Operative Versus Nonoperative Care of Displaced Midshaft Clavicular Fractures: A Meta-Analysis of Randomized Clinical Trials

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Background: Recent studies have suggested benefits following primary operative fixation of substantially displaced midshaft fractures of the clavicle. We reviewed randomized clinical trials of operative versus nonoperative treatment of these fractures, and pooled the functional outcome and complication rates to arrive at summary estimates of these outcomes.

Methods: A systematic review of the literature was performed to identify studies of randomized clinical trials comparing operative versus nonoperative care for displaced midshaft clavicular fractures.

Results: Six studies (n = 412 patients, mean Detsky score = 15.3) were included. The nonunion rate was higher in the nonoperatively treated patients (twenty-nine of 200) than it was in patients treated operatively (three of 212) (p = 0.001). The rate of symptomatic malunion was higher in the nonoperative group (seventeen of 200) than it was in the operative group (0 of 212) (p < 0.001).

Conclusions: Operative treatment provided a significantly lower rate of nonunion and symptomatic malunion and an earlier functional return compared with nonoperative treatment. However, there is little evidence at present to show that the long-term functional outcome of operative intervention is significantly superior to nonoperative care.

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

A midshaft fracture of the clavicle is a common skeletal injury that accounts for 2.6% to 10% of all adult fractures1,2. Older studies report that the nonunion rate with conservative treatment is low (less than 1%)3,4. Recent prospective studies focusing on the nonoperative treatment of displaced midshaft fractures in the adult population describe nonunion rates of 15% to 20%, objective shoulder muscle strength loss of 18% to 33%, poor early functioning of the injured shoulder, and up to 42% of patients with residual sequelae at six months after injury5-7.

Due to the increasing recognition of suboptimal outcome following nonoperative treatment, primary operative fixation has become increasingly popular for these injuries. Operative implants and techniques vary, and include intramedullary osteosynthesis and plate fixation8-11. There are a number of recently published, randomized prospective clinical trials12-17. Since this injury commonly afflicts a young, active population, rapid return to function and early union is a priority in addition to the more traditional outcomes, such as recovery of muscle strength, range of motion, and the...
avoids long-term complications (such as nonunion and symptomatic malunion).

There are numerous studies on nonoperative and operative care, but few randomized clinical trials have prospectively compared the two. In this systematic review, the primary aim was to use Level-I evidence from recent randomized clinical trials to arrive at summary estimates of treatment effect, potential harm, and patient outcome.

Materials and Methods

Research Questions

We posed three questions with regard to the treatment of acute, displaced midshaft fractures of the clavicle: (1) Is there a significant difference in patient and surgeon-assessed outcomes of primary operative fixation versus nonoperative treatment? (2) What are the differences in the rate and severity of a defined set of complications (nonunion or delayed union, symptomatic malunion, infection, hardware removal, neurologic compromise, and refracture) for operative fixation versus nonoperative treatment at one year? and (3) Is there evidence that, when compared with nonoperative care, primary fixation of displaced midshaft clavicular fractures minimizes disability and improves function at twelve months after injury?

Eligibility Criteria

Studies were included in this review if they were randomized prospective trials of operative versus nonoperative treatment of acute, completely displaced midshaft fractures of the clavicle. Quasi-randomized studies (nonrandom treatment allocation) were excluded, as were studies that included delayed union or nonunion, children (i.e., younger than sixteen years of age), or pathological fractures.

Literature Search and Review of the Proceedings of Annual Meetings

An online MEDLINE database was used with the search string "clavicle" [keyword] and "fracture" [keyword] and randomized clinical trial [publication type: ptyp]. The two senior authors of this paper (M.D.M. and E.H.S.) reviewed the titles, and appropriate abstracts were reviewed. Content experts were contacted to inquire about unpublished trials or trials in progress. Proceedings of the annual meetings of the American Academy of Orthopaedic Surgeons (AAOS), Orthopaedic Trauma Association (OTA), and American Shoulder and Elbow Surgeons (ASES) for the years 1990 to 2010 (inclusive) were also manually reviewed by one of the authors (R.C.M.). Abstracts for all eligible citations were reviewed by the two senior authors (M.D.M. and E.H.S.) for inclusion with use of the above criteria.

