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Mid-term results with an anatomic stemless shoulder prosthesis in patients with primary osteoarthritis

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ABSTRACT

Objective: The introduction of a stemless prosthesis in shoulder arthroplasty represents a novel design whereby the proximal humerus is restored anatomically, while leaving the diaphysis of the humerus untouched. The aim of this study was to present the mid-term results of total evolutive shoulder system (TESS; Biomet®), a stemless shoulder prosthesis.

Methods: The study included 38 consecutive patients (18 men and 20 women; mean age: 66 years; range: 55-81 years) treated with shoulder arthroplasty between 2009 and 2011 with TESS for primary glenohumeral arthritis. Total shoulder arthroplasty (TSA) was performed in 28 cases (74%), hemi-shoulder arthroplasty (HSA) in 10 (26%). Constant score, active range of motion, patient satisfaction rate, and radiological assessment were analyzed. Mean time of follow-up was 37 months.

Results: Constant score improved from 21.8 points (28.6 adjusted for age) preoperatively to 74.1 points (86.6 adjusted for age) postoperatively. Active range of motion increased significantly from the pre- to postoperative status. Eighty-nine percent were very satisfied or satisfied with shoulder replacement surgery. One cemented glenoid was revised due to aseptic loosening. None of the components were found to be loose at the final follow-up. No signs of stress shielding were seen.

Conclusions: This study shows promising results of this implant concept in the short- to mid-term. These results are comparable with the results achieved with long-established arthroplasty designs.

Level of Evidence: Level IV, Therapeutic Study.

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Introduction

Shoulder arthroplasty has evolved in recent years into an effective treatment option in end-stage osteoarthritis, post-traumatic sequelae, and other pathologies of the shoulder joint. The long-term clinical results are good to very good.[1–3]

There is a clear trend towards total shoulder arthroplasty (TSA).[4,5] The glenoid part is the most problematic area in TSA In the long term.[6,7] A loosening rate of up to 70% has been described, although most of these seem to be of little or no clinical significance.[2,8]

With regard to the humerus, developments in prosthetic design have helped to restore the important anatomical parameters of the proximal glenohumeral joint.

Restoring the original center of rotation should be one of the main goals of shoulder arthroplasty. This results in anatomic kinematics and reduces tension on the rotator cuff and eccentric stress on the glenoid component.[9] Anatomy should be restored to the greatest extent possible.[10]

Humeral stem prostheses may also cause problems in TSA. Fractures of the proximal humerus represent one complication. The literature describes intraoperative proximal humeral fractures at a rate of 1%–2%.[11]

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The humeral component does not appear to be the problematic aspect of TSA in the long term; however, revision surgery involving exchange of the humeral component may be necessary in younger patients. Stems, whether cemented or uncemented, may cause difficulties in explantation surgery. Especially in cases of a cuff tear or glenoid loosening in total shoulder arthroplasty, revision surgery might be necessary and difficult to perform in conventional stemmed prosthesis.

Additionally, in the case of periprosthetic fractures or infection, revision surgery involving explantation of the prosthesis may be necessary and can be challenging and complex.

The above-mentioned limitations led to the development of the fifth generation of shoulder prostheses, which introduced a stemless design offering the possibility to restore proximal humeral parameters and the original centre of rotation without dissecting the diaphyseal part of the proximal humerus.

The total evolutive shoulder system (TESS; Biomet®) was introduced in France in 2003 by Biomet Inc (Warsaw, IN, USA) and uses a stemless design that has its fixation in the metaphyseal part of the humerus, making it possible to restore shoulder joint anatomy without dissecting the diaphyseal part or causing periprosthetic fractures.

The aim of the present study was to describe our mid-term clinical and radiological results in patients with primary osteoarthritis.

Materials and methods

At total of 480 shoulder arthroplasties were performed at our institution between 2009 and 2011. Of these, 72 shoulders were treated with the anatomical variant of the stemless shoulder prosthesis, TESS.

Inclusion criteria for our study were: (a) patients with primary osteoarthritis of the shoulder, (b) an intact rotator cuff, and (c) minimum follow-up of 2 years. 41 patients fulfilled the inclusion criteria; 34 patients with 38 shoulders could be recruited and examined for follow-up at our outpatient clinic. Clinical and radiological evaluations were performed. The study was approved by the ethical board of the university.

