



TITANIUM ELASTIC NAILING SYSTEM IN MID-SHAFT CLAVICLE FRACTURE- A PROSPECTIVE STUDY.

Orthopaedics

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ABSTRACT

Introduction: Young and active persons are liable for clavicle fractures, most common among Racing individuals, sports persons and in athletes due to high velocity injury. Clavicle fractures are about 2.5% of all fractures and it is the most common. Satisfactory results with high union rates and less complications have been reported from various techniques for operating Clavicle fractures. The clavicle is a long bone with broad medial and flat lateral end and is treated best with Intramedullary elastic devices. So, titanium elastic nailing system is the recommended procedure for all displaced midshaft clavicle fractures to reduce the rate of malunion, non-union, delayed union, symptomatic malunion, and Other complications. **Aim Of The Study:** To analyze the functional outcome of displaced middle third clavicle Fractures treated by titanium elastic nailing system that will keep the Anatomical shape and length of the clavicle. **Materials And Methods:** The study was provisionally approved by the institutional ethics committee, Andhra medical College, visakhapatnam. This prospective study of displaced midshaft Clavicle fractures treated by titanium elastic nail system was done at the Department of Orthopedics, King George Hospital, Andhra Medical college, Visakhapatnam, from September 2019 to September 2021. Over a period of 2 years with in my academic years from may 2019 to may 2022. **Conclusion:** Titanium elastic nailing system for displaced midshaft clavicle fracture is a safe minimally invasive technique with good functional and radiological outcomes and has better cosmetic appearance. Clavicular fractures which are displaced at middle third are best treated with titanium elastic nailing system with less operative time of 30-45 minutes compared with clavicular plating which takes more than 60-90 minutes. This procedure has better functional outcome than conservative treatment. A good reliable sophisticated minimally invasive technique for midshaft clavicular fractures are fixed by Closed nailing or minimal open reduction at fracture site.

KEYWORDS

INTRODUCTION

Young and active persons are liable for clavicle fractures, most common among racing individuals, sports persons and in athletes due to high velocity injury. Clavicle fractures are about 2.5% of all fractures and it is the most common bone to be fractured. The most common site is the middle third due to fall on lateral shoulder and are about 80% of all clavicle related injuries.

Earlier studies suggested that a displaced fracture of the clavicle shaft, was a benign injury with an inherently good prognosis when treated non-operatively. (3, 36). With the conservative management, Neer reported in his studies about 0.1% of non union rate in clavicle fractures.

Treating conservatively, Hill et al. reported a 15% of non-union rate With respect to the initial shortening greater than 2 cms. 31% of patients who were reviewed in the study group of Hill et al. were not satisfied with treatment results. (7)

Thus, clavicle fractures with displacement can cause significant problem. Thus, there is a trend towards surgery for clavicle fractures based on the unsatisfactory data obtained from conservative treatment. Satisfactory results with high union rates and less complications have been reported from various techniques for operating clavicle fractures. The clavicle is a long bone with broad medial and flat lateral end and is treated best with intramedullary elastic devices.

So, titanium elastic nailing system is the recommended procedure for all displaced midshaft clavicle fractures to reduce the rate of malunion, non-union, delayed union, symptomatic mal-union, and other complications.

AIM OF THE STUDY

To analyze the functional outcome of displaced middle third clavicle fractures treated by titanium elastic nailing system that will keep the anatomical shape and length of the clavicle.

MATERIALS AND METHODS

The study was provisionally approved by the institutional ethics committee, Andhra medical College, visakhapatnam. This prospective study of displaced midshaft clavicle fractures treated by titanium elastic nail system was done at the Department of Orthopedics, King George Hospital, Andhra medical college, Visakhapatnam, from September 2019 to September 2021 over a period of 2 years with in my academic years from may 2019 to may 2022.

Inclusion Criteria:

A total of 20 patients who fit into the criteria are included in the study.

- All patients after skeletal maturity.
- Displaced diaphyseal fractures with or without simple comminution.
- clavicle fractures (>2cm displacement) – AO classification for clavicle 15 B1 and B2 type of fractures.
- Fractures with shortening of more than 2cm.
- Fractures less than one week.

Exclusion Criteria:

- Fractures with gross comminution.
- Neurovascular upper limb injuries.
- Fractures older than one week
- Pediatric fractures
- Pathological fractures
- Open fractures
- Congenital anomaly or bone disease.
- Any medical contraindication for surgery.

SURGICAL TECHNIQUE:

Titanium Elastic Nail System For Midshaft Clavicle Fractures.

After providing anesthesia (either general/regional), place the patient in a beach chair supine position with a radiolucent towel under the

scapular subway . The injured extremity was scrubbed ,painted and draped over clavicular region. Care must be taken to ensure that the SC joint should be exposed properly.

