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Comparative Evaluation of Results after Internal Fixation of Fracture Clavicle by Titanium Elastic Nailing System/Plate

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What to Learn from this Article?

In this article, no significant difference was found in function and non-union rate in both groups but major complications and union time are more in plate fixation group than TENS group.

Abstract

Background: Fractures of clavicle are common injuries with incidence of 2.6-8% of all fractures and 44% of all shoulder injuries [1].

Aim: The aim of this study is to compare the results and complications of internal fixation with titanium elastic nailing system (TENS)/plates in displaced fracture midshaft of clavicle.

Materials and Methods: In a prospective study from December 2014 to June 2016, we analyzed 62 patients of displaced fracture midshaft clavicle treated by TENS (31) (Group I) and plate and screws (31) (Group II). Average age in the two groups was Group I (30.22) and Group II (30.34). The majority of the patients were males (65%) in both groups. Mechanism of injury was road traffic accident (67.74%) which was most common others are fall from height and assault. According to Allman classification, all midshaft clavicle are Type I.

Results: No significant difference was found in function and non-union rate in both groups but major complications and union time are more in plate fixation group than TENS group.

Conclusion: Callus formation was early in TENS group, and healing was faster as compare to plate group. TENS is a safe, minimally invasive surgical technique with a lower complication rate, faster return to daily activities, excellent cosmetic and comparable functional results, and can be used as an equally effective alternative to plate fixation in displaced midshaft clavicle fractures.

Keywords: Displaced middle one-third shaft clavicle fractures, titanium elastic nailing system.

Introduction

Fractures of clavicle are common injuries with incidence of 2.6-8 of all fractures and 44% of all shoulder injuries [1]. Clavicle fractures are more common in males (68%) as compared to females. Left side is involved in 61% of cases. Fracture of clavicle can occur at any site, but middle third is commonly involved in 81% of cases [1]. Clavicle is a short long bone of axial skeleton that connects the shoulder girdle to trunk.clavicle has three main functions:

- Attaches the upper limb to the trunk
- Protects the underlying neurovascular structures supplying the upper limb
- Transmits force from the upper limb to the axial skeleton.

The clavicle is the only long bone in the body that lies orizontally. Medially, it articulates with the sternum at the sterno-lavicular joint. At its lateral end it articulates with the acromion, at the acromioclavicular joint. Clavicle acts as a "strut" that keeps the


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upper limb away from the torso for efficient shoulder and upper limb function, and also transmits forces from upper limb to the trunk. The medial segment is pulled superiorly by the sternocleidomastoid. The weight of the arm pulls the lateral segment inferiorly through the coracoclavicular ligaments, but is opposed by the trapezius. In addition, the pectoralis major and latissimus dorsi pull the lateral segment inferomedially with resultant shortening and displacement whichleads to poor cosmetic and functional results. Fractures of clavicle are known since ancient time, earliest description of fracture clavicle is found in the Egyptian literature in 3550 BC [2]. Clavicle is short–long bone of skeleton and helps in translation of weight from hand to axial skeleton and provides attachment to the various muscles. Initially, the aim of treatment was union of fracture in whatsoever position fracture unites. Many methods of conservative treatment, namely, triangular sling, cuff and collar sling, three sling method, figure of eight bandage, figure of eight plaster of Paris shoulder Spica, clavicular brace, arm shoulder pouch, and many others have been described from time-to-time [7, 8, 9, 10]. All these methods did not involve the reduction of fracture or unable to hold the fracture reduced hence the results were malunion/non-union in various cases [7, 8].

The malunion resulted in shortening, deformation, disfigurement, and poor cosmoses shortening (reduced distance between sternoclavicular joint to the shoulder joint) resulted in biomechanical disadvantage, persistence of pain, limitations of functions, and reduction of strength in upper limb in some of these cases.

With increasing awareness and demand of the patient and consumer protection court surgeons felt the need for operative intervention and perfect alignment of this fracture to achieve perfect alignment of fragments. Better operative technique; improve metallurgy and availability of image intensifiers made the operative techniques as a method of first choice by more and more surgeons [3, 4, 11].

Various surgical treatment described is K wire fixation, Austin Moore pins, Knowles pins, Rockwood pin, intramedullary screw fixation, Steinman pins, external fixator, titanium elastic nailing system (TENS), plate, and screw.

Materials and Methods

The study was conducted in Department of Orthopedics, M.L.B. Medical College and Hospital, Jhansi, Uttar Pradesh, India between December 2014 and June 2016. On 62 cases of displaced fracture midshaft clavicle which were treated by two different modalities of internal fixation, i.e., TENS (n = 31) or plate and screws (n = 31).

