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A Prospective Study to Assess Radiological and Functional Outcomes in the Surgical Management of Displaced Middle Third Clavicle Fractures Fixed with TENS Titanium Elastic Intra-Medullary Nail

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Abstract

Introduction: Clavicle fractures are common injuries, accounting for 5%-10% of total fractures. The middle third of the clavicle is fractured in 69% of cases, the distal third is fractured in 28% of cases, and the proximal third is fractured in 3% of cases. Early displaced midshaft clavicle fractures were treated conservatively after studies it has being defined that there is nonunion with decreased functional outcome. Surgery is indicated in the event of substantial fracture displacement and accompanying neurovascular damage. Plate osteosynthesis is the conventional approach for treating fractures requiring internal fixation with various complications. Intramedullary fixation using the titanium elastic nailing system (TENS) is becoming a more preferred method for internal fixation of displaced mid-clavicular fractures with minimal incision and better functional outcomes.

Methodology: A prospective study was undertaken with a sample size of 30 patients over two years, with all cases followed up for 12 months. A complete clinical examination of the patient was conducted to evaluate associated injury radiological assessment of the intramedullary diameter of the clavicle was also done. Following approval and clearance from the institutional ethics committee, patients who met the inclusion criteria were enrolled in the study after providing informed consent. The functional outcomes of the study included ASES, CONSTANT, and VAS.

Result: The mean operation time was 40 min, 3 days after surgery the VAS score was 2-3, Union in weeks mean was 10 weeks and functional score after 12 months ASES Score 3 cases of 51-70 22 cases of 71-90 5 cases of 91-100 and at last CONSTANT Score- 12th month 1 cases 56-70 15 cases of 71-85 14 cases of 86-100

Conclusion: TENS is a safe, stable, minimally invasive surgical technique in indicated cases with reduced duration of the surgery, decrease the surgical site morbidity, early mobilization, faster return to daily activities, excellent cosmetic results with a lower complication rate.

Keywords: TENS, Clavicle, Union

Introduction

Clavicle fractures are a common injury, accounting for 5% to 10% of all fractures. The middle portion of the clavicle is the most common fracture site, accounting for roughly 70% to 80% of all clavicle fractures. Displacement occurs in approximately 73% of all midshaft clavicle fractures. These fractures are typically associated with RTA automobile accidents or sports injury in young adults, but they are associated with falls in children and elderly patients [1, 2, 3]. Thus, displaced or comminuted fractures increase the likelihood of symptomatic malunion, nonunion, and poor functional outcomes with cosmetic problems [4, 5]. The contemporary trend is trending towards internal fixation of the misplaced midshaft of the clavicle

According to recent studies, when treated conservatively, few occurrences of nonunion and malunion occur. This is typical in older individuals, high-energy traumas, smokers, and fractures that have overlapped or been shortened. Fractures that heal in a shortened position might result in unsatisfactory outcomes such as an unfavourable hump and impaired shoulder function. However, this is typically an issue for overhead workers and sportsmen. Surgery is indicated when there is considerable fracture displacement and/or shortening of more than 20 mm, potential skin perforation, floating injury. which leads to a higher mal-union and non-union rate and is a stronger reason for surgical treatment. Studies suggest that 15.1% non-union incidence in non-operatively treated displaced clavicle fractures. Studies suggest that initial fixation of displaced clavicle fractures has been shown to produce good results with high union rates and few comorbidities. Internal fixation methods include open reduction and internal fixation (ORIF) with LCP/reconstruction plates, closed reduction and internal fixation with intramedullary nailing, titanium elastic nailing system (TENS) [6].

The adoption of an intramedullary device has the following advantages: smaller incision, better cosmetic outcomes, less soft tissue

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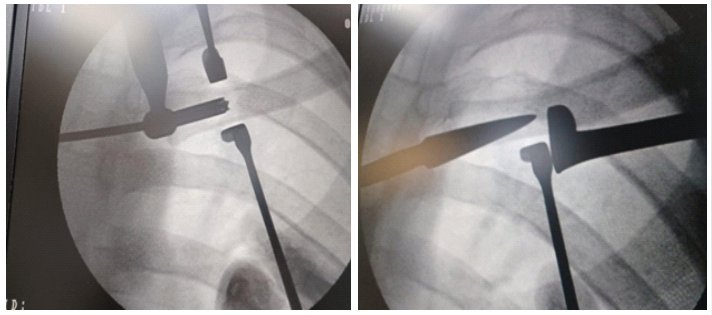

