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FUNCTIONAL OUTCOME OF DISPLACED MIDSHAFT CLAVICLE FRACTURES TREATED BY PLATE OSTEOSYNTHESIS VERSUS MINIMALLY INVASIVE TITANIUM ELASTIC NAIL FIXATION.

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ABSTRACT

The management of clavicle fractures has dramatically changed over the last decade. Classic teaching had suggested that even if both ends of the clavicle were to be widely separated, it wound go on to heal. However longitudinal studies in Sweden and recent experience throughout North America and Europe have suggested that this old aged may no more to valid now.In a review of 690 clavicle fractures 82% involved the middle-third segment of the bone. Patients presenting with fracture clavicle male predominantly (male to female ratio2:1) between the ages of 10 and 40 years, and injured in a road traffic accident, fall from height or sporting activity, especially cycling.This was greatly influenced by two influential articles from 1960's. Neer and Rowe reported a non-union rate of 0.1% in 2235 patients and 0.8% in 69 patients respectively with mid-shaft

KEYWORD

midshaft clavicle fracture, plate osteosynthesis, titanium elastic nail fixation.

ARTICLE HISTORY

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INTRODUCTION:

The emerging gold standard for displaced mid-shaft clavicular fractures is fixation. Two operative techniques are commonly used for internal fixation of displaced mid-shaft clavicle fracture viz; Plate fixation and Intra-medullary nailing with a titanium elastic nail.Functional results after both the techniques proved to be superior compared with nonoperative treatment of displaced mid-shaft clavicle fracture.Moreover, a recent meta-analysis revealed a significant lower non-union rates after surgical treatment.Plate fixation was the standard surgical therapy for midshaft clavicular fractures.A 2.2% non-union rate was reported in a review synthesizing the results of earlier studies on displaced clavicular fractures treated by plate fixation. However, clavicular plates require larger skin incisions and extensive soft tissue stripping, which increase the risk for non-union, wound infection and an unsightly scar. Moreover,clavicle re-fracture occurred after plate removal in around 8% of the patients. The Knowles pin, the Rockwood pin, and the titanium elastic nail have been subsequently developed to minimize post-operative complications. From a bio mechanical perspective, intra-medullary implant positioning is ideal.

With the advantages of intact fracture hematoma, maintenance of reduction, less soft tissue dissection and periosteal stripping, all of which can enhance accelerate fracture healing. Thus intra-medullary fixation has, of late, been gaining attention for its superior performance. Unfortunately, hardware migration (including medial migration and lateral perforation) has been a problem with intra-medullary fixation. The rate of titanium elastic nail migration ranges between 4.5% and 26.6% in the literature. Overall, different complication rates were reported for these two fixation methods, but no significant differences were noted for most of them. Significantly more instances of symptomatic hardware, infection, non-union, wound dehiscence, and refractures were reported with plate fixation than with intra-medullary fixation in these studies. Implant removal in the plating group needed another surgery done under general anaesthesia, and a large-sized incision would have to be made, while in the titanium elastic nail group the nail was removed as an out-patient procedure

AIM OF THE STUDY

This short term prospective study is designed to compare the clinical, functional and radiological outcomes and patient satisfaction in displaced mid-shaft clavicular fractures treated with titanium elastic intra-medullary nailing and plate osteosynthesis. The results shall be tabulated and analyzed using the Constant Shoulder Score and DASH scoring system.

REVIEW OF LITERATURE

Traditionally, clavicle fractures have been treated with non-

operative management, but high-quality randomized studies have recently begun to change the evidence based management of these fractures. Conservative management of these fractures results in an approximately 5 % of nonunion rate.[30] While non-operative management remains the mainstay of treatment for most mid-shaft clavicle fractures, the indications for surgery may be expanding. Recent studies have showed a poorer outcome in cases of displaced midshaft clavicle fractures that were treated non-operatively. In comparison to surgically treated patients. Three types of fixation are available for middle-third clavicle fractures: intramedullary devices, plates, and external fixators. Intramedullary fixation can be done by smooth or threaded K- wires, Steinman pins, Knowles pins, Hagie pins, Rush pins or cannulated screws. Plate fixation can be done with a 3.5-mm dynamic compression plate (DCP), low-contact dynamic compression plates, reconstruction plates or anatomical locking compression plates with at least three screws (six cortices) in both the medial and lateral fragment each, and an inter-fragmentary lag screw whenever the fracture pattern shall permit it. Currently, open reduction and internal fixation with a anatomical locking compression plate is the standard method; however, intra-medullary fixation is an equally effective alternative Poigenfurst et al., followed 122 patients after plating of displaced clavicle fractures. There were four re-fractures after plate removal. The reason behind this higher refracture rate after implant removal in the plating group is that plate fixation provides a rigid fixation leading to primary bone healing: that's why, after plate removal, the mechanical strength of the healed fracture site is reduced, explaining higher re-fracture rates. Along with this, screw holes may act as focal points for stress, leading to re-fractures. Secondary bone healing occurs in cases of fractures treated with intramedullary fixation devices so the re-fracture rate after removal of the implant is significantly lower in these cases.

SURGICAL AND APPLIED ASPECTS:

The clavicle is an S-shaped bone that acts as the only osseous link between the upper extremity skeleton and the thorax. It serves as a solid strut to position the upper limb away from the trunk and enhance more global positioning and use of the limb. When this strut is fractured and either left untreated or not repaired adequately, clavicular mal-union can occur. The subsequent shortening of the clavicle decreases the moment-generating capacity of the upper extremity and results in impaired mobility. Preserving the length and anatomy of the clavicle is therefore very important in maintaining optimal function of the upper extremity.

