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Original Research

Comparative Analysis Of Clinical And Radiological Outcomes Of Management Of Mid-Shaft Clavicle Fractures Treated By Titanium Elastic Nailing System (Tens) Versus Plating - A Prospective Study Of 40 Cases

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Abstract
Background: Clavicle fractures, accounting for 2.6% of all fractures, are common, especially in active adults and children. The middle third is the most frequent fracture site. Currently, there's a preference for primary surgical fixation due to unsatisfactory conservative treatment outcomes. Plating has historically been the standard procedure, but intramedullary nailing has emerged over the last decade due to better cosmetic outcomes.
Aims and Objectives: To study, compare and evaluate the Radiological and Clinical outcomes of mid-shaft clavicle fractures after surgical fixation using Titanium elastic nailing system (TENS) versus plating.
Patient and methods: This study includes 40 patients. They were divided into 2 groups: 20 patients treated with TENS and the other 20 with plating. The study aims to compare the clinical and radiological outcomes of these two treatments. All patients were followed up and assessed at 4 weeks intervals up-to 24 weeks or radiological union, whichever is later.All the diaphyseal non-comminuted clavicle fractures – AO Classification (A1 – A3, B1 – B2) and Fractures with shortening < 2 cm were included in the study.
Results: Operative time was much less in TENS(mean 35mins) vs plating(mean47mins)
Post-op pain was much less in TENS patients with average VAS score 3.25 on post-op day3 (vs 6.35 for plating).
On follow-ups, Constant-Murley scores were found to be better in TENS patients compared to plating.
There was no incidence of post operative infection in TENS (20% cases of infection in plating)
Conclusion: The study found that TENS procedure has several advantages over the Plating method having shorter operative time, less post-operative pain, faster return to normal shoulder function, less risk of infection and smaller surgical scar. In the long run follow-up (after 16weeks) both TENS and plating produce similar functional outcome
Keywords: Clavicle, Nailing, Plating, Operative time, Constant Murley score. VAS Score, Infection, Functional outcome, Radiological outcome

Introduction-

Clavicle fractures, accounting for 2.6% of all fractures, are common, especially in active adults and children[1,2]. The middle third is the most frequent fracture site[3]. A meta-analysis by Zlowodzki et al[9] found a 15.1% non-union rate for non-operatively treated displaced mid-shaft clavicle fractures. Hill et al reported a 15% non-union rate and 31% patient dissatisfaction with conservative treatment[9]. Currently, there's a preference for primary surgical fixation due to unsatisfactory conservative treatment outcomes[7,8,9]. Plating has historically been the standard procedure, but intramedullary nailing has emerged over the last decade due to better cosmetic outcomes. The study aims to compare the functional outcomes of fractures treated by intramedullary titanium elastic nails (TENS) fixation versus plating.

Materials and method-

This study includes 40 patients who satisfy our inclusion criteria. They were divided into 2 groups: 20 patients treated with TENS and the other 20 with plating. After surgery they were followed up at 4

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weekly intervals, upto 24 weeks/Bone union, whichever is later

The cases will be enrolled in our study as per the inclusion and exclusion criteria given below. An informed written consent of the patients will be obtained once the patients fulfil the inclusion criteria. Clinical history, general physical examination and local examination will be performed as per the proforma attached. Patients will be investigated for operative and anesthetic purposes. Prior approval from ethical committee of the institution will be taken for this study.

The study aims to compare the clinical and radiological outcomes of these two treatment groups. All patients were assessed accordingly.

The study follows ethical guidelines and all patient's consents were obtained.

Results:

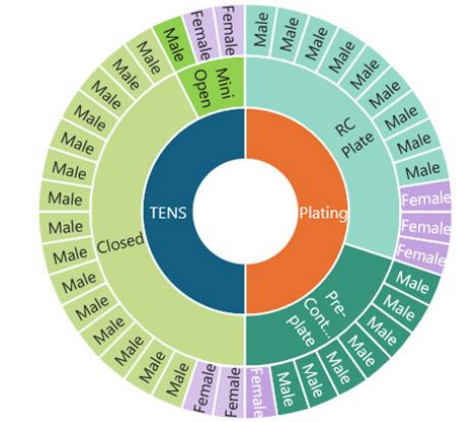
Overview:

- 40 patients were selected via the previously mentioned criteria.
- 20 patients were operated with TENS.
  - Among them 17 patients had closed surgery.
  - 3 mini open.

20 patients were operated via plating. With both superior and anterior approaches.

