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A Study of Functional Outcome of Tens Nailing in Midshaft Clavicle Fractures

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ABSTRACT
Mid-shaft clavicle fractures are commonly encountered in orthopedic practice, particularly among active individuals. Traditional management methods, including conservative treatment, have shown varying results, with some patients experiencing non-union or malunion. Titanium Elastic Intramedullary Nails (TENs) have emerged as a minimally invasive surgical alternative, promising improved outcomes. This study aimed to evaluate the functional outcomes, time to bony union and complication rates associated with the use of Titanium Elastic Intramedullary Nails in the treatment of mid-shaft clavicle fractures. A prospective study was conducted on 20 patients treated with Titanium Elastic Nails for mid-shaft clavicle fractures between [2022] and [2024] at Government Medical College Baroda and SSG Hospital Vadodara Gujarat. The primary outcome measures included the time for bony union, the incidence of complications and functional recovery, assessed using the Constant Muerly Score over a follow-up period of 3 months. The mean time to bony union was 6 weeks. Functional recovery was achieved in 95.5% of patients, with minimal complications such as Implant impingement at insertion site and Extraction of Implant. The majority of patients returned to their pre-injury levels of activity within 12 weeks. Titanium Elastic Intramedullary Nailing is an effective and safe technique for treating mid-shaft clavicle fractures, demonstrating high union rates, early functional recovery and a low incidence of complications. This technique is particularly beneficial for active individuals requiring rapid rehabilitation.

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Key Words
Functional outcome, tens, midshaft, fractures, orthopedic practice

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INTRODUCTION

Clavicle fractures are frequently observed in children and young adults, particularly in individuals under the age of 25. This injury is prevalent due to the clavicle's anatomical characteristics, including its superficial position just beneath the skin and its slender midshaft, which make it susceptible to trauma. Clavicle fractures represented 2.6% of all fractures in Adult and 10% to 15% in Children and comprise about 44% of those in the shoulder girdle[1]. Clavicle fractures affect 1 in 1000 people per year. They are the most common fractures during childhood and approximately two-thirds of all clavicle fractures occurring in males. There is a bimodal distribution of clavicle fractures, with the 2 peaks being men younger than 25 (sports injuries and Road traffic accidents) and patients older than 55 years of age (falls)[2]. Approximately 20 percent of females and >one-third of males with clavicular fractures are between 13-20 years old[3,4]. The middle third of the clavicle is fractured in 79% of cases, the distal third is fractured in 19% of cases and the proximal third is fractured in 1.4% of cases[5]. Midclavicular fractures are generally managed conservatively, e.g. with a figure-of-eight-bandage. Imminent perforation of the skin, impending or existing neurovascular compromise and the floating shoulder and gross displacement of fracture fragments are absolute indications for operative treatment[6]. Significantly displaced fractures in the middle portion of the collarbone can lead to substantial and lasting disability, even when the bone heals properly. This has contributed to a growing trend towards surgically fixing these fractures, driven by unsatisfactory outcomes from conservative treatment[6,7,8,9]. In the last few years, several publications have described the technique of minimally-invasive osteosythesis using Elastic stable intramedullary nails (ESINs) for displaced midshaft clavicle fracture in order to minimize the rate of non union and symptomatic malunion with early functional recovery and a rapid return to daily activities[10,11]. In recent years, there has been a growing interest in surgical intervention for displaced mid-shaft clavicle fractures, especially in active patients who require a faster return to their pre-injury level of function. Various surgical techniques have been developed, with plate fixation being the most commonly employed. However, plate fixation is associated with complications such as infection, hardware irritation, and the need for subsequent hardware removal[12-14]. To address these concerns, Titanium Elastic Intramedullary Nails (TENs) have been introduced as a minimally invasive alternative that offers the potential for reduced operative time, smaller incisions, and fewer complications[15-19]. Despite the growing use of TENs in clinical practice, there is still limited data on the long-term functional outcomes and complication rates associated with this technique. The present study aims to evaluate the effectiveness of TENs in the treatment of mid-shaft clavicle fractures, focusing on key outcomes such as time to bony union, functional recovery and the incidence of complications. By providing a comprehensive analysis of these outcomes, this study seeks to contribute to the existing body of evidence and guide clinicians in making informed decisions regarding the optimal treatment of mid-shaft clavicle fractures.

MATRIALS AND METHODS

Study Design: This Prospective study was conducted at Government Medical College Baroda and SSG Hospital Vadodara Gujarat between September 2022 and June 2024. The study was approved by the Institutional Ethics Committee for Biomedical and Health Research (IECBHR) Medical College and SSG Hospital Bardoa all procedures followed ethical guidelines consistent.

