

“Intramedullary Fixation vs. Plate Fixation for Clavicle Fracture: A Comparative Study”

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Abstract

Background: Clavicle fracture is common fracture in day to day orthopaedics practice because of its subcutaneous and relatively its anterior position. Fracture clavicle constitutes approximately up to 44% of injury to shoulder. Mid third part clavicle fractures are most common. Previously to treated clavicle fracture conservative treatment was very common but because of complications (mal-union and non-union). In recent years with changing trends in treatment of displaced mid shaft clavicle fracture operative treatment remains the standered procedure for fixation.

Material and Methods: This was a prospective and RCT of 54 patients who were randomized in two groups to be treated surgically with either plate (group A-27 patients) or a single TEN fixation (group B-27 patients) in a 1:1 ratio by odd and even method. All patients were followed up at 4th week, 12th week and 24th week. Results were compared for outcomes using DASH Score (The Disabilities of the Arm, Shoulder and Hand Score).

Results: On comparison between DASH Scores of patients at 24 weeks in both groups, it is found to be not statistically significant with P-value more than 0.01. Thus showing patients undergone plate fixation or intramedullary fixation have similar out come at 24 weeks showing both techniques are equally effective in treatment of clavicle fractures.

Conclusion: This study shows that operative treatment with plate fixation or intramedullary fixation by titanium elastic nail, for displaced clavicle fractures have comparable and satisfying functional results. Thus both procedures are equally effective alternatives for surgical fixation of displaced clavicle fractures

Keywords: Clavicle fracture, plate and screws, intramedullary titanium elastic nail, DASH score.

Date of Submission: 02-05-2019

Date of acceptance: 16-05-2019

I. Introduction

Clavicle is one of the most common fractured bones in the human body. Clavicle fractures account for 5–10% of all fractures¹. Studies indicate that 29–64 per 100,000 adolescents and adults suffer from a clavicle fracture each year². More recent data, based on detailed classification of fractures, suggest that the incidence of nonunion in displaced comminuted mid-shaft clavicle fractures in adults is between 10 and 15%.³ Several studies shows that poly-trauma patient with clavicle fracture have poor prognosis with mortality rate of 20% to 30%³.

Among clavicle fractures, mid shaft fractures are the most common with a reported incidence of 80% as it is the thinnest segment of the clavicle and it is not stabilized by ligaments. Distal third fractures have incidence of 15% to 20% while medial third fractures are least common with incidence of 5%⁴. A direct blow on the point of the shoulder is the commonest reported mechanism of injury that produces a fracture of the clavicle⁵.

Older studies showed that clavicle fractures had good results with very low incidence of nonunion when treated non-operatively and poor outcome after primary operative fixation of clavicle fractures⁶. Hence traditionally clavicle fractures are being treated non-operatively.

However, recent studies have shown that the union rate for non-operatively treated displaced clavicle fractures is not as favorable as previously thought^{7,8}. Patient-oriented outcome measures have shown functional and strength deficits in the upper extremity. Decreased shoulder abduction and flexion was the main cause of patient dissatisfaction despite bony union when treated non-operatively. These recent studies also reported high success rates after primary operative fixation with union rates ranging from 94% to 100% and low rates of infection and surgical complications.

Open reduction internal fixation with plate is considered to be the gold standard when it comes to operative intervention. However, there is also a considerable amount of surgeons that favor close or open reduction internal fixation with intramedullary nail or pin for clavicle fractures.

This study is planned to directly compare the outcomes of operative intervention by plate and screws fixation with intramedullary titanium elastic nail fixation for clavicle fractures.

II. Material and Methods

This study was a prospective and RCT, was conducted at Department of Orthopaedics, L.L.R.M. Medical College Meerut between January 2015 to April 2016 on 54 patients who were attended in OPD and emergency. The patients were randomly divided into two groups, Group A (n-27) and Group B (n-27) in a 1:1 ratio by odd and even method as decided by inclusion and exclusion criteria. Informed written consent was taken from every patient and approval was taken from the college ethical committee. We used most common Allman classification system for clavicle fractures. During the period the patients who were attended the hospital were enrolled as sample size. Analysis of results was done by using **DASH Score⁹** (The Disabilities of the Arm, Shoulder and Hand Score).

Statistical analysis is done by using SPSS 16.0 version software. For intra group comparison of means, paired student t-test was used and for comparison of means between two groups, unpaired student t-test is used. $P < 0.01$ is considered significant.

Inclusion Criteria:

1. A unilateral, close fracture and completely displaced (>2 cm) fracture of the clavicle up to 4 weeks injury.
2. Age between eighteen to sixty years.
3. Ready to give informed consent and follows up to 6 months.

Exclusion Criteria:

1. A pathological fracture
2. Head injury, associated fracture and neurovascular injury.
3. Contraindication to surgery and anesthesia.

