



Clinical evaluation of a new custom offset shoulder prosthesis for treatment of complex fractures of the proximal humerus

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Primary hemiarthroplasty of the shoulder is an accepted procedure to treat complex proximal humeral fractures. The goal of this study was to assess the functional outcome in patients treated with hemiarthroplasty using a custom offset shoulder prosthesis, either for an acute four-part fracture of the proximal humerus or following failed primary treatment of a complex humeral fracture .

Thirty seven patients were followed up for a mean of 17 months after shoulder replacement (Group A : four-part-fractures ; n = 26, Group B : post-traumatic necrosis/non-union after failed primary treatment ; n = 11). The Constant-Murley-Score and radiological score according to Neer's classification were used for postoperative functional and radiological assessment.

Following hemiarthroplasty, Group A achieved an average Constant Score of 52 and Group B of 46. The pain relief after hemiarthroplasty was about 53% in Group A and only 33% in Group B. The least satisfying partial function was shoulder mobility in both groups. Radiographic evaluation did not correlate with the Constant Score.

Patients secondarily treated with arthroplasty seem to have less chance to achieve a satisfying functional outcome compared to those with immediate hemiarthroplasty. These results emphasise the importance of a careful initial decision to select the most appropriate treatment modality in complex fractures of the proximal humerus.

Keywords : proximal humerus fracture ; shoulder hemiarthroplasty ; Constant-Murley Score ; custom offset prosthesis.

INTRODUCTION

Fractures of the humeral head represent about 4-5% of all fractures in adult patients. The overall incidence per 100,000 is 48 in men and 142 in women, with an exponential increase in the 5th decade (12). Osteoporosis represents one of the main predisposing factors in elderly women. A complex fracture type, defined by angulation greater than 45° or displacement greater than 1 cm, is present in 15% of all proximal humeral fractures (15) and still remains a great challenge for the trauma surgeon. The choice of treatment for a patient with a three- or four- part fracture is controversial and is based on conservative treatment modalities, minimally-invasive osteosynthesis (K-wires combined with tension band wiring), locking nail, conventional and angular proximal humerus plates or shoulder arthroplasty (8, 11, 13, 14, 19, 21).

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Primary arthroplasty in complex proximal humeral fractures was first advocated by Neer (16) in 1970 and is now used for treatment of fractures that are impossible to reconstruct with internal fixation techniques. These fractures are categorised as displaced four-part fractures, four-part fractures with dislocation of the humeral head and fractures with a head split involving more than 40% of the articular surface (13). Advanced age favours a treatment regimen involving the performance of a shoulder hemiarthroplasty.

In shoulder replacement attention should be paid to the restoration of humeral length and offset, retrotorsion of the prosthesis, center of rotation and to osseointegration of the tuberosities. To preserve the anatomical features of a healthy shoulder, new shoulder prostheses of the third generation called custom offset prostheses were recently developed. These new models allow for adjustment of the ante- and retrotorsion in the head-neck-axis and a three-dimensional positioning of the prosthesis head relative to the stem to restore the kinematics of the glenohumeral joint. The possibility to tune the retrotorsion is useful, since in a non-modular prosthesis system the alignment of the prosthesis stem is eventually determined by the reamed bone marrow channel.

Another indication for shoulder hemiarthroplasty is failed primary treatment following a complex fracture of the proximal humerus. Aetiological factors for failure include the development of avascular bone necrosis as well as secondary displacement, either after operative or conservative treatment. Conservative fracture treatment is known to be associated with a high degree of secondary displacement, mal-union and non-union of the fracture. Some authors have achieved good results in treating these complications secondarily with a second generation hemiarthroplasty (1, 2, 17). However, there is a lack of data concerning the clinical evaluation of custom offset prostheses in primary and secondary treatment of humeral head fractures.

We therefore undertook this study to evaluate the functional outcome of 37 patients treated with an EPOCA custom offset prosthesis after acute 4-part fracture and after failure of initial treatment of a complex proximal humeral fracture, respectively.

Our second objective was to compare the clinical results of both patient subsets after a short-term follow-up.

