A PROSPECTIVE STUDY OF FUNCTIONAL OUTCOME OF DISPLACED MIDSHAFT CLAVICLE FRACTURES TREATED WITH INTRAMEDULLARY TITANIUM ELASTIC NAIL SYSTEM

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ABSTRACT

BACKGROUND
Clavicle fractures are common injuries in young and active individuals, especially those who participate in sports where high-speed falls (e.g., bicycling, motorcycles) or violent collisions (e.g., football, hockey) are frequent. Whereas in children and elderly, they are related to falls and they account for approximately 2.6% of all fractures. The most common site of fracture in the clavicle occurs at the middle third which accounts for almost 80% of all clavicle fractures. Displaced midshaft clavicle fractures can cause significant, persistent disability, even if they heal uneventfully. The clavicle which is similar to other long bones is usually best treated with intramedullary methods. So elastic stable intramedullary nailing (ESIN) is recommended for all simple displaced midshaft clavicle fractures in order to minimise the rate of delayed union, non-union, symptomatic malunion and other complications.

MATERIALS AND METHODS
This is a prospective case series to study the functional outcome of 40 cases of displaced midshaft clavicle fractures, satisfying the inclusion criteria, treated by intramedullary titanium elastic nail system done at the Department of Orthopaedics, Government Kilpauk Medical College Hospital, Chennai from September 2013 to July 2015. All cases were treated with TENS under the guidance of the image intensifier as per standard methods.

RESULTS
In the group, 24 patients had A0 class B1 and 16 had A0 class B2 fractures. All the patients achieved clinical and radiological union at a mean of 8.8 weeks (Range 6-12 weeks). Eleven of the 24 patients had closed nailing while 16 patients (40%) required open reduction of their fracture. The average size of the titanium flexible nail used was 2.5 mm (range 2-3 mm). The average constant score was 89.8 (range 78-95).

CONCLUSION
From this study, we recommend the use of minimally invasive antegrade titanium elastic nail for fixation of displaced midshaft clavicle fractures in view of faster fracture union, quicker rehabilitation, lesser morbidity, easier implant removal and fewer complications.

KEYWORDS
Clavicle Fracture, ESIN, A0 Class B1 and B2.


BACKGROUND
Clavicle fractures accounting for approximately 2.6% of all fractures1 are usually common in young and active individuals and usually due to high velocity injuries whereas simple fall is the common aetiology of clavicle fracture in elderly and young children. By far the commonest site of clavicle fracture is the middle third region accounting for almost 80% of all clavicle fractures. Older studies usually advised conservative line of management in fractured clavicle, even when displaced significantly, deeming it to be benign in nature.2,3

Non-union rates according to Neer were 0.1% with conservative management which was corroborated by Rowe in 1968 whose studies showed non-union occurring at the rate of 0.8% in conservatively managed clavicle fractures.4 But since that no authors have achieved quite similar good results with conservative line of management in clavicle fractures.5,6

Złowodzki et al did meta-analysis of the literature from 1975-2005 and found that the non-union rate for conservatively managed midshaft clavicle fractures was 15.1% higher than described previously.7

Further study by Hill et al reported non-union rate of 15% in patients treated by conservative methods who presented with shortening greater than 2 cm after injury. Hill et al also reported that 31% of patients were not satisfied with their final result obtained by conservative means.8

All these evidences clearly suggest that mid shaft clavicle fractures indeed produce significant disability even though their healing were uneventful. Clavicle is similar to other long bones and can be treated with intramedullary fixation. Elastic Stable Intramedullary Nailing (ESIN), thus is a good option...
for displaced midshaft clavicle fracture which effectively minimises delayed union, reduces incidence of non-union, reduces symptomatic malunion and other complications.

MATERIALS AND METHODS
This is a prospective case series to study the functional outcome of 40 cases of displaced midshaft clavicle fractures treated by intramedullary titanium elastic nail system done at the Department of Orthopaedics, Government Kilpauk Medical College Hospital, Chennai from September 2013 to July 2015. The study was formally approved by hospital ethics committee.

Inclusion Criteria
- All skeletally mature patients.
- All the displaced diaphyseal non-comminuted/simple comminuted clavicle fractures (>2 cm displacement) – AO 15 B1 and B2 fractures.