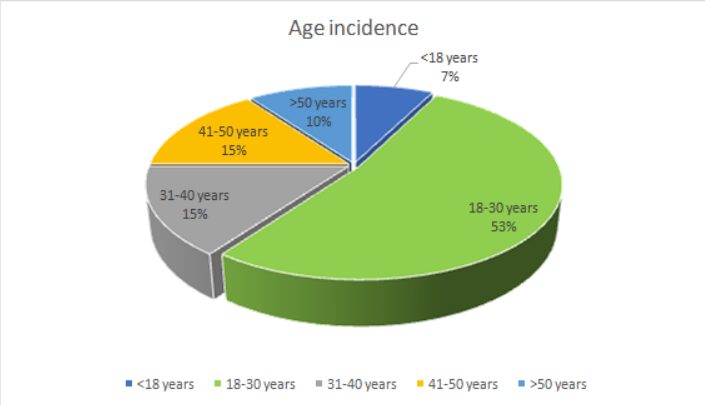
Among them, 8 patients were operated via pre-contoured plating

12 patients were operated via RC plating



Age Incidence:

Age group	No. of cases	percentage
<18	3	7%
18-30	21	53%
31-40	6	15%
41-50	6	15%
>50	4	10%



Majority of patients in our study were in the age group of 18-30 years(53%), 6 patients (15%) in 31- 40 age group, 6 patients (15%) in 41-50 age group.

3 patients (7%) were less than18years age, while 4 patients (10%) were more than 50 years old.

Youngest patient in our study was 16 years old and oldest patient in our study was 67 years.

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The average age in our study was 33years.

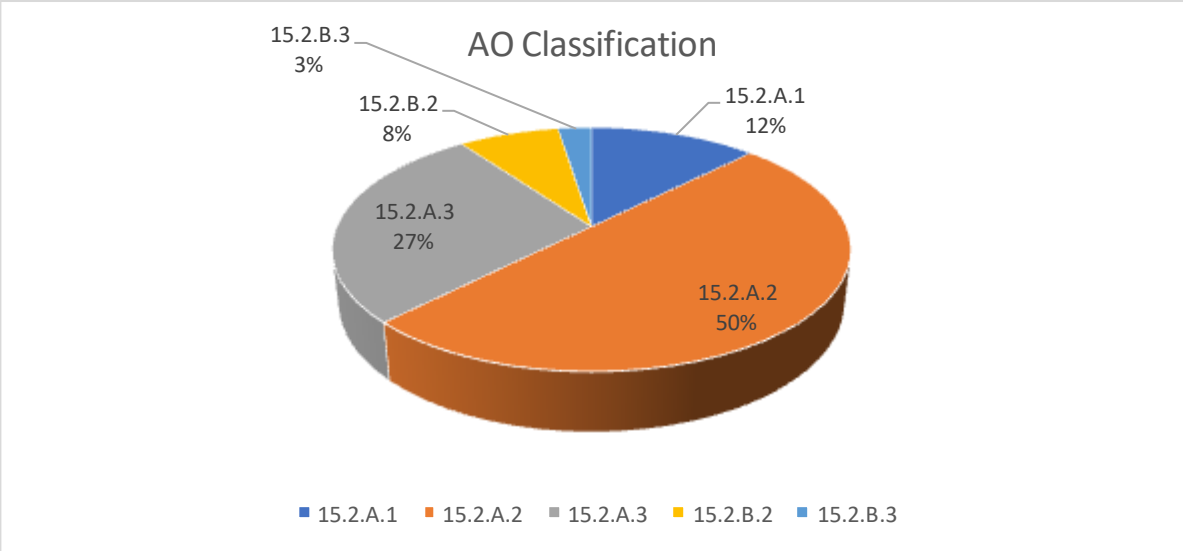
Gender Incidence

Gender	Number of cases	percentage
Male	**32**	**80**
Female	**8**	**20**

In our study majority patients were males- 32 (80%) and 8 patients (20%) were females.
It is seen that RTA was predominant mode of injury due to outdoor activities especially in males.

Type of Fracture-

Type of fracture according to AO classification	Number of cases	percentage
15.2.A.1	**5**	**12%**
15.2.A.2	**20**	**50%**
15.2.A.3	**11**	**27%**
15.2.B.2	**3**	**8%**
15.2.B.3	**1**	**3%**



5 patients (12%) in our study were type 15.2.A.1 fractures according to A.O classification, 20 patients (50%) in our study were 15.2.A.2 fractures, 11 patients (27%) were 15.2.A.3, 3 patients (8%) was 15.2.B.2 and 1 patient (3%) had fracture
according to 15.2.B.3 fracture pattern.

