

# A Prospective Comparative Study: Comparing Titanium Elastic Nailing to Anatomical Plating for Displaced Midshaft Clavicle Fractures

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**Abstract:** ***Background:** The accepted surgical procedure for treating displaced midshaft clavicle fractures is plate fixation. TENS has also drawn a lot of attention over time because of its smaller scar, shorter recovery period, and minimally invasive nature. The Constant Murley score and the disability of the arm, shoulder, and hand score are used to determine the functional prognosis of middle third displaced clavicle fractures treated either by plate or intramedullary TENS fixing. **Methods:** At our institute, a prospective randomized trial involving patients with displaced midshaft clavicle fractures was carried out between May 2022 and April 2023. Midshaft clavicle fixation was performed on a total of 56 patients (TENS; n=25, plating; n=31), who were categorized by the Orthopaedic Trauma Association. They underwent follow-up for at least a year. **Results:** Scar length in the TENS group was small when compared to the incision in the plating group (1.86+1.23 and 11.01+3.29). At the end of 1 year the constant shoulder score measured for TENS group was 90.77+9.01 and for the plating group was 92.63+6.04, not significant statistically (p=0.269). The mean DASH score was also not significantly different (p=0.552) between the TENS group 6.01+11.09 and plating group 6.32+10.33 respectively. **Conclusions:** The nailing procedure requires small incision, less invasive and has shorter duration of hospital stay in comparison with plate fixation with no statistically significant difference in terms of functional outcome. Hence TENS technique is recommended for the fixation of displaced mid-shaft non/minimal comminuted clavicular fractures, especially for young individuals and can be used as alternative to plate fixation.*

**Keywords:** Clavicle plating, intramedullary clavicle nailing, middle 1/3<sup>rd</sup> clavicle fractures, Titanium elastic nailing system.

## 1. Introduction

In all skeletal fractures clavicle fractures comprises of 5 - 10%, due to its unique shape and configuration central third is the weakest and accounts for 69.2 to 81.3% of all clavicle fractures. However, the outcome measures used in many earlier research were either radiograph or surgeon based, which may not have picked up on subtle impairments. While numerous techniques have been documented for the closed reduction of displaced clavicular shaft fractures, none have proven to be consistently effective in both attaining and preserving the reduction. Consequently, displaced midshaft fractures of the clavicle usually heal roughly where the initial radiographs showed them, with the lateral fragment exhibiting a distinctive inferior, medially translated, and anteriorly rotated deformity. Over the past ten years, more recent research has shown that initial operative reduction and fixation have significantly improved outcomes, but nonoperative treatment has been associated with higher rates of non-union and worse functional outcomes. There is currently much discussion over the advantages of primary operative treatment for clavicular non-unions and malunions since these injuries can have a satisfactory functional outcome after surgery. Numerous studies have demonstrated that the use of plates or intramedullary nails for fixation is rising in surgical therapy. Although plating was the gold standard for surgically fixing a fractured middle third clavicle, intramedullary nailing has become more popular in the past ten years as a good surgical fixation method with improved cosmetic results. The aim of this study was to examine the functional outcome using the

disability of the arm, shoulder, and hand (DASH) score and the Constant Murley score for middle third displaced clavicle fractures treated either by anatomical plating or titanium elastic nail system (TENS) fixation.

## 2. Methods

We performed a prospective comparison analysis on patients with displaced midshaft clavicle fractures at our hospital between May 2022 and April 2023. According to the categorization of the Orthopaedic Trauma Association (OTA), clavicle middle third fractures were divided into three categories: B1 - type (simple fractures, two pieces), B2 - type (fractures with bending wedge), and B3 - type (complicated fractures).

### Inclusion Criteria:

The present study's inclusion criteria included patients who had multiple ipsilateral rib fractures with respiratory insufficiency, a markedly displaced midshaft clavicle fracture with skin tenting, a shortening or overriding of the clavicle >2 cm on radiographs, and an age greater than 18 years with the capacity to provide complete information, sign a consent form, complete questionnaires, and attend routine follow-ups.

