Hemiarthroplasty for Humeral Four-part Fractures for Patients 65 Years and Older

A Randomized Controlled Trial

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Abstract

Background Four-part fractures of the proximal humerus account for 3% of all humeral fractures and are regarded as the most difficult fractures to treat in the elderly. Various authors recommend nonoperative treatment or hemiarthroplasty, but the literature is unclear regarding which provides better quality of life and function.

Questions/purposes We therefore performed a randomized controlled trial to compare (1) function, (2) strength,

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Introduction

Proximal fractures of the humerus represent approximately 4% to 5% of all fractures seen in the emergency department [15]. In the elderly, this fracture has the second highest incidence of fractures in the upper extremity [1]. Risk factors for proximal humeral fractures in the elderly (65 years or older) are female sex, white race, increasing

and (3) pain and disability in patients 65 years and older with four-part humeral fractures treated either nonoperatively or with hemiarthroplasty.

Methods We randomly allocated 50 patients to one of the two approaches. There were no differences in patient demographics between the two groups. The Constant-Murley score was the primary outcome measure. Secondary outcome measures were the Simple Shoulder Test, abduction strength test as measured by a myometer, and VAS scores for pain and disability. All patients were assessed at 12 months.

Results We found no between-group differences in Constant-Murley and Simple Shoulder Test scores at 3- and 12-months followup. Abduction strength was better at 3 and 12 months in the nonoperatively treated group although the nonoperatively treated patients experienced more pain at 3 months; this difference could not be detected after 12 months.

Conclusions We observed no clear benefits in treating patients 65 years or older with four-part fractures of the proximal humerus with either hemiarthroplasty or nonoperative treatment.

Level of Evidence Level I, therapeutic study. See Instructions for Authors for a complete description of levels of evidence.

age, and osteoporosis [2, 24]. Owing to aging of the population, the incidence of proximal humeral fractures is expected to increase as much as three times in the next few decades [26]. Four-part fractures account for approximately only 3% of all humeral fractures but are regarded as the most difficult to treat [8].

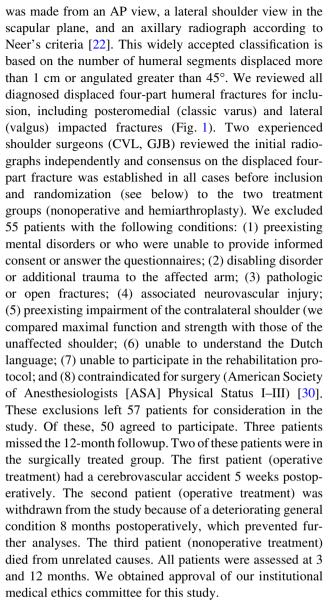
In a systematic review of 66 retrieved articles (two of which were randomized) involving 2155 patients, Lanting et al. found no clear consensus or guidelines regarding the best treatment for proximal humeral fractures owing to various problems with the study designs [19]. However, in another systematic review encompassing 1096 patients with three- and four-part fractures, den Hartog et al. reported higher Constant-Murley scores (CMS) in nonoperatively treated patients compared with patients treated with an arthroplasty [9]. The authors suggested selection bias, unreliable classification of the fracture, and interobserver differences in the assessment of the CMS might have contributed to this difference. However some studies have reported no differences in quality-of-life perception (Euro-Qol-5D) and CMS after nonoperative treatment [36, 38].

In the elderly with comminuted, displaced, and osteoporotic three- or four-part fractures of the humerus treated operatively numerous authors question treatment with open reduction and internal fixation [16, 31, 35, 37], and hemiarthroplasty is supported by numerous authors [22, 28, 35, 37]. There are few published randomized clinical trials (RCTs) comparing nonoperative treatment versus hemiarthroplasty for four-part fractures of the humerus in the elderly. Stableforth, in 1984, reported a prospective trial comparing hemiarthroplasty versus nonoperative treatment of four-part fractures of the humerus in 32 patients [33]. The hemiarthroplasty group performed better with respect to function, pain, and muscle strength. Recently, Olerud et al. compared hemiarthroplasty versus nonoperative treatment of proximal humeral fractures in 55 elderly patients, with better quality of life scores in patients treated by hemiarthroplasty at 2 years' followup [25]. Based on our interpretation of the literature, it appears there is no consensus in the literature regarding the best treatment option for four-part humeral fractures in the elderly.

We therefore performed a RCT to compare (1) function (CMS, Simple Shoulder Test [SST]), (2) strength, and (3) pain and disability (VAS) in elderly patients with fourpart humeral fractures treated either nonoperatively or with hemiarthroplasty.

