Comparing the Functional outcome of Plate Fixation vs Elastic Intramedullary Nailing for Displaced fractures of the clavicle in the active adult population

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Abstract: Comparing the Functional outcome of Plate Fixation vs Elastic Intramedullary Nailing for Displaced fractures of the clavicle in the active adult population. Background: Displaced midshaft clavicle fractures have historically been treated conservatively. Nevertheless, there have been recent reports of poor results following conservative therapy for these fractures, including non-union of the fracture, shortening of the clavicle, or significant functional limitations.[2–3] In displaced midshaft clavicle fractures, clavicle length shortening of > 2 cm (i.e., no cortical contact between the proximal and distal pieces radiographically) is generally recognised as a criterion for surgical intervention.[4] The two implants that are most frequently utilised to treat displaced clavicle fractures are plates or intramedullary devices. Method: A comparative study was conducted of 18 months duration at Department of Orthopedics, Rural Medical College, Pravara Institute of Medical Science, Loni, Maharashtra on patients with displaced clavicle fractures. Inclusion criteria were: (1)A markedly displaced clavicle fracture (no cortical contact between the proximal and distal fragments on radiography and/or > 2 cm of shortening) (2) Patients older than 16 years; and (3)Patient's ability to provide complete information, sign a consent form, fill out questionnaires, and attend further follow up. Exclusion criteria: (1) Pathologic fracture; (2) Previous clavicle fracture nonunion; (3) inability to provide complete information, sign a consent form, fill out questionnaires, or attend further follow up. Following surgery, follow-up both clinically and plain radiography was conducted every 2nd, 6th and subsequently every month. The amount of clavicle length shortening was measured as the bilateral clavicle length difference. The Constant Murley shoulder score was used to gauge the injured shoulder's functional outcome Result: In both group at 16 weeks radiological union was observed. Post operatively in Group A (Plate Fixation) 3.33% cases were observed with pain at incision site and superficial infection respectively whereas in group B(TENS Fixation) 11.11% cases were observed with skin impingement. At follow up in both groups most of the cases were observed with excellent result which shows no statistical difference in the CMS score between both groups. Conclusion: Functional outcomes from the TEN system for the treatment of displaced midshaft clavicle fractures are on par with plate fixation. There was no statistically significant difference in the functional outcomes between the TENS and plate groups. Thus, TENS is a less invasive surgical approach than plate fixation and can be utilised to fixate displaced midshaft clavicle fractures.

Keywords: Clavicle, Plate Fixation, TENS, Functional Outcome

INTRODUCTION

2.6% of all fractures are clavicle fractures, with the middle portion of the clavicle accounting for more than 80% of these cases.[1] Displaced midshaft clavicle fractures have historically been treated conservatively. Nevertheless, there have been recent reports of poor results following conservative therapy for these fractures, including non-union of the fracture, shortening of the clavicle, or significant functional limitations.[2–3] In displaced midshaft clavicle fractures, clavicle length shortening of > 2 cm (i.e., no cortical contact between the proximal and distal fragments radiographically) is generally recognised as a criterion for surgical intervention.[4] The two implants that are most frequently utilised to treat displaced clavicle fractures are plates or intramedullary devices. The most popular kind of implant is the plate kind, yet there have been reports of issues such as wound infection, wound dehiscence, numbness or discomfort on the skin, implant failure, and subpar cosmetic outcomes.[5,6] Thus, to treat displaced midshaft clavicle fractures, intramedullary implants utilising minimally invasive surgical techniques were designed. These offer the benefits of reducing wound dehiscence, lowering infection rates, preventing plate discomfort, and improving cosmetic satisfaction. Additionally, intramedullary implants may improve the formation of a callus at the fracture site by

maintaining the periosteum, soft tissue envelope, and vascular integrity surrounding the fracture location.[7-9] When treating displaced midshaft clavicular fractures, the use of intramedullary implants appears to offer more benefits than plate fixation.[10] One kind of intramedullary device is the Titanium Elastic Nail (TEN) system from Synthes Holding AG in West Chester, Pennsylvania, USA. Displaced midshaft clavicle fractures have been successfully treated using TENS; benefits include the system's elastic nature, ease of insertion, minimal incision site, low infection rate, high union rate, and high satisfaction rate with good functional outcomes.[7,11,12] However, due to the telescope effect following TENS fixation, problems associated with TENS fixation in midshaft clavicle fractures include medial migration of the nail tip and clavicle length shortening after fracture healing, particularly in comminuted fractures.[13]

MATERIAL AND METHODS

A comparative study was conducted of duration 18 months at Department of Orthopaedics, Rural Medical College, Pravara Institute of Medical Sciences, Loni, Maharashtra on patients with displaced clavicle fractures.

