Prospective study of double-eccentric hemi shoulder arthroplasty in different aetiologies: midterm results

Ulrich Irlenbusch · Georges Blatter · Katja Gebhardt ·
Geza Pap · Peter Zenz

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Abstract This prospective study aimed to analyse the effect of a newly developed double-eccentric adjustable stemmed prosthesis on reconstruction of the osseous anatomy, range of motion, strength and pain relief. A total of 91 consecutive hemiprostheses were evaluated preoperatively and three, six, 12, 24 and 48 months postoperatively (mean±SD 46.2±10.9 months) by the American Shoulder and Elbow Surgeons (ASES) and Constant scores as well as radiological assessment. Clinical evaluations showed an increase in Constant score from 21.9 to 64.8 points and in ASES score from 24.9 to 77.9 points after two years. The results depend mainly on the underlying pathology. The best results were observed for primary osteoarthritis and avascular necrosis of the humeral head. All heads were eccentrically positioned. Specific stem-related complications were not observed. Because of the eccentric positioning of all heads it is reasonable to use adjustable shaft prostheses. The clinical results are comparable to data in the literature. Additional study provided a better or comparable clinical outcome and a low revision rate, when compared with other modern adjustable implants in the literature.

Introduction

Modern prostheses of the third and fourth generation can be adjusted exactly to the individual anatomy of the proximal humerus to avoid deviations from the anatomical geometry (e.g. misalignments and malpositioning of the joint centre). The kinematics of the joint are therefore less affected by these prostheses when compared with conventional prostheses of former generations [22, 26]. Optimal reconstruction of anatomy results in optimised freedom of action and reduces the risk of subacromial impingement. In particular, the exact reconstruction of the centre of rotation is necessary to maintain normal function of the rotator cuff and to minimise eccentric loading of the glenoid [5, 9, 11, 20]. Initial experimental and clinical results suggest that modern third and fourth generation prostheses are beneficial for later function [3].

In our study we used the Affinis prosthesis (Mathys Ltd., Bettlach, Switzerland) that allows independent relocation of the cone and eccentric adjustment of the head position resulting in double-eccentric adjustability (Fig. 1a–c). In contrast to implants with single-eccentric adjustment where the selectable head positions comprise a circular path, the head position of the Affinis prosthesis is freely selectable within the full adjustment range. This enables optimal adjustment to the individual anatomy and reconstruction of the rotational centre of the humeral head (Fig. 2). The medial-lateral and anterior-posterior ranges of adjustment of the Affinis prosthesis are ±6 and ±3 mm, respectively. This corresponds to the variability that has been observed in cadaver tests [9, 26].

The aim of this study was to compare prospectively the clinical and radiological outcomes and complications observed with the newly developed shaft prosthesis in different aetiologies. Furthermore, we evaluated whether the variable

U. Irlenbusch (✉) · K. Gebhardt
Marienstift Arnstadt, Orthopaedic Surgery,
Wachsenburgallee 12,
99310 Arnstadt, Germany
e-mail: ulrich.irlenbusch@ms-arn.de

G. Blatter
Rosenberg Clinic, Orthopaedic Surgery,
Heiden, Switzerland

G. Pap
Park Clinic, Orthopaedic Surgery,
Leipzig, Germany

P. Zenz
Otto-Wagner-Spital, Orthopaedic Surgery,
Vienna, Austria

Fig. 1 Principle of double-eccentric adjustment of the head (Affinis prosthesis, Mathys Ltd., Bettlach, Switzerland). **a, b** Extreme lateral and medial positions of the head result from adjustment of the cone and maximal eccentric positioning of the head. **c** Eccentric positioning of the cone in the humeral head

adjustment options of the head position are required and whether they are needed in routine clinical practice.

Materials and methods

A total of 94 consecutive patients receiving a hemi shoulder prosthesis were enrolled between April 2003 and December 2006 in this prospective study; 88 prostheses were analysed (Arnstadt 36, Vienna 22, Magdeburg 13, Heiden 20). Patients without a 24-month follow-up assessment were not included in the study. Six patients did not show up for follow-up (three had died, two could not be reached and travelling was too far for one). Clinical and radiological evaluations were performed preoperatively as well as three, six, 12, 24 and 48 months postoperatively (mean±SD 46.2±10.9 months) for all enrolled patients. The status of the rotator cuff was assessed intraoperatively. Only patients with intact or partial ruptured cuff were included.

