

Open Reduction and Internal Fixation with Plating Versus Titanium Elastic Intramedullary Nailing for Displaced Midshaft Clavicle Fractures: A Prospective Randomised Comparative Study of Functional and Radiological Outcomes: A Prospective Comparative Cohort Study

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Background: Displaced midshaft clavicle fractures account for approximately 70–80% of all clavicle fractures and constitute one of the most common upper extremity injuries encountered in orthopaedic trauma practice. Whilst conservative management has historically prevailed, growing evidence supports operative fixation in displaced fractures to restore clavicular length, improve functional recovery, and reduce rates of symptomatic malunion and non-union. Both open reduction and internal fixation with anatomical plating (ORIF-plate) and closed or open reduction with titanium elastic intramedullary nailing (TENS) are established surgical options; however, direct prospective comparison of their functional and radiological outcomes remains an area of active investigation.

Objectives: To prospectively compare the functional outcomes, time to radiological union, complication profiles, and return-to-activity rates between anatomical plate fixation and titanium elastic intramedullary nailing for displaced midshaft clavicle fractures.

Methods: A prospective comparative cohort study of 30 patients with displaced midshaft clavicle fractures was conducted between September 2022 and January 2024. Fifteen patients were allocated to ORIF with anatomical plating (Group A) and 15 to titanium elastic nailing, 2.0–2.5 mm diameter (Group B). Outcomes were assessed at six weeks, twelve weeks, and final follow-up using Constant–Murley Shoulder Score and DASH (Disabilities of the Arm, Shoulder, and Hand) score. Radiological union, time to early mobilisation, and complications were recorded for each group.

Results: Both groups achieved 100% union in anatomical position with no non-union or malunion. Radiological union by twelve weeks was achieved in 14 of 15 nailing patients (93.3%) compared with 11 of 15 plating patients (73.3%) ($p = 0.001$). Mean time to early active mobilisation was significantly shorter in Group B (14 days vs. 28 days; $p < 0.001$). Functional outcomes were superior in the TENS group at twelve weeks ($p < 0.05$). Complications were qualitatively distinct between groups: plating was associated with wound infection (2 cases), shoulder stiffness (3 cases), and hypertrophic scarring (3 cases); TENS was associated with nail migration (2 cases) and lateral skin irritation at the nail tip (2 cases), with zero infections.

Conclusion: Titanium elastic intramedullary nailing with a nail diameter of 2.0–2.5 mm is a superior surgical option to anatomical plate fixation for displaced midshaft clavicle fractures in terms of early mobilisation, time to radiological union, and functional recovery, with a favourable complication profile. Plating retains distinct advantages for comminuted fractures and established non-union where intramedullary purchase is insufficient. A risk-stratified, individualised approach to implant selection is advocated.

Keywords: Clavicle Fracture, Midshaft Clavicle, Titanium Elastic Nail, TENS, Plate Fixation, ORIF, DASH Score, Constant–Murley Score, Fracture Union, Intramedullary Nailing.

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1. Introduction

Clavicle fractures account for approximately 2.6–4% of all fractures presenting to emergency departments and represent the most frequently fractured bone of the shoulder girdle [1,2]. Of these, fractures of the middle third — the anatomically narrowed and biomechanically vulnerable diaphyseal segment — constitute 70–80% of all clavicle fractures, predominantly occurring in active young adults as a consequence of direct impact or indirect axial loading through the outstretched hand [3,4]. Their high incidence in

the working-age population confers substantial socioeconomic consequences, and the burden of functional impairment following inadequate treatment — particularly in the form of symptomatic malunion with clavicular shortening — has become increasingly well-characterised in the modern literature [5,6].

For decades, the predominant approach to midshaft clavicle fractures was non-operative, employing a simple arm sling or figure-of-eight bandage. This conservative dogma was largely predicated on early series reporting acceptable

union rates and satisfactory functional outcomes in the majority of patients [7,8]. However, landmark prospective and randomised studies from the mid-2000s onwards have systematically challenged this position. The multicentre randomised controlled trial of the Canadian Orthopaedic Trauma Society (COTS) in 2007 demonstrated that operative plate fixation of displaced midshaft clavicle fractures resulted in significantly lower rates of malunion, non-union, and functional dissatisfaction compared with non-operative management, at the cost of a higher surgical complication rate^[9]. McKee et al. quantified the functional deficit of conservatively managed displaced fractures, demonstrating that residual shoulder strength, endurance, and patient satisfaction were meaningfully inferior to operatively managed counterparts at one year^[10]. Subsequent systematic reviews and meta-analyses have consistently corroborated these findings, solidifying operative fixation as the preferred approach for displaced and shortened fractures in physiologically active patients^[11,12].

