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Original Research Article

Functional and radiological outcomes of mid-shaft clavicle fracture managed by flexible intramedullary nailing

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ABSTRACT

Background: Clavicle fracture is a common injury accounting for 2.6-5% of all injuries. The commonest site of fracture is the midshaft. Historically clavicle fractures were managed conservatively with figure-of-eight bandage resulting in higher non-union and symptomatic malunion rates. With the advent of operative fixation of these fractures the ideal surgical technique remains elusive. Flexible intramedullary nailing stands out as a minimally invasive and effective method with excellent outcomes for fixation of these fractures.
Methods: A prospective study was carried out over 18 months. A total of 26 patients met the inclusion criteria and were operated with flexible intramedullary nailing. Regular follow up was done till 14 weeks. At each postoperative visit patients were evaluated for shoulder function using constant score and DASH score. Radiographs were taken at each visit to evaluate for fracture alignment and union.
Results: In this prospective study a total of 26 patients with closed midshaft clavicle fracture were managed using flexible intramedullary nail. Average time to radiological union was 7.5 weeks. Average disabilities of arm, shoulder and hand (DASH) score at 14 weeks was 13 and average constant score was 95 suggesting excellent functional outcome.
Conclusions: Flexible intramedullary nailing is a simple, minimally invasive surgical technique with excellent functional outcomes for management of midshaft clavicle fractures.

Keywords: Clavicle fractures, Internal fixation, Flexible intramedullary nailing, Functional outcomes of clavicle nail

INTRODUCTION

"Midclavicular fractures heal without the doctor, with the doctor, and despite the doctor!".[1] Clavicle is the only long bone which is situated horizontally. It is the only bony strut connecting upper limb to the trunk. The clavicle varies in its cross section throughout its length. It is S-shaped with convex forwards medially and concave forward laterally. The outer third of the bone is flat while medial third is tubular with middle third being transition area for the two cross-sections. This makes middle third of the clavicle a weak link making it a fracture prone area. The clavicle articulates laterally with scapula through acromio-clavicular joint and medially with sternum via sterno-clavicular joint.

Fractures of the clavicle are common injuries of adults, accounting for about 2.6-5% of all injuries.[2-5] Mechanism of injury is either a direct blow to the anterior chest wall or by a fall on the outstretched hand.[6] Clavicle fractures are categorized into proximal, mid-shaft and distal fractures. The commonest site of fracture in clavicle is the mid-shaft where the typical compressive force applied to the shoulder and the narrow cross section of the bone combine to cause bony failure. Mid shaft clavicle fractures account for 80% of all clavicular fractures.[7] They exhibit some degree of displacement. While distal third fractures account for 15-20% of all fractures.[8] Medial third fractures are rarest accounting for only about 0-5% of all clavicular fractures.[9]

Many of these mid shaft fractures can be treated conservatively with arm sling or a figure of eight bandage. In a landmark 1960 study, Neer reported a non-union rate of 0.1% with conservative treatment and Rowe corroborated these findings in 1968 and showed a non-union rate of 0.8% in conservatively managed patients. At the same time malunion of the mid shaft clavicle fracture was assumed to be of radiographic importance only without having any adverse functional or clinical consequences.

Recent evidence has suggested that actual rate of malunion or non-union may be higher for more severe fracture types.[10] Multiple authors have shown malunion of clavicle to be a distinct clinical entity with characteristics patient symptomatology. Scapular malposition has as well been shown to be a cause for the patient symptomatology.[11,12]

In recent studies good results with high union rate and low complications have been reported from various techniques for primary internal fixation of displaced mid shaft clavicle fractures.[13-15] The common indications for surgery include a displacement >2 cm, shortening >2 cm, comminuted fracture, segmental fractures, open injuries and fractures with neurovascular compromise.[16]

McKee et al in a recent meta-analysis of six RCTs of operative vs non-operative management of mid shaft clavicle fractures have demonstrated a symptomatic non-union and malunion rate of 23% in non-operative group compared with 1.4% in the operative group.[17] Many studies followings that have documented clear benefits to primary operative fixation of mid-shaft clavicle fractures with reference to symptomatic mal-union, non-union and a quicker return to pre-fracture activity levels.

Although there are multiple indications for primary operative fixation of a mid-shaft clavicle fracture, a majority of these fractures can and should be treated non-operatively. Although plate fixation is the current gold standard in the management of displaced mid shaft clavicle fractures Intra-medullary fixation systems are a lucrative alternative which leads to a smaller scar, a reduced operative time and equally effective outcomes as compared to plate fixation.