The 91 hemiprostheses were implanted in 30 men and 61 women with a mean age at surgery of 68.2 years (range 41.2–91.3 years). The right shoulder was operated on 48 times and the left shoulder 43 times. In 43 cases, the prostheses were cementless and in 48 cases cemented.

Indications for implantation were: 41 primary and 15 post-traumatic osteoarthritis (especially dislocation arthropathy and secondary osteoarthritis occurring after fractures without significant malformation healing), malformation healing of 14 fractures (types 1 and 2 fracture sequelae according to Boileau), 13 rheumatoid arthritis, four avascular necroses of the humeral head, two chondromatoses and two cases of Gaucher's disease.

Clinical criteria

Shoulder function was evaluated by the Constant and American Shoulder and Elbow Surgeons (ASES) scores. Strength was assessed in seated patients using a spring balance at the wrist joint, with the arm abducted to 90° in the scapular plane. All assessments were performed by investigators not directly involved in the surgical procedure.

Radiological assessment

In all patients, radiographs were taken preoperatively and at follow-up visits, using anteroposterior (AP) and axillary views.

Surgery

All operations were performed by only one surgeon of each clinic. All used an agreed-upon technique with delto-pectoral approach. Osteotomy of the humeral head was performed

Fig. 2 Examples for Affinis hemiprosthesis. **a, b** Cementless implantation in avascular necrosis. **c–f** Cemented implantation in fracture sequelae—the adjustment of the prosthesis to the fracture that had healed in an abnormal position is clearly visible. Status post two-stage plate removal and infection treatment

with a resection guide of 130° inclination and according to the anatomical retrotorsion. After opening the humeral shaft and preparation of the bearing, the rasp was used as a trial shaft and completed with a medial-lateral shifting cone with an offset of 3 mm in both directions (Fig. 1a, b). The head of the prosthesis possesses a borehole with a 3-mm offset to the humeral head (Fig. 1c). In combination with the sliding cone this results in a functional double eccentric providing a combined offset of 12 mm in the medial-lateral direction and 6 mm in the dorsal-

ventral direction. The settings of the cone and the head positions achieved in the trial implantation were then applied to the original implant.

Statistical methods

Descriptive statistics comprise mean and standard deviation as well as median and range (min., max.) of results at the last follow-up.

Fig. 3 Comparison of Constant scores (a) and ASES scores (b) preoperatively as well as 3, 6, 12, 24 and 48 months post surgery ($n=91$; median value; box = 25th and 75th percentiles, whisker = max. and min. value)

Constant scores by diagnosis were compared by multiple regression models (i.e. covariance and variance analysis, respectively). The distribution of the residuals in comparison with normal distribution was analysed by Q-Q plots or scatter plots of the residuals against estimated values. Separate models for the clinical evaluations at three, six, 12, 24 and 48 months postoperatively were estimated.

Constant score, abduction, flexion, external rotation and strength were tested for association with diagnosis by nonparametric Wilcoxon/Kruskal-Wallis tests. The P values were adjusted according to Bonferroni for all comparisons for diagnosis, abduction, flexion and power values. Pre- to postoperative improvement was tested by a two-sided paired t test with a 5% level of significance. All statistical evaluations were performed with SAS version 9.1.3 (SAS Institute Inc., Cary, NC, USA).

Results

Clinical evaluations showed an increase in Constant score from 21.9 to 50.5 points and in ASES score from 24.9 to 64.2 points within the first three months (Fig. 3a, b). Functionality expressed by Constant and ASES scores improved continuously to 64.8 and 77.9 points, respectively, until the two year follow-up. Further progression showed a slight decrease in both scores. Of note, the function achieved by many patients postoperatively was above the age-adjusted average.

Functional improvement indicated by the Constant score was confirmed by the consistent and significant improvements of all components: strength, mobility and pain relief (Table 1). Postoperative radiographs showed no evidence of essential radiolucent lines or loosening of the prosthesis shaft.