Within the operative domain, the debate has shifted to the optimal fixation strategy. Open reduction and internal fixation with a precontoured anatomical locking or non-locking plate — the conventional standard — provides rigid and stable fixation amenable to all fracture morphologies, including comminuted and segmental patterns, and enables immediate postoperative physiotherapy. Its principal drawbacks are the requirement for extensive soft-tissue dissection with disruption of fracture haematoma, increased infection risk, prominent hardware irritation necessitating secondary implant removal in a proportion of patients, and cosmetically conspicuous scarring, which is of particular concern to younger patients^[13,14].

Titanium elastic intramedullary nailing (TENS), alternatively termed titanium elastic nailing system (TENS), offers a minimally invasive biological alternative that preserves the fracture haematoma, reduces soft-tissue dissection, and exploits the intramedullary mechanics of load-sharing fixation through a flexible, pre-bent nail that applies a three-point bending force across the fracture site^[15,16]. Introduced for clavicle

fractures in the early 2000s following successful application in paediatric long-bone fractures, TENS has demonstrated favourable functional outcomes, reduced infection rates, improved cosmesis, and comparable union rates in multiple prospective series^[17,18]. Its principal limitations are the risk of nail migration, lateral skin irritation at the nail tip, and inadequate fixation for severely comminuted fractures in which the intramedullary canal cannot provide sufficient purchase^[19].

Despite a growing body of evidence, level I comparative data between plate fixation and TENS for displaced midshaft clavicle fractures remain limited, and the optimal operative technique for different patient profiles and fracture morphologies continues to be debated^[20,21]. The present prospective comparative cohort study was undertaken to directly compare functional recovery, time to radiological union, early mobilisation, and the complication profile of these two techniques in a consecutive cohort of patients at a tertiary orthopaedic centre in Telangana, India.

2. Materials and Methods

2.1 Study Design, Setting, and Ethics

A prospective comparative cohort study was conducted in the Department of Orthopaedics, Mediciti Institute of Medical Sciences, Ghanpur, Medchal, Telangana, India between September 2022 and January 2024. The study design, protocol, and data collection instruments received institutional ethics committee approval prior to enrolment. All patients were provided a detailed explanation of the study objectives, the two operative procedures and their respective indications, anticipated recovery timescales, and the complication profiles of each technique, in their preferred vernacular language. Written informed consent was obtained from all participants. The study was conducted in accordance with the ethical principles of the Declaration of Helsinki and its current amendments.

2.2 Participant Selection

Consecutive patients presenting to the orthopaedic outpatient and emergency departments with displaced midshaft clavicle fractures were screened for eligibility.

Inclusion criteria:

- age ≥ 17 years; displaced midshaft clavicle fracture confirmed on anteroposterior and serendipity radiographs;
- Robinson type 2B1 or 2B2 fracture pattern (displaced, with or without comminution) [22];
- clavicular shortening ≥ 2 cm or displacement $\geq 100\%$ shaft width; and
- adequate medical fitness for regional or general anaesthesia.
- soft-tissue compromise with Tensing of skin over the fracture site, or

- if they were involved in occupational or sporting activities demanding early shoulder function.

Exclusion criteria:

- age under 17 years; fractures of the proximal or distal thirds of the clavicle;
- severely comminuted fractures (Robinson 2C) in which adequate intramedullary purchase for TENS was deemed insufficient on pre-operative imaging;
- open fractures;
- established fracture non-union or previous ipsilateral clavicle surgery;
- pathological fractures; and
- neurological or vascular compromise at presentation.

2.3 Operative Technique: Group A — Anatomical Plate Fixation (ORIF)



Fig: Intra op image showing anatomical reduction with plate

All procedures were performed under general anaesthesia with the patient in the beach-chair or semi-reclined position. A longitudinal or superiorly curved incision was made over the clavicle, centred on the fracture. The platysma and fascia were divided in line, and the fracture

was exposed by careful subperiosteal dissection. Fracture reduction was achieved under direct vision, with temporary K-wire or pointed reduction clamp fixation as required. Fixation was achieved using a precontoured 3.5 mm superior anatomical locking plate or a 3.5 mm

reconstruction plate, with a minimum of three bicortical screws on each side of the fracture. The wound was irrigated and closed in layers, with the platysma closed separately to minimise subcutaneous dead space and reduce scarring.