FRACTURE BIOMECHANICS:

The clavicle being an S- shaped long bone has biomechanical behavior dissimilar to that of a straight tubular long bone. Under compression load, along the axis, the force produces middle third clavicle fractures.

RISK FACTORS FOR NON-UNION OF MID-SHAFT CLAVICULAR FRACTURES:

Clavicle shortening >15-20mm, Female sex, Fracture comminution, Fracture displacement, Greater extent of initial trauma, Older age.

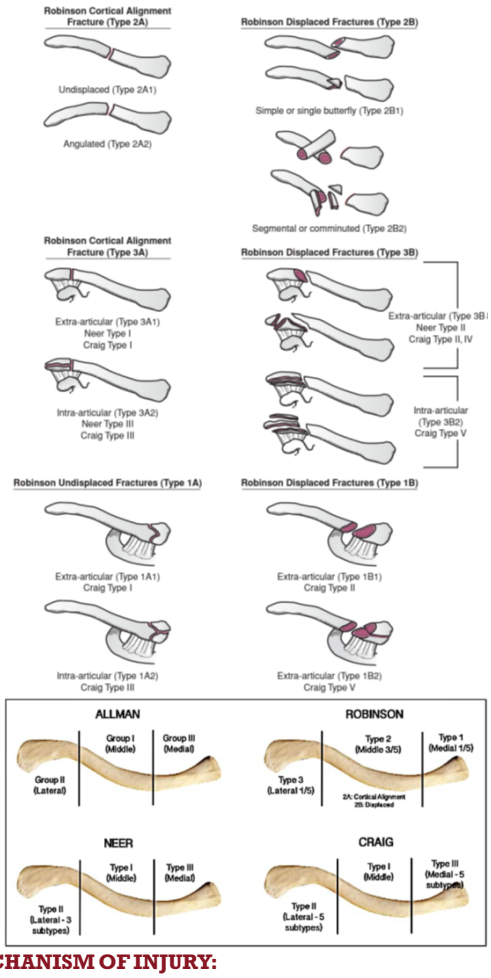
FRACTURE CLASSIFICATION USED IN THE PRESENT

Table 1
Classification of Clavicle Fractures

Group/ Type	Allman Classification	Neer Classification	Robinson Classification	Craig Classification
1	Group I: Middle third fracture	Type I: Middle third clavicle fracture	Type 1: Medial fifth clavicle fractures: Nondisplaced Extra-articular Intra-articular Displaced Extra-articular Intra-articular	Type I: Middle third fractures
2	Group II: Fracture distal to CCL, nonunion common	Type II: Lateral third fracture; split into 3 subtypes: Type I, fracture medial to CCL Type II, fracture occurs at level of CCL-trapezoid remaining intact with distal segment Type III, fracture lateral to CCL entering the AC]	Type 2: Middle 3/5th clavicle fractures: Type 2A: Cortically aligned fractures Nondisplaced Angulated Type 2B: Displaced fractures Simple wedge type Multifragmentary, segmental	Type II: Distal third fractures: Minimally displaced Displaced fractures, fracture medial to the CCL and trapezoid intact Conoid torn, trapezoid intact Articular surface fracture Fractures in children Intact CCL attached to periosteal sleeve, proximal fragment displaced Comminuted fractures
3	Group III: Proximal end clavicle fractures	Type III: Medial third fractures	Type 3: Lateral fifth clavicle fractures: Nondisplaced Extra-articular Intra-articular Displaced Extra-articular Intra-articular	Type III: Proximal third fractures: Minimally displaced Displaced Intra-articular Epiphyseal separation Comminuted

Abbreviations: ACI, acromioclavicular joint; CCL, conoclavicular ligament.

STUDY: ROBINSON CLASSIFICATION:



MECHANISM OF INJURY:

1. Traumatic - Most common cause: Fall on affected shoulder (87%), Direct impact (7%), Fall onto an out-stretched hand (6%).
2. Non-traumatic causes-Stress fractures, Pathological fractures (Infection, Tumour, AV mal-formations),,Due to violent muscle contractions during seizures.
3. Birth injuries:8/ 1000 live births associated with forceps delivery, Prolonged second stage labour, Right side mostcommonly affected because Left Occipito-Anterior position (LOA).

ASSOCIATED INJURIES:

-9 % Clavicular fractures associated with rib fractures, Brachial plexus injuries most common with proximal third fractures, medial cord mostly affected, Acromio- clavicular and sterno-clavicular dislocations, Scapulo- thoracic dissociation, Head and neck injuries ,Pneumo- thorax, haemo-thorax, injury to trachea andbronchi, Vascular injuries: Uncommon due to covering by subclavius and deep fascia, Very rarely open injuries.

INDICATIONS FOR PRIMARY FIXATION OF MIDSHAFT CLAVICLE FRACTURES:

Displaced fractures with displacement > 2cm, Shortening >2cm, Fractures with comminution, Open fractures, Impending soft tissue compromise, Scapulo-thoracic dissociation, Neuro-vascular injuries, Floating shoulder (clavicle fracture with glenoid neck fracture; fixation for clavicle alone), High energy closed fractures, Poly-trauma patient requiring upper extremity function, Patient motivation with early return of activities, Painful non-union, Fracture of the lateral end near the AC joint in adults, Bilateral clavicle and segmental fracture

MATERIALS AND METHODS

Study design : Prospective Comparative Study
Study period : august 2019 to september 2021 (26Months)

Recruitment period : 14 Months.

