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A COMPARATIVE STUDY OF PLATE VERSUS TITANIUM ELASTIC NAIL (TEN) IN THE TREATMENT OF DISPLACED MIDSHAFT CLAVICLE FRACTURES

Orthopaedics

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ABSTRACT

Background: As treatment approaches for displaced midshaft clavicle fractures (DMCF) evolve, plating continues to be the standard fixation method. An appealing alternative is titanium elastic nailing (TEN). However, there is a scarcity of prospective randomized studies that compare these two fixation techniques. In this study, we evaluated the effectiveness of minimally invasive antegrade TEN versus plating for treating DMCF. **Materials and Methods:** 70 unilateral displaced midclavicular fractures operated between September 2022 and September 2024 were included in study. This prospective comparative study was conducted at JNUIMSRC Jaipur, after approval by the ethical committee. Follow-ups were at 2nd and 6th weeks and subsequently at 3,6,12 months postoperatively. Primary outcome was measured by the Constant score, union rate and difference in clavicular length after fracture union. Secondary outcome was measured by operative time, intraoperative blood loss, wound size, cosmetic results and complications. **Results:** In our analysis, there were 32 patients in the plate group and 29 in the TEN group. While there was no significant difference in Constant scores between the two groups, the TEN group demonstrated faster fracture union, shorter operative time, reduced blood loss, easier implant removal, and fewer complications. **Conclusion:** The use of minimally invasive antegrade TEN for fixation of displaced midshaft clavicle fractures is recommended in view of faster fracture union, lesser morbidity, better cosmetic results, easier implant removal and fewer complications; although for comminuted fractures plating remains the procedure of choice.

KEYWORDS

Clavicle fractures, internal fixation of clavicle fractures, plate, titanium elastic nailing

INTRODUCTION:

Clavicle fractures are common injuries, accounting for 2.6-10% of all fractures, with about 80% occurring in the midshaft, and over half of these being displaced. Traditionally, midshaft clavicle fractures have been treated conservatively using a sling or figure-of-eight bandage.

The functional outcome of midshaft clavicle fractures is influenced not only by healing but also by the length of the bone. The clavicle serves as a "strut," maintaining the upper limb's position away from the torso for optimal shoulder and upper limb function, while also transmitting forces from the arm to the trunk. Consequently, displaced or comminuted fractures pose a risk of symptomatic malunion, nonunion, and poor functional outcomes, often accompanied by cosmetic deformity. Recently, there has been a shift toward internal fixation for displaced midshaft clavicle fractures (DMCF).

Two primary surgical techniques for internal fixation of DMCF are plate fixation and intramedullary nailing using a titanium elastic nail (TEN). Recent prospective randomized studies have shown that functional outcomes after both methods are superior to conservative treatment. Furthermore, a recent meta-analysis indicated a significantly lower nonunion rate following surgical intervention.

However, there is a lack of prospective randomized studies directly comparing these two surgical techniques for treating DMCF.

MATERIALS AND METHODS:

Study Design:

This prospective comparative study was conducted at Jaipur National University Institute for Medical Science and Research Centre between September 2022 and September 2024.

Inclusion Criteria:

- Unilateral
- AO classification B1 and B2
- Displacement of more than shaft width
- Shortening by over 2 cm or threat of skin perforation at the fracture ends.

Exclusion Criteria:

- Patients with pre-existent morbidity concerning arm, shoulder or hand
- Moderate to severe head injury (Glasgow coma scale <12)
- Multi-trauma patients
- Open fractures
- Pathological fractures
- Fractures of >1 month duration
- Bilateral clavicle fractures
- Segmental fracture
- Fractures with associated neurovascular injury.