PATIENTS AND METHODS

Patients

Between September 2000 and November 2002, 37 EPOCA – C.O.S (Custom Offset) hemiarthroplasties (Argomedical, Cham, Switzerland) were performed at the Department of Orthopaedic and Trauma Surgery at the University Medical Center of Freiburg. Indications were either four-part-fractures of the proximal humerus (Neer Classification (15) (Group A ; n = 26, m : f = 7:19) or posttraumatic necrosis and pseudarthrosis after failed treatment of three- or four-part fracture of the proximal humerus (Group B, n = 11, m : f = 1:10). Shoulder arthroplasty was only used for co-operative medically healthy patients, who had a normal shoulder function prior to the injury. The mean age was 70.3 +/- 10.4 years in Group A and 76.6 +/- 8.9 years in Group B (table II). Injury was almost equally distributed to both shoulders.

All patients in the study reported normal shoulder function prior to the injury and reported ability to raise the affected arm above shoulder height. No patient had undergone previous surgery involving the ipsilateral shoulder.

Operative procedure and postoperative treatment regimen

Antithrombosis and antibiotic prophylaxis was administered preoperatively to all 37 patients. A deltopectoral approach was used to perform shoulder joint replacement. An EPOCA Custom Offset Shoulder prosthesis was implanted in all patients for whom treatment with hemiarthroplasty had been elected. The humeral implant consists of three components : stem, eccentric and head. Components with appropriate sizes were combined and positioned to reconstruct length, size and height of the head component. The medial and posterior offsets as well as the retrotorsion of the prosthesis were adjusted intraoperatively. Stabilisation of the stem was performed with Palacos bone cement. The tuberosities were subsequently repaired with stainless-steel-wire and fixed to the prosthesis.

Postoperatively all patients were treated with a Gilchrist-sling for two weeks. On the second postoperative days the patients started with passive range-of-motion exercises, stepwise active-assisted range-of-motion exercises and after six weeks active-range-of-



Fig. 1. — 76-year-old woman with a 4-part fracture of the proximal humerus (A, B). The fracture was treated with an EPOCA C.O.S. shoulder prosthesis (C) 11 days after the injury and 8 weeks after injury (D). The patient was followed-up for 11 months and achieved a Constant Score of 73.

motion exercises. Postoperative therapy was performed under supervision of a physiotherapist. All patients were provided with an individual training program which they could perform independently at home.

Radiographic assessment

The preoperative, initial postoperative and the current radiographs were evaluated. Conventional radiographs in two planes were used for radiographic analysis (fig 1). Eight different radiographic criteria according to Neer were examined (23): assessment included rotation and angle, congruity of the joint, position of the tuberosities, implant failure, heterotopic ossification, pseudarthrosis and bone necrosis. The value of each criteria varies

between 0 (major change) and 10 (no change) (table III). All appropriate criteria were listed and an average score was calculated for each patient.

Functional Assessment

Functional outcome of all patients was assessed using the standard Constant-Murley Score (4). It is classified in four different subscores analysing degree of pain, activities of daily living, range of motion and strength. Additionally, it consists of a clinical examination as well as a questionnaire. Questions were recorded using a visual analog scale (VAS). The individual strength was measured with a tension spring balance and each value was repetitively controlled.

Table I. — Epidemiologic data of all treated patients. Thirty seven hemiarthroplasties were performed in patients with either recent 4-part fractures of the proximal humerus (Group A) or with a posttraumatic necrosis or pseudarthrosis after failed treatment of 3- or 4- part fracture of the proximal humerus (Group B)

	Group A (n = 26)	Group B (n = 11)
Age (mean ± SD)	70.42 ± 10.37 years	76.64 ± 8.9 years
Days of admission (mean ± SD)	17.85 ± 7.04 days	26.9 ± 12.9 days
Time to operation (mean ± SD)	7.6 ± 4.4 days	149 ± 163,1 days
Operation time (mean ± SD)	129 ± 27.9 min	136.89 ± 45.16 min
Gender (m:f)	7:19	1:10

Compliance assessment

The postoperative outcome relies on the compliance and collaboration of the patient. We therefore used a five-grade-score to measure compliance (table V) which is based on the collaboration during physiotherapy (no collaboration, minimal collaboration, good initial collaboration, good collaboration (no personal initiative), good collaboration with stand-alone training program).