Randomization: Patients were randomized to either TENS group or Plate group in a 1: 1 ratio by odd and even method.

History was taken from each patient regarding mode of injury, time since injury. All patients were examined clinically and investigated thoroughly. A day before surgery the patients were subjected to pre anaesthesia checkups, surgical site of each patient was prepared and informed consent were taken from each patient or his/her attendants. Each patient was received a single dose antibiotic half an hour before induction of anaesthesia. I.V antibiotic was given to all patients for 7 days. Pain was relieved by analgesic. Wound dressings were done at 3rd post operative day in routine or anytime when needed for proper care. Stitches were removed on 10-12th post op day. The limb was kept in a sling post-operatively for 1 week.

Operative procedure for Plating: After proper anaesthesia patient was taken on OT table in supine position on a radiolucent operating table. A small roll or folded towel is placed between the scapula to allow retraction of the shoulder and to assist with reduction. A horizontal incision is placed over the superior surface of clavicle dissection is performed carefully and, if possible, perforating supraclavicular sensory nerves are identified and saved. Division of platysma is performed. Two main fragments are distracted and the length of the clavicle is restored. If bone ends are angled or oblique, reduction with a pointed or serrated reduction forceps is done. Any large comminuted fragments are reduced and temporarily stabilized with K-wires. Independent lag screws or lag screws through the plate are applied for maintaining the reduction, if required. Determine plate length and contour the plate if not precontoured. Insert plate and screws. Plate is positioned on the reduced bone and attached temporarily with the plate holding forceps and 3.5 mm cortex screw or locking screws applied for fixation. Over penetration of inferior cortex is avoided due to close proximity of the subclavian artery and brachial plexus. Wound closed in layers. Patient shifted to post-op ward with stable vitals. The post-operative radiograph is then obtained and proper post op care of the patient is done.

Operative procedure for intramedullary fixation by TENS: After administration of anesthesia, the patient was placed in beach chair position with injured extremity prepared and draped from the midline to the upper arm. A vertical skin incision was made at the fractured site. The subcutaneous fat was incised along with platysma. The pectoral fascia was divided in line with the skin incision followed by careful elevation of the underlying musculature from the clavicle. An appropriate sized titanium nail was inserted from the fractured site towards the lateral end of clavicle and taken out just proximal to acromioclavicular joint postero-lateral aspect

of clavicle. The nail was then passed from the lateral side and across the reduced fracture into the medial end of clavicle. Nail was cut and bent to prevent migration. Wound closed in layers and the patient shifted to post-operative ward with stable vitals. The post-operative radiograph is then obtained and proper post op care of the patient is done.

The results of the study would be evaluated primarily by using DASH Score (The Disabilities of the Arm, Shoulder and Hand Score) at preop, at 4 weeks, at 12 weeks and 24 weeks. Secondly by intraoperative blood loss, surgical scar size, operative time, post-operative hospital stay and Fracture union time.

III. Observations and Results

The study comprised of total of 57 patients who were dividing into two groups to be treated surgically with either plate (plate group) or a single TEN fixation (TEN group) by odd and even method. Two patients in plate group and one patient in TEN group were lost in follow up. Hence we included 54 patients in the study. The patients were followed up in the OPD after discharge at regular interval. Statistical analysis is done by using SPSS 16.0 version software. For comparison of means between two groups, unpaired student t-test was used.

In Plate group the mean age of the patients was 33.89 years with standard deviation of 11.91 while mean age of the patients for intramedullary group was 31.14 years with standard deviation of 10.08.

In plate group 19(70.37%) patients were male and 8(29.63%) patients were female while in intramedullary group 18(66.67%) patients were male and 9(33.33%) patients were female. Thus out of 54 patients included in the study 37 patients (68.52%) were male and 17 patients (31.48%) were female giving an overall male to female ratio of 2.18: 1.

In this study Road traffic accident was found to be main mechanism of injury; 33 patients (61.11%), followed by fall on shoulder 11 patients (20.37%), Assault 4 patients (7.41%) while Others (sports, fall on outstretched hand, etc.) had 6 patients (11.11%).

Table 1: Comparison of DASH Score between pre-op and post-op at 4, 12 and 24 weeks for patients who underwent Plate fixation.

	Mean	SD	Median	Min-Max	P-value
Pre-OP	81.28	±4.86	84.48	75 - 91.17	<0.01
Post-OP 4 weeks	57.59	±4.46	56.67	50.83-65.83	
Post-OP 12 weeks	26.18	±4.67	28.33	18.33-34.48	
Post-OP 24 weeks	6.18	±3.7	5.83	1.67-18.33	

Pre-operative DASH score of the patients who underwent plate fixation had median value of 81.28 and mean value of 84.43 with Standard deviation of 4.86. After 4 weeks post-operative period improvements in DASH score was seen with median value of 56.67 and mean value of 57.59 and Standard deviation of 4.46.

