Evaluation of minimally invasive fixation with ESIN in the management of displaced mid-shaft clavicle fractures: a case series with minimum of 2 years follow-up

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ABSTRACT

Background: Over the last few years, operative treatment has become the standard for treatment of clavicle fractures. Both plating and intra-medullary pinning techniques are available for treating clavicle fractures. The aim of the study was to evaluate the role of minimally invasive technique using elastic stable intramedullary nailing (ESIN) in surgical treatment of displaced mid-shaft clavicle fractures.

Methods: It is a prospective case series study conducted at the Department of Orthopaedics of a tertiary care centre. 44 cases of acute displaced mid-shaft clavicle fractures with a mean age of 32.7 years were treated by intramedullary pinning with titanium elastic stable nails and were followed-up for a mean period of 30.6 months (range= 24-40 months). Functional outcomes were evaluated by using Constant Shoulder score. The results obtained were analysed using student’s t-test.

Results: Union was achieved in all except one case which showed delayed union. 7 cases were complicated by telescoping (incidence= 15.9%) and 6 out of these 7 cases also had medial nail protrusion (incidence= 13.6%) simultaneously. 9 cases had shortening of less than 1cm and 2 had shortening of more than 1cm. No other complication was reported from any of the case. Mean constant shoulder scores improved from 15 to 85.6 (p value <0.001) after 12 months from surgery. However, no further improvement was seen after 12 months of surgery, with no statistical difference (p value= 0.789) between the mean scores at 12 (85.6) and 24 (85.7) months.

Conclusions: ESIN offers the advantages of treating displaced mid-shaft clavicle fractures with minimal incision and decreased surgery time with minimal intra-operative blood loss. The results were excellent in terms of functional outcomes. The complication rates were low and return to normal activity was quiet fast. ESIN is a minimally invasive technique with good cosmetic and functional results. This method should be seen as an alternative to plate fixation and non-operative treatment.

Keywords: Clavicle shaft fracture, Elastic stable intramedullary nail (ESIN), Constant shoulder score

INTRODUCTION

Clavicle fractures constitute nearly 2.6% of all the fractures managed by orthopaedic surgeons.¹ Nearly 85% of the fractures are mid-third in location.¹ Traditionally, they have been treated conservatively.² With better understanding of shoulder biomechanics and increasing demands, operative intervention with plating osteo-synthesis has become the standard management.³⁶ But, plating osteo-synthesis was found to have complications...
like scar mark, implant prominence, neurovascular injury and pleural injury. Intra-medullary nailing using 3.2 mm Steinmann pins, K-wires, locking pins like Rockwood pins is also being widely used. Recently, treatment scenario has been revolutionized after the entry of Elastic Stable Intramedullary Nailing (ESIN) with less implant complications and better treatment outcomes. 

**METHODS**

A 4 year prospective case series study was conducted from 1st January 2012 to 1st January 2016 at the Department of Orthopaedics, VSS Medical College, Sambalpur, India (tertiary care centre). Total number of patients was 44 (male=38, female=6). Mean age was 32.7 years (range=20-50 years). The inclusion criteria as given in Table 1 were set as unilateral, displaced, isolated, acute, closed fracture of clavicle located in mid-third without any associated medical or surgical comorbidity and neurovascular abnormality. Cases with open fractures, pathological fractures, age less than 20 or more than 50 years and fracture more than 7 days old were excluded from the study. Radiographic evaluation was done using AP and Zanca views of the involved clavicle and fractures were classified according to OTA classification system. After general and systemic evaluation, patients were operated as soon as possible. Evaluation was done using constant shoulder score, which was recorded by an independent evaluator at 2 weeks, 1, 3, 6, 12 and 24 months post-operatively. Statistical analysis was done using student’s t-test.

**Table 1: Inclusion and exclusion criteria.**

<table>
<thead>
<tr>
<th>S. no.</th>
<th>Inclusion criteria</th>
<th>Exclusion criteria</th>
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<tbody>
<tr>
<td>1</td>
<td>Isolated fracture of clavicle</td>
<td>Fractures of medial or lateral third</td>
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<tr>
<td>2</td>
<td>Age between 20-50 years</td>
<td>Pathological or open fractures</td>
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<tr>
<td>3</td>
<td>Unilateral displaced closed fracture of mid-shaft clavicle</td>
<td>Additional pathological conditions affecting limb function</td>
</tr>
<tr>
<td>4</td>
<td>No other medical or surgical comorbidities</td>
<td>Associated neurovascular injury</td>
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<tr>
<td>5</td>
<td>Acute fractures (less than 7 days old)</td>
<td>Fracture more than 7 days old</td>
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**Surgical technique (A-I)**

