

Mid Shaft Clavicle Fractures- Plate vs Titanium Elastic Nail System

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ABSTRACT

It was believed that “all clavicle fractures heal well” is no longer valid. Recent trend is towards operative management, consists of Pre-contoured plate or Titanium Elastic Nail System (TENS) application. Plate fixation remains the mainstay of treatment but Titanium Elastic Nail System application has gained attention in recent years. This study highlights the comparison between two most common modalities available for treatment of mid-shaft clavicle fractures.

Objectives: Compare the functional outcome using Neer’s scoring system, radiological outcome and secondary outcomes between two treatment groups.

Methods: Patients satisfying inclusion criteria were included in our study and randomized into Group A-operated with plate fixation and Group B-operated with TENS. Routine postoperative protocol and physiotherapy followed. Regular follow up carried out and assessed as per protocol.

Results: We had 15 patients in each group by end of our study. There was no significant difference between the two groups in terms of demographics, time to surgery, fracture types. Duration of hospital stay, mean fracture union time were significantly shorter and cosmetically more satisfied in TENS group. Operative time, length of incision, peri-operative blood loss was significantly higher in plate group and length of clavicle better restored. Functional outcome was excellent with no significant difference between two groups.

Conclusion: Both methods return the patients to their pre-injury functional levels without significant complications with excellent functional outcome. Titanium Elastic Nail System application has a shorter operative time, lesser duration of hospital stay, lower infection rate and better cosmetic outcome suggesting this is the preferred method with no comminution whereas plate fixation is superior in comminuted fractures.

KEYWORDS: Clavicle fractures, Titanium Elastic Nail System, Precontoured plate, Neers score

INTRODUCTION

Clavicle fractures are the most common orthopedic injuries accounting for 2.6 to 4% of all fractures and 44% of injuries around the shoulder girdle. Out of which more than 80% occur in the mid-shaft, at least 50% fractures displaced. [1, 2] Midshaft is where the typical compressive forces are applied and tubular narrow cross-section of the bone combined with lack of soft tissue coverage results in bony failure. [3]

Common in young active individuals involved in outdoor activities with male predominance, with peak incidence in third decade. [3] Most common mode of injury is fall or direct blow to the shoulder leading to axial compressive force. Traditionally, Clavicle fractures were treated nonoperative either by figure of eight bandage or arm sling. It was believed “all clavicle fractures heal well” [3, 4] and success in treating was fracture union, but functional outcome is not only related to its union but also depends on its length. [5] Older studies depicts rate of non-union as low as 0.9%. [4] Recent studies have documented non-union rates of more than 15%, loss of muscle strength around the shoulder of 18 to 33% and poor functional outcome managed conservatively. [5, 6] Probability of the non-union increases with increasing age, increase in comminution, increasing displacement and female sex with the soft tissue interposition. [3]

Currently, diverse operative treatment options are available. Plate fixation was advocated as the preferred method because surgeon can perform direct reduction. However, the need for increased exposure, stripping of periosteum, damage to supra clavicular nerves which can cause numbness is inevitable with this method and results in a subsequent incapacitation of bone and increased blood loss, slightly higher rates of infection. Furthermore, large incision can be unacceptable in cosmetically conscious patients.

Recent emerging mode is intramedullary fixation using titanium elastic nail system [TENS]. The advantages include shorter operative time, hospital stay, less blood loss, soft tissue injury, easier implant removal, cosmetic satisfaction with small postoperative scar. However, insufficient rotational stability, pin migration, weaker compressive forces at the fracture site are its known disadvantages.

When mid shaft Clavicle fractures managed surgically both the options have better patient satisfaction, clinical and radiological outcome than managed conservatively. In this prospective study, we aimed to assess the two most common fixation modalities available and compare them in terms of function, clinical, radio graphic outcome and complications associated with them.

