ORTHOPAEDIC SURGERY



Radiological and functional outcomes 2.7 years following conservatively treated completely displaced midshaft clavicle fractures

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Abstract

Objectives It is unclear whether all completely displaced midshaft clavicle fractures require primary surgical intervention. The aim of this study was to elucidate the radiological and clinical outcomes after conservative treatment, and to identify subgroups at risk of an inferior outcome.

Design Retrospective case series.

Setting Level II trauma center.

Patients Between 2005 and 2008, 122 patients were conservatively treated for a completely displaced midshaft clavicle fracture of whom 92 were eligible for inclusion in this study. Of these, 59 completed the study after a median of 2.7 years after the fracture (min–max, 1.1–4.9).

Intervention The patients received the standard treatment administered at our institution at the time: nonsurgically with a sling without physiotherapy. Patients with painful nonunions were subsequently offered surgery.

Main outcome measurements At follow-up, the patients' Disabilities of Arm, Shoulder, and Hand (DASH) and the Constant scores were evaluated. Radiographs were taken at follow-up and compared to those taken acutely.

Results Nonunion was found in 9 of the 59 (15.3 %) patients. Twenty-four (24 %) patients reported a fair-to-poor DASH score (i.e. >20). Patients with fractures that were vertically displaced by more than 100 % (one bone width) were significantly less satisfied than those with

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fractures vertically displaced at 100 % (p = 0.04). Initial shortening of more than 15 mm was not associated with a worse outcome or nonunion. The odds ratio of developing a nonunion increased with age (p = 0.04).

Conclusions By treating completely displaced midshaft clavicle fractures conservatively with a sling and offering plate fixation for eventual painful nonunions, we found a 24 % risk of a fair or poor clinical result with a DASH score over 20. A vertical displacement of more than 100 % between the main fragments on the initial radiograph was associated with an inferior clinical outcome in this study. *Level of evidence* IV.

Introduction

Clavicle fractures are common, reportedly accounting for 2.6–4 % of all fractures, with midshaft fractures constituting approximately 80 % of all clavicle fractures [1, 2]. Midshaft clavicle fractures are traditionally thought to have a good prognosis, and most are treated nonsurgically with a sling or a figure-of-eight bandage. Studies by Neer and Rowe in the 1960s demonstrated very low nonunion rates of 0.1–0.7 % [3, 4]. More recent studies have distinguished between adults and children, the latter of whom have an inherently good prognosis [5], and found a higher incidence of symptomatic malunion and nonunion after conservatively treated displaced fractures than was previously reported for adults [6–12]. In adults, 4–7 % of diaphyseal fractures result in nonunion, and this increases to 15–20 % for completely displaced fractures [13, 14]. Several studies have revealed a

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somewhat better clinical outcome of surgically managed displaced midshaft clavicle fractures than sling treatment. Although the differences are statistically significant, their clinical significance is uncertain [15–21]. The number of patients needed to treat to avoid a painful mal- or nonunion has been reported to be 3.3–4.6 [22, 23]. The subgroups of completely displaced midshaft clavicle fractures to whom primary osteosynthesis should be offered to avoid these complications have yet to be identified, although displacement, shortening, gender, and age have been suggested as risk factors for a worse outcome [13].

The aim of this study was to determine the radiological and clinical outcomes in a series of completely displaced midshaft clavicle fractures treated with a sling, with a followup period of 1–4 years. We sought to identify patient and fracture characteristics that would provide prognostic information for the orthopaedic surgeon when considering the right primary treatment for individual patients.

Patients and methods

Patients and study design

At the time of inclusion, Akershus University Hospital served a population of about 320,000 inhabitants. From the hospital information system, 145 cases of midshaft clavicle fractures displaced one bone width or more were identified between January 1, 2005 and December 31, 2008 in patients aged 16-60 years who were treated at our institution. At the time of the study, the department's main treatment method was conservative with a sling for 2 weeks, after which the patients were encouraged to perform increasing pendulum exercises below 90° of abduction for the first 6 weeks. Physiotherapy was not routinely administered. Patients who had undergone primary plate fixation, were unable to fill out forms, had an open fracture, neurovascular injury, other shoulder injury or a concomitant medical condition that would compromise the calculation of shoulder scores was excluded from the study. Patients not living within the hospital's catchment area were also excluded from the study, as follow-up information was not available in our medical files.

