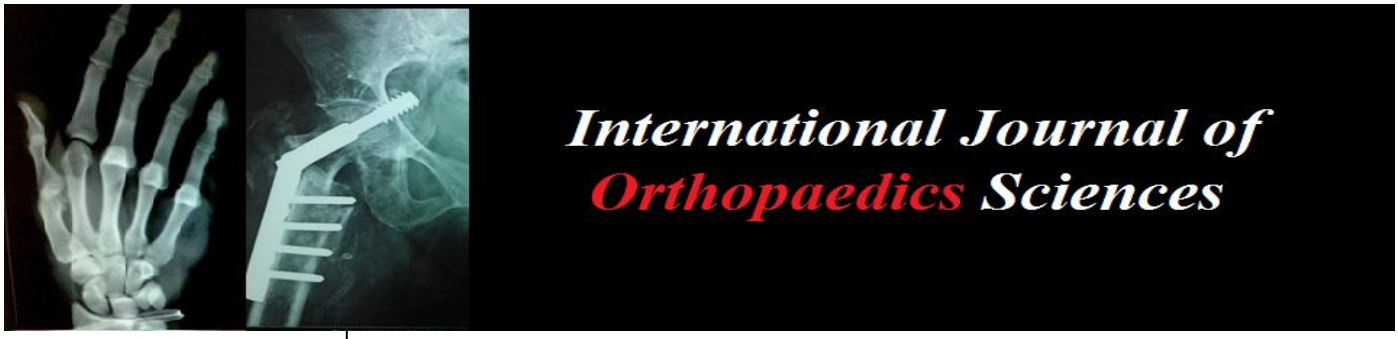

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A comparative study of displaced midshaft clavicle fracture managed by precontoured locking compression plates and titanium elastic nails

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Abstract
Background: Results of conservatively managed mid-shaft clavicle fractures are not as good as previously thought. This has lead to increasing interest in primary fixation of these fractures. There are two main techniques of internal fixation, namely, plate fixation and intra-medullary nail fixation. We have evaluated pre-contoured locking compression plates and titanium elastic nails for fixation of mid-shaft clavicle fractures and compared their results
Material and Methods: Between July 1st 2015 and June 30th 2017 42 cases of unilateral displaced mid-shaft clavicular fracture were studied. 23 were managed by open reduction internal fixation with pre-contoured locking compression plates and 19 were managed by closed or open reduction and internal fixation by Titanium Elastic nails. Patients were followed up monthly for 4 months and at 6 months and 9 months. Final results were computed at end of 6 months. Functional outcome was compared using Constant Score. Other complications like non-union, delayed union, infection, implant failure, hardware prominence, refracture and wound dehiscence were also studied.
Results: There was significant difference in constant score of two group with plating group performing better. Nail impingement was major concern after intra-medullary nailing. Union time was slightly better in nailing group.
Conclusion: Pre-contoured locking compression plates gave better functional outcome and were associated with complications in fewer cases as compared to titanium elastic nails when used for surgical fixation of displaced mid-shaft clavicle fractures.

Keywords: Clavicle fracture, TENS, Plate fixation, intra-medullary nailing

Introduction
Clavicle fractures were considered essentially benign injuries with inherently good prognosis even if treated conservatively [1]. Recent studies have shown that results of conservative management of displaced mid shaft clavicle fractures are not as good as previously believed [2-4]. The reason for this change in belief is due to the fact that early researchers evaluated the outcome using radiographic evidence of union alone. Factors like change in length of the clavicular strut [5] and malunion which have greater bearing [6] on the functional outcome of treatment were not considered by early authors. Recent studies have drawn our attention towards these facts and have led to an increasing inclination towards primary fixation of displaced mid-shaft clavicle fractures [7-9].
There are 2 common techniques for treating displaced mid-shaft clavicle fractures, namely, open reduction and plate fixation and open/closed reduction with intramedullary nail fixation [12]. Studies have found both these techniques to be superior to conservative management [8, 9]. This led to need of further studies to compare these two modalities of surgical treatment. Although orthopaedics journals have abundant articles comparing conservative management with surgical, there are relatively less publications comparing the two common modalities of surgical treatment. The aim of this study is to evaluate the results of internal fixation of displaced mid-shaft clavicle fractures using antero-superior precontoured locking plates and minimally invasive antegrade titanium elastic nails and to compare both these modalities of treatment.