Outcome Scores

A variety of outcome scores were acknowledged in this review, including the Constant Shoulder Score (CS), the Disabilities of the Arm, Shoulder and Hand (DASH) score, the L’Insalata Shoulder Rating Questionnaire, and the Single Assessment Numeric Evaluation (SANE)18,21. Secondary outcome measures of this review include complications, range of motion, return to work, and clavicular shortening.

Validity Assessment

Two senior authors (M.D.M. and D.B.W.) independently assessed the methodological quality of the selected studies, without blinding, with use of the Detsky score, a fourteen-item index containing questions arranged in five equally weighted categories of randomization, outcome measures, eligibility criteria, interventions, and statistics22. The Detsky scale was chosen as it has been utilized previously to determine the scientific quality of published orthopaedic randomized trials and has demonstrated consistency and reliability23.

Data Extraction and Analysis

Two senior authors (M.D.M. and D.B.W.) independently extracted data from all included studies with the use of a prespecified data extraction form. A third investigator (R.C.M.) then reviewed the forms for completeness and agreement and entered the data (population demographics, mechanism of injury, operative methods, shoulder range of motion, and patient and surgeon outcome scores, complications [nonunion or delayed union, symptomatic malunion, infection, hardware removal, neurologic compromise, and refracture], and return to activity and/or work) into a custom spreadsheet. Disagreements in data extraction were resolved by discussion and consensus. Data across the six studies were pooled and summary estimates of treatment effect (relative risks with associated 95% confidence intervals) were calculated. A random effects model was used to ensure that these studies represent a random sample of all potentially available studies24. In the pooled analysis, studies were weighted by the inverse of the variance for the reported outcome. Homogeneity across the studies was assessed with a chi-square analysis, with p ≤ 0.10 being considered significant. The Review Manager (RevMan) software program25 (The Nordic Cochrane Centre, Copenhagen, Denmark), provided by The Cochrane Collaboration, was used for graphical representation of the pooled data.

Source of Funding

This study was supported by an internal educational grant from the St. Michael’s Hospital Orthopaedic Research and Education Fund (to R.C.M.). Research Ethics Board approval is not required for this type of study at our institution.

Results

Literature Search and Review of the Proceedings of Annual Meetings

The keywords “clavicle” and “fracture” produced 988 hits, of which twelve were randomized clinical trials. Eight trials were excluded because of repeated citations (n = 2), lack of a nonoperative control group (n = 4), lack of an operative group (n = 1), or because the study was a cadaver study (n = 1). The remaining four articles were included in this meta-analysis. Content expert knowledge and meeting abstracts yielded four additional studies: two are in progress (no data were available), one had been accepted for publication (full manuscript was available for review), and one had been published in abstract form (unpublished article and data were forwarded by the author) (Fig. 1). These latter two are included in this review.

Six studies (four published, one accepted for publication, and one abstract with unpublished data available) were included (n = 412 patients, 212 treated operatively, 200 treated nonoperatively); all were randomized clinical trials that enrolled patients with completely displaced midshaft clavicular fractures. The studies were performed in various countries, including Finland14,16, the United States14,16, Canada12, and Germany13 (Table I). There were no significant differences in baseline demographics between the operative and nonoperative groups (Appendix), and individuals enrolled in all six studies were homogeneous, consisting of young (mean age range, 25.0 to 41.3 years), predominantly male patients. Two studies examined specific subgroups (Judd et al. studied active duty military personnel15, and Witzel studied athletes15). Operative techniques included plate fixation in three studies and intramedullary pin fixation in three studies. Nonoperative treatment consisted of a standard sling in all six studies.
Validity Assessment

Of the six studies, only one study reported its level of evidence (Therapeutic Level I) in the publication itself. Study quality was independently assessed through the use of the Detsky score (five articles). One study was in abstract form and an accurate score could not be assigned. The mean Detsky score was 15.3 (range, 14 to 16) (Table II). All five studies that reported the method of randomization used a sealed envelope technique, a method considered suboptimal by modern trial standards.

Treatment

Fixation was accomplished with a variety of small fragment plates as the operative technique in three studies and with pin osteosynthesis in three studies (i.e., small-diameter \[2.0, 2.5, \text{or } 3.0 \text{ mm}\] intramedullary titanium pins in two studies and a modified Hagie pin in one study). The postoperative rehabilitation was similar in all four studies in which it was described: a sling for comfort for ten days, followed by early active range-of-motion exercises. At six weeks postoperatively, strengthening and a gradual return to sport and/or heavy lifting, overhead, or repetitive activities was allowed. All studies used a standard sling for nonoperative care, with institution of range-of-motion exercises, as pain allowed, followed by physiotherapy.

