



DISPLACED MID-SHAFT CLAVICULAR FRACTURES TREATED SURGICALLY BY INTRAMEDULLARY NAILING: A CLINICO-RADIOLOGICAL AND FUNCTIONAL OUTCOME EVALUATION

Somnath Manna^{1.}, Ayon Das^{2*.}, Arijit Das³ and Swarnendu Samanta⁴

^{1,4}Department of Orthopaedics Peerless Hospital & B. K. Roy Research Centre, Kolkata, West Bengal, India

^{2,3}Department of Orthopaedics IPGMER & SSKM Hospital, Kolkata, West Bengal, India

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ABSTRACT

Background: The traditional conservative treatment of clavicular fractures has shown higher incidences of malunion, non-union, cosmetic deformities and patient dissatisfaction. Intramedullary nailing with Titanium Elastic Nail (TEN) is a promising mode of treatment for displaced midclavicular fractures, which may be an alternative to plate fixation. The aim of this study was to evaluate the functional results in patients with displaced mid-shaft clavicle fracture managed by closed/open reduction and internal fixation using an intramedullary nail.

Materials and Methods: This was a prospective study conducted at a Tertiary care Private Hospital in Kolkata, between July 2019 to January 2021 on patients who underwent intramedullary fixation using TEN for post-traumatic displaced mid-shaft clavicle fracture. All patients were followed up at an interval of 2 weeks, 6 weeks, 12 weeks, 6 months and 9 months. The patients were evaluated for radiological union and Constant Murley score was used to assess their functional outcome.

Results: In a total of 45 patients, 37 (82.2%) patients showed Excellent and 6 (13.3%) patients had Good results whereas 2 (4.5%) patient demonstrated Poor surgical result at the final follow-up. 88.9% patients did not have any complication. All the patients achieved clinical and radiological union at a mean of 3.34 months. By the end of 9 months, the average Constant Murley score for 45 patients was 92.00 ± 10.48 .

Conclusion: Operative treatment with intramedullary nail is a safe, simple and minimally invasive surgical technique having high success rate, quick recovery after surgery, lower rate of complications, faster return to daily activities, excellent aesthetic and comparable functional results as it engenders faster osseous healing and better restoration of clavicle length.

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INTRODUCTION

The clavicle is easily fractured because of its subcutaneous, relatively anterior location and frequent exposure to transmitted forces. The mid-shaft clavicle fractures account for 3 to 5% of all injuries and 70 to 80% of all clavicle fractures.¹ The mid-shaft of the clavicle undergoes a change in shape from concave to convex in the coronal plane, from round to flat in cross-section and as a result of this adjustment, most of the fractures occur in the mid shaft of clavicle.²

Mid-shaft clavicular fractures are most common with variable incidence of 69.2% to 76.2% and about 3/4th of these fractures are appreciably displaced.^{3, 4} The combined working forces of sternocleidomastoid pulling the medial fragment superiorly and posteriorly; and pectoralis major, deltoid and gravity pulling the lateral fragment inferiorly and anteriorly, results in net displacement and shortening of the mid-shaft fractures.⁵

Mid-shaft fractures of the clavicle have been traditionally managed non-operatively with an arm sling or a figure of eight clavicle brace.^{6, 7} However, recent studies have uncovered the disadvantages of conservative management. The relatively high number of non-unions, brachial plexus irritation, residual deficits in shoulder strength and endurance, persistent pain and disappointing cosmetic results might have led to unsatisfactory results in approximately 30% of the patients with displaced mid-shaft clavicular fractures.⁸⁻¹⁰

The clavicle length plays an important role to maintain anatomical relationship and function of the shoulder girdle.¹¹ So early surgical treatment in displaced mid-shaft clavicular fractures improves the functional outcome by decreasing the rates of non-union and symptomatic malunion. Surgery has been indicated for fractures which are completely displaced, which has skin perforation, having shortening of more than 20mm, neurovascular injury, bilateral fractures, polytrauma

*Corresponding author: Ayon Das

Department of Orthopaedics IPGMER & SSKM Hospital, Kolkata, West Bengal, India

and floating shoulder.¹² The proponents of early fixation of fresh clavicular fractures is to prevent complications like malunion and non-union, emphasize the value of accurate reduction and fixation in affording quick pain relief and promoting early functional recovery.