Patient Selection: A total of 20 patients with displaced mid-shaft clavicle fractures were included in this study. Inclusion criteria were as follows. Patients age above 18 years with radiographically confirmed displaced mid-shaft clavicle fractures AO type 15.2 (A,B,C). Fractures treated surgically using Titanium Elastic Intramedullary Nails (TENs). A minimum follow-up period of 3 months post-operatively.

Exclusion Criteria Included: Patients with Age less than 18 years and fractures involving the lateral (AO type 15.3) or medial third (AO type 15.1) of the clavicle, Uncooperative patient for post operative rehabilitation, Patient not giving consent and medically unfit patient. Incomplete follow-up data.

Surgical Procedure: All surgeries were performed by experienced orthopedic surgeons under general anesthesia and/or Brachial block. The patients were placed in the beach chair position. A small incision 1cm was made near the medial end of the clavicle and the medullary canal was accessed using a Kirschner wire and Awl. Titanium Elastic Intramedullary Nails were then introduced into the canal, crossing the fracture site and advancing toward the lateral end of the clavicle. Fracture reduction was confirmed radiographically and the nails were cut at the entry point, leaving a small portion outside the bone to facilitate removal.

Post-Operatively: The arm was placed in a sling for comfort. Passive range of motion exercises were initiated after 2nd post operative day, with a gradual progression to active range of motion at 6 weeks and strengthening exercises based on patient tolerance.

Data Collection: Patients were followed up at regular intervals every 4th week for 3 months. The primary outcome measures included.

Time for Bony Union: Defined as the absence of pain at the fracture site and radiographic evidence of cortical bridging callus in at least two cortices.

Functional Outcomes: Assessed using the Constant-Murley Score at each follow-up visit.

Complications: Documented complications included implant impingement.

Statistical Analysis: Descriptive statistics were used to summarize the demographic and clinical characteristics of the patients. Categorical variables such as Constant Muerly Score, Complication rates, were expressed as percentages.

RESULTS AND DISCUSSIONS

Mode of Injury: Of the 20 patients 15 patients (75%) fracture occurred due to road traffic accident, 4 (20%) patients sustained fracture due to indirect injury, fall on outstretched hand and 1 patients (5%) due to Direct trauma. In all the patients fractures were closed type.

Table 1: Age Incidence

Age in years	No of patients	Percentage
18-29	8	40%
30-39	6	30%
40-49	3	15%
50-59	2	10%
60-69	1	5%

Gender Incidence: In our study majority 15 patients (75%) were males and 5 patients (25%) were females.

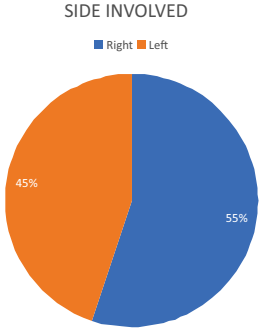


Fig. 1: Side Affected

Side Involved

Side	No of patients	Percentage
Right	11	55%
Left	9	45%

Classification: Plain radiograph antero-posterior view with shoulder to assess the fracture pattern (like displacement, angulation, comminution). in our study AO/OTA (ortho trauma association) followed.

Table 2: Classification of Patients Percentage

Classification	No of patients	Percentage
AO classification		
15.2A	17	85%
15.2B	03	15%
15.2C	0	0%

Pre-Operative Shortening and Displacement: Length of clavicle on the affected side measured from suprasternal notch to Acromioclavicular joint and compared with normal side for any shortening. 14 patients (70%) had 1.5-2cm shortening and 6 patients (30%) had shortening 2-2.5cm.

Time Interval For Surgery: All patients were operated once the general condition of the patients were stable 2 patients (20%) were operated in one day 14 patients (65%) were operated from 2-6 days. 4 patients (15%) were operated from 7-14 days. The operative treatment was performed an average of 5 days (range: from 1-14 days)

Table 3: Type of Implant Used

TENS Nail Size	No patients	Percentage
1.5mm	4	20%
2mm	16	80%

Table 4: Surgical Technique

Nature of surgery	No of patients	Percentage
Closed	15	75%
Mini open	5	25%

Post op Visual Analogue Scale[20]: Pain was measured with visual analogue scale at 24 hours post surgery. The score averaged 2.35 cm.

Post Operative Shortening: Post operatively 18 patients (90%) had no shortening and 2 patients (10%) had <0.5cm.

