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ORIGINAL STUDY

Two-year results of stemless total shoulder arthroplasty in patients with primary osteoarthritis

Thomas WESTPHAL, Thomas WILLERT, Tony SCHMIDT, Josephine GEHRING, Jörg WEBER

From the Klinikum Südstadt Rostock, Department of Orthopaedic Trauma, Orthopaedics and Hand Surgery, Rostock, Germany

This study presents functional and radiological results of a single surgeon series of consecutive patients who underwent stemless total shoulder arthroplasty (Eclipse, Arthrex, Naples, FL, USA) for primary osteoarthritis at a mean follow-up of 24 months. From January 2010 to December 2014, 18 patients underwent 20 stemless shoulder arthroplasties. In all cases, we implanted the Eclipse prosthesis (Arthrex, Naples, FL, USA) and a cemented polyethylene glenoid with keeled design. Patients were followed at 3, 12 and 24 months. The main outcomes were functional results. The Constant–Murley score improved from 35 to 68 points ($p<0.05$, Wilcoxon test), which represents an increase of 41 to80% ($p<0.05$, Wilcoxon test) for the age- and sex-adjusted scores within twelve months. The DASH improved from 57 to 28 points. This study shows that the Eclipse prosthesis provides consistent functional and radiological results compared to other stemless prostheses, as well as stemmed shoulder arthroplasty for primary osteoarthritis. Subject to further investigations, stemless prostheses can be considered as an alternative to modern stemmed prostheses in patients with osteoarthritis.

Keywords: Arthroplasty Replacement ; Shoulder Joint; Osteoarthritis ; Treatment Outcome.

INTRODUCTION

Various approaches to humeral component fixation in shoulder replacement are currently available. In addition to cementless or cemented conventional humerus stems, humerus resurfacing, short stem, and stemless fixation have been developed by medical device companies. In 2004, Biomet (Warsaw, IN, USA) introduced the first stemless shoulder prosthesis and Arthrex (Naples, FL, USA) followed in 2005 *(7,17)*. The idea behind these developments was to avoid difficulties that can occur during implantation of conventional humerus stems or in case of revisions of shoulder arthroplasty. Especially in malunited proximal humerus fractures reconstruction of the centre of rotation is sometimes impossible. The advantage of stemless prostheses is the ability to reconstruct

■ Thomas Willert.
■ Tony Schmidt.
■ Josephine Gehring.
■ Jörg Weber.
Klinikum Südstadt Rostock, Department of Orthopaedic Trauma, Orthopaedics and Hand Surgery, Rostock, Germany.
Correspondence: Dr. Thomas Westphal, Klinikum Südstadt Rostock, Klinik für Unfallchirurgie, Orthopädie und Handchirurgie, Südring 81, 18059 Rostock, Germany. Tel.:0049 38 144 014 019
E-mail : thomas.westphal@kliniksued-rostock.de

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the centre of rotation independent of the humerus shaft axis and thus to avoid the need for additional osteotomies *(17,20)*.

First experiences with stemless prostheses showed encouraging results *(4)* so that indications were extended to primary and secondary osteoarthritis of the shoulder. There are some ongoing clinical trials seeking Food and Drug Administration approval for use in the United States *(7)*. Only one of these studies has been published to date *(8)*. Therefore, most of the few available data come from European study centres. To the best of our knowledge only nine studies exist presenting short or midterm results of stemless shoulder arthroplasty *(2,4,8,17,20,22,25,30,35)*. Data presented in these studies are heterogeneous regarding diagnosis, follow-up intervals, number of participating centres respective surgeons, and implants. In addition, some studies do not differentiate between hemi and total shoulder arthroplasty.

Therefore, we present functional and radiological results of a series of consecutive patients with one diagnosis (primary osteoarthritis), one implant (Eclipse, Arthrex, Naples, FL, USA) operated on by a single surgeon (T.W.). All patients received a total shoulder arthroplasty and were systematically followed. Data presented here are results of the two years' follow-up.

The aim of the study was to provide more information on the functional and radiological course after the implantation of a stemless shoulder prosthesis and to compare the results with those published previously.

MATERIALS AND METHODS

The annual frequency of shoulder replacements ranges from 30 to 40 procedures at our institution, which employs two certified shoulder and elbow surgeons. From January 2010 to December 2014, 25 patients underwent 27 stemless shoulder arthroplasties in our department. In all cases, we implanted the Eclipse prosthesis (Arthrex, Naples, FL, USA) and a cemented polyethylene glenoid with keeled design. One surgeon (T.W.) performed all surgeries.

