Single, Superiorly Placed Reconstruction Plate Compared with Flexible Intramedullary Nailing for Midshaft Clavicular Fractures

A Prospective, Randomized Controlled Trial

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Background: Previous studies have shown good clinical results in patients with midshaft clavicular fractures treated with reconstruction plate fixation or elastic stable intramedullary nailing. The objective of this study was to compare these methods in terms of clinical and radiographic results.

Methods: In this prospective, randomized controlled trial, fifty-nine patients with displaced midshaft clavicular fractures were randomly assigned to receive fixation with either a reconstruction plate (thirty-three patients), known as the plate group, or elastic stable intramedullary nailing (twenty-six patients), known as the nail group. The primary outcome was the six-month Disabilities of the Arm, Shoulder and Hand (DASH) score. The secondary outcomes included the Constant-Murley score, time to fracture union, residual shortening, level of postoperative pain, percentage of satisfied patients, and complication rates.

Results: The mean six-month DASH score was 9.9 points in the plate group and 8.5 points in the nail group (p = 0.329). Similarly, there were no differences in the twelve-month DASH and Constant-Murley scores. Time to union was equivalent (p = 0.352) between the groups at 16.8 weeks for the plate group and 15.9 weeks for the nail group, whereas the residual shortening was 0.4 cm greater in the plate group (p = 0.032). The visual analog scale pain score and the satisfaction rate were similar between the groups. Implant-related pain was more frequent in the nail group (p = 0.035). There were no differences in terms of major complications.

Conclusions: Reconstruction plates and elastic stable intramedullary nailing yielded similar functional results, time to union, level of postoperative pain, and patient satisfaction rates. Both methods were safe in terms of major complications.

Level of Evidence: Therapeutic Level I. See Instructions for Authors for a complete description of levels of evidence.
Intramedullary fixation represents a less invasive technique, but there has been no consensus on the superiority of either method.\(^1\)

Reconstruction plates have been classically used to treat midshaft clavicular fractures\(^2,3\). Regarding their advantages, they can be molded to the “S” shape of the clavicle, and they are widely available in orthopaedic centers, whereas their main disadvantage is a reduced stiffness.\(^4\) In the past few years, stiffer precontoured plates have been increasingly used for the treatment of these fractures.\(^5\) Recently, elastic stable intramedullary nailing has become a common procedure for clavicular fixation\(^6\). Its theoretical advantages include reduced invasiveness and elastic stability. Its main disadvantages include skin irritation and frequent need for implant removal.\(^7\) Comparative studies have documented advantages for elastic stable intramedullary nailing over reconstruction plates during the early postoperative stages\(^8,9\), but with similar results in longer follow-up.

The objective of this study was to compare the clinical and radiographic results of patients with displaced midshaft clavicular fractures treated with reconstruction plates or elastic stable intramedullary nailing fixation. The primary outcome was the Disabilities of the Arm, Shoulder and Hand (DASH) score at six months postoperatively. Our hypothesis was that there would be no difference between the groups in the primary outcome.

**Materials and Methods**

**Study Design and Participants**

This study was a single-center, prospective, randomized controlled trial. Patients with displaced midshaft clavicular fractures were allocated to one of the treatment groups: plate or elastic stable intramedullary nailing. All of the patients provided written informed consent to participate, and the local institutional review board approved the study. The study was registered at ClinicalTrials.gov (NCT01410032). The inclusion criteria were an age between sixteen and sixty years; a radiographic result of patients with displaced midshaft clavicular fractures treated with reconstruction plates or elastic stable intramedullary nailing has become a common procedure for clavicular fixation\(^10\). Its theoretical advantages include reduced invasiveness and elastic stability. Its main disadvantages include skin irritation and frequent need for implant removal.\(^11\) Comparative studies have documented advantages for elastic stable intramedullary nailing over reconstruction plates during the early postoperative stages\(^12,13\), but with similar results in longer follow-up.

The objective of this study was to compare the clinical and radiographic results of patients with displaced midshaft clavicular fractures treated with reconstruction plates or elastic stable intramedullary nailing fixation. The primary outcome was the Disabilities of the Arm, Shoulder and Hand (DASH) score at six months postoperatively. Our hypothesis was that there would be no difference between the groups in the primary outcome.

