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SURGICAL OUTCOME OF MIDSHAFT CLAVICULAR FRACTURES TREATED BY FLEXIBLE INTRAMEDULLARY NAILING VERSUS PLATING – A PROSPECTIVE COMPARISON STUDY

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Abstract:

Background: Middle third fractures of the clavicle have been traditionally managed non-operatively. But recent studies have emphasised the role of surgical management either by plate and screws or titanium elastic nails. The aim of this study is to compare the surgical outcome of middle third clavicle fractures treated by plate fixation and flexible intra medullary nailing.

Materials and methods: 28 consecutive patients who presented with midshaft clavicle fractures and satisfying the inclusion/exclusion criteria between August 2012 and August 2014 were included in the study. Out of them, 15 patients underwent plate fixation and 13 patients underwent flexible intra medullary nailing inserted through the sternal end of the clavicle. Patients were followed up regularly at 3 weeks, 6 weeks, 12 weeks and then every 2 months up to a minimum period of 1 year post-operatively. Clinical and radiological assessments were performed during each visit. The functional outcome of both the procedures was compared using Constant shoulder score.

Results: Average duration of hospital stay, mean operation time and mean time to union were significantly less in the TEN group. There was no significant difference in Constant score between the two groups. However, the incidence of hardware prominence was higher in the TEN group, but this difference was statistically insignificant ($p>0.05$).

Conclusion: Both the techniques were found to be effective in treating displaced middle third clavicle fractures showing better functional outcomes than non operative treatment. However the TEN fixation is a less invasive technique with lesser operating time and faster fracture union making it more favourable for young and active individuals.

Key words: *Displaced mid shaft clavicle fractures, plating, flexible intramedullary nailing.*

Introduction

Fractures of the clavicle are common injuries accounting for 5-10% of all adult fractures.[1,2] Approximately 80% of these fractures involve the middle third and over 73% fractures are displaced.[3,4] Midshaft fractures of the clavicle have been traditionally managed non-operatively with an arm sling or a figure of eight clavicle brace.[5,6] Early reports on conservative treatment suggested that clavicular non-unions were rare and clavicular malunions resulted in little functional loss despite substantial residual radiographic malalignment.[7,8] However the functional outcome of midshaft clavicle fractures is not only related to its union but also to its length as clavicle acts as a strut between the trunk and upper extremity ensuring mobility and support to the function of upper extremity.[9] Thus conservative treatment of these fractures can lead to symptomatic non-union and poor functional outcome.[8,10,11]

It was not till the early nineties that surgical fixation of these fractures started emerging with the advent of newer methods and techniques. This led to various studies that reported a better functional outcome and lesser complications with operative treatment as compared to that of non operative management.[8,12]

Various methods of fixation such as Kirschner wires, pins (Rush pin, Knowles pin, Rockwood pin), titanium elastic nail (TEN), plates with screws and external fixation are available for displaced midthird clavicular fractures.[13-15] Of these, plate fixation and intramedullary nailing with TEN are commonly used nowadays for internal fixation of displaced midshaft clavicle fractures.[16]

The purpose of this prospective study is to compare the surgical outcome of plate fixation and flexible intramedullary nailing in displaced midshaft clavicular fractures.

Materials and methods

The study was conducted at the Department of Orthopaedics, Sri Manakula Vinayagar Medical College and Hospital, Pondicherry after obtaining approval from the institutional ethical committee. From August 2012 to August 2014, 28 consecutive patients with a displaced midshaft clavicular fracture were included in this prospective comparison study. Inclusion criteria were age group 16-60 years of both sexes, duration less than 2 weeks, unilateral or bilateral fractures with displacement of at least one shaft width of distance, shortening of over 15mm or severe skin tenting. Open fractures, pathological fractures, fractures with associated neurovascular injury or head injury and polytrauma patients were excluded. All patients provided a written informed consent to participate in the study. The clavicular fractures were classified according to the Orthopaedic Trauma Association (OTA) classification. Of the 28 patients, 15 patients underwent plate fixation and 13 patients underwent flexible intramedullary nailing using titanium elastic nail (TEN) after random allocation. Detailed clinical assessment was done at the time of admission. Special attention was given to the mode of injury and duration following which they presented to the hospital. All surgeries were performed by two senior surgeons. One dose of intravenous antibiotics was administered pre-operatively.

Surgical technique

Plate fixation

Under general anaesthesia, patient was placed in supine position with a sand bag positioned in the interscapular region. After preparing the parts, a transverse incision centering the fracture site was made at the lower clavicular border, approximately measuring about 5-7 cm in length depending on the fracture geometry. This avoided a scar directly over the clavicle. After dissecting the underlying soft tissue, fracture site was exposed, fracture ends were cleared from soft tissue attachment, reduced and fixed with plate using one of the following implants; locking compression plate, pelvic recon plate or anatomically contoured plate as per the surgeon's preference. The plate was placed superiorly and the fracture was fixed with at least three 3.5 mm cortical screws on either side. If significant comminution was encountered, careful re-approximation of the smaller fragments was performed with one or two 3.5 mm interfragmentary screws followed by plating. Wound was closed in a routine fashion.