Figure 1,2: INTRAOPERATIVE

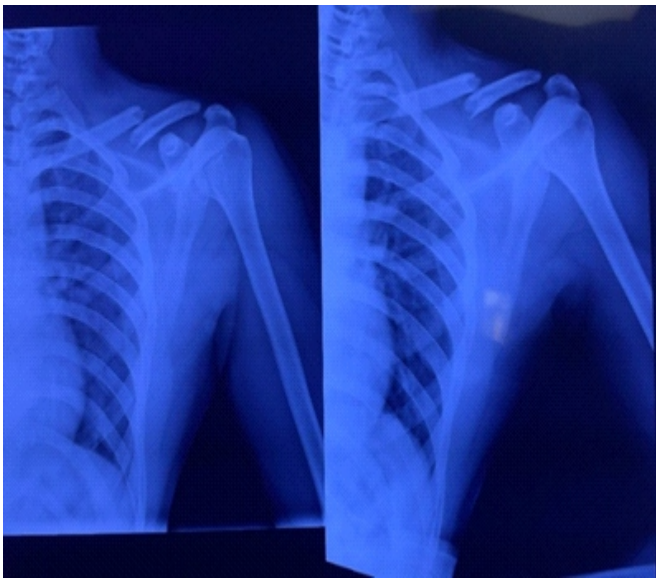

Figure 4: PREOPERATIVE X-RAY

dissection, load-sharing fixation with relative stability, and profuse callus production. The titanium ESIN has the advantage of being able to block itself in the bone while also providing a three-point fixation within the S-shaped clavicle. So, there is growing increasing evidence of intramedullary fixation [7, 8, 9].

Material Methods

Aims of the study

Our study aims to evaluate the functional, clinical, radiological outcomes, and complications in clavicle fractures treated by intramedullary nailing

This study is being done to assess:

1. Functional outcome
2. The duration of the surgery
3. Clinical and radiological union
4. Decreased surgical site morbidity

Inclusion criteria

1. Diaphyseal fractures AO 15.2 A, 15.2 B with spiral, transverse, or oblique pattern and wedge (Intact spiral, Intact bending, Fragmentary)
2. Age: Above 18 - 55 years of age
3. Signed informed consent by the patient or a legal representative
4. Fractures with shortening Shortening & Displacement >2cm in any view
5. Fractures with skin tenting
6. Floating shoulder
7. Bilateral clavicle fractures