**Interventions**

**Plate Group**

The patients were placed in the beach-chair position. An anterior approach to the clavicle was undertaken so that the scar would not lie over the plate. The supraclavicular nerve was isolated and was protected when identified. After a direct reduction, the fracture was fixed with use of a 3.5-mm non-locked reconstruction plate (Synthes), positioned on the superior clavicular surface. At least three screws were fixed in each main fragment, and lag screws were used when the fracture obliquity or the size of the intermediate fragment was favorable. Neither radiography nor fluoroscopy was routinely utilized intraoperatively. Implant removal was not routinely scheduled and was instead performed when there was evidence of compete fracture union, according to the patients’ wishes.

**Nail Group**

The patients underwent the operation in the supine position, and the procedure was performed through a 1.0-cm skin incision over the medial end of the clavicle. The anterior cortex was opened with use of an awl, and one nail (Titanium Elastic Nail [TEN], Synthes) was inserted per fracture through the medial fragment. The nail diameters were 2.0, 2.5, or 3.0 mm. Closed fracture reduction was attempted with towel clamps attached percutaneously to each main fragment. When closed reduction was not achieved, a 5.0-cm vertical surgical approach was utilized. After being advanced into the lateral fragment, the medial end of the nail was cut as close as possible to the entry point (see Appendix). Fluoroscopy was routinely used. Implant removal was recommended for all patients after complete fracture union, regardless of symptoms related to the implant, and ideally not earlier than six months.

**Postoperative Course**

The rehabilitation protocol for both groups consisted of sling immobilization for four weeks and active range of motion with physiotherapy starting at two weeks. Weight lifting and return to full activities were allowed after complete fracture-healing.

**Outcomes**

**Functional Outcomes**

The functional evaluations consisted of the DASH and Constant-Murley scores\(^14\), assessed at six and twelve months postoperatively. The lead investigator conducted the functional assessments.

**Radiographic Parameters**

Radiographs of both clavicles from anteroposterior and 30° cephalad directions were scheduled at two weeks and monthly thereafter until complete fracture union. Union was considered to be complete bone bridging on the superior and inferior cortices. Time to union was measured in weeks and was defined as the time elapsed between surgery and the first radiograph to reveal complete union. Residual shortening was assessed on the 30° cephalad view, deducting the length of the fractured side from that of the contralateral side.

**Other Assessments**

A visual analog scale (VAS) for pain was administered on the first postoperative day. Satisfaction with the treatment was assessed as a binary parameter (satisfied or dissatisfied) at six and twelve months.

**Complications**

Adverse events were assessed on a binary basis (present or absent) by the lead investigator (E.B.A.-S.). They were defined as minor if there was no additional surgery or permanent deficit or as major if one of these factors was present. Minor complications included acromioclavicular pain, implant-related pain, implant bending (deformation of >10°), incision paresthesia, partial implant migration (with no loss of fixation), sternoclavicular pain, superficial infection, and transient neurological deficits. Major complications included deep infection, shoulder elevation deficit (after complete fracture union), nonunion (fracture not healed at six months), permanent neurological deficits, refracture, reoperation (secondary to complication), total implant failure, and total implant migration (with loss of fixation).

All participants, including the patients and outcome evaluators, were aware of the allocation groups.

**Sample Size Calculation**

The sample size calculation was based on the minimal clinically important difference for the DASH score. As suggested by Gummesson et al., we considered a 10-point difference as the minimally important difference for the mean DASH score\(^15\). Based on the same study, we set the standard deviation at 13 points. With a power of 0.8 and a significance level of 0.05, twenty-seven patients were required in each group. Expecting a 10% rate of loss to follow-up, we enrolled a total of fifty-nine patients.

**Statistical Analysis**

Continuous data are presented as means and standard deviations, and categorical data are presented as absolute numbers and percentages. Continuous variables...
were analyzed with use of the Student t test when normally distributed or with the Mann-Whitney U test when non-normally distributed. Categorical variables were analyzed with use of the chi-square test or the Fisher exact test. Mean or median imputation was implemented when necessary. Missing values for functional outcomes at twelve months were addressed with use of the last observation carried forward method, based on the six-month score. Significance was set at \( p < 0.05 \).

**Source of Funding**

There were no external funding sources for this study.

**Results**

**Participant Flow**

From May 2010 to January 2013, fifty-nine patients were enrolled in the study. Thirty-three patients were randomly assigned to receive plate fixation and twenty-six patients were randomly assigned to receive elastic stable intramedullary nailing fixation. Four patients in the plate group and one patient in the nail group did not attend at six and twelve months and were considered lost to follow-up, resulting in twenty-nine patients in the plate group (88%) and twenty-five patients in the nail group (96%) \( (p = 0.372) \). All patients received the treatment that they were originally assigned. Patients lost to follow-up were excluded from the final analysis (Fig. 1). Male patients represented the majority in both groups, and motorcycle accidents represented the most common mechanism of injury (Table I).

