



Original Research Article

Surgical management of midshaft clavicle fracture by titanium elastic nailing system

Mohammed Aquib Shakeel^{1,*}, Sreenivasa N¹¹Dept. of Orthopaedics, VIMS, Bellary, Karnataka, India

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ABSTRACT

Introduction: Midclavicular fractures accounts for about 76% of all clavicular fractures and are common clinically. Recent studies have revealed a previously unrecognized incidence of non-union and malunion after conservative treatment of more severe midclavicular fractures. Our aim was to evaluate the clinical outcomes of midclavicular fractures treated with titanium elastic nails.

Methods: A hospital based prospective study conducted between April 2018 to April 2020 at VIMS bellary. 30 patients with displaced midshaft clavicle fracture between 18 to 50 years were assessed clinically and confirmed radiologically were operated with intramedullary nailing with titanium elastic nail (TEN). Mean operative time, postoperative complications, duration of union was recorded. The outcomes were evaluated with radiographic assessment and the disabilities of the arm, shoulder, and hand (DASH) score.

Results: Closed operation with TENS was undertaken in 28 cases, and mini open technique was performed in 2 cases. Satisfactory reduction was achieved in all patients, who were followed up for a mean of 10 months. The mean union time was 11.2 weeks. TENS led to a significantly shorter time to union, especially for simple fractures. In TENS group, all patients got fracture union, of which 4 cases had medial skin irritation due to implant prominence. No severe complication occurred in any patient. TENS removal done at 10 months after surgery, no re-fracture and non union was found in any our patient. Average DASH score was 3.0023.

Conclusion: Intramedullary fixation with TENS might be a effective and safe treatment for displaced midshaft clavicular fractures with few complications, satisfactory clinical therapeutic effects, good functional recovery and cosmetic appearance.

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1. Introduction

Clavicular fracture is one of the most common bony injuries. In adult it accounts for 2.6% to 4% fractures and 35% of injuries to the shoulder girdle.

The clavicle is a S-shaped bone that acting as a strut between the sternum and the glenohumeral joint. It also has a suspensory function to the shoulder girdle. The shoulder hangs from the clavicle by the coracoclavicular ligament.¹ The present consensus that great majority of clavicular fractures heal with non operative treatment is no longer valid. Pressure from a displaced fragment on

the retro clavicular part of the brachial plexus may cause symptoms after conservative treatment. Recent studies have shown that higher rate of non-union and specific deficits of shoulder function in subgroups of patients with these injuries. Hence they can be treated as a spectrum of injuries requiring careful assessment and individualized treatment. Nonunion after a clavicular fracture is an uncommon occurrence, although the prevalence is higher than previously reported. Also persistent wide separation of fragments with interposition of soft tissue may lead to failure of closed reduction. There is 15% non-union rate in widely displaced fractures of middle-third of the clavicle treated without surgery. And all fractures with initial shortening of more than 2cm resulted in nonunion.²

* Corresponding author.

E-mail address: aquib71@gmail.com (M. A. Shakeel).

The indications for surgery include the need for earlier functional mobilization in the patient with an isolated injury, in addition to open fractures, floating shoulders and patients with poly trauma.³ Hence, more recently, there has been a trend toward surgical fixation. A systematic review showed relative risk reduction of 72% and 57% for non-union when using intramedullary fixation and plate fixation, respectively, when compared with non-operative treatment of mid shaft clavicle fractures.⁴ Intramedullary devices behave as internal splints that maintain alignment without rigid fixation. One advantage of the TENS is that it can block itself in the bone and provide a three-point fixation within the S-shaped clavicle.⁵ However, some studies have shown a relatively high complication rate and technical difficulties with intramedullary nailing.⁵

The main aim of this study is to evaluate the functional outcome of mid shaft clavicle fracture fixation by titanium elastic nailing system.

2. Materials and Methods

2.1. Objectives of study

1. To study the rate of union with displaced mid shaft clavicle fractures treated with Titanium Elastic Nail.
2. To study the functional outcomes of patients treated with Titanium Elastic Nail.
3. To study the advantages of Titanium Elastic Nail,

2.2. Source of data

The proposed study is a hospital based prospective study centered in VIMS Ballari, during the period from April 2018 to April 2020.

