Titanium Elastic Nail versus plate fixation of displaced midshaft clavicle fractures: A retrospective comparison study

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This study has two purposes: (1) to compare the clinical results between the Titanium Elastic Nail (TEN) and plate fixation of the displaced midshaft clavicle fracture; and (2) to demonstrate the relationship between length shortening and functional outcome after TEN fixation, especially in the comminuted fracture pattern. A retrospective, case-controlled study was conducted and 55 patients were included in our study: 25 in the TEN fixation group (TEN group) and 30 in the plate fixation group (plate group). All patients were classified into four subgroups: simple fracture in the TEN group (ST; n = 13), simple fracture in the plate group (SP; n = 15), comminuted fracture in the TEN group (CT; n = 12), and comminuted fracture in the plate group (CP; n = 15). Wound size was significantly smaller in the TEN group (p < 0.001). The injured clavicular length after fracture healing was significantly shorter in the TEN group (p = 0.036). There was no significant difference in the mean Constant and DASH scores. Injured clavicle shortening was significantly larger in the CT subgroup (p = 0.018). However, there was no statistically significant difference in Constant score and DASH score while comparing the CT subgroup to other subgroups. Although TEN fixation may lead to a higher degree of length shortening after bony union especially in cases of comminuted fracture pattern, no statistically significant difference was observed in objective functional results as
Introduction

Clavicle fractures account for 2.6% of all fractures, and > 80% involve the middle third of the clavicle [1]. Traditionally, conservative treatment has been used to treat displaced midshaft clavicle fractures. However, poor outcomes after conservative treatment for such fractures have been reported recently, resulting in fracture non-union, clavicle length shortening, or marked functional deficits [2–4]. Generally, clavicle length shortening of > 2 cm (no cortical contact between the proximal and distal fragments radiographically) is widely accepted as a criterion for surgical intervention in displaced midshaft clavicle fractures [5,6].

Plate or intramedullary devices are the two implants most commonly used to fix displaced midshaft clavicle fractures. The plate type implant is the most commonly used, although complications reported include wound infection, wound dehiscence, skin irritation or numbness, implant failure, and poor cosmetic results [7–11]. Therefore, intramedullary devices which utilize minimally invasive surgical techniques were developed to treat displaced midshaft clavicle fractures. These have the advantages of preventing plate irritation, decreasing the infection rate, avoiding wound dehiscence, and providing greater cosmetic satisfaction with the results. Intramedullary devices may also preserve the soft tissue envelope, periosteum, and vascular integrity around the fracture region, potentially enhancing fracture site callus formation [12–18]. Application of intramedullary devices seem to have more advantages than plate fixation for treatment of displaced midshaft clavicular fractures [19–21].

The Titanium Elastic Nail (TEN) system (Synthes Holding AG, West Chester, PA, USA) is one type of intramedullary device. TEN had been used with satisfying results to treat displaced midshaft clavicle fractures; advantages include the elastic property of the TEN system, easier insertion, small incision wound, lower infection rate, high union rate, and high satisfaction rate with good functional results [12,22–25]. However, complications related to TEN fixation in midshaft clavicle fractures include medial migration of the nail tip and clavicle length shortening after fracture healing, especially in comminuted fractures due to the telescope effect after TEN fixation [12,25,26].

Few studies have examined the differences between TEN and plate fixation of displaced midshaft clavicle fractures and the functional outcomes associated with clavicle length shortening after TEN fixation [27–29]. To clarify the clinical results between TEN and plate fixation of displaced midshaft clavicle fractures, we introduced a case-controlled study. Our study has two aims: (1) to compare the clinical results of TEN and plate fixation of displaced midshaft clavicle fractures; and (2) to determine the relationship between length shortening and functional outcomes after TEN fixation of midshaft clavicle fractures, especially comminuted fractures. We hypothesized that results for TEN fixation would be as good as those for traditional plate fixation in treating displaced midshaft clavicle fractures, even in patients with comminuted fractures and postoperative shortening.

Materials and methods

A retrospective, case-controlled study was conducted from November 2006 to December 2011 at our institute on patients with displaced midshaft clavicle fractures. Inclusion criteria were: (1) a markedly displaced midshaft clavicle fracture (no cortical contact between the proximal and distal fragments on radiography and/or > 2 cm of shortening) [5,6]; (2) patients being older than 16 years; and (3) patient’s ability to provide complete information, sign a consent form, fill out questionnaires, and attend further follow up. Exclusion criteria were presence of any of the following: (1) pathologic fracture; (2) previous clavicle fracture nonunion; or (3) inability to provide complete information, sign a consent form, fill out questionnaires, or attend further follow up. None of the patients had an open fracture or neurovascular-associated injuries. The study protocol was approved by the hospital’s Institutional Review Board.