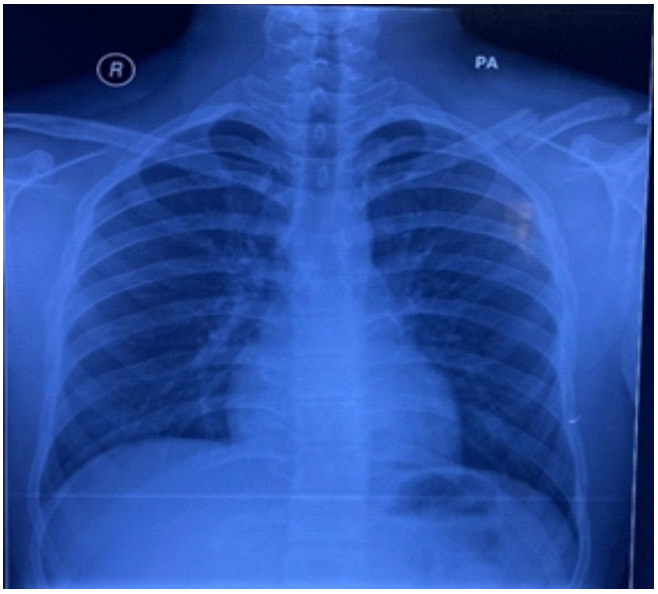

Figure 3: PREOPERATIVE X-RAY

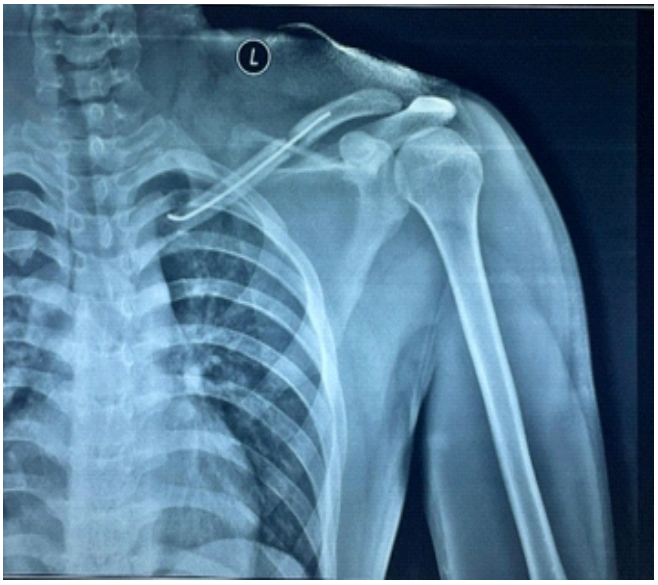

Figure 5: POST OPERATIVE 1 DAY

Exclusion criteria

1. Severely comminuted AO 15.2 C and Medial and lateral third fractures AO 15.1, AO 15.3
2. Intramedullary diameter is very less evaluated on X-ray
3. Medical contra-indications to general/regional anaesthesia: Brachial plexus injuries
4. Pathological fractures
5. Associated vascular injury.
6. Compound injury

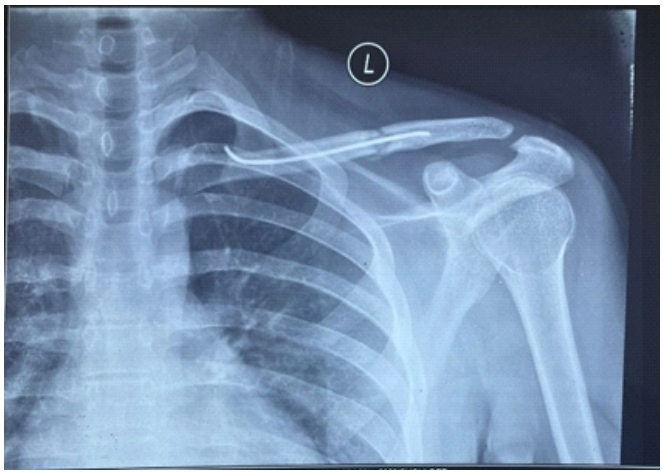

Figure 6: POST OPERATIVE 1 MONTH

Figure 7: POST OPERATIVE 3 MONTH

Figure 8: POST OPERATIVE 12 MONTH

Figure 9: INTRA OPERATIVE INCISION

Figure 11: POST OPERATIVE SCAR 12 Months

It is a prospective study conducted in the department of orthopaedics at a tertiary-level hospital in Delhi, India, between July 2023 and June 2025; 30 patients with midshaft clavicle fractures were treated with internal fixation using intramedullary titanium elastic nails.

Operative procedure

Positioning

After the administration of anaesthesia (either general or regional), the patient is placed in the beach chair position on the table with a sandbag under the same side shoulder.

Surgical approach/technique

A 1-2 cm incision was taken about 2 cm lateral to the sterno-clavicular joint, subcutaneous fat and tissue were incised along with the platysma. The pectoral fascia was divided in line with the skin incision, followed by careful elevation of the underlying musculature from the clavicle.

A drill hole was made into the anterior inferior cortex using a 2.7 mm drill bit, and the medullary canal was entered using an awl. pointed laterally in line with the clavicle and angled at around 30° to the coronal plane.

After being loaded in T handle, appropriate sized TENS 2mm,2,5 mm, or 3 mm was inserted (The size of the nail was measured using this formula = 0.4 × canal diameter in mm). Under C arm control, the attempt was made to reduce the fracture by elevating the inferiorly displaced lateral fragment. If the fracture could not be reduced by closed means, then a separate mini open was used at the fracture site for direct manipulation of fragments. Vertical incision was used as it was parallel to Langer's lines and minimized the risk of damage to the supraclavicular nerves to avoid dysesthesia of skin and scar neuromas reduced under vision, holding a clamp. We prefer a gentle tap on the T-handle to advance the nail in a controlled fashion rather than a vigorous push. Continuous visualization under an image intensifier using anteroposterior and oblique views aided the advancement of the nail. The bent tip of the nail was rotated to negotiate the entry into the lateral fragment. The tip of the nail is advanced as far laterally as possible without perforating the dorsolateral cortex just medial to the AC joint. Always confirm after hammer fracture should be in compression, not in distraction. A threaded end cap may be used and inserted over the medial end of the nail to prevent backing out of the nail and leaving sufficient surface for extraction later. Figure 1 to 11

Postoperative protocol

Patients were given a shoulder immobiliser postoperatively, but were advised to begin elbow mobilisation on the second day, with early shoulder mobilisation beginning in the second week if tolerated. The shoulder immobiliser was removed after approximately 4 – 6 weeks, and activities of daily living were resumed, but those requiring lifting heavy things were postponed until radiological and clinical union was established.