Study site : Sree Balaji Medical College& Hospital, Chrompet, Chennai-44.

Study population : Patients attending our Orthopaedic out-patient department and Casualty.

Minimum Follow-up period: 26months.

INCLUSION CRITERIA:

1. Male and female in the age group 26 to 45 were included in the study.
2. Fractures reporting within 15 days of injury alone were included.
3. In this study we have included angulated mid-shaft clavicle Robinson (type 2A2) fractures and displaced mid-shaft clavicle Robinson (type 2B1) fractures.

EXCLUSION CRITERIA:

1. Patients not confirming to the above age group were excluded.
2. Fracture reporting later than 15 days.
3. Open fractures were excluded.
4. Pre-existent morbidity of the ipsilateral arm, shoulder or hand, were excluded.
5. Pathological fractures were excluded.
6. Presence of associated neuro-vascular injury was excluded.

EVALUATION

CLINICAL EVALUATION:

Patient presenting at the OPD or casualty of the hospital with suspected clavicular fracture were first given analgesic injection (diclofenac or piroxicam) and the arm was supported in a arm sling. Skin assessment was done and the neurovascular status checked. Status of acromio-clavicular and sterno-clavicular joint is clinically checked. X-Ray of relevant side was ordered and pre-operative investigations were sought.Medical and anaesthetic fitness were obtained on priority basis.

CONSTANT SHOULDER SCORE:

Appendix 1: Data capture sheet: shoulder Score of Constant and murley

Constant Shoulder Score

Clinician's name (or ref) ----------

Patient's name (or ref) ----------

Answer all questions, selecting just one unless otherwise stated

During the past 4 weeks.....

1. Pain

- Severe
- Moderate
- Mild
- None

2. Activity Level (check all that apply)

- yes / no Unaffected Sleep
- yes / no Full Recreation/Sport
- yes / no Full Work

3. Arm Positioning

- Up to Waist
- Up to Xiphoid
- Up to Neck
- Up to Top of Head
- Above Head

4. Strength of Abduction [Pounds]

0	13-15
1-3	15-18
4-6	19-21
7-9	22-24
10-12	>24

RANGE OF MOTION

5. Forward Flexion

- 31-60 degrees
- 61-90 degrees
- 91-120 degrees
- 121-150 degrees
- 151-180 degrees

6. Lateral Elevation

- 31-60 degrees
- 61-90 degrees
- 91-120 degrees
- 121-150 degrees
- 151-180 degrees

7. External Rotation

- Hand behind Head, Elbow forward
- Hand behind Head, Elbow back
- Hand to top of Head, Elbow forward
- Hand to top of Head, Elbow back -
- Full Elevation

8. Internal Rotation

- Lateral Thigh
- Buttock
- Lumbosacral Junction
- Waist (L3)
- T12 Vertebra
- Interscapular (T7)

Grading the Constant Shoulder Score
(Difference between normal and Abnormal Side)

>30 Poor 21-30 Fair 11-20 Good <11 Excellent

The Constant Shoulder Score is ____

DASH SCORING SYSTEM:

The Disabilities of the Arm, Shoulder and Hand (DASH) Score

Clinician's name (or ref) ..... **Patient's name (or ref** .....

INSTRUCTIONS: This questionnaire asks about your symptoms as well as your ability to perform certain activities. Please answer *every question* , based on your condition in the **last week**. If you did not have the opportunity to perform an activity in the past week, please make your *best estimate* on which response would be the most accurate. It doesn't matter which hand or arm you use to perform the activity; please answer based on you ability regardless of how you perform the task.

Please rate your ability to do the following activities in the last week.

