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Hemiarthroplasty for the treatment of complex proximal humeral fractures: does a trabecular metal prosthesis make a difference? A prospective, comparative study with a minimum 3-year follow-up

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Background: Proper positioning and healing of the greater tuberosity are key for functional shoulder recovery after hemiarthroplasty for complex proximal humeral fractures. The purpose of this study was to compare the outcomes after hemiarthroplasty between a trabecular metal prosthesis and a conventional prosthesis in the treatment of complex proximal humeral fractures.

Methods: A prospective, comparative study was performed. We compared a trabecular metal shoulder prosthesis for the treatment of complex proximal humeral fractures in a cohort of 35 consecutive patients (TM group) with a conventional prosthesis in a cohort of 38 consecutive patients (conventional group). All the patients, with a mean age of 63.9 years, were prospectively followed-up for a mean time of 4.6 years (range, 3-6 years) after surgery.

Results: At the last follow-up, radiographic complication rates related to the greater tuberosity were lower in the TM group (6.1%) than in the conventional group (25.7%) ($P = .028$). The mean functional shoulder scores, as well as mean active forward elevation and external rotation, were better in the TM group than in the conventional group.

Conclusions: Radiographic complication rates related to the greater tuberosity were significantly lower in the TM group than in the conventional group. The functional shoulder scores and active forward elevation and external rotation were all better in the TM group than in the conventional group. These findings could imply better healing potential of the greater tuberosity after hemiarthroplasty with a trabecular metal prosthesis to treat complex proximal humeral fractures.

Level of evidence: Level II, Prospective Cohort Design, Treatment Study.

Keywords: Shoulder arthroplasty; proximal humeral fracture; shoulder reconstruction; trabecular metal

This study was approved by the Beijing Ji Shui Tan Hospital Institutional Review Board (study No. 2207018C).

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Shoulder hemiarthroplasty is one of the treatment options for complex proximal humeral fractures. Most of the literature has reported satisfactory pain relief but differing results regarding postoperative shoulder function recovery.[1-3,6,9,11,15,19] Although several risk factors, including advanced age, female sex, preoperative delay, poor initial position of the prosthesis, and poor position of the greater tuberosity, have been suggested,[3,6,10] the postoperative healing status of the greater tuberosity is still the principal concern.[3,10,12,16,20] Trabecular metal (TM) materials have recently been used in hip and knee arthroplasties to facilitate bone ingrowth.[7,13] However, reports on TM humeral prostheses in the treatment of proximal humeral fractures have been rare.

The purpose of this study was to compare the clinical and radiographic outcomes of patients treated with TM prostheses with those of patients treated with conventional prostheses. We hypothesized that patients treated with TM prostheses would have better functional results, as well as a lower radiographic complication rate related to the greater tuberosity, than patients treated with conventional prostheses.

Materials and methods

In this prospective study, the inclusion criteria were as follows: (1) patients underwent shoulder hemiarthroplasty to treat complex proximal humeral fractures; (2) acute fractures were treated within 3 weeks after injury; (3) an anatomically reconstructed greater tuberosity was confirmed postoperatively by immediate radiographs; and (4) patients agreed to undergo both clinical and radiographic examinations at both preoperative and postoperative time points until the final follow-up. The exclusion criteria were as follows: (1) prior surgery on the affected shoulder, (2) open fractures or concomitant neurovascular injuries to the ipsilateral upper extremity, (3) initial greater tuberosity malpositioning immediately after surgery, and (4) glenoid pathology that required a total shoulder replacement.