Duration for Union: The fracture was considered to be united when clinically there was no tenderness, radiologically the bridging callus was seen and full unprotected function of the limb was possible. In 19 patients (90%) fracture united by the end of 12th week post operatively. 2 patients (10%) patients fracture united by 16-18 weeks. All 2 patients were above 50 years.

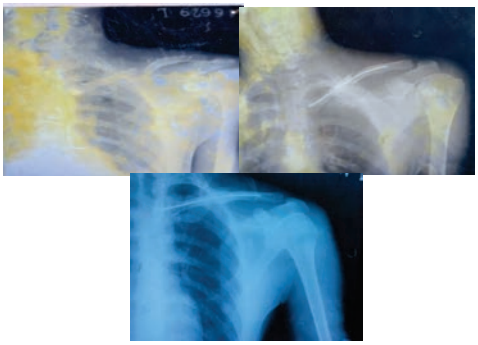
Table 5: Functional Outcome at 3 Months

Constant score	No of patients	Percentage
Excellent	17	85%
Good	3	15%
Fair	1	5%
Poor	0	0%

The Average Constant Murley Score[21,22] was 95.5.

Complications: Skin irritation due to prominent nail on the medial side occurred in 5 patients (25%). 3 patients required nail removal at 14 weeks fracture union was achieved by the time. No post op infection was seen.

Case 1:



Pre-op Post-op 3 Month follow up

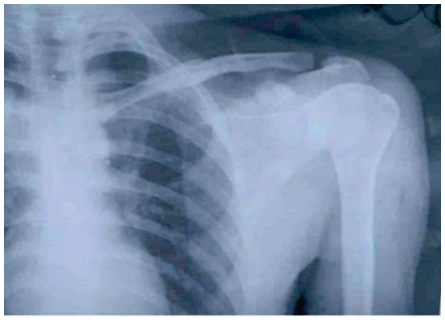
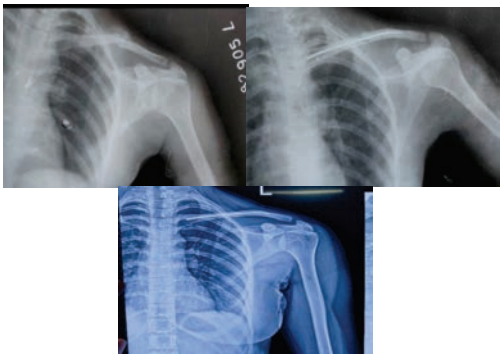


Fig. 1: After Implant Extraction

Fig. 2: Functional Outcome

This study prospectively evaluated the outcomes of Titanium Elastic Intramedullary Nailing (TEN) in the treatment of mid-shaft clavicle fractures in 20 patients, and the results were compared to those of Hartmann[18] who retrospectively reviewed a consecutive series of 15 patients. Our findings provide valuable insights into the efficacy and safety of TENs in managing these fractures, particularly when comparing our results with those from Hartmann[18] study.

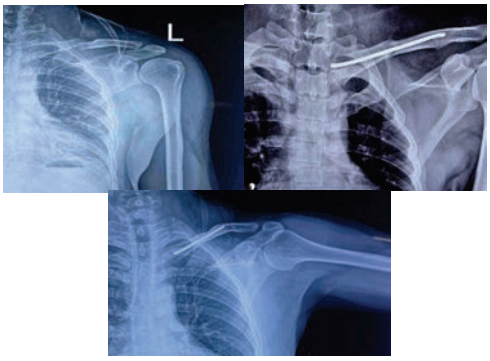
Case 2:



Pre-op Post-op 3 Month follow

Fig 3: Functional Outcome

Case 3:



Pre-op Post-op 3 Month follow up

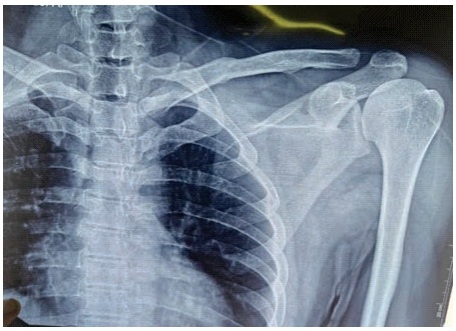


Fig 4: After Implant Extraction

Fig 5: Functional Outcome

Patient Demographics and Injury Mechanism: In our cohort, the majority of fractures (75%) resulted from road traffic accidents, followed by falls from height (20%) and direct trauma (5%). This distribution contrasts with Hartmann *et al.*'s findings, where traffic accidents accounted for 47% of injuries, sports accidents 40% and falls from height 14%. The higher proportion of road traffic accidents in our study likely reflects differences in patient activity levels and injury patterns between the two populations. Our study included patients with a wide age range (18-68 years), with a mean age of 37.45 years, similar to Hartmann[18] study, where the mean age was 36.7 years. Both studies observed a male predominance, with 75% of our patients and 80% of Hartmann *et al.*'s patients being male, indicating that mid-shaft clavicle fractures are more common in young, active men.

