

Functional Outcome of Operative Titanium Elastic Nailing System Versus Non-Operative Figure-of-Eight Bandage in Displaced Mid-Shaft Clavicle Fractures: A Randomized Controlled Study

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Learning Point of the Article:

Titanium elastic nailing system (TENS) provides superior early functional recovery and earlier return to daily activities than the figure-of-eight bandage in displaced midshaft clavicle fractures, while both treatment modalities achieve comparable fracture union and long-term functional outcomes.

Abstract

Introduction: Displaced midshaft clavicle fractures are commonly treated either conservatively using a figure-of-eight bandage or operatively with the Titanium Elastic Nailing System (TENS). However, evidence comparing these modalities remains limited. This study compared the functional and radiological outcomes of TENS with conservative management in adults with displaced midshaft clavicle fractures.

Materials and Methods: This randomized controlled study was conducted over 2 years at the Department of Orthopaedics, Indira Gandhi Medical College and Research Institute, Puducherry. Sixty adults with Allman Group I displaced midshaft clavicle fractures were randomized into TENS (n = 30) and figure-of-eight bandage (n = 30) groups. Functional outcomes were assessed using the Constant–Murley Score and Disabilities of the Arm, Shoulder and Hand (DASH) score at 6 weeks, 3 months, and 6 months. Radiological union, complications, return to activity, and patient satisfaction were also evaluated.

Results: Fifty-eight patients completed follow-up. The TENS group demonstrated significantly better early functional recovery with lower DASH scores at 6 weeks (59.55 ± 3.55 vs. 65.12 ± 4.72 ; $P < 0.001$), while Constant–Murley scores were higher but not significantly different. At 6 months, both groups achieved comparable Constant scores (96.48 ± 1.68 vs. 96.46 ± 2.85 ; $P = 0.857$) and low DASH scores. Fracture union was achieved in all patients, with slightly earlier radiological union and earlier return to activity (9.6 vs. 10.8 weeks) in the TENS group. Minor implant-related complications occurred following TENS but did not influence the outcome. Patient satisfaction was high in both groups.

Conclusion: TENS provides superior early functional recovery, earlier return to daily activities, and high patient satisfaction compared with figure-of-eight bandage treatment, while both treatment modalities achieve excellent fracture union and comparable long-term functional outcomes. The treatment should be individualized according to patient characteristics, fracture pattern, and functional demands.

Keywords: Clavicle fracture, Midshaft clavicle fracture, titanium elastic nailing system, figure-of-eight bandage, intramedullary fixation, conservative management, Constant–Murley score, disabilities of the arm, shoulder and hand score, functional outcome, randomized controlled trial.

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Introduction

Clavicle fracture is a common injury which accounts for approximately 5–10% of all fractures and nearly 1/3rd of injuries involving shoulder girdle. Clavicle fractures are frequently encountered in orthopedic and emergency practice, particularly in active individuals. The annual incidence ranges between 29 and 64/100,000 population, reflecting high prevalence in the general population [1, 2].

Clavicle fractures demonstrated a bimodal age distribution. It is found that the first peak occurs in young active males <30 years of age, typically associated with high-energy trauma. The second peak is observed in elderly females due to osteoporotic bone and low-energy fall [3]. The displacement and shortening are important outcome determinants. Complete displacement (100% translation) or shortening (above 2 cm) of fractures have been found to be associated with increased risk of nonunion and symptomatic malunion. Nonunion was experienced in about 6%, which has been found to rise to 15% in the displaced. The absolute risk of nonunion in the case of surgical fixation was considerable in patients who were selected [4].

Surgical techniques like operative fixation methods such as plate fixation and intramedullary devices such as Titanium Elastic Nailing System (TENS) have gained increasing popularity. Many studies have demonstrated that operative fixation provides better anatomical alignment, earlier functional recovery, and improved patient satisfaction compared to conservative treatment. In spite of several findings, there is a lacuna in the optimal treatment modality, particularly for mid-shaft clavicle fracture.

While it is important to mention that several existing studies primarily compared plate fixation with conservative management, relatively fewer randomized studies have specifically evaluated intramedullary fixation using TENS versus figure-of-eight bandage treatment in adults with displaced midshaft clavicle fracture.

