

ORIGINAL RESEARCH

Comparative Study Of Open Reduction Internal Fixation With Plating Versus Percutaneous Titanium Elastic Nailing System For Treatment Of Mid Shaft Clavicle Fracture In Tertiary Care Centre

Dineshram Devakumar¹, Rameejan Begum², Pratheesh Mohanraj³, Adhiyamaan RV⁴, F. Abdul Khader⁵, Samutirika Devi Manoharan⁶, Misab Bin Muhammad⁷, Harish. S⁸, Naim Akbar⁹, Rupesh Kanna¹⁰

¹ Post Graduate, Shri Sathya Sai Medical College and Research Institute, Ammapettai, Chengalpet District, Tamilnadu – 603108, India.

² Assistant Professor, Chettinad Medical College & Hospital, Kelambakkam, Chengalpet District, Tamilnadu – 603103, India.

³ Assistant Professor, Shri Sathya Sai Medical College and Research Institute, Ammapettai, Chengalpet District, Tamilnadu – 603108, India.

⁴ Assistant Professor, Shri Sathya Sai Medical College and Research Institute, Ammapettai, Chengalpet District, Tamilnadu – 603108, India.

⁵ Professor, Shri Sathya Sai Medical College and Research Institute, Ammapettai, Chengalpet District, Tamilnadu – 603108, India.

⁶ Senior Resident, ACS Medical College & Hospital, Velappanchavady, Chennai – 600077.

⁷ Post Graduate, Shri Sathya Sai Medical College and Research Institute, Ammapettai, Chengalpet District, Tamilnadu – 603108, India.

⁸ Post Graduate, Shri Sathya Sai Medical College and Research Institute, Ammapettai, Chengalpet District, Tamilnadu – 603108, India.

⁹ Post Graduate, Shri Sathya Sai Medical College and Research Institute, Ammapettai, Chengalpet District, Tamilnadu – 603108, India.

¹⁰ Post Graduate, Shri Sathya Sai Medical College and Research Institute, Ammapettai, Chengalpet District, Tamilnadu – 603108, India.

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ABSTRACT

Background: To compare and study the functional outcome of displaced midshaft clavicle fractures Between surgical fixation using Open reduction with internal fixation (ORIF) plating and Titanium Elastic nailing system (TENS). **Methods:** A total of 65 patients with displaced midshaft clavicle fractures (aged between 20-65 years) were randomly allocated to ORIF (n=34; Mean age 43.59±15.55 years; 55.9% males) or TENS (n=31; Mean age 43.36±16.08 years; 61.3% males) groups. Preoperative demographic, clinical characteristics and functional status in terms of Disabilities of Shoulder and Hand (DASH) scores were noted. Intraoperative blood loss and transfusion need were noted. Post-operative complications, duration of hospital stay and mobilization time were noted. The patients were followed up at 2 weeks, 3 months and 6 months follow-ups. At each follow-up functional outcome was noted in terms of DASH scores. Final functional status was measured at 6 months. Data was compared using chi-square and student 't'-tests. **Results:** The two groups were matched statistically for preoperative demographic, clinical and functional characteristics. Mean preoperative DASH scores were 78.47±2.85 and 78.16±3.26 respectively in ORIF and

TENS groups. No significant difference in intraoperative and postoperative clinical course was seen between the two groups. Time taken for mobilization was 5.97 ± 1.51 and 5.90 ± 1.25 days respectively in ORIF and TENS groups whereas mean duration of hospital stay was 12.15 ± 1.42 and 11.87 ± 1.98 days respectively in the corresponding group. At six months DASH scores were 24.32 ± 7.27 and 25.00 ± 8.15 respectively in ORIF and TENS groups. An improvement of 69% and 68% in mean DASH scores was seen in the two study groups showing the difference not to be significant. Conclusion: Both ORIF as well as TENS have comparable clinical and functional outcome in management of displaced midshaft clavicle fractures. Trial registration: Clinical Trials Registry-India (ICMR-NIMS) - CTRI/2022/12/048509

URL of the trial registry: <http://www.ctri.nic.in>.

Key words: Open reduction and internal fixation (ORIF), Titanium Elastic Nailing System (TENS), Midshaft clavicle fractures, Functional outcome, Disabilities of Shoulder and Hand (DASH).

