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Canadian Orthopaedic Trauma Society

J Bone Joint Surg Am. 2007;89:1-10. doi:10.2106/JBJS.F.00020

This information is current as of January 23, 2011

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Publisher Information

The Journal of Bone and Joint Surgery
20 Pickering Street, Needham, MA 02492-3157
www.jbjs.org

Nonoperative Treatment Compared with Plate Fixation of Displaced Midshaft Clavicular Fractures

A Multicenter, Randomized Clinical Trial

By the Canadian Orthopaedic Trauma Society

Background: Recent studies have shown a high prevalence of symptomatic malunion and nonunion after nonoperative treatment of displaced midshaft clavicular fractures. We sought to compare patient-oriented outcome and complication rates following nonoperative treatment and those after plate fixation of displaced midshaft clavicular fractures.

Methods: In a multicenter, prospective clinical trial, 132 patients with a displaced midshaft fracture of the clavicle were randomized (by sealed envelope) to either operative treatment with plate fixation (sixty-seven patients) or nonoperative treatment with a sling (sixty-five patients). Outcome analysis included standard clinical follow-up and the Constant shoulder score, the Disability of the Arm, Shoulder and Hand (DASH) score, and plain radiographs. One hundred and eleven patients (sixty-two managed operatively and forty-nine managed nonoperatively) completed one year of follow-up. There were no differences between the two groups with respect to patient demographics, mechanism of injury, associated injuries, Injury Severity Score, or fracture pattern.

Results: Constant shoulder scores and DASH scores were significantly improved in the operative fixation group at all time-points ($p = 0.001$ and $p < 0.01$, respectively). The mean time to radiographic union was 28.4 weeks in the nonoperative group compared with 16.4 weeks in the operative group ($p = 0.001$). There were two nonunions in the operative group compared with seven in the nonoperative group ($p = 0.042$). Symptomatic malunion developed in nine patients in the nonoperative group and in none in the operative group ($p = 0.001$). Most complications in the operative group were hardware-related (five patients had local irritation and/or prominence of the hardware, three had a wound infection, and one had mechanical failure). At one year after the injury, the patients in the operative group were more likely to be satisfied with the appearance of the shoulder ($p = 0.001$) and with the shoulder in general ($p = 0.002$) than were those in the nonoperative group.

Conclusions: Operative fixation of a displaced fracture of the clavicular shaft results in improved functional outcome and a lower rate of malunion and nonunion compared with nonoperative treatment at one year of follow-up. Hardware removal remains the most common reason for repeat intervention in the operative group. This study supports primary plate fixation of completely displaced midshaft clavicular fractures in active adult patients.

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

Clavicular fractures are common injuries, accounting for 2.6% of all fractures¹, and they occur most commonly in young active individuals². Fractures of the middle third (or midshaft) account for approximately 80% of all clavicular fractures^{1,2}, and they have traditionally been treated nonoperatively, even when substantially displaced. This treatment strategy was based on early reports that suggested that clavicular nonunion was extremely rare, with a prevalence of four nonunions in 566 patients in one series and three

nonunions in 2235 patients in another^{3,4}. Clavicular malunion was described as being of radiographic interest only, with no clinical importance¹⁻⁴.

However, more recent studies of displaced midshaft clavicular fractures have shown a nonunion rate of 15% (eight of fifty-two patients) in one series as well as a rate of unsatisfactory patient-oriented outcomes of 31% (sixteen of fifty-two patients) in one report and 32% (twenty-two of sixty-eight patients) in another, which are much higher rates than previ-

Disclosure: In support of their research for or preparation of this manuscript, one or more of the authors received grants or outside funding from the Orthopaedic Trauma Association and Zimmer Inc. None of the authors received payments or other benefits or a commitment or agreement to provide such benefits from a commercial entity. A commercial entity (Zimmer Inc.) paid or directed, or agreed to pay or direct, benefits to a research fund, foundation, educational institution, or other charitable or nonprofit organization with which the authors are affiliated or associated.



Fig. 1-A
Anteroposterior radiograph of a displaced midshaft clavicular fracture. Note the difference in diameter of the clavicular shaft of the proximal and distal fragments at the fracture site, suggesting that a substantial degree of rotation has occurred.