Inclusion criteria were:

(1) a markedly displaced clavicle fracture (no cortical contact between the proximal and distal fragments on radiography and/or > 2 cm of shortening) [5,6];

(2) patients older than 16 years; and

(3) patient's ability to provide complete information, sign a consent form, fill out questionnaires, and attend further follow up.

Exclusion criteria:

(1) pathologic fracture;

(2) previous clavicle fracture nonunion;

(3)inability to provide complete information, sign a consent form, fill out questionnaires, or attend further follow up.

Data collection:

Patients' consent was taken after giving proper information. There were two groups of cases. Group B is the nail group, and Group A is the plate group. Individuals in the TENS cohort had TENS fixation, which involved a 1-2 cm incision and insertion from the sternal end of the clavicle. The nail tip was inserted through the proximal clavicle and into the fracture site with the aid of a fluoroscopic guide. Using the closed technique, the fracture was reduced. In a few cases a tiny incision was made right above the fracture site to enable direct visual reduction in the event that closed reduction proved unsuccessful. To avoid irritating the skin, the nail's proximal end was cut close to the cortex. A 3.5 mm reconstruction plate or clavicle plate applied in the anterior or superior position, depending on the fracture pattern and the shape that best fit the clavicle, were used in the plate group to fix the fracture ends of the clavicle. Immediately following the procedure, a sling was given to protect each patient. For a duration of four weeks, patients were instructed to undertake early, cautious, passive shoulder mobility while wearing the sling. Active shoulder range of motion was permitted with both abduction and forward flexion > 90° following the removal of the sling. Active shoulder range of motion was allowed two weeks following surgery in nail-fixed individuals with stable bone contact on radiography. Following surgery, follow-up both clinically and plain radiography was conducted every 2nd week, 6th week and subsequently every month. The amount of clavicle length shortening was measured as the bilateral clavicle length difference. The Constant Murley shoulder score were used to gauge the injured shoulder's functional outcome (CMS: range 0-100 points; best Z 100).[14] The independent t test was used to compare the two groups' functional outcomes and complications.

Statistical analysis:

IBM SPSS Ver. 26 was used to calculate statistics. Independent 't' test was used to compare functional outcome. Microsoft Excelbook 2021 was used to prepare tables. P value < 0.05 was set for the significance.

Results:

Table 1: Demographic profiles

Demographic profile	Group A (Plate group) n = 30		Group B (Nail Group) n = 9		P value
Age (in years)					
≤20	1	3.33	1	11.11	0.23
21 – 30	7	23.33	4	44.44	
31 – 40	6	20.00	2	22.22	
41 – 50	10	33.33	1	11.11	
51 – 60	4	13.33	1	11.11	
> 60	2	6.67	0	0.00	

Mean±SD	39.57±12.09		34.11±1087		
Gender					
Male	29	96.67	8	88.89	
Female	10	33.33	1	11.11	

In the present study in Group A most of the cases were observed in 4th decade of age where in Group B most of the cases were observed in 2nd decade of the age. Statistically no significant difference was observed in age between both groups. In Group A 53.33% cases were observed with # middle 1/3rd shaft clavicle followed by 30% with # lateral end clavicle, 10% with segmental #shaft clavicle and 6.67% with # lateral 1/3rd shaft clavicle whereas in Group B All the cases were diagnosed with # middle 1/3rd shaft clavicle. In group A right was the most affected side where as in Group B left side was the most affected site. Statistically significant difference was observed in operating time between both groups. In both group at 16 weeks radiological union was observed. Post operatively in Group A 3.33% cases were observed with pain at incision site and superficial infection respectively whereas in group B 11.11% cases were observed with skin impingement. At follow up in both groups most of the cases were observed with excellent result which shows no statistical difference in the CMS score between both groups. (p=0.812)

Table 2: Clinical Features

Clinical feature	Group A (Plate group) n = 30		Group B (Nail Group) n = 9		P value
Diagnosis					
#lateral 1/3rd shaft clavicle	2	6.67	0	0	
#lateral end clavicle	9	30.00	0	0	
#middle 1/3rd shaft clavicle	16	53.33	9	100	
segmental #shaft clavicle	3	10.00	0	0	
Side					
Left	13	43.33	6	66.67	
Right	17	56.67	3	33.33	
Operating time	89.53±12.70		57.22±2.22		< 0.0001***
Radiological union					
12 weeks	6	20.00	1	11.11	
16 weeks	21	70.00	7	77.78	
20 weeks	3	10.00	1	11.11	

