

**BJMHR**British Journal of Medical and Health Research
Journal home page: www.bjmhr.com

Displaced Midclavicular Fractures In Adults – Which Is Better? Titanium Elastic Nail Or 1/3rd Tubular Plate

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ABSTRACT

Clavicle fractures were traditionally treated nonoperatively, but due to higher rates of delayed union, non-union, symptomatic, malunion cosmetic deformity and other complications there is an increasing trend for operative management. Plating and intramedullary nailing are the most popular surgical options. Functional results after both the techniques proved to be superior compared with conservative treatment of DMCF in some recently reported prospective randomized studies. The aim of this study was to compare the clinical result, functional outcome along with complications rate in minimally invasive antegrade TEN for the treatment of DMCF with that of 1/3rd tubular plating anteriorly. Prospective study was conducted between 2009 and 2016 in which 66 patients (49 males and 17 females) with type b DMCFs underwent surgical fixation with antegrade TENS and 1/3rd tubular plate. They were randomized in two groups—one with TENS & other with plate fixation with 1/3rd tubular plate. Evaluation done by constant-murley shoulder outcome and dash scores at 6, 12 weeks, 3, 6, and 12 months to determine outcomes. During analysis we have 34 pts in TENS group & 32 pts in plate group. There was no significant difference in union time, CONSTANT & DASH score. Lesser operating time, less blood loss, easier implant removal & minimal complication with no any case of deep infection seen in TENS group but shortening [>0.5 cm] was noted in few cases. In plate group there were no major complications, only minor complications of superficial infection, deep infection, hypertrophied scarring without pain, limited shoulder motion with no case of shortening. There is no significant difference regarding union [clinical and radiological] and stability. However TENS is preferable for treating simple displaced fracture of DMCFs in view of lesser morbidity, better cosmetic result, easier implant removal. Fixation with plate seems to be little more stable & its the implant of choice in comminuted fracture.

Keywords: Clavicle TENS 1/3rd tubular plate displaced

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Received 05 June 2019, Accepted 19 June 2019

Please cite this article as: Borthakur B *et al.*, Displaced Midclavicular Fractures In Adults – Which Is Better? Titanium Elastic Nail Or 1/3rd Tubular Plate. British Journal of Medical and Health Research 2019.

INTRODUCTION

Fractures of the clavicle commonly seen by fall on an outstretched hand or by direct injury comprise 35% of all shoulder injuries. [1] They are common injuries in young individuals especially those who participate in activities and sports where high-speed falls or violent collisions are frequent and account for 2.6-10% of all fractures.[2]

The majority of clavicular fractures (80-85%) occur in midshaft of the bone with over half of these being displaced where the typical compressive forces applied to the shoulder and the narrow cross-section of the bone combined and result in bony failure. [3]

In the past decade, operative treatment of dislocated mid shaft clavicular fractures has become more common. The evidence in favor of operative treatment still grows, as recent studies show lower nonunion and symptomatic malunion rates and earlier return to work compared with conservative treatment [4-7]. With the development of the more advanced anatomically preshaped plates, the discussion is shifting from indications for operation towards the choice of implant for the midshaft clavicle [8-10]

Open reduction with internal plate fixation and intramedullary fixation are the two most important surgical techniques for treating displaced midshaft clavicular fracture. Plate fixation has been the more common method of operative treatment. However intramedullary pinning provides an alternate method of fixation with improved functional outcomes and decreased non union case in operatively treated case.

MATERIALS AND METHOD

This study describes a prospective study in all patients with a displaced midshaft clavicular fracture treated with TENS & 1/3rd tubular plate between 2009 and 2017 in a teaching hospital, Dibrugarh, Assam . In this study patients are randomized into two groups . Patients were included for analysis if they met the following-

Inclusion criteria:

- Age 18 to 65 years.
- Displaced, midshaft clavicular fracture (fracture type Robinson 2a/2b) [10]
- ≥ 2 cm shortening,
- Compromised skin,
- Skin tenting
- Neurovascular injury

Exclusion criteria

- Fracture older than 2 weeks
- Nonunion or malunion of a previous fracture
- Open fractures

- Pathological fracture

Operative Technique and Rehabilitation

TENS

Operative Technique:

Patients were placed in supine position on OT table and general anaesthesia was administered. The sternoclavicular joint was palpated and marked. A small skin incision was made 1 cm lateral to the sternoclavicular joint. The entry point in the anterior cortex was made with a pointed awl. A titanium elastic nail (of size 2 mm or 2.5 mm according to canal diameter and patients stature) fixed to a T-handle was inserted via the entry point (Fig. 1a). Prior to introduction, nail tip was straightened slightly to allow better gliding in the medullary canal. The nail was advanced with corkscrew movements until it reached the fracture site. Closed reduction was performed under fluoroscopic control using percutaneously introduced towel clips (Fig. 1b). If closed reduction failed, an accessory incision of 3-4 cm was made directly over the fracture site for manipulation.

