

**A COMPARATIVE STUDY OF SURGICAL AND FUNCTIONAL OUTCOMES IN PATIENTS TREATED WITH INTRAMEDULLARY NAILING AND PLATING FOR MID-SHAFT CLAVICULAR FRACTURES**

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**Abstract**

**Introduction:** Traditionally, mid-shaft clavicular fractures were treated non-operatively; however, they have been associated with higher non-union rates and poor functional outcomes in certain types of fractures. We aimed to objectively compare the surgical outcomes in patients with mid-shaft clavicular fracture treated either with nailing or plating and assess their functional outcomes over a follow up period of one year.

**Methodology:** Our prospective sample was chosen from a pool of patients visiting casualty of our Hospital for fracture clavicle between March 2015 and March 2017. Patients either underwent open reduction and plate fixation with a 3.5 mm superior clavicular plate or a 2.0 mm to 3.5 mm titanium nail. Intraoperative parameters and postoperative functional outcomes over a period of 12 months were compared between the two patient groups.

**Results:** During the study period 65 patients with clavicular fracture were operated in our department, 35 patients with dynamic compression plating and rest intramedullary fixation and nailing. Patients undergoing nailing had a significantly lesser operative time, incision length, blood loss and hospital stay as compared to plating (p value < 0.001). Mean Constant Murley score throughout the follow up period was higher in the group of patients undergoing plating, though the difference was not significant at any follow up point. Nailing was associated with more frequent implant migration and irritation of skin and there was need of significantly more number of intraoperative image intensifier shoots, resulting in higher radiation exposure, as compared to plating. Nailing and plating resulted in mean shortening of clavicle length by 0.5 cm (range 0.4 to 2.1 cm) and 0.2 cm (range 0.2 to 1.8 cm) respectively.

**Conclusions:** We found no difference in the functional outcome and nonunion rates between nails and plates fixation for displaced midshaft clavicular fractures but nailing was associated with higher rates of complications.

**Keywords:** Clavicle fracture, midshaft, intramedullary fixation, plate fixation, osteosynthesis, trauma

**Introduction**

Fractures of the clavicle are common, accounting for 2.6% to 4% of all fractures, of which majority occur in the middle third of the bone.<sup>i</sup> The middle third is the thinnest segment of clavicle and is devoid of any protective muscular or ligamentous attachment, thus making it the weakest part of the bone. Traditionally, mid-shaft clavicular fractures were treated non-operatively; however, they have been associated with higher non-union rates and poor functional outcomes in certain types of fractures.<sup>ii</sup> A recently published meta-analysis of randomized clinical trials revealed that patients treated non-operatively had higher risk of non-union and symptomatic malunion than those who received operative treatment.<sup>iii</sup> Accordingly, there has been a trend towards operative treatment in patients with displaced clavicular fractures. Two of the most common surgical approaches include open reduction and internal fixation with pre-contoured plate fixation, and

intramedullary nailing using a titanium endomedullary nail. Though, both techniques demonstrate adequate stability biomechanically, plate fixation results in lesser displacement when higher loads are applied, which may be a beneficial factor during the rehabilitative protocol.<sup>iv</sup> However, this difference in functional outcome is not appreciable clinically. Major concern is with hardware displacement and tissue irritation associated with the use of intramedullary nailing in clavicle midshaft fractures.<sup>v</sup> We aimed to objectively compare the surgical outcomes in patients with mid-shaft clavicular fracture treated either with nailing or plating and assess their functional outcomes over a follow up period of one year.