All patients were advised to have regular follow-ups at one, two, three, six, and twelve months. All patients were evaluated clinically and radiographically for implant placement, fracture union, and complications. Constant, DASH, and VAS scores were used to assess the functional result.

Result

In the study of the 30 patients, which we conducted, 23 were male (76.6 %) Female 7 (23.33 %) patients fracture right side 22 (73.33%) left side 8 (27.66 %) occurred due to road traffic accident 20 (66.66 %),7 (23.33%) due to fall from height and 3 (10%) patients due to sport injury. Four cases were associated with rib fracture, undisplaced scapula fracture, head injury, and shaft humerus fracture

In our study, 6 (20 %) patients were in the age group of 20–30 years, 16 (53.33%) patients in the 30–40 age group,7 (23.33%) patients in 40–50 age group, and 1 (3.33%) patient in the age group of 50–55

Table 1: Patient Demographic

Parameters	cases
1.SEX	
Male	23
Female	7
2.SIDE	
Right	22
Left	8
3.AGE	
20 – 30	8
30 – 40	19
40 – 50	2
50 – 55	1
4.TIME OF INJURY TO SURGERY - Days Presentation	5
Mean	
5.TYPE OF INJURY	
RTA	20
Fall	7
Sport Injury	3
Associated injury	4

TABLE 2: Perioperative outcomes of surgery

1.OPERATIVE TIME (MIN) Mean	40 min
2.LENGTH OF STAY (DAYS) Mean	2 days
3.LENGTH OF INCISION (cm) Mean	
Close	2.0 cm
Open	4.4 cm
4.REDUCTION OF FRACTURE	
Close	10
Open	20
5. VAS SCORE	
Before surgery	08- 09
3rd day	02- 03

UNION WEEKS	
Union	
Radiological Union	10 weeks

TABLE 3: Postoperative Complications	
COMPLICATION	
Loss of reduction	1
Nonunion	0
Delayed union	1
Implant Failure	0
Refracture	0
SSI	2
Implant prominent	3
Neurovascular Damage	1

TABLE 5: Postoperative Outcomes of Surgery	
2. CONSTANT SCORE - 3rd month	
> 56	1
56-70	4
71-85	11
86-100	14
2. CONSTANT SCORE - 6th month	
> 56	0
56-70	2
71-85	14
2. CONSTANT SCORE - 12th month	
56-70	1
71-85	15

TABLE 4: Outcome Score	
1. ASES SCORE - 3rd month	
0-30	0
31-50	0
51-70	6
71-90	20
91-100	4
1. ASES SCORE - 6th month	
0-30	0
31-50	1
51-70	4
71-90	20
91-100	5
1. ASES SCORE - 12th month	
0-30	0
31-50	0
51-70	3
71-90	22
91-100	5

years. The youngest patient in our study was 22 years old, and the oldest patient in our study was 54 years. The average age was 37 years (range from 20 to 55).

In our study, 6 (20%) patients were operated on day 1, and 20 patients (66.66%) were operated on from 2 to 7 days, 4 (13.33%) operated after 7 days of presentation in view of associated injuries. Operative treatment was performed an average of 4 days (range: from 1 to 14 days).

In our study, 10 (33.33 %) patients of the fracture were fixed by closed reduction, and 20 (66.66%) patients open reduction was done.

In our study, the mean surgical time was 40 minutes, with an incision medial end opening was mean of 2 cm in the closed reduction method and a mean of 4.4 cm in the open reduction method.

In our study, 3 patients had hardware prominence at the medial entry point, and all of them had skin irritation; hence, early implant removal was performed for all four of them after the union of the fracture clinically and radiologically. 1 patient was loosed reduction; the same patient developed a delayed union. Later, simple bone grafting united the case; 2 patients got SSI where treated with long-duration antibiotics for 2 weeks, which got settled. Only one case has numbness in fingers, a neuropraxia injury, which recovered within 2 weeks

During the study period, one of the patients posted for TENS fixation had to be converted into plate fixation intraoperatively as the medullary canal was obliterated in the distal fragment. Hence, that case was excluded from the study.

In our study, the VAS Score mean range after three days of surgery was 2-3, the ASES Score after 12 months was 89.4, and the CONSTANT Score after 12 months was 90.1 (Table 1 to 5)

Surgical precision is important in TENS for clavicle fractures due to the close proximity to the major neurovascular structures.

