

## Titanium elastic intramedullary nailing for midclavicular fractures: Clinical outcomes

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### Abstract

**Aim:** To assess the surgical outcome of displaced midshaft clavicular fracture using intramedullary fixation by titanium elastic nail.

**Materials and Methods:** 17 cases of displaced midshaft clavicular fracture underwent surgery with Intra medullary fixation by titanium elastic nail. The study was conducted from July 2014 to August 2015 admitted to Navodaya Medical College and research center, Raichur. We evaluated the Constant score to determine the outcomes.

**Results:** All fractures got united in our study. Average time taken for full clinical and radiological union was 11.8 weeks (Range 10- 14 wks). In our study minor complications were noted in total 41.17% patients. There were no major complications noted. Average Constant Score at final follow up was 95.16.

**Conclusion:** Minimally invasive fixation with TENS is a safe method and can be performed with minimal complications. This method of fixation of displaced midclavicular fractures should result in less soft tissue injury, shorter operating time, satisfactory stabilization, a good cosmetic appearance, quick pain relief, early return to work and easy implant removal under local anaesthesia as an outpatient department procedure.

**Keywords:** Midshaft clavicle fractures, intramedullary nailing, Titanium elastic nailing System (TENS).

### Introduction

Clavicle fractures are frequent injury and represent 5% to 10% of all fractures seen in orthopaedics.<sup>(1)</sup> 70% of all clavicle fractures are localized to the middle third of the clavicle and approximately 80% of these fractures are displaced.

Displaced midshaft fractures have traditionally been treated non-operatively in the form of a simple sling, figure of eight, clavicular brace etc. Studies have historically reported a high rate of union and insignificant sequelae from malunited fractures.<sup>(2,3)</sup> However, recent studies have found higher rates of delayed union, nonunion, shoulder pain, shoulder weakness and residual pain with non-operative treatment.<sup>(4)</sup> Recent data suggest that some displaced midshaft clavicular fractures will have better outcomes with operative reduction and internal fixation.<sup>(5)</sup> Elastic stable intramedullary nailing (ESIN) of the clavicle is a minimally invasive procedure and aims at restoration of the clavicular length with early return to full activity, with a good cosmetic result and minimal morbidity.

This study was taken to assess the surgical outcome of displaced midshaft clavicular fracture using Intra-medullary fixation by titanium elastic nail.

### Materials and Methods

It is a prospective study of 17 patients carried out from July 2014 to August 2015 admitted to Navodaya Medical College and research center, Raichur, after approval from institutional ethical committee.

A detailed history was elicited from the patients to reveal the duration of injury and the mode of injury. Radiographs of the fractured clavicle were obtained in

anteroposterior and 45° cephalic tilt views. We classified the fractures based on the Orthopaedic Trauma Association (OTA) classification scheme for midclavicular fractures.<sup>(6)</sup> Patients were recruited according to particular inclusion and exclusion criteria.

#### Inclusion criteria

1. Patients above 18 years and less than 60 years age.
2. OTA type A and B fractures
3. Fracture with minimum 2 cm displacement
4. Fractures with impending skin puncture

#### Exclusion criteria

1. OTA type C fractures
2. Open and pathological fractures
3. Clavicle fractures with associated neurovascular injuries
4. Polytrauma patients
5. Patients who were surgically unfit

After obtaining necessary investigations and surgical fitness, patients were informed for usual surgical risks and additional incision for open reduction. Then patients were subjected to intramedullary fixation with titanium elastic nail system by the closed/open reduction method under Image intensifier control. The timing of the operation was 2 days to 10 days post-injury. The surgery was performed under general anaesthesia.

**Technique:** After general anesthesia, the patient was positioned in the beach-chair position with a folded sheet under the affected shoulder. Parts were painted with povidine iodine solution and sterile drapes were applied with adequate exposure of the whole clavicle and whole ipsilateral upperlimb draped free.

Elastic intramedullary nailing was done using the technique described first by Jubel.<sup>(7)</sup>

A small skin incision was made approximately 1cm lateral to the sternoclavicular joint. The medullary cavity of the clavicle was opened using an awl. Titanium nail was bent at tip about 15deg to facilitate insertion. T- Handle was used to push and rotate the nail into the medullary cavity under fluoroscopic control until it reaches the fracture site. Single elastic nails of different diameters varying from 2 to 3.5mm were used, depending on the width of the bone. Closed reduction was done under an image intensifier and provisionally fixed with two percutaneously pointed reduction clamps. In 6 cases close reduction of the fracture site could not be done, so an additional small incision was made above the fracture site for direct manipulation of the main fragments before the nail was introduced into the lateral fragment and the fracture was compressed. After adequate engagement in lateral segment, nail cut after little bent on medial side and buried under skin.