Therefore, the present study was undertaken to compare the functional outcomes, radiological union, and complication rates between operative management using TENS and non-operative management using figure-of-eight bandage in patients with displaced midshaft clavicle fractures. Thereby, we can address the existing gap in evidence and contribute to the identification of an optimal treatment strategy. The study aims to study the functional outcome of operative – TENS versus non-operative figure-of-eight bandage treatment for adults presenting with Allman group I displaced middle one-third clavicle fracture. We compared the functional outcome of operative – TENS versus non-operative figure-of-eight bandage treatment for adults presenting with Allman group I displaced middle one-third clavicle fracture in terms of

Constant–Murley and disabilities of the Arm, Shoulder, and Hand (DASH) scores.

Materials and Methods

Study design

The present study was based on a randomized controlled trial conducted to compare the functional outcomes of operative management using TENS and non-operative management using a figure-of-eight bandage in patients with displaced middle 1/3rd clavicle fractures.

Study setting

The study was conducted in the Department of Orthopaedics, Indira Gandhi Medical College and Research Institute, Puducherry, India.

Duration of the study

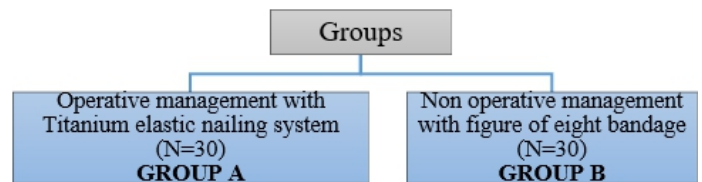
Duration of the study was 2 years.

Study population

The population included adult patients presenting to the casualty and outpatients in the Department of Orthopaedics with Allman group I displaced fracture of the middle 1/3rd of the clavicle.

Sample size

- The sample size of the present study was 60
- There are two groups: Group A and Group B.



- **Group A:** Operative management with TENS (n = 30)
- **Group B:** Non-operative management with figure-of-eight bandage (n = 30).

Patient presented with mid-clavicle fractures



Both anteroposterior and 10–20° cephalad tilted radiographs



After explaining that there are two methods of treatment available and explaining the purpose, procedure and method of study, informed consent was obtained



Patients are selected based on the inclusion criteria

After eligibility assessment and obtaining informed consent, participants were randomly allocated in a 1:1 ratio to the operative TENS group or the non-operative figure-of-eight bandage group using a permuted block randomization method. The randomization procedure was performed before treatment allocation

Pre-treatment demographic data were collected for each patient

Conservative Treatment (Control)	TENS Treatment (Intervention)
Follow-up was started on the day of inclusion with radiological assessment	Follow-up was started at the post operative day 1 with radiological assessment
1 st 2 weeks, patients were used figure-of-eight bandage and arm sling and advised to perform pendulum exercises after instruction by a physiotherapist, followed by more active movement up to the horizontal plane. At 6 weeks, full range of motion was permitted and strengthening exercises were started.	1 st 2 weeks, patients were used figure-of-eight bandage and arm sling and advised to perform pendulum exercises after instruction by a physiotherapist, followed by more active movement up to the horizontal plane. At 6 weeks, full range of motion was permitted and strengthening exercises were started.
2 weeks – clinical and radiological assessment	2 weeks – clinical and radiological assessment
6 weeks – clinical, radiological and functional assessment	6 weeks – clinical, radiological and functional assessment
3 rd month – clinical and functional assessment	3 rd month – clinical and functional assessment
6 month – clinical, radiological and functional assessment	6 month – clinical, radiological and functional assessment

Inclusion criteria

Age between 18 and 65 years, Allman group I displacement in the middle 1/3rd of clavicle, displacement ≥ 2 cm, injury duration < 2 weeks, Patients willing to participate and provide informed consent.

Exclusion criteria

Pathological fracture, fractures associated with neurovascular injury, polytrauma patients, previous fracture, surgery involved in the ipsilateral side, open fracture, patients unfit for anesthesia.

