Results of a new stemless shoulder prosthesis: Radiologic proof of maintained fixation and stability after a minimum of three years' follow-up

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Hypothesis: In total shoulder arthroplasty, the humeral component, particularly the stem, can be involved in some of the complications and technical difficulties increase in posttraumatic arthritis with proximal humeral malunion. To decrease the intraoperative complications related to the stem, the TESS (Biomet Inc, Warsaw, IN) humeral implant, was designed in 2004 hypothesis that we can obtain a good fixation with a stemless prothesis. This investigation reports the preliminary results of this prosthesis with more than 3 years of follow-up.
Methods: Between March 2004 and June 2005, 70 patients underwent 72 shoulder replacements with the TESS humeral prosthesis. Sixty-three patients were reviewed with a follow-up of more than 36 months (average, 45.2 months; range, 36-51 months). The mean preoperative Constant score was 29.6.
Results: Gain in active mobility was 49° for forward flexion and 20° for external rotation. The postoperative Constant score was 75. Radiographic analysis showed no radiolucencies or implant migration. Functional results are comparable with previous reports on prosthetic glenohumeral replacement.
Discussion: Our clinical results are similar to this with classical prosthesis. The humeral head removal facilitates the glenoid exposure and implantation. After the initial cases any specific complication was seen.
Conclusions: Owing to the automatic central positioning of the implant, an anatomic reconstruction was achieved. In malunions, no tuberosity osteotomy was required. At 3 years of follow-up, there is radiologic evidence of maintained implant stability. These encouraging preliminary results confirm our belief that a stemless prosthesis can be used to obtain an anatomic reconstruction of the proximal humerus. A longer-term follow-up study is needed to validate these results.
Level of evidence: Level IV, Case Series, Treatment Study.
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Keywords: Stemless shoulder arthroplasty; shoulder arthroplasty; resurfacing cap; tuberosity malunion

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Currently, more than 6000 shoulder prostheses are implanted annually in France. Difficulties with the glenoid implants are well known.[24] Exposure of the glenoid and

fixation of the implant are particularly demanding. Furthermore, the rate of glenoid loosening increases with the length of follow-up.[23] For these reasons, many surgeons prefer a hemiarthroplasty to a total shoulder arthroplasty (TSA), even if the pain relief is better with TSA according to the literature.[18,20]

Problems related to the humeral component of the shoulder prosthesis are not so infrequent, however. The most challenging part of the procedure is to anatomically reconstruct the proximal part of the humerus, particularly in cases of malunions. An anatomic reconstruction is the best way to restore stability and mobility of the prosthetic shoulder and improve implant durability.[10] The anatomic variations in the population have well been described by Boileau et al.[5] The most important difficulty with the prosthetic stem is the offset between the center of rotation of the head and the axis of the diaphysis. This offset is essentially posterior and medial.

Intraoperative humeral fractures are often caused by forceful shoulder manipulation and may be further induced by the reaming of the humeral shaft. The result is a long spiral fracture. Another cause for iatrogenic humeral fractures may be a mistake in the introduction of the stem into the diaphysis axis. The reported frequency of this kind of complication is about 3%.[2] A malpositioning of the humeral stem will affect the position of the humeral head.[16] Modular prosthetic designs of the humeral component have considerably improved the adaptation to the individual anatomy of the proximal humerus; however, a perfect anatomic match is not always possible.[16,17]

Postoperative complications related to the humeral component are dominated by fractures (between 1% and 3%),[6,8,11] particularly in elderly patients with osteoporotic bone and loosening of the stem (7%).[3,21] Another potential difficult problem is stem removal in case of revision surgery. A vertical osteotomy is frequently necessary, particularly with cementless stems or when a large plug of cement is present. This procedure has considerable morbidity, and the fixation of the new stem in the situation of important bone loss is difficult and often requires the use of a long, massive stem.

Different solutions have been proposed to avoid these complications. The monobloc prostheses that were initially used have been replaced by modular prosthesis. The aim of the modularity is to allow for a precise reconstruction of the anatomy of the humeral head. If this solution is frequently efficient, in some cases, we have to deal with distorted geometry, which particularly occurs in malunions.

Humeral head resurfacing is the second solution to avoid the stem problems and to preserve the bone stock. Levy et al[14] have described the good and durable results of the Copeland prosthesis; however, this prosthesis is not indicated in post-traumatic malunion or in necrosis with total collapse of the humeral head. Finally, exposure and access to the glenoid is difficult when the humeral head is still in situ. Adequate glenoid exposure is demanding and requires an extensive

Figure 1   The corolla: the 6 are arms covered by hydroxyapatite and the prosthetic head is in place.

circumferential release. This may explain the relatively high 10% revision rate of the glenoid component.[13]

In an effort to reduce stem complications and to avoid the loosening of the humeral component, a new stemless prosthesis with metaphysial fixation has been developed (Fig. 1): the TESS anatomic prosthesis (Biomet Inc, Warsaw, IN). The goal of the TESS prosthesis is to restore the anatomy of the humeral head without the need for a stem, with automatic centering, through a simple and reproducible technique, with preservation of the bone stock and an adequate exposure of the glenoid. This prospective study was conducted to demonstrate the feasibility of the procedure and to evaluate the radiologic stability of the TESS stemless corolla after a minimum of 3 years of follow-up.

