Section: Orthopaedics

Original Research Article

PROSPECTIVE ANALYSIS OF FUNCTIONAL OUTCOME OF CLAVICLE FRACTURES MANAGED WITH TITANIUM ELASTIC NAIL SYSTEM (TENS) NAIL OSTEOSYNTHESIS

Raju Rayapuram[1], Sudheer Kumar[2], Muralidhar Bandi[3], Vijaya Kumar Gannu[4], Venkat Lakavath[5]

[1]Assistant Professor, Department of Orthopaedics, Government Medical College and General Hospital, Mahabubabad, Telangana, India
[2]Assistant Professor, Department of Orthopaedics, Government Medical College and General Hospital, Mahabubabad, Telangana, India
[3]Assistant Professor, Department of Orthopaedics, Government Medical College and General Hospital, Mahabubabad, Telangana, India
[4]Assistant Professor, Department of Orthopaedics, Government Medical College and General Hospital, Mahabubabad, Telangana, India
[5]Professor and Head, Department of Orthopaedics, Government Medical College and General Hospital, Mahabubabad, Telangana, India

Received : 10/04/2024
Received in revised form : 15/05/2024
Accepted : 31/05/2024

Keywords:
Clavicle, Mid third fractures, Intra-medullary nailing, Titanium elastic nail system.

Corresponding Author:
Dr.Vijaya Kumar Gannu,
Email: gannuvijay4@gmail.com

DOI: 10.47009/jamp.2024.6.3.56

Source of Support: Nil,
Conflict of Interest: None declared

Int J Acad Med Pharm
2024; 6 (3); 263-267

Abstract

Background: Clavicle fractures accounting for approximately 2.6% of all fractures are usually common in young and active individuals and usually due to high-velocity injuries whereas simple fall is the common aetiology of clavicle fracture in elderly and young children. **Materials and Methods:** This was a prospective study carried out in 30 patients with simple mid-third clavicular fractures, who were treated with closed intra-medullary fixation with TENS nailing. Post-operatively range of movements and ability to get back to routine work were assessed and noted. **Result:** In this study, all 30 patients were in the follow-up group with 22 male and 8 female patients. The mean age was 34.6 years (between 22 and 55 years) in the group. Out of the 30 patients, at 3 months 18 (60%) patients experienced no pain. At 6 months, 22 (73.33%) patients experienced no pain with 5 points. Out of 30 patients, at 3 months 10 (33.33%) patients experienced mild pain and at 6 months 5 (16.67%) experienced mild pain with 4 points. comparing fracture type and union time statistically significant. Comparing constant score with fracture type, statistically not significant. **Conclusion:** Thus, the intramedullary fixation of a displaced midshaft clavicle fracture is a safe minimally invasive technique. The present study advises the use of minimally invasive antegrade titanium elastic nails for the fixation of displaced midshaft clavicle fractures. However, for comminuted fractures plating remains the procedure of choice.

INTRODUCTION

Clavicle fractures accounting for approximately 2.6% of all fractures.[1] are usually common in young and active individuals and usually due to high-velocity injuries whereas simple fall is the common aetiology of clavicle fracture in elderly and young children.[2] By far the commonest site of clavicle fracture is the middle third region accounting for almost 80% of all clavicle fractures. Older studies usually advised a conservative line of management in the fractured clavicle, even when displaced significantly, deeming it to be benign.[3, 4] Older studies suggested that a fracture of the shaft of the clavicle, even when significantly displaced, was a mostly benign injury with an inherently good prognosis when treated nonoperatively.[5,6] Neer[7] reported a nonunion rate of 0.1% with conservative treatment, and Rowe[8] findings the anatomy and treatment of mid-clavicular fractures and showed a nonunion rate of 0.8% in conservatively managed patients. Since then, however, any other authors have failed to demonstrate similar good results with conservative treatment.[9, 10] This may be because the first series included the children and adolescents and their enormous potential for bone healing, may have shown inaccurate results. Those patient-based scoring systems were not used in the first series to record the outcome. Treating conservatively, Hill et al[9] and Smekal et al[11] reported a nonunion rate of 15% in correlation with initial shortening greater than two centimetres. 31% of all patients who were reviewed in the study of Hill et al[9] and Smekal et

al[11] were not satisfied with the treatment results. Thus, displaced mid-shaft clavicle fractures can cause significant, persistent disability, even if they heal uneventfully. Therefore, there is a trend towards the surgical fixation of clavicle fractures based on the unsatisfactory data obtained from conservative treatment. Excellent results with high union rates and low complication rates have been reported from a variety of techniques for the primary fixation of displaced fractures of the clavicle. The clavicle, which is similar to other long bones, is usually best treated with intramedullary methods. So elastic stable intramedullary nailing (ESIN) is recommended for all simple displaced mid-shaft clavicle fractures to minimize the rate of complications like delayed union, non-union, and symptomatic malunion.

