# EFFECT OF PLATELET-RICH PLASMA ON HEALING OF LABRUM FOLLOWING ARTHROSCOPIC BANKART REPAIR: A CASE-CONTROL STUDY



## Thesis

# Submitted to All India Institute of Medical Sciences, Jodhpur In partial fulfillment of the requirement for the degree of MASTER OF SURGERY (MS) (ORTHOPAEDICS)

JUNE 2022 AIIMS, JODHPUR

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## **DECLARATION**

I hereby declare that this thesis titled "Effect of Platelet-Rich Plasma on healing of labrum following arthroscopic Bankart repair: a casecontrol study" is the bonafide work of Dr. SHEIKH AZHARUDDIN, carried out in partial fulfillment of the requirement for the degree of Post Graduate Resident Department of Orthopedics under our guidance and supervision, in Department of Orthopedics, All India Institute of Medical Sciences, Jodhpur.



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## **CERTIFICATE**

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Dr. Sheikh Azharuddin

# **IN MEMORY OF MY GRANDFATHER** (NANA) **DEDICATED TO MY FAMILY MY TEACHERS AND MENTORS**

S.No.	PARTICULARS	PAGE NO.
1	List of Abbreviations	1
2	List of Tables	2
3	List of Graphs	3
4	List of Figure	4
5	List of Appendices	5
6	Summary	6
7	Introduction	7-10
8	Review of literature	11-32
9	Aim and Objectives	33
10	Materials and methods	34-42
11	Statistical analysis	43
12	Results	44-59
13	Discussion	60-65
14	Conclusion	66
15	Summary and research results	67-68
16	Bibliography	69-75
17	Atlas of Images	76-78
	Annexures	79-91

## CONTENTS

# LIST OF ABBREVIATIONS

PRFPlatelet Rich FibrinPRGFPlatelet Rich in Growth FactorsTGF -β1Transforming Growth Factor - β1VEGFVascular Endothelial Growth FactorEGFEpidermal Growth FactorFGFFibroblast Growth FactorPDGFPlatelet-Derived Growth FactorIGFInsulin-like Growth FactorCEAPClinical, Etiology, Anatomy and PathophysiologyABOSAmerican Board of Orthopedic SurgeryTNFTumor Necrosis FactorWBCWhite Blood CellRBCRed Blood CellASESConstant shoulder and Elbow Surgeons Shoulder ScoreSDStandard deviationCIConfidence IntervalLR-PRPLeukocyte Platelet Rich PlasmaRPMRotations per minuteL-PRFPure platelet rich fibrinP-PRFPure platelet rich fibrin	PRP	Platelet Rich Plasma
PRGFPlatelet Rich in Growth FactorsTGF -β1Transforming Growth Factor - β1VEGFVascular Endothelial Growth FactorEGFEpidermal Growth FactorFGFFibroblast Growth FactorPDGFPlatelet-Derived Growth FactorIGFInsulin-like Growth FactorCEAPClinical, Etiology, Anatomy and PathophysiologyABOSAmerican Board of Orthopedic SurgeryTNFTumor Necrosis FactorWBCWhite Blood CellRBCRed Blood CellASESAmerican Shoulder and Elbow Surgeons Shoulder ScoreDASH scoreDisabilities of Arm, Shoulder, and Hand scoreCSConstant shoulder scoreSDStandard deviationCIConfidence IntervalLR-PRPLeukocyte Platelet Rich PlasmaRPMRotations per minuteL-PRFLeukocyte and platelet-rich fibrin	PRF	Platelet Rich Fibrin
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LR-PRPLeukocyte Platelet Rich PlasmaRPMRotations per minuteL-PRFLeukocyte and platelet-rich fibrin	SD	Standard deviation
RPM     Rotations per minute       L-PRF     Leukocyte and platelet-rich fibrin	CI	Confidence Interval
L-PRF Leukocyte and platelet-rich fibrin	LR-PRP	Leukocyte Platelet Rich Plasma
	RPM	Rotations per minute
P-PRF Pure platelet rich fibrin	L-PRF	Leukocyte and platelet-rich fibrin
	P-PRF	Pure platelet rich fibrin
PRFM Platelet-rich fibrin matrix	PRFM	Platelet-rich fibrin matrix
LH labral height	LH	labral height
GH glenoid height	GH	glenoid height
LGHI labrum glenoid height index	LGHI	labrum glenoid height index
aLGHI Anterior labral glenoid height index	aLGHI	Anterior labral glenoid height index
aSlope anterior labral Slope	aSlope	anterior labral Slope

# LIST OF TABLES

Table No.	Table Description	Page No.
1	Controlled clinical studies investigating the use of Platelet-Rich Plasmain rotator cuff lesions.	31-31
2	Controlled clinical studies investigating the use of PLATELET- RICH PLASMAin rotator cuff tendinopathy	32
3	Distribution of patients among both groups.	44
4	Stratification of study population in different age groups	44
5	Comparison of Age distribution between the Groups by Pearson's Chi-Square test	45
6	The table shows the gender distribution	46
7	Comparison of Gender distribution	47
8	The table shows Site distribution	48
9	Comparison of Site distribution	48
10	Comparison of ASES Scoring at 3 months	50
11	Comparison of DASH scoring done at 3 months	52
12	Comparison of CSS scoring done at 3 months	53
13	Comparison of ASES Score, DASH Score, CSS scoring done at presentation and 3 months	54
14	Comparison of ASES Score, DASH Score, CSS scoring done at presentation and 3 months	55
15	Comparison of Labrum height (LH) done at 3 months	56
16	Comparison of Labrum Glenoid Height Index (LGHI)	57
17	Comparison of Slope angle done at 3 months	58

LIST	OF	GRAPHS
------	----	--------

Graph No.	Graph Description	Page No.
1	Histogram showing the distribution of study population based on age.	45
2	Stacked bar chart showing the distribution of study population based on Age distribution between Groups	46
3	Pie chart showing gender distribution of the population.	47
4	Pie chart showing the size distribution of the study population	48
5	Stacked bar chart showing Gender distribution between Groups	48
6	Stacked bar chart showing Site distribution between Groups	49
7	Bar chart showing the distribution of American Shoulder and Elbow Surgeon (ASES) system at 3 months between Groups	51
8	Bar chart showing the distribution of Disabilities of the Arm, Shoulder, and Hand (DASH) at 3 months between Groups	52
9	Bar chart showing the distribution of at 3 months constant shoulder score CSS between Groups	53
10	Bar chart showing Comparison of ASES Score, DASH Score, CSS scoring done at presentation and 3 months between the Groups	54
11	Bar chart showing Comparison of ASES Score, DASH Score, CSS scoring done at presentation and 3 months between the Groups	55
12	Bar chart showing the distribution of labrum height (LH) at 3 months between Groups	57
13	Bar chart showing the distribution of glenoid labrum height index (GLHI) at 3 months between Groups	58
14	Bar chart showing the distribution of Slope angle at 3 months between Groups	59

Figure No.	Figure Description	Page No.
1	Flowchart Depicting The Workflow Of The Study	36
2	Procedure of Platelet-Rich Plasma preparation	38
3	Vials used for blood sample collection.	39
4	Centrifuge used for Platelet-Rich Plasma preparation	39
5	Platelet-Rich Plasma in ACD tube and syringe.	39
6	Ray diagram of Labrum Glenoid Height Index (LGHI) was calculated as the quotient of labral height (LH) to glenoid height (GH). anterior labral glenoid height index (aLGHI)	42
7	Ray diagram of showing quotient of Anterior labral slope (ALS) (aSlope)	42
8	MRI T2-weighted trans-axial slices showing the maintained anterior labral height and Slope	42
9	The patient was positioned in the left lateral decubitus position for a left shoulder arthroscopy before preparation and draping.	76
10	Superior view of a right shoulder identifying the surface landmarks of the shoulder	76
11	Superior view of a right shoulder identifying the surface landmarks, anterior portals, Antero-lateral portal	77
12	Injections of Platelet-Rich Plasma in the shoulder during the arthroscopic labral repair.	78
13	Globule threaded onto the suture anchor suture was delivered to the repair site	78

# LIST OF APPENDICES

Annexure No.	Annexure description	Page No.
1.	Ethical clearance certificate	79
2.	Ethical justification	80
3.	Documentation of informed consent (English)	81-82
4.	Documentation of informed consent (Hindi)	83-84
5.	Patient information sheet (English)	85
6.	Patient information sheet (Hindi)	86
7.	Patient Proforma	87
8.	American Shoulder and Elbow Surgeon (ASES) score	88
9.	Constant shoulder (CSS) score	89
10.	Disabilities of the Arm, Shoulder and Hand (DASH) Score	90
11.	Master chart	91

## SUMMARY

**Background:** Because of reporting inconsistencies, it's difficult to assess the treatment success of Ortho biologic therapy for a labral tear.

**Purpose:** Assessment of healing rate in labrum after arthroscopic repair in recurrent shoulder dislocation.

**Methods**: Data for 40 patients were included, out of which there were 36 males and 4 females. Pearson's Chi-Square test and Unpaired t-test were used to analyze data.

**Results**: A total of 40 patients were included in this study. Across all, The ASES scoring done at 3 months between Groups by Unpaired t-test was t- value=2.660, p-value=0.011 < 0.05 which shows statistical significance difference at p < 0.05 level.

DASH scoring done at 3 months between Groups by Unpaired t-test was t-value=8.370, p-value=0.0005 < 0.01 which shows highly statistical significance difference at p < 0.01 level.

The CSS scoring done at 3 months between Groups by Unpaired t-test were t-value=1.917, p-value=0.063>0.05 which shows no statistical significance difference at p > 0.05 level.

The LH scoring done at 3 months between Groups by Unpaired t-test were t-value=3.591, p-value=0.001 < 0.01 which shows highly statistical significance difference at p < 0.01 level.

The LGHI between Groups by Unpaired t-test were t-value=1.027, *p*-value=0.311>0.05 which shows no statistical significance difference at p > 0.05 level.

The Slope scoring done at 3 months between Groups by Unpaired t-test was t-value=2.329, *p*-value=0.025 < 0.05 which shows statistical significance difference at p < 0.05 level

**Conclusion**: To improve healing and clinical outcomes after arthroscopiclabral repair, large randomized clinical studies are needed to establish the benefits of these techniques. More research is needed to find the optimum biological agents, uses, concentrations, and administration routes.

## **INTRODUCTION**

Platelet-Rich Plasma is a component of autologous blood plasma fraction with a platelet content above baseline(1). In the 1970s, hematologists coined the term Platelet-Rich Plasma to characterize plasma with a platelet count higher than that of peripheral blood, which was initially utilized as a transfusion product to treat thrombocytopenia patients (2). Platelet-Rich Plasma was first used in maxillofacial surgery as platelet-rich fibrin (PRF) ten years later. Platelet-Rich Plasma (PRP)'s antiinflammatory qualities boosted cell proliferation, while fibrin exhibited the potential for adhesion and homeostatic capabilities. (3). Platelet-Rich Plasma has since mostly been employed in the musculoskeletal field for sports injuries. It has received substantial media attention as a result of its use in professional athletes, and it has been widely employed in this industry. (4). Cardiac surgery, pediatric surgery, gynecology, urology, plastic surgery, and ophthalmology are among the medical specialties that use Plateletrich plasma (5). Platelet-Rich Plasma is becoming increasingly popular as a treatment for many ailments, including degenerative and musculoskeletal disorders. With the help of Platelet-rich plasma (PRP), the balance between degeneration and regeneration is restored in favor of regeneration.

