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A prospective and comparative study of Intramedullary TENS and Plate Osteosynthesis for midshaft fractures of the Clavicle

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Abstract

Background/Aim: Background: Midshaft clavicle fractures represent a significant proportion of traumatic shoulder girdle injuries. Although non-operative treatment has historically been the standard, recent studies have revealed high rates of malunion and nonunion with conservative management, especially in displaced fractures. As a result, operative management using either plating or intramedullary nailing techniques is increasingly preferred. However, the ideal fixation method remains debated.

Objectives: To compare the clinical, radiological, and functional outcomes of two common surgical techniques for displaced midshaft clavicle fractures: (1) Open reduction and internal fixation with anatomically contoured locking compression plates and (2) Intramedullary fixation using Titanium Elastic Nailing System (TENS).

Methods: This prospective, randomized comparative study was conducted at SS Institute of Medical Sciences & Research Centre, Davangere from February 2023 to February 2025. A total of 40 patients with Robinson type 2B midshaft clavicle fractures were enrolled and randomized into two equal groups. Group A (n=20) underwent plate fixation, and Group B (n=20) underwent TENS fixation. Patients were followed clinically and radiologically at regular intervals up to 6 months. Constant-Murley shoulder score was used to evaluate functional outcomes. Radiological union was assessed through standard imaging. Complications, including infection, implant failure, and hardware-related symptoms, were recorded.

Results: The mean age of participants was 32.92 ± 9.18 years, with a male predominance. Road traffic accidents were the most common mode of injury. Right-sided fractures were slightly more common. Clinical and radiological union occurred significantly earlier in the TENS group (mean radiological union at 7.4 weeks) compared to the plate group (mean 9.3 weeks). At 6 months, the mean Constant-Murley score was significantly higher in the TENS group (90.4) than in the plate group (85.3). The TENS group experienced fewer complications, with only one case of nail backout and one superficial infection, whereas the plate group had two cases of wound dehiscence, two instances of implant prominence, and one superficial infection.

Conclusion: Both plate fixation and TENS provide good clinical and functional outcomes in displaced midshaft clavicle fractures. However, TENS demonstrated superior performance with respect to operative invasiveness, time to union, complication profile, and cosmetic results. It may be considered the preferred option for appropriate cases.

Keywords: Clavicle fracture, midshaft, plate fixation, titanium elastic nail, functional outcome, constant-murley score

Introduction

Fractures of the clavicle are among the most common injuries involving the shoulder girdle, accounting for approximately 2.6% of all fractures and nearly 44% to 66% of shoulder fractures[1–3]. Among these, the midshaft region is most commonly affected—comprising nearly 70–80% of clavicle fractures[4]. This prevalence is largely attributable to the clavicle's unique S-shaped configuration and its function as a mechanical strut between the sternum and the shoulder girdle, which predisposes it to axial and torsional stresses. Additionally, its subcutaneous location and limited surrounding musculature make it vulnerable to both direct and indirect trauma.

Historically, midshaft clavicle fractures have been managed nonoperatively based on early studies suggesting favorable outcomes and low rates of complications. Seminal works by Neer and Rowe reported nonunion rates of 0.1% to 0.8% in patients treated conservatively [6, 7]. These findings led to the widespread adoption of conservative modalities such as figure-of-eight bandaging or arm sling immobilization.

However, recent high-quality evidence has challenged the dogma of universal conservative management. Contemporary studies have reported significantly higher nonunion rates of up to 15% in displaced midshaft fractures managed nonoperatively [8, 9]. Moreover, functional limitations, cosmetic deformity, and patient dissatisfaction have become increasingly recognized as significant sequelae of nonoperative treatment [10, 11, 12].

Operative fixation provides mechanical stabilization, restores anatomical alignment, and allows early mobilization. Two major operative approaches are currently in use: open reduction and internal fixation (ORIF) using plates and screws, and minimally invasive intramedullary fixation using devices such as the Titanium Elastic Nailing System (TENS). Locking compression plates (LCP) offer rigid stabilization with rotational control, particularly in comminuted patterns[13]. However, they require soft tissue dissection and are associated with complications such as wound dehiscence, implant prominence, and infection [14].

Intramedullary fixation using TENS offers a less invasive alternative with reduced surgical morbidity. This technique preserves periosteal blood supply, minimizes soft tissue disruption, and is cosmetically superior due to smaller incisions[15]. However, concerns exist regarding rotational instability, implant back-out, and technical challenges, particularly in complex fractures [16, 17].

