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A prospective comparative study to evaluate the functional outcome of intramedullary nailing versus plate fixation in cases of mid-shaft clavicle fractures

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Abstract
Background: Clavicular fractures, constitutes about 2.6% to 5% of all fractures in adults, mostly involving midshaft clavicle. Clavicle fracture management has evolved over the centuries from supervised neglect to internal fixation. Studies have shown better functional outcome with nailing, as it overcomes the complications of the plate fixation significantly. Thus, this comparative study was taken up.
Methods: Study was conducted on 72 patients who underwent surgery for mid-shaft clavicle fractures at Manipal hospital, Bangalore from August 2018-August 2019. Patients were divided into 2 groups,36 in each group of plate fixation or nailing, based on the surgeon's choice. In intramedullary fixation, 2.5mm TENS nail was used. Plate fixation was done with 3.5 mm pre-contoured LC-DCP. Clavicle length measurement was done with help of plain radiographs. Constant shoulder scores were used for evaluation of the functional outcome at each follow up done at 6 weeks, 12 weeks, 6 months and 12 months.
Results: Nailing group has a faster recovery compared to the plating group at 6 weeks, mean CSS at 6 weeks was 57.89 in nailing group and 44.78 in plating group. The CSS was compared in both groups based on age, gender, dominance of hand and smoking status of patient, and found to not affect the functional outcome, except in nailing group, the dominant hand side found to be recovered significantly faster at 6 weeks (P value 0.002) and 12 weeks (P value 0.010). Clavicle length restoration was found to be significant in nailing group which was 1.78cm and that of plating group was 1.30cm. Mean operating time in nailing group was 41.53 minutes which was less and that of plating group 80.72 minutes. Mean incision length of plating was 11.5cm and that of nailing was 3.3cm.
Conclusion: Nailing is superior in management of mid-third clavicle shaft fractures considering early recovery, smaller incision, less scar, clavicle length restoration, simple procedure and lesser complications than plate fixation

Keywords: Clavicle fracture, LC-DCP, TENS nail, clavicle length

Introduction
The incidence of clavicle injuries has increased along with the mobile and energetic way of life. Clavicular fractures, constitutes about 2.6% to 5% of all fractures in adults, mostly involving the midshaft of the clavicle with different degrees of displacement [1-3]. Although the fracture union usually occurs regardless of the treatment selected, controversy exists regarding the optimal management [4, 5].
Nonoperative management, was the most common approach to nondisplaced clavicular fractures in adults, consists of immobilization in a sling or figure-of-8 dressing followed by range-of-motion (ROM) exercises. Though these methods have been commonly used for midshaft clavicular fractures treatment, resulted in various unsatisfactory complications such as non-union, malunion and shoulders asymmetry [6-8]. The rate of malunion after conservative treatment for the midshaft clavicular fractures reached 15%, and about 30% patients were unsatisfied [9]. Recent studies have shown that surgical treatment may diminish non-union and sequelae.
Operative repair, especially early fixation, results in improved outcomes and lower incidence rates of non-union and malunion compared with nonoperative management and is recommended for patients with multiple risk factors for non-union, especially when

there is a significant displacement or clavicle shortening [10]. Options for operative repair are open or closed reduction with plate fixation or intramedullary fixation. Open reduction and plate-screw fixation was considered as the gold standard treatment with the advantages of firm fixation and earlier postoperative mobilization, but also with disadvantages of larger incision and more organizations being exposed, thus presenting with many postoperative complications [11-13].

In surgical treatment, a 3.5 mm dynamic compression plate is a usual choice. However, the complex contour of the clavicle may limit its use. Reconstruction plates were first designed for pelvi-acetabular fixation and then later applied for the repair of clavicular fractures, as these plates could better comply to the contour of the clavicle [14-15]. Clinical outcomes are better with the reconstruction plates than with the dynamic compression plate [16].