Study Synopses (Table III)

Virtanen et al. (2010)

Virtanen et al. randomized sixty patients to sling (n = 32), or plate (n = 28) treatment. At one year, twenty-six operatively treated patients and twenty-five nonoperatively treated patients had been followed and Constant Shoulder Scores (a mean of 86.1 for the nonoperative group and 86.5 for the operative group, \(p = 0.90\)), DASH scores (a mean of 7.1 for the nonoperative group and 4.3 for the operative group, \(p = 0.81\)), and visual analog scale scores for pain (on a scale from 1 to 100 [with 1 representing no pain and 100 representing the worst pain imaginable], a mean of 7 for the nonoperative group and 3 for the operative group, \(p = 0.88\)) were recorded. There were six nonunions in the nonoperative group versus none in the operative group (six \(24\%\) of twenty-five versus 0 \(0\%\) of twenty-six, \(p = 0.01\)).

Smekal et al. (2009)

Smekal et al. randomized sixty-eight patients to sling or elastic titanium intramedullary pin fixation. Sixty patients (thirty in each group) were assessed two years after the injury occurred. Time to union was shorter in the operative group (12.1 weeks) compared with the nonoperative group (17.6 weeks) (\(p = 0.04\)). The DASH scores remained significantly lower (\(p < 0.05\)) in the operative group for the first eighteen weeks after injury. The CS was significantly higher (\(p < 0.05\)) at both the six month and two-year follow-up in favor of the operative group. Delayed union (no evidence of healing at twenty-four weeks after injury) developed in six patients in the nonoperative group (six \(24\%\) of twenty-five versus 0 \(0\%\) of twenty-six, \(p = 0.01\)).

Judd et al. (2009)

In the study by Judd et al., fifty-seven military personnel were randomized to Hagie pin fixation (twenty-nine) or a standard
sling (twenty-eight). The SANE and L’Insalata scores were significantly higher at week three for the operative group (p < 0.044 and p < 0.015). There were no significant differences between these two groups at any other time. One patient in each group developed a nonunion (one [3%] of twenty-nine in the operative group versus one [4%] of twenty-eight in the nonoperative group). This study is notable for the high complication rate in the operative group (48%) compared with the nonoperative group (7%). The high complication rate for the operative group was due primarily to minor complications from pin prominence posterolaterally (causing pin-track infections and/or requirement for early pin removal).

**Canadian Orthopaedic Trauma Society (COTS) (2007)**
The COTS study randomized 132 patients to a standard sling (sixty-five) or small-fragment plate fixation (sixty-seven). Forty-nine nonoperatively treated patients and sixty-two operatively treated patients completed the one year follow-up. The CS and DASH scores were significantly better at all time points for the operative group of this study (p < 0.01). There were two nonunions in the operative group (3%) and seven nonunions in the nonoperative group (14%) (p = 0.042).

**Witzel (2007)**
The study by Witzel randomized thirty-three patients to nonoperative care (sling) and thirty-five to operative fixation with an elastic intramedullary pin, and it concentrated on distinguishing differences in early return to function. Early (one-month) pain scores were significantly better for the operative group (p = 0.05), as was strength (p = 0.01). It was also noted that, on the sixtieth day, 80% of the operatively treated patients resumed athletic activity, while only 55% of nonoperatively treated patients did.

**Smith et al. (2000)**
In a randomized clinical trial, Smith and colleagues randomized one hundred patients to a sling or small-fragment plate fixation; only thirty-five nonoperatively treated and thirty operatively treated patients completed follow-up (mean follow-up, 18.5 months). Of the thirty operatively treated