Table 3: Post op evaluation

Complications	Group A (Plate group) n = 30		Group B (Nail Group) n = 9		P value
Diagnosis					
Pain at Incision site	1	3.33	0	0.00	
Superficial Infection	1	3.33	0	0.00	
Skin Impingement	0	0.00	1	11.11	
None	28	93.33	8	88.89	
The Constant-Murley score					
Excellent	21	70	7	77.78	0.812
Good	9	30	2	22.22	
Mean±SD	86.33±3.86		86±2.83		

DISCUSSION

Currently, the two main implant types used for internal fixation of clavicle fractures are plates and intramedullary devices. The usual surgical procedure for treating displaced midshaft clavicle fractures is plate fixation. But there isn't any clear, compelling data to back up this practice. Comparing intramedullary TENS fixation versus plate fixation for displaced midshaft clavicle fractures, our study showed that the former provides better clinical outcomes. The Constant Murley score did not differ significantly (p=0.812). TEN fixation required less surgical incision than plate fixation in our investigation. Because of the displaced fracture site and the clavicle's S-shaped morphology, plate fixation of a midshaft clavicle fracture requires a large incision in order to fit the plate to the bone[33]. The hardware and the big surgical wound, pain at the site of the incision, and superficial infection are the most often reported problems associated with plate fixation of displaced midshaft clavicle fractures.[5,7,9] According to recent studies, the intramedullary TEN system for treating clavicle fractures has a high patient satisfaction rate and produces great functional benefits for the shoulder.[7,11,16,17] In comparison to standard plate fixation, the TEN system fixes the displaced midshaft clavicle fracture with less soft tissue stripping, less blood loss, a shorter surgical time, and superior cosmetic outcomes.[10, 18, 19] Some writers have stated that because length maintenance is an issue with the TEN system, it is not appropriate for treating comminuted clavicle fractures.[17,20] When fixing comminuted clavicle fractures, some studies still advise using a plate rather than intramedullary implants.[13, 21] The patients in the SP and ST subgroups had a simple fracture pattern with satisfactory functional outcome, which may be the reason why the Constant score in these subgroups was significantly different from the CP subgroup. According to our research, 11.11% of the TENS group's patients had discomfort from skin impingement, which may require nail removal following fracture union. According to some writers, moving the entry site to the lower end of the medial clavicle rather than its centre aids in improving fixation stability and preventing nail migration.[11] A pre-bent hook-shaped nail was suggested by Tarng et al. [17] for improved three-point fixation in the TEN system. In order to stop nail migration, they twisted the nail tip and embedded it beneath the collarbone and soft tissue. In order to engage the thinner and narrower distal clavicle, we have found that it is best to insert the nail tip as far into the clavicle end point as possible[7,15]. After that, we cut the nail tip as close to the cortex as we can to improve fixation and stop it from perforating or migrating. To ensure adequate attachment stability, the nail must also be advanced as far into the lateral fragment as feasible. Under fluoroscopy, the stability should always be verified by firmly pulling the forearm.[13,16] It is possible to reduce the occurrence of nail tip irritation by using these suggested approaches. A few noteworthy limitations of our investigation are its retrospective study methodology, small patient population, and brief follow-up duration. To give a stronger degree of evidence and to further corroborate findings, a prospective study with more data and a longer follow-up period might be required.

CONCLUSION

Functional outcomes from the TEN system for the treatment of displaced midshaft clavicle fractures are on par with plate fixation. There was no statistically significant difference in the functional outcomes between the TENS and plate groups. Thus, TENS is a less invasive surgical approach than plate fixation and can be utilised to fixate displaced midshaft clavicle fractures.