### Exclusion Criteria:

The current study's exclusion criteria included individuals with floating shoulder, ipsilateral upper limb or brachial plexus bone injuries, bilateral clavicle fractures, pathologic

fractures, open clavicle fractures, and clavicle fractures lasting more than two weeks.

**Table 1:** Demographic data of patients

	TENS (n=31)	Plating (n=25)	P Value
Age (years)	34.5 (18 - 55)	36.5 (18 - 58)	0.067
Sex			
Male	22	17	0.456
Female	09	08	
Total	31	25	
Fracture type (OTA)			
Type B1	18	12	0.269
Type B2	05	03	
Type B3	08	10	
Side affected			
Left	21	13	0.091
Right	10	12	

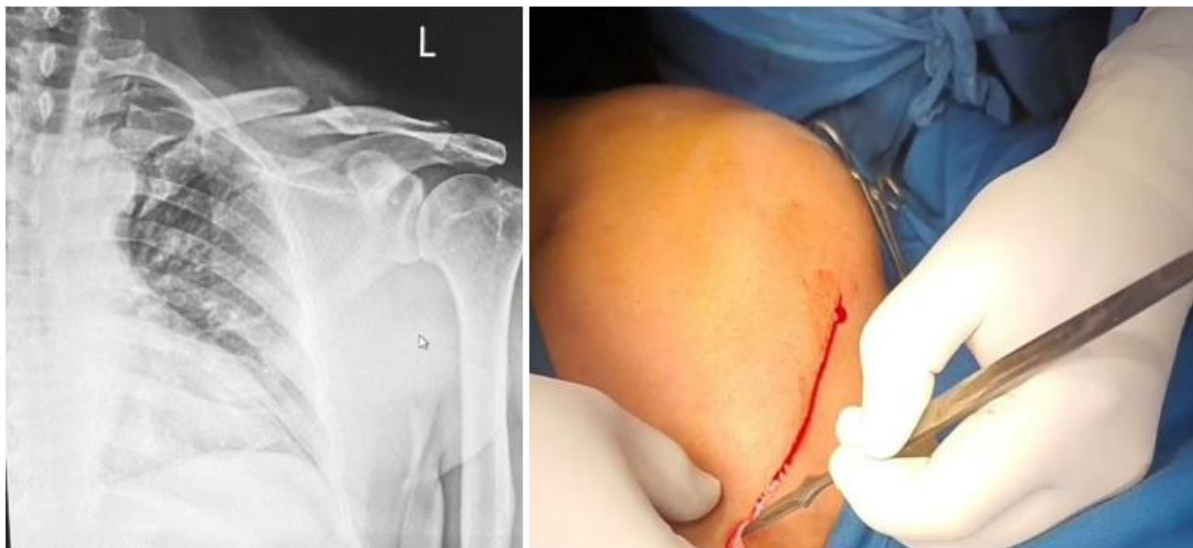
### 3. Procedure

A recurring intra operative issue that was noted was the challenge of properly positioning the nail at the clavicle's lateral end as it curves posteriorly and flattens out laterally. The smooth laterally transit of the nail was facilitated by opening the fracture site with a two centimeter incision and using towel clips or reduction forceps. Under general anaesthesia, all patients underwent surgery while positioned on a beach chair. A 1 - cm skin incision was performed parallel to the clavicle in the TENS group. The anterior cortex was opened using an awl under fluoroscopic supervision, approximately 1.5 cm lateral to the sternoclavicular joint. A TENS (2.5 mm) was then introduced and progressed to the fracture site, mounted over a T - handle. There was a closed reduction of the fracture. A 2 cm skin incision was created at the level of the fracture site if closed reduction was unsuccessful, and the reduction was temporarily maintained using a tiny reduction forceps or towel clip. Next, using small rotating motions, the nail was