Between March 2007 and March 2010, 121 patients underwent shoulder arthroplasties at our institution to treat proximal humeral fractures. We excluded 8 patients who underwent total shoulder arthroplasties, 10 patients with delayed fractures, 13 patients with non–anatomically reconstructed greater tuberosities (6 in the conventional group and 7 in the TM group), and 17 patients who refused to participate. A total of 73 consecutive shoulders in 73 patients who met the inclusion criteria were enrolled in this study. According to the classification of Neer,[17] there were 15 three-part fractures (9 dislocations), 44 four-part fractures (32 dislocations), and 14 head-splitting fractures. All of the fractures were evaluated by 1 independent observer (X.L.) using preoperative radiographs and computed tomography scans. The initial 38 patients in the series, who were treated with a conventional humeral prosthesis (B/F; Zimmer, Warsaw, IN, USA), were assigned to the conventional group, and the subsequent 35 patients, who were treated with a TM humeral prosthesis (Trabecular Metal Humeral Stem; Zimmer), were assigned to the TM group.

Surgical technique

All of the operations were performed by the senior surgeon (C.J.) using the same technique, with patients in the beach-chair position. A deltopectoral approach was used in all patients. The cephalic vein was preserved and retracted laterally. Traction sutures were placed through the bone-tendon junction of the greater and lesser tuberosity fragments for later reduction. For patients with fracture dislocations, great care was taken to avoid neurovascular injury when removing the humeral head from a dislocated position. All of the humeral stems were cemented at a retroversion angle of 15° to 20° and at proper heights. The tuberosity fragments were then reconstructed to the proximal prosthesis, to the humeral shaft, and to each other with preset high-performance sutures in cerclage fashion. A titanium cable (Cable-Ready; Zimmer) was placed around the tuberosity fragments in the same cerclage fashion for better fixation stability. A cancellous bone graft, harvested from the humeral head, was placed between the tuberosity fragments and between the diaphysis and tuberosity fragments to facilitate bony union. Pre-existing full-thickness rotator cuff tears were identified in 4 patients in the conventional group and in 3 patients in the TM group. All 7 of these patients had small- to medium-sized tears, and they underwent rotator cuff repair in a transosseous fashion. Biceps tenodesis was performed in all of the patients.

Postoperative rehabilitation

The postoperative rehabilitation protocol was the same for both groups. The arm was put in a neutral brace with slight external rotation for 6 weeks after surgery. Passive exercises of the hand, wrist, and elbow were initiated on the first postoperative day, depending on the patient's tolerance. Passive range-of-motion exercises of the affected shoulder began at 3 weeks after surgery. After the immobilization device was removed at 6 weeks after surgery, active rehabilitation was started. Strengthening exercises were not allowed until 3 months after surgery. All of the patients were instructed to participate in a physical therapy program supervised by a physical therapist for at least 1 year after surgery.

Clinical evaluation

All of the patients were asked to undergo follow-up interviews in the outpatient clinic at 3 weeks, 6 weeks, 3 months, 6 months, and 12 months postoperatively, as well as every full year after the operation until the last follow-up. The American Shoulder and Elbow Surgeons (ASES) score; the University of California, Los Angeles (UCLA) score; and the visual analog scale (VAS) score for pain assessment were obtained for the evaluation of the affected shoulder at every full year after the operation and during the last interview. The active range of shoulder motion was measured with a standard goniometer. All of the clinical evaluations were performed by 1 independent observer (G.W.), who was blinded to the type of prosthesis that had been applied.

Radiographic evaluation

Postoperative radiographs were obtained immediately after the operation, with the arm in neutral rotation, to determine the initial

