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## Prospective comparative study of functional outcome of displaced midshaft clavicle fractures treated by locking plating versus minimally invasive titanium elastic nail fixation

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### Abstract

**Introduction:** The clavicle is the most commonly fractured bone, which accounts for 5–10% of all fractures. More than half of these fractures are displaced.

Traditionally clavicle fractures are treated non-operatively. But recent studies show higher rates of nonunion upto 15% and unsatisfactory functional outcomes despite fracture union with conservative management. Operative management of these fractures had better outcomes and a lower rate of nonunion and symptomatic mal union when compared with non-operative treatment.

Commonly either plating or nailing is done for middle third clavicle fractures. It is imperative to know the complications and outcomes with both these procedures.

**Aim:** The aim of our study is comparative analysis of outcome of Displaced middle third clavicle fractures in patients treated with plate osteosynthesis and intramedullary tens nail.

**Materials and Methods:** This is a comparative study undertaken in the department of Orthopaedics, Meenakshi Medical College and research institute, Enathur from 01/ 09/2017 to 31/08/2018. Within the period of study, 40 patients with displaced middle third clavicle fractures were operated alternatively with Plating and nailing (titanium elastic nail). We had 20 patients who were operated with Locking plate (20 Precontoured Clavicle Plate) and 20 Patients who were operated with nailing (titanium elastic nail). Outcome measures Like Blood loss, operative time, wound size, union rate and union time and Complications like infection, Nonunion, implant irritation and shortening Were compared between the two groups. Functional outcome was based on Quick DASH score.

**Results:** The mean blood loss in plating group was 89 ml and nailing Group was 35.5ml ( $p < 0.001$ ). The mean operative time in plating was 53.75 and in nailing was 49 ( $p = 0.309$ ). Mean wound size in plating was 10.05 cms and nailing was 4.15 cms ( $p < 0.001$ ). We had 100% union rate in both the groups. The mean time for clinical and radiological union in Plating group was 7.50 weeks and 11.75 weeks whereas in nailing group it was 7 weeks and 12.7 weeks ( $p = 0.172$  and  $p = 0.003$ ). We had excellent Outcomes in 13 patients (65%), good outcome in 5 patients (25%) and poor outcome in 2 (10%) patients in the plating group whereas in the nailing group we had 12 patients (60 %) with excellent, 8 (40%) patients with good outcome. No poor outcome in nailing group. We had superficial infection in 2 patients (%) in plating group and no patients in nailing group. Implant irritation occurred in 3 patients (15%) in plating and no patient in nailing groups. Lateral TENS protrusion occurred in 2 patients in nailing group (10%).

**Conclusion:** We conclude that though nailing has advantage over plating during Surgery and postoperative period, on long term follow up there is no significant functional difference between plating and nailing for displaced Middle third clavicle fractures.

**Keywords:** clavicle fractures, locking plate, precontoured plate, titanium elastic nail

### Introduction

The clavicle is the most commonly fractured bone, which accounts for 5–10% of all fractures and 44% of all shoulder injuries [1-3]. Biomechanical studies reveal that, due to the unique configuration and unique shape of the clavicle, the middle third is the weakest and accounts. For 80% of clavicle fractures and more than 50 percent of these fractures are displaced [1-2]. The rate of mid clavicle fractures is more than twice high in men as in women. The peak incidence occurs in the third decade of life [4].

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Various options for treatment of acute clavicle fractures are Non Operative Treatment (mostly sling /figure-of-eight bandage), open reduction and internal fixation with plates and screws, and closed/open reduction and internal fixation with intramedullary device (wire, pins, or Nail).

Traditionally, these fractures were treated non operatively. Earlier studies reported nonunion rate of less than 1% with conservative management [5, 6]. But those, however, were all not standardized study. They had variable proportions of patients in various ages, variable site of fracture and of variable nature of fracture. They also included many cases of children who have excellent results with conservative treatment due to their good remodeling capacity.

Recent studies show higher rates of nonunion upto 15% and unsatisfactory functional outcomes despite fracture union with Conservative management [7-15]. Moreover, even malunion of the fracture Clavicle has been described to be a separate clinical entity [19].

Operative management of these fractures had better outcomes and lower rates of nonunion and symptomatic mal union when compared with non-operative treatment. Primary internal fixation of displaced Middle third clavicle fractures leads to predictable and early return to function [22].