In this context, there remains a paucity of consensus regarding the optimal surgical modality for displaced midshaft clavicle fractures. This prospective and comparative study was undertaken to evaluate and compare the clinical, functional, and radiological outcomes of patients treated with either locking plate osteosynthesis or TENS, and to determine the incidence of complications associated with each technique. The findings aim to assist surgeons in making evidence-based decisions for optimal treatment of this common orthopedic injury.

Review of Literature

1. Historical Perspective

Clavicle fractures have been recognized and documented since antiquity. Hippocrates, in 400 BC, noted the clavicle's ability to unite rapidly, and opined that deformity following fracture had little impact on function or aesthetics [6]. This view persisted for centuries, reinforced by 19th-century surgeons such as Dupuytren and Malgaigne, who advocated simple immobilization with arm slings or pillows [6].

In the 20th century, large retrospective analyses further endorsed conservative treatment. Neer, in 1960, reviewed 2235 patients and reported a nonunion rate of merely 0.13% in conservatively treated midshaft clavicle fractures [7]. Similarly, Rowe's 1968 analysis of 566 cases found a 0.8% nonunion rate[7]. These studies, however, lacked classification-based subgroup analysis and often included pediatric populations known for superior remodeling potential [6, 7].

2. Evolving Understanding of Conservative Treatment Limitations

The late 1990s witnessed a paradigm shift. Hill *et al*. (1997) evaluated 52 adults with displaced midshaft clavicle fractures and found a 15% nonunion rate, with 31% reporting unsatisfactory outcomes and 25% reporting persistent pain. Notably, shortening greater than 2 cm was significantly associated with poor results ($p < 0.001$) [8].

Matis *et al*. (1999) corroborated these findings, observing impaired shoulder function in patients with shortening >2 cm. Nowak *et al*. (2004) found that 46% of conservatively treated patients continued to experience pain or dysfunction several months after injury [10].

Robinson *et al*. (2004) analyzed over 1000 cases and demonstrated that displaced midshaft fractures had an 18.5-fold higher risk of nonunion compared to undisplaced fractures[22]. McKee *et al*. further reported strength deficits of 10%–35% in patients managed nonoperatively, highlighting the longterm implications for active individuals [23].

Meta-analyses by Zlowodzki *et al*. (2005) reinforced these concerns, reporting a 15.1% nonunion rate in displaced fractures treated conservatively[24]. Lazarides *et al*. observed that nearly one-third of patients treated nonoperatively were dissatisfied, and 13.6% had measurable loss of shoulder motion [25].

3. Emergence of Operative Management

With growing evidence of conservative management's limitations, interest in surgical intervention increased. Wun-Jer Shen *et al*. (2000) reported 94% satisfactory results using plating in displaced fractures[26]. The Canadian Orthopaedic Trauma Society's multicentric RCT in 2007 showed that operative fixation resulted in better Constant and DASH scores, faster union, and lower nonunion rates than conservative treatment [27].

Kulshrestha (2008) found that plating allowed early return to function and prevented complications associated with nonoperative treatment [28]. Modi *et al*. (2011) and Mathur *et al*. (2013) further confirmed that anatomic locking compression plates offer reliable fixation and early mobilization [30, 31].

4. Evolution of Intramedullary Fixation – TENS

The concept of elastic intramedullary fixation was originally proposed for pediatric femoral fractures by Ligier in 1988 [32]. Jubel *et al*. (2002) adapted this technique for clavicle fractures using antigrade intramedullary insertion of a single titanium elastic nail (TEN) [33]. This method gained popularity due to its minimally invasive approach, reduced blood loss, and superior cosmetic outcomes.

Kadakia *et al*. (2010) reported 100% union in 38 patients treated with TENS, with an average union time of 11.3 weeks [36]. Rehm *et al*. and Kettler *et al*. independently confirmed these findings with low rates of nonunion and hardware-related complications [13, 15]

Thyagarajan *et al*. (2009) compared three modalities—plate fixation, TENS, and conservative treatment—and concluded that intramedullary fixation offered the best balance of functional recovery and complication avoidance [39].

Assobhi (2011) found that while both TENS and plating had comparable functional results, the

TENS group had shorter operative times, less blood loss, and better cosmetic satisfaction [40]. Similarly, Wang *et al*. (2015) concluded that TENS could be considered for even comminuted patterns, with outcomes equivalent to plating [42].