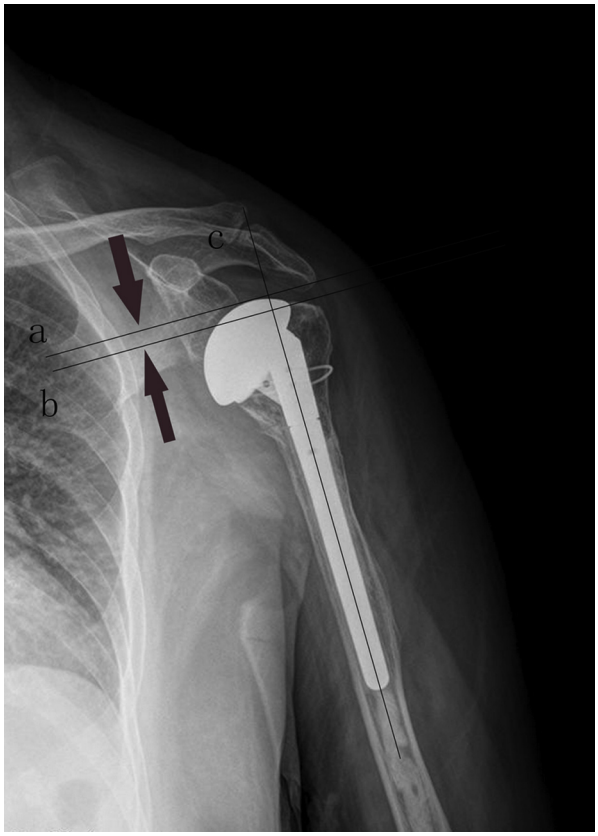

Figure 1 *Line a* was tangent to the top of the prosthetic head and perpendicular to the axis (*line c*) of the stem. *Line b* was perpendicular to the axis (*line c*) of the stem and tangent to the summit of the greater tuberosity. If the distance (*arrows*) between line a and line b, along the direction of line c, was less than 5 mm or more than 10 mm, the greater tuberosity was considered malpositioned vertically.

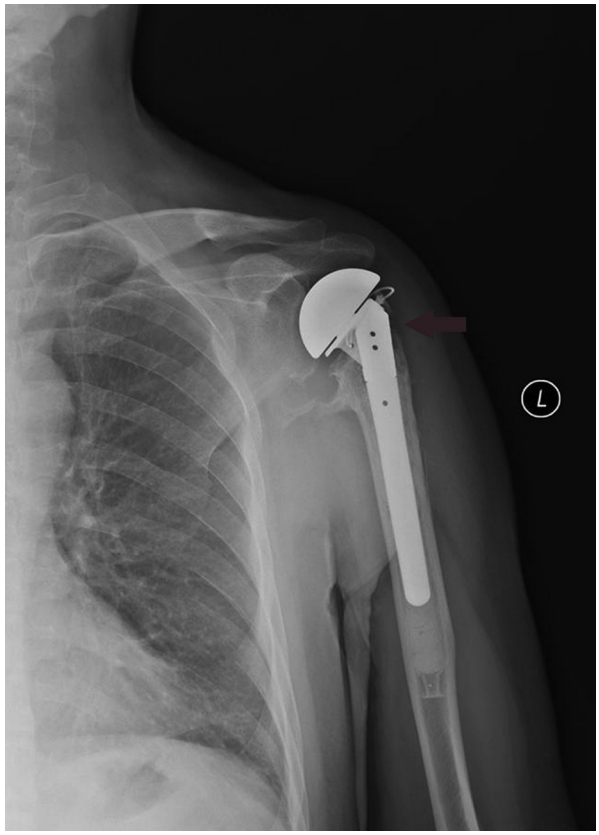

Figure 2 AP radiograph showing disappearance of greater tuberosity (*arrow*), with arm in neutral rotation.

position of the reconstructed tuberosity. Only patients with initially well-reconstructed greater tuberosities were included in this study. At each follow-up time point, all of the patients underwent a standardized series of radiographs, including the anteroposterior (AP) view with the arm in 3 rotations (neutral, external, and internal), the lateral view, and the axillary view. All of the postoperative radiographs were evaluated by 1 independent observer (X.L.), who was not involved during the operations.

The postoperative radiographic complications were defined as follows: (1) malpositioning of the greater tuberosity, (2) tuberosity resorption, and (3) superior migration of the prosthesis. They were all recorded for both groups. Using Boileau's system,[3] the greater tuberosity was considered well positioned in the vertical plane when its summit was between 5 and 10 mm below the line tangent to the top of the prosthetic head and perpendicular to the axis of the stem (Fig. 1); otherwise, the greater tuberosity was considered vertically malpositioned. If the greater tuberosity was not visible on the postoperative AP view in neutral rotation (Fig. 2) but was found to have migrated posteriorly on the AP view in internal rotation or on the axillary view (Fig. 3), the greater tuberosity was then considered malpositioned horizontally. Greater tuberosity resorption was confirmed by the disappearance of the greater tuberosity on any view of the postoperative radiographs. Both tuberosity malpositioning and resorption were considered radiographic complications related to the greater tuberosity. Proximal migration of the proximal humerus was evaluated by measurement of the acromiohumeral distance on the AP view in neutral rotation. A distance of less than 7 mm indicated proximal migration of the humerus.[8]