Inclusion criteria

a. Age between 16 and 60 years
b. Within 2 weeks of fracture clavicle
c. Displaced fracture of midshaft clavicle
d. Shortening >2 cm
e. Segmental fractures
f. Bilateral clavicle fracture
g. Clavicular fracture associated with other injuries
h. Grade I and II compound fractures.

Exclusion criteria

a. Pre-existing pathology in shoulder or elbow or both
b. Scapular malposition and winging on initial examination
c. Floating shoulder
d. Patient who do not give consent
e. Grade III compound fractures.

Patients were clinically examined; first aid was given in the form of, cuff and color sling, analgesics, antacids, and was subjected to A-P view, Lardotic view radiograph of full-length clavicle to decide the plan of definitive management. If needed computed tomography scan and magnetic resonance imaging were also taken. Those requiring surgery were classified as per Allman classification and investigated for fitness for anesthesia and surgery.

The relevant data were recorded in the working pro forma. Selected patients were randomly divided in Group I and Group II. Patients of Group I were treated by closed/open reduction and internal fixation (CRIF/ORIF) by TENS and Group II by open reduction and internal fixation by plate and screws. Patients were followed periodically at 2 weeks, 6 weeks, 3, 6, and 12 months. Results were evaluated by constant scoring system given by Murley [4, 5].

Operative procedure

TENS fixation

Instruments required for nailing:

a. Set of TEN (1.5 mm, 2 mm, 2.5 mm)
b. Awl,
c. Impactor,
d. T-handle.

Procedure

Patients will be placed in supine position on OT table after general anesthesia. Scrubbing, painting, and draping were done. The insertion point is made approximately 1 cm lateral to the sternoclavicular joint. A one-centimeter vertical skin incision is made and a hole is made in the anterior cortex with the help of awl then an TEN inserted (diameter of nail depending on the width of the medullary canal) in the medullary canal of the clavicle with T-handle. With oscillating movements, the nail is advanced until it reaches the fracture site. If closed reduction is unsuccessful, an additional skin incision is needed at the level of the fracture site for open reduction of the fragments. Although the clavicle is S shaped, the tip of the TENS is curved which helps the surgeon to pass the elastic nail into distal fragment. After adequate engagement of the distal fragment, the medial end of nail shortened and skin closed over it. The procedure is performed under fluoroscopic guidance. Postoperatively, patients will be given a arm shoulder pouch, but were encouraged for early shoulder mobilization, starting with range of motion (ROM) exercises from the second day.

All patients will review at 2 and 6 weeks, 3, 6, and 12 months after surgery. At each visit, patients will be assesses clinically and radiograph was taken and functional outcome was assessed by the constant score of Murlley (Fig. 1 and 2).

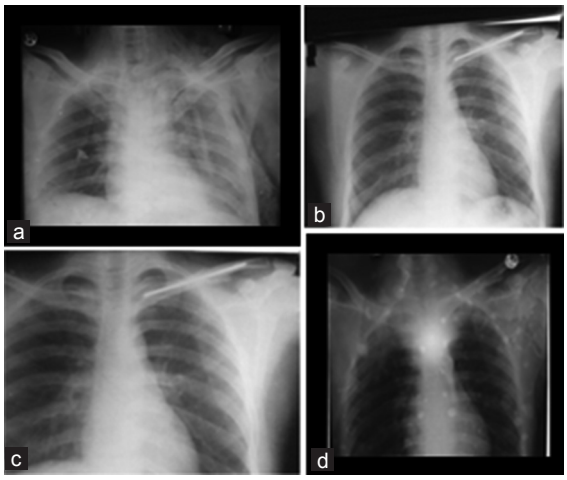

Figure 1: Titanium elastic nailing system group case 1. (a) Pre-operative X-ray. (b) Immediate post-operative. (c) 6 month post-operative. (d) After implant removal.

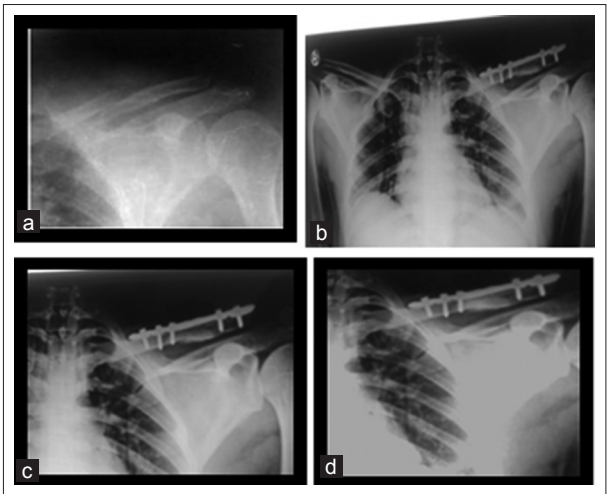

Figure 3: Plate group case 1. (a) Pre-operative X-ray. (b) Immediate post-operative. (c) 3 months post-operative. (d) 12 months post-operative.