Operative time-

0-30 mins	11 (55%)	0
31-40 mins	6 (30%)	4 (20%)
41-50 mins	2 (10%)	14 (70%)
>50 mins	1 (5%)	2 (10%)
Mean	35.75 mins	47 mins
Median	30 mins	45 mins
Mode	30 mins	45 mins
Standard Deviation	1.859	1.1697

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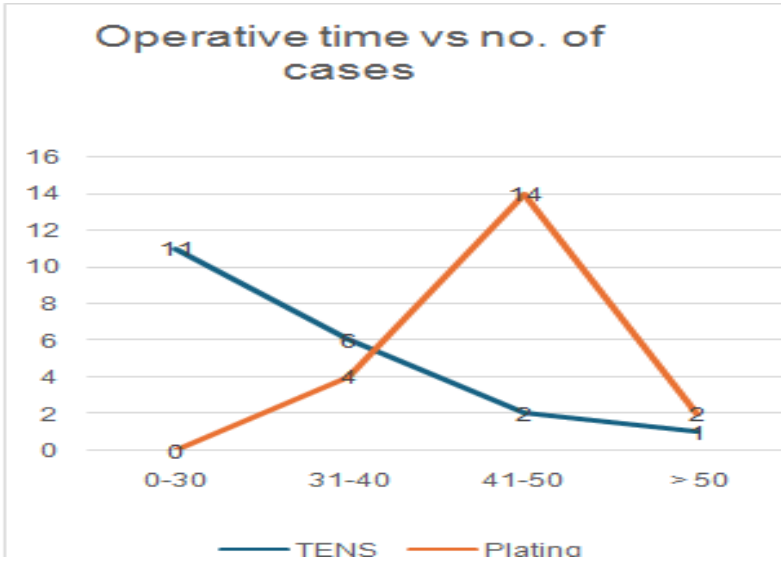
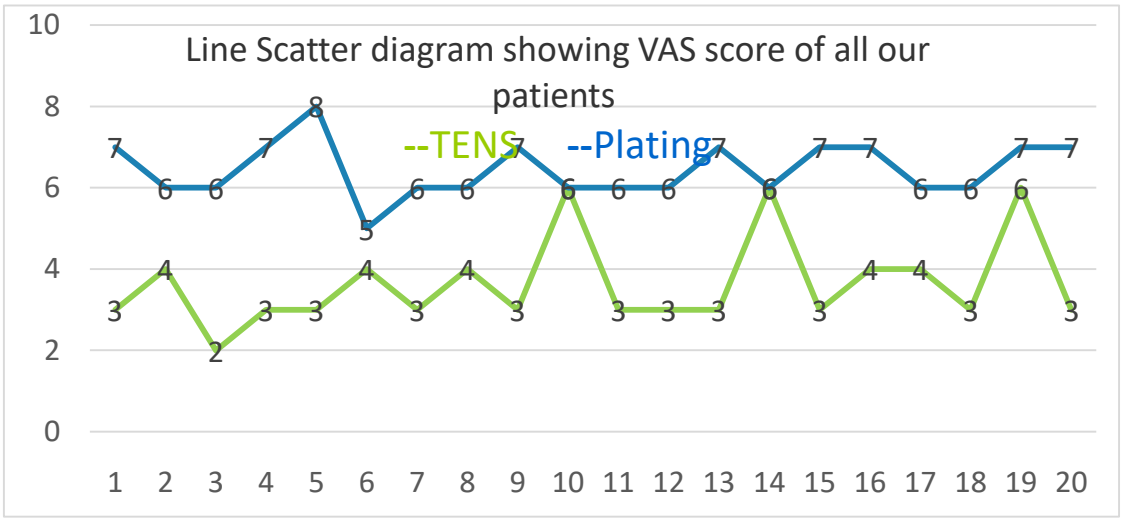


When comparing the results, operative time was significantly lower in TENS group when compared to plating (P value: 0.00)

Post operative pain on 3rd post operative day(Assessed via VAS Score)

	TENS	Plating
Mean	3.65	6.45
Median	3	6
Mode	3	6
SD	0.254	0.153

The results were analysed. The post operative pain in TENS patients were much lesser than those plating with an average score of 3.65 vs 6.45(p-value <0.05)



Post operative hospital stay:

	TENS	Plating
Mean	**3.4 days**	**9.25 days**
Median	**3 days**	**10 days**
Mode	**3 days**	**10 days**
Standard Deviation	**0.233**	**0.463**

The post operative hospital stay of all our patients were noted. Although post operative hospital stay depends on a lot of factors, the average hospital stay was lesser in patients of TENS when compared to plating.

