



**FUNCTIONAL OUTCOME OF CLOSED MIDSHAFT CLAVICLE FRACTURES
TREATED WITH TITANIUM ELASTIC NAIL SYSTEM VS NON OPERATIVE
MANAGEMENT - A COMPARATIVE STUDY**

Dr. Akshaya*

Post Graduate, Anil Nilaya Swastik Nagar, Bilgundi Layout, Kalaburagi, Gulbarga, Karnataka, India.

***Corresponding Author: Dr. Akshaya**

Post Graduate, Anil Nilaya Swastik Nagar, Bilgundi Layout, Kalaburagi, Gulbarga, Karnataka, India.

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ABSTRACT

Introduction: Clavicle fracture is the most common type of all fractures. Traditionally, clavicle fractures are treated non-operatively with a clavicle brace and broad arm sling, Outcomes of non-operative treatment are not always excellent. In recent year's, operative modality is being preferred by many surgeons. **Methodology:** Study conducted in department of orthopaedics, mahatma gandhi medical college and research institute Pondicherry, After obtaining Human Ethical committee approval 40 patients were included in the study, Total of 40 patients were selected for the study, patient were allowed to choose the type of treatment after explaining the advantage and disadvantage of both the procedure, were divided into two groups, group A for TENS nailing, Group B assigned for non operative, patient's were assessed using constant murley score system. **Results:** 10 Patients who underwent TENS nailing showed faster union time then non operative group. Significant Shortening of clavicle was seen in the non-operative group. **Conclusion:** Operative treatment yielded in lesser complications such as malreduction, and shortening of the clavicle compared to non operative treatment and also showed early fracture union time and functional outcome remains the same irrespective of the type of treatment approach.

INTRODUCTION

Clavicle fracture is the most common type of all fractures. It accounts for about 2-6% of all fractures and the most common type being mid shaft fractures (80%).^[1] It is the most common fracture of childhood. A fall onto the lateral shoulder is the most frequent cause of a clavicle fracture.

Clavicle fractures are treated non-operatively with a clavicle brace and broad arm sling, but most of the non operative treatments need regular adjustment, and is inconvenient to the patients. Surgical treatment options for mid shaft clavicle fracture include intramedullary fixation by TENS nailing and plating. Patient treated non-operatively had a non-union rate of 5.9% while those who were treated with intramedullary fixation had a non-union rate of 1.6%.^[4]

Outcomes of non-operative treatment are not always excellent, there has been increasing evidence that the outcome of non-operatively treated (especially displaced or shortened) mid shaft fractures is not as optimal as was once thought. Whereas patient treated with operative management like TENS nailing had better outcome. Furthermore, a recent meta-analysis showed a significant decrease for developing non-union after operative treatment.^[5]

As discussed above, the management of clavicle fracture has progressed over the last decade, notably with wider use of surgery in midshaft fracture and also new techniques for lateral end fracture fixation. Midshaft clavicle fracture treatment needs to be personalized and adapted to the patient's required activity level.

This study aims to compare the functional outcome using constant murley shoulder score for closed mid shaft clavicle fracture treated with two different options which are TENS nailing and non operative management.

METHOD

- A prospective comparative study done at Mahatma Gandhi medical college and Research Institute, Pondicherry, India.
- Between Feb2020-April2021 where all the patients coming to OPD and casualty, diagnosed as closed mid shaft clavicle fracture, satisfying inclusion and exclusion criteria were included. The study was started after ethics committee approval.
- Total of 40 patients were selected for the study, patient were allowed to choose the type of treatment after explaining the advantage and disadvantage of both the procedure including total expenditure.
- They were divided into group A and group B.
- Group A consisting of 20 patients were treated by non-operative.

- Group B consisting of 20 patients were treated by titanium elastic nail.

INCLUSION CRITERIA

- Age 18-80years.
- Closed simple mid shaft clavicle fracture.
- Clavicle fracture (with more than 2cm displacement).

EXCLUSION CRITERIA

- Patients with un displaced fracture,
- Open fractures,
- Comminuted fractures,
- Pathological fractures,
- Floating shoulder,
- Ipsilateral upper limb fracture,
- Associated neurovascular damage.

PROCEDURE

Non-Operative Method

Non-operative treatment consists of strapping and clavicle brace.

FOLLOW UP

- X-ray were taken on the following post reduction days 7,14,21 and 28th day and followed by that on 6th week, 3rd month and 6th month. At the end of 1st week pendulum exercise was started and at 4th week the range of movements of the pendulum swings was increased gradually up to 90°.
- At 6th week full range of movements was started.
- All patients were advised to return to light work and day to day activities according to their pain tolerance.