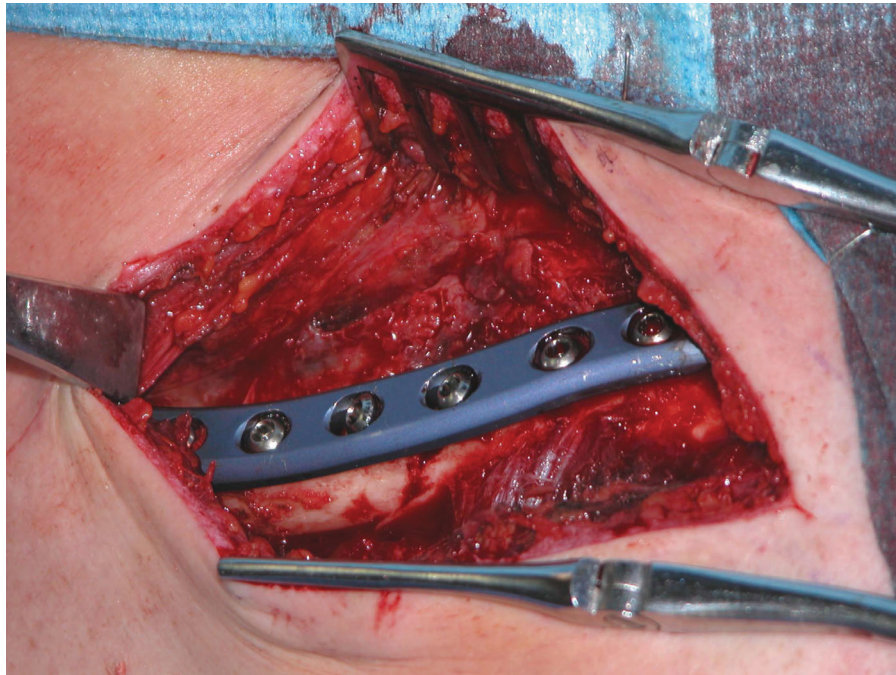


Fig. 1-B
Intraoperative photograph of open reduction and internal fixation of a displaced midshaft clavicular fracture with a contoured small-fragment plate.

ously reported⁵⁻⁷. In addition, clavicular malunion has recently been described by multiple authors as a distinct clinical entity with characteristic clinical and radiographic features⁸⁻¹². Possible explanations for the increased residual disability seen following the nonoperative care of these fractures may be the survival of critically injured trauma patients with more severe fracture patterns⁵, increased patient expectations, more complete follow-up (including patient-oriented outcome mea-

asures), and the elimination of information on children (who have an inherently good prognosis and remodeling potential) from the data analysis^{13,14}.

While it is becoming accepted that the results of closed treatment are much inferior to those described in early reports, primary operative intervention has not been shown to be superior. Numerous recent studies have examined the safety and efficacy of primary open reduction and internal fix-

ation for completely displaced midshaft clavicular fractures and have noted a high union rate with a low complication rate¹⁴⁻¹⁶. However, none of those studies prospectively compared operative fixation with nonoperative care in a randomized fashion, considered to be the so-called gold standard of comparative studies. A recent meta-analysis of available data on displaced midshaft clavicular fractures described a reduced nonunion rate after primary treatment with plate fixation (2.2%; ten of 460 patients) compared with nonoperative care (15.1%; twenty-four of 159 patients), a relative risk reduction of 86% (95% confidence interval, 71% to 93%)¹⁴. The purpose of the present multicenter, prospective, randomized clinical trial was to compare patient-oriented and surgeon-based outcomes after nonoperative treatment with those after operative treatment of completely displaced midshaft clavicular fractures.

Materials and Methods

This was a multicenter, prospective, randomized clinical trial involving eight centers, including St. Michael's Hospital, Toronto; Sunnybrook and Women's College Health Sciences Centre, Toronto; McMaster University Medical Center, Hamilton; Brantford General Hospital, Brantford; London Health Sciences Centre, London, Ontario; Royal Columbian Hospital, New Westminster, British Columbia; Montreal General Hospital, Montreal, Quebec; and Foothills Medical Centre, Calgary, Alberta, Canada. Institutional approval was obtained from the research ethics board at each participating site prior to the initiation of the study. Between April 2001 and December 2004, 132 patients were enrolled in the study from eight

participating study centers (seven university-affiliated and one community hospital). Eligible patients (see below) were randomized to nonoperative or operative care for completely displaced (no cortical contact between the proximal and distal fragments) midshaft fractures of the clavicle. Patients with isolated fractures and those with concomitant shoulder girdle fractures were included. The primary outcome measure was the Disability of the Arm, Shoulder and Hand (DASH) score¹⁷, while secondary outcome measures included the Constant shoulder score, union rate, and complication rates. The null hypothesis was that there would be no differences between the operative and nonoperative groups with respect to surgeon-based and patient-based upper extremity outcome scores.

Inclusion Criteria

Patients were included in the study if they had (1) a completely displaced midshaft fracture of the clavicle (no cortical contact between the main proximal and distal fragments), (2) a fracture in the middle third of the clavicle (a fracture amenable to plate fixation with a minimum of three screws in each proximal and distal fragment), (3) an age between sixteen and sixty years, (4) no medical contraindications to general anesthesia, and (5) provided informed consent.

Exclusion Criteria

Patients were excluded from the study if they had (1) an age of less than sixteen years or greater than sixty years, (2) a fracture in the proximal or distal third of the clavicle, (3) a pathological fracture, (4) an open fracture, (5) a fracture seen more than twenty-eight days after the injury, (6) an associated neu-

