

## Assessment of the Outcome after Treatment of the Displaced Midshaft Clavicular Fractures Using two Different Approaches

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### Abstract

**Aim:** The aim of this study to determine the intramedullary Nailing Versus Plate Fixation for the Treatment Displaced Midshaft Clavicular Fractures. **Methods:** A prospective randomised trial was conducted in the Department of Orthopedics, MGM Medical College Jamshedpur, Jharkhand, India from Feb 2020 to February 2021. Those consenting to participation were randomised to open reduction and plate fixation with a 3.5 mm superior clavicular plate or a 2.0 mm to 3.5 mm titanium elastic nail in the second group. Patients with Age 18 to 58 yrs, Mid-shaft fracture, Displacement by one bone width, Tenting/compromised skin, Initial shortening of more than 15 mm, Angulation exceeding 30 were included in this study. Total of 100 fractures of the clavicle were included in this study and divided into 2 equal groups. Demographic data were recorded at presentation and patients completed a baseline Disabilities of the Arm, Shoulder and Hand (DASH) score to describe their shoulder function the week before injury. Standard standing radiographs with 15° caudal and 15° cephalad and a 'panorama' view of both clavicles were performed. **Results:** There were no demographic differences between the groups (Table 1) and they had the same baseline mean DASH score of 0.5 (0 to 6.8 for plate *versus* 0 to 15.9 for ESIN,  $p = 0.7$ ). The duration of surgery was shorter for ESIN (mean 52.4 minutes, 21 to 119) than for plate fixation (mean 68.7 minutes, 34 to 105;  $p < 0.001$ , independent samples *t*-test). After 12 months, there was no difference in DASH score between the plate fixation and ESIN, with both approaching their DASH baseline values of 0.5. Individual differences between baseline data and the DASH score after one year showed no statistical difference (1.5, -4.3 to 12.2 for plate *versus* 2.1, -14.3 to 28.4 for ESIN;  $p = 0.5$ , independent samples *t*-test). Compared with baseline values, 1 patient (2%) with plate fixation had a DASH score which worsened by ten points compared with 4 patients (8%) in the ESIN group. Both groups demonstrated similar satisfaction with their shoulder at 12 months as measured by VAS (9, 0 to 10 for plate fixation *versus* 9, 3 to 10 for ESIN;  $p = 0.87$ , independent samples *t*-test). **Conclusion:** Fixation with plate or ESIN in completely displaced midshaft fractures of the clavicle produce equally excellent functional results at 12 months. In addition, nailing should not be undertaken with implants less than 2.5 mm in diameter.

**Keywords:** midshaft fractures, outcome, nail, plating

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## Introduction

Clavicle fractures are common injuries accounting for 2.6 to 4.0% of all fractures.[1] It has been previously published that mid-third fractures constitute approximately 80% of all clavicle fractures.[2] Over the last 15–20 years, treatment of adult clavicle fractures has dramatically changed. Traditionally, midshaft clavicle fractures (MCFs) have been treated non-operatively with the expectation of good clinical outcomes and a high rate of fracture union.[2] Recent studies, however, demonstrated that malunion and non-union rates with non-operative treatment are higher than anticipated. According to a meta-analysis of recent randomized studies, the nonunion rate for nonoperative treatment was 16.5%, which is higher than the 1.9% found after surgical treatment.[3] Additionally, analysis of functional outcomes showed better results following surgical treatment. Accordingly, the proportion of clavicle fractures being treated with surgery is increasing.[4] Plate fixation is the standard surgical method for MCFs.[5] This method is advantageous because of restoration and preservation of the natural anatomy and length of the clavicle.[3,5] However, reported complications include wound infection and non-union because of extensive periosteal stripping.[5,6] And other complications are skin numbness and poor cosmetic results due to the larger incision.[5–7] Another surgical option for MCFs is intramedullary (IM) nailing. IM devices utilize minimally invasive surgical techniques, resulting in smaller incisions, preserved periosteum and shorter operation times.[8,9] Because of these, advantages of IM nailing are lower incidence of infection, nonunion, skin numbness and scar.[8,9] Various devices for IM clavicle fixation are available, including Kirschner-wires, Rockwood Pins, Hagie Pins, Rush pins, Kuntschner nails and Knowles pins.[5,8] However, the most widely used and studied implant is the titanium elastic nail (TEN).[5,8] TEN has been successfully used for treating MCFs and shows

comparable results in terms of functional outcomes and union rates to plate fixation.[10]

## Materials and methods

A prospective randomised trial was conducted in the Department of Orthopedics, MGM Medical College Jamshedpur, Jharkhand, India from February 2020 to February 2021, after taking the approval of the protocol review committee and institutional ethics committee.