Material and Methods

42 displaced mid-shaft clavicle fractures admitted to our institute during a period of 2 years (2016-2017) were included in the study. Inclusion criteria were age between 16 to 60, closed displaced mid-shaft clavicle fracture with shortening with or without comminution falling under Robinson classification as type 2B1 and 2B2. The exclusion criteria were open fractures, pathological fractures, any shoulder co-morbidity and poly trauma patients. Patients were randomly divided into two groups.

Surgical Technique

After intensive preoperative planning and preparations patient are anaesthetised and postioned supine on OT table. Affected shoulder is prepared and draped.

A) Plate Fixation

- Anterior approach to mid-shaft clavicle is used.
- Attempts are made to spare the supraclavicular nerve.
- After fracture is exposed, reduction is achieved using small fragment/ pointed reduction clamps.
- A precontoured locking compression plate is placed on anterosuperior surface of the bone and fixed to medial or lateral fragment (depending on fracture pattern) using a single bicortical screw.
- Plate is fixed to the other segment using a compression screw.
- Wherever amenable lag screws are placed through the plate or separately if needed.
- If possible a minimum of 3 bicortical screws are used on both sides of fracture.
- Fascia, subcutaneous tissue and skin are closed in layers.
- An arm pouch sling is given for support and pain relief.

B) Intramedullary Nailing

- Image intensifier is used to determine the entry site which is about 1.5 to 2cm lateral to sternoclavicular joint in the middle of the anterior cortex
- Entry is obtained using a 2.5mm drill bit after giving a stab incision.
- The entry is enlarged using a awl.
- A 2 to 2.5 mm titanium elastic nail inserted and gradually advanced using oscillating movements.
- Pointed reduction clamps are used percutaneously to reduce the fracture.
- If a closed reduction is not possible a small incision directly over the fracture site to perform a limited open a limited open reduction is helpful.
- Nail is passed into the lateral fragment and is advanced as far lateral as possible.
- The medial end is then cut and buried subcutaneously.
- An arm pouch sling is given for pain relief.

An arm pouch sling was given and early mobilization in form of pendulum exercises where allowed as soon as patient is comfortable (typically 2-3 days). Sutures were removed on 12th post-operative day. The sling was gradually discontinued after this and unrestricted range of motion exercises were allowed. Strengthening exercises were allowed after 6 weeks post-op radiograph showed bony union. If delayed union was evident aggressive activities were avoided. Return to manual labourer work and rigorous exercises were allowed only after 12 weeks when radiograph showed satisfactory bony union. Implant removal was done only on need to do basis.

Patients were followed up monthly for first 4 months. Thereafter they were followed at 6 months and 9 months. Radiographs were taken at every visit. Both radiographic and clinical union were assessed. Delayed union was considered only after 4 months. Functional outcome was assessed using 'Constant Score' [11]. Other parameters studied were infection, wound dehiscence, implant failure, symptomatic malunion, non-union, delayed union, implant prominence and refracture after implant removal.