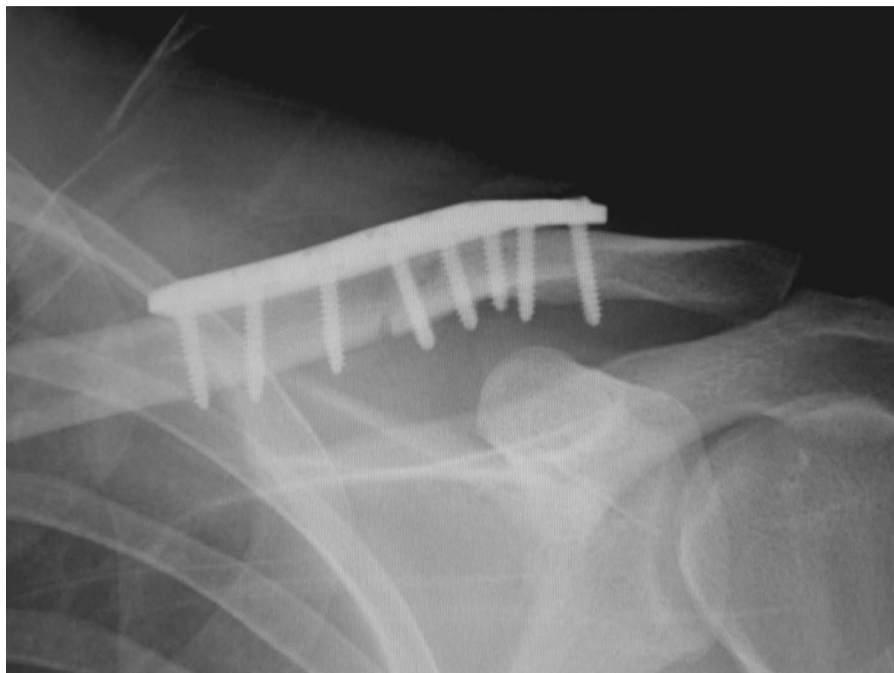


Fig. 1-C

Postoperative radiograph after open reduction and internal fixation of the displaced midshaft clavicular fracture.

rovascular injury with objective neurological findings on physical examination, (7) an associated head injury (a Glasgow Coma Scale score of <12), (8) an upper extremity fracture distal to the shoulder, (9) an inability to comply with follow-up (a transient or an inability to read or complete forms), (10) a medical contraindication to surgery and/or anesthesia (such as heart disease, renal failure, or active chemotherapy), and (11) a lack of consent.

Sample Size Calculation

Before beginning of the study, a power analysis was performed. The choice of sample size was made on the basis of the primary outcome of shoulder function scores. Assuming a beta error of 0.05 and a power of 0.80, it was anticipated that sixty patients would be required in each group in order to demonstrate a 15% difference in the shoulder scores between the two groups.

Randomization

In the fracture clinic or emergency room, the attending surgeon or orthopaedic resident identified a patient as being eligible for the study and the study protocol was introduced. The patient was then seen by the research nurse, the nature of the study was explained, and consent was obtained. Typically, the patient took a consent form home for perusal and completion. Once consent was obtained, randomization was made by the research nurse using a sequentially numbered, opaque, sealed envelope to either nonoperative care (a sling) or open reduction and plate fixation in a 1:1 ratio.

Nonoperative Care

Patients randomized to nonoperative care received a standard sling for six weeks, although compliance was variable: most patients discarded the sling when the pain subsided. There is no convincing clinical evidence that a closed reduction of a displaced clavicular fracture can be maintained¹⁸. In a prior randomized clinical trial comparing a sling and a figure-of-eight bandage for displaced clavicular shaft fractures, Andersen et al. showed no functional or radiographic difference at the time of final follow-up and the patients favored the sling¹⁸. Therefore, no attempt was made at a closed reduction nor was a figure-of-eight bandage applied. Following healing, a course of physiotherapy for strengthening was prescribed.

Operative Technique

Patients randomized to plate fixation had the operation within twenty-eight days after the injury. Prophylactic antibiotics were given. Under a general anesthetic, the patient was positioned in a beach-chair semi-sitting position. The involved shoulder was prepared and draped, and an oblique incision was made over the fracture site. Larger branches of the identifiable supraclavicular nerves were identified and protected throughout the procedure; smaller branches were sacrificed at the surgeon's discretion. The fracture site was identified, and the fracture was reduced and fixed with a small-fragment plate

on the superior surface of the bone, with the goal being a minimum of three screws in the main proximal and distal fragments (forty-four patients were managed with limited contact dynamic compression plates; fifteen, with 3.5-mm reconstruction plates; four, with precontoured plates; and four, with other plates) (Figs. 1-A, 1-B, and 1-C). Reconstruction plates were used for physically smaller individuals (<70 kg). Comminuted fragments were secured with lag screws if possible, with care being taken to preserve soft-tissue attachments, and a longer plate was selected to maintain a minimum of three screws in the primary proximal and distal fragments. If the fragments were too small to accept fixation, they were loosely sutured into place with number-1 absorbable suture and positioned under the plate. Bone-grafting was not performed. The deltotracheal fascia was closed with interrupted number-1 absorbable sutures as a distinct layer, followed by skin closure. No drains were used.

A sling was used for comfort for seven to ten days, and then a physiotherapist instructed the patient in active range-of-motion exercises that were performed at home. When fracture union (defined as radiographic union [see below] with no pain or motion with manual stressing of the fracture) was evident, typically at six weeks, strengthening was allowed, with a return to full activities (including sports) at three months. However, compliance with this regimen was variable as the patients were predominantly young men, and many returned to more aggressive recreational and occupational activities earlier than recommended.

Assessment

Following enrollment in the study, the patients were seen at six weeks and at three, six, and twelve months. Assessment included standardized clinical evaluation and completion of the Constant shoulder score and the Disability of the Arm, Shoulder and Hand (DASH) score. Both an anteroposterior and a 20° cephalad radiograph were made for each patient. Radiographic union was defined as complete cortical bridging between proximal and distal fragments on both radiographs as determined by the treating surgeon.

Adverse Events and/or Complications

An adverse event or complication was defined as any event that necessitated another operative procedure or additional medical treatment. Nonunion was defined as the lack of radiographic healing with clinical evidence of pain and motion at the fracture site at one year. Radiographic malunion, defined as loss of anatomic contour of the clavicle, was universal in the nonoperative group. Symptomatic malunion was defined as union of the fracture in a shortened, angulated, or displaced position with weakness, easy fatigability, pain with overhead activity, neurologic symptoms, and shoulder asymmetry with a completed or planned corrective osteotomy. Complex regional pain syndrome was diagnosed by the presence of dysesthetic pain and hyperesthesia extending into the hand of the involved limb, vasomotor changes, skin atrophy, and diffuse osteopenia¹⁹.

