Screw Intramedullary Elastic Nail Fixation In Midshaft Clavicle Fractures: A Clinical Outcome in 36 Patients

Abstract

Background: Surgical stabilization of displaced midshaft clavicle fracture can be achieved by an intramedullary nail or plate. When intramedullary nail is used, one of the dreaded complications is the migration of nail. We have used a screw intramedullary device with screw mechanism at one end which can get hold in the medial cancellous bone, thus preventing chances of nail migration. The aim of our study was to evaluate the clinical outcome following elastic stable screw intramedullary nailing for the fixation of midshaft clavicle fractures. Materials and Methods: 36 patients of midshaft clavicular fractures, who met inclusion criteria, were included in this retrospective study. There were 28 males and 8 females. The mean age was 36.6 years. Twenty one patients were managed by close reduction and fixation with screw intramedullary nail. Fifteen patients required mini-open reduction. Followup examination was done at 1 month, 3 months, and 6 months using patient’s subjective evaluation, functional outcome, radiographic assessment, and other complications. Results: Union was achieved at average of 11.6 weeks in 31 cases and five patients went to delayed union. The average followup was 6 months. The average constant score was 90%. Three patients had medial nail protrusion which required early removal after union. Conclusion: Screw intramedullary nail is a safe, minimally invasive surgical technique with a lower complication rate, faster return to daily activities, excellent cosmetic and good functional results, and can be used as an equally effective alternative to plate fixation in displaced midshaft clavicle fractures.

Keywords: Clavicle fracture, elastic stable intramedullary nailing, midshaft fractures, plating

MeSH terms: Fracture fixation intramedullary; clavicle; fracture fixation, internal

Introduction

The fractures of clavicle account for 5%–10% of all fractures.1 The most common site is middle third of clavicle and accounts for approximately 81% all clavicle fractures.2 Most midshaft clavicle fractures generally unite with any method of immobilization; therefore, nonoperative treatment was accepted modality of treatment in these fractures in the past. This mode of management had extremely low nonunion rates as shown by various studies done earlier. A nonunion rate of 0.1% reported by Neer in 1960 and 0.8% by Rowe in 1968 with conservative treatment.3-5 However, recent studies have shown suboptimal outcomes, such as functional impairment of the shoulder and a noncosmetic bump at the base of the neck possibly due to shortening of the clavicle and exuberant callus formation, and a very high nonunion rate when displaced fractures are managed conservatively.5,6 The reduced patient satisfaction due to asymmetry and cosmesis following malunion in patients with more than 20 mm shortening was noted by McKee.7 Restoration of normal length and alignment by surgical methods can prevent these drawbacks of conservative treatment. Hence, more recently, there has been a trend toward surgical fixation.5,9

Surgery has been indicated for completely displaced fractures, potential skin perforation, shortening of the clavicle by more than 20 mm, neurovascular injury, and floating injury. Open reduction and plate fixation has become the standard mode of managing these fractures operatively.10 However, open reduction and internal fixation (ORIF) with plating has also got its own disadvantages such as surgical site infection, hypertrophic scar, hardware prominence, and a repeat surgery for implant removal at times. The use of an intramedullary device carries advantages of a smaller incision, less soft tissue dissection, and load sharing fixation with

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relative stability that encourages copious callus formation. Different techniques and implants of intramedullary fixation devices have been reported and include the hoagie nail, Knowles pin, Rockwood pins, and titanium elastic nails. Intramedullary devices behave as an internal splints that maintain alignment without rigid fixation but are commonly complicated by nail migration and breakage of nail.

This study investigates the results of displaced midshaft clavicle fractures treated by screw intramedullary nailing in terms of functional outcome, rate of nonunion, malunion, and overall reduction in the incidence of nail migration.

Materials and Methods

36 patients of displaced midshaft clavicle fractures who met the inclusion criteria and operated with screw intramedullary nail between December 2012 and December 2015 were included in the study. The mean age of study population was 36.6 years (range 22-68 years). Table 1.