Fracture union:

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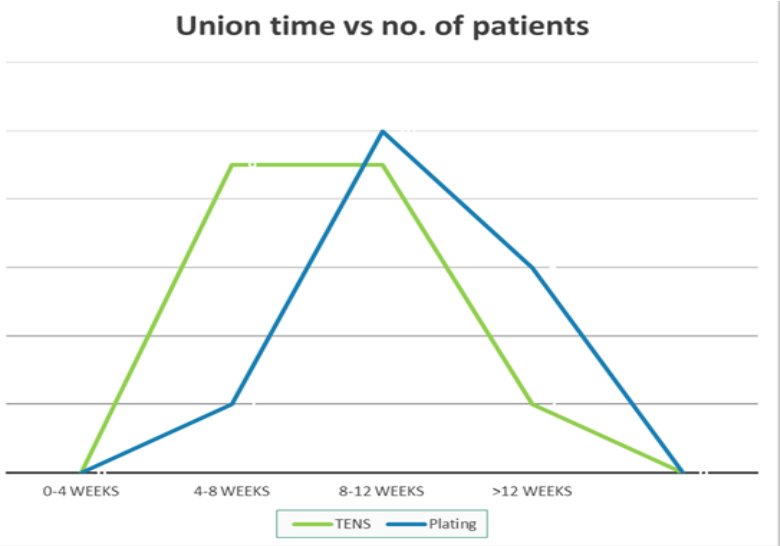
The fracture was considered to be united when clinically there was no tenderness, radiologically the fracture line was not visible and full unprotected function of the limb was possible.

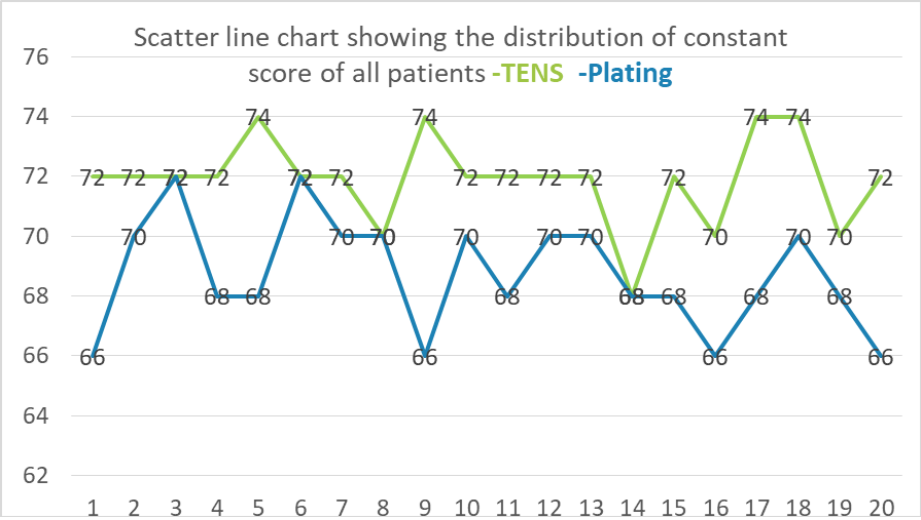
	TENS	Plating
4-8 weeks	9	2
8-12 weeks	9	10
>12 weeks	2	6



Upon comparing the 2 groups we observed that the Union time was less in TENS patients when compared to plating.

Functional outcomes at follow ups-
At 4 weeks

Constant Murley score	TENS patients	Plating patients
<64	0	0
65-69	1	11
70-74	19	9
≥75	0	0
Mean Median Mode	71.9 72 72	68.7 68 70
Standard Deviation	0.339	1.866



At 4 weeks Constant score was better in TENS patients when compared to plating. (P value= 0.00)

