



A COMPARATIVE STUDY OF FUNCTIONAL OUTCOME BETWEEN LOCKING PLATING AND TITANIUM ELASTIC NAILING IN MIDDLE THIRD CLAVICLE FRACTURES

Orthopaedics

Dr. Sachin Joshi Professor & HOU, Department of Orthopaedics, GMC Kota.

Dr. Aaditya Patni* Junior Resident, Department of Orthopaedics, GMC Kota. *Corresponding Author

Dr. Nitin Kumar Bairwa Senior Resident, Department of Orthopaedics, GMC Kota.

ABSTRACT

Context: Clavicular fracture is a common trauma presentation due to superficial location. Common techniques of fixation include an open reduction and internal fixation by antero-superior precontoured locking plate or open/closed intramedullary fixation with Titanium Elastic Nail. **Aims:** Aim of this study was to evaluate and compare results of internal fixation of displaced middle third clavicle fractures using these two modalities. **Settings And Design:** Hospital based Prospective Comparative Randomized interventional study **Methods And Material:** Two groups were made for each modality with 25 cases each. Patients were followed for up to 6 months. Primary outcome measures were Constant and Murley scores, and clinical and radiological union. Secondary outcome measures included complications. **Statistical Analysis:** Chi square test, and independent t tests were performed to calculate p value and hence the significance of the results. **Results:** Mean time of clinical union of plating group was 7.36 weeks v/s 9.68 weeks for the nailing group. Mean time of radiological union was 9.60 weeks in plating group v/s 12.16 weeks for nailing group. Constant scores were 91.24 for plating group while it was 87.36 for nailing group at the end of the 6 month follow up. 76% of patients in plating group had no complications while 64% of patients in nailing group were free of complications. Nailing group had more delayed union, nail migration, skin irritation, and 1 case had peri-implant fracture. **Conclusions:** Open reduction Internal fixation of displaced middle third clavicle fractures with precontoured locking plate led to better fracture union rates, less complications, and better functional outcomes as compared to Closed/open reduction internal fixation with titanium elastic nail system.

KEYWORDS

Clavicle, locking compression plates, titanium elastic nail, constant score

INTRODUCTION

The clavicle is a horizontal 'S' shaped bone which forms a strut between the sternum and scapula, playing a suspensory role. Fracture of clavicle is a very common presentation due to its relative superficial location. Previously surgical fixation was not preferred due to frequent complications, and studies suggesting excellent outcomes with conservative management^{2,3}. But later recent studies suggest non union rates to be higher than previously reported.¹

Common techniques for fixation include either an open reduction internal fixation by a recon or precontoured plate; or open/closed reduction intramedullary fixation.¹

Orthopaedic journals are filled with studies comparing surgical and conservative management. But a scarcity exists comparing the two modalities of operative fixations of middle third clavicle fractures.

Hence the purpose of this study was to compare the results of internal fixation of displaced mid shaft clavicle fractures using antero-superior precontoured locking plates and closed/open reduction and ante/retrograde Titanium elastic nail.

Subjects And Methods:

This was a hospital based comparative prospective randomised interventional study.

The study was approved by the institute's Ethical committee. Study duration was 2 years.

The patients were allocated the type of surgery on an alternate basis, i.e. the 1st patient was operated with plating, next by nailing and so on. Hence 2 groups were formed; A sample size of 25 cases were included in each of the groups. Patients aged 18 to 50 years of age with middle third clavicle fractures, consenting to participate in the study were included in the study. Patients with (1) neurovascular injuries, (2) open fractures, (3) pathological fractures, (4) segmental fractures, (5) those who underwent operation after 7 days of date of injury (6) pre-existing shoulder abnormalities and (7) Fractures associated with Acromioclavicular or Sterno-Clavicular joint involvement were excluded from the study.

OPERATIVE TECHNIQUE

Patients were kept fasting for 6 hours before surgery. A systemic antibiotics usually Inj. Ceftriaxone 1gm intravenously administered 30 minutes before surgery to all patients. All patients were operated

under inter-scalene block or general anaesthesia. Patient in supine position with one bolster in between the scapula. The neck, chest, axilla, shoulders and arm prepared.

Orif With Plating

An incision made, about 7-9 cms on the line joining sternal notch to anterior edge of acromion centered over fracture site. The skin subcutaneous tissue divided without undermining the edges and platysma released from lateral side and supraclavicular nerves protected with a sling. The overlying clavipectoral fascia and periosteum next divided. The osseous ends freed from surrounding tissue. Fracture fragments reduced and plate applied over the antero-superior aspect of the clavicle. Comminuted fragments, if any, secured with lag screws wherever possible. At the junction of the medial and middle third of the clavicle, the inferior surface was exposed so that a protective instrument could be inserted during drilling to prevent injury to neurovascular structure underneath it. The locking compression plate was fixed to the medial and lateral fragment with locking screws/ cortical screws and at least three screws in medial and lateral fragment applied. Wound closed in layers after ensuring meticulous hemostasis and sterile dressing applied.

