

Prospective Study Of Fracture Shaft Clavicle Treated With Titanium Elastic Nail System (Tens)

Dr. Syed Tariq Mahmood, Dr. Mrudul Shah, Dr. Gautam Chatterji, Dr. Anshuman Sharma,

Designation: Associate Professor - Orthopaedics Institute: PCMS & RC, Bhopal (M.P.)

Designation: Assistant Professor - Orthopaedics Institute: PCMS & RC, Bhopal (M.P.)

Designation: Assistant Professor - Orthopaedics Institute: PCMS & RC, Bhopal (M.P.)

Designation: Associate Professor - Community Medicine Institute: Shyam Shah Medical College, Rewa, (M.P.)

Abstract

BACKGROUND

Clavicular shaft fracture are most common type of clavicular fracture and there are recent trend to fixation of these fractures. This is prospective study to evaluate the result of TENS in clavicular shaft fractures.

MATERIAL AND METHODS

Study of 33 (23 male & 10 female) consecutive patients of clavicular shaft fracture treated by TENS and follow up done for radiological and functional evaluation at 4, 8, 12, 16 weeks.

RESULT

The average follow up of 13 weeks and union achieved in all 33 cases. Length of incision, hospital stay, blood loss, operation time were less significant. There medial protusion of nail in 4 patient that requires medial trimming of nail, one case of open reduction was got infected treated by early implant removal. No other significant complication were observed.

CONCLUSION

TENS provide good restoration of clavicular length and allow early mobilization of extremity to achieve normal range of movements also good cosmetic appearance.

Keywords: Clavicular shaft fracture, Titanium elastic nailing system

Introduction

The clavicle is gentle S-shaped bone, medial end convex forward and lateral end concave forward, it provide attachments to muscle apart from this no other useful function of this bone but due to superficial location of this bone it is prone to trauma as well as cosmetic significance. Fracture of clavicle is common injury with an incidence of 2.6 to 10%⁽¹⁾. About 80% fractures involves mid-shaft of the clavicle and half of these are displaced^(2,3). Most patients who suffer a clavicular fracture particularly young adult will give history of fall directly onto the shoulder. The vast majority of fracture will result from simple fall⁽⁴⁾. Traditionally the mid-shaft fracture clavicle treated conservatively with sling or figure of eight bandage^(5,6,7). Close reduction prior to immobilization has not been clearly demonstrated to aid in fracture healing or permanently improve in alignment⁽⁸⁾.

For open fractures, imminent skin perforation, neurovascular involvement, floating shoulder or in combination with multiple ipsilateral rib fractures, open reduction and plating is generally accepted.⁽³⁾ While fracture healing and functional outcome is generally good for non-operatively treated mid-clavicular fractures, a poor cosmetic result due to shortening and angulation is not uncommon.⁽⁴⁾ Non-unions occur in an average of 5%⁽⁹⁾. Furthermore, decreased shoulder function due to clavicular shortening of more than 1-2 cm after non-operative fracture management has been reported.⁽¹⁰⁾

Whereas a mild decrease in shoulder function is easily tolerated by most patients, restoration of the clavicle length and early return to full activity with unimpaired function is of great importance for every individual irrespective of the profession or socio-economic group they belong to. As non-operative treatment is successful in most cases for this fracture, relevant clinical benefit may be limited to a selected group of patients with a high demand on shoulder function.

Two operative technique are commonly used for internal fixation of displaced midshaft clavicular fracture plate fixation and intramedullary nailing with tens .functional results after both technique proved to be superior compared with conservative treatment^(11,12).

Titanium Elastic Nailing System (TENS) of the clavicle is a minimally invasive procedure and aims at exact restoration of the clavicular length with early return to full activity, with a good cosmetic result and minimal morbidity. The aim of this study was to assess the effectiveness of tens.

Material And Method

Between FEB 2017 and FEB 2018, a total of 33 patients with closed displaced midclavicular fractures were admitted in DEPARTMENT OF ORTHOPAEDICS PEOPLES COLLEGE OF MEDICAL SCIENCES & REASARCH CENTRE BHOPAL (M.P) Patients were recruited according to particular inclusion and exclusion criteria.