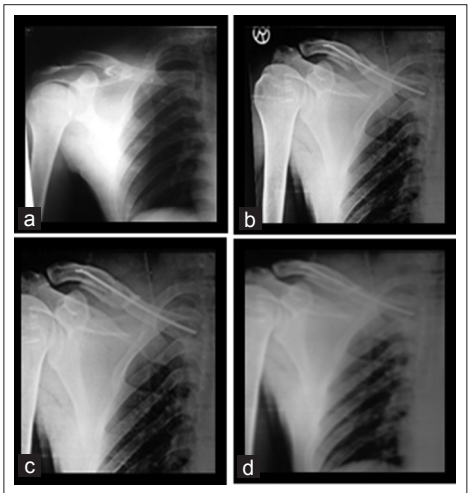

Figure 2: Titanium elastic nailing system group case 2. (a) Pre-operative X-ray. (b) Immediate post-operative. (c) 6 months post-operative. (d) 12 months post-operative.

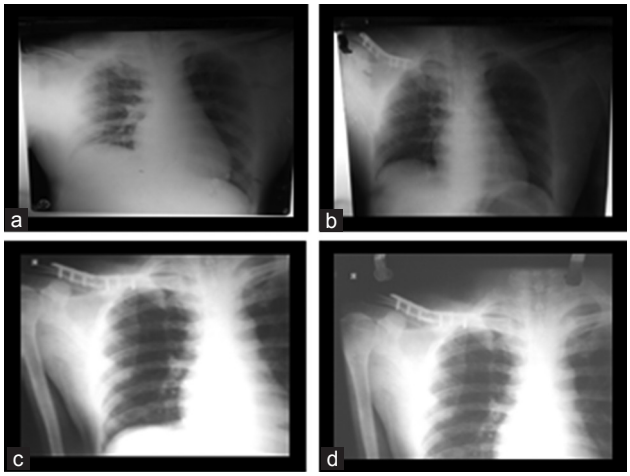

Figure 4: Plate group case 2. (a) Pre-operative X-ray. (b) Immediate post-operative. (c) 6 months post-operative. (d) 12 months post-operative.

Plate fixation

Instruments required for plating:

a. Locking Recon Plate/locking anatomical plate
b. Non-locking Recon plates
c. Sleeves
d. Drill bit 2.7 mm, 2.5 mm, 3.5 mm
e. Tap
f. Depth gauge
g. Locking screw 3.5 mm
h. Cortical screw 3.5 mm
i. Screw drive.

Procedure

Patient placed supine/beach chair position after giving general anesthesia on OT table, place a sand bag between the medial border of the scapula and the spine. The incision was made transversely just under the fracture site. Supra clavicular nerves will be identified and spared wherever possible. After reduction of fractures, an appropriate size of locking plate was fixed on the anterosuperior surface of the bone by appropriate size screw. After reduction recon locking plate was fixed. In oblique or complex fractures, inter fragmentary lag screws were used to achieve compression. The fascia and skin were closed in layers (Fig. 3 and 4).

Data extraction and analysis

Included studies were summarised in a data extraction form, including the following items: type of study, surgery (type of plate fixation or specified method of intramedullary fixation), descriptive data (sample size, missing data, and follow-up), patient characteristics, functional outcome, operation characteristics (amount of blood loss and duration of the surgery), and complications. Functional outcome was defined as shoulder function with the DASH and constant scores. The DASH questionnaire is a self-administered outcome instrument developed as a measure of self-rated upper extremity disability and symptoms.

The constant score includes an analysis of pain, shoulder motion, strength, and function. Shoulder function was evaluated according to the constant score (100-point scoring systems). These scoring systems combine assessments of subjective symptoms and objective findings. In the constant scoring system [4, 5], 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 (or difference between normal and abnormal side, <11 excellent, 11-20 good, 21-30 fair, and >30 poor).

Complications were recorded and compared between both groups. Non-union was defined as an unsuccessful healing of the bone after 9 months, clinically manifesting as pain at the fracture site and radiologically as a visible gap between the fracture parts. Deep infection was defined as infection requiring implant removal. Refracture was defined as a fracture of the clavicle within 3 months of implant removal without any history of retrauma.