**Methodology**

**Study design and sampling**

All patients consented to their inclusion in this study and ethical approval in accordance with the Helsinki declaration was obtained from the Institutional Ethical

Committee. Those consenting to participate either underwent open reduction and plate fixation with a 3.5 mm superior clavicular plate or a 2.0 mm to 3.5 mm titanium nail. The operating surgeon chose the surgical technique and was performed by surgeons with at least 3 years experience of using both nails and plates. Our prospective sample was chosen from a pool of patients visiting casualty of our hospital for fracture clavicle between March 2015 and March 2017. Patients who were aged above 18 years, with displaced mid-shaft fracture clavicle were included in the study. Patients with open fracture, a concomitant injury, pathological fracture, fracture more than 2 weeks old, congenital bone abnormality, local site infection and neurovascular injury were excluded from the study. During the study period, there were many patients who were treated conservatively, who were not included in the study as well. Patients who were lost to follow up were not included in the final analysis. Affected shoulder Antero-posterior views were taken. Fractures were classified according to AO/OTA classification system for fractures.<sup>vi</sup>

### Operative procedure

**Plate fixation:** In a supine position, involved shoulders were prepared. Transverse incision was made and supra clavicular nerves were spared wherever possible. After soft tissue dissection, fractures were reduced and a small fragment locking plate was fixed on the anterosuperior surface of the bone using bicortical screws. The fascia and skin were closed in layers.

**Nailing:** In supine position and with image intensification in 45°-cephalad and 45°-caudal directions, an incision was made 1 cm lateral to the sternoclavicular joint. The anterior cortex was opened using a sharp, pointed awl and a titanium nail with diameter varying from 2 to 2.5 mm depending on the width of the bone was inserted. Closed reduction was performed under fluoroscopic control using two percutaneously introduced pointed reduction clamps, which if failed, an additional incision (miniopen) was made above the fracture site for direct manipulation of the main fragments. Under fluoroscopic control, nail was advanced in to acromioclavicular joint. The fracture was compressed and the nail was cut close to entry point to avoid tissue irritation. The fascia and skin were closed in layers.

### Data Collection and Data Analysis

Demographic data of the patients were recorded at the time of admission in a pre-designed semi-structured case report form. Standard standing radiographs with 15° caudal and 15° cephalad of both clavicles were obtained. Intraoperative parameters like operative time, length of incision and blood loss were noted for all patients by the operative team. Patients were followed up in the outpatient clinic at one, three, six and 12 months with

anteroposterior view of shoulder radiographs until union of the fracture. They were given a simple sling for comfort for one to two weeks and encouraged to start pendulum movements as soon as possible, but not transmit load or abduct the arm by more than 90° until six weeks post-operatively. Physiotherapy was not routinely administered. Postoperative variables like length of hospital stay and time to union were noted as well. The functional outcome was assessed with Constant Murley (CM) score at each follow up point for all patients.<sup>vii</sup> CM score includes pain assessment (15 points maximum), daily activities (20 points), shoulder movement (40 points) and strength (25 points) with a maximum score of 100. Complications experienced by the patients during the follow up period were noted. A non-union was defined as absent osseous bridging of more than one cortex at six months. All statistical analyses were performed using SPSS version 23 (IBM, Armonk, New York) and a threshold of  $p < 0.05$  was set for statistical significance. The data are presented as n (%) or mean and standard deviation and was analysed by chi-square test or Fisher's exact test and Student's t test, depending on distribution.

### Results

During the study period 65 patients with clavicular fractures were operated in our department. 40 out of 65 patients were from age group 21 to 40 years and more than three fourths of the patients were males (Table 1). Majority of the fractures belonged to AO/OTA type B1.1 (29), followed by B2.1 (14) and B1.3 (9). Of all the patients, 35 patients underwent dynamic compression plating and 30 patients underwent intramedullary fixation and nailing. Fifteen patients among the nailing group required miniopen technique. Table 2 compares the patient related variables between those undergoing nailing and those undergoing plating. We observed that patients undergoing nailing were significantly younger ( $30.97 \pm 9.29$  years vs  $37.69 \pm 12.48$  years,  $p$  value 0.018), and gender distribution was similar in both the groups. Intraoperatively, the operative time was significantly lesser in patients undergoing nailing ( $46.07 \pm 3.57$  minutes) as compared to those undergoing plating ( $71.63 \pm 9.92$  minutes). Similarly, smaller incision length and lesser blood loss was observed in patients undergoing nailing and the difference was statistically highly significant ( $P$  value  $< 0.001$ ). Number of image intensifier shoots were significantly higher among patients undergoing nailing as compared to plating ( $42.2 \pm 8.59$  vs  $6.37 \pm 2.03$ ,  $p$  value  $< 0.001$ ). Furthermore, patients undergoing nailing had an average length of hospital stay of 2.38 days, which was significantly less than in those undergoing plating ( $p$  value  $< 0.001$ ). Average union time was lower in patients undergoing nailing (14.33 weeks) as compared to those undergoing plating (15.03 weeks), though the difference was not statistically significant. Mean Constant Murley