Patients who fulfilled the inclusion criteria were eligible for this prospective study. We collected all data required for completing the extended version of the German shoulder prosthesis registry. The registry is approved by various ethical committees and patients gave informed consent before participation. The inclusion criteria were a primary osteoarthritis operated upon with a stemless shoulder replacement and cemented glenoid resurfacing with keel. Patients who were operated on for other diagnosis and those who had complications that were not implant related were excluded.

The implant consists of three components on the humeral site: a trunnion, a cage screw, and a humeral head *(17)*. All components are available in different sizes. After resection of the humerus head along the anatomical neck, the surgeon chooses the size of the trunnion according to the diameter of the resection plane. The trunnion is then fixed by the cage screw compressing the trunnion against the resection plane. Eventually, the humeral head is fixed by a cone mechanism on the trunnion. If a total arthroplasty was intended, keeled glenoids of various sizes were available for cemented application, as known from conventional shoulder arthroplasty.

Indication was primary osteoarthritis with adequate bone stock. In cases of osteoporosis or big bone cysts implantation of the Eclipse is not recommended because of difficulties to anchorage the trunnion.

Preoperative assessment included a survey and a clinical examination of the shoulder. During the survey, patients were asked to complete the DASH (Disabilities of the Arm, Shoulder and Hand) questionnaire *(15,19)* and all required questions for completing the Constant-Murley score *(10)*. Clinical examination included ROM (range of motion) measurement by a goniometer and measurement of the abduction strength according to the recommendations of Constant and Murley.

All patients had radiographs in three planes before surgery (true anteroposterior, axillary, and scapular Y views). We measured the size of osteophytes according to Samilson *(33)*, the joint space width, and assessed the glenoid inclination as well as the glenoid protrusion according to Habermeyer *(16)*. In order to characterize the glenoid type according to Walch *(38)* and the rotator cuff status a CT and MRI was performed as well.

Follow-up assessments were performed after three, 12 and 24 months and included the same protocol as preoperative except for MRI and CT examinations. Functional assessment comprised range of motion measurements, the Constant–Murley score, and the DASH score. Radiological assessment included the occurrence of radiolucent lines, migration of the humeral head and rotator cuff deficiency. We defined the radiological outcomes according to Habermeyer *(17)* for the humerus component and according to Franklin *(24)* for the glenoid.

Functional results according to the Constant–Murley score, raw and adjusted for age and sex as recommended by Katolik *(23)*, and the DASH score were the main outcomes. Further outcomes were the radiological parameters.

All statistical analyses were performed using SPSS 22.0 (IBM Corp, Ehningen, Germany). We compared the data of preoperative functional examination and each follow-up assessment. For the data of range of motion, we used the Student's paired sample t-test, and for the score data we used the Wilcoxon signed-rank test. A p-value less than .05 was considered significant.

RESULTS

Five of 25 patients were excluded because of diagnoses other than primary osteoarthritis (secondary post-traumatic arthritis resulted from glenoid fractures 2, malunited proximal humerus fractures 2, and rheumatoid arthritis 1). Two further patients were excluded because of complications that were not implant related. In one case, explantation was required within six months because of low-grade infection. In another case, an intraoperative glenoid fracture occurred, which necessitated fracture fixation. In this case a glenoid resurfacing was not possible during the first surgery and an explantation was done within two years because of failure of the fixation. 18 patients with 20 shoulder replacements left for final analysis.

The cohort consisted of 14 women and four men, with a mean age of 64 years (range, 41-78, SD 7.4) at the time of surgery. Nine patients were operated on at the right and seven at the left shoulder. Two patients had surgeries on either side. The mean body mass index was 31 (range 22-48, SD 9.7). Mean Follow-up was 3.1 (range 2-4, SD, 0.6), 11.7 (range 10-13, SD, 0.7), and 23.6 (range 23-26, SD, 0.7) months.

Clinical assessment

Functional results at each follow-up are presented in Table I. Patients showed improvement in all parameters three and twelve months after surgery. Except for the DASH after twelve months these were statistical significant ($p<0.05$, t-test respective Wilcoxon test). We did not find further significant improvement after 24 months ($p>0.587$, t-test respective Wilcoxon test). No implant specific complication was observed.