The standard treatment of displaced mid-shaft clavicular fractures is plate osteosynthesis as it restores length and anatomical alignment, also the implant is mechanically stronger. But this method has its own complications such as large skin incision, extensive soft tissue dissection that potentially results in damage to the supraclavicular nerves and subsequent paresthesia, implant prominence, infection, scarring, hardware failure and re-fracture after implant removal, and mostly the patients have aesthetic complaints.^{13, 14}

Intramedullary fixation has emerged as an excellent alternative since it behaves as an internal splint by sharing load and maintains alignment without rigid fixation.¹² It can block itself in the bone and provide a three-point fixation within the S-shaped clavicle.¹⁵ The use of an intramedullary device carries advantages of a smaller incision, better cosmetic results, less soft tissue dissection, preserving the soft tissue envelope, periosteum, and vascular integrity of the fracture site. It works on the principle of relative stability that encourages copious callus formation.¹⁶

The objective of this study was to represent our experience comprising cases of displaced mid-shaft clavicular fracture which were treated by internal fixation using intramedullary nailing to see whether the technique achieves acceptable reduction, stable fixation with minimum soft tissue damage and if this technique achieves favorable radiological union along with improved clinical and functional outcome.

MATERIALS AND METHODS

This study was performed in accordance with the ethical standards of the institutional review board. 45 patients with post-traumatic displaced mid-shaft clavicular fracture which were treated by intramedullary nailing in the Department of Orthopaedics, Peerless Hospital & B. K. Roy Research Centre, Kolkata from July 2019 to January 2021 and fulfilling the inclusion criteria were considered in this study.

Inclusion criteria

- Skeletally mature patients above 18 years of age
- Closed injury
- Fresh fracture (<2 weeks old)
- Simple non-comminuted fractures
- Unilateral fracture

Exclusion criteria

- Open wound
- Floating shoulder
- Pathological fractures
- Any other pre-existing morbidity of ipsilateral upper limb
- Associated other fractures or neurovascular injury on ipsilateral side
- Patients with polytrauma or head injuries that definitely influence rehabilitation

Operative Procedure

The patients were subjected to a thorough history, clinical examination and pre-operative routine laboratory investigations, which was supplemented by radiographs in antero-posterior and 30° cephalic tilt view of the shoulder joint.

All the patients were operated under General anaesthesia. Patients were positioned supine on a radiolucent operating table and a sandbag was kept under the interscapular region in order to provide shoulder extension allowing it to fall back and hence aiding in reduction.

A small incision 1 cm long was made over the medial end of clavicle 2 cm lateral to the sternoclavicular joint. A hole was made into the anterior cortex using a drill bit and the medullary canal was entered using a small curved or straight bone awl. An appropriate sized Titanium Elastic Nail (TEN) was inserted then with the aid of the universal T-handle chuck. The nail is manually inserted in unreamed fashion with oscillating movements under fluoroscopic guidance and advanced to the fracture site. Once the fracture was reached, attempt was made for closed reduction of the fracture by using two percutaneously introduced pointed reduction clamps. If the fracture could not be reduced by closed means, then a small separate vertical incision (mini open technique) was used at the fracture site to aid fracture reduction. Then the nail was advanced across the fracture site into the lateral fragment until it reaches just medial to the acromioclavicular joint. Continuous visualization under fluoroscope was used to aid advancement of the nail. The medial end of the nail was cut close to the entry point after bending and buried in the soft tissue to avoid irritation and also leaving sufficient length behind for easy extraction if required later on. Surgical wound was closed in layers. Sterile dressings were applied to the surgical incisions and an arm pouch support was applied.