score throughout the follow up period was higher in the group of patients undergoing plating, but the difference was not significant at any follow up point (Table 2). At three month postoperative follow up point, the difference in the mean Constant Murley score between patient groups undergoing nailing and plating almost reached statistical significance ( $p$  value = 0.051). Table 3 describes the post-operative complications of the patients. During the follow up period, 5 out of the 30 patients undergoing nailing had implant migration (four migrated to medial side and one to both medial and lateral side), which was significantly higher than those undergoing plating ( $p$  value = 0.012). Additionally, two cases with nailing had non-union, while no such instances were recorded with plating. Cases of implant migration were treated with implant removal if found united. In case they were not united they were treated with plating which was followed by good functional outcome at 6 months follow up. The two non-union cases of nailing were treated with implant removal, freshening of fracture edges followed by plating. Both patients showed good union and had good functional outcome at 6 months follow up. One patient with plating had removal of hardware due to hardware prominence and one case had screws backed out at 4 months followed by screw exchange and union at 7 months. Nailing resulted in mean shortening of clavicle length by 0.5 cm (range 0.4 to 2.1 cm). Plating resulted in mean shortening of clavicle by 0.2 cm (range 0.2 to 1.8 cm).

## Discussion

There is a lack of consensus on to which is the best method to treat mid-shaft clavicle fractures. Complications like non-union, brachial plexus irritation and bone shortening have been reported in approximately one-third of cases with mid-shaft clavicular fracture treated with non-surgical methods.<sup>viii</sup> Conservative management in such patients can result in non-union in up to 15% of the cases.<sup>ix</sup> Factors predisposing to non-union included marked displacement, comminuted fracture, and more than 2 cm initial shortening at the fracture site. In response, there is a general trend towards operative management of clavicular fractures and various implants like screws, nails, plates and intramedullary wires have been developed for reduction of mid-shaft clavicular fractures.<sup>x</sup>

Patients in our study who underwent nailing had a significantly lower operative time, incision length, blood loss and length of hospital stay as compared to those who underwent plating. Nailing was not possible in cases with closed medullary canal and such patients underwent plating. Additionally, nailing was associated with implant migration and irritation of skin and there was need of more number of intraoperative image intensifier shoots, resulting in higher radiation exposure. Mueller et al compared nailing in clavicle fracture with plating and

commented that an extensive surgical approach was required to fix an extramedullary splint so as to avoid breakage of clavicle.<sup>x</sup> This has been shown to result in repeated implant loosening, significant soft tissue damage and re-fracture after plate removal.<sup>xi</sup> On the other hand, titanium nails are flexible, not fixed to cortex and its intramedullary position is biomechanically ideal. Additionally, we observed approximately double incision size in plating as compared to nailing (4.16 cm vs 9.40 cm). This might explain why patients who underwent plating had a significantly longer hospital stay. Future investigators should explore the possibility of minimally invasive plating technique, which would include shorter incisions, extensive mobilization of subcutaneous tissues, sliding of the plate under the myofascial layer, and the use of small stab incisions through the myofascial layer for placement of the screws as suggested by Altamimi et al.<sup>xii</sup> Additionally, there was no significant difference in non-union rate for nailing and plate fixation ( $p$  = 0.12). Plating has traditionally been described as a more stable biomechanical system as compared to nailing.<sup>xiii</sup> Because intramedullary fixation with K-wires in displaced fractures provides little control over the fragments of the fracture, it allows excessive motion of these fragments.<sup>xiv</sup> This might account for the higher non-union rates observed in patients undergoing nailing. Recent use of Rockwood pin has been associated with lower non-union rates by attempting to control fracture movement by providing medial and lateral stability.<sup>xv</sup>