MATERIALS AND METHODS

The present study was a prospective evaluation of the outcome of closed, displaced mid-shaft clavicle fractures treated by intramedullary titanium elastic nail system (TENS) which was done in the Department of Orthopedics, GMC GGH Mahabubabadfrom March 2022 to February 2024. The patient was enrolled based on the following inclusion and exclusion criteria. Before the start of the study institutional ethics committee approval was taken and written and informed consent was taken from all patients before enrolling them for study.

Inclusion Criteria

Inclusion criteria a total of 30 patients who meet the following criteria are included in the study, all skeletally mature patients, closed fractures, all the displaced diaphyseal non-comminuted/simple comminution clavicle fractures (>2 cm displacement) - AO 15 B1 and B2 fractures, fractures with shortening of over 20mm, middle third clavicle fractures, and fractures within one week.

Exclusion Criteria

Exclusion criteria were fractures with marked comminution (complex comminution), brachial plexus injuries, fractures older than one week, pediatric fractures, pathological fractures, open fractures, congenital anomaly or bone disease, lateral and medial third clavicle fractures, and any medical contraindication for surgery.

Methodology

The patient was placed in the supine position on a radiolucent table with a sandbag under the ipsilateral shoulder. After administration of anaesthesia (either general/regional), preparation and draping of an injured extremity are done from midline to the upper arm from the entry point the sternoclavicular joint should be accessible then care should be taken in this way the shoulder region is secured using an image to intensifier to confirm this access.

Approach

A horizontal incision of about 1 cm is given lateral to the sternoclavicular joint, where the sagittal diameter of the clavicle is at its maximum and there is no risk of intra-thoracic migration of the nail. The subcutaneous fat was incised along with platysma. The skin incision and pectoral fascia are incised in the same plane followed by careful separation of the underlying musculature. With the help of awl, an entry point is made directly or using a 2.7 mm drill bit can also be used. Titanium ESIN with T-handle was inserted (the size of the nail was measured using formula=0.4* canal diameter in mm). Under fluoroscopy with the help of reduction clamps attempt is made to reduce the fracture. For easy access, a nail was used to create a path in the lateral end of the clavicle later nail was passed from the medial side through the reduced fracture into the lateral end of the clavicle until it was just medial to the acromioclavicular joint. After passing the pin to the lateral end nail is cut close to soft tissue to prevent delicate tissue irritation care must be taken so that sufficient length is left behind for easy extraction. Skin and fascia closed in layers.

Outcome assessment

A constant score assesses the functional outcome. The evidence of bridging callus or obliteration of fracture lines defines the radiographic union.

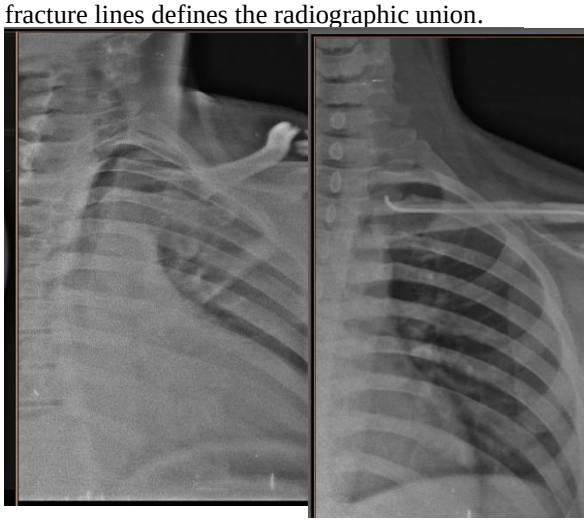

Figure 1 (a and b): Mid-shaft clavicle fractures treated with intramedullary TENS

The absence of tenderness at the fracture site defines the clinical union. The time required for the union of the bone was recorded. The linear difference in lengths of the clavicle from the sternal end to the acromial end between the operated and rational side was measured clinically after the union. This gives the amount of shortening of the clavicle after the union. The perioperative data like the size of the surgical wound, amount of blood loss, and operative time; are the secondary outcome measures. Complications like malunion, nonunion, wound infection, implant failure, implant migration, neurovascular injury, refracture after implant

ISSN (O): 2687-5365; ISSN (P): 2753-6556

removal, soft tissue irritation and cosmetic outcomes regarding scars, hardware prominence under the skin and visible deformity.