The initial popularity of Platelet-Rich Plasma grew from its promise as a safe and natural alternative to surgery. Platelet-Rich Plasma advocates promoted the procedure as an organically based therapy that enabled healing through the use of one's own natural growth factors. (6) In recent years, scientific research and technology have provided a new perspective on platelets. Studies suggest that platelets contain an abundance of growth factors and cytokines that can affect inflammation, postoperative blood loss, infection, osteogenesis, wound, muscle tear, and soft tissue healing. Since platelets are renowned as the major sources of healing factors within blood clots, the idea that concentrating them at the injured site could somewhat accelerate and optimize the healing mechanisms set the rationale for the development of Platelet-Rich Plasma (PRP). Some of the growth factors in Platelet- Rich Plasma include: platelet-derived growth factor (VEGF), transforming growth factor-beta (TGF- $\beta$ ), vascular endothelial growth factor (VEGF), and epithelial growth factor (EGF)(7,8) Platelet-Rich Plasma has been used in the shoulder for various indications but has never been used for bankart repairs. Recurrent shoulder dislocation is a common injury and the success of arthroscopic repair depends on the labrum healing in this study. We want to assess the effect of Platelet-Rich Plasma on labrum healing. The success of bankart repair depends upon the healing of the labrum on the glenoid and unites well. This decides the recurrence rate after arthroscopic repair along with other factors.

The shoulder is one of the most mobile joints in the human body. The girdle contains the sternoclavicular joint, which joins the upper limb to the axial skeleton. The shoulder's high range of motion comes at the expense of the joint's decreased stability. (9)

The acromioclavicular and glenohumeral joints make up the shoulder. The acromioclavicular joint is formed by the acromion, a piece of the shoulder blade (scapula), and the collar bone (clavicle). The glenohumeral joint is the connection between the ball (humeral head) and the socket (glenoid). The rotator cuff is made up of four tendons that connect the humerus to the scapula: supraspinatus, infraspinatus, teres minor, and subscapularis. Tendons are the fibrous tissue that connects muscle to bone. Muscles then pull on tendons, causing bones to move. The rotator cuff muscles keep the humerus firmly in place in the socket. The glenoid, commonly known as the socket, is shallow and flat. It is surrounded by a soft tissue known as the labrum, which forms a deeper socket that conforms to the humeral head. A joint capsule surrounds the shoulder joint. It is a fluid-filled sac that maintains joint lubrication. The superior, middle and inferior glenohumeral ligaments connect to form a soft tissue complex that acts as a joint static stabilizer. Each component of this ligamentous structure contributes differently to joint stability at different levels of motion. The coracohumeral ligament works in tandem with the superior glenohumeralligament to prevent inferior translation of an adducted shoulder joint(6). In various degrees of shoulder abduction and external rotation, the middle and inferior glenohumeral ligaments offer anterior support. In an abducted and externally rotated shoulder, the anteroinferior section of the glenohumeral ligament complex is theweakest.

The anterior labrum is important for anteroposterior stability because it deepens the glenoid cavity by up to 50%.(2). As a result, injuries that cause the

labrum to detach from its original anatomic placement might result in recurrentanterior instability. A Bankart lesion, defined as anteroinferior glenoid labral separation, is found in 87 percent to 100 percent of first-time dislocations (3–5).

The deltoid muscle and the rotator cuff are the principal dynamic stabilizers that are active during shoulder motion in all directions. The deltoid muscle and rotatorcuff pathologies not only limit the range of motion of the shoulder joint but also compromise its biomechanical stability. Recurrent anterior shoulder instability has been linked to muscle weakness and/or imbalance of the dynamic stabilizers. (7–10)

One of the most common disorders found in the clinical practice of orthopedic traumatology is anterior glenohumeral dislocation during sports or social activities. The prevalence of anterior glenohumeral instability has been estimated to be 2%. The glenohumeral joint is the most often displaced synovial joint in the human body, according to research. Forced shoulder abduction and external rotation might result in anterior dislocation and instability. Athletic participation can exert extreme strain on the musculoskeletal system, particularly the shoulders of those who conduct overhead activities. Shoulder instability is most common in adults in their late teens to mid-thirties. The significant incidence of recurrence in young individuals after a primary traumatic anterior shoulder dislocation is a big issue.

According to Rhee et al., these injuries occur at a younger age, with higher rates of recurrence and shorter intervals between the first injury and subsequent instability episodes among athletes. Because people of all ages are becoming more involved in physical activities, health care providers who interact with trauma patients must understand the anatomy, pathophysiology, risk factors, and treatment options for anterior shoulder instability. The most common cause of degenerative arthropathy in the shoulder joint is chronic instability.

The glenohumeral articulation, labrum, glenohumeral ligaments, rotator cuff, and deltoid muscle all work together to keep the shoulder stable. The humeral head's contact surface with the glenoid is around 30%, indicating that the joint has a limited osseous constraint and that major stability is attributable to other soft tissue components rather than osseous contact. (10) This provides for a very wide range of motion, but it also increases the risk of subluxation or dislocation.

According to Mazzocca et al. (J Bone Joint Surg Am. 94(4):308–16, 2012), despite efforts to standardize and classify Platelet-Rich Plasma formulations, there is still significant variation in the composition, preparation, and administrationtechniques of Platelet-Rich Plasma (PRP), limiting the conclusions that can be drawn about the utility and effectiveness of this biologic treatment.

Platelet-Rich Plasma has been used in the shoulder for various pathology e.g., rotator cuff tear (RCT), subacromial impingement (SA impingement) but never for Bankart procedures. The efficacy of arthroscopic repair in recurrent shoulder dislocation is dependent on labrum recovery.

We're interested in seeing how Platelet-Rich Plasma aids labrum repair. The arthroscopic Bankart repair is the most common surgical treatment for symptomatic shoulder instability. Arthroscopic Bankart repair was first described in 1993, and as arthroscopic instrumentation and methods have improved over time, so has its popularity. (11) The American Board of Orthopedic Surgery (ABOS) examined surgical trends in Bankart repair and found a considerable increase in the percentage of Bankart repairs performed arthroscopically versus open (16). The labrum on the glenoid must be repaired and reassembled properly for Bankart repair to be successful. The recurrence rate after the arthroscopic repair is determined by labrum healing.

Multiple studies have been done using PRP injection in and around the shoulder joint. Authors have used and studied PRP injection in frozen shoulder, rotator cuff tear (RCT), calcific tendinitis, subacromial injections. The results have been favorable overall with most studies reporting improvement in terms of pain and function.

There has been only one case series of two patients, where PRP injections have been studied in shoulder dislocation patients for Bankart lesion labrum healing. (6). The authors have reported many preliminary results in functional improvement, which cannot be used to draw any specific conclusion. Hence, we have to design this research to study the effect of PRP injection on labrum healing. To assess the healing of the labrum we have done MRI in follow-up and assessed based on the study by (12) using various parameters.

#### **REVIEW OF LITERATURE**

According to current estimates, anterior glenohumeral instability is responsible for up to 96 percent of all shoulder dislocations (13) and up to 85 percent of all instability episodes classified as subluxations. (14) Within a general population, the broader prevalence of anterior instability is 0.08 per 1,000 in the United States, although other studies from Europe show substantially higher rates ranging from 0.17 to 0.28 per 1,000 in an urban setting. (3)

Shoulder instability may be an order of magnitude more common among higher-risk groups, impacting up to 3% of military duty members in the United States each year. (4) Given that up to 64% to 73% of young (i.e., 20-year-old) high-risk or contact athletes develop recurrent instability,(15) Many people have argued that early surgical intervention is preferable to nonsurgical therapy. Although some authors argue that selective open Bankart or coracoid transfer procedures are preferable in certain high-risk cohorts,(16) the vast majority of authors advocate arthroscopic repair techniques for the treatment of anterior shoulder instabilitywithout critical bone loss, which has traditionally been defined as.20 percent anterior glenoid involvement. (7)

Arthroscopic surgery for primary shoulder instability has resulted in an absolute risk reduction of up to 80% for recurrent instability, increased quality of life, and a faster return to sports. (8) However, the likelihood of postoperative revision following anterior labral surgery remains between 5% and 15%.(17) At up to a 6-year to 14-year follow-up using a contemporary suture anchor technique. Actual failure rates after index surgery may be much higher, especially when other surrogates are considered, such as the presence of any instability recurrence (i.e., dislocation or subluxation), provocative apprehension, persistent pain in an abducted and externally rotated position, or suboptimal patient-reported outcomes, including secondary arthropathy. (9) As a result, the approach to failed arthroscopicBankart repair needs more clinical attention. Over the last several years, the use of plateletrich plasma (PRP)) or platelet-rich fibrin matrix as a biological treatment topromote rotator cuff tendon healing has grown in favor. Platelet-Rich Plasma(PRP), which is most simply defined as a sample of autologous blood with platelet concentrations above baseline values, can be delivered to healed tissues either

through direct injection or physical application of a Platelet-Rich Plasma matrix scaffold. (10) Following the release of growth factors from alpha granules, given platelets will manufacture and secrete more factors for 7 to 10 days, which corresponds to the inflammatory and repair phases of tendon healing. Despite the solid theoretical foundation and interest in employing Platelet-Rich Plasma to boost the possibility for rotator cuff repair, there is an ongoing debate about Platelet-Rich Plasma (PRP)'s clinical usefulness. To the best of our knowledge, no systematic review has been published in the literature that addresses this question. The goal of this systematic review was to identify and evaluate the existing information to establish the efficacy of arthroscopic rotator cuff repair in patients with full-thickness rotator cuff injuries who were also receiving Platelet-Rich Plasma treatment. We predicted that there would be no difference in retear rates or functional results between patients who received Platelet-Rich Plasma after arthroscopic repair of full-thickness rotator cuff injuries and those who did not.

#### **ETIOPATHOGENESIS**

Shoulder dislocations account for half of all major joint dislocations, with anterior dislocation being the most prevalent. Because of the short glenoid that only articulates with a small portion of the humeral head, the shoulder is an unstable joint. (11–13). Because the shoulder moves in numerous directions, it can dislocate forward, backward, or downward, completely or partially, but most dislocations occur via the front of the shoulder. Furthermore, the connective tissue connecting your shoulder's bones can be stretched or pulled, worsening the dislocation.

To pull the bones out of place, a significant force, such as a direct impact to the shoulder, is necessary. Excessive shoulder movement may cause the ball of your upper arm bone to pop out of its socket. When your upper arm bone is partially inside and partially outside of your shoulder socket, you have a partial dislocation. A dislocated shoulder may be caused by:

• **Sports injuries.** A strong force, such as a direct collision to the shoulder, is required to pull the bones out of place. Excessive shoulder movement may cause the upper arm bone's ball to pop out of its socket. A partial dislocation occurs when your upper arm bone is partially inside and partially outside of your shoulder socket.