Radiological assessment

Table II shows all preoperative radiological findings. There was no patient with rotator cuff tear and one patient with glenoid type C according to Walch *(38)*. At 24 months one patient showed

Table I. — Longitudinal changes in functional parameters and results of statistical analyses (mean (SD, p-value))

	before surgery	3 months	12 months	24 months
Abduction	71 (SD 39.5)	110 (47.4, p=0.007)	142 (36.8, p=0.005)	138 (37.4, p=1)
Flexion	87 (SD 39.7)	130 (38.5, p=0.002)	150 (33.9, p=0.011)	144 (33.3, p=1)
External Rotation	20 (SD 60.9)	31 (9.6, p=0.023)	42 (20.4, p=0.002)	39 (14.1, p=0.948)
Constant (pts)	35 (SD 15.2)	59 (15.5, p=0.001)	68 (14.0, p=0.005)	68 (13.6, p=0.744)
Constant (%)	41 (SD 16.2)	69 (18.5, p=0.001)	80 (16.7, p=0.006)	79 16.0, p=0.695)
DASH	57 (SD 13.8)	35 (17.7, p=0.001)	28 (19.8, p=0.07)	27 (21.5, p=0.587)

DASH Disabilities of the Arm, Shoulder and Hand

Table II. — Preoperative radiological findings

Radiological Parameter	Findings	N
Joint space width	normal	1
	partial decreased (<4mm)	4
	complete decreased (<3mm)	15
Osteophytes	mild	1
	moderate (>3mm)	9
	severe (>7mm)	10
Glenoid Protrusion	grade 1	7
	grade 2	5
	grade 3	8
Glenoid Inclination	type 0	3
	type 1	3
	type 2	11
	type 3	3
Glenoid Type (Walch[16])	A1	1
	A2	3
	B1	7
	B2	9
	C	1

radiolucent lines of the humeral component at Zone C on the antero-posterior plane. We did not observe additional radiolucent lines. Five patients showed a migration of the humerus head.

DISCUSSION

Since Neer introduced the Neer II Prosthesis *(27)* and implanted the first cemented glenoid, shoulder replacement has been continuously enhanced. A large number of functional and radiological results have been published since then *(29,36)* and strategies to avoid or treat complications *(1,3,6,11,21)* as well as revision strategies *(9,12,18,26,31,32)* have been developed. The average survival of a stemmed prosthesis has been increased *(21,37)*. This implicates that each new implant must achieve equal results to be able to compete *(28,29)*.

This statement applies to stemless shoulder prosthesis too. To date, only few studies presenting results of stemless shoulder arthroplasty are available. We found nine studies with heterogeneous groups of patients, follow-up intervals, and implants. The data of these studies are presented in Table III. If the studies used different outcomes or if it was not possible to extract the data for total shoulder arthroplasties in patients with osteoarthritis from the articles *(20,22)* data were not taken over into the table. Four studies analysed the Total Evolutive Shoulder System (TESS) from Biomet, four studies the Eclipse prosthesis from Arthrex, and one study analysed the Simplicity prosthesis from Wright Medical (Wright Medical, Memphis, TN, USA, formerly Tornier)

Huguet et al. *(20)* conducted a multi-centre study and reported on 70 patients with 72 shoulder replacements of which 61 patients with 63 prostheses were followed up for a minimum of three years. Only 19 of the prostheses were total shoulder arthroplasties. The number of patients with osteoarthritis was only given for the whole cohort. Therefore, we could not compare the data with those from other authors. Nevertheless, the authors showed an improvement from 30 to 75 points for the Constant–Murley score and an improved range of motion that was comparable to the other published data.

Berth et al. *(2)* published a single centre study. 49 of 86 patients suffered from osteoarthritis and received a total shoulder replacement. Range of motion and scores improved significantly at an average of 33 months after surgery and was similar to those of other authors. Kadum et al. *(22)* summarized the results of two types of prostheses implanted for different indications. In addition, they defined different outcomes and used different score systems so that this study is not eligible for comparison. In contrast to this study Razmjou et al. *(30)* analysed the results of three shoulder prostheses. Amongst others, they presented the data of 17 patients who received a TESS total shoulder arthroplasty at two years of follow-up. Although the aim of the study was to examine the difference in clinical and radiologic outcomes of total shoulder replacement among three prostheses with different designs this study provides a well examined cohort of patients with a stemless total shoulder arthroplasty. The authors did not find differences in functional results between three prosthesis designs and the presented data of stemless prosthesis are comparable with those from the other studies.

Table III. — Currently published functional results for stemless total shoulder arthroplasty in patients with osteoarthritis

Author	Implant	N	FU (m)	ABD (°)	FLE (°)	ERO (°)	Constant (pts)	Constant (%)	DASH (pts)
Huguet *(20)*	TESS	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Berth *(2)*	TESS	49	33	105	116	55	55	73	46
Kadum *(22)*	TESS	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Razmjou *(30)*	TESS	17	24	121	135	54	n.a.	92.	n.a.
Habermeyer *(17)*	Eclipse	25	68	140	153	46	68	78	n.a.
Brunner *(4)*	Eclipse	66	21	135	145	41	n.a.	89	n.a.
Schoch *(35)*	Eclipse	96	13	105	145	40	66	n.a.	n.a.
Maier *(25)*	Eclipse	12	6	86	97	n.a.	48	n.a.	n.a.
This study	Eclipse	20	24	138	144	39	68	79	27
Churchill *(7)*	Simplicity	149	24	147	n.a.	56	81	104	n.a.

