Plate Fixation Compared with Nonoperative Treatment for Displaced Midshaft Clavicular Fractures

A Multicenter Randomized Controlled Trial

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Background: The use of operative treatment for clavicular fractures is increasing, despite varying results in previous studies. The aim of this study was to compare plate fixation and nonoperative treatment for displaced midshaft clavicular fractures with respect to nonunion, adverse events, and shoulder function.

Methods: In this multicenter, prospective, randomized controlled trial, patients between 18 and 60 years old with a displaced midshaft clavicular fracture were randomized between nonoperative treatment and open reduction with internal plate fixation. The primary outcome was evidence of nonunion at 1 year. Other outcomes were secondary operations, arm function as measured with the Constant shoulder score and Disabilities of the Arm, Shoulder and Hand (DASH) score, pain, cosmetic results, and general health status. Outcomes were recorded at 6 weeks, 3 months, and 1 year following trauma.

Results: One hundred and sixty patients were randomized. The rate of nonunion was significantly higher in the nonoperatively treated group than in the operatively treated group (23.1% compared with 2.4%; $p < 0.0001$), as was the rate of nonunion for which secondary plate fixation was performed (12.9% compared with 1.2%; $p = 0.006$). The rate of secondary operations was 27.4% in the operatively treated group (16.7% for elective plate removal) and 17.1% in the nonoperatively treated group ($p = 0.18$). Nineteen percent of the patients in the operatively treated group had persistent loss of sensation around the scar. No difference was found between the groups with respect to the Constant and DASH scores at all time points.

Conclusions: For patients with a diaphyseal fracture of the clavicle displaced at least 1 shaft width, plate fixation improves the chances that the bone will heal; however, the rate of patients who need a second operation is considerable. In addition, the procedure does not improve shoulder function or general symptoms, and it does not decrease limitations compared with nonoperative treatment in a sling.

Level of Evidence: Therapeutic Level I. See Instructions for Authors for a complete description of levels of evidence.

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Midshaft clavicular fractures have a long history of being treated nonoperatively. This strategy originates from the time of Hippocrates, who was the first to describe that these fractures merely need benign neglect from the physician[1]. Many centuries later, in the 1960s, this vision was supported by the results of 2 large studies that showed extremely low nonunion rates following nonoperative treatment (0.71% and 0.13%, respectively)[2,3]. By the turn of the century, however, more evidence became available showing that the true prevalence of nonunion after nonoperative treatment was much higher than previously thought, i.e., approximately 10% to 15%[4,5]. Also, sequelae such as pain and cosmetic defects were shown to remain in a quarter of the patients up to 10 years after nonoperative treatment[5]. In 2007, the Canadian Orthopaedic Trauma Society published the first randomized controlled trial (RCT) comparing nonoperative treatment with plate fixation, showing lower nonunion rates and a better arm function after plate fixation[6]. That study appears to have led many surgeons to

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consider routine operative treatment for displaced fractures of the midshaft of the clavicle to be superior to nonoperative treatment. Although several other RCTs have been published since then, the issue remains very relevant because the question of whether operative treatment is most suitable for all patients with a displaced midshaft clavicular fracture remains unsettled, and published meta-analyses are equivocal[7-11].

The aim of the present multicenter randomized trial was to compare the results of open reduction and plate fixation with nonoperative treatment in patients with a displaced midshaft clavicular fracture with respect to nonunion, adverse events and secondary operations, shoulder function, and general health status.

Materials and Methods

Design and Setting

Approval for this multicenter RCT was obtained from the institutional ethics review committee of each participating hospital. The trial was registered in the Netherlands National Trial Register (NTR2399). Patients were recruited between June 2010 and December 2013 in 16 teaching and nonteaching hospitals in the Netherlands, including 4 university hospitals (see Appendix). The results were reported following the Consolidated Standards of Reporting Trials (CONSORT) guidelines[12].

Inclusion Criteria

Patients were eligible for inclusion if they had (1) a fracture of the middle third of the clavicle with displacement of at least 1 shaft width (Robinson type 2B1 or 2B2[13]), (2) an age between 18 and 60 years old, (3) no contraindications for surgery or general anesthesia, and (4) provided signed informed consent.