2.3. Method of collection of data

The complete data is collected from the patients in a specially designed Case Record Form (CRF) by taking history of illness and by doing detailed clinical examination and relevant investigations.

Finally after the diagnosis patients are selected for the study depending on the inclusion and exclusion criteria. Post operatively all the cases are followed until fracture union occurred for the minimum period of 6 months to 12 months. Results were analyzed both clinically & radiologically.

2.4. Inclusion criteria

1. Patients of both the sexes aged between 18 to 50 years are included in the study.
2. Patients with closed displaced Mid shaft clavicle fractures.
3. Patient fit for surgery.

2.5. Exclusion criteria

1. Open fractures.
2. Undisplaced clavicle fracture.
3. Patients <18 years and >50 years.

2.6. Sample size

Minimum of 30 cases satisfying the inclusion and exclusion criteria and who were willing to participate in the study were taken as study subjects and were operated in the time period between April 2018 to April 2020 were included in the study.

$$n = \frac{z^2 \times \hat{p}(1-\hat{p})}{\epsilon^2}$$

where

z is the z score

ϵ is the margin of error

N is population size

\hat{p} is the population proportion

2.7. Study period

Time period of 2 years, between April 2018 to April 2020.

2.8. Evaluation

The results are evaluated with The Disabilities of the Arm, Shoulder and Hand (DASH) Score.

2.9. Investigations

In our study the following investigations are conducted in each patients. All the patients included in the study are investigated thoroughly with Routine blood investigations, HIV, HbsAg, Radiological examination pre operatively are done.

X rays of the chest including shoulder joint -AP view.

Apical and oblique view of clavicle if necessary.

Before subjecting the patients for investigations and surgical procedures, written/informed consent was obtained from each patient/legal guardian. Radiological examination was done post-operatively and at the end of 6 weeks, 12 weeks and 6 months intervals. Patients was followed up at 6 weeks, 12 weeks and at 6 months.

3. Surgical Technique

Patient is placed in the supine position on a radiolucent table. All the necessary instruments required for the operative procedure were arranged on a sterile trolley (Figure 1). A small towel kept under the interscapular region to elevate the shoulder. A skin incision of 1-1.5cm is made parallel to the clavicle at the sternal end of the clavicle (Figure 2). With a bone awl about 1-1.5

cm lateral to the sternoclavicular joint (Figures 3 and 4), the anterior cortex was opened. Under c arm guidance a TEN (average diameter 2mm) is inserted and advanced to the fracture site(Figures 5 and 6). Subsequently, the fracture is reduced in a closed manner (Figure 5). If closed reduction is not possible, a 1-2cm skin incision (mini open technique) at the level of the fracture site is made for open or mini-open fracture reduction (Figure 8). Provisionally reduction is maintained with a small reduction forceps/ with manipulation percutaneously. The nail is subsequently advanced across the fracture into the lateral fragment with gentle rotational movements. Care must be taken that the implant is not advanced too laterally in order to avoid penetration into the acromio clavicular joint. The medial end of the nail is cut and the overlying skin is sutured after the wash.(Figure 7)



Fig. 1: Instruments required for the intramedullary fixation of clavicle with titanium elastic nailing system (Tens)



Fig. 2: Small incision of 1-1.5cm

4. Results

Study consisted of 30 patients with displaced midshaft clavicle fracture treated by Titanium elastic intramedullary nail (TENS) from April 2018 to April 2020.

Mean age of patients were 34 years ranging from 18 to 50 years. Mean follow up time was 10 months ranging 6-12