Rehabilitation

Postoperatively, the patients were kept in an arm pouch support for 2 weeks. Pendulum exercises and pain-dependent passive mobilization were started immediately. Arm pouch was discarded after 2 weeks and active range of movements were started but the patients were strictly instructed to avoid overhead (>90°) abduction and flexion along with heavy weight lifting for 6 weeks. Full range of motion and shoulder strengthening exercises were commenced after 6 weeks. Patients were encouraged to resume their normal daily activities after a 6-week post-operative period.

Follow-up

The patients were regularly followed up for 9 months (2 weeks, 6 weeks, 12 weeks, 6 months and 9 months) for clinical as well as radiological evaluation. Except for the first visit, in which only range of motion and local wound condition was addressed, subsequent visits included thorough clinical and radiological assessment. Functional assessment of the patients was done at the final follow-up as per the Constant Murley Score.

Statistical analysis

Continuous variables were expressed as mean, median and standard deviation which were compared across the groups using Mann-Whitney U test. Categorical variables were expressed as number of patients and percentage of patients and

compared across the groups using Fisher's Exact Test. The statistical software SPSS version 20 was used for the analysis. An alpha level of 5% was taken, i.e., if any p value was less than 0.05 it was considered as significant.

RESULTS

Age Distribution

The mean age in this study was 28.04 years. The youngest patient was 18 years old and the eldest patient was 42 years old. Overall, 88.9% patients were between the age group of 20-40 years. It might be because younger peoples are more active and involved in outdoor and sports activities which makes them more prone to injuries.

Table 1 Age Distribution

Age (years)	No. of Patients	Percentage (%)	P value
18-20	3	6.7	0.176
21-30	29	64.5	
31-40	11	24.4	
41-50	2	4.4	
Total	45	100.0	

Sex Distribution

38 patients (84.4%) were male and 7 patients were female (15.6%). Majority of patients were Male which may be because of more outdoor and sports related activities makes them more vulnerable to accidents and trauma.

Side of Injury Distribution

All fractures were unilateral on the Left side in 28 (62.2%) shoulders which was higher in comparison to Right in 17 (37.8%).

Mode of Injury Distribution

30 (66.7%) were involved in Road traffic accident, 11 (24.4%) patients suffered a fall, and 4 (8.9%) sustained trauma during sports activities.

Fracture type Distribution

The clavicle fractures were selected and classified as per the AO classification.

Table 2 AO Classification Distribution

AO fracture type	No. of patients	Percentage (%)
B1	33	73.3
B2	12	26.7
Total	45	100.0

Type of Reduction during surgery

Closed reduction was enough for internal fixation with TENS nail in 24 (53.3%) patients whereas Open reduction after mini-incision was required in 21 (46.7%) patients.

Interval between injury and surgery

The mean interval between injury and surgery was 3.38 ± 1.77 days (range 1-7 days).

Duration of surgery

The mean duration of surgery was 40.89 ± 8.74 mins (range 30-65 mins).

Duration of Hospital stay

The mean duration of hospital stay was 2.31 ± 0.63 days (range 2-4 days).

Time to radiological union

The average time to union as seen in radiographs was found to be 3.34 ± 0.45 months (range 3-4.5 months).