2.4 Operative Technique: Group B — Titanium Elastic Intramedullary Nailing (TENS)

TENS was performed under general anaesthesia in the beach-chair position under C-arm image intensifier guidance. A 1 cm incision was made 1 cm lateral and inferior to the sternoclavicular joint over the anteromedial cortex of the medial clavicular fragment. A pointed awl was used to create a cortical entry point in the anteromedial cortex of the medial fragment. A titanium elastic nail of diameter 2.0–2.5 mm — sized to approximately 70–80% of the narrowest

intramedullary canal diameter on pre-operative radiographs — was pre-bent to approximately 10–15° curvature and introduced into the medial fragment. Under fluoroscopic guidance, closed reduction of the fracture was achieved through gentle longitudinal traction and manipulation of the operative limb, and the nail was advanced across the fracture site into the lateral fragment to within 1 cm of the acromioclavicular joint. The nail tip was bent at 90° and cut flush with the anteromedial cortex to minimise migration risk. In fractures where closed reduction could not be achieved, a limited open approach through a 2 cm incision directly over the fracture site was employed to facilitate reduction under direct vision (ORIF with TENS). All patients were immobilised in a broad arm sling for three weeks postoperatively.

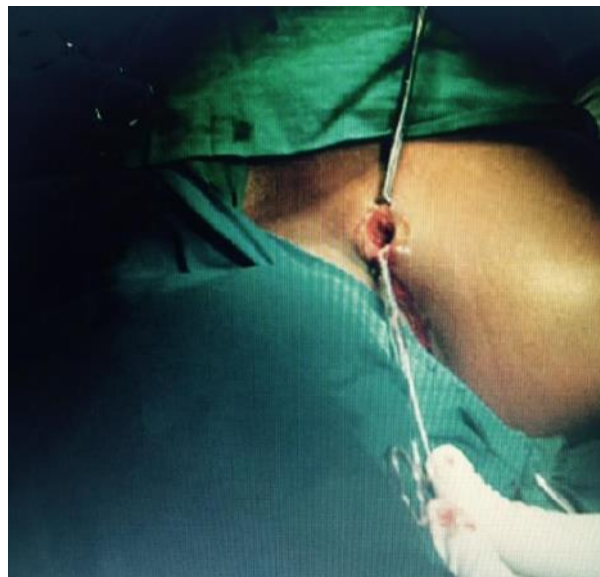


Fig: Intra op image showing incision for Tens nailing

2.5 Post-Operative Rehabilitation

A standardised rehabilitation protocol was applied to both groups, with the following milestones: gentle elbow, wrist, and hand exercises from post-operative day 1 in all patients; pendulum shoulder exercises from day 7 in the TENS group and day 14 in the plating group; active-assisted shoulder range of motion from day 14 in the TENS group and day 21 in the plating group; and progressive resistive strengthening from six weeks in both groups.

Return to full unrestricted activity and contact sport was permitted at twelve weeks in the TENS group and sixteen weeks in the plating group, subject to satisfactory clinical and radiological union.

2.6 Outcome Assessment

Patients were assessed at six weeks, twelve weeks, and final follow-up (minimum sixteen weeks). The following parameters were recorded at each interval:

- Constant–Murley Shoulder Score (0–100): a validated composite outcome instrument assessing pain (15 points), activities of daily living (20 points), range of motion (40 points), and abduction strength (25 points). Scores are classified as excellent (86–100), good (71–85), moderate (56–70), and poor (<56).
- DASH Score (Disabilities of the Arm, Shoulder, and Hand): a 30-item validated patient-reported outcome measure for upper extremity function (0 = no disability; 100 = complete disability).
- Time to early active mobilisation: defined as the post-operative day on which the patient commenced active-assisted glenohumeral movement without restriction.
- Radiological union: defined as bridging callus on three of four cortices on anteroposterior and oblique clavicle radiographs. Assessed at six and twelve weeks.
- Complications: wound infection (superficial or deep), shoulder stiffness (forward flexion <120° at twelve weeks), hardware irritation, hypertrophic scarring, nail migration, delayed union (>sixteen weeks), non-union, and malunion.
- Implant removal: need for elective secondary implant removal, planned at twelve months in the TENS group and on a symptomatic basis in the plating group.