Completely displaced fractures (presented 1–10 days from injury) of the midshaft clavicle (type 2: middle 3/5th clavicle fractures), 2 cm or more shortening, with no cortical contact between the medial and lateral clavicle fragments and high-energy fracture patterns that have minimal comminution with a vertically displaced fragment were included in the study (Robinson classification b1. simple, wedge comminution).

Patients with severe brain injury, intubated patients, open fractures, ipsilateral limb fractures, fractures with delayed presentation and fractures that were grossly comminuted, and osteoporotic fractures were excluded from the study.

| Table 1: Clinical details of patients |
|-------------------------------------|
| Demographic parameters          | Numbers (n) |
| Age (mean) (in years)          | 36.6        |
| Sex                                 |
| Male                               | 28          |
| Female                             | 8           |
| Mode of injury                     |
| Road traffic accident              | 21          |
| Fall                               | 12          |
| Sports injury                      | 3           |
| Side affected                      |
| Dominant                            | 19          |
| Nondominant                         | 17          |
| Presence of associated injuries    |
| Present                             | 7           |
| Robinsons classification            |
| Type 2B: Middle 3/5th clavicle fractures |
| Displaced fractures                |
| b1. Simple or wedge comminution    | 18          |
| b2. Multifragmentary               | 14          |
| b2. Segmental                      | 2           |

Implant specification

Screw elastic intramedullary nail is available in diameter of 2, 2.5, and 3 mm. Nail has a beveled tip at one end and a threaded head positioned at other. This design allows the self-cutting thread to be advanced and screwed in with a 3.5 mm screwdriver. The distal beveled end of the nail aids in fracture reduction and helps in engaging in the subchondral area of the bone, thereby imparting stability [Figure 1a and b].

The nails (titanium nail or steel) are manufactured by K-AIMS ORTHO Implants, Mumbai, Maharashtra, India. This study was conducted with approval from ethical committee of our institute. All patients are explained regarding this new method of fixation of clavicle fractures. Written informed consent was obtained from all patients and explained about the pros and cons of new implant and procedure.

Operative procedure

Operative procedure was carried out under interscalene block or general anesthesia. Affected shoulder was elevated by a bolster so that clavicle becomes more prominent. The procedure was performed under fluoroscopic guidance. A 1 cm skin incision was made over the medial end of clavicle, and a hole was drilled in the anterior cortex with a 3.2 mm drill bit. The insertion point was made approximately 1 cm lateral to the sternoclavicular joint. The entry portal was then enlarged with a curved awl. The reaming of canal was done with sequential reamer and then an elastic nail of appropriate diameter and length was inserted in the medullary canal of clavicle with a universal chuck or T-handle. With oscillating movements, the nail was advanced until it reaches the fracture site. With the help of percutaneously placed towel clips, fracture fragments were approximated. If closed reduction was unsuccessful, an additional skin incision was made at fracture site for open reduction of the fragments.
Fifteen patients required mini-open reduction. The reduction was checked under C-arm and then the nail was advanced through the fracture site till it reached distal end of the clavicle. In general, nail can be negotiated 1 cm short of the acromioclavicular joint. After adequate engagement of the distal fragment, the medial end of screw nail was screwed in the metaphyseal region of the medial end of clavicle and skin closed over it [Figures 2 and 3].

Postoperatively, arm pouch sling was given for 3 weeks. Gentle pendulum exercises of the shoulder were allowed as per pain tolerance immediately after surgery. We tend to limit extreme overhead activities for 3–6 weeks. At 3–6 weeks, active assisted range of motion in all planes was allowed. We defined radiological union as visible bridging callus or invisibility of fracture line and clinical union as no bony tenderness at fracture site [Figure 4a-d]. When fracture union was evident, muscle-strengthening exercises were also allowed. At 8–12 weeks, isometric and isotonic exercises were prescribed for shoulder girdle muscles with return to full activities (including sports) at 3 months. The evaluation of shortening was done by taking X-ray of both the clavicle from the same distance.