The grouping of the results by diagnosis resolves the variability seen in the overall population (Table 2). As expected, good results were achieved in primary osteoarthritis and avascular necroses of the humeral head; however, they were also achieved in post-traumatic osteoarthritis. Functional

Table 1 Pre-/postoperative functional gain in categories of Constant score (hemi shoulder arthroplasty, $n=91$)

Parameter		Preop.	Last FU	P
Pain (max. 15 points)	Mean	1.8	11.1	<0.001
	SD	2.8	4.2	
	Median	0.0	10.0	
	Min.	0.0	0.0	
	Max.	15.0	15.0	
Strength (max. 25 points)	Mean	5.3	12.5	<0.001
	SD	3.9	7.4	
	Median	5.0	13.0	
	Min.	0.0	0.0	
	Max.	17.0	25.0	
Abduction (°)	Mean	48.7	101.3	<0.001
	SD	31.7	43.6	
	Median	45.0	105.0	
	Min.	15.0	15.0	
	Max.	165.0	165.0	
Fwd. flexion (°)	Mean	65.3	111.0	<0.001
	SD	34.2	37.4	
	Median	75.0	105.0	
	Min.	15.0	45.0	
	Max.	165.0	165.0	
Ext. rotation (°)	Mean	2.1	6.4	<0.001
	SD	2.0	3.3	
	Median	2.0	8.0	
	Min.	0.0	0.0	
	Max.	8.0	10.0	

Last FU investigation at time of last follow-up, P = level of significance for comparison between preop. and last FU

Table 2 Comparison of hemi shoulder arthroplasty in different aetiologies

Aetiology	Parameter	Constant, absolute		Constant, adjusted		<i>P</i>
		Preop.	Last FU	Preop.	Last FU	
Primary OA, <i>n</i> =41	Mean (SD)	23.6 (12.4)	60.0 (22.3)	31.9 (15.7)	81.7 (31.1)	< 0.0001
	Median	22.5	64.5	31.4	81.9	
	Min./max.	4/55	21/98	4.8/66.3	30.4/128.6	
Post-traumatic OA, <i>n</i> =15	Mean (SD)	21.1 (11.1)	76.5 (20.6)	26.8 (15.1)	96.7 (27.0)	< 0.0001
	Median	22.0	82.0	27.7	100.0	
	Min./max.	5/48	29/100	5.6/68.6	29.6/130.4	
Fracture sequelae, <i>n</i> =14	Mean (SD)	18.2 (5.5)	50.1 (18.9)	23.7 (7.7)	64.7 (22.9)	< 0.0001
	Median	18.5	52.0	23.7	63.0	
	Min./max.	9/25	22/82	10.8/36.2	26.5/98.8	
RA, <i>n</i> =13	Mean (SD)	23.9 (7.8)	58.1 (21.9)	30.5 (12.1)	74.8 (32.9)	0.00024
	Median	21.0	64.0	26.5	70.7	
	Min./max.	12/40	27/90	15.0/57.1	30.0/123.3	
Various, <i>n</i> =8	Mean (SD)	18.4 (9.1)	72.0 (18.6)	24.8 (12.3)	96.4 (21.4)	< 0.0001
	Median	17.5	69.5	25.2	101.0	
	Min./max.	2/33	41/96	2.9/45.2	58.6/121.7	
Total, <i>n</i> =91	Mean (SD)	21.9 (10.5)	62.0 (22.4)	29.0 (14.0)	81.9 (30.1)	<0.0001
	Median	21.0	66.5	26.5	84.3	
	Min./max.	2/55	21/100	2.9/68.6	62.5/130.4	

Last FU investigation at time of last follow-up, OA osteoarthritis, RA rheumatoid arthritis, *P* = level of significance for comparison between preop. and last FU for corrected and uncorrected Constant score

improvements in rheumatoid arthritis were less pronounced and were the lowest in the group “fracture sequelae”. Although the differences between the diagnostic groups were remarkable, they were not significant.

Fig. 4 Projection of the rotation centres of the humeral head to the osteotomy level. The calculation resulted from the position of the prosthesis cone and the head eccentric (*n*=91). Circle: orbit of adjustable head centres of a single eccentric prosthesis, in this example with 3-mm radius. Graph not true to scale

All head prostheses were eccentrically positioned. Based on the positions of the sliding cone (± 3 mm) and the head component (1–12 o'clock position) the genuine positions of the head centres were calculated (Fig. 4). These points result from the adjustment to the anatomy of the bone and correspond to the projections of the individual rotational centres in the resection plane. The origin of the coordinate system corresponds to the virtual rotational centre of a conventional prosthesis without eccentric. Interestingly, not one single anatomically defined rotational centre in our patient population coincided with the virtual rotation centre of a conventional prosthesis. Also prostheses with a single eccentric that allow adjustment of the rotational centre on a circuit with 3-mm radius cover only a minority of anatomically defined rotational centres (approximately 17). The majority of rotational centres lie within or outside of this orbit.