Exclusion Criteria

Patients were excluded if they had ≥1 of the following criteria: (1) a pathologic fracture, (2) an open fracture, (3) a neurovascular injury of the shoulder region with objective neurologic findings on primary physical examination, (4) an associated head injury (Glasgow Coma Scale score of <12), (5) an ipsilateral upper extremity fracture, (6) first presentation >14 days after injury, (7) preexisting impaired shoulder function or previous surgery of the shoulder, and (8) an inability to comply with follow-up.

Sample Size

The sample size calculation was based on a difference of 15 percentage points in nonunion rates between the treatment groups. The initial calculation suggested that 350 patients were needed[14], but after the trial had started, this was discovered to be incorrect. No interim analysis was performed. The sample size was recalculated with the same power (80%), significance level (0.05), and drop-out rate (10%), using evidence available at that time that showed a difference in nonunion rates of 13 percentage points (15% compared with 2%)[15], which indicated that 160 patients were needed to find a significant difference in nonunion rates between groups. The recalculation was approved by the scientific and ethics review committee. Accordingly, the trial inclusion was stopped after the 160th patient.

Randomization

All eligible patients received verbal and written study information at the emergency room or outpatient clinic. All participants provided written consent. Minimization randomization was accomplished with the online registration and randomization program TENALEA (Trans European Network for Clinical Trials Services). Patients were randomly assigned to nonoperative treatment or to open reduction and plate fixation in a 1:1 ratio stratified by hospital. For each subsequent participant, the allocation depended on the included participants to minimize imbalance[16].

Nonoperative Treatment

For patients assigned to nonoperative treatment, follow-up started at the day of inclusion. During the first 2 weeks, patients used a sling and were advised to perform non-weight-bearing pendulum exercises after instruction by a physiotherapist, followed by more active movement up to the horizontal plane. After 6 weeks, full range of motion was permitted and strengthening exercises were started. If an indication for surgical treatment arose, secondary plate fixation (with bone-grafting if judged appropriate by the treating surgeon) was offered to the patients.

Operative Treatment

Patients assigned to operative treatment had the operation within 3 weeks after injury. Follow-up started on the day of the operation. All operations were performed by, or under direct supervision of, a fracture surgeon. In the Netherlands, fractures are generally treated by trauma surgeons rather than orthopaedic surgeons. Surgery was performed according to the AO standards for osteosynthesis (i.e., 6 cortices on each side of the fracture and use of a lag screw if possible). There were no restrictions regarding incision, plate location, or type of plate. All patients received single-dose preoperative antibiotic prophylaxis. The postoperative mobilization protocol was the same as for nonoperatively treated patients.

Outcome Measures

Study evaluation points were at 6 weeks, 3 months, and 1 year. Radiography consisted of an anteroposterior and a 30° caudocephalad radiograph made after injury and at each follow-up examination. Radiographs were evaluated by the surgeon.

The primary outcome was evidence of nonunion at 1 year, defined as the absence of complete osseous bridging of the fracture on the radiograph after ≥6 months. Also, nonunion was scored if it was evident during a secondary operation at least 4 months after trauma.

Secondary outcomes were arm function, adverse events, pain, general health status, and satisfaction with the cosmetic appearance. These were assessed at 6 weeks, 3 months, and 1 year. Function was measured with the Constant score[17] and with the Disabilities of the Arm, Shoulder and Hand (DASH) outcome measure[18]. As part of the Constant score, strength was measured using a dynamometer (microFET2; Hoggan Scientific), which is a handheld dynamometer measuring the force a patient can produce against a stationary counterforce.

Adverse events and secondary operations were assessed by the investigator. Secondary operations were all procedures apart from the initial operation for fracture treatment (e.g., surgery for nonunion or plate failure, debridement for deep infection, and implant removal). Symptomatic malunion was diagnosed if secondary surgery was performed in an attempt to address symptoms thought to be related to deformity of the clavicle.

Adverse events were all unexpected and unwanted outcomes related to the treatment or admission (e.g., perioperative pneumothorax, infection, and nonunion).