Fig. 3: Entry point

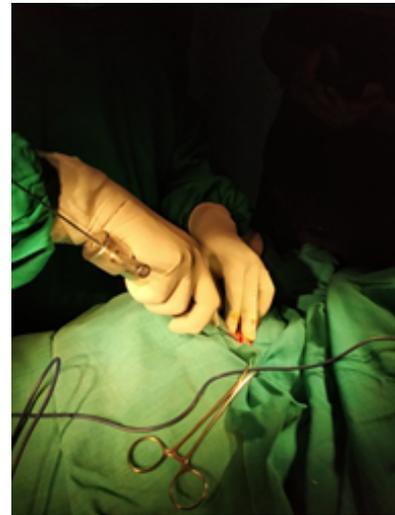


Fig. 4: Tens with T-handle

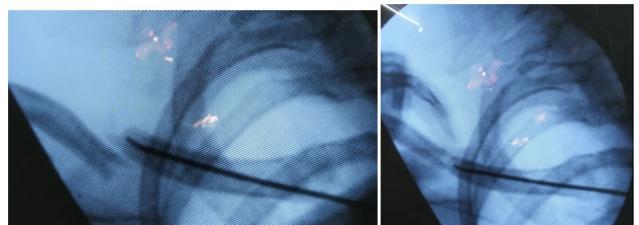


Fig. 5: Reduction done percutaneously

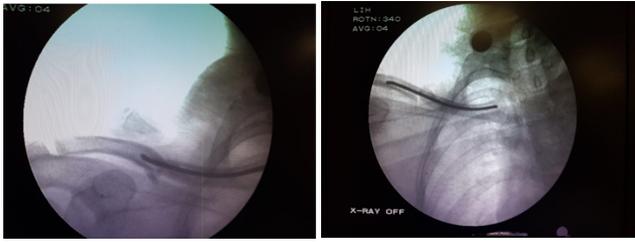


Fig. 6: Intraoperative C arm pictures

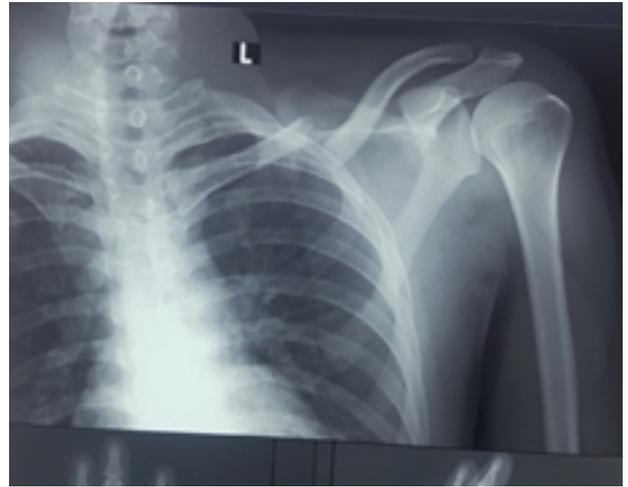


Fig. 9: Pre operative X-ray

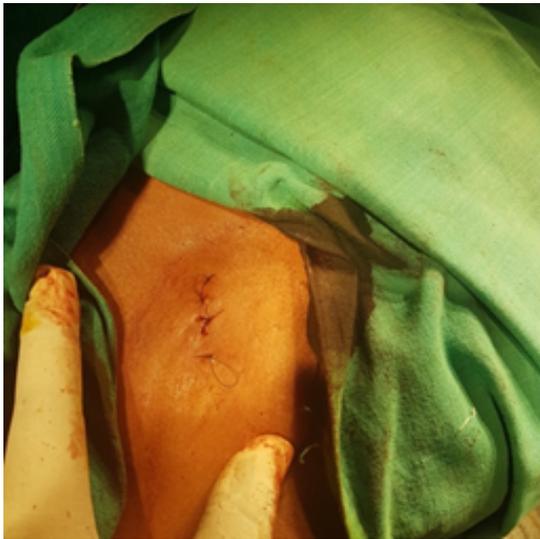