Allocation into plate fixation group or TEN fixation group was done alternatively (i.e. every even number patient underwent TEN fixation). Thus, each group was allocated 35 patients each. All the patients were operated within 4 weeks from the date of injury

Operative Procedure

Plate fixation

After administering anesthesia, patients were positioned in a "beach-chair semi-sitting" position. The affected shoulders were prepared and draped for access. A transverse incision was made just below the fracture site. The supraclavicular nerves were identified and preserved whenever possible, while minimizing soft tissue dissection. Once the fractures were reduced, a small fragment locking plate was secured to the anterosuperior surface of the bone, starting from the medial side using bicortical screws. In cases of oblique or complex fractures, interfragmentary lag screws were utilized to achieve compression. The fascia and skin were then closed in layers.

TEN Fixation

After anesthesia, patients were positioned supine. The sternoclavicular joint was palpated and marked on the affected side. We utilized image intensification in both 45° cephalad and 45° caudal directions, providing images in two planes that were 90° apart. A small incision was made approximately 1 cm lateral to the sternoclavicular joint, and the anterior cortex was accessed with a sharp, pointed awl. A titanium elastic nail (TEN) was then inserted, with diameters ranging from 2 to

3 mm depending on the width of the bone. Before insertion, the original curvature of the small, flattened nail tip was slightly straightened to facilitate smoother passage through the narrow medullary canal.

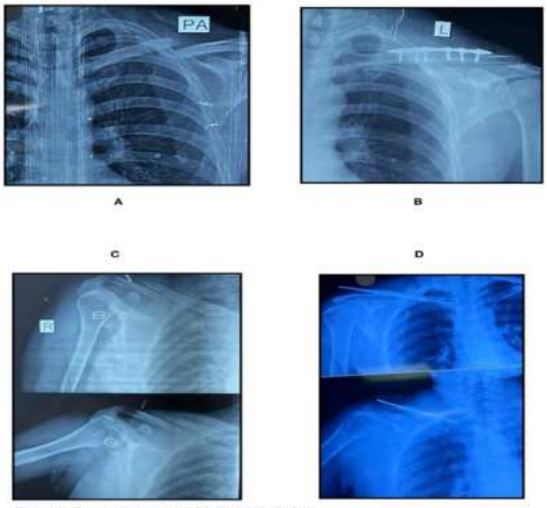

Figure A- Traumatic fracture mid-shaft left clavicle.

Figure B- Post-operative radiograph of left clavicle treated with clavicular plate and cortical screws , the fracture shows good reduction.

Figure C- Fracture of right mid-shaft clavicle.

Figure D- Post-operative radiograph of right clavicle fracture treated with TEN nail, showing good reduction without displacement of the TEN nail.

Closed reduction was conducted under fluoroscopic guidance using two pointed reduction clamps introduced percutaneously. If closed reduction was unsuccessful, an additional mini-open incision was made above the fracture site for direct manipulation of the main fragments. The nail was advanced manually until it was positioned just medial to the acromioclavicular joint. Careful maneuvering of the nail tip was essential under fluoroscopic control to avoid penetrating the thin dorsal cortex. Once the endpoint was reached, the fracture was compressed, and the nail was cut close to the entry point to reduce soft tissue irritation, while leaving enough length for easy removal later. The fascia and skin were then closed in layers.

Postoperatively, patients were provided with a sling but encouraged to begin early shoulder mobilization (as tolerated), starting with pendular exercises. After a week, active range of motion exercises were initiated, although overhead shoulder abduction was permitted only after two weeks. Daily living activities could commence afterward, but those involving heavy lifting were postponed until union. All patients were seen at 2 and 6 weeks, as well as at 3,6 and 12 months post-surgery. At each visit, clinic-radiological assessments were performed to evaluate primary and secondary outcome measures.

Functional outcomes were measured using the Constant score. Radiographic union was defined as the presence of bridging callus or the obliteration of fracture lines, while clinical union was indicated by the absence of tenderness at the fracture site. The time required to achieve union was recorded. After union, the shortening of clavicular length was clinically measured as the linear difference between the lengths of the clavicle from the sternal end to the acromial end on the operated side compared to the normal side.