MATERIALS AND METHODS

This is a prospective comparative study conducted in our department from June 2020 -December 2021. Exclusion criteria were open fractures, Pathological fractures, associated acromioclavicular joint dislocation, Congenital anomaly or bone disease, with neurovascular deficits. As per criteria 30 patients were included in our study, randomized into group A -15 patients underwent open reduction internal fixation with plate and screws and group B-15 patients underwent titanium elastic nail system (TENS) application. Informed written consent obtained, basic details noted. Detailed history regarding the mode of injury, medical history affecting the outcome were noted. Functional demands of the patient was taken into consideration. With suitable anesthesia, patient put to beach chair position with roll bag behind the involved shoulder which aids in fracture reduction. Operative limb painted and draped in a sterile manner such that it is freely movable. Robinson classification system was used to classify fractures.

Operative procedure for plate fixation: Oblique skin incision of appropriate size centered superior over the fracture site. Superficial dissection carried out, subcutaneous tissue and platysma divided and kept together as one layer and mobilized. Myofascial layer over the Clavicle is divided and elevated. Hence, during closure two soft tissue layers provide coverage.

Fracture ends identified and cleaned of debris and hematoma, free fragment of sufficient size should be preserved and reduced with a lag screw. Fracture reduced by using reduction forceps and stabilized temporarily either by K wire or lag screw. Precontoured plate of sufficient length placed over the superior surface and fixed by at least three bi cortical screws on either side of the fracture.

Operative Procedure for Titanium Elastic Nail System (TENS) Application: C-arm positioning is crucial. C-arm positioned at head end, image intensification in 45° cephalad and 45° caudal directions provided us with images in two planes, 90° apart. Ensure before starting surgery satisfactory views can be obtained.

Sternoclavicular joint palpated and marked on the affected side. An incision of 2cm taken at sternal end. Dissection carried out to reach bone. Anterior cortex opened with an Awl and nail of appropriate size inserted, before introduction flattened nail tips straightened slightly to allow better gliding in medullary canal and advanced to fracture site TENS-group. Fracture reduced by closed manner performed under fluoroscope control or by using percutaneously introduced pointed reduction clamps. If a closed reduction failed, an additional incision above the fracture site made for direct manipulation of main fragment. Nail is advanced with gentle rotational movements under the guidance of C-arm. Fracture compressed and the nail cut nearer to entry point to minimize soft tissue irritation.

Post-operative care as follows-Pendular exercises started on second day. Two weeks postop, arm pouch discontinued and active ROM exercises started with restriction of overhead abduction. At 4 to 6 weeks postop unrestricted ROM exercises allowed with restriction of sporting activities. Activities of daily living started but those requiring lifting of heavy objects were delayed until union.

RESULTS

Data analyses of two groups done with the help of computer assisted SPSS software with independent student T test for analyzing the difference between the two groups. P value less than Considered significant.

We had 15 patients in group A and 15 patients in group B by the end of follow up. There were 11 male and 4 female patients in plate group and 10 male and 5 female patients in Titanium Elastic Nail System (TENS) group. The time interval to surgery was 7.07 + 2.40 days in plate group and 6.60 + 1.50 days in TENS group. Out of 15 patients in plate group, 8 had 2B1 fracture and 7 had 2B2 fracture according to Robinson classification. In TENS group, 10 had 2B1 fracture and 5 had 2B2 fracture. There was no significant difference between the two groups with respect to age [0.18], sex, time to Surgery [0.53]. Table-1 shows comparison of study groups. Mean duration of hospital stay was 13.40 days in plate group, TENS group 9.20 days, significantly low hospital stay in TENS group [P=0.001]. A mean duration to achieve bony union in the plate group was 14.43 weeks and in TENS group 12.40 weeks, achieved union two weeks earlier in TENS group [P=0.017]. TENS group, the mean operative time was 52.8 min whereas in plate group 76.67 min, significant shorter in TENS group [0.001]. Mean operative blood loss was significantly low in TENS [P=0.001]. The mean difference in length of clavicle after fracture union was significantly higher in TENS group [P=0.001] whereas length of the Clavicle was better restored in plate group. Mean length of the incision was significantly higher in plate group.

It was noted that there was no significant difference between two groups in terms of functional outcome assessed by Neer's score.

