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"A Comparative Study Of Plating Versus Titanium Elastic Nailing System in management Of Displaced Midshaft Clavicle Fractures".

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ABSTRACT: BACKGROUND: Clavicle is one of the most common bones to sustain injuries. Despite the high frequency, the choice of proper treatment is still controversial. A randomized comparative study was planned to compare Plating versus TENS to manage clavicle fractures.

METHODS: Study was conducted in the Department of Orthopaedics, Narayana Medical College, Nellore from August 2018 to March 2020. Patients aged 20-55 years with closed displaced were included in the study. Patients were randomized in two groups- One group (25 patients) treated with TENS and second group (25) with the plate. The outcome assessed by pain VAS score, Constant &Murley score, DASH score, cosmetic result, radiological fracture healing time.

RESULTS: Mean fracture union time in TENS group was 11.4±2.12 weeks and in plate group 13.4±3.46 weeks (difference was significant p=0.016). Mean pain VAS score in TENS group was 2.56±0.91 and in plating group 3.12±0.8 (p=0.023). TENS group were cosmetically more satisfied (mean score 4.48±0.7) than plate group (mean score 3.8±1.0, p=0.009). Mean DASH and Constant Shoulder Score in TENS group were 1.87±3.4, 9.36±7.04 and the plate group 4.8±9.0 and 15.08±9.4 respectively.Both were significant (p=0.039, p=0.000).

CONCLUSIONS: Our study found that patients treated with TENS showed excellent outcome in 84%cases while 60% in plating group for displaced mid-shaft clavicle fracture. Results in TENS group were better in terms of Constant &Murley score and DASH score than treated with the plate.

I. INTRODUCTION

A clavicle fracture is one of the most common bony injuries. Approximately 2% to 5% of all fractures in adults and 10% to 15% in children involve the clavicle.1 Studies Indicate that 29 to 64 per 1,00000 suffer from a clavicle fracture each year.1,2 A weak spot in the midclavicular region accounts for most fractures. Despite the high frequency, the choice of proper treatment is still a challenge for an orthopaedic surgeon.3 In particular, it is not clear whether surgery produces better outcomes than non-surgical management. In this scenario, a randomized comparative study was planned to compare Plating versus Titanium Elastic nail System (TENS) for clavicle fractures and compare with respect to the incidence of non-union, shortening, functional outcome, cosmetic aspects and complications. The study aims to analyze TENS management and surgical treatment by plating of displaced midshaft clavicle fracture. It also aimed to compare the functional outcome of a displaced fracture of the middle third of clavicle treated with TENS and Plating management.

II. METHODS

The study was conducted in the Department of Orthopaedics, Narayana Medical College, Nellore. The study period was from August 2018 to March 2020.

INCLUSION CRITERIA

Patients aged 20-55 with a closed, displaced, isolated fracture of the middle third of clavicle were included in this study.

EXCLUSION CRITERIA

Those who were not medically fit for surgery, not given consent, have a pathological fracture, with neurovascular deficits, concomitant injury, and previous fracture clavicle non-union were excluded. Patients coming to the Emergency and OPD of the Department of Orthopedics of the Narayana Medical College, Nellore within the study period and who qualified the inclusion criteria were randomized in two groups- One group were treated with TENS and second group with the plate. Simple randomization was used for the patient's allocation to groups. During the study period 78 clavicle fractures, which require

International Journal Dental and Medical Sciences Research
Volume 3, Issue 1, Jan-Feb 2021 pp 534-542 www.ijdmsrjournal.com ISSN: 2582-6018

surgical treatment were analyzed. Out of which only 50 cases of mid clavicle fracture were included in this study. Upon admission to the emergency unit or OPD, the patient was initially resuscitated and stabilized (if required). All the cases were initially investigated with radiograph to assess fracture type and post-traumatic clavicular shortening and routine haematological investigation, urine and stool examination, ECG and cardiological check-up. Fractures were classified as per AO/OTA classification. In both cases, patients were operated under general anaesthesia.