Surgical options include either plate osteosynthesis or intramedullary nailing. While both plating and nailing are commonly done for clavicle fractures, it is important to compare the outcome and Complications with both these procedures.

#### Aim of the study

This prospective comparative study was done to evaluate the functional outcome of implants of different design - titanium elastic intramedullary nail versus locking plating in treatment of displaced Midshaft clavicular fractures.

#### Materials and Methods

This comparative analysis of displaced middle third clavicle fractures in 40 patients treated with plate osteosynthesis and intramedullary nailing is a prospective study undertaken at the Department Of Orthopaedics, Meenakshi medical college and research institute, Enathur from 1<sup>st</sup> September 2016 to 31<sup>st</sup> august 2017. Based on previous studies sample size was calculated to be 40 and the patients were alternatively taken for plating and tens nailing making it a total of 20 in each group. The study was approved by the ethical committee of our college. Prior written informed consent was obtained from all the patients. The statistical analysis was done using paired T test.

#### Inclusion criteria

- Age >16 and <65 years of age
- Duration <2 weeks
- Dislocation, defined as at least one shaft width difference in height between the fracture parts, regardless of the reduction.

#### Exclusion criteria

- Compound fractures.
- Pre-existent morbidity of the ipsilateral arm, shoulder or hand.
- Presence of neurovascular injury

Our study consisted a total of 40 patients with middle third clavicle fractures over a period of 14 months from September

2016 to august 2017. The patients who were admitted with displaced middle third clavicle fractures meeting the inclusion criteria are operated alternatively with plating(locking plate) and nailing(TENS). Over the period of study in which 40 patients were operated, the patients are grouped into two. One group with 20 patients were operated with open reduction and internal fixation with plate osteosynthesis (locking clavicle plate) and another group with 20 patients were operated with closed / open reduction and titanium elastic nailing.

The patients were followed up 1 month, 3months and 6 months.

Postoperatively and clinical and radiological union are assessed.

#### All the cases were analyzed as per the following criteria:

- Age distribution
- Sex distribution
- Side of injury
- Planning of treatment
- Time interval between injury and surgery

**Table 1: Age Distribution**

S. No	Age group	No of patients		Percentage	
		Plating	Nailing	Plating	Nailing
1	20-29	4	8	20%	40%
2	30-39	6	8	30%	40%
3	40-49	4	3	20%	15%
4	50-59	4	1	20%	5%
5	60-69	2	0	10%	0
	Total	20	20	100%	100%

**Table 2: Sex Distribution**

S. No	Sex	No of patients		Percentage	
		Plating	Nailing	Plating	Nailing
1	Male	18	17	90%	85%
2	Female	2	3	10%	15%
	Total	20	20	100%	100%

**Table 3: Side of Injury**

S. No	Side of injury	No of patients		Percentage	
		Plating	Nailing	Plating	Nailing
1	Right	8	11	40%	55%
2	Left	12	9	60%	45%
	Total	20	20	100%	100%

#### Planning of treatment

On arrival Xray is taken and temporary cuff and collar sling was given for pain relief. Day 1 after injury cases were planned for plating or nailing and conservative management patients were excluded from the study.

**Table 4: Mean time delay between injury and surgery**

S. No	Parameter	Plating	Nailing
1	Mean delay between injury and surgery (days)	4.65	2.55

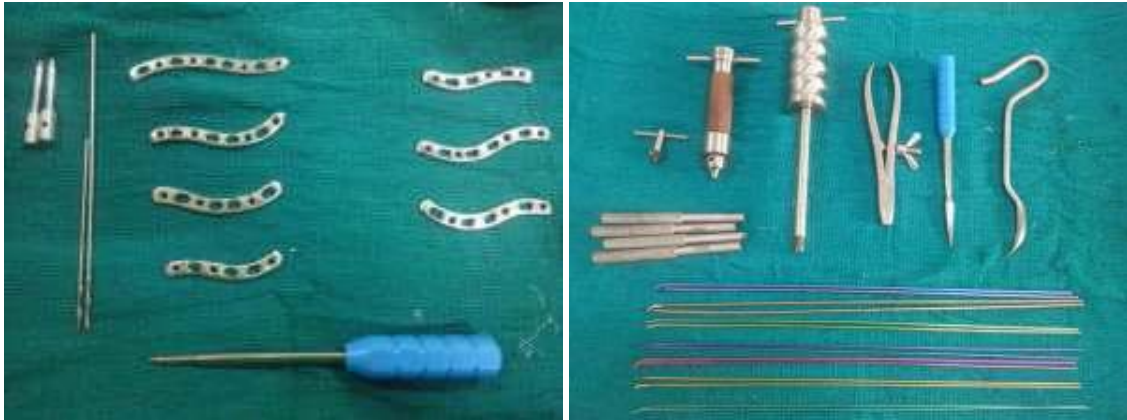
#### Implant

##### Plating

Plating is done using locking clavicle plate.