The nail was then advanced till it reached medial to the acromioclavicular joint. Care was taken to prevent penetration of the thin dorsal cortex. After complete introduction, the nail was cut short and slightly bent at the medial end to prevent soft tissue irritation at the same time maintaining enough length for easy extraction later on. The fascia and skin were closed in layers.



Figure 1a:A titanium elastic nail fixed to a T-handle was inserted via the entry point

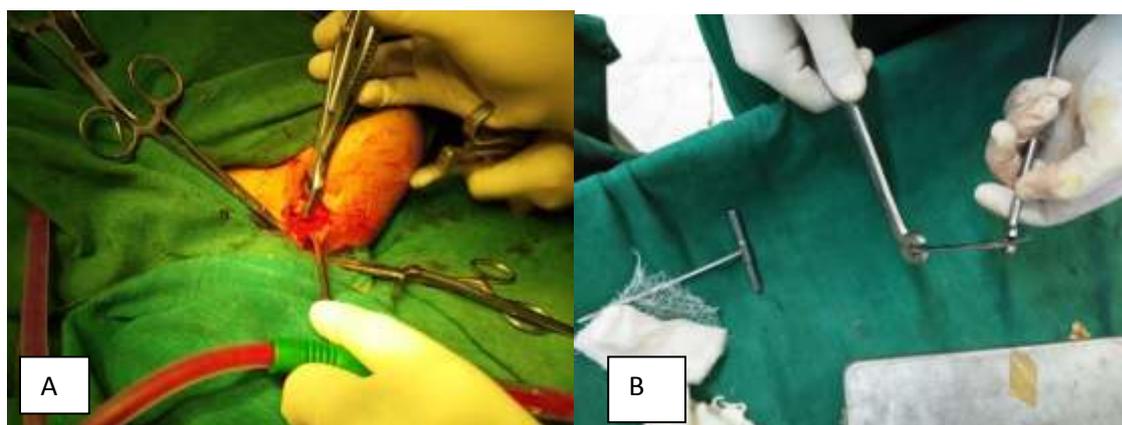


Figure 1b: Closed reduction was performed under fluoroscopic control using percutaneously introduced towel clips

PLATE FIXATION

Operative procedure:

A transverse skin incision was made along the anterior border of the clavicle under general anesthesia or brachial block. Fixation was performed following a reduction with minimal periosteal stripping. Each plate was contoured to the shape of the clavicle. To obtain maximum fixation strength, ≥ 3 screws were used in the proximal and distal areas, respectively. (Fig 2a,2b,2c,2d)If necessary, a circlage wire and lag screw were used in cases where fracture reduction could not be achieved due to a severe comminuted fracture with ≥ 2 -3 bone fragments. In cases where severe comminution was observed in the inferior surface of the clavicle, autogenous iliac bone grafting was also performed to avoid nonunion or fixation failure or metal breakage caused by tension. Bone grafting was performed in 4 cases from autogenous ipsilateral iliac crest An arm sling was used for approximately 2 weeks after surgery, and pendulum exercise and active range of motion exercise were then started.



