"A HOSPITAL BASED PROSPECTIVE COMPARATIVE STUDY OF FUNCTIONAL OUTCOME BETWEEN SURGICAL MANAGEMENT AND CONSERVATIVE MANAGEMENT OF FRACTURE MIDDLE THIRD CLAVICLE IN ADULTS."

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LIST OF ABBREVIATIONS USED

SN	ACRONYM	FULL FORM
1.	FOOSH	Fall On Outstretched Hand
2.	RTA	Road Traffic Accident
3.	PO	Plate Osteosynthesis
4.	IMN	Intra-Medullary Nailing
5.	SC	Sterno-Clavicular
6.	AC	Acromio-Clavicular
7.	CC	Coraco-Clavicular
8.	CA	Coraco-Acromial
9.	SCM	Sternocleidomastoid
10.	SA	Scalenus Anterior
11.	ROM	Range Of Motion
12.	AP	Antero-Posterior
13.	ORIF	Open Reduction Internal Fixation
14.	OPD	Out Patient Department
15.	MSFOC	Mid-Shaft Fracture of Clavicle
16.	CT	Computerised Tomography
17.	MRI	Magnetic Resonance Imaging
18.	PA	Postero-Anterior
19.	FOEB	Figure-Of-Eight Bandage
20.	RCT	Randomised Controlled Trial
21.	DASH	Disabilities of the Arm, Shoulder and Hand
22.	CMSS	Constant Murley Shoulder Score
23.	K-wire	Kirschner wire
24.	OSS	Oxford Shoulder Score
25.	NCS	Nottingham Clavicle Score
26.	DAL	Daily Activities of Living
27.	PROM	Patient-Reported Outcome Measure
28.	IS	Imatani Score
29.	SF-36	36-item short form health survey

30.	CR	Closed Reduction
31.	RR	Relative Risk
32.	QoL	Quality of Life
33.	Post-op	Post-Operative
34.	CI	Confidence Interval
35.	LCP	Locking Compression Plates
36.	DCP	Dynamic Compression Plates
37.	N	Newton
38.	Hz	Hertz
39.	Recon	Reconstruction
40.	LCDCP	Low Contact Dynamic Compression Plates

ABSTRACT

TITLE: "A HOSPITAL BASED PROSPECTIVE COMPARATIVE STUDY OF FUNCTIONAL OUTCOME BETWEEN SURGICAL MANAGEMENT AND CONSERVATIVE MANAGEMENT OF FRACTURE MIDDLE THIRD CLAVICLE IN ADULTS"

INTRODUCTION

The clavicle performs one of the most important mechanical functions of the skeletal framework, connecting the axial skeleton to the upper limb. Additionally, it provides a bulwark for the underlying neurovascular bundles from direct compression injury or sudden axial weight transmission. It is one of the most common bony injury, standing at 2.6% to 4% of all fractures in adults and 76% to 82% of these fractures occur in the middle third. Despite the sheer volume of this injury, its management is astonishingly still debatable. Some prefer conservative while the others prefer surgical intervention.

AIMS AND OBJECTIVES

To compare the results of middle third clavicle fractures treated by open reduction using plate osteosynthesis to those treated by conservative management, in terms of functional and radiological outcome.

MATERIALS AND METHODS

Data was collected from patients coming to or brought to the Out-Patient Department, Casualty or referred to the Department of Orthopaedics after clinical and radiological confirmation of mid-shaft clavicle fracture provided, they fulfilled the

inclusion criteria and exclusion criteria. They were segregated into two groups with group A treated conservatively and group B surgically. The functional and radiological outcomes were evaluated using plain radiographs and various scoring systems.

RESULTS

A total of 44 patients were studied with 22 managed conservatively and the other 22 using plate osteosynthesis. The Constant-Murley shoulder score, Nottingham Clavicle Score and DASH score were significantly better in the operative group during the 1st and 2nd follow-up at 6 weeks and 3 months respectively (p value<0.05). However, the CMSS and DASH score were comparable at the 3rd follow-up at 6 months (p value > 0.05) while NCS remained significantly better in the operated group (p value <0.05). The subjective evaluation of the patient measured by satisfaction score out of 10 was significantly better in operated group (9.86) as compared to conservative group (8.86). The latter group had a higher number of complications than the former.

CONCLUSION

Although there is little difference from functional outcome standpoint between the two groups in the longer run, surgical fixation gives a significantly better short-term results with a considerably lesser number of complications and loss of daily working hours. Additionally, patient satisfaction was higher in the operated group. Hence, for the best results, we suggest the use of operative intervention in majority of the cases.

KEYWORDS: Clavicle fracture, mid-shaft, operative, conservative, plating

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INTRODUCTION

The etymology of the "Clavicle" dates back to as early as the 17th century when it was derived from the Latin word 'clavicula' which literally translates to 'small key' albeit of a musical note. Staying true to its name, the clavicle performs one of the most important mechanical functions of the skeletal framework, connecting the axial skeleton to the upper limb. Thereby, not only does it maintain the bony continuity, acting as a scaffolding for the overlying soft tissue structures, but also provides a passage and maintains a bulwark for the underlying neurovascular bundles (originating from the cervical spine) from direct compression injury or sudden axial weight transmission. The subcutaneous course of the clavicle in the entirety of its length makes it prone to fracture following direct trauma due to the lack of supportive soft tissue structures [1-3].

In addition to this, the fact that it transmits weight of the upper limb to the axial skeleton, and vice versa, also makes it amenable to injury following a fall on the outstretched ipsilateral hand (FOOSH).

Even though literature has been biased towards fall on the outstretched ipsilateral hand being the major mechanism of injury, recent data suggests an increasing trend of direct compression injuries causing clavicle fractures owing to an ascendance in the frequency of road traffic accidents (RTA) [4-7]. Together, they account for upwards of 90% of the cause of these fractures [8,9]. It is one of the most common bony injury, standing at 2.6% to 4% in adults, 10% to 15% in children and more than a third of all injuries involving the shoulder [2,10]. The mechanism of injury predisposes men to a higher rate of fracture than females, in a ratio of 2:1 to 4:1, with

the latter more vulnerable after the age of 60 years due to osteopenic and osteoporotic changes in the bone [3,10]. Every year 29 to 64 out of 100,000 people fracture their clavicles. [11-13]

The sigmoid shape of the clavicle, with an anterior bowing medially and a posterior bowing laterally when visualized from the head end of the patient, combined with the cephalo-caudad curve means the axis of weight transmission is not through the centre of the bone, thereby giving rise to a weak point. Additionally, it has an ill-defined medullary cavity with a flat lateral third and comparatively prism-shaped medial two thirds, making this junction its Achilles heel. Hence, 76% to 82% of fractures of the clavicle occur in the middle third of the bone with medial third (5%-6%) and lateral third (12%-20%) making up the rest of the cases. [1,14-16] Complications of mismanagement include a wide array of relatively less serious yet debilitating conditions such as delayed, malunion or non-union of the bone, to sequalae causing severe morbidity and possible mortality like injury to the brachial plexus, major vessels, trachea, oesophagus, neurovascular bundle and lung along with adjacent pleura. [6,17-22]

Classification of these fractures is traditionally done radiographically based on Antero-Posterior radiographs of the affected side. Various systems have been tried and tested over the years, such as the classifications described by Allman, Neer, Craig, Nordqvist and Petersson, and Robinson. Allman remains the most basic anatomical classification, dividing the clavicle into three equal parts based on the length. Changes were incorporated by Neer and Craig to elaborate lateral third fractures and differentiate between lateral third ligament damage, intra-articular and fractures in children respectively. Nordqvist and Petersson included displacement and

comminution as a distinguishing factor while Robinson divided the bone into medial and lateral one fifth and middle three-fifths. For all practical purposes, Allman's group I is considered as the middle third group and to an extension, Robinson's group 2, as has been done in previous studies. [11,12,23-26]

Despite the sheer volume of this injury, added to the ever-increasing incidence of the precipitating risk factors, its management is astonishingly still debatable. There are two schools of thought, one favouring conservative management by sling immobilization and/or figure of 8 bandage, and the other, surgical fixation by Plate Osteosynthesis (PO) or Intra-Medullary Nailing (IMN).[27] The debate is further accentuated in cases of displaced fractures. In early 1960s Neer et al conducted a study in relation to conservative management of fracture middle third clavicle stating that only 3 out of 2,235 patients reported non-union. [28] In 1997 Hill JM, et al countered the previously formed beliefs in literature by conducting a study on 66 consecutive patients with middle third clavicle fracture based on patient-oriented outcome measures, reporting a 31% unsatisfactory outcome and a 15% non-union rate.[20]

In addition, another study dated 2007 published by McKee et al, assessed 132 patients with displaced midshaft clavicle fractures were randomized to 2 groups, non-operative who were treated with a sling (65 patients) and operative, treated by plate fixation (67 patients). At 1-yr follow-up, improved functional outcome and a lower rate of malunion and non-union was found for the operative fixation group as compared with the non-operative group. [29] Pujalte et al. in 2008 suggested that there is an increased scope of surgical management based on meta-analysis of literature concluding there to be a better functional outcome in patients treated operatively.

They also suggested that non displaced fractures can be treated conservatively with very good long-term outcomes. At the same time citing a need for additional number of studies to help make a better judgement.[30]

Recent studies have shown better, if not comparable results of PO over IMN.[31-33] Hence, we carried out this study to compare the functional and radiological outcomes between conservative management and PO of such fractures.

AIM AND OBJECTIVE

To compare the results of middle third clavicle fractures treated by open reduction using plate osteosynthesis to those treated by conservative management, in terms of functional and radiological outcome.

REVIEW OF LITERATURE

ANATOMY OF THE CLAVICLE

EMBRYOLOGY: Apart from its uniqueness of being the only horizontally aligned long bone, the clavicle has multiple features that makes it an intriguing focus of study. It bears the privilege to be the first bone in the human body to start ossification at mere 40 days of gestation from the lateral mesoderm. It bridges the gap between the sternum and acromion and attaining its characteristic S shape within 2 months. [34-36] The lateral end along with most of the length of the body undergoes membranous ossification whereas the sternal end ossifies by enchondral method. Both the methods, eventually resulting into a lamellar bone. [35,36]

The clavicle is also distinct in the fact that it completes its ossification after all the other bones at the age of 24-26 years. [37] In a study involving 961 patients, it was found that the clavicle grew to a length of 161.3 ± 10.8 mm (145.75 to 190.44mm) in males and 149.2 ± 12.3mm (119.45 to 171.52mm) in females at a rate of 8.4mm per year in both genders till 12 years of age. After the age of 12 years, male clavicles grew at a rate double than the females (5.4mm/year vs 2.6mm/year) with the female population attaining 80% of its total growth three years before their male counterparts. [38]

However, there was no significant difference found between the two clavicles in the same individual (average difference of 0.036mm) which leads us to believe that the uninjured clavicle can be used as a reliable control to measure shortening in cases of unilateral clavicle fractures. [39] In the Indian population, the final length was ascertained to be in the region of 145.31±13.27mm with the length approximately

10mm shorter in the female population according to the study conducted in India by Mohamed Faheem Kotekar et al. published in 2020. They also stated the diameter of the cortex at the mid-point of the bone to be 11.20±1.20mm with male population having a thicker cortex by approximately 0.5mm. [40]

ANATOMY: The Clavicle has long been a subject of interest for medical science owing to some of the exemplary features it possesses despite being a long bone. Features such as horizontal orientation, subcutaneous position throughout its length, ossification by two primary centers, majorly membranous ossification and having negligible medullary cavity has made it an enigma for the treating physicians when the topic of its management from any kind of pathology emerges. [1,34-36] It has been a subject of multiple research studies to identify its cortical and medullary anatomy, the compression and tension sites associated with fractures, the cross-sectional structure, various curves, effect of surrounding soft-tissues and muscle attachments, treatment modalities and even the correct procedure to be followed whilst undertaking the said procedure. Despite the exponential number of studies, the management of these fractures is astonishingly, still debatable.

It acts as a beam connecting the sternum (axial skeleton) to the acromion (appendicular skeleton), and hence transmits forces from the appendicular skeleton to the axial and vice versa. It provides a scaffolding for the overlying soft tissue structures and at the same time protects the major neurovascular and pulmonary structures below it. [1,2,5] The shoulder girdle comprises of four major joints, namely Scapulothoracic, Glenohumeral, Sternoclavicular (SC) and Acromioclavicular (AC). So, considering the fact that the clavicle is involved in two out of the four joints forming the shoulder girdle, any level of mismanagement can lead to functionally

debilitating sequalae in the patient. [41] It is a sigmoid bone, with anterior convexity in the medial part and concavity in the lateral end when seen while directly facing the patient from the front. The medial end is quadrilateral and augmented, bearing a large facet for articulating with the manubrium sternii to form the SC joint. The lateral end is comparatively flattened caudally, housing a small facet for articulating with the medial surface of acromion to form the AC joint [5].

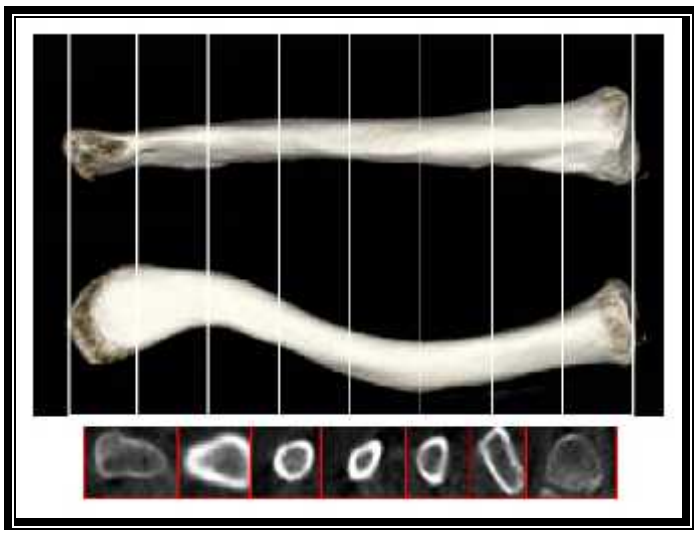


Figure 1: *Anatomical orientation and cross-sectional views of clavicle from lateral (left) to medial (right) in antero-posterior and superior views (Qiu XS et al. 2016).*

It gives attachments to multiple muscles and soft tissue structures too. Medially, the borders of the quadrilateral give rise to the fibrous capsule encapsulating the SC joint. Just superior to it, the interclavicular ligaments are attached which connects it with the contralateral clavicle giving the joint a certain degree of rigidity [42]. The lateral too mimics the medial end, giving rise to the fibrous capsule of the AC joint along with attachments to the main stabilizing ligaments of the shoulder girdle namely Coracoclavicular (CC) - both trapezoid and conoid and AC ligaments, roofed by the Coracoacromial (CA) ligament [43].

The shaft is grossly divided into lateral third and medial two thirds for clinical understanding. Superior aspect of medial aspect is the origin for clavicular head of Sternocleidomastoid (SCM) muscle while the inferior aspect provides attachment to the thin subclavius along with the subclavian groove. In the sagittal plane, anterior surface of medial part gives origin to the clavicular part of pectoralis major muscle while the posterior surface to the Sternohyoid muscle. The posterior surface also bears the costal tuberosity where the costoclavicular ligament is inserted giving additional stability to the SC joint. Superior aspect of lateral third is the site of insertion of the Trapezius muscle while the anterior surface gives origin to the anterior deltoid muscle, extending superiorly and inferiorly [44].

Talking about distraction forces on the clavicle, laterally, the anterior deltoid exerts shoulder flexion forces on the clavicle, weighing it down along with the weight of the arm and the trapezius stabilizes the scapula. The pectoralis major is responsible for flexion, adduction and internal rotation of proximal end of humerus and subsequently pulls the medial part of the clavicle medially and inferiorly (Net direction of vector of pull). Medially, the subclavius depresses the shoulder, subtending anteroinferior pull on the clavicle while the SCM pulls the medial segment postero-superiorly (Net direction of vector of pull) [45].

It has been postulated that this support of SC ligaments medially, the support of AC and CC ligaments laterally keeps the either ends of the clavicle stabilized and resistant to compression forces. In addition to this the SCM, pectoralis major, deltoid and trapezius are responsible for distraction forces as described above. This leaves the middle segment bare and devoid of any soft tissue coverage or enveloping muscle bulk while at the same time making it vulnerable to opposing distracting forces from

both the ends. The transition in cross-sectional anatomy from circular to flattened, smallest cortical diameter, anatomical and physiological stress points due to the natural curvature of the bone along with the minimal soft-tissue support renders the middle third segment of the clavicle comparatively weaker. Consequently, it is more susceptible to fractures, displacements and eventually shortening, malunion and even nonunion [1].

Owing to the fact that it has arguably no medullary cavity, the "thick compacta" as described by Gardner et al., has found to be devoid of any nutrient artery. It derives its blood supply form the periosteal supply provided by the thoracoacromial artery, the suprascapular artery, and the internal thoracic artery [46]. Neurological innervation of the clavicle is still a topic of debate with little clarity about the absoluteness of the nerves responsible for transmitting sensations from the clavicle. The subclavian nerve, supraclavicular nerve, long thoracic nerve/ suprascapular nerve are all advocated to supply the bone in various combinations, compartments or each by itself [47]. In some patients, the perforating branch of intermediate supraclavicular nerve (cutaneous nerve) pierces the superior aspect of the bone. The presence of osseous grooves and tunnels accommodating this nerve is said to be responsible for the entrapment neuropathy that is associated with clavicular fractures. However, this is a topic that still requires further research [48].

Apart from the unique features of the clavicle that make its management controversial, the main reason for the need of a conscientious approach towards its treatment is the close proximity it shares with multiple major structures. Damage to any of these structures can result in severe active or residual morbidity and in some cases, even mortality. This includes major vessels, nerves, organs, and soft tissues.

Complications such as arterial injury, pseudoaneurysm, arteriovenous fistula, venous injury, venous air embolism, deep vein thrombosis, brachial plexus injury, thoracic outlet syndrome, damage to esophagus, trachea, lung apex and pleura can manifest [49].Not only does it affect the surgical techniques and approach but their location is also important in predicting the possible complications and sequalae based on the fracture pattern. The scalenus anterior (SA) muscle originating from the spinous processes of second to seventh cervical vertebrae and inserting to the first two ribs is considered as a vital reference point for all these major structures [49].

The medial clavicle is in immediate vicinity to the subclavian vein. However, the subclavian artery is separated from the osseous structure by the SA muscle and a small portion of the subclavius muscle at its attachment. These muscles are interposed between them and the artery is present at an average distance of 26mm from the former [50]. As they (subclavian artery and vein) pass laterally towards the first rib, beyond which they are called as axillary vessels, the safety of the muscle is reduced to just the subclavius and clavipectoral fascia (CPF). They lie posteriorly and inferiorly to the middle third of the clavicle. While the axillary artery is 17mm away, the vein is at a distance of just 13mm from the bone. In some patients it can stay dangerously close to the middle third, merely 5mm apart [50]. Going further laterally, they are comparatively far from the lateral third of the clavicle with the artery 46mm and vein more than 60mm away despite being dead inferior to it [50].

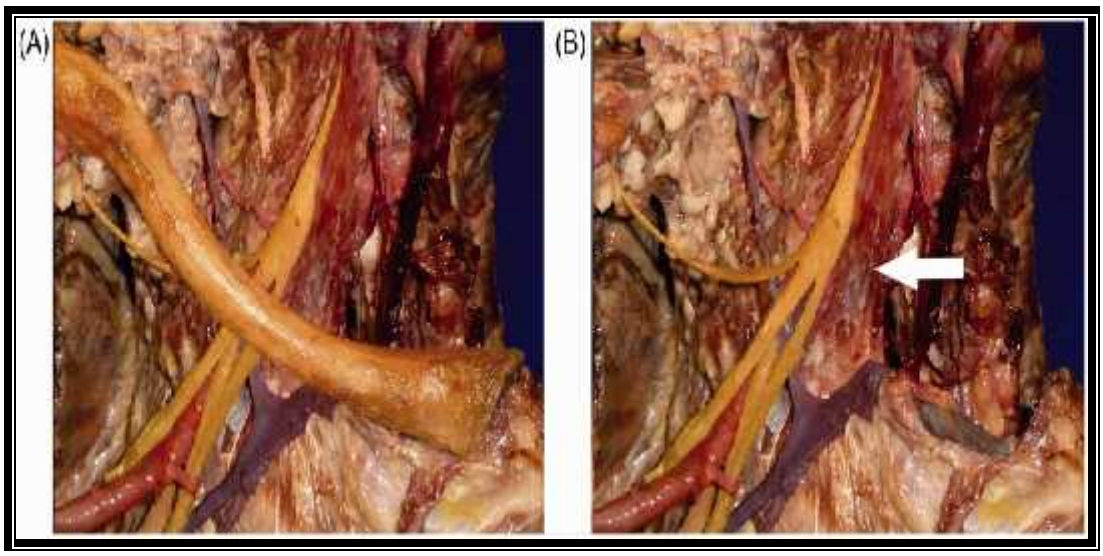


Figure 2: *Right anterior neck dissection with clavicle present (A) and clavicle removed (B). (A) Neuro-vascular structures adjacent to the medial two thirds of the clavicle. (B) Brachial plexus and subclavian artery posterior to scalenus anterior (white arrow). Subclavian vein crossing first rib anterior to scalenus anterior and directly posterior to the medial clavicle and sternoclavicular joint (excised). At the medial end of the clavicle, the subclavian artery and brachial plexus are relatively protected by the scalenus anterior. White arrow = scalenus anterior muscle. Colouring of the neurovascular structures has been enhanced to demonstrate them clearly. Subclavian/axillary artery: red; subclavian/axillary vein: blue; brachial plexus, yellow; sternoclavicular joint (excised): black. (Clitherow HD et al. 2015)*

The brachial plexus accompanies the subclavian artery in the medial third, barricaded behind the scalenus muscle. It can get as close as 12mm to the clavicle, most commonly at the junction of medial three-fifths and lateral two-fifth [51]. The trachea, esophagus and apex of lung lie at an average distance of 22.5±3mm, 40.7±2.1mm and 56.1±1.2mm from the ipsilateral SC joint [52].

Other than its protective function, the clavicle also has mechanical, functional and clinically relevant functions. It ensures the satisfactory functioning of the ipsilateral upper limb by keeping it at an optimal distance away from the trunk thereby providing enough room for the entire range of motion (ROM) of the shoulder

joint without any kind of hindrance [5]. Its beam-like mechanics provides a conducive lever for the scapula to easily move along the posterior wall, granting the complete motion of the upper limb [5,53]. Clinically, the mid-clavicular line is a vital reference point for approximation of numerous findings such as locating the cardiac apex, estimating the severity of hepatomegaly and location of the gallbladder [54].

CLASSIFICATION OF CLAVICLE FRACTURE

Traditionally, plain radiographs in Antero-Posterior (AP) and 15 degrees caudal AP views are used as the determining factor for classification of a clavicle fracture. Over the years many systems have been proposed to assist in easier decision making and prognostic evaluation of this injury. These include purely anatomical classifications of the bone and also modifications of just the lateral end fractures, associated ligamentous injuries, displacement, degree of comminution, joint involvement and pediatric age group [26]. The very first anatomical classification was explained by Allman in 1960s wherein he divided the bone lengthwise into three distinct parts namely the middle third (Group I), lateral third (Group II) which lies distal to the CC ligaments and medial third (Group III).

Allman's classification is the most commonly used classification system for research purposes based on its ease of application. A number of studies have been conducted to assess the incidence of clavicle fractures based on the site of the bone in relation to this classification. The general consensus is that middle third shaft (Group I) is the most commonly fractured region, accounting for 69% to 82% of all fractures in this bone out of which approximately 73% present as displaced fractures [1,3,8,12,14,15]. This is followed by lateral third (Group II) responsible for 12% to 19.3%

[1,26]. Medial third (Group III) fractures are reported to be the least in number with just 1% to 6% cases belonging to this category [1,26].

Despite reporting it as early as 1963, Neer merely modified the pre-existing Allman classification by more comprehensively describing the lateral third fractures into six further types (I, IIA, IIB, III, IV, V) based on the relation to and involvement of the CC ligaments, the conoid and trapezoid as individual assets [23,55]. This was further elucidated by Craig by incorporating the patterns of ligamentous injuries, involvement of joints in the lateral end and these fractures in children [25,56]. The use of degree of comminution and displacement was first done by Nordqvist and Petersson in 1994 to describe clavicular fractures [11].

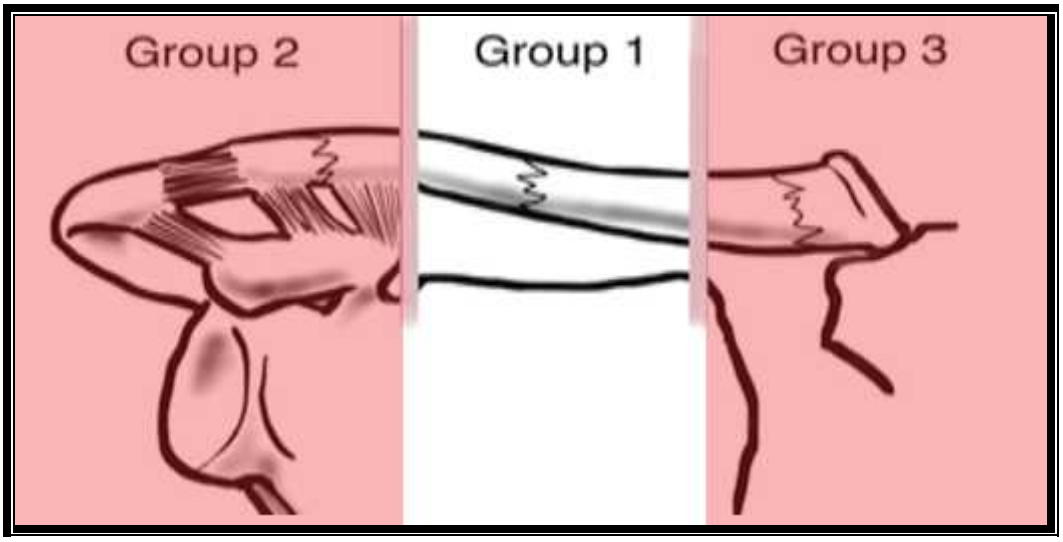


Figure 3: *Allman classification. Group 1 fractures were included in this study.*

The most exhaustive classification (Edinburgh classification) was provided by Robinson in 1998 which included two unique features. First, he divided all fractures into two broad groups based on the degree of displacement. Group A includes those with less than 100% translation and Group B those with more than 100% translation whereas other classifications consider any percentage of translation as displacement.

Secondly, he divided the clavicle into three parts, type I to III constituting medial fifth, middle three-fifth and lateral fifth respectively. Furthermore, subgroups 1 and 2 were described for lateral and medial fractures (Type III and I) based on non-articular (subgroup 1) and articular involvement (subgroup 2). Type II or middle three-fifth was subclassified into subgroups 1 and 2 based on fracture pattern and degree of comminution where subgroup 1 denotes simple/wedge fractures whereas subgroup 2 denotes segmental/comminuted fractures.

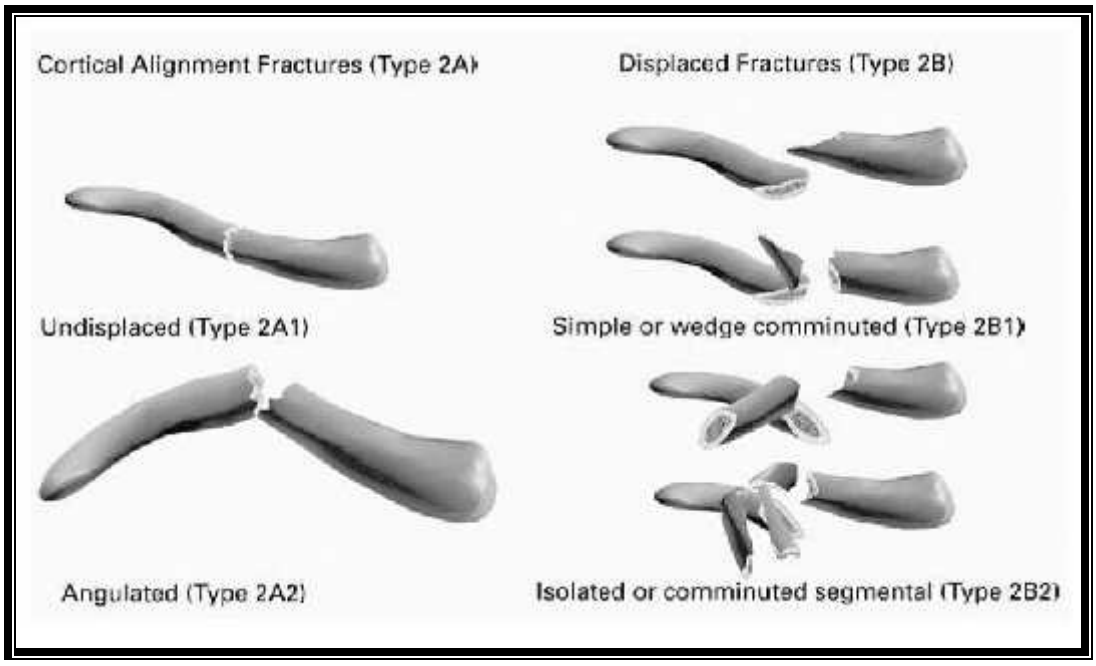


Figure 4: *Robinson classification Type 2 fractures which were included in the study.*

An extensive retrospective study was undertaken by O'Neill et al in 2010 over a period of two years, studying just under 500 cases wherein they segregated these fractures in accordance to all five classification systems and studied their incidence and rates of non-union so as to comb the classification system most apt for studying prognosis of clavicle fractures when it comes to healing and in turn the radiological outcome [26]. They concluded that the systems described by Craig and Robinson were

the best indicators of prognosis for lateral third and middle third clavicle fractures. Hence for all practical purposes, we shall consider Robinson classification for its accuracy and Allman classification for its ease of use and universal acceptance in this study. They studied the incidence of fracture patterns based on all the 5 classifications and concluded that the maximum involvement was Allman group I (79.3%) and Robinson type II (79.4%) [26].

When considered as a basis for calculation of sequalae such as nonunion and delayed union, maximum cases of nonunion was reported in lateral third fractures with 9.6% of Allman group II and 30.2% of Robinson type 3, followed by middle third, that had 6% of Allman group I and 22.4% of Robinson type II fractures. However, 50% of nonunions in the middle third required open reduction and internal fixation (ORIF) as compared to <25% of lateral third. Edelson reported malunions to the tune of 85.7% in lateral third, 80% in middle third and 50% in medial third injuries from his sample size [2]. This shows that despite lesser incidence of malunion and nonunion in middle third clavicle fractures as compared to lateral third fractures, the prognosis for healing of nonunion is worse in the former whereas the severity or degree of angulation in malunion is worse for the latter. Hence, it is essential that middle third clavicle fractures are meticulously treated so as to avoid the burden of additional future surgeries [2,26].

EPIDEMIOLOGY

Clavicle fractures are well known entities since a very long time. Over this period many studies have been done to ascertain the epidemiology of this condition. One of the oldest studies done was conducted from 1952 to 1987 by Nordqvist A. and Petersson P. to calculate the incidences of this fracture with age and gender

specifications. Having studied 2035 cases and classifying them according to Allman classification, they further segregated them into displcaed and undisplaced groups in addition to which was a comminuted midshaft subgroup. 76% belonged to group I, 21% to group II, 3% to group III. The average age of patients belonging to each group were 13 years, 47 years and 59 years respectively. Men had significantly more involvement in each of these groups with an increasing trend of incidence of overall number of cases with every passing year [11].

The following year a study undertaken in Edinburgh from 1988 to 1994 evaluated a thousand adults with clavicle fractures. Robinson C. M. observed that in males the highest incidence per year was in the age group below the 20-year mark with the numbers decreasing till the seventh decade. However, in females it was more or less similar with a slight preponderance towards the teenage years and the advanced age groups. RTA and sports contributed majorly to fractures in young adults, mainly affecting the diaphysis. Self falls were attributed to distal fifth fractures and were seen more in older age group [12].

Postacchini F et al. published a study in 2002, done over a period of 11 years starting in early 1990s on 535 patients presenting with only fracture clavicle. Variation with respect to age, gender, mechanism of injury, involved side and seasons were studied. A general cross-sectional incidence of clavicle fractures as a whole was found to be 2.6% of all fractures and 44% of fractures involving the shoulder girdle. Higher rates were found in men (68%) with increased involvement of the left side (61%). They too classified them based on the Allman system. 81% had midshaft fractures with just under half displaced and 19% comminuted. Involvement of group I decreased whereas incidence of displacement in all groups increased with ag. RTA

was yet again found to be the most common cause with no statistical difference of occurrence with respect to time and seasons [57].