Operative (TENS) - group A

- The procedure is performed under image intensifier guidance with the patient in a supine or beach chair position (Fig. 1)
- Skin incision made 2 cm medial to the sternoclavicular joint
- A medial entry point is created approximately 1.5–2 cm lateral to the sternoclavicular joint, and a flexible TEN (2–3.5 mm) is inserted into the intramedullary canal
- Closed reduction is usually achieved with shoulder traction and manipulation; however, limited open reduction may be required in some cases
- The nail is advanced across the fracture site into the lateral fragment to maintain alignment and rotational stability while preserving fracture biology.

Post-operative procedure

- 1st 2 weeks, arm immobilized with arm sling
- 2nd–6th week pendulum exercise followed by active-assisted movements
- After 6 weeks, full range of motion exercise and strengthening exercise initiated.

Figure-of-eight bandage (Group B)

- The patient is positioned in a sitting or upright position with the shoulders gently retracted
- A soft pad is placed between the scapulae and axilla to provide comfort and support
- A soft roll was passed over each shoulder, under the axilla, and crossed over the back to form a figure-of-eight configuration
- The straps are tightened gradually to pull the shoulders

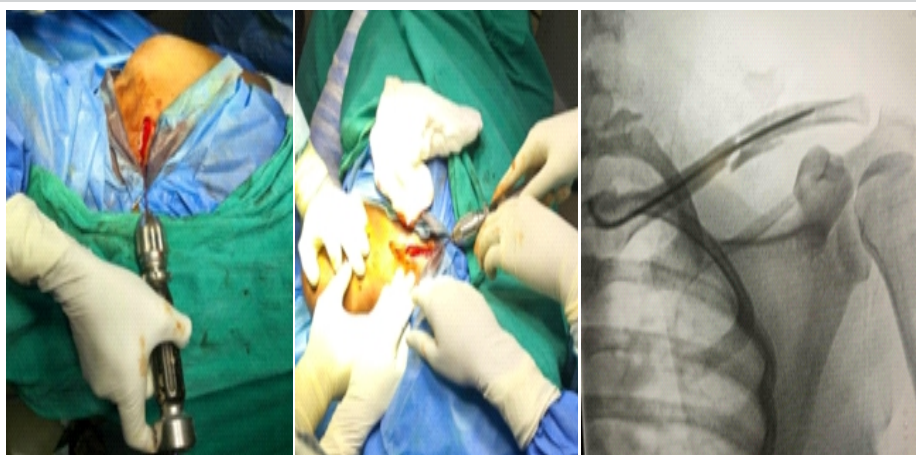


Figure 1: Surgery position: Patient lying in beach chair position, preoperative positioning and surgical draping for clavicle fracture fixation, opening the medial clavicular cortex to introduce the TENS, Operative step showing creation of entry portal for intramedullary fixation of clavicle fracture and C-arm guidance during advancement of TENS in the clavicle medullary canal. TENS: Titanium elastic nailing system.



Figure 2: Figure-of-eight bandage (Indira Gandhi Medical College hospital and Research institute).

backward into a retracted position, thereby stabilizing the fracture fragment

- After application, neurovascular status of the upper limbs is checked to ensure that the bandage is not excessively tight (Fig. 2)
- Patients were reviewed regularly for adjustment and compliance.

Post-operative procedure

- 1st 2 weeks, arm immobilized with arm sling
- 2nd–6th week pendulum exercise followed by active-assisted movements
- After 6 weeks, full range of motion exercise and strengthening exercise initiated.

Statistical analysis

The data were entered into an Excel sheet and analyzed using the Statistical Package for the Social Sciences version 17.0. The continuous variables were expressed in mean and standard deviation; categorical variables were presented as frequencies and percentages. Shapiro–Wilk test was used to test the normality of distribution. Independent t-test (or Mann–Whitney U test) was used for comparison between two groups – TENS and non-operative figure-of-eight bandage in middle one-third clavicle fracture. Chi-square test was done to validate the categorical variables. $P < 0.05$ was considered statistical significance.