Intramedullary fixation treatment for midclavicular fractures has been favoured due to its strengths including small incision, less periosteal striping, dispersion of stress and simple to operate [17]. In 2002, Titanium Elastic Nailing System (TENS) was first applied in the treatment of displaced midclavicular fractures, and showed good clinical therapeutic outcomes as an alternative to conservative treatment but with the poor force of anti-rotation and anti-shortening [18]. Common TENS resulted in various complications including hardware irritations, medial perforations, lateral penetrations, TEN breakage and dislocations [19]. Thus, further advancements have been tried in TENS nailing to overcome the complications, by adding locking screws in the lateral end. Surgical management has been established as the better resort in treatment of the clavicle fractures, since a lot of studies as already proven the better functional scores comparing to the conservative management. Coming to the surgical method, plating the fracture with pre-contoured DCP or reconstruction plates has been commonly practised widely, but intramedullary nailing with TENS has been gaining popularity over the decade, has it overcomes the complications of the plate fixation significantly.

Thus, the purpose of this study was to prospectively compare the results of plating and intramedullary nailing fixation for completely displaced acute midshaft clavicle fractures.

Materials and Methods

- **Study site:** Manipal hospital Bangalore.
- **Study period:** August 2018 - August 2020
- **Study design:** Prospective comparative study
- **Study population:** This prospective study was conducted on 72 patients who underwent surgery for mid-shaft clavicle fractures at Manipal Hospital, Bangalore during the period August 2018 - August 2019. The patients were allocated into the two study groups based on the surgeon's choice. Considering the inclusion and exclusion criteria, all cases were taken as per the case proforma prepared for the study. Informed consent was obtained from the patient.
- **Methods of collection of data:** Mean operation time in titanium elastic nails (TEN) fixation group and Reconstruction plate group was 48.25 (±19.76) and 66.49 (±22.47) minutes respectively. (Ref: Chen YF *et al*., 2012) [14].

Sample size $n = \frac{(Z_{\alpha/2}+Z_{\beta})^2 \times 2 \times \sigma^2}{d^2}$

n = 36

$Z_{\alpha/2}$= $\alpha/2^{th}$ quantile of normal distribution

Z_{β}= $(\beta)^{th}$ quantile of normal distribution

D= difference in means

σ^2= population variance

Sample size calculated is around 36 at 95% confidence interval.

So, sample size required is 36 patients in each group.

Statistical Analysis: For data analysis all the findings were entered in an Excel spread sheet on Microsoft Excel. Statistical analysis was done by using descriptive and inferential statistics, using student's unpaired t test, Fischer's exact test or Chi-Square test to analyse the significance of difference between frequency distribution of data. The Statistical software SPSS (Statistical package for social sciences) Version 22.0 and GraphPad Prism 6.0 version was used for the analysis of the data.

P value <0.05 has been considered as level of significance.

Inclusion criteria

1) All patients who underwent surgery for mid-shaft clavicle fracture during our study period.
2) Isolated, displaced mid-shaft clavicular fractures with no cortical contact between the main fragments.
3) Age between 18 and 65 years.

Exclusion criteria

1) Fractures of the medial or lateral third of the clavicle,
2) Pathological or open fractures,
3) Fractures with an associated neurovascular injury,
4) Contraindication for surgery in general anesthesia,
5) Complex comminuted fractures,
6) Moderate-to-severe head injury at time of trauma (Glasgow Coma Scale [GCS] <12)

Investigations required for the study

1) As per the routine pre-operative work up for patients posted for surgery.
2) X-ray of Chest, Antero-posterior view to compare the clavicle length.

Methodology

1) All patients with above mentioned inclusion criteria were included in the study.
2) Patient's details were collected as follows.,

- Age
- Sex
- Occupation
- Side of Injury
- Dominant Hand
- Smoking Status

All necessary pre-operative investigations were done. With pre-operative consent each patient received either intramedullary nailing (TENS) or Plate fixation with a 3.5-mm pre-contoured (LC-DCP) both performed by the same surgeon. The surgical method allocated was based on surgeon's choice. All the patients were operated within 1 week of injury.

Surgical technique

1. Intramedullary nailing

For TENS fixation, each patient was placed on a radiolucent operating table in the 20-30 degree inclined position, and a