Statistical analysis

All data were analysed with SPSS Version-11 software package (SPSS, Chicago, Illinois, USA). Descriptive statistics were applied using median, mean value and standard deviation of the mean. The correlation was calculated with the Pearson method.

RESULTS

Patient data

Postoperatively 30 of 37 patients (81%) were followed-up over a period of 15 months (range : 8 to 27), and an average follow-up time of 17 months and 15 months respectively in Group A and B was achieved. Six patients died within one year after surgery from unrelated causes and one patient denied examination. Twenty six patients in Group A proceeded to operation within eight days following trauma and 11 patients in Group B underwent

shoulder hemiarthroplasty approximately six months after the injury (table I). Six patients in Group B (55%) had three- or four- part fractures with secondary displacement following conservative treatment in five cases and operative treatment in one case. A four-part malunion was observed in two patients (18%) (fig 2) and postoperative osteonecrosis was observed in three patients in group B (27%) conservatively (n = 1) and operatively (n = 2) treated prior to shoulder replacement.

Radiographic results

With an overall radiographic score from 6 to 10 points, Group A achieved a mean of 5 points and Group B a mean of 4 (table II). There was no significant difference observed ($p > 0.3$). The radiographic outcome did not correlate with the corresponding Constant Scores.

Functional assessment (Constant Scores)

The Constant Score for all 27 patients was 50 ; Group A achieved a score of 52 and Group B a score of 46 (table II).

Specific subscores were determined for pain, activities of daily living, range of motion and power. The subscore for pain was 7 (of 15), Group A had a score of 8 and Group B a score of 5. The subscore for power was 19 (of 25) and both groups achieved similar values. The score for range of motion was 14 (of 40) in both subsets and the score for activities of the daily-living was 10 (of 20) (fig 3).

To assess the physiological loss of function, the Constant Score (CS) of the healthy shoulder was calculated (CS of Group A and B : 91) and compared to the injured shoulder. However, we observed that patients with a poor score for the healthy shoulder had a worse functional outcome for the injured shoulder.

All patients were asked to assess their shoulder function by themselves in percent of the healthy contralateral shoulder (100%). They reported on average 50% function of the injured shoulder postoperatively. The functional self-assessment correlated with the Constant Score (Pearson-Coefficient 0.783).

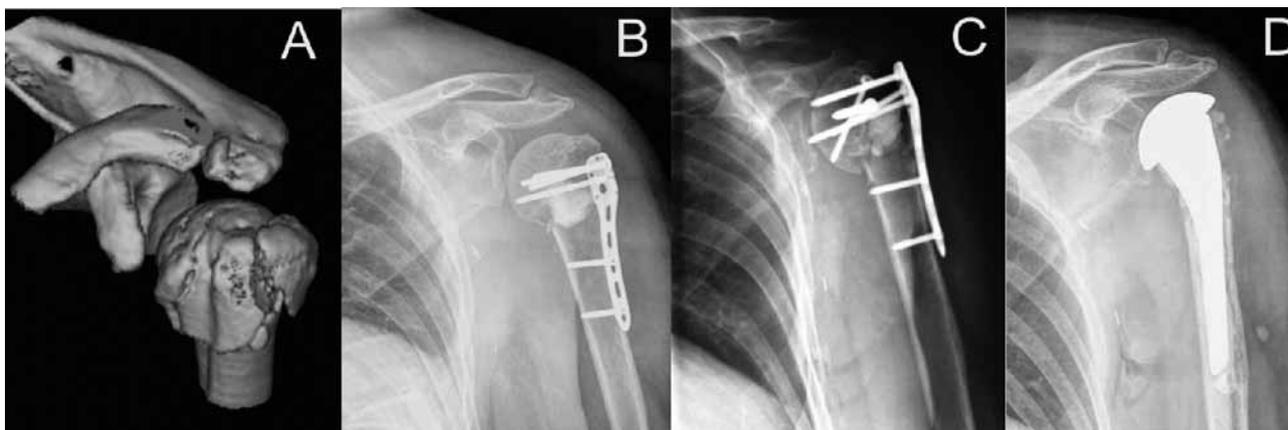


Fig. 2. — 78-year-old woman with a 3-part fracture of the proximal humerus (CT reconstruction) (A). As initial treatment an open reduction and internal fixation with a proximal humerus plate was performed (B). The treatment lead to a necrotic non-union of the humeral head 4 months after the injury (C). The non-union was treated with an EPOCA C.O.S. shoulder prosthesis. (D) The patient was followed-up for 1.5 years after implantation of the shoulder prosthesis and reached a Constant Score of 37.