In 2009, a research comprising 2035 patients was published by Khan et al. They reported 2.6% to 4% incidence of clavicle fracture among adults and just over a third of shoulder girdle injuries with 29 to 64 people per 100,000 per year affected [7]. 69% to 82% involved the midshaft, 21% to 28% involved the lateral end and a mere 2%-3%, the medial end. The two peaks as reported by the previous studies too, included that of young males and elderly females. The former was mainly following sports injuries or RTA due to direct impact after fall on unguarded shoulder and the latter was attributed more to decreased bone mineral density as is seen in women with advanced age [3].

The occurrence of bilateral clavicle fractures is a rare phenomenon with the incidence standing at a measly 0.5% of all clavicle fractures. They are believed to be caused by the traumatic forces getting propagated from the shoulder girdle primarily impacted to the contralateral one or by consecutive trauma directly on both the clavicles. The simultaneous occurrence of thoracic injuries or a more severely displaced fracture of one side compared to the other may lead to the underreporting of this condition upon primary survey. Lakhotia D et al. in 2016 reported three such cases of bilateral clavicular fractures following trauma [58]. In a literature review by Cagatay U et al. dated 2015, the occurrence of clavicle fractures was reported to be 2%-5% in adults, 10%-15% in pediatric age group ad 35% of shoulder girdle injuries. In the pediatric population 90% are midshaft fractures [59,60].

In Sweden, 2422 clavicle fractures in the Swedish fracture register were assessed and their epidemiology was compiled by Kihlström C et al. in 2017. A male to female incidence of 2.2:1 was observed with the average age of sample size standing at 48 years. Major bulk of the sample was 15 to 24-year-old (21%). Males suffered more in the younger age group (43±21 years) as compared to their female counterparts (59±21 years). There was a higher preponderance for the left side (52%). The burden of the condition reversed in the elderly age group (≥65 years) with a female inclination of 1:0.8. This inferred that the younger population affected involved more of males as they were secondary to RTA whereas the older population involved more of female populace with the pathomechanism shifting more towards falls. This was confirmed by the fact that 28% of the fractures were due to high-energy trauma with males involved in more than double the number of incidents than females. Only 0.7% of the cases were attributed to atraumatic causes such as pathological fractures, stress fractures and spontaneous fractures. It was noted that midshaft was most commonly involved with 9 out of 10 such fractures displaced or angulated. Fractures of the proximal and distal ends were more in elderly and vice-versa. Only 10% of distal fractures were intra-articular and was reported more in females while displaced midshaft was more in males (47% vs 35%). 4 cases of bilateral and 11 cases of multiple clavicle fractures on the ipsilateral or contralateral side within the 2-year period were seen. Compound fractures bore only 0.7% of the load of all clavicle fractures in this study [61].

Mechanism of injury was studied extensively by Eskola A et al and Jeray KJ who in 1986 and 2007 respectively came to a similar conclusion. Medium and high-energy trauma inflicted during an RTA or sports injury in young and low-energy fall in older individuals are the amin culprits for clavicular fracture [62]. They refuted the

earlier belief of FOOSH being the primary cause of these fractures by stating that failure under direct compressing translational forces causes the majority of such injuries. Out of 122 clavicle fractures, 87% were a result of direct fall on the shoulder, 7% of a direct blow and 6% of FOOSH [63].

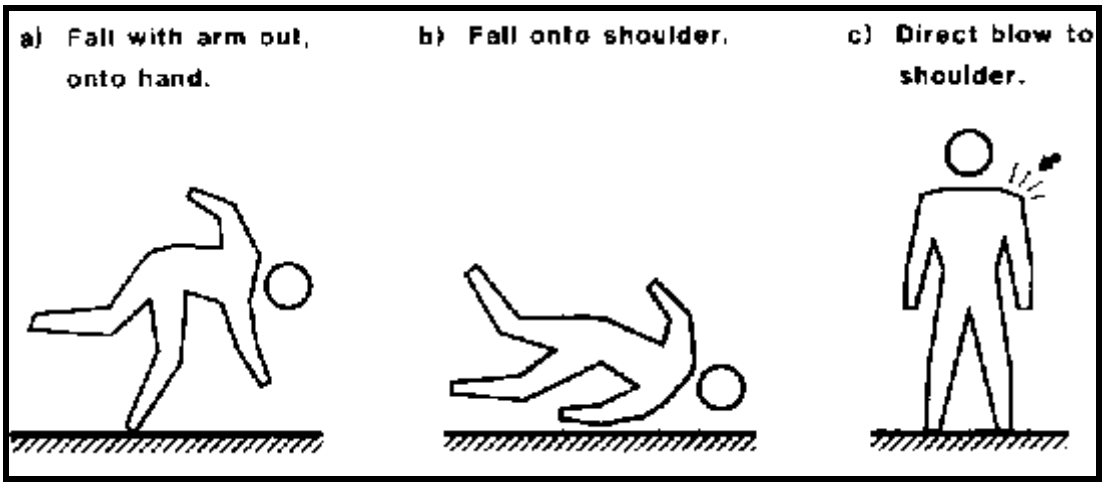


Figure 5: *Mechanisms of clavicle fracture. [Trowbridge E., & Norris S.H. (2005)]*

A segmental fracture is a fracture that is composed of at least two fracture lines in a single bone that isolate a segment of it. Such segmental fractures are extremely rare in case of clavicle. and are more often reported in the adolescent age group. Throckmorton and Kuhn documented a meagre 0.8% incidence (n=5) of such fractures among 614 fractured clavicles [64]. Injuries involving the medial and lateral ends (also known as bipolar injury) without damage to the diaphysis are even more rare [65-67]. The pathomechanism of a segmental clavicular fracture is still an enigma with some hypothesizing the existence of two separate but contemporaneous forces at different sites in the same bone [68,69]. This pattern of injury is more common in adolescent age group rather than adults [70].

Taking neonatal age group into consideration, all the deliveries that were accompanied by clavicle fractures of the baby were evaluated between January 1996 and march 1999 by Beall MH and Ross MG at Harbor-UCLA Medical Center. They reported 26 deliveries complicated by clavicular fractures out of the total 4297 (0.5% incidence). Strong association was found with advanced maternal age, meconium passage, other neonatal Orthopaedic birth defects and weight of the baby more than 4 kg at birth. There was no relation with shoulder dystocia or vaginal delivery advocating surgical intervention reported [71].

NATIONAL BURDEN

Indian Orthopaedic literature is depleted of adequate number of studies focussing on the burden of clavicle fractures on the healthcare system of the country. A couple of such research articles have reported epidemiology which concurs with that of the rest of the world. One such publication done by Honnungar RS et al. in 2015 studied 50 cases retrospectively and documented a male to female ratio of 5.25:1. The number of left sided fractures were more than half as that of right side. They reported a higher number of medial end fractures compared to middle and lateral end; contradicting rest of the studies reviewed till now. Although, 8% of the sample size had compound fractures, there was no case of bilateral fracture clavicle seen [72].

The following year, a study published by Agarwal S. and Das A. based in Uttar Pradesh, India, showed the data of 60 clavicle fractures with a male to female ratio of 4:1. In this report, 60% fractures belonged to Allman group 1, and 8.4% fractures were compound fractures, majority of which involved the middle third. The left side was affected more in a ratio of 3:2. Maximum cases reported, had the

precedent cause as RTA (40%), followed by fall (35%) and workplace injury (25%) [73].

Given the gross insufficiency of research work dedicated to assessing the incidence of these fractures, their most common cause and sites of affliction, it is of utmost importance that further studies are undertaken in this sphere to provide a better and a clearer idea regarding clavicular fractures. This will help the Indian physicians to identify, quantify and subsequently manage these cases faster and more efficiently.

PRESENTATION

Fracture of the clavicle are most often a result of low or high velocity trauma. This means that the patient commonly presents in the emergency department and hence gives an acute history in most cases. A direct trauma following an RTA, fall on the shoulder or outstretched hand followed by realization of bony snap and associated with severe pain over the shoulder and base of neck should raise the suspicion of a clavicle fracture. Elucidation of the entire history is of prime importance to gauge the intensity of the compression or transmitted force to the affected side as high intensity injuries are routinely associated with ipsilateral with/without contralateral thoracic injuries. Additionally, patient's dominant side should be enquired as it is vital in deciding the treatment strategy [21].

The patient generally presents with an adducted arm supported by the opposite hand when confronted on out-patient (OPD) basis. This is due to the downward pull exerted by the pectoralis major, latissimus and the weight of the arm and upward pull of SCM especially in midshaft fractures of clavicle (MSFOC). Locally, presence of contusive injury over the skin surrounding the clavicle (posterior or anterior) is

visualized in cases of direct trauma. There may be associated ecchymosis or skin tenting owing to severely displaced or angulated fragments, both of which are indications for surgical intervention [18]. In worse cases, swelling or hematoma are present [75]. A bony deformity may be visualized directly due to the subcutaneous nature of the clavicle which can be confirmed by palpation along the lower border of the bone. A break in continuity along with tenderness and crepitus is clinically diagnostic [76,77].

81% cases of clavicle fractures had concomitant injuries in a study done by Asadollahi et al. in Melbourne, Australia. The most common association noted was that of thoracic injuries standing at 47% [74]. Injury to the costal structures, rest of the shoulder girdle, scapula, bones and structures of the upper extremity of the same side should especially be clinically assessed in patients belonging to the lesser age group as they are more commonly involved in vehicular accidents. Mere range of motion tests (active and passive), palpation of the respective structures and a chest compression test are enough to elicit injuries to these structures [76]. It is essential to look for pulmonary stigmata such as acute shortness of breath, laborious breathing and reduction in air filling upon auscultation as they all point towards a compromised lung apex secondary to the clavicle fracture, or in worse cases costal fractures [77].

Keeping the proximity of major neurovascular structures to the clavicle in mind, the assessment of brachial plexus and vessels are mandatory and any defect has to be documented upon examination. Testing of sensation over the proximal and lateral arm and deltoid contour should be done to rule out axillary nerve injury. Similarly, median, ulnar and radial nerves should be evaluated. Palpation for distal pulsations along with the temporal comparison of capillary refill with the contralateral

upper limb should be done and noted. Any kind of discolouration or neurovascular compromise requires prompt attention and intervention [21,76,77].

INVESTIGATIONS

Across literature the oldest and most commonly used radiograph for diagnosis, measurement of the degree of comminution, displacement, angulation, classification, prognostic assessment and pre-operative planning has been plain radiograph of the affected clavicle in the AP view. Over time the trend has changed towards an additional radiograph taken with a cephalad tilt of 30 to 45 as it helps to delineate the bone accurately by negating the overlap of the proximal ribs and scapula so as to minimalize artefacts [18,77]. Despite some physicians suggesting the entire shoulder series, it is not routinely recommended [12].

In case of lateral fractures of the clavicle, a 15 tilt is considered adequate. A stress view, axillary view and scapular Y view are also suggested for these injuries for a better fracture pattern visualization and to rule out further articular involvement of the lateral end of the shoulder girdle. A chest radiograph has been advised to make sure there is no pulmonary or pleural involvement such as pneumothorax [79-83]. While lateral fractures may need further investigative procedures such as Computerised Tomography (CT) or Magnetic Resonance Imaging (MRI) to ascertain the anatomical and soft tissue configuration, middle third fractures are generally straightforward due to minimal muscular and ligamentous envelope [12]. In addition, routine blood investigations are required as per the respective institution's guidelines for a pre-operative work and anaesthetic clearance if the patient has been planned for surgery.

STUDIES FAVOURING CONSERVATIVE MANAGEMENT

The earliest of clavicular fractures have been treated conservatively by attempting to achieve closed reduction using manipulation of the upper limb ipsilateral to the affected clavicle, irrespective of the anatomical location of the fracture. This is followed by immobilization by a sling, cuff and collar, a figure-of-eight (FOEB) bandage or a combination of these modalities. It was believed that clavicle has a high healing capacity and that the non-union rates are less. This was established by the results of a study done by Neer C.S which had a multitudinous sample size of 2235 patients with clavicle fractures. He reported that out of all these patients, only 3 patients had documented non-union of the fracture. However, over the course of time, literary reviewers have highlighted major drawbacks in this study such as the inclusion of paediatric population, inadequate and incomplete follow-ups, the lack of radiographical evidence and no functional measures for the assessment of symptomatic and asymptomatic mal-unions [28].

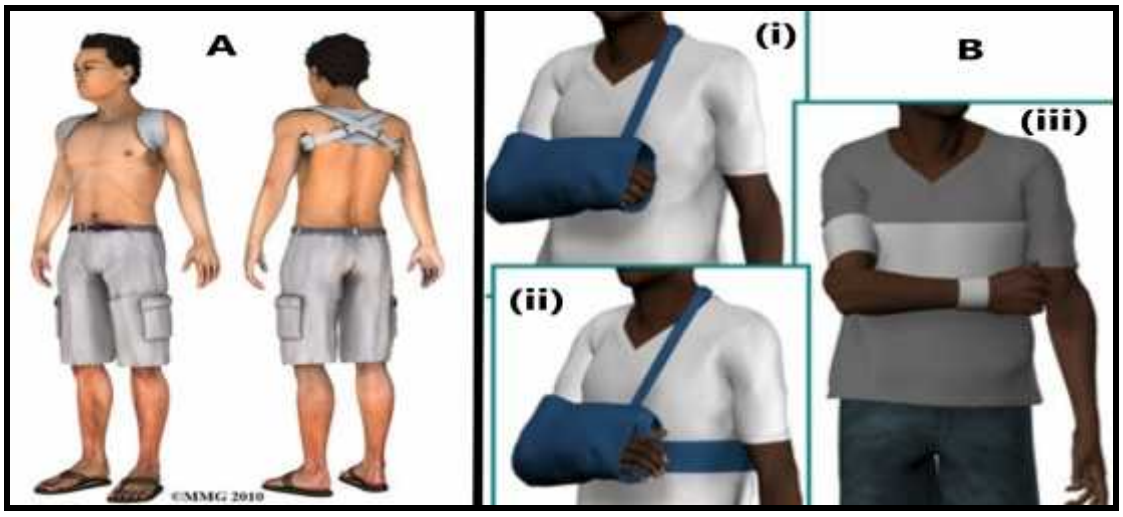


Figure 6: *Methods of conservative management. (A) Figure-of-8 brace. (B) i. Arm pouch ii. Shoulder immobilizer iii. Special shoulder immobilizer.*

Slowly but steadily there was an increasing clarity regarding the relatively high non-union rates associated with conservative management hence the discourse shifted towards assessing whether there was any functional discrepancy in the long term as a result of these differential treatment approaches. In 1998, Nordqvist A. et al studied the long-term clinical effect of these fractures with respect to the degree of displacement and comminution. Retrospective assessment of 225 patients was done radiologically as well as clinically. 197 of them had been managed by immobilization using FOEB while 24 patients were allowed shoulder ROM immediately after the visit. Out of the patients that were available for follow-up after a mean period of 17 years since intervention, reportedly only 7 had a non-union which was graded good by the author. They concluded that only a finite number of cases of MSFOC entailed surgical intervention [84].

A comprehensive meta-analysis was done by Zlowodzki et al in 2005, in which they compared the results of conservative and operative management in a sample size of 2144 fractures from January of 1975 to April 2005. They reported 5.9% non-union in the 1145 fractures managed non-operatively and 15.1% in the displaced group exclusively. Female sex, comminution, increased age and displacement cited as risk factors for the same. Hence, their results concurred with that of Paladini P. et al, who in 2012 said in their study that conservative management of MSFOC, especially the undisplaced fractures is routinely advocated. They cited the meagre incidence of 0.03% – 5.9% as the reason for this recommendation [84-86].

Even though the period of immobilization in cases of non-operative management is not well-established, with literature providing a wide range of 2 to 6 weeks [77,87,88], the general consensus is that a sling is to be preferred over the FOEB.

In accordance to the feedback of 61 patients treated by either of these methods, Anderson et al. summarized in 1987 that even though all fractures united, 26% of patients treated using the FOEB were not satisfied which was limited to just 7% of the other group [89].

Analgesic and calcium supplementation can be considered along with immobilisation. Rehabilitation may include ROM exercises for other joints to prevent stiffness and eventually for the affected shoulder. Adjuvant strengthening exercises can be taught as and when tolerated. Involvement in sporting activities particularly those involving contact such as football, basketball, rugby, hockey, etc should be prohibited for 16-20 weeks. Paladini P. et al in 2012, as aforementioned and Jeray KJ in 2007 stated that although the non-union rates were low in undisplaced fractures, they increased alarmingly in those with risk factors as explained by Zlowodzki et al and so such cases call for surgical fixation. They called for additional prospective studies to supplement their results [21,77].

Sambandam B et al. while primarily studying the distal end clavicle fractures, commented that owing to their inherent stability of Allman type 1 fractures, if they are bereft of displacement, they require merely the neutralization of weight of the ipsilateral arm by a sling support [78]. In the year 2013, a multicentric, randomised controlled trial (RCT) was carried out by Robinson CM et al in Edinburgh. It included 200 patients of acute MSFOC, ranging from 16 to 60 years of age. Following randomisation, intervention by ORIF by PO or conservative management was carried out and the clinical assessment was done at regular intervals for 6 months by Disabilities of the Arm, Shoulder and Hand (DASH) and Constant Murley Shoulder score (CMSS). 3-Dimensional CT scan was used to assess the union [90].

According to their findings, the number of non-unions (1 vs 16), DASH score (3.4 vs 6.1), CMSS (92 vs 87.8) were all better in the operated patients at the 1-year follow-up. When they evaluated only those patients without non-union, the statistical difference in the scores between the two groups was insignificant. Despite lesser complaints regarding the cosmetic aspects of the shoulder in operative group, the cost of treatment was significantly higher. Hence, they concluded that the better results following ORIF by PO was secondary to decreased frequency of non-unions in these cases. Considering the high cost of treatment and implant related consequences in these patients, they advocated for non-operative treatment in even in cases of displaced MSFOC [90].

Closed reduction by FOEB or support by sling with or without swathe is the most common method of dealing with MSFOC as both these methods have uncanny similarity in terms of rate of union. Coppa V. et al upon comparing conservative treatment to threaded Kirschner wire (K-wire) fixation asserted that non-surgical management results in lesser complications and a faster healing time as compared to those undergoing surgery unless associated with factors that independently increase the chances of non-union such as displacement, comminution, shortening, etc. In these patients, they advised ORIF by PO or IMN for such patients [91].

Finally, a detailed research of studies published from 1980s through 2015 was done by Hoogervost P. et al which was published in 2018. They came forward with multiple observations which confirmed that FOEB is inferior to sling support or shoulder immobilizer splints as the former led to axillary pressure sores. They recommended early ROM exercises to prevent secondary frozen shoulder especially in diabetics. Shortening of more than 2 cms was confirmed as an independent factor

for non-union, 66% of whom underwent corrective surgery. Malunion, neurological symptoms and differing scapula-thoracic kinematics were also reported. They also called for trials to ascertain the role of kinesiotape application in such cases. Although they had an association with arthritis of the gleno-humeral joint, there was no visible functional deficit at 16 weeks follow-up. The eventual conclusion was that surgeons should prefer non-operative treatment over surgical management and that the latter should be reserved only for symptomatic malunions and non-unions [75].

SCORING SYSTEM

Scoring systems are the primary tools for evaluating the progress of a patient following an injury and its subsequent treatment. They help pinpointing the condition of the patient in that cross-section of time by converting subjective answers of the patient to objective results. The most formidable tool for scoring and in-turn, gauging the adequacy or need for digression of treatment is the system with high inter observer reliability as well as reproducibility by the same observer. Another important aspect is the ease of temporal computation as different follow-up periods assume different scale of improvement in the patient. Last but not the least, an apt scoring system should be able to assist the physician in assessing the prognosis and giving an indication of the level of residual functional or clinical impairment in a patient at that point of time and in the future by extrapolation.

Multiple scoring systems have been advocated for the clinical, functional and patient-specific assessment of patients with clavicle fractures. Given its involvement in forming the shoulder girdle, scoring systems that calculate the functional ability of the ipsilateral shoulder and upper limb have long been used in literature. These scores include the DASH score, CMSS, Oxford shoulder score (OSS), etc [92-95]. However,

owing to the increasing demand of individualisation in the medical field, more specific tests have been implicated such as the Nottingham clavicle score (NCS) [96,97]. For its ease of use, the QuickDASH score has also been experimented in many situations [92,96]. DASH score is a well-established 30-item questionnaire used for the functional & symptomatic assessment of a patient suffering from any kind of injury to the shoulder joint, in the form of a series of well-structured questions whose answers are reported by the patient himself. Verbrugge invented it in 1994 as a systemic tool & not just for the affected limb [93]. The average score of population is said to be 10.1[98].

The QuickDASH is an abbreviated subset of the DASH score which involves just 11 questions. Although it takes lesser time, the DASH is more reliable [96]. The DASH score includes 21 questions pertaining to physical function, 6 symptom-related and 3 revolving around social role of the patient. It is further classified into 2 module, one specific for musicians and athletes and the second for working population. The fact that it is self-reported, neutralizes observer bias and can be done over telecommunication and does not warrant physical presence of the patient when a follow-up is not possible due to unavoidable circumstances. Every question is answered on a scoring of one to five and all the scores are added up to form a raw score (maximum: 150, minimum: 30). From this total, the minimum score possible i.e. 30 is subtracted and the total is divided by the total range of the score ie (150-30)/100. Hence, the final scoring calculation looks like [92]:

$$\text{DASH SCORE} = \frac{\text{Raw score} - 30}{1.2}$$

Alternatively, if the patient does not answer all questions, it is calculated as:

$$\text{DASH SCORE} = \left\{ \left[\frac{\text{Sum of responses}}{\text{Number of responses}} \right] - 1 \right\} * 25$$

A minimum of 27 questions need to be answered for its applicability and the score ranges from 0 to 100 with 0 denoting minimal functional impairment and 100 representing maximum disability. There are no pre-determined cut-off values for categorizing a DASH score as poor, fair, good, etc. but a score below 30 is generally considered enough for the patient to be considered to be at the threshold for return to daily activities with awareness of limitations [92].

In 1987, Constant CR and Murley AH set out to formulate a scoring system that would fill the voids left by previous scoring systems in assessing the functions of the shoulder joint. An exclusive scoring system not confounded by an aberration in other diagnostic modalities secondary to any pathology, be it traumatic or nontraumatic was the aim. They proclaimed that their system, called the Constant-Murley shoulder score was reproducible and required minimal time of the physician to complete the evaluation of the patient [94]. Despite being devised for shoulder pathologies in general, and the lack of a specific scoring scale, the CMSS has been used since its inception for the functional assessment of a patient of clavicle fracture.

To ascertain its reliability, Roy J-S et al. and Ban I et al. published their research papers in 2010 and 2016 respectively [99,100]. Roy J-S et al. undertook a systemic review of 35 published articles from Medline, EMBASE and CINAHL databases and in their study of level 1 evidence, studied the psychometric evidence associated with CMSS. Even though the studies pointed towards some glaring deficiencies in standardization, the CMSS had a strong correlation with questions specific to the shoulder (≥ 0.70) and a high reliability coefficient ($\rho > 0.80$). It also exhibited appreciable levels of progression assessment following an intervention with the standard response mean >0.80 for various kinds of shoulder conditions. It does call out for better standardization and attention during interpretation of the final scores when the original method is concerned. However, the fact that it had exceptional responsiveness to intervention and widespread applicability due to ease of use, they concluded that CMSS is a valuable tool for the assessment of pathologies related to the shoulder [99].

Ban I et al. concluded excellent inter-rater reliability of CMSS (coefficient 0.94) with a low minimal detectable change of 13.6 points. The constituents of CMSS had good internal consistency (Cronbach $\alpha = 0.85$) and a strong correlation with the DASH score [100].

The CMSS is scored from 0 to 100 with higher scores indicating increasingly good shoulder function. Out of these 100 points, 35 are reserved for subjective evaluation (Pain and Daily activity of living (DAL)) while 65 are for objective assessment (ROM and motor functions). Hence, there are a total of four variables that are assessed with maximum scores as follows:

Sr. No.	Variable	Maximum points	Type
1.	Pain	15	Subjective
2.	DAL	20	Subjective
3.	ROM	40	Objective
4.	Strength	25	Objective
MAXIMUM TOTAL		100	

A study was conducted in 2010 in Indonesia by Magetsari R, to determine the sensitivity of the CMSS and the QuickDASH score. In this prospective cohort study, the author included 64 patients with MSFOC and evaluated them at 3- and 6-months post injury based on effect size (ES) and standard response mean (SRM). Both the systems had high sensitivity (CMSS: ES= 0.628; SRM=1.45 vs QuickDASH: 0.711; SRM: 1.46). As evident, the latter had higher sensitivity but both the tests were deemed incredibly accurate for evaluation of such patients at 3- and 6-months follow-up [101]. As the DASH score has a higher sensitivity to the QuickDASH, we evaluated the patients based on DASH score and CMSS in our study.

The Oxford shoulder score (OSS) was introduced in the 1990s for shoulder specific surgical and non-surgical management. It was primarily devised for the conditions causing instability of the shoulder joint but was gradually incorporated into other conditions such as rotator cuff injuries, clavicle fractures, bicipital tendon tear, etc. Consisting of 12 questions graded from one to five based on degree of impairment, the final score ranges from 0 to 60 with a higher score indicating a higher degree of impairment. Multiple review studies have been carried out to test its

accuracy and efficiency in clinical practice with Dawson J. et al (1996 and 2001) [102,103], and Olley M. et al (2008) [95] proving its reliability, convenience and sensitivity to any kind of alteration in the clinical findings of a patient post conservative or surgical management of a shoulder joint related pathology [95,102,103].

Eventually a scoring method specific to the clavicle, the Nottingham clavicle score was contrived. It constitutes 10 subsets with the first four evaluating shoulder-specific pain, night pains, pain during DAL and during recreational and sporting activities. The capability of lifting heavy objects, overhead strength, cosmetic acceptance, motion, and neurological symptoms such as tingling and dragging sensation form the other 6 items. The range of scoring is from 20 (maximum disability) to 100 (minimum disability). Item 4 makes it more relevant than OSS as a patient-reported outcome measure (PROM) due to inclusiveness of athletic habits [97,104].

FINAL NCS	**INTERPRETATION**
80-100	Excellent
60-79	Good
40-59	Fair
<40	Poor

Not only did it accurately assess clavicular fractures, but also AC joint and SC joint pathologies including instability, especially in young and active patients who are more susceptible to these types of injuries. In accordance to the cohort study done by Charles E. et al. in 2017, the NCS is highly reproducible, has excellent sensitivity

to change, the largest effect size (1.92) and internal consistency (α=0.87) as compared to OSS, CMSS, Imatani score (IS), and EQ-5D [104]. Before this, Vascellari et al.in 2015 assessed the validation of NCS with respect to the OSS, DASH score, and 36-item short form health survey (SF-36). They reported appreciable internal consistency of NCS with all these scores. However, it was noted by both these sets of authors that the final score and in-turn the interpretation was skewed in some cases due to the question regarding cosmetic satisfaction of the patient which is highly subjective and transient. Sensitivity was shown to increase by the elimination of this criteria [104,105]. Its validity and responsiveness in assessing clavicular fractures was confirmed by Vishwanathan K. et al. in 2018 [96].

Taking all of the aforementioned into account, we assessed the patients on the basis of CMSS, DASH score, NCS. We used the Likert scale for cosmetic and miscellaneous questions related to subjective satisfaction of the patient with the treatment modality and the function at that follow-up as it has been well established in medical literature to be a reliable method for evaluation of patient satisfaction especially when it comes to the quality of life and PROM [106-110].

STUDIES FAVOURING SURICAL MANAGEMENT

The findings of Neer C.S.in 1960 regarding the efficiency of conservative treatment in managing MSFOC was considered as the holy grail for a long time by physicians and Orthopaedic surgeons [28]. Eventually after a better part of four decades, in 1997 Hill JM, McGuire MH and Crosby LA countered the previously formed beliefs in literature by conducting a study on 66 consecutive patients with middle third clavicle fracture based on patient-oriented outcome measures, reporting a 31% unsatisfactory outcome and a 15% non-union rate [20]. There was a change in narrative regarding the efficacy of surgical treatment after this with more and more authors publishing their research work showing inclination towards operative fixation.

Talking about the increasing number of studies in favour of surgical management, In a study by McKee, M.D., E.M. Pedersen, C. Jones, et al titled "Deficits following non-operative treatment of displaced midshaft clavicular fractures" in 2006, showed deficits in shoulder strength and endurance in 30 patients treated non-operatively for displaced midshaft clavicle fractures. It was later assumed that the difference in the study reports over the years might be due to lack of usage of patient dependent outcome measures and inclusion of pediatric and adolescent age group in the study which skewed the findings [111].

In the following year, another study dated 2007 was published by McKee, M.D., H.J. Kreder, S. Mandel, in which 132 patients with displaced MSFOC were randomized to either non-operative treatment with a sling (65 patients) or operative treatment with plate fixation (67 patients). At 1-yr follow-up, improved functional outcome and a lower rate of malunion and non-union was found for the operative fixation group as compared with the non-operative group [29].

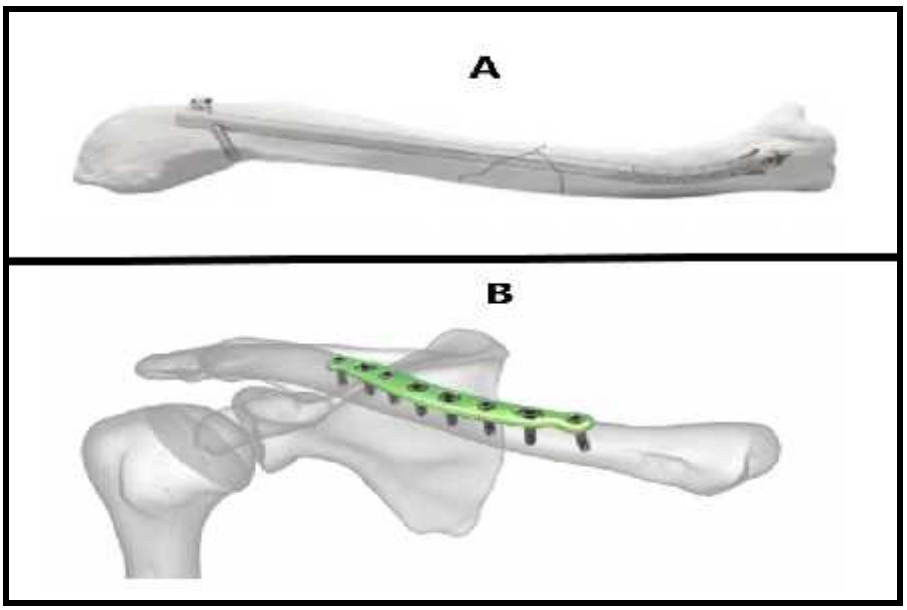


Figure 7: *Operative management options. (A) Intra-medullary nailing. (B) Plate osteosynthesis.*

Pujalte, George Guntur A. Housner, Jeffrey A in 2008 suggested that there is an increased scope of surgical management of middle third clavicle fractures based on meta-analysis of literature concluding there to be a better functional outcome in patients treated operatively. They also suggested that non displaced fractures can be treated conservatively with very good long-term outcomes. At the same time citing a need for additional number of studies to help make a better judgement in management of middle third clavicle fractures [30].

In 2009, another publication in the international journal for shoulder surgery by Thyagarajan DS, Day M, Dent C,Williams R and Evans R, after a retrospective study of 17 patients each in those treated operatively and non-operatively reported an 18% rate of non-union in conservatively treated patients and 6% in in those treated by plate fixation. It also stated a better satisfaction rate in patients who underwent surgery in the long term [112].

A comprehensive review of the Orthopaedic literature was carried out by Hillen RJ. et al in 2010 wherein they studied the available treatment options over a period of 15 years. They published that considering the fact that there was a marked improvement in shoulder functions after correction of a clavicular malunion [113-118], it should be considered as an independent clinical entity and should be analyzed in detail. In accordance to their review, majority of the authors including the likes of Hippocrates have said that attaining alignment of the clavicle using only closed reduction (CR) is not possible. However, the same has been achieved using ORIF using PO or IMN, rendering them better than merely CR and immobilization [1,13,119-126]. The former was said to be extremely successful by quite a few publications due to its mechanical strength and ability to maintain length and anatomical alignment better than CR [127]. IMN by using k wires or elastic nails using the antegrade or retrograde approach was well elucidated by a number of researchers too [128-133]. All of these studies do provide certain drawbacks too of operative management but the overall results show higher preference, satisfaction, functionality and stability with OR instead of CR and immobilization [134].