Corresponding Author: Dr. F. Abdul Khader, Professor, Shri Sathya Sai Medical College and Research Institute, Ammapettai, Chengalpet District, Tamilnadu – 603108, India.

INTRODUCTION

Clavicle connects the shoulder girdle with the trunk. Clavicle is helpful in ensuring the mobility and support during functioning of upper extremities. As it is located subcutaneously, hence clavicle is highly prone to traumatic injuries around the shoulder girdle. Clavicular fractures most commonly affect the young males. Although their frequency is only 2.6-4% of total fractures in adults yet they assume high significance as they affect the most productive proportion of our population¹. As many as 70% of the affected patients are males and majority

are below 45 years of age^{2,3,4}. The annual incidence of clavicular fractures has been reported to be 50/100,000. This incidence is more than two times higher in males (71/100,000) as compared to that in females (30/100,000)³. There are increasing trends in the incidence of clavicular fractures in the recent years⁵. The gender differences are reflected in age and types of fractures too with men being young in age and more often at risk to incur comminuted fractures as compared to women³.

Clavicular fractures can be classified as medial, midshaft or lateral fractures depending upon the site of involvement⁶. Among these three, midshaft fractures predominate. It has been reported that out of every four clavicle fractures, 3 are midshaft clavicular fractures³.

Conservative management through non-surgical modalities being a reliable option despite existence of notable displacement, it has been reported to be associated with substantial residual malalignment have drawn attention towards use of surgical management as the option. It has been shown in the previous studies that patients generally are dissatisfied owing to clavicle

malunion as it results in weakness and fatigue, specially in those having over head work.

Surgical management is helpful in reducing the incidence of limb shortening and displacement substantially apart from curbing comminution and other short-term adverse outcomes. Some of the commonly used surgical options are “superior plating, anterior-inferior plating, dual plating, and intramedullary nail fixation”⁷. In the recent years, 3-D printing technology has also emerged as an aid in the operative management of clavicular fractures^{8,9}. Functional outcomes hold an important key in determining the patient satisfaction. It must be noted that functional outcome of midshaft clavicle fractures is not

only related to its union, but also to its length¹⁰. The significance of clavicle as a *strut*, that is helpful in keeping the upper limb away from the torso for efficient shoulder and upper limb function. At the same time, it also transmits forces from upper limb to the trunk. Hence, displacement or comminution may result in symptomatic malunion/non-union and could also be related with poor function and esthetic outcome^{11,12,13}. The surgical management is gaining popularity as it has been shown to result in a better clinical outcome as compared to non-surgical approaches, particularly in terms of improvement in functional outcome.

Two operative techniques that are commonly used for internal fixation of displaced midshaft clavicular fracture (DMCF) are - Plate fixation and 2 percutaneous intramedullary nailing with a titanium elastic nail (PTEN). Use of open reduction and internal fixation (ORIF) surgical techniques is particularly indicated in “open clavicular fractures, fractures in the lateral third region, floating shoulders, fractures combined with multiple ipsilateral rib fractures, and fracture complicated by compromised skin integrity”¹⁴. Open reduction and internal fixation with plating has been shown to be beneficial in the early recovery stage for displaced midshaft clavicular fractures in adult non-geriatric population¹⁵. In view of the satisfactory clinical and functional outcomes it is often considered as the gold standard surgical management technique for midshaft clavicular fractures. However, despite its promising functional and clinical outcomes and acceptance as a gold standard, it is often criticized for a larger incision¹⁶. Extensive periosteal stripping is one of the essential requirements for plating. This could result in affecting the blood supply at the fracture site and could delay fracture healing. Moreover, rigid plates generate stresses at the fixation site which could be responsible for recurrence of fracture in a substantial number of cases. The procedure is time consuming and is also associated with risk of infection in upto one-fifth of the cases. Moreover, owing to being an invasive procedure, post-operative large scar is another issue of concern from the esthetic and cosmetic point of view. Moreover, patients often complain of discomfort caused by presence of subcutaneous plate which may force the need for additional procedures for plate removal¹⁷. Percutaneous intramedullary nailing with a titanium elastic nail (PTEN) has emerged as a viable option that is minimally invasive, better load sharing fixation and higher stability resulting in promotion of callus formation. Owing to their elastic nature, titanium nails can adapt to the S-shaped clavicle by providing a 3-point fixation¹⁸. In view of these characteristic features, it is becoming very popular and is seen as an alternative to plate-fixation, however, its clinical and functional performance against plate-fixation is not fully established. Hence, the present study was planned to compare open reduction internal fixation with plating (ORIF-plating) and Percutaneous “titanium elastic nailing system” (PTENS) for treatment of mid shaft clavicle fracture in tertiary care centre in Chengalpattu

OBJECTIVES

To compare the functional outcome of plate fixation versus TENS for displaced middle third clavicle fractures.