roll of towels was placed between the scapulae to fully extend the clavicle. Surgical site was prepared and draped. After clavicle extension, fluoroscopy was used to check for overlap of the fracture site. A 1- to 2-cm skin incision was made just above the sternal end of the clavicle. Approximately 2 cm lateral to the sternoclavicular joint, an entry hole was created in the anteroinferior cortex of the sternal end of the clavicle with a 2.5-mm drill and was then widened by use of an awl. The TENS, measuring 2.5mm, was pre-bent for the ease of entry and then fixed in a T-handle. By use of oscillating hand movements, the unreamed TENS was advanced until it reached the fracture site. Under fluoroscopic monitoring, the nail was introduced into the lateral fragment by closed manipulation of the fragment (Image 1 and 2). If closed reduction failed, an accessory incision of 2 to 3 cm was made above the fracture site to enable direct manipulation of the lateral fragments. The nail was then advanced under fluoroscopic guidance. Care was taken to ensure that the nail tip was in close proximity to the far cortex, as well as to avoid protrusion into the posterior cortex. We made a bony shallow trough at the entry site to accommodate the cut end of the nail to prevent nail migration and skin irritation. The protruding end of the nail was cut off at an appropriate length at the site of entry.

Post operatively support was given with a sling for 3 weeks. For the first 3 weeks, only pendulum motion was allowed, from 3 to 6 weeks active abduction and flexion up to the horizontal plane was initiated and after 6 weeks, fully active motion. Return to full activities was permitted after 3 months.

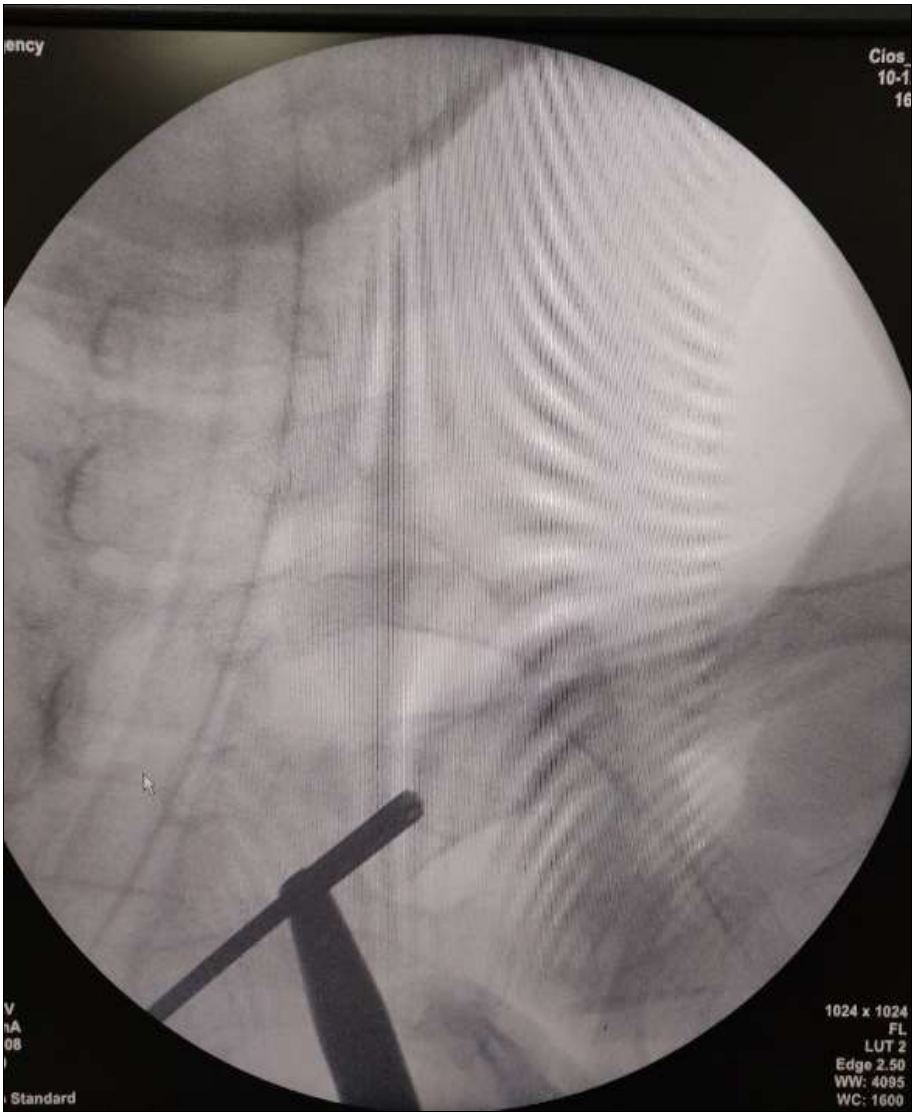

Fig 1: Fluoroscopic image showing entry of TENS nail.