Constant Score Results

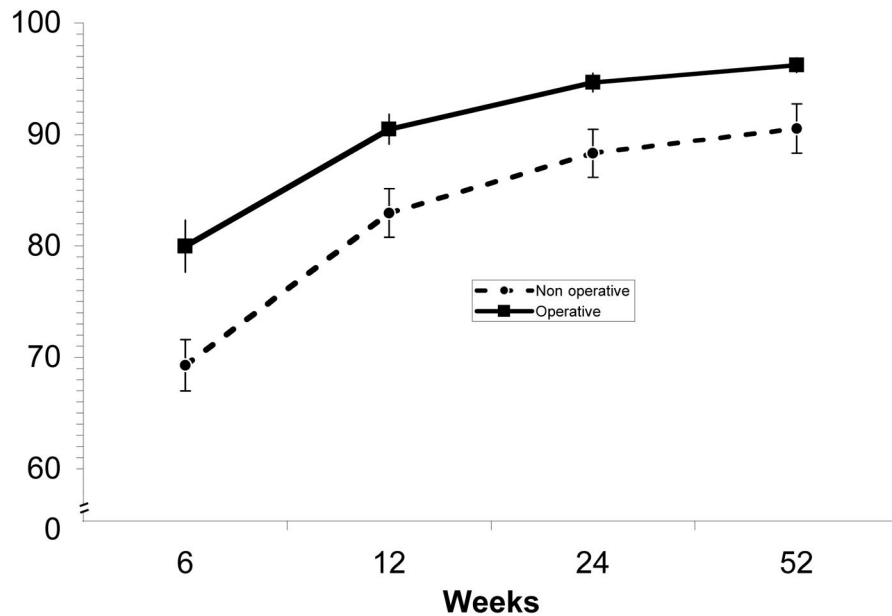


Fig. 2

Graphic analysis comparing the mean Constant shoulder scores in the operative and nonoperative groups at six, twelve, twenty-four, and fifty-two weeks of follow-up. The values are improved for the operative group at each time-point ($p < 0.01$ for all).

DASH Results

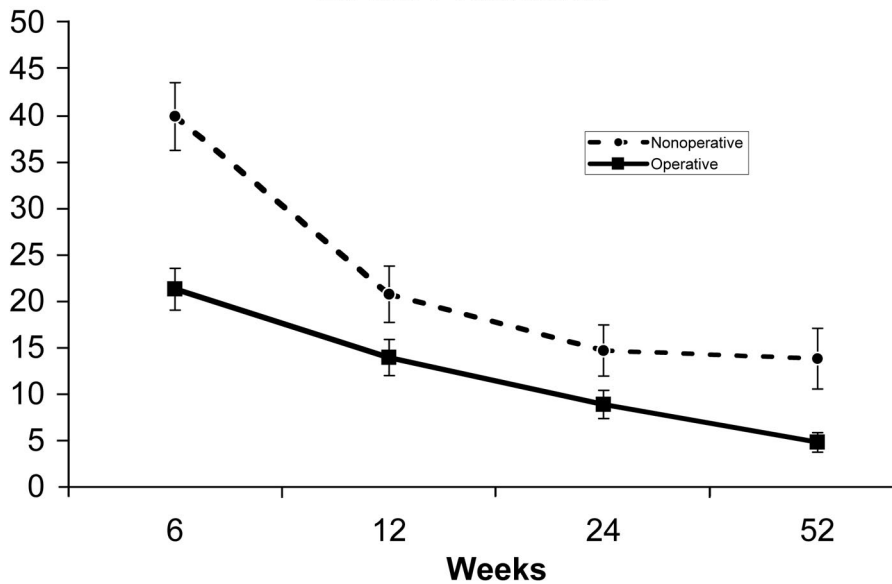


Fig. 3

Graphic analysis comparing the mean Disability of the Arm, Shoulder and Hand (DASH) scores in the operative and nonoperative groups at six, twelve, twenty-four, and fifty-two weeks of follow-up. The DASH is a disability score where a "perfect" extremity would typically score 0 (mean values for a "normal" extremity range from 4 to 8). Values are worse in the nonoperative group at each time-point ($p < 0.01$ at six weeks, $p = 0.04$ at twelve weeks, $p = 0.05$ at twenty-four weeks, and $p < 0.01$ at fifty-two weeks).