After 12 weeks post-operative period improvements in DASH score was seen with median value of 28.33 and mean value of 26.18 and Standard deviation of 4.67.

The improvement in DASH score was seen during post-operative period of 24 weeks with median value of 5.83 and mean value of 6.18 and Standard deviation of 3.7.

Table 2: Comparison of DASH Score between pre-op and post-op at 4, 12 and 24 weeks for patients who underwent interamedullary fixation.

	Mean	SD	Median	Min-Max	P-value
Pre-OP	84.38	±3.70	84.48	75 - 91.17	<0.01
Post-OP 4 weeks	64.94	±5.23	64.66	55.36-74.1	
Post-OP 12 weeks	29.83	±3.92	29.16	23.28-41.67	
Post-OP 24 weeks	6.17	±5.05	4.16	1.67-23.28	

Pre-operative DASH score of the patients who underwent intramedullary fixation had median value of 84.48 and mean value of 84.38 with Standard deviation of 3.70. After 4 weeks post-operative period improvements in DASH score was seen with median value of 64.66 and mean value of 64.94 and Standard deviation of 5.23.

After 12 weeks post-operative period improvements in DASH score was seen with median value of 29.16 and mean value of 29.83 and Standard deviation of 3.92.

After 24 weeks post-operative period improvement in DASH score was seen with median value of 4.16 and mean value of 6.17 and Standard deviation of 5.05.

Table 3: Comparison of DASH Score between patients who underwent plate fixation and intramedullary fixation for clavicle fractures at 4 weeks.

Technique	Patients	Mean	SD	Median	Min-Max.	P-value
Plate fixation	27	57.59	±4.46	56.67	50.83-65.83	<0.01
Intramedullary fixation	27	64.94	±5.23	64.66	55.36-74.1	

Comparison of DASH Score between patients who underwent plate fixation and intramedullary fixation for clavicle fractures at 4 weeks is found to be statistically significant with P-value less than 0.01. Thus showing patients undergone plate fixation has better recovery in 4 weeks post-operative period.

Table 4: Comparison of DASH Score between patients who underwent plate fixation and intramedullary fixation for clavicle fractures at 12 weeks.

Technique	Patients	Mean	SD	Median	Min-Max.	P-value
Plate fixation	27	26.18	±4.67	28.33	18.33-34.48	<0.01
Intramedullary fixation	27	29.83	±3.92	29.16	23.28-41.67	

Comparison of DASH Score between patients who underwent plate fixation and intramedullary fixation for clavicle fractures at 12 weeks is found to be statistically significant with P-value less than 0.01. Thus showing patients undergone plate fixation has better recovery in 12 weeks post-operative period.

Table 5: Comparison of DASH Score between patients who underwent plate fixation and intramedullary fixation for clavicle fractures at 24 weeks.

Technique	Patients	Mean	SD	Median	Min-Max.	P-value
Plate fixation	27	6.19	±3.7	5.83	1.67-18.33	>0.01
Intramedullary fixation	27	6.17	±5.05	4.16	1.67-23.28	

Comparison of DASH Scores between patients at 24 weeks post-op treated by plate fixation and DASH Scores of patients at 24 weeks post-op treated by intramedullary fixation, it is found to be not statistically significant with P-value more than 0.05. Thus showing patients undergone plate fixation or intramedullary fixation have similar outcome at 24 weeks showing both techniques are equally effective in treatment of clavicle fractures.

Post-operative hospital stay in patients undergone plate fixation showed minimum 5 days and maximum 12 days(SD±1.97), while post-operative hospital stay in patients undergone intramedullary fixation showed minimum of 2 days and maximum of 7 days(SD±1.81).

Fracture union in patients undergone plate fixation showed union minimum in 13 weeks and maximum 22 weeks (SD±1.77), while fracture union in patients undergone intramedullary fixation showed union minimum in 12weeks and maximum of 23 weeks (SD±2.17).

IV. Discussion

In this study the age of the patients were between 18 years to 60 years with mean age of 32.52 which is similar to study by **Dhoju D et al¹⁰, Partha Saha et al¹¹**.

Out of 54 patients included in the study 31 patients (57.41%) had clavicle fracture on Right side and 23 patients (42.59%) had clavicle fracture on Left side this was similar to studies **Jamal E. H. Assobhi et al¹²**.

In this study Road traffic accident was found to be main mechanism of injury; 33 patients (61.11%) which is similar to study conducted by **Olivier A. van der Meijden et al¹³**. This is due to a direct blow on the point of the shoulder as a person is being thrown from a vehicle or bicycle or from the intrusion of objects or vehicle structure during a motor vehicle accident.