Fig 2: TENS nail advanced beyond fracture site and negotiating into lateral fragment.

Fig 3: TENS nail holding both medial and lateral fragment.

Fig 4: Post-operative radiograph following TENS nail fixation.

2. Open reduction internal fixation with plating:
Patients were placed in the beach-chair position and prepared and draped in a standard fashion. A longitudinal incision parallel to the clavicle, the length of which depended on the fractured segment, was made, and the fracture was identified. Following fracture reduction, a plate, having 6-8 holes, was positioned on the anterosuperior surface of the clavicle and fixed with nonlocking and locking screws. The aim was to place at least 3 bi-cortical screws in the medial and lateral main fragments (Image 5). The length of the plate was determined according to the grade of the comminution of the fracture. The type of plate was selected according to the surgeon's preference. A minimum of three bi-cortical screws was placed on each side of the fracture to ensure rigid fixation. If interfragmentary compression was possible, lag screws were placed first. No bone grafting was included.
Postoperatively, the arm was immobilized in a sling for 3 weeks. The postoperative rehab protocol was similar to that in the nailing group.

Fig 5: Post-operative radiograph following plate fixation.

For analyzing the functional outcome, patient reported Constant Shoulder Score (CSS) was used. It considers four parameters pain, level of activity, range of movements (ROM) and power [20]. On comparing the CSS with the normal side, it has been graded as poor, fair, good and excellent [21[. Constant shoulder scores were assessed pre-operatively and during 6 weeks, 12weeks, 6 months, 1 year of follow-up. The scores of each patient were collected and entered in excel sheet for statistical analysis.

Clavicle length restoration
It has been established by now that shortening of more than 2 cm is absolute indication for surgery. The measurement of shortening in our study was done with plain radiograph of chest in AP projection (Image 6,7). The length of the clavicle was measured from tip of the medial end to the tip of lateral end. Length of both the clavicles were measured and noted down pre-operatively. After the surgery, measurement of the involved side was done. All the values were noted for statistical analysis. The length of contralateral clavicle was taken as reference for original length of the clavicle. Thus, amount of shortening after injury and amount of restoration after surgery was calculated.
Mean operation time was noted in every case and Incision length was measured and tabulated.

Fig 6: (A,B). Measurement of both the clavicle length in a pre-op radiograph. Measurement of clavicle length in a post-op radiograph following plating in the same patient and we can notice the restoration of length.

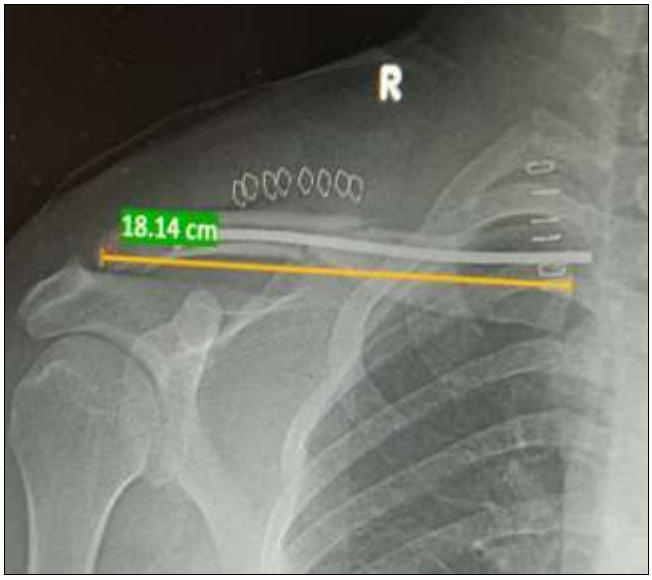

Fig 7: Measurement of clavicle length in a post-op radiograph following nailing.

Results: In our study we have evaluated the Constant Shoulder Score (CSS) in both groups pre-operatively and post-operatively at regular interval at 6weeks, 12weeks, 6months and 1 year follow up. We also compared the scores

between the two groups and also compared the scores based on age, gender, dominance of hand and smoking status of the patient.