5. Comparative Studies and Meta-Analyses

Multiple studies have compared plating versus TENS for displaced midshaft fractures

- Ferran *et al*. (2006): No significant functional difference at 12 months [37]
- Liu *et al*. (2006): Similar union rates and outcomes[38]
- Narsaria *et al*. (2014): Initial advantage with plating but comparable results at 1 year [41]
- Zhang *et al*. (2015) & Xu *et al*. (2017): Meta-analyses favoring TENS due to shorter operative time, less blood loss, and better early function [43, 44]
- Li *et al*. (2020): Superior Constant and DASH scores with TENS in the early postoperative period [46]

Methodology

1. Study Design and Setting

This was a prospective, randomized, comparative clinical study conducted in the Department of

Orthopaedics at SS Institute of Medical Sciences and Research Centre (SSIMS & RC), Davangere, Karnataka. The study period spanned from February 2023 to February 2025. The objective was to compare the functional and radiological outcomes of two surgical techniques—intramedullary Titanium Elastic Nailing System (TENS) versus open reduction and internal fixation with anatomically contoured locking compression plate (LCP)—in the management of displaced midshaft clavicle fractures.

2. Ethical Considerations

Ethical clearance was obtained from the Institutional Ethics Committee prior to the initiation of the study. Written

informed consent was taken from all patients prior to participation. The study adhered strictly to the principles outlined in the Declaration of Helsinki.

3. Inclusion Criteria
- Patients aged 18–60 years
- Radiologically confirmed displaced midshaft clavicle fractures (Robinson Type 2B)
- Duration of injury ≤2 weeks
- Closed fractures
- Willingness to participate and provide informed consent

4. Exclusion Criteria
- Open clavicle fractures
- Associated neurovascular injuries
- Pathological fractures
- Polytrauma patients requiring ICU care
- Non-displaced fractures
- Patients with medical comorbidities precluding surgical intervention

5. Sample Size and Randomization

A total of 40 patients fulfilling the inclusion and exclusion criteria were enrolled and randomized into two groups using a simple randomization method
- **Group A (n=20):** Treated with locking compression plate fixation (LCP)
- **Group B (n=20):** Treated with intramedullary TENS fixation

Randomization was performed using sealed opaque envelopes prepared by an independent assistant not involved in the study.

6. Preoperative Assessment

All patients underwent a standardized clinical and radiological evaluation, including:
- Thorough physical examination
- Standard clavicle AP and 45° cephalad tilt radiographs
- Baseline blood investigations and anesthetic fitness

Fractures were classified using the Robinson classification system to ensure homogeneity of fracture types across both groups.

7. Surgical Techniques

7.1. Plate Fixation Technique (Group A)
- General or regional anesthesia was administered.
- Patients were placed in a supine position with a sandbag between the scapulae.
- A 7–9 cm longitudinal incision was made over the clavicle.
- Dissection was carried through skin, subcutaneous tissue, platysma, and periosteum to expose the fracture.
- Anatomical reduction was achieved using bone-holding forceps.
- A precontoured 3.5 mm locking compression plate (LCP) was applied over the superior surface of the clavicle.
- At least three cortical screws were placed on either side of the fracture.
- Wound was irrigated, hemostasis achieved, and closed in layers.
- Sterile dressing and arm pouch were applied.

7.2. TENS Fixation Technique (Group B)
- General or regional anesthesia was administered.
- Patients were positioned supine or in a beach-chair position.
- A 1–2 cm skin incision was made 1.5–2 cm lateral to the sternoclavicular joint.
- Entry point into the clavicle was created using an awl.
- A titanium elastic nail (2.0–3.5 mm diameter, selected based on canal size) was introduced into the intramedullary canal using a T-handle.
- Fracture reduction was achieved closed under C-arm guidance: if closed reduction failed, a small incision at the fracture site was used to aid reduction.
- The nail was advanced into the lateral fragment and cut flush at the entry site.
- Wound was irrigated and closed in layers. A small portion of nail was left protruding for future removal.