A 1 cm vertical or horizontal incision was made a side of sternoclavicular joint on the index side . Dissection done through the subcutaneous fascia and splitting the platysma. The pectoral fascia was divided horizontally and careful exposure of the medial side of the clavicle. Make an entry point using a drill or k -wire with help of drill guide or sleeve, do not use bone awl directly over the medial end because there is chance to injure the underlying structures . After drill then use the bone awl to create a suitable entry for the nail to pass. Appropriately sized TENS loaded into the T- handle (Formula for nail size = $0.4 \times \text{canal diameter in mm}$). Under C-ARM control, try to pass the fracture site and to reduce the fracture without opening the fracture site.

We can also use percutaneously reduction clamps. If the fracture is not reduced by any means then a mini- incision was made at the fracture site to manipulate the distal fragment. The proximal fragment was controlled using the TENS and try to negotiate the fracture site . There is no need to pass the nail completely into the lateral fragment as it may penetrate the cortex because it is flat. Stop the nail at coraco – clavicular ligament junction. Check 30 degree cephalic and caudal views to confirm the position of the nail . Using the Nail cutter , cut the nail and bang it under the skin , wound wash should be given and skin closed in single layer , sterile dressing should be done.

POSTOPERATIVE PROTOCOL:

Postoperatively, all patients are advised to wear a arm pouch for 1 week until pain subsides but initially we start rehabilitation for early range of motion. Wall walking physiotherapy was adviced as pain subsides and we usually discharge the patients on 5th postoperative day. After seven days, passive and active range of motion for shoulder were started, and overhead abduction was allowed after 2 weeks. The arm pouch was discarded around two weeks; after those activities of the daily work was initiated and those with heavy weight lifting and gymnastics were restricted until they attain clinical union. All patients are advised to visit our OP department number 10 in King George hospital, Visakhapatnam at 2nd week for physiotherapy and suture removal and 6th week, later 3, 6, 12 months after surgery. At each visit, patient were addressed to evaluate the functional outcome and fracture union. We collect the date and preserved in dissertation book after every visit.

OUTCOME ASSESSMENT

The Functional outcome was assessed by using the Constant- murley scoring system. Radiological union was attained by the presence of periosteal bridging callus.

Clinical union was acceptable when there is no jog of movement and when there is no tenderness at the site of fracture Probable time to achieve union was noted . After union was achieved, we must measure the difference in clavicle lengths from sternum to acromial end between operated limb and normal side for any shortening.

Other outcome measures include total procedure time, closed / mini open procedure, blood loss and size of the wound; complications like , refracture at the time of implant removal and cosmetic outcome like deformity, scars, and nail prominence etc.

By the end of 6th month of follow up , we do implant removal routinely.

CONSTANT-MURLEY SCORE TECHNIQUE

This scoring system consists of 4 parameters that are used to assess the over all function of the shoulder girdle . We assess the right and left shoulders separately.

The subjective parameters are pain and ADL (recreation / sport, working ability and sedentary) which gives a total score of 35 points. The objective parameters are range of movements and strength which give a total of 65 points.

RANGE OF MOVEMENTS

Active range of movements should always be measured as part of the CONSTANT- MURLEY Score. There is specific way recommended by ESSES (European Society for Shoulder and Elbow Surgery) for measuring range of movements. Patient should be seated on a chair or bed, with body weight evenly distributed between the spine and the

pelvis . No rotational movements of the upper part of the body should take place during the shoulder examination.

In case of active range of movement, the patient lifts his arm up to a pain free range. The range of movement is determined in degrees at which the pain starts. If we measure the active range of movement with pain, this should be noted. The CONSTANT-MURLEY score should not be applied beyond the initiation of pain.

SCORING

0-55 - POOR
56-70 - MODERATE
71-85 - GOOD
>85 - EXCELLENT

OBSERVATION

The study included a total of 20 patients, among them there were One male and six females. In our study, the maximum no. of patients was in the 20 -30 yrs. age group. The maximum number of cases were due to Road traffic accidents. Right side involvement was more in the study patients, with 12 patients involving right clavicle and 8 patients left clavicle. In the study group, we had only 2 patients with associated injuries, which includes a contralateral humerus fracture and another case with ipsilateral fracture femur both were addressed simultaneously. 12 patients belong to AO B1 type (Diaphysis simple) and 8 patients belong to AO B2 type (Diaphysis wedge). All the patients were admitted and operated within 7 days after injury, most of them are within 3 days. The mean surgical duration for this technique is 49.5 minutes (range 30-60 minutes).