Statistical analysis

According to Michener et al,[14] a difference of 6.4 points in the ASES score was considered the minimal clinically important difference between groups. A preliminary study of the first 10 cases in this series was performed to calculate the standard deviation. A power analysis was performed with power of 0.9 and α of .05 to determine that a sample size of 31 patients was necessary for each group.

The Student *t* test was used to analyze the differences between groups regarding continuous variables, and the χ^2 test was used for categorical variables. The level of significance was set at $P < .05$ for all of the analyses.

Results

Demographic characteristics

A total of 68 patients, with a mean age of 63.9 $\pm$ 10.8 years, were available for follow-up at a mean time of 4.6 years (range, 3-6 years). Of the 68 patients, 23 were aged younger

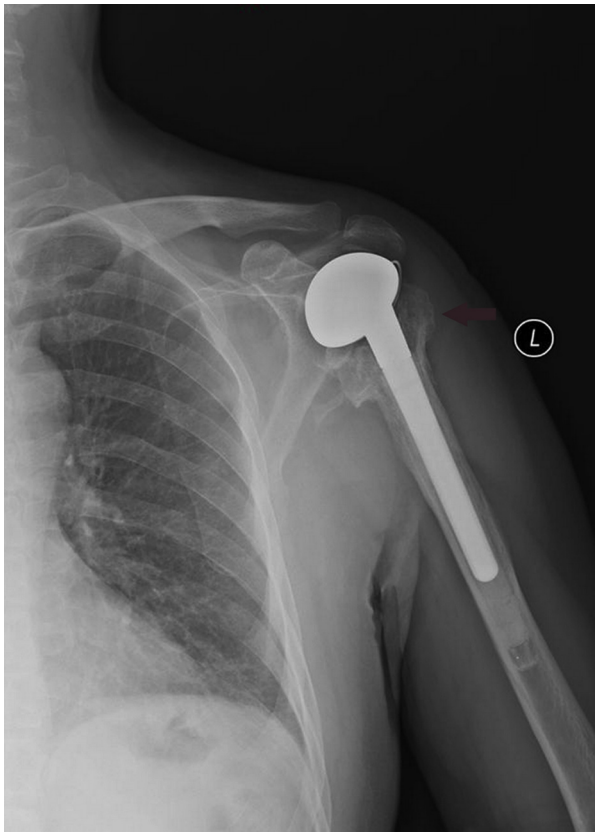

Figure 3 AP radiograph of same shoulder in Figure 2 showing posteriorly migrated greater tuberosity (*arrow*), with arm in internal rotation.

than 60 years. Among these relatively younger patients, head-splitting fractures were found in 13 patients with a mean age of 60.2 ± 9.6 years; the other 10 patients all presented with severe osteoporosis and thin humeral heads that made stable internal fixation difficult. There were 35 patients in the conventional group and 33 patients in the TM group. No differences were detected between the groups regarding age, sex, hand dominance, interval between injury and surgery, fracture pattern, or concurrency of rotator cuff tears (Table I).

Radiographic outcomes

At the last follow-up, 26 patients in the conventional group and 31 patients in the TM group were found to have well-attached greater tuberosities. Six patients in the conventional group and 2 patients in the TM group were found to have horizontally malpositioned greater tuberosities. A vertically malpositioned greater tuberosity was found in 1 patient in the conventional group and no patients in the TM group. Resorption of the greater tuberosity was detected in 2 patients in the conventional group and no patients in the TM group. The overall radiographic complication rate related to the greater tuberosity was significantly higher in the conventional group (9 of 35, 25.7%) than in the TM group (2 of 33, 6.1%) ($P = .028$).