8. Postoperative Protocol

Both groups followed a standardized rehabilitation protocol

Time Frame	Intervention
Post-op Day 1–2	Arm supported in a sling: check X-rays
Day 3–5	Gentle pendulum exercises
2 Weeks	Suture removal and passive ROM started
4–6	Weeks Active ROM in forward flexion and abduction up to 90 °
6–8 Weeks	Full ROM permitted if union evident
12 Weeks	Final functional and radiological assessment

9. Outcome Measures

Outcomes were assessed at 4, 8, 12, and 24 weeks postoperatively using
- **Radiological Union:** Defined by bridging callus on at least three cortices and obliteration of fracture line.
- **Clinical Union:** Defined as absence of pain and tenderness at the fracture site.
- **Functional Outcome:** Assessed using Constant-Murley Shoulder Score.
- **Complications:** Recorded systematically (infection, implant prominence, hardware failure, nonunion, hypertrophic scar, etc.)

Results

1. Demographic Data

Parameter	Group A (Plate)	Group B (TENS)
Number of Patients	**20**	**20**
Mean Age (years)	32.65 ± 9.2	33.15 ± 9.5
Gender (M:F)	18:2	18:2
Affected Side (R:L)	13:7	14:6
Mechanism of	RTA: 65%, Fall	RTA: 65%, Fall
Injury	35%	35%

Most patients were young males involved in road traffic accidents. The right side was more commonly involved.

2. Radiological and Clinical Union

Parameter	Group A (plate)	Group B (Tens)	P value
Mean Clinical Union (weeks)	**7.3 ± 1.1**	**5.6 ± 1.0**	**<0.05**
Mean Radiological Union (weeks)	**9.3 ± 1.2**	**7.4 ± 1.1**	**<0.05**

- The TENS group showed statistically significant earlier union both clinically and radiologically.
- All patients eventually achieved union.

3. Functional Outcome (Constant-Murley Score)

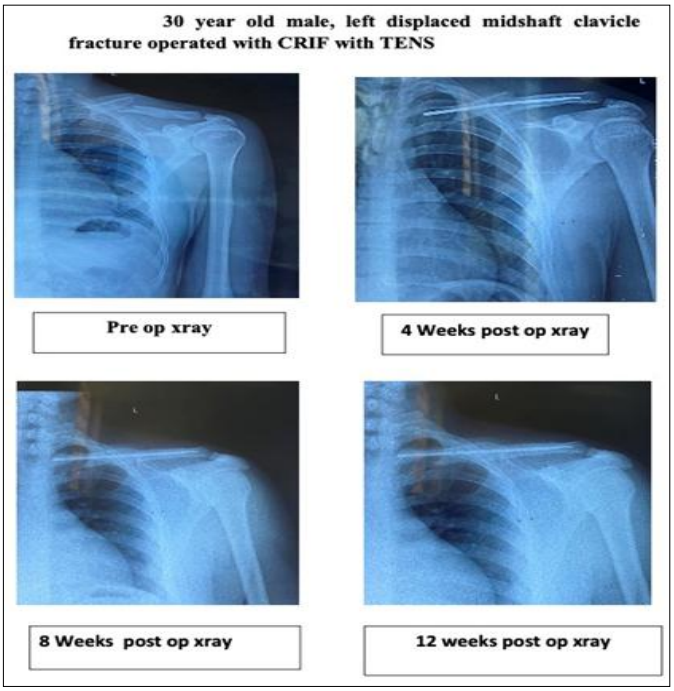
Time	Group A (plate)	Group B (Tens)	P value
6 Months	85.3 ± 6.2	90.4 ± 4.5	<0.05

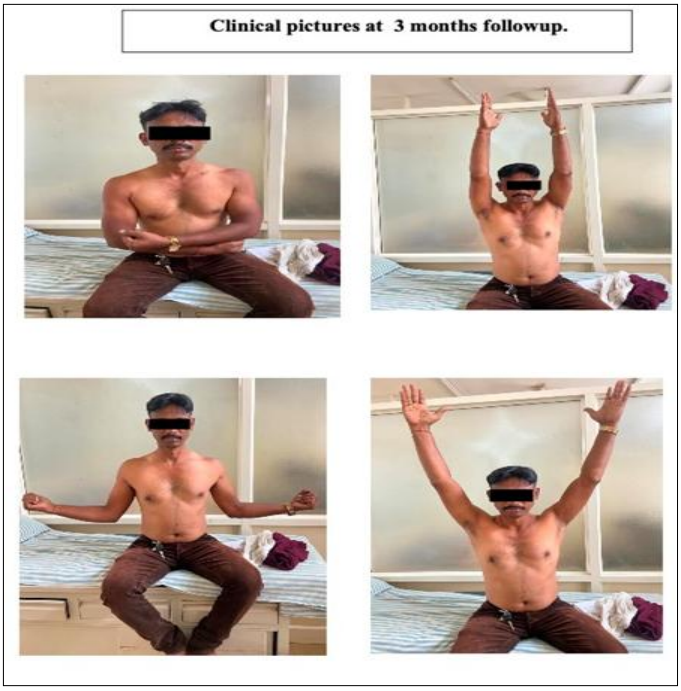
The TENS group demonstrated significantly better functional outcome at 6 months.