moved over the crack and into the lateral fragment. After that, the nail was filed down, buried behind the skin, and twisted to avoid irritating it. In the plating group, the anterior technique was used to open reduce the shattered ends of the clavicle, and a 3.5 mm anatomical locking plate (Sharma surgicals) was put in a superior position to fix the break. In situations of severe comminution, bone grafting was performed. Following surgery, an arm sling was placed on each patient (TENS and plating group). Beginning on the second post - operative day and continuing for three weeks, early, mild, and passive shoulder mobilization exercises were given to every patient. Three weeks after the procedure, an X - ray check was suggested to determine alignment. Three weeks following surgery, active mobilisation commenced. After six weeks, the arm sling was removed, and overhead range of motion was started.

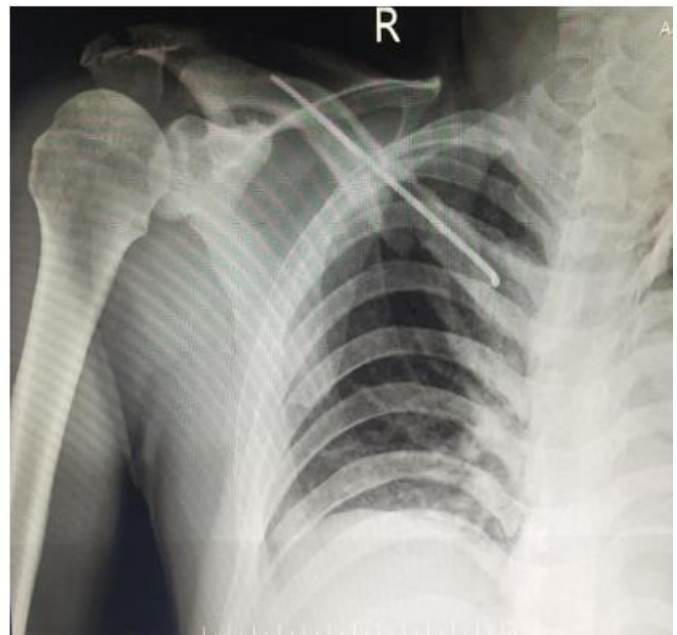
Two weeks following surgery, individuals with uncomplicated and simple fractures were allowed to resume active shoulder range of motion. After surgery, regular follow - up was conducted every two, six, and then month. At the one year mark following the procedure, we measured the bilateral clavicle length difference for clavicle shortening (from the notch of the sternum to the ridge of the acromion), the shoulder's functional status using the Murley and constant shoulder scores, and the arm, shoulder, and hand score for disability.

Fisher's exact test was used to compare the TENS and plating groups for characteristics like age, sex, fracture type, and side. Using the independent 't' test, the functional outcomes and complications for both groups were compared. Analysis of variance (ANOVA) was used to compare the post - operative clavicle length shortening, DASH score, and Constant score. The statistical software SPSS version 20.0 was used for all comparisons.