A similar review was published by Italian researcher Paladini P et al in 2012 by compiling the results of a number of studies from 1968 to the year 2011. They concluded that over those 20 years operative management of MSFOC showed better results with their analysis showing significant depreciation in the relative risk of non-union cases even in undisplaced MSFOC by 72% in IMN and 57% in PO patients. In the cases of displaced MSFOC these numbers rose to 87% and 86% respectively. Even the PROM were significantly better in those who underwent surgery early, more so with PO [21].

Lenza M et al (2013) conducted a meta-analysis of randomised and quasi-randomised control trials in what is considered as one of the highest levels of evidence studies published in Orthopaedic literature. They initially included studies up to 2011 which was later updated in 2019 to include studies till the December of 2017. By analysing 14 studies involving just under 1500 patients of adult age group, they compared the treatment methods with respect to pain, function and quality of life (QoL). Studies by Ahrens PM et al(2017)[135], COTS(2007)[127], Figueiredo EA et al(2008) [136], Melean PA et al(2015) [137], Mirzatolooei F et al(2011) [138], Robinson CM (2013)[90], Naveen BM et al(2017) [139], Tamaoki MJS et al(2017) [140], Virtanen KJ et al(2012) [141], Woltz S. et al (2017) [142], Smekal V et al(2009) [133], Koch HJ et al(2008) [143], Judd DB et al(2009) [144], Chen QY et al(2011) [145] were included. They concluded that all the studies had a low or very low evidence level. They showed that surgical treatment may not improve the aforementioned criteria after a yearlong follow-up but the percentage of failures decreased. Cosmetic satisfaction though was in favour of the surgical group, the post-operative (post-op) complications need to be balanced by joint stiffness and higher non-unions with conservative management. These reports do show better results with ORIF by PO [90,127,135-142] or IMN [133,143-145] but further studies are required with a better level of evidence. They suggested individualized management protocol for every patient till the availability of concrete evidence [146].

A comparatively definitive conclusion was given by Xin-Hua Wang et al in 2015 by their literature review of 13 articles from multiple Orthopaedic databases spanning over a period of 48 years from 1966 to 2014. Out of a total of 959 patients included in the studies that were reviewed, 507 underwent surgical fixation. Operated group showed better statistics with respect to number of nonunions and PROM

scoring namely DASH score and CMSS (RR- 0.16; 95% Confidence interval (CI)- 0.09-0.30; p<0.00001). The same trend was noted while comparing the CMSS and DASH scores of the two groups. Despite reporting a better outcome in operative group, they suggested the need of an individualised approach to each patient even with a displaced MSFOC instead of indiscriminate surgeries [147].

Mishra A. et al undertook a study with a more specific population group that is manual labourers who need overhead abduction as a necessary tool for their work. They assessed the results of treatment options in these groups in Uttar Pradesh, India in 2017. A total of 36 patients were recruited (17 conservative, 19 ORIF by PO) and followed up every month for 1 and a half years radiologically and clinically by CMSS. At the 4-week interval they found excellent clinical results in operative group while non-operative group had above average scores. After 12 weeks, all operated cases had healed (average time 8 weeks) while 4 cases from the conservative group remained unhealed and underwent fixation. The former also showed better final functional outcome than the latter, hence concluding that these fractures should ideally be surgically fixed in this population group of manual labourers as it can significantly affect their mainstay of livelihood [148].

Shobha HP et al compared antero-superior clavicle plating with conservative approach in diaphyseal clavicular fracture management. According to the report published in 2018 in national journal of Orthopaedics, 100 patients were included from 2014 to 2017 in this prospective comparative study. 50 patients were treated using 3.5mm anatomical pre-contoured locking compression plates (LCP) and the other half was managed by conservative approach using clavicle brace and arm pouch. The operated group showed significantly better results with respect to

radiological union (14 weeks vs 23 weeks), return to functional activity (5.2 weeks vs 7.3 weeks), CMSS (93.74+/- 5.81 vs 88.21 +/- 4.42) and DASH score (3.8 +/- 2.4 vs 7.4 +/- 5.8) at 1-year follow-up. While 80% of those who underwent surgery showed excellent outcome, only 6% did do in the conservative group along with 40% malunion and 26% non-union [149].

Hoogervorst P. et al published a detailed literature review in 2018 of all studies pertaining to various treatment modalities, their cost-effectiveness, short and long-term outcomes, both functionally and in accordance to patient satisfaction. They documented multiple findings regarding treatment options. Surgical fixation was reported to give better patient satisfaction, earlier return to work and sports, better functional outcome, better restoration of anatomical length and alignment and lower non-union rate (2%). ORIF using PO was said to be gold standard as it gave better four-point stability compared to IMN. Although accompanied by their own complications, surgical fixation also proved to be more cost-effective [150]. This was due to the lesser working days missed (8.4 vs 35.2), less dependency for DAL (3 days vs 7 days) and less net expenditure on physiotherapy ($971.76 vs $1820). Hence the lesser cost incurred is not just dependant on the cost of treatment but also on the temporal magnitude and degree of disability and dependency post-treatment [151]. They finally suggested a shared decision-making model between the physician and the patient for such fractures [75].

To make up for the dearth of literature focussing on Indian population, Kotekar MF et al published a research in 2018, studying the anatomy of the clavicle in the Indian population and defining its application for pre-countered anatomical clavicle plates. They specifically studied these plates due to their low-profile,

acceptable mechanical strength and minimal soft tissue irritation. CT scans performed on 144 patients between 2013 and 2017 were reviewed and considered for this study. The mean length was found to be 145.31±13.27mm with mean cortical diameter 11.20±1.20mm. The superior-anterior plates showed better fit than purely superior plates (89.3% vs 71.6%) with significant difference between the mean travel distances of these two plates too (29.49 ± 11.62 mm vs 22.92 ± 14.39 mm). They finally suggested the use of pre-countered superior-anterior plates for south Indian population as it had 98% good or excellent fit sans additional intra-operative moulding [40].

All patients with clavicle fractures registered between January 2010 and May 2018 were analysed retrospectively and those who underwent surgery were maintained prospectively with a minimum 6-week follow-up period by Kluijfhout WP et al who assessed patients treated conservatively and compared the results between acute and delayed surgical fixation (mean 162 days post injury) of the clavicle. 93% of those treated conservatively showed excellent results. When analysing the operative group, it was noted that those who underwent acute surgery showed better CMSS (96.2 ± 5.9 vs. 84.4 ± 16.6 ($P < .001$)) and DASH score (5.4 ± 6.4 vs. 15.1 ± 13.2 ($P < .001$)) at the end of 6-week follow-up. Complications too were found to be higher in the delayed surgery group (31.3% vs 12.3%). They concluded by saying that though conservative treatment showed excellent results in majority of patients, surgical fixation should be preferred in those who have high demand or in athletes. The need for shared decision making was again highlighted in this study [152].

In addition to these, multiple studies that were done from 2011 to 2020 showed similar trend and conclusions when comparing the two modalities of treatment. The prospective studies done by Kulshrestha V et al (2011)[153] and O'Neill

BJ et al (2011)[26] stated that operative treatment showed lesser rates of symptomatic malunion and non-union and better PROM especially in displaced MSFOC. In 2016, Burnham JM et al reported better outcome scores and patient satisfaction with operative clavicle fixation in their critical literature review [154] while Sheps D commented that operative fixation regularly resulted in excellent outcomes in displaced MSFOC in terms of return to activity and functional outcome especially with second generation plating systems. There were lesser incidences of hardware related complications too in these patients. Hence, he advised the used of this approach particularly in displaced MSFOC [155]. This was reflected in the recent research published by Hyland S et al (2020) in which they mentioned that owing to the deforming forces acting on MSFOC, the degree and incidence of displacement even after closed reduction and immobilization is high. They stated the need for surgical intervention in these cases either by PO or IMN [156] confirming everything that the aforementioned studies favouring surgical management have cited as an advantage over conservative management be it clinical, functional, radiological, or economical [5].

There has been a long-standing debate regarding not just the approach to the management of these fractures but also with regard to patient selection, the surgical method to be used for reduction and fixation and even the positioning of these implants on the bone owing to its irregular anatomy. The debate regarding indications of surgical intervention still remains a grey area in the literature. Some studies have been done indication definitive and relative indications for the same. However, no conclusive protocol or guidelines exist for patient selection of either PO or IMN in these fractures.

One such study was done by De Giorgi S et al in 2011 studying 71 patients for the restoration of structural and functional integrity of the shoulder gridle. They noted a shortening in the range of 15 to 23 mm, more so with conservative treatment. Considering that physiologically the length of the clavicle can vary from anything between 140 and 158mm. They suggested 9.7% shortening as the lower limit for predicting failure of non-surgical treatment [157]. Hence degree of shortening was considered as one of the indications for surgery.

In the subsequent year (2012) Paladini et al conducted a literature review and proposed multiple absolute and relative indications for surgical management. Compound fractures, tenting of the skin, neurovascular deficit, multiple traumas, floating shoulder and shortening of more than 2 cm were the absolute indications suggested while shortening between 1.5-2cms, cosmetic deformity, young age group and active patients were touted as the relative indications for surgery. These were reflected by the study of Lenza M et al (2013) who also stated compound fractures, severe comminution, overlying skin condition (chances of possible compromise) and neurovascular compromise as absolute and complete displacement, high degree comminution, high energy trauma as relative indications [146].

Ban I et al undertook a more comprehensive research in 2016 with respect to factors that contribute to the decision making of operative treatment. According to their report higher association is found with displacement by more than one bone width, shortening by more than 2cm, large intermediary fragment, severe comorbidity, alcohol abuse and to a lesser extent with angulation in absence of displacement, advanced age and smoking [158]. Waldmann S et al added associated serial ipsilateral rib fractures, compromised overlying skin condition, female gender

and floating shoulder to the above list in 2018 based on their detailed review of the Orthopaedic literature [159].

With the increasing advent of surgical procedures for the fixation of these fractures, the focus shifted towards determining which surgical modality had the best combination of pros and cons. Many procedures were proposed from ORIF using PO or IMN to CR and external fixation. One of the first studies that attempted to find a solution to this dilemma was conducted by Golish SR et al in 2008. They studied the biomechanics of plating and IMN for MSFOC in 8 sets of cadaveric clavicles matched with each other. Using 3.5mm dynamic compression plates (DCP) and 3.8mm or 4.5mm IMN for fixation, they loaded the clavicles at 6 distinct loads for 3000 cycles at 1 Hz with 180 N and then doubling it to 360 N at 2 Hz. They concluded that plate constructs were far more adept at controlling displacement during specific loading and when the loading is increased with the displacement kept constant with 4-point bending. This may facilitate early ROM and rehabilitation for patients treated with PO [33].

This was backed up by Khan LA et al [3] literature review in 2009 where they exhaustively reviewed the treatment option for all segments of the clavicle. With respect to the middle third, they concurred that PO provides a more stable fixation with better pain subsidence and early rehabilitation [20,23,121,160-162]. They also suggested an anterior-inferior plating apart from superior fixation to reduce complication rates although the former showed less secure fixation [125]. They also reviewed the differences between DCP, LCP and pre-countered locking plates with reinforced locking screw option. They concluded that the recon plates, despite being superior in terms of low profile and hardware prominence, it had inferior rigidity and

was vulnerable to get deformed at the maximal stress site due to the fracture [127,163]. They also warned against the possible complications such as infection [122], implant failure [122], scarring [164], pull-out [122,165], refracture post-removal [120,122,165], and intra-op neurovascular compromise [166].

A few publications like the one by Houwert RM et al in 2012 show no significant difference between PO and IMN [32]. Based on their meta-analysis, they reported from 1 high quality and 3 low quality studies (Ferran NA et al(2010) [167], Liu HH et al(2010) [168], Thyagarajan DS et al(2009) [112], Böhme J et al(2010) [169]) that when it comes to displaced MSFOC, both PO and IMN show similar trends of functional outcomes after 12 months and 18 months based on DASH score and CMSS. No statistical difference between these two modalities was noted either [112,167-169]. Wang XH et al (2015) [147] conducted yet another literature review to supplement the one by Houwert RM et al. The compilation of their results showed no significant discrepancy between the PROM (DASH and CMSS) at 6 months follow-up [170-172], as well as no statistically significant difference between the incidence of complications between PO and IMN [167,170,171].

Asadollahi S et al (2016) reviewed all 138 patients from 2002 to 2010, who had undergone operative intervention for MSFOC at their trauma centre in Australia. PO was done in 80% of these patients while the rest were treated by IMN. They reported significantly lower rates of complications in the group treated by PO as compared to IMN (10% vs 32%). However, they also noted that a greater number of patients required removal of the implant due to hardware problems in the PO subset. The fact that close to 35% complications were touted to be secondary to inadequate

surgical technique, warrants more attention to detail so as to stem the incidence of such avoidable complications [173].

In 2016, Huang TL et al published a study comparing positioning of the clavicular plates and concluded that the maximum structural rigidity was provided by anterior plating under cantilever loading and superior plating under axial compression. Spiral plates gave better multi-directional stability but was inferior to both the aforementioned models [174].

STIFNESS	CANTILEVER BENDING	AXIAL COMPRESSION	AXIAL TORSION
ANTERIOR PLATING	33.2 N/mm	56.1 N/mm	0.252 Nm/deg
SUPERIOR PLATING	10.9 N/mm	163.7 N/mm	0.244 Nm/deg
SPIRAL PLATING	15.1 N/mm	100 N/mm	0.241 Nm/deg

Ropars M et al in 2017 studied the bone morphology with respect to plating more comprehensively and made some important observations. The clavicle is said to be structured around a medial anteriorly convex and laterally posteriorly convex (radius 66mm vs 36mm) which helps it resist compression forces more efficiently [175]. When it comes to segmentation, the middle segment is 1.7 times the lateral and medial is 1.5 times the lateral thus making the lateral segment the shortest [175]. Discussing PO vs IMN, they cited two studies (both in 2015), one prospective and the other a meta-analysis by Andrade-Silva et al [176] and Wang et al [147] respectively which showed no significant difference between the two in terms of PROM, pain, period of consolidation, complication rate or patient satisfaction [177].

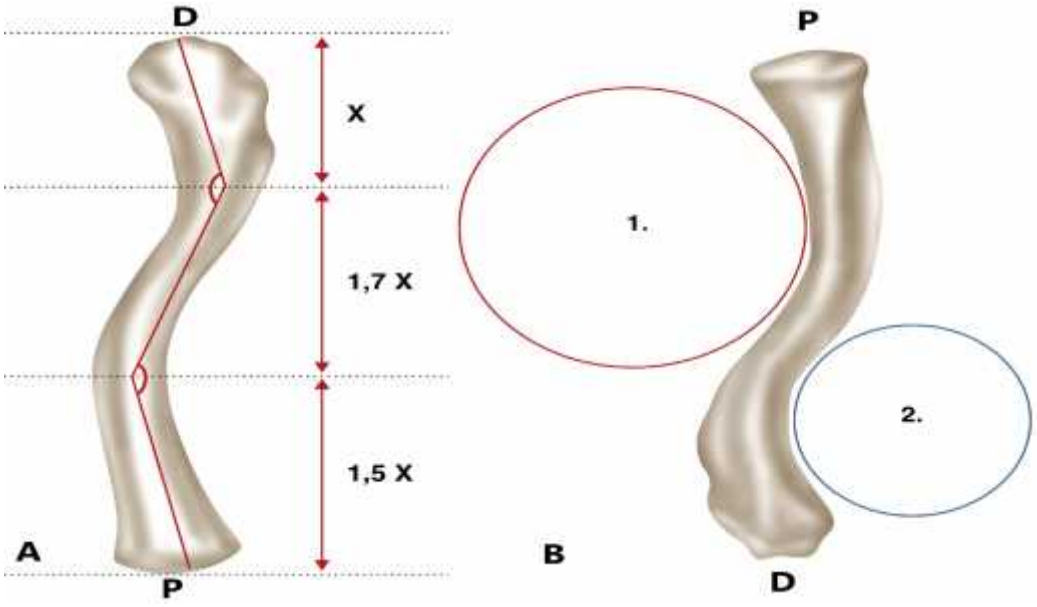


Figure 8: *(A)Clavicle segmentation according to Bachoura. P. Proximal. D. Distal. X is the width of the lateral segment; 1.7 X is the corresponding middle segment length, and 1.5 X the medial segment length. The segmentation is based on the clavicle curve angles. (B) Clavicle curves. A. Proximal. B. Distal. 1. Great medial curve. 2. Lesser lateral curve. Drawing: Anne-Christel Rolling.*[175]

The study published by Hoogervost P et al (2018) [75] was in agreement with the findings of majority of the aforementioned studies. They said Low contact DCP(LCDCP) to be better than recon plates and that positioning of the plate had no say in the final functional outcome of the patient or the rate of infection [178]. They also proposed dual mini-fragment plating which however requires further studies [179]. The necklace incision was ascertained to be a more patient oriented incision than the regular longitudinal incision [180].

METHODOLOGY

This study was conducted at KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, and Charitable Hospital, Belagavi from January 2019 to December 2019.

Study design

The study design was a one-year hospital based non-random prospective comparative study.

Duration and period of study

Present one-year study was conducted from January 2019 to December 2019.

Place

This study was done in the Department of Orthopaedics, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, and Charitable Hospital, Belagavi

Source of Data

Patients coming to or brought to the OPD, Casualty or referred to the department of Orthopaedics in KLES Dr. Prabhakar Kore Hospital and Medical Research Centre and Charitable Hospital, Belagavi after clinical and radiological confirmation of mid-shaft clavicle fracture were studied.

Sample Size

A total of 44 patients coming to or brought to the OPD, Casualty or referred to the Department of Orthopaedics, KLES Dr. Prabhakar Kore Hospital and Medical

Research Centre, and Charitable Hospital, Belagavi after clinical examination with radiological confirmation of mid-shaft clavicle fracture. They were segregated into two groups comprising 22 patients each based on the modality of treatment, Conservative (Group A) or Surgical (Group B).

Sample size calculation

All patients who fulfill the inclusion criteria at the over a period of one year with a minimum target of 36 patients (18 in each group). The sample size was calculated based on the average number of documented clavicle fixation surgeries done per year over the last 5 years at KLE'S Dr. Prabhakar Kore Hospital & Medical Research Centre, Belagavi, as per the medical records department. However, there is a scope for increasing the number of cases depending on their availability within the study period based on the following formula which shall be used in case the number exceeds the determined sample size.

$$n= 2S^2(Z\alpha+Z\beta)^2/d^2$$

where n= Sample Size

S= average of standard deviation of shoulder abduction between two groups

d=Mean difference in shoulder abduction between two groups

The mean d1 and standard deviation S1 for group A is 3.20 and 3.201. The mean d2 and standard deviation S2 for group B is 7.698 and 4.03 (as determined from a similar past study).

Zα = 1.96 at 5% alpha error

Zβ = 0.842 at 20% beta error

n is 19.657 participants in each group. Rounding off to 20. Substituting these values in the formula, n = 20 and enrolment ratio is 1:1. Hence, the sample size was a

minimum of 40 patients (minimum 20 in each group). Accordingly, 22 patients each were included in group A and group B.

Selection Criteria

Inclusion

- All patients with age between and inclusive of 18 years and 60 years.
- All closed middle third clavicle fractures determined clinically and radiologically.

Exclusion

- Pathological fractures
- Patient not fit for surgery
- Patients with fatal brain injury, intubated patients.
- Patients with open fractures or ipsilateral upper limb fracture.
- Patients with diabetes mellitus, congenital osseous or cartilaginous pathologies, or conditions that can delay the healing process.
- Patients with injury precluding operative fixation within 7 days of admission.

Implants used in plate osteosynthesis

- The plate and screws are manufactured from 316L stainless alloy or titanium with gun drilling technique.
- The locking compression plates and pre-contoured plates of 3.5mm thickness are available from 6 holes to 10 holes with 3.5mm limited contact dynamic plates also available.
- Anatomically pre-contoured plates have anterior bowing and softer edges.
- Locking and non-locking screws are available of sizes 2.7mm cortical, 3.5mm cortical, and 4mm cancellous.
- The head of locking screws are threaded which get locked to the plate when tightened.
- Lag screws are also available of the aforementioned sizes and are most commonly used as 3.5mm with 2.8mm drill bit.

A standard LCP implant and instrument set

SURGICAL PROCEDURE

1. After a thorough radiographic evaluation has been completed, the patient is placed in a beach chair position with the head rotated and tilted 5° to 10° degrees away from the operative side. A bolster is placed between the shoulder blades allowing the injured shoulder girdle to retract posteriorly. The patient's involved upper extremity is prepped and draped in a sterile fashion allowing the arm to be manipulated to help further reduce the fracture.

2. A transverse (medial to lateral) infraclavicular incision is made parallel to the long axis of the clavicle so that the scar does not lie over the plate.

3. The subcutaneous fat is incised together with any fibers of the platysma. Identifying and protecting branches of the supraclavicular nerves preserves cutaneous sensation inferior to the incision. The pectoralis fascia is divided in line with the incision and elevated with electrocautery to create thick flaps that can be closed over the plate at the end of the procedure. It is important to keep soft tissue attachments to the butterfly fragments in an attempt to maintain vascularity. Prior to placement of the plate, lag screw fixation across the major fracture fragments may be performed for neutralization or axial compression.

4. Once the plate's ideal positioning has been selected, it is provisionally stabilized to the clavicle with plate tacks or bone clamps. Ideally the plate should be applied in compression mode to reduce the risk of delayed union or non-union. The plate may be applied to one of the major fracture fragments and used as a tool to reduce other major fragments to this bone-plate construct.

5. Non-locking screws may be placed either unicortical or bicortical. If bicortical screws are used, it is important not to over-penetrate the inferior cortex and potentially risk neurovascular injury. A curved retractor or other means of protection should be placed under the inferior surface of the clavicle to protect the neurovascular structures from over-penetration of the drill bit. For early stability, the first two screws placed should be medial and lateral to the fracture site. The other screws are fixed similarly.

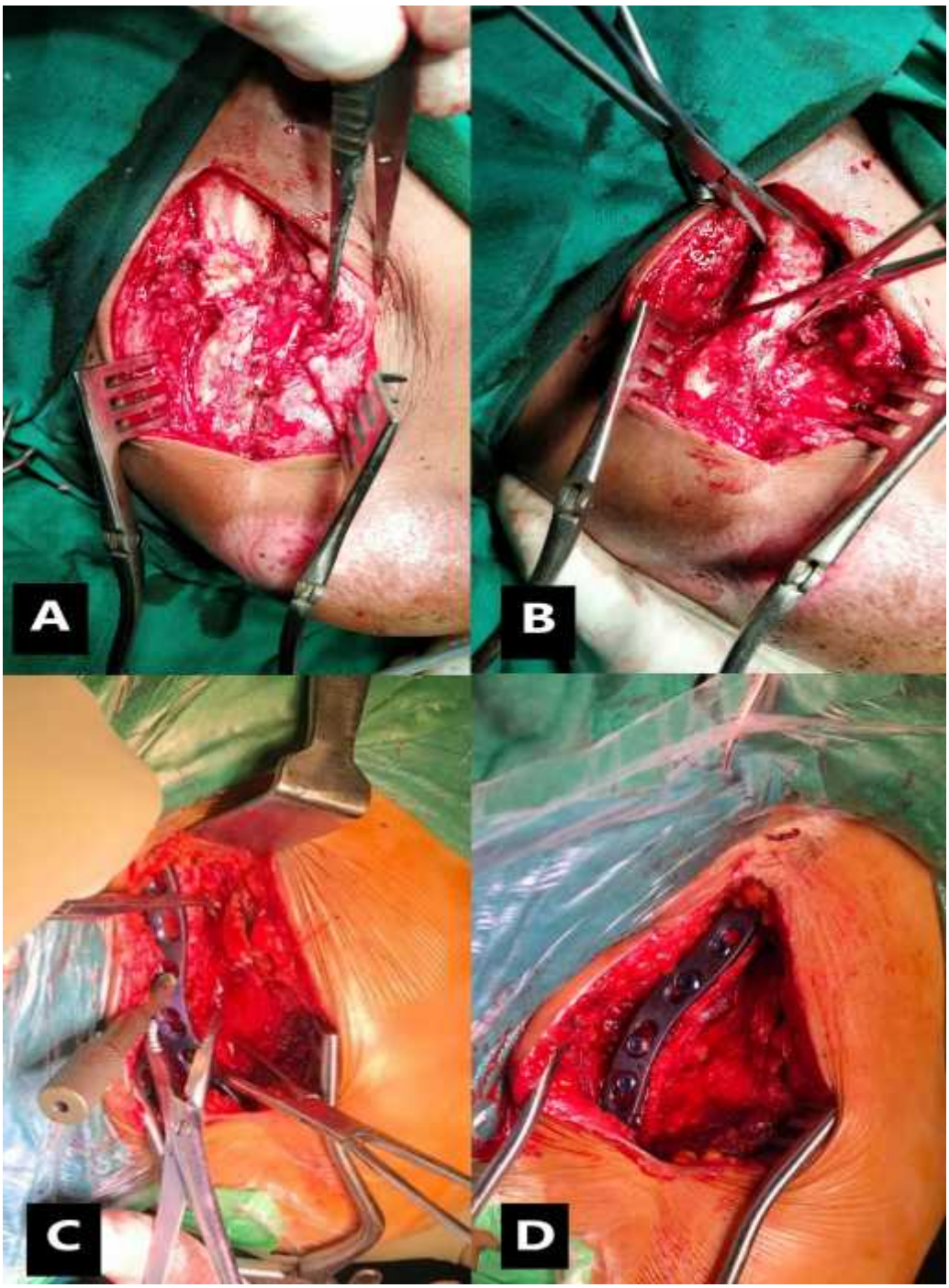
6. After radiographic evaluation and thorough irrigation, the clavipectoral fascia is closed over the clavicle and the plate, followed by closure of the subcutaneous tissue and musculature in separate layers. Finally, close the skin by using interrupted absorbable sutures with a subcuticular stitch and sterile dressing of the wound is done.

POST-OPERATIVE PROTOCOL: Regular dressing and a short course of antibiotics were given as per hospital protocol. For the first four weeks, the patient is placed in either an arm sling or shoulder immobilizer. Passive ROM exercises were initiated for the first four weeks which included pendulum, Codman, isometric bicep, and elbow and wrist motion. Patients were made to avoid any activity involving heavy lifting, pushing or pulling. Depending on the amount of comminution and the stability of fixation, active assisted exercise was started from four to six weeks, and active strengthening at six to eight weeks post-operatively, once healing is seen radiographically. A full return to activities was permitted once healing has occurred.

FOLLOW-UP: All patients were followed up at 6 weeks, 3 months and 6 months. They were evaluated clinically, radiologically and functionally.

Patient positioning in beach chair position

Transverse incision from medial to lateral



Photograph 1: Intra-operative pictures of fixation of patient. (A) Exposure of fracture fragments. (B) Reduction of fracture fragments. (C) Positioning of pre-contoured combo-plate. (D) Fixation of the plate.

Ethical clearance

Prior to the commencement, approval for the study was obtained from the Institutional Ethical Committee, KAHER, Jawaharlal Nehru Medical College, Belagavi.

Informed Consent

The patients who fulfilled the selection criteria were informed about the nature of the study. They were also explained about the procedure, possible complications and the need for religious follow-ups in their own vernacular language following which a written informed consent was obtained to participate in the study (Annexure I).

Data collection

Demographic data such as age, sex, occupation and dominant side were noted. Extensive history taking was carried out in the patient's vernacular language regarding the side affected, mode of injury, direct or indirect trauma to the clavicle, injury to the ipsilateral upper limb, other systemic complaints and days since the injury. Past history was elicited regarding underlying co-morbidities and congenital conditions. Further these patients were subjected to local and systemic clinical examination to confirm clavicle fracture and rule out concomitant injuries.

Thorough clinical examination was done to rule out compound injuries or overlying skin damage that precluded surgical intervention. Following clinical examination, the patients were sent for radiography namely plain radiograph in the antero-posterior and axial view (30-degree cephalic tilt) of the affected clavicle and

additional radiographs as needed. Once radiological confirmation of Allman type 1 clavicular fracture was made, they were classified based on Robinson classification and the degree of displacement was noted.

The patients were then explained in detail about the study and informed written consent was taken of those who wished to participate. The patients were explained in detail regarding the associated risks and benefits of both the treatment modalities and underwent either undergo immobilization of the ipsilateral upper limb using figure-of-8 bandage and Arm pouch/sling/special shoulder immobilizer or Open Reduction and Internal Fixation by plating (with screws) depending on their choice. The patients were operated as per fitness for the surgery. The surgery was performed by a single specialist Orthopaedic surgeon.

Post-operatively patients were given anti-biotics for three days and subsequently discharged as and when deemed fit for the same. Patients were followed up at 6 weeks, 3 months and 6 months post-intervention, irrespective of the treatment modality and duration of hospital stay. As is standard protocol, those treated conservatively were immobilized for a minimum period of 6 weeks while their counterparts for 2 weeks following which physiotherapy was started to regain range of motion and strength. Weight lifting assisted exercises were encouraged once callus formation was observed on radiograph. Patients were evaluated radiographically as well as clinically using the Constant-Murley Shoulder Score, Nottingham Clavicle Score and DASH score using the respective scoring techniques that included questionnaires as well as functional outcome as observed by the Orthopaedician. Finally, a subjective evaluation was done out of 10 based on the satisfaction level of the patient. All the data was collected, noted, documented and compiled.

Outcome variables

- **Radiological:** Time to union, Malunion, Non-union
- **Functional:** Constant-Murley Shoulder Score, Nottingham Clavicle Score, DASH score, overall patient satisfaction, Time to mobilization, Time to return to daily work, clinical complications.

Statistical analysis

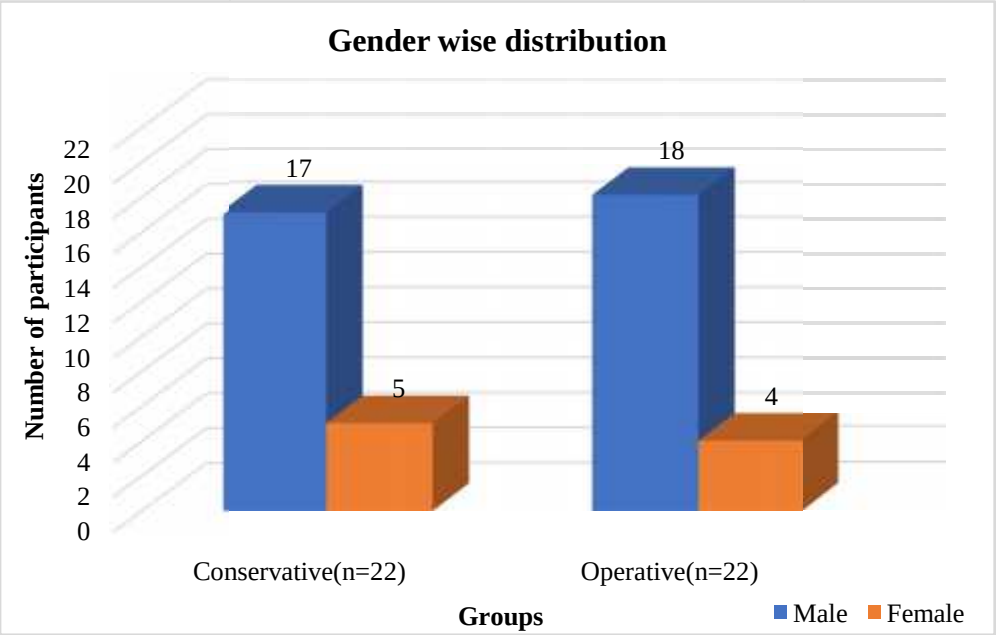
Data obtained was compiled and entered into Microsoft Excel spreadsheet (Annexure III). The categorical and descriptive data were expressed as rates, ratios and percentages. The continuous data was expressed as mean ± S.D. Intergroup comparison of outcome measures was done using Man Whitney U Test. Intra-group comparison of PROMs were done by Friedmann's test. A probability (p) value of less than 0.05 was considered as statistically significant.