Exclusion Criteria
- Fractures with shortening of over 20 mm
- Fractures within one week

Classification
We used AO/OTA classification in our study.

Outcome Assessment
Functional outcome was assessed by the Constant score. Radiographic union was defined as evidence of bridging callus or obliteration of fracture lines.

Clinical union was considered as absence of tenderness at the fracture site. Time to achieve union was recorded. After union, shortening of clavicular length was measured clinically as the linear difference of clavicle lengths from Sternal end to Acromial end between operated and normal side.

Secondary outcome measures include perioperative data like operative time, amount of blood loss and size of the surgical wound; complications such as neurovascular injury, wound infection, nonunion, malunion, implant migration, implant failure, soft tissue irritation, re-fracture after implant removal and cosmetic outcome with regards to visible deformity, scars and hardware prominence under the skin. Implant removal was done routinely in our study.

Statistical Analysis
The collected data was analysed with IBM SPSS version 22 for independent sample t-test. The results are obtained in the form of range, mean and standard deviation. The probability value ‘p’ of less than 0.05 was considered statistically significant.

RESULTS
Case 1.

Figure 9. Preoperative X-ray
Figure 10. Immediate Post-op
Figure 11. Six Weeks Post-op
Figure 12. Six Months Post-op
Figure 13. After Removal
Figure 14. Postoperative Range of Movements

Case 2.

Figure 15. Preoperative X-ray
Figure 16. Immediate-Post-op

Figure 17. One Month Post-op
Figure 18. Eight Months Post-op

Figure 19. After Removal

Figure 20. Postoperative Range of Movements

Figure 21. Pre-operative X-ray
Figure 22. Immediate Post-op

Figure 23. Six Weeks Post-op
Figure 24. Three Months Post-op

Figure 25. After Removal
This 45-year-old female had medial implant prominence and local infection which was treated with antibiotics. But the implant has to be removed at about 3 months post-op when she presented with skin perforation. By the time the fracture had united both clinically and radiologically resulting in no complications after implant removal.

**Associated Injuries**

In the study group, we had only two patients with associated injuries, which included: One case of ipsilateral spine of scapula fracture and another case with ipsilateral fracture both bone leg, both of them were addressed simultaneously.

**Fracture Classification**

In the study group, we had only two patients with associated injuries, which included: One case of ipsilateral spine of scapula fracture and another case with ipsilateral fracture both bone leg, both of them were addressed simultaneously.
The mean surgical time for the procedure is 49.5 minutes, ranging from 15 to 90 minutes.

### Table 1. Range of Movements

<table>
<thead>
<tr>
<th>Fracture Type</th>
<th>Average Time For Union (WEEKS)</th>
<th>Average Constant Score (mean ± standard deviation)</th>
</tr>
</thead>
<tbody>
<tr>
<td>AO 15 B1</td>
<td>8.25</td>
<td>90.50 ± 4.011</td>
</tr>
<tr>
<td>AO 15 B2</td>
<td>9.63</td>
<td>88.75 ± 3.715</td>
</tr>
<tr>
<td>Overall (B1+B2)</td>
<td>8.8</td>
<td>89.80 ± 3.943</td>
</tr>
</tbody>
</table>

### Table 2. Time Taken for Fracture Union

<table>
<thead>
<tr>
<th>Sl. NO.</th>
<th>Result</th>
<th>Constant Score</th>
<th>No. of Patients</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Excellent</td>
<td>86-100</td>
<td>36</td>
<td>90%</td>
</tr>
<tr>
<td>2</td>
<td>Good</td>
<td>71-85</td>
<td>4</td>
<td>10%</td>
</tr>
<tr>
<td>3</td>
<td>Fair</td>
<td>56-70</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td>4</td>
<td>Poor</td>
<td>1-55</td>
<td>0</td>
<td>0%</td>
</tr>
</tbody>
</table>