Objective of the study

This study was undertaken to evaluate the effectiveness and outcomes of flexible intramedullary fixation as a method of fixation for mid shaft clavicle fracture.

METHODS

This prospective interventional study was carried out at a tertiary care hospital in Central India. Patients who presented to the institution with injury/trauma to mid-shaft clavicle were evaluated in detail, clinically and radiographically. This study was carried out over a period 18 months from January 2019 to June 2020.

Study design

The design of the study was prospective interventional study.

Sample size

Estimated sample size considering the outcome with respect to constant score reported in the article by Shishir et al with following assumption-96.4%.[18] Percent of patients had excellent functional outcome with respect to the constant score with absolute precision of 7% and 95% confidence interval. Sample size required for study was 26.

Ethical clearance was taken from institutional ethical committee as per the institutional requirements.

Statistical analysis

Collected data were entered into Microsoft word spreadsheet. Tables and charts were prepared using Microsoft word and excel spreadsheet. Continuous variables (demographic, biochemical and hemodynamic parameters) were presented as mean±standard deviation (SD). Categorical variables were expressed in frequency and percentages. Continuous variables (DASH score, constant score and pain on VAS were compared at different follow-up period by performing one-way analysis of variance (ANOVA) test for non-normalized data and Kruskal Wallis one-way ANOVA for categorical data. Categorical variables were compared by performing chi-square test. For small numbers, Fisher exact test was used wherever applicable. Multiple comparison test was performed by Bonferroni test for continuous parameters and Dune's test for categorical data. $p<0.05$ was considered as statistical significance. Statistical software STATA version 14.0 was used for statistical analysis.

Inclusion criteria

Patients with age >18 years were included in the study: closed fractures; mid shaft clavicle fracture; no medical contraindication for general anesthesia; and both male and female patients were included.

Exclusion criteria

Patients not willing for study; fractures in proximal third of clavicle; fractures in distal third of clavicle; pathological fractures; associated acromio-clavicular joint dislocation; associated with neuro-vascular injury; compound fractures; and stablished non-union from previous fracture were excluded.

Radiographs

Anterior-posterior perpendicular to cassette, and fractures were classified using Neer's classification and AO classification.

Procedure

All the patients attending the emergency/out-patient department of the hospital which fit the inclusion criteria were included in the study. All the patients were evaluated and necessary fitness for anesthesia was taken. All the patients were operated on elective basis after optimization of their medical conditions.

Operative procedure for TENS intramedullary nailing for midshaft clavicle fracture

After administration of general anesthesia, the patient was placed in beach chair position with a bolster kept between the two scapulae with injured extremity prepared and draped from the midline to the upper arm to allow complete free movement of the ipsilateral shoulder. Care was taken to make sure that the sternoclavicular joint was accessible for the entry point. Preoperatively, the shoulder region was screened using image intensifier to confirm this access. A horizontal skin incision was made just lateral to the sternoclavicular joint. The subcutaneous fat was incised along with platysma. The pectoral fascia was divided in line with the skin incision followed by careful elevation of the underlying musculature from the clavicle. The entry point was then made using the awl or a drill bit 1.5 cm lateral to sternoclavicular joint and appropriately sized titanium elastic nail was inserted. The size of the nail was measured using this formula given.

$$Nail\ size = 0.4 \times canal\ diameter\ in\ mm$$

This was done using a T-handle or Chuck provided in the implant set. The nail was pre-bent to allow easy passage through the curved intra-medullary canal of clavicle. Attempt was made to close reduce the fracture using the maneuver- traction, abduction, and external rotation. If the fracture could not be reduced by closed means, then a separate vertical/horizontal incision was used at the fracture site to aid fracture reduction. Vertical incision was preferred as it is parallel to Langer's lines and minimized the risk of damage to supraclavicular nerves to avoid dysesthesia of skin and scar neuromas. Fracture site was opened, callus and fibrous tissue was nibbled out and both ends were aligned using bone clamps. At that time, the nail was used to create a path in the lateral end of the clavicle for subsequent easy access. The nail was then passed from the medial side and across the reduced fracture into the lateral end of clavicle.

Care was taken to make sure that the nail has sufficient hold in the lateral fragment. Minimum distance engaged in the lateral cortex was till the middle of the coracoid process as visualized on Antero-posterior radiograph. The position of nail was confirmed using C-arm guidance and various obliques views to make sure nail doesn't perforate cortex in distal fragment.

