International Journal of Health Sciences and Research
[Indexed, Peer-Reviewed Journal]
Volume 16; Issue: 8; August 2026
Website: www.ijhsr.org
Original Research Article *ISSN: 2249-9571*

Plate Fixation Versus Titanium Elastic Nailing for Displaced Midshaft Clavicle Fractures: A Prospective Study

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DOI: https://doi.org/10.52403/ijhsr.20260806

Received: 05/04/2026; Revised: 24/06/2026; Accepted: 29/07/2026

ABSTRACT

Background: Displaced midshaft clavicle fractures are increasingly managed surgically because of the higher risk of non-union and functional impairment associated with conservative treatment. Plate fixation and titanium elastic intramedullary nailing (TENS) are commonly employed surgical techniques; however, evidence regarding their comparative functional outcomes remains limited.

Methods: This prospective comparative non-randomized study was conducted at a tertiary care teaching hospital to compare the clinical and functional outcomes of anterosuperior plate fixation and titanium elastic intramedullary nailing (TENS) in adults with displaced midshaft clavicle fractures. Based on a priori sample size estimation, 40 patients were enrolled and prospectively allocated to either the plate fixation group (n=20) or the TENS group (n=20). Patients were followed for six months. Primary outcome measures included time to fracture union and functional outcome assessed using the Constant Shoulder Score. Secondary outcomes included postoperative complications. Data were analysed using the Mann–Whitney U test, independent Student's *t*-test, repeated-measures ANOVA with Bonferroni post hoc analysis, and Fisher's exact test.

Results: Baseline demographic and injury characteristics were comparable between the two groups. The mean time to fracture union was 10.50 ± 1.47 weeks in the plating group and 10.40 ± 2.01 weeks in the TENS group, with no significant difference (p=0.86). At one month, the TENS group demonstrated significantly higher Constant Shoulder Scores than the

plating group (74.1 ± 4.8 vs. 68.4 ± 5.2), with a mean difference of 5.7 points (95% CI: 2.5–8.9; p=0.001) and a large effect size (Cohen's d=1.14). No significant differences were observed at three months (p=0.16) or six months (p=0.17). Repeated-measures ANOVA demonstrated significant improvement in Constant Shoulder Scores over time within both groups (p<0.001). Postoperative complications were infrequent and comparable between groups (Fisher's exact test, p=0.83), with no cases of deep infection or non-union.

Conclusion: Both anterosuperior plate fixation and titanium elastic intramedullary nailing are safe and effective surgical options for displaced midshaft clavicle fractures, achieving comparable fracture union and low complication rates. TENS provides significantly superior early functional recovery, although long-term functional outcomes are similar between the two techniques. The choice of fixation should therefore be individualized according to fracture characteristics, patient factors, and surgeon expertise.

Keywords: Clavicle fracture; plate fixation; titanium elastic intramedullary nailing; TENS; Constant Shoulder Score; functional outcome.

INTRODUCTION

Clavicle fractures are among the most common injuries of the shoulder girdle, accounting for approximately 2–5% of all fractures, with nearly 70–80% involving the midshaft region [1,2]. These fractures typically occur following direct trauma to the shoulder, most commonly due to road traffic accidents, falls, or sports-related injuries. Traditionally, midshaft clavicle fractures were managed conservatively with immobilization, as earlier studies reported high rates of fracture union and satisfactory functional outcomes. [3]

However, recent literature has challenged this traditional approach, particularly in displaced midshaft fractures. Several studies have demonstrated that non-operative management of displaced fractures may be associated with higher rates of malunion, non-union, residual pain, and functional impairment. [4,5] This has led to a paradigm shift toward surgical fixation, especially in active individuals and those with significant displacement or shortening.

Among the various surgical options available, plate fixation and intramedullary fixation using titanium elastic nails (TENS) are the most commonly employed techniques. Plate fixation provides rigid stabilization, restores anatomical alignment and allows early mobilization, but may be associated with complications such as implant prominence and soft tissue irritation. [6,7] In contrast, TENS is a minimally invasive technique that preserves the periosteal blood supply and fracture biology, offering advantages such as reduced soft tissue disruption and improved cosmetic outcomes. [8]

Several systematic reviews and meta-analyses have compared plate fixation and intramedullary fixation for displaced midshaft clavicle fractures. Although previous studies have consistently demonstrated comparable fracture union and long-term functional outcomes, intramedullary fixation has been associated with earlier functional recovery and less soft tissue disruption. [1,5,11-13] Nevertheless, variations in study design, implant selection, rehabilitation protocols, and patient characteristics continue to limit the generalizability of these findings. Therefore, further prospective comparative studies are required to evaluate the clinical effectiveness of these treatment modalities in different practice settings.