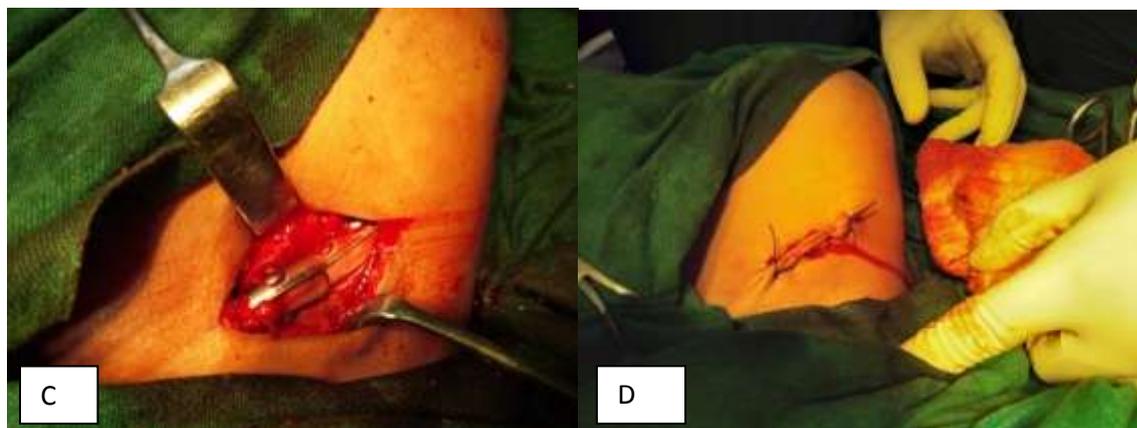


Figure 2: clinical pictures showing the operative procedures. A. reduction of fracture with bone clamps B. precontouring of the 1/3rd tubular plate C. plate fixed with screws D. wound closure

Assessment of Treatment Outcomes

Postoperatively, patients were given a sling, but were encouraged for early shoulder mobilization, (as tolerated), starting with pendular exercises from the second day. After 7 days, active range of movement exercises were started, however, overhead shoulder abduction was allowed only after 2 weeks. Activities of daily living were started thereafter, but those requiring lifting heavy objects were delayed until union was achieved. All patients were reviewed in the outpatient department at 2 and 6 weeks, 3, 6, 12, 18 and 24 months after surgery. At each visit, patients were assessed clinic radiologically for primary and secondary outcome measures.

Functional outcome was assessed by the Constant score. Radiographic union was defined as evidence of bridging callus or obliteration of fracture lines. Clinical union was considered as absence of tenderness at the fracture site. Time to achieve union was recorded. After union, shortening of clavicular length was measured clinically as the linear difference of clavicle lengths from sternal end to acromial end between operated and normal side.

Secondary outcome measures include perioperative data like operative time, amount of blood loss and size of the surgical wound; complications such as neurovascular injury, wound infection, nonunion, malunion, implant migration, implant failure, soft tissue irritation, refracture after implant removal and cosmetic outcome with regards to visible deformity, hypertrophic scars and hardware prominence under the skin. Implant removal was not done routinely in our study. It was done as per need and will of the patient after fracture union. The number of days to return to normal activities after implant removal was noted.

Statistical analysis

During analysis of data, only those patients were considered who attended at least 4 of the 6 follow-up visits starting from 6 weeks after surgery. The differences between the two groups at the end of the follow-up period with regards to the primary and secondary outcome

measures were evaluated for statistical significance using ‘independent group means comparison’ for analyzing the difference between the two proportions ($P < 0.05$ was considered significant). However, the data of our study has no external validity.

RESULTS AND DISCUSSION

At the end of the study, we had 34 patients in the TENS group and 32 in the Plate group for comparison. In the TENS group, we had 26 male and 8 female patients, whereas there were 23 male and 9 female patients in the plate group. The mean age was 39.1 yrs (range 15-58 years) in the TENS group and 34.5 years (range 15-55 years) in the plate group. The trauma surgery delay was 5.91 days (range 2-10 days) in the TENS group and 5.47 days (range 4-27 days) in the plate group. In the TENS group 28(82.35%) patients had AO class B1 and 3 (8.82 %) had AO class B2 fractures and 3 (8.82 %) had AO class B3, whereas it was 23 (71.9%) B1 and 05(15.6 %) B2 and 04 (12.5%) in the Plate group. There was no significant difference between the two groups with respect to age , sex and trauma to surgery delay ($P = 0.5$). Out of the 34 patients in the “TENS” group, a nail diameter of 2 mm was used in 6 patients, 2.5 mm in 20 patients and 3 mm in 8 patients. Closed reduction and nailing was achieved in 20 patients while the remaining 14 cases required open reduction (mini open). The mean followup period was 25.12 ± 3.28 months (range 18-30 months) for the plate group and 24.60 ± 2.42 months (range 18-30 months) for the TENS group.

The constant scores were not significantly different between the two groups in the followup period [Table 3] and there was not much alteration after 1 year postoperatively. At final evaluation, the overall results using the constant score were 26 excellent, 9 good and 2 fair in the plate group; while in the TEN group it was 28 excellent and 6 good results.