Inclusion Criteria:

1. Isolated fracture midshaft clavicle 18-50 years age group
1. Closed mid-clavicular fracture (OTA 06-A/B) with shortening of at least 1 cm.
2. Lack of interfragmentary contact.

Exclusion Criteria:

1. Clavicular fractures with marked comminution.
2. Duration of more than 4 weeks.
3. Open fractures.
4. Pre-existent morbidity of the ipsilateral arm, shoulder or hand.
5. Presence of neurovascular injury, and ipsilateral injuries.
6. Pathological fracture

Informed consent was obtained. Radiographs of the fractured clavicle were obtained in anteroposterior and 45° cephalic tilt views. No additional imaging for the assessment of the clavicle was performed. Operation time, intraoperative technical problems, local complications and functional outcome were analysed. The patients were encouraged to use their shoulder without restriction immediately after surgery. Standard analgesia was given (Diclofenac and Tramadol) when required. Clinical examinations and radiological studies were performed on days 4,8,12,16 WEEKS. Clavicular length was clinically measured when bony consolidation was evident (distance from the centre of the jugular fossa to the lateral tip of the acromion) and compared with the contralateral side. Functional outcome was assessed using the Constant shoulder score. ⁽⁵⁾ Hardware removal was performed once bony consolidation was evident or later according to the patient's preference.

Surgical Procedure

The intervention was performed under inter-scalene & superficial cervical nerve blocks. Standard antibiotic single shot prophylaxis (Cefuroxime 1.5 g IV) was given. The patient was placed on a radiolucent operating table in the supine position. A towel roll was placed between the scapulae to provide extension of the shoulder girdle. It is important to scrub the whole ipsilateral upper extremity to allow free manipulation of shoulder and arm during the procedure. A single image intensifier was used for the procedure. A short skin incision of about 1 cm was made just lateral to the sternoclavicular joint centered above the medial end of the clavicle (Fig. 1). The medullary cavity of the clavicle was opened using a k-wire about 1 cm lateral to the sternoclavicular joint. The k-wire was pointed laterally in-line with the clavicle and angled at about 30 degrees to the coronal plane (Fig. 2). Care was taken not to perforate the dorsal cortex in order to avoid major complications. Once the medullary cavity was opened, a 3 mm awl was used to widen the entry point (Fig. 3) and a preselected TENS was carefully inserted. The implanted nails had diameters between 2.0 and 3.0 mm according to the patient's dimensions. No reaming was necessary. The nail was fixed in a universal chuck with a T handle and advanced with oscillating movements (Fig. 4) once the Titanium nail reached the fracture site (Fig. 5), closed reduction by direct pressure on the fragments combined with manipulation of the arm was performed. Usually, reduction was facilitated when a small pointed reduction forceps was applied percutaneously to the lateral fragment. The fracture was bridged using the rounded and angled tip to guide the Titanium nail into the lateral fragment. To determine the exact position of the Titanium nail, fluoroscopy with true perpendicular views is crucial. In some cases, closed reduction may not be accomplished. In these cases, a short incision directly over the fracture site (2 cm) with minimal dissection is suggested to reduce the fracture. The TENS was then pushed gradually into the distal part of the clavicle close to its extremity by oscillating it. The protruding medial end of the nail was left out of the cortex and shortened close to its entry point into the bone followed by wound closure and sterile dressing given.

Result

TABLE: 1 AGEWISE DISTRIBUTION OF MALE & FEMALE

AGE	MALE	FEMALE
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18-28 YEARS	14	06
28 -38 YEARS	05	03
ABOVE 38 YEARS	04	01

14 males were of age group 18 to 28 years while 6 females were of age group 18 to 28 years, 23 males and 10 females were in study population.

