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ORIGINAL ARTICLE

Is the stemless humeral head replacement clinically and radiographically a secure equivalent to standard stem humeral head replacement in the long-term follow-up? A prospective randomized trial

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Background: Stemless humeral head replacement represents a young generation of shoulder arthroplasty. This study evaluated the differences of this new stemless design compared with the fourth-generation standard stemmed design.
Methods: Total shoulder arthroplasty was performed in 20 patients with a stemless shoulder prosthesis (group 1) and in 20 patients with a standard stem humeral head replacement (group 2). Twenty-nine patients were examined clinically and radiographically at a minimum follow-up of 2 years and a minimum follow-up of 5 years. Functional results were assessed using the age- and gender-related Constant Score (CS). The radiographic analysis used native x-rays in 3 planes.
Results: The postoperative CS improved significantly in both groups, with no significant difference between the minimum of 2-year and 5-year follow-up. The difference in the CS, its subcategories, and active range of motion between the implant groups was not significant. A significant difference was observed in the radiographic analysis for the zone adjacent to the humeral calcar, with a lower bone mineral density in 41% of group 2 and in 0% in group 1. Radiolucent lines were statistically more frequent in group 2. No statistical differences were observed between the implant groups for the change of the inclination angle, the medial offset, and the lateral offset.
Conclusion: Both implants showed consistently good functional and radiologic results without a significant difference and achieved an anatomic reconstruction of the humeral head geometry in the coronal plane.
Level of evidence: Level II; Randomized Trial; Treatment Study

Keywords: Shoulder arthroplasty; stemless prosthesis; Eclipse; prospective; osteoarthritis; shoulder prosthesis

IRB statement

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The stemless generation of humeral head replacements was introduced in 2004 and 2005 with the Total Evolutive Shoulder System (TESS; Biomet Inc Warsaw, IN, USA) and the Eclipse stemless shoulder prosthesis (Arthrex, Freiham, Germany), respectively. These systems are anchored in the metaphysis of the humerus instead of using a stem that is anchored in the diaphysis of the humerus. The benefit, which is achieved by the stemless replacement of the humeral head, is the reconstruction of the rotational center independent of the axis of the humeral shaft. This system also allows an unimpeded access to the glenoid cavity for reconstruction of the glenoid. The advantages in revision surgery after shoulder arthroplasty using a stemless design are the preservation of metaphyseal bone stock and the lack of an osteotomy of the humeral shaft because of the absence of a diaphyseal anchorage.

The anatomical reconstruction of the glenohumeral joint using an Eclipse prosthesis was evaluated in a finite-element study[9] in 2012. A similar load transfer was found after stemless arthroplasty compared with a healthy humerus.[13]

Shoulder arthroplasty using a standard stem humeral head replacement is described as providing good clinical results with a reasonable complication rate.[5,18,22] Comparable results in functional and radiographic outcome have been shown for the stemless shoulder arthroplasty in the short-term to midterm follow-up.[2-4,7,8,10] Bone remodeling caused by stress distribution after shoulder arthroplasty has been described.[12,16,18] Those studies concluded that a shorter stem benefitted the proximal bone stock because of proximal stress distribution at the bone-to-implant interface.

This prospective randomized trial evaluated the clinical and radiographic outcome of the Eclipse stemless replacement of the humeral head compared with the standard fourth-generation Univers II stemmed shoulder prosthesis (Arthrex).

Materials and methods

Clinical follow-up

From November 2005 to May 2008, 40 patients with primary osteoarthritis of the shoulder were included into a prospective randomized trial and treated by total shoulder arthroplasty implanting the Univers II standard shaft prosthesis or the stemless Eclipse prosthesis. Exclusion criteria were prior surgery of the affected shoulder, lesions of the rotator cuff, osteoporosis, formation of subchondral cysts, prior infection, and secondary arthritis due to instability, fracture sequelae, or rheumatoid arthritis.

The patients were randomized into 2 groups. Group 1, comprising 20 patients (10 women, 10 men) with a mean age of 65 years at the time of operation, received a total shoulder replacement using an Eclipse stemless humeral head replacement. Group 2, also comprising 20 patients (13 women, 7 men), with a mean age of 69 years at the time of operation received the Univers II, a fourth-generation anatomical total shoulder arthroplasty. The glenoid cavity in all patients was resurfaced using a metal-backed Univers Mark 2 glenoid or a keeled polyethylene glenoid (Arthrex).

Thirty-three patients (82.5%), 15 group 1 patients and 18 group 2 patients, were examined at a minimum of a 2-year follow-up, and 29 of these patients (72.5%) were recruited for a further follow-up examination at 5 years. Fourteen patients of group 1 were examined at a mean follow-up of 68 months (range, 59-84 months). Nine patients of group 1 received a metal-backed Univers Mark 2 glenoid and 5 received a keeled polyethylene glenoid, because we changed our philosophy about the use of cementless glenoid components as a result of a higher complication rate of cementless glenoid components after a mean of 5 years.[11] Fifteen patients of group 2 were examined at a mean follow-up of 70 months (range, 60-81 months). Thirteen patients of group 2 received a metal-backed Univers Mark 2 glenoid, and 2 patients received a keeled polyethylene glenoid.

The patients were objectively evaluated using the Constant score (CS)[6] as well as the age- and gender-related CS.[24] Strength of the CS was measured with the arm 90° abducted in the scapular plane using an ISOBEX dynamometer (IsoForceControl, MDS AG, Oberburg, Switzerland), and was set at 0 if the patient could not reach this position.

Eleven patients were lost for follow-up. Seven patients could not be reached by phone and mail, 2 patients were not able to attend the examination because of long-term disease not related to the shoulder, 1 patient had died, and 1 patient declined further participation in the study.

The statistical evaluation was performed using SPSS 21 software (IBM Corp., Armonk, NY, USA) using the Wilcoxon signed rank test, the Mann-Whitney *U* test, and by the calculation of Spearman rank correlation coefficient.

Radiographic follow-up

The radiographic follow-up was assessed on standardized native x-rays in 3 planes (true anteroposterior [AP], axillary, and Y views). The glenoid morphology was assessed on the preoperative axillary view x-rays and graded as described by Walch et al.[23] In group 1, 4 patients were graded as type A2, 5 as type B1, and 5 as type B2. In group 2, 4 patients were graded as type A2, 8 as type B1, and 3 as type B2. No patients were graded type A1 or type C.

The humeral bone-to-prosthesis interface was divided into 3 zones in the coronal plane, with zone A below the cranial trunnion, zone B at the cage screw or the humeral stem for the Eclipse prosthesis and the Univers prosthesis, respectively, and zone C below the caudal trunnion. A similar division was used for the axillary view, with zone A below the anterior trunnion, zone B at the cage screw of the Eclipse prosthesis (Fig. 1) or the humeral stem of the Univers prosthesis (Fig. 2), and zone C below the posterior trunnion. The glenoid component was similarly divided into 3 zones in the true AP radiograph and the axillary radiograph.

The radiographic changes were divided into 5 groups for both the humeral and the glenoidal implant. No radiographic changes were classified as group 0. Group 1 was classified as a reduction in bone mineral density at the bone prosthesis interface of the humeral implant or the presence of an osteolysis at the bone prosthesis interface of the glenoidal implant. The presence of radiolucent lines was classified depending on the degree: radiolucent lines of less than 1 mm were classified as group 2, radiolucent lines with 1 to 2 mm were classified as group 3, and radiolucent lines greater 2 mm were classified as group 4.

Also evaluated was the presence of a cranial migration of the humeral head, defined by a loss of the gothic arc in the AP