The present study aimed to compare fracture union, functional outcomes assessed using the Constant Shoulder Score, and postoperative complications following anterosuperior plate fixation and titanium elastic intramedullary nailing (TENS) in adults with displaced midshaft clavicle fractures.

MATERIALS AND METHODS

Study Design and Setting

This prospective comparative study was conducted in the Department of Orthopaedics at Sapthagiri Institute of Medical Sciences and Research Centre, Bengaluru, a tertiary care teaching hospital. The study was carried out over a period of two years from May 2024 to October 2025 (18 months), after obtaining approval from the Institutional Ethics Committee. Written informed consent was obtained from all participants before inclusion in the study. The study was conducted in accordance with the ethical principles of the Declaration of Helsinki.

Study Population and Patient Selection

All adult patients presenting to the Orthopaedics outpatient department or emergency department with displaced midshaft clavicle fractures during the study period were screened for eligibility. A total of 50 patients were assessed for eligibility, of whom 10 were excluded (6 did not satisfy the inclusion criteria and 4 declined participation). The remaining 40 patients were enrolled and included in the study. A flow diagram (Fig.1) was used to depict patient selection, allocation, follow-up, and final analysis.

Sample Size Calculation

The sample size for the present study was estimated using a formula-based approach for comparing two independent means, with the Constant Shoulder Score at one month as the primary outcome measure. Based on the reference study by Yadav et al. (2022) [15], the expected mean difference between groups was 5.7 with a pooled standard deviation of approximately 5.0. Considering a two-tailed alpha of 0.05 and a desired power of 90% ($Z_{\alpha/2} = 1.96$, $Z_{\beta} = 1.28$), the calculated sample size was 16 patients per group. After adjusting for a 20% allowance for potential dropouts, the final required sample size was 20 patients per group, yielding a total of 40 patients.

Fracture Classification

Fractures were classified according to the AO/Orthopaedic Trauma Association (AO/OTA) classification system, and only displaced midshaft clavicle fractures (AO/OTA type 15.2) that were considered suitable for operative fixation were included in the study. Standard anteroposterior and 30° cephalic tilt radiographs of the clavicle were obtained for fracture assessment and surgical planning.

Inclusion and Exclusion Criteria

Patients were included if they were aged more than 18 years, had a closed displaced midshaft clavicle fracture, presented within two weeks of injury, and were willing to provide written informed consent and comply with follow-up. The rationale for these criteria was to ensure a homogeneous adult population with acute displaced fractures requiring operative management.

Patients were excluded if they had open fractures, pathological fractures, fractures involving the medial or lateral third of the clavicle, associated neurovascular injury requiring separate intervention, polytrauma preventing early surgical fixation, previous fracture or surgery involving the same clavicle, or any medical contraindication to anaesthesia or surgery. Patients who declined to participate were also excluded from the study.

Patient Allocation

After enrolment, the 40 eligible patients were prospectively allocated into two equal treatment groups comprising 20 patients each. Group A underwent open reduction and internal fixation using an anterosuperior pre-contoured locking plate, whereas Group B underwent intramedullary fixation using a titanium elastic nail (TENS). As this was a prospective comparative non-randomized study, allocation was performed according to surgeon preference and implant availability after discussing the treatment options with the patient. No formal random sequence generation or allocation concealment method was employed.

Surgical Technique

Plate Fixation (Group A)

All procedures were performed under general anaesthesia with the patient placed in the beach-chair position. A longitudinal incision was made over the superior aspect of the clavicle, centred over the fracture site. After careful dissection through the platysma and preservation of the surrounding soft tissues, the fracture fragments were exposed and anatomically reduced. Temporary reduction was achieved using reduction clamps when required. Definitive fixation was performed using an anterosuperior pre-contoured locking compression plate of appropriate length, ensuring fixation with at least three bi-cortical screws on either side of the fracture whenever feasible. The wound was irrigated thoroughly, haemostasis was secured, and the layers were closed in a standard fashion.