Secondary outcome measures included perioperative data such as operative time, blood loss, and surgical wound size; complications like neurovascular injury, wound infection, nonunion, malunion, implant migration, implant failure, soft tissue irritation, refracture after implant removal, and cosmetic outcomes regarding visible deformities, hypertrophic scars, and hardware prominence beneath the skin. Implant removal was not performed routinely in our study; it was done based on necessity and the patient's preference after fracture union. The number of days required to return to normal activities following implant removal was also documented.

Statistical Analysis:

In analysing the data, patients who attended all follow-up visits starting from six weeks post-surgery were included. The differences between the two groups regarding primary and secondary outcome measures at the end of the follow-up period were assessed for statistical significance using an independent group means comparison to evaluate the differences between the two proportions (with $P < 0.05$ considered significant). However, it is important to note that our study's data lacks external validity.

RESULTS:

At the conclusion of the study, we compared 32 patients in the Plate group and 29 in the TEN group. In the Plate group, there were 25 male and 7 female patients, while the TEN group comprised 25 male and 4 female patients. The mean age was 32.02±12.65 years (ranging from 15 to 59 years) in the Plate group and 32.31±11.84 years (ranging from 15 to 56 years) in the TEN group. The delay from trauma to surgery was 11.83±5.91 days (ranging from 4 to 28 days) in the Plate group and 12.78±5.91 days (ranging from 5 to 29 days) in the TEN group. In the Plate group, 17 patients had AO class B1 fractures and 15 had AO class B2 fractures, compared to 18 B1 and 11 B2 fractures in the TEN group. There were no significant differences between the two groups regarding age ($P = 0.92$), sex ($P = 0.41$), and trauma to surgery delay ($P = 0.5$). Among the 29 patients in the TEN group, a nail diameter of 2 mm was used for 4 patients, 2.5 mm for 19 patients, and 3 mm for 6 patients. Closed reduction and nailing were successfully achieved in 22 patients, while the remaining 7 required open reduction (mini-open).

At the final evaluation, the overall results based on the Constant score showed 24 excellent, 6 good, and 2 fair outcomes in the Plate group. In the TEN group, there were 25 excellent and 4 good results.

The average time of union was significantly shorter in the TEN group compared to the Plate group ($P = 0.025$). Additionally, the mean difference in clavicular length after union was significantly greater in the TEN group than in the Plate group ($P = 0.001$) [Tables 1 and 2]. The mean operative time was also significantly reduced in the TEN group compared to the Plate group ($P < 0.001$). Furthermore, the mean intraoperative blood loss was significantly lower in the TEN group ($P < 0.001$) [Table 1]. The average wound size was considerably smaller in the TEN group (22 closed, 7 mini-open) than in the Plate group.

Table 1 Outcome Comparisons

Variable	Mean±SD (range)		P value
	Plate group	TEN group	(S)
Union time (weeks)	21±6	17.96±5.96	0.025
Shortening of clavicle (mm)	3.75±2.27	6.30±3.75	0.001
Operative time (min)	66.84±14.40	49.18±16.23 (20-80)	<0.001
Preoperative blood loss (ml)	114.49±37.64	45.79±44.74	<0.001

TEN= Titanium elastic nail, SD= Standard deviation, S=Significant

Table 2 Comparison Of Clavicle Length Shortening (mm)

AO class	Plate group	TEN group	P value
B1 fractures	2.72±2.15 (N=17)	4.07±2.18 (N=18)	0.06
B2 fractures	4.84±2.02 (N=15)	9.89±2.99 (N=11)	<0.001 (S)
Overall (B1+B2)	3.74±2.29 (N=32)	6.31±3.73 (N=29)	0.001 (S)

TEN= Titanium elastic nail, S= Significant

Complications

Major complications were noted in 4 patients [infection (*n*=3) and nonunion (*n*=1)] in the plate group, while none in the TEN group [Table 3]. Infections were controlled by debridement followed by intravenous antibiotics without removing the implants (as fixation was stable). The nonunion case in our series required revision surgery with bone grafting and healed thereafter uneventfully. In the plate group, hardware prominence (*n*=6), ugly scar (*n*=4). when compared to patients in the TEN group hypertrophic callus (*n*=1) medial hardware prominence (*n*=9) and lateral hardware prominence (*n*=1).