All surgeries were conducted by one experienced surgeon at our institute. Twenty-five patients included in the TEN group were operated on early, from November 2006 to August 2009, and 30 patients in the plate group were operation on later, from September 2009 to December 2011, for the purpose of having a case-controlled comparison group. Patients in the TEN group received TEN fixation, inserted from the sternal end of the clavicle with a 1–2 cm incision wound. Under fluoroscopic assistance, the nail tip was passed through the proximal fragment of the clavicle until it reached the fracture site. The fracture site was reduced with the closed method. If closed reduction was not successful, a small incision was made directly over the fracture site to allow direct visual reduction. The proximal entry end of the nail was cut off near the ventral cortex to prevent skin irritation (Figure 1). In the plate group, the fractured ends of the clavicle were fixed with a 3.5 mm small reconstruction plate or dynamic compression plates applied in either the anterior or superior position, according to the fracture pattern and the shape that best fit the clavicle (Figure 2).

All patients were protected with a sling immediately after the operation. Patients were given instructions in performing early gentle and passive shoulder motion cautiously under sling protection for a period of 4 weeks.

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After sling removal, active shoulder range of motion was allowed with both abduction and forward flexion > 90°. In patients with nail fixation who had simple or stable bone contact on radiography, active shoulder range of motion was permitted 2 weeks after surgery.

Clinical and plain radiographic postoperative follow up was performed at 2 weeks, 6 weeks, and then monthly. At 12 months post operation, we checked: (1) bilateral clavicle length difference (from the notch of the sternum to the ridge of the acromion) [30]; (2) status of fracture healing; (3) length and condition of the surgical wound; and (4) functional status of the injured shoulder. The bilateral clavicle length difference was recorded as the amount of clavicle length shortening. The functional outcome of the injured shoulder was measured using the Constant and Murley shoulder scores (Constant score; range 0–100 points; best = 100) [31] and the standardized subjective Disability of the Arm, Shoulder, and Hand score (DASH score; range 0–100 points; best = 0) [32].

Category variables of sex, age, side of fracture and fracture type were compared between the TEN and plate groups using Fisher’s exact test. The functional outcomes and complications for the two groups were compared using the independent t test. All patients were divided into four groups by fracture type and treatment: simple fracture with TEN fixation (ST), simple fracture with plate fixation (SP), comminuted fracture with TEN fixation (CT), and comminuted fracture with plate fixation (CP), using the Orthopedic Trauma Association (OTA) classification of fracture pattern. The Constant score, DASH score, and postoperative clavicle length shortening of the four subgroups were compared using analysis of variance (ANOVA). Statistical significance was set at p < 0.05. All statistical comparisons were made using SPSS version 18 (SPSS Inc., Chicago, IL, USA).

Results

A total of 55 patients with displaced midshaft clavicle fractures who met the study criteria were enrolled in the study, with a mean age of 37.5 years (range 16–66 years) and these patients were followed up for at least 12 months. 25 patients accepted TEN fixation, and 30 patients had
plate fixation. 13 patients in the TEN group (ST subgroup) and 15 patients in the plate group (SP subgroup) had OTA 15-B1 non-comminuted fracture type, classified as a simple fracture. 12 patients in the TEN group (CT subgroup) and 15 patients in the plate group (CP subgroup) had 15-B2 wedge comminuted fracture type, classified as the comminuted group. The demographic data for the TEN and plate group is listed in Table 1. The TEN and plate groups did not differ in age, sex, fracture type, or injured side.