- **Trauma is not related to sports.** A strong hit to the shoulder during an automobile accident is a common cause of dislocation.
- **Falls.** A forceful blow to the shoulder during a car collision is a common cause of dislocation.

#### **Predisposing Factors for Shoulder Dislocation**

Young age, participation in high-demand contact sports, a history of ipsilateral traumatic dislocation, the presence of a Hill-Sachs or osseous Bankart lesion, ipsilateral rotator cuff, or deltoid muscle insufficiency, and underlying ligamentous laxity have all been identified as risk factors for recurrent anterior shoulder dislocation. (20) Traumatic anterior shoulder instability is linked to a significant riskof recurrence in young people, according to Ramsey et al (21). In 21 skeletally immature patients treated with a sling, Marans et al(10) found a 100% re-dislocation rate. According to Porcellini et al., age at the time of the original dislocation, malesex, and the period between the first dislocation and surgery were all significant risk factors for recurrence. (22) In a prospective multicenter clinical study with a twenty- five-year follow-up, however, no significant gender differences were discovered. (23) According to the findings of Level-I prospective cohort research, those with a history of glenohumeral joint instability were nearly five times more likely to experience a future instability event, regardless of direction. (24) Although glenoid bone loss is more common, recurring instability can also be caused by engaged Hill-Sachs lesions.

(25) In as many as 90% to 100% of people with shoulder instability, a Hill-Sachs lesion was discovered, which is an osseous defect generated by severe impaction on the posterolateral side of the humeral head during anterior dislocation. (26) Immobilization was not shown to be connected with the probability of re-dislocation, according to Hevelius et al.

#### Pathophysiology

#### Anatomy

The ball-and-socket glenohumeral joint provides for coordinated motion in the frontal, transverse, and sagittal planes. It's a multiaxial articulation that's intricate and dynamic. The latter allows for complete circumduction in either direction. To allow for a wide range of physiologic motion, the much bigger humeral head articulates with the comparatively shallow glenoid fossa.

Furthermore, the joint capsule is saggy. Shoulder movements are the consequence of the dynamic and coordinated articulations of four distinct joints:

- Acromioclavicular
- Sternoclavicular
- Scapulothoracic
- Glenohumeral

#### Static and Dynamic Stabilizers

Static stabilizers include the glenohumeral articulation, labrum, glenohumeral ligaments, rotator cuff interval structures, and negative intra-articular pressure. The dynamic stabilizers are made up of the rotator cuff muscles, the deltoid, and the scapular and periscapular stabilizers.

#### **Shoulder Instability Cascade**

Shoulder instability has pathophysiology and a pathologic cascade, as do acute episodes, recurrence, and long-term repercussions. The degree of shoulder translation varies greatly in asymptomatic, healthy adults. Shoulder instability, on the other hand, is a pathologic condition in which the humeral head is translated too far into the glenoid, causing discomfort, weakness, and shoulder dysfunction. Several anatomic risk factors have been identified as potential contributors to shoulder instability development. For example, anterior shoulder instability is associated with increased glenoid version away from neutral and a lower glenoid vault inclination. (14)

When diagnosing and classifying shoulder instability, it's critical to distinguish joint laxity from real instability. The occurrence of symptoms in the presence of abnormal laxity characterizes the latter. Pathologic soft tissue laxity can be caused by repetitive microtrauma, high-energy acute trauma (e.g., traumatic dislocations), or inherent soft tissue laxity. When the glenohumeral joint's static and/or dynamic stabilizers, such as the osseous structures, capsule, labrum, and glenohumeral ligaments, are disrupted, shoulder instability ensues. In this situation, the anterior and posterior bands of the inferior glenohumeral ligament (IGHL) are the most significant ligamentous elements for shoulder stabilization.

#### **Unidirectional Instability**

Acute trauma or a succession of low-energy instability events might cause unidirectional instability. The latter may be present in the case of unidirectional instability with or without hyperlaxity. When there is soft-tissue hyperlaxity, a capsule labral lesion is less common. As a result, unidirectional instability is frequently attributed to the patulous capsular tissue, which predisposes the shoulder torecurrent instability occurrences. The same unidirectional instability scenario in a patient without soft-tissue hyperlaxity, on the other hand, is more likely to result in a capsule labral injury.

Following a traumatic primary shoulder dislocation, a considerable number of patients will develop chondral or osteochondral lesions to some degree.(26,27) Bony deficits can arise on the humeral, glenoid, or both sides of the joint. Bony malformations on either side have been proven to significantly enhance the likelihood of recurrent instability.

#### **Humeral Sided Defects**

The Hill-Sachs lesion is an impaction injury to the posterior superolateral humeral head that happens in the context of anterior instability. Hill and Sachs (28) described the so-called line of condensation that could be seen on the posterior superolateral humeral head and was best seen on an internal rotation shoulder radiograph in 1940. The Hill-Sachs lesion occurs when the humeral head dislocates Antero inferiorly and the aforementioned area of the humeral head abuts the anterior glenoid rim, forming a compression fracture on the humeral head. The real incidence of Hill-Sachs lesions is unknown, although studies have linked it to anterior shoulder instability occurrences in anywhere from 40% to almost 100% of instances, with the highest rates reported in patients of recurrent anterior instability. (15)

Because the aberrant anterior soft tissue laxity predisposes the Hill-Sachslesion to frequently abut on the tougher cortical bone at the anterior glenoid, the impact of recurrent instability on the Hill-Sachs lesion becomes troublesome. (29) Hill-Sachs lesions can also be either engaged or non-engaging. Palmer and widen were the first to characterize engaging lesions, followed by Burkhart and De Beer.

(30) These occur when the Hill-Sachs lesion's long axis coincides with the long axis of the anterior glenoid rim, causing the lesion to contact with the rim in any of the

shoulder's positions. The authors previously described the athletic position of the shoulder (i.e., 90 degrees of abduction and from 0 to 135 degrees of external rotation). A non-engaging lesion will not engage the anterior glenoid rim when the shoulder is abducted and externally rotated. A comparable lesion seen in the context of posterior shoulder instability is the reverse Hill-Sachs lesion. It's a deformity in the humeral head that's located in the Antero superomedial area.

#### **Glenoid Sided Defects**

Although most writers agree that in the setting of recurrent instability, some degree of glenoid bone loss will occur, the prevalence of glenoid bone loss is not consistently described in the literature. According to certain studies, up to 22% of patients will arrive with some degree of glenoid deficit after an initial dislocation event, rising to 25% to 90% of patients presenting with recurrent instability, and 90% of patients presenting state after unsuccessful main stabilization treatments. (38,39)

The nature of glenoid anomalies is best understood on three-dimensional CT scans, which can discriminate between a genuine bony Bankart lesion and the more erosive modifications that can be detected suggesting an attritional bone loss state. The former is a genuinely broken fragment, with a piece of the front glenoid rim included. The latter is often rounded off with blunted edges on imaging, indicating a more chronic, erosive process induced by repetitive instability or, in the acute setting, a low-energy compression fracture. The position of these flaws is sometimes described in terms of a clock face made by drawing a circle around the glenoid. The most typical location of glenoid abnormalities in the setting of anterior instability, according to Saito et al., is between 2:30 and 4:20.(21) the pathogenesis of glenoid bone anomalies is likely complicated. The following circumstances can result in blunted osseous glenoid deformities:

- Attrition, chronic/recurrent, low-energy Changes in erosive changes and al deficit across time
- Acute Compression fracture and low energy.

After a high-energy index dislocation occurrence that creates an initial glenoid lesion, chronic attritional glenoid erosive changes may emerge over time. If thedamage is not treated nonoperatively or surgically, it might lead to future instability and glenoid erosion. Glenoid rim fractures and acute avulsion injuries are common in high-energy collisions. Severe dislocations with glenoid injuries can also occur in huge anterior glenoid rim fracture fragments or lesser glenoid rim avulsion injuries. The presence of an acute glenoid rim fracture, according to Burkhart and De Beer, indicates that the glenoid rim was subjected to a large axial load during the dislocation. The study compared shoulder dislocations in South African rugby players to those in American football players. In this study, the former had a 10% incidence rate of linked glenoid rim fractures, whereas American football players had a 0% association risk of glenoid rim fractures. (18) The authors reasoned that the discrepancy was due to a stronger axial load force being transferred from the humerus to the glenoid during rugby, resulting in the characteristic anterior glenoid rim fracture.

In football, however, the anterior dislocation mechanism is more rotational, resulting in a less severe anterior glenoid rim avulsion injury because the inferior glenohumeral ligament pulls the fragment off during the anterior dislocation.

#### **Multidirectional Instability**

There has been debate over the pathologic indicators and objective criteria for diagnosing multidirectional shoulder instability (MDI) since the first report. Clinical confusion is exacerbated by the lack of a precise description for MDI. MDI was first defined as anterior and posterior instability with involuntary inferior subluxation or dislocation by Neer and Foster. Other writers have characterized MDI as instability in at least two to three directions. The estimated prevalence of MDI is also unknown due to the aforementioned issues.

#### **Biomechanics of the Shoulder Girdle**

The available articular arc is reduced by glenoid bone loss, resulting in a glenoid-humeral mismatch. The former produces a shorter articular arc length and a smaller surface area, which improves the glenoid cavity's ability to withstand transmitted axial forces from the proximal humerus. As a result, even if glenoid bone loss is corrected during surgical fixation, a restored capsulolabral contact will be subjected to high shear stresses.

The static and dynamic scapular movements vary in the presence of glenohumeral instability. Scapular dyskinesia affects up to 80% of those who are in a

state of insecurity. Excessive anterior tensile stresses and shear pressures are a result of at-risk scapular position, according to biomechanical study.

- Internal rotation
- Protraction
- Anterior tilting

Scapular dyskinesia is characterized by reduced upward rotation of the scapula during scapulothoracic motions, which can contribute to anterior shoulder instability. As a result of aberrant scapular position, the anterior band of the inferior glenohumeral ligament is subjected to elevated tensile stresses and shear pressures (aIGHL).

#### **Recurrent Instability**

Any of the underlying pathophysiologic pathways listed above might cause recurrent instability. Furthermore, both nonoperative and surgical treatment options might lead to recurrent instability. According to multiple studies, a Bankart lesion or abnormal glenoid form that alters overall glenohumeral joint biomechanics causes over 90% of contact athletes and up to two-thirds of non-contact athletes with significant glenoid bone loss to fail surgical stabilization.

#### **Dislocation Arthropathy**

In 1982, Neer was the first to identify a subgroup of individuals who acquired glenohumeral arthritis after a history of shoulder instability occurrences (or surgical stabilization operations). Dislocation arthropathy was the official name for the disorder, and Samilson and Prieto reported in 1983 that arthritic changes might occur after just one dislocation. The pathophysiology underlying the development of dislocation arthropathy is likely related to acute changes that occur during a primary traumatic instability event, followed by long-term arthritic predisposition secondary to altered glenohumeral joint biomechanics and progressive, attritional, erosive osseous changes that occur secondary to the recurrent instability events. Dislocation arthropathy is a term that explains degenerative abnormalities in the shoulder joint.