OPERATIVE METHOD

Instruments

- T handle
- Chuck key
- Bone nibbler
- Bone awl
- Hammer
- Jumbo cutter
- Various size Titanium Elastic Nail.(1.5-4mm)

Figure 3: Instruments used in TENS nailing.

SURGICAL APPROACH

- A 2cm skin incision was made over the clavicle just lateral to the sternoclavicular joint.

Figure 4: Bony landmark.

NAIL ENTRY

- An awl was used to make the nail entry, first perpendicularly and then directed along the axis of the clavicle. Confirming the position under fluoroscopy.

Figure 5: Entry of the TENS nail.

Figure 6: Intra-operative C-arm image.

REDUCTION OF THE FRACTURE

- With two pointed clamps one on medial and one on lateral fragment was held percutaneously and the reduction was attempted.
- Nail was advanced across fracture site by oscillating movements.
- The assistant then lifted the lateral fragment up to align it with the medial fragment.
- The nail was advanced to the distal end of the clavicle making sure it stayed 1cm short to acromioclavicular joint.

POST-OPERATIVE FOLLOW UP

- Postoperatively the limb was immobilised with sling. Active range of motion (ROM) exercises - elbow, wrist and hand under the supervision of a physiotherapist was started on day one after the surgery, the affected limb was supported with a broad arm sling for 3 weeks.
- At the end of 1st week pendulum exercise was started. At 4th week the range of movements of the pendulum swings was increased gradually up to 90°.
- At 6th week full range of movements was started. All patients were advised to return to light work and their day to day activities based on their pain tolerance.

RESULTS

- Data contains measurements on 21 subjects whose age ranges from 18 - 60 years with mean age 34.9 ± 12.26 years. The following table gives the distribution of different variables.
- Out of 21 subjects, 20 (95.24%) were males and only 1 (4.76%) was female.
- Majority (85.71%) had RTA while (14.29%) has history of fall from height.
- 10 (47.62%) had non operative management and 11 (52.38%) had TENS management.
- 12 (57.14%) had injury at right side and 9 (42.86%) had injury at left side.
- Only 1 (4.76%) subject had complication (Nail backout).
- 10(100%) non operative patients and 11(100%) TENS had shortening of mean of 8.4, and 3.2 respectively.
- 10(100%) had malreduction in non operative group.

Figure 8: From two sample t test, we observe that, there is significant difference in mean time to union over management. Further, it is observed that, time to union is more for non-operative management. There is no significant difference in mean age over management.

Table 1: Comparison of different variables over management.

Variables	Sub Category	Management		p-value
		Non-Operative	TENS	
Age (years)	Mean \pm SD	37.6 \pm 12.38	32.45 \pm 12.19	0.3498 ^t
	Median (Min, Max)	39 (19, 58)	28 (18, 60)	
Gender	Male	1 (10%)	0	0.4883 ^{MC}
	Female	9 (90%)	11 (100%)	
Mode of Injury	Fall from height	2 (20%)	1 (9.09%)	0.5877 ^{MC}
	RTA	8 (80%)	10 (90.91%)	
Fracture Type	Type 1	10 (100%)	11 (100%)	0.8273 ^C
Side	Left	5 (50%)	4 (36.36%)	0.6817 ^{MC}
	Right	5 (50%)	7 (63.64%)	
Complication	NAIL BACKOUT	0	1 (9.09%)	1 ^{MC}
	Nil	10 (100%)	10 (90.91%)	
Time to union	Mean \pm SD	20.97 \pm 2.41	14.9 \pm 1.92	< 0.001 ^{t*}
	Median (Min, Max)	21.1 (17, 24.5)	15 (12, 18)	
Non-Union	No	10 (100%)	11 (100%)	0.8273 ^c
Shortening	Median, Average \pm Standard deviation	8.4, 8.31 \pm 0.72	3.2, 3.3 \pm 1.16	<0.001 [*]
Malreduction	Yes	10	0	<0.001
	No	0	11	

- Abbreviation: C – Chi square test, MC -Chi square test with Monte Carlo simulation, t – Two sample t test, * indicates statistical significance.

Table 2: Comparison of constant murley score with management.