Statistical Analysis

Data was collected on an Excel sheet and analyzed by SPSS software version 17. For analysis of data percentage mean and standard deviation were used.

RESULTS

In this study, all 30 patients were in the follow-up group with 22 male and 8 female patients. The mean age was 34.6 years (between 22 and 55 years) in the group.

The evaluation of pain is shown in Table 1. Out of the 30 patients, at 3 months 18 (60%) patients experienced no pain. At 6 months, 22 (73.33%) patients experienced no pain with 5 points. Out of 30 patients, at 3 months 10 (33.33%) patients experienced mild pain and at 6 months 5 (16.67%) experienced mild pain with 4 points. Out of 30 patients, at 3 months 2 (6.67%) patients experienced pain after unusual activities (heavy weight lifting), at 6 months 3 (10%) patients experienced pain after unusual activities (heavy weight lifting) with 3 points. Muscle strength, out of the 30 patients, at 3 months 22 (73.33%) patients' muscle strength was normal, at 6 months 26 (86.67%) patients' muscle strength was normal. Out of 30 patients 8 (26.67%) patients have muscle strength against resistance is seen and at 6 months 4 (13.33%) muscle strength against resistance is seen (Table-1). Occupation status of patients, out of the 30 patients, at 3 months 23 (76.67%) patients were able to do regular work. At 6 months 27(90%) patients were able to do regular work. Out of 30 patients 7 (23.33%) patients were able to do restricted work 3 (10%), patients were able to do restricted work shown in Table.

Table 1: Evaluation of pain, Muscle strength and Occupation status of patients

Parameters		No. of patients	
		At 3 months N (%)	At 6 months N (%)
Evaluation of pain			
Pain scale	**Points**		
Complete disability	0	-	-
Marked pain	1	-	-
Pain at rest	2	-	-
Pain after unusual activities (heavy weights lifting)	3	2 (6.67%)	3 (10%)
Mild pain	4	10 (33.33%)	5 (16.67%)
No pain	5	18 (60%)	22 (73.33%)
Muscle strength			
Normal		22 (73.33%)	26 (86.67%)
Against resistance		8(26.67%)	4(13.33%)
Against Gravity		-	-
Elimination of gravity		-	-
Flicker		-	-
Paralysis		-	-
Occupation status			
Regular work		23 (76.67%)	27 (90%)
Restricted work		7(23.33%)	3 (13.33%)
Unable to work		-	-

Out of 30 patients shoulder range of movements, average (mean ± SD) in flexion is 168.62 ± 8.89, abduction is 171.36 ± 9.56, external rotation is 71.92 ± 5.42, and internal rotation is 73.33 ± 4.53. The table shows the range of movements in patients.

Table 2: Range of movements

Shoulder movements	Average (mean ± SD)
Flexion	168.62 ± 8.89
Abduction	171.36 ± 9.56
External rotation	71.92 ± 5.42
Internal rotation	73.33 ± 4.53

Out of 30 patients, fracture type AO 15 B1, the Average time for union is 8 weeks with average constant score (mean ± SD) is 92.36 ± 4.98, out of 30 patients, fracture type AO 15 B2, average time for union is 10 weeks with average constant score (mean ± SD) is 88.62 ± 3.25, out of 30 patients, fracture type B1+B2, average time for union is 8.4 weeks with average constant score (mean ± SD) is 91.27 ± 2.89, comparing fracture type and union time we obtained p-value 0.046 statistically significant. Comparing the constant score with fracture type, the p-value of 0.51 is statistically not significant.

Table 3: Time taken for fracture union

Fracture type	Average time for union (weeks)	Average constant score (mean ± SD)	P value
AO 15 B1	8	92.36 ± 4.98	0.046

ISSN (O): 2687-5365; ISSN (P): 2753-6556

AO 15 B2	10	88.62 ± 3.25	0.51
Overall (B1+B2)	8.4	91.27 ± 2.89	-

Out of 30 patients, 27 patients 90% functional evaluation using a constant score is excellent, 2 patients 6.67% functional evaluation using a constant score is good, and 1 patient 3.33% functional evaluation using a constant score was fair (Table-4).