Patients and Methods

Between June 2004 and July 2009 we treated 105 patients 65 years or older who had displaced proximal humeral fourpart fractures. The diagnosis of a four-part humeral fracture



A power calculation revealed, to detect a clinically important difference of 15 points or more between the non-operatively treated group and the hemiarthroplasty group with respect to the CMS at the 0.05 alpha level with 80% power, 50 patients needed to be enrolled in the study [6].

After written informed consent was received, patients were randomly allocated to nonoperative treatment or hemiarthroplasty. The randomization list was generated by an independent statistician and the resulting treatment allocations were stored in sealed opaque envelopes in the statistician's room. Randomization was performed during the outpatient consultation by the orthopaedic surgeon the first week after the patient experienced the fracture. If possible the patient had an immediate consultation with the involved orthopaedic surgeon in the emergency room. Otherwise, an appointment was made within 3 days. A computer-generated variable block schedule was used for



Fig. 1A–D (A) AP and (B) lateral views show a valgus impacted four-part fracture. These (C) AP and (D) lateral views show varus four-part fractures as seen in the emergency room



randomization of the 50 patients to either hemiarthroplasty (n=25) or nonoperative treatment (n=25) (Fig. 2). Analysis of the baseline characteristics between the two groups showed no differences (Table 1). Based on plain radiographs, both groups consisted of four valgus impacted and 21 classic four-part fractures.

Surgery was planned for within 7 days after trauma for patients who were allocated to hemiarthroplasty. A standard procedure was performed by two experienced shoulder surgeons (CVL, GJB) from our institution. Patients received general anesthesia and were placed in the beach chair position. A prophylactic antibiotics regimen of 2 g systemic cefazolin was administered in all cases. We used a deltopectoral approach. In all patients, we used the Global FX shoulder fracture endoprosthesis (DePuy, Leeds, UK). Care was taken to restore stem height and retroversion with the medial calcar and bicipital groove as landmarks for correct tuberosity alignment. Three drill holes were made in the

humeral shaft and loaded with three Number 5.0 Ethibond® (Ethicon, Inc, Somerville, NJ, USA) nonabsorbable sutures. All endoprostheses were cemented after application of Biostop[®] (DePuy) with Palamed[®] G gentamicin cement (Heraeus Medical GmbH, Wehrheim, Germany) using a cement gun. After insertion of the stem cancellous bone graft was retrieved from the removed articular part of the humeral head and applied on the proximal endoprosthesis stem before restoration of the tuberosities to enhance healing. The inferior part of the tuberosity was restored to the humeral shaft with the preloaded sutures. The superior part of the tuberosity was fixed to the designed holes in the endoprosthesis and encircled with Number 5.0 Ethibond® sutures to enhance anatomic restoration. Postoperative AP radiographs were obtained the day after surgery and patients wore a shoulder immobilizer for 6 weeks.

Patients who were allocated to nonoperative treatment wore a shoulder immobilizer for 6 weeks.



Fig. 2 A flow diagram shows the selection process of the patients through the study.

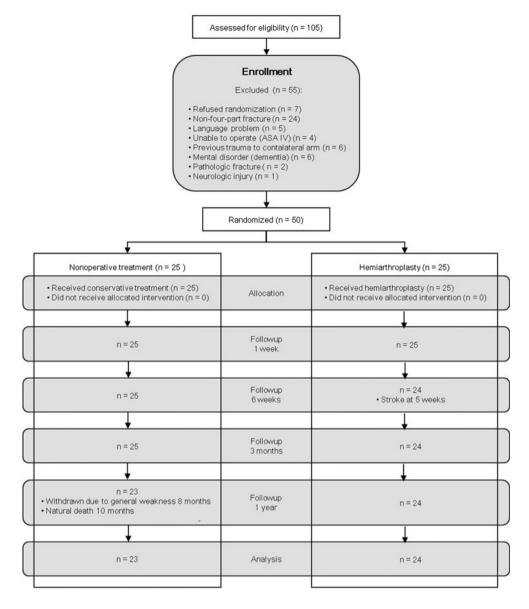


Table 1. Baseline characteristics of the two groups.

Parameter	Nonoperative	Hemiarthroplasty		
r di dilicici	Nonoperative			
Randomization	25	25		
Sex, number (%)				
Male (%)	2 (8)	1 (4)		
Female (%)	23 (92)	24 (96)		
Age (years)	79.9 (7.7)	76.4 (5.6)		
VAS pain before treat	ment			
Number (range)	82 (16–99)*	86 (49–98)*		
VAS disability before	treatment			
Number (range)	95 (52–98)*	94 (72–98)*		

^{*}Median value; all others are mean.