Total cases – 30

Follow-up duration -12 Months Al Nail removed after 12 months on an average

Comparing with other studies, our study proves that Intramedullary nailing is a minimally invasive surgery with short duration, earlier union rate, excellent functional outcome, and satisfactory cosmetic result.

Discussion

With a 5%–10% incidence, clavicle fractures are among the most frequent fractures. The middle third of the clavicle is fractured in 69% of cases, the distal third is fractured in 28% of cases, and the proximal third is fractured in 3% of cases.

Fangling Shi, study concluded that Non-surgical treatment has a high

Table 6: Comparison of Various Studies

	CASES	AGE	INCISION cm	OPERATION TIME min	UNION weeks	VAS POST OP	CONSTANT	ASES	DASH	COMPLICATION
OUR STUDY 2026	30	37	4.2	40	10		90.1	89.4		INFECTION 2 DELAYEDUNION 1 PROMINENCE 3
PARTHA SAHA PLATE 2014	37	33		67	22		91			INFECTION 4 NONUNION 1 PROMINENCE 3
PARTHA SAHA NAIL 2014	34	33		21	18		93			PROMINENCE 9
BOHRA PLATE 2018	25	46	10	65		5	54			INFECTION 1 NONUNION 2 PROMINENCE 2 FAILURE 3
BOHRA NAIL 2018	23	38	4.2	38		4	72			INFECTION 0 NONUNION 1 PROMINENCE 3
AYMAN PLATE 2026	16	31		116	12				20	INFECTION 0 NONUNION 2 PROMINENCE 3
AYMAN NAIL 2026	14	37		110	10				18	INFECTION 1 NONUNION 1 PROMINENCE 11
VAJRANGI PLATE 2022	19	42			12	5			12	INFECTION 0 NONUNION 1 PROMINENCE 1 FAILURE 3
VAJRANGI NAIL 2022	19	31			12	5			11	INFECTION 1 NONUNION 2 PROMINENCE 3 FAILURE 2
JUN SUNG PLATE 2020	48	41	10			7.3				INFECTION 1 NONUNION 1 PROMINENCE 2 FAILURE 1
JUN SUNG NAIL 2020	49	36	01-Feb			8.2				INFECTION 1 NONUNION 1 PROMINENCE 10 FAILURE 3 SKIN NUMBNESS 2
CHANDRA PLATE 2018	33	31	10		24		0.6333			INFECTION 1 NONUNION 1 PROMINENCE 3 FAILURE 2
CHANDRA NAIL 2018	33	28	4.8		24		81.81% Excellent			INFECTION 1 NONUNION 1 PROMINENCE 1 FAILURE 1

rate of nonunion for clavicular fractures with obvious displacement and notable comminution. Surgical treatment reduces the nonunion rate and leads to better functional scores at long-term follow-up.[10]

Yuki Matsubara Long term conservative treatment outcomes for midshaft clavicle fractures: a 10 to 30 year follow up result. The ASES scores of the affected side were significantly lower than those of the unaffected side, and the SPADI of the affected side was significantly higher than that of the unaffected side. [11]

46% of patients had symptoms, according to a Nowak et al. study that had 208 patients and a 10-year follow-up for sequelae. [12]

In order to prevent shortening, Ledger et al. suggested open reduction and/or internal fixation, emphasising that short malunion restricts shoulder function. Shoulder dysfunctions result from the tethering effect on the scapula, as shortening (≥15 mm) increases by 10.7° at sternoclavicular joint angulations and 6.1° in the scapular version. Flavin et al. discovered that after three years of follow-up, there was 74% malunion, 3% nonunion, average angulation of 13.9°, and shortening of 15 mm using Biodex isokinetic assessment with Constant–Murley scoring system for Allman Type 1 conservatively treated clavicle. These findings significantly impaired the shoulder's isokinetic function and caused patients'symptoms.[13]

Surgical techniques for fixing clavicle fractures include external fixation in compound injury, plate osteosynthesis, simple recon plate or LCP, and intramedullary fixation with K-wire, screw, TENS Nail, recently. The conventional technique for fixing clavicle shaft fractures is currently described as plate osteosynthesis with a simple recon plate or contoured LCP, with the benefit being a good reduction with rigid fixation. However, problems following plate osteosynthesis are frequently encountered.