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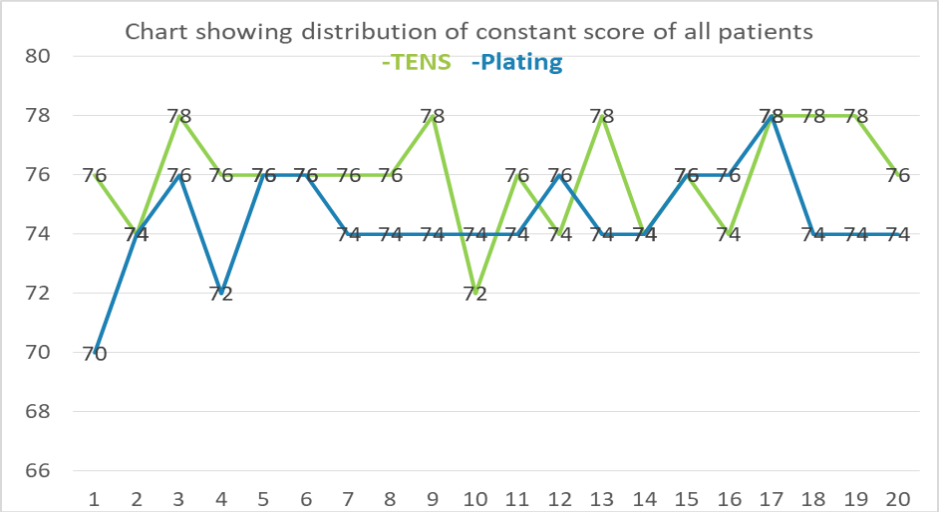
Functional outcome at 8 weeks

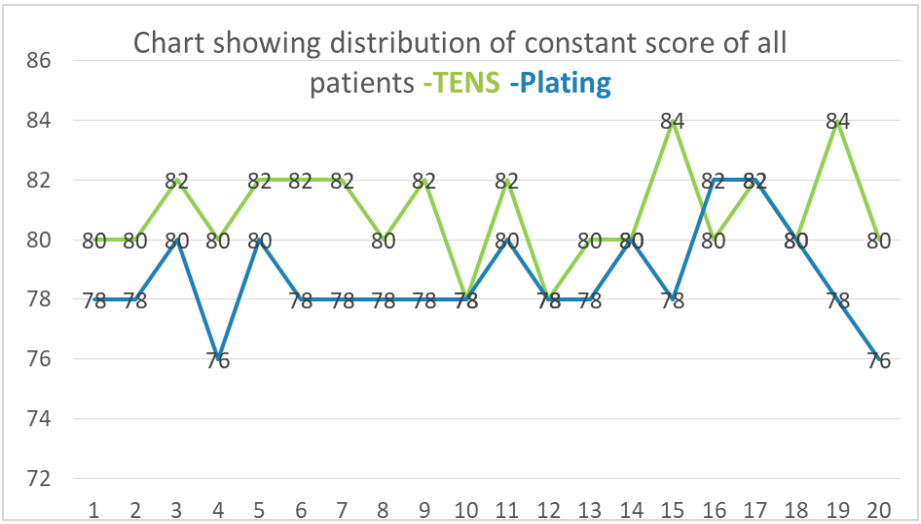
Constant Murley score	**TENS**	**Plating**
65-69	0	0
70-74	5	13
75-79	15	7
≥80	0	0
Mean- **Median-** **Mode-**	76 76 76	74.5 74 74
SD	0.383	0.380



At 8 weeks Constant score was better in TENS patients (**P value- 0.0043**)

Functional outcome at 12 weeks

Constant Murley score	**TENS**	**Plating**
<74	0	0
75-79	2	13
80-85	18	7
≥85	0	0
Mean- **Median-** **Mode-**	80.9 80 80	78.7 78 78
SD	0.369	0.363



At 12 weeks Constant score was better in TENS patients (P value- 0.001)

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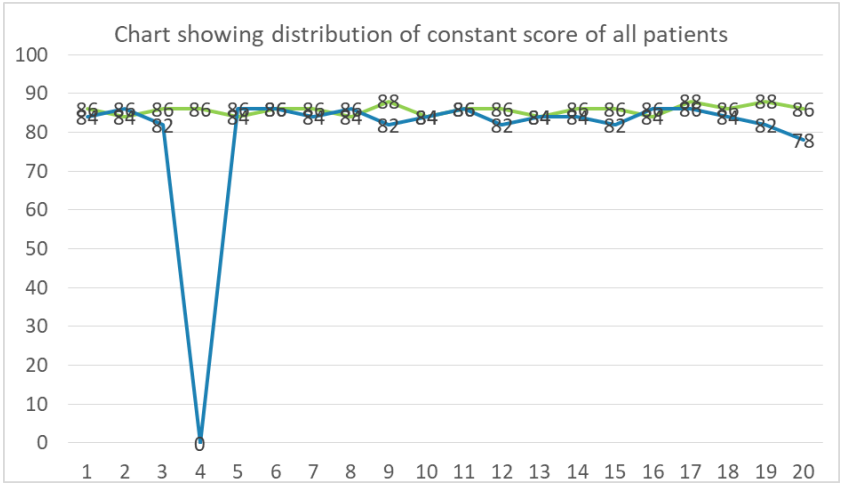
Functional outcome at 16 weeks