Clinical evaluation was based on the Constant score (adjusted to age and sex), range of motion in flexion, abduction, and external rotation, as well as patient satisfaction. Patients were able to choose between “very good,” “good,” “satisfied,” or “disappointed” to classify their satisfaction with shoulder replacement surgery at final follow-up.

Radiographic evaluation

A true anteroposterior (AP) view and an axillary view of the affected shoulder were taken preoperatively. Furthermore, an MRI or CT scan was performed to evaluate whether the rotator cuff was intact and to analyze the glenoid morphology according to Walch.[12]

At the time of final follow-up, standard AP and axillary views of the shoulder were made.

For loosening the radiographs were analyzed due to radiolucent lines around the cemented glenoid component by two surgeons specialized in shoulder arthroplasty. The analysis based on the classification by Molé et al.[13] The ap as well as the axillary view were analyzed due to radiolucent lines and points for radiolucent lines were given. The points in the ap as well as the axillary view were added. Furthermore the thickness of the radiolucent line was measured. With up to six points there was no risk of loosening, 7–12 points with a risk for glenoid loosening. The glenoid component was found to be loose with 12 points up. The protocol has been described in detail.[2]

Furthermore, anatomical restoration of the proximal aspect of the glenohumeral joint was evaluated. The lateral offset and head–greater tuberosity distances were measured.

Surgical technique

The surgical technique has been well described in the literature.[14] The glenoid was not replaced in cases of an A1 glenoid and in two cases of an A2 glenoid, while the left A2, B and C glenoids were replaced.

Intraoperative complications

Glenoid perforation at the tip of the anchorage occurred in one case, involving leakage of a small volume of cement outside the glenoid. No further treatment was necessary.

Postoperative complications

There was one postoperative complication. In one case the glenoid was loose one year postoperatively. Revision surgery was necessary due to pain. The glenoid component was explanted and a bone block from the iliac crest was placed in the glenoid bone stock left.

Results

Patient collective

The patient collective comprised 18 (47%) men and 20 (53%) women. Hemi-shoulder arthroplasty (HSA) was performed in 10 patients (26%) and TSA in 28 patients. HSA was performed in cases of an A1 glenoid type according to Walch. Two patients with an A2 glenoid were treated with HSA as well.

The left shoulder was treated in 20 (53%) cases, the right shoulder in 18 (47%). The dominant arm was treated in 18 (47%) cases, the non-dominant in 20 (53%).

Mean time of follow-up was 37.1 months (24–72 months), while the mean age at the time of surgery was 66.4 years (55–81 years).

Clinical results

The mean Constant score increased from 21.8 (6.0–43.0) to 74.1 (12.0–94.0) points at the time of final follow-up ($p < 0.0001$). The gender and age-adjusted Constant score improved from 28.6 (6.0–24.5) preoperatively to 86.6 (15.0–108.0) points at the time of recent follow-up ($p < 0.0001$).

Range of motion, measured in terms of flexion, abduction, and external rotation, also increased significantly from the pre-to postoperative status (see Table 1 for an overview).

Table 1
Constant score and range of motion.

	Preoperative	Postoperative	p
Constant score (points)	21.8 (SD: 9.8)	74.1 (SD: 19.8)	<0.0001
Constant score adjusted	28.6 (SD: 13.3)	86.6 (SD: 23.2)	<0.0001
Pain	2.5 (SD: 2.4)	13.3 (SD: 3.5)	<0.0001
Activity	6.8 (SD: 2.8)	17.7 (SD: 4.4)	<0.0001
Mobility	12.2 (SD: 6.7)	31.9 (SD: 10.4)	<0.0001
Power	0.5 (SD: 1.3)	11.2 (SD: 5.4)	<0.0001
Range of motion (°)			
Flexion	83.7 (SD: 28.6)	136.2 (SD: 39.1)	<0.0001
Abduction	65.0 (SD: 30.6)	138.4 (SD: 41.3)	<0.0001
External Rotation	5.6 (SD: 10.2)	33.0 (SD: 12.4)	<0.0001

Glenoid evaluation

The glenoid type intraoperatively found was described according to Walch.[12] Table 2 provides an overview of the glenoid type found.

Radiographic evaluation

In eighteen patients (47%) radiolucent lines around the glenoid component were found.