Pain was scored by the patient on a numeric rating scale from 0 (no pain) to 10 (extreme pain). General health status based on general symptoms and limitations was measured using the Short Form (SF)-36 questionnaire, expressed as the physical and the mental component summary score[19]. A score of 50 represents the expected value for the general population. Satisfaction with the cosmetic appearance of the shoulder was scored on a 3-point Likert scale (as unsatisfied, partly satisfied, and [very] satisfied).

All patients who did not return for follow-up or had missing radiographs after 1 year were contacted by telephone to ask whether they had complaints and whether they had received (operative) treatment for their clavicular fracture elsewhere.

Statistical Analysis

Statistical analysis was performed using SPSS statistical software (version 20; IBM). Differences in percentages for the primary outcome were analyzed using

the chi-square test. Constant, DASH, and SF-36 scores were compared using the Student t test. Pain scores were analyzed using the Mann-Whitney test. Differences among >2 groups were analyzed using analysis of variance and post hoc Bonferroni tests.

In the review process, it was noted that we did not plan for how to address missing data prior to the trial and we did not use the preferred strict intention-to-treat approach for randomized trials. With the help of a statistician, we compared our original analysis with an analysis using multiple imputations to address missing data, found no differences in the analysis, and decided to present our original complete case analysis.

Results

Between June 2010 and December 2013, 160 patients were included, and of those, 86 were randomized to operative treatment and 74 to nonoperative treatment (Fig. 1). Baseline features of the included patients are shown in Table I. One patient who was randomized to nonoperative treatment received plate fixation within a week because of pain and was analyzed in the nonoperative group according to the intention-to-treat principle.

Most operatively treated patients (80%) were treated with a precontoured clavicular plate (various manufacturing companies). The plates were placed superiorly (52%), anteriorly (12%), or anterosuperiorly (21%); placement was not documented for 15%.

At 1 year, no radiograph was made for 18 patients. Six of them had already reached radiographic consolidation earlier and were regarded as having achieved union. Six others (1 in the operatively treated group and 5 in the nonoperatively treated group) could be reached by telephone and reported that they had excellent function, no pain, and no complaints. They were regarded as lost to follow-up for the primary outcome (radiographic nonunion), but were counted as not having a symptomatic nonunion. Six patients (3.8%; 2 in the operatively treated group and 4 in the nonoperatively treated group) were lost to follow-up before the union status was determined and could not be reached by telephone after 1 year.

Fracture-Healing

At 1 year, 2 patients (2.4%) in the operatively treated group and 15 (23.1%) of 65 patients with radiographs available in the nonoperatively treated group had developed nonunion ($p < 0.0001$). The number needed to treat to prevent 1 nonunion was 4.8 patients.

One patient in the operatively treated group was diagnosed with nonunion when the plate loosened after 9 months. The plate was removed, and the nonunion was treated nonoperatively. The other patient sustained an early spontaneous refracture after elective plate removal 1 year after primary surgery and was treated with secondary plate fixation with bone-grafting, during which nonunion was confirmed. The fracture healed.

In the nonoperatively treated group, a nonunion developed in 15 patients and 9 of them had symptoms requiring secondary plate fixation. Five of them received secondary plate fixation within 1 year after fracture (at 4 months [3 patients], 8 months [1 patient], and 9 months [1 patient]), whereas the other 4 received the plate after the study follow-up period. Secondary plate fixation for nonunion was performed in 1.2% in the operatively treated group and in 12.9% (9 of 70 patients with data available) in the nonoperatively treated group ($p = 0.006$).