<table>
<thead>
<tr>
<th>Year</th>
<th>Author</th>
<th>Journal or Meeting</th>
<th>No. of Patients Followed</th>
<th>Operative Type</th>
<th>No. of Nonunions per Total No. of Patients Followed</th>
<th>Outcome Scores</th>
<th>Operative</th>
<th>Nonoperative</th>
</tr>
</thead>
<tbody>
<tr>
<td>2010</td>
<td>Virtanen et al.¹³</td>
<td>Annual Meeting of the American Academy of Orthopaedic Surgeons</td>
<td>51</td>
<td>Plate</td>
<td>0/26/625</td>
<td>CS = 96.5, DASH = 4.3</td>
<td>CS = 96.1</td>
<td>DASH = 7.1</td>
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<td>2009</td>
<td>Smekal et al.¹⁷</td>
<td>Journal of Orthopaedic Trauma</td>
<td>60</td>
<td>Pin</td>
<td>0/30/330</td>
<td>CS = 97.9, DASH scores were significantly better for the first 18 weeks in the operative group</td>
<td>CS = 93.7</td>
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<td>2009</td>
<td>Judd et al.¹⁶</td>
<td>The American Journal of Orthopedics</td>
<td>57</td>
<td>Pin</td>
<td>1/29/128</td>
<td>3-weeks SANE = 49.8, 1-year SANE = 93.5, CS = 96.1, DASH = 5.2</td>
<td>CS = 90.8, DASH = 13.0</td>
<td></td>
</tr>
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<td>2007</td>
<td>Canadian Orthopaedic Trauma Society (COTS)¹²</td>
<td>The Journal of Bone and Joint Surgery (American)</td>
<td>111</td>
<td>Plate</td>
<td>2/62/749</td>
<td>Postoperative mobility and strength measures were significantly better in the operative group</td>
<td>NA/35</td>
<td>NA/33</td>
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<td>2007</td>
<td>Witzel¹⁵</td>
<td>Zeitschrift für Orthopädie und Unfallchirurgie</td>
<td>68</td>
<td>Pin</td>
<td>NA/35/33</td>
<td></td>
<td>NA/NA</td>
<td></td>
</tr>
<tr>
<td>2000</td>
<td>Smith et al.¹⁴</td>
<td>Annual Meeting of the American Shoulder and Elbow Surgeons</td>
<td>65</td>
<td>Plate</td>
<td>0/30/12/35</td>
<td></td>
<td>Weighted average of CS, 94.3</td>
<td>Weighted average of CS, 90.2</td>
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<tr>
<td>Totals</td>
<td></td>
<td></td>
<td>412</td>
<td></td>
<td>3/212/29/200</td>
<td></td>
<td></td>
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</tbody>
</table>

*CS = Constant Score, DASH = Disabilities of the Arm, Shoulder and Hand score, SANE = Single Assessment Numeric Evaluation score, NA = not available.
patients, there were no nonunions or symptomatic malunions (0%), and twenty-five patients were satisfied with their outcome (five were dissatisfied). Of the thirty-five nonoperatively treated patients, there were twelve nonunions (34%) and four symptomatic malunions (11%); twenty-six patients were satisfied with their outcome, and nine were dissatisfied.

Outcome Scores

Three studies used Constant Shoulder Scores\(^1\)\(^{2,13,17}\). From these three studies, the weighted average CS for the operative group was 94.3, and the weighted average CS for the nonoperative group was 90.2 (n = 222 total patients followed) at one year. DASH scores were also used in those three studies, but actual numbers were only found for two of the three studies: one study represented the DASH in graphical form only. The weighted average DASH favors the operative treatment (4.9) at one year in comparison with conservative care (10.7) (n = 162). The study that reported DASH scores graphically noted a statistically better (lower) DASH score in the operative group for the first eighteen weeks.

Complications

We defined a specific set of complications that were reported in all of the trials: nonunion (usually defined as no evidence of healing at fifty-two weeks after injury)/delayed union (no evidence of healing at twenty-four weeks after injury), symptomatic malunion, infection, hardware removal, neurologic symptoms, and refracture. The complication rate was found to be sixty-two complications (29%) in 212 operatively treated patients and forty-one complications (21%) in 200 nonoperatively treated patients (n = 412 total patients followed, p = 0.0075) (Fig. 2). Thus, patients treated nonoperatively were more likely to develop a complication than those treated with primary operative repair. When complications are summated across studies, an unweighted chi-square analysis shows a lower complication rate in the operative group. However, in the weighted test for overall effect, this difference does not reach significance (Fig. 2). The predominant complications in the nonoperative group were nonunion, neurologic (including brachial plexus irritation and compression), and symptomatic malunion. The commonest operative complications consisted of local hardware irritation or