TEN fixation

Under general anaesthesia, patient was placed in supine position with a sand bag positioned in the interscapular region. After preparing the parts, an incision measuring 1-2 cm was made over the sternal end of the clavicle. Soft tissue was cleared and using a bone awl, entry was made through the anterior cortex about 1.5 cm lateral to the sternoclavicular joint. A titanium elastic nail of average diameter 2 mm was inserted using a T handle and advanced to the fracture site. The fracture site was then reduced

in a closed manner under fluoroscopic guidance. In the eventuality of not being able to reduce the fracture in a closed manner, the fracture site was opened through a 1.5-2 cm incision, fracture was reduced and the nail was gently passed into the distal fragment with gentle rotational movements. The medial end of the nail was then cut, bent and buried under the soft tissue. The skin was then closed using ethilon or skin staples.

Postoperatively, the operated limb was supported with an arm pouch. Check radiograph was taken for checking alignment and fixation. Two doses of intravenous antibiotics were administered post-operatively. Sutures were removed on the twelfth post-operative day. Rehabilitation was started 2 weeks after surgery in the form of pendulum exercises. At 4 - 6 weeks, active range of movements was started as tolerated by the patient with a limited abduction of 90 degrees. After 8 weeks active full range movements were encouraged in all planes with shoulder strengthening exercises.

Patients were followed up regularly at 3 weeks, 6 weeks, 12 weeks and thereafter every 2 months up to a minimum period of 1 year. During each visit, patients were assessed for tenderness, implant prominence or evidence of infection and check radiographs were taken to assess union. The functional outcome was assessed using the Constant and Murley shoulder score.[17] All data were analysed using Epi-Info software. The test of significance was calculated using Chi square test. A probability value $p \leq 0.05$ was considered as statistically significant.

Results

In our study, a total of 28 patients with displaced midshaft clavicle fractures who met the inclusion/ exclusion criteria were enrolled. The plate group consisted of 15 patients while the TEN group had 13 patients. The demographic profile of the study subjects is shown in Table 1 along with comparison. The mean age was 34.2 years (range 16-50 years) in the plate group and 37.05 years (range 25-60 years) in the TEN group. There were 12 males and 3 females in the plate group while the TEN group consisted of 11 males and 2 females. Right side was involved in 5 patients and left side in 10 patients in plate group whereas TEN group showed right side involvement in 7 patients and left side in 6 patients. No significant difference was noted between the two groups with respect to age (p=0.475), sex (p=0.75) or side involvement (p=0.274). Both the groups had road traffic accident as the mode of injury except one in TEN group who suffered a fall from a height. In the plate group, 9 patients (60%) had class A fractures, 5 patients (33.3%) had class B fractures and 1 patient (6.7%) had class C fracture according to OTA classification. All the patients in the TEN group had class A fractures. Three patients (20%) in the plate group had ipsilateral neck of scapula fracture which was treated conservatively. All the three cases united well with good functional outcome. We could achieve closed reduction and nailing in 6 patients while the remaining 7 cases required open reduction. All the fractures progressed to union. But significant statistical difference was noted with respect to the average duration of hospital stay, mean surgery time and mean union time between the two groups (Table 2). There were no cases of infection, non union or implant failure in either group. However, hardware prominence was noted in two patients in TEN group and shoulder stiffness in one patient each in the plate group and TEN group and the difference was found to be statistically insignificant (Table 3).

Constant shoulder score was assessed during every follow-up visit. Though the analysis showed significantly higher score in the TEN group than in the plate group at 3 months period, the final score at 12 months showed no significant difference between the two groups (Table 4). At 1 year follow-up, the overall results were 4 excellent, 7 good, 3 fair and 1 poor in the plate group, while in the TEN group it was 8 excellent and 5 good results.

Table: 1 Demographic characteristic of study subjects

	Plating group (n=15)	**TEN group (n=13)**		**P value**
Mean age*	34.2	37.05	t = 0.7240	0.475
Sex#				
Male	12	11	X2=0.101	0.750
Female	3	2		
Side of injury#				
Right	5	7	X2=1.20	0.274
Left	10	6		

*t test was used
# Chi square test was used
TEN = Titanium elastic nail

Table: 2 Comparison of peri-operative outcomes

Outcome	Plating (n=15)	TEN (n=13)	t value	P value
Mean duration of hospital stay (days)	12.4±2.94	6.92±3.35	4.612	0.0001*
Mean operation time (min)	68.33±7.23	46.92±6.30	8.288	0.0001*
Union rate	100%	100%	-	-
Union time (weeks)	22.4±4.85	18.62±3.4	2.351	0.026*

*p value significant

Table: 3 Comparison of complications

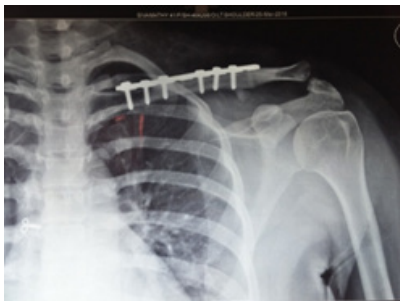
Complications	Plating (n=15)	TEN (n=13)	X2 value	P value
Hardware prominence	0	2	2.49	0.115
Shoulder stiffness	1	1	0.110E-01	0.916