Results

A total of 60 patients with displaced middle one

third clavicle fractures were enrolled in the study, and we were able to randomly allocate into two equal groups. Group A (TENS) consisted of 30 patients; all of them completed follow-up and were included in the final analysis. Group B (Figure-of-Eight Bandage) also included 30 patients initially; however, there were 2 patients who were lost to follow-up. Therefore, Group B consisted of 28 samples which were available for final analysis. Thus, out of 60 enrolled patients, 58 patients (96.7%) were analyzed for functional and radiological outcomes. The distribution of patients between the two groups was comparable (Table 1).

All patients had Allman Group I displaced midshaft clavicle fractures with ≥ 2 cm displacement (Fig. 3). Mean shortening was 0.8 cm versus 0.7 cm, and mean translation was 110% versus 103% in the TENS and figure-of-eight groups, respectively. Comminution was present in 30% versus 35% of cases. Simple/short-oblique fractures occurred in 18 patients in each group, while wedge/segmental-comminuted fractures occurred in 12 and 10 patients, respectively. Robinson classification showed 2B1 in 18 patients in each group and 2B2 in 12 versus 12 patients, indicating broadly comparable fracture characteristics (Table 2).

The mean age of patients in Group A (TENS) was 35.80 ± 12.77 years, with the youngest sample age was being 18 years and the oldest patient aged for the study is 65 years of age. Group B, the

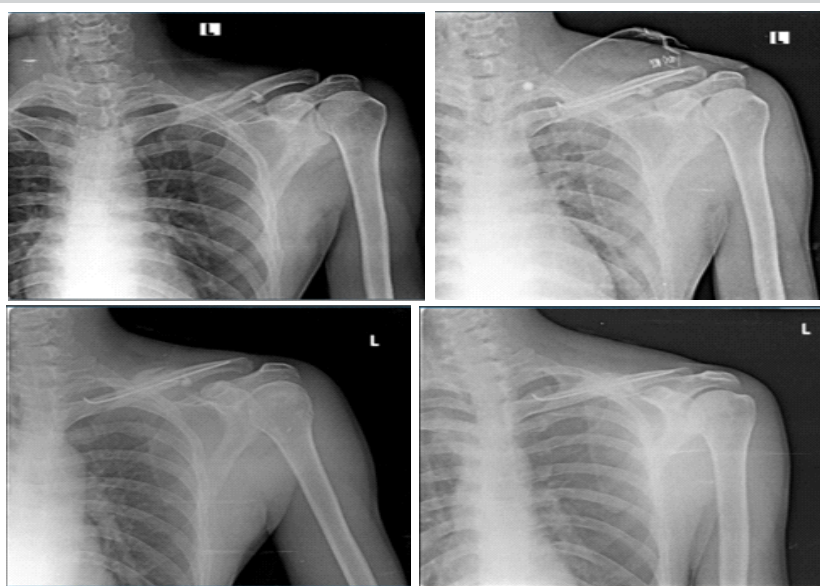


Figure 3: Preoperative X-ray showing displaced midshaft clavicle fracture prior to TENS fixation (Pre-operative), 2-week postoperative X-ray showing TENS in situ with maintained fracture alignment, 6-week postoperative X-ray demonstrating early callus formation and progressing union after TENS fixation and 6-month postoperative X-ray showing complete fracture union with TENS in situ. TENS: Titanium elastic nailing system.

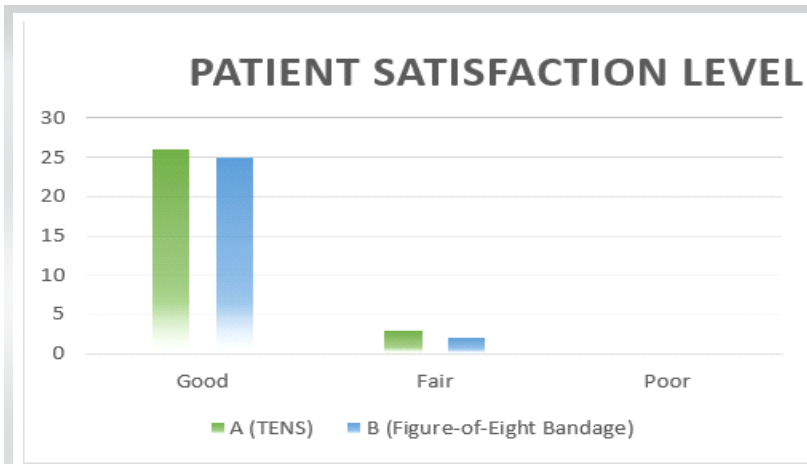


Figure 4: Patient satisfaction comparison between titanium elastic nailing system group A and figure-of-eight group.