Table 3 Major And Cosmetic Complications

Complications	Plate group	TEN group
Major		
Infection	3	0
Non-union	1	0
Cosmetic		

Hypertrophic callus	0	1
Ugly scar	4	0
Troublesome hardware prominence	6	10

TEN= Titanium elastic nail, S= Significant

DISCUSSION:

Traditionally, midshaft clavicle fractures were treated nonoperatively. In the 1960s, Neer and Rowe recommended conservative treatment for clavicular fractures based on their studies, which reported very low non-union rates of 0.1% and 0.8%, respectively. However, these results have not been replicated in subsequent research. Recent studies have indicated significantly higher non-union rates in patients treated conservatively, ranging from 10% to 15%. As a result, current recommendations advocate for operative fixation of displaced midshaft clavicle fractures. Plating remains the standard surgical procedure, performed either anterosuperiorly or anteroinferiorly. Another emerging fixation method is intramedullary (IM) fixation using titanium elastic nails (TENs), either antegrade or retrograde. This study aims to compare the outcomes of anterosuperior plating with antegrade IM fixation using TEN.

In the Plate group, good to excellent results were achieved in 30 out of 32 patients, while all 29 patients in the TEN group had good to excellent outcomes. Overall, our study reported no unsatisfactory results, in contrast to the 5.3% incidence of unsatisfactory outcomes following operative treatment of DMCFs reported in the literature.

The average time to achieve union was significantly shorter in the TEN group compared to the Plate group (P = 0.025). This difference may be attributed to the reduced soft tissue dissection associated with the TEN approach. While plating offers absolute stability that promotes primary bone healing, TEN provides relative stability, facilitating secondary bone healing through callus formation.

In our study, clavicular lengths were significantly better preserved with plating (P = 0.001) compared to TEN, particularly in AO type-B2 fractures [Table 2]. However, this degree of clavicular shortening does not have a significant impact on functional outcomes. According to Lazarides and Zafiropoulos, only a final clavicular shortening of more than 18 mm in males and more than 14 mm in females is significantly associated with unsatisfactory results. Therefore, for comminuted DMCFs or fractures with large butterfly fragments, plate fixation remains the preferred surgical option, as it provides superior clavicular length maintenance.

We observed 4 major complications in the Plate group, including 3 cases of infection and 1 case of non-union. The incidence of infection after plating in our study was 10.81%, while reported rates in the literature vary from 0% to 18%.

In the TEN group, a notable but minor complication was the medial prominence of the hardware, which caused skin irritation or perforation in 9 patients. Two primary causes of this issue have been discussed in the literature: inadequately cut medial ends of the nail during the initial surgery and nail displacement due to secondary clavicle shortening or telescoping. The first cause, a surgeon-related factor, can be addressed postoperatively by properly trimming the nail. The second cause is more challenging to manage but can be minimized through anatomical reduction, intraoperative compression, and avoiding shoulder abduction beyond 90° during the first two weeks after surgery. Additionally, using medial end caps can help reduce medial protrusion.

A limitation of our study is the small sample size. Nevertheless, we recommend the use of minimally invasive antegrade TEN for the fixation of displaced midshaft clavicle fractures due to its advantages in achieving faster fracture union, lower morbidity, easier implant removal, and fewer complications; however, for comminuted fractures, plating remains the preferred surgical option.

CONCLUSION:

The use of minimally invasive antegrade TEN for fixation of displaced midshaft clavicle fractures is recommended in view of faster fracture union, lesser morbidity, better cosmetic results, easier implant removal and fewer complications; although for comminuted fractures plating remains the procedure of choice.

MeSH Terms: Fractures, clavicle, fracture fixation, internal, bone plates, intramedullary nailing

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