RESULTS

EVALUATION OF PAIN:

Pain scale	Points	No. of patients	
		At 3 months	At 6 months
No pain	5	12(60%)	17(85%)
Mild pain	4	6(30%)	2(10%)
Pain after unusual activities	3	2(10%)	1(5%)
Pain at rest	2		
Marked pain	1		
Complete disability	0		

RANGE OF MOVEMENTS:

S. No.	Shoulder Range Of Movements	Average (Mean $\pm$ Standard Deviation)
1	Flexion	165.75 $\pm$ 9.21
2	Abduction	166.25 $\pm$ 10.49
3	External rotation	72.5 $\pm$ 6.5
4	Internal rotation	74.25 $\pm$ 5.19

MUSCLE STRENGTH:

S. No	Muscle Strength	No. Of Patients	
		At 3 months	At 6 months
1.	Normal	15(75%)	18(90%)
2.	Against resistance	5(25%)	2(10%)
3.	Against gravity	-	-
4.	Elimination of gravity	-	-
5.	Flicker	-	-
6.	Paralysis	-	-

OCCUPATION LIMITATIONS:

S. No	Occupation Status	No. Of Patients	
		At 3 months	At 6 months
1.	Regular work	15(75%)	18(90%)
2.	Restricted work	5(25%)	2(10%)
3.	Unable to work		

DURATION FOR FRACTURE UNION:

Type Of Fracture	Average Duration For Union(weeks)	Average Constant- murley Score (mean $\pm$ Standard Deviation)
AO 15 B1	8	90.33 $\pm$ 3.91
AO 15 B2	10	89.5 $\pm$ 3.16
Overall (B1+B2)	8.8	90 $\pm$ 3.5

Comparing the duration for union and type of fracture and we procure a p value of 0.047 – which is statistically significant.

Comparing CONSTANT - MURLEY score with the fracture pattern , p

value 0.521 –which is not statistically significant.

FUNCTIONAL EVALUATION USING CONSTANT SCORE:

S. No.	Result	Constant Score	No. Of Patients	Percentage
1	EXCELLENT	86-100	18	90%
2	GOOD	71-85	2	10%
3	FAIR	56-70	0	0%
4	POOR	1-55	0	0%

Statistical Analysis

The data was collected and analyzed. To describe about the data descriptive statistics frequency analysis, percentage analysis was used for categorical variables and the mean & S.D were used for continuous variables. To find the statistical significant difference between the samples in independent groups the Mann-Whitney U - test was used. To assess the relationship between the variables Spearman's rank Correlation was used. In both the above statistical tools the probability value of 0.05 is considered as reliable significant level.

Fracture Type Compared With Time For Union And Constant – Murley Score:

Ranks				
AO CLASS		N	Mean Rank	Sum of Ranks
TIME FOR UNION	B1	12	8.33	100.00
	B2	6	13.75	112.00
	Total	20		
CONSTANT SCORE	B1	12	11.25	135.00
	B2	6	9.38	75.00
	Total	20		

Test Statistics ^a					
	Mann-Whitney U	Wilcoxon W	Z	Asymp. Sig. (2-tailed)	Exact Sig. [2* (1-tailed Sig.)]
TIME FOR UNION	22.000	110.000	-2.705 ^b	.048	.047 ^b
CONSTANT SCORE	59.000	75.000	-.705	.478	.521 ^b

a. Grouping Variable: AO CLASS

b. Not corrected for ties.

When type of fracture and duration for union are compared, we obtained p value of 0.047 which is statistically significant, whereas fracture type and the resultant constant score does not show any statistical significance as the p value obtained is 0.521.

Non-Parametric Correlations:

Correlations				
Spearman's rho	TIME FOR UNION	Correlation Coefficient	1.000	-.015
		Sig. (2-tailed)		.949
		N	20	20
CONSTANT SCORE	Correlation Coefficient	-.015	1.000	
	Sig. (2-tailed)	.949		
	N	20	20	

There is no statistical significance when the variables, duration for union and CONSTANT – MURLEY score are compared as the p value is 0.949, which is not statistically significant.

DISCUSSION

Plate osteosynthesis, external fixation, and intramedullary fixation are the possible surgical treatment options for the clavicular fractures. Clavicular plate osteosynthesis is still consider as a standard method for the surgical treatment of clavicle fractures.

The advantage of clavicular plating is good reduction and rigid fixation. However, complications with clavicular plating are common. A study - prospective randomized trial, clavicular plating had better functional outcome than non-operative treatment of displaced clavicle fractures with less chance of non-union and symptomatic malunion.