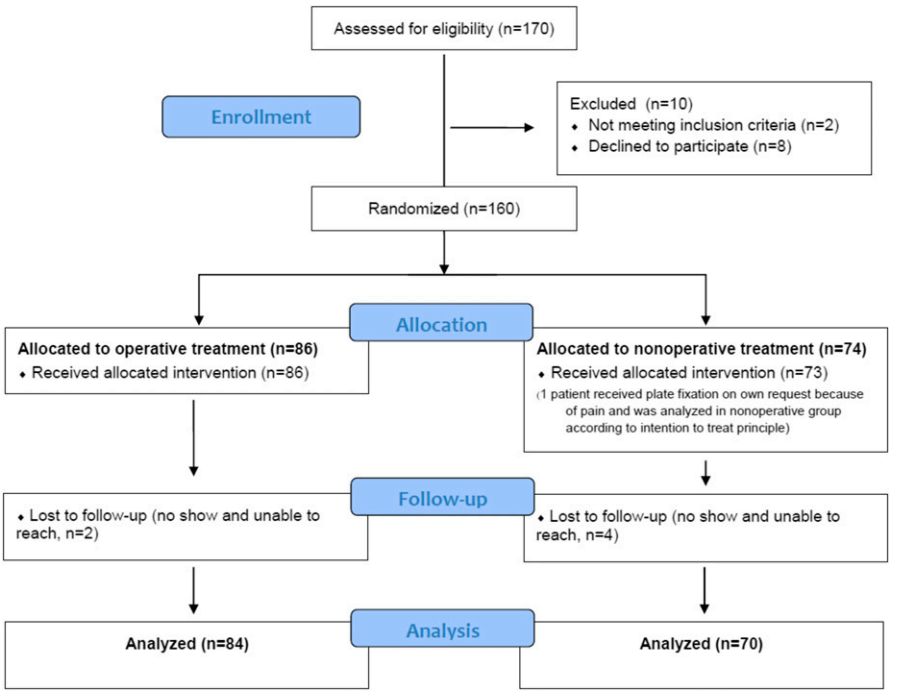

Fig. 1

Flowchart of the included patients. The imbalance of the treatment groups was probably a result of stratification by hospital, with some hospitals including only a few patients.

TABLE I Baseline Characteristics of Included Patients

	Plate Fixation (N = 86)	Nonop. Treatment (N = 74)
Male patients *(no. [%])*	80 (93)	66 (89)
Age* *(yr)*	38.3 ± 12.7	37.2 ± 12.5
Current smoker† *(no. [%])*	18 (22)	19 (27)
Trauma mechanism‡ *(no. [%])*		
Traffic	42 (49)	31 (43)
Sports	33 (38)	33 (46)
Fall from a height	3 (4)	2 (3)
Other	8 (9)	6 (8)
Dominant arm§ *(no. [%])*	36 (44)	30 (42)
Robinson classification# *(no. [%])*		
2B1	50 (60)	37 (53)
2B2	34 (40)	33 (47)

*The values are given as the mean and the standard deviation. †Data not available for 6 patients (3 in each group). ‡Data not available for 2 patients in the nonoperative treatment group. §Data not available for 4 patients in the plate fixation group and 2 in the nonoperative treatment group. #Data not available for 2 patients in the plate fixation group and 4 in the nonoperative treatment group.

Functional Outcomes

After 1 year, the functional scores of 75 (87%) of 86 patients in the operatively treated group and 58 (78%) of 74 patients in the nonoperatively treated group were available for analysis. Constant scores were similar for both treatment groups at all time points, as were DASH scores (Table II).

At the 1-year follow-up evaluation, the mean functional scores of the patients who received secondary plate fixation because of nonunion within 1 year were similar to those of the patients with a primarily united fracture in both treatment groups (the mean Constant scores [and standard deviations] were 98.5 ± 2.8 and 96.3 ± 6.7, respectively, and the mean DASH scores were 2.9 ± 4.2 and 3.3 ± 6.1). The 5 patients with a nonunion who had not received surgery at that time had significantly poorer function scores at 1 year than the patients with a united fracture (the mean Constant scores were 86.2 ± 11.7 and 96.3 ± 6.7, respectively [p = 0.01], and the mean DASH scores were 14.7 ± 14.6 and 3.3 ± 6.1 [p = 0.005]).

Secondary Operations

In the operatively treated group, a reoperation for adverse events was performed in 9 patients (10.7%) because of deep wound infection (2 patients), early implant failure (5 patients), late implant failure (1 patient), and nonunion that became manifest with a refracture after implant removal (1 patient) (Table III). After 1 year, implant removal was performed in or scheduled for 16.7% (14) of the 84 patients. There were no differences between different plate positions with regard to implant failure (p = 0.69) or plate removal (p = 0.53).

In the nonoperatively treated group, 11 patients (15.7%) had a secondary operation for adverse events including nonunion (9 patients), malunion (1 patient), and late neurologic complications (1 patient). One patient who underwent secondary plate fixation because of nonunion later had the plate removed. The secondary operation rate did not differ significantly between the treatment groups (p = 0.47 for adverse events and p = 0.18 for adverse events including elective implant removal operations) (Table III).