Fig. 7: After wound closure

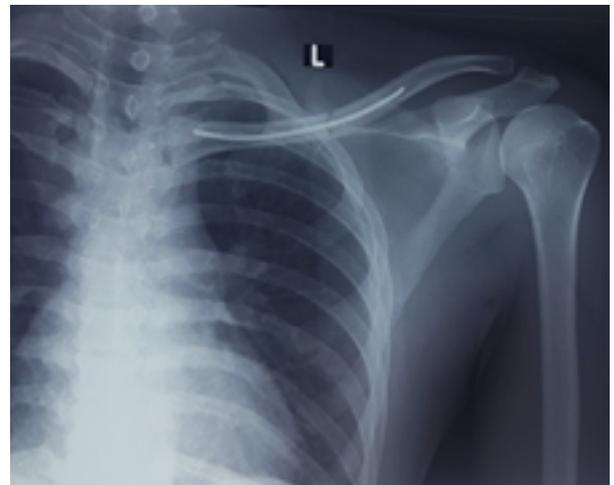


Fig. 10: Post op day 1



Fig. 8: Mini open technique at the fracture site

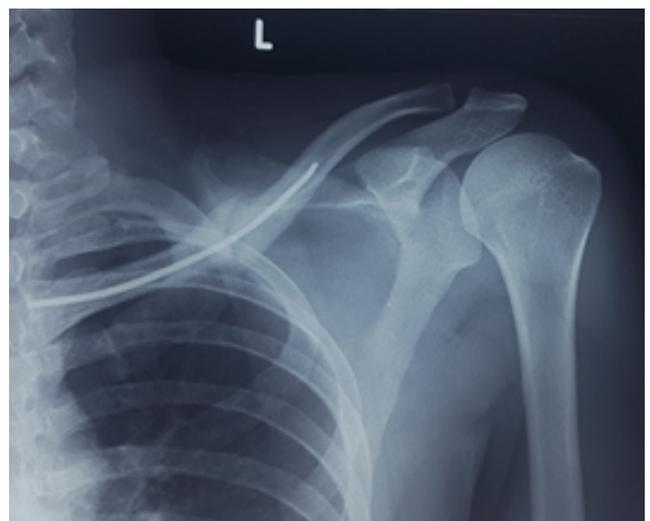


Fig. 11: 6 weeks follow up

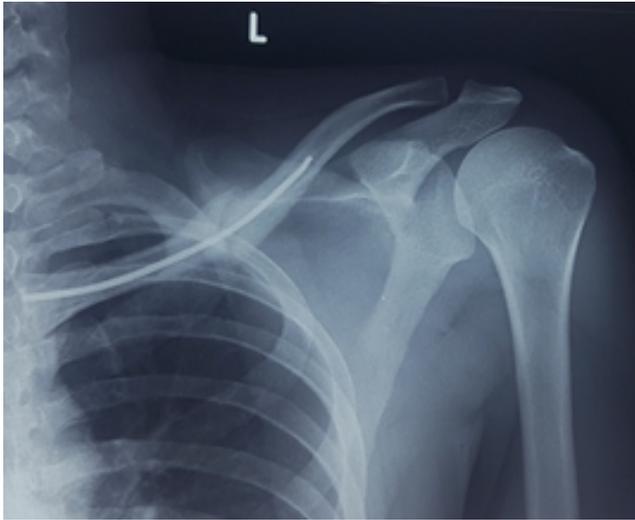


Fig. 12: 12 weeks follow up

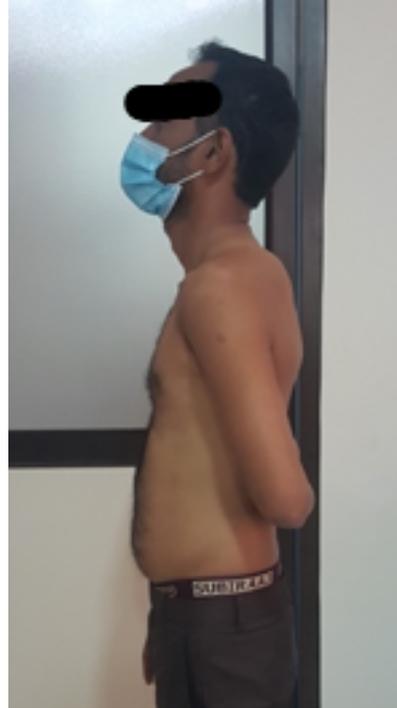


Fig. 14:



Fig. 13:



Fig. 15:

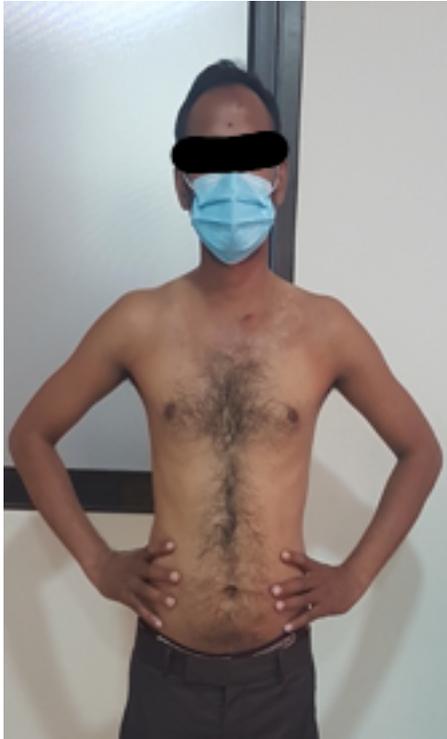


Fig. 16:

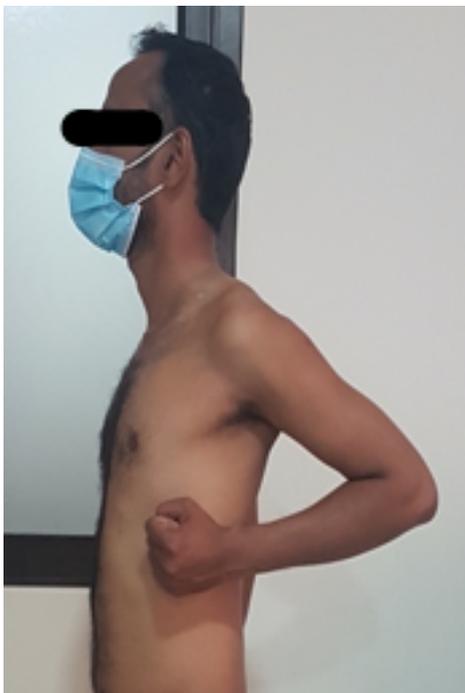


Fig. 17:



Fig. 18: Minimal and surgically satisfactory scar

months. In our study, the mode of injury was by Road traffic accident (24), fall from height(3), fall on an outstretched hand(3). The fractures were graded according to Robinsons classification and OTA (Orthopaedic trauma classification) classification. 3 patients (10%) were operated on day one.24 patients (80%) were operated from 2-7 days.

3 patients (10%) were operated from 7-14 days. The operative treatment was performed an average of 3-4 days (range: from 1 to 14 days).TEN of size 1.5mm (n=6), 2.0mm (n=24), were used according to the patient’s dimensions. Mean intraoperative time was 45 minutes (20-90 minutes). No intraoperative complications were noted in any patients. 4 patients had medial entry point skin irritation (Figure 19) due to implant prominence and which subsided once the implant was removed after the union.All the patients achieved clinical and radiological union by a mean time of 11.2 weeks (8-12 weeks). No delayed union or Nonunion were reported. Open reduction (mini-open technique) was carried out in 2 patients out of 30 patients in the form of mini-open technique with a short incision of 1-2 cm over the fracture site. DASH (Disabilities of Arm, Shoulder and Hand score) had significantly improved postoperatively excellent (Figures 13, 14, 15, 16, 17 and 18) in 24(80%) patients and Good in 6(20%) patients compared to preoperative DASH score. All the patients were discharged within 3 days of surgery. The mean time for implant removal was 10.2 months. Anatomical reduction, functional recovery and appearance were satisfactory in all patients. Average DASH score in our study being 3.0023.

Table 1: Mode of injury

	No of patients	Percentage
Road traffic accident	24	80%
Fall from height	3	10%
Fall on outstretched hand	3	10%
Total	30	100%