TABLE I Demographic Data on the Patients and Characteristics of the Fractures

Parameter	Operative Group (N = 62)	Nonoperative Group (N = 49)	P Value
Male	53	34	0.062
Female	9	15	0.062
Mean age (yr)	33.5	33.5	0.644
(Mean) height (cm)	173.9	167.0	0.213
Mean Injury Severity Score	5.8	7.2	0.232
Associated fractures	8	6	0.756
Dominant arm	26	20	0.561
Smokers	19	16	0.624
Mean fracture angulation (deg)	11.9	12.7	0.563
Mean fracture shortening (mm)	15.7	14.3	0.209
Mean total fracture displacement (mm)	20.1	19.3	0.478
Mechanism of injury (no. of patients)			>0.05 for all
Fall	9	7	
Sports	9	6	
Motor-vehicle or motorcycle accident	16	14	
Skiing or snowboarding	7	10	
Bicycling	15	8	
Other	6	4	

Statistical Analysis

Statistical analysis was performed with SPSS software (version 13.0; SPSS, Chicago, Illinois). All scale variables were tested for normality with the Kolmogorov-Smirnov test. The main effect of treatment on the DASH and Constant scores was analyzed with use of a two-way analysis of variance with treatment (operative or nonoperative) and time (six, twelve, twenty-four, fifty-two, and 104 weeks) as independent factors and the Tukey post hoc method for the comparison of means. The Student t test was used for the comparison of means for parametric scale variables in independent groups. Nominal variables were tested by the chi-square or Fisher exact test. The Pearson correlation coefficient was used for comparison of the DASH scores at one year with the Injury Severity Scores (ISS) and total vertical and horizontal displacement (total xy). All tests were two-sided. The results were considered to be significant at $p < 0.05$.

Results

One hundred and thirty-two patients with 132 fractures were entered in the study between April 2001 and December 2004. Sixty-seven patients were randomized to the operative group and sixty-five to the nonoperative group. One patient randomized to operative repair declined surgery, and one patient randomized to nonoperative treatment insisted on operative repair. Both were followed in their original groups with use of the intention-to-treat principle²⁰. One patient in the nonoperative group died in a subsequent motor-vehicle accident, and fifteen were lost to follow-up by one year. Five patients in the operative group were lost to follow-up at one

year. Significantly more patients in the nonoperative group were lost to follow-up ($p = 0.008$; see Discussion). Thus, sixty-two patients in the operative group and forty-nine in the nonoperative group completed the one-year assessment. There were no demographic differences between the operative and nonoperative groups, and there were no differences with regard to mechanism of injury, associated fractures and/or injuries, or ISS between the groups (Table I).

Constant Shoulder Scores

The operative group had significantly superior Constant shoulder scores at all time-points ($p < 0.01$) (Fig. 2). This difference persisted at one year ($p = 0.001$), and the magnitude of the difference was approximately 10 points, which is considered a clinically measurable amount²¹.

DASH Scores

The operative group had significantly superior (i.e., lower) DASH scores at all time-points (Fig. 3), persisting to one year ($p < 0.01$). The magnitude of this difference was approximately 10 points, which is considered a clinically relevant amount¹⁷.

Patient Satisfaction

At each assessment, patients were asked "Are you satisfied with your shoulder?" At each assessment, patients in the operative group were more likely to reply "yes" to this question ($p = 0.02$, odds ratio = 3.8 at six weeks; $p = 0.001$, odds ratio = 4.4 at twelve weeks; $p = 0.03$, odds ratio = 3.2 at twenty-four weeks; and $p = 0.002$, odds ratio = 3.5 at fifty-two weeks).

TABLE II Complications

Adverse Event	Operative Group (N = 62)	Nonoperative Group (N = 49)	P Value
Nonunion	2*	7	0.042
Malunion requiring further treatment	0	9	0.001
Wound infection and/or dehiscence	3	0	0.253
Hardware irritation requiring removal	5	0	0.065
Complex regional pain syndrome	0	1	0.441
Surgery for impending open fracture	0	2	0.192
Transient brachial plexus symptoms	8	7	0.690
Abnormality of the acromioclavicular or sternoclavicular joint	2	3	0.653
Early mechanical failure	1	0	1.000
Other	2	2	0.784
Total	23 (37%)	31 (63%)	0.008

*One patient who was randomized to operative fixation declined surgery. He had a nonunion of the fracture at one year. According to the "intention-to-treat" principle, the complication was included in the operative group as a nonunion. See text.

Range of Motion

Range of motion was well maintained, and there were no significant differences in measured range of motion between the two groups. No patient lost $>10^\circ$ of motion in any plane.

Fracture Union

The mean time to union was 16.4 weeks in the operative group and 28.4 weeks in the nonoperative group ($p = 0.001$). Nonunion occurred in two patients in the operative group and in seven in the nonoperative group (Table II). One nonunion in the operative group was in the patient who had been randomized to operative fixation but declined surgery and had subsequent development of the nonunion. He was followed with the intention-to-treat principle²⁰, although technically this was not a failure of operative intervention.

Adverse Events and/or Complications

Complications, including nonunion and symptomatic malunion, were more frequent in the nonoperative group. Com-

plications in the operative group tended to be hardware-related (plate irritation and removal, and wound problems). Wound infection and dehiscence following plate fixation of the clavicle has been a feared complication. We had three patients with such complications, and all were managed with antibiotics and local wound care. Once fracture union had occurred, each patient underwent hardware removal and irrigation and/or débridement with successful resolution of the infection (Table II). One patient in the operative group experienced premature hardware failure in an all-terrain vehicle accident six weeks after fixation and required repeat fixation.

Appearance of the Shoulder

Patients were specifically questioned about their satisfaction or dissatisfaction regarding the appearance of the shoulder (and incision, if applicable) at one year following the injury (Table III). Patients in the operative group were more likely to be satisfied with the appearance of the shoulder ($p = 0.001$).

