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Elastic Stable Intramedullary Nailing Versus Plate Osteosynthesis of Mid-Clavicular Fractures-A Comparative Study.

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ABSTRACT

Background: The biomechanical characteristics of midshaft clavicular fractures treated with titanium elastic nail is not well studied. This study aimed to present a analysis of titanium elastic nail fixation and reconstruction plate fixation for midshaft clavicular fractures. **Methods:** Forty-four patients between 18 and 65 years of age were included in this study. They were randomized in two groups to be treated with either elastic intramedullary nail (ESIN) or plate. Clinical and radiological assessments were performed at regular intervals. Outcomes and complications of both groups over 2 years of follow-up time were compared. **Results:** Length of incision, operation time, blood loss and duration of hospital stay were significantly less for the ESIN group. American Shoulder and Elbow Surgeons (ASES) and Constant Shoulder scores were significantly higher (p\0.05) in the plating group than the EIN group for the first 2 months but there was no significant difference found between the two groups regarding functional and radiological outcome at the 2-year follow-up. **Conclusion:** ESIN is minimally invasive surgical technique with a lower complication rate, faster return to daily activities, excellent cosmetic and comparable functional results, and can be used as an equally effective alternative to plate fixation in displaced midshaft clavicle fractures.

Keywords: elastic nail, fixation and reconstruction plate, midshaft clavicular fractures.

INTRODUCTION

The clavicle is one of the most commonly fractured bones, accounting for 5–10% of all fractures and about 40% of all injury to shoulder girdle. Around 80% of clavicle fractures involve the middle -third and over half of these fractures are displaced, lateral- third constitutes 15-20% and medial –third less than 5%.[1]

Previous thinking about clavicle fracture was "Midclavicular fractures heal without the doctor, with the doctor, and despite the doctor!" Midshaft fractures have traditionally been treated non-operatively with a sling or a figure of eight bandage, even when substantially displaced. The non-operative treatment strategy was based on early reports suggesting that clavicular non-unions are very rare. Clavicular mal-union, if present, was reported as being of radiographic interest only, without clinical importance. Moreover, surgical treatment of acute midshaft fractures was not favoured due to relatively frequent and serious complications such as infection, non-union, pin migration, broken plates, and necessity of removal of hardware.[2]

Recent studies, however, conclude differently, and suggest the outcomes of displaced fractures might not be as favourable as once thought The relatively high number of non-unions, residual deficits in shoulder strength and endurance, persistent pain and disappointing cosmetic results might have led to unsatisfactory results in approximately 30% of the patients with displaced .midclavicular fracture.

In addition, clavicular malunion has recently been described by multiple authors as a distinct clinical entity with characteristic clinical and radiographic features. Possible explanations for the increased residual disability seen following the nonoperative care of these fractures may be the survival of critically injured trauma patients with more severe

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fracture patterns, increased patient expectations, more complete follow-up (including patient-oriented outcome measures), and the elimination of information on children (who have an inherently good prognosis and remodeling potential) from the data analysis.[3]

Therefore there is a tendency towards surgical treatment for Displaced midclavicular fracture. Open reduction and internal plate fixation and intramedullary fixation are two of the most commonly used surgical techniques for treating displaced midclavicular fractures. For plate fixation different types of plates are available: (precontoured) dynamic compression plates (DCP), tubular plates or reconstruction plates. For intramedullary fixation the Knowles pin, Rockwood pin or Elastic stable intramedullary nailing (ESIN) using a titanium elastic nail (TEN) have been described. In recently published prospective randomised studies, functional results after both plate fixation and intramedullary fixation proved to be superior compared to nonoperative treatment of displaced midclavicular fractures.[4]

Theoretically, both plate fixation and intramedullary fixation have their own advantages. A biomechanical study shows that plate fixation provides a more rigid stabilisation compared to intramedullary fixation and may provide a stronger construction for early rehabilitation protocols .On the other hand, intramedullary fixation has the advantage of preserving the soft tissue envelope, periosteum, and vascular integrity of the fracture site. Therefore infection rates may be decreased and fracture callus formation enhanced.