Table II. — Constant Scores of all patients.

37 Hemiarthroplasties were performed in patients with either 4-part-fractures of the proximal humerus (Group A) or with a posttraumatic necrosis or pseudarthrosis after failed treatment of 3- or 4-part fracture of the proximal humerus (Group B)

Constant Score	Group A	Group B
Injured Shoulder (mean ± SDM)	52.2 ± 15.8	46.43 ± 17.61
Healthy Shoulder (mean ± SDM)	91.2 ± 10.42	89.33 ± 11.43
Radiology Score (mean ± SDM)	4.94 ± 2.46	4.00 ± 3.74
Performance Rating Injured Shoulder (mean ± SDM)	49.75 ± 26.68	41.67 ± 24.88

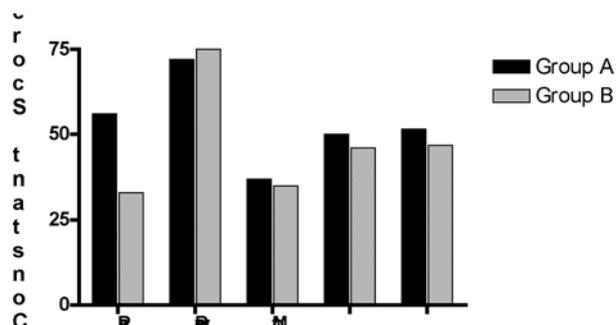


Fig. 3. — Constant Score and Constant Subscores Pain, Power, Activity, Motion in Group A and B in Percent. Group A : Patients with 4-part-fractures of the proximal humerus, Group B : Patients with a posttraumatic necrosis or pseudarthrosis after failed treatment of 3- or 4-part fracture of the proximal humerus.

Prognostic predictors for functional outcome

Patient age, gender, type of fracture, presence of dislocation, rotator cuff tear, presence of neurological deficit and open fracture are considered prognostic predictors for the functional outcome of patients treated for complex fractures of the proximal humerus (5, 20). Seven patients had a fracture-related ipsilateral dislocation of the shoulder and were followed-up for 12 months. They had a Constant Score of 61 of the injured shoulder and 90

of the contralateral shoulder. Three patients with a rotator cuff tear were followed up for 13 months, one of which was secondarily treated with a prosthesis and two underwent primary arthroplasty of a four-part fracture. The total Constant Score of these patients was 67, the motion subscore 27. Two patients with a tuberosity dislocation were followed up for 19 months and achieved a mean Constant Score of 43. The presence of a neurological deficit was observed in one patient with a Constant Score of 47.

Table III. — Radiology Score according to Neer : The preoperative, initial postoperative and the most recent radiographs were evaluated. Conventional radiographs in two planes were used for radiographic analysis. The assessment was carried out with a 10-point-system for each single criterion and a total score was calculated

Criteria	Change	Points
Assessment of rotation and angle, incongruity of the joint,	no	10
Position of the tuberosities, implant failure,	less	8
Heterotopic ossification, pseudarthrosis and bone necrosis	moderate serious	4 0-2

Compliance assessment

The overall mean compliance level was four of five points, there were no differences between both groups. No correlation between compliance score and Constant score was observed.

DISCUSSION

The treatment of complex fractures of the proximal humerus is still a challenge. The choice of treatment is dependent on many factors such as the type of fracture, the experience of the surgeon and the age of the patients. A newly developed prosthesis for shoulder replacement is one of the options for the treatment of complex fractures of the proximal humerus, permitting an anatomical reconstruction of the shoulder joint. In this study, we evaluated the functional outcome following treatment of a four-part fracture of the proximal humerus with a shoulder hemiarthroplasty of the third generation. Moreover our objective was to compare the functional outcome of patients who underwent hemiarthroplasty as a first line treatment (Group A) or after failure of another treatment (conservative treatment or ORIF) (Group B).

