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Antero superior plate osteosynthesis versus conservative treatment for diaphyseal clavicle fractures: A prospective comparative study

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Abstract
Background: Clavicle fractures were traditionally treated conservatively but there is growing awareness of non-unioun, mal-unioun leading to shoulder girdle malfunction resulting in unsatisfactory outcomes. Operative intervention is increasingly being advocated to prevent these complications and achieve better outcomes.
Aim: To compare functional outcome, fracture union rates and complication rates of clavicle fractures treated conservatively vs those treated operatively with anatomical locking plate.
Methods: This prospective comparative clinical study conducted at a tertiary trauma center from May 2014 to June 2017.100 patients were enrolled. Fractures were classified according to Allman and AO/OTA scheme. Patients underwent conservative treatment or operative fixation with 3.5mm locking compression plate. Regular follow up at 6 weeks and 3,6,12 months was done clinically and radiologically. Functional outcome was measured using constant murley and DASH score, and complications if any were noted.
Results: Mean time for fracture union was shorter in operative group (14weeks) compared to non-operative group (23weeks). Mean time for functional recovery in operative group was 5.2 weeks compared to 7.3 weeks in conservative group. At 12months, Mean DASH score was 3.8 in operative group and 7.4 in conservative group, and mean Constant Murley Score at 12 months was 93.74 in operative group vs 88.21 in conservative group. Mean DASH and constant murley score was better in operative group throughout the course of study. Conservative group had 26% non-union and 40% malunion rates.10% pts in operative group had prominent hardware, 6 % had superficial surgical site infection, 2% had deep infection. In conservative group, 6% had excellent, 32% had well, 26% had fair and 36% had poor outcome. In operative group 80% had excellent, 16% had well and 4% had fair outcome.
Conclusion: Antero superior plate osteosynthesis helps to achieve anatomical reduction in acute clavicle fractures especially in displaced and comminuted fractures resulting in early healing, faster return to functional activity and better functional outcome while avoiding complications such as non-union and mal-union. It may be considered the standard of care in patients with high functional demand.

Keywords: clavicle fractures, conservative vs operative management, complications, functional outcome

Introduction
The clavicle is named after the musical symbol clavicula (&) for its S shaped curvature with an anterior apex medially and a posterior apex laterally. It is an important part structurally and functionally of the shoulder girdle. Thus maintaining the length, alignment, rotation and angulation after a clavicle fracture is necessary for optimal shoulder joint function.
The middle third of the clavicle represents a transitional zone both in curvature and cross-sectional anatomy thus rendering it a mechanically weak area. It is the thinnest and narrowest portion of the bone and is not supported by any muscles or ligaments.
4% of all fractures involve the clavicle representing 35% of all fractures in the shoulder region. The overall incidence of clavicle fractures is increasing as a result of increase in sports and high velocity injuries and injuries following a fall [1]. 76% of these fractures involve the the middle 1/3 [2-5].
The clavicle fails most commonly in compression. In adults and adolescents it is typically due to moderate-high energy injury such as MVA, sports injury, blow to the point of the shoulder or direct injury to the clavicle. In elderly, it typically occurs after low energy injury such as a simple fall.

The optimal treatment of midshaft clavicle fractures remains controversial. According to Neer, only 3 (0.1%) of 2235 patients with midclavicular fractures treated conservatively failed to heal, whereas nonunion developed in 2
(4.4%) of 45 treated with immediate open reduction and fixation[6].Rowe found a 0.8% incidence of nonunion after closed treatment versus 3.7% after initial surgical treatment [7]. Other studies found 5-20% patients with mid-shaft clavicle fractures develop non-union if treated conservatively [8-11]. Better functional outcome and improved union rates were reported with primary internal fixation compared to non-operative management [12].This has resulted in the pendulum swinging towards increased operative intervention which is associated with its own sets of complications.
In this study we aim to find out whether primary fixation of diaphyseal fractures is assosciated with improved outcomes and describe and compare the complications associated with both operative and non-operative management.

Materials and Methods
Study Design: This clinical study was conducted in a tertiary trauma care and referral center. Duration of study was 3 years rom May 2014 to June 2017.Hundred consenting patients were enrolled into this prospective comparative study after institutional ethical clearance.50 patients were treated conservatively with clavicle brace and arm pouch.50 patients underwent open reduction and internal fixation with 3.5mm pre-contoured locking compression antero-superior plating.