All patients, nonoperatively or operatively treated, underwent the same rehabilitation protocol. Experienced shoulder physical therapists instructed the patients for

40-minute sessions three times a week up to 12 weeks. Every patient started with a shoulder immobilizer for 2 weeks postoperatively or posttrauma with light passive ROM movements. Between 2 and 6 weeks, passive ROM up to 45° forward flexion and abduction and active ROM up to 30° forward flexion and abduction were allowed if pain control was adequate. External rotation was still restricted to 0°. After 6 weeks, passive glenohumeral exercise was unlimited, with active ROM up to 90° in forward flexion and abduction. External rotation was allowed up to 30°. After the 3-month visit, patients were seen by the physical therapist every month until the 12-month followup, with an emphasis on maximizing ROM and strength and return to daily activities with their existing limitations.

All patients were seen in the outpatient department 1 week, 6 weeks, 3 months, and 12 months after surgery or trauma. The CMS was the primary outcome measure.



Secondary outcome measures were the SST [27], abduction strength, VAS for pain and disability [34], and ROM. We obtained the CMS at the 3- and 12-month visits according to the original recommendations [7]. The CMS uses two subjective and two examiner-derived components to assess shoulder function. Pain, everyday activities, ROM, and power are recorded, with a maximum of 100 points. The higher the score, the better the shoulder function. We performed the SST at 3 and 12 months. The SST is a shoulder-specific outcome instrument consisting of 12 yes (1) or no (0) questions to assess the functional limitations of an affected shoulder in the context of the patient's daily activities [14, 29]. Again, higher score means better function. The patients used a 100-point VAS to score their pain (100 = maximum pain, 0 = no pain) and disability (100 = no restrictions, 0 = maximally disabled) at 3 and 12 months. In addition, the abduction strength (in Newtons) was objectively quantified at 45° abduction with a Mecmesin Myometer® (Hartech, Wormerveer, The Netherlands). We recorded the average maximum strength during 4 seconds. For comparison with normal abduction strength, the baseline strength and CMS of the nonaffected arm were measured at the 1-week followup.

AP and lateral radiographs were obtained at every appointment in both groups. To evaluate the hemiarthroplasty position and decrease the known interobserver variability, three of us (HWB, JHG, CVL) independently evaluated tuberosity position and fracture healing [5, 16, 32]. Possible signs of nonunion or osteonecrosis (ON) in both groups were

assessed by tuberosity malpositioning, detachment, migration, and bone resorption [4]. Perioperative and postoperative complications and secondary interventions were recorded. Patients were withdrawn from the trial in the event of death or any reason that would prevent standardized rehabilitation before the 12-month followup.

We analyzed differences between groups with Student's t-test and Mann-Whitney U test for continuous variables (CMS, SST, abduction strength, both VAS scores). The Levene test was used to check the assumption of equalgroups variance. To assess normality, we used the Kolmogorov-Smirnov and Shapiro-Wilk tests. We used two-tailed tests. Data analysis was conducted by an accredited epidemiologist (SvG) using SPSS[®] Version 15.0 (SPSS Inc, Chicago, IL, USA).

Results

There were no differences in the CMS between the two groups at the 3- and 12-month followups (Table 2). The nonoperatively treated and hemiarthroplasty groups had an improved (p = 0.037 and p = 0.001 respectively) CMS at 12 months compared with 3 months postoperatively. Forward flexion and abduction were better 3 months after nonoperative treatment (p = 0.001, p = 0.02), but no longer at 12 months.

Abduction strength was greater at 3 (p = 0.015) and 12 (p = 0.008) months in the nonoperatively treated group

Table 2. Differences in eff ect between the two groups during the first year of followup.

Variable	3-month followup			12–month followup		
	Nonoperative treatment	Hemiarthroplasty	p value	Nonoperative treatment	Hemiarthroplasty	p value
VAS pain	37 (21.3)	19 (18.0)	0.002	25 (1–93)*	23 (1–65)*	0.725
VAS disability	42 (25.6)	50 (20.6)	0.282	31 (24.7)	46 (25.7)	0.051
SST	48 (20.2)	41 (18.4)	0.209	23 (0-92)*	25 (8–100)*	0.592
Abductor strength (N)%	30 (0-98)*	20 (0-35)*	0.015	42 (28.5)	24 (12.5)	0.008
contralateral shoulder				71	54	0.051
ROM						
Forward flexion (°)	88 (45–130)	68 (45–105)	0.00	94 (45–165)	98 (45–165)	0.86
Abduction (°)	78 (30–130)	61 (45–75)	1	87 (30–130)	77 (45–165)	0.36
External rotation (°)	14 (5–20)	13 (5–20)	0.02	19 (15–25)	17 (10–25)	0.10
Internal rotation (lumbar level)	L5	L5	0.66	L3	L3	
CMS	54 (14.1)	48 (13.4)	0.125	60 (17.6)	64 (15.8)	0.413
Total pain (15)	9 (2.7)	11 (3.3)		10 (3.6)	13 (2.6)	
Activity (20)	11 (4.5)	9.3 (4.1)		12 (4.9)	13 (5.4)	
Mobility (40)	15 (4.8)	12 (4.5)		18 (6.9)	20 (8.3)	
Strength (25)	18 (5.0)	15 (5.7)		19 (4.7)	18 (4.7)	
Percentage contralateral shoulder				62	65	0.479