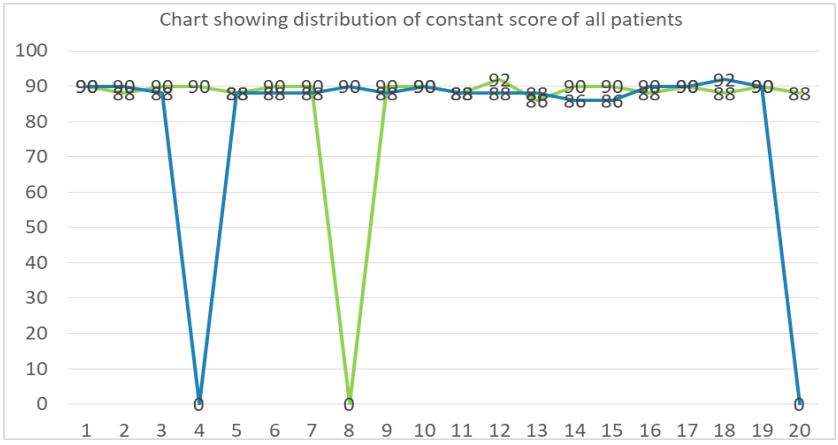
Constant-Murley Score	**TENS**	**Plating**
<78	0	2
80-84	6	11
85-89	14	7
≥90	0	0
Mean- **Median-** **Mode-**	85.7 86 86	79.7 84 86
SD	0.3	4.22



At 16 weeks 1 patient operated with RC plate had implant failure.
When The constant score of patients were compared, TENS patients had marginally better score than plating as visible from the scatter diagram. The P-value of the observation is 0.0822 making the difference non-significant.

Functional outcome at 20 weeks

Constant Murley Score	**TENS**	**Plating**
<80	0	2
80-84	0	0
85-89	8	10
≥90	12	8
Mean- **Median-** **Mode-**	89.3 90 90	79.9 88 88
SD	0.3	6.11



At 20 weeks 1 more patient operated with RC plate had implant failure. While one patient operated with TENS nail had implant failure

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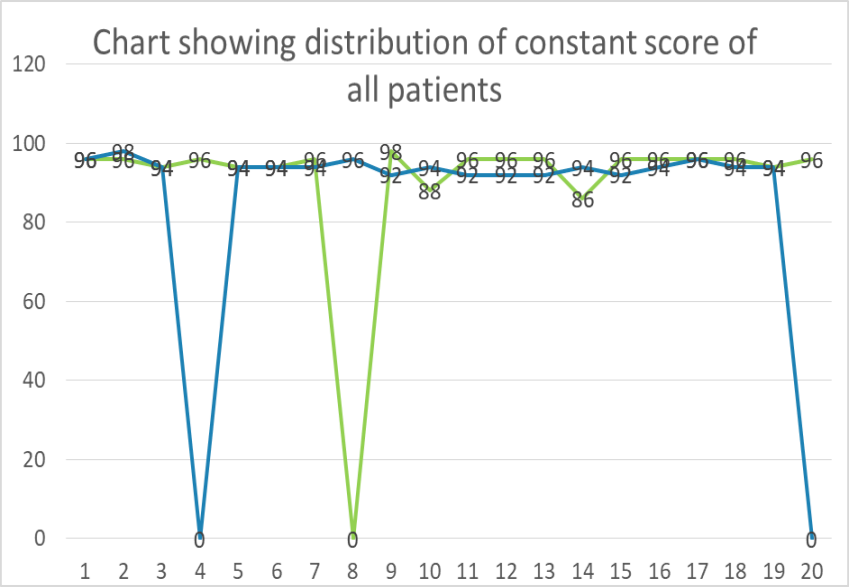
When The constant score of patients were compared, TENS patients had marginally better score than plating as visible from the scatter diagram. The P-value of the observation is 0.0666 making the difference non-significant.