Regular followup was done every fortnight for initial 6 weeks, then 3 months, and 6 months using patient’s subjective evaluation, functional outcome, and radiographic assessment. The functional evaluation was done by the Constant–Murley score.14

Results

Twenty one of the 36 patients had closed nailing while fifteen patients required mini-open reduction of their fracture. The average size of the titanium flexible nail used was 2.5 mm (range 2–3 mm). Thirty one patients achieved clinical and radiological union at a mean of 11.3 weeks, and five patients required more than 16 weeks; therefore, they were termed as cases of delayed union but eventually all fractures united (range 9–20 weeks) [Figure 4a-d]. Eight patients had complications such as prominence of nail at sternoclavicular joint in three cases and delayed union was observed in five cases, in which open reduction

![Figure 2: Peroperative photographs showing operative procedure (a) position of the patient (b) Marking entry point (c) Negotiation of bone awl (d) Insertion of nail (e) Reduction of fracture (f) Final position of the nail](image1)

![Figure 3: X-ray of left clavicle anteroposterior view showing (a) Fracture clavicle middle one third (b) Postoperative X-ray showing screw intramedullary nail in clavicle](image2)
was required. The stiffness of the shoulder was noticed in three cases, responded very well to physiotherapy. Average shortening of the clavicle in our series ranged from 3 mm to 5 mm in ten cases, but there was no functional impairment [Figure 5a-d].

The mean Constant Murley score was 71.80 (standard deviation [SD] = 4.87), 83.63 (SD = 4.82), and 94.00 (SD = 2.99) at the end of 6 weeks, 3 months, and 6 months, respectively. In our series, complications were generally related to surgical technique and the implant. Overall, the complication rate was relatively lower.

**Discussion**

The multiple recent trials after nonoperative management of fracture clavicle have revealed higher incidence of residual pain, nonunion, malunion, shoulder weakness, decreased shoulder endurance, inferior patient and surgeon-oriented outcome scores, and lower overall satisfaction.5–10 Consideration should be given to the prevention of shortening of 1.5–2 cm by ORIF, especially in the young, active age group to improve the functional outcome.11,12 Plate fixation has been the standard operative fixation method. A recent meta analysis revealed higher nonunion rates for displaced fractures treated nonoperatively (15.1%) than operatively (2.2%) with modern internal fixation techniques of plating. A multicenter trial reported better functional outcomes, lower malunion and nonunion rates, and a shorter overall time to union after plate fixation.10,15

However, a large and strong plate is generally required to overcome the bending and torsional forces on clavicle. Plates can, therefore, be prominent and superficial. Wijdicks et al. reported higher rates of refracture (7.0%), major revision surgery (11.6%), and implant failure (14.0%) after plate fixation.16 Recent literature quotes intramedullary stabilization is an established alternative fixation method. Intramedullary implants are optimal from biomechanical point of view as the tension side of clavicle changes with respect to rotation of arm and direction of loading.17–19

The benefits of intramedullary nailing include smaller incision, minimal periosteal stripping, and load sharing device properties. Its relative stability allows copious callus formation during the healing process. However, the frequent complications include skin irritation from the prominent medial and lateral end of the nail, and this frequently leads to either trimming of the nail or its premature removal. Analysis of 45 patients by Mueller et al.20 with a mean followup of 24 months, iatrogenic perforation of the lateral cortex occurred twice, and medial prominence in eight patients. Superficial skin infection developed in one. Nail breakage after fracture healing was observed twice. Another study of the 58 patients reported 15 (25.8%) complications occurred in 14 patients (24.1%) after intramedullary nailing.21 Frigg
et al.\textsuperscript{31} have shown in their study seven medial perforations, seven lateral penetrations, one titanium elastic nail breakage, one titanium elastic nail dislocation, and seven hardware irritations. Author demonstrated using end cap can prevent medial migration and pain significantly. Same principle is used here instead of end cap screw intramedullary nail is used with medial entry point to prevent migration of nail. A randomized control trial between intramedullary nailing and nonoperative treatment reported by Smekel et al.,\textsuperscript{19} better disabilities of arm, shoulder, and hand and constant scores and 100\% union rate with intramedullary nailing. No significant difference was found between functional outcome and nonunion rate following plate fixation and intramedullary fixation (titanium elastic nails) of displaced midshaft clavicle fractures.\textsuperscript{17,22}