^{*}Median value (range), all others are mean (SD); SST = Simple Shoulder Test; CMS = Constant-Murley score.



Fig. 3A-C (A) An AP view of a nonoperatively treated left shoulder shows ON 12 months after trauma. (B) AP and (C) lateral views show a pseudarthrosis of the fracture, seen in Fig. 1C-D, 12 months after trauma.

compared with the hemiarthroplasty group. In both groups, improved strength (nonoperative treatment, p=0.005; hemiarthroplasty, p=0.004) was observed at 12 months compared with 3 months postoperatively. SST scores were not different between the two groups at 3 and 12 months. Both groups improved (nonoperative treatment, p=0.023; hemiarthroplasty, p=0.001) between the 3- and 12-month followups.

With no difference at 12 months, the mean values for pain as measured on a VAS scale at 3 months were better (p = 0.002) in the hemiarthroplasty group (18.7, SD = 18.0) than in the nonoperatively treated group (37.3, SD = 21.3). The mean VAS scores for disability were similar between groups at 3 (p = 0.282) and 12 (p = 0.051) months.

In the nonoperative group at 12 months followup, 20 patients (80%) had bony union of their fractures. Two patients (8%) had ON of the head with consequent radiographic narrowing and eventually vanishing articular surface (Fig. 3). No revision was required with CMSs of 58 and 62 at 12 months followup. Three patients (12%) had a nonunion of the four-part fracture (Fig. 3). Owing to pain and impairment of the affected shoulder with a CMS of 7 after 12 months, one patient who was treated nonoperatively was operated on 13 months after fracture with a hemiarthroplasty as used in the operative group. Since the crossover occurred after 12 months, this patient remained in the nonoperative group. No cases of heterotopic ossification were observed. In the hemiarthroplasty group, there were no superficial or deep postoperative infections. One patient had an early postoperative complication and underwent revision surgery after 1 week because of head-stem separation. Postoperative radiographs showed malpositioning of the greater tuberosity in four patients (16%). In three patients the tuberosity was positioned too low (> 10 mm inferior to the tangent line of the head) and in one patient too high (< 5 mm superior to the tangent line of the head) [4]. Secondary superior migration of the greater tuberosity after 12 months was observed in five patients (20%) with partial resorption of bone in two patients. One patient showed proximal migration of the hemiarthroplasty at 12 months with an acromiohumeral distance less than 7 mm indicating a possible secondary cuff tear [4]. A nonunion of the greater tuberosity was observed radiographically in two patients (8%). No cases of heterotopic ossification were observed.

Discussion

In the elderly, the best treatment for four-part fractures of the proximal humerus remains unclear owing to the paucity of well-performed RCTs [19]. The low percentage of true four-part fractures (2%–8% of all proximal humeral fractures) might be a reason for this lack of evidence [8]. We therefore performed an RCT to compare the results (CMS, SST, abduction strength test, VAS scores for pain and disability) of nonoperative treatment with those of hemiarthroplasty for four-part humeral fractures in the elderly at 12 months followup.

There are several limitations to our study. First, as the incidence of true four-part fractures of the proximal humerus is low, it took almost 5 years to include 50 patients in our cohort in this single-institution RCT. We