RESULTS

Table 1: Gender wise distribution of study participants across two groups

Gender	Conservative(n=22)	Operative(n=22)	Total
Male	17 (77.3%)	18 (81.8%)	35 (79.5%)
Female	5 (22.7%)	4 (18.2%)	9 (20.5%)

Graph 1: Gender wise distribution of study participants across two groups

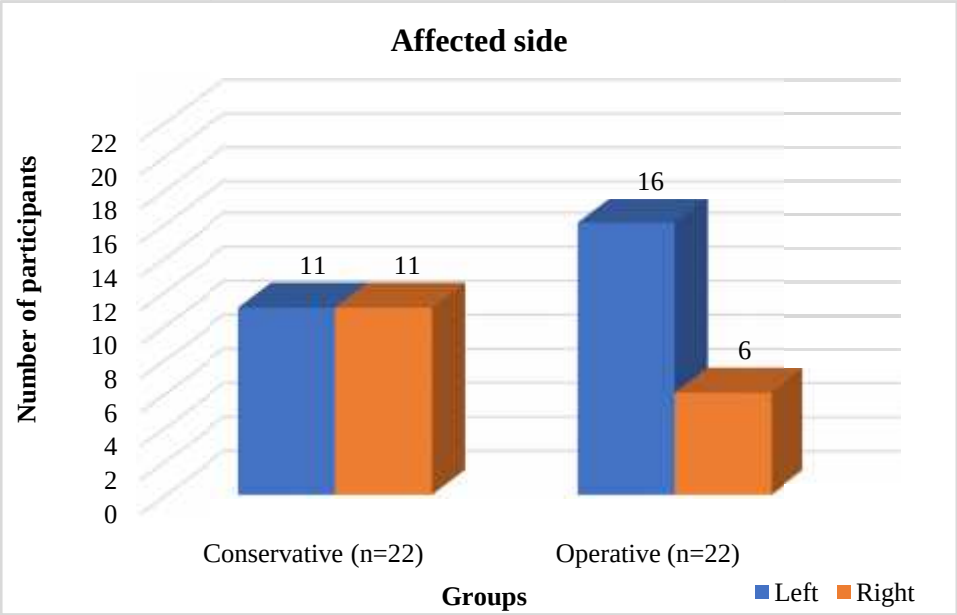


The total number of participants (n) in the study were 44 which involved 35 males (79.5%) and 9 females (20.5%). The intergroup distribution was similar with conservative group having 3.4:1 while operative group having 4.5:1 male to female ratio. A male preponderance was noticed as has been well established in the literature [57,61].

Table 2: Affected side wise distribution of study participants across two groups

Affected side	Conservative(n=22)	Operative(n=22)	Total
Left	11 (50%)	16 (72.7%)	27 (61.36%)
Right	11 (50%)	6 (27.3%)	17 (38.64%)

Graph 2: Affected side wise distribution of study participants across two groups

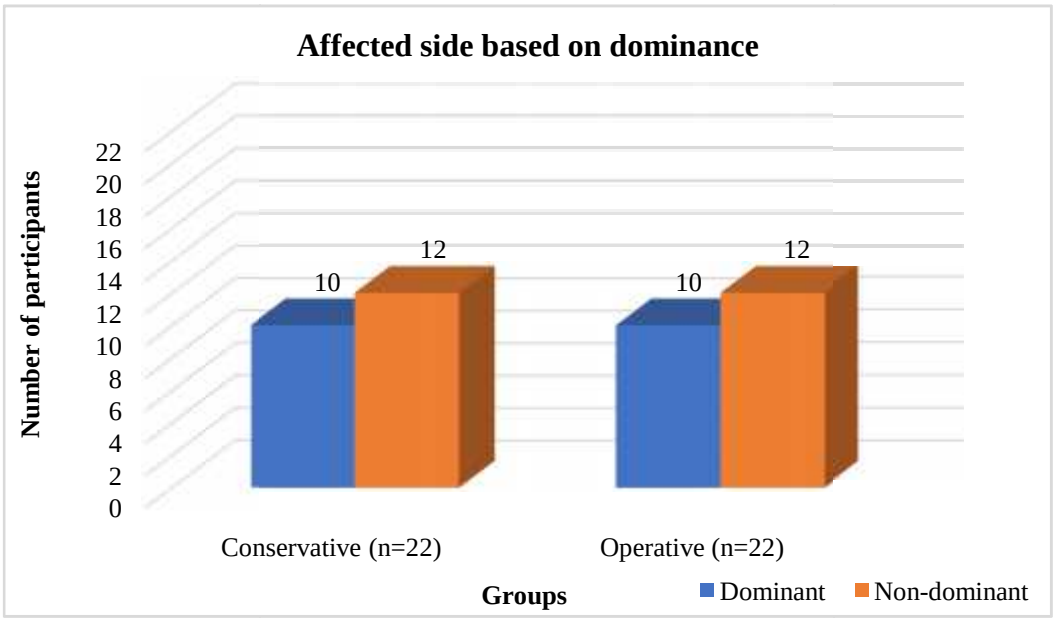


A higher number of patients presented with left-sided clavicle fracture as compared to the right side which is in agreement to the study conducted by Postacchini F et al. [57] and Kihlström C et al. [61]. A total of 27 (61.36%) left-sided fractures were noted as compared to right side (38.64%). Conservative group had a relatively balanced ratio of 1:1 while the Operative group had higher number of left-sided fractures in the ratio of 2.67:1.

Table 3: Affected size based on dominance wise distribution of study participants across two groups

Affected side	Conservative(n=22)	Operative(n=22)	Total
Dominant	10 (45.5%)	10 (45.5%)	20 (45.5%)
Non-dominant	12 (54.5%)	12 (54.5%)	24 (54.5%)

Graph 3: Affected size based on dominance wise distribution of study participants across two groups

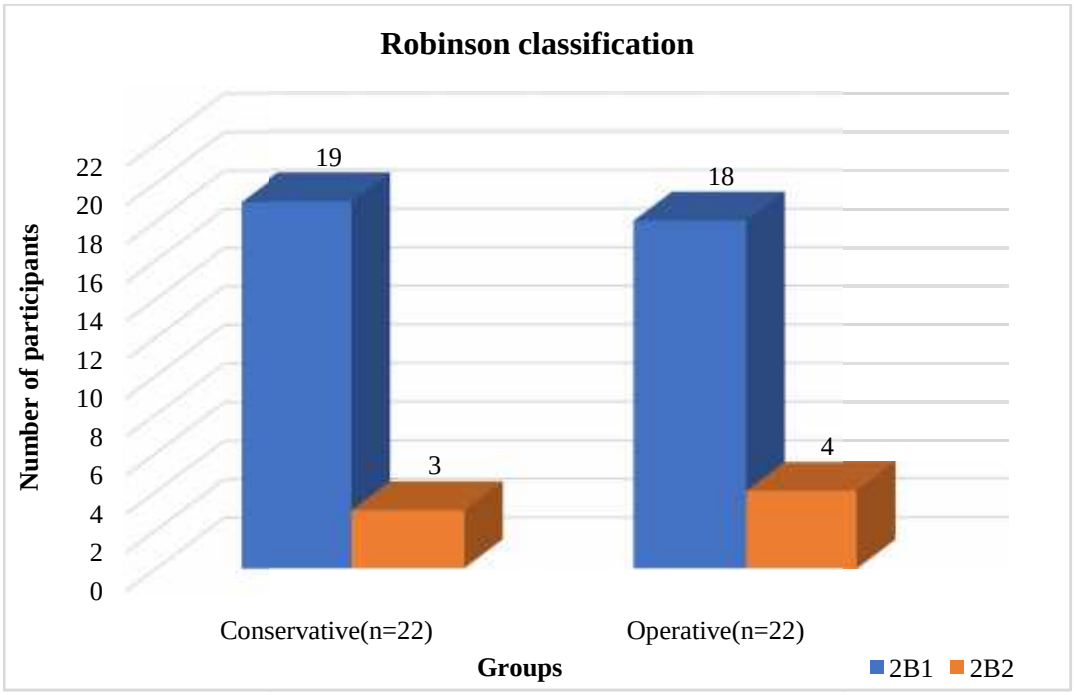


We noticed that 24 (54.5%) of our patients suffered from the fracture on their non-dominant side with 20 (45.5%) suffering on the dominant side. The intergroup analysis was startlingly similar with both the groups having a non-dominant to dominant ratio of the affected side as 1.2:1. Further studies may be needed to establish this co-relation.

Table 4: Distribution of participants according to Robinsons classification across two groups

Robinson classification	Conservative(n=22)	Operative(n=22)	Total
2B1	19 (86.4%)	18 (81.8%)	37 (84.1%)
2B2	3 (13.6%)	4 (18.2%)	7 (15.9%)

Graph 4: Distribution of participants according to Robinsons classification across two groups

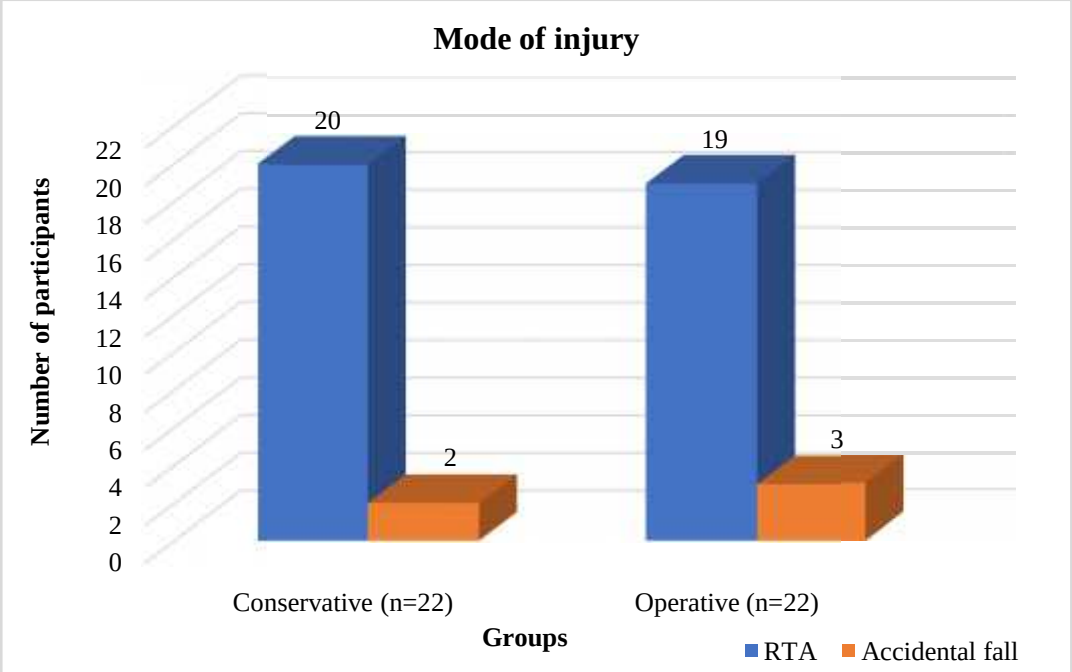


Radiological classification of the fractures revealed that 37 (84.1%) of the patients had Robinson type 2B1 fracture with the remaining 7 (15.9%) having Robinson type 2B2 fracture. Resemblance was noted between the two groups with Conservative group having the ratio of 2B1 to 2B2 as 6.33:1 and Operative group as 4.5:1.

Table 5: Distribution of Participants according to the mode of injury across two groups

Mode of injury	Conservative(n=22)	Operative(n=22)	Total
RTA	20 (90.9%)	19 (86.4%)	39 (88.6%)
Accidental fall	2 (9.1%)	3 (13.61%)	5 (11.4%)

Graph 5: Distribution of Participants according to the mode of injury across two groups

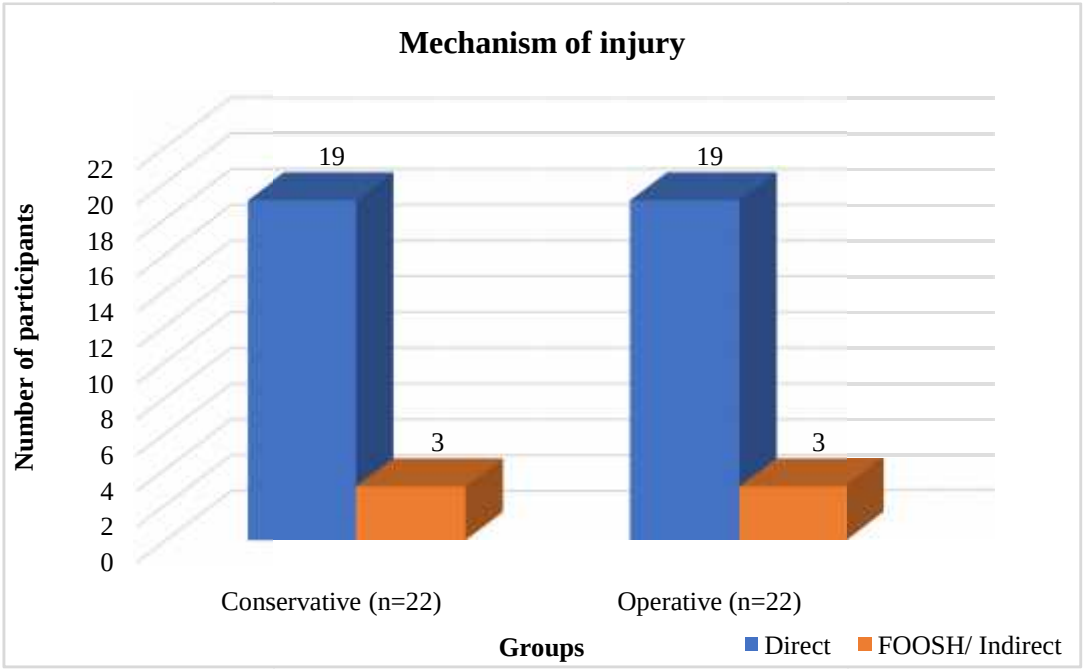


The epidemiological statistics of our study were in correspondence to the multiple previously published researches which stated that RTA was the most common cause of injury. The fact that 39 (88.6%)of our patients suffered from RTA as opposed to a mere 5 (11.4%) from accidental fall confirms the aforementioned. With both the groups maintaining the ratio of RTA to fall at 10:1, it may also explain the higher male population in our study as they are more predisposed to the same.

Table 6: Distribution of participants according to the mechanism of injury across two groups

Mechanism of Injury	Conservative(n=22)	Operative(n=22)	Total
Direct	19 (86.4%)	19 (86.4%)	38 (86.4%)
FOOSH/ Indirect	3 (13.6%)	3 (13.6%)	6 (13.6%)

Graph 6: Distribution of participants according to the mechanism of injury across two groups

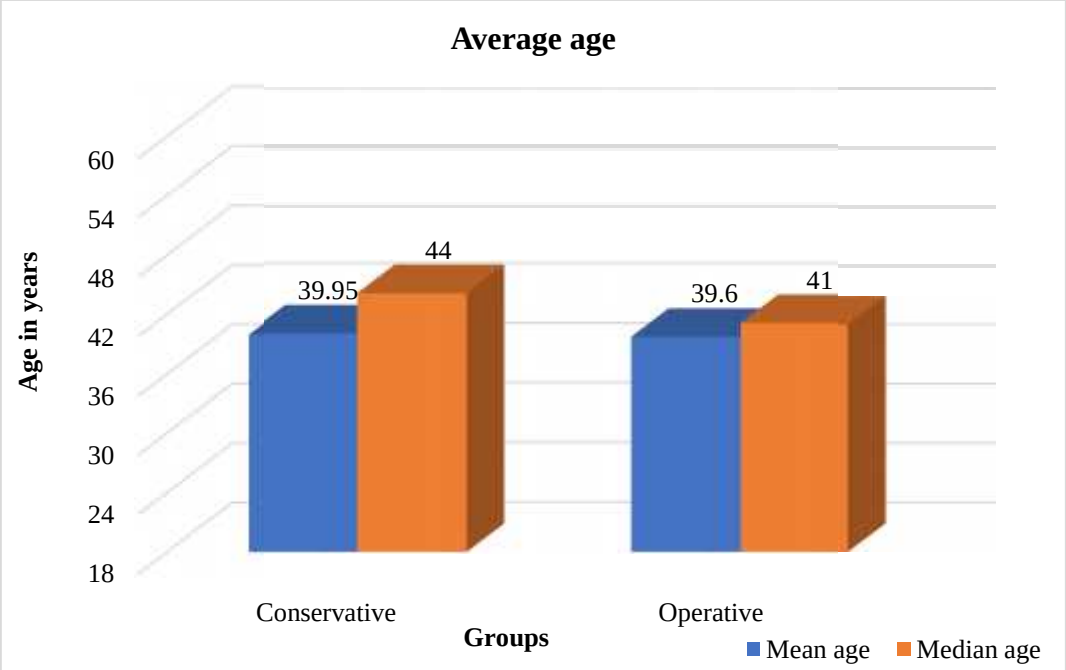


With a higher proportion of patients giving a history of RTA, the mechanism of injury was direct in 38 (86.4%) patients and by FOOSH or indirect in 6 (13.6%) patients. 19 patients (86.4%) each in both the groups gave a history of direct injury while the rest 3 (13.6%) gave a history of indirect injury in the ratio of 6.33:1.

Table 7: Age Wise distribution across groups of the participants in years

Age	Conservative	Operative
Mean age(+/- S.D)	39.95 (±13.304)	39.6 (±13.72)
Median age (IQR)	44.0 (41,49)	41 (49.25,26.75)

Graph 7: Age wise distribution across groups of the participants

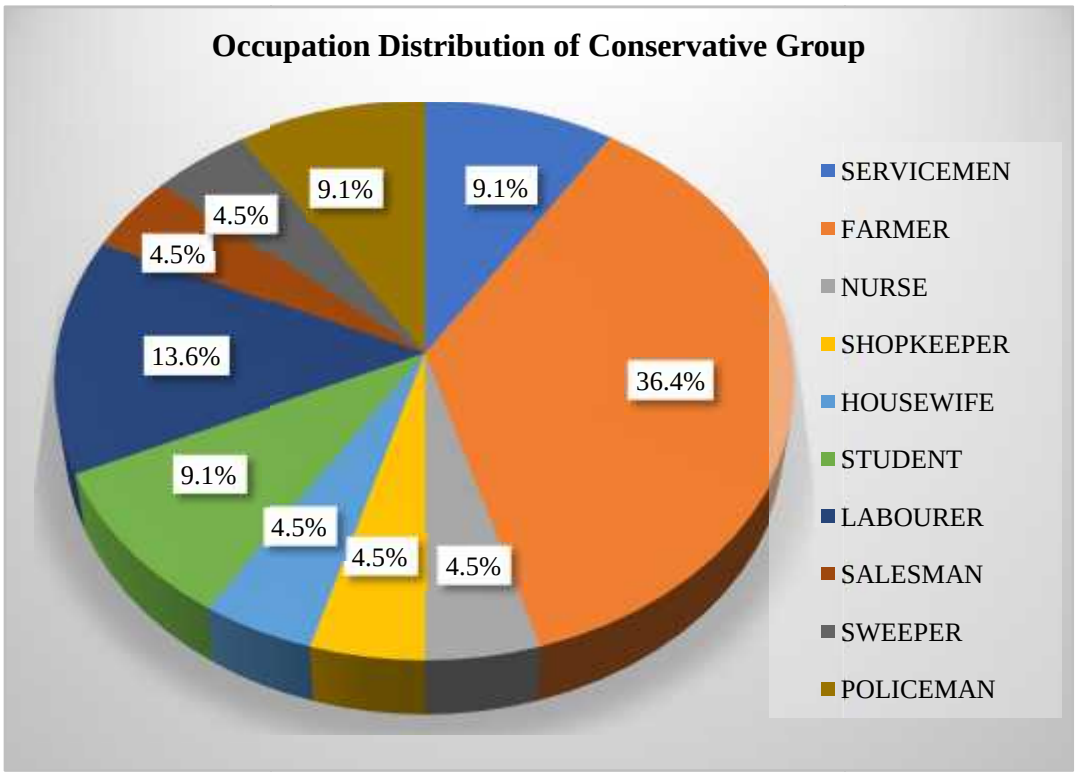


The mean age of Conservative group in our study was 39.95 years with a standard deviation of ±13.304 and the range of 18 – 60 years. The mean age of Operative group in our study was similar, that is 39.6 years with a standard deviation of ±13.72 and the range of 20 - 60 years. The median age of the two groups was found to be 44 years and 41 years respectively.

Table 8: Occupation Wise distribution of the participants treated conservatively

Occupation	Frequency	Valid Percent
SERVICEMEN	2	9.1
FARMER	8	36.4
NURSE	1	4.5
SHOPKEEPER	1	4.5
HOUSEWIFE	1	4.5
STUDENT	2	9.1
LABOURER	3	13.6
SALESMAN	1	4.5
SWEEPER	1	4.5
POLICEMAN	2	9.1
Total	22	100.0

Graph 8:Occupation Wise distribution of the participants treated conservatively

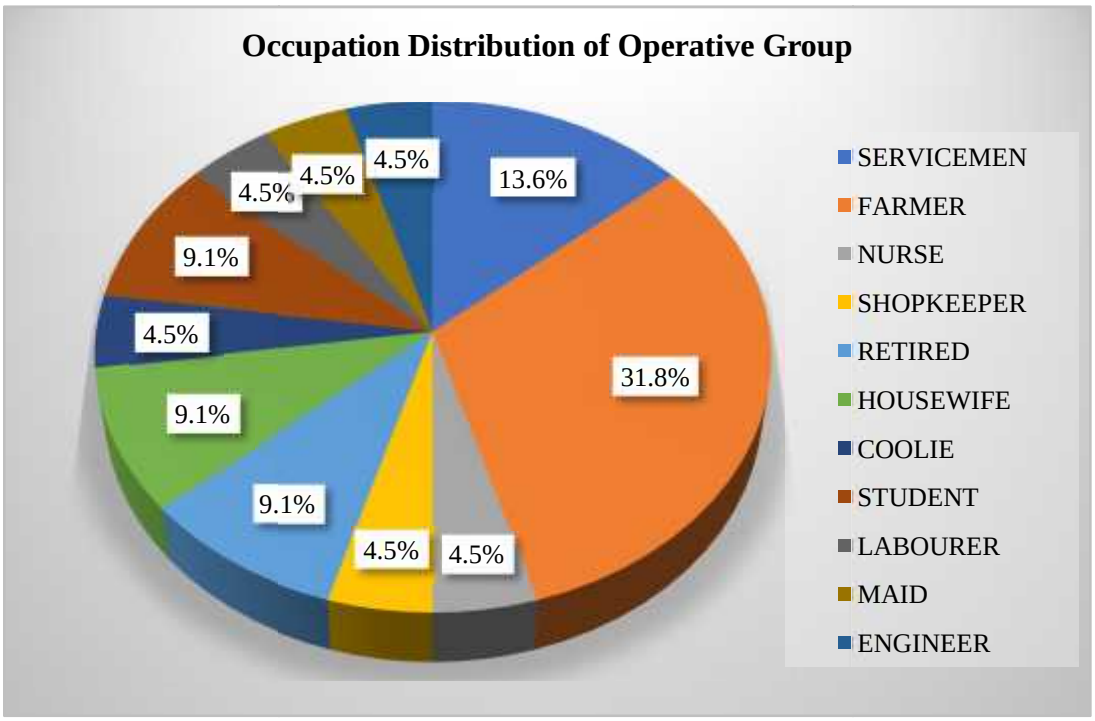


Majority of the patients in both the groups had an active lifestyle. Conservative group comprised of 8 (36.4%) farmers; 3 (13.6%) labourers; 2 (9.1%) each policemen, servicemen and students; 1 (4.5%) each sweeper, salesman, nurse, shopkeeper and housewife.

Table 9: Occupation Wise distribution of the participants treated operatively

Occupation	Frequency	Valid Percentage
SERVICEMEN	3	13.6
FARMER	7	31.8
NURSE	1	4.5
SHOPKEEPER	1	4.5
RETIRED	2	9.1
HOUSEWIFE	2	9.1
COOLIE	1	4.5
STUDENT	2	9.1
LABOURER	1	4.5
MAID	1	4.5
ENGINEER	1	4.5
Total	22	100.0

Graph 9:Occupation Wise distribution of the participants treated operatively

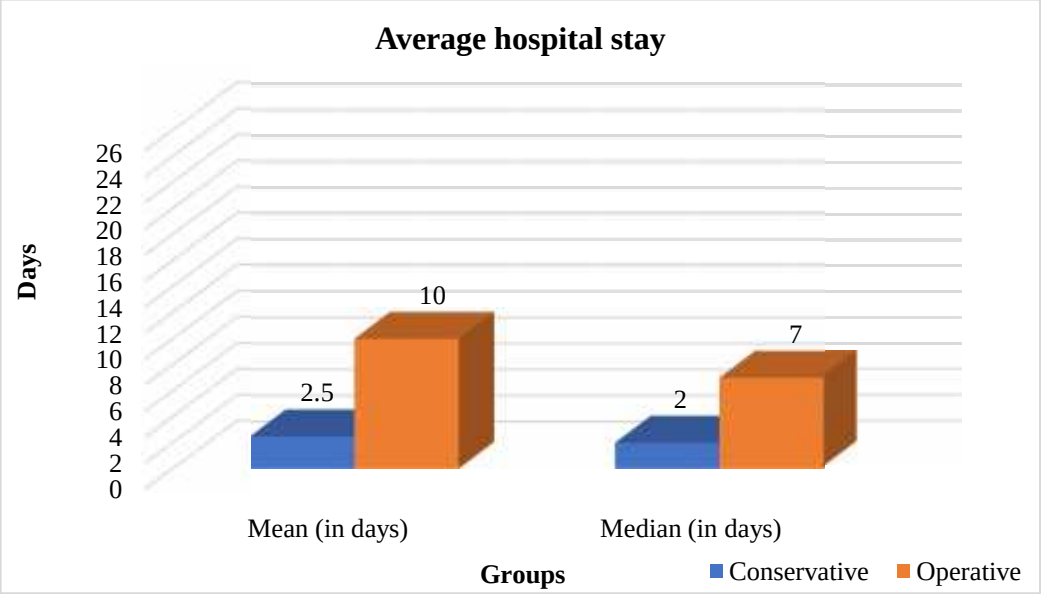


Operative group comprised of 7 (31.8%) farmers; 3 (13.6%) servicemen; 2 (9.1%) each retired personnel, housewives and students; 1 (4.5%) each coolie, maid, nurse, shopkeeper and engineer.

Table 10: Intergroup comparison of mean hospital stay in days (MAN-WHITNEY U TEST) (*p value<0.05 is statistically significant)

Mean Hospital stay	Mean	Standard deviation	Median (IQR3,IQR1)	Z score	P value
CONSERVATIVE	2.49	3.29	2(0.75,2)	4.801	**0.000***
OPERATIVE	10	6.6	7(5.75,15.25)		

Graph 10: Intergroup comparison of mean hospital stay (MAN-WHITNEY U TEST)

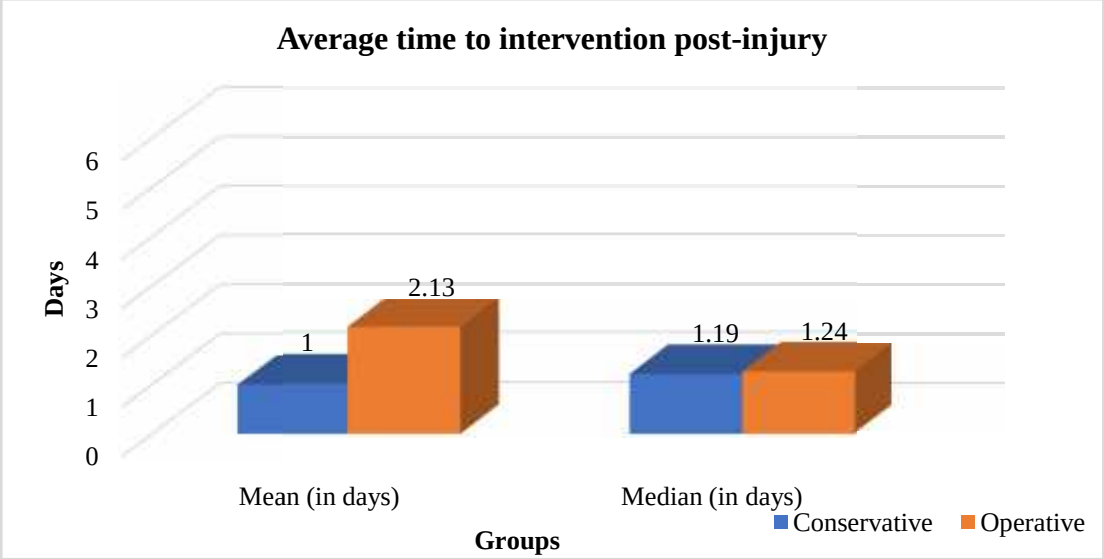


The mean number of days spent in the hospital for those treated conservatively were 2.49 (±3.29) days and the median was 2 days. This was found to be (statistically) significantly lower (p value < 0.05) as compared to the mean stay of 10 (±6.6) days and median 7 days of the operative group. Hence the mean expenditure of conservative treatment during that period can be inferred to be notably lower as compared to its counterpart.

Table 11: Intergroup comparison of mean post injury period to intervention in days

Intervention period post-injury	Mean	Standard deviation	Median (IQR3,IQR1)
CONSERVATIVE	1	1.19	1(0,1)
OPERATIVE	2.14	1.24	2(1,3)

Graph 11: Intergroup comparison of mean post injury period to intervention in days

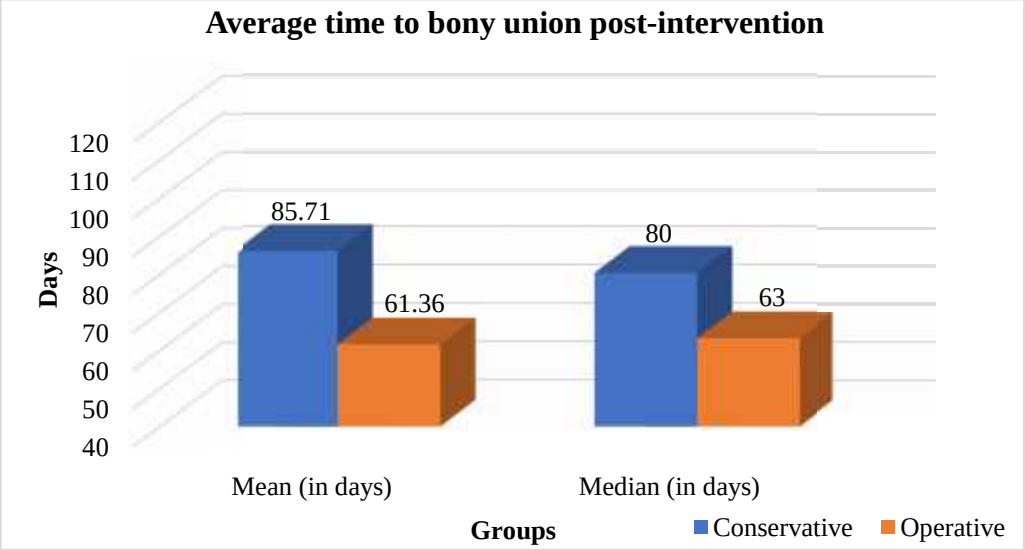


Intervention was notably faster in those treated conservatively with the mean time to intervention post-injury 1±1.19 days and median of 1 day (Range: 0 - 4 days). Those who were operated had a mean time to intervention post-injury of 2.14±1.24 days and median of 2 days (Range: 1 - 5 days). This difference can be attributed to factors such as pre-operative work-up cum formalities and the need to address the more serious co-morbid conditions or associated injuries of the patient before he/she was deemed fit for this surgery.

Table 12: Intergroup comparison of average time to bony union post-intervention in days (Man-Whitney U test) (*p value<0.05 is statistically significant)

Bony union time	Mean	Standard deviation	Median (IQR3,IQR1)	Z score	P value
CONSERVATIVE	85.71	19.82	80(99.5,74.0)	4.413	**0.00***
OPERATIVE	61.36	12.06	63(68,51.5)		

Graph 12: Intergroup comparison of average time to bony union post-intervention in days

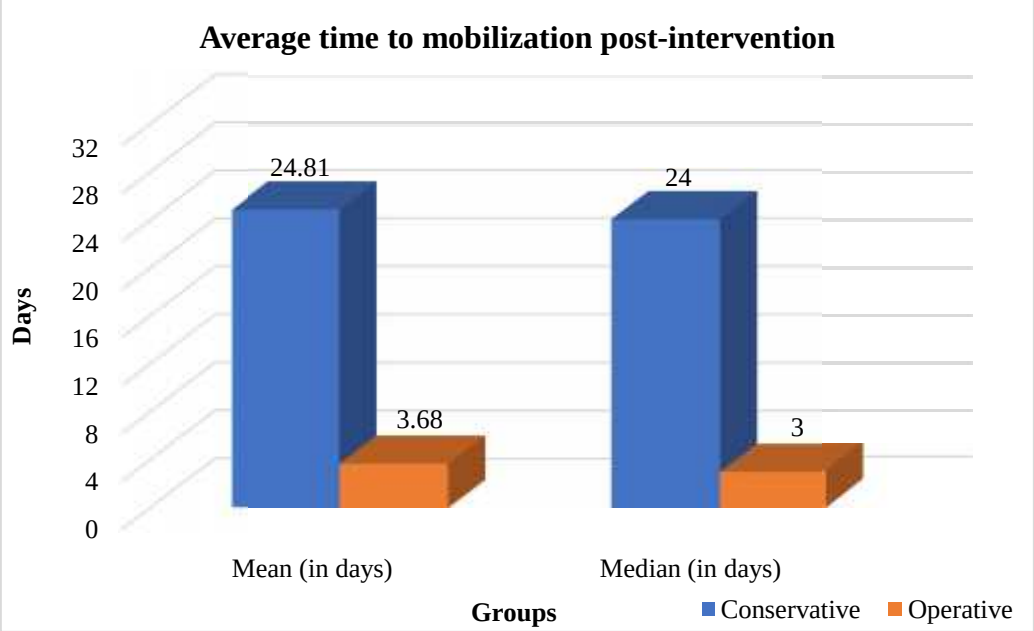


Mean time to bony union as determined radiologically of the conservatively treated group was seen to be 85.71±19.82 days with a median of 80 days as compared to a mean 61.36±12.06 days and median 63 days of the operated group. With a p value less than 0.05 according to Man-Whitney U test, the difference was determined to be statistically significant in favour of the operative group.

