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## Functional outcome after surgical fixation of middle third clavicular fractures by titanium elastic nailing system (TENS): A prospective study

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### Abstract

This study is based on the technique of minimally-invasive osteosynthesis using Titanium elastic nails (TENS) in OTA Type a midclavicular fractures with displacement or shortening more than 2 cm. The aim of the study was the evaluation of the operative technique and post-operative outcome after fixation of displaced midclavicular fractures with TENS. The study was carried out on 21 cases at, Bangalore medical College and research Institute for a period of 1 year. The mean age of all patients was  $29 \pm 11.25$  years. All cases were treated with open reduction. Clinical union was seen at  $7.8 \pm 3.2$  weeks (range 6-12 weeks) in all cases and the mean time for radiological union  $19.8 \pm 16.47$  weeks (range 12-24 weeks). The functional outcome was measured using DASH and Constant Shoulder score. Results of our study showed that the Titanium Elastic Nail is an excellent implant for achieving reduction and union middle one third clavicular fractures with minimal surgical exposure during fixation and implant removal, minimal complications, and early rehabilitation.

**Keywords:** Hip fracture; Bone turnover markers; CTX; PINP; Vitamin D

### Introduction

In the modern era of industrialization, clavicle fractures account for 3-5% of all fractures, out of which 70-80% fractures are of midshaft <sup>[1, 2]</sup>. In the young adults, road traffic accidents are the major cause of injury whereas in children and elderly sports injury and domestic falls are consistently related <sup>[1, 2]</sup>. Stanley, *et al.* mentioned that 94% of the clavicle fractures are caused by fall on shoulder and not by fall on outstretched hand <sup>[3]</sup>.

Clavicle fractures were treated mostly by conservative methods in the bygone days, but the increased number of documented clavicle fractures and patient's dissatisfaction with the complications following non-operative intervention have changed many ideas of surgeon regarding the treatment protocol. Acute complications of clavicle fractures i.e neurovascular injury, skin perforation and delayed complications i.e visible deformity, and thoracic outlet syndrome; non-union and chronic shoulder pain/stiffness particularly when the fracture/displacement was more than 2 cm have been mentioned in the literature in the previous year <sup>[4]</sup>.

Till date, clavicle fractures have been surgically treated by open reduction and plate fixation, intramedullary pinning with K-wire, rush nails, knowel's pin, Steinman pin, Haige pin, TENS <sup>[5]</sup>.

Intramedullary fixation of clavicle fractures was first described by Peroni, *et al.* in early 50s but the use of Titanium nail as intramedullary device came late <sup>[6]</sup>. Jubel, *et al.* in 2003 first described and published several papers on fixation of midshaft clavicle fractures with TEN <sup>[7-9]</sup>. Rehm, *et al.* and Mueller, *et al.* also pioneered towards this new surgical dimension <sup>[10]</sup>

### About the Implant

TENS, made of Titanium alloy, by virtue of its intrinsic chemical and mechanical properties has been proved as an excellent implant for diaphyseal fractures of long bones in paediatric patients <sup>[11]</sup>. When used in clavicle, TEN is strong and flexible enough to hold the fragments in place by 3 points fixation principle by virtue of the S-shape of the clavicle.

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Eventually it controls the rotation, angulation and shortening of fragments [12].

**Materials and Methods**

This prospective study was conducted in 21 patients aged between 18 to 60 years over a period of 1 year on selective patients with AO type A midclavicular fractures (simple fractures with two fragments) with displacement/shortening of more than 2 cm. Compound fractures, comminuted fractures (OTA type B and C) were excluded from the study [13, 14].

Non-union was defined as lack of radiological signs of union between 6-9 months. Delayed union was defined as lack of radiological signs of union between 3-6 months after surgical intervention [15-17].

Equipments used in the study included: TENS, Flexible hand reamers, Radiolucent table, Image intensifier and basic Orthopaedic instruments.

**Pre-operative planning**

The required diameter of the nail to be used can be calculated by using the formula ( $= 0.4 \times$  the narrowest canal diameter in mm) [18-22]. Moreover, the degree of displacements, shortening and comminution must be quantified before operation. Two radiological views are sufficient for this purpose [18-22].

AP view (with 20 degree cephalad) 45 degree craniocaudal view

**Surgical Technique**

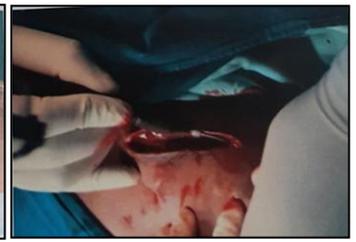
The technique was based on original operative principle and surgical technique described by Ligier, *et al.* in 1988.