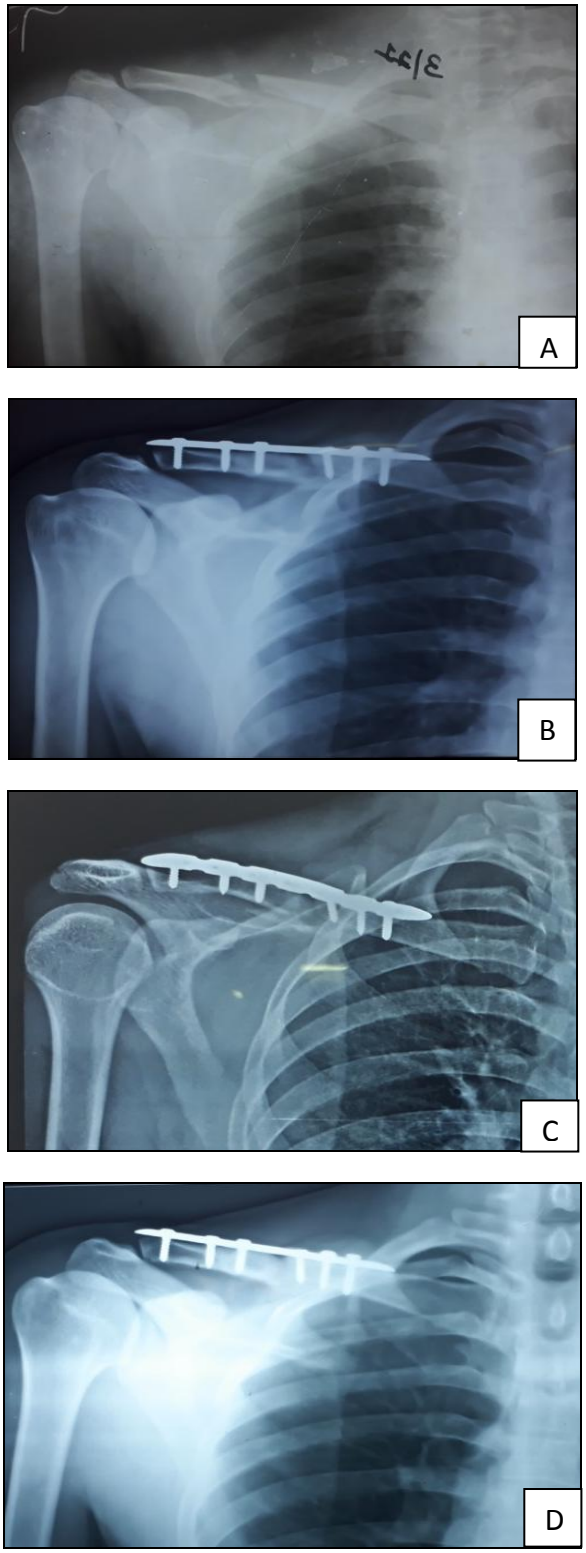

Fig 1(A-D): Skiagram of 32 year old male with Robinson 2B2 clavicle fracture(R) fixed by Pre-contoured locking compression plate. A) Pre-operative B) immediate post-operative C) 1month post-operative D) 4 month post-operative

Fig 2 (A-D): Skiagram of 28 yr old female with Robinson 2B2 clavicle fracture (R) fixed by titanium elastic nail. A) Pre-operative B) immediate post-operative C) 4 month post-operative D) 6 month post-operative after implant removal

Results

There were a total of 42 patients studied 32 of them were males and 10 females. Patients were randomly allocated to plating group (I) or nailing group (II). 23 patients ended up in plating group and rest 19 in nailing group.

Table 1: Group wise distribution of cases

S. No	Group	Description	No. of cases	Percentage
1.	I	Patients managed with ORIF locking plates.	23	54.76%
2.	II	Patients managed with intra-medullary nails.	19	45.23%

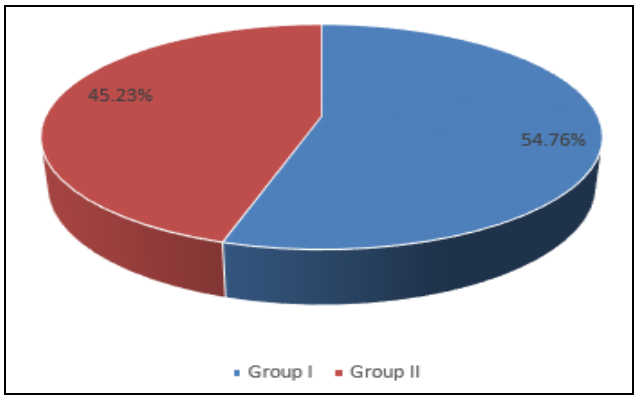

Fig 3: group wise distribution of cases.

Patients of group 1 had a mean age of 30.17 years and those in group 2 had a mean age of 24 years. 6 (31.57%) of patients in Group II were female as compared to 4 (17.39%) in Group I.

