

Original Research Article

A prospective study of functional outcome of closed displaced mid-shaft clavicle fractures treated with intramedullary titanium elastic nail system

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ABSTRACT

Background: Clavicle fractures are most 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. In contrast, 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 is a middle-third shaft; it accounts for 80% of all clavicle fractures.

Methods: This was a prospective study carried in 20 patients with simple mid third clavicular fractures, who were treated with closed intra-medullary fixation with TENS nailing. Post-operatively range of movements, ability to get back to routine work were assessed and noted.

Results: At the end of the study, all the 20 patients in the follow-up group with 14 male and 6 female patients. The mean age was 34.9 years (between 22-55 years) in the group. The mean time interval between injury and surgery was 3.55 days (range 1-6 days). All the patients are achieved clinical and radiological union at a mean of 8.6 weeks (range, 6-12 weeks).

Conclusions: Thus, the intramedullary fixation of a displaced midshaft clavicle fracture is a safe minimally invasive technique. The present study advises the use of minimally invasive antegrade titanium elastic nail for fixation of displaced midshaft clavicle fractures. Although, for comminuted fractures plating remains the procedure of choice.

Keywords: Clavicle, Mid third fractures, Intra-medullary nailing, TENS

INTRODUCTION

Clavicle fractures are most 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.^{1,2} In contrast, 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 is a middle-third shaft; it accounts for 80% of all clavicle fractures. Older studies suggested that a fracture of the

shaft of the clavicle, even when significantly displaced, was a mostly benign injury with an inherently good prognosis when treated nonoperatively.³ Neer, reported a nonunion rate of 0.1% with conservative treatment, and Rowe corroborated these findings in 1968 and showed a nonunion rate of 0.8% in conservatively managed patients.^{3,4} Since then, however, any other authors have failed to demonstrate similar good results with conservative treatment.^{5,6} This may be because of the first series included the children and adolescents and their enormous potential for bone healing, may have shown

inaccurate results. That patient-based scoring systems were not used in the first series to record the outcome. Treating conservatively, Hill et al reported a nonunion rate of 15% in correlation with initial shortening greater than two centimeters. 31% of all patients who were reviewed in the study of Hill et al were not satisfied with treatment results.⁷ Thus, displaced mid-shaft clavicle fractures can cause significant, persistent disability, even if they heal uneventfully. Therefore, there is a trend towards the surgical fixation of clavicle fractures based on the unsatisfactory data obtained from conservative treatment. Excellent results with high union rates and low complication rates have been reported from a variety of techniques for the primary fixation of displaced fractures of the clavicle. 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 to minimize the rate of complications like delayed union, non-union, symptomatic-malunion.

METHODS

Present study was a prospective evaluation of outcome of closed, displaced midshaft clavicle fractures treated by intramedullary titanium elastic nail system which has been done in the Department of Orthopedics, Konaseema Institute of Medical Sciences and Research Foundation from September 2017 to July 2019. Patient were enrolled based on following inclusion and exclusion criteria.

Inclusion criteria

Inclusion criteria were a total of 20 patients who meet the following criteria are included in the study, all skeletally mature patients, closed fractures, all the displaced diaphyseal non-comminuted/simple comminution clavicle fractures (>2 cm displacement) - AO 15 B1 and B2 fractures, fractures with shortening of over 20mm, middle third clavicle fractures, and fractures within one week.

Exclusion criteria

Exclusion criteria were fractures with marked comminution (complex comminution), brachial plexus injuries, fractures older than one-week, pediatric fractures, pathological fractures, open fractures, congenital anomaly or bone disease, lateral and medial third clavicle fractures, and any medical contraindication for surgery.

Ethics

Before start of the study institutional ethics committee approval was taken and a written and informed consent was taken from all patients before enrolling them for study.

Methodology

The patient placed in the supine position on a radiolucent table with a sand bag under the ipsilateral shoulder. After

administration of anesthesia (either general/regional), preparation and draping of an injured extremity are done from midline to the upper arm from the entry point the sternoclavicular joint should be accessible then care should be taken in this way the shoulder region was secured using an image to intensifier to confirm this access.