METHODOLOGY

The present study was conducted as randomised controlled trial (registration number - CTRI/2022/12/048509) in Department of Orthopedics, “Shri Sathya Sai Medical College & Research Centre (SSSMCRI), Ammapettai, Chengalpattu District”. among patients who present with mid shaft clavicle fractures willing for “titanium elastic nailing system” in department of orthopaedics over the study period.

After approval from ethical committee, a total of 60 patients, aged 20 to 65 years, scheduled for elective surgery- “titanium elastic nailing system” or open reduction and internal fixation were enrolled in the study. A written and informed consent in their vernacular language was obtained from all the patients before enrolling them in the study. Included patients were randomly divided into two groups by sealed envelope technique. Patients were monitored by the surgeon and surgical intervention as per the “Group A” allocation was provided, outcomes of patients were monitored

Inclusion Criteria

Patient aged between 20 and 65 years with unilateral displaced midshaft clavicle fracture with displacement more than shaft width

Exclusion Criteria

Patient with pre - existing morbidity concerning shoulder , arm or hand , open injuries , open fracture , pathological fracture , severe comminuted clavicle fracture , loss to follow up were excluded from study

Method of collection of data

Patients who were clinically diagnosed with mid shaft clavicle fracture fulfilling the inclusion criteria, willing for “titanium elastic nailing system” and open reduction and internal fixation were enrolled after obtaining a written and informed consent in their vernacular language. Pre anaesthetic opinion was obtained. Patients were selected and divided into two “Group B” by closed envelope method, patient explained in detail about the procedure.

“GROUP A” (n=30): patients were subjected to mid shaft clavicle fracture with “open reduction with internal fixation”.

“GROUP B” (n=30): patients were subjected to mid shaft clavicle fracture with “titanium elastic nailing system”.

Statistical analysis

The data was collected on a semi-structured questionnaire. Records of all the test reports were maintained. All observations were made under direct supervision of the supervisor.

“The data so collected was fed into computer using MS Excel 2013 or compatible software which was subjected to statistical analysis. The statistical analysis was done using SPSS (Statistical Package for Social Sciences) Version 21.0 statistical Analysis Software. The values were represented in Number (%) and Mean±SD”

RESULTS

All the patients of clavicle fracture were invited to participate in the study, of these 60 fulfilling the inclusion criteria and giving consent of inclusion were enrolled in the study. Patients were randomly divided into two groups using sealed envelope technique.

Table 1: “Group wise Distribution of Study Population”

SN	Group	Description	No. of cases	Percentage
1-	“Group A”*	Mid shaft clavicle fracture with “open reduction with internal fixation”	30	50.0
2-	“Group B”	Mid shaft clavicle fracture with “titanium elastic nailing system”	30	50.0
		Total	65	100.0

*19 Anatomical and & 11 reconstructive plate

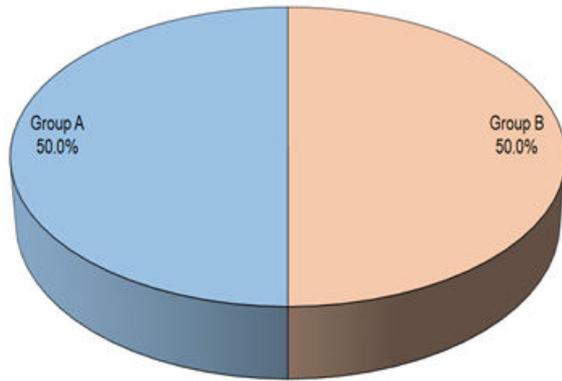


Figure 1: “Group wise Distribution of Study Population”

Out of 60 patients of mid shaft clavicle fracture, 30 (50%) each were randomly managed by “open reduction with internal fixation” (“Group A”) and “titanium elastic nailing system” (TENS) (“Group B”) respectively.