Inclusion criteria: skeletally mature patients, acute closed midshaft clavicle fracture, with complete clinical, demographic and radiological data until fracture healing or development of non-union

Exclusion Criteria: non consenting individuals, previous fracture of the clavicle, open or pathological fracture, fracture more than 2 weeks old. Floating shoulder/other multifocal shoulder girdle injury. Patients with head injury requiring neurosurgical intervention, patients with neurovascular deficits, patients with stroke, patients with ipsilateral upper limb fracture. Any medical/surgical contraindication to surgery.
Thorough history was taken to assess for the mechanism and energy of injury, risk factors, co-morbidities, tobacco-use. Physical examination to asses the condition and integrity of the skin over the fracture, presence of skin tenting, abrasions, neurovascular deficits. Presence of any associated fractures and injuries was noted. The fractures were classified based on Allman classification and AO/OTA classification
Patients were divided into either of 2 groups: Group A consisted of 50 patients managed conservatively. Clavicle brace was applied and an arm pouch was given. Patients were encouraged to perform active shoulder and elbow exercises as tolerated by pain. Load bearing was restricted for upto 6 weeks.
In Group B, 50 patients were treated operatively. After regular blood investigations, ECG, physician fitness and pre anesthetic clearance, patients underwent open reduction and internal fixation with 3.5mm precontoured LCP with antero-superior plating.
Patient is positioned on a radiolucent table in a beach chair position or with a bump to elevate the ipsilateral shoulder. After regional anesthetic block (interscalene) or under general anesthesia, part preparation of the entire upper extremity, the upper chest wall, the sternum and manubrium sternum is done.
Surgical Approach: A gentle curvilinear incision along the superior edge of the clavicle is utilized to expose the platysma and delto-trapezial fascia. Sub-cutaneous dissection is done to identify and preserve the supra-clavicular nerve sensory branches. The platysma is divided and periosteum over the clavicle is exposed at the deltotrapezial fascia. Fracture is exposed after minimal periosteal dissection, taking care to retain the soft tissue attachments of the comminuted fragments. The 2 main fragments are distracted to restore the length of the clavicle. pointed/serrated reduction forceps is used to reduce the angled bone ends in oblique fractures. Large comminuted fragments are temporarily reduced with small pointed bone clamps or k-wires or lag screws if necessary. Thus length, alignment, rotation and axis angulation are restored anatomically.
A 3.5mm precontoured anatomical LCP of appropriate length is selected. The palte is positioned on the reduced bone and attached using plate holding forceps. cortical screws are inserted first either side followed by locking screws. The LCP plate can be used either in compression mode in case of simple transverse/oblique fractures or for biological bridging osteosynthesis in case of comminuted fractures. The final fixation and reduction is assessed and full ROM and stability is confirmed by direct visualization and image intensification. Hemostasis was achieved, the wound closed in layers, and sterile dressing done.
Post operatively patients are given an arm pouch and advised to mobilize the extremity as tolerated by pain. Shoulder abduction upto 90^0 is advised upto 6 weeks. Overhead abduction is restricted.
Follow up was done at 1, 3, 6, and 12months.patient was assessed for clinically and radiologically with a shoulder AP radiograph. Clinically the Range of motion, Pain, condition of the scar, tenderness over fracture site, Dash score and constant murley score were assessed. Radio logically, the progress of fracture unioun was assessed and stability of fixation, loosening of screws, and shortening if any especially in conservatively treated cases was noted. Complications if any were documented.

Results and Observations
Total patients enrolled in the study was 100.50 patients were enrolled in Group A (Conservative treatment) and 50 patients were enrolled in Group B (operative treatment).The average age of patients was 35y (17-74y) in conservative group and 33y (18-67y) in group B. There was preponderance of male patients in both the groups (42 males out of 50 pts in conservative group and 38 males out of 50 pts in operative group). The right side was predominantly involved (76% in conservative groupand 70% in operative group).80% cases in conservative group and 76% cases in operative group involved the dominant hand.44% patients in conservative group and 60% patients in operative group were active smokers.
The most common cause in both the groups was due to motor vehicle accident which accounted for 86% cases. Next most common cause was self fall/fall from height (12%) and 2 patients in operative group suffered direct physical assault with canes and sticks which resulted in the clavicle fracture.
24% patients enrolled in the study had associated injuries.13 patients had single/multiple rib fractures which were treated conservatively.1 patient had diaphyseal femur fracture and 1 patient had diaphyseal tibial fracture both of which were treated by intramedullary nailing.1 patient had an ankle bi-malleolar fracture which was treated surgically.
The mean time to surgery in the operative group was 4.5 days (range 1-13 days).Majority of the patients were operated in the

first week of admission(88%). 12% patients were operated in the second week of admission due to the fixed weekly operative days schedule in our hospital.