All our patients underwent surgery within first 10 days. Majority of the patients in our series returned to their preinjury activity levels by around 16 weeks without any major complication. Although clavicle is S-shaped bone, tip of the screw intramedullary nail is elastic, and tip can be made curved which helps the surgeon to pass the elastic nail into distal fragment. In our series, all patients united within 11–16 weeks. The nail was removed in three cases because of symptomatic medial prominence. The iatrogenic perforation of lateral cortex and infection is not observed in our series. Average shortening of clavicle in our series ranged from 3 mm to 5 mm in ten cases, but there was no functional impairment; therefore, it may be concluded that screw intramedullary nail prevents shortening and medial migration of the nail because screw of nail sits well in the metaphysis.

In our series, eight patients suffered some complication out of 36. Symptomatic pain at nail insertion site was more common in initial phases of followup. However, there was no incidence of surgical site infection, nonunion, lateral migration of nail, nail breakage, complex regional pain syndrome, or neurovascular problems in any of our patients. In the present study, there were five patients with symptomatic delayed union, but pain disappeared after union of fractures. Three cases of shoulder stiffness were managed with physiotherapy, and all three patients regained full movements. Our complication rate is lower as compared to the series published in literature.\textsuperscript{12,19-21}

The mean constant shoulder score in our study was 71.80, 83.63, and 94.00 at 6 weeks, 3 months, and 6 months, respectively. At the end of 6 months, 93.33\% patients achieved an excellent result (constant score $>90$) treated by the screw intramedullary nailing. The present evidence from this meta-analysis suggested that intramedullary fixation was better method for the treatment than plate for midshaft clavicle fractures.\textsuperscript{17,23} Our results in thirty six cases with regard to various radiological, functional outcomes and complications compare well with the existing literature and the published studies on the subject without nail

Figure 5: (a) Initial radiograph of clavicle anteroposterior view showing displaced comminuted fracture clavicle. (b) Fracture fixation with screw intramedullary nail. (c) Followup X-ray after 1 year of surgical treatment showing union with remodeling of clavicle. (d) Clinical photograph showing function of the shoulder.
migration. The major strength of the study was the 100% followup though it was only averaged minimum 6 months. We have noticed that time to union was shorter with almost 100% union rates. The constant shoulder scores were also significantly higher at all followups. The problem of nail migration is prevented by two reasons, one being screw intramedullary nail fits snugly in the medial metaphyseal area of clavicle after screwing preventing its back out and medial end being larger than lateral end prevents lateral migration. It should also be noted that the removal of nail as additional surgical procedure requires only small incision and short duration. Smekal et al. do not recommend nailing in the comminuted fracture because this procedure can lead to telescoping of the nail with shortening of the clavicle, but we believe that this fixation system can maintain length of the clavicle in minimally comminuted fractures, and it is minimally invasive procedure though ORIF with plating is particularly beneficial in osteoporotic and severely comminuted fractures. However, this method is technically demanding and beginner may often require to open the fracture. It is not a comparative study of different methods of treatment; therefore, this is the shortcoming of our study.

**Conclusion**

Percutaneous elastic screw intramedullary nailing of the clavicle is a safe, reliable method for fixation of displaced midshaft clavicle fractures. It is less invasive and allows rapid healing by callus formation. Complication rates are low, with better functional and cosmetic results.

**Declaration of patient consent**

The authors certify that they have obtained all appropriate patient consent forms. In the form the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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**Conflicts of interest**

There are no conflicts of interest.

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