem in 4-part fractures treated with a hemiarthroplasty and reported no complications related to the locked stem in a prospective study with a minimum of 2 years of follow-up.

Our results demonstrated a decrease not only in external rotation in patients without tuberosity healing but also in the remaining ROM that generated a fall in the Constant score of 18 points, with clinical and statistical significance ($P < .05$). The only case of luxation was associated with a poor tuberosity reconstruction, which makes even more remarkable the importance of tuberosity reconstruction.

Recent publications underline the importance of tuberosity integration and consolidation in the treatment of proximal

humeral fractures with an arthroplasty.¹⁶ The use of dedicated fracture stems obtained a consolidation rate of approximately 75%.¹⁷ There is strong evidence that supports a key role of tuberosity consolidation in reverse arthroplasty.²⁴ This is supported by our outcomes, with a difference in the Constant score of 18 points ($P < .05$) between patients with and without consolidated tuberosities. We agree with other authors who underline that tuberosity reconstruction is essential and that a dedicated fracture stem when performing an arthroplasty for the treatment of proximal humeral fractures may help to achieve these goals.^{4,20}

Noncemented and cemented stems seem to have similar outcomes,^{23,36} but from a fracture perspective, we believe the use of cement to fix the stem can affect fracture consolidation and promote a fibroblastic response that impairs healing.³² Recent data suggest that surgeons should avoid the entry of cement into the tuberosities to facilitate consolidation.³³ Tuberosity healing in our series was increased in noncemented stems, with an odds ratio of 0.36 (95% confidence interval, 0.12-1.12) that did not reach statistical significance.

There is enough evidence obtained from studies performed in elective RTSA replacement that we believe that if we use diaphyseal press-fit stems in fracture replacement, we can induce a proximal stress shielding area that can lead to tuberosity resorption.²¹ All of these reasons encouraged us to decide to choose a locked stem to provide temporary

diaphyseal fixation until tuberosity healing. The stem has a plasma spray coating in the metaphysis to improve proximal osteointegration and to provide a favorable environment for tuberosity healing and achieve metaphyseal fixation in the context of a fracture. In our series, we have not seen tuberosity resorption during follow-up in consolidated patients. It is true that follow-up is short and variable, and we cannot affirm that the prosthesis design will avoid this resorption in the future.

As previously demonstrated, the use of dedicated fracture stems increased tuberosity union²⁴ and function. With the described changes in the stem design, we have increase tuberosity healing with an odds ratio of 0.36 (95% confidence interval, 0.12-1.12) that favors noncemented stems, which even though not statistically significant is clinically relevant, with an increase in the Constant score that is statistically significant ($P < .05$). We also have a more modular implant because we can change depth and version of the implant without exchanging the definitive stem. We have not recorded any complication related to the fixation method, and it is helpful to prevent the use of a revision stem in some complications such as a periprosthetic proximal fracture.

No conversions to a cemented stem were required in our series. We believe that fractures repaired with cemented stems would achieve similar outcomes, but with the disadvantage of definitive fixation after cementation. Cemented fixation is still the most used technique in stems for proximal humeral fractures and has demonstrated to be a safe and effective technique.¹⁷ We have seen complications in the noncemented stem. These complications did not reach statistical significance between groups.

Our study has several limitations. First, it is a retrospective study with prospective data of patients operated on in our institution from 2012 to January 2017. Prospective randomized trials will provide more evidence. We have changed from a stem for primary replacement to a fracture-dedicated stem. To prevent bias, a cemented stem for fractures should be compared with a noncemented locked stem. Last, the power of our study is low, limited to the number of patients treated in recent years, and we believe that this is main reason that the odds ratio for tuberosity healing only touches statistical significance.

Conclusion

Tuberosity healing is an important predictor of function in RTSA used to treat proximal humeral fractures. Noncemented fracture-dedicated locked stems provide better function measured through the Constant score than cemented stems not specifically designed for fracture management and seem to be a reasonable option to be used in these situations. Consolidation in noncemented fracture-dedicated locked stems was 76% in our series.

Disclaimer

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