Figure 3a: Comminuted Fracture of Clavicle with Significant Shortening. 3b: Postoperative Radiograph Showing Good Reduction and Maintenance of Alignment and Length with TENS



Figure 4a: Preoperative x-ray showing displaced midshaft clavicle fracture (OTA B2. 1). 4b: Immediate postoperative x-ray showing good reduction. 4c: Postoperative after implant removal showing union and maintenance of length



Figure 5: Cosmetically Acceptable Small Surgical Scar

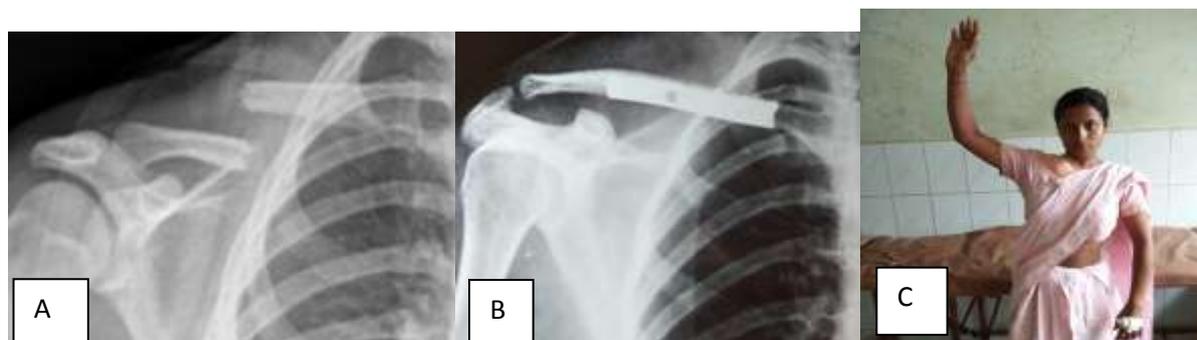


Figure 6: A. preoperative x-ray B. immediate post-operative x-ray C. clinical pics showing full range of motion(2wks post op)

Table 1

| Characteristic | Study group | |
|----------------------------|-------------------|------------------|
| | Plate | TENS |
| Age, years (Mean \pm SD) | 34.56 \pm 11.05 | 39.1 \pm 10.02 |
| Sex | Male,% | 23(71.9%) |
| | Female,% | 09(28.15%) |
| Side | Left,% | 13(38.24%) |
| | Right,% | 21(61.76%) |

| | | | |
|----------------|-----------|-----------|------------|
| Fracture type | B1,% | 23(71.9%) | 28(82.35%) |
| | B2,% | 05(15.6%) | 3(8.82%) |
| | B3,% | 04(12.5%) | 3(8.82%) |
| Mode of injury | RTA,% | 19(59.4%) | 24(70.59%) |
| | Fall,% | 6(18.8%) | 5(14.71%) |
| | Assault,% | 3(9.4%) | 5(14.71%) |
| | Others,% | 4(12.5%) | |

Table 2

| Parameters Analysed | Results | |
|---|-----------------|-----------------|
| | Tens | Plate |
| Duration of injury, Days(Mean \pm SD) | 5.47 \pm 3.11 | 5.91 \pm 1.96 |
| Union , n | 100 % | 34(100%) |
| Union time, weeks(Mean \pm SD) | 9.38 \pm 1.44 | 9.66 \pm 1.75 |

Table 3

| | Constant Score (Mean \pm SD) | | DASH Score (Mean \pm SD) | |
|-----------|--------------------------------|------------------|----------------------------|------------------|
| | Tens | plate | Tens | plate |
| 6 Weeks | 72.5 \pm 4.28 | 61.5 \pm 4.58 | 11.96 \pm 5.55 | 12.96 \pm 4.45 |
| 3 Months | 82.75 \pm 6.06 | 77.5 \pm 6.53 | 7.48 \pm 2.65 | 7.98 \pm 3.65 |
| 6 Months | 91.48 \pm 3.54 | 89.48 \pm 4.14 | 5.94 \pm 2.86 | 6.94 \pm 3.89 |
| 12 Months | 93.37 \pm 3.06 | 91.09 \pm 4.18 | 5.63 \pm 2.66 | 6.09 \pm 1.17 |
| P value | p < 0.001 | p < 0.001 | p < 0.001 | p < 0.001 |

Table 4

| Complications | TENS (No.) | Plate (No.) |
|--|------------|-------------|
| Superficial infection | 3(8.82%) | 2 |
| Hypertrophied scar | - | 2 |
| Limited shoulder motion | - | 2 |
| Painful shoulder | - | 2 |
| screw loosening causing neither pain nor functional disability | - | 1 |
| Medial TEN protrusion | 7(20.59%) | - |
| Shortening > 0.5cm | 3(8.82%) | 0 |