CRIF/ORIF with TENS

The sternoclavicular joint was palpated and marked on the affected side. We used image intensification in 45° cephalad and 45° caudal directions. This provided us with images in two planes, 90° apart. A small incision made approximately 1 cm lateral to the sternoclavicular joint. The anterior cortex opened using a sharp, pointed awl. A TENS inserted (the diameter varied from 2 to 3 mm depending on the width of the bone). Before introduction, the original curvature of the small and flattened nail tip straightened slightly to allow better gliding in the small medullary canal. We attempted closed reduction under fluoroscopic control using two percutaneously introduced pointed reduction clamps. If closed reduction failed, an additional incision (mini-open) made above the fracture site for direct manipulation of the main fragments. The nail was then advanced manually until it was just medial to the acromioclavicular joint. Accurate maneuvering of the nail tip is necessary under fluoroscopic control to avoid penetration of the thin dorsal cortex. After reaching the end point, the fracture was compressed and the nail cut close to the entry point to minimize soft tissue irritation, at the same time leaving sufficient length behind for easy extraction later on. The fascia and skin closed in layers.

POST OPREHABILITATION

Patients were discharged with the pouch arm sling.

Immediate post operative – Gentle pendulum exercises were started according to the pain tolerance.

3 weeks – Gentle active range of motion exercises allowed with abduction limiting to 90°.

4-6 weeks – Active to active assisted range of motion in all planes.

Fracture union – When fracture union (defined as radiographic union with no pain or motion with manual stressing of the fracture) was evident, muscle strengthening exercises were initiated.

8-12 weeks – Isotonic and Isometric exercises were administered.

3 months – Full unrestricted activities were allowed including sports activities.

Follow up

Patients were followed up for a period of 6 months.

Functional outcomes were measured using Constant score.

Clinical Union was assessed by absence of crepitus/abnormal movement at the fracture site, absence of pain or tenderness at the fracture site on weight-bearing, absence of pain on palpation at the site of fracture, and the ability to weight-bear.

Radiological union was assessed by callus size, cortical continuity, and progressive loss of fracture line.

Secondary outcome measures included complications like infection, mal union, non union, implant prominence, migration and skin irritation.

Statistical Analysis

The primary and secondary outcomes were noted at the end of the follow-up period and compared for statistical significance for analyzing the difference between the 2 groups ($p < 0.05$ was considered to be significant).

RESULTS:

Total 25 patients were present at the end of the study duration in each group. Mean age in the plating group was 29.64 +/- 11.796 years and the TENS group was 32.64 +/- 9.869 years. In both of the groups, 10 (40%) patients were female while 15 (60%) were male. Right side was involved more than the left side in both the groups [15 (60%) patients in plating group, and 16 (64%) in the TENS group]. Most common mode of injury was Road traffic accidents, followed by falls and assaults respectively as depicted in table 1.

	RTA	Falls	Assault
Group 1 (Plate)	17 (68%)	6 (24%)	2 (8%)
Group 2 (TENS)	14 (56%)	8 (32%)	3 (12%)

Most patients were operated within 3-5 days of the date of injury. This is shown in table 2.

	<3 Days	3-5 days	>5 days
Group 1 (Plate)	6 (24%)	14 (56%)	5 (20%)
Group 2 (TENS)	8 (32%)	13 (52%)	4 (16%)

There was no statistical difference between the 2 groups in terms of the time lapsed between the injury and surgery.

Among the TENS group, 16 cases (64%) were done by closed reduction while 9 cases (36%) required (mini)open reduction.

Primary Outcomes

Patients treated with plating showed earlier signs of clinical union than that of the TENS group. The mean number of weeks of clinical union was 7.360 in the Group I and 9.680 in the Group II. The difference between the groups was statistically significant (p value = 0.001), depicted in table 3.

	Mean weeks of clinical union	Standard Deviation	Standard Error
Group 1	7.360	1.577	0.315
Group 2	9.680	1.625	0.325

This was true for the signs of radiological union too, where the patients in the plate group showed early signs of radiological union compared to the TENS group. The mean number of weeks of clinical union was

9.600 in the Group I and 12.160 in the Group II. The difference between the groups was statistically significant (p value = 0.001), depicted in table 4

	Mean weeks of radiological union	Standard Deviation	Standard Error
Group 1	9.600	1.914	0.382
Group 2	12.160	2.267	0.453

The constant scores also showed similar trends with the plating group exhibiting significantly better scores than the TENS group (p value = 0.001). The mean Constant and Murley score was 91.240 in the Group I and 87.360 in the Group II as seen in table 5.

	Mean constant scores	Standard Deviation	Standard Error
Group 1	91.240	4.446	0.889
Group 2	87.360	5.581	1.116

Secondary Outcome

The secondary outcomes like infections, delayed union, implant prominence etc. were also measured.

19 out of 25 patients (76%) in the Plating group were free of any type of complications, while 16 out of 25 patients (64%) in the TENS group were complications free. The difference between the 2 groups was significant (p value < 0.043).

Infection was seen in 2 patients (8%) of the plating group, which was treated with oral antibiotics.