Table 2: Between Group Comparison of Demographic Profile

SN	Demographic characteristics	“Group A” (n=30)		“Group B” (n=30)		Total (N=60)	
		No.	%	No.	%	No.	%
1-	Age Group						
	≤25 years	5	16.7	7	23.3	12	20.0
	26-40 years	8	26.7	7	23.3	15	25.0
	41-60 years	13	43.3	10	33.3	23	38.3
	>60 years	4	13.3	6	20.0	10	16.7
	Statistical significance	$\chi^2=1.190$; $p=0.755$					
	Mean age±SD (Range) in years	43.13±15.04 (20-65)		42.97±16.21 (20-65)		43.05±15.50 (20-65)	
	‘t’=0.041; $p=0.967$						
2-	Gender						
	Male	16	53.3	19	63.3	35	58.3
	Female	14	46.7	11	36.7	25	41.7
	Statistical significance	$\chi^2=0.617$; $p=0.432$					

Both the groups had comparable age and gender ratio.

Table 3: “Between Group Comparison of Time lapse to Surgery (Difference of time of injury and time of surgery)”

SN	Time lapse	“Group A” (n=30)		“Group B” (n=30)		Total (N=60)	
		No.	%	No.	%	No.	%
1-	1 day	1	3.3	2	6.7	3	5.0
2-	2 days	9	30.0	3	10.0	12	20.0
3-	3 days	17	56.7	13	43.3	30	50.0
4-	4 days	3	10.0	11	36.7	11	23.3
5-	5 days	0	0.0	1	3.3	1	1.7

$\chi^2=9.438$; $p=0.051$

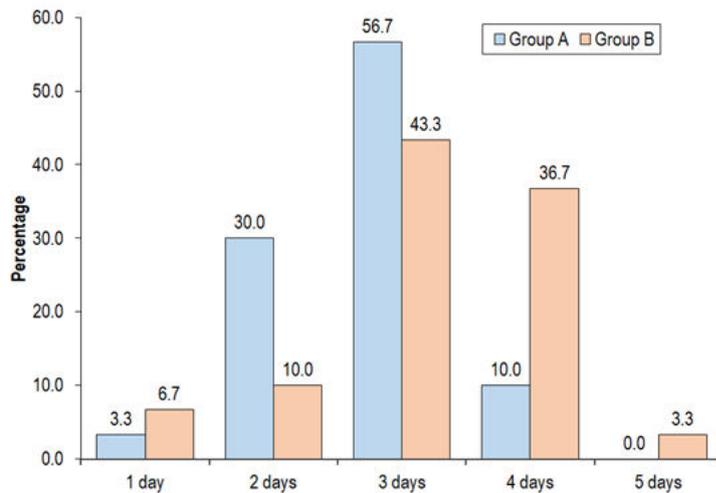


Figure 2: Between Group Comparison of Time lapse to Surgery

Though proportion of those undergoing the procedure before two days was higher in Group 1 (33.3%) as compared to that in “Group B” (16.7%) whereas proportion of those undergoing the procedure at 4th or 5th day was higher in “Group B” (40%) as compared to that in “Group A” (10%) yet this difference was not significant ($p=0.051$).

Table 4: Between Group Comparison of Loss of blood (ml) during surgery

Group	No. of patients	Min.	Max.	Mean	SD
“Group A”	30	100	300	140.00	50.45
“Group B”	30	100	320	130.67	45.48
Total	60	100	320	135.33	47.85

‘t’=0.753; $p=0.455$

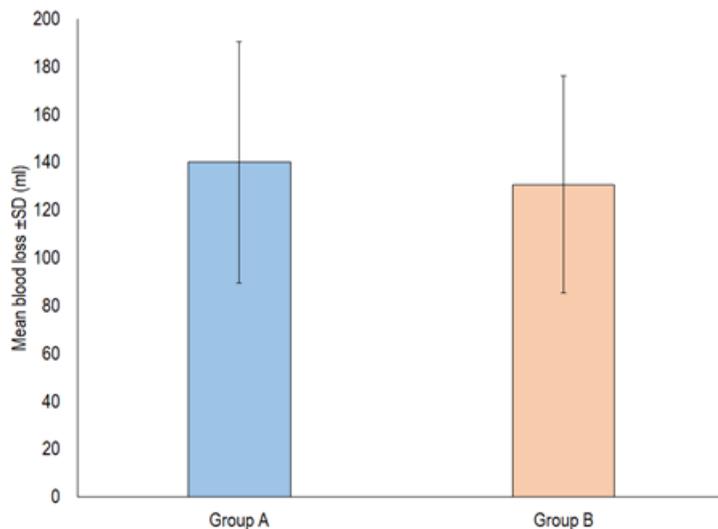


Figure 3: Between Group Comparison of Blood loss during Surgery

Though more blood loss was observed in “Group A” (140.00 ± 50.45 ml) as compared to that in “Group B” (130.67 ± 45.48 ml) yet this difference was not found to be significant ($p=0.455$).