Patients included in the nailing group had mean age of 38.72 years with standard deviation of 12.69 years and patients included in the plating group had mean age of 41.53 with standard deviation of 12.56 years. Maximum number of cases in both the groups were from age group 30-40 years. In both the groups male dominance is observed. In nailing group out of 36 cases 21 (58.33%) were male and 15 (41.67%) were female whereas in plating group out of 36 cases 27 (75%) were male and 9 (25%) were female. Most of the cases having mid-shaft clavicle fracture are engineers, businessman and home makers (43, 59.72%). Out of 36 cases of nailing 20 (55.56%) cases had left side involvement and 16 (44.44%) cases had right side involvement whereas out of 36 (55.56%) cases of plating 20 (44.44%) cases had left side involvement and 16 cases had right side involved. Out of 36 cases of nailing 17 (47.22%) cases had dominant and 19 (52.78%) cases had non dominant side involved whereas out of 36 cases of plating 16 (44.44%) cases had dominant and 20 (55.56%) cases had non dominant side involved. Out of 36 cases of nailing 20 (55.56%) cases were non-smokers and 16 (44.44%) cases where smokers whereas out of 36 (55.56%) cases of plating 20 (44.44%) cases were non-smokers and 16 (44.44%) cases were smokers. Plating procedure had larger operation time than nailing procedure and difference was seen to be significant (p-value<0.001) (table 1).

After operation, nailing method had more improvement in clavicle length than the plating method and the increase in length was significant (table 2). Comparing post-operative clavicle length with the opposite side, the nailing method has 35 cases with less than 0.5cm of residual shortening and only one case had greater than 1cm of residual shortening. Whereas in plating method, 12 cases had less than 0.5cm of residual shortening, 18 cases had 0.5-1 cm of residual shortening and 6 cases had greater than 1cm of residual shortening. Nailing method had better improvement than plating method with respect to increase in clavicle length post operatively (table 3).

When analysing the Constant Shoulder Score, nailing group had a faster recovery compared to the plating group at 6 weeks, mean Constant Shoulder Score at 6 weeks was 57.89 (SD±13.35) in nailing group and 44.78 (SD±13.93) in plating group. As time increases constant shoulder score increases and nailing procedure had good improvement in the score than the plating procedure (table 4). The Constant Shoulder Score was compared in both groups based on age, gender, dominance of hand and smoking status of the patient, and based on the statistical analysis it was found that it did not affect the functional outcome, except in nailing group, the dominant hand side found to be recovered significantly faster at 6 weeks (P value 0.002) and 12 weeks (P value 0.010) (table 5). Considering the side involvement (whether right or left side being involved), nailing procedure had better score than the plating procedure. At end of 6 weeks, significant difference observed in the score in either of the side between nailing and plating procedures (P value 0.008 for left side and P value 0.002 for right side), but at 12 weeks significant difference was observed in constant shoulder score only in the right side involved cases (P value 0.018) (table 6). Out of 36 cases of nailing procedure 1 case had lateral migration, 2 cases had medial migration, 1 had non-union complications whereas in plating procedure 1 cases had implant loosening, 2 cases had joint stiffness, 1 case had non-union and 2 cases had Surgical Site Infection. Plating procedure had more complications than nailing method.

Table 1: Operation time between both groups

	Nailing	**Plating**	**P value**
Operating Time (min)	41.53±7.70	80.72±11.67	<0.001

Table 2: Comparing clavicle length between both groups.

	Nailing	**Plating**	**P value**
Pre-operative	14.11±1.30	14.08±1.15	0.924
Post-operative	15.92±1.20	15.39±1.07	0.054
Post-operative increase in clavicle length	1.78±0.55	1.30±0.46	<0.001

Table 3: Comparison of residual shortening of clavicle post-surgery.

Decrease in length (cm)	**Nailing**	**Plating**	Total	**P value**
<0.5	35	12	47	<0.001
0.5-1	00	18	18	
>1	01	06	07	
Total	36	36	72	

Table 4: Constant Shoulder Score between both groups.

Time	**Nailing**	**Plating**	**P value**
Pre-Operative	12.44±5.12	11.67±4.96	0.514
6 weeks	57.89±13.35	44.78±13.93	<0.001
12 weeks	75.47±9.74	70.78±9.65	0.044
6 months	82.14±9.18	79.81 ±9.28	0.287
1 years	91.11±8.14	89.47±7.61	0.381

Table 5: Comparison of Constant Shoulder Score with hand dominance.