Table 2: Demographic Profile of the Patients

S. No	Parameter	Group I		Group II	
1.	Mean Age in years	30.17		24	
2.	**Gender**	**No.**	**%**	**No.**	**%**
	Male	19	82.60	13	68.42
	Female	4	17.39	6	31.57

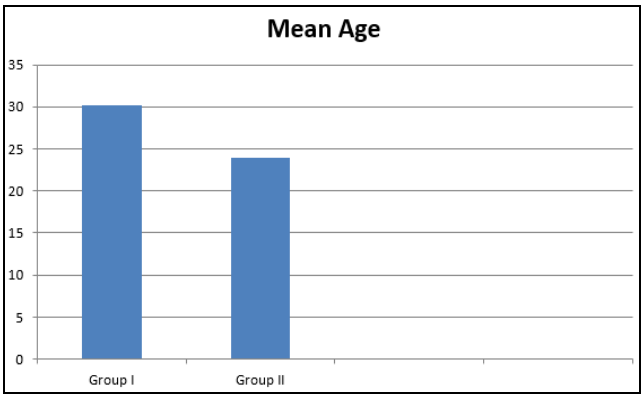

Fig 4: Age distribution of each group

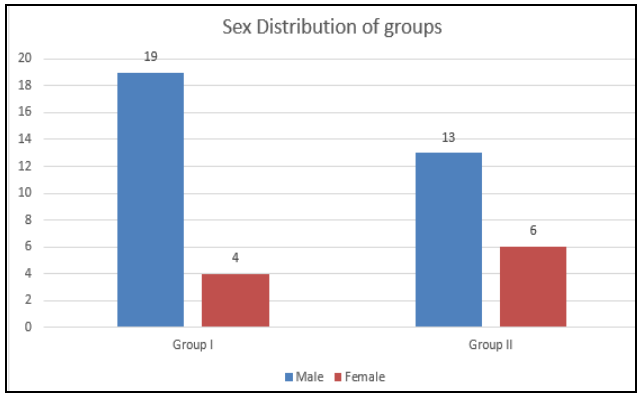

Fig 5: Sex distribution of each group

The delay between trauma and surgery in group 1 was an average 9.8 days and in group 2 was 11.3 days. In group 1 18 patients were Robinson type 2B1 fractures and 5 where 2B2 fractures. In group 2, 17 were 2B1 and 2 were 2B2 fractures.

Table 3: Evaluation at Presentation

S. No	Parameter	Group I		Group II	
		No.	%	No.	%
1.	**Type of fracture**				
	2B1	18	78.3	17	89.47
	2B2	5	21.7	2	10.52
2.	**Side involved**				
	Left	10	36.4	7	36.84
	Right	13	63.6	12	63.15
3.	Mean injury time (days)	8.1 days		9.3 days	

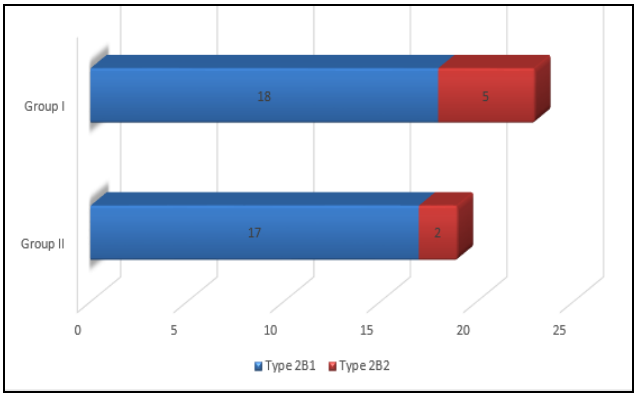

Fig 6: Dristibution of fracture pattern.

Overall, time taken for union ranged from 3 to 9 months with a mean value of 3.57 ± 2.32 months. Union time was slightly longer in Group I (4.00 ±2.82 months) as compared to Group II (3.14 ± 1.82 months) but the difference between two groups was not significant statistically.