Time points	Management		p-value
	Non-Operative	TENS	
6 Weeks	73.10 \pm 7.26	77.27 \pm 4.84	0.1345 ^t
	76.5 (60, 80)	79 (68, 82)	
3 Months	84.90 \pm 5.43	85.18 \pm 4.26	0.8956 ^t
	87.5 (74, 90)	86 (77, 91)	
6 Months	89.70 \pm 4.92	90.45 \pm 2.58	0.6606 ^t
	91 (78, 94)	91 (85, 94)	

From repeated measures of ANOVA, we observe that, There was no significant difference of CM score between the two groups at 6th week (p-value = 0.134), 3rd month (p-value = 0.896) and 6th month (p-value = 0.661).

1. DISSCUSSION

One of the most common fractures found in orthopaedics is the clavicle fracture which accounts for 2.6% of all orthopaedic fractures. Among this clavicle fractures the most common type is mid shaft fractures, prevalence of which is about 80%.^[1]

Clavicle acts as a "strut" that keeps the upper limb away from the torso for efficient shoulder and upper limb function while also transmitting forces from upper limb to the trunk. Traditionally, clavicle fracture is being treated non-operatively with a figure-of-eight bandage or a broad arm sling.^[4]

As the research progressed, the treatment of midshaft fracture clavicle has been in the form of a simple sling, figure of eight clavicle brace, crepe bandage as a figure of eight and so on. Whereas the almost all conservative treatments need regular adjustment which a quite cumbersome and inconvenient to the patients.^[3,4]

Outcomes of non-operative treatment are not always excellent. In Rockwood and Green's Fractures in Adults they observed that there has been increasing evidence that the outcome of non-operatively treated midshaft fractures is not as optimal as was once thought. Hence the operative management specially with TENS has showed the better outcome in majority of the evidences. Hence we conducted a study to compare the outcome of conservative versus the patients treated with TENS for the management of mid clavicle fracture.^[1]

In our study, 21 subjects were recruited based on the inclusion criteria. Mean age of the recruited sample was 34.9 \pm 12.26 years. Out of these 21 subjects, 20 (95.24%) were males and only 1 (4.76%) was female. Similar to our study, **Shetter VG et al**^[7] also reported the increased incidence of mid shaft clavicle fractures among the young adults with males predominance in their study. **Nowak J et al**^[16] in their epidemiology of clavicle fracture also had observed that the incidence of clavicle fracture as such was lesser as the age progressed and the incidence of male patients was significantly high. Another study by **Paladini et al**^[17] also had reported the mean age of 29.3 years and the incidence decreasing significantly after the second decade of life. They also observed that the males were affected approximately twice than females (67.9% vs 32.1%).

In our study, the cause for fracture is about 85.71% due to RTA while 14.29% had fell from height. **Browner BD et al**^[18] had discussed that the younger individuals often sustain clavicle injuries due to motor vehicle accidents or sports injuries, whereas elderly individuals are more likely to sustain injuries because of the sequela of a low-

energy fall. And they had also observed that pathological fracture of clavicle is the least expected cause.

In our study, 10 (47.62%) patients were managed non-operative and 11 (52.38%) by TENS management.

We observe that, there was no significant association of gender, mode of injury, fracture type, side of injury, complications, non union with management. From two sample t test, we observe that, there is significant difference in mean time to union over management. Further, it was observed that, time to union was more for non-operative management. There was no significant difference in the side of clavicle involved and the type of fracture.

We observe that, there was no significant difference in functional outcome between the TENS and non operative group at all 3 time intervals at 6th week, 3rd month, 6th month respectively.

The average duration required for the union of fracture was 20.97 ± 2.41 and 14.9 ± 1.92 among the conservative and TENS group respectively with the significant p value of <0.01 . This finding is in consistent with **Shetter VG et al**^[7] among which the union rate of our study for operative treatment is 13.16 weeks and management for CM score.

In our study, shortening of clavicle was measured after the union and it was found that, the mean shortening was 3.2mm and 8.4mm in TENS and non operative group respectively with significant p value of <0.01 , the finding was consistent with **Shetter VG et al**.^[7]

In our study, none of the patients were presented with non-union of the fracture in operative treatment whereas 5.26% non-union rate in non-operative treatment. Contrary to this, in **Zlowodzki et al**^[4] the non-union rate was 4% by operative and 6% by non-operative management.

2. LIMITATIONS

- Smaller sample size in view of prevailing covid pandemic.
- Single centered study.

3. CONCLUSION

- Operative treatment (TENS) yielded in lesser complications such as malreduction, and shortening of the clavicle compared to non operative treatment and also operative (TENS) treatment showed early fracture union time.
- Irrespective of type of treatment whether operative (TENS) or non operative, functional outcome remains the same.