



## Outcome of Operative Fixation of Midclavicular Fractures by Titanium Elastic Nailing System (TENS) - A Prospective Study in 21 Patients

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### ABSTRACT

This study is based on the technique of minimally-invasive osteosynthesis using Titanium elastic nails (TENS) in OTA Type Amidclavicular 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 Silchar Medical College & Hospital for a period of 2 years. The mean age of all patients was  $29.20 \pm 11.05$  years. Total 15 cases were treated with open reduction and 6 cases were treated with closed reduction and internal fixation with TENS. Clinical union was seen at  $7.3 \pm 3.06$  weeks (range 6-12 weeks) in all cases and the mean time for radiological union  $19.6 \pm 16.67$  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 of OTA Type Amidclavicular fractures with minimal surgical exposure during fixation and implant removal, minimal complications, and early rehabilitation.

**Keywords:** Clavicle, Osteosynthesis, TENS

### 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 [1,2]. 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 [1,2]. Stanley, et al. mentioned that 94% of the clavicle fractures are caused by fall on shoulder and not by fall on outstretched hand [3].

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 viz. neurovascular injury, skin perforation and delayed complications viz. malunion leading to shortening of shoulder, 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 [4].

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, TEN and external fixation [5].

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 [6]. Jubel, et al. in 2003 first described and published several papers on fixation of midshaft clavicle fractures with TEN [7-9]. Rehm, et al. and Mueller, et al. also pioneered towards this new surgical dimension [10].

#### About the implant

TEN, 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 [11]. 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. 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 OTA 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 (Pitkar®, Adler®, Biomed®), Radiolucent table, Image intensifier and basic Orthopaedic instruments [18-22].

### 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 (Figure 1) [18-22].

- 1) AP view with shoulder in hanging position
- 2) 45 degree craniocaudal view

### Surgical technique

The technique was based on original operative principle and surgical technique described by Ligier, et al. in 1988. Patient is positioned supine on radiolucent operating table. Beach chair position is not of much use in this procedure. A bolster is placed between the scapulae to make the clavicle more prominent and to make the reduction easier. The image intensifier is placed in such a way that 2 orthogonal views can be taken without moving the base of the machine. Draping is done with the arm of the affected side free to help manipulation of the extremity at the time of reduction. The nail is introduced from medial to lateral direction. This prevents medial migration of the nail while moving away from the central neurovascular structures and therefore safer. The entry point is made 1 cm lateral to the sternoclavicular joint [18-22]. After exposing the anterior cortex, the entry point is made using 3.2 mm drill bit followed by an awl making an angle of 30-45 degrees with the horizon. Now the nail is inserted with the help of a chuck using oscillatory movement. Hammering should not be done. When the nail tip reaches the fracture site, this is the time when the fracture needs to be reduced accurately. Reduction is achieved by manipulation of the arm and by the use of Weber's clamp applied percutaneously. The bolster kept between the scapulae also helps in the reduction manoeuvre. The nail is progressed until it reaches the distal end of medullary cavity. The whole procedure is carried out under C-arm guidance. The tip of the nail is cut medially leaving 5 mm of the nail outside the cortical bone which later makes removal of the nail easier, though post-operative skin irritation/perforation by the medial nail tip is a usual complication. To avoid this complication, the nail can be cut off at the skin before fully seating it, then driving it another 5-10 mm with a punch. No bending is required before trimming the nail. The wound is closed in layers. If closed reduction fails, the fracture site is opened with a 2-3 mm skin incision for reduction and nail is introduced accordingly (Figures 2 - 5) [18-22].



Figure 1 Two orthogonal radiographic views



Figure 2 IITV Image of closed reduction



Figure 3 Closed reduction of fracture



Figure 4 Open reduction of fracture

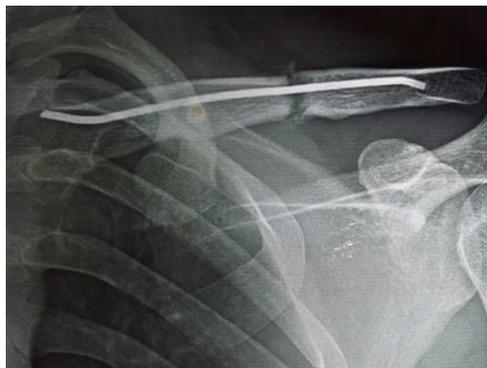


Figure 5 Immediate postoperative x-ray



Figure 6 Radiograph after 5 months of consolidation



Figure 7 After removal of TENS



Figure 8 Minimal post-operative scar

### 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 [18-22]. Patients are then followed up after 3 weeks, 6 weeks, 4 months, and 6 months. During follow up patient's functional outcome is evaluated using DASH score and Constant shoulder score [23-25]. 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 (Figures 6 and 7) [16,17]. 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  $29.20 \pm 11.05$  years. The age group 21-30 years and 31-40 years comprised the highest number of patients (33% each). Associated injuries were seen in 5 (23.80%) patients. Total 21 patients were operated out of which closed reduction was done in 6 (28.57%) patients and open reduction with minimal tissue exposure was done in 15 (71.42%) cases. One patient left the study group after the second follow up (6 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 (52%) and fall on shoulder (90%) was the most common mechanism of injury. The right clavicle was involved in 11 (52%) patients, the left clavicle in 9 (43%) patients and bilateral clavicle was involved in 1 (5%) patient.