The protruding end of the nail is cut as close to the bone as possible. Wound wash was given and wound was closed in layers and skin closure was done. Sterile dressing was done. Patient was put in an arm sling.

Post-operative protocol

Postoperatively the operated limb was immobilized in an arm pouch. IV antibiotics were continued for 48 hours and switched over to oral antibiotics on the 3rd day and continued till the 5th day. Wound was inspected on 3rd postoperative day and sutures were removed on 14th postoperative day. Patient were discharged on 3rd postoperative day but some patients were discharged later due to associated injuries and co morbidity.

Post-operative follow-up and rehabilitation

Patients were followed up on 14th day for suture removal and then at 6-8 weeks and 14-16 weeks. Rehabilitation was started at end of 2 weeks. Gentle pendulum exercises to the shoulder in the arm pouch were allowed but abduction was limited to 80 degrees. At 6-8 weeks active range of motion in all planes were allowed. Regular follow up was done for 16 weeks. All the patients came for scheduled follow up visits. At each follow up patients were assessed clinically and radiologically. Functional assessment was done by constant-Murley score and DASH score.

Fracture union was defined by radiographic criteria and a clinical criterion as given by Dijkman et al.[19]

Radiographic criteria for fracture union: bridging of the fracture by bone, callus, or trabeculae; bridging of the fracture at three cortices; and obliteration of the fracture line and/or cortical continuity. Clinical criteria for fracture union: absence of pain or tenderness when weight bearing; absence of pain or tenderness on palpation or examination; and the ability to bear weight**.**

Based on the above the criteria used in this study was the following: radiographic criteria- bridging of the fracture by callus; and clinical criteria- absence of pain or tenderness on palpation.

Functional outcome assessment tools include: constant-Murley score and DASH score.[20,21]

Implants used include: flexible intra-medullary titanium elastic nail was used for the procedure.

RESULTS

In our study 26 patients with midshaft clavicle fracture were included who qualified according to the inclusion criteria. All patients were regularly followed as per the study protocols.

Fracture morphology

All mid shaft clavicle fractures were included in the study. Fractures were classified according to the AO/OTA

classification. AO type 15B1 was the most common type of fracture (42.31%), followed by AO type 15B2 (34.62%) and AO type B3 (23.08%) When comminution in the fracture was studied, it was found that 57.69% patients had comminuted midshaft clavicle fractures while 42.31% had no comminution.

Fracture union

By 6 weeks follow up 23 of the 26 patients (88.46%) had signs of clinical union as determined by lack of mobility at fracture site and no pain at fracture site.

Radiological union was found in 21 of those patients (80.77%). Thus, radiological union lags behind clinical union.

By 14 weeks all the cases had clinical and radiological union.

Functional outcomes

DASH score and constant score at each follow up visit of 2 weeks, 6 weeks and 14 weeks was used as a measure of functional outcome after fracture fixation.

There was a decrease in DASH score from a mean of 60 at 2 weeks to 23.46 at 6 weeks and 13.07 at 14 weeks suggesting an improvement in shoulder function.

Constant score improved significantly from a mean of 82.23 at week 2 to 94.84 at week 14 follow up visit.

Evaluation of constant score

The constant score was classified as Excellent, good, fair and poor. The mean constant score at each follow up was divided into above categories and tabulated as follows.

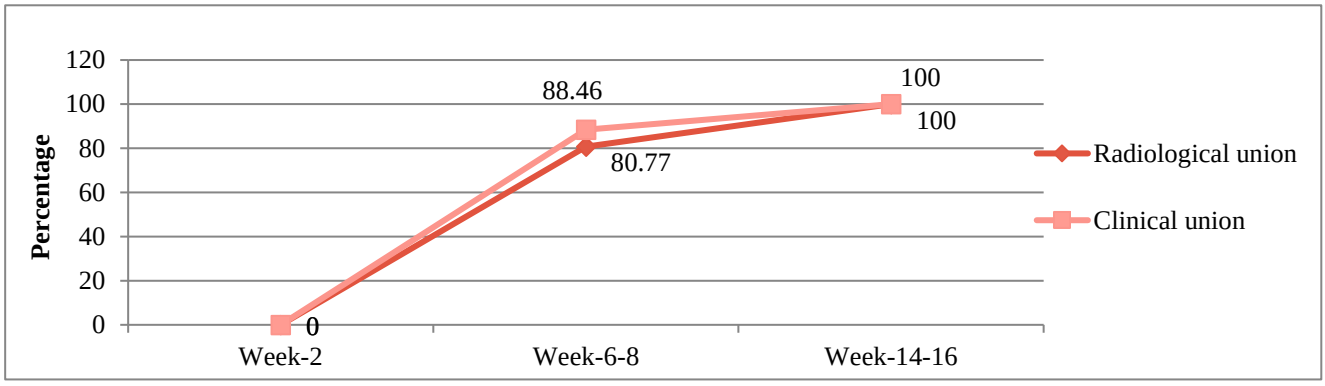

Figure 1: Assessment of radiological and clinical union.