Other Adverse Events

Perioperative complications were thrombosis of the cephalic vein, superficial wound infection, and a cardiovascular event in 1 patient each. More than half of the operatively treated patients experienced numbness of the skin around the scar during follow-up, and it persisted in 15 (19.2%) of 78 patients 1 year after surgery.

TABLE II Functional Results for the Treatment Groups

	Plate Fixation		Nonop. Treatment		
Scoring System	No.	Score*	No.	Score*	P Value
Constant score					
6 wk	76	87.3 ± 11.9	68	83.6 ± 12.7	0.07
3 mo	80	93.8 ± 8.2	62	93.8 ± 7.4	1.00
12 mo	75	95.4 ± 7.8	58	96.6 ± 6.3	0.35
DASH questionnaire					
6 wk	77	15.2 ± 12.6	70	19.0 ± 14.4	0.08
3 mo	75	7.3 ± 9.8	64	6.9 ± 8.0	0.79
12 mo	80	4.5 ± 7.6	64	3.2 ± 7.4	0.30

*The values are given as the mean and the standard deviation.

TABLE III Secondary Operations

Indication	Plate Fixation* (N = 84)	Nonop. Treatment* (N = 70)	P Value
Adverse events	9 (10.7)	11 (15.7)	0.47
Nonunion	1 (1.2)†	9 (12.9)	
Malunion	0	1 (1.4)	
Deep infection	2 (2.4)	0	
Early implant failure†	5 (6.0)	0	
Late implant failure§	1 (1.2)	0	
Neurologic complications	0	1 (1.4)	
Elective implant removal	14 (16.7)	1 (1.4)#	
Total (all)	23 (27.4)	12 (17.1)	0.18

*The values are given as the number of patients, with the percentage in parentheses. †Nonunion was diagnosed when spontaneous refracture occurred after plate removal. ‡All early implant failures occurred within 2 months. In 2 patients (1 with a broken plate and 1 with a loose plate), plate fixation was repeated. In 2 other patients, the plate had broken or become loose (in 1 each) and was removed after union had been achieved. In 1 patient, a loosened screw was removed. §Late implant failure occurred after 9 months. The loose plate was removed, and the concomitant nonunion was treated nonoperatively. #One patient who had nonoperative treatment received secondary plate fixation for nonunion and later had the plate removed.

TABLE IV General Health Status

	Plate Fixation		Nonoperative Treatment		
SF-36	No.	Score*	No.	Score*	P Value
Physical component score					
6 wk	78	49.3 ± 7.3	70	46.7 ± 7.8	0.03
3 mo	76	53.5 ± 7.1	63	53.4 ± 6.9	0.92
12 mo	79	55.2 ± 6.1	64	56.1 ± 5.7	0.36
Mental component score					
6 wk	78	51.6 ± 8.6	70	53.1 ± 7.1	0.25
3 mo	76	53.6 ± 7.1	63	54.9 ± 6.1	0.25
12 mo	79	52.6 ± 9.1	64	52.2 ± 9.3	0.80

*The values are given as the mean and the standard deviation. A score of 50 represents the expected score for the general population.

General Health Status

The SF-36 physical component score was somewhat lower in the nonoperatively treated group ($p = 0.03$), but only at 6 weeks (Table IV). The mental component scores were comparable with the score for the general population in both groups.

Pain and Cosmetic Results

Pain scores were somewhat higher in the nonoperatively treated group, but only at 6 weeks (median score, 2 compared with 1; $p = 0.04$). Five percent of the patients in the operatively treated group and 18% in the nonoperatively treated group indicated that they were unsatisfied with the cosmetic result after 1 year ($p = 0.06$).

Discussion

The present RCT demonstrated a significantly lower rate of nonunion after plate fixation than after nonoperative treatment for patients with a displaced midshaft clavicular fracture. There was no difference in functional outcomes. The rate of secondary operations was considerable and was not significantly different between both groups. Pain scores and general physical health status were marginally better after operative treatment, but only at 6 weeks, and the clinical relevance can be disputed.