We observed mean clavicular shortening of 0.5 cm and 0.2 cm among patients undergoing nailing and plating respectively. Lazarides and Zafiropoulos observed that clavicular shortening of more than 1.8 cm in male patients and more than 1.4 cm in female patients would significantly impact the final clinical outcome.<sup>xvi</sup> McKee et al, further, suggested that shoulder function is well preserved until a critical threshold of deformity is reached, after which the shoulder function dramatically reduces and that abduction function may be well preserved with < 2 cm of shortening.<sup>xvii</sup> In support of this, a randomised clinical trial by the Canadian Orthopedic Trauma Society reported that displacement and shortening of the clavicle after fracture are strongly linked with poor clinical outcome, and operative treatment with plate fixation is preferable, if the shortening is 2 cm or more.<sup>xviii</sup>

There are a few limitations in our study. Firstly, we did not randomize the patients to either treatment or surgeons' familiarity and patients' preference for a particular procedure may have introduced some bias. Secondly, group of patients who underwent nailing was significantly younger as compared to those undergoing plating. Demographics like age influence the chance of clavicular fracture and the way they heal.<sup>xix</sup> Also, we excluded children below 18 years of age, who have been known to

have a better prognosis as compared to adult clavicular fractures.<sup>xx</sup> Lastly, this being a single centre study, the conclusions might not be generalizable to other surgical centres.

**Conclusion**

Nailing of clavicular fracture was found to have lesser operative time, incision length, blood loss and hospital stay but was associated with more frequent complications like implant migration, skin irritation and radiation exposure to image intensifier. However, both plating and nailing achieved similar functional outcomes over a follow up period of 12 months. Future randomized controlled studies are required to compare conservative, nailing and plating methods for clavicular fractures.

**Table 1:** Distribution of patients according to their demographic and clinical characteristics

	n
Total patients	65
<b>Age distribution</b>	
Less than 20 years	07
21 to 40 years	40
41 to 60 years	17
More than 60 years	01
<b>Gender distribution</b>	
Females	14
Males	51
<b>Clavicular fracture according to AO/OTA Classification of Fractures and Dislocations</b>	
B1.1	29
B1.2	7
B1.3	9
B2.1	14
B2.2	01
B3.1	01
B3.2	4
<b>Surgical procedure</b>	
Intramedullary fixation with nailing	30
Dynamic Compression Plate	35

**Table 2:** Surgical outcomes in clavicle fractures treated by nailing or plating

	Surgical procedure		p value
	Nailing (n=30)	Plating (n=35)	
<b>Demographic variables</b>			
Mean age (years)	30.97 ± 9.29	37.69 ± 12.48	0.018
Females	05	09	0.384
<b>Intraoperative variables</b>			
Operative time (minutes)	46.07 ± 3.57	71.63 ± 9.92	<0.001
Incision length (cm)	4.16 ± 0.33	9.40 ± 0.74	<0.001
Blood loss (ml)	35.67 ± 19.06	108.00 ± 22.57	<0.001
Number of image intensifier shoots	42.2 ± 8.59	6.37 ± 2.03	<0.001
<b>Postoperative variables</b>			
Length of hospital stay (days)	2.38 ± 0.59	3.57 ± 0.60	<0.001
Union time (weeks)	14.33 ± 4.27	15.03 ± 3.30	0.463
Mean CM* score at 1 month	88.17 ± 2.24	89.20 ± 2.54	0.098
Mean CM score at 3 months	90.83 ± 2.39	91.94 ± 2.10	0.051
Mean CM score at 6 months	92.90 ± 2.31	93.66 ± 1.79	0.14
Mean CM score at 12 months	95.20 ± 1.25	95.71 ± 1.42	0.69

\*CM: Constant Murley; mean compared using independent t test, proportions compared using chi square test