Subjective Variables

- Pain

Table 3 Pain Incidence

Pain	No. of Patients	Percentage (%)
Nil	40	88.9
Mild	3	6.7
Moderate	2	4.4
Severe	0	0
Total	45	100.0

- Activities of Daily Living

Working ability

Table 4 Working ability Incidence

Working ability	No. of Patients	Percentage (%)
No limitation	38	84.4
Moderate limitation	7	15.6
Severe limitation	0	0
Total	45	100.0

Recreation/Sports ability

Table 5 Recreation/Sports ability Incidence

Recreation/Sports	No. of Patients	Percentage (%)
No limitation	39	86.7
Moderate limitation	6	13.3
Severe limitation	0	0
Total	45	100.0

Sleep

Table 6 Sleep Incidence

Sleep	No. of Patients	Percentage (%)
Unaffected	42	93.3
Affected sometimes	3	6.7
Total	45	100.0

Arm Positioning

Table 7 Arm Positioning Incidence

Arm Positioning	No. of Patients	Percentage (%)
Above head	34	75.6
Up to top of head	9	20
Upto neck	2	4.4
Total	45	100.0

Objective Variables

- Range of Motion

Flexion

Table 8 Flexion Incidence

Flexion	No. of Patients	Percentage (%)
0-30°	0	0
31-60°	0	0
61-90°	0	0
91-120°	2	4.4
121-150°	7	15.6
>150°	36	80
Total	45	100.0

Abduction

Table 9 Abduction Incidence

Abduction	No. of Patients	Percentage (%)
0-30°	0	0
31-60°	0	0
61-90°	2	4.4
91-120°	0	0
121-150°	9	20
>150°	34	75.6
Total	45	100.0

External Rotation

Table 10 External Rotation Incidence

External Rotation	No. of Patients	Percentage (%)
Full elevation	40	88.9
Hand above head & elbow back	3	6.7
Hand above head & elbow forward	2	4.4
Hand behind head with elbow forward	0	0
Total	45	100.0

Internal Rotation

Table 11 Internal Rotation Incidence

Internal Rotation	No. of Patients	Percentage (%)
Upto interscapular region	10	22.2
Upto T12 vertebra	19	42.2
Upto waist	11	24.5
Upto SI joint	3	6.7
Upto buttock	2	4.4
Upto lateral thigh	0	0
Total	45	100.0

B. Strength

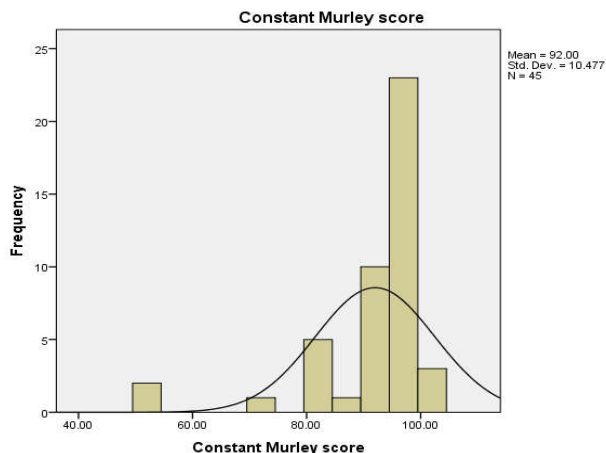
Table 12 Strength Incidence

Strength	No. of patients	Percentage (%)
25 points	43	95.6
<25 points	2	4.4
Total	45	100.0

Constant Murley Score

At the end of 9 months, the average Constant Murley score for 45 patients was 92.00 ± 10.48

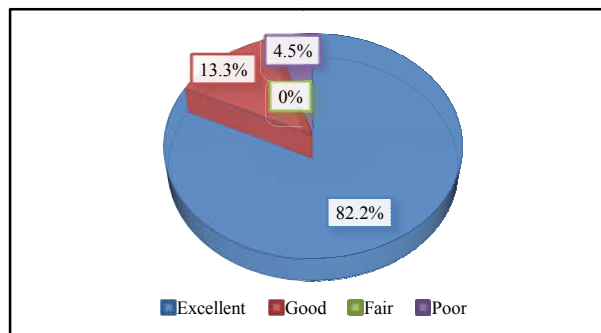
Table 13 Constant Murley Score Frequency



Constant Murley Functional Outcome

37 (82.2%) patients showed Excellent and 6 (13.3%) patients had Good results whereas 2 (4.5%) patient demonstrated Poor surgical result. None of the patients had Fair outcome at the end of final follow-up.

