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Evaluation and comparison of the complications of internal fixation by TENS method and plate and screws method for clavicle fracture

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Abstract
Background: Fractures of clavicle are common injuries with incidence of 2.6% of all fractures and 44% of all shoulder injuries. Better operative technique; improve metallurgy and availability of image intensifiers made the operative techniques as a method of first choice by more and more surgeons. So the study was conducted to evaluate and compare the complications of these two methods of fixation. **Methodology:** The study was conducted on 62 patients with fracture of clavicle. Selected patients were treated by, closed/open reduction & internal fixation by TENS and Group II by open reduction & internal fixation by plate& screws. Patients were followed periodically at 2weeks, 6 weeks, 3, 6, 12 months, 18 months and 24 months. Results were evaluated by Constant scoring system given by Murley (1987). **Results:** Overall plate had more intra op and post op complications like more blood loss, more operative time, superficial infections, deep infections, implant protuberance, ugly scar, difficult implant removal than TENS fixation. In this study nonunion was equal in both TENS and plate fixation groups. **Conclusion:** In our study no significant difference was found in function and nonunion rate in both the groups but major complications and union time are more in plate fixation group than TENS group so, TENS fixation is the preferred treatment of choice for fracture middle 1/3rd clavicle.

Keywords: Internal fixation, TENS method, plate and screws method and clavicle fracture

Introduction
Fractures of clavicle are common injuries with incidence of 2.6% of all fractures and 44% of all shoulder injuries [1].
Clavicle is short long bone of Skeleton and helps in translation of weight from hand to axial skeleton and provides attachment to the various muscles [2].
All these methods did not involves the reduction of fracture or unable to hold the fracture reduced hence the end results was malunion (25%)/nonunion (33.3%) in various cases [3, 4].
The malunion resulted in shortening, deformation, disfigurement and poor cosmoses shortening (reduced distance between sternoclavicular joint to the shoulder joint) resulted in biomechanical disadvantage, persistence of pain, limitations of functions and reduction of strength in upper limb in some of these cases [5, 6].
With increasing awareness and demand of the patient and consumer protection court surgeons felt the need for operative intervention and perfect alignment of these fracture to achieve perfect alignment of fragments [7, 8].
Better operative technique; improve metallurgy and availability of image intensifiers made the operative techniques as a method of first choice by more and more surgeons.
So the study was conducted to evaluate and compare the complications of these two methods of fixation.

Methodology
The study was conducted on 62 patients with fracture of clavicle, attending Emergency and Outpatient Department of Orthopedics, M.L.B. Medical College and Hospital, Jhansi (U.P.) between December 2014 to June 2016.
Patients age between 16 years to 60 years, within 2 weeks of fracture clavicle, displaced fracture of Mid shaft clavicle, Shortening > 2 cm, Segmental fractures, bilateral clavicle

fracture, Clavicular fracture associated with other injuries, Grade I and II compound fractures were included in the study. Patient age below 16 years and above 60 Years, preexisting pathology in shoulder or elbow or both, fracture more than 2 weeks, fracture of lateral end clavicle and medial end, scapular malposition and winging on initial examination, floating shoulder, patient who do not give consent, Grade III compound fractures were excluded in the study.

Patients were clinically examined; first aid was given in the form of, cuff and color sling, analgesics, antacids and was subjected to A-P view, Lardotic view radiograph of full length clavicle to decide the plan of definitive management. If needed CT scan and MRI were also taken. Those requiring surgery were classified as per Allman classification and investigated for fitness for anesthesia and surgery. Selected patients were randomly divided in Group I and Group II. Patients of group I were treated by, closed/open reduction & internal fixation by TENS and Group II by open reduction & internal fixation by plate& screws. Patients were followed periodically at 2weeks, 6 weeks, 3, 6, 12 months, 18 months and 24 months. Results were evaluated by Constant scoring system given by Murley (1987) [9] Postoperatively, patients will be given a sling, but were encouraged for early shoulder mobilization, starting with pendular exercises from the second day. After 7 days, active range of movement exercises will be started. However, overhead shoulder abduction was allowed only after 2 weeks. Activities of daily living was started thereafter. But those requiring lifting heavy objects were delayed until union was achieved. All patients were reviewed at 2 and 6 weeks, 3, 6, 12, 18 and 24 months after surgery. At each visit, patients will be assesses clinic radiologically for primary and secondary outcome measures. Functional outcome was assessed by the Constant score [10, 11].

Radiographic union was defined as evidence of bridging callus or obliteration of fracture lines. Clinical union was considered as absence of tenderness at the fracture site. Time to achieve union was recorded. After union, shortening of clavicular length was measured clinically as the linear difference of clavicle lengths from sternal end to acromial end between operated and normal side.

Implant removal was not done routinely in our study. It was done as per need and will of the patient after fracture union.

The observation are based on 62 patients with fracture of clavicle, attending Emergency/Outpatient Department of Orthopedics, M.L.B. Medical College and Hospital, Jhansi (U.P.) between December 2014 to June 2016.