Dominance	CSS	Nailing	Plating	P-value
Dominant	Pre-operative	14.06±5.34	12.19±4.94	0.305
	6 weeks	64.88±10.62	48.94±16.06	0.002
	12 weeks	78.82±7.74	71.19±8.40	0.010
	6 months	83.94±7.37	81.19±8.10	0.315
	1 year	93.06±4.57	91.38±4.48	0.294
Non Dominant	Pre-operative	11.00±4.67	11.11±5.15	0.944
	6 weeks	50.17±11.17	39.89±9.14	0.003
	12 weeks	71.83±10.46	69.68±10.47	0.525
	6 months	80.22±10.68	78.26±10.27	0.562
	1 year	89.11±10.40	87.68±9.41	0.654

Table 6: Comparison of Constant Shoulder Score with side involvement.

Side involvement	CSS	Nailing	Plating	P-value
Left	Pre-operative	11.75±5.55	11.80 ± 5.89	0.978
	6 weeks	53.50±14.74	41.70±12.01	0.008
	12 weeks	73.20±10.75	70.45±10.75	0.423
	6 months	81.55±10.90	78.80±10.28	0.416
	1 year	89.60±9.95	88.00±9.27	0.601
Right	Pre-operative	13.31±4.51	11.50±3.63	0.220
	6 weeks	63.38±9.11	48.63±15.54	0.002
	12 weeks	78.31±7.71	71.19±8.40	0.018
	6 months	82.87±6.70	81.06±7.98	0.492
	1 year	93.00±4.71	91.31±4.45	0.305

Discussion

Clavicle fracture management has evolved over the centuries from supervised neglect to internal fixation. The incidence has been widely distributed among different age groups and both the genders [22]. The basic aim is to restore the function of the patient, as much as possible to the pre injury state. With decades of research and recent advances in the techniques and availability of implants, whenever indicated, it is better to surgically operate rather than conservative management [23-25]. Studies have shown the better shoulder score in surgical fixation and reduced incidence of non-union [24].

In our study we have compared the outcome of plating of mid shaft clavicle fractures with the intramedullary nailing using TENS. Total study population include 72 subjects, with 36 patients each subgroup.

Patients included in the nailing group has mean age of 38.72 years (SD± 12.69 years) and patients included in the plating group had mean age of 41.53 years (SD± 12.56 years) (P value 0.300). Maximum no of cases in both the groups were from age group 30-50 years. No statistical significance was observed in the age distribution between the two groups. Even in other studies the age distribution was found to be not significant between the two groups [26-28].

In both the groups male dominance is observed. In nailing group out of 36 cases 21 (58.33%) were male and 15 (41.67%) were female whereas in plating group out of 36 cases 27 (75%) were male and 09 (25%) were female. But comparing between both the groups, gender distribution was statistically not significant (P value 0.134). This observation was similar to the other studies [23, 26-28].

In our study, the side of injury and dominance of the side injured was found to be not significant between both the groups. Out of 36 cases of nailing 17 (47.22%) cases had injury on dominant side and 19 (52.78%) cases had injury on non-dominant side whereas out of 36 cases of plating 16 (44.44%) cases had injury on dominant and 20 (55.56%) cases had injured their non-dominant side (P value 0.947) which was statistically not significant. Similar observations were made in other comparative studies also [23, 28].

Out of 36 cases of nailing 20 (55.56%) cases were non-smokers and 16 (44.44%) cases where smokers whereas out of 36 (55.56%) cases of plating 20 (44.44%) cases were non-smokers and 16 (44.44%) cases were smokers (P value 1). The distribution was not significant between both the groups and similar observation was done in other study by Virtanen KJ *et al.* [23].

Comparing the mean operation time, nailing was found to be a significantly faster procedure. Mean operating time in nailing group is 41.53±SD 7.70 minutes and that of plating group is 80.72±SD 11.76 minutes (P value <0.001). Thus, this significantly shows the ease of the procedure and reduces the intra operative bleeding significantly. The incidence of infection can be drastically reduced in nailing group compared to that of plating due to reduced operative time. In a study King *et al*., [27] on average, the nailing group had a shorter operating time (43±8 minutes versus 60±19 minutes, p = 0.0029) and study by Beigang Fu [29], mean operative time 46.417±9.232 comparable to our study.