Surgery was planned in properly selected cases. General anaesthesia was used. Patient was positioned supine on the fluoroscopy compatible table. C-arm fluoroscopy was used with C-arm placed comfortably so as it did not obstruct the surgeon. Skin prepared from neck to axilla including the whole chest and supraclavicular area of the involved side. 1.5 cm skin incision was taken over sternal end of clavicle. Opening of anterior cortex was made with awl. Elastic titanium nail of size 2.5 mm or 3.0 mm in males and 2 mm in females was used. Close reduction achieved under fluoroscopy control. When close reduction could not be achieved, then additional small incision was given over fracture site for direct manipulation. Under fluoroscopy control, nail was inserted across the fracture site into the distal fragment. Medial end of nail was cut off as short as possible. Skin was closed with 3-0 nylon sutures in one layer as shown in Figure 1.

**Figure 1: (A-I) Surgical technique- A) Patient position; B) Skin incision with exposure of entry site; C) C-arm view of entry point; D) Nail entry; E) C-arm view of nail entry; F) Nail reaching fracture site; G) Manual reduction under C-arm guidance; H) Cutting the nail; I) After skin closure.**

**Post-operative protocol**

Broad arm sling was given for seven days. Pain dependent mobilization exercises were started immediately and were increased as was tolerable. Activities like weight lifting, pushing, etc. were restricted for two weeks, after which they were permitted as tolerable. Participation in sports was restricted for 10 weeks.

**RESULTS**

It was observed that nearly 86% of the cases were males, with approximately 70% of the patients belonging to the younger age group of 20-35 years as in Figure 2. 17 (38.6%) out of 44 cases were result of fall on shoulder at home or at work place, whereas 15 (34.1%) cases were result of sports related injuries and 12 (27.3%) cases were result of road traffic accidents as shown in Figure 3. On classification according to occupation, nearly 56% of the patients were office-goers. Apart from them, there were 6 teachers, 6 students, 5 manual labourers and 2 housewives in this study as in Figure 4. As per OTA classification, majority of cases were 15B1.2 type followed by 15B1.1 type as in Figure 5. Mean injury to surgery time was 4.1 days (range= 2-8 days). Mean admission to surgery time was 1.7 days (range= 1-3
days). Mean surgery time was 26.3 minutes (range=18-47 minutes). Mean follow-up period was 30.6 months (range=24-40 months).

Union (incidence= 97.8%) was achieved in all except one case which went into delayed union (incidence= 2.2%) as shown in Figure 6. Average union time was 12.8 weeks (range=10-23 weeks) as in Figure 6-9.

Figure 2: Gender distribution of cases.

Figure 3: Mode of injury distribution of cases.

Figure 4: Occupational distribution of cases.

Figure 5: OTA classification of fractures.

Figure 6: Union time (weeks).

Figure 7: X-ray images of Case 1: A) Pre-op; B) 2 weeks post-op; C) 3 months post-op; D) 6 months post-operatively.

Figure 8: X-ray images of Case 2: A) Pre-op; B) 2 weeks post-op; C) 3 months post-op; D) 6 months post-operatively.
Figure 9: X-ray images of Case 3: A) Pre-op; B) 2 weeks post-op; C) 3 months post-op; D) 6 months post-operatively.

7 cases were complicated by telescoping (incidence=15.9%), out of which 3 belonged to OTA category 15B1.1 (incidence=25%), 2 belonged to category 15B2.1 (incidence=50%) and 1 each from category 15B2.2 (incidence=33.33%) and 15B2.3 (incidence=33.33%) as presented in Table 2 and Figure 10.

Table 2: Complications.

<table>
<thead>
<tr>
<th>S. no.</th>
<th>Complication</th>
<th>Incidence</th>
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<tbody>
<tr>
<td>1</td>
<td>Delayed union</td>
<td>2.2%</td>
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<tr>
<td>2</td>
<td>Telescoping</td>
<td>15.9%</td>
</tr>
<tr>
<td>3</td>
<td>Medical nail protrusion</td>
<td>13.6%</td>
</tr>
<tr>
<td>4</td>
<td>Clavicle shortening less than 1 cm</td>
<td>20.5%</td>
</tr>
<tr>
<td>5</td>
<td>Clavicle shortening more than 1 cm</td>
<td>4.5%</td>
</tr>
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Figure 10: Fracture-wise complications.