After general anesthesia, the patients were positioned in the beachchair position with a folded towel under the affected shoulder. The affected upper extremity was draped free to allow manipulation in a sterile manner. The image and its monitor were placed in front of the surgeon on the opposite side of the operating table so that perpendicular shots and those with 20-45° of cephalic tilt could be taken to view the I-and-S-shaped forms of the clavicle, respectively. A small incision 3-4 cm long is made over the fracture site to enable direct manipulation of the fragments. A minimal amount of soft tissue and periosteum is then released. The medial fragment is grasped with small bone holding forceps and lifted out of the wound. A drill bit with a diameter that is similar to that of the proposed nail diameter is inserted inside the medullary canal of the medial fragment, pointing slightly anteriorly to penetrate the anterior cortex. When the tip of the drill bit is felt beneath the skin, another tiny skin incision is made over it. The nail, which is fixed to a universal chuck with a T-handle, is passed retrograde across the fracture into the predrilled medullary canal under fluoroscopic control and allowed to exit from the medial incisions. The protruded end is grasped again by a universal chuck and the nail is pulled medially until clear of the fracture, which is then reduced. The nail is next driven across the fracture site into the medullary cannal of the lateral fragment until resistance is felt by the surgeon. To ensure the correct placement and depth of the nail into the lateral fragment, fluoroscopic control is used. The protruding end of the nail is cut off and bent as close to the bone as possible. Using the impactor, the bent end of the nail is impacted and the skin is closed over the bent end of the nail [18-22].

**Operative techniques**



Painting



Skin incision



Fracture exposure and reduction.



Nail entry through medial end of clavicle.

**Case 1**



Pre-op



Immediate post-op.



3 Weeks.



12 weeks.

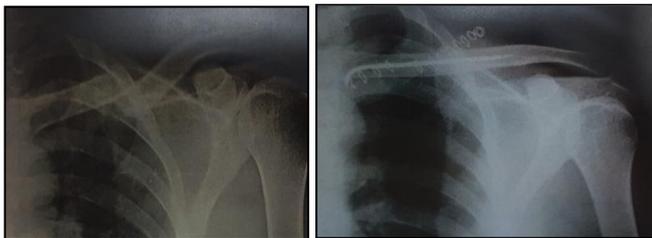


24 weeks post op. (implant removal)

**Functional outcome**



**Case 2**



Pre op

Immediate post op



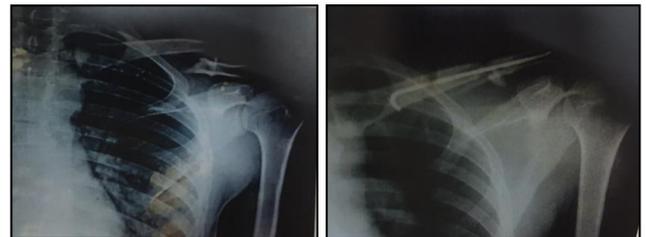
24 weeks

60 weeks post op (implant removal)

**Functional outcome**



**Case 3**



Pre op

Immediate post op



3 weeks

12 weeks



24 weeks

60 weeks post op. (implant removal)

### Functional outcome



### Post-operative follow-up

Shoulder exercises are started from the second post-operative day and patient is advised to use arm-sling pouch for 3-4 weeks. Patient is advised to avoid shoulder abduction and forward flexion beyond 90 degrees (which tends to rotate the distal fragment) and lifting heavy weight (which droops the shoulder) until 4 weeks to prevent distraction of the fracture fragments and nail migration<sup>[18-22]</sup>. Patients are then followed up after 3 weeks, 6 weeks, 16 weeks, and 24 weeks. During follow up patient's functional outcome is evaluated using DASH score and Constant shoulder score<sup>[23-25]</sup>. The signs of union/consolidation are assessed clinically by seeing tenderness at the fracture site and radiologically by looking for the signs of callus formation<sup>[16, 17]</sup>. In the absence of complications, the nail is removed after radiological consolidation.

### Observations and Results

Out of the 21 patients 17 were males and 4 were females (M:F = 4:1), ranging from 18-60 years of age. The mean age of all patients was  $29 \pm 11.25$  years. The age group 19-29 years and 30-39 years comprised the highest number of patients (75%). Total 21 patients were operated open reduction with minimal tissue exposure was done in 21 (100%) cases. One patient left the study group after the second follow up (12 weeks) and remaining (20) patients were followed up for a mean period of  $5.98 \pm 4.12$  (range 3-10 months).