Hevelius and Rahme studied 257 primary anterior shoulder dislocations in 255 participants in a prospective analysis. After a 25-year follow-up, 27% of the participants had mild glenohumeral arthritis, whereas 34% had moderate to severe

arthrosis. (9) The pathophysiology behind the development of dislocation arthropathy may be connected to acute alterations during main or recurring traumatic instability episodes, changed glenohumeral joint biomechanics, and/or attritional changes that arise owing to the recurrent instability.

#### Histopathology

Several histologic investigations have looked into the proprioceptive characteristics of the soft tissue parts of the glenohumeral joint. Ruffini corpuscles and Pacini corpuscles can be found throughout the capsuloligamentous complex. (33) The afferent endings are vulnerable to injury during instability events, resulting in delayed proprioceptive signaling, signal transmission delays, and delayed and/or dysfunctional muscle responses, jeopardizing both the static and dynamic soft tissue stabilizing elements supporting the glenohumeral joint. (34) During intraoperative arthroscopy, the macroscopic degree/grade of damage detected after surgery was compared to histopathologic examinations comparing biopsied static stabilizing devices. The scientists noticed very minor alterations in cell density, matrix edema, and collagen fiber discontinuities. (34)

History and Physical

- Clinicians examining people with acute or chronic shoulder instability should take a thorough history. Providers should capture any particular facts concerning the index injury, whether it is a first-time or chronic presenting dislocator. The following are some of the most common features.
- First-time dislocations:
  - Patients who present after a single traumatic event almost always have a recent history of high-energy trauma or a collision impact that produced the dislocation.
  - Clinicians should ask the following questions: Trauma severity (high- or low-energy impact mechanisms)
    - Based on sports activity and postures, distinguish a true dislocation from a subluxation occurrence.

- On-field or on-site, elicit the need for manual reduction; bring to the emergency department +/- sedation requirements.
- Chronic cases

Patients frequently present after a length of time has passed, when their range of motion limitations start to interfere with everyday activities. Clinicians should acquire a comprehensive history for any bouts of mental instability. The initial damage may be neglected, leading to persistent instability and recurrence in the patient. If the patient ever had seizures or electrical shocks, clinical suspicion should be roused. Cases of low-energy, recurrent subluxation Polytrauma in which shoulder instability was ignored or overlooked Shoulder instability during sleep might be a signof a more serious condition including significant bone loss. Clinicians should inquire about any medical comorbidities or a family history of underlying connective tissue disorders or widespread hyperlaxity during the examination. A thorough history includes sports participation and positions, occupational history and current job status, hand dominance, any history of the shoulder(s) and/or neck injury/trauma, and any relevant surgery history.

#### **Physical Examination Pearls**

#### **Shoulder Exam**

In the bilateral shoulder girdles, examiners should check for asymmetry, scapular posturing, muscle bulk comparisons, or atrophic abnormalities. Check the skin for any previous surgical incisions, lacerations, scars, erythema, or induration. Asymmetry is almost usually seen in patients with chronic instability. Deltoid muscle atrophy is common in chronic dislocators. The results, particularly in obese persons, can be subtle.

In the case of prolonged anterior instability, the doctor may detect a palpable anterior fullness. In comparison to the anterior fullness, the posterior shoulder will seem relatively flat when viewed from the patient's side. Patients with chronic anteriorand posterior instability may develop acromial prominences that are identical on the posterior and anterior sides. Scapulothoracic motion and scapular winging should be examined during active and passive motion. After the observational section of the physical examination, the active and passive ranges of motion are documented. This exam finding may be restricted at the first clinic follow-up after an acute instability episode or any complex instability case, especially if glenoid bone loss is present.

Although chronic dislocators usually have a good deltoid function and internal and external rotator strength, the doctor should assess the axillary nerve's current state in cases of chronic anterior instability. It might be difficult to test the supraspinatus muscle precisely when passive ROM is limited. Any symptoms of significant muscle weakness might be a sign of a neurologic condition.

A complete sensory examination should be performed on all individuals with acute or chronic instability. Motor function of the elbow, wrist, and hand, as well as axillary nerve function, should be examined to rule out the possibility of brachial plexus injury associated with the dislocation. Distal pulses should also be monitored on the wrist.

For older persons and in the case of suspected concurrent shoulder pathologies (e.g., rotator cuff injuries or biceps tendon pathology), specialized testing for concomitant shoulder pathologies (e.g., rotator cuff injuries or biceps tendon pathology) should be explored.

#### **Provocative Testing**

#### **Considerations for Shoulder Instability**

Examining glenohumeral translation and hypermobility at the shoulder joints, as well as other joints in the body if applicable, should be done to determine global tissue laxity.

#### **Anterior Apprehension Test**

An examination table is used to perform the anterior apprehension test on a supine subject. The examiner places the shoulder in 90 degrees of abduction and 90 degrees of external rotation while delivering an anteriorly directed force to the proximal humerus. The test is deemed positive if it reproduces the symptoms of anterior instability.

Lower levels of abduction fear might be a sign of glenoid bone loss. Patients may defend their shoulders during the examination, but the provider can usually detect if the cautious stance reflects the patient's fears about anterior shoulder instability.

#### **Jobe Relocation Test**

The Jobe relocation test is utilized in conjunction with the previous apprehensive testing maneuver. When a patient reports a subjective experience of recreating shoulder instability symptoms, the examiner applies a posteriorly directed push while keeping the shoulder in the same concerned posture. The elimination or improvement of symptoms indicates a positive test result.

#### Load-and-shift Test

The examiner exerts axial stress through the elbow with one hand to center the humeral head inside the glenoid. An anterior and posterior directed force is supplied at 0 degrees, 45 degrees, and 90 degrees of shoulder abduction. The IGHL is impaired when there is an increased translation with increasing degrees of shoulder abduction. The load-and-shift test can identify unidirectional and multidirectional instability with high sensitivity, but it can also detect unidirectional and multidirectional instability with moderate sensitivity.

#### **Other Exam Considerations**

The shoulder should also be examined for concurrent posterior and multidirectional instability. Every patient undergoing surgery should have an anesthetic evaluation, with the outcomes compared to the unaffected contralateral side. Depending on the patient's age, the doctor may predict varying degrees of linked shoulder disorders. Rotator cuff injuries, for example, are prevalent in older people who have acute shoulder instability. Pain with weakness against resisted abduction or external rotation may suggest the presence of concurrent rotator cuff problems. At end-range postures, patients with anterior shoulder instability, for example, exhibit some degree of external rotation weakness. Greater passive external rotation with the arm at the side indicates a subscapularis tendon rupture, whereas reduced external rotation with 90 degrees of abduction indicates a medically treated Bankart lesion. (33)

#### **Evaluation**

#### **Radiographs**

A complete radiographic trauma series is advised, including a genuine anteroposterior (AP) picture of the glenohumeral joint (i.e., the "Grashey" view). The true AP image is taken on the coronal plane, with the subject rotated 30 to 45 degrees off the tape. While the patient is in the coronal plane neutral, the beam can also be rotated. In addition to AP imaging, an axillary lateral radiograph should be taken. This attitude may be tough to develop in stressful circumstances. On the other hand, the importance of obtaining a full radiography series with sufficient orthogonal imaging cannot be emphasized. It is typical to overlook shoulder dislocations, especially posterior dislocations when just an inadequate radiographic assessment is available.

#### **Advanced Imaging Modalities**

The recommended imaging approach for identifying associated labral injuries is magnetic resonance imaging. Intra-articular contrast (MR arthrography) enhances the sensitivity and specificity of identifying associated injuries. MRI imaging can aid doctors in making an accurate diagnosis of osseous glenohumeral joint avulsions or glenohumeral abnormalities (off the glenoid or humeral sides).

CT imaging is the best imaging modality to use when seeking to measure bone loss. Although there are a variety of quantification methods accessible, threedimensional reconstruction techniques surpass two-dimensional evaluations. Adequate sagittal alignment along the long axis of the glenoid is required to adequately evaluate the glenoid bone loss. (28)

Three-dimensional en face reconstructions of the glenoid with humeral subtraction have become the gold standard for glenoid evaluation due to their ability to give an easily reproducible measurement of glenoid morphology. (23)

#### Posterior shoulder dislocation

The most common causes of posterior shoulder dislocation include a blow to the front region of the shoulder, axial loading of an adducted and internally rotated arm, or severe muscular contractions following a seizure or electrocution(29,34) Examining the shoulder reveals a prominent posterior shoulder with anterior flattening. The coracoid process is noticeable. The patient is unable to externally rotate his arm because it is held in adduction and internal rotation(30)

Imaging investigations - On a conventional anteroposterior (AP) view, radiographic evidence of a posterior shoulder dislocation is modest and may go unnoticed in up to 50% of cases. (38) The "light bulb" sign, rim sign, and trough line sign are all diagnostic clues.

The light bulb sign occurs when the humeral head is internally rotated and the tuberosities no longer protrude laterally, giving the humeral head a circular look.

The distance between the medial aspect of the humeral head and the anterior glenoid rim is known as the rim sign. Although this distance may be normal with a posterior dislocation, posterior dislocation should be suspected if these two structures are superimposed or if the joint space is expanded (>6 mm).

When two parallel lines of cortical bone are visible on the medial cortex of the humeral head, the trough line sign is evident. The medial cortex of the humeral head is shown by one line, while the anterior articular surface of the humeral head is represented by the "trough" of an impaction fracture (also known as the "reverse Hill-Sachs's lesion") (31).

Computed tomography (CT) and ultrasound are two more imaging modalities that may be beneficial. When normal radiographs are insufficient to determine the presence of a posterior dislocation, CT can be useful(32). A reverse Hill-Sachs impaction fracture can also be measured using a CT scan.

According to Preliminary case reports, ultrasonography can help detect posterior shoulder dislocations and confirm their successful reduction. More research into this intriguing strategy is required.

Injuries resulting from the accident — Tuberosity and surgical neck fractures of the humerus, reverse Hill-Sachs lesions, and injuries to the labrum and rotator cuff are all common causes of posterior shoulder dislocations(21). When plain radiographsare inconclusive for dislocation, computed tomography is diagnostic and indicates the extent of the articular surface impaction fracture, allowing the orthopedics surgeon to choose the best treatment option

#### Inferior shoulder dislocation (luxatio erecta)

Axial loading with the arm fully abducted or violent hyperabduction of the arm are the most common causes of inferior dislocations. Patients typically have this dislocation when they fall and grab something above their heads, causing hyperabduction.

Examination - Patients with this injury are unable to abduct the affected arm above their head. (28) The forearm is pronated and rests on the top of the head in most cases. Neurologic dysfunction affects over 60% of patients, with the axillary nerve being the most typically affected. (23) Following a decrease, neurologic impairment usually resolves on its own. In 80% of instances, rotator cuff tears or larger tuberosity fractures are found. Arterial damage affects about 3% of patients and manifests as a radial pulse that is missing or irregular.

Radiographs indicate the humeral head beneath the coracoid or glenoid in imaging examinations. The greater tuberosity (most common), acromion, scapula, humeral head, coracoid, and glenoid are all associated fractures.