The mean time to functional recovery was better in the operative group (5.2 weeks) compared to conservative group (7.3weeks). The mean time for fracture union was 14 weeks in operative group compared to 23 weeks in conservative group. In the conservative group, 64% of fractures united by 23 weeks with 10% fractures having delayed union with the rest going for non-union(26%).In the operative group,96% of fractures united by 14 weeks while 4% of fractures had delayed union.

The mean operative time was 62.58 mins and the mean intra-operative blood loss was 112.80 ml.

The mean Constant and Murley score and DASH score was better in the operative group throughout the course of the follow-up. At 12 months, the mean Constant-Murley score was higher(better) in operative group (93.74+/- 5.81) compared to conservative group(88.21 +/- 4.42) and the mean DASH score at 12m was lower (better) in operative group (3.8 +/- 2.4) than conservative group (7.4 +/- 5.8)

There was 40% malunion rate and 26% non-union rate in conservative group. No cases of non-union or malunion were observed in operative group. In conservative group 26 patients had a cosmetically significant bump and in 30 cases shortening was present compared to 4 cases of shortening in operative group. In operative group 1 patient had decreased sensation in the infraclavicular area, 1 patient had a hypertrophic scar, [5] cases had prominent hardware causing symptoms [3] cases had superficial surgical site infection with subsided with IV antibiotics and regular dressing, case had deep infection leading to plate exposure which was treated by debridement, secondary closure, regular dressings and IVantibiotics.4 patients had persistent pain/irritation at the incision site.

In the conservative group,6%(n=3) had excellent outcome,32%(n=16) had good outcome,26%(n=13) had fair outcome and 36%(n=18) had poor outcome. In the operative grouo, 80% (n=40) had excellent outcome, 16% (n=8) had good outcome and 4%(n=2) had fair outcome.

	Group A: Conservative Management	**Group B: ORIF with antero-superior plate osteosynthesis**
Patient Demographics		
No.of patients	n=50	n=50
Age(years) mean(range)	35 (17-74)	33 (18-67)
Male:Female	42:8	38:12
Dominant side	40	39
Right:left	36:14	35:15
Smokers	22	30
Mechanism of Injury:		
MVA	42	44
Self fall/Fall from height	8	4
Assault	-	2
Assosciated Injuries		
Abrasions	2	6
Rib Fracture	3	10
Femur Diaphyeal Fx	-	1
Tibia diaphyseal Fx	-	1
Ankle bi-malleolar Fracture	-	1
Operative data		
Mean time to surgery (days)	-	4.5 days (1 day-13 days)
Operative time (mins) (mean+/- SD) (range)	-	62.58+/- 12.80 (range 40-95 mins)
Intra-operative blood loss (ml)	-	112.80 +/- 30.76
Radiological Outcome		
Mean time for fracture union (weeks) mean+/- SD (range)	23 weeks +/- 1.08 (range 6-32 weeks)	14 weeks +/- 0.9 (range 6-25 weeks)
Clinical Outcome		
Mean time to functional recovery (weeks) mean+/- SD (range)	7.3 weeks +/- 1.26 (range 3.5 – 10 weeks)	5.2 weeks +/- 1.14 (range 2-7 weeks)
Constant Murley Scores (mean +/- SD)		
6 weeks	66.45 +/- 6.24	70.10 +/- 5.30
3 months	77.18 +/- 5.47	82.54 +/- 4.28
6 months	84.98 +/- 4.96	89.62 +/- 6.44
12 months	88.21 +/- 4.42 (range 62-97)	93.74 +/- 5.81 (range 74-98)
Dash Score at 12 Months	7.4 +/- 5.8 (range 4-24)	3.8 +/- 2.4 (range 2-16)
Functional Outcome based on Constant Score		
Excellent outcome	n=3 (6%)	n=40 (80%)
Good Outcome	16 (32%)	8 (16%)
Fair Outcome	13 (26%)	2 (4%)
Poor Outcome	18 (36%)	0
Complications		
Mal-union	n=20 (40%)	0
Non-union	N=13 (26%)	0
Cosmetic bump	26	0
Shortening	30	4
Peri-incisional numbness/dysesthesia	0	1
Incision site- persistent pain/irritation	0	4

Hypertrophic scar	0	1
Prominent hardware	0	5
Superficial surgical site infection	0	3
Hardware exposed	0	1