Patients were divided in two groups, randomly, patients of GROUP- I, were treated by closed/open reduction and internal fixation by TENS and those in GROUP II were treated by open reduction and internal fixation by PLATE and screws. Necessary data and relevant observations were collected in already prepared Proforma. The data was tabulated and observations made are being presented as below.

Observation & Results

Table 1: Shows Age Distributions In Patients Of Fracture Clavicle.

Age distribution (in years)	Numbers	Percentage
16-20	4	6.25 %
21-30	30	48.39%
31-40	20	32.26%
41-50	5	8.06%
51-60	3	4.84%
Total	62	100 %

In our study the youngest of the patients was a 17 years old male and the oldest was 60 years old elderly female, but most (48.39%) of the patients were in age group between 21 to 30 years. average age, overall, of 62 patients was 30.58 years, and that of group I was, 30.22 years and group II was, 30.34 years. Thus the average age was not significantly different in both groups of patients.

Table 2: Table Shows Sex Distributions in Patients of Clavicle Fractures

Sex	Number	Percentage
Male	40	65%
Female	22	35%
Total	62	100%

In our study of 62 patient of fracture clavicle 40 (65%) patients were male and 22 (35%) patients were female. This observation clearly shows male preponderance (65%) in cases of fracture clavicle.

Sex distribution was quite similar in both group of patients with 67.74 % male in group I and 61.29 % male in group.

Table 3: Post-Op Complications

Complications	GP I	%	GP II	%
Superficial infection	5	16.12	3	9.67
Deep infection	--	--	2	6.45
Neurovascular injury	--	---	--	---
Non union	2	6.45	2	6.45
Ugly scar	---	----	3	9.67
Implant protuberance	---	---	2	6.45
Pin migration	2	6.45	---	-----
Implant failure	---	----	----	-----
No complication	22	67.74	19	61.29
Total	31	100	31	100

Overall plate had more intra op and post op complications like more blood loss, more operative time, superficial infections, deep infections, implant protuberance, ugly scar, difficult implant removal than TENS fixation. In this study nonunion was equal in both TENS and plate fixation groups.

Discussion

This study was conducted in the Department of Orthopedics, M.L.B. Medical College and Hospital, Jhansi (U.P.) on 62 patients of fracture of middle 1/3rd of clavicle, which were randomly divided in two groups, Group I & Group II. Patients of group I were treated by Closed/Open reduction and internal fixation by TENS and patients of group II were, treated by ORIF by plate and screws.

In our study there was no difference in results, in comminuted fracture clavicle whether treated by TENS/plate and screws. However the workers reported better results by open reduction and internal fixation by plate and screws.

Fewer complication encountered were superficial infection, deep infection, ugly scar, implant protuberance, pin migration, nonunion. Superficial infection occurred in 5 cases of group I (TENS) at the entry point whereas 3 patients had superficial infection and two patients had deep infection at site of incision in plating group (group II).None of the cases treated by TENS had any evidence of deep infection at fracture site.

Clavicle is the percutaneous bone without muscle coverage hence two patients had protuberance of plate and 3 patients had ugly scar in patients treated with plate whereas 2 patients had pin migration in TENS group. Incidence of nonunion was

same in each group.

Zeng *et al.* (2015) [12] observed that plate fixation can provide more rigid stabilization than intramedullary pin fixation and may facilitate early mobilization and offer a superior construct for highly comminuted fractures where the bridge plating technique can be implemented. However, this technique may require large incisions and extensive exposure and soft tissue insult which could cause complications such as infection, scarring, and refracture after the removal of the plate. Intramedullary fixation provides an alternative and less invasive technique for the treatment of displaced midshaft clavicular fractures. It has the advantages of obtaining relatively stable fixation that allows axial compression, and preserving the soft tissue envelope, the periosteum and the vascular integrity of the fracture site, which enhances healing.

Chen *et al*. [13] observed that TENS fixation allows for earlier relief of shoulder pain and a more cosmetically satisfactory appearance than plate fixation. In addition, the infection rates may be decreased and fracture callus formation enhanced. However, the main complications of intramedullary fixation are superficial infection, hardware migration, skin irritation. In our study complications are more in plating group as compare to TENS group, which is in accordance of available literature [14-16].

Finally in our study no significant difference was found in function and nonunion rate in both the groups but major complications and union time are more in plate fixation group than TENS group so, TENS fixation is the preferred treatment of choice for fracture middle 1/3rd clavicle.

Over all plate had more intra op and post op complications like more blood loss, more operative time, superficial infections, deep infections, implant protuberance, ugly scar, difficult implant removal than TENS fixation. In this study nonunion was equal in both TENS and plate fixation groups.

Finally in our study no significant difference was found in function and nonunion rate in both the groups but major complications and union time are more in plate fixation group than TENS group so, TENS fixation is the preferred treatment of choice for fracture middle 1/3rd clavicle.

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