The mean time to operation was  $6.09 \pm 3.74$  (2-15 days) after the initial episode of trauma and the mean duration of operation was  $29.76 \pm 5.70$  (range 20-40 min). In 16 (76%) patients Titanium Elastic nail of diameter of 2 mm was used and in 5 (14%) patients nail with 2.5 mm diameter was used. The mean duration of hospital stay was  $1.76 \pm 0.53$  (range 1-3 days).

Clinical union was seen at  $7.3 \pm 3.06$  weeks (range 6-12 weeks) in all cases and the mean time for radiological union  $19.6 \pm 16.67$  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), medial skin perforation (1 patient) iatrogenic lateral cortex perforation followed by skin perforation (1 patient), and extrusion of the nail at fracture site (1 patient).

Based on the assessment parameters (Disability of Arm Shoulder and Hand) Score, the mean DASH score was  $25.03 \pm 3.36$  (range 20-30),  $18.56 \pm 3.46$  (range 14-25) and  $6.83 \pm 1.53$  (range 5-10) at the end of 6 weeks, 16 weeks, and 24 weeks respectively.

Based on the Constant Shoulder Score, the mean score was  $55.96 \pm 3.5$  (range 50-60),  $85.36 \pm 3.52$  (range 80-90) and  $98.40 \pm 1.77$  (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 11 (55%) patients, Good in 6 (30%) patients and Fair in 3 (15%) patients.

### DISCUSSION

In the today's arena of Orthopaedics, displaced midclavicular fractures are no longer treated conservatively. Plate fixation has been considered as gold standard for clavicle fractures but intramedullary nailing is always superior to plating in terms of minimal soft tissue exposure (Figure 8), 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. Elasticity of the construct allows ideal circumstances for micromotion and copious callus formation thereby making the healing process more biological [26-28].

Our study is comparable with the studies of Mueller, et al. (study on 32 patients) [18], Chen, et al. (study on 41 patients) [29], Kadakia, et al. (study on 38 patients) [30] and Mishra, et al. (study on 73 patients) [21]. Closed reduction was possible in 6 (28.57%) patients and open reduction was done in remaining 15 (71.42%) patients. This may be related to the timing of operation. The mean time of operation after the initial episode of trauma was  $3.16 \pm 0.98$  days (range 2-4 days) in the closed reduction group and  $7.26 \pm 3.80$  days (range 3-15 days) 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 was iatrogenic lateral cortex perforation during nail insertion in the first operated case which eventually led to skin perforation and superficial infection, however, it apparently did not influence the fracture healing process. The patient was 40 years old female with porotic bone and this complication may be related her poor bone quality. Posteromedial cortex is the thinnest cortical region of clavicle.

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 [22]. 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. Out of the 3 cases, 1 had skin perforation by medial tip of the nail. The discomfort was relieved by trimming of the nail in all 3 cases. This complication can be attributed to medial migration of the nail due to its smaller diameter than required. 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 OTA type Amidclavicular fractures, preferably transverse or short oblique fracture and preferably within 1 week of injury in a patient with good bone mass.