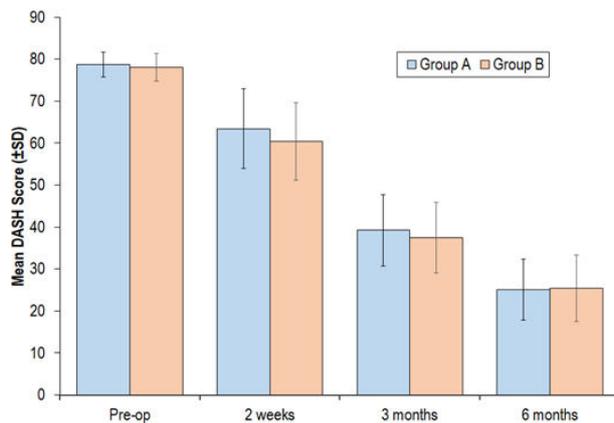
Table 5: Between Group Comparison of post-op Complications

SN	Complications	“Group A” (n=30)		“Group B” (n=30)		Total (N=60)	
		No.	%	No.	%	No.	%
1-	Bed sores	1	3.3	0	0.0	1	1.7
2-	Delayed union	0	0.0	1	3.3	1	1.7
3-	No complication	29	96.7	29	96.7	58	96.7

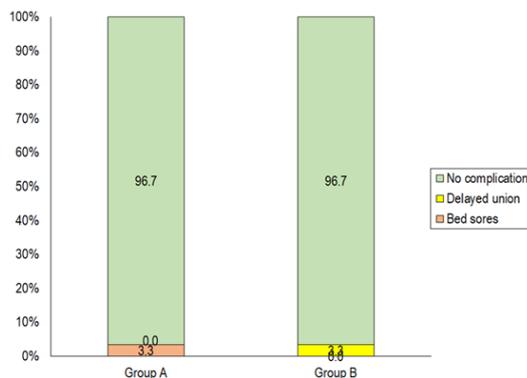
$\chi^2=2.000$; $p=0.368$

Table 6: Between Group Comparison of DASH Scores at different time intervals

SN	Time	“Group A” (n=30)		“Group B” (n=30)		Student ‘t’ test	
		Mean	SD	Mean	SD	‘t’	‘p’
1-	Pre-op	78.67	2.96	78.10	3.29	0.700	0.486
2-	2 weeks	63.40	9.49	60.40	9.22	1.242	0.219
3-	3 months	39.23	8.50	37.43	8.40	0.825	0.413
4-	6 months	25.10	7.21	25.43	7.92	-0.170	0.865

**Figure 4: Between Group Comparison of DASH Scores**

DASH scores of both the groups were comparable at all the periods of observation (Pre-op, 2 wks, 3 months, 6 months).

**Figure 5: Between Group Comparison of Post-op. complications**

Post-op complications had been observed in 1 patient each in above two groups. In “Group A” 1 (3.3%) patient had bed sores, while 1 (3.3%) patient of “Group B” had delayed union.

DISCUSSION

Fractures of clavicle are quite common in younger population in active phase of their life. It accounts for 5 to 15% of total fractures in children and young adults and comprises nearly 35 to 44% of total shoulder injuries in this age group I. Thus, it happens to be one of the most common orthopedic injury disabling the young and productive population. The management of these fractures is not only directed towards a clinical or radiological union only but also targets an early recovery, restoration of normal routine and good functional outcome. In the recent years, surgical management of midshaft clavicle fractures has shown a definitive superiority over the conservative management as it avoids malunion and provides early functional restoration. Open reduction and internal fixation (ORIF) and “titanium elastic nailing system” (TENS) are two most popular and widely used surgical procedures for the management of midshaft clavicle fractures, however, there is still debate regarding which of these two modalities has better adaptability in our environment. In the present study we made an attempt to compare the two modalities in terms of their functional outcomes.