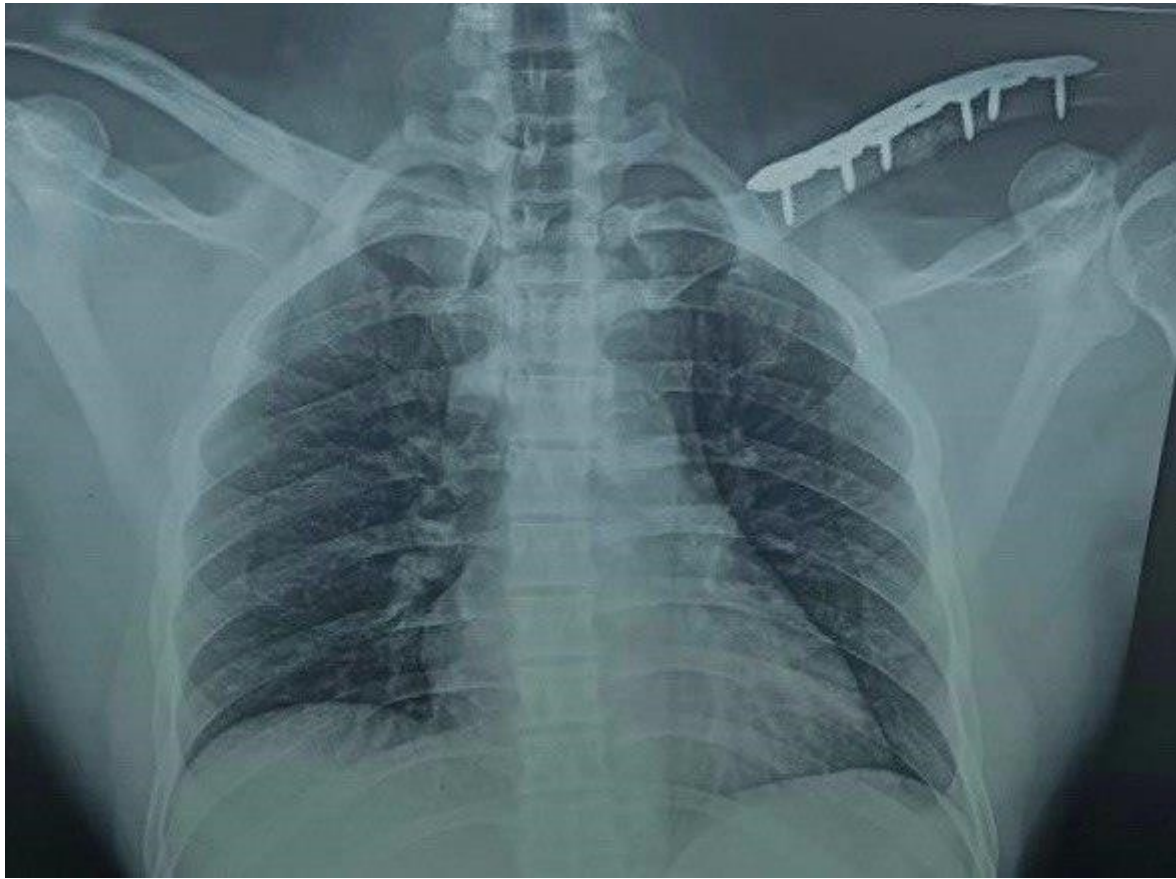


Figure 1: Case Plate : P/25yr/M Radiographic image showing union at fracture site in follow up x rays 6 months follow up