##### Nailing

Titanium elastic nail made of alloy such as Ti-6Al-7Nb is used.



**Surgical technique for plating**

**Preoperative planning**

The preoperative radiographic assessment was done to determine the length of the plate to be used and to determine the number and position of screws.

**Anesthesia**

General anesthesia/regional block

**Position and preparation**

Supine position with sand bag in the interscapular region. Operative site including the arm was prepared and draped so that it can be Intra-operatively mobilized and used as a reduction aid. *Pre-operative antibiotics* were usually given within one hour before surgery after a test dose.

**Surgical approach for Plating**

**Skin incision** - A curvilinear incision along the skin crease lines was made.

The platysma was divided to expose the periosteum. Minimal dissection of periosteum was done to expose the fracture. The fracture ends were distracted and the fracture reduction was done.

Temporary fixation with k wires are done if necessary.

**Lag screws**

**Plate length**

Appropriate plate was selected for the fracture. If bending is needed the locking plates drill sleeve was inserted into the threaded hole to avoid damage to LCP threads.

**Temporary fixation of the plate**

Plate was positioned on the reduced bone and temporarily fixed with plate holding forceps.

**Screw Insertion**

If in case both locking and cortical screws was to be used, cortical screw was applied before locking screws to pull the bone to the plate.

**Screw fixation-3.5mm cortical screws**

Using the 2.5 mm drill bit along with the 3.5 mm universal drill guide both cortex were predrilled. Using the depth gauge the length of the cortical screw required was measured. The appropriate 3.5 mm cortical screw was inserted using the hexagonal screwdriver.

**Fixation with 3.5 mm locking screws**

If the locking screw is to be inserted first it was made sure that the fracture is well reduced and the plate is close to the bone. After measuring the screw length the locking screw was inserted using hexagonal screwdriver and tightened until it got locked. After thorough irrigation, absorbable interrupted sutures to close the myofascial layer was done so that it covers the hardware. Subcutaneous layer closure done with absorbable interrupted sutures. Skin closed with subcuticular sutures to make it cosmetically better scar. Sterile dressing was applied. Suction drain not applied for any case. Arm sling was applied for protection and to minimize the operative site pain.



**Patient positioning**



**Skin incision**



**Final position of plate**

### **Surgical technique for tens nailing**

#### **Anesthesia**

General anesthesia/regional block.

#### **Position**

Supine position with sand bag in the interscapular region.

#### **Approach**

Skin incision of size 1-2 cm was made 1.5 cm lateral to sternoclavicular end. With a 2.5mm drill bit, an opening was made in the anterior cortex of the clavicle and then widened using a small bone awl. The titanium elastic nail of 2-2.5 and 3 mm diameter depending upon the medullary diameter of the patient was taken and was fixed in a universal chuck with a T handle. With oscillating movements the nail was advanced up to the fracture site.

If closed reduction was not possible an additional small incision of size 2 to 3 cm was made over the fracture site to negotiate the fragments. The nail was advanced into the lateral fragment. The nail was cut off at the entry site leaving about 1 cm for removal. Skin was sutured without drain.



**Patient positioning**



**Nail entry**



**Fracture reduced and nail advanced**

#### **Postoperative care and rehabilitation**

The post op protocol for both group of patients are same. The arm is not elevated above 120 in any plane till 4 weeks postop.

The arm was maintained in a sling on a full-time basis for two weeks.

The patients are instructed not to lift objects > 2 kg in the operated side for 6 weeks.

The patients are encouraged to maintain good upright shoulder girdle posture.

#### **1<sup>st</sup> Week**

- Exercises (3x per day):
- Pendulum exercises
- Ball squeezing exercises

- Isometric exercises of rotator cuff external and internal rotations with arm by the side are started
- Isometric shoulder abduction, adduction, extension and flexion with arm at side are started.