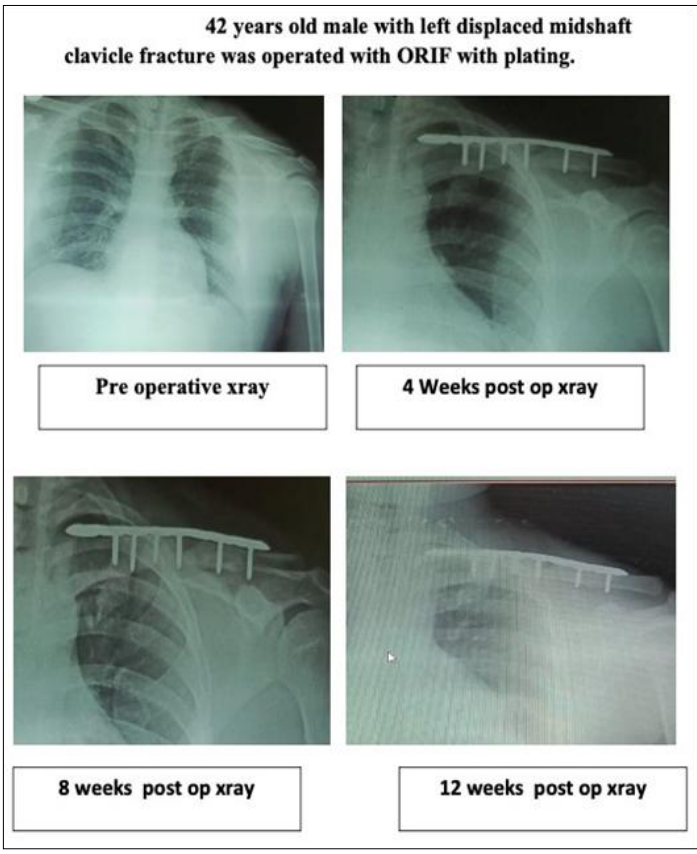
4. Complications

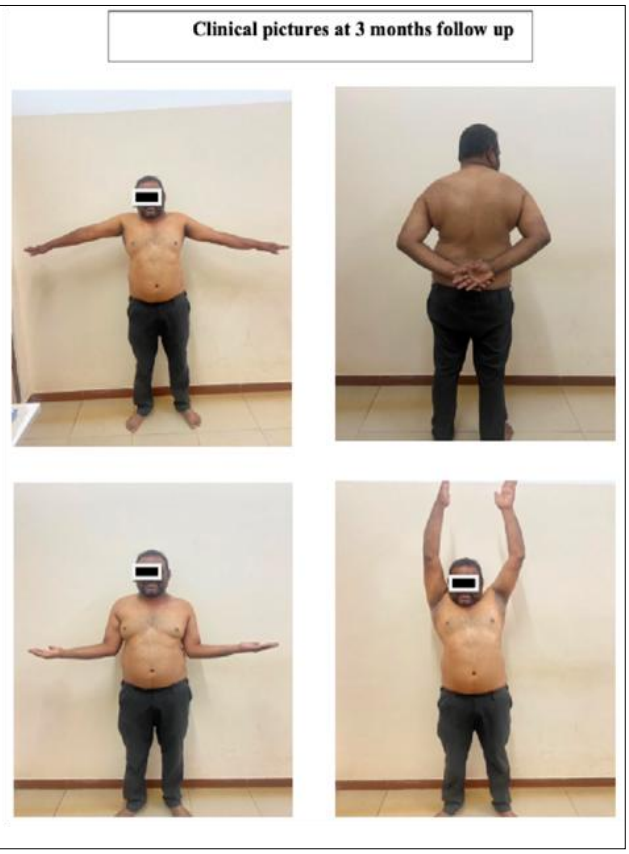
Complication	Plate Group (n=20)	TENS Group (n=20)
Super fical infection	1	1
Wound dehiscence	2	0
Implant prominence	2	1
Nail black-out	0	1
Hypertrophic scar	2	0
Non-union	0	0

- The plate group had higher rates of soft-tissue-related complications.
- One patient in the TENS group had nail back-out but did not require revision.