The mean surgical wound size was 2.46 ± 1.22 cm (1–3.5 cm) in the TEN group and 9.50 ± 1.12 cm (8–12.5 cm) in the plate group. The TEN group had a significantly smaller wound size than the plate group (p < 0.001). Generally, the TEN group had significantly more length shortening after fracture union as compared to the plate group [0.36 ± 0.60 cm (−1.5 to +1 cm) and 0.08 ± 0.27 cm (−1.5 to 0 cm), respectively]. Details of the wound size and injured clavicle length shortening of the two groups are summarized in Table 2. Table 3 shows that the injured clavicle length shortening differed significantly between the four subgroups (p = 0.036) more length shortening after fracture union as compared to the plate group [0.36 ± 0.60 cm (−1.5 to +1 cm) and 0.08 ± 0.27 cm (−1.5 to 0 cm), respectively]. Details of the wound size and injured clavicle length shortening of the two groups are summarized in Table 2. Table 3 shows that the injured clavicle length shortening differed significantly between the four subgroups (p = 0.018). Further analysis with post-hoc comparison revealed that the mean clavicle length shortening of the CT group (0.55 ± 0.58 cm) was significantly greater than that of the ST group (0.15 ± 0.59 cm; p = 0.026), SP group (0.03 ± 0.12 cm; p = 0.003), and CP group (0.12 ± 0.34 cm; p = 0.008; Table 3).

The mean Constant scores in the TEN group and plate group were 93.88 ± 8.91 (range 100–66.5) and 90.60 ± 9.90 (range 100–57), respectively, with no significant difference observed (p = 0.193). The mean DASH score was also not significantly different (p = 0.733) between the TEN group and the plate group, at 5.51 ± 10.49 (range 0–33) and 6.51 ± 11.53 (range 0–58.6), respectively. The functional results of these two groups are summarized in Table 2. As seen in Table 3, the Constant score differed significantly between the four subgroups (p = 0.043). Post-hoc analysis revealed that the ST (6.65 ± 11.70) and SP (3.82 ± 4.64) subgroups were significant different from the CP (8.52 ± 14.57) subgroup. The CT (4.28 ± 9.37) subgroup did not differ significantly with regards to Constant score from the other subgroups. The DASH score did not differ significantly between the four subgroups (p = 0.591). The results of the Constant and DASH scores for the four subgroups are shown in Table 3.

One patient in the plate group developed a wound infection during the follow-up period. Secondary surgery with wound debridement and implant removal was performed. After 1 month of being given systemic antibiotic treatment without further signs of infection, this patient received another operation to fix the clavicle fracture with a plate. The patient then achieved clavicle fracture union without further wound infection. One patient in the plate group had early implant failure with combined plate and screw loosening during the follow-up period due to poor rehabilitation compliance after surgery. We performed revision surgery with longer plates, and the patient had smooth fracture healing after revision surgery. Eight patients in the plate group complained of skin irritation due to the prominent plate and screws over the surgical site. Patients in the TEN group had a higher implant migration rate (p = 0.01) than those in the plate group; five patients in the TEN group had a forward proximal nail insertion site causing skin irritation. Skin numbness occurred in two patients in the TEN group and three patients in the plate group. None of the patients in the series had non-union or refracture after implant removal. All complications are outlined in detail in Table 4.

**Table 2** Wound size, injured clavicle length shortening, and objective function outcome between the Titanium Elastic Nail (TEN) and plate groups.

<table>
<thead>
<tr>
<th></th>
<th>TEN (n = 25)</th>
<th>Plate (n = 30)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wound size (cm)</td>
<td>2.46 ± 1.22</td>
<td>9.50 ± 1.12</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>Length</td>
<td>0.36 ± 0.60</td>
<td>0.08 ± 0.27</td>
<td>0.036**</td>
</tr>
<tr>
<td>shortening (cm)</td>
<td>93.98 ± 8.91</td>
<td>90.60 ± 9.90</td>
<td>0.193</td>
</tr>
<tr>
<td>Constant score [27]</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DASH score</td>
<td>5.51 ± 10.49</td>
<td>6.51 ± 11.53</td>
<td>0.733</td>
</tr>
</tbody>
</table>

Data are presented as mean ± SD.

* p < 0.05.

**p < 0.05.

DASH score = The Disabilities of the Arm, Shoulder and Hand (DASH) Score [28]; SD = standard deviation.

**Table 1** Demographic data of patients in the Titanium Elastic Nail (TEN) fixation and plate fixation groups.

<table>
<thead>
<tr>
<th></th>
<th>TEN (n = 25)</th>
<th>Plate (n = 30)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (y)</td>
<td>41.5 (16–66)</td>
<td>34.6 (16–60)</td>
<td>0.057</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>17</td>
<td>21</td>
<td>&gt; 0.99</td>
</tr>
<tr>
<td>Female</td>
<td>8</td>
<td>9</td>
<td></td>
</tr>
<tr>
<td>Fracture type</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Simple (15-B1)</td>
<td>13</td>
<td>15</td>
<td>0.6</td>
</tr>
<tr>
<td>Comminuted (15-B2)</td>
<td>12</td>
<td>15</td>
<td></td>
</tr>
<tr>
<td>Affected side</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Right</td>
<td>8</td>
<td>16</td>
<td>0.117</td>
</tr>
<tr>
<td>Left</td>
<td>17</td>
<td>14</td>
<td></td>
</tr>
</tbody>
</table>

Data are presented as n or mean (range).

