MAK HILL Publications Research Journal of Medical Sciences

Research Article
doi: 10.59218/makrjms.2024.2.342.347

OPEN ACCESS

Key Words
Mid-shaft clavicular fractures, titanium elastic nailing (TEN), plate

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Received: 18 January 2024
Accepted: 18 February 2024
Published: 28 February 2024

Citation: Kishan Gopal Nama, Ramkhiladi Meena, Dharmraj Meena, Sachin Joshi and Ekaansh Karir, 2024. Functional Outcome of Fracture Clavicle Treated with Plate vs. TENS Nail: A Randomized Controlled Study. Res. J. Med. Sci., 18: 342-347, doi: 10.59218/makrjms.2024.2.342.347

Functional Outcome of Fracture Clavicle Treated with Plate vs TENS Nail: A Randomized Controlled Study

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ABSTRACT

Clavicle fractures are one of the most common injuries encountered by the orhopedic surgeon. Surgical treatment of displaced mid-third clavicle fractures is a controversial topic till date. Although plating is the gold standard, lately TENS has been seen as a viable alternative. To assess the functional outcomes of mid-shaft clavicle fractures treated with TENS vs Plate. A comparative randomized controlled study was carried out in the Department of Orthopedics where A total of 100 patients with mid-shaft clavicle fractures were selected. Fifty patients were operated with and fifty were operated with TENS. Regular follow-up was performed for 14 weeks. At each postoperative visit, shoulder function was evaluated using a constant score and DASH score. X-rays were taken at each visit to evaluate healing. Out of the total patients, 68% were males. Forty percent of the injuries resulted from road accidents, and 37% resulted from falls. The mean age was 39.7 years, ranging from 18 to 64 years. The right side was involved in 66 (66%) patients. Most of the fractures (59%) were simple transverse fractures. Union time was delayed in the TENS group (21.4±6.3 weeks) compared to that in the plate group (17.5±5.2 weeks). Shortening of the clavicle and wound size were less common in the TENS group as compared to than in the plate group. The majority of complications, such as infection, nonunion, and ugly scarring, were more common in the plate group than in the TENS group. Our study found that functional outcomes were better in the TENS group when compared to the plate group. Compared with plate fixation, titanium elastic nailing is a simple, safe, cosmetically preferred, and minimally invasive technique for mid-shaft clavicular fractures with good functional outcomes and fewer complications.

INTRODUCTION

Clavicle fractures are common, with an incidence of 5-10% of all fractures. Clavicle fractures are categorized into proximal, mid-shaft distal fractures. Approximately 80% of these fractures are mid-shaft fractures[1,2]. Clavicle fractures most frequently result from direct axial blow on the shoulder, a fall with an outstretched arm, road traffic accidents, sports accidents, or a fall from height[3]. Previously, most midshaft clavicular fractures were treated conservatively, resulting in poor outcomes such as nonunion, malunion, clavicle length shortening marked functional defects[4]. Hence, an increasing number of fractures are treated surgically even though the traditional indications for surgical fixation are impending skin perforation, neurovascular compromise, a floating shoulder gross displacement[5,6]. Currently, surgeons prefer internal fixation for displaced mid-shaft clavicle fractures[7]. Two operative techniques are commonly used for the internal fixation of DMCFs: plate fixation and intra-medullary nailing with a titanium elastic nail (TEN) [8]. Titanium elastic nails (TENs) are commonly used to repair displaced mid-shaft clavicular fractures. Although several clinical studies have shown that the use of TENs is more effective and less invasive than traditional plate fixation, high rates of complications associated with TENs have been reported. Intra-medullary nailing using a titanium elastic nail (TEN) is a technically easy, inexpensive minimally invasive method with fewer complications (a smaller scar and reduced operative time). Although plate osteosynthesis is considered the gold standard, it has higher complication rates[9,10]. TENS is a successful alternative for treating mid-clavicle fractures and has good functional outcomes and union rates[11]. Despite of high frequency, choice of proper treatment is still a challenge for orthopedic surgeon. In particular it is not clear whether surgery produces better outcomes than non-surgical management. The aim of the study is to analyze the result of TENS management and surgical treatment by plating of displaced mid-shaft clavicle fracture. It also aimed to compare the functional outcome of displaced fracture of the middle third of clavicle treated with TENS and Plating management.