Discussion

The aim of this prospective comparative study was to evaluate and compare the functional and radiological outcomes of two widely used surgical techniques—open reduction and internal fixation with anatomically contoured locking compression plates (LCP) and intramedullary fixation with Titanium Elastic Nailing System (TENS)—for the treatment of displaced midshaft clavicle fractures. Forty patients were enrolled and evenly divided into two groups. The results indicated a statistically significant advantage of TENS over plating in terms of union time, functional scores, and complication rates.

Interpretation of Demographic Trends

The average age of the patients in both groups was in the early 30s, with a clear male predominance (90%), and a higher frequency of right-side involvement. These findings are consistent with global literature, which attributes the higher incidence in young males to greater involvement in road traffic accidents and high-energy trauma mechanisms[1–3]. The clavicle, being subcutaneous and anatomically positioned as a strut, is particularly susceptible to injury in such cases.

Functional Outcome Comparison

The Constant-Murley score, a comprehensive tool assessing pain, daily activities, range of motion, and strength, was significantly higher in the TENS group at the 6-month follow-up. While both groups showed good to excellent recovery, patients treated with TENS demonstrated earlier functional recovery and return to activities. These findings are congruent with those reported by
Assobhi[40] and Narsaria *et al*.[41], who noted that intramedullary fixation enables early rehabilitation due to minimal soft tissue disruption and pain.

Radiological Union Analysis

Patients treated with TENS had a significantly shorter time to both clinical and radiological union, with average union at 7.4 weeks compared to 9.3 weeks in the plating group. This observation supports previous reports by Kadakia *et al*.[36] and Rehm *et al*.[13], who demonstrated accelerated healing with intramedullary techniques due to elastic stability, preserved periosteal blood supply, and micro-motion at the fracture site.
Earlier studies by Hill *et al*.[8] and McKee *et al*.[23] emphasized that malalignment or shortening >2 cm could significantly impair shoulder function, especially in young, active individuals. TENS, by preserving length and alignment with minimal dissection, likely mitigates this risk better than plates, particularly in simple or moderately comminuted fractures.

Complications

The plate group had higher incidences of wound dehiscence, superficial infection, implant prominence, and hypertrophic scarring. In contrast, TENS-related complications were minimal and limited to one case of superficial infection and one instance of nail back-out. No case of nonunion was observed in either group.
These results mirror those from Assobhi[40] and Zhang *et al*.[43], who reported higher complication rates with open plating, especially implant-related irritation and prominent scarring. While plating offers robust fixation in highly comminuted or osteoporotic bone, the invasiveness, need for extensive dissection, and risk of neurovascular injury remain concerning[52,74].
Although TENS is technically demanding in complex fracture morphologies or narrow medullary canals, its advantages in select patient groups—especially cosmetically conscious or younger individuals—are clear. However, correct implant selection, proper surgical technique, and patient compliance are essential to avoid complications such as nail migration or improper fixation.

Comparison with Literature

Several studies have attempted similar comparisons:

- Narsaria *et al*.[41] showed initially better scores in plating, but TENS caught up at 12 months.
- Zhang *et al*.[43] and Xu *et al*.[44] in their meta-analyses concluded that TENS provides shorter operative time, lower blood loss, earlier union, and similar long-term outcomes.
- Li *et al*.[46] observed superior Constant and DASH scores in the TENS group, affirming our findings.

These results suggest that both techniques have their place in orthopedic practice. Plating may be superior in comminuted fractures, osteoporotic bone, or when rotational control is critical. TENS, on the other hand, offers minimally invasive, cosmetically favorable, and cost-effective management in relatively simple displaced fractures.

Conclusion

This prospective comparative study demonstrated that both locking compression plating and intramedullary TENS are effective in treating displaced midshaft clavicle fractures, offering good to excellent clinical and radiological outcomes. However, the TENS group showed:

- Significantly shorter time to clinical and radiological union
- Better Constant-Murley functional scores at 6 months
- Fewer complications
- Superior cosmetic outcomes

Intramedullary TENS fixation emerges as a reliable, minimally invasive technique with faster recovery and improved patient satisfaction, particularly suited for young and active individuals with simple or mildly comminuted fractures.
That said, plating continues to have a vital role in managing complex fracture patterns, nonunions, and osteoporotic bones. Surgeon expertise, patient profile, and fracture configuration should guide the treatment choice.

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