The optimal surgical approach for displaced midclavicular fracture remains controversial

On this basis, we plan to conduct a prospective randomized trial comparing operative plate fixation and intramedullary nailing with TEN for midclavicular fracture and compare with respect to the incidenc of non-union, functional outcome, pain scores, Quality of Life, cosmetic aspects, and complications

MATERIALS AND METHODS

This study Elastic Stable Intramedullary Nailing Versus Plate Osteosynthesis of Mid-Clavicular Fractures was done to compare the rate of radiological union and functional outcome of midclavicular fractures in two groups. Study was undertaken in the Department of Orthopaedics, P.R.M Medical College, Baripada, Odisha, in association with the attached emergency unit. The study period was from July 2017 to April 2019. A Prospective randomized study that include midclavicular fractures with displacement at least there was no cortical contact between two main fragments. Patients allocated to either plate fixation or intramedullary nailing through randomization. 44 cases of midclavicular fractures were included in our study. Patient on admission to emergency unit was initially resuscitated and stabilized (if required), then screening for other injury was done. Then was admitted under trauma word. Patients are sceened for eligibility according to criteria listed below.

Inclusion Criteria

1. Unilateral displaced midclavicle fracture
2. No medical contraindication to G.A.

Exclusion Criteria

1. Age<18 and >60 yrs
2. Fracture >1 month old
3. Pathological fracture
4. Open fracture and communitated fracture

We than randomized the patient in two groups, group 1 underwent intramedullary fixation by titanium elastic nail and group 2 underwent open reduction and plating. All cases were initially investigated with 20° cephalad anteroposterior and thorax showing bilateral clavicle posteroanterior radiograph to assess fracture type and post traumatic clavicular shortening. A single preoperative dose of prophylactic antibiotics was given. Patient was placed on radiolucent operative table in supine position with a large bump placed between the scapulae, allowing the injured shoulder girdle to fall posteriorly, helping to restore length. The insertion point was made approximately 1 cm lateral to the sternoclavicular joint. A one centimeter skin incision was made and a hole is drilled over the anterior cortex with a 2.5mm drill bit and guide.

The entry portal may be enlarged with an awl and then an elastic nail (diameter between 2 to 3.5 mm) inserted in the medullary canal of the clavicle with a universal chuck and T-handle under fluoroscopic control. With oscillating movements the nail is advanced until it reaches the fracture site. Reduction was performed by manipulating the fracture while moving the free-draped arm or with the help of pointed clamps or towel clips. If closed reduction was unsuccessful, an additional skin incision of size 1-2cm was made parallel to langers line for open reduction of the fragments. After adequate engagement of the distal fragment, the medial end of nail shortened and skin closed over it. Care was taken to avoid perforation of dorsolateral cortex of the lateral clavicle. The procedure is performed under fluoroscopic guidance.

A single preoperative dose of prophylactic antibiotics was given The patient was placed in the supine position with a large bumpplaced between the scapulae, allowing the injured shouldergirdle to fall posteriorly, helping to restore length and exposureto the clavicle. The entire upper extremity

was draped free toallow manipulation, if needed. The skin incision was centeredover the fracture and followed a line connecting the sternalnotch to the anterior edge of the acromion, Dissection was first performed along the medial fragment which has usually flexed up away from the vital infraclavicular structures. If possible, supra-clavicular nerves are identified and spared Reduction was then performed and held with bone holding clamps .A 3.5 mm Recon plare, LCDC, or third-tubular plates was then contoured with bending irons for application to the superior surface of the clavicle or anteroinferior surface . The fracture was reduced and fixed on the superior surface or anteroinferior surface of the bone using a minimum of three screws in the main proximal and distal fragments. In the case of long oblique or wedge comminuted fractures, lag screws were used where possible with care being taken to preserve soft tissue attachments. For comminuted fractures, a sufficiently long plate with nine or12 holes was used to bridge the fracture and obtain at least six cortex fixations on each side of the fracture.