R.K.S. Dhakad. In this study, early primary plate fixation of comminuted midshaft clavicular fractures results in improved patient-oriented outcomes, improved surgeon-oriented outcomes, earlier return to function, and decreased rates of non-union and malunion. When compared with conservative management [14]

Johney Juneja, this study, early primary plate fixation of comminuted midshaft clavicular fractures results in improved patient-oriented outcomes, improved surgeon-oriented outcomes, earlier return to function and decreased rates of non-union and malunion.[15]

There are various complications related to plate osteosynthesis

Bostman, The major complications included deep infection, plate breakage, nonunion, and refracture after plate removal. The most common of the minor complications was plate loosening, resulting in malunion. [16]

Frans-Jaspe Compared to other studies, we report higher rates of refracture (7.0 %), major revision surgery (11.6 %), and implant failure (14.0 %) after plate fixation.[17]

An alternative fixing technique is intramedullary stabilisation. Over time, reports of threaded Steinmann pins, rush pins, Kirschner wire, cancellous screws, and other intramedullary fixation devices with varying advantages and disadvantages have been made. Jubel et al. were the first to describe using titanium elastic nails to treat midshaft clavicle fractures.[18]

From a biomechanical perspective, this is ideal because the clavicle's tension side varies depending on the direction of loading and arm rotation. Smaller incisions, load sharing device characteristics, and little to no periosteal stripping are advantages of this fixation technique. During the healing process, callus development is made possible by its relative stability.

The complication associated with Skin irritation from the prominent medial end of the nail, which is in a reducing trend as using end cap. In AO 15.2 C, it is not advisable because it cannot preserve the clavicle's length in these circumstances, and the comminuted fractures it is

excluded.

Mark Kettler, Flexible intramedullary nailing, a minimally invasive technique for stabilization of displaced midshaft clavicle fractures, has minor risks and complications.[19]

Martin, in his study, intra-medullary screw fixation has various advantages over standard non-operative therapy, including increased fracture stability, lower non-union rates, and improved functional outcomes. Complications from this procedure, such as implant migration or discomfort, are often minor and controllable.[20]

Weina Ju Advocated for intramedullary nail fixation with a minor complication earlier union rate.[21]

Jun Sung Patient satisfaction with TEN fixation was higher than that of plate fixation, but TEN fixation had a higher incidence of early postoperative pain and migration in type C fractures. Therefore, type A and B fractures can successfully be treated with plate or TEN fixation, but type C fractures should be treated with plate fixation.[22]

Hrushikesh Saraf. This study suggests that there is no difference in the functional outcome or rate of union after closed or open reduction and intramedullary nail fixation for displaced middle third fractures of the clavicle. [23]

Partha Saha The use of minimally invasive antegrade TEN for fixation of displaced midshaft clavicle fractures is recommended in view of faster fracture union, lesser morbidity, better cosmetic results, easier implant removal, and fewer complications; although for comminuted fractures, plating remains the procedure of choice.[24]

Summary

1. Use a Thin Flexible reamer before inserting the nail 2. The entry should be anteroinferior as the medial end of the clavicle curvature is upward, S-shaped, so that the entry of the nail is in line with the trajectory and also after surgery, when the nail is cut, it will not irritate. 3. Endcap elastic nail is better in most cases as it has no implant prominence 4. Bending and torsional loads in the clavicle are better compensated for by an intramedullary flexible nail than a rigid plate, which is only fixed on one side of the bone. 5. Diaphyseal fractures, Severely comminuted AO 15.2 C is not recommended for nailing. 6. The implant removal of nailing is very simple with no refracture, perhaps difficult in plating with refracture chances. 7. Nail migration is more common in comminuted fractures than in transverse fractures. 8. When larger diameter nails were used, it was observed that flexibility was reduced, and manipulation by close insertion was difficult 9. The canal diameter has to be measured on the X ray Preoperatively, and an alternative method of surgical fixation has to be available in the inventory.

Conclusion

Antegrade flexible intramedullary nailing techniques have advantages such as less operative site morbidity, minimal periosteal stripping, Soft tissue dissection, wound dehiscence, infection, scarring, and so on, shorter operating time and hospital stay, less blood loss, better cosmetic satisfaction, and minor surgery to remove the implant. TENS is a safe, stable, minimally invasive surgical technique with a lower complication rate, faster return to daily activities, excellent cosmetic and comparable functional results in indicated cases, once potential technical pitfalls are appreciated.

The limitation of our study was a small sample size

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

Conflict of Interest: None, **Source of Support:** None

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