Figure 2: Preoperative x ray

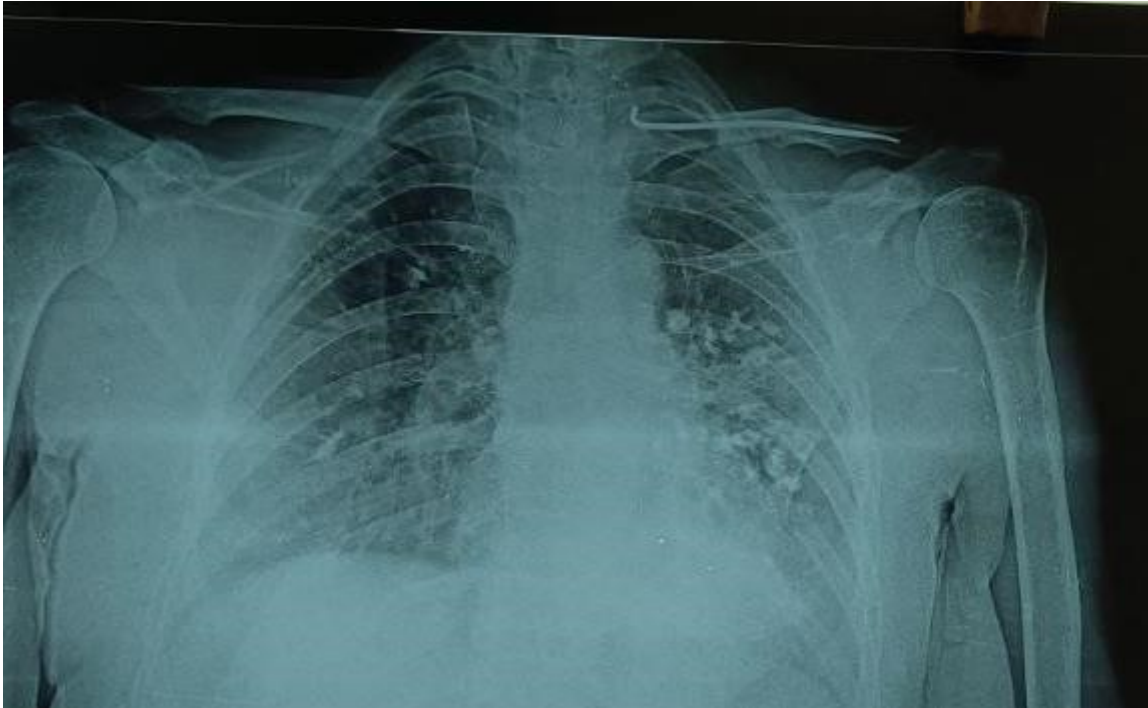


Figure 3: Case:TENS/48yr/F Radio graphic image at 6 months follow up

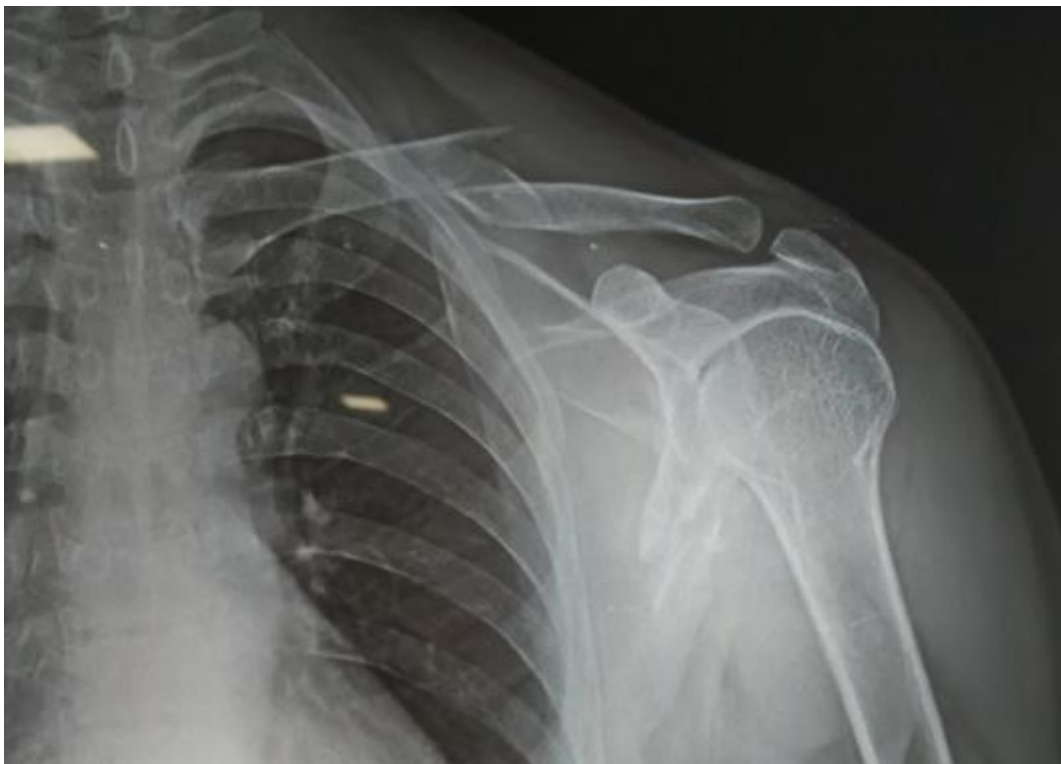


Figure 4: Pre operative x ray

	PLATE GROUP	TENS GROUP	P VALUE[S]
Age	30.27+/-6.50	34.53+/-10.20	0.18
Duration of hospital stay	13.40+/-2.50	9.20+/-1.32	0.001
Union time	14.40+/-2.61	12.40+/-1.35	0.17
Operative time	76.67+/-6.18	52.8+/-3.69	0.0001
Length of incision	10.53+/-1.36	4.00+/-1.92	0.001
Shortening of clavicle	4.13+/-1.51	7.87+/-1.69	0.0001

Age in years, Duration of hospital stay is in days, Union time in weeks, Operative time in minutes, Length of incision in centimeters, Shortening of clavicle in millimeters

Table 1: Comparison of study groups

Authors, Year	Our study	Chen et al 2011	Narsari a et al 2014	Saha et al 2014	Van der meijden et al 2015
Age	30.2±6.5 34.5±10	50±5 46±17	40±11 39±9	33±11 33±12	38+_15 40+_13
Operative time	76.6±6.1	66.4±22.4 48.3±19.7	58.4 40.2	67±14 51±16	
Length of incision	10.5±1.4 4±92		10.2 4.5		
Union time	14.4±2.6 12.4±1.3	14.4±4.7 12.4±4.2	24 19	22±6 18±6	14+_2.2 13+_1.8
Functional outcome	No significant difference	Titanium Elastic Nail System Favorable	No Significant difference	No Significant difference	No significant difference

Duration of hospital stay is in days, Union time in weeks, Operative time in minutes, Length of incision in centimeters

Table 2: Study Characteristics of mid shaft clavicle fractures studies

DISCUSSION

In this study, we have compared anterior superior pre-contoured plate fixation and intramedullary Titanium Elastic Nail System (TENS) applications either by closed or open reduction in terms of their functional outcome, secondary outcomes and complications. Comparison of study characteristics of different studies is depicted in Table 2.