Since the start of the present study, a number of RCTs that have shown a similar reduction in the rate of nonunion after operative treatment have been published, leading to an explosive increase in routine surgical fixation of clavicular fractures. However, the clinical interpretation of some of the previous results can be debated[6,11,20-22].

For instance, in the first RCT that was published in 2007, all patients with a nonunion underwent secondary surgery; however, it was not mentioned whether they had complaints and chose to have surgery, or if nonunion was regarded as the indication for the operation[6]. In another RCT by Virtanen et al.[20], all 6 patients with a nonunion in the nonoperatively

treated group declined the offered surgical treatment, suggesting that they did not have sufficient symptoms or limitations to choose surgery. Also, this assumption is supported by the fact that functional scores did not differ between the treatment groups. Mirzatolooei described a difference in function in favor of plate fixation[22]. That study noted an exceptionally high number of malunions in the nonoperatively treated group (73%) and was the only one that found no difference in nonunion rates. Recently, Robinson et al.[21] demonstrated a moderately better function after plate fixation (a mean difference in the Constant score of 4.2 points; $p = 0.01$); however, when only fractures that had united were analyzed, the functional difference between the operatively treated and nonoperatively treated groups ceased to exist.

These results endorse our findings that plate fixation itself does not improve functional outcomes, especially not in the long term. Also, since many hospitals cannot provide immediate surgery, operative treatment does not remove possible disadvantages of nonoperative treatment for the patient in the first week.

Even though plate fixation considerably reduces the rate of nonunion compared with nonoperative treatment, it fails to reduce the risk of a secondary operation. Secondary operations were performed in 27.4% of the operatively treated patients, and this number is likely to increase in the second year after surgery since more patients are expected to have their plate removed after longer follow-up.

Potter et al. showed that delayed fixation of a nonunited, nonoperatively treated clavicular fracture led to functional outcomes similar to those after immediate operative treatment[23]. Our results showed the same, despite the small numbers, which suggests that failed nonoperative treatment does not preclude the opportunity of effective treatment, although it does result in a longer recovery time.

The present study had several limitations. First, there was an imbalance between the groups regarding treatment allocation (86 had plate fixation compared with 74 who had nonoperative treatment). This was probably caused by having very few patients enrolled from some hospitals and using stratification per hospital and not central or block randomization.

Second, there was substantial loss to follow-up, especially regarding the functional scores (the Constant score was not available for 12.8% in the operatively treated group and 21.6% in the nonoperatively treated group). Although loss to follow-up is frequently higher after nonoperative treatment because patients have less commitment to return to the hospital than do those after an operation, this could have led to a bias and reduces the power for these outcomes.

Third, the surgical treatment protocols varied among the participating hospitals, resulting in differences in plate type, plate position, and incision. However, this heterogeneity within the study group reflects daily clinical practice and enhances the external validity of the outcomes of this study.

Also, radiographs were judged by the treating surgeon only, which could have biased the results because of a possible underestimation of the complication rate of the surgeon's own work and less than perfect interobserver reliability. Finally, because of the duration of inclusion, new publications on the topic became available, resulting in a stronger tendency of treating physicians toward operative treatment and a subsequent reduction in the patient inclusion rate.

Since neither treatment option is clearly superior for all patients, the clavicular fracture is preeminently suitable for shared treatment decision-making, in which the personal values and beliefs of the patient are addressed along with medical information about both treatment modalities in a way that individualizes treatment. In this process, it is important to explain to patients that they have a choice: patients with pain, deformity, and striking radiographic findings might imagine that they have no other option than fixation. If surgeons help patients to fully understand the data that are currently available to guide them, they might realize that their first impressions are not consistent with their values and their true preference is to avoid surgery.

In conclusion, the present study shows a significantly lower nonunion rate after plate fixation of the fully displaced midshaft fracture of the clavicle compared with nonoperative treatment in a sling. However, the rate of secondary operations was comparably high in both groups, and there were no differences in functional outcomes or general symptoms and limitations. We therefore do not advocate routine operative treatment for displaced midshaft clavicular fractures. Initial nonoperative treatment is a good option for the majority of patients with normal requirements regarding their arm function. If patients have high physiological demands shortly after surgery, high pain scores, or a strong preference for surgery, early plate fixation can offer advantages. ■

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