Bibliography

1. Postacchini F, Gumina S, De Santis P, Albo F. Epidemiology of clavicle fractures. J Shoulder Elbow Surg 2002;11:452e6.
2. Hill JM, McGuire MH, Crosby LA. Closed treatment of displaced middle-third fractures of the clavicle gives poor results. J Bone Joint Surg Br 1997;79:537e9.
3. Robinson CM, Court-Brown CM, McQueen MM, Wakefield AE. Estimating the risk of nonunion following nonoperative treatment of a clavicular fracture. J Bone Joint Surg Am 2004; 86:1359e65
4. Canadian Orthopedic Trauma Society. Nonoperative treatment compared with plate fixation of displaced midshaft clavicular fractures. A multicenter, randomized clinical trial. J Bone Joint Surg Am 2007;89:1e10.
5. Liu PC, Hsieh CH, Chen JC, Lu CC, Chuo CY, Chien SH. Infection after surgical reconstruction of a clavicle fracture using a reconstruction plate: a report of seven cases. Kaohsiung J Med Sci 2008;24:45e9.
6. Schwarz N, Ho¨cker K. Osteosynthesis of irreducible fractures of the clavicle with 2.7-MM ASIF plates. J Trauma 1992;33: 179e83.
7. Liu PC, Chien SH, Chen JC, Hsieh CH, Chou PH, Lu CC. Minimally invasive fixation of displaced midclavicular fractures with titanium elastic nails. J Orthop Trauma 2010;24:217e23.
8. Chu CM, Wang SJ, Lin LC. Fixation of mid-third clavicular fractures with knowles pins: 78 patients followed for 2e7 years. Acta Orthop Scand 2002;73:134e9.
9. Capicotto PN, Heiple KG, Wilbur JH. Midshaft clavicle nonunions treated with intramedullary Steinman pin fixation and onlay bone graft. J Orthop Trauma 1994;8:88e93.
10. Wang J, Meng XH, Guo ZM, Wu YH, Zhao JG. Interventions for treating displaced midshaft clavicular fractures: a Bayesian network meta-analysis of randomized controlled trials. Medicine 2015;94:e595.

11. Mueller M, Burger C, Florczyk A, Striepens N, Rangger C. Elastic stable intramedullary nailing of midclavicular fractures in adults: 32 patients followed for 1e5 years. Acta Orthop 2007;78:421e3.
12. Jubel A, Andermahr J, Schiffer G, Tsironis K, Rehm KE. Elastic stable intramedullary nailing of midclavicular fractures with a titanium nail. Clin Orthop Relat Res 2003;408:279e85.
13. Frigg A, Rillmann P, Perren T, Gerber M, Ryf C. Intramedullary nailing of clavicular midshaft fractures with the titanium elastic nail: problems and complications. Am J Sports Med 2009;37:352e9.
14. Constant CR, Murley AH. A clinical method of functional assessment of the shoulder. Clin Orthop Relat Res 1987;214: 160e4.
15. Andermahr J, Jubel A, Elsner A, Johann J, Prokop A, Rehm KE, et al. Anatomy of the clavicle and the intramedullary nailing of midclavicular fractures. Clin Anat 2007;20:48e56.
16. Kettler M, Schieker M, Braunstein V, Ko¨nig M, Mutschler W. Flexible intramedullary nailing for stabilization of displaced midshaft clavicle fractures: technique and results in 87 patients. Acta Orthop 2007;78:424e9.
17. Tarng YW, Yang SW, Fang YP, Hsu CJ. Surgical management of uncomplicated midshaft clavicle fractures: a comparison between titanium elastic nails and small reconstruction plates. J Shoulder Elbow Surg 2012;21:732e40.
18. Zhu Y, Tian Y, Dong T, Chen W, Zhang F, Zhang Y. Management of the mid-shaft clavicle fractures using plate fixation versus intramedullary fixation: an updated meta-analysis. Int Orthop 2015;39:319e28.
19. Chen YF, Wei HF, Zhang C, Zeng BF, Zhang CQ, Xue JF, et al. Retrospective comparison of titanium elastic nail (TEN) and reconstruction plate repair of displaced midshaft clavicular fractures. J Shoulder Elbow Surg 2012;21:495e501.
20. Smekal V, Irenberger A, Struve P, Wambacher M, Krappinger D, Kralinger FS. Elastic stable intramedullary nailing versus nonoperative treatment of displaced midshaft clavicular fracturesda randomized, controlled, clinical trial. J Orthop Trauma 2009;23:106e12.
21. Smekal V, Irenberger A, Attal RE, Oberladstaetter J, Krappinger D, Kralinger F. Elastic stable intramedullary nailing is best for mid-shaft clavicular fractures without comminution: results in 60 patients. Injury 2011;42:324e9.
22. McKee MD, Pedersen EM, Jones C, Stephen DJ, Kreder HJ, Schemitsch EH, et al. Deficits following nonoperative treatment of displaced midshaft clavicular fractures. J Bone Joint Surg Am 2006;88:35e40