### Methodology

Those consenting to participation were randomised to open reduction and plate fixation with a 3.5 mm superior clavicular plate or a 2.0 mm to 3.5 mm titanium elastic nail in the second group. Patients with Age 18 to 58 yrs, Mid-shaft fracture, Displacement by one bone width, Tenting/compromised skin, Initial shortening of more than 15 mm, Angulation exceeding 30 were included in this study.

Total of 100 fractures of the clavicle were included in this study and divided into 2 equal groups. Demographic data were recorded at presentation and patients completed a baseline Disabilities of the Arm, Shoulder and Hand (DASH)[11,12] score to describe their shoulder function the week before injury. Standard standing radiographs with 15° caudal and 15° cephalad and a ‘panorama’ view[13] of both clavicles were performed.

### Assessment of clinical outcomes

The functional outcome was assessed with the DASH questionnaire and the modified Constant Score.[11] The DASH score consists of 30 questions providing a patient-rated score from zero points (perfect extremity) to 100 (completely disabled limb), while the surgeon records a Constant Score from 100 (perfect) to zero (completely disabled).[11,12,14,15] Patients completed the shorter 11-question Quick DASH[16] questionnaire weekly for the first six post-operative weeks, while the

DASH and Constant Scores were recorded at each outpatient attendance.

At 12 months, the patients rated their satisfaction with the cosmetic and general results of the procedure on a 10 cm visual analogue scale (VAS), where zero indicated a poor and ten a perfect result. They were also asked for yes/ no responses about pain over the implant, incisional numbness, and whether they experienced complete recovery of their shoulder function.

#### Assessment of radiological outcomes

Calibrated radiographs of the injured shoulder were obtained at each attendance until union was seen. Additionally, a calibrated panorama view of both clavicles was obtained pre-operatively and after union to evaluate shortening. A nonunion was defined as absent osseous bridging of more than one cortex at six months.

#### Statistical analysis

To detect a statistically significant difference between groups of 10 points in the DASH score with a power of 80% and a significance level of 5%, 36 patients were required in each group. Groups were compared with the independent samples *t*-test or chi-squared testing, as appropriate.

#### Results

There were no demographic differences between the groups (Table 1) and they had the same baseline mean DASH score of 0.5 (0 to 6.8 for plate *versus* 0 to 15.9 for ESIN,  $p = 0.7$ ). The duration of surgery was shorter for ESIN (mean 52.4 minutes, 21 to 119) than for plate fixation (mean 68.7 minutes, 34 to 105;  $p < 0.001$ , independent samples *t*-test).

**Clinical outcome.** According to the linear mixed model, plate fixation led to a better recovery as measured by Quick DASH during the first five weeks and at six weeks and three and six months as measured by

both DASH and Constant Score. After 12 months, there was no difference in DASH score between the plate fixation and ESIN, with both approaching their DASH baseline values of 0.5. Individual differences between baseline data and the DASH score after one year showed no statistical difference (1.5, -4.3 to 12.2 for plate *versus* 2.1, -14.3 to 28.4 for ESIN;  $p = 0.5$ , independent samples *t*-test). Compared with baseline values, 1 patient (2%) with plate fixation had a DASH score which worsened by ten points compared with 4 patients (8%) in the ESIN group. Both groups demonstrated similar satisfaction with their shoulder at 12 months as measured by VAS (9, 0 to 10 for plate fixation *versus* 9, 3 to 10 for ESIN;  $p = 0.87$ , independent samples *t*-test). Those in the ESIN group were, however, significantly more satisfied with their cosmetic results (mean 8.7, 3.6 to 10 *versus* mean 7.8, 0 to 10;  $p = 0.04$ , independent samples *t*-test).