Aims and Objectives: The aim of this study is to evaluate and compare the functional outcomes of mid shaft clavicle fractures treated with TENS vs Plate method.

MATERIALS AND METHODS

This prospective randomized control study was carried out in the Department of Orthopedics at a tertiary care hospital in India. Patients who presented to our hospital with injury/trauma to the mid-shaft clavicle and who were diagnosed with a fractured clavicle radiographically were enrolled in this study.

Inclusion Criteria:

- Patients >18 years of age
- Traumatic Closed and Mid-Shaft Clavicle Fractures
- Patients who have no medical contraindications for general anesthesia
- Patients who provided written informed consent for the study

Exclusion Criteria:

- Patients <18 years of age
- Proximal or distal third clavicle fractures pathological fractures or compound fractures
- Fractures associated with neurovascular injury and established nonunion of old fractures
- Polytrauma patients
- Patients not willing to study

All the patients were evaluated the necessary fitness for anesthesia was taken. The patients were randomized into two groups, one was implated with a clavicle plate whereas the other group was implanted with a TENS. All the patients underwent surgery on an elective basis after optimization of their medical conditions. All surgeries were performed under general anesthesia with standard aseptic precautions. All pre-operative and post-operative protocols were same for both the groups. Postoperatively, the patient was placed in an arm pouch sling. An X-ray was taken pendulum exercises were begun immediately. Active mobilization was started depending on pain tolerance. The arm pouch was discarded at one month overhead activities were allowed. Further X-rays were taken at 6 weeks, 3 months six months. At each follow-up, patients were assessed clinically and radiologically. Functional assessment was performed using the Constant-Murley score and DASH score[12]. Fracture union was defined by radiographic criteria and clinical criteria as described by Dijkman *et al*[13]. The criteria used in this study were as follows: radiographic criteria-bridging of the fracture by callus-and clinical criteria-absence of pain or tenderness on palpation.

Statistical Analysis: Statistical analysis was performed using SPSS 22.0 (SPSS, Inc., Chicago, IL, USA). Appropriate parametric (Student's t test) and non-parametric tests (Fisher's exact test) were conducted to identify significant differences in functional outcomes between the two interventions. $p<0.05$ was considered significant.

RESULTS AND DISCUSSION

A total of 100 patients with midshaft fracture clavicles admitted to our hospital during the study period were randomly divided into two groups: the titanium elastic nail (TEN) xation group and the plate fixation group (50 patients in each group). Of the total patients, 68% were males 32% were females. Forty percent of injuries resulted from road accidents 37% resulted from falls. The mean age was 39.7 years, ranging from 18-64 years. The right side was involved in 66 (66%) patients. Most of the fractures (59%) were simple transverse fractures. The mean operation time was 65.84±12.31 min in the TENS group and 49.23±11.70 min in the plate fixation group. Union time was delayed in the TENS group (21.4±6.3 weeks) compared to that in the plate group (49.23±11.70 weeks). Shortening of the clavicle and wound size were