Complications

Because of painful secondary glenoid erosion, a second glenoid implantation was necessary in four cases at a mean of 26 months after the index procedure (Fig. 5, Table 3). This led to an improvement in all patients. A two-stage revision with reimplantation was necessary in one patient with a late infection, and in another patient an infected haematoma had to be revised. In both cases the patients had undergone previous surgery and were in the group “fracture sequelae”.

Fig. 5 Painful shoulder joint due to secondary glenoid erosion, probably as the result of overstuffing (insufficient head resection). **a** Postoperatively 6 May 2003. **b** Follow-up 7 January 2005 (62-year-old woman)

One patient developed a frozen shoulder postoperatively, which was treated by manipulation under anaesthesia, and in one patient a secondary rotator cuff tear led to postoperative impingement.

Discussion

In shoulder arthroplasty long-term survival of the implant is of utmost importance; however, the ability to reconstruct the osseous anatomy to the best of the surgeon's ability is a major aspect. This study aimed to show whether the newly developed Affinis prosthesis, with relocatable cone and eccentric head allowing for double-eccentric adjustability, provides a better or comparable clinical outcome and acceptable revision rate, when compared with other modern generation implants in the literature.

Many patients achieve more than 100% in age- and gender-corrected Constant score, i.e. above the age-adjusted average. The mean results are, however, comparable to those of other modern prostheses (Fig. 3a, b; Tables 2 and 4); adjusted Constant scores of 97% have been reported by Godenèche et

al. for the Aequalis prosthesis in primary osteoarthritis (268 endoprostheses, mean follow-up 30 months) and 93% by Habermeyer and Engel for the Univers prosthesis (97 cases, mean follow-up 31 months) [6, 7]. Overall, this indicates satisfying accordance, especially when considering the different preoperative values (see Table 2). Additionally most investigated endoprostheses in Table 4 were total replacement with commonly better results.

As certain parameters carry different weight, the ASES score shows a steep increase in the first postoperative months (Fig. 3a, b). However, for both scores the maximum was reached after a follow-up period of two years. The decrease seen after this period was not a result of complications incurred through surgery or secondary glenoid erosion. Since the decrease was most pronounced in the groups "rheumatoid arthritis" and "fracture sequelae", it was most likely due to different factors, such as secondary ruptures of the rotator cuff. Although we found no clinical or sonographic evidence to support this hypothesis, there is no doubt that the decreasing level of care in these patients, in particular less intensive physiotherapy, plays a major role. After attaining good results after two years, the discipline and the activity of the patients may decline. The gradual deterioration could go unnoticed and the patients could then adapt to the increasing loss of function. Furthermore, the increasing age of the patients may have an additional effect.

Since the results of the overall population showed a broad variance (Fig. 3a, b) we grouped them by the initial diagnosis (Table 2). Interestingly, the group with post-traumatic osteoarthritis achieved the best results with 96.7%, followed by the group with other indications (including the four avascular necroses of the humeral head) with 96.4%. Improvements in these groups might be facilitated by the younger age of the patients, short disease duration and limitation of impairment to the humeral head. Accordingly,

Table 3 Complications (total group, $n=91$)

Complication	<i>n</i>
Secondary glenoid implantation	4
Two-stage revision (late infection)	1
Haematoma revision (infected)	1
Secondary frozen shoulder	1
Secondary rotator cuff rupture	1
Luxations	None
Neurological complications	None

Table 4 Results after implantation of shoulder endoprotheses for primary osteoarthritis of the shoulder joint