Table I Demographic data in conventional and TM groups

Variable	Conventional group (n = 35)	TM group (n = 33)	*P* value
Age (y)	63.3 ± 11.3	64.5 ± 10.4	.643
Sex			.667
Female	24	21	
Male	11	12	
Side			.532
Dominant	23	24	
Nondominant	12	9	
Time to surgery (d)	10.1 ± 5.7	10.5 ± 4.9	.811
Fracture pattern			.491
3 Part	8	5	
4 Part	22	20	
Head splitting	5	8	
Concomitant rotator cuff tears	4	3	.751

Continuous data are presented as mean ± standard deviation and categorical data as number of patients.

Among the 11 patients with radiographic complications related to the greater tuberosity, 2 patients in the conventional group were first found to have malpositioned tuberosities at 6 weeks after surgery (posterior horizontal migration); the remainder of these complications were identified at 3 months after surgery.

Clinical outcomes

At the final follow-up, mean active forward elevation and external rotation were significantly better in the TM group than in the conventional group (131° vs 116° [$P = .044$] and 38° vs 30° [$P = .015$], respectively), with no difference in internal rotation between the groups (L3 vs L3, $P = .671$) (Table II). The mean ASES score and mean UCLA score were significantly higher in the TM group than in the conventional group (81 points vs 72 points [$P = .012$] and 28 points vs 25 points [$P = .007$], respectively). No difference was noted regarding the mean VAS score between the groups ($P = .088$) (Table II).

When we excluded all of the cases with tuberosity complications in both groups, no differences were detected between the groups regarding any parameter (Table III).

Considering the entire series, we found that active forward elevation, external rotation, and internal rotation and the mean ASES score, UCLA score, and VAS score were all significantly better in patients with a well-attached greater tuberosity than in patients with complications of the greater tuberosity (Table IV).

Complications

No infections, cases of prosthetic loosening, or neurovascular injuries related to the operation were identified at the final follow-up. Superior migration of the prosthesis

Table II Comparisons of clinical outcomes between conventional and TM groups

	Conventional group (n = 35)	TM group (n = 33)	*P* value
Forward elevation (mean ± SD) (°)	116 ± 32	131 ± 25	.044
External rotation (mean ± SD) (°)	30 ± 14	38 ± 9	.015
Internal rotation [mean (range)]	L3 (T10 to buttock)	L3 (T10 to LS junction)	.671
ASES score (mean ± SD) (points)	72.1 ± 15.7	80.8 ± 12.0	.012
UCLA score (mean ± SD) (points)	24.9 ± 5.0	28.1 ± 4.2	.007
VAS score [mean (range)] (points)	0.9 (0-4)	0.4 (0-4)	.088

Table III Comparisons of clinical outcomes of patients without complications of greater tuberosity between conventional and TM groups

	Conventional group (n = 26)	TM group (n = 31)	*P* value
Forward elevation (mean ± SD) (°)	130 ± 23	133 ± 24	.644
External rotation (mean ± SD) (°)	34 ± 11	38 ± 9	.253
Internal rotation [mean (range)]	L3 (T10 to buttock)	L3 (T10 to LS junction)	.900
ASES score (mean ± SD) (points)	78.0 ± 11.7	81.6 ± 11.9	.255
UCLA score (mean ± SD) (points)	27.0 ± 3.2	28.3 ± 4.2	.181
VAS score [mean (range)] (points)	0.4 (0-3)	0.4 (0-4)	.779

was found in all 11 patients with radiographic complications of the greater tuberosity and in 5 patients without any complications of the greater tuberosity. The correlation test showed that superior migration of the proximal humerus was significantly associated with complications of the greater tuberosity ($P < .001$).