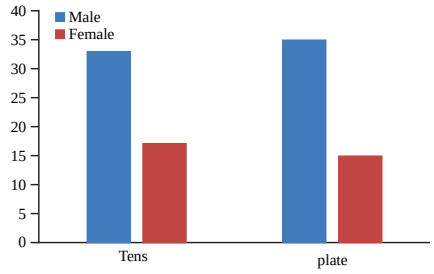

Fig. 1: Comparison of Gender

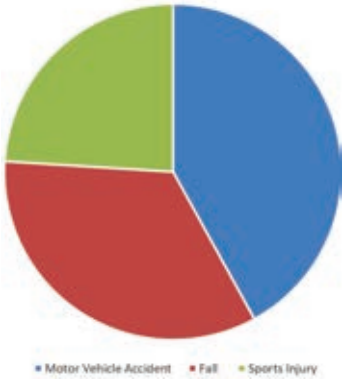

Fig. 2: Mechanis of Injury in TENS Group

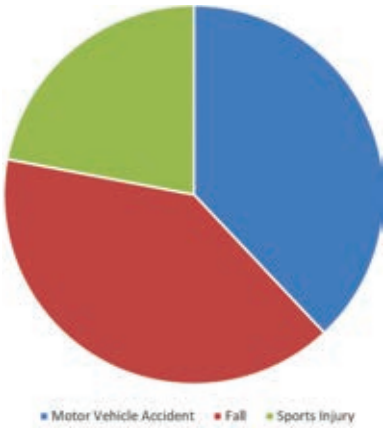

Fig. 3: Mechanism of Injury In Plate Group

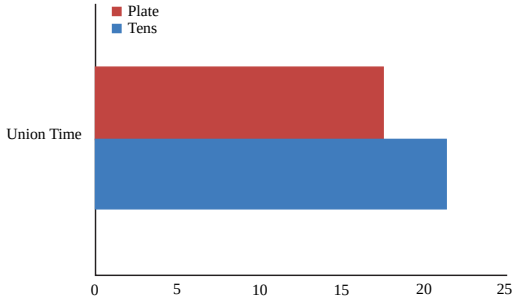

Fig. 4: Comparison of Union Time of Clavicle (In Weeks)

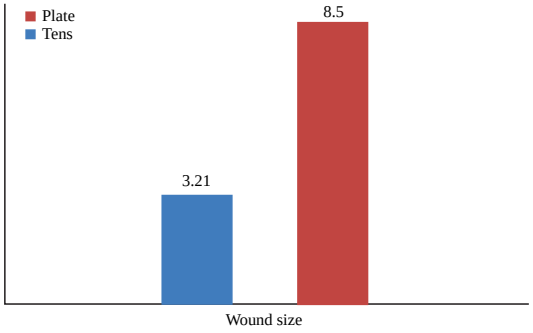

Fig. 5: Comparison of wound size

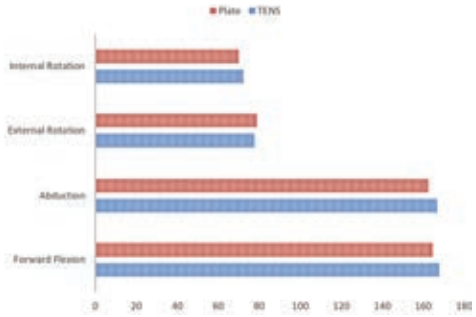

Fig. 6: Comparison of shoulder rom

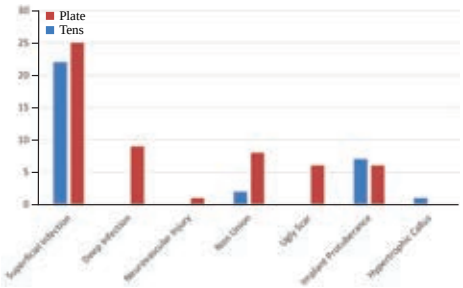

Fig. 7: Comparison of complications

less common in the TNES group than in the plate group. Blood loss during surgery was greater in the TENS group than in the plate group. The functional outcomes were significantly different between the two groups ($p<0.05$). The shoulder range of motion was greater in the TENS fixation group than in the plate fixation group, but the difference was not statistically significant ($p>0.05$).

Table 1: Demographic data of patients in the TENS fixation and plate fixation groups

Demographic data		TENS fixation (n=50)	Plate fixation (n=50)	p-value
Age in years (mean)		39.7 (18-64)	35.6 (18-60)	0.532
Gender	Male	33 (66%)	35 (70%)	0.668
	Female	17 (34%)	15 (30%)	
Fracture type	Simple	30 (60%)	29 (58%)	0.838
	Comminuted	20 (40%)	21 (42%)	
Affected side	Right	34 (68%)	32 (64%)	0.672
	Left	16 (32%)	18 (36%)	
Mechanism of injury	Motor vehicle accident	21 (42%)	19 (38%)	0.824
	Fall down	17 (34%)	20 (40%)	
	Sports injury	12 (24%)	11 (22%)	