Authors	Type of prosthesis	n	FU (months)	Total/hemi	Flexion (°) pre/post	Pain pre/post	Constant pre/post	ASES pre/post
Neer et al. (1982) [18]	Neer	40	39	40	51° gain	— —	Neer rating system: 90% excellent, 8% sufficient	
Matsen et al. (2000) [16]	Global	134	41	134 0	— —	— —	39 P 61 P	— —
Mansat et al. (2002) [15]	Neer Monoblock ×27 Neer Modular ×24	51	60	43 8	73 140	1.5 ^b 12 ^b	— 91%	— —
Norris and Iannotti (2002) [19]	Global	176	46	133 43	102 138	74 ^c 14 ^c 73 ^c 20 ^c	— —	33 85 35 79
Godenèche et al. (2002) [6]	Aequalis	268	30	251 17	94 145	3.6 ^b 12.5 ^b	38% 97%	— —
Iannotti and Norris (2003) [10]	Global	128	46	95 33	— —	74 ^c 14 ^c 73 ^c 20 ^c	— —	33 86 35 79
Orfaly et al. (2003) [21]	—	65	52	37 28	100 147	68 ^c 8 ^c 56 ^c 16 ^c	— —	37 91 42 84
Edwards et al. (2003) [4]	—	15	37	11 4	89 146	— —	32 P 71 P	— —
Habermeyer and Engel (2004) [7]	Univers	97	31	—	— —	5.3 ^b 13.3 ^b	46% 93%	— —
Haines et al. (2006) [8]	Global	95	61	64 31	— 114 106	— 1.8 ^a 2.5 ^a	— 60 P 52 P	— 71 55
Our study (2010)	Affinis	92	48	— 91	65 111	1.8 ^b 11.1 ^b	29% 82%	25 75

FU follow-up, P points absolute Constant score, % = adjusted Constant score

^a Max. 10 points/visual analogue scale

^b Max. 15 points

^c Max. 100 points

the constitution of the soft tissue and musculature might be more favourable compared to the other groups. In general, very good results after implantation of an endoprosthesis for avascular necroses have been reported [14]. Also in osteoarthritis following shoulder instability good or very good results have been reported [23]. Matsoukis et al. showed an increase in Constant score from 30.8 to 65.8 points after a mean follow-up of 45.0 months in patients with multiple prior surgery for dislocation [17].

Also good results can be achieved in primary osteoarthritis in the range of the mean results of the overall population (Table 2) and the results reported for other modern implants (Table 4). Mansat et al. reported similar results for the Neer prosthesis, a second generation implant [15].

Results for rheumatoid arthritis and the group “fracture sequelae” (Table 2) are less favourable [2, 12, 13]. Boileau et al. achieved a Constant score of 62 points in patients with type 1 fracture sequelae among 203 patients with malunited fractures after a mean follow-up of 42 months [2]. For rheumatoid arthritis, reported results vary, whereas several authors noted that results strongly depend on the state of the rotator cuff [12]. Woodruff et al. reported Constant scores of

47.9 and 59.0 points, respectively, for the hemi shoulder arthroplasty [27].

Our results support the need for an adjustable prosthesis. All humeral heads were implanted eccentrically to achieve optimal adjustment to the medial and dorsal offset (Fig. 4). The distribution of rotational centres shows a lateral cluster due to the optimisation process during positioning of the humeral head. Since the humeral resection plane has an oval or irregular shape, and never a circular one, the circular humeral head must be adjusted. The prosthesis allows for free placement of the head component; the surgeons focused on optimal transition from the humeral head to the insertion of the supraspinatus tendon. Thus, the prosthesis allows for optimal reconstruction of the humeral geometry, a prerequisite for good function of the prosthesis and something which has been requested by many authors [5, 11, 20, 22, 26].

Neither serious intraoperative complications nor an increased risk of postoperative complications were observed, in particular no implant-specific complications (Table 3). No postoperative luxations were observed in our patient population. The rate of secondary glenoid implantations (4.4%, 4 of 91 head prostheses) is below the reported range in

different studies [23, 25]. Also periprosthetic infections (1.1%, 1 of 91) are in the range of 0–3.9% reported in the literature [1, 24].

Conclusion

In summary, the clinical results of the Affinis prosthesis system are comparable to other modern shaft prostheses. No implant-specific complications were observed. Results depended mainly on the underlying pathology whereas the best results were achieved in avascular necroses, post-traumatic osteoarthritis without excessive malpositioning of the components and primary osteoarthritis. Also for rheumatoid arthritis and fracture sequelae significant functional improvement and pain relief were achieved, however, to a lesser extent when compared with the other indications.

All humeral head components were eccentrically positioned for optimal adjustment to the variable anatomical proportions, supporting the use of adjustable prostheses. Reconstruction of the proximal humeral anatomy is fundamentally easier and more accurate compared to older prosthesis systems.

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Ethics standard The study protocol was reviewed and approved by the Ethics Committee, St. Gallen, Switzerland, the Institutional Review Board of the Marienstift Arnstadt, Germany and the Ethics Committee of the Town of Vienna, Austria. All patients were informed preoperatively and provided their consent to participate in this study on a consent form.

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