Associated injuries — Among all forms of shoulder dislocations, inferior shoulder dislocations have the highest frequency of axillary nerve (60%) and artery (3%) damage, in addition to the fractures mentioned above. (28)

#### TREATMENT

Following a catastrophic dislocation, recurrent anterior shoulder instability might be so severe that it prohibits an athlete from returning to sports. If left untreated, chronic instability can develop into degenerative arthropathy of the shoulder joint. The most frequent surgical therapies address the most common underlying disorders, labral tears and capsular laxity. As part of the treatment approach, any concomitant rotator cuff damage should be surgically corrected. Even though multiple surgical techniques for treating traumatic recurrent anterior shoulder instability have been documented, the best treatment is still up for dispute. The adoption of a precise surgical technique with sufficient exposure is required for a favorable clinical result. The primary objective of therapy should be to repair the sick state that causes recurrent instability as anatomically as feasible. The method that allows for joint surface examination offers anatomical restoration, preserves range of motion, and can also be used with low rates of issues and recurrence is crucial to providing the best possible outcome for any specific patient.

In individuals with traumatic recurrent anterior instability of the shoulder that has not responded to conservative therapy, open and arthroscopic surgeries are alternatives. The arthroscopic treatment of glenohumeral instability necessitates the attainment and maintenance of a certain degree of skill. (20)Although open stabilization was formerly thought to be more successful than arthroscopic stabilization in terms of post-operative recurrence rates in the 1990s, clinical results have now become equivalent. Improvements in arthroscopic instruments, as well as the creation of novel surgical methods as a consequence of accumulated experience and a better knowledge of the circumstances that contribute to failure in these patients, have all played a part. (20)

In terms of recurrence, Fabbriciani et al (24) found no difference between arthroscopic and open surgical correction of Bankart lesions. According to the findings of another recent prospective randomized clinical trial comparing open and arthroscopic techniques, the difference in the quality of life between the two groups attwo years follow-up was neither significant nor clinically important; however, patients who preferred open repair had a significantly lower risk of recurrence. (25) The surgical treatment of athletes who compete in contact sports is still debatable.

Rhee et al(35) evaluated the effects of arthroscopic and open stabilization in young contact athletes and found that 25% of the arthroscopic group and 13% of the open stabilization group had recurrent instability. Athletic activity, according to some writers, plays a bigger effect in post-operative recurrence than the surgical approach employed for stabilization. (18)

Recurrent shoulder dislocations can be caused or complicated by bone loss on the glenoid or humeral head. Recurrent periods of anterior shoulder instability can cause Hill-Sachs or osseous Bankart lesions to become bigger, leading to even more instability. (28–30) As a result, a single Bankart repair is rarely adequate for the surgical care of patients with osseous defects. In their research, they looked at the shape of the glenoid cavity in individuals with recurrent anterior shoulder instability.

According to Sugaya et al, 10% of the participants did not have the osseous disease, 40% had bony erosion, and 50% had an osseous Bankart lesion. If the glenoid

surface has lost more than 25% of its bone, surgical therapy should involve a bony rebuilding technique. (36) The best surgical method for treating bony abnormalities in the glenoid rim is debatable. The methods for restoring the normal width and depth of the glenoid cavity include reduction and fixation of the displaced glenoid rim fracture, transfer of the coracoid process to the anterior glenoid, and reconstruction with autograft or allograft bone block. To prevent recurrent instability, all surgical interventions aim to restore more anatomic glenoid morphology.

Following the effective repair of the glenoid fracture in its anatomic site, pieces join and survive for one year without resorption, according to Park et al (38) Transfer of the coracoid process to the anterior glenoid rim as a structural block is an optimum option when bone loss is higher than 25% of the glenoid surface with a missing fragment. Bristow, Latarjet, and Trillat procedures are the most successful, well-known, and extensively utilized coracoid transfer methods into the glenoid lesion. The Latarjet method is the transfer of the coracoid process via the subscapularis tendon to produce an osseous block during joint mobility. It was initially reported in 1954.

The Bristow treatment involves transferring the coracoid's terminal 1 cm, together with the conjoint tendon, to the scapula's neck through a horizontal incision in the subscapularis muscle. The coracoid is osteotomized after an arthrotomy, then dislocated and secured with a coracoscapular screw in the Trillat surgery. Following coracoid transfer in 47 patients, Burkhart et al (30) reported that no recurrent instability was observed after a mean follow-up of 4.9 years. After earlier surgery correction connected with anomalies of the anterior glenoid rim and an intact subscapularis muscle, the Latarjet technique was also described as properly restoring glenohumeral stability.

The term "engaging Hill-Sachs's lesion" was used by Burkhart et al (30) to characterize a compression fracture on the posterosuperior portion of the humeral head that descends beyond the glenoid rim in external rotation of an abducted shoulder and is linked to recurrent instability. Tenodesis of the infraspinatus into the lesion, sometimes known as "remplissage," and bone grafting of the defect are the surgical therapies reported to address the osseous insufficiency on the humeral head.

In the treatment of patients with a significant bone defect on the humeral head, Boileau et al found that arthroscopic Hill-Sachs remplissage in conjunction with Bankart repair was a successful approach. The authors also determined that at the most recent follow-up, 98 percent of the patients had a stable shoulder joint with roughly 10 degrees of external rotation limitation, which did not significantly impair return to sports activity. In the treatment of patients with a significant bone defect on the humeral head, Boileau et al found that arthroscopic Hill-Sachs remplissage in conjunction with Bankart repair was a successful approach. The authors also determined that at the most recent follow-up, 98 percent of the patients had a stable shoulder joint with roughly 10 degrees of external rotation limitation, which did not significantly impair return to sports activity.

There are a variety of treatment options for disorders of the soft tissues and bones, which can lead to a complicated condition. As a result, while dealing with the clinical therapy of recurrent anterior shoulder instability, one should always properly examine the patient-specific pathologies and investigate therapeutic options depending on each case's needs. A broad guideline is necessary in this respect.

## PLATELET-RICH PLASMA (PRP)

Platelet-Rich Plasma is autologous plasma that has been supplemented with platelet concentrations that are higher than usual. Platelet-Rich Plasma has been used to describe plasma with higher platelet counts compared to normal counts in the peripheral blood since 1970. Hematologists initially used it for transfusion in thrombocytopenic patients. (19) Androgenetic alopecia (39), atrophic acne scars (40), skin graft enrichment, knee osteoarthritis, lateral epicondylitis, and tendinopathies have all been demonstrated to benefit from Platelet-Rich Plasma (PRP). (41)

#### Mechanism Of Action of Platelet-Rich Plasma (PRP)

Platelet-Rich Plasma represents a complex mixture of growth factors, cytokines, and chemokines including VEGF, PDGF, and TGF-beta. (42) One model for Platelet-Rich Plasma action is that local application of Platelet-Rich Plasma causes supra-physiological concentrations of these biologically active substances with modulation of pathways implicated in inflammation and tissue repair. To understand the potential function of Platelet-Rich Plasma in disease, it is instructive to examine

the consequences of injection into healthy tissue. Platelet-Rich Plasma was injected into various soft tissues including the skin of 18 healthy rabbits. (43) Histological examination at two weeks revealed fibrosis and neovascularity. At six weeks there was a chronic inflammatory infiltrate with fibrosis and calcium deposits. No changes were observed at the site of control saline injections. Thus, it is plausible that Platelet-Rich Plasma is biologically active, however, whether it will prove neutral, beneficial, or deleterious for a particular disease process can only be determined by carefully designed trials. A variety of in vitro mechanistic studies have been reported. Application of Platelet-Rich Plasma to cultured fibroblasts increases fibroblast matrix protein synthesis and proliferation, although a similar magnitude of the effect was also observed for platelet-poor plasma. (44)

#### How They Help:

Localized mesenchymal and epithelial cells are told to migrate, divide, and produce more collagen and matrix, resulting in fibrous connective tissue and scarring. Platelets are used to speed tissue maturation, which is often neglected in clinical evaluations that focus on pain, range of motion, and daily activities. Even though no human studies have been conducted to date, overdosing on platelet-rich plasma can cause overstimulation of cells, resulting in a poorly differentiated, chaotic scar, and some of the released growth factors may cause adverse events, such as suppression of osteoclast generation. Additional high-quality research is needed to determine the ideal formulation, administration modalities, and application techniques, given the significant inter-product variability and the diverse application tactics

A few clinical trials are looking at the usage of Platelet-Rich Plasma in rotator cuff injuries.

Table 1: Controlled clinical studies investigating the use of PLATELET-RIC	CH PLASMA in rotator cuff lesions

		Surgical use of PLATELE	T-RICH PLASM	A in arthrosc	copic rotator cuff repair
Author	Evidence	Platelet-Rich Plasma formulation	Surgical technique	Number of patients	Comments
Randelli et al. (2011)(45)	Level 1 Randomized controlled	Injectable Platelet-Rich Plasma (GPS System)	Single row	53	Better clinical outcomes at 3 months; better clinical outcomes at 12, 24 months for smaller tears with platelet-rich plasma (PRP)
Ruiz-Moneo et al. (2013)(46)	Level 1 Randomized controlled	Injectable Platelet-Rich Plasma (PRGF Endoret system)	Double row	63	No differences in rotator cuff healing or function at 1 year
Antuna et al. ~ (2013)(47)	Level 2 Randomized controlled	Injectable Platelet-Rich Plasma (Vivo stat system)	Single row	28	No differences in clinical outcomes and the healing rate at 2 years
Charousset et al. (2014)(48)	Level 3 Case-control	Injectable Platelet-Rich Plasma (GPS system)	Double row	70	No differences in cuff healing or function at 2 years A significant advantage for the L- Platelet-Rich Plasma patients in terms of smaller iterative tear
Gumina et al. (2012)(49)	Level 1 Randomized controlled	Suturable Platelet-Rich Plasma (RegenKit-THT system)	Single row	76	Lower retear in the Platelet-Rich Plasma group; no differences for clinical outcomes
Jo et al. (2011)(50)	Level 2 Prospective cohort	Suturable Platelet-Rich Plasma (COBE spectra system)	Trans osseous equivalent	42	The trend for lower re-tearing in the Platelet-Rich Plasma group; no differences for recovery and function
Jo et al. (2013)	Level 1 Randomized controlled	Suturable Platelet-Rich Plasma (COBE spectra system)	Trans osseous equivalent	48	Lower retear and function at 1 year in the

Castricini et al. (2011)(51)	Level 1 Randomized controlled	Suturable Platelet-Rich Plasma (Cascade system)	Double row	88	No difference for clinical outcomes at 16 months; better restoration of footprint in Platelet-Rich Plasma group Lower retear using the chi-square test for binomial in Arnoczky [14] analysis
Rodeo et al. (2012)(52)	Level 2 Randomized controlled	Suturable Platelet-Rich Plasma (Cascade system)	Single OR double row/trans osseous equivalent	67	No difference in tendon healing, tendon vascularity, and clinical scores at 1 year
Barber et al. (2011)(53)	Level 3 Case-control study	Suturable Platelet-Rich Plasma (Cascade system)	Single row	40	Single row 40 Lower retear in the PLATELET-RICH PLASMA group; better healing for smaller tears with PLATELET-RICH PLASMA (PRP)
Bergeson et al. (2012) (54)	Level 3 Cohort study	Suturable Platelet-Rich Plasma (Cascade system)	Single or double row	37	Higher retear rate in patients with at-risk rotator cuff tears with PRFM; no difference in functional outcome scores Historical control group
Weber et al. (2013)(55)	Level 1 Randomized controlled	Suturable Platelet-Rich Plasma (Cascade system)	Single row		No difference in perioperative morbidity

Table 2: Controlled clinical studies investigating the use of PLATELET-RICH PLASMA in rotator cuff tendinopath	hy

		PLATELET-RICH PLASM	A injections for ro	otator cuff to	endinopathy
Author	Evidence	Platelet-Rich Plasma formulation	Surgical technique	Number of patients	Comments
Rha et al. (2013)(56)	Level 1 Randomized controlled	2 Platelet-Rich Plasma (3 mL) injections at a 4-week interval	2 dry needling procedures at a 4-week interval	<u>39</u>	Platelet-Rich Plasma was superior concerning pain, function, and range of motion over 6 months
Kesikburun et al. (2013)(57)	Level 1 Randomized controlled	1 injection of Platelet-Rich Plasma (5 mL)	1 injection of saline solution (5 mL)	40	No difference for the quality of life, pain, disability, and range of motion at 1 year

# **AIM AND OBJECTIVES**

Aim: To study whether platelet-rich plasma accelerates healing in Bankart lesions in recurrent shoulder dislocation

OBJECTIVE: Assessment of healing rate in labrum after arthroscopic repair in recurrent shoulder dislocation.