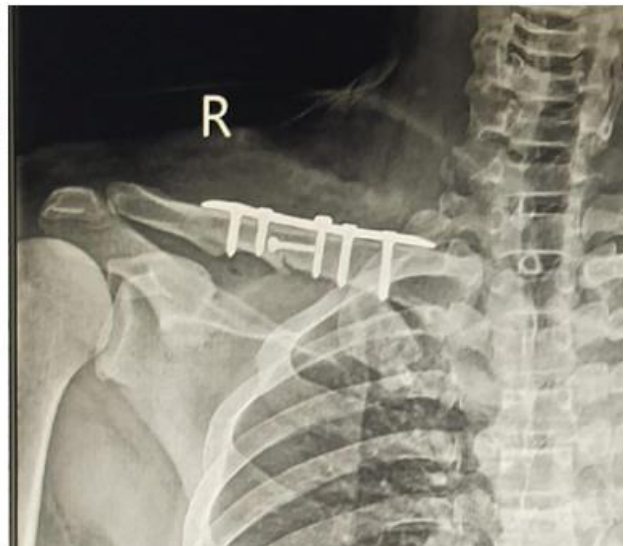


Case 1: Pre Op X - Ray, intra Op & Post Op X - Ray of Plating



Case 1: Pre Op & Post Op X-Ray of TENS nailing





Case 2: Pre Op and Post Op X-Rays of Plating

#### 4. Results

Anatomical locking plates or TENS were used to secure the midshaft clavicle in 56 patients in all. Every patient received at least one year of follow - up. Thirty one of the 56 patients had nail work done, and twenty - five had plating. Patients in the nailing group had a mean age of 34.5 years (18 - 55 years), while those in the plating group had a mean age of 36.5 years (18 - 58 years). To determine whether there was a difference of any kind between the two groups, the mechanism of injury and the kind of fracture pattern were examined. The most frequent cause in both groups road traffic accidents was identified as  $n = 20$  (nailing) and  $n = 18$  (plating); total = 38 (67.86%). Of these, 47% ( $n = 18$ ) had simple fractures, 21.1 % ( $n = 8$ ) had wedge fractures, and 31.6 % ( $n = 12$ ) had comminuted fractures. Eleven instances (19.64%) were attributed to falls from height, while seven cases (12.5%) were caused by direct blows to the clavicle. A total of 18 patients in the TENS group and 12 patients in the plating group had a simple fracture with an OTA 15 - B1 non - comminuted fracture type. 15 - B2 wedge comminuted fracture type was present in 5 patients in the TENS group and 3 patients in the plating group. 15 - B2 wedge comminuted fracture type was present in 8 patients in the TENS group and 10 patients in the plating group (Table 1). Of the 31 patients who had nailing, 15 (4 - B1, 2 - B2, and 9 - B3) required open reduction, which involved making a 2 cm incision at the fracture site to facilitate TENS passage. This suggests that communication was the decisive determinant in the decision to perform open reduction. In these situations, the scar's length was determined by adding the scars from the fracture site and the nail entry point.

The nailing group's average hospital stay lasted  $4.13 \pm 2.38$  days, while the plating group's average stay lasted  $7.24 \pm 4.10$  days ( $p=0.001$ ). In the TENS group, the average surgical wound size was  $1.86 \pm 1.23$  cm, while in the plating group it was  $11.01 \pm 3.29$  cm. The wound size of the TENS group was notably less than that of the plating group ( $p<0.001$ ). In comparison to the plating group, the TENS group saw a substantial mean clavicle shortening following union ( $0.76 \pm 0.93$  and  $0.09 \pm 0.29$  cms, respectively;  $p=0.044$ ) (Picture 1). The TENS group's scar length was notably

shorter than that of the plating group's incision ( $1.86 \pm 1.23$  and  $11.01 \pm 3.29$  cms, respectively;  $p<0.001$ ). In comparison to one patient (female) in the TENS group, five patients (four female and one male) in the plating group experienced heterotrophic scar formation ( $p=0.046$ ). The average union time did not differ significantly between the two groups ( $10.17 \pm 1.84$  and  $10.88 \pm 2.44$  weeks, respectively;  $p=0.430$ ) (Figures 2 and 3). After a year, the TENS group's constant shoulder score was  $90.77 \pm 9.01$ , while the plating group's was  $92.63 \pm 6.04$ , not statistically significant ( $p=0.269$ ). Additionally, there was no statistically significant difference ( $p=0.552$ ) in the mean DASH score between the plating group and the TENS group, which was  $6.32 \pm 10.33$  and  $6.01 \pm 11.09$ , respectively.

Five superficial infections total—three in the plating group and two in the TENS group - and one deep infection in the plating group were reported. Systemic antibiotics were used to treat all superficial infections, with a duration of 7 to 10 days. In the follow - up period, a patient in the plating group experienced a profound infection. Six weeks after surgery, implant removal and wound debridement were carried out. The fracture healed completely after receiving systemic antibiotic therapy for 15 days.