Table 4: Comparison of mean Constant score

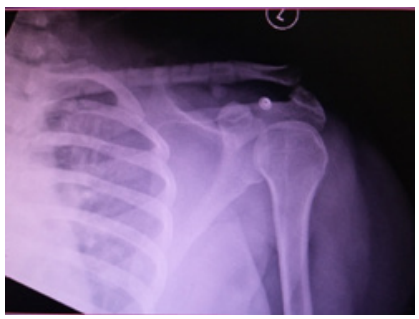
Assessment period	Mean ±SD		t value	P value
	Plating	TEN		
3 months	74.53 ± 6.70	79.38 ± 4.99	2.14	0.0416*
12 months	85.60 ± 6.68	89.38 ± 4.35	1.74	0.093

*statistically significant

Case 1: (Plate group)



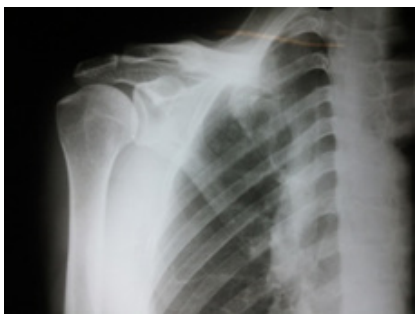
Post-operative X-ray



After implant removal

Case 2: (TEN group)

Post-operative X-ray



After implant removal

Discussion

The best treatment modality of displaced midshaft clavicular fractures is still debatable. Traditionally these fractures were treated non-operatively owing to less non-union rates as shown by Rowe[5] and Neer[7] in their studies. However recent studies have shown increasing rates of non-union and poorer functional outcomes following conservative treatment whereas the results of surgical treatment have been improving considerably.[8,9,18]

Various types of fixation like plates, intramedullary nails and external fixators are available for midshaft clavicular fractures. Paladini[19] refers to plating as the gold standard of surgical fixation of middle third clavicle fractures with acceptable complications and good functional outcomes. On the contrary, numerous other studies show that there is an increasing trend of surgical fixation by intramedullary nailing technique as a safe and good means to achieve a good functional outcome with lesser cosmetic defects.[15,20,21] Hence the better fixation technique still remains a topic of debate. In this study, the functional outcomes were studied and statistically compared to find if there was any significant difference between the two surgical methods of fixation, plate versus intramedullary nailing.

In our study, functional score was significantly higher in TEN group than plate group at 3 month follow-up visit, but at 1 year follow-up, there was no significant difference observed between the two groups. Overall fair to excellent results were obtained in 14 of 15 patients in plate group as compared to good to excellent results in all the 13 patients in TEN group. We had one poor result in the plate group. The incidence of unsatisfactory result was 3.6% in our study whereas

the incidence reported in literature is 5.3%.[22]

In our study, all the fractures in both groups progressed to union. The average time to union was significantly faster in the TEN group than in the plate group (p=0.026). The reason could be due to less soft tissue dissection, relative stability and secondary bone healing seen in TEN fixation whereas plating requires considerable periosteal stripping and provides absolute stability leading to primary bone healing.

The mean operating time in our study was found to be significantly less in the TEN group than the plate group (p=0.0001). This could be because TEN fixation is a less invasive procedure with smaller wound size as compared to plate fixation, although we have not recorded the wound size in our study.

The mean duration of hospital stay in our study was also found to be significantly less in the TEN group than the plate group (p=0.0001). As wound size is considerably larger in the plate group, most patients in our locality tend to stay longer till the time of suture removal.

We encountered two cases (15.38%) of hardware prominence in the TEN group causing skin irritation and perforation. In the literature, the incidence of nail prominence is 5.2-38.8%.[12,23,24] There could be two causes for the problem, one is insufficient cutting of the TEN after the primary treatment. The other is the displacement of the TEN to the sternal end of the clavicle by secondary shortening of the clavicle. Secondary shortening or telescoping especially occurs in the fractures with an intermediate zone of instability.[9]

The limitations in our study are a small sample size with shorter follow-up period. A larger prospective study with longer follow-up may be needed to provide a higher level of evidence.

Conclusion

With the present day advancement in surgical method and technique and a better understanding of patho-anatomy and biomechanics of clavicle, the management of clavicle fractures by surgical fixation has evolved. However it is essential to stringently adhere to the basic principles of management, having an understanding of the various fracture configuration and their idiosyncrasies.

The data of this study demonstrates that operative treatment of displaced midshaft clavicular fractures with TEN results in an excellent functional outcome. This technique provides more rapid free movement of the shoulder and an earlier return to daily activities than conservative management.

In comparison with plate fixation, the procedure is less invasive and requires smaller incision and a shorter duration of hospital stay. Hence the TEN is a suitable alternative to plate for the fixation of displaced mid shaft clavicular fractures, especially for young active individuals.

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Conflict of interest: Nil

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