**Functional Scores, Radiographic Parameters, and Other Assessments**

The differences between the groups in the mean DASH score were 1.4 points at six months \( (p = 0.329) \) and 1.2 points at twelve months \( (p = 0.496) \); both of these differences were less than the minimal clinically important difference. Similarly, the boundaries of the 95% confidence intervals (95% CIs) at six months \( ( -5.1 \) to \( 8.0 \) points) and twelve months \( ( -5.4 \) to \( 7.8 \) points) were less than the minimal clinically important difference (Table II). The differences in the Constant-Murley scores were also neither clinically relevant nor significant (Table II). The mean time to union was similar \( (p = 0.352) \) between the groups at 16.8 weeks for the plate group and 15.9 weeks for the nail group, whereas the mean residual shortening was greater in the plate group \( (p = 0.032) \) but not clinically important \( (0.4 \) cm [95% CI, 0.1 to 0.8 cm]) (Table II). The VAS for pain on the first postoperative day and the rate...
of satisfied patients at six and twelve months were similar between the groups (Table II).

**Complications**

**Minor**

Ten patients in the nail group (40%) presented with implant-related pain, including seven with medial skin irritation (28%) and three with lateral nail protrusions (12%), compared with four patients (14%) in the plate group (p = 0.035) (see Appendix). Overall, the patients with implant-related pain presented with worse functional scores at six months than did patients without pain; the mean DASH scores were 16.7 points for the patients with implant-related pain and 6.7 points for the patients without pain (p = 0.005), and the mean Constant-Murley scores were 84.3 points for the patients with implant-related pain and 93.2 points for the patients without pain (p = 0.002). Eleven patients in the plate group (38%) presented with implant bending, compared with one patient in the nail group (4%, p = 0.003) (see Appendix). In the plate group, fractures fixed with lag screw augmentation exhibited a 10% rate of implant bending, compared with a 53% rate in cases with no additional fixation (relative risk, 5.3 [95% CI, 3.5 to 7.0]; p = 0.044) (see Appendix). The rate of implant-related pain was not significantly different between patients with or without lag screw fixation (p = 0.163). When present, the mean degree of implant bending was 25° (range, 10° to 45°), and patients with this complication presented with greater clavicular shortening due to the bending deformity at the fracture site (see Appendix). Paresthesia was significantly more frequent in the plate group (p = 0.005). There was no significant difference between the groups with regard to partial implant migration (p = 0.229) or superficial infection (p = 0.999) (see Appendix).

**Major**

There was no significant difference between the groups with respect to any type of major complication (see Appendix). There was a single case of nonunion in the overall sample, presented by a patient in the nail group who sustained a refracture after nail removal was performed at four months. Initially, the patient declined reoperation, progressing to nonunion and functional limitation, and the twelve-month DASH score was 53.6 points. This patient eventually underwent open reduction, plate fixation, and

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Plate Group* (N = 33)</th>
<th>Nail Group* (N = 26)</th>
</tr>
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<tbody>
<tr>
<td>Age (yr)</td>
<td>31.2 ± 12.2</td>
<td>28.3 ± 9.4</td>
</tr>
<tr>
<td>Male sex</td>
<td>28 (85%)</td>
<td>19 (73%)</td>
</tr>
<tr>
<td>Smoking</td>
<td>11 (33%)</td>
<td>5 (19%)</td>
</tr>
<tr>
<td>Involvement of the dominant arm</td>
<td>11 (33%)</td>
<td>13 (50%)</td>
</tr>
<tr>
<td>Mechanism of injury</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Motorcycle accident</td>
<td>16 (48%)</td>
<td>16 (62%)</td>
</tr>
<tr>
<td>Car accident</td>
<td>1 (3%)</td>
<td>1 (4%)</td>
</tr>
<tr>
<td>Hit by vehicle</td>
<td>2 (6%)</td>
<td>1 (4%)</td>
</tr>
<tr>
<td>Fall</td>
<td>6 (18%)</td>
<td>6 (23%)</td>
</tr>
<tr>
<td>Sports</td>
<td>2 (6%)</td>
<td>2 (8%)</td>
</tr>
<tr>
<td>Bicycling</td>
<td>3 (9%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Other</td>
<td>3 (9%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Associated lesions</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Head trauma</td>
<td>3 (9%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Thoracic trauma</td>
<td>2 (6%)</td>
<td>1 (4%)</td>
</tr>
<tr>
<td>Contralateral upper limb</td>
<td>1 (3%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Lower limb</td>
<td>1 (3%)</td>
<td>1 (4%)</td>
</tr>
<tr>
<td>AO/OTA classification</td>
<td></td>
<td></td>
</tr>
<tr>
<td>B1</td>
<td>11 (33%)</td>
<td>12 (46%)</td>
</tr>
<tr>
<td>B2</td>
<td>14 (42%)</td>
<td>10 (39%)</td>
</tr>
<tr>
<td>B3</td>
<td>8 (24%)</td>
<td>4 (15%)</td>
</tr>
<tr>
<td>Fracture displacement (cm)</td>
<td>2.4 ± 0.7</td>
<td>2.1 ± 0.7</td>
</tr>
<tr>
<td>Fracture shortening (cm)</td>
<td>0.9 ± 0.8</td>
<td>1.0 ± 0.7</td>
</tr>
<tr>
<td>Time to surgery (d)</td>
<td>14.0 ± 6.2</td>
<td>10.1 ± 5.9</td>
</tr>
</tbody>
</table>