**Rationale:** Platelet-Rich Plasma has been used extensively in RC repair and only 1 case report has been published using Platelet-Rich Plasma and Bankart lesion. No trialhas been done using Platelet-Rich Plasma in Bankart repair.

## **Research question:**

- Whether the use of Platelet-Rich Plasma in arthroscopic Bankart repair improves the rate and quality of healing.
- Does Platelet-Rich Plasma Injection translate into better functional outcomes.

## **Research hypothesis:**

**Null hypothesis:** There is an insignificant difference in the rate and quality of Arthroscopic bankart repair healing between patient's undergoing arthroscopic repair with Platelet-Rich Plasma used intraoperatively as compared to Patients without Platelet-Rich Plasma injection at 3 months

Alternative hypothesis: There is a significant difference in the rate of Arthroscopic bankart repair healing between patients who have undergone Arthroscopic repair with Platelet-Rich Plasma used intraoperatively as compared to Patients without Platelet-Rich Plasma injections.

## **MATERIALS AND METHODS**

#### Study design

The study design was a case-control study. Originally according to the proposal, it was a randomized controlled trial (RCT) but due to the Pandemic and resultant disrupted clinical services a revised proposal was made and approval was taken from the institutional ethical committee for modification of the study design. Finally, the study design was changed to case control study with prospective recruitment of case. the recurrent shoulder dislocation patients operated in the department before start of the study were taken as retrospective controls. the study was a case control study. The sampling frame was initially from 1 July 2019 till 1st March 2021 but was extended to 31st December 2021 due to the COVID19 pandemic. The protocol was approved by Institute's Ethical Committee (AIIMS/IEC/2019- 20/975). The study was conducted as per the Declaration of Helsinki and Good Clinical Practices guidelines. Written informed consent was taken from all the eligible patients as the regulatory criteria for inclusion in the study

The study was started after approval taken from Clinical Trials Registry-India (CTRI) (Reg.No CTRI/2020/08/027206).

#### **Place of study**

The study was conducted at the Department of orthopedics with support from the Department of Radiology and Department of transfusion medicine, All India institute of medical sciences, AIIMS, Jodhpur

## **Inclusion criteria:**

 Patients diagnosed and treated with recurrent shoulder dislocation at AIIMS Jodhpur from July 2019 to March 2021

2) Diagnosis of anteroinferior traumatic recurrent shoulder dislocation and planned for arthroscopic repair.

3) Subjects had to be willing and able to give written informed consent.

#### **Exclusion criteria:**

1. Recurrent shoulder dislocation which needs open surgery

2. Patients with previous shoulder pathology or symptoms before shoulder dislocation.

3. Multidirectional shoulder dislocation or posterior shoulder dislocation

4. Patient with generalized joint laxity

### Sample size:

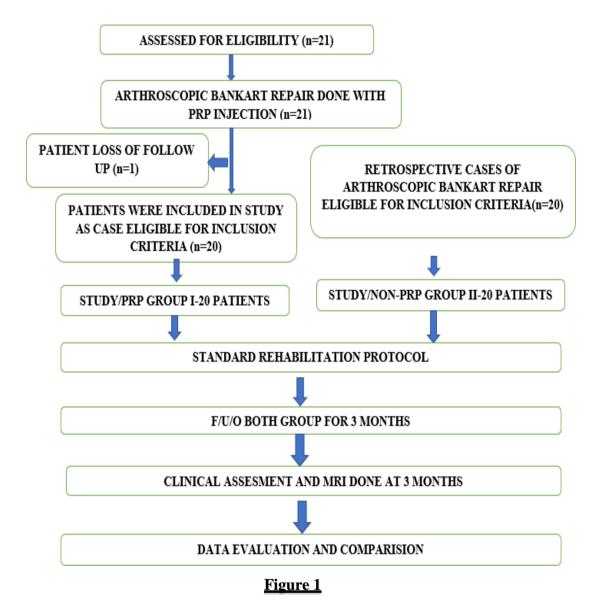
The sample size kept in accordance to the average incidence of shoulder dislocations patients in OPD in a year. We decided to keep No of cases at 30 and control at 30 accordingly.

However, due to the unfortunate COVID-19 pandemic crisis, and resulting reduction in OPD and patient foot falls. We revised the protocol of study with approval of department of orthopedics and thesis committee of institute. We were able collect DATA of 21 patients in the Platelet-Rich Plasma group 20 in non- Platelet-Rich Plasma (PRP).

The Recurrent shoulder dislocation patients which were operated earlier in the department of orthopedics All India institute of medical sciences, (AIIMS) Jodhpur and had completed the required follow-up, were included as retrospective controls.

All the prospective patients were given Platelet-Rich Plasma Considered as Group I (Cases). All the retrospective patients with follow-up who did not receive Platelet-Rich Plasma injection were Considered as Group II (Control). following this same inclusion and exclusion criteria were recruited. 21 patients who were administered Platelet-Rich Plasma injection (Group 1) and 20 patients as controls in non- Platelet-Rich Plasma injection (Group 2).

## FLOWCHART DEPICTING THE WORK FLOW OF THE STUDY:



Study procedure and data collection methods:

**Group I** (Cases): All the Recurrent shoulder dislocation (RSD) patients attending AIIMS Jodhpur OPD between 1st July 2019 to 1<sup>st</sup> March 2021 were evaluated by taking a clinical history and a thorough physical examination was performed. Each patient's clinical history included the mechanism of the initial event, the period from the first dislocation to recurring instability, activities that contribute torecurrence or apprehension, the number of dislocations, and history of reducibility without an emergency visit. A detailed Clinical examination of both shoulder wasdone that included, inspection, palpation and evaluation of range of movements. Any

obvious deformity and/or muscular atrophy in the contralateral shoulder, as well as any scar tissue from previous trauma or surgery, are all crucial and easily detectable with a careful examination. Every patient's active and passive range of motion in all planes was measured and recorded for both shoulders. They were evaluated for generalized ligamentous laxity, as well as verification of distal neurovascular condition.

Special tests like Apprehension test and relocation tests and Provocative tests were used for clinical diagnosis of shoulder instability.

Confirmation of diagnosis and presence of any pathophysiological lesion of labral tear was made by magnetic resonance imaging (MRI) scan. MRI were evaluated for any other pathology also noted e.g., Hill Sach lesion, biceps tendon tear, recurrent cuff tear etc.

Patient was explained about the surgery and use of Platelet-Rich Plasma injection and consent was taken. Platelet-rich plasma was obtained using plateletpheresis and injected on the same day of surgery. Single/double-loaded knotless suture anchors were used in labral repair surgeries. Autologous Platelet-Rich Plasma was made by using a standard double spin protocol, soft spin at 1500 rpm for 15 minutes followed by hard spin at 2500 rpm for 10 minutes. Autologous Platelet- Rich Plasma was given to the first group at the tissue bone interface after completing Bankart repair and standard treatment without Platelet-Rich Plasma given to thesecond group. Both groups of patients underwent a standard postoperative protocol of rehabilitation. Both groups of patients followed for 3 months after recurrent shoulder dislocation. MRI Evaluation was performed at 3 months by a consultant radiologist who is blinded to the study with observation.

PLATELET-RICH PLASMA was injected with long spinal needle inserted through anterior portal. The injection was given at bone labrum interface after the repair. It was made sure to inject Platelet-Rich Plasma all along the repair from superior to inferior.

**Group II** (**Controls**): previously operated Recurrent shoulder dislocated patients were called in OPD for Follow-up evaluation. Data regarding clinical, demographic and Radiological presentation was collected from hospital records. Repeat MRI were done at Follow-up along with Scoring. The surgical technique of repair was similar for controls and cases and all surgeries were done by singlesurgeon.

# PREPARATION OF PLATELET-RICH PLASMA AND DELIVERY TECHNIQUES

There are three techniques for producing Platelet-Rich Plasma (PRP).

1.Plateletpheresis and blood filtration

Because of this, there are large amounts of human platelets and PDGFs and a few contaminating leucocytes.

2. Single-spinning centrifugation, which yields platelets up to three times the baseline level;

3. Double-spinning centrifugation yields platelets with a high leucocyte content up to eight times the baseline level.



Figure 2: Procedure of Platelet-Rich Plasma preparation

These give rise to four product categories.

1. Pure Platelet-Rich Plasma (P- Platelet-Rich Plasma (PRP)) with a low leucocyte concentration.

This can be administered as a gel or as a liquid.

2. Platelets are more concentrated in leucocyte-rich PLATELET-RICH PLASMA (LR-PLATELET-RICH PLASMA (PRP)) than in P-PLATELET-RICH PLASMA (PRP).

It can be injected intra-articularly as an activated gel or in a liquid state, similar to

- P-Platelet-Rich Plasma (PRP).
- 3. Platelet-rich fibrin in its purest form (P-PRF).

Double-spinning centrifugation is used to achieve this. The final output is a plateletrich fibrin scaffold that is stiffer than traditional Platelet-Rich Plasma and has a gel-like consistency.

4. Leucocyte- and platelet-rich fibrin (L-PRF), which is a non-injectable, topically applied leucocyte-rich gel.

On the day of admission 17 ml of autologous blood was withdrawn in ACD tubes (Figure 4) and LR- Platelet-Rich Plasma was prepared using double spin method protocol standardized by the institute. Autologous blood was first centrifuged in a centrifuge (Remi R8 C fixed angle microcentrifuge) at 1500 rpm for 15 minutes, from which plasma was separated; then it was again centrifuged at 2500 rpm for 10 minutes (Figure). Prepared Platelet-Rich Plasma was later kept in platelet agitator (Terumo Penol platelet incubator and agitator PI400) for 30 minutes for activation.



Figure 3: Vials used for blood sample collection.