mean age was 35.53 ± 13.09 years, with an age range of 18–62 years. In the age distribution between the two groups, we found there is no statistical significance. Group A (TENS): 26 (86.7%) and 4 (13.3%) patients (30 patients) were male and female, respectively. Figure-of-eight bandage (Group B) had 28 patients who were analyzed, of which 20 (71.4%) patients were male, and 8 (28.6%) were female (Table 3).

Mean constant score at 6 weeks in Group A (TENS) was 42.79 ± 3.40 . Whereas in Group B (figure-of-eight bandage) the mean constant score was 40.08 ± 5.97 . The TENS group demonstrated better early functional recovery compared to the conservative group at 6 weeks. At 3 months follow-up, the mean constant score in Group A was 68.55 ± 6.09 , while in Group B the mean score was 66.19 ± 4.68 . Although both groups showed progressive improvement, the operative group continued to demonstrate superior functional scores during the intermediate follow-up period. At 6 months, the mean constant score was 96.48 ± 1.68 in the TENS group and 96.46 ± 2.85 in the figure-of-eight group. By the end of 6 months, both groups achieved comparable and excellent functional outcomes with no significant difference between the two groups. The results indicate that operative management with TENS provides better

early functional recovery at 6 weeks and 3 months. But interestingly, both treatment groups resulted in similar excellent functional outcomes at 6th month follow-up. 6th week follow-up mean DASH score in group A (TENS) was 59.55 ± 3.55 where in group B (figure-of-eight bandage) the mean score was 65.2 ± 4.72 . Since lower DASH scores indicated better functional status, patients in the TENS group demonstrated significantly ($P < 0.001$) better early functional improvement compared to the conservative group at 6 weeks. 3rd month mean DASH score in Group A was 31.45 ± 5.38 , while in Group B the mean DASH score was 31.15 ± 3.21 . Both groups showed marked improvement compared to 6th week follow up and differences between groups

were minimal at this stage. At 6 months follow up mean DASH score was 1.97 ± 1.05 in the TENS group and 1.50 ± 1.14 in the figure-of-eight bandage group. By the end of the 6th month, both groups achieved near-normal functional outcomes with very low DASH scores, and the difference between the two groups was not clinically significant. The findings at the 6th month clearly indicated that the TENS group showed better early functional recovery at 6 weeks, as evidenced by lower DASH scores.

In Group A (TENS), nearly 26 patients 86.7% reported good satisfaction, while 3 patients reported fair satisfaction; no patients reported poor satisfaction.

Table 2: Comparative fracture characteristics of displaced Midshaft clavicle fractures in the TENS and figure-of-eight groups

Fracture characteristic	TENS group (n=30)	Figure-of-eight group (n=30 initially; n=28 analyzed)
Allman classification	Group I	Group I
Displacement	≥ 2 cm	≥ 2 cm
Mean exact shortening (mm/cm)	0.8 cm	0.7 cm
Mean degree of translation (%)	110%	103%
Comminution present in	30% of cases	35% of cases
Fracture morphology/pattern		
Simple/short-oblique	18 patients	18 patients
wedge-comminuted/segmental-comminuted	12 patients	10 patients
Robinson classification		
2B1	18	18
2B2	12	12
TENS: Titanium elastic nailing system		

Table 1: Socio-demographic details of participants in both groups

Variable	TENS group (n=30)	Figure-of-eight group (n=28)
Age	35.80 ± 12.77	38.53 ± 13.09
Gender (%)		
Male	26 (86.66)	20 (71.42)
Female	4 (13.33)	8 (28.57)
TENS: Titanium elastic nailing system		