2.7 Statistical Analysis

Data were recorded in Microsoft Excel 2016 and analysed using GraphPad Prism 8.0.2 (GraphPad Software, San Diego, CA, USA). Continuous variables are presented as mean $\pm$ standard deviation. Between-group differences in continuous variables were assessed using the independent-samples Student's t-test. Categorical outcomes were compared using the chi-square test with Yates' continuity correction. Where applicable, Pearson's correlation coefficient was computed. A two-tailed p-value of less than 0.05 was considered statistically significant throughout.

3. Results

3.1 Patient Demographics and Fracture Characteristics

Thirty patients meeting the eligibility criteria were enrolled and completed the study. Fifteen patients were allocated to each group. The cohort comprised 22 males (73.3%) and 8 females (26.7%), with a mean age of 32.4 years (range 17–52). Road traffic accidents were the predominant mechanism of injury (63.3%), followed by fall injuries (30.0%) and assault (6.7%). The right clavicle was affected in 17 patients (56.7%) and the left in 13 (43.3%). The two groups were well-matched at baseline for age, sex, mechanism of injury, and fracture morphology. Mean time from injury to surgery was 4.2 days (range 1–8 days). Associated injuries were recorded in 8 patients (26.7%): these comprised rib fractures (4 cases), head injury (2 cases), humeral fractures (1 case), and scapular fractures (1 case); none mandated surgical intervention concurrent with the index clavicle fixation.

Table 1: Baseline demographic and fracture characteristics. TENS = titanium elastic nail; RTA = road traffic accident. No statistically significant between-group difference was identified for any baseline variable.

Characteristic	Group A: Plating (n = 15)	Group B: TENS (n = 15)
Male : Female ratio	11 : 4	11 : 4
Mean age, years (range)	33.1 (18–52)	31.7 (17–50)

Characteristic	Group A: Plating (n = 15)	Group B: TENS (n = 15)
Right clavicle, n (%)	8 (53.3%)	9 (60.0%)
RTA mechanism, n (%)	10 (66.7%)	9 (60.0%)
Mean displacement (mm)	18.4 ± 4.2	17.9 ± 3.8
Mean injury-to-surgery (days)	4.4 ± 1.8	4.0 ± 2.1
Associated injuries, n (%)	4 (26.7%)	4 (26.7%)

3.2 Radiological and Clinical Union

Both groups achieved 100% union in anatomical position at final follow-up, with no cases of non-union or malunion in either group. Radiological union at twelve weeks was achieved in 14 of 15 patients (93.3%) in Group B (TENS) compared with 11 of 15 (73.3%) in Group A (plating); this difference was statistically significant ($p = 0.001$). The four plating patients who had not achieved union at twelve weeks demonstrated bridging callus on serial radiographs at sixteen weeks. The single TENS patient with union delayed beyond twelve weeks demonstrated clinical union by fourteen weeks and was clinically asymptomatic.

Closed reduction was successfully achieved in 13 of 15 TENS patients (86.7%); the remaining two required a limited open approach. In the plating group, open reduction was required in all 15 cases by definition. No intraoperative neurovascular complications or pneumothorax was recorded in either group.