In this study we examined a patient cohort of 38 patients with a mean age of 70 years in Group A and 77 in Group B. Despite a certain difference in age between both groups, we could not observe any obvious difference between both groups regarding the overall health status or the function of the unin-

jured shoulder in clinical examination. This was confirmed by an identical Constant score which was 91 in Group A and B. Therefore we think that the assessment of the injured shoulder can be compared between both groups. All patients reached a total Constant Score of 50 for the injured shoulder and had to assess their shoulder function after the operative treatment. The functional rating of the injured shoulder correlated with the achieved Constant Score. The Constant Score seemed to be a valid instrument to follow-up patients with an invalid shoulder function and to assess their improvement after operation.

The analysis of the Constant subscores demonstrated that pain relief was good to moderate, but functional recovery was less consistent following hemiarthroplasty. Despite advances in designing new and better shoulder prostheses, we could not attain a better functional outcome in our study compared to the results reported with prostheses of the first or second generation (3, 9, 10, 20). Besides prosthesis design, factors such as operative technique, mechanism of injury and patient collective bias the functional outcome after hemiarthroplasty. One of the major problems in shoulder replacement is the refixation of the tendons and the tuberosities on the prosthesis. Failed osseointegration and osteolysis of the re-fixed tuberosities can be observed in many patients and results in a poor range of motion. This might be one of the main reasons for the low mobility level, resulting in a subscore of 15/40 points in our study. Our patient collective mainly consists of female patients with a mean age of about 70 years and with a high prevalence of osteoporosis. Parsch and Wittner (18) observed a high rate (5%) of spontaneous rotator cuff tears in patients with proximal humerus fractures older than 65 years. We could find a major defect of the rotator cuff in 14% of all patients, which was repaired intraoperatively. Advanced age and comorbidities in our patient subsets might have been responsible for a moderate functional outcome. Despite the fact that the contralateral healthy shoulder still had a good function in both groups, our postoperative results may be affected by osteoporotic bone or weak tendon structure as frequently seen in old patient collectives. However, shoulder

replacement in complex humeral fractures is considered to be the appropriate treatment, particularly for older patient. Resch *et al* (19) obtained good to excellent results in a younger patient cohort with percutaneous fixation techniques after three- or four- part fractures of the humerus. At the moment a recently developed locked proximal humerus plate (LPHP) is tested in clinical practice in our institution to treat proximal humerus fractures. Plates with locking screws have an improved stability and make percutaneous plating easier (22). But there are no reliable data demonstrating a superiority of arthroplasty over osteosynthesis or vice versa (7).

In this study, patients were distributed in two groups : Group A patients treated primarily with a hemiarthroplasty following their injury, and Group B patients with failure of conservative treatment or internal fixation, who underwent shoulder replacement after an average of 150 days. Patients in Group A achieved a Constant Score of 52 and Group B of 47 points, indicating a trend that the poorer outcome of group B is possibly based on a less effective pain relief than in Group A. This finding can be explained by a higher number of surgeries and longer immobilisation time following failed primary treatment. Antuna *et al* (1, 2) followed 27 patients with non-union of the proximal humerus treated with shoulder arthroplasty and detected a significant pain relief and moderate improvement in shoulder mobility. All patients with a tuberosity non-union or resorption had an unsatisfactory result. Shoulder pain was more intense in patients with a failed initial operative treatment or with osteonecrosis (1, 2). The incidence of post-traumatic osteonecrosis varies between 0% and 70% ; it is caused by the disruption of the blood supply to the humeral head in complex fractures involving the medial column segment. Gerber *et al* (6) could achieve an improved Constant Score in patients with post-traumatic avascular necrosis which were anatomically reduced, compared to those in which open anatomic reduction was not achieved. Therefore the authors favour shoulder joint replacement if anatomic reduction is not possible (6). In our study, the onset of postoperative osteonecrosis led to shoulder replacement in 27%

of patients in Group B, thus contributing to less pain relief. Those patients with an osteonecrosis achieved an average Constant Score of 45 following treatment with custom offset shoulder prosthesis.

Consequently, hemiarthroplasty can be considered as an appropriate treatment in three- and four-part proximal humeral fractures in elderly patients. Our results point out the importance of careful decision making with respect to the treatment modality including sufficient radiographs, computer tomography and intraoperative evaluation in these complex fractures, because failure of primary treatment can lead to a less favourable outcome following secondarily performed hemiarthroplasty.

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