Student's *t*-test was used to analyze the difference of means for different parameters. Mean, standard deviation, and standard error of mean for the variables were also calculated. The test was referenced for a two-tailed *P* value, and a 95% confidence interval was constructed around a sensitivity proportion using a normal approximation method. Statistical analyses were performed using SPSS software. A value of <0.05 was considered statistically significant.

Results

In this study, from December 2014 to June 2016, 62 patients with displaced midshaft clavicle fractures were included as per inclusion criteria and underwent surgical fixation.

In the TENS group, closed fracture reduction and internal fixation were done in 27 cases (87.09%), and open reduction was required in the remaining 4 patients (12.90%). There were less operative time, less blood loss, and lesser length of hospital stay in TENS group.

The bone union time was shorter in the TENS group as compare to plating group.

Three cases in the plate group and five cases in the TENS group developed superficial infection. However, infection was controlled by oral antibiotics in all eight cases. There was two cases in plate group develop deep infection one subsided by i/v antibiotics other need wound wash, but infection was completely controlled. Non-union occurred in two cases in each groups. No implant failure occurred in both groups. In plate group, three patients having ugly scar after healing. Implant protuberance seen in two patients of plating group. Pin migration seen in two patients of TENS group.

Constant score of Murley [4, 5] were assessed at every follow-up visit and the 2-month post-operative follow-up visit showed significantly higher Constant scores of 71.35 ± 8.22 in the plating group than in the TENS group (67.03 ± 8.14) ($P = 0.01$). The final scores at the 12-month follow-up visit showed no significant difference between two groups, as shown in Table 3 ($P > 0.05$).

Table 1: ORIF/CRIF

Procedure	Group I (%)	Group II (%)
CRIF	27 (87.09)	-
ORIF	4 (12.90)	31 (100)
Total	31 (100)	31 (100)

ORIF: Open reduction internal fixation, CRIF: Closed reduction internal fixation

Table 2: Comparison of complications of both groups

Complications	Group I (%)	Group II (%)
Superficial infection	5 (16.12)	3 (9.67)
Deep infection	-	2 (6.45)
Neurovascular injury	-	-
Non-union	2 (6.45)	2 (6.45)
Ugly scar	-	3 (9.67)
Implant protuberance	-	2 (6.45)
Pin migration	2 (6.45)	-
Implant failure	-	-
No complication	22 (67.74)	19 (61.29)
Total	31 (100)	31 (100)

Table 3: Final functional assessment

ROM (constant score)	Mean±SD		*P* value (NS)
	Group I (TENS)	Group II (plate)	
2 weeks	67.03±8.14	71.35±8.22	0.01
6 weeks	81.19±9.19	81.80±7.88	0.34
3 months	86.25±9.25	86.87±7.68	0.33
6 months	91.03±9.19	90.16±6.80	0.40
12 months	94.19±8.88	95.45±4.28	0.25

TENS: Titanium elastic nailing system, SD: Standard deviation, ROM: Range of motion

Discussion

The best treatment strategy for displaced midshaft clavicle fractures remains a topic of debate. Conservative management of these fractures results in an approximately 15-20% nonunion rate [16]. While non-operative management remains the mainstay of treatment for most midshaft clavicle fractures, the indications for surgery may be expanding. Recent studies have showed a poorer outcome in cases of displaced midshaft clavicle fractures that were treated non-operatively [9, 49, 50] in comparison to surgically treated patients. Initially, these fractures were managed conservatively which did not involves the reduction of fracture and is unable to hold the fracture reduced hence the end results was malunion/non-union/shortening, and deformation, which decreases the functional capability of affected upper limb, disfigurement and poor cosmoses [7, 8, 9, 10].

To overcome above disadvantages of conservative treatment and increasing awareness and demand, by patient's surgeons considered operative management of these fractures, which involved closed/open reduction of these fractures and internal fixation. Conservative treatment is indicated only in, undisplaced fractures or less demanding patients.