Table 4: Union Time (months)

Group	N	Mean	Std. Deviation	Minimum	Maximum
I	23	4.00	2.82	3	9
II	19	3.14	1.82	3	7
Total	42	3.57	2.32	3	9

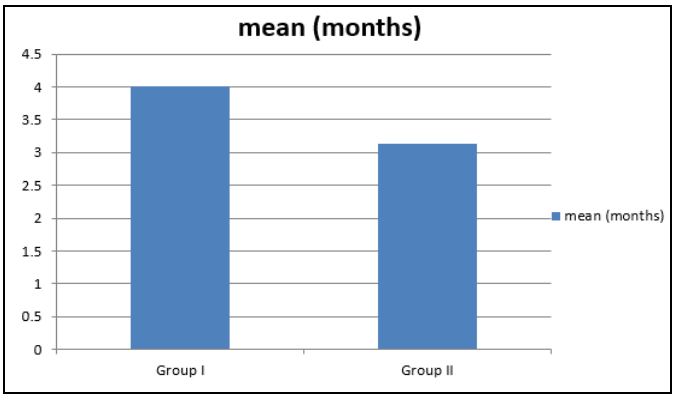

Fig 7: Union time in months

In Group I, excellent outcome was seen in 15 (65.21%), good in 3 (13.04%), fair in 3 (13.04%) and poor in 2 (8.69%) cases as compared to Group II where excellent outcome was seen in 8 (42.10%), good in 2 (10.52%), fair in 6 (31.57%) and poor in 3 (15.78%) cases. The proportion of patients with excellent and good outcome to fair and poor outcome was higher in Group I as compared to Group II and this difference was significant statistically

Table 5: Final Functional Outcome

S. No	Final Outcome	Group I		Group II	
		No.	%	No.	%
1.	Excellent	15	65.21	8	42.10
2.	Good	3	13.04	3	15.78
3.	Fair	3	13.04	6	31.57
4.	Poor	2	8.69	2	10.52

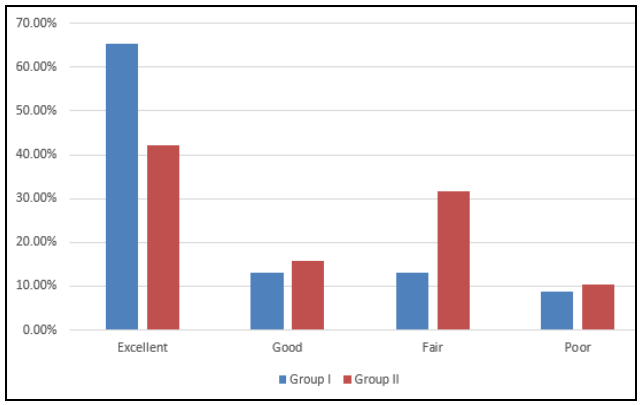

Fig 8: Final Functional Outcome

Complications

In Group I, infection was reported in 1 (3.1%) patient. 1 (3.1%) patient had delayed union. 3 (13.04%) cases had plate prominence. None of the patients had non-union, wound dehiscence, symptomatic malunion, refracture and plate loosening, implant failure.

In Group II, 3 (15.98%) patients had delayed union and 6 (31.58%) patients had skin impingement by nail at entry site. This was the main indication for implant removal in Group II. No other complication was noted in Group II.

A significant difference between two groups was observed for delayed union and implant prominence (impingement in case of nail) which was observed to be significantly associated with Group II (p=0.022). Also Infection was associated with Group I only which was statically significant as well. For other complications and outcomes, the difference between two groups was not significant statistically (p>0.05).