Discussion

Although shoulder hemiarthroplasty is a reliable procedure to treat complex proximal humeral fractures regarding pain relief, its role in functional recovery is unpredictable.[2,3,9,10,15] The results are very variable according to the literature. Neer[18] showed that more than 80% of patients could gain excellent or good results after shoulder arthroplasty for 3- and 4-part fractures. However, Compito et al[5] could show excellent results in only 48.5% of patients. In a multicenter, retrospective study of 167 patients by Kralinger et al,[10] only 41.9% of the patients showed forward elevation of more than 90° postoperatively.

Much of the literature has stated the belief that the healing status of the greater tuberosity after shoulder arthroplasty is crucial for functional shoulder recovery.[3,10,12,16,20] According to Tanner and Cofield,[22] postoperative displacement of the greater tuberosity was the most common complication after shoulder arthroplasty to treat proximal humeral fractures. Boileau et al[3] showed that migration and malunion of the greater tuberosity could lead to subacromial impingement, superior migration of the prosthesis, joint stiffness, and consistent pain of the shoulder. Our results also showed that patients with greater tuberosity complications had inferior functional outcomes compared with patients without greater tuberosity complications (Table IV). If no complication of the greater tuberosity occurred, no significant difference was found regarding functional scores or range of motion between the two prosthetic designs (Table III). So, proper healing of the greater tuberosity in an anatomic position is our major goal when hemiarthroplasty is adopted for the treatment of complex proximal humeral fractures.

The incidence of tuberosity malunion or nonunion was reported to be 12.5% to 50% in early case series.[3,6,19] The recent literature has shown a 20% nonunion rate, even with fracture-specific prostheses.[4,12,21] Quite a few attempts to avoid tuberosity complications after shoulder arthroplasty have been reported, including cerclage fixation, decreased humeral retroversion, postoperative neutral-position braces, and delayed postoperative rehabilitation.[3,10] The application of bone ingrowth materials is another approach. The recently developed metal tantalum has a highly porous, 3-dimensional trabecular structure, with porosity of up to 80%. This type of material could increase biomechanical strength by enhancing the potential for bone ingrowth. Trabecular tantalum has already been applied in hip and knee arthroplasties, with promising results.[7,13] However, there have been few clinical studies of its effectiveness in shoulder arthroplasties to treat proximal humeral fractures.

To preclude factors that might have caused bias, patients with initially malpositioned greater tuberosities, confirmed by immediate postoperative radiographs, were not included in this study. The incidence of a secondary migration of the greater tuberosity was our major focus. We attempted to compare the difference in bone-healing potential between the two prosthetic designs. According to our data, the results supported our hypothesis that the patients treated with TM prostheses would obtain better outcomes in active forward elevation and external rotation and better shoulder functional scores (ASES, UCLA), as well as a lower radiographic complication rate related to the greater

Table IV Comparison of clinical outcomes between patients with and patients without complications of greater tuberosity

	Patients with GT complications (n = 11)	Patients without GT complications (n = 57)	*P* value
Forward elevation (mean ± SD) (°)	81 ± 18	132 ± 23	< .001
External rotation (mean ± SD) (°)	22 ± 15	36 ± 10	.014
Internal rotation [mean (range)]	L4 (L2 to LS junction)	L3 (T10 to buttock)	.025
ASES score (mean ± SD) (points)	57.6 ± 13.4	80.0 ± 11.8	< .001
UCLA score (mean ± SD) (points)	20.0 ± 4.7	27.7 ± 3.8	< .001
VAS score [mean (range)] (points)	1.9 (0-4)	0.4 (0-4)	< .001

GT, Greater tuberosity.