1. Open a tight or new jar	○ No difficulty	○ Mild difficulty	○ Moderate difficulty	○ Severe difficulty	○ Unable
2. Write	○ No difficulty	○ Mild difficulty	○ Moderate difficulty	○ Severe difficulty	○ Unable
3. Turn a key	○ No difficulty	○ Mild difficulty	○ Moderate difficulty	○ Severe difficulty	○ Unable
4. Prepare a meal	○ No difficulty	○ Mild difficulty	○ Moderate difficulty	○ Severe difficulty	○ Unable
5. Push open a heavy door	○ No difficulty	○ Mild difficulty	○ Moderate difficulty	○ Severe difficulty	○ Unable
6. Place an object on a shelf above your head	○ No difficulty	○ Mild difficulty	○ Moderate difficulty	○ Severe difficulty	○ Unable
7. Do heavy household chores (eg wash walls, wash floors)	○ No difficulty	○ Mild difficulty	○ Moderate difficulty	○ Severe difficulty	○ Unable
8. Garden or do yard work	○ No difficulty	○ Mild difficulty	○ Moderate difficulty	○ Severe difficulty	○ Unable
9. Make a bed	○ No difficulty	○ Mild difficulty	○ Moderate difficulty	○ Severe difficulty	○ Unable
10. Carry a shopping bag or briefcase	○ No difficulty	○ Mild difficulty	○ Moderate difficulty	○ Severe difficulty	○ Unable
11. Carry a heavy object (over 10 lbs)	○ No difficulty	○ Mild difficulty	○ Moderate difficulty	○ Severe difficulty	○ Unable
12. Change a lightbulb overhead	○ No difficulty	○ Mild difficulty	○ Moderate difficulty	○ Severe difficulty	○ Unable
13. Wash or blow dry your hair	○ No difficulty	○ Mild difficulty	○ Moderate difficulty	○ Severe difficulty	○ Unable
14. Wash your back	○ No difficulty	○ Mild difficulty	○ Moderate difficulty	○ Severe difficulty	○ Unable
15. Put on a pullover sweater	○ No difficulty	○ Mild difficulty	○ Moderate difficulty	○ Severe difficulty	○ Unable
16. Use a knife to cut food	○ No difficulty	○ Mild difficulty	○ Moderate difficulty	○ Severe difficulty	○ Unable
17. Recreational activities which require little effort (eg cardplaying, knitting, etc)	○ No difficulty	○ Mild difficulty	○ Moderate difficulty	○ Severe difficulty	○ Unable
18. Recreational activities in which you take some force or impact through your arm, shoulder or hand (eg golf, hammering, tennis, etc)	○ No difficulty	○ Mild difficulty	○ Moderate difficulty	○ Severe difficulty	○ Unable
19. Recreational activities in which you move your arm freely (eg playing frisbee, badminton, etc)	○ No difficulty	○ Mild difficulty	○ Moderate difficulty	○ Severe difficulty	○ Unable
20. Manage transportation needs (getting from one place to another)	○ No difficulty	○ Mild difficulty	○ Moderate difficulty	○ Severe difficulty	○ Unable
21. Sexual activities	○ No difficulty	○ Mild difficulty	○ Moderate difficulty	○ Severe difficulty	○ Unable

22.	During the past week, *to what extent* has your arm, shoulder or hand problem interfered with your normal social activities with family, friends, neighbours or groups?	Not at all	Slightly	Moderately	Quite a bit	Extremely
23.	During the past week, were you limited in your work or other regular daily activities as a result of your arm, shoulder or hand problem?	Not limited at all	Slightly limited	Moderately limited	Very limited	Unable
	Please rate the severity of the following symptoms in the last week					
24.	Arm, shoulder or hand pain	None	Mild	Moderate	Severe	Extreme
25.	Arm, shoulder or hand pain when you performed any specific activity	None	Mild	Moderate	Severe	Extreme
26.	Tingling (pins and needles) in your arm, shoulder or hand	None	Mild	Moderate	Severe	Extreme
27.	Weakness in your arm, shoulder or hand	None	Mild	Moderate	Severe	Extreme
28.	Stiffness in your arm, shoulder or hand	None	Mild	Moderate	Severe	Extreme
29.	During the past week, how much difficulty have you had sleeping because of the pain in your arm, shoulder or hand?	No difficulty	Mild difficulty	Moderate difficulty	Severe difficulty	So much I can't sleep
30.	I feel less capable, less confident or less useful because of my arm, shoulder or hand problem	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree

Thank you very much for completing all the questions in this questionnaire.

The Disabilies of the Arm, Shoulder and Hand (DASH) Score is 0

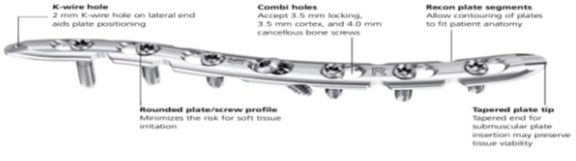
(**NB.** A DASH score may not be calculated if there are greater than 3 missing items.)

Grading as per DASH Scores Achieved
Excellent : Less than 70
Good : 71-80
Fair : 81-90
Poor : 91-100

NATURE OF IMPLANT USED

1. OPEN REDUCTION AND INTERNAL FIXATION WITH PLATES AND SCREWS:

Pre-contoured clavicle locking plates were used which were side specific. Plates were placed anteriorly or on the superior surface of clavicle (Tension site). At least 3 cortical screws (6cortices) were engaged on both sides of the fracture site and additional if possible, a lag screw was also engaged either through the plate or outside it.



2. CLOSED/OPEN REDUCTION AND INTRAMEDULLARY FIXATION:

Tens nail size of 2 to 2.5 mm were used. With the help of image intensifier entry point was made 1.5 cm lateral to sternal end of clavicle. If any difficulty was encountered in negotiating the nail, a small incision was made at the fracture site to guide the nail.

ADVANTAGES AND DIS-ADVANTAGES OF THE TWO IMPLANT SYSTEMS

ADVANTAGES:

-Good anatomical reduction in plating, Early mobilization in plating, Minimal soft tissue dissection, in nailing, Less incidence of post-traumatic stiffness, in nailing, Fewer incidences of mal-union and non-union, in plating.

DISADVANTAGES:

-Infection, especially superficial infection in plating where there is a longer operating time, a longer incision and more of soft tissue dissection, Injury to underlying neuro-vascular structures, in plating, nailing Injury to supra-clavicular nerve leading to persistent pain, in plating, Danger of migration of pins into thorax, in plating, Screw loosening with implant failure, in plating, Cosmetic problem, in plating, Possibility of re-fracture after implant removal, in plating, Necessary to remove implant, in nailing with migration.