Postoperative Protocol

A Sling was used for 7-10 days then active range of motion exercise were initiated and encouraged to use the arm without heavy lifting, pushing and pulling activity. After operation patient took diclofenac 50mg twice daily for 2-3 days. Full return of activities was permitted once healing occurred. Active movements of the shoulder (over 90° abduction or flexion) should be limited for 3-4 weeks, since increasing rotational loads on the clavicle may result in proximal migration of the nail

RESULTS

In our study "Elastic Stable Intramedullary nailing versus Plate Osteosynthesis in Midclavicular Fractures", the following observations were made and statistically analysed. The Chi-square test without Yates' correction and Student's t-test were used to compare the two groups. The SPSS 10.0 statistical software package was used to analyse the data; p values below 0.05 were considered to be significant. Mean follow up time was 15 months (12-18 month). Follow up rate was 100% at each examination.

The age range of the patient was from 18-55years.The mean age for nail group was 32.95±10.73 yrs and plate group was 33.45±10.51 yrs. (p=0.8767)

Table 1: Age Distribution of patients in our series.

Age (Years)	Esin Group		Plate Group	
	No. Of Cases	Percentage	No. of case	Percentage
10-20	2	9.09%	2	9.09%
20-30	9	40.9%	7	31.81%
30-40	6	27.27%	8	36.36%
40-50	2	9.09%	2	9.09%
50-60	3	13.63%	3	13.63%

Table 2: Gender Distribution.

Sex	Esin Group		Plate Group	
	No. Of Cases	Percentage	No. Of Cases	Percentage
Male	16	72.72%	15	68.18%
Female	6	27.27%	7	31.81%

The injury being a result of trauma was commonly found in male population compared to female in both the group. (p=0.7411)

Table 3: Distribution of Mode of Injury

Mode Of Injury	Esin Group		Plate Group	
	No. Of Case	Percentage	No. Of Case	Percentage
RTA	12	54.54%	13	59.09%
Fall From Height	3	13.63%	4	18.18%
Sports Injury	5	22.72%	3	13.63%
Fall On Out Stretched Hand	2	9.09%	2	9.09%

The mode of injury was uniformly distributed in both the groups with almost more than fifty percentages of cases resulting from road traffic accident. (p>0.1)

Table 4: Side Affection of the Patient

Side	Esin Group		Plate Group	
	No. Of Cases	Percentage	No. Of Case	Percentage
Dominant Side	13	59.09%	14	63.63%
Non Dominant Side	9	40.9%	8	36.36%

In both the group the dominant side of the patient was more affected nearly 60%. (Chi square = 0.096, p = 0.75)

Table 5: Type of Fracture as per OTA Classification

Fracture Type	Esin Group		Plate Group	
	No. Of Cases	Percentage	No. Of Cases	Percentage
B1 (Simple)	14	63.63%	15	68.18%
B2 (Wedge)	8	36.36%	7	31.81%

Table 6: Time Interval between Injury & Surgery

Days	Esin Group		Plate Group	
	No. Of Cases	Percentage	No. Of Case	Percentage
1-2	2	9.09%	1	4.54%
2-3	7	31.81%	13	59.09%
3-4	10	45.45%	4	18.18%
4-5	3	13.63%	4	18.18%

Table 7: Diameter of Nail used in Nail Series

Diameter Of Nails(Mm)	No. Of Cases	Percentage
2.0	2	9.09%
2.5	11	50.00%
3.0	8	36.36%
3.5	1	4.54%

The surgery was done on an average delay of 3.386±0.755 days in nail group and 3.52±0.756 days from day of injury in our series. (p=0.6204)
In our nail series size 2.5mm and 3.0mm TEN mostly used, combined 86% of cases.2mm size TEN used in narrow medullary canal in adolescent patients.