Table 2: Complications

	TENS (n=31)	Plating (n=25)	P value
Infection			
Superficial	2	3	0.345
Deep	0	1	0.455
Skin irritation	4	5	0.078
Non - union	1	1	0.587
Implant failure	0	1	0.121
Implant prominence (subjective)	7	6	0.784
Loss of sensation over the clavicle	1	3	0.471
Heterotopic scar formation	1	5	0.046
Malunion	2	1	0.060
Implant exit	29	5	0.007
Re - fracture after implant exit	0	0	0.899

The patient's functional outcome was good, and after a year, their final constant score was 90.45. Another patient 40 year old man who came to see us had plate exposure at three

months of follow - up, following superficial infection. Fracture had united. Therefore, he was debrided, under a drain's cover, remove the plate and complete closure. The wound then healed without experiencing any more issues. When the driver of a public bus suddenly braked, one of the plating group's patients suffered re - injury to the operated clavicle, leading to implant failure. A new locking anatomical S plate was used for re - fixation after implant exit, and further bone grafting was carried out to cover the defect and expedite healing

Seven TENS group patients and six plating group patients, out of the 56 patients who answered questions on the prominence of the implant, voiced their concerns. An out - patient department procedure was necessary for one TENS group patient who complained of substantial prominence and skin irritation. The procedure involved cutting the medial end of the nail under local anaesthesia. *Acinetobacter baumannii* growth was suggested by intraoperative deep cultures. Debridement and implant removal were completed. Antibiotics were used to treat a subsequent infection, and radiographs revealed non - union at the fracture site. Following the implant departure, no unusual mobility was observed at the fracture site in a clinical manner. The patient's shoulder joint was functionally pain - free throughout its entire range of motion. In contrast, at the 4 - month follow - up, the patient in the nailing group who had the non - union had revision surgery with plate and bone grafting. After three months, the fracture healed together without any more issues. Anteroposterior radiograph angulation greater than 10 degrees was considered malunion. Of the 31 patients, two had asymptomatic mal - union that we noticed. Their unions were superiorly angulated. A mean follow - up of 6.56 months (range: 6 to 9 months) was required for the removal of the majority of TENS (29 out of 31). Although patients were not frequently advised to have their plates removed, five of them asked to have their implants removed. For these five patients, the follow - up period averaged 12.5 months (range: 10 to 15 months).

## 5. Discussion

Good functional and radiological results are still achieved with conservative treatment for clavicle fractures. Despite ongoing debate, there seems to be a growing body of evidence supporting surgical fixation of midshaft clavicle fractures. Three - quarters of clavicle fractures occur in eighty percent of cases. As more patients experience unhappiness from conservative treatment for a clavicle malunion particularly when working overhead trauma surgeons are investigating surgical fixing options. The accepted surgical procedure for treating displaced midshaft clavicle fractures is plate fixation. TENS has also drawn a lot of attention over time because to its shorter recovery period, smaller scar, and minimally invasive nature. Our research showed that for displaced midshaft clavicle fractures, intramedullary TENS fixation produced equal clinical outcomes to plate fixation. Between the TENS and plating groups, there was no discernible difference in the constant shoulder score ( $p=0.269$ ) or DASH ( $p=0.552$ ). According to published research, a wider incision is necessary to insert the plate onto the bone because of the displaced fracture site and the clavicle's S - shaped structure