SURGICAL STEPS:

- All patients informed about the procedure, complications

and post-operative protocols and informed consent obtained from the patients, Prophylactic third generation cephalosporin parenteral antibiotics were given on induction. Under GA, with patient in the supine posture, with sand bag in interscapular region, parts are painted and draped, Anterior approach to mid-shaft clavicle was used, Attempts are made to spare the supraclavicular nerve, After fracture was exposed, reduction was achieved using small fragment pointed reduction clamps, A pre-contoured locking compression plate is placed on antero-superior surface (tension side) of the clavicle and fixed to medial or lateral fragment (depending on the fracture pattern) using a single bi-cortical screw, Plate is fixed to the other segment using a compression screw, Wherever amenable, lag screws were placed through the plate or separately, If possible a minimum of 3 bicortical screws are used On Both sides of the fracture, Fascia, subcutaneous tissue and skin were closed in layers, An arm pouch sling was given for support and pain relief.

Intra-Op Pictures:


POST-OPERATIVE PROTOCOL FOR PLATING GROUP

In the immediate post-operative period patient's arm was supported by arm sling for patient comfort. POD-2 drain if kept removed and the dressing changed. Post-operative check X-Rays were taken for fracture reduction and plate fixation. 5th postoperative day patient discharged from the wards. 13th day sutures removed, sling discontinued and gentle pendulum exercises started. But resisted works, strengthening exercises and hard work not allowed. At 6 weeks X-Ray taken again for evaluation of bony union.If X-Ray showed signs of union patient allowed for resisted and strengthening exercises.

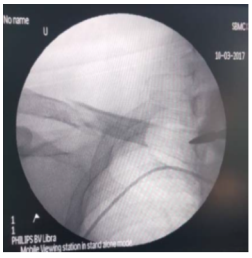
OPERATIVE PROCEDURE OF CRIF/ORIF WITH TENS

Step by step pictorial representation of surgical steps of Nailing procedure All patients informed about the procedures, complications and post-operative protocols. Informed consent had been obtained,Prophylactic antibiotics were given at the time of induction. Under GA, patient positioned in a radiolucent table. In Beach Chair position with sand bag in the interscapular region parts were painted and draped,1 to 2 cm incision made in the medial end of clavicle 1.5 cm from the Sterno-clavicular joint, With the help of 2.5mm drill bit a small window created in the anterior wall of clavicle, the window widened with the help of small bone awl,Then elastic nail size of 2 or 2.5 mm size introduced with a T handle, with gentle oscillating movements the nail was advanced up to the fracture site,With the help of image intensifier nail passed into the lateral segment, if closed reduction found to be unsuccessful a small incision made at the fracture level to negotiate the fragments,The nail was advanced into the lateral segment and nail was cut off at the site of insertion leaving 1cm length for easy removal,Skin was closed without a drain, and sterile dressing applied.

Intra-Operative Pictures:



Intra-Operative C-Arm Pictures:




RESULTS:

Age Range (In Years)	Plating Group		Intra-Medullary Nailing group		Sample Total 'n' (% age)
	Male 'n' (% age)	Female 'n' (% age)	Male 'n' (% age)	Female 'n' (% age)	
26-30	9(45)	1(5)	8(40)	3(15)	21(52.5)
31-35	4(20)	1(5)	5(25)	0(0)	10(25)
36-40	3(15)	0(0)	1(5)	1(5)	5(12.5)
41-45	1(5)	1(5)	1(5)	1(5)	4(10)
Total	17(85)	3(15)	15(75)	5(25)	40(100)

TABLE : SIDEDNESS OF INJURY

Side	Plating Group		Intra-Medullary Nailing group		Total 'n' (%age)
	Male 'n' (%age)	Female 'n' (%age)	Male 'n' (%age)	Female 'n' (%age)	
Right	13(65)	2(10)	12(60)	3(15)	30(75)
Left	4(20)	1(5)	3(15)	2(10)	10(25)
Total	17(85)	3(15)	15(75)	5(25)	40(100)

TABLE:MODE OF INJURY

Mode of Injury	Plating Group		Intra-Medullary Nailing group		Total 'n' (%age)
	Male 'n' (%age)	Female 'n' (%age)	Male 'n' (%age)	Female 'n' (%age)	
RTA	9(45)	1(5)	10(50)	2(10)	22(55)
Fall on Outstretched hand	3(15)	1(5)	2(10)	2(10)	8(20)
Fall from height	2(10)	0(0)	1(5)	0(0)	3(7.5)
Sports Injury	2(10)	1(5)	1(5)	1(5)	5(12.5)
Assault	1(5)	0(0)	1(5)	0(0)	2(5)
Total	17(85)	3(15)	15(75)	5(25)	40(100)

FRACTURE TYPE – ROBBINSON TYPE 2A2 AND 2B1 INJURIES:

Fracture type	Plating Group		Intra-Medullary Nailing group		Total 'n' (%age)
	Male 'n' (%age)	Female 'n' (%age)	Male 'n' (%age)	Female 'n' (%age)	
2A2	6(30)	1(5)	5(25)	2(10)	14(35)
2B1	11(55)	2(10)	10(50)	3(15)	26(65)
Total	17(85)	3(15)	15(75)	5(25)	40(100)

TIME ELAPSED BETWEEN INJURY AND SURGERY:

Days elapsed between injury and surgery (in days)	Plating Group		Intra-Medullary Nailing group		Total 'n' (%age)
	Male 'n' (%age)	Female 'n' (%age)	Male 'n' (%age)	Female 'n' (%age)	
0-3	9(45)	2(10)	11(55)	3(15)	25(62.5)
4-7	3(15)	1(5)	3(15)	2(10)	9(22.5)
8-11	4(20)	0(0)	1(5)	0(0)	5(12.5)
12-15	1(5)	0(0)	0(0)	0(0)	1(2.5)
Total	17(85)	3(15)	15(75)	5(25)	40(100)

TABLE: ASSOCIATED INJURY

Associated Injuries	Plating Group 'n' (%age)	Intra-Medullary Nailing group 'n' (%age)	Total 'n' (%age)
Isolated Clavicle	15(75)	13(65)	28(70)
Ribs	1(5)	2(10)	3(7.5)
Pneumothorax	1(5)	1(5)	2(5)
Cervical Spine	0(0)	2(10)	2(5)
AC Joint Disruption	1(5)	0(0)	1(2.5)
Humeral Head	0(0)	1(5)	1(2.5)
Maxillary Bone	1(5)	0(0)	1(2.5)
Head Injury	1(5)	1(5)	2(5)
Neurovascular Injury	0(0)	0(0)	0(0)
Total	20(100)	20(100)	40(100)

Nature of Complication	Plating Group 'n' (%age)	Intra-Medullary Nailing group 'n' (%age)
Superficial Infection	1(5)	1(5)
Deep Infection	1(5)	0(0)
Delayed Union	1(5)	0(0)
Shoulder Stiffness	1(5)	0(0)
Nail Migration	0(0)	1(5)
Implant/Screw Loosening	0(0)	0(0)
Total	4(20)	2(10)

COMPLICATIONS:

DURATION OF HOSPITAL STAY AFTER SURGERY:

No of days of hospital stay post-surgery	Plating Group 'n' (%age)	Intra-Medullary Nailing group 'n' (%age)
3-5	0(0)	4(20)
6-8	0(0)	4(20)
9-11	4(20)	4(20)
12-14	10(50)	5(25)
15-17	6(30)	3(15)
Total	20(100)	20(100)

FUNCTIONAL OUTCOME SCORING: COMPARATIVE STUDY AS ASSESSED BY CONSTANT SHOULDER SCORE

CSS Grading	Plating Group 'n' (%age)	Intra-Medullary Nailing group 'n' (%age)
Excellent	7(35)	12(60)
Good	10(50)	6(30)
Fair	2(10)	2(10)
Poor	1(5)	0(0)
Total	20(100)	20(100)

FUNCTIONAL OUTCOME SCORING COMPARATIVE STUDY ASASSESSED BY DASH SHOULDER SCORE:

DASH Grading	Plating Group 'n' (%age)	Intra-Medullary Nailing group 'n' (%age)
Excellent	3(15)	8(40)
Good	10(50)	10(50)
Fair	4(20)	2(10)
Poor	3(15)	0(0)
Total	20(100)	20(100)

FUNCTIONAL OUTCOME COMPARISON BETWEEN CONSTANT SHOULDER SCORE vs DASH SCORE

Grading	Plating Group		Intra-medullary nailing Group	
	CSS 'n' (%age)	DASH 'n' (%age)	CSS 'n' (%age)	DASH 'n' (%age)
Excellent	7(35)	3(15)	12(60)	8(40)
Good	10(50)	10(50)	6(30)	10(50)
Fair	2(10)	4(20)	2(10)	2(10)
Poor	1(5)	3(15)	0(0)	0(0)
Total	20(100)	20(100)	20(100)	20(100)

RESULTS:

Conforming to our inclusion criteria, 20 patients got recruited each in the plating group and in the intra-medullary nailing group. There was a male preponderance of 85% in the plating group and of 75% in the intra-medullary nailing group. Maximum number of patients were in the age group of 26 to 30 years, viz; 50% (n=10) in the plating group and 55% (n=11) in the intra-medullary nailing group. Right sided clavicular injuries were common in our study viz; 75 (n=15) of cases in the plating group and 75% (n=15) in the intramedullary nailing group. With regard to the mode of injury RTA dominated in both the groups viz; 50% (n=10) of cases in the plating group and 60% (n=12) in the nailing group. Among the fracture pattern treated 35% (n=7) cases were of the 2A2 Robinson type in the plating group and 35% (n=7) in the intra-medullary nailing group. Robinson type 2B1 constituted 65% (n=13) of cases in the plating group and 65% (n=13) of cases in the intra-medullary nailing group. Locking compression side specific clavicular plates were used for all cases in the plating group. In the nailing group TENS nail of diameter 2.5mm were used for 12 male patients and in the remaining 8 female cases 2mm TENS nail were used. The mean time elapsed between injury and surgery was 3.9 days for the plating group and 3.1 days for the intramedullary nailing group. Associated other injuries existed in 25% of the cases in the plating group and in 35% of the cases in the 62 medullary groups. There were in all 20% (n=4) of cases of complication in the plating group and 10% (n=2) of cases with complications in the intra-medullary nailing group. The mean duration of stay post-surgery was 13.3 days in the plating group and 9.85 days in the intra-medullary nailing group.