\*CS = Constant Score, DASH = Disabilities of the Arm, Shoulder and Hand score, COTS = Canadian Orthopaedic Trauma Society. †Detsky score is designed to evaluate the quality of a randomized clinical trial (maximum score is 20 for surgical trial).
pin protrusion (treated with removal of hardware), and wound infection (Table III). One study was a statistical outlier in that the complication rate in the operative group was 48% (consisting primarily of hardware-related complications from prominence of the pin posterolaterally), compared with 7% in the nonoperative group*. This was a significant source of heterogeneity in

<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>Operative Group (N = 212 Patients)</th>
<th>Nonoperative Group (N = 200 Patients)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Virtanen et al.13 (2010)</td>
<td>1 refracture</td>
<td>1 brachial plexus irritation</td>
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<tr>
<td></td>
<td>3 delayed unions</td>
<td>2 refractures</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2 symptomatic malunions</td>
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<tr>
<td></td>
<td></td>
<td>1 delayed union</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6 nonunions</td>
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<tr>
<td>Smekal et al.17 (2009)</td>
<td>1 delayed union</td>
<td>6 delayed unions</td>
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<td></td>
<td>2 implant failures</td>
<td>2 symptomatic malunions</td>
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<tr>
<td></td>
<td>5 medial nail protrusions</td>
<td>3 transient neurogenic compromises</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3 nonunions</td>
</tr>
<tr>
<td>Judd et al.16 (2009)</td>
<td>6 pin track infections</td>
<td>1 refracture</td>
</tr>
<tr>
<td></td>
<td>3 pin removals</td>
<td>1 nonunion</td>
</tr>
<tr>
<td></td>
<td>1 transient radial nerve palsy</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1 delayed union</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1 pin fracture</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1 refracture</td>
<td></td>
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<tr>
<td></td>
<td>1 nonunion</td>
<td></td>
</tr>
<tr>
<td>Canadian Orthopaedic Trauma Society (COTS)12 (2007)</td>
<td>3 wound infections</td>
<td>9 symptomatic malunions</td>
</tr>
<tr>
<td></td>
<td>5 hardware irritations (removal required)</td>
<td>7 transient brachial plexuses</td>
</tr>
<tr>
<td></td>
<td>8 transient brachial plexuses</td>
<td>7 nonunions</td>
</tr>
<tr>
<td></td>
<td>2 nonunions</td>
<td></td>
</tr>
<tr>
<td>Witzel (2007)15</td>
<td>NR*</td>
<td>NR*</td>
</tr>
<tr>
<td>Smith et al. (2000)14</td>
<td>3 mild nerve compressions</td>
<td>17 mild nerve compressions</td>
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<tr>
<td></td>
<td>15 hardware removals for discomfort</td>
<td>4 symptomatic malunions</td>
</tr>
<tr>
<td></td>
<td></td>
<td>12 nonunions</td>
</tr>
<tr>
<td>Total Complications</td>
<td>62</td>
<td>84</td>
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</table>

*NR = not reported.

Graph showing complication rates comparing operative (experimental) versus nonoperative (control) groups (p = 0.18). The size of each square is proportional to the weight of the study. Cots = Canadian Orthopaedic Trauma Society. Z = p value of weighted test for overall effect, CI = confidence interval, df = degrees of freedom, I² = test statistic.
the assessment of complication rates ($p = 0.01$). The use of this intramedullary implant (Hagie pin) in this fashion is associated with a high rate of requirement for removal.