Table 3: Scoring post-intervention in both groups

Scoring	Duration	TENS group	Figure-of-eight group	P-value
Constant–Murley Score	6 weeks	42.79±3.40	40.08±5.97	0.14
	3 rd Month	68.55±6.09	66.19±4.68	0.233
	6 th Month	96.48±1.68	96.46±2.85	0.857
Disabilities of the arm, shoulder and hand score	6 weeks	59.55±3.55	65.12±4.72	<0.001
	3 rd Month	31.45±5.38	31.15±3.21	0.564
	6 th Month	1.97±1.05	1.50±1.14	0.118
TENS: Titanium elastic nailing system				

While in Group B (Figure-of-eight bandage) nearly 25 patients 89.3% reported good satisfaction, and 2 patients 7.1% reported fair satisfaction. None of the patients reported poor satisfaction. Overall, we found that a very high level of patient satisfaction was observed in both groups, with the majority of patients in both groups expressing good satisfaction at the end of the 6th month (Fig. 4). With an increased level of satisfaction among the patients, our morale increases (Table 4).

Return to activity

Mean time required returning to occupational work, heavy physical activity, and routine daily activity was reported at 9.6 weeks in Group A (TENS). Whereas Group B (Figure-of-eight bandage) mean was 10.8 weeks. The patients in the TENS group returned to their regular activity earlier compared to those managed conservatively. From the above findings, we found that both group able to recover, but the TENS group was associated with a relatively faster return to functional activity.

Discussion

The primary objective of the present study was to compare functional outcomes using the Constant–Murley Score and DASH Score between TENS fixation and conservative treatment with a figure-of-eight bandage. The demographic profile was comparable to previous studies, with a male predominance and a mean age of 35.9 ± 10.6 years, similar to Kumar et al. [5].

At 6 weeks, the TENS group demonstrated significantly better early functional recovery, with a higher Constant score (42.79 ± 3.40 vs. 40.08 ± 5.97) and a lower DASH score (59.55 ± 3.55 vs. 65.12 ± 4.72) than the conservative group, indicating better shoulder function and less disability. At 3 months, the TENS group continued to show slightly superior outcomes (Constant score 68.55 ± 6.09 vs. 66.19 ± 4.68). However, by 6 months,

both groups achieved nearly identical Constant scores (96.48 ± 1.68 vs. 96.46 ± 2.85), suggesting comparable long-term functional recovery.

These findings are consistent with Kumar et al., who reported superior Constant scores following operative management (90.6 ± 6.1 vs. 82.3 ± 8.7) [5]. Hill et al. also demonstrated poorer outcomes following conservative treatment in displaced midshaft clavicle fractures with significant displacement [6]. The Canadian Orthopaedic Trauma Society reported improved early function and patient satisfaction following operative fixation

[7]. Similar early functional benefits with intramedullary fixation have been reported by Smekal et al. [8] and Ganesh et al., [9] attributing improved outcomes to stable fixation and early mobilization.

The lower DASH scores observed in the TENS group during early follow-up are consistent with the findings of Rahangdale et al. [10] and Zhu et al., [11], who reported reduced disability and faster rehabilitation after TENS fixation. However, as fracture healing progressed, DASH scores between the groups became comparable, similar to the observations of Kothale et al., who reported equivalent long-term functional outcomes once union was achieved [12].

Complications

No cases of non-union were observed in either group. The TENS group experienced minor implant-related complications, including scar-related issues, implant prominence, friction bursitis, delayed wound healing, and transient numbness. The conservative group mainly experienced skin irritation and occasional need for reapplication of the figure-of-eight bandage. Defroda et al. reported that although operative treatment facilitates earlier recovery, it is associated with implant-related complications

Table 4: Return of activity comparison between Group A and Group B

Group	Mean time (Weeks)	P-value
A (Titanium elastic nailing system)	9.6 weeks	0.257
B (Figure-of-eight bandage)	10.8 weeks	

[7]. In the present study, these complications were minor, manageable, and did not adversely affect final functional outcomes.

Return to activity

Patients treated with TENS resumed normal activities significantly earlier (9.6 weeks) than those managed conservatively. Early mechanical stability following intramedullary fixation likely facilitated faster rehabilitation. Similar findings have been reported by Defroda et al., who demonstrated earlier return to sports following operative fixation [7] and by Rahangdale et al., who observed earlier fracture union and faster return to work with TENS fixation [10].