Delayed union was seen in 4 patients (16%) in TENS group [out of these 4, 3 were done with mini open while 1 was done closed nailing] against the 1 patient (4%) in plating group.

3 of the patients (12%) in the Plating group had complaints of shoulder stiffness, which relieved on regular physiotherapy.

Patients in the TENS group also suffered with implant related complications like nail migration (2 patients, 8%), 1 patient (4%) had peri implant fracture, which was treated with exchange nailing. It was noted at the time of removal, that the nail size was of 2 mm, which may have been the reason of the peri-implant fracture. 2 of the patients in this groups complained of skin irritation due to nail prominence. This can be seen in table 6.

	No complication	Infection	Delayed Union	Shoulder stiffness	Nail migration	Peri implant fracture	Skin irritation
Group 1	19 (76%)	2 (8%)	1 (4%)	3 (12%)	0	0	0
Group 2	16 (64%)	0	4 (16%)	0	2 (8%)	1 (4%)	2 (8%)

DISCUSSION:

Clavicle fractures are one of the most common fractures encountered in the casualty and orthopedic outpatient department. Previously it was a common notion to treat these fractures conservatively. But later on studies done in 1997 by Hill et al⁴, and in 2004 by Robinson et al⁵ showed that conservative management of displaced middle third clavicle fractures had a poor functional outcome. Also, better understanding of fracture biomechanics led to better surgical options.

2 broad categories of implants available for clavicle fracture fixation are nail and plate.

Plating has the benefits of maintaining length, specially in comminuted fractures. Implant migration and breakdown are infrequent.

Nailing although causes less soft tissue damage and periosteal stripping and preserves fracture hematoma, but it does have its own disadvantages, like :

1. No locking options.
2. Implant migration can lead to skin irritation, or some more serious complications like injury to infraclavicular structures.
3. The nail can break or bend.
4. Shortening occurs overtime in comminuted fractures.
5. Intramedullary nailing of a straight nail through the curved anatomy of clavicle is in itself a difficult procedure.

In our study, 25 patients were treated with ORIF with Precontoured clavicle plates and 25 with CRIF/ORIF with TENS.

Males were more commonly affected than females. 30 patients were male while 20 patients were female. It is comparable with the studies of Elidrisi mohammed et al⁶ and Dhoju et al⁷ which also showed male predominance. In our study, the mean age group was 31.14 years. This indicates that these fractures are more common in young active individuals.

The mean time of clinical union was found to be 7.36 weeks for the plating group while it was 9.68 weeks for nail group. The difference was statistically significant. (p value 0.001)

Clinical Union was assessed by absence of crepitus/abnormal movement at the fracture site, absence of pain or tenderness at the fracture site on weight-bearing, absence of pain on palpation at the site of fracture, and the ability to weight-bear.

The average duration of radiological union was 9.6 weeks for the group which underwent plating while it was 12.16 weeks for group with TENS nail. The difference was statistically significant. (p value 0.001) Radiological union was assessed by callus size, cortical continuity, and progressive loss of fracture line.

In our study, Constant and Murley score was used to assess the functional outcome. The mean score of the plating group was 91.24 which is Excellent result. The group which underwent nailing had a mean score of 87.36 which is Good result according to the study criteria. The difference was statistically significant (p value 0.001).

These findings were also noted by Nidhi Narsaria et al⁸ in 2014, who did a similar study, and noted higher constant scores in plating group, compared to nailing group at the end of 2 months. Although the significance was noted to be reduced at the end of 2 year follow up. They also noted insignificant difference between infection and revision surgery rates in the either groups.

Various studies has compared the functional outcomes of conservative and plating, conservative and nailing. But very few studies has compared these two modalities of surgical intervention.

	Zlodowski et al ⁹ (2005) 2144 cases			Smekal et al ¹⁰ (2009) 60 cases		Chen QY et al ¹¹ (2011) 60cases		Our study (2022) 50 cases	
Result	Non oper ative meth od	Plat ing	Elastic nailing	Non oper ative meth od	Elastic Nailin g	Non ope rati ve meth od	Elastic Nailin g	Plat ing	Elastic Nailing
Nonun ion	5.90 %	2.50 %	1.60%	3	Nil	3	Nil	Nil	Nil
Malun ion	-	-	-	2	Nil	2	Nil	Nil	Nil
Infecti on	-	2.40 %	-	Nil	Nil	Nil	Nil	2	Nil
Nail migrat ion	-	-	-	-	-	-	5	-	2

Limitation

- Due to limitation of study Follow up of 6 months, a long term follow up of the patients could not be done. A study with a longer follow up would further enhance the quality of the study.
- We had a sample size of 25 patients in each group. Further studies with larger sample sizes are needed to draw better conclusions.
- The study was done in a single city at our department. This can lead to regional biases. A larger study done at multiple centers is recommended.

CONCLUSIONS

In our study, we concluded that Open reduction and internal fixation of displaced middle third clavicular fractures with precontoured clavicular locking plates has led to better fracture union rates, less complications and better overall functional outcomes as compared to CRIF/ORIF with titanium elastic nail systems.

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