Titanium Elastic Nailing System (TENS) Fixation (Group B)

Patients in the TENS group were also operated under general anaesthesia in the beach-chair position. A small incision was made over the medial end of the clavicle approximately 1–2 cm lateral to the sternoclavicular joint. The medullary canal was opened using an awl, and an appropriately sized titanium elastic nail was introduced into the canal under fluoroscopic guidance. Closed reduction was attempted initially; if satisfactory reduction could not be achieved, a small incision over the fracture site was used to facilitate reduction. The nail was advanced across the fracture site into the lateral fragment, and its final position was confirmed fluoroscopically. The medial end of the nail was cut and buried beneath the skin before wound closure.

Postoperative Rehabilitation Protocol

A standardized postoperative rehabilitation protocol was followed for all patients in both treatment groups. Immediately after surgery, the operated upper limb was supported in an arm sling for comfort and soft tissue protection. Sling immobilization was maintained for 2 weeks, although patients were encouraged to perform active movements of the elbow, wrist, and hand from the first postoperative day.

Pendulum exercises and gentle passive shoulder mobilization were initiated as tolerated after the first postoperative day. At 2 weeks, following wound inspection and suture removal, patients commenced active-assisted range-of-motion exercises under the supervision of a physiotherapist. Progression to active shoulder exercises was permitted between 4 and 6 weeks, depending on pain tolerance and radiological evidence of satisfactory fracture healing.

Strengthening exercises and gradual resistance training were introduced after evidence of clinical and radiological union, generally between 8 and 10 weeks postoperatively. Patients were advised to avoid heavy lifting, overhead activities, and contact sports until complete fracture union had been confirmed.

Return to activities of daily living was encouraged as tolerated. Patients performing sedentary work were generally allowed to resume their duties by 4–6 weeks, whereas those involved in manual labour or physically demanding occupations were advised to return only after confirmed fracture union, usually at 10–12 weeks. Return to unrestricted sports and strenuous activities was permitted after complete clinical and radiological healing, typically by 3–6 months following surgery.

Follow-up Protocol

Patients were evaluated clinically and radiographically at 2 weeks, 1 month, 3 months, and 6 months after surgery according to the standardized follow-up schedule. Clinical assessment included evaluation of pain, wound healing, shoulder range of motion, and functional outcome using the Constant Shoulder Score. Standard anteroposterior and 30° cephalic tilt radiographs of the clavicle were obtained at

each visit to assess fracture healing, implant position, and possible complications.

Fracture union was assessed using predefined clinical and radiological criteria. Clinical union was defined as the absence of tenderness at the fracture site and pain during shoulder movement or functional use of the affected limb. Radiological union was defined as the presence of bridging callus across at least three of four cortices with progressive obliteration of the fracture line. Fracture union was independently assessed by two consultant orthopaedic surgeons who were not involved in the operative procedure. Formal blinding of the assessors was not feasible because the type of implant was identifiable on radiographs; however, both assessors evaluated the radiographs independently, and any disagreement was resolved by consensus. Interobserver variability was minimized by using predefined clinical and radiological criteria for fracture union.

Outcome Measures

The primary outcome measures were time to fracture union and functional outcome assessed using the Constant Shoulder Score. Secondary outcome measures included postoperative complications such as delayed union, implant prominence or irritation, superficial or deep infection, implant failure, non-union, and the need for secondary surgical procedures.

Statistical Analysis

Data were entered into Microsoft Excel and analysed using the Statistical Package for the Social Sciences (SPSS) for Windows, version 22.0 (IBM Corp., Armonk, NY, USA). Continuous variables were expressed as mean ± standard deviation (SD), whereas categorical variables were presented as frequencies and percentages.

The normality of continuous variables was assessed using the Kolmogorov–Smirnov and Shapiro–Wilk tests. Age did not satisfy the assumption of normality in one treatment group and was therefore compared using the Mann–Whitney U test. Time to fracture union and Constant Shoulder Scores at 1, 3, and 6 months were normally distributed and were compared between groups using the independent Student's t-test.

Categorical variables were analysed using the Chi-square test when the expected cell frequency was ≥5. Fisher's exact test was used whenever one or more expected cell frequencies were <5, including comparisons of postoperative complications and other low-frequency categorical variables.

Changes in Constant Shoulder Scores over time within each treatment group were analysed using repeated-measures analysis of variance (repeated-measures ANOVA) followed by Bonferroni's post hoc test for pairwise comparisons.