#### **Weeks 2 - 4**

- Suture removal done on 12th post operative day.
- Soft-tissue treatments for associated shoulder and neck musculature for comfort.
- Gentle pulley for shoulder ROM 2x/day.
- Elbow pivots PNF (proprioceptive neuromuscular facilitation), wrist PNF.
- Isometric scapular PNF, mid-range.

#### **Weeks 4 - 8**

- Mid-range of motion rotator cuff external and internal rotation exercises started.
- Active and light resistance exercises (through 75% of ROM as patient's symptoms permit) without shoulder elevation and avoiding extreme end ROM.

#### **Weeks 8 - 12**

- Full shoulder Active ROM in all planes.
- Increase manual mobilizations of soft tissue as well as glenohumeral and scapula thoracic joints for ROM.
- No repeated heavy resisted exercises or lifting until 3 months.

#### **Weeks 12 and beyond**

- More aggressive strengthening program as tolerated were started.
- Increase the intensity of strength and functional training

for gradual return to activities and sports.

- After clinical and radiological union, most patients were allowed to participate in sports activities usually by three to four months.
- All the patients were reviewed on 2nd week, 4th week and then every monthly for the next three months and thereafter once in three months. During follow up, patients were clinically evaluated for pain, activities of daily life, range of movements of shoulder joint and power.

- Radiological evaluation of the union was done by taking serial x-rays.
- Radiological union was taken to be achieved when there is bridging trabeculations across the fracture on three of four cortices at the fracture line in plating and union with callus in nailing. Any changes in the previous alignment, screw pullout or implant failure also noted.
- Functional outcome was based on the Quick DASH scoring system.

**Table 5:** Comparing the functional outcome and quick DASH score

S. No	Outcome	Quick DASH score
1	Excellent	< 10
2	Good	10 – 30
3	Fair	31 – 50
4	Poor	Greater than 50

**Results**

- The results are analysed under the following headings.
- Intra operative details
- Duration of hospital stay
- Post-operative complications
- Outcome

**1. Intra operative details**

**Table 6:** The following parameters are analyzed intra operatively

S. No	Parameter	Plating	Nailing	P value
1	Mean Blood loss (ml)	89	35.5	<0.001
2	Mean Operative time(mins)	53.75	49	0.309
3	Mean wound size(cms)	10.05	4.15	<0.001
4	Closed reduction	-	13	-
5	Open reduction	20	7	-

**Table 7:** Duration of Hospital Stay

S. No	Parameter	Plating	Nailing	P value
1	Mean duration of hospital stay(days)	6.40	6	0.154

**3. Post operative complications**

- 2 (10%) patients in the plating group developed superficial infection on the 3<sup>rd</sup> post-operative day which subsided with i. vantibiotics.
- No patient in the nailing group developed any infection. There was no deep infection in either group.

- We had no cases of Nonunion /malunion.
- 3 (15%) patients in the plating group had implant irritation dueto the prominent hardware.
- 2 (10%) patients had lateral TEN protrusion and no patient had medial TEN protrusion (which led to implant irritation) in the nailing group.
- There was no implant failure in either group and there was no need for re osteosynthesis/ secondary procedure to achieve union in either group.

**Table 8:** Shows the incidence of complications in plating and nailing

S. No	Complication	Plating	Nailing
1	Infection A. Superficial	2 (10%)	0
	B. Deep	0	0
2	Non union	0	0
3	Mal union	0	0
4	Implant failure requiring removal	0	0
5	Implant irritation	3 (15%)	0
6	Medial TEN protrusion	0	0
7	Lateral TEN protrusion	0	2 (10%)
8	Re-osteosynthesis	0	0
9	Secondary procedures	0	0
10	Mean Shortening (mms)	0	0

**4. Outcome**

The final outcome measure consists of union rate, union time (Clinical and radiological) and Quick DASH scoring.

**Table 9:** Shows comparison of outcome between nailing and plating and its P value

S. No	Parameter	Plating	Nailing	P Value
1	Union rate	100	100	-
2	Mean union time (weeks)			
	Clinical union	7.50 weeks	7 weeks	0.172
	Radiological union	11.75 weeks	12.7 weeks	0.003
3	Mean quick DASH score			
	1 month	19.9	13.58	0.19
	3 months	12.15	6.63	0.12
	6 months	9.3	5.29	0.32

**Functional outcome**

Based on the Quick DASH scoring, the following are the outcomes.