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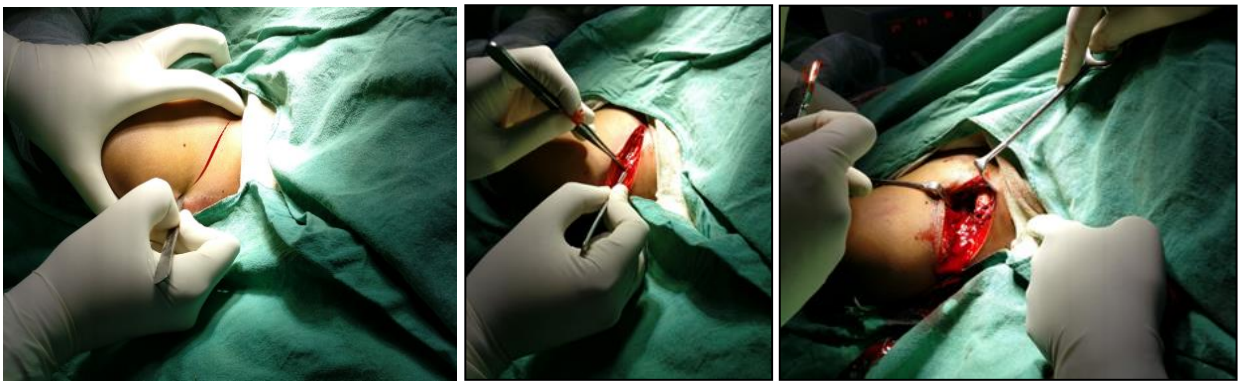
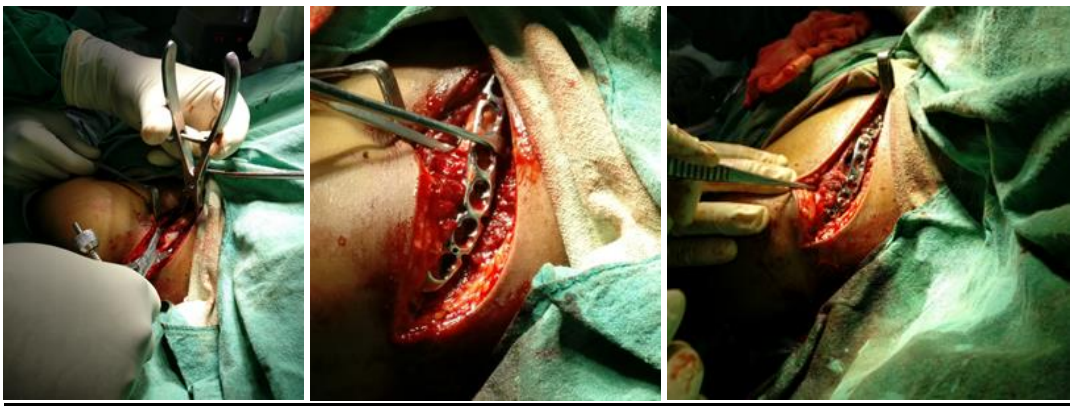
Patint positioning Intrascalene block/GA Surface marking Parts painted & draped



Curvilinear skin incision Deep dissection Exposing fracture site

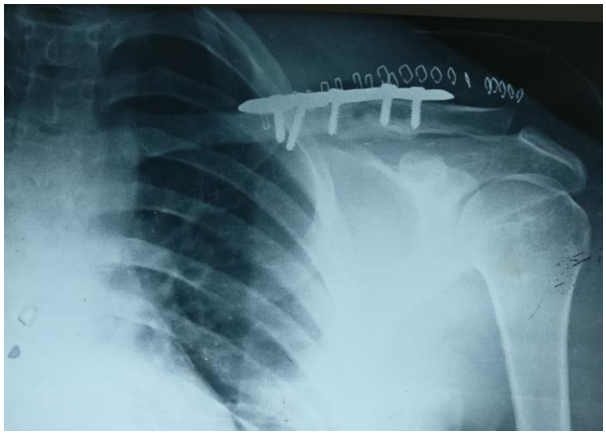


Fracture reduction Plate Positioning Cortical and locking screws fixed

Wound closure

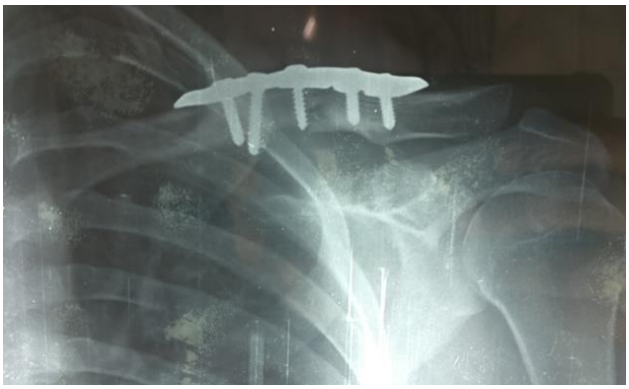
Case 1: 20Y male with acute displaced mid-shaft clavicle fracture following RTA with tenting of skin