Table 8: Method of Reduction in ESIN Group

Method of Reduction	No. of cases	Percentage
Closed	15	68.18%
Open	7	31.81%

Closed reduction was possible in 68.2% of cases and a short incision of about 2-3 cm required in 31.8% of cases in nail group. The open reduction was mostly done in wedge fracture type.

Table 9: Size of the plate used in our series

Size (As Per Hole)	No. Of Cases	Percentage
7	5	22.72%
8	3	13.63%
9	5	22.72%
10	5	22.72%
11	2	9.09%
12	2	9.09%

In most of the type B1 fracture 7-9 hole plate were used .In cases of wedge or long oblique fractures 10-12 hole plate were used, most of the time along with interfragmentary lag screw.

In patient hospital stay
All of the patients in both the group dischagred on day-3, except cases where we get superficial infection stay longer i.e. one case in nail group and two cases in plate group.

Table 10: Operative Time (in Minutes) in our series

Time In Min	Esin Group		Plate Group	
	No. OF CASES	PERCENTAGE	No. OF CASES	PERCENTAGE
30-40	7	31.81%	0	0
41-50	7	31.81%	3	13.63%
51-60	4	18.18%	5	22.72%
61-70	4	18.18%	8	36.36%
71-80	0	0	4	18.18%
81-90	0	0	2	9.09%

Table 11: Incision size (cm) in our series

Incision Size In Cm	Esin Group		Plate Group	
	No. OF CASES	Percentage	No. OF CASES	Percentage
0-2	15	68.18%	0	0
2-4	7	31.81%	0	0
4-6	0	0	0	0
6-8	0	0	0	0
8-10	0	0	6	27.27%
10-12	0	0	8	36.36%
12-14	0	0	4	18.18%
14-16	0	0	4	18.18%

The mean operative time in nail group was 50.23±10.96min. The operative time was much shorter when closed reduction was successful. The mean operative time in plate group was higher i.e.67.73±11.42min. (p<0.0001)

The average incision size in nail group was 2.05±1.08 cm, and plate group was 12.32±1.93cm. (p<0.0001)

Table 12: Operative Blood Loss (in ml) in our series

Blood Loss In Ml	Esin Group		Plate Group	
	No. of Cases	percentage	No. of cases	Percentage
0-50	14	63.63%	0	0
50-100	4	18.18%	0	0
100-150	3	13.63%	15	68.18%
150-200	1	4.54%	6	27.27%
200-250	0	0	1	4.54%

Table 13: Radiological Union Time in our series

Time In Wks	Esin Group		Plate Group	
	No. of cases	Percentage	No. of cases	Percentage
6-9	8	36.36%	6	27.27%
9-12	10	45.45%	8	36.36%
12-15	3	13.63%	3	13.63%
15-18	0	0	0	0
18-21	0	0	0	0
21-24	0	0	0	0
24-27	1	4.54%	I	4.54%

The mean operative blood loss in nail group was 73±46ml and plate group was 158.2±28.1ml. (p<0.0001)

In our series all the fractures in the nail group were united with an average time of 11.91±3.57weeks and in plate group two cases nonunited but rest cases united with average time of 12.35±3.8weeks. (p=0.7004)

The patients in nail group had lower postoperative pain score than plate but in both group pain reduction were significant than preoperative pain. The mean pain score in nail group was2.36±0.85 and in plte group was 3.14±0.83. (p=0.004)

Table 14: Pain as per VAS Score on Day 3

Pain Vas Score	Esin Group		Plate Group	
	No. of cases	Percentage	No. of Cases	Percentage
1	3	13.63%	0	0
2	10	45.45%	5	22.72%
3	7	31.81%	10	45.45%
4	2	9.09%	6	27.27%
5	0	0	1	4.54%
6-10	0	0	0	0