The results of our investigation showed that the scar lengths of the TENS group ( $18.66\pm 1.23$  cms) and plating group ( $11.01\pm 3.29$  cms) were considerably smaller, respectively, suggesting that TENS fixation required less surgery than plate fixation ( $p<0.001$ ). Our study shows that compared to standard plate fixation, TENS leads to less soft tissue stripping, less blood loss, shorter operating times, and superior cosmetic outcomes. The most often documented side effects with plate fixation of clavicle fractures include deep and superficial infections, implant prominence, non - union, and unsatisfactory cosmetic outcome. These issues are also associated with the hardware and the big operating wound.<sup>16</sup> In our study, the plating group experienced three superficial infections and one deep infection, while the TENS group experienced two superficial infections. According to recent studies, employing intramedullary TENS for clavicle fracture repair results in excellent patient satisfaction rates, good shoulder function, and favourable radiological outcomes.<sup>17-19</sup> In the TENS group, there were two cases of asymptomatic radiological malunion, but in the plating group, there was only one case, which happened as a result of removing the contaminated plate as previously reported. TENS is often preferred for treating minor displaced fractures of the midshaft clavicle since it demonstrated a stress distribution similar to that of an intact clavicle according to a biomechanical study by Zeng et al. that compared TENS with plating for midshaft clavicle fixation. On the other hand, TENS offered less stability than plating. In order to prevent failure, they recommended avoiding weight bearing on the ipsilateral shoulder and strenuous exercise in the early postoperative phase. They added that although stress shielding was evident, fixation with a reconstruction plate was more stable than TENS. They came to the conclusion that when patients insisted on an early return to activities, plate fixation was the best option. In order to attain great shoulder functional outcomes following midshaft clavicle fractures, recent studies highlight the significance of retaining clavicle length. Numerous authors have reported that clavicle shortening can cause a change in the scapula's resting position, an increase in the preload stress on the shoulder girdle muscles, an increase in the sterno - clavicle joint angle, and limitations in overhead motion in addition to pain and weakness. Patients with considerable shortening of the mal - united clavicle fractures treated conservatively showed an 11% reduction in shoulder abduction endurance strength and an 8% drop in shoulder external rotation strength, according to Schultz et al.<sup>24</sup> According to Lazarides and Zafiroopoulos, a final clavicle shortening of more than 18 mm in male patients and more than 14 mm in female patients would have a major impact on shoulder girdle motion. as comparison to patients with less than 2 cm of clavicle shortening, patients with more than 2 cm of shortening had a DASH score of more than 30 points. They proposed that achieving a union with less than 2 cm of shortening was crucial for a healthy shoulder girdle mobility. The likelihood of poor functional results grows sharply above this key level. An additional examination of the literature indicates that plate fixation may give a superior design for severely comminuted fractures, help ease early mobilization, and provide more rigid stabilization than intramedullary pin fixation. Large incisions and prolonged exposure, however, may be necessary for this procedure, which increases the risk of

problems such infection, scarring, and refracture following plate removal. In neither of the groups in our study were there any reports of refractures following implant removal.

**Table 3: Results**

Parameters	TENS (n=31)	Plating (n=25)	P Value
Duration of hospital stay (days)	4.13+2.38	7.24+4.10	0.001
Scar length (cms)	1.86+1.23	11.01+3.29	<0.001
Clavicle shortening (cm)	0.76+0.93	0.09+0.29	0.044
Average union time (weeks)	10.17+1.84	10.88+2.44	0.430
DASH Score	6.01+11.09	6.32+10.33	0.552
Constant score	90.77+9.01	92.63+6.04	0.269

## 6. Conclusions

For the fixation of midshaft clavicle fractures, both anatomically shaped clavicle plates and intramedullary TENS are suitable options. Intramedullary TENS fixation is a less invasive technique that may have improved early results with shorter operating times and faster overall fracture healing; however, in the long - term evaluation, there was no significant difference between the two groups in terms of overall union rate and full shoulder motion achieved. The increased implant failure rate linked to TENS fixing might mean that not all fracture patterns are a good fit for this particular implant. For fractures containing a large butterfly fragment or considerable comminution, plate fixation is advised. TENS fixation is less appropriate for rotationally and axially unstable fracture patterns since it is a more technically demanding treatment that requires adequate bone purchase. It should be saved for uncomplicated fractures or those with limited comminution and good cortical apposition.

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