**ESIN – subgroup analysis.** A strong predictor of the functional outcome in the ESIN group was the degree of fracture comminution as described by the number of intermediary fragments. The 12 patients with no intermediary fragments had a functional recovery comparable with that of those who underwent plate fixation, whereas patients with 2 or more fragments recovered significantly slower than those with fewer. These findings were not replicated in the plate group.

**Radiological outcome.** All fractures united in the plate group. There was 2 nonunion in the ESIN group, where the nail was removed early due to pain, 12 weeks post-operatively. 5 patients in the ESIN group exhibited shortening of  $> 15$  mm after union. This did not affect the clinical result at 12 months with a mean DASH of 0.9 (0 to 3.4) compared with 2.3 (0 to 28.4) for those with shortening  $< 15$  mm ( $p = 0.3$ , independent samples *t*-test).

**Table 1: Patient demographics and fracture characteristics**

Variable	ESIN, n = 50	Plate, n = 50
Mean age at injury (yrs) (range)	35.4 (18.5 to 55.2)	33.6 (18 to 58.1)
Mean time elapsed before surgery (days) (range)	5.4(0 to 12)	5.8 (0 to 16)
Gender (male/female) (n)	43/7	43/7
<b>Mechanism of injury (n)</b>		
Simple fall	12	12
Motor vehicle accident	13	15
Sports	22	20
Other	3	3
Fracture characteristics		
Affecting the right side	22	25
<b>Intermediary fragments (n, %)</b>		
0	12 (24)	13(26)
1	14 (28)	12 (24)
2	17 (34)	17 (34)
≥ 3	7 (14)	8(16)
Initial displacement (bone width) (range)	1.58(0* to 3)	1.62(1 to 3)
Initial shortening (mm) (range)	8.7(-14 to 33)	11.3 (-5 to 39)
*angulation > 30°		
ESIN, elastic stable intramedullary nailing		

**Table 2: Variables increasing the odds of performing open elastic stable intramedullary nailing in 50 patients with isolated completely displaced mid-shaft fractures of the clavicle**

Variable	Multivariate logistic regression model	
	OR (95% CI)	p-value
Mean age (yrs)	0.96 (0.9 to 1.1)	0.5
Mean time to surgery (five days)	1.8 (1.5 to 2.2)	<b>0.03</b>
<b>Intermediary fragments</b>		
0 – ref.	1.1	-
1	7.3 (1.1 to 47.2)	<b>0.05</b>
2	5.8 (0.9 to 35.3)	0.07
3	34.8(1.8 to 621.4)	<b>0.03</b>

Open reduction was performed in 28 fractures, while 22 were closed procedures. Closed reduction resulted in a significantly better functional outcome at all points in all three measures ( $p < 0.05$ ) except for the Constant Score at 12 months. Closed procedures were performed after a mean of 4.5 days (0 to 12) and open procedures at

6.8 days (1 to 14) after injury ( $p = 0.03$ , independent samples  $t$ -test). Multivariate logistic regression demonstrated an 82% increase in odds ( $p = 0.03$ ) of an open procedure if surgery was delayed five days. Fractures with intermediary fragments also had higher odds of open reduction (Table 2).

**Table 3: Complications and additional procedures in 100 patients treated surgically for displaced mid-shaft fractures of the clavicle**

Variable	ESIN (n)	Plate (n)	p-value <sup>§</sup>
<b>Major complications requiring revision surgery under general anesthesia</b>			
Revision surgery for deep infection	0	3	
Nonunion	2	0	
Implant failure	2	0	
<b>Minor complications</b>			
Superficial infection	0	6	
Wound dehiscence	5	0	
Incisional numbness at 12 mths	9	28	<b>&lt; 0.001</b>
Pain over nail entry point or over plate at 12 mths	17	24	0.3
Implant failure	1	4	
Re-fracture	0	1	
<b>Implant removal</b>			
Local anaesthesia	22	0	<b>&lt; 0.001</b>
General anaesthesia	10	4	<b>&lt; 0.001</b>

\*2 shortened in local anesthesia, all removed after bony healing, †2 mm nail prematurely removed after 12 wks, ‡2 mm nail that was not sufficiently anchored laterally and lost reduction early, §chi-squared test, More than one complication could occur in a single patient. Bold p-values are statically significant