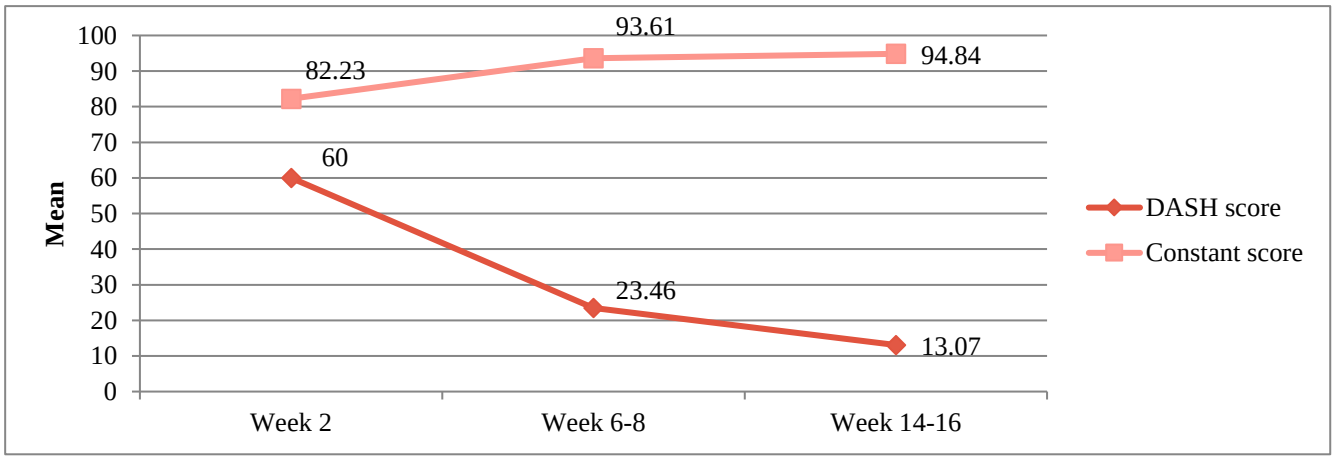

Figure 2: Average DASH and constant scores at follow up visits.

Table 1: Functional evaluation using constant score.

Result	Constant score	Week-2	(6-8) week	(14-16) week
Excellent	86–100	0	26	26
Good	71–85	26	0	0
Fair	56–70	0	0	0
Poor	1–55	0	0	0

All the patients at week 2 follow up had good constant score which improved to an excellent score at week 6 and week 14 follow up.

DISCUSSION

Usually, clavicle fractures are treated conservatively. Since early 1960s many authors have documented poor long-term results following conservative management of midshaft clavicle fractures in few patients. with numerous studies showing poor outcome of nonoperative management of clavicle fracture focus was shifted towards operative management for fractures of midshaft clavicle. A search for ideal method for fixation of midshaft clavicle fracture was started. Hill et al in 1997 and McKee et al in 2006 reported on poor results following conservative management of midshaft clavicle fractures.[22,23] Robinson et al in 2004 in a multivariate analysis identified risk factors associated with nonunion of midshaft clavicle fractures.[24] Altamimi et al in 2008 in a multicenter study found higher rate of nonunion and unsatisfactory outcomes in the form of poor DASH and constant score after conservative management of midshaft clavicle fracture.[25] Thus, with numerous studies showing poor outcome of nonoperative management of clavicle fracture focus was shifted towards operative management for fractures of midshaft clavicle. Studies were done to determine the fracture patterns and fracture morphology more suited for operative fixation. Among the operative fixation various modalities were considered. The initial enthusiasm of plate fixation for midshaft clavicle fracture was dampened with the advent of newer intramedullary fixation devices. Smaller operative scar, maintaining the fracture micro-environment in an intramedullary situated implant, smaller operative times, lesser dissection required led surgeons to consider intramedullary fixation for midshaft clavicle a suitable alternative to plate fixation. Numerous studies were then undertaken to compare the effectiveness of intramedullary fixation against nonoperative management and against plate fixation. Plate fixation for midshaft clavicle fracture which once was the standard of care is now being weighed against equally effective intramedullary fixation devices. Thus, this study was undertaken to define the patient and fracture outcomes in a midshaft clavicle fracture treated with TENS Nailing. The relevance of this study lies in the fact that it helps us to determine the outcomes of patients in the form of fracture union rate and the functional outcome of the shoulder after the fracture fixation.