The mean radiolucent line score in the true ap-radiographic view was 2.75 points (SD: 1.48). The mean radiolucent line score in the axillary view was 1.4 points (SD: 0.89). The overall mean radiolucent line score was 3.3 points (SD: 2.1). There was no radiolucent line >1 mm of thickness. None of the glenoid components were found to be loose (>= 12 points) at the time of final followup, whereas three glenoids were found to be at risk for loosening (7 points). In detail there were three patients with a radiolucent line score of 1 (8%), six patients with a score of 2 (16%), three patients with a score of 3 (8%), one patient with a score of 4 (3%), two patient with a score of 6 (5%) and three patients with a score of 7 (8%).

The mean radiolucent line score in patients with a B1 glenoid was 2.5 (SD: 0.7). The mean radiolucent line score in patients with a B2 glenoid was 3.2 (SD: 2.4) and in patients with a C glenoid the score was 3.9 (SD: 2.3).

Furthermore we found cranial migration of the humeral component in eight cases (12%). No loosening or stress shielding around the humeral component was found.

Figs. 1 and 2 give an example with the pre- and postoperative radiograph of a patient with total shoulder arthroplasty and no cranial migration.

Figs. 3 and 4 give an example with pre- and postoperative radiographs of a patient with total shoulder arthroplasty and a slight cranial migration at final follow-up. However, we did not find a correlation to clinical data.

Lateral offset and head–greater tuberosity distances were measured preoperatively and at the time of final follow-up.

The lateral offset was 53.8 mm (45.8–54.5 mm) preoperatively and 53.1 mm (44.8–53.8) at the time of follow-up.

The distance from the humeral head to the greater tuberosity was 7.5 mm (3.2–7.6 mm) preoperatively and 6.8 mm (3.2–6.7 mm) at the time of final follow-up.

Patient satisfaction

Patients were also asked about their satisfaction with surgery at final follow-up. A total of 26 patients (70%) were very satisfied with their shoulder replacement surgery, seven patients (19%) were satisfied, and four (11%) were not or were less satisfied with surgery.

Discussion

This study yielded satisfactory and acceptable results following shoulder replacement surgery with a stemless prosthetic design (TESS, Total Evolutive Shoulder System; Biomet).

Table 2
Glenoid type according to Walch.[12]

Glenoid type	Frequency
A1	8 (21%)
A2	5 (13%)
B1	9 (24%)
B2	9 (24%)
C	7 (18%)

Fig. 1. Pre-operative radiograph.

Fig. 2. Post-operative radiograph.

Restoring the anatomy of the proximal aspect of the humerus is essential to ensuring a good outcome.[9] With the parameters measured, we showed that we could restore the anatomy of the proximal aspect of the glenohumeral joint. The different anatomic parameters of the proximal humerus have been well described.

Fig. 3. Pre-operative radiograph.

Fig. 4. Post-operative radiograph.

The lateral humeral offset, with a mean of 55 mm, and the distance between the head and the greater tuberosity, with a mean of 8 mm, are two of the main parameters.[15,16] Our measurements were very close to these, showing that good anatomic reconstruction can be achieved with this type of prosthesis. We did not find any components to be loose at final followup, however in one cases revision surgery was needed before for aseptic glenoid loosening. There were three glenoids found with risk of looseing. However, we did not see an effect on the clinical outcome and no further treatment was necessary in these cases. We found cranial migration in 12% of the shoulders. Also in these cases no further treatment was needed. There was no correlation between cranial migration and clinical outcome. Therefore we rate the cranial migration as a radiographic finding. Long-term data is necessary to see, if that might lead to further complications. This correlates with the findings by Raiss et al. They did not find correlation between cranial migration and clinical outcome after anatomic shoulder arthroplasty surgery at a minimum ten-year follow-up.[2] In clinical examination in our patients the rotator cuff function was intact at time of final follow-up, even in patients with cranial migration in the x-ray. Furthermore there was no stress shielding. The mean time of follow-up might explain this, since problems such as loosening are well described in TSA, especially in the long term. However, this might not show any clinical effect.[2]

There were virtually no postoperative or intraoperative complications in our study. The easier technique for implanting the prosthesis while leaving the entire diaphyseal part of the humerus untouched might be one reason for this.

Another reason might be the relatively short time of follow-up. Of particular note is that no fissures or fractures of the proximal humerus occurred.