Figure 4: Centrifuge used for Platelet-Rich Plasma preparation.



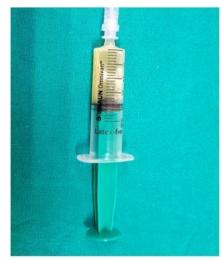


Figure 5 Platelet-Rich Plasma in ACD tube and syringe.

#### The Steps of shoulder joint arthroscopy are as follows:

**Primary Portals:** This was the first portal made. Posterior portal was used as primary viewing portal for diagnostic arthroscopy. It was located 2 cm inferior and 1 cm medial to the posterolateral corner of acromion the portal track passes may pass between infraspinatus (suprascapular nerve) and teres minor (axillary nerve) or through the substance of infraspinatus.

Anterior portal: It was used as working portal and was made lateral tocoracoid process and anterior to the AC joint. This portal passes between pectoralis major (medial and lateral pectoral nerves) and deltoid (axillary nerve) and is usually placed under direct supervision from the posterior portal with aid of spinal needle.

**Lateral portal**: It was made for working and repair located 1-2 cm distal to the lateral edge of the acromion portal and passes through deltoid (axillary nerve). Patients were told about the use of PLATELET-RICH PLASMA before surgery and consent was taken.

**Post-op rehabilitation:** Rehabilitation protocol was standard of care at department of orthopedic.

Rehabilitation protocol was same for all patient, both group I and group II. Passive forward elevation, rotation and pendular movement started on post-op day one (POD1)

At 2 weeks suture removal was done and passive Forward elevation was increased to 160 deg. Passive- active exercise were started at 4 weeks in forward elevation and external rotation was permitted till 15 deg.

Active forward elevation and extension, Internal Rotation are started at 6 weeks. Arm pouch sling was given for 6 weeks. Active Assisted exercises were started at 3 months.

**Follow-up:** Outcomes were assessed preoperatively and at 3 months after surgery concerning functional scores as determined using the following scoring systems American Shoulder and Elbow Surgeon (ASES) system, Constant shoulder score (CSS), Disabilities of the Arm, Shoulder and Hand (DASH) system. Repaired labral structural integrities was assessed by magnetic resonance imaging.

40

# Repaired labral structural integrities were assessed by magnetic resonance imaging.

**MRI Evaluation:** Analysis of the postoperative MRI images was performed by a musculoskeletal radiologist (SS). A mixed sample was assessed without the knowledge of administration of the Platelet-Rich Plasma to the patients. Glenoid depth, Labral height, and glenoid angle were calculated along with the repaired labrum for all cases. Axial PDFS (proton density fat-suppressed images) or MARSPD (metal suppression sequence) images were analyzed for the measurements of the patient and control group randomly. Labral morphology was assessed on sagittal and coronal Proton Density images as well and bony glenoid was assessed on coronal T1WI. The signal characteristics of the labrum were assessed on T2W coronal and PDFS axial images.(12) The parameters that were assessed included:

 Glenoid Height (GH): It was defined as the maximum distance of osseous glenoid height in a millimeter. from a straight line to the lowest portion of glenoid cavity. (Figure)

Line A: connecting highest point of glenoid cavity.

Line B: Straight line tangent to the lowest portion of glenoid cavity.

Glenoid Height (GH) is measured on axial sections as perpendicular distance between line A and line B.

 Labral Height (LH): The Labral height/capsule Labral height was assessed as the maximum distance of a straight line drawn at the maximum height of capsulo-Labral complex and lowest portion of glenoid cavity.

Labral Height (LH) is measured on axial sections as perpendicular distance between line B and line C.

- 3. Labrum glenoid height index (LGHI): Labral height divided by the glenoid height was assessed to calculate LGHI.
- 4. Labral Slope: The Labral Slope was assessed as an acute angle measure between line B and line D i.e., from tip of maximum Labral height and the lowest portion of glenoid cavity.

3 months after arthroscopic Bankart repair, MRI T2-weighted trans axial slices show the restored anterior labral height and Slope. The anterior labral glenoid height index (aLGHI) and anterior labral slope (ALS) (aSlope)

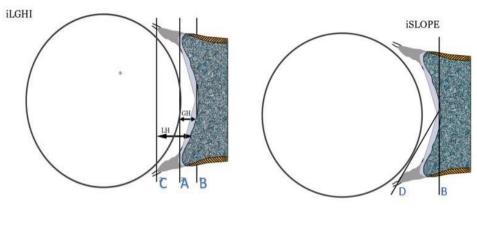




Figure 7

Ray diagram of showing Labrum Glenoid Height Index (LGHI) was calculated as the quotient of labral height (LH) to glenoid height (GH). anterior labral glenoid height index (aLGHI), Anterior labral slope (ALS) (aSlope).

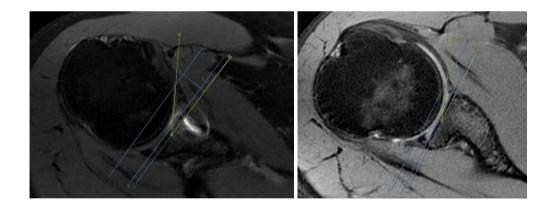


Fig 8. MRI T2-weighted trans axial slices showing the quotient of labral height (LH) to glenoid height (GH) was used to create the Labrum Glenoid Height Index (LGHI) (GH). The angle between the tangent to the lowest section of theglenoid Cavity (I) and the segment between the tip of the maximal labral height and the lowest portion of the glenoid cavity was designated as the labral Slope (II). These characteristics were assessed using T2-weighted trans axial slices for the anterior region and coronal slices for the inferior portion

# STATISTICAL ANALYSIS

The collected data were analysed with IBM SPSS Statistics for Windows, Version 23.0. (Armonk, NY: IBM Corp). To describe about the data descriptive statistics frequency analysis, percentage analysis was used for categorical variables and the mean & S.D were used for continuous variables. To find the significant difference between the bivariate samples in independent groups the Unpaired sample t-test was used. To find the significance in categorical data Chi-Square test was used similarly if the expected cell frequency is less than 5 in  $2\times 2$  tables then the Fisher's Exact was used. In all the above statistical tools the probability value .05 is considered as significant level.

# **RESULTS**

Total 41 patients of recurrent shoulder dislocation with MRI confirmed glenoid labrum tear were evaluated in this study. Total patients in the present study were 40 of which 20 patients were in Platelet-Rich Plasma group I 20 patients were present in non-Platelet-Rich Plasma group II.

PRP GROUP I.	Non-PRP GROUP II.	TOTAL
20	20	40

Table 3: Distribution of patients among both groups	<b>Table 3: Distribution of</b>	patients among	both groups
-----------------------------------------------------	---------------------------------	----------------	-------------

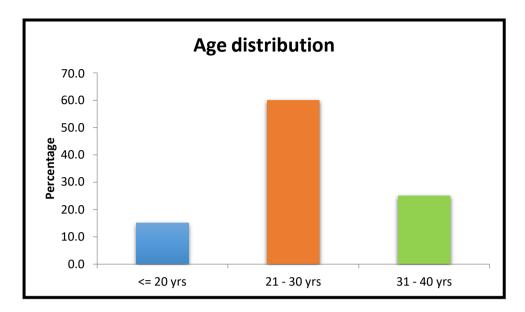
## **1. DEMOGRAPHIC VARIABLE**

## AGE

Total 40 Patients were evaluated in this study and were grouped into various age groups: 2nd decade ( $\geq$ 20 years), 3rd decade (21-30 years), 4th decade (31-40) and >40 years.

Age distribution					
Frequency Percent					
$\leq 20$ yrs.	6	15.0			
21 - 30 yrs.	24	60.0			
31 - 40 yrs.	10	25.0			
>40	0	0			
Total	40	100.0			
$Mean \pm SD = 26 \pm 6 \text{ yrs.}$					

Table 4: Stratification of study population in different age groups





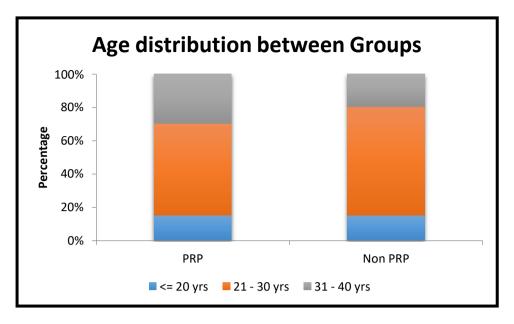
The above table shows Age distribution were  $\leq 20$  years is 15.0%, 21-30 years is 60.0%, 31 - 40 years is 25.0%. The above table shows Age distribution where  $\leq 20$  years (n=6) is 15.0%, 21-30 years(n=24) is 60.0%, 26-31-40 (n=10) years is 25.0%.

In the present study maximum number of patients belonged to 21-30 years of age for both the Platelet-Rich Plasma (n=11) and non- Platelet-Rich Plasma (n=13) group population, and minimum number of patients belong to below 20 years in non-Platelet-Rich Plasma group (n=03), where in Platelet-Rich Plasma group the minimum number of patients were in age group below 20-year years (n=02) (Table 1).

		Groups			□ 2 −		
			PRP	Non PRP	Total	value	<i>p</i> -value
	$\leq 20$	Count	3	3	6		
	yrs.	%	15.0%	15.0%	15.0%		
Age	21 - 30	Count	11	13	24		
distribution	yrs.	%	55.0%	65.0%	60.0%	0.567	0.753 #
	31 - 40	Count	6	4	10	0.307	0.755 #
	yrs.	%	30.0%	20.0%	25.0%		
Tota	1	Count	20	20	40		
Tota	1	%	100.0%	100.0%	100.0%		
# No Statistical Significance at p > 0.05 level							

 Table 5: Comparison of Age distribution between the Groups by Pearson's Chi

Square test



Graph 2

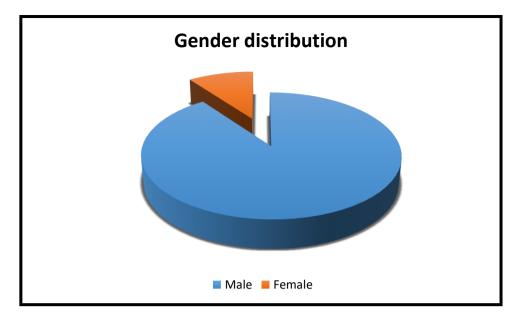
The above table shows comparison of Age distribution between Groups by Pearson's Chi-Square test were  $\Box 2=0.567$ , p=0.753>0.05 which shows no statistically significance difference of age distribution between Groups.

## GENDER

In this present study 36 patients were male (19 patients were in non- Platelet-Rich Plasma group and 17 patients were in Platelet-Rich Plasma group I and 4 patients were female (1 patients were in non- Platelet-Rich Plasma group and 3 patients were in Platelet-Rich Plasma group). (Table 6)

Gender distribution					
Frequency Percent					
Male	36	90.0			
Female	4	10.0			
Total	40	100.0			

90%(n=36) of total male subjects and 10%(n=4) of total female subjects had history of recurrent shoulder dislocation. In this study, a significantly higher proportion of male subjects had a history of recurrent shoulder dislocation with respect to female subjects.