### REFERENCES

- [1] Duan, Xin, et al. "Plating versus intramedullary pin or conservative treatment for midshaft fracture of clavicle: a meta-analysis of randomized controlled trials." *Journal of Shoulder and Elbow Surgery* 20.6 (2011): 1008-1015.
- [2] Schiffer, Gereon, et al. "Midclavicular fracture. Not just a trivial injury." *Deutsches Ärzteblatt International* 107.41 (2010): 711-717.
- [3] Stanley, D., E. A. Trowbridge, and S. H. Norris. "The mechanism of clavicular fracture. A clinical and biomechanical analysis." *Bone & Joint Journal* 70.3 (1988): 461-464.
- [4] Frigg, Arno, et al. "Intramedullary nailing of clavicular midshaft fractures with the titanium elastic nail problems and complications." *The American Journal of Sports Medicine* 37.2 (2009): 352-359.
- [5] Khalil, Ayman. "Intramedullary screw fixation for midshaft fractures of the clavicle." *International Orthopaedics* 33.5 (2009): 1421-1424.
- [6] Peroni, L. "Medullary osteosynthesis in the treatment of clavicle fractures." *Archivio di ortopedia* 63.4 (1949): 398-405.
- [7] Jubel, Axel, et al. "Elastic stable intramedullary nailing of midclavicular fractures in athletes." *British Journal of Sports Medicine* 37.6 (2003): 480-484.
- [8] Jubel, Axel, et al. "Elastic stable intramedullary nailing of midclavicular fractures with a titanium nail." *Clinical Orthopaedics and Related Research* 408 (2003): 279-285.
- [9] Jubel, Axel, et al. "Treatment of mid-clavicular fractures in adults. Early results after rucksack bandage or elastic stable intramedullary nailing." *Der Unfallchirurg* 108.9 (2005): 707-714.
- [10] Rehm, Klaus E., Jonas Andermahr, and Axel Jubel. "Intramedullary nailing of midclavicular fractures with an elastic titanium nail." *European Journal of Trauma* 31.4 (2005): 409-416.
- [11] Hunter, James B. "The principles of elastic stable intramedullary nailing in children." *Injury* 36.1 (2005): S20-S24.
- [12] Chen, Yun-feng, et al. "Clinical outcomes of midclavicular fractures treated with titanium elastic nails." *Canadian Journal of Surgery* 53.6 (2010): 379.
- [13] Fracture and dislocation compendium. Orthopaedic Trauma Association Committee for Coding and Classification. *Journal of Orthopaedic Trauma* 10 Suppl 1 (1996):v-ix, 1-154.
- [14] Marsh, J. L., et al. "Fracture and dislocation classification compendium-2007: Orthopaedic Trauma Association classification, database and outcomes committee." (2007): S1-S6.
- [15] Simpson, Shaun N., and Jesse B. Jupiter. "Clavicular nonunion and malunion: evaluation and surgical management." *Journal of the American academy of Orthopaedic Surgeons* 4.1 (1996): 1-8.
- [16] Davids, Paul HP, et al. "Operative treatment for delayed union and nonunion of midshaft clavicular fractures: AO

- reconstruction plate fixation and early mobilization.” *Journal of Trauma and Acute Care Surgery* 40.6 (1996): 985-986.
- [17] Wilkins, Ross M., and Renner M. Johnston. “Ununited fractures of the clavicle.” *Journal of Bone & Joint Surgery - American Volume* 65.6 (1983): 773-778.
- [18] Mueller, Marcus, et al. “Minimally invasive intramedullary nailing of midshaft clavicular fractures using titanium elastic nails.” *Journal of Trauma and Acute Care Surgery* 64.6 (2008): 1528-1534.
- [19] Smekal, Vinzenz, et al. “Elastic stable intramedullary nailing is best for mid-shaft clavicular fractures without comminution: results in 60 patients.” *Injury* 42.4 (2011): 324-329.
- [20] Wisanuyotin, Taweetchok, et al. “Geometry of the clavicle and reliability of measurement using PACS.” *Surgical and Radiologic Anatomy* 36.6 (2014): 573-577.
- [21] Mishra, Pankaj Kumar, Anuj Gupta, and Suresh Chandra Gaur. “Midshaft Clavicular Fracture and Titanium Elastic Intra-medullary Nail.” *Journal of Clinical and Diagnostic Research: JCDR* 8.1 (2014): 129.
- [22] Lu, Cheng Chang, et al. “Complications and technical pitfalls of titanium elastic nail fixation for midclavicular fractures.” *Orthopedics* 37.4 (2014): e377-e383.
- [23] Magetsari, R. “Sensitiveness of Constant Murley’s Shoulder and quick DASH as an Outcome Measure for Midshaft Clavicle Fracture.” *Malaysian Ortho J* 4.1 (2010): 4-7.
- [24] Hudak, Pamela L., et al. “Development of an upper extremity outcome measure: the DASH (Disabilities of the Arm, Shoulder, and Hand).” *American Journal of Industrial Medicine* 29.6 (1996): 602-608.
- [25] Constant, C. R., and A. G. Murley. “A clinical method of functional assessment of the shoulder.” *Clinical Orthopaedics and Related Research* 214 (1987): 160-164.
- [26] Nordqvist, Anders, Claes J. Petersson, and Inga Redlund-Johnell. “Mid-clavicle fractures in adults: end result study after conservative treatment.” *Journal of Orthopaedic Trauma* 12.8 (1998): 572-576.
- [27] Wijdicks, Frans-Jasper, et al. “Complications after plate fixation and elastic stable intramedullary nailing of dislocated midshaft clavicle fractures: a retrospective comparison.” *International Orthopaedics* 36.10 (2012): 2139-2145.
- [28] Wu, Chi-Chuan, et al. “Treatment of clavicular aseptic nonunion: comparison of plating and intramedullary nailing techniques.” *Journal of Trauma and Acute Care Surgery* 45.3 (1998): 512-516.
- [29] Chen, Yun-feng, et al. “Clinical outcomes of midclavicular fractures treated with titanium elastic nails.” *Canadian Journal of Surgery* 53.6 (2010): 379.
- [30] Kadakia, Anish P., et al. “Titanium elastic stable intramedullary nailing of displaced midshaft clavicle fractures: A review of 38 cases.” *International Journal of Shoulder Surgery* 6.3 (2012): 82.