### Table 3. Functional Evaluation Using Constant Score

<table>
<thead>
<tr>
<th>Age</th>
<th>n</th>
<th>Mean</th>
<th>S.D.</th>
<th>t</th>
<th>Df</th>
<th>Statistical inference</th>
</tr>
</thead>
<tbody>
<tr>
<td>B1</td>
<td>24</td>
<td>34.71</td>
<td>10.071</td>
<td>-0.145</td>
<td>38</td>
<td>0.886&gt;0.05 Not Significant</td>
</tr>
<tr>
<td>B2</td>
<td>16</td>
<td>35.19</td>
<td>10.572</td>
<td>-0.726</td>
<td>38</td>
<td>0.472&gt;0.05 Not Significant</td>
</tr>
</tbody>
</table>

| Days before surgery | B1 | 24 | 3.42 | 1.412 | -0.726 | 38 | 0.472>0.05 Not Significant |
| Days before surgery | B2 | 16 | 3.75 | 1.438 | -0.726 | 38 | 0.472>0.05 Not Significant |

| FU months | B1 | 24 | 8.58 | 2.104 | -0.835 | 38 | 0.409>0.05 Not Significant |
| FU months | B2 | 16 | 9.13 | 1.857 | -0.835 | 38 | 0.409>0.05 Not Significant |

| Union | B1 | 24 | 8.25 | 1.800 | 2.356 | 38 | 0.024<0.05 Significant |
| Union | B2 | 16 | 9.63 | 1.821 | 2.356 | 38 | 0.024<0.05 Significant |

| Flexion | B1 | 24 | 165.42 | 10.521 | 0.399 | 38 | 0.692>0.05 Not Significant |
| Flexion | B2 | 16 | 164.06 | 10.523 | 0.399 | 38 | 0.692>0.05 Not Significant |

| Abduction | B1 | 24 | 164.79 | 10.160 | -0.248 | 38 | 0.805>0.05 Not Significant |
| Abduction | B2 | 16 | 165.63 | 10.782 | -0.248 | 38 | 0.805>0.05 Not Significant |

| External Rotation | B1 | 24 | 72.71 | 6.252 | 0.702 | 38 | 0.487>0.05 Not Significant |
| External Rotation | B2 | 16 | 71.25 | 6.708 | 0.702 | 38 | 0.487>0.05 Not Significant |

| Internal Rotation | B1 | 24 | 73.54 | 6.164 | -0.447 | 38 | 0.657>0.05 Not Significant |
| Internal Rotation | B2 | 16 | 74.38 | 5.123 | -0.447 | 38 | 0.657>0.05 Not Significant |

### Table 4. T Test

| Result | B1 | 24 | 1.88 | 0.338 | 0.632 | 38 | 0.531>0.05 Not Significant |
| Result | B2 | 16 | 1.94 | 0.250 | 0.632 | 38 | 0.531>0.05 Not Significant |

At the end of the study, we had all the 40 patients in the followup group with 28 male and 12 female patients. The mean age was 34.71 years (range 22-55 years) in the group.

The mean time interval between injury and surgery was 3.55 days (range 1-6 days). In the group, 24 patients had AO class B1 and 16 had AO class B2 fractures.

All the patients achieved clinical and radiological union at a mean of 8.8 weeks (Range 6-12 weeks). Eleven of the 24 patients had closed nailing while 16 patients (40%) required open reduction of their fracture. The average size of the titanium flexible nail used was 2.5 mm (range 2-3 mm).

The patients were followed up postoperatively and Constant scores were calculated at 6 weeks, 8 weeks, 10 weeks, 3 months and 6 months. The average constant score was 89.80 (range 78 – 95).

The nails were removed at an average of 6 months postoperatively, after the fracture had clinically and radiologically healed. One patient had medial protrusion of the nail with local skin perforation which was subsequently removed early after fracture has united at around 3 months.

There were no major complications in our series with only one case of local skin infection due to medial hardware prominence. No other complications like scar neuromas, non-unions or perforation of the posterior cortex were reported. And there were no cases of re-fracture after implant removal.

Comparing fracture type and union time t test values obtained was 0.024 which is statistically significant. Comparing constant score with fracture type t test values obtained was 0.172 which is statistically not significant. No other factors are statistically significant.

### DISCUSSION

**Surgical Technique**

The patient was placed in supine position on radiolucent table with a sandbag under ipsilateral shoulder. Care was taken to make sure that the sternoclavicular joint was accessible for the entry point.
A one cm horizontal incision was made just lateral to the Sternoclavicular joint. The pectoral fascia was divided in line with the skin incision followed by careful elevation of the underlying musculature from the clavicle.

The entry point was then made using the awl directly or can be pre-drilled with a 2.7 mm drill bit to make a footprint.