In our study, mean age was slightly higher in TENS group [34.53+/_10.20] as compared to plate group [30.27+/_6.50] which was statistically not significant [P=0.183]. In literature, the most common age group treated operative vary between 25–46 years. Fulgesang et al study had mean age at injury 36.4 years in TENS group and 34.6 years in plate group.^[7] In Saha et al study, plate group had mean age of 33.03 years and TENS had mean age of 33.32 years.^[8] Most of the patients belong to the age group between 18 – 35 years and these findings were consistent with literature. The incidence of Clavicle fractures is predominant in males, with literature distribution varying from 30- 80%. Out of 30 patients in our study, 21 patients were males, accounts for 70% which is

consistent with the literature.

Most common mode of injury is direct trauma to the shoulder. Kihlstrom et al. study on 2422 clavicle fractures, 90.5% resulted from direct trauma. In our study, 27 patients [90 %] sustained a direct injury to the shoulder - motor vehicle accident [50%], direct fall on shoulder [40%]. 10% sustained injury by fall on the outstretched hand.^[9] 18 patients [60%] had left side Clavicle fracture and remaining had right side without bilateral clavicle fractures. In Saha et al. study, duration between injury and surgery varied from 3 - 27 days with a mean duration of 12.84 days.^[8] Fulgesang et al. study, mean time elapsed before surgery was 5.5 days in plate group and 5.9 days in TENS group.^[7] In our study, time to surgery was 7.07 days +/- 2.40 days in plate group and 6.6 days +/- 1.50 days in TENS group. There was no significant difference between the two groups with the earliest patient operated at 4 days and maximum delay was 13 days post injury. Saha et al study, had mean operative time of 67.84 min in plate group and 51.18 min in TENS group.^[8] Lee et al. had mean operative time of 27.5 min in Knowles fixation whereas 68.4 min in plate group.^[10] In our study, the mean