Table 2: Comparison of functional outcomes between the TENS and plate fixation groups

Variable	TENS fixation group (n=50) Mean±SD (range)	Plate fixation group (n=50) Mean±SD (range)	p-value
Union time (weeks)	21.4±6.3 (14-30)	17.5±5.2 (12-22)	0.001
Operative time (min)	65.84±12.31 (40-80)	49.23±11.70 (20-60)	<0.001
Shortening of clavicle (mm)	3.86±1.97 (0-9)	6.49±2.75 (0-15)	<0.001
Intraperative blood loss (ml)	98.89±34.64(50-200)	48.65±29.74 (10-100)	<0.001
Wound size (cm)	3.21±1.22	8.50±2.31	<0.001

Table 3: Comparison of shoulder range of motion at the final follow-up between the groups

Active range of motion of shoulder (degrees)	TENS fixation group (n=50) (Mean±SD)	Plate fixation group (n=50) (Mean±SD)	p-value
Forward flexion	167.8+10.6	164.5+12.4	0.155
Abduction	166.6+16.8	162.4+15.3	0.194
External rotation	77.6+9.2	78.8+10.1	0.536
Internal rotation	72.3+12.6	70.0+11.7	0.346

Table 4: Evaluation of functional outcomes using the Constant score and DASS

		DASS score		
Functional outcomes	**Constant score**	**2nd week**	**6-8 week**	**14-16 week**
Excellent	86-100	-	75	100
Good	71-85	100	25	-
Fair	56-70	-	-	-
Poor	1-55	-	-	-

Table 5: Comparison of postoperative complications between the TENS and plate fixation groups

Complications	TENS fixation group (n=50)	Plate fixation group (n=50)
Superficial infection	22 (44%)	25 (50%)
Deep infection	0	9 (18%)
Neurovascular injury	0	1 (2%)
Nonunion	2 (4%)	8 (16%)
Ugly scar	0	6 (12%)
Implant protuberance	7 (14%)	6 (12%)
Hypertrophic callus	1 (2%)	0

The DASH score and Constant score was measured at each follow-up visit at 2 weeks, 6 weeks 14 weeks and was used as comparison of functional outcome after fracture fixation. All the patients at 2 weeks of follow-up had good consistency scores, which improved to excellent scores at 6 weeks and 14 weeks follow-ups. The majority of complications, such as infection, nonunion ugly scarring, were more common in the plate group than in the TENS group, whereas implant protuberance and hypertrophic callus were more common in the TENS group. Mid-clavicular fractures in our country are being treated conservatively until date. Rowe[10] and Neer[2] in the 1960's recommended non-operative treatment, because they observed a very small number of non-unions. Recent evidence on the treatment of displaced mid-clavicular fractures has shifted from the old concept of conservative treatment to surgical fixation. The problems of prolonged immobilization and delay in returning to work are avoided by surgical fixation. Plate removal is a major procedure and is associated with an increased risk of refracture after removal. TENS is financially superior, technically easier cosmetically superior. However, this approach has the disadvantage of increased radiation exposure and is not suitable for treating severe comminuted fractures. Nail removal can be performed under local anesthesia [14].In our study, the majority of the clavicle fracture patients were younger and predominantly male, which was supported by many other previous studies: Mishra PK *et al*[15]. and Pranav VM *et al*[16]. Usually, young patients often experience fractures of the middle third of the clavicle because they are more active in jobs and activities. In the present study, the most common mode of injury was motor vehicle accidents, followed by falls. Our results are consistent with those of Yadav *et al*[117]. and Oliveira AS *et al*[18]. This also explains why road traffic accidents are more common among outdoor workers, as males are more vulnerable to these injuries than females are, as males are more involved in outdoor activities. Shoulder rotation of movement at the final follow-up showed satisfactory results in both the plate and TEN fixation groups there was no statistically significant difference between the two groups, in agreement with Park *et al*[19]. The current study revealed a progressive decrease in the