Functional outcome at 24 weeks

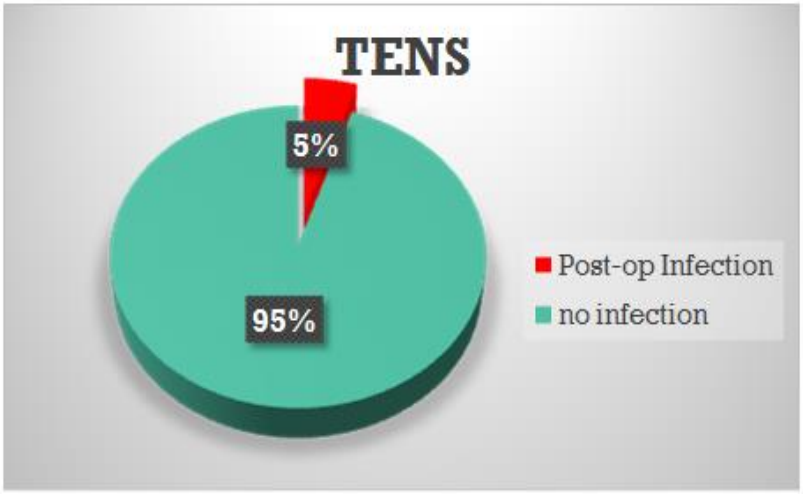
Constant-Murley Score	**TENS**	**Plating**
<85	0	2
85-89	2	0
90-94	5	14
≥95	13	4
Mean- **Median-** **Mode-**	94.6 96 96	84.6 94 94
SD	0.65	6.479



At 24 weeks the functional outcome of both groups were almost similar. With both producing satisfactory Constant murley score. (P value 0.065)

Incidence of infection:

1 out of 20 TENS nail patient had post operative infection. The mode of surgery was mini open.Incidence= 5%



4 out of 20 plating patients had post-operative infection.Incidence= 20%

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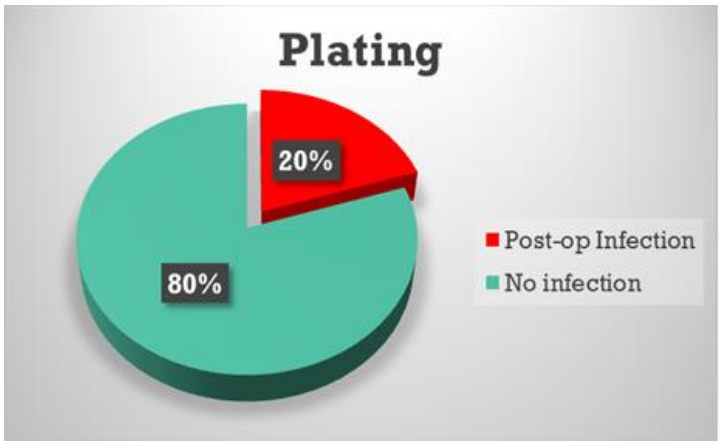
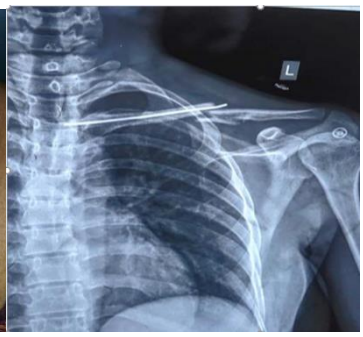


Other complications in TENS

- Skin irritation due to prominent nail on the medial side occurred in 2 patients. (Incidence=10%).
- 1 patient (5%) had proximal nail migration.
- 1 patient (5%) had implant failure

Image showing skin irritation at the site



Xray showing proximal migration of nail

Of entry of nail

Xray showing Implant failure of TENS nail

Other complications in plating

- 2 plating patients had implant failure. Both had been operated via RC plating. (incidence=10%)

Both were on right side.
Both of them had history of heavy weight lifting and exercise.
One of them presented at 16 weeks, the other at 20 weeks.

- No Incidence of skin irritation, but cosmetic concern due to scar was present.
-

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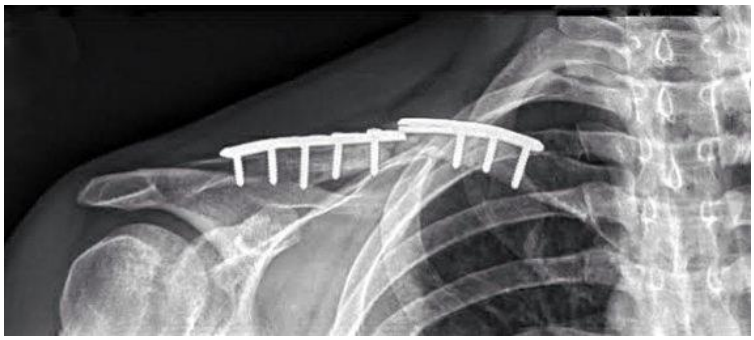

Xray showing implant failure of RC Plating clavicle.