All statistical tests were two-tailed, and a p value <0.05 was considered statistically significant. Effect sizes were estimated using Cohen's d for between-group comparisons and partial eta squared (η^2) for repeated-measures ANOVA. Ninety-five percent confidence intervals (95% CI) were calculated for the primary outcome measures.

Ethical Approval

The study protocol was reviewed and approved by the Institutional Ethics Committee of Sapthagiri Institute of Medical Sciences and Research Centre, Bengaluru. Written informed consent was obtained from all participants before enrolment in the study.

RESULTS

Demographic Data

A total of 50 patients were assessed for eligibility, of whom 10 were excluded. Forty patients fulfilling the inclusion criteria were enrolled and equally allocated to the plating (n=20) and TENS (n=20) groups. Baseline demographic and injury characteristics were comparable between the two groups.

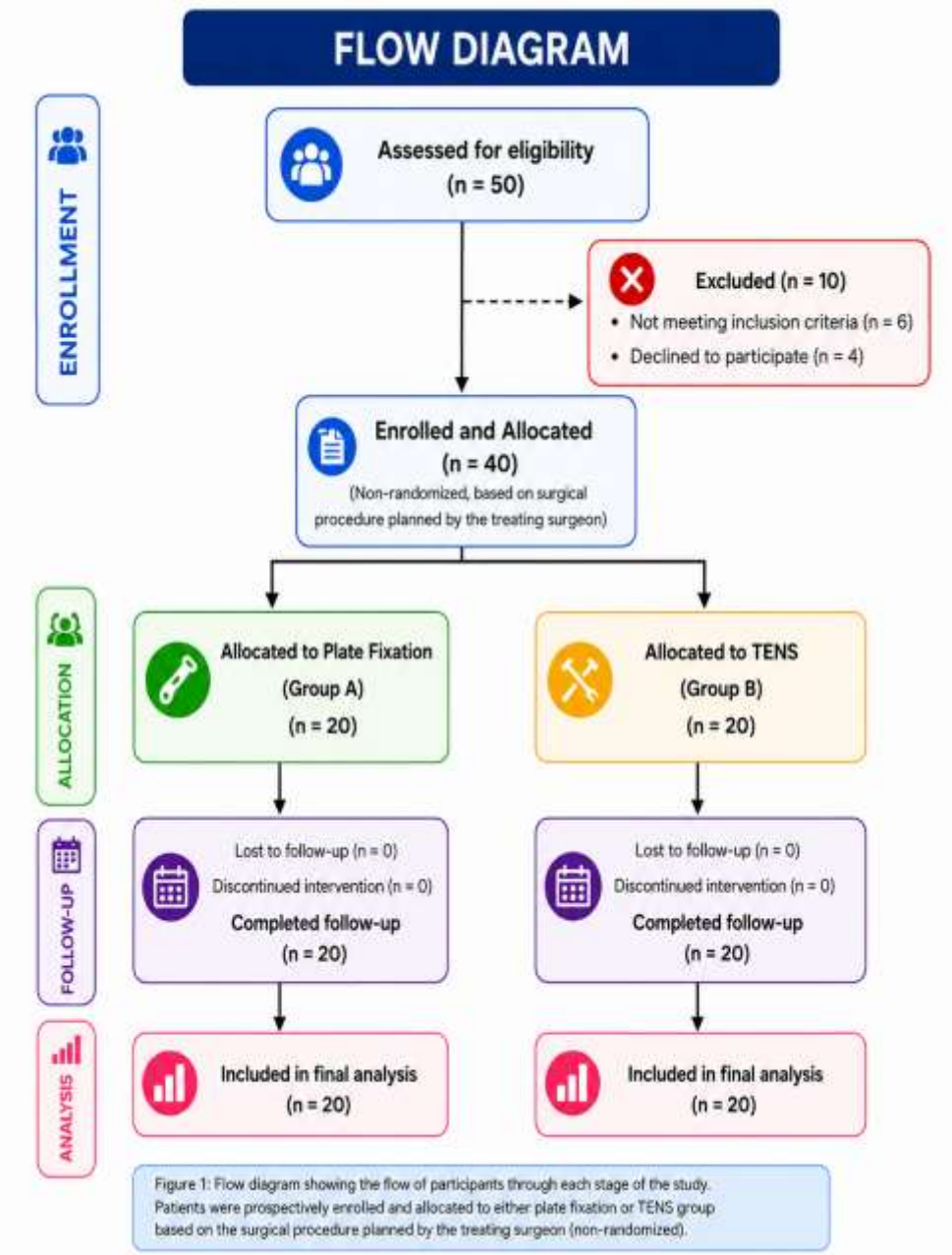

Figure 1. Flow diagram showing the flow of participants through each stage of the study