Patient satisfaction

High patient satisfaction was observed in both groups, with slightly higher satisfaction among patients treated with TENS. Kumar et al. similarly reported a greater proportion of excellent outcomes following operative management [5]. The improved early function, reduced disability, and earlier return to activity likely contributed to better patient satisfaction in the operative group.

Loss to follow-up

A small number of patients, predominantly from the conservative group, were lost to follow-up during the study. These patients were excluded from the final functional and radiological analyses to ensure the accuracy and validity of the study findings.

Fracture union

Fracture union was achieved in all patients in both treatment groups with some degrees of acceptable residual displacement or shortening, reflecting the excellent healing potential of clavicle fractures. Although complete union occurred in all cases, radiological union was observed slightly earlier in the TENS group, likely due to stable intramedullary fixation while preserving the biological environment for fracture healing. Previous studies have reported higher rates of non-union and symptomatic malunion following conservative treatment of displaced fractures [9]. Nevertheless, both groups achieved successful union in the present study.

Return to daily activities

Patients treated with TENS returned to routine daily activities earlier than those managed with a figure-of-eight bandage. Early

stabilization, reduced pain, and improved shoulder biomechanics likely contributed to this advantage. Similar observations have been reported by Smekal et al., [8] who demonstrated earlier return to work after elastic intramedullary nailing, and by Jubel et al., who highlighted faster recovery and earlier restoration of pre-injury activity levels following intramedullary fixation [13]. These findings support the role of TENS in promoting early rehabilitation while maintaining comparable long-term outcomes.

Cosmetic outcome

Cosmetic outcome is an important consideration in clavicle fracture management. TENS fixation requires only a small incision with minimal soft-tissue dissection, resulting in minimal scarring and satisfactory cosmetic appearance. Jubel et al. reported superior cosmetic results with intramedullary fixation compared with plate fixation because of the smaller incision and less prominent implants [13]. In contrast, conservative treatment may result in visible deformity due to clavicular shortening or malunion, as reported by Zhu et al. [10]. Patients in the TENS group generally expressed greater satisfaction with cosmetic appearance, while the low incidence of surgical complications was comparable with the findings of Yadav et al. [14].

Limitations

Detailed randomization procedures, including sequence generation and allocation concealment, were not documented, and outcome-assessor blinding could not be confirmed, potentially introducing selection and measurement bias. The small sample size (60 enrolled; 58 analyzed) and two losses to follow-up may limit statistical power, generalizability, and introduce attrition bias; intention-to-treat analysis was not possible because outcome data were unavailable. Longitudinal outcomes were analyzed at individual time points rather than using repeated-measures or mixed-effects models, and confidence intervals and effect sizes were not reported. Complications were descriptively reported without standardized grading, limiting safety comparisons and detection of uncommon events. The conservative protocol used a figure-of-eight bandage with an arm sling for 2 weeks, but compliance and tolerance were not quantitatively assessed, limiting generalizability to other non-operative strategies. Finally, the 6-month follow-up was insufficient to assess long-term complications and functional outcomes, including symptomatic malunion, persistent dysfunction, refracture, implant-related problems, and post-traumatic degenerative changes.

Conclusion

TENS fixation provides faster early functional recovery and earlier return to routine activities compared with figure-of-eight bandage treatment for displaced midshaft clavicle fractures. However, overall functional outcomes at 6 months and fracture union were comparable between the two groups. The early functional advantage of TENS should therefore be weighed against the additional surgical risks and implant-related complications, including implant prominence, friction bursitis, scar-related problems, delayed wound healing, and transient numbness. The treatment should be individualized according

to fracture characteristics, patient preferences, functional demands, and the relative benefits and risks of operative versus conservative management.

Clinical Message

TENS is a safe and effective treatment for displaced midshaft clavicle fractures, providing superior early functional recovery, earlier return to daily activities, and high patient satisfaction while achieving fracture union and long-term functional outcomes comparable to conservative figure-of-eight bandage treatment.

Declaration of patient consent: The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient has given the consent for his/ her images and other clinical information to be reported in the journal. The patient understands that his/ her names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

Conflict of interest: Nil **Source of support:** None

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Consent: The authors confirm that informed consent was obtained from the patient for publication of this article

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