Acute displaced Mid-clavicular fracture causing tenting of the skin

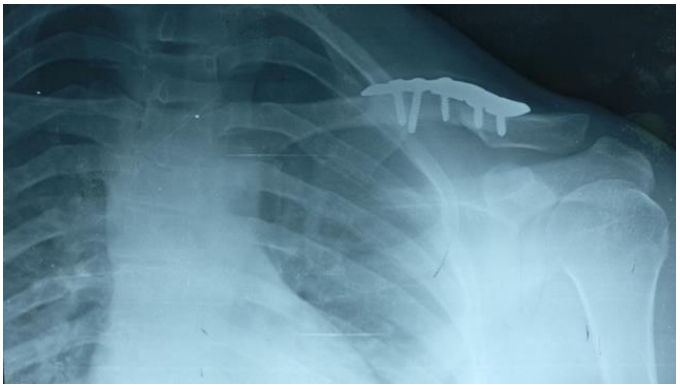


Immediate post-operative pic showing ORIF with antero-superior plating

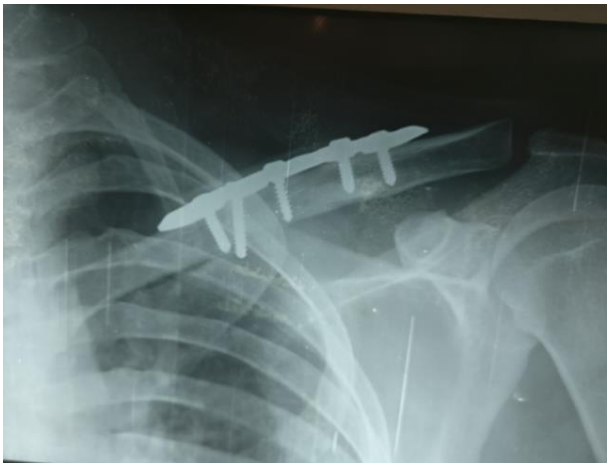
Post-operative 1 month



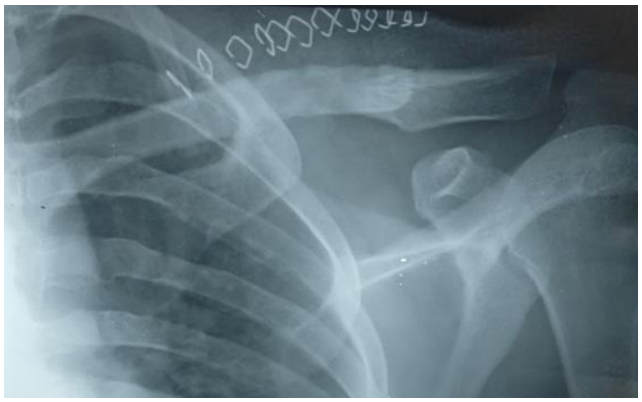
Post-operative 3 months



Post-operative 6 months



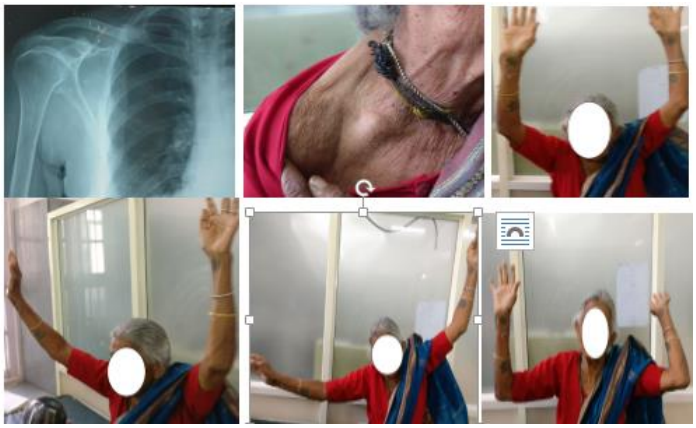
Post-operative 1 year



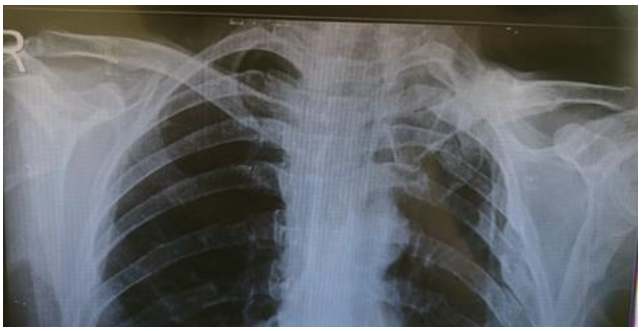
Following implant removal

CASE: 42 y male with clavicle non-union

CASE: 74y female with clavicle mal-union

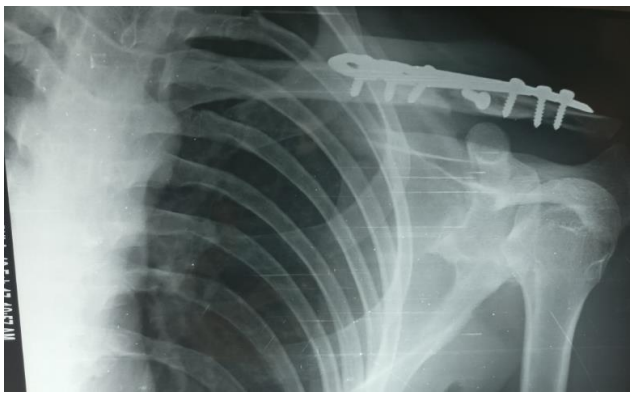


CASE: 72 y male with clavicle mal-union and cosmetic bump



Complications

Patient with hypertrophic scar at the incision site



Cosmetic bump

Discussion

Almost all clavicle fractures were treated conservatively in the past irrespective of the degree of displacement or comminution. Studies by Neer[4] and Rowe[5] had a non-union rate of 0.1% and 0.8% and thus they advocated conservative treatment as the standard of care. But later studies [9, 13-16] showed that the incidence of non-union was much higher in conservatively treated fractures with high incidence of residual pain, mal-union, shoulder stiffness, weakness with poor outcome scores. operative treatment significantly improved union rates and had better patient and surgeon oriented outcome scores. Thus the focus and aim of treatment has shifted from just the prevention of non-union by conservative management to achieve better outcomes through operative intervention.

The mean operative time was 62.58 mins. All patients in operative group underwent an early primary fixation.

The mean time for fracture union was shorter in the operative group. The mean time for functional recovery was shorter in the operative group. Operated patients could be mobilized earlier

and had increased and pain-free ROM as compared to non-operative group who had initial painful and limited ROM. Thus these patients had more rapid fracture healing and early return to work. This is important in decreasing the economic, social and psychological burden of clavicle fractures.