TABLE III Appearance of Shoulder

Condition	Operative Group (N = 62)	Nonoperative Group (N = 49)	P Value
"Droopy" shoulder	0	10	0.001
Bump and/or asymmetry	0	22	0.001
Scar	3	0	0.253
Sensitive and/or painful fracture site	9	10	0.891
Hardware irritation and/or prominence	11	0	0.001
Incisional numbness	18	0	0.001
Satisfaction with appearance	52	26	0.001

Radiographic Outcome

Anatomic reduction was obtained and maintained in all sixty-two patients in the operative group except for one in whom early mechanical failure of the plate occurred at six weeks. Correlating displacement and outcome in the operative group was not possible since anatomic reduction was obtained and maintained in all patients, but an association was found between total displacement at the fracture site (vertical displacement and shortening combined) and DASH scores at one year in the nonoperative group ($r = 0.326$, $p = 0.05$); that is, greater displacement correlated with a higher DASH score or more patient-related disability. With the numbers available, patients with multiple shoulder girdle injuries did not demonstrate significantly worse scores than those with isolated injuries ($p = 0.24$).

Discussion

Traditionally, clavicular fractures have been treated nonoperatively. In the 1960s, Neer and Rowe reported on the nonoperative treatment of clavicular fractures^{3,4}. Neer reported nonunion in only three of 2235 patients with middle-third fractures treated by closed methods³, while Rowe reported nonunion in four of 566 clavicular fractures⁴. This information dominated the clinical approach to displaced clavicular fractures. These studies also suggested a higher nonunion rate with operative care. However, more recent studies have shown that the union rate for displaced midshaft fractures of the clavicle may not be as favorable as once thought. In a prospective, observational cohort study, Robinson et al. described a consecutive series of 868 patients with clavicular fractures, 581 of whom had a midshaft diaphyseal fracture²². They found a significantly higher nonunion rate (21%) for the displaced, comminuted midshaft fractures ($p < 0.05$). In a letter to the editor, Brinker et al. analyzed the data in that study and suggested a nonunion rate ranging between 20% and 33% for displaced, comminuted fractures in males²³. Similarly, in a study of fifty-two displaced midshaft clavicular fractures, Hill et al. reported that eight patients had a nonunion and sixteen patients had an unsatisfactory outcome on the basis of patient-oriented measures⁶. They concluded that displacement of the fracture fragments by >2 cm was associated with an unsatisfactory result. A meta-analysis of recent studies revealed that the rate of nonunion for displaced midshaft clavicular fractures was 2.2% (ten of 460 patients) after plate fixation compared with 15.1% (twenty-four of 159 patients) after nonoperative care, a relative risk reduction for nonunion of 86%¹⁴. That meta-analysis also showed that primary plate fixation was, contrary to prevailing opinion, a safe and reliable procedure¹⁴.

Previously, malunion of the clavicle (which is typical with displaced fractures) was thought to be of radiographic interest only and required no treatment. However, it is becoming increasingly apparent that clavicular malunion is a distinct clinical entity with radiographic, orthopaedic, neurologic, and cosmetic features. Nowak et al. examined the late sequelae in 208 adult patients with clavicular fractures and found that, at

ten years after the injury, ninety-six patients (46%) still had symptoms despite the fact that only fifteen (7%) had a nonunion²⁴. McKee et al. described the typical inferior, shortened, and anteriorly rotated position of the distal fragment in clavicular malunion and the symptoms that resulted from it⁸. Corrective osteotomy and plate fixation improved the DASH score from 32 to 11, with fourteen of fifteen patients who were satisfied with the procedure²⁵. Similar results were found with corrective osteotomy for clavicular malunion in studies by Basamania, Bosch et al., and Chan et al.⁹⁻¹¹. In the forty-nine patients in our study who were treated nonoperatively and had a healed fracture, many (nine; 18%) had the typical symptoms of malunion develop and they elected corrective osteotomy²⁶⁻²⁹. Most of the malunions were associated with substantial clavicular displacement and shortening, although the effect of shortening on function remains controversial^{30,31}. Our study found (in the nonoperative group) a direct relationship between increased displacement and a worse DASH score.

While it is unclear why there is such a dramatic difference between the outcome of clavicular fractures in previous reports and those in contemporary studies, there are several possibilities. The initial reports often included data on clavicular fractures in children, who have inherent healing abilities and remodeling potential, and their data may have artificially improved the overall results¹⁻⁴. Second, the use of patient-oriented outcome measures, as in the studies by Hill et al. and McKee et al., has been shown to reveal functional deficits in the upper extremity that are not detected by traditional surgeon-based scores; it is unlikely that such patient dissatisfaction would be detected in a 1960 study that focused on radiographic outcome^{6,8}. A related issue is changing patient expectations: most active clinicians are acutely aware that a patient today is more likely to expect a rapid return to pain-free function following a fracture (and be more vocal when this does not occur) than his or her 1960 counterpart. Last, it may be that injury patterns are changing. In one study of clavicular shaft fractures in patients with polytrauma, the presence of a clavicular fracture was found to be associated with a mortality rate of 32% (thirty-four of 105 patients) (mainly due to concomitant chest and head injuries)⁵. Survivors displayed a substantial level of residual disability in the involved shoulder. Most studies have revealed a correlation between fracture comminution (and displacement) and worse outcome, and these fracture features are associated with higher-energy trauma^{5,6,14,22}. Thus, there are surviving patients with clavicular fractures who have an intrinsically worse prognosis and in whom long-term sequelae may be more common.

In contradistinction to earlier case series, modern studies on primary plate fixation of acute midshaft clavicular fractures have described high rates of successful results with rates of union ranging from 94% to 100% and low rates of infection and surgical complications: a recent meta-analysis of plate fixation for 460 displaced fractures revealed a nonunion rate of only 2.2%¹⁴⁻¹⁶. With improved implants, prophylactic antibiotics, and better soft-tissue handling, plate fixation has been a reliable and reproducible technique.