**Discussion**

Plate and intramedullary devices are the two major types of implants currently used for internal fixation of clavicle fractures. Plate fixation is the standard operative method for fixing displaced midshaft clavicle fractures. However, no obvious strong evidence supports this practice. Our study demonstrated that intramedullary TEN fixation has good clinical results when compared to plate fixation of displaced midshaft clavicle fractures. No significant difference was found in the Constant (p = 0.193) or DASH (p = 0.733) scores between the TEN and plate groups. In our study, the TEN group had significantly smaller wound size (2.46 ± 1.22 cm vs. 9.50 ± 1.12 cm, p < 0.001), indicating that TEN fixation was less surgically invasive than plate fixation. Plate fixation of a midshaft clavicle fracture needs a large opening in order to fit the plate to the bone,
due to the displaced fracture site and the S-shape anatomy of the clavicle [33]. The most commonly reported complications in plate fixation of displaced midshaft clavicle fractures are related to the hardware and the large operative wound, including deep infection, implant breakage, non-union, and poor cosmetic appearance [5,7,9]. Current studies show high patient satisfaction rates and good shoulder functional results after using the intramedullary TEN system for clavicle fracture fixation [12,22–24,27]. The TEN system uses a minimally invasive technique to fix the displaced midshaft clavicle fracture, resulting in less soft tissue stripping, less blood loss, shorter operative time, and better cosmetic results than with traditional plate fixation [19,20,27–29].

Recent studies of the relationship between the amount of clavicle shortening and the shoulder functional results have emphasized the importance of preserving clavicle length after midshaft clavicle fractures. Many authors have stated that clavicle shortening may lead to static changes of the shoulder girdle such as an increase in the sterna clavicle joint angle, a change in the resting position of the scapula and an increase in the preload stress on the muscles of the shoulder girdle; these may lead to limitations in overhead motion, pain, and weakness [2,4,34–37]. Schultz et al. [38] reported an 8% decrease in maximal shoulder external rotation strength and an 11% loss of shoulder abduction endurance strength in patients with significant shortening of the clavicle after bone healing with conservative treatment. Lazarides and Zafiropoulos [35] concluded that final clavicle shortening of > 18 mm in male patients and > 14 mm in female patients would significantly impact results. McKee et al. [4] reported a DASH score of > 30 points in patients with ≥ 2 cm of clavicle shortening compared with those with < 2 cm of shortening after fracture union. They proposed that abduction function may be well preserved with < 2 cm of shortening. After this critical threshold of deformity is reached, the percentage of poor outcomes increases dramatically.

Because of the issues cited above, some authors have declared the TEN system not suitable for fixing comminuted clavicle fractures, since length maintenance is a concern with this device [25,27]. Some studies continue to recommend the use of a plate instead of intramedullary devices for fixation of comminuted clavicle fractures [26,39]. In our study, the injured clavicle length shortening in the TEN group was significantly shorter than in the plate group (0.36 ± 0.60 cm vs. 0.08 ± 0.27 cm; p = 0.36). Clavicle length shortening was significantly greater in the CT subgroup than in the ST subgroup (p = 0.026), SP subgroup (p = 0.003), or CP subgroup (p = 0.008; Table 3). The Constant score differed significantly in the SP and CT subgroups from the CP subgroup, which may be due to the fact that patients in these groups had a simple fracture pattern with good functional result. DASH score was not significantly different between subgroups. The function result in the CT subgroup did not differ from the other subgroups, as shown by Constant and DASH scores. Our clinical data showed that the length shortening in all patients in the TEN group was ≤ 2 cm, the critical threshold for impaired shoulder function after clavicle fracture [4]. We suggest that this is the reason that patients in the TEN groups with shortened clavicles, especially those with comminuted fractures, achieved good clinical functional outcomes. Traditionally, we made every effort to prevent form length shortening after fracture union, which included avoiding the usage of TEN on comminuted fracture pattern. However, no current data statistically uncovered the relationship between length shortening and functional outcomes. Our results between length shortening and functional outcome clearly revealed that TEN could be applied to