Three types of fixation are available for middle-third clavicle fractures: Intramedullary devices, plates, and external fixators. Intramedullary fixation can be done by smooth or threaded K-wires [3], Steinman pins, Knowles pins, Hagie pins, Rush pins, or cannulated screws [51, 52]. Plate fixation can be done with a 3.5 mm dynamic compression plate (DCP), low-contact DCPs, reconstruction plates or locking compression plates with at least three screws (six cortices) in both the medial and lateral fragment each, and an interfragmentary lag screw whenever the fracture pattern allow it. Plating of displaced mid shaft clavicle fractures is advocated as the preferred fixation method by many authors [4, 31]. Biomechanically, plate fixation is superior to intramedullary fixation because it better resists the bending and torsional forces that occur during elevation of the upper extremity above shoulder level [36]. Patients treated with plate fixation can be allowed full ROM once their soft tissues have healed. 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 [19]. Open reduction and internal fixation with a 3.5 mm DCP is the standard method in comminuted fracture midshaft clavicle which maintained lenth of clavicle better as compared to TENS fixation, so plate and screw fixation is better implant of choicein comminuted fracture clavicle. In segmental fracture, TENS is the treatment of choice. In this study, both methods of fixation were compared in terms of outcomes and complications.

Early callus formation and faster healing of fracture were observed in TENS group which were treated by closed or limited exposure technique and fixation of fracture by percutaneous method as compare to plate group where ORIF was done.

Similar observation about faster healing and union in patients treated by intramedullary nail as compare to plate has also been reported by Wu *et al.* [29], Mueller *et al.* [34], Hartmann *et al.* [35], and Liu *et al.* [38] independently.

Some other workers Thyagarajan *et al.* [25], Shishir *et al.* [40], Mishra *et al.* [42], Gao *et al.* [48], Kadakia [44], and Jain *et al.* independently reported similar observations of faster union. Fewer complication encountered were superficial infection, deep infection, ugly scar, implant protuberance, pin migration, and nonunion. Superficial infection occurred in five cases of Group I (TENS) at the entry point whereas three patients had superficial infection and two patients had deep infection at site of incision in plating group (Group II). None of the cases treated by TENS had any evidence of deep infection at fracture site. Clavicle is the percutaneous bone without muscle coverage hence two patients had protuberance of plate and three patients had ugly scar in patients treated with plate whereas two patients had pin migration in TENS group. Incidence of nonunion was same in each group. Zeng *et al.* [43] observed that plate fixation can provide more rigid stabilization than intramedullary pin fixation and may facilitate early mobilization and offer a superior construct for highly comminuted fractures where the bridge plating technique can be implemented. However, this technique may require large incisions and extensive exposure and soft tissue insult which could cause complications such as infection, scarring, and refracture after the removal of the plate. Intramedullary fixation provides an alternative and less invasive technique for the treatment of displaced midshaft clavicular fractures. It has the advantages of obtaining relatively stable fixation that allows axial compression, and preserving the soft tissue envelope, the periosteum, and the vascular integrity of the fracture site, which enhances healing.

Chen *et al.* observed that TENS fixation allows for earlier relief of shoulder pain and a more cosmetically satisfactory appearance than plate fixation. In addition, the infection rates may be decreased and fracture callus formation enhanced. However, the main complications of intramedullary fixation are superficial infection, hardware migration, and skin irritation. In our study, complications are more in plating group as compare to TENS group, which is in accordance of available literature, Kadakia *et al.* [44], Zeng *et al.* [43], and Sharma *et al.* (2016), Ygao *et al.* [48]. Shorter operative time, shorter hospital stay, and shorter time of union in patients treated by close reduction internal fixation by TENS as compared to patients treated with ORIF by plate and screws has also been observed independently by Wu *et al.* [29], Mueller *et al.* [34], and Hartman *et al.* [35]. At final evaluation, the overall results were evaluated using the constant scoring system of Murley. In Group II (plate), 29 patients scored <11 point as per constant scoring system of Murley and were graded as excellent two patients scored between 11 and 20 and were graded as good. Whereas 29 excellent, one good and one poor in TENS group. Although there was early callus formation and faster healing in patients treated by intramedullary fixation but at 1 year post-operative treatment constant score in two group was not significantly different.

In our study, functional shoulder scores were significantly higher for the plating group than the TENS group in the first 2 weeks, but at the 12-month follow-up visit, there was no significant difference observed between the two groups in terms of shoulder scores.

Conclusion

The primary limitation of our study was that it was a small prospective comparative 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 of plates and TENS in displaced midshaft clavicle fractures. Still, we can conclude from our study that both plating group and TENS group are equally effective alternatives for surgical fixation of displaced midshaft clavicular fractures. TENS group have advantages such as less soft tissue injury, shorter operating time and hospital stay, less blood loss, more cosmetic satisfaction, and minor surgery needed to remove the implant. TENS is a safe, minimally invasive surgical technique with a lower complication rate, faster return to daily activities, excellent cosmetic and comparable functional results, which can be regard as an alternative to plate fixation of displaced midshaft clavicular fractures.

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