Study Design and Sample Size

For this purpose, a prospective randomized study was carried out that had a total of 60 patients (30 in ORIF and 30 in TENS group). Randomized controlled studies are the hallmark of clinical research and provide the most robust clinical evidence to differentiate between two or more drugs/interventions for their efficacy for the property being investigated¹. However, they could be considered to be perfect only if they do not have any confounding factor. While experimental studies can be made free of any confounder by controlling both the characteristics of the samples being investigated and their surrounding environment yet it is not possible to do so in case of living beings, particularly human beings. Each human being is an individual on his/her own. In randomized-controlled trials it becomes even more difficult as the investigator does not have control to allocate a person with a particular set of characteristics (even for age and sex) and hence the principle of statistical matching instead of identical matching is employed. The adequacy of a sample size can be gauged by two factors, first whether the sample size is adequate enough to rule out the differences in demographic and pre-intervention clinical characteristics of two groups owing to random allocation and secondly against a pre-determined projected estimate. In the present study, we calculated the sample size on the basis of projections made using the outcomes in a previous study¹⁹. As far as adequacy in terms of matching of two groups for the confounding factors like age, sex, mode of injury, level of disability and other clinical characteristics was concerned, in the present study, the two groups had a statistically matched profile for this and hence the sample size could be considered as adequate from this point of view too.

Associated Injuries

In the present study, there was only one patient in TENS group having an associated skeletal injury (Bennet fracture). In fact, owing to strict exclusion criteria that excluded a number of conditions that could have intervened as associated injuries. This was done in order to rule out the confounding effect of these injuries.

Time Lapse to Surgery

In the present study, majority of patients (75%) had 3 or more days gap between injury and surgery. Vajrangi *et al.*²⁰ in their study also reported mean gap between injury and surgery to be above 3 days. A similar time gap between injury and surgery was also reported by Pandian *et al.*²¹ in their study, however, in their study the time gap was shorter in TENS (2.55 days) as compared to that in ORIF (4.65) group. In the present study, however, there was no such mismatch between the groups and both the groups were comparable with respect to time gap between injury and surgery.

Duration of Surgery

In the present study length of surgical procedure ranged from 85 to 180 minutes. Mean duration of surgery was 126.67 ± 25.51 minutes in ORIF as compared to 133.00 ± 30.39 minutes in TENS group. Though the mean duration of surgery was slightly longer in TENS as compared to ORIF group yet this difference was not significant statistically.

Although Sharma *et al.*²² too did not find a significant difference in mean time taken for surgical procedure, however, in their study the duration of surgery was reported to be much shorter than that in the present study. In their study, the mean duration of surgery was reported to be 58.38 and 52.39 minutes respectively for the two study groups as compared to 126.18 and 132.58 minutes in the present study. In another study, Pandian *et al.*²¹ also did not find a significant difference in mean duration of surgery between the two groups, however, they also reported the operative time to be much shorter (53.75 and 49 minutes in two groups) than that in the present study.

The reason for this could be the difference in method of calculation of surgical duration. In the present study, the duration of surgery was calculated by entire time spent in the operative room as against some studies calculating it from the time of placement of incision only. In the present study, we calculated duration of surgery in such a manner as both the techniques require some preliminary preparations and we felt it appropriate that the duration of surgery should be interpreted in terms of entire time spent in the operative room.

Blood Loss during surgery and Transfusion Need

In the present study, mean amount of blood loss during surgery was 140.00 ± 50.45 ml in ORIF and 130.67 ± 45.48 ml in TENS groups. Intraoperative blood loss was similar in two groups without any difference in statistical terms. Only 3 (10%) patients in ORIF and 2 (6.7%) in TENS group required one unit of blood transfusion. Blood transfusion need was also similar in two groups in statistical terms.

Compared to present study, Sharma *et al.*²² in their study reported intraoperative blood loss to be significantly higher in ORIF (130.21 ml) as compared to that in the TENS (72.63 ± 1.68 ml). It must be noted that the age of patients in their study was much younger with as many as 72% of TENS group patients being <30 years of age. In the present study majority of patients were mature adults aged >40 years. It must be noted that as the age increases the skin hardness increasesⁱⁱ and becomes difficult to penetrate by the elastic wires as compared to that in the younger age and hence the blood loss during the procedure is equivalent to that in ORIF. In another study, Yadav *et al.*²³ also reported amount of blood loss to be higher in ORIF as compared to TENS group, however, in their study too there was a dominance of those aged <40 years and the difference from their study could only be attributed to difference in age profile of patients in two studies.