In 2010, 92 eligible patients received a written invitation, of which 59 (64 %) attended an ambulatory follow-up visit at the hospital with one of the investigating orthopaedic surgeons. Radiological and physical examinations were performed and clinical outcomes were assessed using standardized questionnaires. We also reviewed the medical records to obtain information about the injury mechanism, presence of surgical treatment for nonunion and assessment of initial radiographs.

The study was approved by the South East Regional Ethics Committee of for Medical and Health Research Ethics of Norway (Ref. s-09378c2009/7999).

Radiological assessment

All patients were submitted to radiography at the time of injury to produce standing 15° cranial and 15° caudal views (initial radiographs). Anteroposterior panoramic radiographs of both clavicles were obtained at the follow-up to evaluate shortening by comparing the length of the injured clavicle with that on the contralateral uninjured side [24]. Both the primary and follow-up radiographs were examined for shortening, measured in millimetres. Because panoramic radiographs were not obtained at the time of injury, the initial degree of shortening was estimated by measuring the shortening between the overlapping bone ends on the initial radiographs [10, 25] (Fig. 1). The vertical displacement in the cranio-caudal direction was measured in per cent, where one bone width displacement was set as 100 %. We divided the group into patients with cortical contact of the main fragments (100 % vertical displacement) and without bony contact (>100 % vertical displacement). Nonunion was defined as no bridging callus formation 6 months after injury.

Assessment of clinical outcomes

The clinical outcome was assessed with the Disability of Arm, Shoulder and Hand (DASH) questionnaire [26] and the modified Constant Shoulder (CS) score [27, 28]. DASH and CS scores were considered as the primary outcome variables.

The DASH questionnaire is a patient-oriented score, validated in Norwegian [29], and is scored from 0 (perfect extremity) to 100 (completely disabled limb). The minimal clinically important difference for the shoulder has been determined to be 10.2 for the DASH score [30]. Since patients with previous shoulder injury or concomitant injuries that would compromise shoulder function were excluded from this study, a score of ≤ 10 was considered excellent, while a score of 10–20 was considered good, 20–30 as fair, and >30 as poor [5].

The CS is scored by the physician and takes into account pain, activities of daily living, range of movement and power abduction strength. Pain is scored as an average score on a visual analogue scale (VAS) ranging from 0 (no pain) to 15 (maximum possible pain), and graded as no, mild, moderate, or severe pain. Isometric power was measured using a Berkley TDS35 scale in the scapular plane with 90° of shoulder abduction and a constant pull over 5 s. The average of five repetitions was calculated. A perfect shoulder would achieve a score of 100 points, and a lower score indicates a higher level of disability.

VAS scales were used to measure secondary outcome variables. The 15-point VAS scale for pain in the CS was used as a separate evaluation with the score converted to

Fig. 1 Radiographs of a displaced midshaft clavicle fracture in a single patient with outlines of the measurements. a Initial frontal 15° cranial view. Arrow the measured shortening. b Frontal 15° caudal view. Arrow estimated vertical displacement of 200 % in this case. c Panoramic view of both claviculae after healing. Arrows the measured shortening (i.e. length of the normal clavicle minus length of the fractured clavicle). a and b were taken at the time of injury, c at follow-up 19



(b)





0-10 by simply dividing the score by 1.5, because we felt that introducing a second pain scale would be confusing for the patients. The patients were asked if they were satisfied with their overall shoulder function after their clavicle fracture, and marked their result on a 10 cm VAS scale divided into from 0 to 10 points, where 10 indicated complete satisfaction. They were also asked to mark their satisfaction of the cosmetic result after fracture on an identical VAS scale.

Statistical analysis

The normality of the DASH, CS, and the three VAS scores was assessed graphically and with the Shapiro-Wilk test, indicating that the VAS scales for pain and patient satisfaction and the CS and DASH scores had non-normal distributions. Therefore, descriptive statistics are presented for all of these variables using the median and the range between 25th and 75th percentiles. Parametric tests were used for vertical displacement and shortening and Chi square for analysis of categorical data. Parameters with non-normal distributions were log transformed in multivariate logistic and linear regression analysis.

Statistical analysis was performed using Stata 12.1 (StataCorp, College Station, TX, USA). The cutoff for statistical significance was set at p < 0.05 using two-sided tests.