Approach

A horizontal incision of about 1 cm given lateral to the sternoclavicular joint, where the sagittal diameter of clavicle is at its maximum and there is no risk of intra thoracic migration of nail. The subcutaneous fat was incised along with platysma. The skin incision and pectoral fascia incised in the same plane followed by careful separation of underlying musculature. With the help of awl, an entry point is made directly or using a 2.7 mm drill bit can also be used. Titanium ESIN with T-handle was inserted (the size of the nail was measured using formula= $0.4 \times$ canal diameter in mm). Under fluoroscopy with the help of reduction clamps attempt is made to reduce the fracture. For easy access, a nail was used to create a path in the lateral end of clavicle later nail is passed from the medial side through the reduced fracture into the lateral end of clavicle until it is just medial to acromioclavicular joint. After passing the pin to lateral end nail is cut close to soft tissue to prevent delicate tissue irritation care must be taken so that sufficient length is left behind for easy extraction. Skin and fascia closed in layers.

Outcome assessment

A constant score assesses the functional outcome. The evidence of bridging callus or obliteration of fracture lines defines the radiographic union.

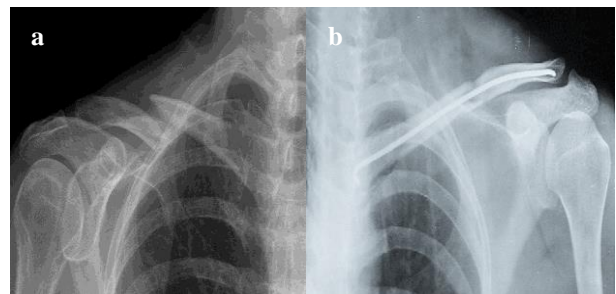


Figure 1 (a and b): Mid-shaft clavicle fractures treated with intramedullary titanium elastic nail system.

The absence of the tenderness at the fracture site defines the clinical union. Time required for union of the bone was recorded. The linear difference of lengths of the clavicle from sternal end to acromial end between operated and rational side was measured clinically after the union. This gives the amount of shortening of the clavicle after the union. The perioperative data like the size of the surgical wound, amount of the blood loss, operative time; are the

secondary outcome measures. Complications like malunion, nonunion, wound infection, implant failure, implant migration, neurovascular injury, refracture after implant removal, soft tissue irritation and the cosmetic outcomes regarding scars, hardware prominence under the skin and visible deformity.

Statistical analysis

Data was collected on excel sheet and analyzed by SPSS software version 17. For analysis of data percentage mean and standard deviation was used.

RESULTS

Out of the 20 patients, at 3 months 12 (60%) patients experienced no pain. At 6 months, 17 (85%) patients experienced no pain with 5 points. Out of 20 patients, 6 (30%) patients experienced mild pain and at 6 months 2 (10%) experienced mild pain with 4 points. Out of 20 patients, at 3 months 2 (10%) patients experienced pain after unusual activities (heavy weight lifting), at 6 months 1 (5%) patients experienced pain after unusual activities (heavy weight lifting) with 3 points.

Table 1: Evaluation of pain.

Pain scale	Points	No. of patients	
		At 3 months N (%)	At 6 months N (%)
No pain	5	12 (60)	17 (85)
Mild pain	4	6 (30)	2 (10)
Pain after unusual activities (heavy weights lifting)	3	2 (10)	1 (5)
Pain at rest	2		
Marked pain	1		
Complete disability	0		

Table 2: Range of movements.

Shoulder movements	Average (mean±SD)
Flexion	165.75±9.21
Abduction	166.25±10.49
External rotation	72.5±6.5
Internal rotation	74.25±5.19

Out of 20 patients shoulder range of movements, average (mean±SD) in flexion is 165.75±9.21, abduction is 166.25±10.49, external rotation is 72.5±6.5, and internal rotation is 74.25±5.19.

Out of the 20 patients, at 3 months 15 (75%) patients muscle strength was normal, at 6 months 18 (90%) patients

muscle strength was normal. Out of 20 patients 5 (25%) patients muscle strength against resistance is seen and at 6 months 2 (10%) muscle strength against resistance is seen.

Table 3: Muscle strength.

Muscle strength	No. of patients	
	At 3 months N (%)	At 6 months N (%)
Normal	15 (75)	18 (90)
Against resistance	5 (25)	2 (10)
Against gravity	-	-
Elimination of gravity	-	-
Flicker	-	-
Paralysis	-	-

Table 4: Occupation limitations.

Occupation status	No. of patients	
	At 3 months N (%)	At 6 months N (%)
Regular work	15 (75)	18 (90)
Restricted work	5 (25)	2 (10)
Unable to work		

Out of the 20 patients, at 3 months 15 (75%) patients able to do regular work. At 6 months 18 (90%) patients able to do regular work. Out of 20 patients 5 (25%) patients able to do restricted work. 2 (10%) patients able to do restricted work.

Table 5: Time taken for fracture union.