Table 15: Clavicular Shortening in our series

Clavicular Shortening (Mm)	Esin Group		Plategroup	
	No. Of Cases	Percentage	No. Of Cases	Percentage
No Shortening	13	59.09%	14	63.63%
≤5mm	5	22.72%	6	27.27%
6-10mm	1	4.54%	0	0
>10mm	3	13.635	2	9.09%

Table 16: Functional Outcome in our series

Serial No.	Esin Group		Plate Group	
	Constant Score	Dash Score	Constant Score	Dash Score
1	100	0	100	0
2	100	0	100	0
3	98	1	100	0
4	100	0	98	1
5	92	6	96	2.5
6	100	1	99	0.8
7	99	2.4	90	1
8	100	0	90	8
9	94	11	92	8
10	96	5	100	0
11	98	1	100	0
12	95	8.3	98	1.2
13	100	1.8	99	1
14	96	10.2	100	0.8
15	100	0	90	2.3
16	71	32	90	4
17	92	8.3	80	10.5
18	94	8	68	40
19	100	1.8	70	34
20	100	0.8	100	0
21	100	0	99	1
22	91	8.3	99	1

No clavicular shortening was seen in 59% of nail cases and 63.6% of plate cases, these were mostly simple fracture. The mean shortening in nail group was 3.32±4.81mm and plate group was 2.55±3.74mm. (p=0.5553) in cases of wedge fracture mean shortening in nail group was 7.38±5.71mm and in plate group was 4±4.9mm. (p=0.209)

The mean Constant score in nail group was 96.18±6.43 and in plate group was 93.55±9.51. (p=0.2875) the mean DASH score in nail group was 4.86±7.16 and in plate group was 5.32±10.7. (p=0.8667) the functional outcome score difference

is not statistically significant in between two groups.

Table 17: Cosmetic Scoring in our series

Cosmetic Score	Esin Group		Plate Group	
	No. Of Cases	Percentage	No. Of Cases	Percentage
1 (Very Unsatisfied)	0	0	2	9.09%
2	0	0	3	13.63%
3	2	9.09%	4	18.18%
4	6	27.27%	9	40.90%
5(Very Satisfied)	14	63.63%	4	18.18%

Table 18: Complications

Complication	Esin Group		Plate Group	
	No. of Cases	Percentage	No. of Cases	Percentage
Nonunion	0	0	2	9.09%
Delayed Union	1	4.54%	1	4.54%
Symptomatic Malunion	2	9.09%	2	9.09%
Superficial Infection	1	4.54%	2	9.09%
Deep Infection	0	0	2	9.09%
Transient Plexus Irritation	0	0	1	4.54%
Hypertrophic Scar	0	0	2	9.09%
Telescopy	4	18.18%	0	0
Medial Skin Irritation	4	18.18%	0	0
Impant Failure	0	0	1	4.54%
Refracture	0	0	1	4.54%

In our series, the nail group patients were cosmetically more satisfied with score of 4.55±0.67 than plate group patients with score of 3.45±1.22. (p=0.0007)

No intraoperative complications like neurovascular impairment or pulmonary injury were noticed in both the groups.

One or more complications were seen in 6 out of 22 cases of plate group. Superficial infection was noted in 1case in nail group and 2 cases in plate group which healed well with debridement and antibiotics. One of them in plate group led to deep infection which led to exposure of plate and nonunion for which plate was removed, curettage done and again fixed after infection subsided with plate and bone graft. Another case of nonunion noted in plate group which united after iliac crest bone grafting.1case each in both the group noted delayed union which united after 25 weeks without any intervention. Union with angulation noted in 2cases in both the group with slight restriction of abduction, which gradually improved with physiotherapy. One case of plate breakage required revision fixation. One case of refracture after plate removal required re-fixation with bone graft. In nail group telescopy associated with medial nail prominence noted in 4 cases led to irritation.2 cases required shortening of nail end.