*Continuous data are presented as the mean and the standard deviation. Categorical data are presented as the absolute number, with the percentage in parentheses.
a cancellous bone graft, achieving complete healing and total functional recovery. One patient in the plate group presented with a total implant failure, but progressed to complete union and satisfactory function; the six-month DASH score was 1.7 points.

**Operative Characteristics and Implant Removal**

The mean operative time was significantly longer ($p = 0.012$) in the plate group (65.5 minutes) compared with the nail group (53.2 minutes), but not clinically relevant. In twenty patients in the nail group (77%), open reduction was necessary. Implant removal was performed in eighteen patients in the nail group (72%) at a mean time of 8.8 months (range, four to seventeen months). In one patient, the nail could not be removed because of osseointegration, and the medial protruding end was trimmed. A single patient in the plate group (3%) requested implant removal, which was performed at twelve months. Because implant removal was recommended for all patients in the nail group and not for all patients in the plate group, a statistical comparison was not performed on the rate of implant removal.

**Discussion**

Our findings showed that reconstruction plates and elastic stable intramedullary nailing yielded similar functional results in patients with midshaft clavicular fractures. Additionally, we did not find any differences between the groups in terms of time to union, patient satisfaction, or major complication rates. The most relevant difference was in minor complications, with reconstruction plates associated more often with implant bending and elastic stable intramedullary nailing associated more often with implant-related pain and implant removal. Furthermore, we could demonstrate a greater risk of implant bending in fractures not fixed with lag screw augmentation in the plate group.

In this study, the differences in the DASH scores were neither clinically important nor significant. It should be stated that the study sample was chosen on the basis of the power analysis to find differences of 10 points, and smaller differences might indicate false-negative results. However, even with the existing statistical differences, we were able to adequately demonstrate a lack of clinical importance for differences in both functional scores. As described by Robinson et al., nonunion represents the only independent factor predicting functional outcomes in clavicular fractures. In our study, there was a single case of nonunion in the nail group, whereas there were no cases in the plate group. Aside from this relevant clinical difference, we could not demonstrate statistical differences in major complications. We consider this outcome as the main factor contributing to the similarities in terms of clinical results.

Time to healing of clavicular fractures has been variable in the literature. In our study, both groups presented with complete healing at approximately sixteen weeks, similar to a previous study. Also, the clinical importance of residual shortening remains controversial. Contrary to our expectations, we found greater shortening in the plate group, which could be explained by the higher rate of implant bending in this group. This fact highlights the inability of reconstruction plates to maintain fracture reduction and length, particularly when appropriate bone support is not reached. The fixation of intermediate fragments as well as adequate bone contact in simple fractures should be attempted to prevent this complication when using reconstruction plate fixation. Concerns with regard to shortening in the nail group were not confirmed regardless of the fracture complexity, indicating that the method was reliable for maintaining fracture length.

