



**Research Article**

## **A STUDY ON FUNCTIONAL OUTCOME ANALYSIS OF OPERATIVE – TITANIUM ELASTIC NAILING SYSTEM (TENS) VERSUS NON OPERATIVE TREATMENT OF MIDSHAFT CLAVICLE FRACTURES**

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### **ARTICLE INFO**

**Article History:**

Received 4<sup>th</sup> January, 2022

Received in revised form 25<sup>th</sup>

February, 2022

Accepted 23<sup>rd</sup> February, 2022

Published online 28<sup>th</sup> April, 2022

**Key words:**

Functional Outcome, TENS, Midshaft Clavicle Fractures.

### **ABSTRACT**

**Introduction:** Clavicle fractures account for 2.6% of all fractures. Most common type is mid shaft fracture (80%). Operative treatment is playing an increasingly important role. Most of the conservative treatments need regular adjustment, are cumbersome and inconvenient to the patients.

**Material and Methods:** Study is conducted in the Institute of Orthopaedics, Rajiv Gandhi government general hospital, Chennai. On patients with displaced or comminuted clavicle fractures middle third. Patients divided into Group A (managed conservatively) and Group B (operative fixation with TENS).

**Results:** In all patients of GROUP B union of bone was observed. 12 patients were satisfied with their shoulder functions. Range of movements were better in GROUP B compared to GROUP A.

**Conclusion:** TENS Nailing for clavicle middle third fractures provides an acceptable alternative method for the fixation of displaced midshaft clavicular fractures in active age group and delivers better results in adjacent joint function, radiological union and restoring anatomy than the conservative management.

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## **INTRODUCTION**

The orthopaedic surgeon should not be tempted to treat a fracture of the clavicle by open reduction merely because the patient or family objects to a bony prominence at the fracture. In some patients, the scar produced from surgery can be more unsightly than a bony prominence. About 15 to 25% of patients treated conservatively develop unsatisfactory results clinically, radiologically and subjectively due to shortening of bone, nonunion and malunion with deformity. The concepts of early surgical fixation with plates and screws, closed nailing and exact post operative protocol all have satisfactory functional outcome of the patient to a greater extent. However, a recent meta-analysis revealed higher nonunion rates for displaced fractures treated non-operatively (15%) than operatively (2.2%) with modern internal fixation techniques. Therefore, operative treatment is playing an increasingly important role in the clinical setting, mainly using compression plating or intramedullary nail fixation technique. Although plating is accepted as a standard technique, it has some disadvantages like large scar, nonunion, and difficult application and removal of the plate. The second method, intramedullary nailing of clavicular fracture is relatively new technique done using titanium elastic nails. This technique was attractive when first presented by Jubel et al.

Some articles have recommended it as a technique with little complications, rapid union rate, easy insertion and removal, small scar and no breakage.

So we decided to evaluate functional outcome in patients treated operatively using Intra-medullary fixation by titanium elastic nail and non-operative conservative treatment on the mid shaft clavicle fractures. Our study discusses elastic stable titanium intramedullary nailing of midshaft clavicular fractures as it produces excellent cosmetic and functional results.

### **Aim**

Study the comparison of functional outcome, Radiological evaluation and restoration of anatomy of midshaft clavicle fractures managed by Conservative methods and CRIF/ ORIF with TENS.

## **METHODS & MATERIALS**

This is a prospective study of 37 cases of midshaft clavicular fractures treated by conservative methods and CRIF/ORIF with TENS nailing. Patients were explained about the procedures, complications and postoperative protocols. Informed consent has been obtained from all patients. The period of study and follow up extends from September 2019 to

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november 2020, in the Institute of Orthopedics and traumatology, Rajiv Gandhi general hospital, Chennai.

#### **Inclusion Criteria**

1. Age- 18-55 years
2. Patients with displaced fracture of middle third of clavicle
3. Soft tissue compromise(tenting of skin) at the level of fracture
4. Closed fractures
5. Comminuted fracture mid-shaft clavicle.
6. Associated other limb injuries

#### **Exclusion Criteria**

1. Age less than 18 and more than 55 years
2. Fracture involving proximal and distal third
3. Hemiparesis (on the affected side).
4. Open fractures
5. Old fracture nonunion
6. Pathological fractures
7. Associated with neuro vascular injury

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

1. Fracture type
2. Method of treatment(conservative/ Nailing)
3. Mobilisation Time duration between conservative/ Nailing
4. Associated injuries
5. Complications
6. Duration of hospital stay
7. Nail size
8. Need for implant exit
9. Radiological evaluation of shortening

All patients informed about the procedures, complications and postoperative rehabilitation protocols. Informed consent has been obtained. Prophylactic antibiotics were given at the time of induction. Under General Anesthesia / Local nerve block patient positioned in a radiolucent table. In Beach Chair / supine position with sand bag in the interscapular region parts were painted and draped in strict aseptic manner. 1 to 2 cm incision made in the medial end of clavicle 1.5 cm from the sternoclavicular joint. With the help of 2.5mm drill bit a entry point was created in the anterior wall of clavicle, widened with the help of small bone awl. Then elastic nail size of 2 or 2.5 mm size introduced with a T handle after making mark in the handle to note the side of the tip of TENS, with gentle oscillating movements the nail was advanced upto the fracture site.