DISCUSSION

The present trend is to treat displaced midshaft clavicular fractures by operative methods owing to high rates of malunion, nonunion, prolonged pain, and disability with nonoperative treatment.[11]

Various operative treatment modalities are available including plating, nailing, and external fixation. Plating is the most commonly used procedure and is biomechanically superior to other modalities as it better resists torsional and bending forces.[12] Traditionally, clavicular fractures have been considered better treated nonoperatively in Neer 6 & Rowe 7 m study. But more recently, Robinson et al. in 2004 described a consecutive series of 868 patients with clavicular fractures, 581 of whom had a midshaft diaphyseal fracture

However, plating requires long incision and relatively extensive periosteal stripping leading to ugly scar, dysesthesia, compromised blood supply hindering fracture healing, and hardware prominence. Increased duration of surgery and extensive exposure is associated

with high infection rates up to 18%.[13] Rigid plates cause stress shielding, which leads to higher rates of re-fracture after implant removal.[14]

Intramedullary nailing with TENs have been used for fixations of DMCFs with excellent results and minimal complications.[15] Due to its elastic nature, the nails match the contour of the clavicle without compromising its strength being composed of titanium alloy. The entry through the medial cortex, the tight fit inside the curved cavity, and the anchor at the lateral end by its curved tip provides stable 3-point bony fixation.[14] The incision is considerably smaller giving better cosmetic results (Fig 5) and biological fixation without opening the fracture site can be achieved in majority of the cases leading to better union rates.[14] Micromotion at fracture site leads to secondary bone healing by callus formation. Being intramedullary, there is less stress shielding, which leads to lower refracture rates as compared to plate fixation.

In this study, we compared the results of anterior and antero-inferior plating vs antegrade IM fixation with TEN. in the plate group 26 excellent, 9 good and 2 fair; while in the TEN group it was 28 excellent and 6 good results. Overall, there were no unsatisfactory results in our study, whereas the incidence of unsatisfactory results after operative treatment of DMCFs is 5.3% in literature. [16] The average time to achieve union in this study was almost same in the TEN group and plate group with 9.38 ± 1.44 days & 9.66 ± 1.75 days for TENS and plate group respectively ($P = 0.025$).

Clavicular lengths were significantly better maintained by plating[17] than by TEN in our study, especially in AO type-B2 fractures. 3(8.82%) case of shortening > 0.5 cm was found in the TENS group with no case of shortening found in the plate group. However, this much of clavicular shortening does not affect functional outcome significantly, because as per Lazarides and Zafiropoulos, only final clavicular shortening of more than 18 mm in males and of more than 14 mm in females are significantly associated with unsatisfactory results. [18]

Smekal et al did not recommend the use of TEN in grossly comminuted fractures as it would lead to shortening.

Eventually, in comminuted DMCF or those with large butterfly fragments plate fixation remains the operative procedure of choice as it offers better clavicular length maintenance.

We encountered no major complications in the study. Minor complications in the plate group [superficial infection ($n = 2$), Hypertrophied scar ($n=2$), Limited shoulder motion ($n=2$), screw loosening causing neither pain nor functional disability($n=1$) were noted.

The incidence of superficial infection after plating in our study was 10.81%, whereas the reported rates in literature range from 0% to 18%.[19,20]

An important, although minor, complication of TEN group was the medial prominence of hardware [Figure 5] causing skin irritation or perforation, which was noted in 7(20.59%) In the literature, it is reported to be in the range of 5.2-38.8%.[21-23] Two causes for this problem are discussed in literature.[18] Inadequately cut medial end of the nail at primary surgery and nail displacement due to secondary clavicle shortening or telescoping. The first cause, being a surgeon related factor, may be tackled after primary surgery by adequately cutting the nail. The second cause is somewhat difficult to address however can be minimized by anatomical reduction, intraoperative compression and avoiding shoulder abduction beyond 90° in the first 2 weeks postoperatively. [24]] Another option for reducing medial protrusion is the use of medial end caps.[23]

The limitations in our study were relatively small sample size done at a single center, short follow-up time. There is no significant difference regarding union [clinical and radiological] and stability between the two groups. However TENS is preferable for treating simple displaced fracture of DMCFs in view of lesser morbidity, better cosmetic result, easier implant removal. Fixation with plate seems to be little more stable & its the implant of choice in comminuted fracture

Ethical Standard Statement:

All patients gave the informed consent prior to being included into the study. All procedures involving human participants were in accordance with the 1964 Helsinki declaration and its later amendments. The study was approved by the Research Ethics C

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