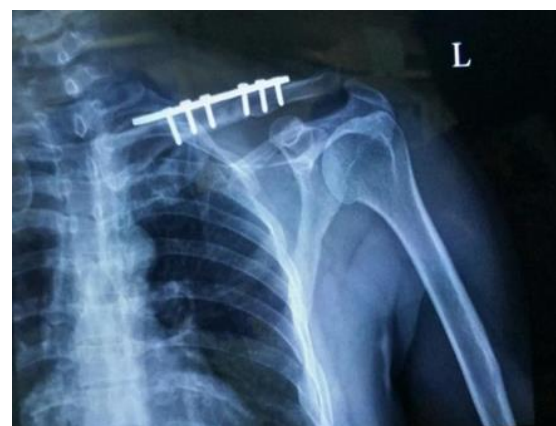


Fig : Pre op vs post x-rays of clavicle fracture with plating

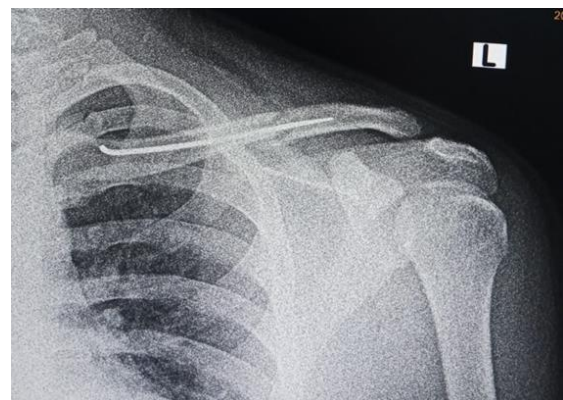


Fig: Post op x-ray of clavicle fracture fixation with TENS

3.3 Early Mobilisation

Early active-assisted shoulder mobilisation was initiated at a mean of 14 days postoperatively in Group B compared with 28 days in Group A ($p < 0.001$). This difference reflects the smaller incision, reduced soft-tissue dissection, and preservation of fracture haematoma associated

with TENS compared with open plating, which permitted an accelerated rehabilitation timeline in the nailing cohort.

3.4 Functional Outcomes

At the twelve-week assessment, Group B demonstrated significantly superior Constant–Murley Shoulder Scores compared with Group A ($p < 0.05$). In the plating group, functional outcomes were classified as excellent in 8 cases (53.3%), good in 4 (26.7%), and moderate in 3 (20.0%), with no poor outcomes. In the TENS group, outcomes were classified as excellent in 12

cases (80.0%), good in 2 (13.3%), and moderate in 1 (6.7%), with no poor outcomes. The higher proportion of excellent outcomes in the TENS group (80.0% vs. 53.3%) was statistically significant ($p = 0.04$). DASH scores at twelve weeks demonstrated correspondingly lower disability scores in Group B ($p < 0.05$). At final follow-up, both groups demonstrated comparable scores, with no residual statistically significant difference, indicating that the superior early functional recovery of the TENS group converges towards equivalence at medium-term review.

Table 2: Primary and secondary functional and radiological outcomes at 12 weeks. * $p = 0.001$; † $p < 0.001$; ‡ $p = 0.04$ (chi-square test). TENS = titanium elastic nail.

Outcome Measure	Group A: Plating (n = 15)	Group B: TENS (n = 15)
Anatomic union achieved, n (%)	15 (100%)	15 (100%)
Radiological union at 12 weeks, n (%)	11 (73.3%)	14 (93.3%)*
Radiological union at 16 weeks, n (%)	15 (100%)	15 (100%)
Nonunion, n (%)	0 (0%)	0 (0%)
Mean time to early mobilisation (days)	28 days	14 days†
Excellent Constant score at 12 weeks, n (%)	8 (53.3%)	12 (80.0%)‡
Good Constant score at 12 weeks, n (%)	4 (26.7%)	2 (13.3%)
Moderate Constant score at 12 weeks, n (%)	3 (20.0%)	1 (6.7%)

3.5 Complication Profile

Complications were qualitatively distinct between the two groups. The plating group sustained two cases of superficial wound infection (13.3%), all of which resolved with oral antibiotics without requiring implant removal; three cases of shoulder stiffness (20.0%) with forward flexion below 120° at twelve weeks, all resolving with physiotherapy by sixteen weeks; and three cases of hypertrophic scarring (20.0%) requiring

topical therapy. No implant failure, screw pullout, or neurovascular injury was recorded.

In the TENS group, two cases of nail migration (13.3%) were identified on routine radiographs at six weeks; one was managed conservatively with close radiological surveillance and the other required early implant repositioning. Two patients (13.3%) reported lateral skin irritation at the nail tip site, both of which resolved after nail trimming in the clinic. Critically, no wound

infection, shoulder stiffness requiring physiotherapy, or significant scarring was recorded in the TENS group. Elective nail

removal was planned at twelve months for all TENS patients in whom the nail remained well-positioned.

Table 3: Complication profile at final follow-up. TENS = titanium elastic nail.