Table 1: Baseline demographic and injury characteristics of the study participants

Variable	Plate (n=20)	TENS (n=20)	p-value
Age (years), Mean ± SD	35.75 ± 12.10	32.50 ± 13.44	0.38[a]
Age range (years)	18–59	16–57	—
Sex			0.61[b]
Male, n (%)	19 (95.0)	17 (85.0)	
Female, n (%)	1 (5.0)	3 (15.0)	
Mode of injury			0.46[b]
Road traffic accident	13 (65.0)	11 (55.0)	
Assault	2 (10.0)	5 (25.0)	
Fall from height	5 (25.0)	4 (20.0)	

[a] Mann–Whitney U test; [b] Fisher's exact test.

The baseline demographic and injury characteristics were comparable between the two groups, with no statistically significant differences observed.

Table 2. Comparison of fracture union time between the two groups

Parameter	Plate (n=20)	TENS (n=20)	Mean difference	95% CI	p-value
Time to union (weeks), Mean ± SD	10.50 ± 1.47	10.40 ± 2.01	0.10	−1.03 to 1.23	0.86

Independent Student's t-test

The mean time to fracture union was comparable between the plating and TENS groups, with no statistically significant difference.

Table 3. Comparison of Constant Shoulder Scores between the two groups

Follow-up	Plate (Mean ± SD)	TENS (Mean ± SD)	Mean difference*	95% CI	p-value	Cohen's d
1 month	68.4 ± 5.2	74.1 ± 4.8	−5.7	−8.9 to −2.5	0.001	1.14
3 months	84.5 ± 4.1	86.3 ± 3.9	−1.8	−4.4 to 0.8	0.16	0.45
6 months	92.1 ± 3.0	93.4 ± 2.8	−1.3	−3.2 to 0.6	0.17	0.45

Independent Student's t-test

Mean difference = Plate − TENS.

At one month, the TENS group demonstrated significantly better functional outcomes than the plating group (p=0.001) with a large effect size (Cohen's d=1.14). However, no statistically significant differences were observed at 3 or 6 months.

Table 4. Within-group comparison of Constant Shoulder Scores over time using repeated-measures ANOVA

Group	1 Month (Mean ± SD)	3 Months (Mean ± SD)	6 Months (Mean ± SD)	Repeated-measures ANOVA p-value	Bonferroni post hoc	Partial η^2
Plate	68.40 ± 5.18	84.50 ± 4.11	92.05 ± 3.03	<0.001	All pairwise comparisons p<0.001	0.96
TENS	74.10 ± 4.83	86.30 ± 3.90	93.35 ± 2.80	<0.001	All pairwise comparisons p<0.001	0.96

Repeated-measures ANOVA followed by Bonferroni post hoc test

Both treatment groups demonstrated significant improvement in Constant Shoulder Scores over time (p<0.001). Bonferroni post hoc analysis showed significant improvements between each follow-up interval. The large partial η^2 (0.96) indicates a very strong effect of time on functional recovery.

Table 5. Comparison of postoperative complications between the two groups

Complication	Plate n (%)	TENS n (%)	p-value
Implant irritation	2 (10.0)	1 (5.0)	
Delayed union	1 (5.0)	1 (5.0)	
Infection	0 (0.0)	0 (0.0)	
No complication	17 (85.0)	18 (90.0)	0.83

Fisher's exact test

Postoperative complications were infrequent and comparable between the two groups, with no statistically significant difference in overall complication rates (p=0.83).