TECHNIQUE OF PLATING

After a preoperative dose of prophylactic antibiotics, the patient was placed in the supine position with a large bump placed between the scapula, allowing injured shoulder girdle to fall posteriorly, helping to restore length and exposure to the clavicle. The reduction was done. A 3.5 mm Recon plate, LCP, the one-third tubular plate was contoured with bending for application to the superior surface of the clavicle or anteroinferior surface. In long oblique fractures or wedge comminuted fractures, lag screws were used where possible with care taken to preserve soft tissue attachment. For comminuted fractures sufficiently long plate with nine or twelve hole was used to bridge the fracture and obtain at least six cortex fixation on each side of fractures.

TECHNIQUE OF TENS

Patients were placed in the supine position. A small incision was made approximately 1cm lateral to the sternoclavicular joint. A TEN (Titanium elastic stable intramedullary nail) was inserted (the diameter varied from 2 to 3 mm depending on the width of the bone). Before introduction, the small and flattened nail tip's original curvature was straightened slightly to allow better gliding in the small medullary canal. Closed reduction was performed under fluoroscopic control using two percutaneously introduced pointed reduction clamps. The nail was then advanced manually until it was just medial to the acromioclavicular joint. Accurate manoeuvring of the nail tip was necessary under fluoroscopic control to avoid penetrating the thin dorsal cortex. After reaching the endpoint, the fracture was compressed, and the nail was cut close to the entry point to minimize soft tissue irritation, at the same time leaving sufficient length behind for easy extraction later on. The fascia and skin were closed in layers.

Postoperative Protocol And Follow Up

For both the groups, Intravenous Antibiotics was given for three days and changed to oral antibiotics for seven days. The operated limb was immobilized in an arm sling. The wound was inspected at 3rd postoperative day, and x-ray was taken to study fracture fragments' alignment. Suture removal was done on 10th postoperative day. Patients were discharged with the arm sling. Rehabilitation of the affected arm was started at the end of 2 weeks. A gentle pendulum exercise of the shoulder in the arm sling was allowed. At 4 to 6 wks gentle range of motion of the shoulder was allowed, but abduction is limited to 80 to 90 degree. At 6 to 8 wks active range of motion in all planes were allowed.

All patients were assessed on day 3, then every three weekly, till radiological signs of the union, then at three months, nine months, and 12 months after surgery. X-ray was taken for all patients at each follow-up to evaluate fracture healing and implant position.

OUTCOME ASSESSMENT

Radiographic healing was defined as evidence of bridging callus across the fracture site or obliteration of fracture line. Clinically fracture healing is defined as the absence of tenderness with firm palpation over the fracture site, full range of motion and the presence of normal strength of upper extremity. Time to achieve union was recorded. After union, shortening of clavicular length was measured clinically as the linear difference of clavicle lengths from sternal end to acromial end between operated and normal side.

We measured subjective pain with a visual analogue scale (VAS) 1 day before and three months after conservative and surgical management. The VAS ranged from 0-10, 0=no pain, to 10=worst pain imaginable. The functional outcomes were assessed by Constant and Murley score and DASH score. In Constant and Murley scoring, subjective variables are pain and ADL (sleep, work, recreation, sports), giving 35 points. The objective variables are range of motion and the strength which give a total of 65 points. Patients were graded as below with a maximum of 100 points. DASH outcome measure is a 30-item, self-report questionnaire designed to measure physical function and symptoms in patients with any of several musculoskeletal disorders of the upper limb. More severely disabled individuals have a higher score on a scale of 0 to 100. After six months, cosmetic results are assessed by patient satisfaction score from1=very unsatisfactory to 5=very satisfactory. All the data were analyzed in SPSS version 16. The Mann- Whitney U test was

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used to compare the means of variables between two groups as the variables were not normally distributed across two groups. P-value below 0.05 was considered to be statistically significant. Secondary outcome measures include perioperative data like operative time, amount of blood loss and size of the surgical wound; complications such as neurovascular injury, wound infection, non-union, malunion, implant migration, implant failure, soft tissue irritation, refracture after implant removal and cosmetic outcome with regards to visible deformity, hypertrophic scars and hardware prominence under the skin. Implant removal was not done routinely in our study. It was done as per need and will of the patient after fracture union. The number of days to return to normal activities after implant removal was noted.