The constant and DASH score were better in the operated group at each point during the follow-up period and at the end of the follow up period. Outcome was better in operative group. More patients in the operative group had excellent outcome (80%) compared to non-operative group (6%). Poor outcome was observed in 36% of patients in the non-operative group.

In the non-operative group, 40% had mal-union and 26% had non-union. These complications were not seen in the operative group. But operative group had its own set of complications which included peri-incisional numbness (2%), persistent pain/irritation at the incision site (8%), hypertrophic scar (2%) which was treated with intralesional steroid, prominent hardware (10%), superficial surgical site infection (6%) which subsided with IV antibiotics, plate exposure (2%) which was treated with secondary closure and IV antibiotics. There were no iatrogenic neuro-vascular injuries or implant failures in the operative group.

Limitations of the study is that this is a single-center study, there is lack of cost-analysis between the two groups, multiple surgeons with varying surgical skill and experience performed the surgery in operative group, limited follow up of 1 year with need of results of long term follow-up.

Conclusion

ORIF with plate osteosynthesis of acute clavicle fractures especially in displaced and comminuted fractures results in earlier fracture union, early return to functional activity, faster recovery, less morbidity, significant decrease in non-union and malunion which are common in conservative management. Operative treatment also results in better functional outcome than conservative management. This is especially important in individuals with high functional demand such as athletes, manual laborers, and young active adults.

Conflict of interest: none

Informed *Consent*: All patients participating in the study were enrolled after taking an informed consent

Ethical Approval: This study was reviewed and approved by the institutional ethics committee.

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