**Table 10:** Shows the final outcome between nailing and palting

S. No	Outcome	Plating	Nailing
1	Excellent	13 (65%)	12 (60%)
2	Good	5 (25%)	8 (40%)
3	Fair	-	-
4	Poor	2 (10%)	-

## Discussion

Clavicle fractures, one of the common fractures of adult population are often treated conservatively since the time of Hippocrates. Thorough understanding of the musculoskeletal anatomy and the dynamic relation between clavicle and shoulder motion is essential in management of clavicle fractures. The deforming forces, the degree of comminution and overriding causes shortening of the clavicle. Shortening more than 2cms influences the outcome in the Midshaft clavicle fractures.

In clavicle fractures, the major determining factor for restoration of function of upper limb is the restoration of clavicular length. As early as 1790, Therselben described that the chief function of clavicle is to keep the shoulder blade away from the axial skeleton which helps in proper functioning of the shoulder<sup>[50]</sup>. His postulates were confirmed by our study with the restoration of clavicular length after surgery resulted in better functional outcome.

For a long period of time clavicle fractures were traditionally managed conservatively. There was unanimous thought to leave these fracture conservatively with a simple sling or figure of 8 bandage.

Based on review of various recent studies on the management of clavicle fractures by conservative methods, the effectiveness of non-operative management is found to be deficient in providing optimal outcome particularly in young population and had unsatisfactory results.

Recent studies suggest that the operative management of middle third clavicle fractures resulted in lower nonunion rates, improved functional outcome, faster mobilization, better cosmesis and increased patient satisfaction<sup>[9-22]</sup>.

Operatively, clavicle fractures are commonly managed either with plate osteosynthesis or intramedullary elastic nailing. It becomes imperative for a surgeon to know the various aspects of plating and nailing and also their advantages and disadvantages to make a proper choice of surgery.

Theoretically, both plate osteosynthesis and titanium nailing have their own advantages. A biomechanical study suggest that plate fixation results in more rigid fixation when compared to nailing and this helps in having an early rehabilitation<sup>[51]</sup>. Plate fixation is technically easy to perform and provides rotational control. Disadvantages include large wound size and implant prominence.

On the other hand, Titanium elastic nailing is less invasive, has lesser rate of implant prominence and after union implant removal can be done as an outpatient procedure with minimal dissection<sup>[52]</sup>. Further, in nailing if closed reduction is achieved this has an advantage of preserving the fracture hematoma which speeds up fracture healing. Disadvantages are that it does not provide rotational control. TEN protrusion leading to implant irritation is also of concern.

There are very limited literature comparing the outcomes with plating and nailing for middle third clavicle fractures.

Ferran *et al.* (2006) analysed 17 patients operated with plate osteosynthesis with LC-DCP and 15 patients operated with ROCKWOOD pin and found that there is no significant difference in functional outcome after 12 months between plate fixation and intramedullary fixation. 20% patients had infection and 40% patients had implant failure requiring removal in plating group. Whereas in nailing 6% patients had implant failure requiring removal, 6% patients had implant irritation and 6% patients had re-osteosynthesis<sup>[26]</sup>.

Thyagarajan *et al.* (2011) did a retrospective comparative analysis of 51 patients of mid shaft clavicle fractures treated with plating (LCDPC), nailing (Rockwood pin) or

conservatively (17 patients in each group). They reported a constant score of 98 for the intramedullary fixation group and of 94 for the plate fixation group after six months. In plating group 12% patients had infection, 6% had nonunion, 12% patients had implant failure requiring removal and 35% had implant irritation. In nailing group 12% patients had infection. None of the other patients in nailing group had complications<sup>[54]</sup>.

We evaluated 40 cases of displaced middle third clavicle fractures of which 20 patients are treated with plate osteosynthesis and another 20 patients with intramedullary TEN nailing.

TEN Nailing resulted in decreased blood loss ( $p < 0.001$ ), decreased operative time ( $p = 0.309$ ), decreased wound size ( $p < 0.001$ ) and decreased hospital stay ( $p = 0.154$ ) when compared to plating. Moreover, the mean Quick DASH score of nailing patients at 30 days after surgery is 13.58 when compared to Quick DASH score of 19.90 for plating at 30 days after surgery. This suggests better patient acceptability and satisfaction in the nailing group. However, the mean Quick DASH score at 6 months after surgery in nailing and plating are 6.63 and 12.15 respectively indicating that there is no significant difference in shoulder function and disability on a long term follow up.