In our study the average time for radiological union was 7.5±1 weeks.

Radiological union was defined as the presence of consolidation callus across the fracture site.

As is seen from Table 2 that there is a great variability in the time to radiographic union as reported by various authors. This is not surprising however because there is no standardized universally accepted definition or any objective analysis defined to call a fracture clavicle as 'united'. This, along with the subjective errors made while reading a radiograph make it very difficult to compare radiographic union times across various studies.

Table 2: Union time for fracture clavicle as reported in various studies.

S. no.	Study	Time to radiological union (weeks)
1.	Kalyansundaram et al[26]	8.8
2.	Sehgal et al[27]	8-12
3.	Kumar et al[28]	8.8
4.	Saraf et al[29]	10.62±2.67
5.	Shettar et al[30]	13.16
6.	Laxmichand et al[31]	10-15
7.	Mckee[32]	14-16
8.	Dugar et al[33]	15.7
9.	Bansal[34]	12
10.	Sambandam et al[35]	12
11.	Hartmann et al[36]	12

We have taken the presence of consolidation across the fracture as the first radiological sign of union as no patients with a consolidatory callus go for non-union. Hence the time for union in our study was slightly less as compared to other studies.

In our study we also report on the functional outcomes after treatment of midshaft clavicle fracture in the form of DASH score and constant score.

The DASH score decreased from 60 at 2 weeks to 23.46 at 6 weeks and then to an average of 13.07 at week 14. While the constant score increased from 82.23 at 2 weeks to 93.61 at 6 weeks and 94.84 at 14 weeks, denoting a gradual improvement in functional outcome.

Thus, there was progressive decrease in the DASH score and an increase in the constant score throughout the follow up period.

Various studies have evaluated functional outcomes in the form of DASH score and constant score. The studies are tabulated in Tables 3 and 4.

As is clear from above there are multiple studies done looking at functional outcomes in the form of DASH and constant scores. Although plate fixation was considered gold standard for the operative management of the midshaft clavicle fractures, multiple studies have demonstrated an equally good functional outcome following TENS nail for midshaft clavicle fractures.

The DASH scores and constant scores are comparable after plating or intramedullary fixation for midshaft clavicle fractures suggesting that TENS nailing is an equally effective and viable implant construct to treat midshaft clavicle fractures.

Table 3: DASH and constant scores after intramedullary fixation of midshaft clavicle fracture as reported by various authors.

Study	Constant score	DASH score
Shishir et al[18]	96.38	
Saraf et al[29]	83.69	
Kumar et al[28]	90	
Kalyanasundaram[26]	90.50	
Fuglesang et al[37]	96	10
Ferran et al[38]	92.1±6	
Lee et al[39]	98	
Thyagrajan et al[40]	85±5	
Liu et al[41]	88±5	13±4
Saha et al[42]	81.91	
Beigang Fu et al[43]	93.4	2.5
Ahrens et al[44]	76.50	15.83
Wang et al[45]	93.88±8.91	5.51±10.41
Andrade-Silva et al[46]	91.8	7.5
Meijden et al[47]	91.3	3.9
Calbiyik et al[48]	92.85	3.82
Narsaria et al[49]	94.6	
Hartmann et al[36]	93.5	