operative time was higher [76.67 minutes] in plate group, statistically significant [$P<0.001$]. In Narsaria et al. study, the mean duration of hospital stay was higher in plate group [2.8 days] than TENS group [1.4 days].^[11] Bohra et al. study had a mean duration of hospital stay of 2.8 days in plate group and 3 days in TENS group.^[12] In our study, overall mean duration of hospital stay was significantly higher in plate group, statistically significant [$P=0.001$]. Traditionally cosmesis was not typically an orthopedic priority, cosmesis is important and ugly scar has been a traditional deterrent in cosmetically conscious patients for operative treatment. Lee et al. study had a mean incision size of 4.1cm in TENS group and 8.4cm in plate group.^[10] Bohra et al. Study had mean incision length of 4.2cm in TENS group and 10.4cm in plate group.^[12] In our study, the mean length of incision was higher in plate group, statistically significant and patients were cosmetically more satisfied in the TENS group. Chen YF et al., retrospective study observed 141 patients, union time was shorter and shoulder score significantly better in TENS group.^[13] Lee et al. had no difference in union rate between the two groups.^[10] In our study, bony union achieved in all patients within six months with mean union time higher in plate group, statistically significant [$P=0.017$]. In plate fixation, it was primary bone healing whereas in Titanium Elastic Nail System secondary bone healing by callous formation. Maintenance of clavicle length is one of the prime goals of operative treatment. Lazarides et al. study, final shortening of more than 18mm in males and more than 14mm in females was associated with unsatisfactory results.^[14] Saha et al. study, clavicle lengths were better maintained by plate especially in 2B2 fractures more the comminution, plate fixation remains the operative technique of choice.^[8] In our study, overall length of the Clavicle was better maintained in plate group.

Meta-analysis by Zlowodzki et al., concluded that there was no significant difference between plate and intramedullary fixation.^[15] Saha et al. study, shows no functional difference at the end of 24 months follow-up.^[8] Narsaria et al., functional shoulder scores was significantly higher in the plate group in the first 12 weeks but after 12 months, there was no significant difference.^[11] Fulgesang et al., plating appears to able to negate the effect of comminution and open reduction in TENS group was the strongest predictor of poor functional outcome at 12 months follow-up.^[7] In study, functional outcome assessed by using Neer's score, 11 had excellent results and four had satisfactory results at the end of 12 months follow-up in both plate and TENS group. There was no significant difference in the functional outcome at 6 weeks, 3,6 and 12 months follow-up. Both operative techniques had excellent functional outcome at the end of follow up.

Infection is the major complication encountered with plate fixation, reported rates in the literature range from 0 -18%. In our study 3 patients [20%] in plate group had superficial infection and one patient [6.66%] in TENS group. All fractures united with no non-union. Although

minor complication of TENS group was medial prominence of hardware resulting in skin irritation, which was noted in six patients [40%].

CONCLUSION

In our study, the treatment of mid-shaft Clavicle fractures either by plate or Titanium Elastic Nail System application provide strong evidence that there is no significant difference between two groups in terms of functional outcome at the end of 12 months follow-up. Both methods return the patients to their pre-injury functional levels without any significant complications. Plate fixation better restored the length in both 2B1 and 2B2 fractures and provides rotational stability and it appears plate fixation is able to negate the effect of comminution by bridging the fracture.

Hence, we conclude, intramedullary TENS application is a safe effective alternative technique for treatment of mid-shaft Clavicle fractures with no comminution whereas plate fixation is superior in comminuted fracture.

Limitation of our study is small sample size and study done at a single center. Surgery was performed by different surgeons with variable experience with the procedure.

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