Results

We identified 145 patients with completely displaced midshaft clavicle fractures, of whom 122 patients were conservatively treated with a sling for 1-2 weeks. The remaining 23 patients were elected to open reduction and

Table 1 Demographic data of all patients

Mechanism of injury and fracture characteristics	Examined $(No. = 59)$	Nonresponders $(No. = 33)$	p value	Primary plate fixation (No. $= 23$)
Mean age at injury (years)	39.1 ± 12.3	34.6 ± 12.2	0.1	33.2 ± 12.3
Male sex	49 (83 %)	28 (85 %)		16 (70 %)
Mechanism of injury				
Simple fall	11 (19 %)	7 (21 %)	0.8	5 (21 %)
Fall exceeding 3 m	2	0		0
Fall less than 3 m	9	7		5
Motor vehicle accidents	25 (42 %)	5 (15 %)	0.008	5 (21 %)
Motorcycle, all-terrain vehicle, snowmobile	20	5		5
Car accident	5	0		0
Sports	23 (39 %)	21 (64 %)	0.02	13 (57 %)
Ski/snowboard/sledge	3	2		7
Soccer	4	4		2
Ice hockey	2	0		0
Bicycle	11	11		3
Horseback riding	3	4		1
Fracture characteristics				
Affecting the right side	29 (49 %)	10 (30 %)		14 (61 %)
Dominant hand	26 (44 %)			
Nonunion	9 (15 %)	5 (15 %)		1 (4 %)
Intermediary fragments				
0	12	6		3
1	20	8		11
2	20	16		9
≥3	7	2		0
Displacement, % of bone width, mean (SD)	143 ± 57.4	133 ± 37.1	0.3	190 ± 65.1
Initial shortening (mm), mean (SD)	17.1 ± 7.1	16.3 ± 6.7	0.6	13.1 ± 10.8

Data are absolute number, mean \pm SD, or absolute number (percentage) values

p value represents comparison of the conservative groups

plate fixation by the surgeon on call because of skin compromise in five patients or displacement (Table 1; Fig. 2). Thirty patients did not meet the inclusion criteria and were excluded from the study.

Of 92 remaining eligible patients, 33 did not respond to the written invitation and thus were lost to follow-up or chose not to participate. The 59 participants had a higher proportion of motor vehicle injuries and a lower proportion of sport injuries than non-participants; otherwise, the demographics and fracture characteristics were not statistically significantly different (Table 1). Five patients (15.2 %) were diagnosed with a nonunion and operated with plate fixation and bone grafting. The median time from injury to follow-up was 2.7 years (min-max, 1.1–4.9).

Radiological outcomes

The median initial shortening was 15 mm (25th–75th percentiles, 12–20 mm) in the entire cohort (n = 59) and

15 mm (7.8–18.3 mm) in the 50 fractures that progressed to primary union. In the fractures that healed, the median difference in length measurement between the initial and final radiographs was 7.5 (4–10 mm).

A nonunion was found in 9 (15.3 %) of the 59 patients (Table 1). One patient with a painful nonunion was discouraged from surgery due to concomitant medical disorders and an unacceptable risk of complications. Three had minor or no complaints, and were thus not offered surgery. The remaining five had a painful nonunion and no contraindications and so underwent surgery with plate fixation prior to the study. There was no difference in initial shortening when compared to fractures that healed primarily.

Multivariate logistic regression analysis revealed that the odds ratio (OR) for the risk of nonunion more than doubled for every 10 years increase in patient age (p = 0.04). Women had an OR of 5.1 versus men to develop nonunion, but with a wide confidence interval (0.8–32.4).

Fig. 2 Flow chart of patient

recruitment



Clinical outcomes

The median DASH score was 6.7 (0.8–19). The DASH score was good or excellent (i.e. <20) in 76 % of the patients; thus, 24 % had a DASH score of over 20. In bivariate linear regression analysis, female sex was associated with a higher DASH score. There was a tendency toward the DASH score being higher in the nonunion group, than for fractures that healed with conservative treatment (p = 0.06). We did not find significantly worse DASH scores with shortening, vertical displacement, or intermediary fragments on the entire cohort (Table 2). In multivariate analysis, only female sex was associated with a higher DASH score. In the five nonunions treated surgically with plate fixation, three ended up with a DASH

score of more than 37 after union, signifying a substantial clinical disability.

The median CS was 81 (69–90) for the entire cohort (n = 59). Females had lower CS scores than males, and those with nonunion had lower scores than those with primary healing (Table 2). In multivariate linear regression analysis, only sex was significantly associated with the lower CS score.