Table 14 Constant Murley Functional Outcome



Complications

In a total of 45 patients, 40 patients (88.9%) did not have any complications.

Shoulder back stabbing pain was complain in 1 (2.2%) patient, medial side implant prominence was observed in 2 (4.4%) and soft tissue irritation at the site of entry was found in 2 (4.4%) patients.

Majority of patients (91.1%), presented within 1 week of injury. No major intraoperative complications such as excessive bleeding, iatrogenic fracture/perforation of cortex or neurovascular damage were encountered during the surgical procedure. Postoperative complications like infection, scar neuroma, nail migration, telescoping, implant failure, malunion, non-union and re-fracture were not seen any of the patients. No revision surgery was required for any patient; however, 2 (4.4%) patients had to undergo implant removal for hardware prominence after fracture union. 93.3% patients returned to their pre-injury activity at the end of 6 months.

[Figure 1-10]



Figure 1 Pre-op X-ray in AP view showing displaced mid-shaft clavicle fracture

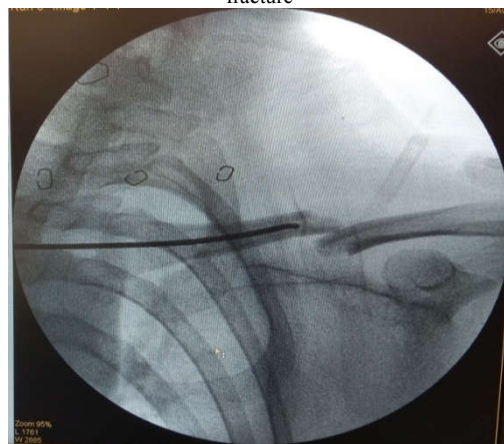


Figure 2 Intra-op fluoroscopic view showing TEN insertion up to fracture site



Figure 3 Intra-op fluoroscopic view showing fracture reduction and passing of TEN beyond the fracture site

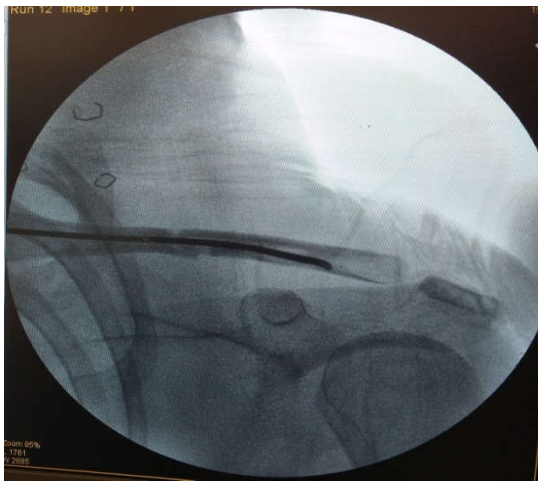


Figure 4 Intra-op fluoroscopic view showing TEN insertion upto the lateral part of clavicle

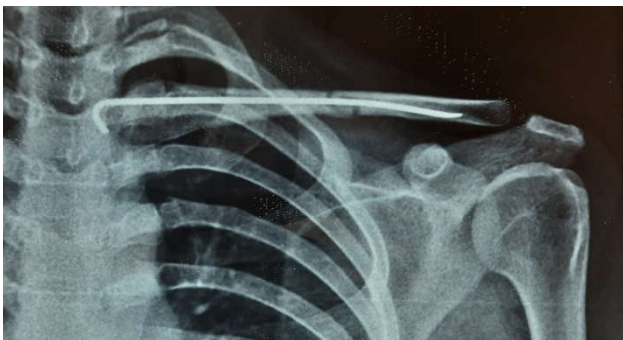


Figure 5 Immediate post-op X-ray showing fracture reduction status with nail in situ