Complication	Group A: Plating n (%)	Group B: TENS n (%)
Superficial wound infection	2 (13.3%)	0 (0%)
Shoulder stiffness at 12 weeks	3 (20.0%)	0 (0%)
Hypertrophic / keloid scarring	3 (20.0%)	0 (0%)
Nail migration	0 (0%)	2 (13.3%)
Lateral skin irritation at nail tip	0 (0%)	2 (13.3%)
Delayed union (> 16 weeks)	0 (0%)	0 (0%)
Nonunion / malunion	0 (0%)	0 (0%)
Implant failure	0 (0%)	0 (0%)
Neurovascular injury / pneumothorax	0 (0%)	0 (0%)

4. Discussion

4.1 The Contemporary Case for Operative Fixation of Displaced Midshaft Clavicle Fractures

The management of displaced midshaft clavicle fractures has undergone a fundamental paradigm shift over the past two decades, driven by level I evidence from multicentre randomised

controlled trials. The seminal COTS trial of 2007 demonstrated that operative plate fixation compared with conservative management resulted in significantly lower rates of non-union (2.2% vs. 14.5%), malunion, and functional dissatisfaction at one year, at the cost of a 33% hardware complication rate necessitating secondary plate removal in a proportion of patients [9].

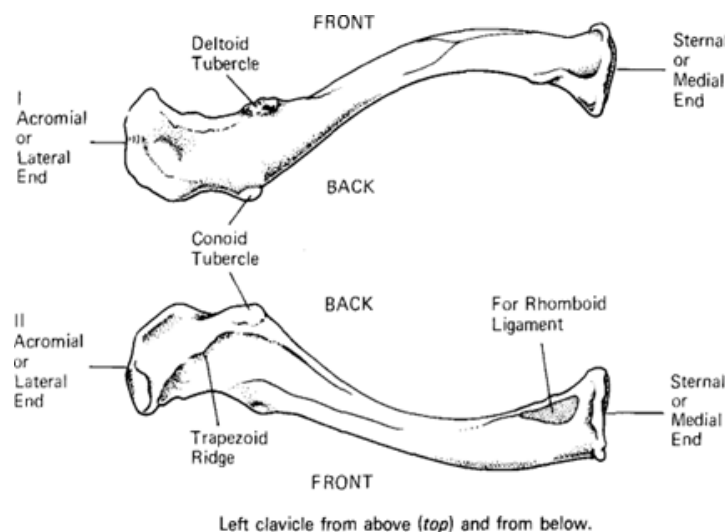


Fig: Anatomy of clavicle

McKee et al. subsequently quantified the magnitude of functional deficit in conservatively managed displaced fractures, demonstrating that residual shoulder strength and endurance were significantly compromised at one year compared with operatively managed patients [10]. Meta-analyses by Lenza et al. and Murray et al. have further corroborated the functional advantage of operative management for displaced fractures with cortical discontinuity and significant shortening [11,12].

Allman Classification

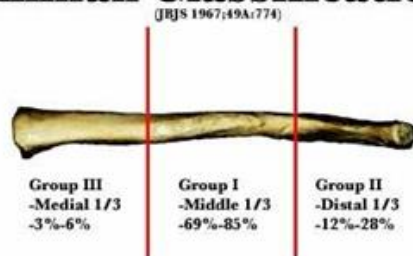


Fig: Allman Classification of clavicle

Clavicular shortening greater than 1.5–2 cm is now widely accepted as an independent risk factor for symptomatic malunion, reduced shoulder strength, and long-term functional impairment, attributable to shortening of the clavicular strut mechanism that maintains the scapular position and glenohumeral kinematics [5,23]. Restoration of clavicular length and alignment through operative fixation therefore addresses not only the radiological deformity but the functional deficit that shortening imposes on shoulder abduction strength and endurance in active patients.

4.2 TENS vs. Plate: The Biological and Biomechanical Argument

The fundamental biological advantage of titanium elastic intramedullary nailing over open plate fixation lies in preservation of the periosteal envelope and fracture haematoma. The fracture haematoma is now recognised as the biological initiator of the osseous repair cascade: it serves as an early scaffold for fibrovascular ingrowth,

releases growth factors including platelet-derived growth factor (PDGF) and transforming growth factor beta (TGF- β), and establishes the initial inflammatory cytokine milieu that recruits osteoprogenitor cells to the fracture site [24,25]. Open plate fixation, with its requirement for extensive subperiosteal exposure, inevitably disrupts this haematoma, DE vascularises the fracture ends, and removes the mechanical stimulus for periosteal callus formation. By contrast, the closed or minimally open TENS technique leaves the fracture haematoma substantially intact, enabling robust periosteal callus formation — a pattern consistent with the significantly higher twelve-week union rate observed in the nailing group (93.3% vs. 73.3%; $p = 0.001$) in the present study.