Table 13: Intergroup comparison of average time to mobilization post-intervention in days (Man-Whitney U test) (*p value<0.05 is statistically significant)

Mobilization time	Mean	Standard deviation	Median (IQR3,IQR1)	Z score	P value
CONSERVATIVE	24.81	4.12	24.0(26,21)	5.73	**0.000***
OPERATIVE	3.68	2.19	3.0(5,3)		

Graph 13: Intergroup comparison of average time to mobilization post-intervention

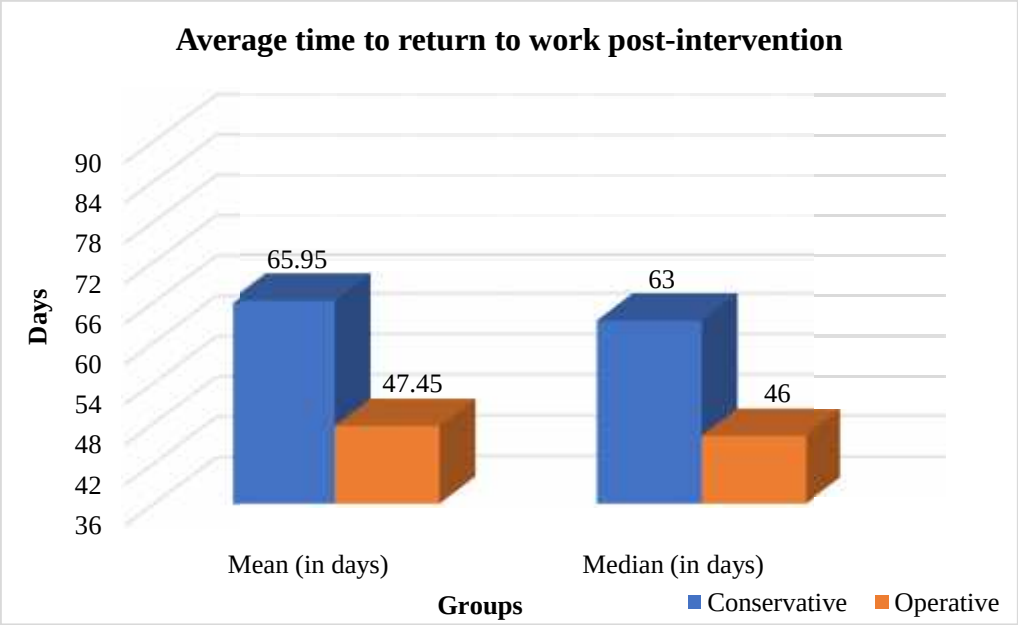


Mean time to mobilization of the affected shoulder joint of the conservatively treated group was started 24.81±4.12 days post-intervention with a median of 24 days as compared to a mean 3.68±2.19 days and median 3 days in the operated group. With a p value less than 0.05 according to Man-Whitney U test, the difference was determined to be statistically significant in favour of the operative group.

Table 14: Intergroup comparison of average time to return to work post-intervention in days (Man-Whitney U test) (*p value<0.05 is statistically significant)

Return To Work	Mean	Standard deviation	Median (IQR3,IQR1)	Z score	P value
CONSERVATIVE	65.95	13.43	63(81.75,56)	4.65	**0.00***
OPERATIVE	47.45	7.682	46(49.25,42.0)		

Graph 14: Intergroup comparison of average time to return to work post-intervention in days



Mean time to return to work post-intervention in the conservatively treated group was noted to be after 65.95±13.43 days with a median of 63 days as compared to a mean 47.45±7.682 days and median 46 days in the operated group. With a p value less than 0.05 according to Man-Whitney U test, the difference was determined to be statistically significant in favour of the operative group.

CONSTANT MURLEY SHOULDER SCORE

Table 15: Intergroup comparison of CMSS at *1ST FOLLOW UP at 6 weeks* (Man-Whitney U test) (*p value<0.05 is statistically significant)

CMSS Follow up 6 weeks	N	Mean Rank	Median(IQR3,IQR1)	Mean Difference compared to normal side	Z score	P value
CONSERVATIVE	22	33.50	44(49.0,41.0)	45.2	5.6	**0.00***
OPERATIVE	22	11.50	24(30.25,20.75)	24.1		

Intergroup analysis at 6 weeks follow-up revealed that the CMSS difference from the contralateral side was a mean 45.2 and median 33.50 while that in the operative group was a mean of 24.1 and median 24. According to Man-Whitney U test the difference between the two groups was statistically significant ($p<0.05$) with the operative group doing better.

Table 16: Intergroup comparison of CMSS at *2ND FOLLOW UP at 3 months* (Man-Whitney U test) (*p value<0.05 is statistically significant)

CMSS Follow up 3 months	N	Mean Rank	Median(IQR3,IQR1)	Mean Difference compared to normal side	Z score	P value
CONSERVATIVE	22	32.98	21.5(26,20)	23.5	5.4	**0.00***
OPERATIVE	22	12.02	12.5(16,10)	13		

Intergroup analysis at 3 months follow-up revealed that the CMSS difference from the contralateral side was a mean 23.5 and median 21.50 while that in the operative group was a mean of 13 and median 12.5. According to Man-Whitney U

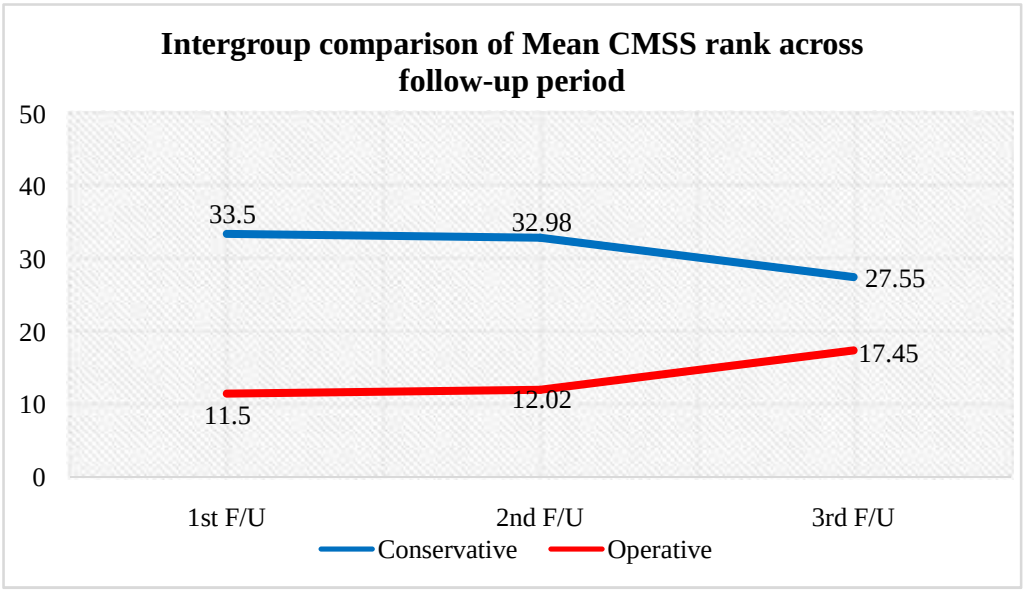
test the difference between the two groups was statistically significant ($p<0.05$) with the operative group doing better.

Table 17: Intergroup comparison of CMSS at 3rd FOLLOW UP at 6 months (Man-Whitney U test) (*p value<0.05 is statistically significant)

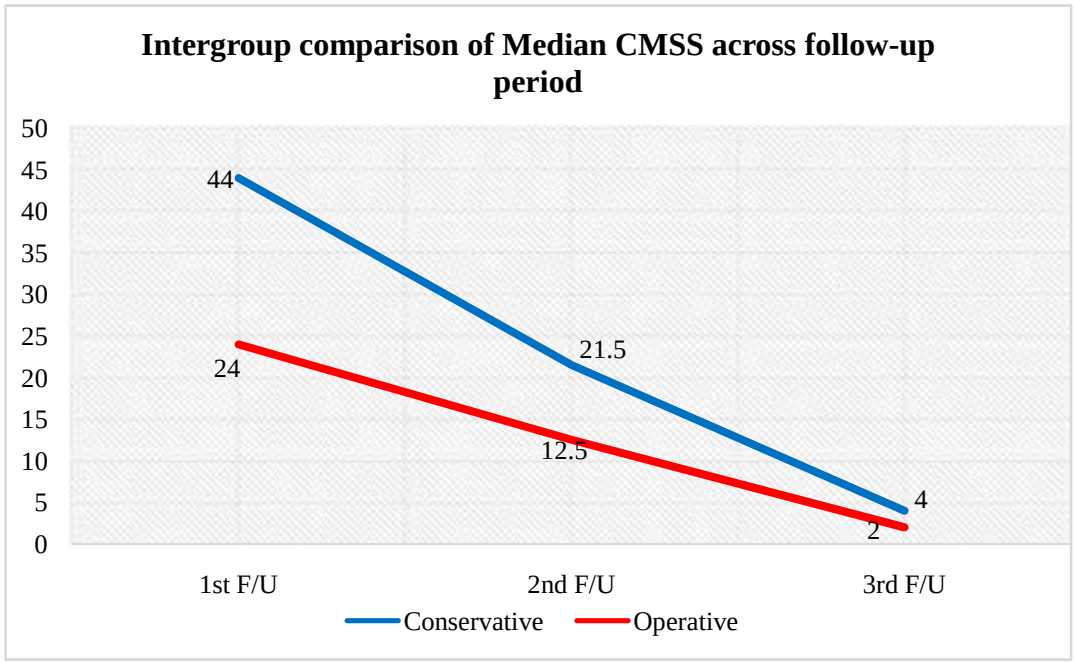
CMSS Follow up 6 months	N	Mean Rank	Median(IQR3,IQR1)	Mean Difference compared to normal side	Z score	P value
CONSERVATIVE	22	27.55	4(8,2)	4.86	2.66	**0.08***
OPERATIVE	22	17.45	2(3.25,0.00)	2.73		

Intergroup analysis at 6 months follow-up revealed that the CMSS difference from the contralateral side was a mean 4.86 and median 4 while that in the operative group was a mean of 2.73 and median 2. According to Man-Whitney U test the difference between the two groups was statistically insignificant ($p>0.05$).

Graph 15: Intergroup comparison of Mean CMSS rank across follow-up period



Graph 16: Intergroup comparison of Median CMSS across follow-up period



Graph 17: Intergroup comparison of Mean difference of CMSS from the normal side across follow-up period

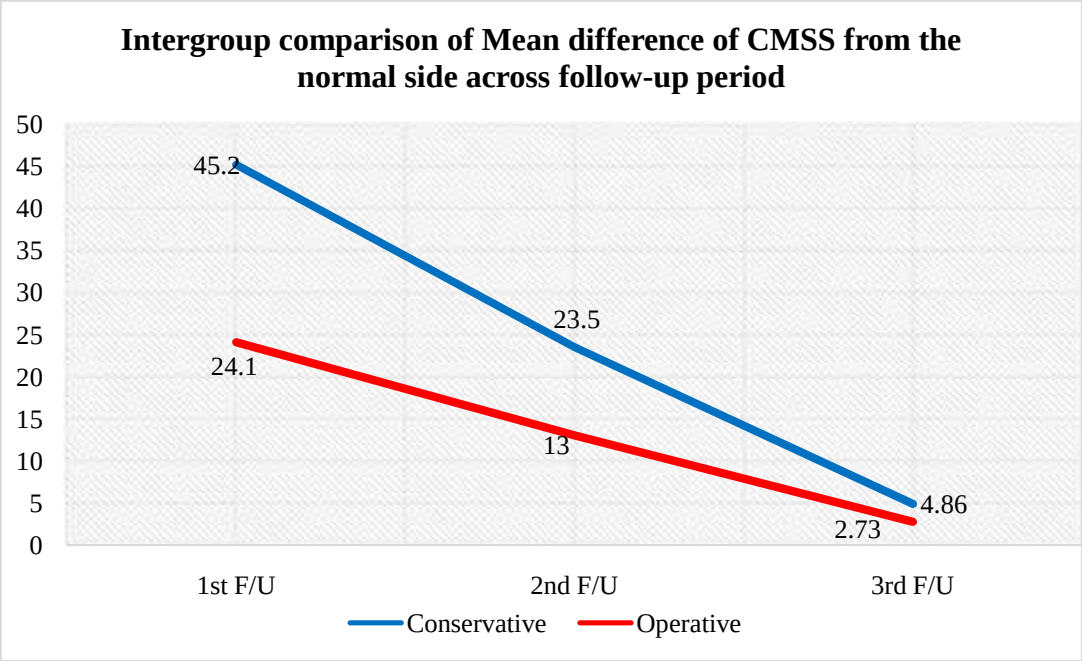


Table 18: Intra group comparison of CMSS score-using Friedmann's test (*p value<0.05 is statistically significant)

Conservative CMSS	N	Median (IQR3,IQR1)	P value
1st follow up	22	44(49.0,41.0)	**0.00***
2nd follow up	22	21.5(26,20)	
3rd follow up	22	4(8,2)	

Intra-group analysis of conservative group across the entire follow-up showed statistically significant improvement in the CMSS score with each follow-up with the median score in 1st, 2nd, 3rd f/u being 44, 21.5, and 4. '

Graph 18: Intragroup comparison of CMSS across follow-up period (Conservative group)

Operative CMSS	N	Median (IQR3,IQR1)	P value
1st follow up	22	24(30.25,20.75	**0.00***

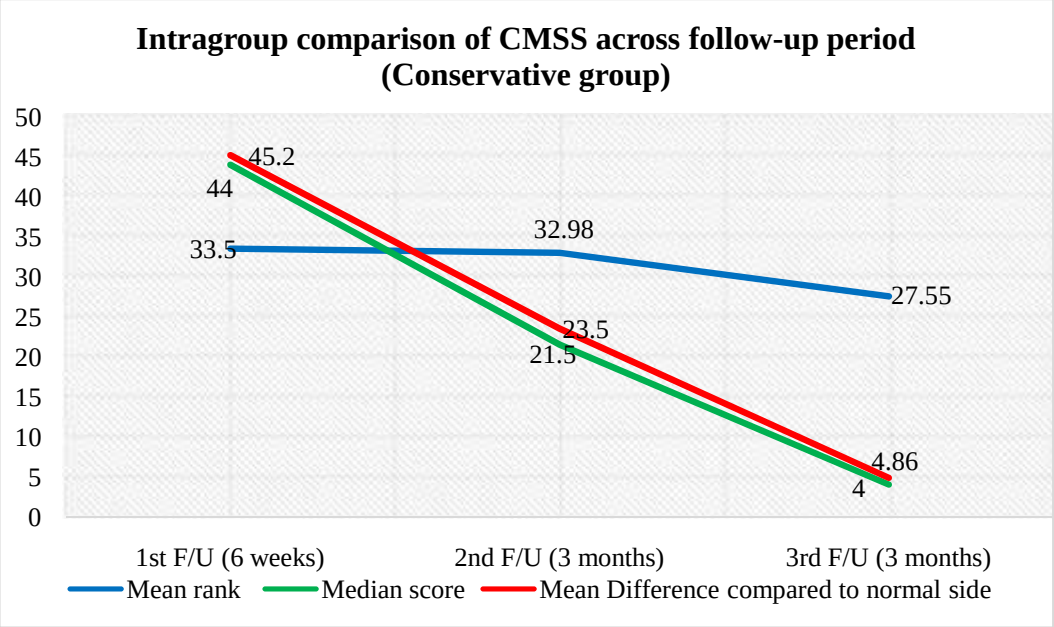
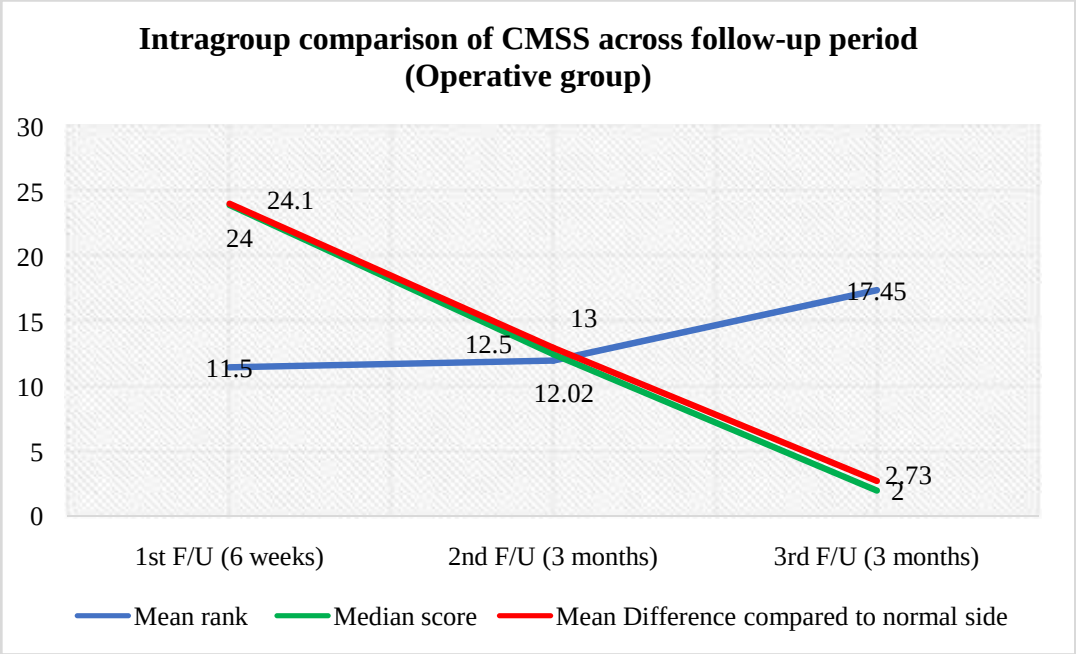


Table 19: Intra group comparison of CMSS score-using Friedmann's test (*p value<0.05 is statistically significant)

2nd follow up	22	12.5(16,10)	
3rd follow up	22	2(3.25,0.00)	

Intra-group analysis of operative group across the entire follow-up showed statistically significant improvement in the CMSS score with each follow-up with the median score in 1st, 2nd, 3rd f/u being 24, 12.5, and 2.

Graph 19: Intragroup comparison of CMSS across follow-up period (Operative group)



NOTTINGHAM CLAVICLE SCORE

Table 20: Intergroup comparison of Nottingham clavicle score at*1st follow-up at 6 weeks* (Man-Whitney U test) (*p value<0.05 is statistically significant)

NCS Follow up 6 weeks	N	Mean score	Mean Rank	Median (IQR3, IQR1)	Z score	P value

CONSERVATIVE	22	65	13.14	64.0(68.0,64.0)	4.8	**0.00***
OPERATIVE	22	73.18	31.86	74.0(76.5,71.5)		

Intergroup analysis at 6 weeks follow-up revealed that NCS was a mean 65 and median 64 while that in the operative group was a mean of 73.18 and median 74. According to Man-Whitney U test the difference between the two groups was statistically significant ($p<0.05$) with the operative group doing better.

Table 21: Intergroup comparison of Nottingham clavicle score *at 2nd follow-up at 3 months* (Man-Whitney U test) (*p value<0.05 is statistically significant)

NCS Follow up 3 months	N	Mean score	Mean Rank	Median (IQR3, IQR1)	Z score	P value
CONSERVATIVE	22	79.8	16.11	77.0(88.5,73.5)	3.3	**0.001***
OPERATIVE	22	88.36	28.89	88.0(94.0,83.5)		

Intergroup analysis at 3 months follow-up revealed that NCS was a mean 79.8 and median 77 while that in the operative group was a mean of 88.36 and median 88. According to Man-Whitney U test the difference between the two groups was statistically significant ($p<0.05$) with the operative group doing better.

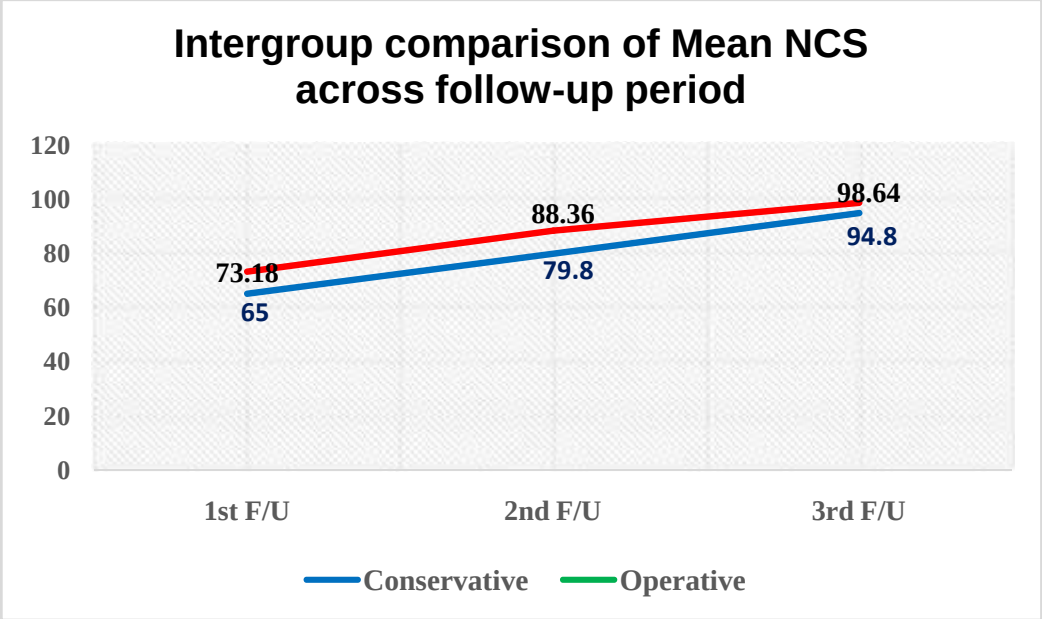
Table 22: Intergroup comparison of Nottingham clavicle score *at 3rd follow-up at 6 months* (Man-Whitney U test) (*p value<0.05 is statistically significant)

NCS Follow up 6 months	N	Mean score	Mean Rank	Median (IQR3, IQR1)	Z score	P value

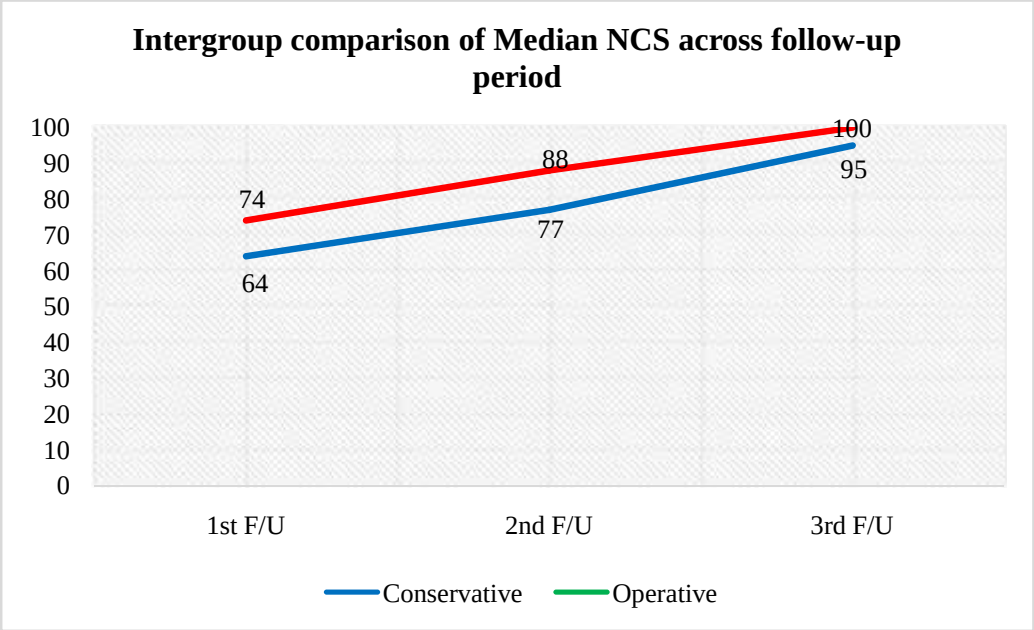
CONSERVATIVE	22	94.8	16.75	95.0(100,92.0)	3.1	**0.002***
OPERATIVE	22	98.64	28.25	100(100,97.5)		

Intergroup analysis at 6 months follow-up revealed that NCS was a mean 94.8 and median 95 while that in the operative group was a mean of 98.64 and median 100. According to Man-Whitney U test the difference between the two groups was statistically significant ($p<0.05$) with the operative group doing better.

Graph 20: Intergroup comparison of Mean NCS across follow-up period



Graph 21: Intergroup comparison of Median NCS across follow-up period



Graph 22: Intergroup comparison of Mean NCS rank across follow-up period

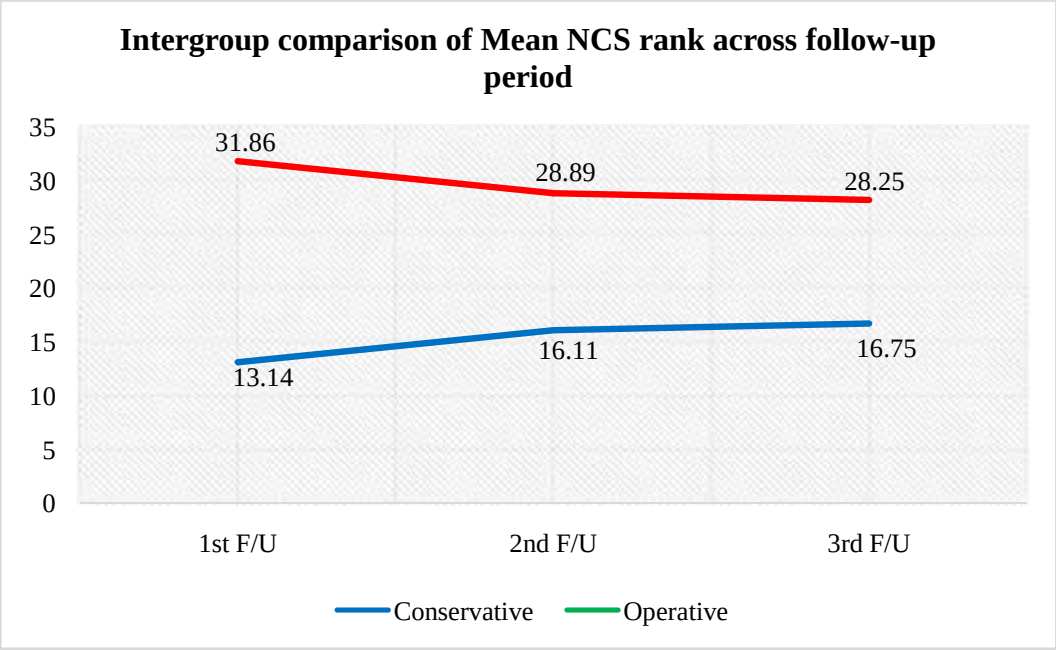


Table 23: Intra group comparison of NCS using Friedmann's test (*p value<0.05 is statistically significant)

Conservative NCS	N	Median (IQR3,IQR1)	P value
1st follow up	22	64.0(68.0,64.0)	**0.00***
2nd follow up	22	77.0(88.5,73.5	
3rd follow up	22	95.0(100,92.0)	

Intra-group analysis of conservative group across the entire follow-up showed statistically significant improvement in the NCS with each follow-up with the median score in 1st, 2nd, 3rd f/u being 64, 77, and 95.

Graph 23: Intragroup comparison of NCS across follow-up period (Conservative group)

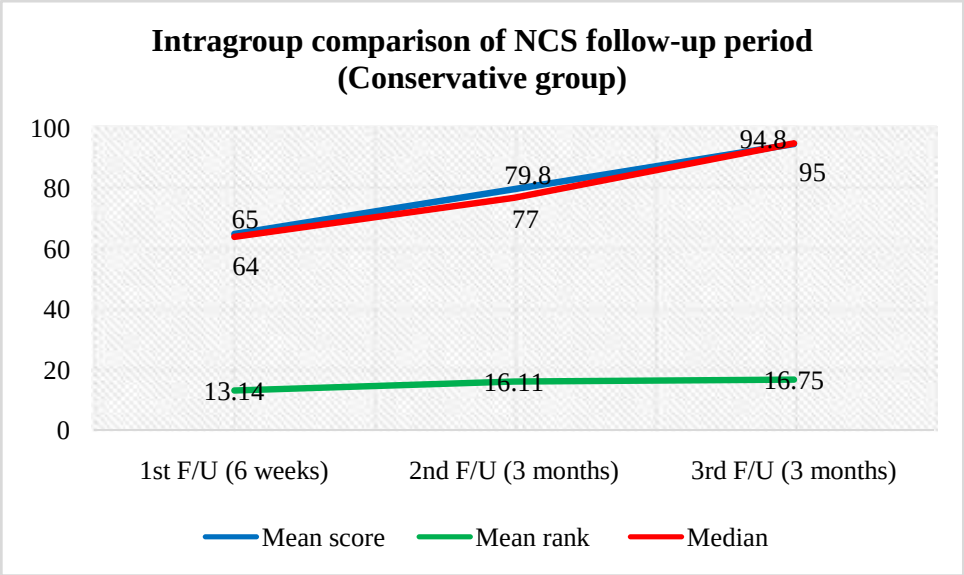
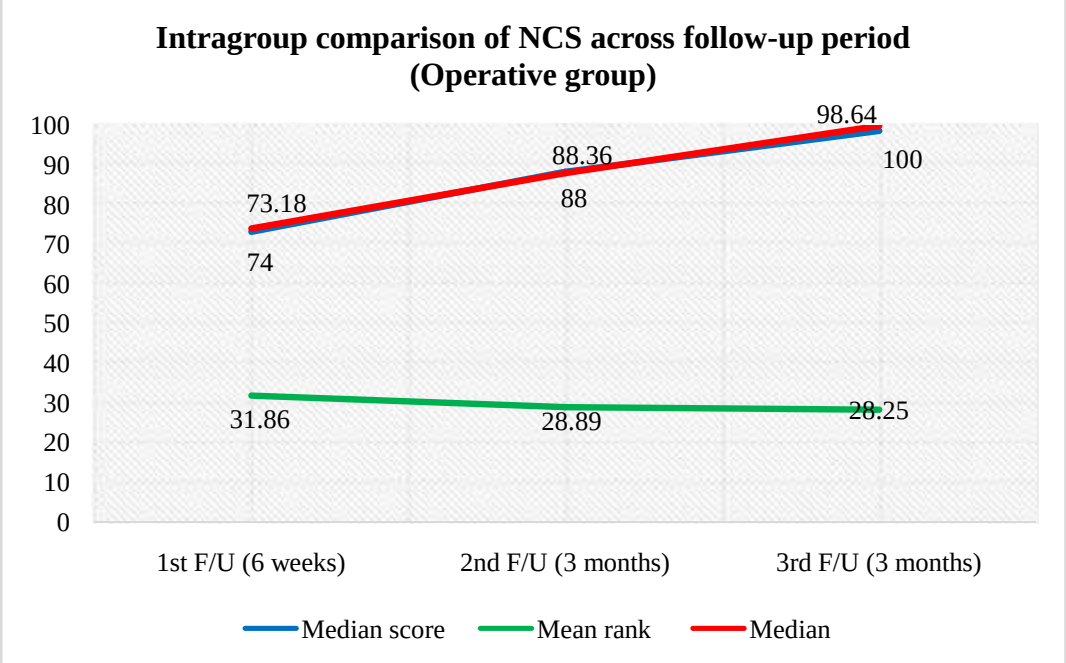


Table 24: Intra group comparison of NCS using Friedmann's test (*p value<0.05 is statistically significant)

Operative NCS	N	Median (IQR3,IQR1)	P value
1st follow up	22	74.0(76.5,71.5	**0.00***
2nd follow up	22	88.0(94.0,83.5)	
3rd follow up	22	100(100,97.5	

Intra-group analysis of operative group across the entire follow-up showed statistically significant improvement in the NCS with each follow-up with the median score in 1st, 2nd, 3rd f/u being 74, 88, and 100.