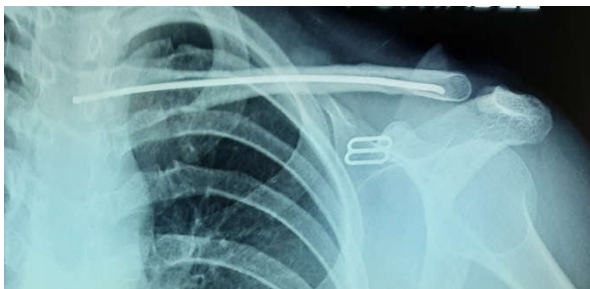


Figure 6 9 months follow-up X-ray showing fracture union

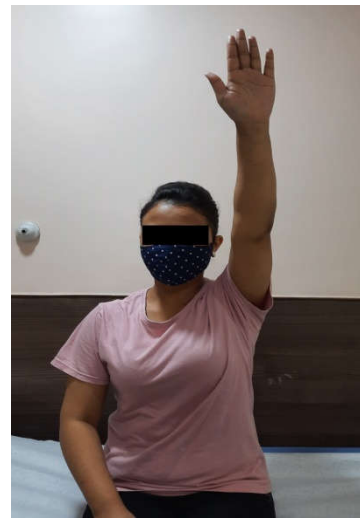


Figure 7 Arm position above head at final follow-up

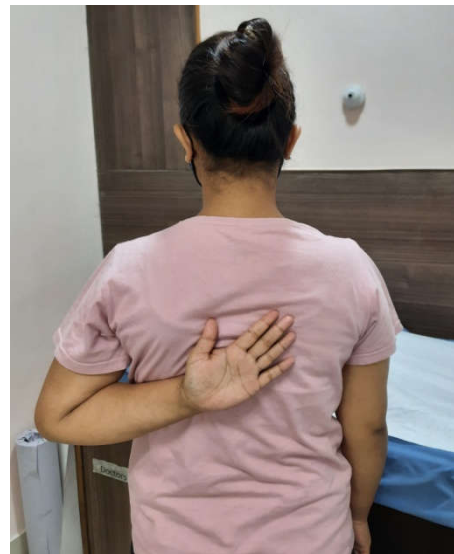


Figure 8 Adduction and Internal rotation at final follow-up



Figure 9 Abduction and External rotation at final follow-up



Figure 10 A post-operative case showing medial side nail prominence (required implant removal later)

DISCUSSION

Fractures of the clavicular shaft are predominantly found in children and young adults, 88.2% of which occur within the first decade of life.¹⁷ The middle third is the thinnest segment of the bone and is devoid of any protective muscular or ligamentous attachment, rendering it as the weakest point and making it prone to fractures.

The goal of treatment is to relieve pain and gain a complete restoration of shoulder function. Clavicular shaft fractures were not considered to be problematic and non-operative treatment played the key role for a long time. However, conservative management reported certain disadvantages such as it needs frequent readjustment and it causes increased discomfort along with complications such as axillary pressure sores, upper extremity oedema and venous congestion, brachial plexus palsy, worsening of deformity and increased risk for non-union and poor functional outcomes.^{11, 18, 19}

Plate osteosynthesis, external fixation and intramedullary fixation have all been described for surgical treatment of clavicle fractures. Plate osteosynthesis is still considered the standard method for the surgical treatment of clavicle shaft fractures. However, this technique requires larger incision and extensive exposure which could cause complications such as infection, implant failure, re-fracture after implant removal, neurovascular injury, non-union, dysesthesia and keloid scar.^{13, 20}

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.^{21, 22} The potential benefits of this technique include smaller incision, minimal periosteal stripping, and load sharing device properties.¹⁶ Its relative stability allows copious callus formation during the healing process. This modality fulfills most of the desired goals of clavicle fracture fixation. It restores the length and alignment of the bone in the least invasive fashion. The operative time is less, intraoperative bleeding is reduced, postoperative pain is decreased and rehabilitation is faster when compared to plate fixation.²³⁻²⁶

