



International Medical Science Research Journal
Vol. 1(3), pp. 50-60, October, 2019
Fair East Publishers
Journal Homepage: www.fepbl.com/index.php/imsrj



CASE STUDY OF TITANIUM ELASTIC NAIL FOR FRACTURES

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Article Received: 08-06-19

Accepted: 10-10-19

Published: 05-11-19

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ABSTRACT

Mostly, clavicle fracture is treated conservatively but because of higher rates of delayed union, non-union, symptomatic, malunion cosmetic deformity and other complications, there is increased used of operative management for clavicle fracture. In this regard, plating and intramedullary nailing are common surgical options. The operative technique is also found to be producing favorable results compare to the traditional method based on recent prospective randomized studies. In this study, the objective is to make a comparison between clinical results, operative method, and resulting complications proportion. The study was conducted on 66 patients who had OTA type B DMCFs and underwent surgical fixation with antegrade TENS and 1/3rd tubular plate. The study participants were divided in to two groups based on TENS and other with plate fixation with 1/3rd tubular plate. We conducted evaluation using constant-murley shoulder outcome and dash scores at 6, 12, weeks, 3, 6, and 12 months for determining outcomes. It was observed that among TENS group, there was easier implant removal and minimal complications, less blood loss, lesser operating time, with only complication of shortening of about 0.5 cm in fewer cases. In the other group which is plate group, no major complications were observed except minor one such as deep infection, superficial infection, hypertrophied scarring without pain, and decreased shoulder motion with no case of shortening. In terms of union and stability, no significant differences were found in both groups. Based on the result, it is suggested that TENS is more preferable since it involves fewer morbidity, better

cosmetic results, and easier implant removal. Fixation with plate seems to be little more stable and its implant of choice is comminuted fracture.

Keywords: Titanium Elastic Nail, Tubular Plate, Displaced Midclavicular,

INTRODUCTION

Almost 35% of shoulder injuries involves clavicle fracture which is mostly due to the fall on an outstretched hand or by direct injury [1]. Individuals who participate in sports activities or traffic related accidents mostly result in such type of fractures [2].

Most clavicular fractures 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]. Previously, the treatment for this type of fracture involved non-operative method, however, now the approach is changing and there is increased use of operative treatment for this fracture is observed in medical field [4]. The increased use of operative treatment is based on benefits associated with this method such as symptomatic malunion rates and lower nonunion [4-7]. With the development of the more advanced anatomically pre-shaped plates, the discussion is shifting from indications for operation towards the choice of implant for the midshaft clavicle [8-10]

Two common surgical techniques include intramedullary fixation and internal plate fixation for treatment of displaced midshaft clavicular fracture. Intramedullary provide improved functional outcome and decreased nonunion case while plate fixation provides better results in most aspects and thus remain the most common method of surgical treatment.

MATERIALS AND METHOD

The study is prospective in nature and based on patients who had displaced midshaft clavicular fracture who undergone TENS & 1/3rd tubular plate in a teaching hospital in Dhaka, Bangladesh. We divided patients in to two randomized groups. The inclusion criteria was age between 18 to 60 years, displaced midshaft clavicular fracture, 2 or greater cm shortening, skin tenting, compromised skin. Those patients who had older fracture such as more than 2 weeks old, open fractures, nonunion or malunion of a previous fracture or some other pathological fracture were excluded from the study.

Operative Technique

General anesthesia was administered after patients were placed in supine position on OT table. The sternoclavicular joint was palpated and marked. Incision of about 1 cm was made to skin lateral to sternoclavicular joint. Pointed awl was used for entry point in anterior cortex. A titanium elastic nail (of size 2 mm or 2.5 mm according to canal diameter and patient's stature) fixed to a T-handle was inserted via the entry point. Nail tip was straightened slightly before introduction in order to get better gliding in the medullary canal. Nail was advanced with cockscrew movement and it continued until nail got to fracture site. Closed reduction was performed under fluoroscopic control using percutaneously introduced towel clips. In case of failure of closed reduction, alternatively, accessory incision of about 3 to 4 cm was used for manipulation purpose. Nail was advanced so that it reaches to medial to the acromioclavicular joint. We took care of preventing 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 1: A titanium elastic nail fixed

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. 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 ≥ 23 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. We used arm sling for about 2 weeks post surgery and patients were advised with pendulum exercises and active range of motion.