Graph 24:Intragroup comparison of NCS across follow-up period (Operative group)



DASH SCORE

Table 25: Intergroup comparison DASH score at *1st follow-up at 6 weeks* (Man-Whitney U test) (*p value<0.05 is statistically significant

	N	Mean score	Mean Rank	Median (IQR3, IQR1)	Z score	P value
CONSERVATIVE	22	68.1	33.0	67.2(73.95,61.2)	5.4	**0.00***
OPERATIVE	22	49.01	12.0	54.2(55.0,37.5)		

Intergroup analysis at 6 weeks follow-up revealed that DASH score was a mean 68.1 and median 67.2 while that in the operative group was a mean of 49.01 and median 54.2. According to Man-Whitney U test the difference between the two groups was statistically significant ($p<0.05$) with the operative group doing better.

Table 26: Intergroup comparison DASH score at*2nd follow-up at 3 months* (Man-Whitney U test) (*p value<0.05 is statistically significant)

	N	Mean score	Mean Rank	Median(IQR3,IQR1)	Z score	P value
CONSERVATIVE	22	28.9	31.0	33.2(36.85,21.15)	4.4	**0.00***
OPERATIVE	22	11.67	13.91	11.25(12.5,9.37)		

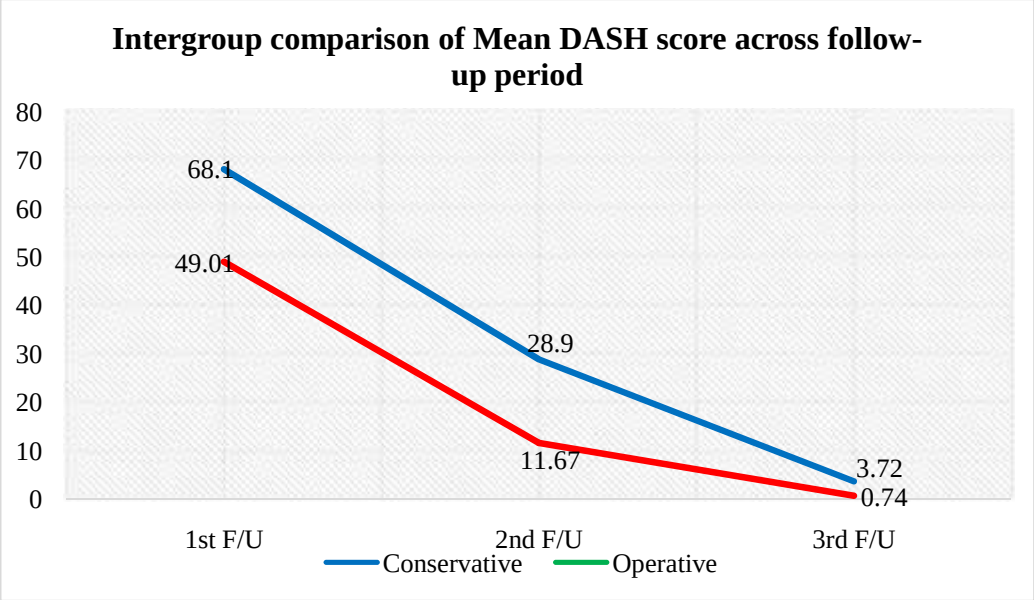
Intergroup analysis at 3 months follow-up revealed that DASH score was a mean 28.9 and median 33.2 while that in the operative group was a mean of 11.67 and median 11.25. According to Man-Whitney U test the difference between the two groups was statistically significant ($p<0.05$) with the operative group doing better.

Table 27: Intergroup comparison of DASH score at*3rd follow-up at 6 months* (Man-Whitney U test) (*p value<0.05 is statistically significant)

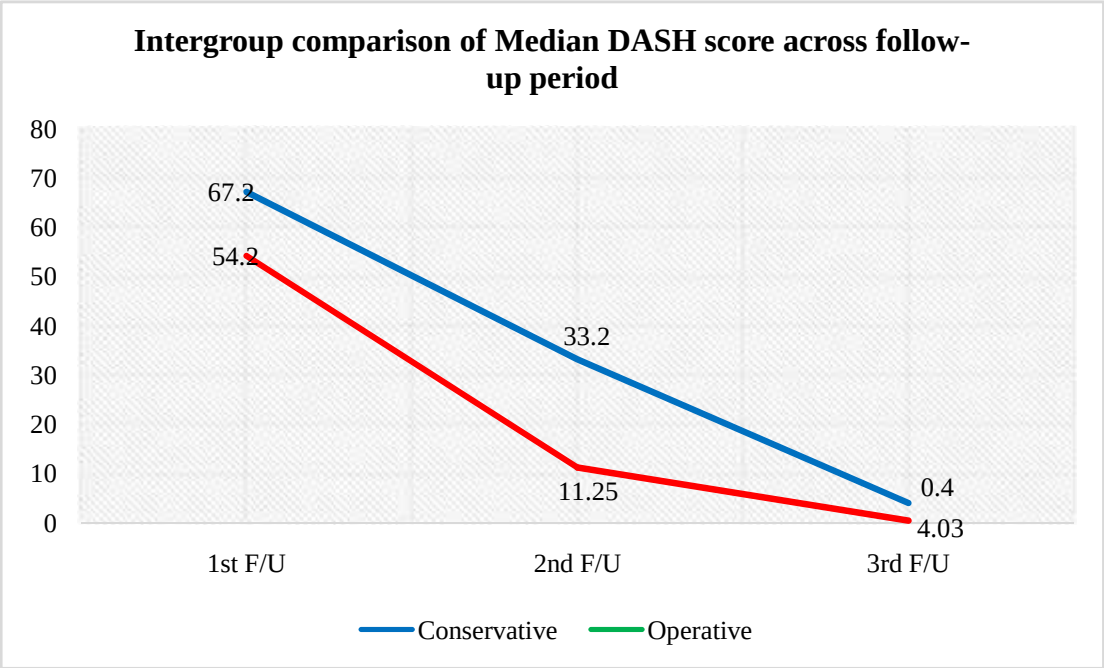
	N	Mean score	Mean Rank	Median(IQR3,IQR1)	Z score	P value
CONSERVATIVE	22	3.72	29.18	4.03(5.2,2.6)	3.54	**0.06***
OPERATIVE	22	0.74	15.82	0.4 (0.8,0)		

Intergroup analysis at 6 months follow-up revealed that DASH score was a mean 3.72 and median 4.03 while that in the operative group was a mean of 0.74 and median 0.4. According to Man-Whitney U test the difference between the two groups was statistically significant (p<0.05) with the operative group doing better.

Graph 25: Intergroup comparison of Mean DASH score across follow-up period



Graph 26: Intergroup comparison of Median DASH score across follow-up period



Graph 27: Intergroup comparison of Mean DASH rank across follow-up period

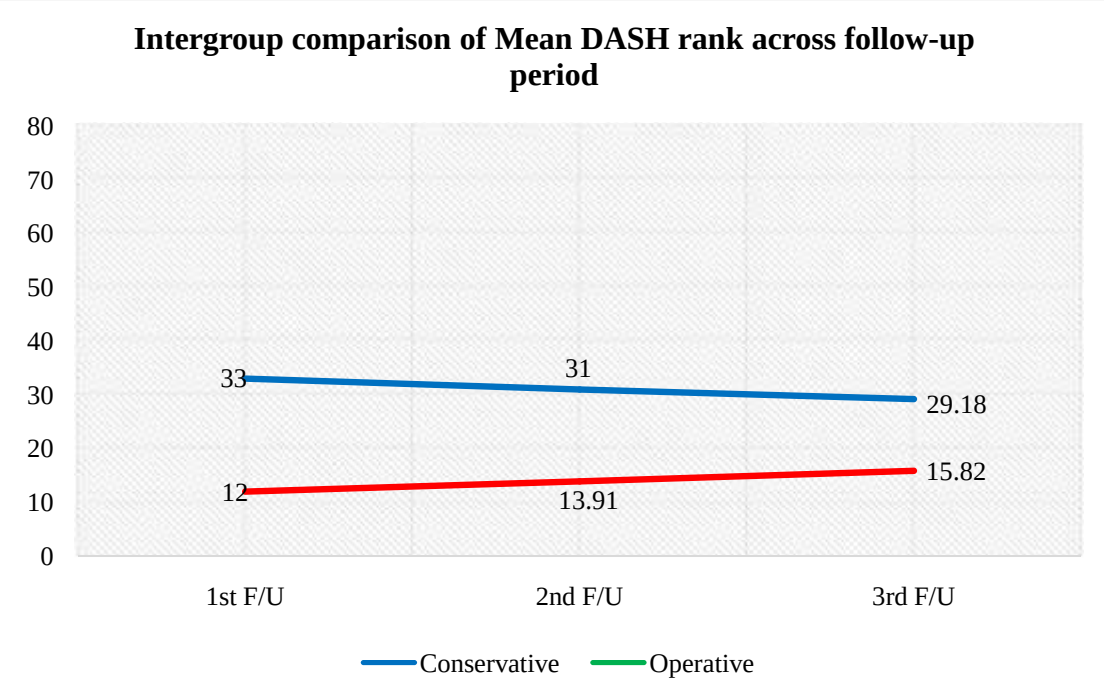


Table 28: Intra group comparison of DASH SCORE using Friedmann's test (*p value<0.05 is statistically significant)

Conservative DASH score	N	Median (IQR3,IQR1)	P value
1st follow up	22	67.2 (73.95,61.2)	**0.00***
2nd follow up	22	33.2 (36.85,21.15)	
3rd follow up	22	4.03 (5.2,2.6)	

Intra-group analysis of conservative group across the entire follow-up showed statistically significant improvement in the DASH score with each follow-up with the median score in 1st, 2nd, 3rd f/u being 67.2, 33.2, and 4.03.

Graph 28: Intragroup comparison of DASH score across follow-up period (Conservative group)

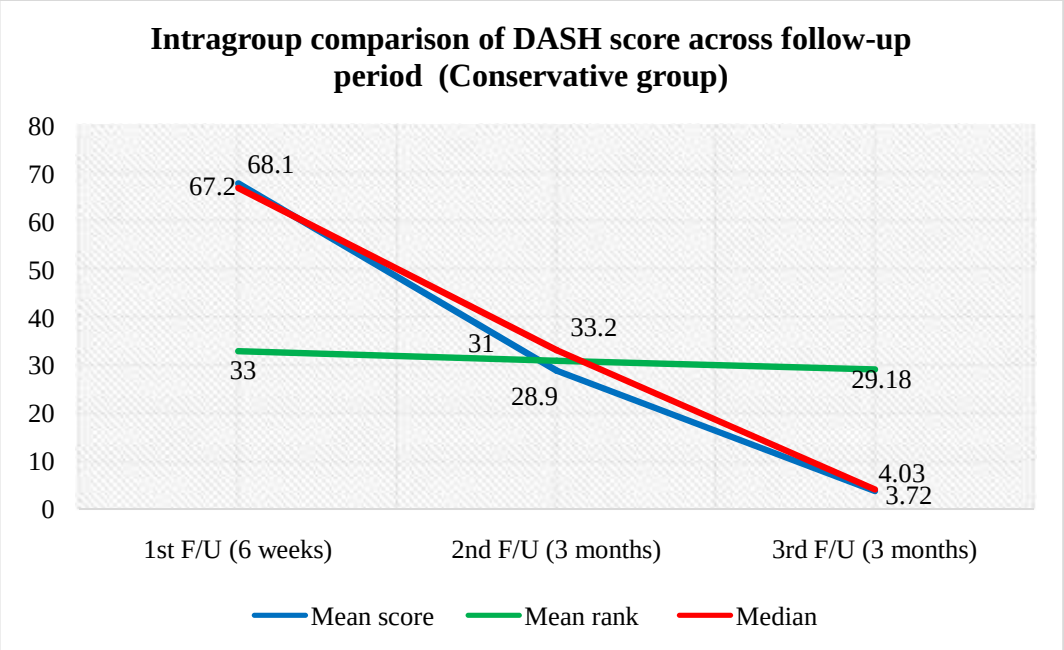
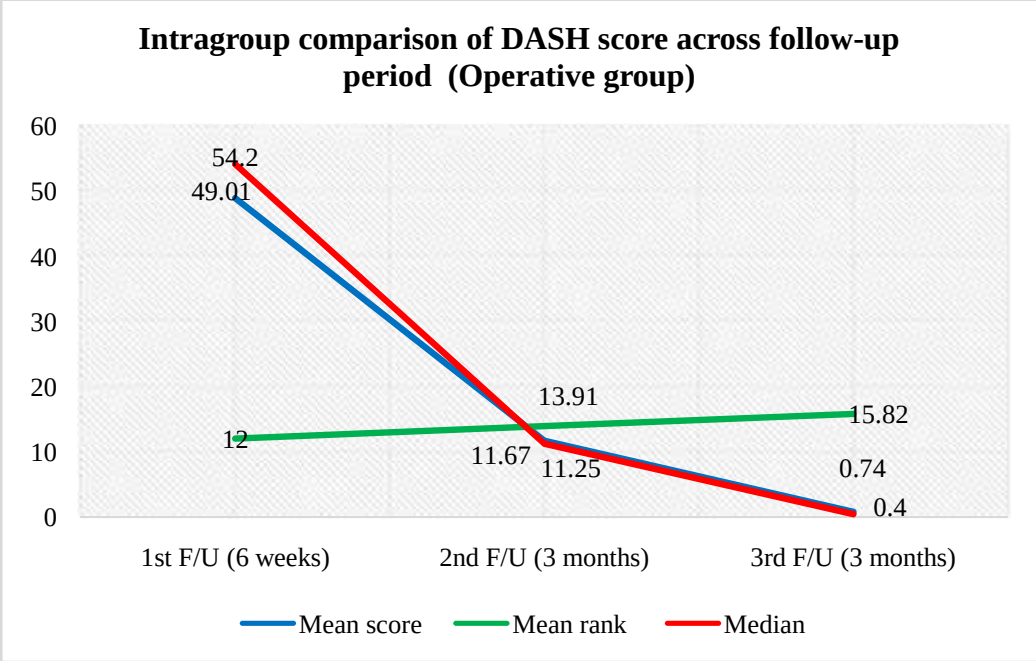


Table 29: Intra group comparison of DASH score using Friedmann's test (*p value<0.05 is statistically significant)

Operative DASH score	N	Median (IQR3,IQR1)	P value
1st follow up	22	54.2(55.0,37.5)	**0.00***
2nd follow up	22	11.25(12.5,9.37)	
3rd follow up	22	0.4 (0.8,0)	

Intra-group analysis of operative group across the entire follow-up showed statistically significant improvement in the DASH score with each follow-up with the median score in 1st, 2nd, 3rd f/u being 54.2, 11.25, and 0.4.

Graph 29:Intragroup comparison of DASH score across follow-up period (Operative group)



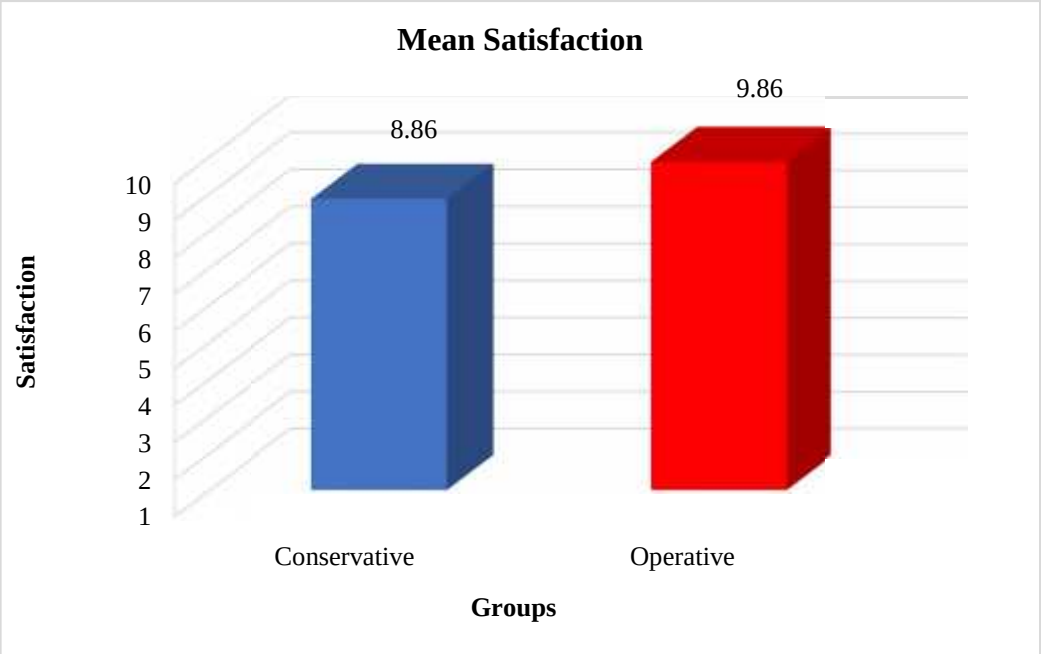
SUBJECTIVE PATIENT SATISFACTION

Table 30: Intergroup comparison of subjective patient satisfaction at 6 months (Man-Whitney U test) (*p value<0.05 is statistically significant)

Satisfaction	N	Mean Satisfaction	P value
CONSERVATIVE	22	8.86	**0.02***
OPERATIVE	22	9.86	

On evaluation of the overall subjective patient satisfaction (out of ten) at the final follow-up with regards to the entire management over the period of 6 months, we noted that the mean satisfaction of both the groups differed by a point with those operated showing a significantly better satisfaction (9.86) as compared to those managed conservatively (8.86) in accordance to the Man-Whitney U test.

Graph 30: Intergroup comparison of subjective patient satisfaction at 6 months



DISCUSSION

The sheer volume and incidence of clavicle fractures per year means it is essential for every Orthopaedic surgeon to have a technical know-how about this fracture, diagnosis, the possible complications and sequalae of mismanagement, need for surgical intervention and skills to perform the same if and when needed. As the entire Orthopaedic community still remains divided over the ideal course of management in case of midshaft clavicle fractures, which constitute the bulk of clavicular fractures, this study was undertaken to provide supplementation to the literature and solve this dilemma by evaluating not only the radiological and functional aspects of the final outcome, but also the subjective overall satisfaction of every patient.

A total of 44 patients coming to or brought to the OPD, Casualty or referred to the Department of Orthopaedics, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, and Charitable Hospital, Belagavi after clinical examination with radiological confirmation of mid-shaft clavicle fracture between January 2019 and December 2019 were enrolled provided they fulfilled the inclusion criteria and exclusion criteria and were willing to give an informed written consent.

With RTA being reported as the major cause of such injuries by multiple authors such as Robinson C. M[12]., Postacchini F et al.[57], Khan et al.[3] and Kihlström C et al[61] and as many as 64 people affected per 100,00 population [7], a physician should have a high degree of suspicion when approaching a patient with a history of RTA. Our observation followed the same trend as 39 (88.6%) of the patients in this study had a history of RTA. The remaining 5 (11.4%) had the injury

secondary to an accidental fall. In addition to this, 38 (86.4%) patients recounted a direct blow to the affected clavicle while the remaining 6 (13.6%) patients either gave a history of FOOSH or did not recollect any direct instance of trauma to the affected clavicle.

Consequently, as RTA is the main cause, the incidence is higher in the male population and in younger age group, as has been demonstrated in the literature. A male to female ratio of 2.2:1[61] to 5.25:1[72] has been reported previously. Our study results were in congruence to the sane with 35 patients (79.5%) out of the total 44 being males and 9 (20.5%) being females (Ratio of Male: Female = 3.8:1). The mean age of the total sample size was 39.78 years with 15 (34%) patients below or equal to the age of 30 years. 5 out of 7 fractures (71.43%) that occurred secondary to accidental fall or FOOSH affected women of age group 40 to 60 years.

A few studies have shown a predominance of left sided affection in cases of clavicle fractures. In our study too, the left clavicle was fractured in 27 (61.36%) patients while the right side in the remaining 17 (38.64%) patients. The percentage was very similar to the statistics of the study published by Postacchini F et al. in 2002 wherein the left side was affected in 61% of the patients too [57]. The dominance of hand when assessing the injured side was not the focus of attention in the publications that we reviewed. By our judgement it may contribute to not only the healing and early rehabilitation of the patient but can be a critical element in deciding the course of treatment that will be the most beneficial. In our study, the dominant side was affected in 20 (45.5%) patients (10 (45.5%) each in conservative and operative group) whereas the non-dominant was affected in 24 (54.5%) patients (12 (54.5%) each in

conservative and operative group). Further studies are recommended in this area for better understanding and facilitating better management.

Although studies have shown a very high association of concomitant injuries along with fractured clavicle, some as high as 81% [74], only 10 (22.7%) patients in our study had such a presentation. Out of these, 4 (40%) patients had thoracic injuries which was in line with the same study [74]. Other injuries included 3 (30%) facial fractures, 2 (20%) ipsilateral tibia fractures and 1 (10%) ipsilateral femur fracture.

Clinical diagnosis of these fractures is relatively straightforward. The patient typically supports the ipsilateral upper limb in an adducted position and flexed at the elbow, with the opposite hand [18]. A contusion, swelling or hematoma over the posterior aspect of the shoulder, superior or anterior aspect is an indicator of the direction of trauma and subsequently the possible direction of displacement. Visible deformity or loss of continuity, crepitus and tenderness on palpation, all confirm the clinical diagnosis of a fractured clavicle [76,77].

Radiological confirmation and classification is of paramount importance in the management. Allman group I or middle third fractures account for as much as 82% of all clavicle fractures [1,3,8,12,14,15]. Additionally, the treatment plan for lateral and medial fractures have enough basis and are generally operated upon. Hence, we concentrated specifically on MSFOC once they were diagnosed on plain radiography in the AP and/or axial tilt view. Having considered all the exhaustive classification systems, Robinson classification was chosen as an adjunct to the Allman classification. 37 (84.1%) patients were type 2B1 out of which 18 (48.65%) were operated and 19 (51.35%) treated conservatively. Out of the 7 (15.9%) type 2B2 fractures, 4 (57.14%) were operated and 3 (42.86%) treated conservatively.

Apart from the obvious reliability of PROMs, evaluation of the amount of time taken by the patient to return to his pre-injury status provides an astute understanding of the efficacy of the management in a more objective manner. Apart from this the major stumbling block in deciding modality of treatment in a developing country like India is the financial aspect of the entire course of management. Studies have shown significant differences in these regards between both the treatment methods with the former being better in patients going under the knife [149,150,151] and the latter favouring those treated with a sling and immobilization [90].

Our study results were very much congruous to the previously performed studies with findings such as mean time to bony union, mobilization, return to daily activity being similar to the study conducted by Shobha HP et al.[149] and Hoogervorst P. et al, both in 2018[150,151]. In the erstwhile studies the patients took (operative vs conservative) *14 vs 23* weeks for union and *5.2 vs 7.3* weeks for return to daily activity which when compared to our results was *61.36* (*±12.06*) days vs *85.71* (*±19.82*) days for bony union and *47.45* (*±7.68*) vs *65.95* (*±13.45*) days for return to activity, both being statistically significant in favour of operative treatment ($p<0.05$). Also, the patients who were operated upon were mobilized significantly faster as compared to their counter-parts (*3.68±2.19 vs 24.8±4.12*) in whom the mandatory immobilization period precluded the possibility of mobilization anytime sooner.

The method of intervention was decided based on the preference of the patient and in some cases based on the expert opinion of the Orthopaedic surgeon. Patients were briefed extensively with regards to the pros and cons of both modalities and subsequently immobilization was done as has been adviced in the literature in patients in whom conservative treatment was deemed fit [28]. Those surgically treated

underwent ORIF using 3.5mm pre-contoured anatomical mixed dynamic and locking compression plates with superior-anterior placement of the implant via the conventional surgical approach. This was done keeping in mind the previous literature studies that favoured pre-contoured and superior-anterior plate placement in general as well as Indian population [40,149-151]. The post-operative protocol was followed as is routine and the affected shoulder was mobilized as per the expert opinion of the physical therapist.

The intervention in both the groups post-injury was done at a fairly similar time so as to prevent the results being confounded due to delayed treatment. Surgeries were carried out at a mean *2.14±1.24* days and immobilization done at a mean *1±1.19* days after the injury. Acute surgery has shown to give better results and hence we followed the same protocol [152].

The absolute functional outcome of any intervention is determined by the PROMs. In this study we advocated the use of CMSS, NCS and DASH score due to their outstanding inter and intra-observer reliability and the observation that as a combination they complement each other by covering range of motion, strength, inhibitions to daily activity, special activities as well as heavy duty work. This is where the Orthopaedic literature remains divided and even though majority of the recent studies have shown significantly better PROM scores in the operated group [20,29,113-126,140,149], there still exist certain authors that have documented otherwise [90].

In this study we noted that the initial follow-ups at 6 weeks and 3 months showed statistically significant differences (p value < 0.05) across all scoring systems as calculated by Man-Whitney U test, with the operative group performing staggeringly better than their counterparts. On 1st follow-up that was done on an

average of 6 weeks post-intervention, the conservative vs operative mean of difference from normal side with respect to CMSS was *45.2 vs 24.1*. NCS was *65 vs 73.18* and DASH score was *68.1 vs 49.01*. The same trend continued at the 2nd follow-up at approximately 3 months post-intervention wherein CMSS difference was *23.5 vs 13*, NCS was *79.8 vs 88.36* and DASH score was *28.9 vs 11.67*.

However, on the final follow-up at approximately 6 months follow-up post-intervention it was noted that the difference between CMSS and DASH score between the two groups shrivelled considerably with there being no statistically significant comparison. The mean CMSS score difference from normal side in conservative vs operative group was *4.86 vs 2.73* and mean DASH was *3.72 vs 0.74* (p value > 0.05 in both the cases). Even though the NCS suggested otherwise, showing a statistically significantly better mean score in the operative group *98.64 vs 94.8* of the conservative group, we did not find any considerable handicap in the latter group and attributed the deficiency to possibly the need of a larger sample size.

The intragroup trends to evaluate the improvement with every serial follow-up in individual groups was done using the Friedmann's test for all three PROMs and it showed that statistically significant improvement happened over the course of 6 months with every follow-up as compared to the previous follow-up. The p-value for median score of CMSS, NCS and DASH score in both the groups remained well below 0.05. Hence, the short-term results of operative management were significantly better than conservative management. However, in the long term, both the management modalities showed little difference. The fact that there was considerable improvement in patient's functional condition over the longer run is considered to be the pivotal reason for the same.

One notable finding was that those surgically treated stated significantly better overall satisfaction from their subjective point of view over the entire course of treatment and rehabilitation as compared to those treated conservatively (*9.86 vs 8.86*). Additionally, it was seen that the overall cost of physiotherapy and rehabilitation in a few cases managed without surgery exceeded the overall cost of operative management. This included the treatment for extended periods of stiffness, weakness and loss of income due to days lost at work.

Higher complication rates have been quite routinely published when it comes to conservative management [20,29,111,112,146] and the compilation of sequalae were no different in this study. Only 2 patients that were operated developed some kind of a complication or unwarranted sequalae with 1 (4.55%) malunion and 1 (4.55%) case of hardware prominence and scar related complaint. On the other hand, there were 5 (22.7%) cases of delayed union, 4 (18.2%) malunion, 1 (4.55%) non-union, 1 (4.55%) refracture, 3 (13.6%) cosmetic dissatisfaction, 1 (4.55%) drooping shoulder and 1 (4.55%) case of persistent pain. The most common complication in operated patients as per literature was stated to be surgical site infection which we managed to avert successfully by using stringent intra-op sterility and post-op antibiotic regimen and wound care.

CONCLUSION

Statistically significant difference exists between the operative and conservatively treated groups in the 1st and 2nd or short terms follow-up (6 weeks and 3 months) with patients showing better radiological and functional outcomes after surgery as compared to those treated non-operatively. In the 3rd or long-term follow-up (6 months) both the groups are comparable in terms of functional outcome bar the NCS which can be attributed to the lack of a larger and a more homogenous sample size. However, a higher number of complications, union defects and days lost due to disability were noted in those treated conservatively. Hence, for the best results, we suggest the use of operative intervention in majority of the cases especially in cases where the dominant hand is affected, comminuted fractures, highly displaced fractures, athletes, labourers, professions requiring cosmetic aestheticism and young individuals. Older individuals with low functional requirement, non-dominant hand and those with sedentary lifestyle can be treated conservatively.

SUMMARY

Clavicle is one of the most commonly injured bone in the human body. It has been reported to occur secondary to FOOSH or accidental indirect falls but most commonly attributed to RTAs. With the crescendo in the number of motorized vehicles and ever-increasing incidents of accidents, the incidence of these fractures is also expected to rise significantly, in turn adding on to the burden of cases in Orthopaedic OPDs and casualties. Despite the load of these cases, the Orthopaedic community remains divided over the ideal line of treatment and patient selection while treating MSFOC cases. Hence, we undertook this study to help alleviate this dilemma.

This one-year hospital based prospective comparative study was conducted from January 2019 to December 2019. A total of 44 patients coming to or brought to the OPD, Casualty or referred to the Department of Orthopaedics, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi after clinical examination with radiological confirmation of mid-shaft clavicle fracture were enrolled provided, they fulfilled the inclusion criteria and exclusion criteria. The salient findings of the study are summarized as below:

- Majority of the patients were males (79.5%) as compared to females (20.5%). Male to female ratio was 3.89:1.
- The left side (61.36%) was affected more than the right side (38.64%).
- The non-dominant side (54.5%) was affected more than the dominant side (45.5%).

- Majority of the patients belonged to Robinson type 2B1 (84.1%) as to 2B2 (15.9%).

- Most common mode of injury was RTA (88.6%) followed by accidental fall (11.4%).

- Direct injuries (86.4%) were seen more than indirect or FOOSH (13.6%).

- The mean age of the patients was 39.8 years with a range of 18 years to 60 years. Mean age of conservative group was 39.95 (±13.304) while operative group was 39.6 (±13.72).

- Most common occupation of the participants was farming with a total of 15 (34.1%) farmers followed by 5 (11.4%) servicemen, 4 (9.1%) labourers, 4 (9.1%) students and the rest made up of policemen, sweeper, salesmen, nurse, shopkeeper, housewife, maid, engineer, retired personnel and coolie.

- Average duration of hospital stay was more for those treated operatively (10±6.6) than those treated conservatively (2.49±3.29).

- Bony union happened faster in operative group (61.36±12.06 days) than conservative (85.71±19.82 days).

- Mobilization was possible earlier in operative (3.68±2.19 days) than conservative group (24.81±4.12 days).

- Post-intervention return to daily work was seen to be possible earlier in patients who underwent surgery (47.45±7.68) than those who did not (65.95±13.43).

- The Constant-Murley shoulder score, Nottingham Clavicle Score and DASH score were significantly better in the operative group during the 1st and 2nd follow-up at 6 weeks and 3 months respectively (p value<0.05). However, the CMSS and DASH score were comparable at the 3rd follow-up at 6 months (p value > 0.05) while NCS remained significantly better in the operated group (p value <0.05).

- The subjective evaluation of the patient measured by satisfaction score out of 10 was significantly better in operated group (9.86) as compared to conservative group (8.86).

- Only 2 (9.1%) patients had notable complications the in operated group while its counterpart had 5 (22.7%) cases of delayed union, 4 (18.2%) malunion, 1 (4.55%) non-union, 1 (4.55%) refracture, 3 (13.6%) cosmetic dissatisfaction, 1 (4.55%) drooping shoulder and 1 (4.55%) case of persistent pain.

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ANNEXURE I – INFORMED CONSENT FORM

TITLE OF THE STUDY: - "A Hospital Based Prospective Comparative Study of Functional Outcome Between Surgical Management and Conservative Management of Fracture Middle Third Clavicle In Adults"

PRINCIPAL INVESTIGATOR: -

GUIDE:

INTRODUCTION AND PURPOSE:

Accounting for 2.6% to 4% of adult fractures and 44% to 66% of injuries to the shoulder girdle, fracture of the clavicle is a major burden in morbidities following a road traffic accident or aftermath of physical trauma. Improper treatment of midshaft fractures can lead to significant acute or residual morbidity including damage to major neurovascular and soft tissue structures. Hence, it is important to judiciously manage the clavicular fractures especially the displaced ones. Considering the existential persisting dilemma regarding the ideal treatment, the purpose of this study is to determine the better modality by comparing the functional and radiological outcome of Surgical and Conservative Management Of Fracture Middle Third Claviclein Orthopaedic department of KLE'S Dr.PrabhakarKore Hospital and Medical Research Centre and Charitable Hospital, Belagavi from 1st January 2019 to 31st December 2019.