DASH score and an increase in the constant score throughout the follow-up period; similar findings were also observed by various other researchers: Wang YC *et al*[20]. and Agrawal P *et al*[21]. Our results revealed faster fracture union, shorter operative time, less blood loss, easier implant removal fewer complications in the TEN group than in the plate fixation group; these results are comparable to those of Thampy JS *et al*[22]. and A Gopalakrishnan *et al*[23]. The most commonly reported complications after TEN fixation were implant protuberance, hardware irritation protrusion, according to Hoogervorst *et* al[24] and Smekal V *et al*[25]. Most of the patients complained about the nail prominence at the sternal end but tolerated it well till removal. The present study revealed higher rates of nonunion, shoulder pain poor functional outcomes in the plate fixation group than in the TENS fixation group, consistent with the findings of Wick *et al*[26]. and Eskola *et al*[27]. Although plate fixation is the gold standard, minimally invasive elastic nailing is an established alternative. In summary, we believe that operative management of mid-shaft clavicle fractures with flexible intramedullary nailing is a safe procedure with excellent clinical and functional outcomes and can be considered as surrogate method to plating.

CONCLUSION

Elastic nailing results in a quicker return to daily activities, small scars, excellent functional outcomes high patient satisfaction rates. It is a good technique for mid-clavicular fracture fixation and can be an alternative to conservative treatment because it allows earlier rehabilitation. In summary, we believe that elastic nailing for mid-clavicular fractures is a less expensive and safer method with excellent functional outcomes.

REFERENCES

1. Nordqvist, A. and C. Petersson, 1994. The incidence of fractures of the clavicle. Clin. Orthop., 300: 127-132.
2. Postacchini, F., S. Gumina, P.D. Santis and F. Albo, 2002. Epidemiology of clavicle fractures. J. Shoulder Elbow Surg., 11: 452-456.
3. Nowak, J., H. Mallmin and S. Larsson, 2000. The aetiology and epidemiology of clavicular fractures. Injury, 31: 353-358.
4. Canadian Orthopedic Trauma Society, 2007. Nonoperative treatment compared with plate fixation of displaced midshaft clavicular fractures. A multicenter, randomized clinical trial. J. Bone Joint Surg. Am., Vol. 89.
5. McKee, M.D., E.M. Pedersen, C. Jones, D.J.G. Stephen and H.J. Kreder *et al*. 2006. Deficits following nonoperative treatment of displaced midshaft clavicular fractures. J. Bone Joint Surg. Am., 88: 35-40.
6. Kong, L., Y. Zhang and Y. Shen, 2014. Operative versus nonoperative treatment for displaced midshaft clavicular fractures: A meta-analysis of randomized clinical trials. Arch. Orthop. Trauma Surg., 134: 1493-1500.
7. Lazarides, S. and G. Zafiropoulos, 2006. Conservative treatment of fractures at the middle third of the clavicle: The relevance of shortening and clinical outcome. J. Shoulder Elbow Surg., 15: 191-194.
8. Denard, P.J., K.J. Koval, R.V. Cantu and J.N. Weinstein, 2005. Management of midshaft clavicle fractures in adults. Am. J. Orthop. (Belle Mead NJ.), 34: 527-536.
9. Kettler, M., M. Schieker, V. Braunstein, M. König and W. Mutschler, 2007. Flexible intramedullary nailing for stabilization of displaced midshaft clavicle fractures: Technique and results in 87 patients. Acta Orthop., 78: 424-429.
10. Saha, P., P. Datta, S. Ayan, A.K. Garg, U. Bandyopadhyay and S. Kundu, 2014. Plate versus titanium elastic nail in treatment of displaced midshaft clavicle fractures. Indian J. Orthop., 48: 587-593.
11. Meijden, O.A.V., R.M. Houwert, M. Hulsmans, F.J.G. Wijdicks and M.G.W. Dijkgraaf et al., 2015. Operative treatment of dislocated midshaft clavicular fractures: Plate or intramedullary nail fixation?. J. Bone Joint Surg., 97: 613-619.
12. Constant, C.R., C. Gerber, R.J.H. Emery, J.O. Sojbjerg, F. Gohlke and P. Boileau, 2008. A review of the constant score: Modifications and guidelines for its use. J. Shoulder Elbow Surg., 17: 355-361.
13. Dijkman, B.G., S. Sprague, E.H. Schemitsch and M. Bhandari, 2010. When is a fracture healed? radiographic and clinical criteria revisited. J. Orthop. Trauma, 24:
14. Hill, J.M., M.H. McGuire and L.A. Crosby, 1997. Closed treatment of displaced middle-third fractures of the clavicle gives poor results. J. Bone Joint Surg., 79: 537-539.
15. Mishra, P.K., A. Gupta and S.C. Gaur, 2014. Midshaft clavicular fracture and titanium elastic intra-medullary nail. J. Clin. Diagn. Res., 8: 129-132.
16. Pranav, V.M., S.N. Chishti, S.N. Singh, R. Maske, D. Soring and D. Parija, 2016. A prospective study of operative management of simple midshaft clavicular fracture with Titanium Elastic Nail (TEN). Int. J. Orthop. Sci., 2: 210-213.
17. Yadav, S., M.O. Phalak, I. Shevate, R. Salunkhe and A. Khandge et al., 2022. Comparative study of postoperative outcomes of clavicle midshaft fracture treated by nailing vs. plating. Cureus, Vol. 14 .10.7759/cureus.22862.