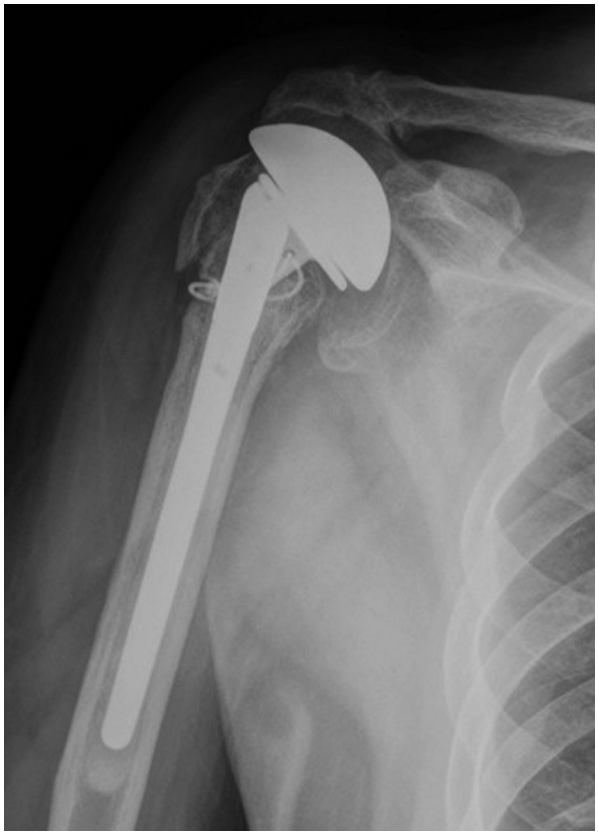

Figure 4 AP view of a right shoulder 1 year after surgery, showing a well-healed greater tuberosity but superiorly migrated proximal humerus, suggesting rotator cuff failure.

tuberosity (2 of 33 patients) compared with the patients treated with conventional stems (9 of 35 patients).

Although the anatomic healing of the greater tuberosity is crucial to postoperative shoulder function, it is not the only determining factor. In our study, superior migration of the proximal humerus still occurred in 5 patients with well-healed greater tuberosities (Fig. 4), resulting in relatively poor range of motion and poor functional outcomes. After we reviewed the surgical records, all 5 patients were found during surgery to have pre-existing degenerative rotator cuff tears (3 in the conventional group and 2 in the TM group). Although rotator cuff repair was conducted meticulously after implantation of the prosthesis and reconstruction of the tuberosities, postoperative superior migration of the prosthetic humeral head still indicated a failed rotator cuff after surgery. Therefore, reverse shoulder arthroplasty might be a better choice for elderly patients with complex proximal humeral fractures and pre-existing degenerative rotator cuff tears.

One strength of our study was that it was a prospective, comparative study of a consecutive series of patients, with all of the operations performed by a single surgeon. Identical surgical techniques and postoperative rehabilitation protocols were applied in both groups. Moreover, only patients with initially properly positioned greater tuberosities were included in this study. Thus, the influence of initial greater tuberosity malpositioning could be diminished. Then, a relatively more accurate comparison between the two prosthetic designs regarding secondary migration of the greater tuberosity could be performed, leading to a more reliable conclusion.

Our study also had several limitations. First, although this was a prospective study, the patients were not randomized. Theoretically, the senior author's technical ability to perform the procedure might improve with more experience at a later stage and might cause bias in the final comparison. However, our senior surgeon (C.J.), who performed all the cases, has a large surgical volume regarding hemiarthroplasty for the treatment of proximal humeral fractures. He had already completed nearly 200 cases by the starting point of this study (March 2007), when the learning curve had already been well passed. The surgical techniques applied during the operation remained consistent, with very little change thereafter. Second, although the independent observer who performed the radiographic evaluation was not involved during the operations, he was not blinded to the type of prosthesis that had been used, which might have caused bias. Third, the healing status of the lesser tuberosity was not evaluated in this study. Fourth, neither computed tomography scans nor the subtraction technique was used in this study, thus making the evaluation of concomitant bone absorption impossible.

Conclusion

The radiographic complication rate related to the greater tuberosity was significantly lower in the TM group than

in the conventional group. Our study showed superior functional scores, as well as better active forward elevation and external rotation, in patients treated with TM humeral stem prostheses than in patients treated with conventional humeral stems. No significant differences were seen between groups when greater tuberosity healing was uncomplicated. These findings could imply better healing potential of the greater tuberosity after hemiarthroplasty with a TM prosthesis for the treatment of complex proximal humeral fractures.

Disclaimer

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