



## Functional Outcome in Clavicle Fractures Treated by Titanium Elastic Nail System

### KEYWORDS

clavicle fracture, titanium elastic nailing system, constant score

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**ABSTRACT** *In recent days there is a trend towards surgical fixation of clavicle fractures based on the unsatisfactory data obtained from conservative treatment. . Good results with high union rates and low complication rates have been reported from a variety of techniques for primary fixation of displaced fractures of clavicle. We would like to share our experience of surgical management of clavicle fracture with titanium elastic nailing system in 200 consecutive cases.*

### INTRODUCTION

Clavicle fractures are common injuries in young and active individuals, especially those who participate in sports where high-speed falls are frequent, whereas in children and elderly they are related to falls and they account for approximately 2.6% of all fractures. (1). Older studies suggested that a fracture of the shaft of the clavicle, even when significantly displaced, was an essentially benign injury with an inherently good prognosis when treated non operatively. (2&3). Neer reported a non-union rate of 0.1% with conservative treatment (2) and Rowe corroborated these findings in 1968 and showed a non-union rate of 0.8% in conservatively managed patients. (4) Since then, however, other authors have failed to demonstrate similar good results with conservative treatment. (5&6) This may be due to the fact that the initial series included children and adolescents and their enormous potential for bone healing may have skewed the results, and that patient-based scoring systems were not used in the initial series to record the outcome.

In a meta analysis of the literature from 1975 to 2005, Zlowodzki et al found that the non-union rate for non operatively treated displaced midshaft clavicle fractures was 15.1%. (7). Treating conservatively, 31% of patients who were reviewed in the study of Hill et al were not satisfied with treatment results. (8). Thus, displaced midshaft clavicle fractures can cause significant, persistent disability, even if they heal uneventfully. Thus, there is a trend towards surgical fixation of clavicle fractures based on the unsatisfactory data obtained from conservative treatment. Good results with high union rates and low complication rates have been reported from a variety of techniques for primary fixation of displaced fractures of clavicle. Elastic stable intra medullary nailing (ESIN) is one of the recommended implants for all simple displaced midshaft clavicle fractures in order to minimize the rate of delayed union, non union, symptomatic malunion and other complications.

### AIM OF THE STUDY

To analyze the functional outcome of displaced midshaft clavicle fractures treated by intramedullary titanium elastic nail system.

### REVIEW OF LITERATURE

Hill et al. did a study on 52 cases of conservatively treated adults with mid-shaft clavicle fractures at a mean of 38 months after injury. Shortening of 20 mm or more finally following fixation was associated with an unsatisfactory result, but not with nonunion. No other patient variable, fracture characteristic or treatment factor had a significant effect on final outcome (7).

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). Other surgical options include intramedullary pinning and external fixation. Among the intramedullary devices, titanium elastic nail has been found to be most acceptable tool for fixing clavicle fracture.

Intramedullary fixation for clavicle fractures was first described by peronei in 1950 (10). A systematic review showed relative risk reduction of 72% and 57% for non-union when using intramedullary fixation and plate fixation, respectively, when compared with non-operative treatment of midshaft clavicle fractures (7). Intramedullary devices act as internal splints which maintains alignment without rigid fixation. Thus the intramedullary device holds advantages of a smaller incision, less soft tissue dissection, load sharing fixation and relative stability that encourages copious callus formation (11). The titanium nail has been successfully used in fixation of pediatric long bone fractures.

Another advantage of the titanium ESIN is that it can block itself in the bone and provide a three-point fixation within the S-shaped clavicle (9&12). In a retrospective analysis between titanium elastic nails and reconstruction plates, Chen et al showed a significantly shorter time to union with the TEN group with no significant difference in non-union or malunion rate between TEN and plating. TEN group showed a faster functional recovery with greater patient satisfaction with cosmesis and overall outcome (13). In a randomized control trial between intramedullary nailing and non-operative treatment by Smekal et al, better DASH and Constant scores and 100% union rate with intramedullary nailing has been reported (8).

## MATERIALS AND METHODS

This prospective study of functional outcome of displaced midshaft clavicle fractures treated by intramedullary titanium elastic nail system was done at the Department of Orthopaedics, Government Kilpauk Medical College Hospital, Chennai and Coimbatore medical college hospital, Coimbatore from September 2010 to July 2015. A Total of 200 patients who met the following criteria were included in the study.

All the displaced diaphyseal non comminuted/simple comminution clavicle fractures (>2cm displacement – AO 15 B1 and B2 fractures) in skeletally mature patients were included in the study. Fractures with marked comminution or older than 1 week, Paediatric fractures, Pathological fractures and Open fractures were excluded. Clavicle fractures with associated Ipsilateral fractures of other bones in the upper limb or scapula and Brachial plexus injuries were also excluded.