TESS Total Evolutive Shoulder System, n.a. not available (explanations see text), FU follow-up period, ABD Abduction, FLE Flexion, ERO External Rotation, DASH Disabilities of the Arm, Shoulder and Hand

Results from the Eclipse prosthesis are similar to those received from the TESS. The study of Habermeyer et al. *(17)* is the only one that presents midterm results of a stemless shoulder prosthesis until now. The authors monitored 25 patients with total shoulder arthroplasties over more than 5 years and could show that there was no deterioration over time. The adjusted Constant–Murley score was less than that in the study of Brunner et al. *(4)* which contained Habermeyer's short-term results but were approximate to the data from Berth *(2)*, Schoch *(35)* and our own data. Range of motion was better than in the study of Brunner. Schoch et al. *(35)* followed 96 patients over 13 months and found similar results. The study of Schoch presents the largest cohort of patients who received an Eclipse prosthesis from one centre. Functional results revealed by our present analysis are in line with those in currently available reports.

Lately, Churchill et al. *(8)* published the first study on the Simplicity prosthesis from Wright Medical and confirmed the excellent results of the other stemless implants. The study was performed at fourteen sites throughout the U. S. and 89% of the subjects achieved an age and sex-adjusted Constant score of more than 85%, which was the defined cut-off point of clinical success of the procedure.

In contrast to the mentioned studies on the newer implants reports on long term results of stemmed shoulder arthroplasty are available. Usually these studies aim for revealing survivorship of humeral and glenoid components, revision rates and complications. Data on functional results are rare or different outcomes were used. Nevertheless, conventional shoulder arthroplasty has demonstrated good and excellent functional results in short term follow-up studies as well *(3,13,30,39)*. Results of stemless prostheses are absolutely comparable to those of conventional shoulder prostheses and prostheses with other humeral fixation concepts *(5,14,34)*.

The radiological results presented in this study did not show signs of humeral component loosening. This is in line with the data of Habermeyer *(17)* who found radiolucent lines in one patient of his whole cohort that comprised of 78 patients with different indications for shoulder replacement. We observed a slight migration of the humeral head in five prostheses. Functional results of these patients did not differ from those without migration. Migration of the humeral head is a well-known problem of stemmed shoulder arthroplasty as well *(40)*. For the Eclipse prosthesis Habermeyer et al. reported an upward migration of the humeral head in 39% of his patients *(17)*. Therefore, a longer follow-up of our cohort is necessary to assess the consequences of these findings.

Shoulder replacement can be associated with a multitude of complications. Early complications

can be implant specific or of general nature. We did not observe any of the typical intra- or early postoperative complications in our monitored cohort. But as outlined above we had two complications in patients who were excluded from the study. Various authors reported complication rates in shoulder replacement with stemmed prostheses. Aldinger et al. *(1)* reported on 11.6% of complications out of 485 primary replacements after a median follow-up of 1.6 years. Bohsali et al. *(3)* analysed 33 series including a total of 2540 shoulder replacements with a mean follow-up of 5.3 years. They found 15.9% of complications. Typical early complications as infection, intraoperative fracture or nerve injuries occurred in only 2.7% of all surgeries. Similar results were reported by Farng et al. *(11)* who analysed the 90-day complication rates in 6009 total shoulder arthroplasties and found 2.8% of complications including bleeding, infection, revision or nerve injury. In the study of Habermeyer *(17)* the overall complication rate in stemless shoulder arthroplasty was 11.9% which is in line with the data from stemmed shoulder replacements.

The limitations of this study are the lack of a control group with stemmed implants, the short follow-up period and the small number of participants. Therefore, comparability with large series of conventional stemmed shoulder replacements and reproducibility of the results are restricted. However, the data were collected prospectively and come from one institution and a single surgeon. In addition, only two studies with a two years' follow-up and a remarkable larger study population are available and only one study that presents midterm results is published to date. Hence, we believe that our results will supplement existing information about stemless shoulder arthroplasties performed using the Eclipse prosthesis.

CONCLUSION

In line with other reports, this study shows that the Eclipse prosthesis provides consistent functional and radiological results compared to other stemless prostheses as well as stemmed shoulder arthroplasty for primary osteoarthritis. However, the follow-up period for this study was too short to draw conclusions regarding loosening of the humeral component or consequences of upward migration of the humerus head. Nonetheless, stemless prostheses can be considered as an alternative to modern stemmed prostheses in patients with osteoarthritis. Further investigations will be required to gather midterm and long-term results.

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