Studies evaluating this kind of prosthesis are rare. Kadum et al. published good results in 56 consecutive patients with a mean follow-up of 14 months.[14]

The TESS group from France showed good results with the TESS prostheses. Altogether, 63 patients were reviewed with a minimum follow-up of 3 years. In 2010, they reported an improvement in forward flexion of 49° and 20° for external rotation. The mean Constant score improved from 29.6 points preoperatively to 75 postoperatively. There were no radiolucent lines or implant migration at radiological evaluation.[17] The results of our study are comparable with these results. However, Kadum's group used different scores to evaluate their outcome to those used by our group and they had a much shorter follow-up than our study. Furthermore, different TESS designs (anatomical, reverse) and different indications were included.

There are also studies on the same prosthetic design concept. Habermeyer et al. recently showed mid-term results with the Eclipse prosthesis (Arthrex, Karlsfeld, Germany). In 78 patients at a mean follow up of 72 months, the Constant score improved to 75.3%. The group also evaluated bone density, which was reduced in 34.9% of older patients without affecting shoulder function. At radiographic assessment, they found partial osteolysis on the humeral part, combined with glenoid loosening. Areas of lower density were found in 53.8% of patients treated with HSA and in 46.2% of patients treated with TSA.[18] Our clinical findings are comparable to the above-mentioned findings. However, the group included different indications and had longer follow-up. Our study had a more homogenous patient collective compared with this group. The fact that we did not find signs of stress shielding or lower bone density might be due to the shorter follow-up. Furthermore, the Eclipse prosthesis is based on a different fixation technique in the humeral bone stock, which might also explain differences in findings. However, it is not clear whether bone density will also

decrease in our collective. We have not seen complications in terms of the humeral fixation technique. Whenever it was not possible to achieve good primary stability intraoperatively with the prosthesis, the system was converted to a stemmed system. This occurred in two cases.

To our knowledge, this is the first study to evaluate the results of stemless shoulder arthroplasty with only one indication for shoulder replacement surgery. Furthermore it is the first study evaluation the T.E.S.S. results beside the group that developed the prosthesis.

Our results need to be compared with results of well-established stem designs.

Young et al. reported long-term results of TSA in 226 shoulders with a mean follow-up of 122.7 months. The Constant score improved from 26.8 pre-to 57.6 points postoperatively. None of the components were found to be loose[3] Our results are comparable, but follow-up time is longer.

The literature clearly shows at trend towards TSA.[4,19] Levine et. al showed overall poor results after HSA at a follow-up of 17.2 years. Flexion and external rotation increased significantly post-operatively. The average Neer score and Neer ranking, however, was higher for concentric glenoid wear compared with eccentric glenoid wear. Only 25% of patients were satisfied with the surgical outcome at final follow-up.[20] However, 42% of patients with a concentrically worn glenoid and only 12% of patients with an eccentrically worn glenoid were satisfied with the surgical outcome at final follow-up. In our collective, patients with an A1 glenoid (concentric wear) were treated with HSA.

We see good short-to mid-term results in our HSA group. The glenoid was left untouched in cases of A1 types according to Walch[12] as well as in two A2 glenoids. No significant cartilage loss and only centric wear was accepted, and TSA was performed in these cases. Furthermore, no differences in the outcome of TSA compared with HSA have been observed. Long-term results are required to verify these findings.

In cases of a B2-glenoid and an intact rotator cuff we also performed anatomic shoulder arthroplasty. There is no literature us known that shows superior clinical outcome in patients with B2-glenoids and an intact rotator cuff undergoing reverse shoulder arthroplasty than anatomic shoulder arthroplasty. Therefore we do not treat these patients with reverse shoulder arthroplasty.

Although implants using a metaphyseal fixation technique have become increasingly popular, mid- and long-term studies are rare. The main advantage of this design is its ability to restore the proximal part of the humerus anatomically without the need to dissect the diaphysis.

The glenoid can be exposed easily when implanting this type of prosthesis. However, the design clearly has its limitations. In cases of acute humeral head fractures, mal-unions following fracture sequelae, and weak cancellous bone, a stemmed prosthesis might be more suitable.[21,22]

The present study also has its limitations. The follow-up is not long enough to see whether this type of prosthesis can withstand classic shoulder arthroplasty. We do not know whether loosening of the humeral component or stress shielding might lead to problems or whether revision surgery may be necessary. Long-term results are needed to clarify these questions.

Conclusion

In conclusion, the present study showed good mid-term results, both clinically and radiographically, with a stemless shoulder arthroplasty design. Long-term results are needed to confirm these results.

Conflicts of interest

None.

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