**Complications – plate group.** 3 patients exhibited loosening of screws medially and three laterally (Table 3). Everyone was observed and given restrictions in load bearing until callus was seen on the radiographs. Another patient had an undisplaced fracture through the medial screw at seven weeks post-operatively, after heavy lifting, and this healed uneventfully after 4 weeks not loading the clavicle. 3 of these patients had their plates removed due to a painful prominence of the hardware. 3 patients with plate fixation acquired a deep infection. They were treated successfully with soft-tissue revision surgery and antibiotics and went on to union. 1 implant was later removed due to persistent infection after union and the other 18 months later due to pain over the implant. Superficial infection developed in 6 patients and was successfully treated with oral antibiotics.

**Complications – ESIN group.** The intramedullary nail was placed outside the medullary canal of the lateral fragment in 2 patients. This was discovered on the post-operative radiograph and the fixation revised. 4 patients were found to have a

very small medullary diameter; of these, 3 crossed over to plate fixation intra-operatively, while a 2 mm nail was used in the other 4. In 2 of these it was advanced only 16 mm into the distal fragment, which, failed early, and was plated. 2 developed a hypertrophic nonunion after the nail was removed prematurely at 12 weeks and went on to be revised to a plate. The nail was bent during introduction, but the fracture healed successfully. These 4 patients were all analysed by intention to treat.

### Discussion

We found that 12 months following displaced mid-shaft fractures of the clavicle treated with either a plate or ESIN, the outcome was excellent. During the first five weeks, there was a statistically significant difference in Quick-DASH favouring plate fixation, and at six weeks to six months in both the DASH score and Constant Score. The minimum clinically important difference for the Quick-DASH is 8 points, indicating that our finding of a mean difference of 8.8 points during the first five weeks is clinically detectable.[17]

The more comminution, the higher were the Quick-DASH and DASH scores during the first six months in the ESIN group. This effect was not reproduced in the plate group. Nailing of fractures without comminution gave broadly the same scores as those of plate fixation. Plating appears to be able to negate the effect of comminution when bridging the fracture. We suggest the effect diminishes over time as callus forms in the nail construct, and the fracture becomes inherently more stable.[18]

Open reduction was the strongest predictor of poor functional outcome at 12 months in the ESIN group, in contrast with Van der Meijden et al[19] who reported no such effect. In our series, 56% were open procedures, compared with 74% in the study of 120 patients by Van der Meijden et al.[19] It is possible that an inadequate number of procedures were performed closed in that study to reach a statistically sound conclusion. The risk of open reduction increased with time elapsed between injury and fixation, and contracture of the adjacent muscles, consolidation of the fracture haematoma and early callus formation all contribute to making closed reduction progressively harder. The high incidence of complications in the patients with narrow medullary cavities who underwent fixation with a 2 mm nail suggests that this is not an appropriate construct, and in patients where a 2.5 mm nail may not be used, conversion to open reduction and internal fixation with a plate is the most appropriate course of action.

The incidence of minor complications related to prominence of the implant and incisional numbness were high in both groups. This is consistent with other studies reporting complaints over the nail to be 20% to 70% and 14% to 44% with plating and the need for secondary surgery with implant removal of 53% to 96% in ESIN and 3% to 63% for plate fixation.[19-21]

One of the limitations of this study is that the degree of fracture comminution was

rated according to the number of fragments. This does not account for the different size of fragments, which is impossible to measure correctly in a radiograph, and we thus chose to report results as higher or lower degree of comminution as this might be more clinically applicable. Some patients did not complete their baseline DASH score correctly, scoring instead their current function; these cases were removed from the analysis. The subgroup analyses were not predetermined; thus no power analyses were performed, meaning their results should be interpreted with caution. While the randomisation procedure was performed by an otherwise uninvolved colleague, computerised randomisation would have arguably been more robust.

### Conclusion

Fixation with plate or ESIN in completely displaced midshaft fractures of the clavicle produce equally excellent functional results at 12 months. In addition, nailing should not be undertaken with implants less than 2.5 mm in diameter. In the presence of comminution, plating may be the superior option.

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