Our choice for studying reconstruction plates was primarily based on the fact that they were a current method of

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**TABLE II Functional Scores, Radiographic Parameters, VAS for Pain on the First Postoperative Day, and Rate of Satisfied Patients According to Treatment Group**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Plate Group* (N = 29)</th>
<th>Nail Group* (N = 25)</th>
<th>Difference†</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>DASH (points)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>At six months</td>
<td>9.9 ± 10.9</td>
<td>8.5 ± 13.0</td>
<td>-1.4 (-8.0 to 5.1)</td>
<td>0.329</td>
</tr>
<tr>
<td>At twelve months</td>
<td>8.7 ± 11.8</td>
<td>7.5 ± 12.5</td>
<td>-1.2 (-7.8 to 5.4)</td>
<td>0.496</td>
</tr>
<tr>
<td>Constant-Murley (points)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>At six months</td>
<td>91.1 ± 9.4</td>
<td>90.6 ± 10.0</td>
<td>-0.5 (-5.8 to 4.8)</td>
<td>0.999</td>
</tr>
<tr>
<td>At twelve months</td>
<td>91.7 ± 9.3</td>
<td>91.8 ± 8.8</td>
<td>0.1 (-4.9 to 5.0)</td>
<td>0.937</td>
</tr>
<tr>
<td>Radiographic parameters</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Time to union (wk)</td>
<td>16.8 ± 3.5</td>
<td>15.9 ± 3.5</td>
<td>-0.9 (-2.8 to 1.0)</td>
<td>0.352</td>
</tr>
<tr>
<td>Residual shortening (cm)</td>
<td>0.6 ± 0.8</td>
<td>0.2 ± 0.4</td>
<td>-0.4 (-0.8 to -0.1)</td>
<td>0.032</td>
</tr>
<tr>
<td>VAS for pain (points)</td>
<td>4.1 ± 2.5</td>
<td>3.8 ± 3.0</td>
<td>-0.3 (-1.7 to 1.2)</td>
<td>0.673</td>
</tr>
<tr>
<td>Satisfied patients</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>At six months</td>
<td>24 (83%)</td>
<td>19 (76%)</td>
<td>0.9 (0.7 to 1.2)</td>
<td>0.539</td>
</tr>
<tr>
<td>At twelve months</td>
<td>27 (93%)</td>
<td>23 (92%)</td>
<td>1.0 (0.9 to 1.2)</td>
<td>0.999</td>
</tr>
</tbody>
</table>

*Continuous data are presented as the mean and the standard deviation. Categorical data are presented as the absolute number, with the percentage in parentheses. †The values are given as the difference between the means of the continuous variables or as the relative risk with respect to patient satisfaction, with the 95% CI in parentheses.
Comparing elastic stable intramedullary nailing with an anatomical plate would be more relevant, given the current clinical practice. Ideally, a blinded evaluator should have assessed the subjective outcomes. The evaluator’s perception on subjective parameters was potentially affected by knowing the treatment method. The system used to generate the random allocation sequence was a suboptimal method, yielding unequal group sizes and carrying the risk of losing the allocation concealment. A computer-generated randomization list with variable block sizes would be more appropriate to guarantee the balance between the groups and to avoid the randomization flaw.

In conclusion, we found that reconstruction plates and elastic stable intramedullary nailing were equally effective in restoring shoulder function and promoting fracture-healing. Reconstruction plates were more susceptible to implant bending when proper surgical technique failed to restore adequate bone support, whereas elastic stable intramedullary nailing was more commonly associated with implant-related pain and the need to perform a second procedure for implant removal. When using the reconstruction plate, we emphasize the importance of achieving adequate bone support.

Appendix

Figures showing a postoperative radiograph made after nailing and a postoperative radiograph showing implant bending after plating as well as tables showing minor and major complications according to the treatment group and showing characteristics of plates, fractures, and relevant complications in the plate group are available with the online version of this article as a data supplement at jbjs.org.

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References
7. Drosdowech DS, Manwell SE, Ferreira LM, Goel DP, Faber KJ, Johnson JA. Bio-
8. Robinson GM, Goudie EB, Murray IR, Jenkins PJ, Akhtar MA, Read EO, Foster CJ, Clark K, Brooksbank AJ, Arthur A, Crowther MA, Packham I, Chessier TJ. Open re-
11. Chen YF, Wei HF, Zhang C, Zeng BF, Zhang CQ, Xue JF, Xie XT, Lu Y. Retro-
spective comparison of titanium elastic nail (TEN) and reconstruction plate repair of displaced midshaft clavicular fractures. J Shoulder Elbow Surg. 2012 Apr;21(4):495-
26. Partal G, Meyers KN, Sama N, Pagenkopf E, Lewis PB, Goldman A, Wright TM, Heffet DL. Superior versus anteroinferior plating of the clavicle revisited: a me-
27. Lazarus MD, Seon C. Fractures of the clavicle. In: Bucholz RW, Heckman JD, Court-Brown CM, editors. Rockwood and Green’s fractures in adults. 6th ed. Phila-
29. Rehm K, Andermahr J, Jubel A. Intramedullary nailing of clavicular frac-