III. RESULTS

A total of 50 patients were studied, among whom 25 belonged to the TENS group and rest belonged to the plating group. The demographic and clinical profiles of patients were depicted in Table 1.There was no significant difference between the two groups with respect to these demographic and clinical profiles. The age range of the patient was from 20 to 55 years. TENS group's mean age was 33.28±10.73, and plate group 34.76±11.87 (p=0.646).

Character	**TENS group (n=25)**	**Plating group (n=25)**
Mean age (in years)	33.28+/-10.7	34.76+/-11.8
Gender (in number (%))		
Male	18 (72)	18 (72)
Female	7 (28)	7 (28)
Mode of injury (in number (%))		
RTA	12 (48)	16 (64)
Fall on an outstretched hand	5 (20)	1 (4)
Fall from height	2 (8)	6 (24)
Sports	6 (24)	2 (8)
Side of affection (in number (%))		
Dominant	19 (76)	13 (52)
Non dominant	6 (24)	12 (48)
Type of fracture as per OTA (%)		
B_1	13 (52)	12 (48)
B_2	12 (48)	13 (52)

Table 1: Demographic and clinical profile of study participants (n=50).

The injury being a result of trauma was commonly found in male population compared to female in both the groups. Male to female ratio 2.5:1. The mode of injury was uniformly distributed in both groups. 56% of cases are due to road traffic accidents, 16% of cases were due to fall from height and sports activity and fall on outstretched hand on 12% cases. In both, the group the dominant side of the patient was more affected (64%). Regarding the type of fracture as per OTA classification, 50% of cases were simple (B1) type and 50% cases were wedge (B2) type. In our study, 13 patients (52%) were used locking compression plate, six patients (24%) recon plate and six patients (24%) semi-tubular plate. As per OTA classification for type B1 simple fracture locking compression plates were used in 8 patients (32%), recon plates in 3 patients (12%) and semi-tubular plates in 1 patient (4%). For type B2 both LCP and STP were used in 20% cases each. Recon plates were used in 3patients (12%) (Table 1).

In our study, the fractures in the TENS group were united with an average time of 11.4±2.12 weeks and in plate group, one case non-united but rest cases united with an average time of 13.4±3.46 weeks and the difference was significant (p=0.016).

International Journal Dental and Medical Sciences Research
Volume 3, Issue 1, Jan-Feb 2021 pp 534-542 www.ijdmsrjournal.com ISSN: 2582-6018

Pain VAS Score	TENS GROUP (n=25) No of Cases	%	PLATE GROUP (n=25) No of Cases	%
0	0	0	0	0
1	2	8	0	0
2	11	44	6	24
3	9	36	11	44
4	2	16	7	28
5	1	4	1	4
6 to 10	0	0	0	0

Table 2: Pain as per VAS score on day 3 among study participants (n=50).

Table 2 showed the pain VAS score on day three among study participants. The mean pain VAS score in TENS group was 2.56±0.91, and in plating group was 3.12±0.83, and the difference was significant (p=0.023) (Table 2).

No clavicular shortening was seen in 32% (8 patients) and less than 5 mm shortening in 28% (7 patients) plate cases. Six patients (24%) in the plate group shows 6 to 10 mm shortening. Majority of the patients (60%) in TENS group shows no shortening. Eight patients (32%) in TENS group shows less than 5 mm shortening. Mean shortening in TENS group was 1.84±2.88 mm, and the plate group was 4.5±4.12 mm, and the difference was significant (p=0.011).

SHORTENING	EXCELLENT (%)	GOOD (%)	FAIR (%)	POOR (%)
<15 mm	36 (100)	1 (16.7)	2 (33.3)	0 (0)
>15 mm	0 (0)	5 (83.3)	4 (66.6)	2 (100)
TOTAL	36	6	6	2

Table 3: Functional outcome in terms of shortening among study participants (n=50).

Table 3 showed the functional outcome in terms of shortening among study participants. Those having shortening <15mm had an excellent result in 100%. 16.7% had good result and fair in 33.3% (Table 3).

COSMETIC SCORING	TENS GROUP (n=25) No of cases	%	PLATE GROUP (n=25) No of cases	%
1	0	0	0	0
2	1	4	3	12
3	1	4	6	24
4	8	32	9	36
5	15	60	7	28

Table 4: Cosmetic scoring among study participants (n=50).