Nonunion and Symptomatic Malunion Rates

We identified nonunion and symptomatic malunion and analyzed them independently. Three of the studies classified a nonunion as no evidence of osseous union radiographically at one year after injury$^{12,13,16}$. Two studies used a similar definition at an earlier time point (five months in one study and six months in the other), and one study reported no nonunions$^{14,15,17}$. Radiographic malunion is ubiquitous following nonoperative treatment of a displaced clavicular fracture: this finding was not included as a complication in these trials. Symptomatic malunion was defined as a patient with symptoms severe enough to warrant corrective osteotomy. Nonunion or symptomatic malunion were significantly more common in the nonoperative group (forty-six [23%] of 200 nonoperatively treated patients versus three [1%] of 212 operatively treated patients, $p < 0.0001$) (Fig. 3). The absolute risk reduction for nonunion and symptomatic malunion (decrease in risk after primary fixation as compared with nonoperative treatment) for operative versus nonoperative treatment was 22% (ranging from a 23% risk with nonoperative treatment to a 1% risk with operative care). The number needed to treat for one patient to benefit from surgical intervention (in terms of the prevention of nonunion or symptomatic malunion) was 4.6 (n = 412 total patients). Of the 212 patients in the operative group, three (1%) developed nonunion. Of the 200 patients in the nonoperative group, twenty-nine (15%) developed nonunion ($p = 0.001$) (Fig. 4). The absolute risk reduction for nonunion for operative versus nonoperative treatment was 14% (ranging from a 15% risk with nonoperative treatment to a 1% risk with operative care). The number needed to treat for one patient to benefit from surgical intervention in nonunion rates was 7.6 (n = 412 total patients). There were no symptomatic malunions (0%) reported in the 212 patients treated operatively and seventeen malunions (9%) in the 200 patients in the nonoperative group ($p < 0.001$). The absolute risk reduction for symptomatic malunion for operative versus nonoperative treatment was 9% (ranging from a 9% risk with nonoperative treatment to a 0% risk with operative care). The
number needed to treat for one patient to benefit from surgical intervention for symptomatic malunion was 11.7.

**Early Return to Function**
There were multiple indicators in these six studies that primary fixation resulted in an earlier return to function. Pain scores at five, nineteen, and thirty-three days after injury were significantly better in the operative group in the study by Witzel. A return to moderate activity on the sixtieth day after injury was possible in 80% of the operatively treated patients but only in 55% of the nonoperatively treated patients in that study. Multiple studies demonstrated significantly superior functional scores early in the period after injury in the operative group; for example, there was a 15 to 20-point improvement in the DASH scores in the operative group in one study.

**Discussion**
The study populations in the clinical trials reviewed were predominantly young, active and male. Our meta-analysis revealed that primary operative fixation does provide more rapid return of function and minimizes early residual disability following fracture. In addition, the prevalence of symptomatic malunion and nonunion is significantly lower (forty-six of 200 in the nonoperative group versus three of 212 in the operative group, p < 0.0001). However, overall functional improvement seen at the one-year follow-up was modest, with approximately a 5-point improvement in mean DASH and CS scores in the operative group. This is generally considered to be below the minimal clinically relevant difference (ten to fifteen points) for these scales. The reasons for this marginal overall difference, despite the fact that these significant complications (nonunion and symptomatic malunion) are lower, are probably multifactorial. The number of individuals in the nonoperative group who developed nonunion or symptomatic malunion was forty-six of 200, a rate of 23%. Although most of these individuals were symptomatic with significantly lower outcome scores (i.e., a mean of sixteen points worse on the DASH score in the nonunion patients in the study by Virtanen et al.), this rate may result in only a modest average decrease in long-term outcome scores for the group as a whole, since most patients treated nonoperatively do well. It is clear that prognostic indicators that would identify the individuals most at risk for developing one of these negative outcomes would be very useful in refining operative indications. The number needed to treat for the prevention of nonunion and symptomatic malunion was 4.6; a lower number (minimizing the number of patients exposed to surgery to benefit one person) would be preferable.

Overall complication rates were higher in the nonoperative group than in the operative group (42% versus 29.6%, p = 0.0075). Many of these complications (e.g., nonunion), require operative intervention that is greater in magnitude (operative time, recovery time, complication rate) than the original intervention (primary fixation) being investigated. The commonest complication in the operative group was hardware irritation (from an implanted plate or prominent pin) that resulted in hardware removal. Theoretically, this complication could be minimized by less prominent implants or improved insertion techniques.

Our review shows that 15% of 200 patients in the nonoperative group developed a nonunion, which is significantly greater (p = 0.001) than the 1% rate of nonunion in the 212 patients of the operative group. The number needed to treat for one person to benefit from operative treatment in relation to nonunion was 7.6. Another complication significantly more common in the nonoperative group is symptomatic malunion (seventeen of 200 in the nonoperative group versus 0 of 212 in the operative group, p < 0.001). However, with the data available, we were not able to draw any specific conclusions as to which patients are most likely to suffer from one of these significant complications.