Mean incision length of plating was 11.5 and that of nailing is 3.3 cm. Only four cases required additional 2 or 3 cm of incision at the fracture site for controlling and guiding the nail into the lateral fragment. It was found that communition at the fracture site required the extra incision at the fracture site for manoeuvring the nail. Thus, nailing has significantly small incision. Especially with increasing distribution of cases in young females, nailing with less scar will be cosmetically appealing (Image 13 & 14). This also accounts to very less bleeding during the surgery. Larger incision and longer operating time in plating procedure, increases the bleeding. Also in open procedure, disturbing the fracture hematoma and soft tissue dissection adds to more bleeding and can hamper the healing process. Mean incision of 3.0 cm in nailing and 7.5 cm in plating (p<0.001) was observed in study by Yih-Wen Tarng *et al*. [26]. Another study by King *et al*., nailing requires shorter incision (38±9 mm versus 118±19 mm, p<0.0001) [22].

With aid of plain radio graphs, in AP view, clavicular length was measured and compared with the contralateral side and the shortening was calculated before and after surgery. Based on these values, nailing group has shown statistically significant restoration of the clavicular length. Mean increase in nailing group is 1.78cm with SD of 0.55cm and that of

plating group is 1.30 with SD of 0.46cm. (P value <0.001)
Thus, significant restoration of clavicle length has been noted in the nailing group.in our study we could achieve anatomical reduction even in comminuted fracture with nailing since manoeuvring of the TENS nail was found practical during the surgery. We divided the residual shortening after surgery into three groups. 35 cases of nailing had less than 0.5 cm residual shortening whereas as compared to only 12 cases in plating group P value (<0.001). In a study Smekal *et al*., [28] TENs fixation significantly improved post-traumatic shortening in simple fractures with a mean improvement of 6.0% to a mean shortening of 2.2%.
The association between clavicle shortening after healing and clinical outcome is still controversial. Study by Hill *et al*., [9] have reported that shortening of the healed clavicle fracture causes shoulder joint disability, whereas study by Nordqvist *et al*., and Nowak *et al*., some have found no association with disability [24, 30]. In recent studies, authors provide different data about the degree of shortening that leads to symptoms such as pain, weakness and rapid fatigability of the shoulder girdle muscles [7, 9].
In our study, Constant shoulder score was used for the evaluation of the functional outcome. It considers four parameters viz., the pain, ability to do daily activities, power and ROM of the shoulder.
Constant shoulder scores were found to be increasing with time in both the groups. But with the nailing, the CSS is significantly better than the plating at the end of 6 weeks of follow up., mean CSS at 6 weeks was 57.89 (SD ± 13.35) in nailing group and 44.78 (SD±13.93) in plating group (P value <0.001), which was found to be statistically significant. With the further follow ups at 12 weeks, 6 months and 1 year the CSS was found to be almost equal in both the groups. Thus, it shows nailing provides advantage of faster recovery from the surgery in the initial few weeks and increased ability for movements due to reduced pain.
In a study by, King *et al*., with mean CSS, nailing has shown better outcome at end of twelve months postoperatively. (96 ±6 in nailing versus 90±18 in plating, p = 0.0122) [27]. In another study by Beigang fu., functional outcome of intramedullary nailing CSS was found to be 93.389±2.749 with mean follow up of 15 months in 36 patients [29]. In another study by Yun-Feng Chen *et al*., comparing outcome based on CSS in 57 TENs patients and 84 plate fixation patients, nailing has shown better outcome at end of six months postoperatively (Nailing 94.0±3.8 and plating 89.7±4.5) and finally at the end of the study both groups had similar CSS [31]. In a study by Yih-Wen Tarng *et al*., the patients in the TENs fixation group showed greater ROM and higher Constant scores than patients in the plating group at the end of 6, 12, and 18 weeks postoperatively. In addition, relief of pain was faster in the TENs group. They concluded that these factors implies a better quality of life in the immediate postoperative period, as well as up to 18 weeks postoperatively, for the patients in the TENs group [26]. However, in our study, there was no significant difference in the CSS at final follow-up between the two groups.
Oddly, in a study by Olivier A. van der Meijden *et al*., similar outcome has been stated based on CSS, but DASH score shows more disability in the nailing group for initial few months and plating has better recovery in initial few months [32]. Also, relatively slower recovery in the plating group can be attributed to the increased pain in the plating group due to the relatively extensive soft tissue dissection, periosteal stripping and lower CSS in the first 6 weeks indicating delayed recovery. Normally, the periosteal blood supply to the clavicle might remain intact in simple fractures [24, 30]. Thus, nailing fastens the fracture union by endosteal healing, as the blood supply is intact. Nailing avoids injury to the periosteal layer thus fracture union starts early, where as in plating group the periosteal stripping makes the fracture union rate relatively slower. Also, nail is a load sharing device and hence could assist better biomechanics.
There is a system of grading of the Constant Shoulder Score, based on comparison with the CSS of the contralateral side [21]. The grading goes by poor, fair, good and excellent. CSS in nailing group was found to be fair or good totally in 28 cases at 3 months of follow up, whereas in plating group in 22 cases.14 cases were having poor CSS at end of 3 months while only 8 cases were poor in nailing group. This again shows the faster recovery from surgery in the nailing group. But at the end of 1 year both were found to be equal. Thus, both plating and nailing gives good outcome finally, but nailing has faster recovery in the initial few months.
In our study, CSS was compared based on different age groups, sex and smoking status. On comparison, CSS was found to be insignificant and thus functional outcome was not found to be dependent on age, sex or smoking. Other studies show similar results [22, 23, 27].
On comparing CSS based on dominance of the side involved, it had been found that dominant side shows significant improvement at 6 weeks (P value 0.002) and 12 weeks (P value 0.010) in nailing group. Thus, the dominant side, shows faster recovery in nailing group compared to the non-dominant hand. In a study by King *et al*., dominance of injured side doesn't had significance on the functional outcome [22].
Fracture union was evaluated with plain radiographs. Callus formation was seen as early as 6 weeks in nailing group, whereas plating group had delay in callus formation. Most of the cases in both groups were united by the end of 12 weeks.
We found total of 6 complications in the plating group and 4 in the nailing group. Out of 4 complications, 3 cases had migration of the nail (2 medial and 1 lateral) and 1 case of non-union. In plating group, one case had non- union, one case with implant loosening, 2 cases with surgical site infections (SSI) and 2 cases with joint stiffness.
In nailing group 3 cases were found to have migration of the nail. The patient came with lateral perforation within 2 weeks after surgery, and fracture was not united. Thus, the nail was removed and plating was done. This was due to perforation of the lateral cortex during nail insertion intra operatively. One case of medial migration reported early, the patient was found to be non-compliant with sling and restriction of movements as advised to him. Since the fracture was not united, nail removal was done changed to plating. Another late case of medial migration came with united fracture. Thus, nail removal was done. We made a bony shallow trough at the entry site to accommodate the cut end of the nail to prevent nail migration and skin irritation.
Nail migration traditionally has been a problem and has resulted in a high rate of hardware removal [18, 28]. Study by Yung-feng chen *et al*., shows higher rates of hardware migration and skin irritation, 29.8% and 7%, respectively [31]. The rate of hardware migration (including medial migration and lateral perforation) of TENS is between 4.5% and 26.6% in the literature [18]. King *et al*., used modern nails such as the Sonoma nail to prevent the nail migration and no signs of hardware migration in the nailing group were observed in their study [22, 27].