Discussion-

This prospective study was conducted in our hospital with 40 patients who had displaced non comminuted mid shaft clavicle fractures, admitted in our department off orthopedics. We excluded the comminuted fractures since nailing cannot maintain the length of clavicle and can lead to telescoping of the nail and shortening of the patient's clavicle. Smekal et al[14] hence recommended against use of intramedullary nail in comminuted fractures with severe shortening.

In our study Majority of patients in our study were in the age group of 18-30 years(53%), 6 patients (15%) in 31- 40 age group, 6 patients (15%) in 41-50 age group. 3 patients (7%) were less than18years age, while 4 patients (10%) were more than 50 years old. Youngest patient in our study was 16 years old and oldest patient in our study was 67 years. The average age in our study was 33years. Narsaria et al[17] conducted a prospective study where his findings showed mean age of 38.9. In a study conducted by Ferran et al[10] in 32 patients mean age was 29.3 years, 27 males (84%) and 5 females 16%. In a study conducted by Smekal V et al[14] mean age was 36.8 years. The patients in this age group (30-40 years) are more active and have more outdoor activities and involved in earning livelihood and hence are prone to more fractures.In our study majority patients were males- 32 (80%) and 8 patients (20%) were females and is comparable to Mueller et al[12] study 24 patients (78%) and 7 patients (22%) were females. In Narsaria et al study[17] there were 50 males (75%) were males and 16 females (25%) (Range 18-65). In a study conducted by Smekal V et al[14] which included 81% male and 19% female. Male are more prone to the fractures due to their occupations, outdoor activities.Operative time in TENS nailing was much shorter than that of plating (35.75 mins vs 47mins) a study done by Hong et al[16] in 22 found similar results. In his case the average time taken for nailing was 31.1mins vs 59.8mins for platingThe post operative pain and hospital stay was also shorter in TENS patients. Post-op pain was much less in TENS patients with average VAS score 3.65 on post-op day3 (vs 6.45 for plating). While the average hospital stay was 3.25 days in TENS vs 9.25 for plating. Similar results were found by Hong et al[16] and Saha p et al[15] . On follow-ups, Constant-Murley scores were found to be significantly better in TENS patients compared to plating during the first 12 weeks (P value <0.05). After 12 weeks, both TENS and plaiting patients had similar results. A study by Narsaria et al[17] compared American Shoulder and Elbow Surgeons (ASES) and Constant Shoulder scores among 66 patients. He found that the constant scores of the intramedullary nailing was significantly better in the first 2 months followup. But there was no significant difference between the two groups in terms of functional and radiological outcome at the 2-year follow-up. Similar results were also documented by Hong et al[16] and Saha p et al[15].The incidence of post-operative infection in TENS was less (only 5%) whereas it was 20% in cases of plating. This again was a statistically significant observation p value <0.05. Studies done by Narsaria et al[17] quoted that infection and revision surgery rates were also higher in the plate group. Studies done by Saha et al also found that post operative infections were significantly higher in plating patients.Other complications were comparable in TENS vs plating groups. Both method had it's pros and cons. In our study 1 TENS patient had implant failure, 1 patient had proximal migration of nail, and 1 patient had skin irritation at site of entry. Similarly, among plating patients two patients had implant failure and needed to be operated. Overall those patients operated with TENS nailing were more satisfied than plating since they had smaller scars, early mobility and shorter hospital stay.

Conclusion-

Our research indicates that TENS-Nailing has multiple benefits over Plating for treating Midshaft clavicle fractures, including shorter operative times, Less blood loss, shorter hospital stay with smaller skin incisions, quicker recovery, better radiological and functional results in the initial post operative period, and higher patient satisfaction overall. Although both methods have similar rates of complications, the positive clinical outcomes point to TENS-Nailing as the potentially favourable method in the Indian subcontinent. These insights add to the body of knowledge that may help future surgeons to make informedevidence based clinical decisions, potentially

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improving patient outcomes and the efficiency of orthopaedic healthcare services.

In our study follow up was done up to 24 weeks. A larger study population with longer follow-up period may provide more insight on this topic. Topics like refracture rate after implant removal needs future studies.

Conflict of Interest

None

Financial support

Not available

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