Figure 2: Clinical picture

Assessment of Treatment Outcomes

Patients were given arm sling but they were advised to start using mobilization up to tolerant level such as pendular exercises. Active range of exercises were started after 7 days. Daily life activities were started after this point with the exception of lifting heavy objects until union is achieved. Patients were required to visit hospital after regular interval for follows up. We accessed each patient clinically for measuring primary and secondary outcomes. Constant score is used for measuring functional outcome. 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. We recorded time took to achieve union. 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.

Perioperative data such as amount of blood loss, operative time, size of the surgical wound, and complications such as wound infection, malunion, nonunion, implant failure, neurovascular injury, were used as secondary outcomes. We also noted the time it took to return to normal activities after fracture union.

Statistical analysis

We included those patients who attended at least 4 follow up session after surgery. The difference between two groups at the end of the follow up period with regards to the primary and secondary outcomes was measured and analyzed using the t-statistics method of 'independent group means comparison'.

RESULTS AND DISCUSSION

Table 1: Study Group Characteristics

		Plate Group	TENS Group
Age, Years	(Mean ± SD)	33.56±10.02	40.23±11.82
Gender	Male	25	29
	Female	07	5
Side	Left, %	12	16
	Right, %	20	16
Fracture Type	B1, %	25	23
	B2, %	05	3
	B3, %	02	6
Mode of Injury	RTA, %	21	21
	Fall, %	7	7
	Assault, %	2	4
	Others, %	2	

There were 32 patients in TENS group and 32 patients in the Plate group whom we used for comparison. There were 25 male and 7 females in plate group and 29 male and 5 female patients in TENS group. The age range of patients was 15 to 55 years in TENS group with mean value of 34.5 years; while, in Plate group, the age range was 15 to 57 with mean age of 33.9 years.

Table 2: Parameters Analyzed

Parameters Analyzed	Results	
	TENS	Plate
Duration of injury, Days (Mean ± SD)	5.98 ± 3.11	5.43±1.96
Union, n	100 %	100 %
Union time, weeks (Mean ± SD)	9.38±1.44	9.66 ± 1.75

The trauma surgery delay was about 5.98 days in plate group with range of 4 to 27 days; and 5.43 average in TENS group with range of 2 to 10 days. In the TENS group, 28 patients which makes up 82% had AO class B1 and 3 patients which makes 9% had AO class B2 fracture and 3 patients which makes 9% had AO class B3. In Plate group, 23 patients which makes 71.9% had B1, 5 patients which makes 15.6% had B2, and 4 patients which makes 12.5% had B3.

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 were achieved in 20 patients while the remaining 14 cases required open reduction (mini open). The mean follow-up 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.

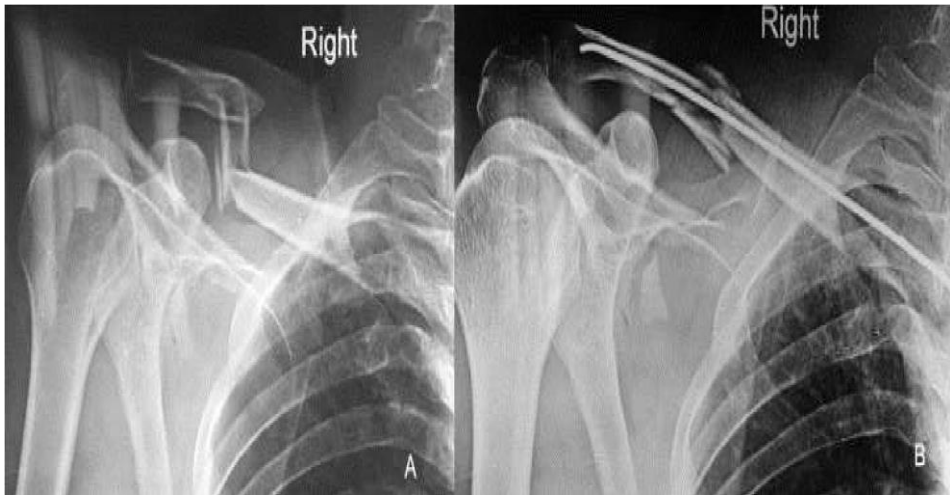


Figure 3: Comminuted Fracture of Clavicle with Significant Shortening.