PROCEDURE: If you consent to be in this study, the relevant data is collected as per the proforma, and the final diagnosis is confirmed after correlating both clinical and radiological evidences. Following this, depending on the line of management preferred, you will be operated or immobilization will be done using figure of 8 bandage/ special

shoulder immobilizer/ arm pouch. Follow up will be carried out at 6 weeks, 3 months and 6 months.

RISKS AND BENEFITS:

CONSERVATIVE MANAGEMENT:

The benefits of undergoing conservative or non-operative management for your conditioninclude a shorter hospital stay, excludes the risk of post-operative infection and othercomplications associated with surgery such as bleeding, failure of the implant used andanesthesia related risks. However, undergoing non-operative management will increase thechances of malunion and non-union of the fracture fragments, in addition to susceptibility torecurrence of fractures. In terms of movement, the range of motion may be restricted andthere may be angulation disturbance.

SURGICAL MANAGEMENT WITH PLATE FIXATION:

The benefits of undergoing surgical management for your condition include a faster and more anatomically acceptable reduction and union of the fracture fragments. It is particularly advantageous if you have a comminuted (multiple fragment) fracture, displaced fracture or if you have osteoporotic or osteopenic bone as it gives a rigid fixation. In addition to axial stability, even the angular stability will be restored which may or may not be the case in conservative management. The risks include malunion and non-union although lesser as compared to conservative management. In addition, there will be expenses for the surgery, surgery related risks and a longer hospital stay for post-operative care.

VOLUNTARY PARTICIPATION / WITHDRAWAL:

Taking part in this study is voluntary. I may choose not to take part in this study, or if I decide to take part I can later change my mind and withdraw from the study. My decision will not change the present or future health care or other services that I receive. The investigator or the sponsor may stop my participation in this study. I will tell of any important new findings that may change my willingness to continue to take part. If I choose not to take part in the study, I will receive the standard treatment for patients with my condition.

COMPENSATION:

As the subject voluntarily consents to be a part of the study, no compensation will be given.

CONFIDENTIALITY:

All information collected about the subject during the course of the study will be kept confidential to the extent permitted by the law. The code numbers will identify the subject in this research record. Information from this study may be presented but the subjects identify will be confidential in any publication.

QUESTION

If any enquiries in the future or in case of study related problems you may contact

If you still have any queries please contact:

Dr. Roopa M Bellad
Professor,
Department of Peadiatrics,
Chairperson,
Institutional Ethics Committee for Human Subjects Research,
KAHER, J.N. Medical College,
Belagavi -590010

CONSENT TO PARTICIPATE IN RESEARCH STUDY

"I voluntarily agree to take part in this study by signing below. I may withdraw at any time. I am not giving up any of my legal rights by signing this form. My signature below indicated that I have read this entire consent form or it has been read to me, and had all my questions answered. I will be given a copy of this consent form."

Signature of the Participant or legally authorized representative

Participant's Name : _____

Signature /Left Thumb Impression :_____

Name of legally authorized representative:_____

Signature /Left Thumb Impression : _____

Witness' Name :_____

Signature /Left Thumb Impression: _____

Investigator's Name and Signature :_____

Date: _____ Place : _____

संशोधनमेंभागलेनेकेलिएसम्मत्तीपत्र

आपकोइससंशोधन " **अहॉस्पिटलबेस्डप्रोस्पेक्टिव्हकम्पेरेटिवस्टडीओफ़फ़न्क्शनल आउटकमबिट्वीनसर्जीकलमॅनॅजमेन्टएन्दकन्सर्वेटिवमॅनॅजमेन्टऑफफ्रॅकचरमिडलथर्डक्लेविवविक लइनएडल्टस** " केलिएके. एल.ई. एस. डॉ.प्रभाकरकोरेहॉस्पिटलऔरएम.आर.सी.बेलगावीमेंभागलेनेकेलिएनिमंत्रितकरताहूँ।यहसंशोध न ,डॉ_____ , पी. जी.विद्यार्थी, ऑर्थोपेडिक्सविभाग, जे.एन.मेडिकलकॉलेजबेलगावीऔरमार्गदर्शक :डॉ. _____, प्रोफेसरवविभागप्रमुख ,ऑर्थोपेडिक्सविभाग, जे. एन.मेडिकलकॉलेजबेलगावी, द्वाराकियाजारहाहै।

प्रक्रिया

:यदिआपइससन्शोधनमेंहिस्सालेनेकेलियेसेहमतिदेतेहैंतोप्रोफ़ोमाकेमुतबिकजानकारीलीजायेगी औरआपकीबीमारीनिश्छितकीजायेगी।इस्केबाद,

आपकेफ़ैस्लेअनुसारसर्जीकीजायेगीयाफ़िरफ़िगरओफ़एटपटीखासशोल्दरइम्मोबिलाय्सरआर्मेपा उचद्वाराहाथहिलानेसेवर्जितकियाजायेगा।आपको६हफ़्ते, ३महिने, और६महिनेबादफ़ोलोअपकनाहोगा।

खत्रेबनामफ़ायदे: यदिआपसर्जेरीनहीचुनतेहैंतोउस्सेसंबन्धितखत्रोंसेबचेंगेजैसेसन्क्रमन, खूनखोना,

इम्प्लान्टवएनेस्थेशीयासंबन्धितधोका।परन्तुहड्डीबराबरनजुडनेकीवदोबाराटूटनेकीसम्भाव्ना भीज़्यादाहै।यहभीहोसक्ताहैकिआपपूरीतरहहाथनघुमापायें।

यदिआपसर्जेरीचुनतेहैंतोहड्डीबराबरजुडनेकीसम्भाव्नाज़्यादाहै।खासकरजबआपकीहड्डीकम्ज़ो रहोयाउस्केकईतुक्डेहोगयेहो।इस्केअलावाघुमावटीकार्यआसानहोंगे।भलेहीहड्डीबराबरनजुडनेकी सम्भाव्नाहैपरवहबोहोतकमहै।सर्जेरीसम्बंन्धितखर्छेवज़्यादादिनअस्पतालमेंनभीरुक्नापड़ेगा।

प्रतिक्रियासहभाग

:मेरेइससंशोधनमेंहिस्सालेणेकेबादसंशोधनकीजरूरतोंकेअनुसारसारीजांचेकीजायेंगीवमेरेअतीत औरवर्तमानकेबारेमेंजानकारीलीजायेगी।

मुझेइससंसोधनकेबारेमेंऔरइसके**फ़ायदेवखतरे**पूरीतरहसेसमझादिएगएहैं।

गोपनीयता:मेरेद्वारादीगयीसभीजनकारीऔरसंशोधनकापरिणामदूसरोंसेगुप्तरखाजायेगा।

नुकसानभरपाई

:संशोधनकेदौरानआरोग्ययिकनुकसानहोणेपररुग्णालयद्वाराकिसीभीप्रकारकीआर्थिकभरपाईन हीकीजायेगी।

मेंअपनीमर्ज़ीसेइससंशोधनमेंभागलेनाचाहताहूँऔरइसकेलिएसहमतिदेताहूँ।मेंअपनीमर्ज़ीसेकभी भीइससंशोधनमेंभागलेनेसेमनभीकरसकताहूँ।मेरेपाससंशोधनकेबारेमेंप्रश्नपूछनेकेलिएपूरासम यहैऔरयहप्रश्नमेंकभीभीपूछसकताहूँ।

इसविषयपरअधिकजानकारीकेलिएसंपर्ककरें :

यदिआपकोइसअध्ययनमेंभागलेनेवालोंकेहककेबारेमेंअधिकजानकारीचाहिएतोआपइनवैद्यको संपर्ककरसकतेहैं।

३. डॉरूपाबेल्ला ,चेअरमन, इन्स्टिट्यूशनलएथिक्सकमिटी, प्रोफेसर, पीडियाट्रिक्सविभाग, जे. एन.मेडिकलकॉलेज, काहेर, बेलगावी।

सम्मतीपत्र

मैं, नीचेहस्ताक्षरकरनेवाल , स्वइच्छितइसअभ्यासमेंभागलेनेकेलिएमान्यतादेताहूँ।मैंअपनानामकिसीभीवक्तइसमेंसेवापस लेसकताहूँ।इससम्मतीकेकारणमैंअपनेकोईभीक़ानूनीहकनहींछोड़रहाहूँ।यहसबऊपरकेविषयकेबारेमेंस्वयंपढकरयासुननेकेबादमेंइससम्मतिपत्रपरअपनाहस्ताक्षरकरकेसभीप्रश्नोंकाउत्तरदियाहूँ ।

सहभागीकानाम :

हस्ताक्षर :

साक्षीदार :

हस्ताक्षर :

संशोधक :

हस्ताक्षर :

दिनांक :

स्थल :

संशोधनअभ्याससाठीसम्मत्तीपत्र

संशोधनअध्ययन: " **अहॉस्पिटलबेस्डप्रोस्पेक्टिव्हकम्पेरेटिवस्टडीओफ़फ़न्क्शनल आउटकमबिट्वीनसर्जीकलमॅनॅजमेन्टएन्दकन्सर्वेटिवमॅनॅजमेन्टऑफफ्रॅकचरमिडलथर्डक्लेविक लइनएडल्टस** " साठीके. एल.ई. एस. डॉ.प्रभाकरकोरेहॉस्पिटलऔरएम.अ□ □.□□.बेलगावीमध्येनिमंत्रितकारतोये .□□□□□, □□_____ ,□□. □□.विद्यार्थी, ऑर्थोपेडिक्सविभाग, □□□□.मेडिकलकॉलेजबेलगावीआणिमार्गदर्शक :□□. _____, प्रोफेसरवविभागप्रमुख ,ऑर्थोपेडिक्सविभाग, □□□□.मेडिकलकॉलेजबेलगावी, □□□ □ □□.

प्रतिक्रीया :तुम्हीमाझ्याअभ्यासातस्वतःनावनोंदणीसहमतअसल्यास, नंतरवैद्यकीयतपाशीलकेलीजाईल, आणित्यानुसारबाकीतपास, तुमच्यासध्यागेल्याआणिकुटुंबइतिहाससंबंधितमुलाखतघेतलीजाईल।तुम्चेनिर्णयअनुसारसर्जरीनाहितरपट्टीटाक्नारआहे।तुम्हालाद्धआथव्ला, □□□□, □□□□मासनन्तरपरतयेनारपाहिजे।

धोकेआणिफायदे

:जरतुम्हालासर्जरीनाहिपाइजेतरतुम्हित्यासम्बन्धितधोकेतेसुरक्शितहोत।पनहेहोउशक्तातकिह ड्डीपूर्णजुडतनाहीअणीतुम्हिहाथव्यवस्थितहालुनाहिशकत।

जरसर्जरीकेलीतरहड्डीव्यवस्थितजुडाय्चीसंभाव्नाजास्तआहेविशेषतःजरतुम्चीहड्डीकमकुवत होतिनहितरजास्ततुक्डेझालेहोते।सर्जरीनाहिकेलिपेक्शाहाताचाहाल्छालव्यवस्थितहोत।परन्तूस रजरीसम्बन्धितधोकेहोउशक्तात,

खर्छाहोईलअणीतुम्हालाअस्पतालमधेजास्तदिवसराहीलापाइजे।

स्वयंमसेवीसहभाग / काढणे :सहभागऐच्छिकआहे . आपणस्वतःलायाअभ्यासातनिवडूशकता.रुग्णालयाशीअसलेल्यासंबंधितकाहीफरकपडणारनाही .तुमीयाअभ्यासातूनकधीहीमाघारयेऊशकता.

पर्याय :आपणअभ्याससहभागसोडलातरीआपलेलाव्यवस्थापननियमाप्रमाणेमिळेल.

गोपनीयता :तुम्हीदिलेलीसंशोधनाचीपरिणामांबाबतचर्चाकरताना, तुम्हीऔळखपटेलअशीमाहितीउघडकेलीजाणारनाही.

नुकसानभरपाई

:काहीहीआरोग्ययिकनुकसानझाल्यातररुग्णालयकोणतीहीआर्थिकनुकसानभरपाइदेण्यासबद्ध नाही.

संबोधनाबाबतकाहीहीप्रश्नअसलेतरसंपर्कसाधावा :

□. डॉरूपाबेल्लाड,□□□□□, इन्स्टिट्यूशनलएथिक्सकमिटी, प्रोफेसर, पीडियाट्रिक्सविभाग, जे□ □□.मेडिकलकॉलेज, □□□□, □□□□□□

<u>सम्मतीपत्र</u>

मीखालीसहीकरणारास्वतःहुनअभ्यासामध्येभागघेण्यासाठीहेमान्यकरतआहे.म□□□□□□□□□□□ नकोणतीहीक्षणीकाढूनशकतो.हाफॉर्मेसहीकेल्यामुळेमीमाझेकोणतीहीनैतिकअधिकारसोडूनदेत नाहीआहे.एवाचुनआणिपाहिल्यानंतरकिवानेवाचुनदाखविल्यानंतरमीमाझीसहीयासम्मतीपत्राव □□□□ □ □□अशाप्रकारेमीसर्वप्रश्नांचीउत्तरदेतआहे.

□□□□□□□□□□□ :

सहीअथवाडाव्याहाताचाअंगठा :

साक्षीदारांचेनांव :

साक्षीदारांचेसही :

तपासण्याचेनांव :

तपासण्याचेसही :

तारीख :

ठिकाण□ :

ತಿಳುವಳಿಕೆಯ ಸಮ್ಮತಿ

ಸ್ಪರ್ಧಿ ಶೀರ್ಷಿಕೆ: "ವಯಸ್ಕರಲ್ಲಿ ಮೂಳೆ ಮುರಿತದ ಮಧ್ಯಭಾಗದ ಮೂರನೇ ಗುಂಡಿನ ಶಸ್ತ್ರಚಿಕಿತ್ಸೆಯ ವಿರುದ್ಧ ಸಂಪ್ರದಾಯವಾದಿ ನಿರ್ವಹಣೆಗೆ ಪ್ರಾಯೋಗಿಕ ಫಲಿತಾಂಶವನ್ನು ಪ್ರಾಯೋಗಿಕವಾಗಿ ನಿರ್ಣಯಿಸಲು ಆಸ್ಪತ್ರೆ ಆಧಾರಿತ ನಿರೀಕ್ಷಿತ ಅಧ್ಯಯನ"

ಪ್ರಧಾನ ತನಿಖಾಧಿಕಾರಿ:

ಗೈಡ್:

ಪರಿಚಯ ಮತ್ತು ಉದ್ದೇಶ:ಮುಂಭಾಗದ ಕ್ರೂಸಿಯೇಟ್ ಅಸ್ಥಿರಜ್ಜು ಕಣ್ಣೀರಿನ ಪರಿಣಾಮವಾಗಿ ಉಂಟಾದ ಗಾಯಗಳನ್ನು ಸುತ್ತುವ ಅತ್ಯಂತ ಸಾಮಾನ್ಯ ಅಸ್ಥಿರಜ್ಜು ಕಣ್ಣೀರಿನ ಐಸೋನ್. ಮುಂಭಾಗದ ನಿರ್ಧಾರಕ ಬಂಧಕ ಕಣ್ಣೀರಿನ ಸಂಭವವು ವರ್ಷಕ್ಕೆ ಸುಮಾರು 3, 00,000 ವ್ಯಕ್ತಿಗಳು. ಆಪ್ಟಿರಿಯರ್ ಕ್ರೂಸಿಯೇಟ್ ಅಸ್ಥಿರಜ್ಜು ಕಣ್ಣೀರು ಸೂಕ್ತ ರೋಗಿಯ ಫಲಿತಾಂಶಗಳನ್ನು ಸಾಧಿಸಲು ಆಪರೇಟಿವ್ ಆಗಿ ಚಿಕಿತ್ಸೆ ನೀಡಬೇಕೆಂದು ಹೆಚ್ಚಿನ ಶಸ್ತ್ರಚಿಕಿತ್ಸಕರು ಒಪ್ಪುತ್ತಾರೆ. ಕೀಲು ಪ್ರದೇಶ, ಅಕ್ಷ, ತಿರುಗುವಿಕೆ ಮತ್ತು ಪೂರಲರ್ ಸ್ಥಾಯಿರಜ್ಜು ಮೂಳೆ ನಾಳದೊಂದಿಗಿನ ಟಿಬಿಯಕ್ಕೆ ಸಂಬಂಧಿಸಿದ ಕನೆಕ್ಷನ್ ಪುನರ್ನಿರ್ಮಾಣದ ಅಂಗರಚನಾ ಪುನರ್ನಿರ್ಮಾಣದಲ್ಲಿ ಕನಿಷ್ಠ ಆಕ್ರಮಣಕಾರಿ ಮುಂಭಾಗದ ನಿರ್ಧಾರಕ ಬಂಧಕ ದುರಸ್ತಿಗಾರ್ಡಜ್ಜರ ಚಿಕಿತ್ಸೆಯ ಉದ್ದೇಶ ಸಮಾಧಾನವನ್ನು ಮತ್ತು ಆರಂಭಿಕ ಕ್ರಿಯಾತ್ಮಕ ಪುನರ್ವಸತಿ ಜೊತೆಗೆ. ಮೂಳೆ, ನಾಳೀಯತೆಯ ರಕ್ಷಣೆ, ಕಡಿಮೆ ತೊಡಕುಗಳ ದರ, ಪ್ರಾಥಮಿಕ ಅಥವಾ ದ್ವಿತೀಯಕ ಕಸಿ ಮಾಡುವ ಅಗತ್ಯತೆಗಳು, ಮತ್ತು ಆಪರೇಟಿವ್ ಸಮಯವನ್ನು ಕಡಿಮೆಗೊಳಿಸುವುದು ಮತ್ತು ಯಾಂತ್ರಿಕ ಒತ್ತಡಕ್ಕೆ ಹೆಚ್ಚಿದ ಸ್ಥಿತಿಸ್ಥಾಪಕತ್ವಕ್ಕೆ ಸಹಿತ ಮೂಳೆಯಿಂದ ವೇಗವಾಗಿ ಗುಣಪಡಿಸುವ ಕಾರಣದಿಂದಾಗಿ ಪೇಟೆಲ್ಲರ್ ಸ್ಥಾಯಿರಜ್ಜು ಮೂಳೆ ನಾಳದಿಂದ ಪಡೆದ ಉತ್ತಮ ಫಲಿತಾಂಶಗಳು. ಇದು ಬೇದಿಕೆಯ ತಂತ್ರವಾಗಿದ್ದು, ಅಂಗಾಂಗ ಅಕ್ಷದ ತಿರುಗುವಿಕೆಯನ್ನು ಮರುಸ್ಥಾಪಿಸುವ ಸಲುವಾಗಿ ಎಚ್ಚರಿಕೆಯ ತೀವ್ರವಾದ ಕ್ಲಿನಿಕಲ್ ಮತ್ತು ಫ್ಲೋರೋಸ್ಕೊಪಿಕ್ ನಿಯಂತ್ರಣವನ್ನು ಹೊಂದಿರಬೇಕು.

ಡಾ.ಪ್ರಭಾಕರ್ ಕೋರೆ ಹಾಸ್ಪಿಟಲ್ ಮತ್ತು ಮೆಡಿಕಲ್ ರಿಸರ್ಚ್ ಸೆಂಟರ್ ಮತ್ತು ಚಾರಿಟಬಲ್ ಆಸ್ಪತ್ರೆ, ಬೆಳಗಾವಿ 1 ನೇ ಜನವರಿ 2019 ರಿಂದ 31 ರ ಡಿಸೆಂಬರ್ 2019 ರವರೆಗೆ "ಪ್ಯಾಟೆಲ್ಲರ್ ಸ್ನಾಯುರಜ್ಜು ಬೋನ್ ಗ್ರಾಫ್ಟ್ ಬಳಸಿಕೊಂಡು ಮುಂಭಾಗದ ನಿರ್ಧಾರಕ ಬಂಧಕ ಪುನರ್ನಿರ್ಮಾಣಕ್ಕಾಗಿ" ಅತ್ಯುತ್ತಮ ಕ್ಲಿನಿಕಲ್ ಫಲಿತಾಂಶವನ್ನು ನಿರ್ಧರಿಸಲು ಈ ಅಧ್ಯಯನವು ಉದ್ದೇಶಿಸಲಾಗಿದೆ. ಡಿಸೆಂಬರ್ 2019.

ವಿಧಾನ:
ಸಂಬಂಧಿತ ದೇಣಿಗೆಯನ್ನು ಪ್ರೋಫಾರ್ಮಾದ ಪ್ರಕಾರ ಸಂಗ್ರಹಿಸಲಾಗುತ್ತದೆ ಮತ್ತು P ಟಿ ಬಿ ನಾಳದೊಂದಿಗಿನ ಎ ಸಿ ಎಲ್ ಪುನರ್ನಿರ್ಮಾಣದ ನಂತರ ಪೂರ್ವ ಮತ್ತು ನಂತರದ ಶಸ್ತ್ರಚಿಕಿತ್ಸೆಯ ನಂತರದ ವಿಶ್ಲೇಷಣೆಗೆ ಸಂಬಂಧಪಟ್ಟ ನಂತರ ಅಂತಿಮ ರೋಗನಿರ್ಣಯದನ್ನು ದೃಢೀಕರಿಸಲಾಗುತ್ತದೆ. ಇದರ ಅನುಸಾರ, ವಾಲ್ಗಸ್ ಒತ್ತಡವನ್ನು ಸುಲಿವಿನ ಸ್ಥಾನದಲ್ಲಿ ಇರಿಸಿಕೊಳ್ಳುವಲ್ಲಿ ರೋಗಿಯನ್ನು ನಿರ್ವಹಿಸಲಾಗುತ್ತದೆ. ರೋಗಿಯನ್ನು ಹಿಂಬಾಲಿಸು 9 ತಿಂಗಳಲ್ಲಿ ನಡೆಸಲಾಗುತ್ತದೆ

ಪ್ರಯೋಜನಗಳು:

1) ಸ್ಥಳೀಯ ಎಸಿಎಲ್ಗೆ ತುಲನಾತ್ಮಕವಾಗಿ ನಾಟಿ ಸಾಮರ್ಥ್ಯ ಮತ್ತು ಅದರ ಬಿಗಿತವನ್ನು ಸಮನಾಗಿರುತ್ತದೆ

2) ಮೂಳೆಯ ಸ್ಥಿರೀಕರಣ

ಅಪಾಯಗಳು:

3) ಮುಂತಿ ನೋವು

4) ಡ್ಯಾಟೆಲ್ಡರ್ ಮುರಿತ

ಸ್ವಯಂಪ್ರೇರಿತ ಭಾಗವಹಿಸುವಿಕೆ / ಹಿಂತೆಗೆದುಕೊಳ್ಳುವಿಕೆ:

ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಪಾಲ್ಗೊಳ್ಳುವುದು ಸ್ವಯಂಪ್ರೇರಿತವಾಗಿರುತ್ತದೆ. ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಪಾಲ್ಗೊಳ್ಳಬಾರದು ಎಂದು ನಾನು ಆಯ್ಕೆ ಮಾಡಬಹುದು, ಅಥವಾ ನಾನು ಪಾಲ್ಗೊಳ್ಳಲು ನಿರ್ಧರಿಸಿದರೆ ನಾನು ನಂತರ ನನ್ನ ಮನಸ್ಸನ್ನು ಬದಲಾಯಿಸಬಹುದು ಮತ್ತು ಅಧ್ಯಯನದಿಂದ ಹಿಂತೆಗೆದುಕೊಳ್ಳಬಹುದು. ನನ್ನ ನಿರ್ಧಾರ ಪ್ರಸ್ತುತ ಅಥವಾ ಭವಿಷ್ಯದ ಆರೋಗ್ಯ ರಕ್ಷಣೆ ಅಥವಾ ನಾನು ಸ್ವೀಕರಿಸುವ ಇತರ ಸೇವೆಗಳನ್ನು ಬದಲಿಸುವುದಿಲ್ಲ. ಸಂಶೋಧಕ ಅಥವಾ ಪ್ರಾಯೋಜಕರು ಈ ಅಧ್ಯಯನದಲ್ಲಿ ನನ್ನ ಭಾಗವಹಿಸುವಿಕೆಯನ್ನು ನಿಲ್ಲಿಸಬಹುದು. ಪಾಲ್ಗೊಳ್ಳಲು ಮುಂದುವರಿಸಲು ನನ್ನ ಸಮ್ಮತಿಯನ್ನು ಬದಲಾಯಿಸುವ ಯಾವುದೇ ಹೊಸ ಸಂಶೋಧನೆಗಳನ್ನು ನಾನು ಹೇಳುತ್ತೇನೆ. ನಾನು ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಬಾರದೆಂದು ಆರಿಸಿದರೆ, ನನ್ನ ಸ್ಥಿತಿಯ ರೋಗಿಗಳಿಗೆ ನಾನು ಪ್ರಮಾಣಿತ ಚಿಕಿತ್ಸೆಯನ್ನು ಸ್ವೀಕರಿಸುತ್ತೇನೆ.

ಪರಿಹಾರ:

ವಿಷಯವು ಸ್ವಯಂಪ್ರೇರಣೆಯಿಂದ ಒಪ್ಪಿಗೆಯನ್ನು ಅಧ್ಯಯನದ ಒಂದು ಭಾಗವಾಗಿ ಪರಿಗಣಿಸುವುದರಿಂದ, ಯಾವುದೇ ಪರಿಹಾರವನ್ನು ನೀಡಲಾಗುವುದಿಲ್ಲ.

ಗೌಪ್ಯತೆ:

ಅಧ್ಯಯನದ ಸಮಯದಲ್ಲಿ ವಿಷಯದ ಬಗ್ಗೆ ಸಂಗ್ರಹಿಸಿದ ಎಲ್ಲಾ ಮಾಹಿತಿಗಳನ್ನು ಕಾನೂನು ಅನುಮತಿಸುವ ಮಟ್ಟಿಗೆ ಗೌಪ್ಯವಾಗಿರುತ್ತದೆ. ಕೋಡ್ ಸಂಖ್ಯೆಗಳು ಈ ಸಂಶೋಧನಾ ದಾಖಲೆಯಲ್ಲಿ ವಿಷಯವನ್ನು ಗುರುತಿಸುತ್ತವೆ. ಈ ಅಧ್ಯಯನದ ಮಾಹಿತಿಯು ಪ್ರಸ್ತುತಪಡಿಸಬಹುದು ಆದರೆ ಯಾವುದೇ ಪ್ರಕಾಶನದಲ್ಲಿ ವಿಷಯಗಳು ಗೋಪ್ಯವಾಗಿರುತ್ತವೆ.

ಭವಿಷ್ಯದಲ್ಲಿ ಅಥವಾ ಅಧ್ಯಯನದ ಸಂಬಂಧಿತ ಗಾಯ ಅಥವಾ ಅನಾರೋಗ್ಯದ ಸಂದರ್ಭದಲ್ಲಿ ಯಾವುದೇ ವಿಚಾರಣೆಗಳು ಇದ್ದರೆ, ನೀವು ಈ ಕೆಳಗಿನ ವ್ಯಕ್ತಿಯನ್ನು ಸಂಪರ್ಕಿಸಬಹುದು.

ಸಮ್ಮತಿಯ ಹೇಳಿಕೆ

ಸಮ್ಮತಿಯ ರೂಪದಲ್ಲಿ ನೀಡಲಾದ ಸಂಪೂರ್ಣ ಮಾಹಿತಿಯನ್ನು ನಾನು ಸಂಪೂರ್ಣವಾಗಿ ಓದಿದ್ದೇನೆ ಮತ್ತು ಅಧ್ಯಯನದ ಎಲ್ಲಾ ವಿವರಗಳನ್ನು ವಿವರಿಸುತ್ತದೆ, ಅಂದರೆ, ಒಳಗೊಂಡಿರುವ ಉದ್ದೇಶ, ಕಾರ್ಯವಿಧಾನ, ಅಪಾಯಗಳು ಮತ್ತು ಪ್ರಯೋಜನಗಳು, ಗೌಪ್ಯತೆ ಮತ್ತು ಗೌಪ್ಯತೆ, ಪ್ರೋತ್ಸಾಹಕಗಳು ಮತ್ತು ಫಲಿತಾಂಶಗಳನ್ನು ಪ್ರಕಟಿಸುವ ಅಧಿಕಾರ ಅಧ್ಯಯನ. ಕೆಳಗಿನ ಸಹಿಗಾಗಿ ಒದಗಿಸಲಾದ ಜಾಗದಲ್ಲಿ ನನ್ನ ಸಹಿ ನಾನು ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಲು ಸ್ವಯಂಪ್ರೇರಿತವಾಗಿ ಒಪ್ಪಿಗೆ ಸೂಚಿಸಿದೆ. ಯಾವುದೇ ಕಾರಣಕ್ಕಾಗಿ ನಾನು ನನ್ನ ಪಾಲ್ಗೊಳ್ಳುವಿಕೆಯನ್ನು ಹಿಂತೆಗೆದುಕೊಳ್ಳಬಹುದು ಅಥವಾ ಯಾವುದೇ ಕಾರಣಕ್ಕಾಗಿ ಯಾವುದೇ ಕಾರಣದಿಂದಾಗಿ ತನಿಖಾಧಿಕಾರಿಯಿಂದ ಹಿಂತೆಗೆದುಕೊಳ್ಳಬಹುದು. ಈ ಸಮ್ಮತಿಯ ಫಾರ್ಮ್ಗೆ ಸಹಿ ಹಾಕುವ ಮೂಲಕ ನನ್ನ ಯಾವುದೇ ಕಾನೂನು ಹಕ್ಕುಗಳನ್ನು ನಾನು ಬಿಡುತ್ತಿದ್ದೇನೆ.

ದಿನಾಂಕದೊಂದಿಗೆ ಪಾಲ್ಗೊಳ್ಳುವವರ ಸಹಿ: _____

ಪಾಲ್ಗೊಳ್ಳುವವರ ಹೆಸರು: _____

ದಿನಾಂಕದೊಂದಿಗೆ ತನಿಖಾಧಿಕಾರಿಯ ಸಹಿ: _____

ಸಂಶೋಧಕರ ಹೆಸರು: _____

ANNEXURE II - PROFORMA

"A Hospital Based Prospective Comparative Study of Functional Outcome Between Surgical Management and Conservative Management of Fracture Middle Third Clavicle In Adults"

Serial No._____ OP/IP NO._____

I]NAME: _____

II]AGE: _____Years III] SEX: □a) Male □b) Female

IV]ADDRESS: _____

V]OCCUPATION: _____

VI]MANAGEMENT: □ a) Conservative □b) Surgical

VII]Date of Admission or Presentation: _____ /_____ /20_____

VIII]Date of Discharge: _____ /_____ /20_____

IX]Date of Surgery: _____ /_____ /20_____

X]Dominant hand: □a) Right □ b) Left

XI]CHIEF PRESENTING COMPLAINTS:

□ a) Pain □ b) Swelling □ c) Disability □ d) Wound □ e) Restricted ROM □ f) Deformity

XII]HISTORY OF PRESENT ILLNESS:

1.Nature of injury:

□ a) Road Traffic Accident □ b) Accidental fall

2.Mode of injury:

□ a) Direct □ b) Indirect

XIII]Duration since injury: …….days

XIV] SIGNIFICANT PAST HISTORY:

1. History of

□ a) Diabetes Mellitus □ b) Hypertension □ c) Asthma □ d) Tuberculosis

□ e) other chronic illness_____ □ f) None

2. Previous history of Fractures. If yes, elaborate.

□ a) Yes …….

□ b) No

3. Previous history of any medication received/allergic to

□ a) Yes …….