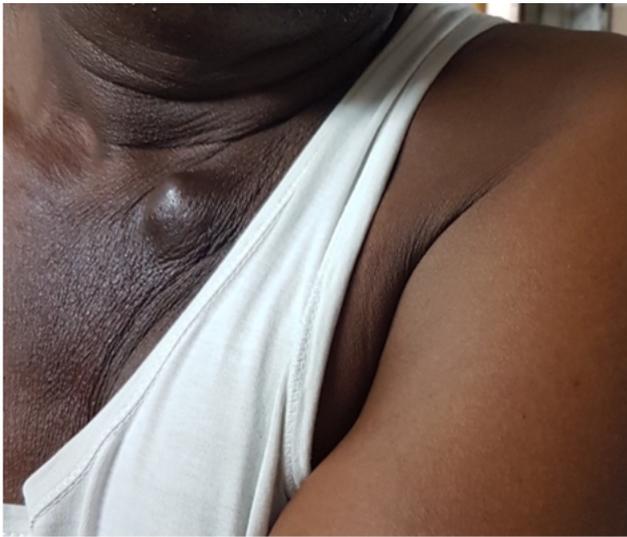


Fig. 19: Medial skin irritation due to implant prominence

Of the 30 patients 24 patients (80%) fracture occurred due to road traffic accident, 3 (10%) patients sustained fracture due to indirect injury, fall on outstretched hand and 3 patients (10%) due to fall from height. In all the patients fractures were closed type.

Table 2: Age incidence

Age in years	No. of patients	Percentage(%)
19-29	21	70
30-39	06	20
40-49	03	10

In our study, 70% were between the age group of 19-29 y, and 20% were between 29-39 y and 10% between 40-49y.

Table 3: Gender incidence

Gender incidence	No. of patients	Percentage(%)
Male	21	70
Female	9	30

In our study, 21 (70%) were males and 9 (30%) were female patients.

Table 4: Side affected

Side affected	No. of patients	Percentage(%)
Right	24	80
Left	06	20

In our study, 24 patients had right sided fracture whereas 06 had it on the left side.

Patients (6.66% had scapula neck #, 3 (10% patients had rib# without haemo or pneumothorax.

Table 5: Associated injuries

Type	No of patients	Percentage
Scapula neck #	2	6.66%
Rib#	3	10%

Table 6: Classification

Classification	No of patients	Percentage
Robinson type B	27	90%
Type B1	03	10%
OTA classification		
15b1	27	90%
15b2	03	10%

In our study, 27 patients (90%) in our study were Robinson Type B and 3 patients (10%) were Robinson type B1. 27 patients (90%) classified as OTA type 15b1 and 3 patients (10%) had OTA type 15b2.

Table 7: Preoperative shortening and displacement

Shortening	No of patients	Percentage
1.5 to 1.9cm	24	80%
2cm to 2.5	6	20%

Length of clavicle on the affected side measured from suprasternal notch to Acromioclavicular joint and compared with normal side for any shortening.

24 patients (80%) had 1.5 to 2cm shortening and 6 patients (20%) had shortening 2 to 2.5cm with average shortening of 1.92cm.

Displacement was measured radiologically. All patients included in the study had displacement >2cm, average displacement 2.2 cm.

Table 8: Surgical technique

Nature of surgery	No. of patients	Percentage(%)
Closed	28	93.33
Open	02	6.66

In our study, closed reduction was achieved in 93.3% (28 patients) and mini open technique was performed in 6.66% (2 patients).

Table 9: Type of implant used

TENS	No. of patients	Percentage
1.5mm	06	20
2.0mm	24	80

In our study, average size of tens used was 2.0mm in 80% of the patients.

Pre operatively all 30 patients had shortening with average shortening of 1.92cm. post operatively 29 patients (90%) had no shortening, and 1 patients (20%) had <0.5cm shortening.

Table 10: Post operative shortening

Shortening in cm	No of patients	Percentage
No shortening	29	96.67%
<0.5cm	1	3.33%

Table 11: Showing complications in patients with TENS

S.No	Complications	No. of Cases (n=30)
1	Entry site irritation	4
2	Pin tract infection	none
3	Refracture	none
4	Non union	none
5	Neurovascular damage	none
6	Superficial Infection	none
7	Iatrogenic perforation of cortex (posterior)	none
8	Lateral nail migration	none

In our study, 4 patients out of 30 had medial skin irritation due to implant prominence and 1 patient had superficial skin infection after 5th postoperative day which settled with oral antibiotics.