With the help of image intensifier nail manipulated into the lateral segment by turning the TENS tip and making shoulder manipulation with inline traction and an external rotation helps the closed reduction, if percutaneous reduction found to be unsuccessful, a small incision made at the fracture level to negotiate the fragments.

The nail was advanced into the lateral segment and nail was cut off at the site of insertion leaving 1cm length for easy removal. Skin closed without drain, sterile dressing applied.

#### **Postoperative Protocol**

All patients were treated with arm sling after operation for 6 weeks. In the immediate postoperative period the arm rested in

a arm sling, second postoperative day wound inspected and dressing changed. Check X-Ray taken to confirm the reduction and position of the nail. In addition, 3 days after surgery, patients were allowed to do passive anteflexion and abduction motion of shoulder joint under the guidance of physiotherapists, and the motion range could be increased gradually depending on the degree of pain. However, the range of passive anteflexion and abduction motion was kept within 90 in 6 weeks after surgery, and the weight-bearing exercise was not allowed. On 13<sup>th</sup> postoperative day sutures removed and patient advised to start resisting and strengthening exercises. The range of passive and active motion were increased gradually according to the condition of fracture union and the weight-bearing exercise was begun gradually after 6 weeks postoperatively. At 6 weeks check X-Ray taken to evaluate bony union. In our study the 11 cases had good radiological union by the end of 8 to 12 weeks and one case union achieved by 14 weeks. The postoperative follow-up visits were scheduled every 2 weeks until union

#### **RESULTS**

The collected data were analysed with IBM.SPSS statistics software 23.0 Version. 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 Unpaired sample t-test was used. To find the significance in categorical data Chi-Square test was used similarly if the expected cell frequency is less than 5 in 2x2 tables then the Fisher's Exact was used. In all the above statistical tools the probability value.05 is considered as significant level. According to Robinson classification, there were 4 cases of typeIIA2 and 33 cases of type IIB1. There into, 16 patients were in right midshaft clavicular fracture and 21 in left. The causes of fractures included traffic injuries (24cases), Assault (1 case), and injuries of falling off (12 cases) . The surgeries were carried out in the following first-seventh days after injuries. The mean follow-up time was 24±4.8 weeks. Among of these cases, 7 patients were followed up via telephone or questionnaire because they could not come to our institute for recheck. And the data of physical examinations and radiographic inspections were provided by the local hospitals during follow-up. All the other patients were evaluated by the clinical function and imaging during the follow-up time.

The mean operative time, peri-operative bleeding and hospital stays were 57.417±9.232 min, 7.2±3.7 ml and 8.056±2.672 d, respectively. There were 6 cases performed with closed reduction, while the other 6 cases was operated by open reduction with small-size incision. Bone union was found in all the operative patients and 25 non operative patients. The mean time of bone union was 11±2 weeks in operative group were 13±5weeks in non operative group. Among 25 cases,3cases malunited with shortening of 2 cm or more, 15 cases were united within 12 weeks, 7 cases within 12-16 weeks, 1case at 20 weeks in conservative group and 2 cases were not united and planned for surgical management. Among 12 cases of operative group, 11 were united within 12 weeks, 1 case united in 14 weeks.

**Table no 1** Comparison of Results

Results	Conservative(25)	Elasticnail (12)
Total united cases	23	12
Union in 12 weeks	15	11
Union in 12-24 weeks	8	1
Nonunion	2	Nil
Malunion	3	Nil
Early return to activity	28 days (11 cases)	14 days (11 cases)
Stiffness of shoulder	2	Nil
Loss of length of clavicle(shortening > 2cms)	1	Nil
Patient compliance and functional outcome	Excellent-12cases Good-6 cases Moderate-5 cases Poor-2	Excellent-11 cases Good- 1 cases Moderate-Nil Poor-Nil
Other Complications	Malunion-2 cases Malunion and shoulder stiffness-1 Non union -2 cases Delayed union with shoulder stiffness-1case	Nail migration-1 case cosmetic Scar and skin puckering-1 Skin irritation-nil Hypertropied scar-nil Infection-Nil

Postoperative complications, such as infection, incision numbness, scar hyperplasia, irritation of nail end, withdrawal and breakage of nails, were not found. The mean diameter and length of our self-designed TEN used was 2.35 mm and 13 cm, respectively. The diameter range was 2.0 mm 2.5 mm, while the length range was 10.5 mm 14.5 mm. After recovery, the implant may cause the aseptic inflammation of muscle tissue around it. Thereby, the TENs were removed after a mean time of 6.2 months after surgery in 6 cases. No re-fracture occurred after removal. one patient complained of pain in sternal region 8 month post-operatively because the nail migrated through the medial cortex, and the pain symptoms were spontaneously resolved after removal. The patient complained that the TEN nail could be touched under the skin, but with no skin irritation. Another patient developed scarring and puckering of skin post operatively and addressed cosmetically.

