



## 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 common injuries in young individuals, mostly related to sports and road traffic accidents. In contrast, in children and elderly, they are related to falls, and account for approximately 2.6% of all fractures. A middle-third shaft clavicle fracture is the most common site (80% of all clavicle fractures). **Methodology:** A study was carried out in 30 patients with simple middle third clavicular fractures who were treated with closed intra-medullary fixation with TENS nailing. Postoperatively range of movements, ability to get back to routine work were assessed and noted. **Results :** At the end of the study, 30 patients in the follow-up group with 21 male and 9 female patients taken. The mean age was 34.9 years noted. The mean time interval between injury and surgery was 3.55 days (range 1–6 days). For all the patients the clinical and radiological union achieved at a mean of 8.6 weeks (Range, 6-12 weeks). seventeen out of the 30 patients had closed nailing while thirteen patients (43%) required open reduction of their fracture. The average size of the flexible titanium nail used was 2.5 mm (range, 2 - 3mm). **Conclusion :** The present study advises the use of minimally invasive antegrade titanium elastic nail for fixation of displaced midshaft clavicle fractures as a safe minimally invasive procedure.

**KEYWORDS :** Clavicle , mid third fractures, intra-medullary nailing, TENS.

### BACKGROUND

Clavicle fractures are common injuries in young individuals, mostly related to sports and road traffic accidents. In contrast, in children and elderly, they are related to falls, and account for approximately 2.6% of all fractures. A middle-third shaft clavicle fracture is the most common site (80% of all clavicle fractures). Older studies suggest that a fracture of the shaft of the clavicle was a mostly benign injury with an inherently good prognosis when treated nonoperatively even if it is significantly displaced. Neer, reported a nonunion rate of 0.1% with conservative treatment<sup>3</sup>, and Rowe corroborated these findings in 1968 and showed a nonunion rate of 0.8% in conservatively managed patients<sup>4</sup>. Since then, however, any other authors have failed to demonstrate similar good results with conservative treatment.<sup>5,6</sup> This may be because they included the children and adolescents in their studies, children and adolescents have enormous potential for bone healing. This may have shown inaccurate results. Treating conservatively, Hill et al. reported a nonunion rate of 15% in correlation with initial shortening greater than 2cm. 31% of all patients who were reviewed in the study of Hill et al. were not satisfied with treatment results.<sup>7</sup> Therefore, 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.

### MATERIALS AND METHODS

Present study is prospective evaluation of outcome of closed, displaced midshaft clavicle fractures treated with intramedullary titanium elastic nail system which has been done in the Department of Orthopaedics, Andhra medical college from October 2017 to August 2019. Patients were enrolled based on following inclusion and exclusion criteria,

#### Inclusion Criteria:

1. All skeletally mature patients.
2. Closed fractures
3. All the displaced diaphyseal non comminuted /simple comminution clavicle fractures (>2cm displacement) – AO 15 B1 and B2 fractures.

4. Fractures with shortening of over 20mm
5. Middle third clavicle fractures
6. Fractures within one week

#### Exclusion Criteria:

1. Fractures with marked comminution (complex comminution).
2. Brachial plexus injuries
3. Fractures older than one week
4. Pediatric fractures
5. Pathological fractures
6. Open fractures
7. Congenital anomaly or bone disease.
8. Lateral and medial third clavicle fractures
9. Any medical contraindication for surgery.

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

### MATERIALS AND METHODS

The patient placed in the supine position on a radiolucent table with a sand bag under the ipsilateral shoulder. Under general/regional anaesthesia, Preparation and draping done from midline to the upper arm. From midline sternoclavicular joint should be accessible. Intensifier adjusted and access was checked.

#### 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 canal also be used. Titanium ESIN with T-handle was inserted (The size of the nail was measured using formula = 0.4 \* 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 radiographic

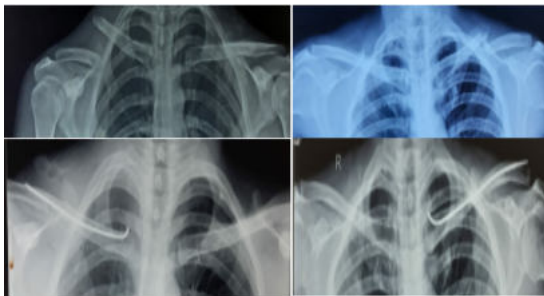
union defined as evidence of bridging callus or obliteration of fracture lines. Clinical union defined as the absence of the tenderness at the fracture site . Time required for unionof the bone was recorded. The linear difference of lengths of the clavicle from sternal end to acromialend between operated and rational side was measured clinically after the union. This gives theamount 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 mal-union, non-union, wound infection, implant failure, implant migration,neurovascular injury, re-fracture after implant removal, soft tissue irritation and the cosmeticoutcomes regarding scars, hardware prominence under the skin and visible deformity.

**Statistical Analysis:-**

Data was collected on excel sheet and analyzed by SPSS software version17.

For analysis of data percentage mean and standard deviation was used.