6 out of 7 cases with telescoping also had medial nail protrusion (incidence=13.6%) except one case from category 15B1.1 which had telescoping only as in Figure 11 and 12. On evaluation for clavicle shortening, 33 cases had no shortening (incidence=75%), 9 had shortening of less than 1 cm (incidence=20.5%) and only 2 cases (incidence=4.5%), one each from category 15B2.1 and 15B2.2 had shortening of more than 1 cm as given in Figure 13. All other cases had a completely uneventful recovery. Implant removal was done after a mean of 8.7 months (range=5-14 months). No other complication was reported in any of the case.
Constant shoulder scores showed constant improvement with a mean of 15 and 85.6 at 2 weeks and 12 months post-operatively, respectively (p value <0.001, highly significant) as given in Table 3 and Figure 14. However, constant shoulder score did not show any significant improvement (p value= 0.789) at 2 year follow with mean being 85.6 and 85.7 at 12 and 24 months, respectively as in Table 3.

### Table 3: Constant shoulder scores analysed by using (T-test).

<table>
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<tr>
<th></th>
<th>CS score at 2 weeks and 1 month</th>
<th>CS score at 1 and 3 months</th>
<th>CS score at 3 and 6 months</th>
<th>CS score at 6 and 12 months</th>
<th>CS score at 12 and 24 months</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>T value</strong></td>
<td>33.04</td>
<td>46.84</td>
<td>18.07</td>
<td>22.43</td>
<td>0.27</td>
</tr>
<tr>
<td><strong>P value</strong></td>
<td>&lt;0.0001</td>
<td>&lt;0.0001</td>
<td>&lt;0.0001</td>
<td>&lt;0.0001</td>
<td>0.789</td>
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### DISCUSSION

Clavicle is the main anchor between axial skeleton and upper limb, without which weight transmission would not be possible between superior extremity and vertebral column. Most of the individuals with clavicle fracture are young active males with active participation in sports. Recently, increased incidence of clavicle fracture has been observed which is mainly attributed to increase in road traffic accidents and increase in sports participation by individuals. It was believed that following conservative treatment, non-union is rare. But recent studies have reported incidence of non-union in conservatively treated cases to be as high as 20% while in operatively treated fractures only around 2.2%. Mal-union, another common complication of conservatively treated cases, was wrongly believed to be of cosmetic importance only. Now it has been proven beyond any doubt that shoulders with mal-united clavicles have poor strength and more incidence of peri-shoulder pain and deformity. Citing these evidences, now more and more trauma centres are advocating operative management for displaced mid-shaft clavicle fractures. For operative management both plating and intramedullary pinning techniques are available. Plating osteo-synthesis has been shown to provide better stability but requires opening up of fracture site. Intramedullary pinning with 3.2 mm Steinmann pin, K-wires or locked pins like Rockwood pin is also being advocated by certain groups. With such pins fractures can be reduced and fixed in completely closed manner and results are also good, but there is significant problem of implant breakage, non-union and intra-thoracic injury due to medial migration of nail. Recently, ESIN has been extensively used in the management of paediatric long bone fractures. They work on the principle of elasticity and are easier to insert and remove. Based upon these properties they have also been advocated for use in mid-shaft clavicle fractures. One major difference between ESIN and other intramedullary nailing systems is that Steinmann pin or Rockwood pin or other intra-medullary devices are inserted from lateral end whereas ESIN are inserted from medial end of clavicle. Although ESIN seems to be a better alternative for intra-medullary fixation of mid-shaft clavicle fractures, but still there is no consensus about it. Various reports showing high incidence of medial nail prominence have been published, but we found the incidence of implant prominence to be insignificant (incidence=13.6%). Also because of medial insertion point the chance of intra-thoracic injury due to medial migration of implant is minimal. In this series timely union was achieved in all the cases except one which showed delayed healing with union at 23 weeks. ESIN technique offered the advantages of minimal invasiveness with a small incision (1.5 cm) and decreased surgery time with minimal blood loss. From patient point of view, ESIN offered the advantages of faster recovery and decreased rehabilitation time with good functional outcome and cosmetic appearance. We found closed reduction and internal fixation of displaced mid-shaft clavicle fractures with ESIN through a medial insertion point as an effective technique with excellent outcomes and minimal complications.

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**Ethical approval:** The study was approved by the from Institutional review board, (IRB no.- 667/14/53E)

### REFERENCES