Complications like deep infection, non-union, implant failure, and fracture after implant removal are noted in minor group of individuals. Lesser complications like superficial infection, keloid scar, loss of sensation over clavicular area are also reported. Intramedullary Nailing is an alternative fixation method.

Intramedullary elastic nails are ideal from the biomechanical point of view as the tension side of clavicle changes with respect to rotation of arm and direction of loading. The benefits of intramedullary elastic nailing include mini-incision, minimal periosteal stripping, and load sharing properties. Its relative stability allows periosteal bridging

callus formation during the healing process and good remodeling occurs due to load sharing property.

The frequent complication is skin irritation from the prominent medial end of the nail and skin perforation can occur leading to premature removal of the nail. Titanium elastic nailing system for comminuted clavicle fractures can result in shortening of the clavicle. Thus, the comminuted fractures are not included in the study with elastic nail that cannot maintain the length of the clavicle.

Smekal et al. recommend not to use intramedullary elastic nail in comminuted fractures with severe shortening. Duan et al. in a randomized controlled trials demonstrated good functional outcome when comparing plating with intramedullary elastic nail fixation. (1) They, however, encountered symptomatic hardware-related problems with clavicular plating. Vologodskiy et al. in a systematic review of around 2000 cases found nonunion rate of 1.6% with intramedullary elastic nail fixation as compared with 2.5% with plate fixation. (1)

Management of midshaft clavicular fractures has gotten many advantages over open reduction and internal fixation with plating because of minimally invasive technique, less operative time, decreased postoperative pain, faster recovery, and cosmetically accepted scar. The present study shows that operative treatment of mid-shaft clavicular fractures by closed titanium elastic nailing is a novel approach. Titanium nails are cheaper than clavicular plates and easily affordable to poor patients.

Titanium elastic nailing system would be choice of treatment for midshaft clavicular fractures displaced more than 2 cms and patients requiring early functional range of movements and overhead activity and early return to work. Overhead activity was started 3 weeks postoperatively.

With conservative management, patients must wear clavicular braces for about six weeks, that results in delayed rehabilitation. Dawson et al. concluded that there were no significant differences in functional outcomes between clavicular plating and intramedullary nailing, but clavicular plating had a higher complication rate than nailing. Muller et al. around 35 cases treated with midshaft clavicular fractures treated by Intramedullary nailing with titanium elastic nail system(TENS), found that intramedullary fixation of midshaft clavicle fractures with Titanium elastic nails were a safe, reliable, and minimally invasive with excellent cosmetic and functional outcomes.

Zhang et al. found that intramedullary elastic nailing has more advantages over clavicular plating with a reduced duration of surgery, a small incision, rapid union time, better shoulder function at 6 months and fewer complications like hardware prominence, refracture during implant removal and hypertrophic scar. (21)

Zahir S et al. Observed that the mean surgical time and mean time of continuous radiological monitoring were significantly shorter in the intramedullary elastic nailing group than those in minimally invasive percutaneous plate osteosynthesis group. Hospital stays and duration for union was significantly shorter in the nailing group as compared to MIPPO group. (30)

As we discussed about various advantages of this minimally invasive technique, despite there were certain complications which we experienced. Achieving a closed reduction was a difficult procedure particularly in AO B2 fractures and in obese patients. We attempted various methods like use of percutaneous reduction clamps and drilling a k-wire or schanz pin into the fragment to manipulate the distal fragment. Despite these trial methods, if still reduction could not be achieved, a mini open incision can be made to reduce the fracture by using a spike. So that the surgical duration as well as the radiation exposure for both the surgeon and patient can be reduced. we achieved good functional, radiological, and cosmetic outcome in midshaft, non-comminuted clavicle fractures with more than 2cm shortening/ displacement with intramedullary titanium elastic nail system with no major complications. In our study there is significant statistical correlation between type of fracture and time for union ($P < .047$) although there is no other variable showed statistically significant.

CONCLUSION

Titanium elastic nailing system for displaced midshaft clavicle fracture is a safe minimally invasive technique with good functional

and radiological outcomes and has better cosmetic appearance .

Clavicular fractures which are displaced at middle third are best treated with titanium elastic nailing system with less operative time of 30-45 minutes compared with clavicular plating which takes more than 60-90 minutes. This procedure has better functional outcome than conservative treatment . A good reliable sophisticated minimally invasive technique for midshaft clavicular fractures are fixed by Closed nailing or minimal open reduction at fracture site.

Pre-requisites are : we need a C-Arm and a radiolucent table in order to perform the surgery in a mini – incision.

In this study, we use minimally invasive titanium elastic nailing system for fixation of displaced midshaft clavicle fractures to achieve:

- fast union rates
- earlier rehabilitation
- lesser morbidity,
- implant removal is easy and
- fewer complications.

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