The flexion and abduction motion ranges of shoulder joint were improved significantly at 2 weeks after surgery. The mean DASH scores were 2.5±3.4 compared to non operative group (6.8±11.2) and all the 12 patients of operative group showed excellent comprehensive recovery results.

**DISCUSSION**

Clavicle fractures are one of the most common fractures of young active individuals. Most of the clavicle fractures managed by conservative method previously but after understanding the fracture biomechanics of clavicle surgical management found to have good functional outcome and early mobilization of patients. Fracture patterns like displaced, comminuted, shortening>2 cm all have impact on union and functional outcome. Compared with plate fixation, intramedullary fixation especially TEN fixation showed better clinical outcomes in the terms of operative time, wound size, subjective time to pain relief, and the postoperative functional scores of shoulder joint during the treatment of displaced midshaft clavicular fractures. In addition, TEN fixation provided a shorter average period of bone union, faster functional recovery, higher patient satisfaction, and a higher satisfaction with appearance. Common TENs anchored only with the arc-shaped nail head, and thereby leading to the poor dislocation capacity of anti-rotation and anti-axis. In addition, collar bone has characters including S-shaped, irregularity and narrow bone marrow cavity. Therefore, the large diameter of TEN was difficult to insert and even lead to split at the distal

part of fracture. For the treatment of midshaft clavicular fractures, the average diameter of common used TEN was 2 mm. Besides, postoperative complications after intramedullary fixation with common TENs occurred frequently, including nail withdrawal, skin irritation, lateral perforation, and even shortening or dislocation at the fracture site. Besides TEN, nails such as ESIN and the locking flexible clavicular nails are currently used in clavicular intramedullary fixation but with various problems. However, Lu *et al* reported that there are significantly displaced clavicle fractures with ESINs treatment. In order to solve these problems, Kaiser *et al* adopt pre-bending with more than 30° to improve the stability of the nail and also reduce the complications. In addition, the end caps used for elastic stable intramedullary nailing could also reduce the risk of altering construct stability. In our study 25 patients treated with Conservative methods for biological healing, another 12 patients treated with CRIF/ORIF with elastic nailing. Though ORIF with plating having advantages of accurate reduction and early mobilization the functional outcome of biological healing (conservative/closed TENS) comparable based on previous studies. In surgical management TENS nailing by closed reduction or miniopen technique is more biological compare to ORIF with plating in which more than half of the clavicle exposed and fracture hematoma washed out. Elastic nailing not indicated for comminuted fractures and fracture nonunion. The advantage of intra medullary fixation and not disturbing the fracture hematoma are additive features of closed nailing. In our study we evaluated 37 cases of midshaft clavicular fractures treated by conservative methods (25 cases) and titanium elastic nailing (12 cases). Functional outcome in terms of early mobilization, clinical union and radiological union found to be significant with p-value of (.019), (.293) and (.030) respectively ( values of mobiliation and radiological union less than <0.05). Hence patients treated with elastic nailing had good functional outcome and good anatomical reduction. Previous literatures and studies compared the functional outcome of conservative methods and plating, conservative methods and nailing. But only small numbers of studies were comparing conservative versus nailing. Our study compared the functional outcome of conservative versus nailing.

**CONCLUSION**

Even though increased popularity of surgical methods most of the clavicle fractures managed by conservative methods till now. Nonsurgical methods are nowadays used in elderly patients with less physiological demand. But increasing evidence of good functional outcome of surgical methods favors fixation for young individuals and elderly patients with physiological demand. Good anatomical reduction and regaining of the length achieved in intramedullary fixation which eventually helpful to achieve early functional outcome with less incidence of nonunion and minimal scarring compared to plating. Intramedullary fixation, minimally invasive and early mobilization are the merits of elastic nailing. But need for implant exit and inadequate fixation for comminuted fractures are demerits of nailing. In conclusion titanium elastic nail size of 2 – 2.5mm diameter is recommended for displaced midshaft clavicle fractures in young active age group compared to conservative methods, closed TENS nailing has excellent functional outcome on early return to activity and restoration of clavicle alignment and

function of adjacent joints and minimal complications and also technically less demanding.

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### How to cite this article:

Anandhakumar P *et al* (2022) 'A Study on Functional Outcome Analysis of Operative – Titanium Elastic Nailing System (Tens) Versus Non Operative Treatment of Midshaft Clavicle Fractures', *International Journal of Current Advanced Research*, 11(04), pp. 610-613. DOI: <http://dx.doi.org/10.24327/ijcar.2022.613.0135>

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