Road Traffic Accidents accounted for majority of fractures (80.95%) and fall on shoulder (0.95%) with fall on outstretched hand (0.95%) was the most common mechanism of injury. The right clavicle was involved in 12 (57.14%) patients, the left clavicle in 9 (42.85%) patients.

The mean duration of operation was  $28.76 \pm 5.80$  (range 20-40 min). In 12(57.14%) patients Titanium Elastic nail of diameter of 2 mm was used and in 7 (33.33%) patients nail with 2.5 mm and in 2(.095%) patients 3mm diameter was used. The mean duration of hospital stay was  $1.66 \pm 0.63$  (range 1-3 days). Clinical union was seen  $7.8 \pm 3.2$  weeks (range 6-12 weeks) in all cases and the mean time for radiological union  $19.8 \pm 16.47$  weeks (range 12-24 weeks).

There was no intra-operative or immediate postoperative complication. Late complications encountered were medial prominence of the nail (3 patients), superficial skin infection (1 patient), delayed union (2 patient). Based on the assessment parameters (Disability of Arm Shoulder and Hand) Score, the mean DASH score was  $26.03 \pm 3.86$  (range 20-30) at the end of 6 weeks,  $17.56 \pm 3.91$  (range 14-25) at the end of 16 weeks and  $6.73 \pm 1.43$  (range 5-10) at the end of 24 weeks respectively. Based on the Constant Shoulder Score, the mean score was  $54.86 \pm 3.5$  (range 50-60),  $84.36 \pm 3.22$  (range 80-90) and  $97.40 \pm 1.38$  (range 95-100) at the end of 6 weeks, 16 weeks, and 24 weeks respectively.

The final results in this study based on Constant Shoulder Score were Excellent in 12 (57.14%) patients, Good in (33.33%) patients and Fair in 2 (.09%) patients.

### Discussion

Platfixation has been considered as gold standard for clavicle fractures but intramedullary nailing is always superior to plating in terms of minimal soft tissue exposure, minimal blood loss, minimal periosteal stripping without disturbance the fracture hematoma. Moreover, removal of the nail can be done as an OPD procedure and so no second operation is required. TEN provides all these advantages over plating with additional advantages by virtue of its intrinsic chemical properties. Also, the suitable handling characteristics of TEN because of its modulus of elasticity being nearer to bone help it to work on the basis of 3 point intramedullary fixation principle. Moreover, the gliding mechanism of the bent flat tip of the nail provides easy passage of the nail through the medullary cavity and across the fracture site, and avoids nail migration laterally. Elasticity of the construct allows ideal circumstances for micromotion and copious callus formation thereby making the healing process more biological<sup>[26-28]</sup>.

Our study is comparable with the studies of Mueller, *et al.* (study on 32 patients)<sup>[18]</sup>, Chen, *et al.* (study on 41 patients)<sup>[29]</sup>, Kadakia, *et al.* (study on 38 patients)<sup>[30]</sup> and Mishra, *et al.* (study on 73 patients)<sup>[21]</sup>. Open reduction was done in all the cases. The mean time of operation after the initial episode of trauma was less than 7 days (14 patients) and more than 7 days in (7 patients) in the open reduction group. The beauty of the procedure lies in closed reduction of the fracture and therefore it may be advisable to operate as soon as possible, preferably in the first week.

Complications were noted in 6 (28%) cases. The major complication were medial nail prominence, superficial skin infection and delayed union. So, gentle insertion of the nail is recommended using oscillatory movement and the tip of the nail should be checked using 2 orthogonal fluoroscopic views<sup>[22]</sup>. Hammering should not be done. The most common complication was medial prominence of the nail observed in 3 cases leading to discomfort due to skin irritation. Extrusion of

the nail at fracture site was observed in 1 case at the time of his 6th week follow up, however the fracture united within the expected time with no other complication. This may be attributed to the use of shorter nail than required.

In the study of Mueller, *et al.*, 28.13% fractures healed with 10 mm shortening, 9.38% fractures healed with 30 mm shortening. This shortening was observed only in OTA type B fractures (wedge fractures with a third fragment) which they included in their studies. No shortening was observed in our study.

### Conclusion

The study shows that fixation of displaced midclavicular fractures with Titanium Elastic Nailing System (TENS) is a technically demanding, minimally invasive and easy to do procedure which gives early pain relief, early functional recovery and 100% rate of fracture union. Cosmetic problems due to post-operative scar formation in minimum with patient's satisfaction. Moreover, the post-operative complications are few and can be treated easily. This study when compared with other studies has given sufficient evidence of the excellence of this procedure provided it is performed in midclavicular fractures, preferably transverse or short oblique fracture and preferably within 1 week of injury in a patient with good bone mass.

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