Our meta-analysis shows that primary fixation of displaced midshaft clavicular fractures has an early effect on decreasing pain and improving function. This is demonstrated by the significantly improved DASH scores (15 to 20 points) at six weeks and three months after injury, higher Constant scores at six weeks and three months, and significantly better pain scores at three weeks (for example, at five, nineteen, and thirty-three days after injury in the study by Witzel). In the Witzel study, all patients were asked to return to moderate activity two months after injury; 80% of the operatively treated patients were able to achieve this, whereas only 55% of the patients randomized to the nonoperative group were physically active at this level. Two of the studies in which these outcome scores were used detected a significantly greater improvement at earlier intervals, but not necessarily at the later (one to two-year) intervals. The DASH scores that were used to evaluate the return to daily activities within the first three months were significantly better for the operative group in the study by Smekal et al. The only significant difference between the two groups in the study by Judd et al. was at the three-week point, in favor of the operative group, with use of the SANE and L’Insalata scores.

Our study has some limitations common to all meta-analyses, and other specific limitations. The conclusions drawn from a meta-analysis are only as unbiased and accurate as the data that are entered. We have attempted to provide conclusions based only on high-quality data from Level-I randomized clinical trials; quasi-randomized trials, single-arm prospective studies, and retrospective reviews were excluded. Bias is inherent in many analyses that focus on a specific population or geographic area. By including all studies available, including those from multiple countries reported in multiple languages, we believe that our conclusions are applicable to most populations. Homogeneity, or the consistency of the patients in the analyzed studies, the treatments used, and the outcomes reported, is critical to the reliability of conclusions drawn in a meta-analysis. While our population was homogeneous in terms of major demographic parameters, there was significant heterogeneity in terms of the complication rates due primarily to one study that had a high (48%) complication rate in the operative group (probably due to the implant used). There was no evidence of heterogeneity in the other specific complications we examined (nonunion and symptomatic malunion). Lastly, despite our best efforts in using multiple search methods.
and content experts, it is possible that we have not detected an eligible existing trial, the results of which may be applicable to our meta-analysis.

Specific limitations of our study include the fact that one of the six randomized trials we analyzed was published in abstract form only. While we were able to obtain additional information from this author, the lack of detailed information and the peer review process limits the assessment of this study. A sensitivity analysis, using only the five peer-reviewed studies, did not show any difference in our conclusions. The variety of different outcome measures used limited our ability to combine outcome scores and make more definitive conclusions; it may also have resulted in a decrease in our ability to identify a true difference where one actually existed. For example, five of six studies reported the nonunion rate and we were able to show a clear decrease in nonunion rate in the operative group; however, we were unable to do so as conclusively for the DASH or Constant scores that only three of the studies employed. Two operative techniques are currently used for primary fixation of midshaft fractures of the clavicle (plate fixation and intramedullary pin insertion), and both were used in the trials we studied; it should be noted that a recent randomized clinical trial comparing locked intramedullary nailing versus plating for displaced midshaft fractures of the clavicle showed a 100% union rate in both groups with similar outcome scores a mean of twelve months after injury. However, the lack of a standard operative protocol must be considered a weakness of our meta-analysis; although both techniques have been associated with excellent results in a variety of reviews, it may be that there are fundamental differences in outcome between the two techniques.

In this meta-analysis of randomized clinical trials comparing the effect of primary operative fixation versus sling treatment of displaced midshaft clavicular fractures in young active individuals, certain benefits of fixation are noted, especially early in the period after injury. A more rapid return to function, a decreased complication rate (especially with regard to the more serious negative outcomes of nonunion and symptomatic malunion), and marginally superior long-term functional outcome scores were observed with operative intervention. It is clear that there is a specific subset of individuals with a completely displaced midshaft fracture of the clavicle who will benefit from fixation. However, this information should not be used to justify an indiscriminate approach to surgical fixation of all clavicular fractures. Patients with a completely displaced midshaft clavicular fracture may be counseled that they will be at a higher risk of sustaining nonunion and symptomatic malunion if the fracture is treated nonoperatively, but that there is no clear evidence that surgical treatment will improve their long-term function in general. They should also be counseled that, approximately 75% of the time, a completely displaced clavicular fracture that is treated nonoperatively will heal with few, if any, long-term consequences. Surgeons can use this information appropriately to help patients make optimal decisions in a shared decision-making process. The patient must weigh this information against the risks of anesthesia, wound infection, nonunion with an operation, and the potential need for hardware removal.

Appendix

A table showing population demographics is available with the online version of this article as a data supplement at jbjs.org.

References