18. Junior, A.S.D.O., B.B. Roberto, M. Lenza, G.F. Pintan and B. Ejnisman et al., 2017. Preferences of orthopedic surgeons for treating midshaft clavicle fracture in adults. Einstein (São Paulo), 15: 295-306.
19. Park, J.S., S.H. Ko, T.H. Hong, D.J. Ryu, D.G. Kwon, M.K. Kim and Y.S. Jeon, 2020. Plate fixation versus titanium elastic nailing in midshaft clavicle fractures based on fracture classifications. J. Orthop. Surg., Vol. 28. 10.1177/2309499020972204
20. Wang, Y.C., Y.C. Fu, S.H. Chou, P.C. Liu, Y.C. Tien and C.C. Lu, 2015. Titanium elastic nail versus plate fixation of displaced midshaft clavicle fractures: A retrospective comparison study. Kaohsiung J. Med. Sci., 31: 473-479.
21. Agrawal, P. and K. Belapurkar, 2022. Functional and radiological outcomes of mid-shaft clavicle fracture managed by flexible intramedullary nailing. Int. J. Res. Orthop.s, 8: 426-433.
22. Thampy, J.S., H.S. Arun, E. Prabhu and S. Hariprasad, 2020. Study of functional outcome in midshaft clavicle fracture treated with titanium elastic nailing system. J. Karnataka Ortho. Assoc., 8: 22-27.
23. Gopalakrishnan, A., K.V. Sreesobh and J. Jose, 2020. Functional outcome of titanium elastic nailing in midclavicular fractures. Indian J. Orthop. Surg., 4: 270-272.
24. Hoogervorst, P., T. van Dam, N. Verdonschot and G. Hannink, 2020. Functional outcomes and complications of intramedullary fixation devices for midshaft clavicle fractures: A systematic review and meta-analysis. BMC Musculoskelet. Disord., Vol. 21 .10.1186/s12891-020-03256-8.
25. Smekal, V., A. Irenberger, P. Struve, M. Wambacher, D. Krappinger and F.S. Kralinger, 2009. Elastic stable intramedullary nailing versus nonoperative treatment of displaced midshaft clavicular fractures-a randomized, controlled, clinical trial. J. Orthop. Trauma, 23: 106-112.
26. Wick, M., E.J. Müller, E. Kollig and G. Muhr, 2001. Midshaft fractures of the clavicle with a shortening of more than 2 cm predispose to nonunion. Arch. Orthop. Trauma Surg., 121: 207-211
27. Eskola, A., S. Vainionpaa, P. Myllynen, H. Patiala and P. Rokkanen, 1986. Outcome of clavicular fracture in 89 patients. Arch. Orthop. Trauma. Surg., 105: 337-338.