Appropriate-sized titanium ESIN, after being loaded in T-handle was inserted (The size of the nail was measured using this formula = 0.4 × canal diameter in mm).

If the fracture could not be reduced by closed means, then a separate mini open incision was used at the fracture site for direct manipulation of fragments.

The nail is then passed from the medial side and after reaching the end point, the nail is cut close as to prevent soft tissue irritation but leaving behind sufficient length for the extraction to be easy later on. The fascia and skin were closed in layers.

**Postoperative Protocol**

Pendular exercises for the shoulder were started from the second day. And all the patients were discharged on the second postoperative day.

After 7 days, active range of movement exercises were started, however, overhead shoulder abduction was allowed only after 2 weeks. Thereafter, activities of daily living were started, but those requiring lifting heavy objects were delayed until radiological and clinical union was achieved.

All patients were reviewed in the outpatient department at 2 and 6 weeks, 8 weeks, 10 weeks, 3 months, 6 months and 12 months after surgery.

The fracture shortening of 20 mm at initial stage showed high significant association with non-union; thus increasing
the chance of an unsatisfactory result. Shortening of 20 mm or more finally following fixation was associated with an unsatisfactory result, but not with non-union. No other patient variable, fracture characteristic or treatment factor had a significant effect on final outcome.5

Surgery has been indicated for completely displaced fractures, potential skin perforation, shortening of clavicle by more than 20 mm, neurovascular injury, and floating injury.9 The gold standard for the surgical treatment has been open reduction and plate fixation through a large incision.9

Plate osteosynthesis8,10,11 external fixation12 and intramedullary fixation13,14,15,16,17 have all been described for surgical treatment of clavicle fractures. Plate osteosynthesis is still considered the standard method for the surgical treatment of clavicle fractures.

The advantage of plate fixation is good reduction with compression and rigid fixation.

However, complications after plate osteosynthesis are fairly common. In a multicentre prospective randomised trial, plate osteosynthesis had better functional outcome than nonoperative treatment of displaced clavicle fractures with decreased rate of non-union and symptomatic malunion.10

Severe complications occur in 10% of the patients and include deep infection, non-union, implant failure and fracture after implant removal. Lesser complications include superficial infection, keloid scar, dysesthesia in the region of scar, as well as implant loosening with loss of reduction.18

Intramedullary stabilisation is an established alternative fixation method.

Intramedullary implants are ideal from the biomechanical point of view as the tension side of clavicle changes with respect to rotation of arm and direction of loading.8,14

The other potential benefits of intramedullary nailing include smaller incision, minimal periosteal stripping and load sharing device properties.19 Its relative stability allows copious callus formation during the healing process.

The frequent complication encountered is skin irritation from the prominent medial end of the nail and this frequently leads to premature removal of the nail.18

Usage of TENS nail in multifragmentary fracture can lead to telescoping of the nail with shortening of the clavicle. Thus, the comminuted fractures were excluded as the nail cannot maintain length of the clavicle in these situations. Smekal et al hence do not recommend use of intramedullary nail in comminuted fractures with severe shortening.18

Duan et al in a meta-analysis of randomised controlled trials demonstrated similar functional outcome when comparing plating with intramedullary fixation.20 They however, showed higher symptomatic hardware-related problems with plating.

Złowodzki et al in a systematic review of 2144 cases found non-union rate of 1.6% with intramedullary fixation as compared with 2.5% with plate fixation.20

Achieving closed reduction was a difficult task especially in AO B2 fractures and in obese individuals. If reduction could not be achieved closed; a mini open incision can be made to reduce the fracture. So that the surgical time as well as the radiation exposure for both the patient and surgeon can be reduced.

Despite all these, we achieved good functional and cosmetic outcome in diaphyseal midshaft, non-committed clavicle fractures with more than 20 mm shortening/displacement with intramedullary titanium elastic nail system with no major complications.

In our study, there is significant statistical correlation between fracture type and time for union (p< .024) although no other variable showed statistical significance.

CONCLUSION
Thus, the intramedullary fixation of displaced midshaft clavicle fracture is a safe and minimally invasive technique.

From this study, we recommend the use of minimally invasive antegrade titanium elastic nail for fixation of displaced midshaft clavicle fractures in view of:

- Faster fracture union.
- Quicker rehabilitation.
- Lesser morbidity.
- Easier implant removal and
- Fewer complications.

REFERENCES