Forty-nine of the 59 experienced residual pain under normal activities, with a median score of 1.3 on a VAS scale from 0 to 10. In bivariate analysis, the reported pain was greater in patients with a nonunion even after successful surgery than in those with fractures with primary healing (Table 2); however, the difference was not statistically significant in multivariate analysis (Table 3).

	DASH	Constant score	Visual analogue scale			
			Pain	Satisfaction	Cosmetics	
Age						
Age below median	6 (1–19)	81 (66–91)	1.3 (0.7-4.3)	5 (4-8.5)	5 (2-8)	
Age above median	8 (0–18)	81 (74-89)	1.3 (0.7–2.7)	7.5 (4.7-8.7)	7 (5–9)	
p	0.8	0.9	0.8	0.4	0.1	
Gender						
Female	22 (13-34)	60 (54–76)	1.5 (1.3-6.7)	5 (2–5)	4.3 (2-7.7)	
Male	6 (0–11)	84 (77–91)	1.3 (0.7–2.7)	7.5 (4.4-8.8)	6 (3.7–9)	
p	0.001	0.0001	0.26	0.07	0.1	
Fragments						
No intermediary fragments	15 (3-43)	71 (54–92)	1.7 (0.9-4.0)	4.9 (2.7-8.5)	6.5 (3.7-8.8)	
Intermediary fragments present	7 (1–15)	82 (74-89)	1.3 (0.7–2.7)	6 (4.4–8.7)	5 (2.5–9)	
р	0.2	0.3	0.5	0.3	0.8	
Displacement						
Displacement 100 %	7 (0–14)	86 (76–92)	1.3 (0.3–2.3)	8 (5–9)	7.9 (3.3–9)	
Displacement >100 %	9 (1–25)	80 (64-85)	2 (0.7–5)	5 (4-7.9)	5 (3-7.7)	
р	0.3	0.08	0.08	0.04	0.1	
Shortening						
Acute shortening less than median	7 (3–27)	80 (64-88)	1.5 (0.7-4.7)	5 (4-8)	5 (2.4-8.6)	
Acute shortening greater than median	7 (0–11)	84 (74–90)	1.3 (0.7–2.3)	8 (5-8.7)	7.3 (3.6–9)	
р	0.1	0.5	0.2	0.2	0.6	
Bony healing						
Union	7 (0-6)	83 (74–91)	1.3 (0.7–2.4)	6.8 (4.3-8.7)	5.5 (2.5-9)	
Nonunion	18 (5-43)	59 (54-82)	2 (1.5-6.3)	5 (3-7.2)	5 (3.5-7.7)	
р	0.06	0.02	0.04	0.2	0.4	

Table 2 Functional outcomes related to radiological and descriptive assessment

All values expressed in median (25th–75th percentile) values. Univariate analysis. Mann–Whitney U test

DASH Disabilities of Shoulder, and Hand questionnaire

Table 3 Association between variables and self-assessed cosmetic result, pain and overall satisfaction on a visual analogue scale

Covariate	Cosmetic result		Log pain			Satisfaction			
	Regression coefficient	95 % CI	р	Regression coefficient	95 % CI	р	Regression coefficient	95 % CI	р
Age, increase in 10 years	0.55	(-0.1 to 1.2)	0.1	0.17	(-0.14 to 0.49)	0.3	-0.08	(-0.7 to 0.5)	0.8
Female vs male	-1.37	(-3.49 to 0.75)	0.2	0.31	(-0.72 to 1.33)	0.6	-1.79	(-3.7 to 0.1)	0.06
Displacement >100 %				0.73	(-0.05 to 1.51)	0.06	-1.35	(-2.8 to 0.1)	0.06
Adjusted R^2	0.05			0.09			0.08		

Multiple linear regression analysis, n = 59

CI confidence interval

The median VAS score for satisfaction after the clavicular fracture was 5 (25th–75th percentiles, 4–8.7). Only 10 % (6/59) of patients scored 10 (perfect), while 58 % (34/59) scored 6 or lower. In bivariate analysis, patients were less satisfied when the vertical displacement was more than 100 % (p = 0.04; Table 2), although the difference was not statistically significant after adjustment for age and sex (Table 3).

The median VAS score for the cosmetic result was 5 (3.3-9.0). Only 9 of the 59 patients were completely satisfied with their cosmetic result. The outcome was not significantly worse for vertical displacement over 100 % or

shortening of greater than the median value of 15 mm (Table 3).