**Fig:- Mid- Shaft Clavicle Fractures Treated With Intramedullary Titanium Elastic Nail System**

**RESULTS:-**

**Table :-1 Evaluation of Pain**

Pain scale	Points	Number of patients	
		At 3 months	At 6 months
No pain	5	18(60%)	25(83%)
Mild pain	4	9(30%)	3(10%)
Pain after unusual activities(heavy weight lifting)	3	3(10%)	2(7%)
Pain at rest	2		
Marked pain	1		
Complete disability	0		

Out of the 30 patients ,At 3 months 18(60%) patients experienced no pain. At 6 months 25(83%) patientsexperienced no pain with 5 points.

Out of 30 patients, 9(30%) patients experienced mild pain and at 6 months 3(10%) experienced mild pain with 4 points.

Out of 30 patients,at 3 months 3(10%) patients experienced pain after unusual activities (heavy weight lifting ) , at 6 months 2(7%) patients experienced pain after unusual activities (heavyweight lifting ) with 3 points.

**Table :-2 Range Of Movements:**

S.NO	Shoulder movements	Average (mean± standard deviation)
1	Flexion	165.75 +9.21
2	Abduction	166.25+10.49
3	External rotation	72.5 +6.5
4	Internal rotation	74.25+5.19

Out of 30 patients shoulder range of movements, Average (mean + standard deviation) in flexion is165.75 + 9.21, Abduction is 166.25 + 10.49, External rotation is 72.5 + 6.5, and internal rotation is 74.25 + 5.19

**Table :-3 Muscle Strength**

S.NO	MUSCLE STRENGTH	NO. OF PATIENTS	
		At 3 months	At 6 months
1	Normal	23(76%)	27(90%)
2	Against resistance	7(24%)	3(10%)
3	Against gravity	-	-

4	Elimination of gravity	-	-
5	Flicker	-	-
6	Paralysis	-	-

Out of the 30 patients ,At 3 months 23(76%) patients muscle strength was normal,At 6 months 27(90%) patientsmuscle strength was normal.

Out of 30 patients,at 3 months 7(24%) patients muscle strength against resistance is seen and at 6months 3(10%) patient muscle strength against resistance is seen.

**Table :-4 Occupation Limitations**

S.NO	OCCUPATION STATUS	NO. OF PATIENTS	
		At 3 months	At 6 months
1	Regular work	23(76%)	27(90%)
2	Restricted work	7(24%)	3(10%)
3	Unable to work	-	-

Out of the 30 patients ,At 3 months 23(76%) patients able to do regular work. At 6 months 27(90%) patientsable to do regular work.

Out of 30 patients 7(24%) patients able to do restricted work. 3(10%) patients able to dorestricted work.

**Table :-5 Time Taken For Fracture Union**

FRACTURE TYPE	AVERAGE TIME FOR UNION(WEEKS)	AVERAGE CONSTANT SCORE (mean ± standard deviation)
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 30 patients, fracture type AO 15 B1, Average time for union is 8 weeks with AVERAGE CONSTANT SCORE(mean + standard deviation) is 90.33 ± 3.91.

Out of 30 patients, fracture type AO 15 B2, Average time for union is 10 weeks with AVERAGE CONSTANT SCORE(mean + standard deviation) is 89.5 ± 3.16.

Out of 30patients, fracture type B1+B2, Average time for union is 8.8 weeks with AVERAGE CONSTANT SCORE(mean + standard deviation) 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.

**Table :-6 Functional Evaluation Using Constant Score:**

S.NO	RESULT	CONSTANT SCORE	NO. OF PATIENTS	PERCENTAGE
1	EXCELLENT	86-100	27	90%
2	GOOD	71-85	3	10%
3	FAIR	56-70	0	0%
4	POOR	1-55	0	0%

Out of 30 patients, 27 patients (90%) functional evaluation using constant score is Excellent, Out of 30patients, 3 patients (10%) functional evaluation using constant score is good.

**DISCUSSION:-**

For the clavicle fractures ,Plate osteosynthesis, external fixation and intramedullary fixation are the surgical options. Plate osteosynthesis is considered as a standard method for the surgicaltreatment of clavicle fractures.<sup>7</sup> However, complications after plate osteosynthesis are relativelycommon. In a multicenter prospective randomized trial, plate osteosynthesis has better functionaloutcome than non-operative treatment of displaced clavicle fractures with a decreased rate of nonunion and symptomatic malunion.<sup>8,9</sup>

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 superficialinfection, dysesthesia in the region of injury, as well as implant loosening with

loss of reduction. Therefore intramedullary stable nailing is an established alternative fixation method.<sup>10,11</sup> 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.<sup>12,13</sup>

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 wire into the fragment to manipulate.<sup>7</sup>

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 do 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, 30 patients in the follow-up group with 21 male and 9 female patients taken. The mean age was 34.9 years noted. The mean time interval between injury and surgery was 3.55 days (range 1–6 days). For all the patients the clinical and radiological union achieved at a mean of 8.6 weeks (Range, 6–12 weeks). seventeen out of the 30 patients had closed nailing while thirteen patients (43%) required open reduction of their fracture. The average size of the flexible titanium nail used was 2.5 mm (range, 2 - 3mm). This finding is supported by the work of Kadakia AP, Rambani R, et al.<sup>14</sup>

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 Saha P, Datta P et al.<sup>15</sup>

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 H and Banga RK support our finding.<sup>16</sup>

## CONCLUSION:-

The present study advise the use of minimally invasive antegrade titanium elastic nail for fixation of displaced midshaft clavicle fractures as a safe minimally invasive procedure. It has 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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