Table 12: Dash score

Score	No.of patients	Percentage(%)
Excellent	24	80
Good	06	20

In our study, Mean DASH score was 3.0023

5. Discussion

Traditionally midshaft clavicle fractures had been treated non-operatively.

Usually clavicle fractures are treated conservatively. Hill et al. 1997⁶ and Mckee et al. in 2006 found poor results following conservative management of displaced midshaft clavicle fractures.⁷ Displaced fractures, fractures with initial shortening of >20 mm was associated with a greater risk of nonunion and a poor clinical outcome.⁷

JUBEL et al.⁸ showed that the correction of clavicular shortening is a prerequisite for good functional outcome. They observed no non union and no poor functional outcome in their study. Surgical procedures using plate fixation have shown major complications such as hematoma, infections, implant failures and non-union, in comparison to conservative management Bostman et al.⁹ Minimally invasive ESIN was thus established as an alternative to plate fixation.

Intramedullary implants are ideal from the biomechanical point of view as the tension side of clavicle changes with respect to rotation of arm and direction of loading.^{10,11}

The other potential benefits of intramedullary nailing include smaller incision, minimal periosteal stripping, and

load sharing device properties.¹² Its relative stability allows copious callus formation during the healing process.

At the end of our study, we had all the 30 patients in the follow up with majority being the males 21(70%) and 9(30%) female patients.

In all the patients fractures were closed type.

In our study of the 30 patients, 24 patients (80%) fracture occurred due to road traffic accident, 3 (10%) patients sustained fracture due to indirect injury, fall on outstretched hand and 3 patients (10%) due to fall from height.

In our study 21 patients (80%) were in the age group of 19-29 years, 6 patients (20%) in 30-39 age group. And 3 patients (10%) in 40-49 age group. Youngest patient in our study was 19 years old and oldest patient in our study was 48 years. The average age was 32 yrs (range from 19 to 49).

27 patients (90%) in our study were Robinson Type B and 3 patients (10%) were Robinson type B1. 27 patients (90%) classified as OTA type 15b1 and 3 patients (10%) had OTA type 15b2.

In our study 2 patients (6.66%) had neck of scapula #, 3 (10%) patients had rib# without haemo or pneumothorax.

In our study 3 patients (10%) were operated in day one. 24 patients (80%) were operated from 2-7 days. 3 patients (10%) were operated from 7-14 days. The operative treatment was performed an average of 3-4 days (range: from 1 to 14 days).

In our study 24 patients (80%) had 1.5 to 2cm shortening and 6 patients (20%) had shortening 2 to 2.5cm with average shortening of 1.80cm.

All patients included in the study had displacement >2cm, average displacement being 2.2 cm.

Post operatively 29 patients (96.67%) had no shortening, and 1 patient (3.33%) had <0.5cm shortening.

In our study 6 patients (20%) patients 1.5mm and in 24 patients (80%) 2mm TEN nails were used with average being 2mm used.

In our study 28 patients (93.33%) the fracture were fixed by closed reduction and 2 patients (6.66%) open reduction (Mini-open technique) was necessary.

In our study 27 patients (90%) fracture united by the end of 12th week post operatively. 3 patients (10%) patients fracture united by 14th weeks. All 3 patients were above 40 years and 2 patients had Robinson type B1 fracture.

In our study the average DASH score was 3.0023 with 24 patients (80%) had excellent score, 6 patients (20%) had good score.

Skin irritation due to prominent nail on the medial side occurred in 4 patients (13.33%), which required nail removal at 14 weeks. Fracture union was achieved by the time in all 4 patients.

In our study no patient had perforation of the dorsolateral cortex.

6. Conclusion

In our study, intramedullary nailing provided early functional recovery in all patients. Minimally invasive techniques can fulfil the objectives of rapid and pain free functional recovery with reduced risk of complications in contrast to conservative treatment. As a result, the mean period of disability is short. TENS is a safe, minimally invasive technique for stabilization of displaced midshaft clavicle fractures with excellent cosmetic and functional results with quick recovery period.

7. Source of Funding

None.

8. Conflict of Interest

The authors declare that there is no conflict of interest.

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Author biography

Mohammed Aquib Shakeel, Junior Resident

Sreenivasa N, Associate Professor

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