Table 4: Functional evaluation using constant score

Result	Constant score	No. of patients (%)
Excellent	86-100	27 (90%)
Good	71-85	2 (6.67%)
Fair	56-70	1 (3.33%)
Poor	1-55	-

DISCUSSION

Plate osteosynthesis, external fixation and intramedullary fixation are the surgical options for fractures of the clavicle. Plate osteosynthesis is considered as a standard method for the surgical treatment of clavicle fractures.[12] The advantage of plate fixation is a sound reduction with compression and rigid fixation. In the present study, 18 patients (60%) have no pain after 3 months and 22 (73.33%) patients have no pain after 6 months. However, complications after plate osteosynthesis are relatively common. In a multicenter prospective randomized trial, plate osteosynthesis has a better functional outcome concerning pain after 3 months and 6 months of treatment than non-operative treatment of displaced clavicle fractures with a decreased rate of non-union and symptomatic malunion which supports our study.[13, 14] Severe complications occur in 10% of all patients and include deep infection, nonunion, keloid scar, implant failure, and fracture after implant removal. Lesser complications include superficial infection, dysesthesia in the region of injury, as well as implant loosening with loss of reduction. Intramedullary stable nailing is an established alternative fixation method. This is supported by the study of Peroni[15] and Zlowodzki et al.[16]

Millett[17] and Mueller et al[18] reported that from the biomechanical point of view, intramedullary nails are ideal, as the tension side of the clavicle changes concerning the rotation of the arm and direction of loading. The other potential benefits of intramedullary nailing include a smaller incision, minimal periosteal stripping, and load-sharing device properties. Its relative stability allows good callus formation during the healing process, this is supported by the work.

The tens nail usage in the multi-fragmentary fracture can lead to telescoping of the pin with shortening of the clavicle. So, the comminuted fractures were excluded as the nail cannot maintain the length of the collarbone in these situations. Hence, Smekal et al[11] do not recommend the use of an intramedullary pin in comminuted fractures with severe shortening. The present study discussed the various advantages of the technique; there were specific difficulties which we experienced. Achieving closed reduction was a difficult task, especially in AO B2 fractures and in obese individuals. We attempted various aids like the use of percutaneous reduction clamps and drilling a k-wire into the fragment to manipulate. Despite these measures, if still reduction cannot be achieved closely, a mini-open incision can be made to reduce the fracture, so that the surgical time, as well as the radiation exposure for both patient and surgeon, can be reduced. The present study does not consider the open reduction of the fracture as unsatisfactory, as despite occur high rate in our practice, we achieved 100% union.

In our study, out of 30 patients, fracture type AO 15 B1, the Average time for union is 8 weeks with average constant score (mean ± SD) is 92.36 ± 4.98, fracture type AO 15 B2, average time for union is 10 weeks with average constant score (mean ± SD) is 88.62 ± 3.25, out of 30 patients, fracture type B1+B2, average time for union is 8.4 weeks with average constant score (mean ± SD) is 91.27 ± 2.89, comparing fracture type and union time statistically significant. Comparing constant score with fracture type, statistically not significant. This finding is supported by the work of Kadakia, Rambani et al.[19]

The patients were followed up postoperatively and constant scores were calculated at two months, three months, and six months. The average constant rating was 27 patients (90%). The nails were removed at an average time of 6 months postoperatively after the fracture had clinically and radiologically healed. One patient had medial protrusion of the nail with local skin perforation, which was subsequently removed early after the fracture had united at around three months which corroborates with the finding of Datta et al.[20]

Kumar et al[21] The experimental document supported our finding, there were no significant complications in our series with only one case of local skin infection due to medial hardware prominence. No other complications like scar neuromas, non-unions or perforation of the posterior cortex were reported. And there were no cases of refracture after implant removal.

CONCLUSION

Thus, the intramedullary fixation of a displaced midshaft clavicle fracture is a safe minimally

ISSN (O): 2687-5365; ISSN (P): 2753-6556

invasive technique. The present study advises the use of minimally invasive ante-grade titanium elastic nails for fixation of displaced midshaft clavicle fractures given, faster fracture union, cosmetic satisfaction earlier rehabilitation, lesser morbidity, easier implant, removal and fewer complications although, for comminuted fractures plating remains the procedure of choice.