Figure 4: Cosmetically Acceptable Small Surgical Scar



Figure 5: X-Ray of Titanium Elastic

Table 3: Comparison

	Constant Score (Mean±SD)		DASH Score (Mean±SD)	
	Tens	plate	Tens	plate
6 Weeks	62.5±4.27	61.5±4.57	11.96±5.55	12.96±4.45
3 Months	72.65±6.06	66.5±6.52	6.47±2.65	6.97± 2.65
6 Months	91.47±2.54	79.47±4.14	5.94±2.76	6.94±2.79
12 Months	92.26±2.06	91.09 ± 4.17	5.62±2.66	6.09 ± 1.16
P value	p < 0.001	p < 0.001	p < 0.001	p < 0.001

Our comparison score based on 6 weeks, 3 months, 6 months, and 12 months follow up shows that there is no significant difference between TENS and Plate group. In other words, both groups had no significant differences.

Table 4: Complications

Complications	TENS (No.)	Plate (No.)
Superficial infection	2	1
Hypertrophied scar	-	1
Limited shoulder motion	-	3
Painful shoulder	-	3
Neither pain nor functional disability	2	3
Medial TEN protrusion	8	-
Shortening >0.5 cm	4	1

The complications are discussed in Discussion section.

Discussion

Currently, the trend is shifting from nonoperative method to use operative method for treating midshaft clavicular fractures due to the associated benefits such as reduced nonunion, reduced malunion, decreased pain, and so on [11]. Different operative treatment modalities are available such as nailing, plating, and external fixation. Among these methods, plating is the commonly used procedure and is biomechanically superior compare to other modalities as it shows better bending forces and better resists torsional [12]. Previously, the thinking among medical professional was that clavicular fracture can be treated nonoperatively [6, 7]. However, now the trend is changing from nonoperative method to using operative techniques [13]. There are some complications involved when it comes to surgical method especially plating since it requires long incision and comparatively extensive periosteal stripping which leads to hardware prominence, compromised blood supply hindering fracture healing, dysesthesia, and ugly scar. It also found to be associated with extensive exposure and increased duration of surgery [13]. Furthermore, due to the rigid plates, there is issue of stress shielding which leads to higher rate 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 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 present study, comparison is made between the results of anterior and antero-inferior plating versus antegrade IM fixation with TEN. We divided patients in to two groups namely TEN group and Plate group. Our comparison of post-surgery follow-up shows that there were no dissatisfactory results found among all of our patients which is similar to the results of other studies [16]. Furthermore, the average time to achieve union was same in both groups as we did not find any statistical differences. We found some small differences as clavicular lengths were better maintained in plates groups compare to the TEN group especially in AO type B2 fracture. These findings are similar to the findings of other studies [17]. However, the differences remained very small and were not statistically very significant. Furthermore, we did not find any case of shortening of greater than 0.5 cm in TENs group and no case in plate group. These results were not unsatisfactory as differences of greater than 18 mm among males and 14 mm in female is considered as unsatisfactory [18].

Clavicular lengths were significantly better maintained by platig [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].

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 causing skin irritation or perforation, which was noted in some cases. 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].

CONCLUSION

Our conclusion is that we did not find any significant differences regarding union including clinical and radiological and stability between the two study groups i.e. Plate and TENS group. However, our results pointed out that TENS is preferable for treating simple displaced fracture of DMCFs since it is associated with reduced morbidity, easier plant removal, and better cosmetic results.

Limitations

Our limitations included small sample size which was based on single teaching hospital in single city and short follows up time. There is

Conflict of Interest

Authors declare no conflict of interest

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