Fracture Classification and Treatment Timing: In our study, 85% of fractures were classified as AO type 15.2A and 15% as AO type 15.2B, while Hartmann *et al.* used the OTA classification, reporting 46% type A and 54% type B fractures. The consistent finding of fracture displacement and shortening in our study (with an average shortening of 1.63 cm and displacement of 2.2 cm) highlights the necessity for surgical intervention in these cases. The timing of surgical intervention varied slightly between studies, with our patients undergoing surgery an average of 3.6 days post-injury (range 1-11 days), compared to Hartmann *et al.,* where surgery was performed an average of 6 days after trauma (range 2-29 days). This earlier intervention in our study could have contributed to the favorable outcomes observed, particularly in terms of reducing complications and facilitating quicker recovery.

Surgical Technique and Outcomes: Our study primarily utilized 2 mm TEN nails in 75% of patients, with the remaining 25% receiving 1.5 mm nails. Hartmann *et al.,* however, used a slightly larger average nail diameter of 2.5 mm. The choice of nail size is crucial, as it affects the stability of the fracture fixation and the potential for irritation at the entry point. Closed reduction was successfully performed in 85% of our patients, with only 15% requiring open reduction. In contrast, Hartmann *et al.* reported a higher rate of open reductions (75%), suggesting that closed reduction may be more feasible with earlier intervention and appropriate patient selection. Our study demonstrated excellent post-operative outcomes, with 85% of patients having no shortening and only 15% experiencing minimal shortening (<0.5 cm). This result underscores the effectiveness of TENs in restoring clavicular length and maintaining fracture alignment. The postoperative pain, as measured by the Visual Analogue Scale, averaged 1.5±0.5, identical to Hartmann *et al.*'s findings, indicating similar levels of postoperative discomfort between the two groups. Radiological union was achieved by the 12th week in 95% of our patients, with the remaining patient achieving union by 16-18 weeks. These results are comparable to Hartmann *et al.,* who observed complete fracture consolidation by 12 weeks. Functional outcomes, as measured by the Constant-Murley score, averaged 95.5 in our study, with 90% of patients achieving excellent scores, further validating the efficacy of TENs in mid-shaft clavicle fractures.

Complications: Skin irritation due to the prominence of the medial nail was observed in 25% of our patients, with 15% requiring nail removal after fracture union. This complication is consistent with other studies, including Hartmann *et al.,* where similar issues were reported, albeit without the need for nail removal in most cases. Importantly, no intraoperative complications or postoperative infections were observed in our study, which aligns with Hartmann *et al.*'s findings, though they reported a single case of acromioclavicular disruption during nail insertion.

Comparison and Clinical Implications: The comparison between our study and that of Hartmann *et al.* reveals consistent results, despite differences in study design, patient demographics and surgical techniques. Both studies highlight the effectiveness of TENs in achieving early fracture union, excellent functional outcomes, and a low incidence of serious complications. The differences in complication rates, particularly regarding skin irritation and the need for nail removal, underscore the importance of careful patient selection, appropriate nail sizing and meticulous surgical technique. Given the positive outcomes observed, TENs should be considered a viable option for the treatment of displaced mid-shaft clavicle fractures,

particularly in active individuals who require a rapid return to function. However, the potential for skin irritation and the need for subsequent nail removal should be discussed with patients during the preoperative consultation.

Limitations and Future Directions: This study is limited by its relatively small sample size and the lack of a control group treated with alternative fixation methods, such as plate fixation. Future research should focus on larger, prospective randomized controlled trials comparing TENs with other surgical techniques to establish definitive treatment guidelines. Additionally, longer-term follow-up studies are needed to assess the durability of TEN fixation and the incidence of late complications.

CONCLUSION

Titanium Elastic Intramedullary Nailing is a safe and effective technique for the management of mid-shaft clavicle fractures, offering high union rates, excellent functional outcomes and a low complication profile. This study adds to the growing body of evidence supporting the use of TENs in clinical practice, particularly for patients requiring early mobilization and return to activity.

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