DISCUSSION

Clavicle fracture represents 5-10% of all skeletal injuries, clavicle fractures are among the most common injuries of human skeleton.[5] Nearly 80% of clavicle fractures are of middle third segment. In majority of patients, clavicle fracture results from direct injury (93%), caused by fall onto the shoulder and direct injury to shoulder.670% of patients are male. Capicotto,[7] in a series of 1000 clavicle fracture, RTA accounts for 27% of cases. In our series direct injury causes 91% of clavicle fracture and out of which 25(60%) of mid clavicular fractures are caused by RTA, due to common use of motorcycles and scooters in our country.74% are male patients. Traditionally clavicle fractures have been treated non operatively. In Celestre,[8] reported on non operative treatment of clavicle fracture. Neer reported non union in only 3(0.14%) of 2235 patients, while Rowe reported nonunion in 4 of 566 clavicle fractures. These studies also suggest a higher nonunion rate with operative care. However more recent study shown that union rate for displaced midshaft clavicle fracture may not favourable as once thought. Plate fixation is the standard operative treatment of displaced midclavicular fracture.[9] The conventional 3.5 mm DCP ,reconstruction plate or semi tubular plate are usually used. Some new type such as locking plate, Mennen plate, 3-D reconstruction plate and precontoured locking plate have been developed to decrease implant irritation and improve fixation stability. In our study we use 3.5mm reconstruction plate, LCDCP and semi tubular plate. These plate need to be contoured to fit the “s” shaped clavicle with large skin incision and extensive soft tissue striping, both leading to potential complications.[10] In our study we use 3.5mm reconstruction plate or semitubular plate or LCDCP in 22 cases of displaced midclavicular fractures with patients age 33.45±10.51yrs ,out of which 15 are male and 7 are female. The mean operative time 67.73±11.42mins. and mean blood loss of 158.2±28.1ml.In 20 cases union took place with a mean time of 12.35±3.8wks. 2 cases(9%) nonunion,one (4.5%) delayed union, 1(4.5%) plate breakage,2 (9%) deep

infection,2 (9%) union with angulation and one (4.5%) case showed refracture after removal. Shen et al(51) in his series of 232 cases of displaced midclavicular fracture treated with plate with avagrage union time 10 wks. Nonunion 7(3%) cases, union with angulation 14(6%) cases, infection 5(2%) cases, sore and skin numbness 49 (21%) cases.

The intramedullary fixation devices for clavicle fractures are k wire, Knowles pin, Rush pin, cancellous screw, hagie pins ,kuntscher's nail.[11-13] The main difficulties encountered when inserting any intramedullary implant are, anatomy of clavicle and fixation strength to resist fracture site motion during healing period. In our study we use a minimally invasive technique to implant an intra medullary TEN to fix displaced midclavicular fracture. The TEN is flexible enough to pass through the midclavicle narrow canal and more along clavicle "s" shaped. Because it is made up of titanium, it is strong enough to resist shoulder motion force and retain to original shape after removal of loading. Muller,[14] reported in series of 32 ESIN ,no nonunion,[12] shortening of more than 5 mm and no refracture. The mean constant score was 95.2 and mean DASH score was 5.0. Remh et al,[15] in their series of 136 cases,60% cases closely reduced, with one nonunion,8 medial migration ,shortening of avg.1.5±0.5cm in 3 patients with communitated fractur The muscle power of shoulder was not accessed by isometric muscle testing on a machine. No independent evaluator was used to access any of the results. This was a small study with short follow up with potential type2 error risk.

CONCLUSION

So we conclude that the treatment of displaced mid shaft clavicular fracture simple or wedge type in active adults with intramedullary fixation with TEN is a safe and minimally invasive surgical procedure. A high bone union rate, good functional outcome, favorable patients cosmetic appearance, early shoulder pain relief and functional recovery can be obtained with few complication.

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