Our study examined 111 patients with completely displaced midshaft clavicular fractures randomized to either traditional sling treatment or open reduction and internal fixation with a plate. There was a clear superiority of operative fixation, with significantly superior surgeon-based (Constant shoulder score) and patient-based (DASH) outcome measures at every time-point in the study. The improvement in scores (approximately 10 points for each) was clinically relevant as well as significantly superior. Patients who underwent operative fixation also had an earlier return to normal function. In addition, there was a significant reduction in the risk of nonunion in the operative group (two of sixty-two patients had a nonunion) compared with the nonoperative group (seven of forty-nine patients had a nonunion) ($p = 0.001$). Complications in the operative group were typically hardware-related (plate irritation and wound complications) and were corrected by plate removal in all cases. Refracture was not seen, despite the fact that many patients returned to heavy contact and so-called extreme sports (fifty-five of 111 patients in the study sustained the fracture during sports, bicycling, or skiing and/or snowboarding). Most of the plates used in our study were straight plates contoured to fit the clavicle. More recently, we changed to anatomically designed s-shaped contoured plates²⁵. Our preliminary experience with these plates suggests a dramatically reduced prevalence (and severity) of soft-tissue irritation, and it is possible that this may decrease the need for plate removal in the operative group.

Appearance is important to patients, and an unsightly scar has been a traditional deterrent to operative treatment of clavicular fractures. We specifically investigated this component of patient satisfaction in our study (see Table III). Despite the prevalence of hardware prominence and incisional complications (numbness and sensitivity) in the operative group, more patients in this group (fifty-two of sixty-two patients) answered "yes" to the question "Are you satisfied with the appearance of your shoulder?" than in the nonoperative group (twenty-six of forty-nine; $p = 0.001$). In this group of predominantly young male patients, a droopy shoulder (nonoperative group) seemed to be of greater cosmetic concern than a scar (operative group).

One of the weaknesses of our study is that we used only plate fixation in the operative group: intramedullary fixation is also an option³²⁻³⁴. A direct comparison between the two techniques in a prospective trial is required. Another weakness of our study is the number of patients who did not complete the assessment period. However, in a group of fracture patients who were predominantly young men, the rate

of patients lost to follow-up in our study is comparable with that in other studies and we do not believe that it jeopardizes our results. Specifically, the greatest concern in a study such as ours is that a number of complications in the (experimental) operative group would be missed because of lack of follow-up. However, we followed sixty-two of sixty-seven operative patients to definitive outcome. We believe that the patients who did not undergo surgery were less likely to feel committed to the study, did not return because of a lack of a requirement for postoperative care, or were potentially unhappy with their allocated treatment. We know of at least two such individuals who obtained operative treatment for a nonunion elsewhere. Lastly, with time, our reintervention rate may increase, especially in the operative group (i.e., for hardware removal).

In conclusion, our study shows that early primary plate fixation of completely displaced midshaft clavicular fractures results in improved patient-oriented outcomes, improved surgeon-oriented outcomes, earlier return to function, and decreased rates of nonunion and malunion. There were no catastrophic complications in the operative group such as brachial plexus palsy, vascular injury, or pneumothorax; hardware removal was the most common reason for reintervention. Patients were more satisfied with the shoulder (and its appearance) following operative intervention. While we stress that our findings are applicable only to a specific subset of clavicular injuries, our data support primary plate fixation of completely displaced midshaft clavicular fractures in active adults. ■

NOTE: The authors acknowledge the advice and knowledge of Lynn A. Crosby and Carl J. Basamania.

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doi:10.2106/JBJS.F.00020

References

1. Neer C. Fractures of the clavicle. In: Rockwood CA Jr, Green DP, editors. Fractures in adults. 2nd ed. Philadelphia: Lippincott; 1984. p 707-13.
2. Crenshaw AH. Fractures of the shoulder girdle, arm and forearm. In: Crenshaw AH, editor. Campbell's operative orthopaedics. 8th ed. St. Louis: Mosby Year Book; 1992. p 989-1053.
3. Neer CS 2nd. Nonunion of the clavicle. JAMA. 1960;172:1006-11.
4. Rowe CR. An atlas of anatomy and treatment of midclavicular fractures. Clin Orthop Relat Res. 1968;58:29-42.
5. McKee MD, Schemitsch EH, Stephen DJ, Kreder HJ, Yoo D, Harrington J. Functional outcome following clavicle fractures in polytrauma patients [abstract]. J Trauma. 1999;47:616.
6. Hill JM, McGuire MH, Crosby LA. Closed treatment of displaced middle-third fractures of the clavicle gives poor results. J Bone Joint Surg Br. 1997;79:537-9.
7. Nordqvist A, Petersson CJ, Redlund-Johnell I. Mid-clavicle fractures in adults: end result study after conservative treatment. J Orthop Trauma. 1998;12:572-6.