□ b) No

XV] PERSONAL HISTORY :

1. Diet : a) Vegetarian / b) Mixed
2. Appetite : a) Increased/ b) Decreased/ c)Unchanged
3. Habits : a)Smoking/ b)Alcohol / c)others/d)None
4. Bowel & Bladder Habits : a)Normal / b) Abnormal

XVI] FAMILY HISTORY : □ a)Nothing significant

□ b)Significant_____

XVII] GENERAL PHYSICAL EXAMINATION :

1.Level of consciousness: □ a)Conscious □ b)Drowsy □ c)Unconscious

2.Built : □ a) Well □ b) Moderate □ c) Poor

3.Orientation to time, place & person:□a)well oriented □b)Disoriented

4.Temperature:_____^{o}F 5. Pulse: /min

6.Blood Pressure: / mmHg 7.Respiratory Rate: /min

8. Others: □ a)Pallor □ b)Cyanosis □ c)Icterus □ d)Clubbing □ e)Edema □ f)Lymphadenopathy

XVIII]SYSTEMIC EXAMINATION :

1.Cardiovascular System : □ a)Significant_____

□ b) Normal

2.Respiratory System : □ a)Significant_____ □ b) Normal

3.Per Abdomen: □ a) Significant_____ □ b) Normal

4.Central Nervous System: □ a) Significant_____ □ b) Normal

5.Associated Injury: □ a) Yes □ b) None

_____

XIX] LOCAL EXAMINATION:

1.INSPECTION :

i.Side Involved: □ a) RIGHT □ b) LEFT

ii.Overlying Skin: □ a)Normal □ b)Blebs □ c)Ecchymosis □ d)Avulsed □ e)Bruise

iii.Swelling: □ a) Yes □ b) No

iv.Visible Deformity: □ a) Yes □ b) No

2. PALPATION : a) Present b) Absent

i. Tenderness
ii. Crepitus
iii. Abnormal mobility
iv. Deformity
v. Loss of transmitted movements
vi. Peripheral Pulses : Radial / Brachial
vii. Neurological Deficit

3. RANGE OF MOVEMENTS OF IPSILATERAL SHOULDER JOINT :

□ a) Painful □ b) Restricted □ c) Not painful □ d) Not restricted

XX]INVESTIGATIONS DONE: a)YES b)NO

1. Blood Hb%, TLC, DLC, ESR, ECG □ □
2. Urine Routine and Microscopy □ □
3. FBS, RBS, Liver function test. □ □
4. Kidney function test and Electrolyte profile □ □
5. HIV, HBsAg, HCV, Coagulation profile □ □
6. X-Ray Chest with both shoulders AP view □ □
7. X-Ray of affected shoulder AP view □ □
8. X-Ray of affected shoulder cephalad view with 30^{o} tilt □ □

XXI] X-RAY BASED CLASSIFICATIONS (MID-SHAFT FRACTURE CLAVICLE):

1)Robinson Classification	2)Allman Classification	3)DISPLACEMENT
TYPE	TYPE I	a.PERCENTAGE: b.DIRECTION:

XXII]PROVISIONAL TREATMENT :

FIRST AID :	a)YES	b)NO
1. Fluid Replacement	□	□
2. Immobilization of the Injured shoulder	□	□
3. Analgesics	□	□
4. Antibiotics Started	□	□
5. Closure if cut lacerated wound present	□	□

XXIII] DEFINITIVE TREATMENT :

A] Conservative management:

□ a) Arm pouch □ b) Special shoulder immoblizer □ c) Strapping

B] Surgical management

1.Relevant Investigations & Medical Fitness for Surgery: □a)Yes □b)No

2.Anaesthesia: □ a) General □ b) Interscalene □ c) Deep Cervical

3.Antibiotic Therapy:

A.Pre-operative □ a)Yes □ b) No

B.Post-operative □ a)Yes □ b) No

XXIV] COMPLICATIONS :

A. Intraoperative	a) YES	b) NO
1. Difficulty in reduction		
2. Excessive bleeding		
3. Neurovascular injury		
4. Pneumothorax/ Haemothorax		

B. Postoperative

Immediate :	a) YES	b) NO

1. Bleeding
2. Infection
3. Numbness/ Neurological deficit

c. Others: □ a)Yes_____ □ b) No

XXV] Duration of hospital stay: _____ days

Follow up (F/U) :

Serial no. :

	6 weeks	**3 months**	**6 months**
1.Date	/ /20	/ /20	/ /20
2.ROM at Shoulder joint i) Flexion ii)Abduction iii)Internal rotation iv) External rotation			
3.Tenderness at the fracture site	□ Yes □ No	□ Yes □ No	□ Yes □ No
4.X-ray findings: i) Callus ii) Malunion iii) Delayed union iv) Non-union v) Hardware failure	 □ Yes □ No □ Yes □ No N.A. N.A. □ Yes □ No	 □ Yes □ No □ Yes □ No □ Yes □ No N.A. □ Yes □ No	 □ Yes □ No □ Yes □ No □ Yes □ No □ Yes □ No □ Yes □ No
5.Clinical signs of union	□ Yes □ No	□ Yes □ No	□ Yes □ No
6.Other complications: i) Wound site infection ii) Drooping shoulder iii)Hardware prominence iv) Hypertrophic scar v) Persistent pain	 □ Yes □ No □ Yes □ No □ Yes □ No □ Yes □ No □ Yes □ No	 □ Yes □ No □ Yes □ No □ Yes □ No □ Yes □ No □ Yes □ No	 □ Yes □ No □ Yes □ No □ Yes □ No □ Yes □ No □ Yes □ No
6.Constant-Murley Shoulder score			
7.Nottingham Clavicle Score			
8.DASH SCORE			

9. Days to mobilization:_____ 10.Days to lifting weight :_____

11. Final Deformity: □ Yes _____□ No

12.Overall Patient Satisfaction at 3rd F/U: □ 1 □ 2 □ 3 □ 4 □ 5 □ 6 □ 7 □ 8 □ 9 □ 10

Clinician's name (or ref) _____ **CONSTANT MURLEY SHOULDER SCORE** Patient's name (or ref) _____

Answer all questions, selecting just one unless otherwise stated

Date: _____

During the past 4 weeks.....

Follow-up: ○1st / ○2nd / ○3rd

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
- ○ 1-3
- ○ 4-6
- ○ 7-9
- ○ 10-12
- ○ 13-15
- ○ 16-18
- ○ 19-21
- ○ 22-24
- ○ >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)

The Constant Shoulder Score is ☐

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

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

Reference for Score: Constant CR, Murley AH. A clinical method of functional assessment of the shoulder. Clin Orthop Relat Res. 1987 Jan;(214):160-4. link to pubmed

Reference for Grading: Fabre T, Piton C, Lachkarec G, Gervais-Delion F, Durandeau A. Entrapment of the suprascapular nerve. J Bone Joint Surg Br. 1999 May;81(3):414-9.

Patient ref. no:..... Follow-up: ◯ 1st/ ◯ 2nd/ ◯ 3rd Date:.....

Nottingham Clavicle Score (for injuries to the collarbone, A/C & S/C Joint)

The following questions relate to the pain levels and difficulties you have experienced around your collarbone/shoulder area **during the last two months.**

1. How would you describe the pain you *usually* had from your shoulder/collarbone?

☐ None	10
☐ Very mild	8
☐ Mild	6
☐ Moderate	4
☐ Severe	2

2. Have you been troubled by pain from your *shoulder/collarbone* in bed at night?

☐ No nights	10
☐ Only 1 or 2 nights	8
☐ Some nights	6
☐ Most nights	4
☐ Every night	2

3. How much has *pain from your shoulder/ collarbone* interfered with your usual work (including housework or driving)?

☐ Not at all	10
☐ A little bit	8
☐ Moderately	6
☐ Greatly	4
☐ Totally	2

4. How much has *pain from your shoulder/ collarbone* interfered with your sporting activities or hobbies?

☐ Not at all	10
☐ A little/occasionally	8
☐ Some of the time	6
☐ Most of the time	4
☐ All of the time	2

5. How much has the *problem with your shoulder/collarbone* interfered with your ability or willingness to lift heavy objects?

☐ Not at all	10
☐ Occasionally	8
☐ Some days	6
☐ Most days	4
☐ Every day	2

6. Has your shoulder/collarbone easily tired or felt weak with overhead activity?

☐ Not at all	10
☐ A little/occasionally	8
☐ Some of the time	6
☐ Most of the time	4
☐ All of the time	2

7. Have you been happy about the appearance of your collarbone area?

☐ Totally happy	10
☐ Very happy	8
☐ Moderately happy	6
☐ A little bit happy	4
☐ Not at all happy	2

8. Have you felt any movements or clicking in the collarbone area that trouble or worry you?

☐ Not at all	10
☐ A little/occasionally	8
☐ Some of the time	6
☐ Most of the time	4
☐ All of the time	2

9. Do you experience tingling or numbness travelling up into your neck or down your arm?

☐ Not at all	10
☐ A little/occasionally	8
☐ Some of the time	6
☐ Most of the time	4
☐ All of the time	2

10. Have you experienced any dragging sensation or feeling of heaviness of your arm?

☐ Not at all	10
☐ A little/occasionally	8
☐ Some of the time	6
☐ Most of the time	4
☐ All of the time	2

Total NCS: ☐

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

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

Date:..... Follow-up: ◯ 1st/ ◯ 2nd/ ◯ 3rd

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

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

Reference for Score: Hudak PL, Amadio PC, Bombardier C. Development of an upper extremity outcome measure: the DASH (disabilities of the arm, shoulder and hand) [corrected]. The Upper Extremity Collaborative Group (UECG)
Am J Ind Med. 1996 Jun;29(6):602-8. Erratum in: Am J Ind Med 1996 Sep;30(3):372.

ANNEXURE-III-ETHICAL CLEARANCE LETTER

K.L.E. ACADEMY OF HIGHER EDUCATION AND RESEARCH
(Deemed – to- be- University)
Accredited 'A' Grade by NAAC (2nd Cycle) Placed in Category 'A' by MHRD (GoI)
JAWAHARLAL NEHRU MEDICAL COLLEGE,
NEHRU NAGAR, BELAGAVI-590010 (KARNATAKA-INDIA)
Website: http//www.jnmc.edu
E-Mail : dome@jnmc.edu
Phone: (+91-(0)831 Office : 2472550
Principal: 2471701
Fax No. +91 (0)831 – 2470759

Ref: MDC/DOME/ 06 **Date: 24/11/2018**

To,

REGISTRATION NO.
BL0118003

Sub: Institutional Ethical Clearance for the study.

With reference to the above, we wish to inform you that your proposed research project titled **"A HOSPITAL BASED PROSPECTIVE COMPARATIVE STUDY OF FUNCTIONAL OUTCOME BETWEEN SURGICAL MANAGEMENT AND CONSERVATIVE MANAGEMENT OF FRACTURE MIDDLE THIRD CLAVICLE IN ADULTS"**, is ethical and justifiable. The proposed research project has been cleared by the JNMC Institutional Ethics Committee on Human Subjects Research.

(Dr. Arathi Darshan)
Member Secretary
JNMC Institutional Ethics Committee
on Human Subjects Research,
J.N.Medical College, Belagavi.

(Dr. Roopa M Bellad)
Chairman,
JNMC Institutional Ethics Committee
on Human Subjects Research,
J.N.Medical College, Belagavi.

10

ANNEXURE IV – PHOTOGRAPHS

Patient serial number: C11

Modality of treatment: Conservative (Group A)

Radiological Result: Complete Union (Malunion)

Photograph 2a: X-ray on presentation

Photograph 2b: 1st Follow-up (6 weeks)

Photograph 2c: 2nd Follow-up (3 months)

Photograph 2d: 3rd Follow-up (6months)

Patient serial number: C11

Modality of treatment: Conservative (Group A)

Photograph 3: ROM at 1st Follow-up (6 weeks)

Photograph 4: ROM at 2nd Follow-up (3 months)

Photograph 5: ROM at 3rd Follow-up (6 months)

Patient serial number: O5

Modality of treatment: Operative (Group B)

Radiological Result: Complete Union

Photograph 6a: Pre-operative X-ray

Photograph 6b: Post-operative X-ray

Photograph 6c: 1st Follow-up (6 weeks)

Photograph 6d: 2nd Follow-up (3 months)

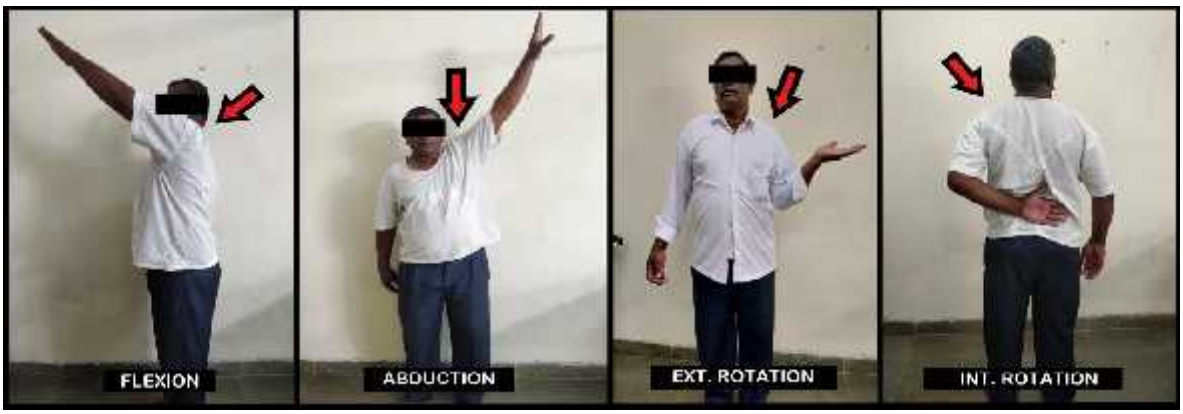
Photograph 2d: 3rd Follow-up (6months)

Patient serial number: O5

Modality of treatment: Operative (Group B)

Photograph 7: ROM at 1st Follow-up (6 weeks)

Photograph 8: ROM at 2nd Follow-up (3 months)



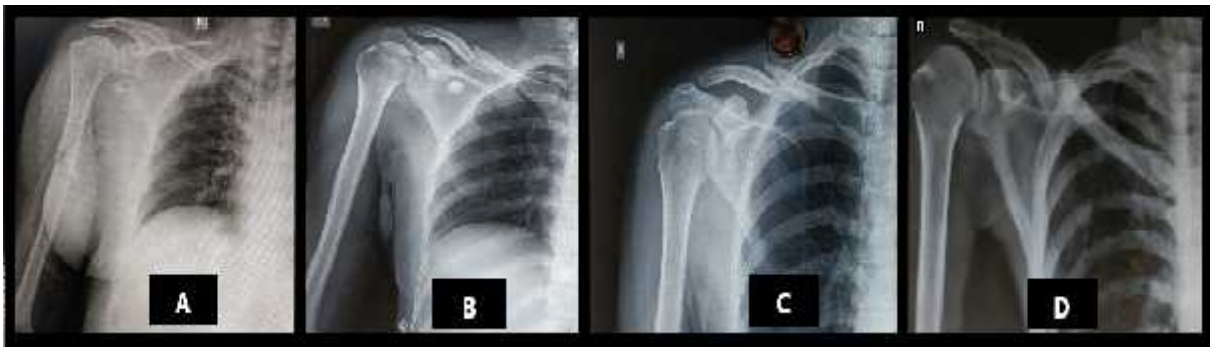
Photograph 9: ROM at 3rd Follow-up (6 months)

Patient serial number: C1

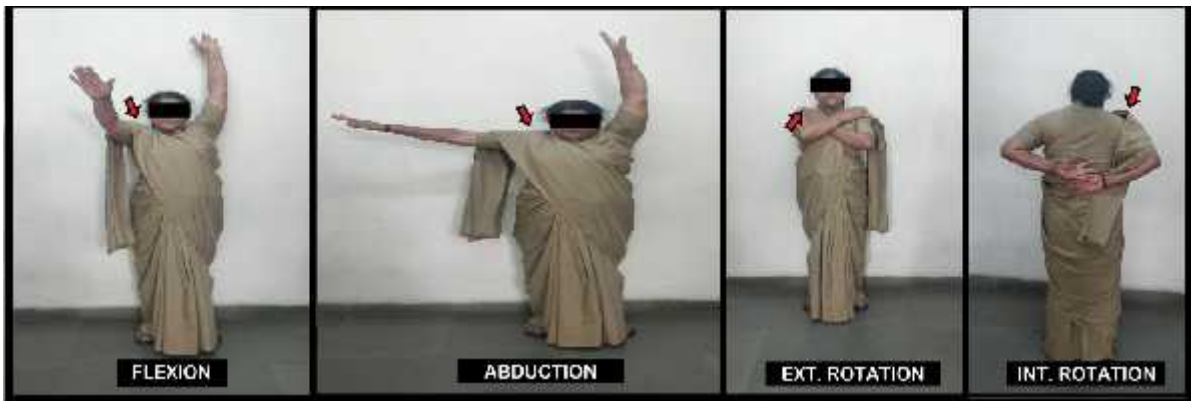
Modality of treatment: Conservative (Group A)

Radiological Result: Non-Union

Functional outcome: CMSS – Good ; NCS – Good; DASH - Excellent



Photograph 10: X-Ray at (A)Presentation (B) 1st Follow-up (C) 2nd Follow-up (D) 3rd Follow-up

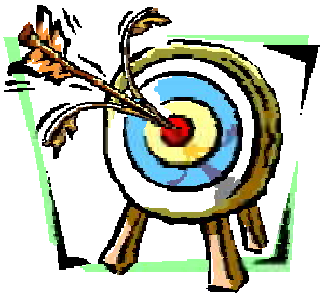


Photograph 11: ROM at 3rd Follow-up (6 months)

SR. NO.	IP/OP NUMBER	AGE	GENDER	OCCUPATION	DOMINANT SIDE	SIDE AFFECTED	ROBINSON CLASSIFICATION (2B1/2)	MODE OF INJURY	FOOSH/DIRECT INJURY	ASSOCIATED INJURIES	POST-INJURY PERIOD FOR INTERVENTION (DAYS)	HOSPITAL STAY	MANAGEMENT	CMSS							NOTTINGHAM CLAVICLE SCORE				DASH SCORE				SATISFACTION (/10)	TIME TO UNION (IN DAYS)	TIME TO MOBILIZATION (IN DAYS)	RETURN TO WORK (IN DAYS)	COMPLICATIONS	
															1ST F/U 6 WEEKS		2ND F/U 3 MONTHS		3RD F/U 6 MONTHS														
														NORMAL SIDE	TOTAL	DIFFERENCE	TOTAL	DIFFERENCE	TOTAL	DIFFERENCE	FINAL RESULT	1ST F/U (6WK)	2ND F/U (3 M)	3RD F/U (6 M)	RESULT	1ST F/U (6WK)	2ND F/U (3 M)	3RD F/U (6 M)	RESULT					RADIOLOGICAL	CLINICAL
1	**900792**	55	**F**	**HOUSEWIFE**	**R**	**R**	**2B1**	ACCIDENTAL FALL	**FOOSH**	**NIL**	**4**	**2**	**C**	**92**	**36**	**56**	**56**	**36**	**78**	**14**	**GOOD**	**54**	**68**	**82**	**GOOD**	**79.5**	**44**	**8.6**	**EXCELLENT**	5	**NONUNION**	**32**	**91**	**NONUNION**	**DROOPING SHOULDER+PERSISTENT PAIN**
2	895924	21	F	STUDENT	R	R	2B2	RTA	DIRECT	NIL	0	2	C	98	58	40	72	26	93	5	EXCELLENT	62	74	94	EXCELLENT	61.2	25.9	2.6	EXCELLENT	9	63	21	51		
3	918534	47	M	FARMER	L	R	2B1	RTA	DIRECT	NIL	0	1	C	98	53	45	75	23	93	5	EXCELLENT	64	78	94	EXCELLENT	71.6	36.2	5.2	EXCELLENT	8	81	26	63	MALUNION	COSMETIC DISSATISFACTION
4	910088	30	F	NURSE	R	R	2B1	RTA	DIRECT	NIL	1	2	C	98	49	49	78	20	93	5	EXCELLENT	64	82	96	EXCELLENT	62.9	32.8	2.6	EXCELLENT	10	80	24	64		
5	5042440	28	M	SALESMAN	R	L	2B1	RTA	DIRECT	NIL	0	0	C	100	53	47	75	25	98	2	EXCELLENT	70	90	100	EXCELLENT	60.3	10.3	0	EXCELLENT	10	74	21	52		
6	920368	48	M	SHOPKEEPER	L	L	2B1	RTA	DIRECT	NIL	1	2	C	100	47	53	78	22	96	4	EXCELLENT	66	76	96	EXCELLENT	67.2	33.6	4.3	EXCELLENT	9	83	25	63	REFRACTURE	
7	5069520	49	F	FARMER	R	L	2B2	ACCIDENTAL FALL	FOOSH	NIL	4	0	C	96	53	43	72	24	88	8	EXCELLENT	64	70	90	EXCELLENT	76.7	38.8	6	EXCELLENT	8	122	28	84	DELAYED+MALUNION	COSMETIC DISSATISFACTION
8	1082874	52	M	SERVICEMAN	R	R	2B1	RTA	DIRECT	NIL	1	1	C	100	47	53	69	31	96	4	EXCELLENT	64	74	96	EXCELLENT	67.2	33.6	4.3	EXCELLENT	10	82	24	63		
9	5176187	19	M	STUDENT	R	L	2B1	RTA	DIRECT	NIL	0	0	C	100	60	40	81	19	100	0	EXCELLENT	68	94	100	EXCELLENT	60.3	8.6	0	EXCELLENT	10	62	20	48		
10	964348	18	M	FARMER	R	R	2B1	RTA	DIRECT	RIGHT 5TH RIB #	0	7	C	100	60	40	81	19	100	0	EXCELLENT	70	94	100	EXCELLENT	60.3	8.6	0	EXCELLENT	10	64	22	48		
11	963723	60	M	SWEEPER	R	R	2B1	RTA	DIRECT	R 4TH RIB, DM,HTN	0	12	C	94	46	48	62	32	82	12	GOOD	62	72	88	EXCELLENT	85.3	44	8.6	EXCELLENT	7	116	34	84	DELAYED UNION + MALUNION	PERSISTENT PAIN
12	966431	54	M	SERVICEMAN	L	R	2B1	RTA	DIRECT	NIL	1	2	C	96	56	40	75	21	88	8	EXCELLENT	64	72	90	EXCELLENT	73.3	35.3	5.2	EXCELLENT	9	81	24	63		
13	964639	53	M	FARMER	R	R	2B1	RTA	DIRECT	LEFT ZYGOMATIC ARCH COMPLEX #	0	11	C	96	56	40	75	21	90	6	EXCELLENT	64	74	92	EXCELLENT	67.2	32.8	4.3	EXCELLENT	9	82	26	63		
14	977384	35	M	LABOURER	R	L	2B1	RTA	DIRECT	NIL	1	2	C	100	54	46	74	26	98	2	EXCELLENT	66	82	96	EXCELLENT	62.9	25.9	2.6	EXCELLENT	10	77	21	63		
15	980312	27	M	LABOURER	L	L	2B1	RTA	DIRECT	NIL	1	1	C	100	58	42	80	20	98	2	EXCELLENT	68	92	100	EXCELLENT	61.2	14.7	0	EXCELLENT	10	72	21	56		
16	983368	43	F	POLICEMAN	R	L	2B1	RTA	FOOSH	NIL	3	1	C	96	53	43	75	21	92	4	EXCELLENT	62	72	92	EXCELLENT	76.7	39.7	6	EXCELLENT	8	118	26	86	DELAYED UNION	
17	985693	30	M	POLICEMAN	R	L	2B1	RTA	DIRECT	NIL	1	2	C	100	54	46	80	20	98	2	EXCELLENT	70	88	100	EXCELLENT	60.3	14.7	0	EXCELLENT	10	75	21	56		
18	993473	45	M	FARMER	R	R	2B2	RTA	DIRECT	NIL	1	2	C	98	56	42	74	24	90	8	EXCELLENT	66	76	94	EXCELLENT	71.6	35.3	5.2	EXCELLENT	8	121	32	88	DELAYED UNION	
19	1012772	27	M	FARMER	R	L	2B1	RTA	DIRECT	NIL	1	2	C	100	58	42	80	20	96	4	EXCELLENT	68	92	100	EXCELLENT	61.2	23.3	2.6	EXCELLENT	10	74	21	58		
20	983378	53	M	LABOURER	L	R	2B1	RTA	DIRECT	NIL	1	1	C	96	47	49	76	20	88	8	EXCELLENT	64	78	94	EXCELLENT	75.9	38.8	6	EXCELLENT	8	116	28	81	DELAYED UNION	
21	1017826	52	M	FARMER	R	L	2B1	RTA	DIRECT	NIL	1	0	C	98	49	49	78	20	96	2	EXCELLENT	64	76	94	EXCELLENT	73.3	36.2	5.2	EXCELLENT	7	80	28	63	MALUNION	COSMETIC DISSATISFACTION
22	1017966	33	M	FARMER	R	L	2B1	RTA	DIRECT	NIL	0	0	C	100	58	42	74	26	98	2	EXCELLENT	66	82	98	EXCELLENT	62.9	23.3	2.6	EXCELLENT	10	77	21	63		
MEAN		**39.95454545**									**1**	**2.409090909**			**52.77272727**	**45.22727273**	**74.54545455**	**23.45454545**	**93.13636364**	**4.863636364**		**65**	**79.81818182**	**94.8181818**		**68.13636364**	**28.92727273**	**3.722727273**		**8.863636364**	**85.71428571**	**24.81818182**	**65.95454545**		

SR. NO.	IP NUMBER	AGE	GENDER	OCCUPATION	DOMINANT SIDE	SIDE AFFECTED	ROBINSON CLASSIFICATION (2B1/2)	% DISPLACED	MODE OF INJURY	FOOSH/DIRECT INJURY	CONCOMITANT INJURY	POST INJURY PERIOD FOR SURGERY ()	HOSPITAL STAY	MANAGEMENT	CMISS								NOTTINGHAM CLAVICLE SCORE				DASH SCORE				SATISFACTION (/10)	TIME TO UNION (IN DAYS)	TIME TO MOBILIZATION (IN DAYS)	RETURN TO WORK (IN DAYS)	COMPLICATIONS
																1ST F/U 6 WEEKS		2ND F/U 3 MONTHS		3RD F/U 6 MONTHS			1ST F/U (6 W)	2ND F/U (3 M)	3RD F/U (6 M)	RESULT	1ST F/U (6 W)	2ND F/U (3 M)	3RD F/U (6 M)	RESULT					
															NORMAL SIDE	TOTAL	DIFFERENCE	TOTAL	DIFFERENCE	TOTAL	DIFFERENCE	FINAL RESULT													
1	875961	39	M	SERVICEMAN	R	R	2B1	80%	RTA	DIRECT	R TIBIA #	4	20	O	98	67	31	84	14	98	0	EXCELLENT	74	92	100	EXCELLENT	54.2	12.5	0.8	EXCELLENT	10	60	10	46	NIL
2	878846	35	M	FARMER	R	R	2B1	80%	RTA	DIRECT	NIL	1	4	O	98	74	24	86	12	96	2	EXCELLENT	72	88	100	EXCELLENT	50	10	0	EXCELLENT	10	56	2	42	NIL
3	876457	46	M	FARMER	R	R	2B1	100%	RTA	DIRECT	R TIBIA #	4	27	O	98	64	34	85	13	96	2	EXCELLENT	68	84	98	EXCELLENT	55	12.5	0.8	EXCELLENT	10	63	7	49	NIL
4	884589	31	M	NURSE	R	R	2B1	100%	RTA	DIRECT	NIL	1	6	O	98	76	22	86	12	96	2	EXCELLENT	72	86	100	EXCELLENT	40.8	10	0	EXCELLENT	10	56	2	42	NIL
5	893982	43	M	FARMER	R	L	2B1	100%	RTA	DIRECT	LEFT FEMUR SHAFT #	4	25	O	98	76	22	85	13	96	2	EXCELLENT	68	90	100	EXCELLENT	50	10	0	EXCELLENT	10	63	7	50	NIL
6	894345	26	M	SHOPKEEPER	L	L	2B1	100%	RTA	DIRECT	NIL	3	17	O	100	83	17	90	10	100	0	EXCELLENT	76	92	100	EXCELLENT	37.5	12.5	0	EXCELLENT	10	48	2	42	NIL
7	900928	44	M	FARMER	R	R	2B1	100%	RTA	DIRECT	NIL	2	8	O	96	72	24	83	13	96	0	EXCELLENT	74	88	100	EXCELLENT	55	12.5	0.8	EXCELLENT	10	68	3	49	NIL
8	902249	29	M	SERVICEMAN	R	L	2B2	100%	RTA	DIRECT	LEFT 3,4,5 RIB #	2	6	O	100	86	14	90	10	98	2	EXCELLENT	76	94	100	EXCELLENT	40.8	10	0	EXCELLENT	10	52	2	42	NIL
9	873486	60	M	RETIRED	L	R	2B1	100%	ACCIDENTAL FALL	FOOSH	NIL	5	7	O	90	58	32	72	18	79	11	GOOD	58	76	94	EXCELLENT	60.8	20	3.3	EXCELLENT	9	91	5	70	MALUNION
10	913580	46	M	SERVICEMAN	R	R	2B1	80%	RTA	DIRECT	NIL	1	11	O	98	76	22	87	11	96	2	EXCELLENT	76	88	100	EXCELLENT	55	10	0.8	EXCELLENT	10	66	4	49	NIL
11	913575	52	F	HOUSEWIFE	R	L	2B1	100%	RTA	DIRECT	LEFT ZYGOMATIC ARCH COMPLEX #	3	12	O	94	67	27	78	16	94	0	EXCELLENT	68	82	96	EXCELLENT	55.8	16.7	2.5	EXCELLENT	10	77	5	56	NIL
12	909433	25	M	COOLIE	L	L	2B1	100%	RTA	DIRECT	NIL	1	7	O	100	76	24	84	16	96	4	EXCELLENT	78	94	100	EXCELLENT	37.5	7.5	0	EXCELLENT	10	44	2	42	NIL
13	918082	20	M	STUDENT	R	L	2B1	100%	RTA	DIRECT	LEFT ZYGOMATIC ARCH COMPLEX #	2	11	O	100	65	35	78	22	96	4	EXCELLENT	70	80	100	EXCELLENT	37.5	6.7	0	EXCELLENT	10	42	2	35	NIL
14	914481	60	M	RETIRED	R	L	2B2	100%	RTA	DIRECT	NIL	2	15	O	96	65	31	78	18	79	17	GOOD	72	82	94	EXCELLENT	61.7	20.8	3.3	EXCELLENT	9	82	6	60	NIL
15	920086	38	M	FARMER	L	L	2B1	100%	RTA	DIRECT	LEFT 2,3 RIB #	2	7	O	98	76	22	90	8	98	0	EXCELLENT	78	96	96	EXCELLENT	54.2	12.5	0.8	EXCELLENT	10	63	2	49	NIL
16	926307	26	M	LABOURER	R	L	2B1	100%	RTA	DIRECT	NIL	1	5	O	100	86	14	89	11	98	2	EXCELLENT	78	94	100	EXCELLENT	37.5	7.5	0	EXCELLENT	10	50	2	42	NIL
17	926233	50	F	HOUSWIFE	R	L	2B1	100%	ACCIDENTAL FALL	DIRECT	NIL	2	16	O	96	66	30	83	13	93	3	EXCELLENT	74	82	96	EXCELLENT	55.8	16.7	0.8	EXCELLENT	10	70	4	56	NIL
18	1017492	48	F	FARMER	R	R	2B1	100%	RTA	DIRECT	NIL	1	5	O	96	72	24	84	12	96	0	EXCELLENT	74	86	100	EXCELLENT	54.2	12.5	0.8	EXCELLENT	10	63	3	46	NIL
19	1016607	52	M	FARMER	R	L	2B2	100%	ACCIDENTAL FALL	FOOSH	NIL	3	7	O	96	67	29	78	18	93	3	EXCELLENT	78	88	98	EXCELLENT	55	10	0.8	EXCELLENT	10	63	4	44	NIL
20	1016560	25	M	STUDENT	L	R	2B1	100%	RTA	DIRECT	NIL	1	5	O	100	83	17	92	8	100	0	EXCELLENT	76	94	100	EXCELLENT	37.5	6.7	0	EXCELLENT	10	49	2	42	NIL
21	1015869	49	F	MAID	R	L	2B2	100%	RTA	DIRECT	NIL	1	7	O	98	76	22	89	9	94	4	EXCELLENT	72	92	98	EXCELLENT	55	12.5	0.8	EXCELLENT	9	68	3	49	HARDWARE PROMINENCE + SCAR RELATED
22	1012772	27	M	ENGINEER	R	L	2B1	100%	RTA	DIRECT	NIL	1	5	O	100	86	14	90	10	100	0	EXCELLENT	78	96	100	EXCELLENT	37.5	6.7	0	EXCELLENT	10	56	2	42	NIL
MEAN		39.59090909										2.136363636	10.59090909			73.5	24.13636364	84.59090909	13.04545455	94.90909091	2.727272727		73.18181818	88.36363636	98.63636364		49.01363636	11.67272727	0.740909091		9.863636364	61.42857143	3.681818182	47.45454545	

Introduction



Objectives

Review of Literature

Methodology

Results

Discussion

Conclusion

Summary

Bibliography

Annexure-I

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Annexure-II

Annexure-III

Annexure-IV

Annexure-V