Assessment using the Constant Shoulder Score yielded 85% (n=17) of cases with good to excellent result in the plating group and 90% (n=18) of cases with good to excellent results in the intra-medullary nailing group. Function outcomes, assessed using the DASH shoulder score yielded 65% (n=13) of cases with good to excellent results in the plating group, as compared to 90% (n=18) of cases in the intra-medullary nailing group. The mean blood loss was 102 ml in the plating group as compared to 48 ml in the intra-medullary nailing group. The mean operating time was 41 minutes for the plating group, as compared to 27 minutes in the intra-medullary nailing group. However there was a 3.5 minute of C-Arm exposure in the intra-medullary nailing group, which was totally avoidable in the plating group. The average time to union was 12.2 weeks in the plating group and was 13.9 weeks in the intramedullary nailing group. Shoulder mobilisation was started POD1 for the plating group and in the intra-medullary nailing group it was delayed upto 3 weeks after surgery.

CASE ILLUSTRATIONS

CASE I (ORIFWITH PLATING)

CASE – II (CRIFWITH NAILING)

COMPLICATIONS

Infection(Plating)

Nail migration

DISCUSSION

From Hippocratic period, the middle one-third clavicle fractures were treated conservatively. Numerous conservative treatment options have been described to immobilize and align the fracture. The closed treatment methods include, arm sling or a figure of eight bandage. It has a very high non-union and mal-union rate.Two-third of the conservatively managed middle one-third clavicle fractures will end up in some degree of mal-union. Shortening of about 1.4–2 cm has been reported to be critical deficit for development of a symptomatic mal-union. This results in pain,loss of strength,rapid fatigability, paraesthesia of the arm andhand, problems with sleeping on the back and cosmetic complaints. The reported incidence of unsatisfactory outcome after closed treatment of displaced middle one-third clavicle fractures varied from 4.4 to 31%.The most common complaints is residual pain during activity or even at rest and loss of strength and they are mainly due to shortened lever arm of the shoulder girdle which changes the orientation of the glenoid with winging of scapula. Change in orientation of glenoid increases the shearing force across the shoulder joint, resulting in protraction as well as tilt of scapula can result in pain during lying on the back.The shortened clavicle has a negative effect on muscle tendon tension resulting in loss of strength and endurability.It also changes the resting angle of the sterno-clavicular joint resulting in change of load in both acromio-clavicular and sterno-clavicular joint with increase incidence of acromio-clavicular arthritis. Large callus formation after mal-union can lead to neurovascular problems as a result of thoracic outlet syndrome.Anatomically aligned united mid one-third shaft of clavicle fracture is always superior over conservatively treated clavicle.The only way to achieve this is an open reduction with internal fixation with plate osteosynthesis or a percutaneous procedure with Titanium elastic nail fixation.Plating is the gold standard operative procedure for middle one-third shaft of clavicle fractures, as it restores length and alignment anatomically and mechanically even in comminuted fractures by becoming the strongest implant.Studies have shown comminution in clavicle fractures is a negative prognostic indicator. Plating is the most discussed and its long term experience in literature is mentioned. It is a less demanding procedure that provides rigid fixation and compression for early rehabilitation. However this technique may require larger incision and extensive exposure which could cause complications such as infections, implant failure, refracture after implant removalneuro-vascular injury, non-union, dysesthesia and keloid scar. Plate fixation is technically easy to perform and long term experience is available. With improved implants, prophylactic antibiotics and better soft tissue handling, plate fixation has been reliable and reproducible technique. Despite experience and improvement of plate fixation, it is not free of complications. Another emerging mode of fixation is percutaneous intramedullary fixation with titanium elastic nail. It is a minimally invasive procedure, conserves fracture haematoma and periosteum that encourages enormous amount of callus formation and improve cosmesis. Intra-medullary fixation with nails or pins has minimally invasive characteristics, including smaller skin incisions, reduced soft tissue stripping, less blood loss, shorter operative time, shorter hospital stay, almost similar time for union as compared with plating, almost zero refracture after implant removal and fewer major complications.It depends upon the degree how much the implant has to be flexible and small enough to be able to pass through the narrow medullary canal and offer a rigid stability needed for the clavicle. In approximately 50% of cases, an additional incision is needed to aid in the fracture reduction and guide the pin through the fracture site. This may impact the outcome due to an increase in incision length and fracture healing due to disruption of periosteum and fracture haematoma.The main complications of titanium elastic nail are their migration and perforation of the device. Although they are minor complications in literature, they are reported to be in range of 5.2–38.8%. It is primarily due to inadequately cut medial end of the nail during surgery and secondarily due to clavicular shortening. These complications can be reduced by adequately cutting the nail, use of medial end caps, good anatomical reduction and intra-operative compression and by avoiding shoulder abduction beyond 90 degrees in first two weeks postoperatively. In this study, both surgical methods of fixation were compared in terms of their clinical, radiological and functional outcomes.

COMPARATIVE ANALYSIS OF VARIOUS STUDIES:COMPARATIVE MEAN AGE, MALE TO FEMALE SEX RATIO AND IDEDNESS OF INJURY DISTRIBUTION DATA:

Parameters	Specific Gears	our study	Nasaria et. al[47]	Zaidenb erg et. al[66]	Fridberg et. al[65]	Srivatsav et. al[68]	Saha et. al[70]	Pal et. al[71]	Beigang Fu et. al[60]
Mean age distribution	Mean Age in Years	31. 9	39. 5	40. 5	36	33	33. 2	29. 9	
Sex Distribution	Male : Female Ratio (% age)	80: 20	77: 23	85: 15	65: 35	66 : 34	85: 15	60: 40	83 : 17
Sidedness of injury	Right: Left (% age)	75: 25	58. 5 : 41. 5	59: 41	66: 34	70: 30	81: 19	69: 31	61. 1 : 38. 9

Our age distribution data matches closely with the study published by Srivatsav et al; Saha et al; and Pal et al;. Our male to female sex ratio matched very closely to that of the studies of Nasaria et al; Zaidenberg et al; Beigang et al; and that of Saha et al;. The right sided injury propensity was matching closely with that of the study of Srivatsav et al;.