Fracture type	Average time for union (weeks)	Average constant score (mean±SD)
AO 15 B1	8	90.33±3.91
AO 15 B2	10	89.5±3.16
Overall (B1+B2)	8.8	90±3.5

Out of 20 patients, fracture type AO 15 B1, Average time for union is 8 weeks with average constant score (mean±SD) is 90.33±3.91, out of 20 patients, fracture type AO 15 B2, average time for union is 10 weeks with average constant score (mean±SD) is 89.5±3.16, out of 20 patients, fracture type B1+B2, average time for union is 8.8 weeks with average constant score (mean±SD) is 90±3.5, comparing fracture type and union time we obtained p value 0.047 statistically significant. Comparing constant score with fracture type, p value 0.521 statistically not significant.

Out of 20 patients, 18 patients 90% functional evaluation using constant score is excellent, out of 20 patients, 12 patients 10% functional evaluation using constant score is good.

Table 6: Functional evaluation using constant score.

Result	Constant score	No. of patients	%
Excellent	86-100	18	90
Good	71-85	2	10
Fair	56-70	0	0
Poor	1-55	0	0

DISCUSSION

Plate osteosynthesis, external fixation and intramedullary fixation are the surgical options for fractures of clavicle. Plate osteosynthesis is considered as a standard method for the surgical treatment of clavicle fractures.⁷ The advantage of plate fixation is a sound reduction with compression and rigid fixation. In present study 60% patients has no pain after 3 month and 85% patient have no pain after 6 months. However, complications after plate osteosynthesis are relatively common. In a multicenter prospective randomized trial, plate osteosynthesis has better functional outcome with respect to pain after 3 month and 6 months of treatment than non-operative treatment of displaced clavicle fractures with a decreased rate of non-union and symptomatic malunion which support our study.^{8,9}

Severe complications occur in 10% of all patients and include deep infection, nonunion, keloid scar, implant failure, and fracture after implant removal. Lesser complications include superficial infection, dysesthesia in the region of injury, as well as implant loosening with loss of reduction. Intramedullary stable nailing is an established alternative fixation method. Which is supported by study of Peroni and Zlowodzki et al.^{10,11}

In the biomechanical point of view, intramedullary nails are ideal, as the tension side of clavicle changes concerning the rotation of arm and direction of loading. The other potential benefits of intramedullary nailing include a smaller incision, minimal periosteal stripping, and load sharing device properties. Its relative stability allows good callus formation during the healing process. this is supported by the work of Millett and Mueller et al.^{12,13}

The tens nail usage in multi-fragmentary fracture can lead to telescoping of the pin with shortening of the clavicle. So, the comminuted fractures were excluded as the nail cannot maintain the length of the collarbone in these situations. Hence, Smekal et al do not recommend the use of intramedullary pin in comminuted fractures with severe shortening. The present study discussed the various advantages of the technique; there were specific difficulties which we experienced. Achieving closed reduction was a difficult task, especially in AO B2 fractures and in obese individuals. We attempted various aids like the use of percutaneous reduction clamps and drilling a k-wire into the fragment to manipulate.⁷

In spite of these measures, if still 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 patient and surgeon, can be reduced. The present study does not consider the open reduction of the fracture as unsatisfactory, as despite occur high rate in our practice, we achieved 100% union.

At the end of the study, all the 20 patients in the follow-up group with 14 male and 6 female patients. The mean age was 34.9 years (between 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, 12 patients had AO class B1, and 8 had AO class B2 fractures. All the patients are achieved clinical and radiological union at a mean of 8.6 weeks (range, 6-12 weeks). Eleven of the 20 patients had closed nailing while nine patients 45% required open reduction of their fracture. The average size of the flexible titanium nail used was 2.5 mm (range, 2-3 mm). This finding is supported by the work of Kadakia, Rambani et al.¹⁴

The patients were followed up postoperatively and constant scores were calculated at two months, three months, six months. The average constant rating was 90 (range 82-94). The nails were removed at an average time 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 the fracture has united at around three months which corroborates with the finding of Datta et al.¹⁵

There were no significant 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 refracture after implant removal. The study of Kumar et al support our finding.¹⁶

CONCLUSION

Thus, the intramedullary fixation of a displaced midshaft clavicle fracture is a safe minimally invasive technique. The present study advises the use of minimally invasive ante grade titanium elastic nail for fixation of displaced midshaft clavicle fractures given, faster fracture union, cosmetic satisfaction earlier rehabilitation, lesser morbidity, easier implant, removal and fewer complications although, for comminuted fractures plating remains the procedure of choice.

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Ethical approval: The study was approved by the institutional ethics committee

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