In this study patients undergone plate fixation shown faster improvement in DASH score during the first 6 months (24weeks) after surgery in comparison to intramedullary fixation which is consistent with studies of **Olivier A. van der Meijden et al¹⁴**. This is due to plate fixation results in a biomechanically stable construction allowing early mobilization and providing for fracture compression.

In this study no significant difference between plate fixation and intramedullary fixation in functional outcome was seen at 6 months (24 weeks) which is similar to study by **Ferran et al (2010)¹³, Barlow T et al¹⁵, and Xiao H et al¹⁶**, showing both techniques equally effective for the treatment of displaced midshaft clavicle fracture.

The post-operative hospital stay in patients undergone plate fixation (7.74 days+1.97) was more than post-operative hospital stay in patients undergone intramedullary fixation (3.74+1.81) showing early discharge from hospital in case of intramedullary fixation this could be due to lesser stitch line in case of intramedullary fixation which is similar to studies conducted by **Tarng YW et al¹⁷**.

In this study, fracture union time in patients who had undergone plate fixation (14.85 weeks +1.77) was more than fracture union time in patients undergone intramedullary fixation (13.41 weeks +2.17). After intramedullary fixation, early post-operative shoulder exercise may result 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 fractures displacement and angular displacement. Meanwhile, the elasticity and tension of the nail in situ can prevent the risk of migration. Intramedullary flexible nail preserve fracture haematoma and does not denude the soft tissue around the fracture so as not to 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. This is in concordance with studies by **CHEN Qing-yu et al¹⁸, Pramod B Itagi and Nishanth Panegaon et al¹⁹**.

V. Conclusion

This study shows that operative treatment with plate fixation or intramedullary fixation by titanium elastic nail, for displaced clavicle fractures have comparable and satisfying functional results. Thus both procedures are equally effective alternatives for surgical fixation of displaced clavicle fractures.

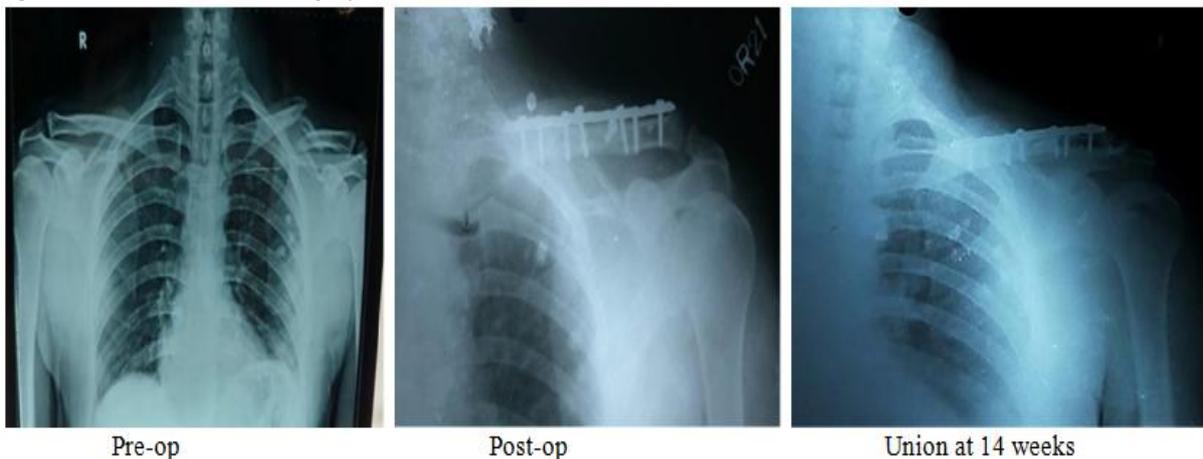
□ Intramedullary nailing techniques have advantages like less soft tissue injury, shorter operating time and hospital stay, less blood loss, more cosmetic satisfaction with small post-operative scar and faster time of union.

□ Plate fixation ensures rapid free movement of shoulder and early return to daily activities because of its stable construct thus decreasing patient's morbidity.

Thus we conclude from this study that although both procedures are equally effective, intramedullary fixation is a safe, minimally invasive surgical technique with a faster union time, excellent cosmetic and comparable functional results and can be regarded as a better alternative to plate fixation for treatment of displaced clavicle fractures.

Case 1: Plate Group

Age – 28 Year/M, Mode of injury – RTA, Side – Left



Case 2: Intramedullary Nail Group

Age-18 years, Mode of injury-RTA, Side-Left



Pre-op X-ray



Post-op X-ray



Union at 12 weeks

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Funding: No funding sources

Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional ethics committee.

Gajraj Singh “Intramedullary Fixation vs. Plate Fixation for Clavicle Fracture: A Comparative Study”. *IOSR Journal of Dental and Medical Sciences (IOSR-JDMS)*, vol. 18, no. 5, 2019, pp 57–62.