<table>
<thead>
<tr>
<th>Group</th>
<th>ST (n = 13)</th>
<th>SP (n = 15)</th>
<th>CT (n = 12)</th>
<th>CP (n = 15)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Length shortening (cm)</td>
<td>0.15 ± 0.59</td>
<td>0.03 ± 0.12</td>
<td>0.55 ± 0.58&lt;sup&gt;b&lt;/sup&gt;</td>
<td>0.12 ± 0.34</td>
<td>0.018&lt;sup&gt;*&lt;/sup&gt;</td>
</tr>
<tr>
<td>Constant Score [27]</td>
<td>96.61 ± 4.79&lt;sup&gt;b&lt;/sup&gt;</td>
<td>94.33 ± 4.32&lt;sup&gt;b&lt;/sup&gt;</td>
<td>90.92 ± 3.29&lt;sup&gt;e&lt;/sup&gt;</td>
<td>87.80 ± 2.67&lt;sup&gt;b&lt;/sup&gt;</td>
<td>0.043&lt;sup&gt;*&lt;/sup&gt;</td>
</tr>
<tr>
<td>DASH score [28]</td>
<td>6.65 ± 11.70</td>
<td>3.82 ± 4.64</td>
<td>4.28 ± 9.37</td>
<td>8.52 ± 14.57</td>
<td>0.591</td>
</tr>
</tbody>
</table>

Data are presented as mean ± SD.

<sup>*p < 0.05.</sup>

ANOVA = analysis of variance; CP = comminuted fracture in plate group; CT = comminuted fracture in TEN group; DASH = The Disabilities of the Arm, Shoulder and Hand Score; SD = standard deviation; SP = simple fracture in plate group; ST = simple fracture in TEN group.

<sup>a</sup> The CT subgroup differed significantly from other subgroups in injured clavicle length shortening (CT vs. ST, p = 0.026; CT vs. SP, p = 0.003; CT vs. CP, p = 0.008).

<sup>b</sup> The ST and SP subgroups differed significantly from the CP subgroup in Constant score (ST vs. CP, p = 0.009; SP vs. CP, p = 0.041).

<sup>c</sup> The CT subgroup did not differ significantly from other subgroups in Constant score or DASH score.
comminuted fracture pattern even with minimal shortening (≤ 2 cm), which is a very different point from previous articles.

Another notable complication after TEN fixation is nail medial migration [12,25,26]. The incidence of medial entry point irritation was from 5.4% to 33.3% [22–24,26]. In our study, five patients in our TEN group had medial insertion site nail migration that caused discomfort, which may necessitate nail removal after fracture union (Table 4). We did not routinely remove TEN after fracture union unless prominent skin irritation was found. Some authors have reported that shifting the entry point from the center of the medial clavicle to the lower end helps achieve better fixation stability and avoid nail migration [22]. Tarng et al. [27] proposed using a pre-bent hook-shaped nail for better three-point fixation in the TEN system. They turned the nail tip to embed beneath the clavicle and soft tissue to prevent nail migration. Frigg et al. [26] reported using the end cap of the TEN to prevent nail tip medial migration. In our experience, we inserted the nail tip as far as possible into the clavicle end point to engage the thinned and narrowed aspect of the distal clavicle [12,33], then cut the nail tip as close to the cortex as possible, to achieve better fixation and prevent the nail tip from perforation or migration. In addition, the distance of nail advancement into the lateral fragment must be as far as possible to provide enough fixation stability. The stability should always be checked by pulling the forearm forcefully under fluoroscopy [24,26]. With these proposed techniques, the incidence of nail tip irritation might be lowered.

Limitations worth highlighting with regards to our study include the retrospective study design, the limited number of patients and the short follow-up period. A prospective study, with more data and longer follow up may be needed to provide a higher level of evidence and to further verify findings.

In conclusion, the TEN system for fixation of displaced midshaft clavicle fractures produces functional results as good as those of plate fixation. Although TEN fixation of midshaft clavicle fractures may lead to greater length shortening after bony union, especially for comminuted fractures, we found no statistically significant difference in functional results between the TEN and plate groups. Therefore, TEN can be used for fixation of displaced midshaft clavicle fractures, even comminuted fractures, indicating that it is an effective and less surgically invasive option than plate fixation.

References