**Table 3:** Post-operative complications in the patients

	Surgical procedure	
	Nailing (n=30)	Plating (n=35)
<b>Complications during follow up period</b>		
Screws backed out	N/A	01
Hardware prominence	00	01
Implant migration	05	00
Non-union	02	00



**Figure 1:** Clavicle plating - Case 1 – Preoperative Radiograph showing midshaft clavicle fracture



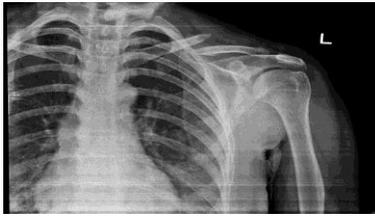
**Figure 2:** Clavicle plating – Case 1 – immediate postoperative radiograph



**Figure 3:** Clavicle plating – Final follow up at 1 year showing good union.



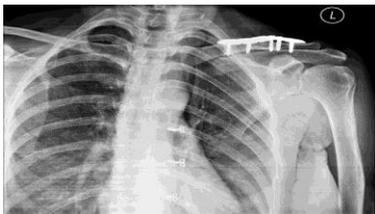
**Figure 4:** Clavicle plating Case 1 – Patient shows good functional range of motion at 1 year follow up



**Figure 5:** Clavicle plating – Case 2 – pre-operative Radiograph



**Figure 6:** Clavicle plating Case 2 – immediate postoperative Radiograph



**Figure 7:** Clavicle plating Case 2 – Follow up Radiograph at 1 year follow up shows good union.



**Figure 8:** Clavicle plating - Case 2 – shows well healed surgical scar at 1 year follow up



**Figure 9:** Clavicle plating – Case 2 – Patient shows good functional outcome at 1 year follow up



**Figure 10:** Clavicle intramedullary nailing - Case 1 – pre-operative radiograph



**Figure 11:** Clavicle nailing - Case 1 – immediate postoperative radiograph



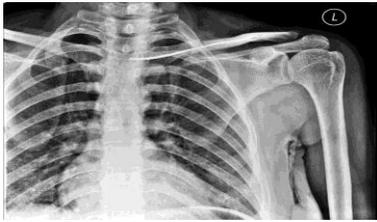
**Figure 12:** Case 1 – clavicle intramedullary nailing – final follow up at 1 year shows good union.



**Figure 13:** Case 1 – Clavicle nailing – Patient shows good functional outcome at 6 months follow up.



**Figure 14:** Clavicle intramedullary nailing - Case 2 – pre-operative radiograph.



**Figure 15:** Clavicle intramedullary nailing – Case 2 immediate postoperative radiograph.



**Figure 16:** Clavicle intramedullary nailing – Case 2 – Final follow up at 6 months shows good union.



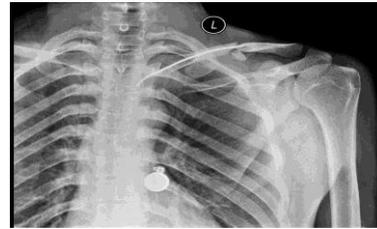
**Figure 17:** Clavicle Intramedullary nailing – case 2 – Patient shows good functional outcome at 1 year follow up.



**Figure 18:** Case 3 - Clavicle intramedullary nailing with complication of medial migration and non-union. Pre-operative Radiograph.



**Figure 19:** Case 3 - Clavicle intramedullary nailing with complication of medial migration and non-union Immediate postoperative Radiograph.



**Figure 20:** Case 3- Clavicle intramedullary nailing with complication of medial migration and non-union Follow up at 4 months shows medial migration of intramedullary nail.



**Figure 21:** Case 3 - Clavicle intramedullary nailing with complication of medial migration and non-union Patient was then treated with hardware removal followed by freshening of fracture edges and plating .



**Figure 22:** Case 3 - Clavicle intramedullary nailing with complication of medial migration and non-union Follow up Radiograph at 6 months after 2<sup>nd</sup> surgery shows good union.



**Figure 23:** Case 3 - Clavicle intramedullary nailing with complication of medial migration and non-union Follow up at 6 months after 2<sup>nd</sup> surgery (plating) show s good clinical outcome

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