Funding: No funding sources

Conflict of interest: None declared

Ethical approval: The study was approved by the institutional ethics committee.

REFERENCES

1. Ropars M, Thomazeau H, Huten D. Clavicle fractures. Orthopaedics & Traumatology: Surgery & Research. 2017;103(1):S53-9.
2. Pecci M, Kreher JB. Clavicle fractures. American family physician. 2008;77(1):65-70.
3. Kalyanasundaram K, Kumar SS, Srinivasan A, Ramesh B. A prospective study of functional outcome of displaced midshaft clavicle fractures treated with intramedullary titanium elastic nail system. nature. 2018;2:3.
4. Patel YC, Lathiya HR, Shah SA, Majumdar S, Gohil PD. A study of functional outcome of clavicle fractures treated by clavicle plating. International Journal of Orthopaedics. 2023;9(1):559-66.
5. Lian J, Chan FJ, Levy BJ. Classification of Distal Clavicle Fractures and Indications for Conservative Treatment. Clinics in Sports Medicine. 2023.
6. Kim W, McKee MD. Management of acute clavicle fractures. Orthopaedic Clinics of North America. 2008;39(4):491-505.
7. Neer CS. Nonunion of the clavicle. Journal of the American Medical Association. 1960;172(10):1006-11.
8. Rowe C. An Adults of anatomy and treatment of mid-clavicular fractures. Clin. Orthop. 1968;58:43-50.
9. Hill JM, McGuire MH, Crosby LA. Closed treatment of displaced middle-third fractures of the clavicle gives poor results. The Journal of Bone & Joint Surgery British Volume. 1997;79(4):537-8.
10. McKee MD, Pedersen EM, Jones C, Stephen DJ, Kreder HJ, Schemitsch EH, Wild LM, Potter J. Deficits following nonoperative treatment of displaced midshaft clavicular fractures. JBJS. 2006;88(1):35-40.
11. Smekal V, Irenberger A, Struve P, Wambacher M, Krappinger D, Kralinger FS. Elastic stable intramedullary nailing versus nonoperative treatment of displaced midshaft clavicular fractures-a randomized, controlled, clinical trial. Journal of orthopaedic trauma. 2009 ;23(2):106-12.
12. Tamaoki MJ, Matsunaga FT, da Costa AR, Netto NA, Matsumoto MH, Belloti JC. Treatment of displaced midshaft clavicle fractures: figure-of-eight harness versus anterior plate osteosynthesis: a randomized controlled trial. JBJS. 2017;99(14):1159-65.
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. The American Journal of Sports Medicine. 2009 Feb;37(2):352-9.
14. Khalil A. Intramedullary screw fixation for midshaft fractures of the clavicle. International orthopaedics. 2009;33:1421-4.
15. Peroni L. Medullary osteosynthesis in the treatment of clavicle fractures. Archivio di ortopedia. 1950;63(4):398-405.
16. Zlowodzki M, Zelle BA, Cole PA, Jeray K, McKee MD. Treatment of acute midshaft clavicle fractures: systematic review of 2144 fractures: on behalf of the Evidence-Based Orthopaedic Trauma Working Group. Journal of orthopaedic trauma. 2005 ;19(7):504-7.
17. Millett PJ, Hurst JM, Horan MP, Hawkins RJ. Complications of clavicle fractures treated with intramedullary fixation. Journal of shoulder and elbow surgery. 2011;20(1):86-91.
18. Mueller M, Rangger C, Striepens N, Burger C. Minimally invasive intramedullary nailing of midshaft clavicular fractures using titanium elastic nails. Journal of Trauma and Acute Care Surgery. 2008;64(6):1528-34.
19. Kadakia AP, Rambani R, Qamar F, McCoy S, Koch L, Venkateswaran B. Titanium elastic stable intramedullary nailing of displaced midshaft clavicle fractures: A review of 38 cases. International Journal of Shoulder Surgery. 2012;6(3):82.
20. Saha P, Datta P, Ayan S, Garg AK, Bandyopadhyay U, Kundu S. Plate versus titanium elastic nail in the treatment of displaced midshaft clavicle fractures: a comparative study. Indian journal of orthopaedics. 2014;48:587-93.
21. Kumar H, Banga RK, Boparai RS, Singh J. Flexible intramedullary nailing for fixation of displaced midshaft clavicle fractures. Journal of Medical Sciences. 2018;38(2):67-72.

ISSN (O): 2687-5365; ISSN (P): 2753-6556