For all patients arm sling support was given to all the patients for 2 weeks postoperatively. The sling prevented the arm from drooping and interfering with bone union while allowing passive exercises in the early post-operative period. Early mobilization was started if pain was reduced. Patients were encouraged to resume their normal daily activities after 4-week post-operative period.

Shoulder function was evaluated according to shoulder Constant score.<sup>(8)</sup> In the Constant scoring system, the overall grading is excellent if the total score ranges from 90 to 100, good for 80–89, fair for 70–79 and poor if the scores are 69 or less. Patients called up for follow-up at monthly intervals for 4 months. After clinical and radiological union, they were called up after sixth, ninth and at 12 month.

## Results

All the patients were available for follow up in our study. The average age was 38 years (Range 22 to 48 years). Out of the 17 patients, 12(70.58%) were male and 5(29.41%) were females. 11(64.70%) patients sustained injury to right clavicle compared to 6(35.29%) who sustained injury to the left clavicle. Out of 17 patients, 10 (58.8%) got injured due to fall on the ground, 6(35.29%) patients met road traffic accident and 1(5.88%) patient sustained injury in sport activity. Patient demo-graphic and clinical data are presented in Table 1.

**Table 1: Demographic and clinical characteristics of 17 patients who underwent intramedullary fixation with titanium elastic nail**

Characteristic	No. (%)
Age in years (mean)	38 years
Male	12(70.58%)
Female	5 (29.41%)
Right clavicle	11(64.70%)
Left clavicle	6(35.29%)
RTA	6(35.29%)
Fall	10 (58.8%)
Sports activity	1(5.88%)

The mean duration of surgery was 62.39 minutes (range: 40-90 min). In 11(64.70%) patients we could achieve closed reduction and internal fixation under fluoroscopic control. In 6 (35.29%) patients, we achieved reduction by open method and holding the fracture fragments together while passing the nail. Minor complications were noted in total 7(41.17%) patients. Nail prominence was felt in 3(17.64%) patients at the sternal end, but was not of much concern to the patient. 3(17.64%) patients had wound (superficial infection) at the medial end of clavicle at the nail insertion site and after nail removal (done earlier after three month of full union), healed by secondary intention. 1(5.88%) patient landed in delayed union. There were no major complications noted i.e. non union, deep infection or refracture. There were no neurovascular complications. The average time of union was 11.8 weeks (Range 10 and 14 weeks) except one case which went for delayed union and healed by 20 weeks after surgery. The pin was removed once clinical and radiographic sign of fracture healing was obtained and this was typically performed in an outpatient setting.

Patients had returned to their previous activity level at approximately 4 months follow-up with full range-of- motion and strength in the affected extremity. Follow-up period ranged between 9 months and 18 months with an average of 12 months. Radiographic course of a displaced midshaft clavicular fracture of a 23 year old patient is depicted in the [Fig. 1, 2, 3 and 4]. Intraoperative and postoperative Pictures are depicted in [Fig. 5, 6, 7] and [Fig. 8 & 9] respectively.



**Fig. 1 : Pre-op xray**



**Fig. 2: Immediate Post-op xray**



**Fig. 3: Post-op x-ray at final follow up**



**Fig. 4: X-ray after implant removal**



**Fig. 9: Photograph depicting ROM**



**Fig. 5: Intra-op pic Making window medial end of clavicle**



**Fig. 6: Intra-op pic Inserting TENS through the window**



**Fig. 7: Guiding TENS through distal fragment under c-arm guidance**



**Fig. 8: Clinical photograph of healed wounds**

The mean constant shoulder score at 6 weeks was 59.98 (range: 48-70), 3 months was 85.17 (range: 57-97), 6 months was 92.15 (range: 74-98), 12 months was 95.75 (range: 79-100) and 18 months was 95.16 (range: 88-100). Statistical detail of Constant Score is Max=100, Min=88, SD=2.3, Standard error = 0.27, Skewness= -0.52 and the study was considered significant ( $p < 0.05$ ).