- 8.** McKee MD, Wild LM, Schemitsch EH. Midshaft malunions of the clavicle. *J Bone Joint Surg Am.* 2003;85:790-7.
- 9.** Basamania CJ. "Claviculoplasty" and intramedullary fixation of malunited, shortened clavicular fractures. *J Shoulder Elbow Surg.* 1999;8:540.
- 10.** Bosch U, Skutek M, Peters G, Tscherne H. Extension osteotomy in malunited clavicular fractures. *J Shoulder Elbow Surg.* 1998;7:402-5.
- 11.** Chan KY, Jupiter JB, Leffert RD, Marti R. Clavicle malunion. *J Shoulder Elbow Surg.* 1999;8:287-90.
- 12.** Kuhn JE. Symptomatic malunions of the middle clavicle. *J Shoulder Elbow Surg.* 1999;8:539.
- 13.** Robinson CM. Fractures of the clavicle in the adult. Epidemiology and classification. *J Bone Joint Surg Br.* 1998;80:476-84.
- 14.** Zlowodzki M, Zelle BA, Cole PA, Jeray K, McKee MD; Evidence-Based Orthopaedic Trauma Working Group. Treatment of midshaft clavicle fractures: systemic review of 2144 fractures: on behalf of the Evidence-Based Orthopaedic Trauma Working Group. *J Orthop Trauma.* 2005;19:504-7.
- 15.** Poigenfurst J, Rappold G, Fischer W. Plating of fresh clavicular fractures: results of 122 operations. *Injury.* 1992;23:237-41.
- 16.** McKee MD, Seiler JG, Jupiter JB. The application of the limited contact dynamic compression plate in the upper extremity: an analysis of 114 consecutive cases. *Injury.* 1995;26:661-6.
- 17.** Hudak PL, Amadio PC, Bombardier C. Development of an upper extremity outcome measure: the DASH (disabilities of the arm, shoulder and hand) [corrected]. The Upper Extremity Collaborative Group (UECG). *Am J Ind Med.* 1996;29:602-8. Erratum in: *Am J Ind Med.* 1996;30:372.
- 18.** Andersen K, Jensen PO, Lauritzen J. Treatment of clavicular fractures. Figure-of-eight bandage versus a simple sling. *Acta Orthop Scand.* 1987;58:71-4.
- 19.** Doro C, Hayden RJ, Louis DS. Complex regional pain syndrome type I in the upper extremity. *Clin Occup Environ Med.* 2006;5:445-54, x.
- 20.** Heritier SR, Gebiski VJ, Keech AC. Inclusion of patients in clinical trial analysis: the intention-to-treat principle. *Med J Aust.* 2003;179:438-40.
- 21.** Yian EH, Ramappa AJ, Arneberg O, Gerber C. The Constant score in normal shoulders. *J Shoulder Elbow Surg.* 2005;14:128-33.
- 22.** Robinson CM, Court-Brown CM, McQueen MM, Wakefield AE. Estimating the risk of nonunion following nonoperative treatment of a clavicular fracture. *J Bone Joint Surg Am.* 2004;86:1359-65.
- 23.** Brinker MR, Edwards TB, O'Connor DP. Estimating the risk of nonunion following nonoperative treatment of a clavicular fracture [letter]. *J Bone Joint Surg Am.* 2005;87:676-7.
- 24.** Nowak J, Holgersson M, Larsson S. Can we predict long-term sequelae after fractures of the clavicle based on initial findings? A prospective study with nine to ten years of follow-up. *J Shoulder Elbow Surg.* 2004;13:479-86.
- 25.** McKee MD, Wild LM, Schemitsch EH. Midshaft malunions of the clavicle. Surgical technique. *J Bone Joint Surg Am.* 2004;86 Suppl 1:37-43.
- 26.** McKee MD, Pedersen EM, Jones C, Stephen DJ, Kreder HJ, Schemitsch EH, Wild LM, Potter J. Deficits following non-operative treatment of displaced midshaft clavicular fractures. *J Bone Joint Surg Am.* 2006;88:35-40.
- 27.** Chen DJ, Chuang DC, Wei FC. Unusual thoracic outlet syndrome secondary to fractured clavicle. *J Trauma.* 2002;52:393-9.
- 28.** Fujita K, Matsuda K, Sakai Y, Sakai H, Mizuno K. Late thoracic outlet syndrome secondary to malunion of the fractured clavicle: case report and review of the literature. *J Trauma.* 2001;50:332-5.
- 29.** England JD, Tiel RL. AAEM case report 33: costoclavicular mass syndrome. American Association of Electrodiagnostic Medicine. *Muscle Nerve.* 1999;22:412-8.
- 30.** Nordqvist A, Redlund-Johnell I, von Scheele A, Petersson CJ. Shortening of clavicle after fracture. Incidence and clinical significance, a 5-year follow-up of 85 patients. *Acta Orthop Scand.* 1997;68:349-51.
- 31.** Orok PK, Buchan M, Winkler A, Kelly IG. Does shortening matter after clavicular fractures? *Bull Hosp Jt Dis.* 1999;58:6-8.
- 32.** Jubel A, Andermahr J, Schiffer G, Tsironis K, Rehm KE. Elastic stable intramedullary nailing of midclavicular fractures with a titanium nail. *Clin Orthop Relat Res.* 2003;408:279-85.
- 33.** Boehme D, Curtis RJ Jr, DeHaan JT, Kay SR, Young DC, Rockwood CA Jr. Nonunion of fractures of the mid-shaft of the clavicle. Treatment with a modified Hagie intramedullary pin and autogenous bone-grafting. *J Bone Joint Surg Am.* 1991;73:1219-26.
- 34.** Ring D, Holovacs T. Brachial plexus palsy after intramedullary fixation of a clavicular fracture. A report of three cases. *J Bone Joint Surg Am.* 2005;87:1834-7.