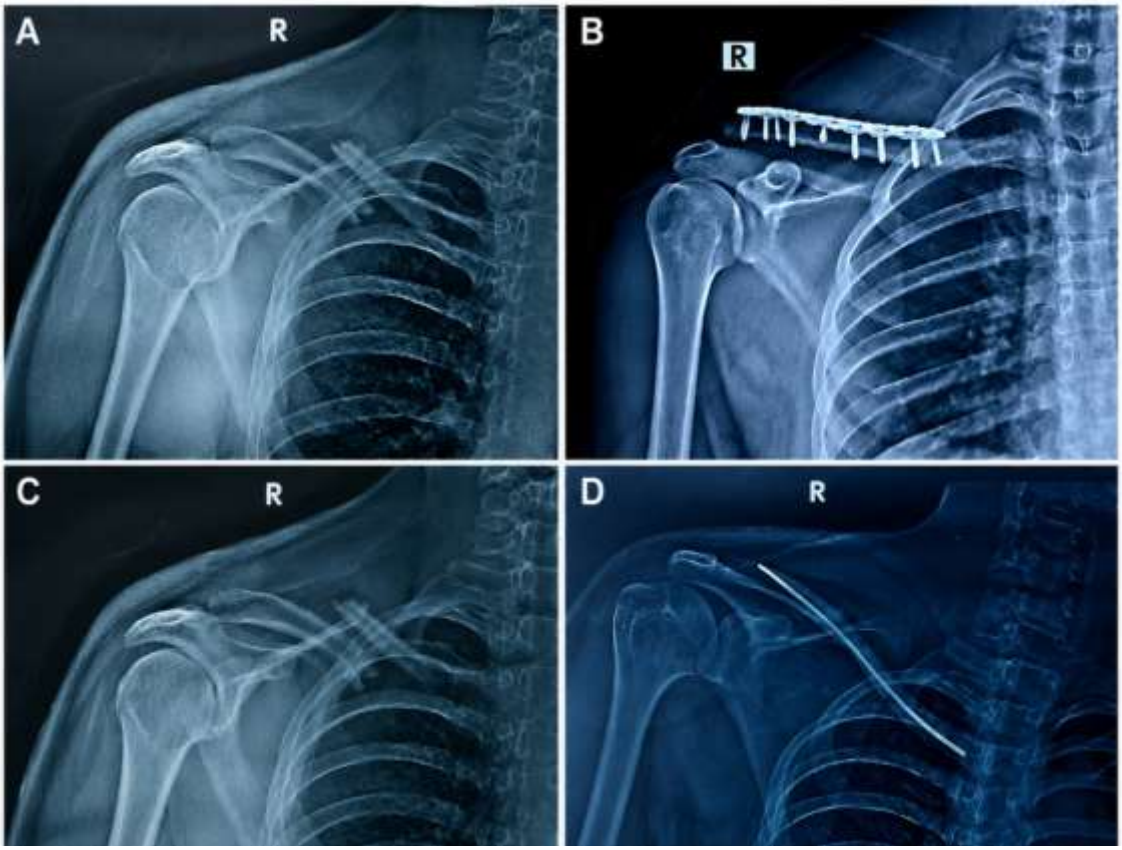

Figure 3. Radiographic images showing preoperative and postoperative radiograph of midshaft clavicle fractures using plate fixation and TENS.

DISCUSSION

The present prospective comparative study evaluated the clinical and functional outcomes of anterosuperior plate fixation and titanium elastic intramedullary nailing (TENS) in the management of displaced midshaft clavicle fractures. The principal findings demonstrated that both techniques achieved comparable fracture union with low complication rates. However, TENS resulted in significantly superior early functional recovery at one month, whereas no significant differences were observed at three or six months.

Fracture union was achieved within a similar timeframe in both groups, with a mean union time of 10.50 ± 1.47 weeks for plating and 10.40 ± 2.01 weeks for TENS (p=0.86). These findings indicate that both fixation methods provide equally reliable biological healing and are consistent with previous meta-analyses by Duan et al. [1] and Zhang et al. [5], which reported no significant differences in fracture union between plate fixation and intramedullary techniques. Similar observations have also been reported by Li et al. [11] and Ju et al. [12], who concluded that both fixation methods provide comparable rates of fracture healing. These findings are further supported by the randomized controlled trial conducted by Andrade-Silva et al. [6], which demonstrated comparable fracture union and satisfactory functional outcomes following both plate fixation and intramedullary nailing.

Functional recovery differed during the early postoperative period. At one month, patients treated with TENS demonstrated significantly higher Constant Shoulder Scores than those treated with plating (74.1 ± 4.8 vs. 68.4 ± 5.2; p=0.001). The mean difference of 5.7 points (95% CI: 2.5–8.9) exceeded the threshold for statistical significance, and the large effect size (Cohen's d=1.14) suggests that the observed difference was also clinically meaningful. The minimally invasive nature of TENS,

reduced periosteal stripping, and preservation of soft-tissue integrity may facilitate earlier mobilisation, reduced postoperative pain, and more rapid restoration of shoulder function. Similar findings have been reported by Narsaria et al. [9] and Zehir et al. [10], who observed superior early postoperative shoulder function following intramedullary fixation.