There was no difference between two groups in terms of rate of union. All cases had 100% union. There was a slight difference in union time. The mean time period for clinical and radiological union in plating group was 7.0 weeks and 12.70 weeks whereas the mean time period for union in nailing group was 7.5 weeks and 11.75 weeks. Both these were statistically not significant. ( $p > 0.05$ ).

Based on the functional outcome at 6 months, in plating group, we had 13 patients with excellent outcome, 5 patients with good outcome and 2 patient with poor outcome. In nailing group, 12 patients with excellent Outcome, 8 patients with good outcome.

Complications like superficial infection is noted in 2 patients (10 %) in plating when compared to no patient in nailing group. Moreover minor complications like implant irritation occurred in 3 patients (15 %) in plating and no patient in nailing group. There were no case of medial TEN protrusion and 2 cases of lateral TEN protrusion. The lateral TEN protrusion in our study can be attributed to the inadvertent piercing of the cancellous lateral margin of clavicle intra operatively. This problem arises when TEN nailing is performed without image control. We therefore suggest that all TEN nailing of the clavicle whether open or closed to be done under image control to know the lateral extent of the nail. Shortening do occurs in both plating and nailing.

Lazarides S, Zafiropoulos<sup>[14]</sup> reviewed 272 patients with middle third clavicle fractures and found that patients with shortening of more than 18 mm had residual shoulder pain and unsatisfactory results mainly due to altered biomechanics of the shoulder joint that occurs with clavicular shortening.

In our study, the mean shortening in plating group was 0.5 mm and in nailing group was 1 mm. However these amount of shortening did not have any effect on the functional outcome of the patients in our study.

Our study has limitations. Our study is not a randomized control study. Further our study involves limited number of subjects. Therefore statistical significance of our study can be questioned. However our study shows some basic information comparing plating and nailing for clavicle fractures. Our study supports further randomized control trials and with a large number of samples to arrive at a definite conclusion.

### Conclusion

Hence we conclude that though both plating and nailing, fracture union was 100%, nailing has advantage over plating since it heals with callus formation and stronger healing, during surgery and postoperative period, on long term follow up there is no significant functional difference between plating and nailing for displaced middle third clavicle fractures.

### Summary

This is a comparative study undertaken in the department of Orthopaedics, Meenakshi Medical College and research institute, Enathur from 01/ 09/2017 to 31/08/2018. Within the period of study, 40 patients with displaced middle third clavicle fractures were operated alternatively with plating and nailing (titanium elastic nail). Functional outcome was based on Quick DASH score.

The results are analysed under the following headings.

Mean blood loss was 89ml in plating and 35.5 ml for nailing

Mean operative time was 53.75mins for plating and 49mins for nailing.

Mean wound size was 10.05 for plating and 4.15 cms for nailing.

Mean duration of hospital stay was 6.40 days for plating and 6 for nailing.

Post-operative complications was noted in 2 patient of plating group.

### Case Illustrations

#### Nailing

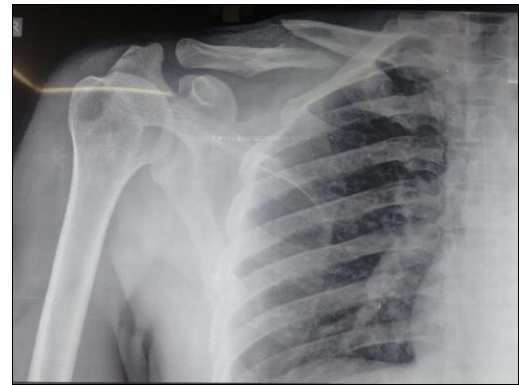


Pre Op

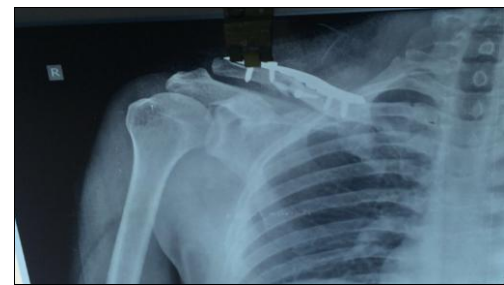


Post Op

### Plating



Pre op



Post op



Functional outcome



Clinical photos

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