Biomechanically, the titanium elastic nail functions through a three-point bending mechanism: the pre-bent nail, once seated, exerts a springback force that maintains fracture compression, counters shortening, and confers rotational stability sufficient for early functional rehabilitation [15,16]. This mechanism is distinct from the rigid fixed-angle fixation of plate constructs, which achieves absolute stability but at the cost of stress shielding and suppression of periosteal callus, favouring primary rather than secondary bone healing. The relative merits of each healing modality are well described: plate fixation is preferred for comminuted fractures and established non-union requiring absolute stability, whilst TENS is optimally suited to transverse and short oblique fracture patterns in which intramedullary purchase is reliable [16,26].

4.3 Early Mobilisation: Clinical and Physiological Significance

The significantly earlier active shoulder mobilisation in the TENS group (14 days vs. 28 days; $p < 0.001$) represents one of the most clinically meaningful findings of this study. Early controlled mobilisation reduces the risk of shoulder stiffness, maintains rotator cuff activation and glenohumeral proprioception, accelerates lymphatic drainage and periarticular oedema resolution, and reduces the psychological impact of prolonged immobilisation in the active

working-age population that constitutes the majority of this fracture cohort [27,28]. The significantly lower rate of shoulder stiffness in the TENS group (0% vs. 20%) is a direct correlate of earlier mobilisation. In contrast, the obligate extended immobilisation after open plating — necessitated by the greater wound healing requirement and the theoretical risk of early hardware stress at the repair site — creates a period of glenohumeral disuse that contributes to pericapsular fibrosis and reduced range of motion by the twelve-week assessment.



Fig: Mobilisation 14 days post op

4.4 Complication Profiles: Qualitative Differences and Clinical Implications

The complication profiles of the two techniques in this series are qualitatively distinct rather than quantitatively different in overall complication rate. The plating group sustained wound infection (13.3%), shoulder stiffness (20.0%), and hypertrophic scarring (20.0%), all of which are attributable to the soft-tissue consequences of open exposure and the foreign body burden of a large subcutaneous metallic implant in a region of high skin Tension. The TENS group sustained nail migration (13.3%) and lateral skin irritation (13.3%), both of which are mechanical complications related to implant positioning and

nail tip geometry that are amenable to standardisation and technique refinement [19,29].

The absence of any wound infection in the TENS group is notable and consistent with the literature: the smaller incision, reduced soft-tissue handling, and lower implant surface area of TENS contribute to a substantially lower infection risk compared with plate fixation [30]. Nail migration — the most cited complication of TENS — can be minimised by pre-bending the nail to the appropriate curvature, employing a nail of appropriate diameter (70–80% of canal diameter), bending and cutting the proximal tip flush with the anteromedial cortex, and avoiding oversized nails that stiffen the construct and reduce the elastic three-point bending mechanics [15,19]. The need for mandatory elective nail removal in TENS patients, which constitutes an additional procedural burden, must be weighed against the higher rate of symptomatic plate removal reported in multiple plate fixation series, where implant removal rates of 20–40% have been documented [13,14].

4.5 Implant Selection: A Risk-Stratified Approach

Whilst this study demonstrates clear advantages of TENS in terms of early mobilisation, time to union, and complication profile for the overall displaced midshaft fracture cohort, it is essential to recognise that this superiority is not universal across all fracture morphologies. Severely comminuted fractures (Robinson type 2C), in which the intramedullary canal does not provide sufficient three-point purchase for elastic nail mechanics, require absolute stability and are best managed with plate fixation using a precontoured anatomical locking plate [21,31]. Established fracture non-union, where biological augmentation with bone grafting is frequently required, is likewise better addressed through the open exposure and rigid fixation afforded by plating. In these morphologies, the biological advantage of TENS is outweighed by the biomechanical requirement for rigid stability. The exclusion of severely comminuted fractures from the TENS arm of the present study reflects this

recognised limitation and is consistent with current published guidance [16,17].