In our study, the TENS group were cosmetically more satisfied with mean score 4.48±0.77 than the plate group with mean score 3.8±1.0 (p=0.009). Table 4 showed cosmetic scoring among study participants (Table 4).

Functional outcome was measured according to Constant Shoulder score and DASH score. In TENS group 21 (84%) patients showed the excellent result, two patients (8%) showed a good result. But in the plate group about 15patients (60%) showed excellent result while 16% of cases showed a good result.

International Journal Dental and Medical Sciences Research
Volume 3, Issue 1, Jan-Feb 2021 pp 534-542 www.ijdmsrjournal.com ISSN: 2582-6018

S.NO	CONSTANT SCORE IN TENS GROUP	DASH SCORE IN TENS GROUP	CONSTANT SCORE IN PLATE GROUP	DASH SCORE IN PLATE GROUP
1	10	4.5	10	1
2	10	3.0	10	1.8
3	9	13	10	1.3
4	6	3.8	10	1.4
5	7	2.7	10	2.0
6	5	3.4	9	1.1
7	9	3.9	8	1.02
8	10	37.4	10	3.8
9	10	5.0	10	1.5
10	6	2.2	10	1.2
11	8	1.9	10	0.8
12	6	2.4	10	0
13	8	3.4	8	0
14	7	2.0	9	10.5
15	6	3.8	10	25
16	5	4.7	12	40
17	4	15.9	14	1.0
18	6	14.6	18	2.5
19	3	3.1	19	0.8
20	6	3.9	26	1
21	5	2.2	27	8
22	16	2.9	25	8
23	13	3.4	23	0
24	22	10.8	28	4.2
25	37	2.8	49	4.2

Table 5: Comparison of different scores among study participants.

COMPARISON OF DIFFERENT SCORES IN OUR STUDY

In our prospective study, mean DASH and Constant shoulder score in TENS group were 1.87±3.4, 9.36±7.04 and plate group 4.8±9.0 and 15.08±9.4 respectively. The P-value for mean DASH score=0.039 and p-value for mean constant score=0.000, which were significant. Table 5 depicted different scores among study participants (Table 5).In TENS group, we found the complications are delayed union in 4%, infection in 4%. In TENS group, the majority of the cases (68%) had radiological union within 9-12 weeks& 7 patients (28%) had a union at 13-15 weeks. But plate group majority (60%) had it in about 9-12 weeks with mean union time 13.4 weeks with 4% having non-union, 4% having delayed union and 4% having mal-union. In addition to it in plate group, the hypertrophic scar was found in 12% cases, plates loosening due to infection in 8% cases, 8% patient showed superficial infection and 4% showed refracture. TENS group is better in terms of infection, plate loosening, hypertrophic scar and plate prominence, refracture or neurovascular injury as no such complication was found in TENS group.

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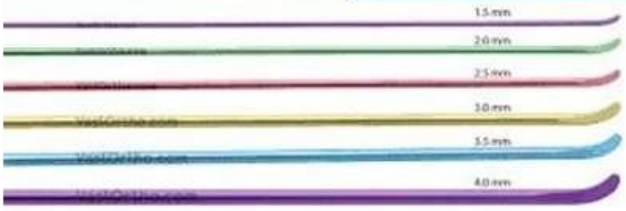
PRECONTOURED CLAVICULAR PLATE



TITANIUM ELASTIC NAILING SYSTEM (TENS)

FRACTURE REDUCTION PLATE FIXATION TENS NAIL INSERTION

CASE ILLUSTRATIONS:

CASE 1

CASE 1

RADIOGRAPHS

PREOP POST OP 6 WEEKS 3 MONTHS 6 MONTHS

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CLINICAL PICTURES

ABDUCTION FORWARD FLEXION EXTERNAL ROTATION INTERNAL ROTATION

CASE 2

RADIOGRAPHS

PREOP POSTOP 3 MONTHS 6 MONTHS AFTER REMOVAL OF IMPLANT

CLINICAL PHOTOGRAPHS

ABDUCTION FORWARD FLEXION EXTERNAL ROTATION INTERNAL ROTATION

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IV. DISCUSSION

The clavicle has an integral role in the mechanics of the pectoral girdle and the function of the upper extremity. Clavicle fractures account for approximately 2.6% of all fracture.1,4-7 The majority of clavicle fractures (80-85%) occur in midshaft of bone where the typical compressive forces applied to the shoulder and narrow cross-section of the bone combine and result in the bony failure.3,4,8,9 Most of them(97%) in this group are mild to moderate displaced and can be treated conservatively. However, 3% of middle third clavicle fractures are completely displaced and shortened. This small group of fractures accounts for 90% of non-union of the middle third fractures and therefore may warrant early open reduction and internal fixation. Our study compared the rate of union and functional outcome in displaced middle third clavicle fractures by surgical management using TENS vs plating. This study was conducted in the Department of Orthopaedics, Narayana Medical College, Nellore from August 2018 to March 2020.

In our study mean age of the patients with displaced midshaft clavicle fracture in TENS group was 33.28 years and in the plate group was 34.76 years. Nordquist et al. reported the mean age to be 29.3 years, and the incidence appears to decrease significantly after the second decade of life.1 Study conducted by Bostman et al. Showed the average age was 33.4 years.10 Nordquist et al. and Bostman et al. in their studies, found that males outnumber the females. Our study also found 72% of participants were males.

Plate osteosynthesis is the gold standard method for clavicular fracture's surgical treatment. Plate fixation can provide immediate rigid fixation. The convenient 3.5 mm DCP, RP, STP are usually used routinely. New type such as LCP, Precounter LCP, LC-DCP have been developed to decrease the hard wire irritation and implant failure. Our study uses 3.5 mm LCP in 52% of patients and RP in 24% and STP in 24% cases. According to our study, the mean radiological union time in TENS group was 11.4±2.12 weeks and plate group 13.4±3.46 weeks. TENS was superior in terms of radiological union for the fracture of the middle third of the clavicle than plate fixation as the mean difference was significant. Our study uses Titanium elastic nail in TENS group and 3.5 mm LCP, RP or STP in plate group.

We found the complications are delayed union (4%), infection (4%) in the TENS group. In the TENS group, most of the cases (68%) had radiological union within 9-12 weeks, and seven patients (28%) had a union at 13-15 weeks. But plate group majority of the plates 60% (15 patients) had it in about 9- 12 weeks with mean union time 13.4 weeks with 1 (4%)having non-union, 1 (4%) having delayed union and 1 (4%) having mal-union. In addition to it in the plate group, the hypertrophic scar was found in 12% cases, plates loosening due to infection in 8% cases, 8% patient showed superficial infection and 4% showed refracture. TENS group is better in terms of infection, plate loosening, hypertrophic scar and plate prominence, refracture or neurovascular injury as no such complication was found in TENS group.

Although plating of the clavicle spares the original fracture site, it rarely involves fixation along its entire length. Refracture secondary to additional trauma either medial and lateral to original occurs and reported at a rate between 1% to 2% by Mckee et al.9 Poigenfurst et al. reported in 4 patients out of 122 patients refracture occurs.11Refracture needs revision surgery. Our study shows a refracture rate of 4% (one patient) in plate group.

Our study's mean constant score in TENS group was 9.36±7.04 and plate group 15.08±9.0. Patients treated by plating showed excellent outcome in 60% cases while 84% in TENS group. The mean DASH score was found to be 1.87±3.4 in TENS group and 4.8±5.9 in plate group. Patients treated with TENS were better in terms of CONSTANT and DASH score than treated with the plate. TENS group had significantly higher mean cosmetic score than the plate group (p=0.039). Saha et al. reported that patients treated by plating of displaced midshaft clavicle fracture, the mean Constant score was 95.2 and mean DASH score was 5.12 Mckee et al. found that mean constant score in CONS group 91.6±14.1 and in plate group 97±4.5 and mean Dash score 4.1±7.0 and 11.49±7 respectively.13

V. CONCLUSION

Our study found that patients treated by plating showed excellent outcome in 60% cases while 84% in TENS group. Patients treated with TENS were better in terms of Constant and DASH score than treated with the plate. TENS group had significantly higher mean cosmetic score than the plate group. So in the management of acute displaced midshaft clavicular fractures, TENS is superior to plating to manage clavicular fracture. Surgery with TENS results in good functional outcome compared with surgical plating treatment.

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