Materials and methods

No investigational review board approval was required for this study because other stemless have already been implanted. All patients and their families were informed that data from their cases would be submitted for publication and provided informed consent.

The TESS anatomic humeral prosthesis consists of a metaphyseal fixation device with 6 arms (the corolla) and a humeral head fixed to the corolla through a Morse taper. The corolla has 4 sizes, and there are 6 head sizes ranging from 41 to 52 mm. The corolla is made of cobalt chrome with a titanium plasma spray and hydroxyapatite coating. The corresponding cemented full polyethylene glenoid prosthesis has 4 sizes. As an alternative cementless option, a titanium alloy metal-backed glenoid baseplate, with titanium plasma spray and hydroxyapatite coating, can be used.

Between March 2004 and June 2005, we implanted 72 TESS anatomic prosthesis in 70 patients (28 men, 42 women), who were

an average age at surgery of 64.5 years (range, 52-76 years). The diagnosis was primary or posttraumatic arthritis in 60 patients and osteonecrosis for the others. The dominant arm was operated on in 41 patients.

Five patients of the initial group were lost to follow-up. Four humeral implants were removed for infection in 1 patient, massive cuff tear with pseudoparalytic arm in 2, and instability in 1. These 4 patients were excluded from this series because the humeral implant was removed for reasons not related to implant fixation failure, leaving 61 patients (63 prostheses) for a minimum 3 years of follow-up (range, 36-51 months).

All the patients were followed-up prospectively at 2, 6, and 12 months, and annually thereafter. Of these 63 prostheses, 44 were hemiarthroplasties and 19 were TSAs. During the early phase of implantation, a full polyethylene glenoid component was not available, which explains the relative high rate of hemiarthroplasties. The preoperative Constant score was 29.6 points with, respectively, 3 points for pain, 7.1 points for activity, 15 points for mobility, and 4.5 points for strength. Preoperative anterior active elevation was 96° and external active rotation elbow at the side was 20°.

All surgeries were performed with the patient under general anesthesia combined with an interscalene bloc or catheter. The procedure was done through a deltopectoral approach, and the management of the surrounding soft tissues was similar to what has been described for the implantation of any other stemmed implant design. The humeral head was exposed, osteophytes were removed, and the subscapularis was released. The anatomic neck was identified, and the osteotomy was done on this level. The center of the cut was marked with a pin, and the size of the corolla was defined. A puncher, introduced on the pin, was used to create the corolla footprint, and the definitive prosthesis was impacted flush to the cut; thus, the corolla was automatically centered. The prosthetic head was impacted on the corolla, and the shoulder was reduced. Stability of the shoulder was tested in different arm positions, and the spontaneous reduction of a posterior drawer was checked.

The glenoid for the total shoulder prosthesis was prepared after impaction of the humeral puncher and careful retraction of the humeral shaft. The center of the glenoid was located with a tool guide and a pinch was introduced to guide the reamer for preparation of the glenoid in one step. Finally, a cemented full polyethylene glenoid component or a cementless metal-backed baseplate was implanted.

The arm was left in a sling postoperatively for 3 weeks. The rehabilitation was started the next day with passive range of motion exercises for 3 weeks, followed by active strengthening exercises.

Postoperative clinical evaluation was done using the Constant score and a subjective score with the Oxford shoulder score.[7] Patient satisfaction was recorded. Active and passive mobility were noted, and anteroposterior and axillary radiographs were done at each clinical evaluation. The quality of the rotator cuff and glenoid bone stock were evaluated preoperatively by computed tomography arthrograms or magnetic resonance imaging.

Results

Seven complications were recorded, of which 5 occurred intraoperatively during the first implantations. In these

Table I Preoperative and postoperative Constant score

Component	Max score	Pre-op	Post-op	Gain
Constant	100	29.6	75	+45
Pain	15	3	12	+9
Activity	20	7.1	18	+11
Mobility	40	15	33	+18
Strength	25	4.5	12	+7.5

Figure 2 Anatomic reconstruction in total shoulder prosthesis.

5 patients, a small crack was noticed on the first postoperative radiograph at the level of the lateral cortex, immediately opposite to the deepest part of the corolla. During surgery, however, no clinical instability of the implant was noticed. These cracks healed within 2 months in all patients without change of the position of the corolla in the metaphysis. In 1 patient, a large hematoma needed drainage, and 1 patient underwent an open surgical release at the 1-year follow-up for persistent stiffness.