Table 6: Postoperative Complications and Follow up Findings

S. No	Parameter	Group I (n=23)		Group II (n=19)	
		No.	%	No.	%
1.	Infection	1	4.34	0	0.0
2.	Implant failure	0	0	0	0.0
3.	Wound dehiscence	0	0	0	0
4.	Non-union	0	0	0	0
5.	Delayed union	1	3.1	3	15.98
6.	Symptomatic malunion	0	0	0	0
7.	Major revision surgery	0	0	0	0
8.	Refracture after implant removal	0	0	0	0
9.	Plate prominence	3	13.04	-	-
10.	Nail Impingement	-	-	6	31.58

Fig 9: ugly scar after plating

Fig 10: nail impingement at entry site

Discussion

Clavicle fractures are usually treated conservatively. In a study conducted to analyze the results of conservative treatment by Hill *et al*. in 1997 [2], Nordqvist *et al*. in 1998 [3] and Robinson *et al*. in 2004(4) found poor results following conservative treatment of displaced middle third clavicle fracture. Also a meta-analysis of the literature from 1975 to 2005 by Zlowodzky *et al*. found non-union rates to be exponentially higher than that claimed earlier [10]. So for specific indications, like displacement with or without comminution in middle third clavicle fracture (Robinson Type-2B1, 2B2), non-operative approach is not optimum. Functional outcome of midshaft clavicle fractures is not only related to its union, but also to its length. Clavicle acts as a "strut" that keeps the upper limb away from the torso for efficient shoulder and upper limb function, while also transmitting forces from upper limb to the trunk. Thus, displaced or comminuted fractures carry a risk of symptomatic malunion [6] and poor functional outcome with cosmetic deformity. The recent trend is shifting towards internal fixation of these displaced midshaft clavicle fractures [8, 9].

A prospective comparative study was carried out in which a total of 42 cases of displaced mid-shaft fractures of clavicle were included, during the period July 1st 2015 and June 30th 2017. 23 cases were operated with internal fixation with pre-contoured locking plate (comprising group I) and 19 patients were treated with titanium elastic nails (comprising group II).

Majority of patients were males, irrespective of the group to which they belonged. There were 4(17.39%) females in Group I and 6(31.57%) in Group II.

Group I, 18(78.3%) patients had type 2B1 fracture and 5 (21.7%) had 2B2 fracture whereas in Group II 17(89.47%) patients had type 2B1 fracture and 2(10.52%) had 2B2 fracture. Statistically, this difference between two groups was significant.

Majority patients had involvement of right side, considering both groups. Left side was involved in 36.4% of Group I and 36.84% of Group II patients. Statistically, this difference did not account as significant.

Mean time taken for procedure was longer in Group I (60.32±9.64 min) as compared to that in Group II (37.67±12.35 min).

Similarly mean length of incision was longer in Group I (11.5±1.42 cm) as compared to that in Group II (3.5±0.59 cm).

For plate fixation a larger incision is required, leading to a higher risk of infection and lesser cosmetic satisfaction. In our study, infection was reported in only one case of plate fixation and in none of the patients treated with nailing**.** 3(13.04%) cases of group I had plate prominence.

The difference in functional outcome between the two groups at the end of 6 months were statically significant. 78.25% (18) of patients in group one had excellent to good outcome whereas in group 2 only 57.88% (11) patients had excellent to good outcome.

In Group I, delayed union was reported in 1(4.34%) patient. Wound dehiscence and major revision surgery were reported in none. None of the patients had non-union, symptomatic malunion and implant failure. Hardware prominence was seen in 3(13.04%).

In Group II, none of the patients had implant failure, major revision and symptomatic malunion. Delayed union was seen in 3(15.74%) patient. Skin impingement by nail at entry site was noted in 6(31.58%) of patients.

No significant difference between two groups was observed for symptomatic malunion. It was not seen in any of the two groups.

For other complications, the difference between two groups was not significant statistically.

In our study no cases of implant breakage or loosening were reported. Absence of these complications in our study was likely due to locking mechanism, lower stress due to better

adaptability of s-shaped plate and small sample size.
Another complication not reported in our study was refracture.
The sample size being small, low prevalence complications were not encountered. Larger sample size will be pre-requisite for knowing the prevalence of the rarer complications like wound dehiscence, symptomatic malunion and refracture. Also results were computed 6 months after surgery and a long term follow up is likely to change the results.

Conclusion
So, we can conclude from our study that pre-contoured plates gave better functional outcome and were associated with complications in fewer cases as compared to titanium elastic nails when used for surgical fixation of displaced mid-shaft clavicle fractures. We recommend the use of pre-contoured locking plates for internal fixation of displaced mid shaft clavicle fractures.

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