COMPARATIVE MODE OF INJURY:

Mode of Injury	Our Study (%age)	Srivatsav et.al[68] (%age)	Beigang Fu et.al[60] (%age)	Thiyagarajan et.al[69] (%age)	Mishra et.al[63] (%age)	Kihlstorm et.al[73] (%age)
Fall on outstretched hand	20	26	27.7	17.6	51.8	55.2
Fall from height	7.5	16	0	0	0	12.3
RTA	55	58	44.4	25.4	35.4	25.4
Sports injury	12.5	0	27.7	37.2	12.6	
Direct fall on shoulder	0	0	0	13.7	0	5.8
Assault	5	0	0	5.8	0	1.3

COMPARATIVE FRACTURE PATTERN DISTRIBUTION DATA:

Fracture Pattern	Our Study (%age)	Beigang Fu et.al[60] (%age)	Kihlstorm et.al[73] (%age)
Robinson 2A2	35	11.1	35.9
Robinson 2B1	65	88.9	64.1

COMPARATIVE TRAUMA-SURGERY DELAY:

Trauma Surgery Delay Mean days (Range)	Our Study Mean	Nasaria et.al[51]	Zaidenberg et.al[66]	Beigang Fu et.al[60]	Saha et.al[70]	Pal et.al[71]
Plating group	3.9 (1-12)	7.2 (1- 14)	4 (1-8)	-	12.8 (3-27)	3.6 (1-7)
IM Nailing group	3.1(1-8)	6.9 (1-13)	-	3.5 (1-7)	13.8 (4-27)	3.6 (1-7)

COMPARATIVE MEAN UNION TIME DISTRIBUTION DATA:

Union Time (in weeks)	Our Study	Saha et.al[70]	Zaidenberg et.al[66]	Saidapur et.al[67]	Lazarus et.al[72]
Plating Group	12.2	22 (12-36)	15.2 (9-23)	12.7 (12-14)	6-12

COMPARATIVE CONSTANT SCORING ACHIEVED DISTRIBUTION DATA:

Grading	Plating Group				IM Nailing Group			
	Our Study (% age)	Pal et. al[71] (% age)	Saha et. al[70] (% age)	Saidapur et. al[67] (% age)	Our Study (% age)	Pal et. al[71] (% age)	Saha et. al[70] (% age)	Subramaniam et. al[61] (% age)
Excellent	35	63.6	70.3	85	60	81.8	82.4	91
Good	50	6.1	24.3	10	30	0	17.6	9
Fair	10	18.2	5.4	5	10	12.1	0	0
Poor	5	12.1	0	0	0	6.1	0	0

COMPARATIVE COMPLICATION DISTRIBUTION DATA:

Nature of Complication	Our Study		Nasaria et.al[47]		Saha et.al[70]	
	Plating Group (%age)	IM Nailing group (%age)	Plating Group (%age)	IM Nailing group (%age)	Plating Group (%age)	IM Nailing group (%age)
Superficial Infection	5	5	0	3.03	0	0
Deep Infection	5	0	6.25	0	10.8	0
Delayed Union	5	0	0	3.03	2.7	0
Shoulder Stiffness	5	0	0	0	0	0
Nail Migration	0	5	0	0	0	5.8
Implant/Screw	0	0	0	3.03	0	0
Wound dehiscence	0	0	9.37	0	0	0
Total	20	10	15.62	9.09	13.5	5.8

CONCLUSION

In our short term prospective study, out of the 40 cases of middle one-third clavicle fractures, 20 patients were treated with plate osteosynthesis and another 20 patients were treated with titanium intra-medullary elastic nail. In our short term study, with a 12 month recruitment period, middle one-third clavicle fractures were found to be more common in the age group of 26 to 30 years and road traffic accidents were the commonest mode of injury. Mean age of our present study is 31.9 years, with a male predominance of 80% In the plating group, pre-contoured side specific clavicular locking compression plate were used as it provides for a rigid fixation and hence enables early mobilization. It also provides for a strong fixation due to locking between thescrew and the plate and preservation of the blood supply due to minimal contact between the plate and the cortical bone. Asit is in the shape of the clavicle and side specific, it provides for a very stable fixation.In the intra-medullary nailing group, titanium elastic nail of size 2.0 for females and 2.5 for males were deployed surgically. It provides lesser stability when compared with plate fixation and therefore aggressive mobilization needs to be delayed for up to 2 weeks post-operatively. Both procedures can achieve equally high rates of bone union, with relatively low rates of infection and implantfailure. However, intra-medullary nailing procedure is quicker, accomplished with a shorter operative time, has lesser,blood loss and has an appealing cosmetic outcome. So, intra-medullary nailing can be regarded as an equally effective alternate to plate osteosynthesis in selected cases of middle one-third clavicle fractures. However, when there is an element of comminution, plate osteosythesis is an betteroption.

We conclude, that in treating middle third displaced clavicular fractures, the operating surgeons experience and training, should take precedence in the final decision. Long term outcomes in the both modalities have similar outcome.

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