At the follow-up, the mean Constant score was 75 points, with a gain of 45 points. All the parameters improved, but the gain was most important for mobility and activity (Table I). The Oxford shoulder test gain was 25 points, from 42 to 17. The rate of satisfied and very satisfied patients was 90%.

The mean anterior active elevation was 145° with a gain of 49°, and the external active rotation elbow at the side progressed from 20° to a mean of 40° degrees.

On each postoperative x-ray image and at the latest follow-up x-ray imaging, the position of the corolla remained unchanged, without any sign of radiolucencies, osteolysis, or stress shielding around the implant. The radiographic appearance of the superior part of the humerus was close to the native anatomy in all patients with primary arthritis (Fig. 2).

Figure 3   A case of malunion is shown.

Figure 4   The solution: the head is fixed according to the tuberosity level without osteotomy.

Discussion

The first-generation Neer prosthesis has been the gold standard for a long time, with good results after a long follow-up, particularly for pain relief.[21-23] This type of prosthesis, however, does not allow for an anatomic reconstruction of the humeral epiphysis in primary arthritis and especially in cases of malunion.

Modular prostheses also have good functional results and give the surgeon the opportunity to closely reconstruct the anatomy of the proximal humerus, but the complication rate on the humeral side is not infrequent, including 3% for operative fractures, 3% for postoperative fractures, and 7% for loosening.[2,3,6,8,11,21] Furthermore, the technical problems encountered in cases of malunion remain unsolved. There is substantial evidence in the literature that an osteotomy of the tuberosities to avoid humeral fractures and center the stem in the diaphyseal axis produces inferior clinical results compared with arthroplasty for primary arthritis.[1,4] Finally, modularity does not solve the potential difficulties encountered in humeral revision surgery.

The resurfacing concept, as developed by Copeland, is particularly attractive and the reported clinical results are good.[12-14] But if we compare the results of TSA and hemiarthroplasty, results are better with hemiarthroplasty, which is unusual, and the rate of glenoid revisions is superior to the other reported series. The authors have provided no explanation, but one possible reason may be the difficult access to the glenoid when the humeral head is not removed, which results in suboptimal preparation of the glenoid, malpositioning of the implant, or inadequate cementing technique.

This study shows that a stemless prosthesis can be used with a reliable and simple surgical technique in obtaining an anatomic reconstruction of the proximal humerus. Our clinical results are similar to these obtained with other reported prosthetic designs[9,15,19] and are better than the Copeland prosthesis, however, with a shorter and smaller

follow-up.[13] The number of patients in this series was insufficient and the follow-up was too short to allow for statistical analysis and differentiation of the results according to the initial pathology or whether the glenoid was resurfaced or not.

Final radiographs at the latest follow-up show satisfactory results, without changes in the position of the implants and without radiolucencies around the prosthesis.

In the patients excluded from this series, where the implants were revised for a reason not related to the humeral implant, we were able to check the ingrowths of the corolla. In all cases, the implants were totally imbedded in the proximal humerus, with bone ingrowth around the arms of the corolla with the aspect of cortical bone. Removal of the implant was possible in every case by using an osteotome to cut the bone around the arms of the corolla, without destroying the metaphysis. Revision surgery was possible using a stemmed corolla combined with an eccentric head or a reversed geometry design humeral implant. In all cases, revision surgery was not compromised after implant removal.

In 5 patients, a small cortical crack was noticed on the immediate postoperative radiograph, exclusively during the initial implantations, when it was the recommendation to have contact between the corolla and the metaphyseal cortex and therefore the largest possible size of corolla should be used. The fixation was judged to be stable during surgery, and the postoperative rehabilitation protocol was not altered. All fractures healed within 2 months, without any radiographic change on the position of the corolla. Under-sizing the corolla, rather than over-sizing, was later advocated to preserve maximal bone stock in the proximal humerus, and as a result, this complication was no longer encountered. Furthermore, this study documented that selecting a smaller corolla did not affect ingrowth or stability of the implant.

Numerous implants have been used in posttraumatic cases with malunion, without performing a tuberosity osteotomy (Figs 3 and 4). The corolla was simply implanted in the metaphysis to replace the humeral head, even if the shape of the superior part of the humerus was totally changed by the trauma. The procedure was not influenced by the distorted anatomy, and the results were comparable with those of the prostheses for primary arthritis.

Conclusions

This study confirms that this innovative implant had a very good primary fixation at 3 years of follow-up. This new concept allows for an anatomic reconstruction of the proximal humerus with a simple surgical technique. The glenoid exposure is identical to existing stemmed devices and the bone stock is preserved, which facilitates possible later revision surgery. The TESS implant can be used in difficult malunion cases and with a stem in acute trauma surgery. In this setting, bone grafting the entire corolla using the removed humeral head may enhance tuberosity healing. Long-term follow-up is required to confirm these promising results.

Disclaimer

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