## Discussion

Traditionally, midshaft clavicular fracture has been managed conservatively with this assumption that it does not hamper shoulder function.<sup>(9)</sup> Although fracture healing and functional outcome is usually satisfactory, significant shortening with mal-union or non-union is described in the literature.<sup>(10,11,12)</sup>

Wick and Eskola observed high rates of non-union, shoulder pain and poor functional results when the fracture had healed with shortening of more than 2cm.<sup>(13,10)</sup> These findings were confirmed by Lazarides and Wild<sup>(14,15)</sup> in comparison to surgically treated patients.<sup>(7)</sup> Open reduction with plate fixation is the operative standard treatment for clavicular shaft fractures.<sup>(11)</sup> However disadvantages of plate fixation include the necessity for increased exposure and soft-tissue stripping, increased risk of damage to the supraclavicular nerve, slightly higher infection rates and the risk of refracture after plate removal.<sup>(5)</sup> In contrast TENS overcomes several disadvantages of plate fixation. Wijdicks in their study found that plating is associated with higher refracture, major revision surgery and implant failure in comparison to elastic stable nail.<sup>(16)</sup> In our study 70.58% were male and 29.41% were female. 64.70% patients sustained injury to right clavicle compared to 35.29% who sustained injury to the left. The average age was 38 years (SD: 24 to 48 years). A study by Meier C has similar comparable data.<sup>(17)</sup> In another study by Peter JM, 77.58% were males, 22.42% were females and the mean age was 38 years old (range 18- 67 years).<sup>(18)</sup>

The mean duration of surgery was 62.39 minutes (range: 40-90 min). In 64.70% patients, we could achieve closed reduction and internal fixation under fluoroscopic control. In 35.29% patients, we achieved reduction by open method and holding the fracture fragments together while passing the nail.

In our study minor complications (3 Nail prominence with skin irritation at the stern al end, 3 superficial wound infection and 1 delayed union) were noted in total 41.17% patients. There were no major complications noted (nonunion, deep infection or refracture) in our study (Table 2). In a study by Peter JM, complications rate was 25.8% which included 8.6% major (5 non-unions requiring revision surgery) and 17.2% were minor (1 delayed union, 2 superficial wound infections, 2 hardware failures after union, 5 skin erosions with pin exposure but without significant infection).<sup>(18)</sup> In another study by Pankaj Kumar Mishra, 20.5% encountered minor complications (3 delayed union in three cases, 2 iatrogenic perforation of lateral cortex, 7 skin irritation, 3 wound superficial infection) There were no major complications noted i.e. non-union or revision surgery.<sup>(19)</sup>

**Table 2: Complications noted after surgery**

Complication	Type	No
Minor	Nail prominence	3(17.64%)
	Wound superficial infection	3(17.64%)
	Delayed union	1(5.88%)
Major	None	

In our study the average time of union was 11.8 weeks (Range 10-14 weeks). In a study by Meier C, all fractures healed, no delayed or non-union was observed.<sup>(17)</sup> Time to healing was 7.7 weeks (range:6 to 12). In another study by Zhang W, the mean union time was 11.5 weeks.<sup>(20)</sup> The mean constant shoulder score at the final follow up was 95.16 (range: 88-100) which was consistent with results of other studies as depicted in Table 3.

**Table 3: Showing comparisons of results of titanium elastic nail for fracture of mid shaft clavicle in terms of constant score**

Sl. No	Study	Shoulder Function in term of Constant Score (mean)
1	Our Study	95.16
2	Meier C et al <sup>(17)</sup>	98
3	Hartmann F et al <sup>(21)</sup>	95.3 ± 3.9
4	Chen YF et al <sup>(22)</sup>	95.2

## Limitations

There are some limitations of the study that should be considered. The primary limitation of our study was that it was a small prospective study including a small number of patients and done at a single center. Larger randomized controlled trials are needed to further evaluate outcomes and complications TENS in displaced midshaft clavicle fractures. We interpreted our results in comparison with those of the studies in the literature that used other methods. However, the outcomes achieved with the technique in this study were favourable.

## Conclusion

Minimally invasive fixation with TENS is a safe method and can be performed with minimal complications. This method of fixation of displaced midclavicular fractures should result in less soft tissue injury, shorter operating time, satisfactory stabilization, a good cosmetic appearance, quick pain relief, early return to work and easy implant removal under local anaesthesia as an outpatient department procedure. It can be seen as an alternative to plate fixation or nonsurgical treatment in displaced midshaft clavicle fractures.



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