After intramedullary fixation, early postoperative shoulder exercise results in sustained stress stimulation and osteoblasts proliferation, and promote bone callus formation. Bending and torsional loads in the clavicle are better compensated for by an intramedullary flexible nail, which provides biomechanical stability by transforming the shear stress caused by displaced fractures into compression and traction force to prevent further

displacement of fracture and angular displacement. Meanwhile, the elasticity and tension of the nail in situ can prevent the risk of migration. TEN does not denude the soft tissue around the fracture so does not induce the incidence of complications such as infection and damage of the surrounding tissues. It does not damage the vascular system of the periosteum, thus protecting the blood supply. All of these lead to a significant faster osseous healing, lower rates of delayed and non-union and better functional results.²⁷

The TEN was initially used in the paediatric fracture treatment with good functional results that led to its use for treatment of adult fractures. In contrast to screws, K-wires or pins, the TEN is flexible with a curved tip that remains fixed in the cancellous part of lateral end of clavicle. This helps it to accommodate the S-shaped contour of the clavicle and adhere tightly to the cortex. From a biomechanical point of view, TEN produces early elastic fixation at the end of the clavicle fracture which advocate stress shielding at the fracture point. Due to this sustained stress-shielding mechanism and with the movement of the shoulder joint, micro-dynamic movement at the fracture point helps to promote callus formation, thus accelerating fracture healing.²⁸ The three-point stabilization and the curved tip of the TEN provide a better anti-bending and anti-torsion load and decrease the occurrence of hardware migration.²⁵

In intramedullary stabilization of the clavicle, our study revealed the following data - 88.9% patients were absolutely pain free after final follow-up and 86.7% patients returned back to normal daily activity by the end of 9 months. 93.3% patients had unaffected sleep at night and 95.6% patients were able to lift their arm upto or above head without any difficulty. In objective shoulder assessment, the mean shoulder flexion and abduction were 161.89 ± 16.9^0 and 159.67 ± 22.8^0 respectively. Only 4.4% patients had limited rotational movement. 95.6% patients gained full power of the affected upper limb compared to normal side. 95.5% patients demonstrated good to excellent result as per the Constant Murley score by the end of 9 months with an average score of 92.00 ± 10.48 . 88.9% patients did not encounter any complication. Only 2 patients had poor result due to chronic pain, occasionally disturbed sleep at night, limited terminal ROM of the shoulder joint which hampered their activities of daily living and reduced grip strength – possibly due to soft tissue irritation at entry site along with implant prominence. Both these patients underwent removal of TEN after union of fracture one year later from initial surgery. Subsequently they improved symptomatically in due course. These findings guide us that this method is a good alternative choice for fixation of simple non-comminuted mid-shaft clavicle fractures.

Limitations of our study include single institution bias, small group of patients, short follow-up period and a lack of Control group. Additional prospective and biomechanics studies should be conducted to confirm these outcomes in the future. A multicentre study with more patients is essential to substantiate benefits of this treatment method.

CONCLUSION

Titanium elastic intramedullary nailing of displaced, non-comminuted, mid-shaft clavicle fractures is a safe, minimally invasive and reliable surgical technique. Due to tremendous advancement in intramedullary fixation methods and devices, its low complication rates, short operating time and hospital

stay, less blood loss, rapid post-operative pain relief, quick recovery, more cosmetic satisfaction, faster return to daily activities, satisfactory union rate, low implant-related complication rate and easier implant removal along with excellent functional results and favourable patient satisfaction; intramedullary fixation can be considered as an alternate and preferable modality of treatment in displaced mid-shaft clavicular fractures when compared to plate osteosynthesis or non-operative management especially in young and active individuals.

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