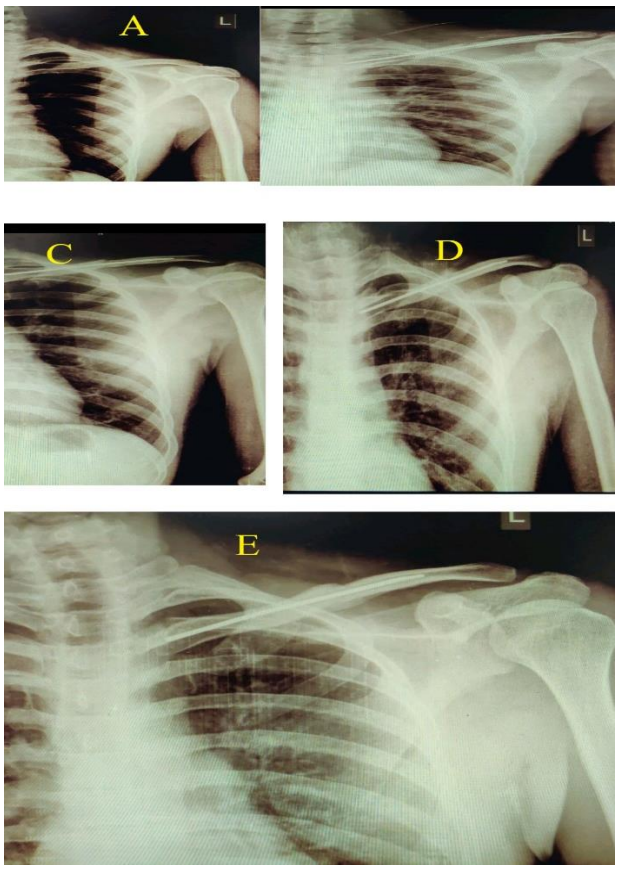

Figure 3: (A) Pre-operative radiograph; (B) immediate post operative radiograph; (C) radiograph at 4 week showing fracture callus; (D) radiograph at 6 week showing signs of fracture union; and (E) radiograph at 14 week showing fracture union.

Table 4: DASH and constant scores following plating for midshaft clavicle fractures as reported by various authors.

Study	Constant score	DASH score
Wang et al[45]	90.60±9.90	6.51±11.53
Andrade-Silva et al[46]	91.7	8.7
Meijden et al[47]	99.2	2.4
Calbiyik et al[48]	90.1	8.19
Narsaria et al[49]	96.2	

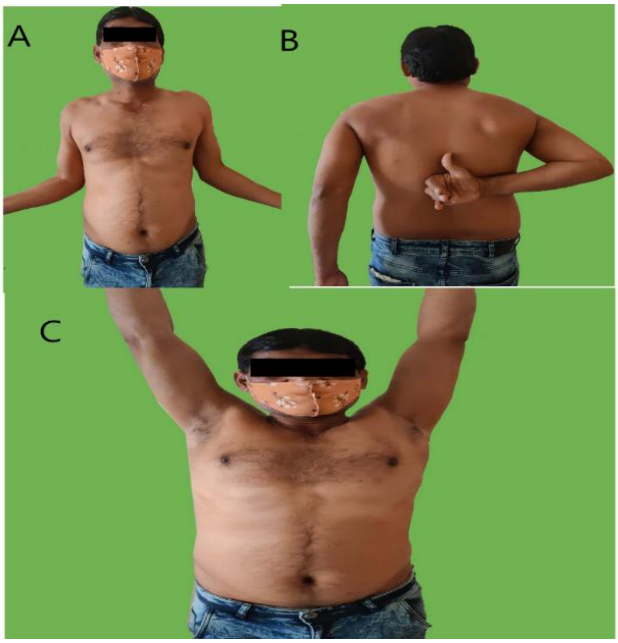

Figure 4: Clinical photographs showing range of motion (A) external rotation in neutral, (B) internal rotation, and (C) forward elevation.

Multiple studies have varying results- some showing a better functional outcome after TENS nailing while some showing a better functional recovery following plate fixation. Despite studies showing better functional outcome in one group, the differences are more or less marginal and not all the studies reached a statistical significance while comparing TENS nailing and plate fixation in terms of functional outcome.

This leads us to conclude that TENS nailing for midshaft clavicle fractures is an effective strategy for operative management with good radiographic union and excellent functional outcome with early return to pre-trauma activity levels. TENS nailing also has an added advantage of being minimally invasive with small scar leading to better cosmesis.

Limitations

A concern in the present study is the low number of cases and the short follow-up. The presented follow-up period seems appropriate for evaluation of bone consolidation, as

in all cases full union was achieved within 14-16 weeks. For this reason, we do not expect major changes in functional and radiographic outcome in mid-term or a longer-term follow-up period. Nonetheless, complications such as implant breakage, refracture may occur later. Even though early results are promising, long-term investigations and larger population studies and meta-analyses are required to confirm the presented data.

CONCLUSION

We conclude that TENS nailing for midshaft clavicle fracture ensure high fracture union rates with excellent radiological and functional outcomes and an early return to the activities of daily living. Thus, flexible intramedullary nailing can be recommended as a fixation method of choice for mid-shaft clavicle fractures.

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Ethical approval: The study was approved by the institutional ethics committee

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