are aware of our relatively small patient cohort and realize our conclusions are based on a followup of only 12 months. However, we properly performed a power analysis based on a relevant, established clinically important difference of the CMS [6]. Second, during our selection process, we randomized all displaced four-part fractures of the humerus and we did no subanalysis based on subclassifications. Although described as the more benign type, valgus impacted four-part fractures do show serious complications related to poor outcome [11]. None of the described complications in the patients treated nonoperatively was in the valgus impacted fractures. Studies on the integrity and position of the medial column of the proximal humerus show it is an important anatomic structure for mechanical stability and blood supply to the head fragment [3, 18]. Because of our small cohort, the nonoperatively treated patients were not subanalyzed. Still, it is important that 17 of 25 nonoperatively treated patients had a disrupted medial column. All the described complications were in these 17 patients. Third, we made the diagnosis of a four-part fracture in our series through plain radiographs according to Neer's criteria [22], which remains the best and most commonly used classification. However, this classification also has its limitations, and more individualized treatment based on an assessment of the characteristics of a particular humeral fracture has been proposed [20]. We also are aware of the existing interobserver variability and intraobserver variability with this classification [5, 22, 23, 32]. To reduce intraobserver variability, all diagnoses were established by the same two experienced shoulder surgeons. The use of three-dimensional CT has been proposed more recently for more accurate classification, outcome, and pattern of the fracture; however, this was not performed in our study [10, 11, 25].

We found no difference between the nonoperatively and operatively treated groups with respect to the total CMS at 3 and 12 months followup. This is in contrast to a systematic review that included 33 studies encompassing 1096 patients with three- or four-part proximal humeral fractures that used the CMS as the outcome measure [9]. In that review, the mean CMS was 66.5 in the nonoperative group and 55.5 in the arthroplasty group. However, the authors stated this difference could be attributed to selection bias, unreliable classification of the fractures, and interobserver differences in the assessment of the CMS [9]. Our CMS results concur with those from the RCT by Olerud et al. [25]. At 12 months' followup, they found comparable CMSs in the hemiarthroplasty group and the nonoperatively treated group. Our average CMS in both groups at 3 and 12 months (51 and 62, respectively) are higher than what they found. With comparable age groups, differences can be explained since they valued the CMS strength score at 90° abduction. If 90° abduction could not be reached they scored 0 points in the CMS. We valued strength at 45° abduction for the CMS and the myometer strength test. Stableforth [33] reported better strength recovery after hemiarthroplasty. We found better abduction strength scores in the nonoperatively treated group at 3 and 12 months. Olerud et al. [25] also observed better CMS strength scores at all followups after nonoperative treatment. An explanation for this outcome may be related to the way the tuberosities are reconstructed. In a biomechanical cadaver study, improper position of tuberosity fragments in the horizontal plane may result in insurmountable postoperative motion restriction [12]. Tuberosity stabilization and anatomic reduction are two important factors that will improve outcome after hemiarthroplasty in four-part proximal humeral fractures [4, 17, 21, 28]. With respect to restoring the anatomic position of the tuberosities, we attempted to reconstruct these with superior cerclage wires through the lateral aspect of the prosthesis. Based on a biomechanical study [13], this method of tuberosity fixation shows inferior resistance to strain forces compared with a circumferential cerclage wire through the medial aspect of the prosthesis. We observed a nonunion of the greater tuberosity in two patients. There may have been more subtly disrupted tuberosities not observed on the plain radiographs in our patients who had hemiarthroplasties. The cuff tuberosities in a nonoperatively treated shoulder that is not additionally traumatized by surgery possibly heals biomechanically more favorably than an operatively treated shoulder.

We observed a favorable VAS score for pain in the hemiarthroplasty group at 3 months. We believe this difference can be attributed to the initially more stable reconstruction of the glenohumeral joint after hemiarthroplasty, compared with the instability of the fracture in nonoperatively treated patients in the first 3 months. In contrast to what Olerud et al. [25] found, at the 12-month followup, this difference had disappeared, probably owing to consolidation of the fracture in the nonoperative group.

In the nonoperatively treated group, two patients had ON with collapse of the humeral head develop after 12 months. This percentage concurs with the findings of Edelson et al. [10], who explained the occurrence of ON as rare with acceptable pain and function in the elderly. Our finding in the nonoperatively treated group showed consolidation of four-part fractures even in severely displaced fractures. Because we used plain radiographs for diagnosis and followup, we might have missed partial ON with minimal clinical symptoms, often seen on CT [11]. At 12 months followup, the two patients with ON had CMSs greater than the average for their group; therefore, no revision surgery was performed. Future followup will show whether the function of these two patients will deteriorate.



After 12 months of followup, we found no differences in function between groups for the CMS and SST. Although the nonoperatively treated patients had increased pain at 3 months compared with patients treated with a hemiarthroplasty, this difference disappeared at 12 months. Abduction strength was better in the nonoperatively treated group than in the hemiarthroplasty group at 3 and 12 months. Despite the limitations of this RCT in terms of total patient number and fracture classification, no clear benefits could be detected in the patients treated with a hemiarthroplasty compared with the patients treated nonoperatively, at a followup of 12 months.

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