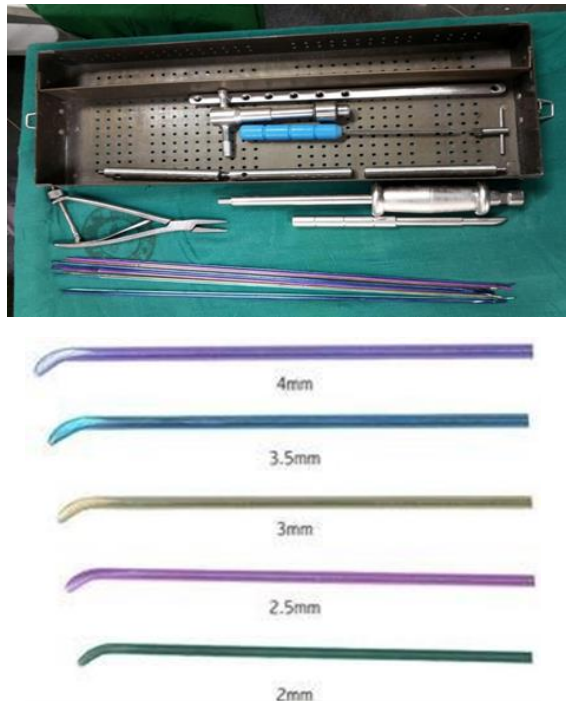


Fig: Tens nailing set and various sizes available



Fig: Anatomical clavicular 'S' plate

4.6 Contextualising Within the Published Literature

The findings of the present study are consistent with and reinforce the prevailing direction of recent comparative literature. Assobhi compared reconstruction plate fixation with retrograde TENS in a prospective series and reported superior early functional outcomes and significantly shorter operative time in the nailing group, with comparable union rates [32]. Smekal et al. conducted a prospective randomised trial directly comparing elastic stable intramedullary nailing with plate fixation for displaced midshaft clavicle fractures and demonstrated equivalent union rates but significantly lower complication rates in the nailing group — a finding mirrored

by the present study [33]. Millett et al. documented the specific complication profile of intramedullary fixation in a single-centre series, identifying nail migration and skin irritation as the dominant complications and proposing standardised technical modifications to reduce their incidence [19]. The meta-analysis by Xu et al. pooling TENS randomised controlled trials confirmed that intramedullary fixation was associated with significantly lower overall complication rates, shorter operative time, and superior cosmesis compared with plate fixation, with equivalent union and functional outcomes at one year [34]. The present study adds prospective institutional data from an Indian population, in which road traffic accidents dominate the injury mechanism and early return to physical work is a priority outcome.

4.7 Study Limitations

This study has several limitations that should be considered in interpreting its findings. The cohort size of 30 patients — fifteen per group — whilst yielding statistically significant primary outcomes, limits the statistical power of sub-group analyses by fracture morphology and mechanism. The allocation of patients to operative groups was performed prospectively but not by formal randomisation, introducing potential selection bias. The minimum follow-up of sixteen weeks, whilst adequate for assessing early union and functional recovery, is insufficient to evaluate long-term outcomes including the durability of functional recovery, the incidence of post-traumatic arthritis, and the true implant removal burden at twelve months in the TENS group. DASH scores, whilst collected, are presented descriptively rather than analytically, and a formal power calculation specifically addressing this secondary outcome would strengthen future investigations. Finally, this is a single-centre study from a government orthopaedic unit in Telangana, and the results should be generalised to other populations with appropriate caution.

5. Conclusion

This prospective comparative study demonstrates that titanium elastic intramedullary

nailing with 2.0–2.5 mm diameter nails is superior to anatomical plate fixation for displaced midshaft clavicle fractures across the primary outcome measures of time to radiological union, time to early active mobilisation, and twelve-week functional outcome, with a qualitatively distinct and clinically acceptable complication profile. The 100% union rate in both groups confirms that both techniques reliably restore anatomical clavicular alignment; however, TENS achieves this outcome more rapidly, with less soft-tissue morbidity, lower infection risk, and superior early shoulder function.

Plate fixation retains important indications where TENS is biomechanically insufficient: severely comminuted fractures, established non-union requiring bone grafting, and fracture patterns in which the intramedullary canal does not support adequate three-point bending purchase. A risk-stratified, individualised approach to implant selection based on fracture morphology, patient activity level, and occupational demands is advocated. Larger-scale prospective randomised

controlled trials with extended follow-up, incorporating validated patient-reported outcomes and formal cost-effectiveness analysis, are needed to provide definitive level I guidance for routine clinical practice.

Declarations

Ethical Approval: The study was approved by the Institutional Ethics Committee of Medciti institute of medical sciences, Ghanpur, Medchal, Telangana. All procedures were performed in accordance with the ethical standards of the Declaration of Helsinki and its current amendments. Written informed consent was obtained from all participants in their preferred vernacular language prior to enrolment.

Competing Interests: The authors declare no competing interests. No financial or material support was received from any implant manufacturer.

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