Discussion

One out of four patients in this study with completely displaced midshaft fractures of the clavicle who were initially treated non-surgically had a fair or poor clinical outcome at a median follow-up of 2.7 years. Nonunion developed in 9 of the 59 patients, of whom 5 underwent surgery but had a reduced clinical outcome even after healing was completed.

Females were more likely to develop a nonunion than were men, in line with other reports [13]. They also had inferior clinical outcome than men, as assessed with the DASH and Constant scores. It is important to note that gender does influence both scoring systems with inferior results in women [31–33]. This might influence the results in our study.

Shortening was not associated with an inferior clinical outcome or with nonunion in either the initial or control radiographs. Several studies have found inferior clinical outcome in the presence of shortening of 1.5–2 cm after healing [9, 10, 14, 34, 35], whereas others have not demonstrated such a relationship [8, 36, 37]. We found that the median initial and final shortening were similar in the group that healed as a whole, but there was a large individual adjustment during the healing process, suggesting that it is not possible to predict final shortening from the initial radiograph. It is important to realize that shortening was measured in different ways in those studies, and that calibrated radiographs were used in very few, raising a question as to the accuracy of measurements.

There was a tendency toward an inferior clinical outcome with vertically displaced fractures greater than 100 %, and these patients were less satisfied with their overall shoulder function. This subgroup can be identified on the acute radiograph due to the presence of clear distance between the main fragments and has been identified in several other studies as an important radiographic marker for pain and inferior clinical outcomes [6, 8, 14, 38]. Vertical displacement has a better intra- and interobserver reliability in radiographs than shortening [25] and may therefore have greater value in predicting the outcome in acute fractures than shortening.

A nonunion developed in 14/92 (15 %) of the eligible patients, which is comparable to the proportions found in recent studies [6, 10, 39]. Female sex and increasing age were found to be associated with a higher probability of developing a nonunion, but there was no association between nonunion and the degree of displacement, initial shortening, or the number of intermediary fragments. Therefore, we were unable to detect any fracture configuration associated with an increased risk of nonunion development. This finding contrast with those of some studies [10, 13, 39, 40], but is supported by a recent randomized controlled trial [17]. Six out of nine nonunions were symptomatic; five of these were suitable for surgery and healed with open reduction and plate fixation. These five had a significantly reduced clinical outcome at followup. In contrast to earlier reports, this suggests that osteosynthesis of an established clavicular nonunion may lead to a substantially reduced shoulder function [41, 42]. This finding raises questions as to the treatment protocol used in the present patient series, in which most displaced midshaft clavicular fractures were allocated to initial conservative treatment on the assumption that nonunions could be dealt with when manifest without loss of prognosis. When seen in light of the DASH scores reported in several RCTs [17, 21, 43], this study lends support to primary surgery in fractures displaced with more than 100 %.

This study was subject to some limitations. Although one-third of the patients were not available for follow-up, this group had the same registered percentage of nonunions and similar descriptive characteristics as those patients completing the study. Acute surgery was performed in 23 patients with more vertically displaced fractures. If this group had been treated conservatively with a sling, we might expect worse results in the entire group. This was a retrospective study with a limited number of patients from a single institution, which might limit the external validity of the results and reduce the power of the analyses. This study also had a potential for type II errors due to the smallness of the sample. Several of the given point estimates indicate clinical importance, but the uncertainty was too large to enable conclusions to be drawn. The presence of acute displacement was assessed on standard radiographs; CT scans would have been superior, but were not available. Notwithstanding these limitations, the strength of our study includes the use of validated patient-oriented outcomes in addition to clinical and radiographic evaluation.

Conclusion

By treating completely displaced midshaft clavicle fractures conservatively with a sling and offering plate fixation for eventual painful nonunions, we found a 24 % risk of a fair or poor functional result with a DASH score over 20. A vertical displacement of more than 100 % between the main fragments on the initial radiograph was associated with an inferior clinical outcome in this study. Acknowledgments Dr. Fuglesang has received funding from Akershus University Hospital and from the Sophies Minde foundation. This funding also paid for radiographs. No other authors received any financial support for this study. We are grateful for the cooperation from Dr. Hasan Banitalebi, Department of Radiology, Akershus University Hospital.

Compliance with ethical standards

Conflict of interest None of the authors have any conflicts of interest.

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