### Surgical procedure

A one cm horizontal incision was made just lateral to the sternoclavicular joint. The entry point was then made using the awl directly or can be pre-drilled with a 2.7mm drill bit to make a foot print. Appropriate sized titanium ESIN, after being loaded in T-handle was inserted. Under fluoroscopic control, attempt was made to close reduce the fracture. Two percutaneously used reduction clamps can be used to aid in reduction. 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 was then passed from the medial side and across the reduced fracture into the lateral end of clavicle until it is just medial to the acromio clavicular joint. After reaching the endpoint, the nail is cut close as to prevent soft tissue irritation but leaving behind sufficient length for the extraction [Figure 1&2].

### Post operative protocol

Postoperatively, patients were given a sling, but were encouraged for early shoulder mobilization as tolerated. After 7 days, active range of movement exercises were started including overhead shoulder abduction as tolerated. All patients were reviewed at 2 and 6 weeks, 3, 6 and 12 months after surgery. At each visit, patients were assessed clinically and radiologically [Figure 3-6].

Functional outcome was assessed by the Constant score. Time to achieve union was recorded. Secondary outcome measures that were observed include perioperative data like operative time, Implant removal was done routinely after 5 to 6 months of index surgery in our study.



Figure 1. Pre operative Xray with 2 cm shortening



Figure 2. Immediate Post operative Xray.



Figure 3. Four months follow up X ray showing solid union



Figure 4. Clinical picture on 2<sup>nd</sup> post operative day



Figure 5. Overhead abduction at 7<sup>th</sup> post operative day

The study included a total of 200 patients, among them there were 142 males and 58 females. 92 % of case were within 20 to 30 years of age. 78% of cases were due to road traffic accident. 15 % were due to sport related injuries and the remaining were due to domestic falls. In 65% the right clavicle was injured. In two cases both clavicles were fractured.

In the study group, we had only two patients with associated injuries, which included fracture both bones leg in one and fracture shaft of femur in another, both of them were addressed simultaneously.

All the fractures were classified according to the AO classification. 152 patients belonged to AO B1 type and 48 patients belonged to AO B2 type. All the patients were operated within 7 days after injury, most of the cases within 3 days. The mean surgical time for the procedure was 29.5 minutes, ranging from 15 to 50 minutes.

The time for union and constant score at union were assessed. [Table 1 & 2].

**Table 1. Time for union and constant score to fracture type**

Fracture type	Average time for union (weeks)	Average Constant score (mean $\pm$ standard Deviation)
AO 15 B1	8	90.33 $\pm$ 3.91
AO 15 B2	10	89.5 $\pm$ 3.16
(B1+B2)	8.8	90 $\pm$ 3.5

**Table 2. Clinical outcome**

Constant score	Outcome	No of patients	Percent
86 – 100	Excellent	182	91%
71-85	Good	18	9%
56-70	Fair	None	0%
< 55	Poor	None	0%

### Complications

We had complications in six patients. Five patients had medial implant prominence. In all of them the implant was removed at 3 months post op. By the time the fracture had united both clinically and radiologically resulting in no complications after implant removal. One patient had local infection at the prominent medial end, which was initially treated with oral antibiotics. But as the prominence was more we cut the medial end by 1cm under local anaesthesia. And the wound healed eventually.

### Statistical analysis

The collected data was analysed with SPSS. To describe about the data descriptive statistics frequency analysis, percentage analysis were used for categorical variables and the mean & S.D were used for continuous variables. To find the significant difference between the bivariate samples in Independent groups the Mann-Whitney U test was used. To assess the relationship between the variables Spearman's rank Correlation was used. In both the above statistical tools the probability value .05 is considered as significant level.

When fracture type and time for union are compared, we obtained p value of 0.047 which is statistically significant, whereas fracture type and the resultant constant score doesn't show any statistical significance as the p value obtained is 0.521. There is no statistical significance when the variables, time for union and constant score are compared as the p value is 0.949, which is statistically not significant.

## DISCUSSION

Plate osteosynthesis, external fixation and intramedullary fixation have all been described for surgical treatment of clavicle fractures. (12, 14-16). 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.

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 (16).

Intramedullary stabilization 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 (8,12). The other potential benefits of intramedullary nailing include smaller incision, minimal periosteal stripping, and load sharing device properties (11).

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 (16).

Duan et al. in a meta-analysis of randomized controlled trials demonstrated similar functional outcome when comparing plating with intramedullary fixation (17). They, however, showed higher symptomatic hardware-related problems with plating. Zlowodzki 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 (7).

In our series, we achieved good functional and cosmetic outcome in diaphyseal midshaft, non-comminuted clavicle fractures with more than 20mm 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 < .047) although no other variable showed statistical significance.

The short falls in our study include absence of a control group.

## CONCLUSION

Intramedullary fixation of displaced midshaft clavicle fracture with TENS 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 the predictable union and functional outcome.

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