Post-operative Complications, Duration of Hospital Stay and Time taken for mobilization

In the present study, no major complication was noted in either of two groups. There was one patient in ORIF who experienced bed sores and one patient in TENS group experiencing delayed union. Time taken for mobilization was 6.07 ± 1.51 days in ORIF and 5.90 ± 1.27 days in TENS "Group A" and mean hospitalization was 12.10 ± 1.51 days in ORIF and 11.80 ± 1.97 days in TENS group. The two groups had similar post-operative complications, time taken for mobilization and duration of hospital stay in statistical terms.

Similar to the present study, Vajrangi *et al.*²⁰ also did not find a significant difference between the two groups for post-operative outcomes like complications and pain but found the mean duration of hospital stay to be significantly shorter in TENS as compared to that in ORIF group. However, Pandian *et al.*²¹ in their study similar to the present study, did not find a significant difference in hospitalization period between the two groups. Both the groups

were matched statistically for post-operative complications in their study too. Devendran and Vasantharaman⁷⁰ and Itagi *et al.*²⁴ also found the two groups to be statistically matched for post-operative complications and outcome. Thus, the findings of the present study are in general in agreement with the findings of other contemporary studies.

Functional Outcome (DASH Scores)

In the present study at baseline mean DASH scores were 78.67 ± 2.96 and 78.10 ± 3.29 respectively in ORIF and TENS groups which reached at 25.10 ± 7.21 and 25.43 ± 7.92 respectively at final follow-up. Thus, an improvement of 53.57 was observed in ORIF and 52.67 in TENS group. However, at none of the time intervals the difference between the two groups was significant statistically.

As far as functional outcomes are concerned, most of the previous studies, similar to the present study did not find a significant difference in functional outcome of two surgical techniques at any of the follow-up periods. Vajrangi *et al.*²⁰ found no significant difference between two groups at 6 months follow-up as also seen in the present study. However, Sahu *et al.*¹⁹ in their study found functional outcomes in TENS group to be significantly better as compared to that in the plate group, however, they did not report about the time at which this evaluation was made. In the present study too, at the early follow-up period (2 weeks and 3 months) DASH scores in TENS group were lower as compared to that in the ORIF group, however, the difference was not significant statistically. The findings in the present study at all the follow-up periods are in agreement with the observations of Pandian *et al.*²¹ who also did not find a significant difference in mean quick DASH scores at 1, 3 and 6 months follow-up intervals.

In another study, at six months follow-up Sharma *et al.*²² also found the functional outcome in two groups to be similar with respect to flexion, abduction, internal rotation and external rotation respectively. Other workers also support similar functional outcome for two techniques in their studies at final follow-up^{25,26,27}.

CONCLUSION

The present study was carried out “to compare the functional outcome of open reduction with internal fixation (ORIF) plating with titanium elastic nailing system (TENS) in management of displaced midshaft clavicle fractures. For this purpose, a total of 60 patients fulfilling the selection criteria were enrolled”. Of these, 30 were managed using open reduction with internal fixation (ORIF) (aged 20-65 years; Mean age 43.13 ± 15.04 years; 53.3% males) whereas remaining 30 were managed using TENS (age range 20-65 years; Mean age 42.97 ± 16.21 years; 63.3% males).

The two groups were matched demographically and clinically before the surgery. There was no statistically significant difference between two groups for intraoperative blood loss, transfusion need and complications. No significant difference between the two groups was observed for time taken for mobilization and duration of hospital stay. The two groups were also matched for post-operative complications.

There was an improvement of 69.0% and 68.0% in functional scores (DASH scores) in ORIF and TENS groups over a six month follow-up period. Good improvement in functional outcome was seen in both the groups and the two groups were similar in statistical terms.

The findings of the present study indicated that both ORIF plating and TENS were comparable techniques for management of displaced midshaft fractures of clavicle and showed good functional outcome. Other parameters of interest need to be evaluated in further studies to mark out the differences between the two techniques.

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