TABLE:2 GENDERWISE INVOLVEMENT OF RIGHT OR LEFT CLAVICLE

MALE	FEMALE
RIGHT CLAVICLE 08	RIGHT CLAVICLE 04
LEFT CLAVICLE 15	LEFT CLAVICLE 06

8 males had right clavicle involved while 6 females had left clavicle involved

TABLE 3- DISTRIBUTION ACCORDING TO MODE OF TRAUMA

MODE OF TRAUMA	NUMBER OF CASES
SIMPLE FALL	23
FALL FROM HEIGHT	02
RTA	05
DIRECT TRAUMA	02
OTHER	01

23 cases had simple fall, 5 cases had RTA

TABLE 4- DISTRIBUTION ACCORDING TO REDUCTION METHOD

REDUCTION	NUMBER OF CASES
CLOSE	21
MINI OPEN	09
OPEN	03

Close reduction was seen in 21 cases, mini open in 9 cases and open reduction in 3 cases

TABLE 5- DISTRIBUTION ACCORDING TO OPERATING TIME

OPERATING TIME	NUMBER OF CASES
UP TO 30 MINUTES	19
UP TO 45 MINUTES	07
UP TO 60 MINUTES	05
>60 MINUTES	01

Operating time was upto 30 minutes in 19 cases and upto 445 minutes in 5 cases

TABLE 6- DISTRIBUTION ACCORDING TO UNION TIME

RADIOLOGICAL UNION	NUMBER OF CASES
4 WEEKS	07
8 WEEKS	18
12 WEEKS	07
16 WEEKS	01

Radiological union was seen 4 weeks in 7 cases and 8 weeks in 18 cases

TABLE 7- DISTRIBUTION ACCORDING TO COMPLICATION

NAME OF COMPLICATION	NUMBER OF CASES
INFECTION	02
NONUNION	00
HYPERTROPHIC CALLUS	02
BAD SCAR	00
HARDWARE PROMINENCE	09

2 cases had infection while 9 had hardware prominence

A total of 33 patients (23 male, 10 female) qualified for the study according to the inclusion criteria between FEB 2017 TO FEB 2018. No potential candidate refused to enter the study by preferring non-operative treatment. Mean age was 34 years (Range: 18 to 50). The mechanism of injury was a simple fall 23 patients, 3 patients fell from

height. 05 from road traffic accident, 02 by direct trauma and 01 from sports activity. The fractures were graded according to the Orthopaedic Trauma Association classification (OTA). There were eighteen 06-A1, ten 06-A2 and three 06-A3 fractures in our series. The operation was performed 04 days (02-21 days) after trauma. Only Titanium nail diameters of 1.5, 2.0, 2.5 and 3.0 mm were used. Most commonly used nail diameter was 2.0 mm. Closed reduction was possible in 21 cases. A short incision of about 2 cm above the fracture site was necessary to obtain fracture reduction in 09 patients. Mean operation time was 38 minutes (Range: 30 minutes to 90 minutes). Operation time was much shorter when closed reduction was successful compared with the open technique 39 minutes (Range: 20 to 60) vs. 84 minutes (Range: 37 to 90). No correlation was found between reduction technique and fracture classification. When the operation was delayed for more than 7 days, closed reduction was never achieved suggesting that patients benefit from an early intervention with better chances for successful closed reduction. A smaller implant should be chosen if it is not possible to advance the Titanium nail by oscillating movements only. No metal fatigue failure was observed with either size of implant. No other intraoperative complication occurred. Hospital stay was 02.3 days (range: 02 to 06). Post-operatively, painless shoulder range of movements was possible in all patients. All the patients could be followed according to the study protocol. Mean follow-up was 12 weeks (range: 10 to 16). Two infection and no migration of the Titanium nail was observed. Both cases of infection were treated by surgical site debridement, but in one case infection was not controlled and treated by early implant removal at 5th weeks at that time fracture was united. So all fractures healed, no delayed or nonunion was observed. Hardware prominence on medial aspect is noted in 9 cases that is due to fracture site collapse and managed by trimming of protrudent part. Two cases observed with hypertrophic callus formation that were managed by proper assurance. Time to healing was 7.7 weeks (range: 4 to 12) determined by visible osseous callus formation on the radiographs. Clavicular shortening was 1.7 mm (range: 0 to 7) compared with the contralateral side measured after fracture healing. Hardware removal was performed electively in 16 patients After 18 weeks after implantation day care surgery. The Constant shoulder score averaged 80 (Range: 37 to 96) after 7 days. Mean Constant shoulder score was 96 (Range: 85 to 100) after 6 weeks. After 4 months, all patients presented with basically normal shoulder function (Mean: 98, range: 93 to 100).