2 cases of SSIs were noted in the plating group, which resolved with oral antibiotics. Study by Yung-feng chen *et al*., shows SSIs were not a statistically significant complication (P<0.531) [31]. 2 cases of joint stiffness were noted in plating group, which resolved with help of physiotherapy. 1 case had implant failure in the plating group, with backing out of the screws. The fracture had healed already and thus, the implants were removed.

In total, 2 cases of non-union were observed, one in each group. Both the cases, implant removal was done and re-osteosynthesis with pre-contoured LC-DCP and autogenous bone grafting was done. Both the cases showed radiographic signs of union by 12 weeks. In a study by Zlowodzki *et al*. [33], the non-union rate of intramedullary fixation is 1.6%, as compared with 2.5% for plate fixation. In our study, the overall complications were lesser in the nailing group compared to the plating group, but statistically not significant (P value 0.084). Similar, observations were made in other studies [34-36].

Conclusion

1) Nailing group is better than the plating group in the early outcome analysis at the end of 6 weeks, compared to the plating group based on CSS, but in the long run, there is no significant difference between both the groups.
2) Dominant hand side shows faster recovery in the nailing group.
3) Clavicle length restoration is better in nailing group.
4) Reduced operating time in nailing shows it's a simpler procedure.
5) Smaller incisions in nailing makes it cosmetically better than plating.

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