Although TENS demonstrated superior early recovery, the differences between treatment groups diminished with time. At three months (p=0.16) and six months (p=0.17), Constant Shoulder Scores were comparable, indicating that both surgical techniques ultimately achieved similar long-term functional outcomes. These findings are in agreement with the systematic reviews by Zhang et al. [5], Li et al. [11], Ju et al. [12], and the recent meta-analysis by Lu et al. [13], all of which concluded that although intramedullary fixation offers better early postoperative recovery, long-term functional outcomes are equivalent to plate fixation.

Repeated-measures ANOVA further demonstrated significant improvement in Constant Shoulder Scores over time within both treatment groups (p<0.001). Bonferroni post hoc analysis confirmed significant improvements between all follow-up intervals in both groups, while the very large partial eta squared (η^2=0.96) indicated that time exerted a substantial influence on postoperative functional recovery irrespective of the fixation technique. These findings emphasise that both surgical methods effectively restore shoulder function as fracture healing progresses.

The incidence of postoperative complications was low in both groups. Implant irritation occurred slightly more frequently after plate fixation, whereas delayed union was observed in one patient in each group. No cases of infection or non-union were encountered, and the overall complication rates were comparable (p=0.83). These observations are consistent with previous comparative studies reporting similar safety profiles for both techniques. [6,7,9] Although plate fixation has been associated with implant prominence and soft-tissue irritation, intramedullary fixation may require implant removal because of medial nail prominence. Nevertheless, both procedures remain safe when meticulous surgical technique and appropriate patient selection are employed.

The present study has several strengths. Standardized rehabilitation and follow-up protocols were followed, functional outcomes were assessed using the validated Constant Shoulder Score, and statistical analyses included confidence intervals, effect size estimation, repeated-measures ANOVA, and appropriate statistical tests based on data distribution. These analyses provide a more comprehensive interpretation of both statistical and clinical significance.

Certain limitations should also be acknowledged. The study included a relatively small sample size from a single tertiary care centre, which may limit the generalisability of the findings. Treatment allocation was non-randomized and based on surgeon preference and implant availability, introducing the possibility of selection bias. Furthermore, assessor blinding was not feasible because the type of implant was visible on postoperative radiographs. Although the six-month follow-up adequately assessed fracture union and functional recovery, longer follow-up would be useful to evaluate implant-related complications, patient satisfaction, and long-term functional outcomes.

Overall, the findings suggest that TENS offers a clinically meaningful advantage during the early postoperative period, whereas both fixation methods provide comparable fracture union, excellent functional recovery at later follow-up, and similarly low complication rates. More recently, Ma et al. [14] reported encouraging functional and radiological outcomes using intramedullary bridge fixation for midshaft clavicle fractures, further supporting the role of minimally invasive fixation techniques in appropriately selected patients.

Consequently, the choice of fixation should be individualised according to fracture morphology, patient characteristics, functional demands, and surgeon experience.

CONCLUSION

Both anterosuperior plate fixation and titanium elastic intramedullary nailing are safe and effective surgical options for the management of displaced midshaft clavicle fractures. The two techniques achieved comparable fracture union times and similarly low complication rates. Although patients treated with TENS demonstrated significantly superior functional recovery during the early postoperative period, long-term functional outcomes at three and six months were comparable between the two groups. Repeated-measures analysis confirmed significant improvement in shoulder function over time irrespective of the fixation method. Therefore, both techniques provide satisfactory clinical outcomes, and the choice of surgical treatment should be individualised based on fracture characteristics, patient expectations, functional requirements, and surgeon expertise. Further multicentre randomized studies with larger sample sizes and longer follow-up are warranted to validate these findings.

Declaration by Authors

Ethical Approval: The study was approved by the Institutional Ethics Committee (SIMS & RC/EC-06/PG-118/2023-24).

Acknowledgement: None

Source of Funding: No funding was received for this study.

Conflict of Interest: The authors declare no conflict of interest.

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How to cite this article: A Rishidhar, Rajagopal H P, Jain J, Shervegar S, Mahesh G, Daddimani RM et al. Plate fixation versus titanium elastic nailing for displaced midshaft clavicle fractures: a prospective study. *Int J Health Sci Res.* 2026; 16(8):55-65. DOI: *10.52403/ijhsr.20260806*

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