All patients returned to their activities within four weeks after the procedure.

Discussion:

Simple closed fracture of the mid-third clavicle is a frequent injury and mostly treated non-operatively. Although fracture healing and functional outcome is usually satisfactory,⁽¹³⁾ significant shortening with mal-union or non-union is described in the literature^(14,15,16). Whereas some authors report good functional results in patients with clavicular shortening,⁽¹⁷⁾ Matis et al.⁽¹⁸⁾ found an impaired shoulder function in half of their patients with a shortening of 1 cm and in 100% when shortening was 2 cm. Hill et al.⁽¹⁹⁾ reported a clear correlation of non-unions (15%) with clavicular shortening of more than 2 cm. They found unsatisfactory results in 31% of completely displaced midclavicular fractures after non-operative treatment. Besides non-union, residual persistent pain, brachial plexus irritation and poor cosmetic results were observed.⁽²⁰⁾ According to Jupiter and Leffert,⁽¹⁴⁾ the initial displacement is one of the most predisposing factors in the development of non-unions. Furthermore, non-operatively treated clavicular fractures cause pain, discomfort and disability which are often not adequately appreciated by the treating physician. For patients with a high demand on shoulder function and good cosmetic appearance, such prospects are barely acceptable. To meet these patient's expectations, a minimally invasive procedure which provides restoration of the clavicular length combined with early resumption of activities, complete functional recovery and a good cosmetic result may be an attractive alternative to non-operative management. Open reduction with plate fixation is the operative standard treatment for clavicular shaft fractures. Potential complications include deep infection, injury to the subclavian vessels, screw loosening with implant failure, non-union and re-fracture after hardware removal. Bostman et al.⁽²¹⁾ reported a complication rate of 23% following plate fixation. The cosmetic results are unsatisfactory caused by an inevitable and often hypertrophic scar⁽²²⁾. Due to these problems non-operative treatment of uncomplicated midclavicular fractures is still favoured by most surgeons. In contrast, TENS as a potential alternative overcomes several disadvantages of plate fixation. The incision is kept short, providing a better cosmetic result. Restoration of clavicular length can reliably be maintained with minimal exposure and a limited amount of hardware. In about half of the interventions, closed reduction of the fracture is successful, which provides the best conditions for undisturbed fracture healing. Even when open reduction cannot be avoided, exposure can be kept to a minimum in order to avoid additional tissue damage. Most patients can be treated as day cases and full mobility of the shoulder is achieved early on. As postoperative instructions for the patients include no restrictions regarding range of motion, the level of activity is determined only by pain and the patient's motivation for an early resumption of full shoulder function⁽²³⁾. Despite this rather aggressive postoperative regimen, we observed neither implant failure nor migration. All fractures healed correctly resulting in a symmetrical shoulder girdle. Resumption of normal daily activities with

full function was achieved by all patients within 4 weeks postoperatively. Intramedullary fixation of clavicular shaft fractures is not a new idea; it dates back to Lambotte at the beginning of the last century. Murray⁽¹²⁾ published his technique of intramedullary Kirschner wire fixation in 1940. Since then, numerous technical variations have been published.⁽²⁴⁾ Implant migration with fatal complications, implant failure and mal- and non-unions have been described in the literature.⁽²⁵⁾ Due to the complication rate which exceeds the problems of non-operative management, all these techniques have never found general acceptance. In contrast to Kirschner wire fixation, TENS is a truly intramedullary stabilisation technique. The flexible Titanium nail is firmly anchored in the S-shaped clavicle according to the principles described by Ligier et al.⁽²⁶⁾

Conclusion:

Titanium Elastic Nailing can be safely performed if the two main fragments have osseous contact after reduction, ensuring correct clavicular length with the Titanium nail in place. From this study we recommended the tens for midclavicular fracture with minimal invasive technique for lesser morbidity, better cosmesis, and faster healing. Limitation of our study was short sample size and may be a short follow up.

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