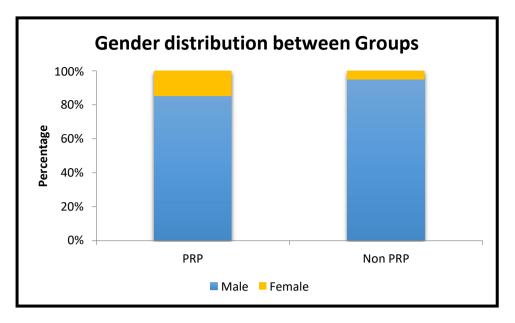
Graph 3

The above table shows Gender distribution where Female is 10.0%, Male is 90.0%.

In this present study 36 patients were male i.e., 90% (19 patients were in non- Platelet-Rich Plasma group and 17 patients were in Platelet-Rich Plasma group) and 4 patients were female i.e., 10% (1 patients were in non- Platelet-Rich Plasma groupand 3 patients were in Platelet-Rich Plasma group). (Table 13). 85% of Male in Platelet-Rich Plasma group and 95% in Non-Platelet-Rich Plasma group. 15% of Female in Non- Platelet-Rich Plasma Group 5.0% of Platelet-Rich Plasma (PRP). Gender distribution between Groups by Pearson's Chi-Square test were  $\Box 2=1.111$ , p=0.605>0.05 which shows no statistically significance difference of Gender distribution between Groups. (Table 7)

			Groups			$\Box 2 - p$	n
			PRP	Non PRP	Total	value	<i>p</i> -value
Male		Count	17	19	36		
Gender	Male	%	85.0%	95.0%	90.0%	1.111	0.605
distribution	tribution Female	Count	3	1	4		
	remate	%	15.0%	5.0%	10.0%	1.111	#
Total Count %		Count	20	20	40		
		%	100.0%	100.0%	100.0%		
# No Statistical Significance at p > 0.05 level							

Table 7: Comparison of Gender distribution between the Groups by Pearson's
Chi-Square test

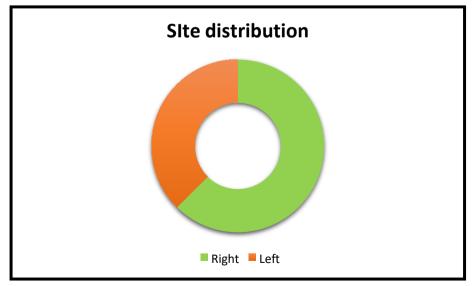




The above table shows comparison of Gender distribution between Groups by Pearson's Chi-Square test were  $\Box 2=1.111$ , p=0.605>0.05 which shows no statistical significance between Gender distribution and Groups.

## SITE: TABLE 8

Site distribution							
	Frequency Percent						
Right	25	62.5					
Left	15	37.5					
Total	40	100.0					



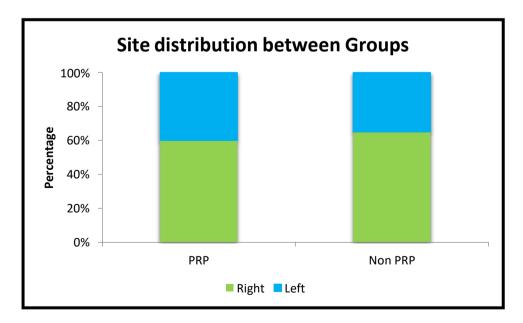
Graph 5

The above table shows Site distribution where Right is 62.5%, Left is 37.5%.

In this present study out of 40 patient, 25 patients were right side recurrent shoulder dislocation i.e., 62.5%. 65% (n=13) patients were in non- Platelet-RichPlasma group and 60% (n=12) patients were in Platelet-Rich Plasma group and 15 patients were left side recurrent shoulder dislocation (n=15)37.5% (35.0 % (n=7) patients were in non- Platelet-Rich Plasma group and 40.0% (n=8) patients were in Platelet-Rich Plasma group) (Table). Site distribution between Groups by Pearson's Chi-Square test were  $\Box 2=0.107$ , p=1.000>0.05 which shows no statistical significance between Site distribution and Groups.

		Gro	Groups		□ 2 −	n	
			PRP	Non PRP	Total	value	<i>p</i> -value
	Right	Count	12	13	25		
Site	Kigin	%	60.0%	65.0%	62.5%		
distribution	Left	Count	8	7	15	0 107	1.000
	Lett	%	40.0%	35.0%	37.5%	0.107	#
Total Course		Count	20	20	40		
		%	100.0%	100.0%	100.0%		
	# N	No Statis	tical Signit	ficance at p	> 0.05 lev	vel	

Table 9: Comparison of Site distribution between the Groups by Pearson's Chi-Square test



Graph 6

The above table shows comparison of Site distribution between Groups by Pearson's Chi-Square test were  $\Box 2=0.107$ , p=1.000>0.05 which shows no statistically significance difference of site distribution between Groups.

## SCORING

## 1: American Shoulder and Elbow Surgeon (ASES) system

Overall ASES at presentation was  $55.5 \pm 7.2$  (range 49.0-63.0) which was increased to  $92.21 \pm 4.2$  (range 88.3-96) at 3 months.

## In PLATELET-RICH PLASMA Group I:

At presentation- Minimum and maximum ASES at presentation were 51.0 and 61.0 respectively and mean ASES 56.1+/7.14.

At 3 rd. month- minimum and maximum ASES was 90.0 and 96.0 respectively and mean ASES was 93.05+/-8.10.

#### In non-PLATELET-RICH PLASMA Group II:

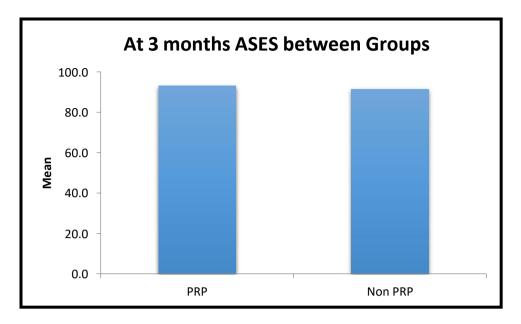
At presentation: Minimum and maximum ASES at presentation were 49 and 63 respectively, mean ASES 54.8 +/-7.88.

At 3 rd. month: Minimum and maximum ASES was 88.3 and 94.9 respectively, mean ASES at was 91.38 +/- 3.94.

ASES scoring done at 3 months between Groups by Unpaired t-test were t- value (It represented units of standard error) =2.660, *p*-value=0.011 < 0.05 which shows statistical significance difference at p < 0.05 level.

Clinical	Groups	Ν	Mean	SD	t-value	<i>p</i> -value	
At 3	PRP	20	93.1	1.9			
months ASES	Non-PRP	20	91.4	2.0	2.660	0.011 *	
* Statistical Significance at p < 0.05 level							

 Table 10: Comparison of at 3 months ASES between the Groups by Unpaired sample t-test



The above table shows comparison of ASES scoring done at 3 months between Groups by Unpaired t-test were t-value (It represented units of standard error) =2.660, p-value=0.011<0.05 which shows statistical significance difference at p < 0.05 level.

## 2: Disabilities of the Arm, Shoulder and Hand (DASH)

Overall DASH at presentation was  $50.9 \pm 7.2$  (range 47.0-58.0) which was decrease to  $13.65 \pm 4.2$  (range 8.9-16) at 3 months.

## In PLATELET-RICH PLASMA Group I:

At presentation- Minimum and maximum DASH at presentation were 47.0 and 58.0 respectively, Mean DASH 50.8 +/- 3.2.

At 3 rd. month- minimum and maximum DASH was 8.9 and 19.0 respectively, Mean DASH at 3rd month was 15.7+/-3.12 and the mean was 11.6+/-7.14.

In non-PLATELET-RICH PLASMA Group II:

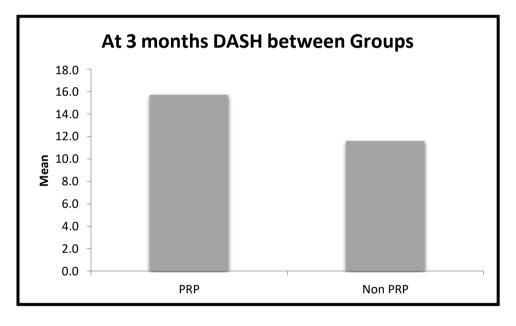
At presentation- maximum DASH at presentation were 46 and 47.5 respectively, mean DASH 11.6 +/-3.12.

At 3 rd. month-minimum and maximum DASH was 8.9 and 14.2 respectively, mean ASES at 3rd month was 91.38 +/- 3.94 in non- Platelet-Rich Plasma group.

The DASH scoring done at 3 months between Groups by Unpaired t-test were t-value=8.370, *p*-value=0.0005 < 0.01 which shows highly statistical significance difference at p < 0.01 level

Clinical	Groups	Ν	Mean	SD	t-value	<i>p</i> -value	
At 3 months DASH	PRP	20	15.7	1.6		0.0005	
	Non PRP	20	11.6	1.5	8.370	**	
** Highly Statistical Significance at p < 0.01 level							

Table 11: Comparison of DASH scoring done at 3 months between the Groupsby Unpaired sample t-test





The above table shows comparison of DASH scoring done at 3 months between Groups by Unpaired t-test were t-value (It represented units of standard error) =8.370, *p*-value=0.0005<0.01 which shows highly statistical significance difference at p < 0.01 level.

## 3: Constant shoulder score (CSS)

Overall CSS scoring at presentation was  $64.5 \pm 7.2$  (range 59.0-71.0) which was increased to  $92.21 \pm 4.2$  (range 88.3-96) at 3 months.

## In PLATELET-RICH PLASMA group I:

At presentation: Minimum and maximum CSS at presentation were 59.0 and 71.0 respectively, mean CSS 64.5.

At 3 rd. month: minimum and maximum CSS was 90.0 and 96.0 respectively, mean CSS Score was 93.2 +/-5.6 and the mean was 56.1+/7.14.

## In PLATELET-RICH PLASMA group II:

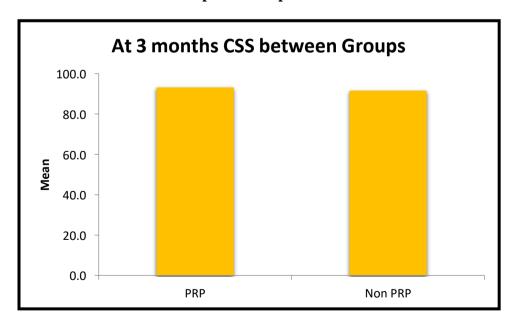
At presentation: Minimum and maximum CSS at presentation were 59 and 68 respectively, mean CSS 64.6 +/- 5.6.

At 3 rd. month: minimum and maximum CSS was 83.0 and 94.0 respectively, mean CSS was 91.5 +/- 5.4 in (Table).

CSS scoring done at 3 months between Groups by Unpaired t-test were t-value=1.917, p-value=0.063>0.05 which shows no statistical significance difference at p > 0.05 level

Clinical	Groups	N	Mean	SD	t-value	<i>p</i> -value	
At 3	PRP	20	93.2	2.8			
months CSS	Non- PRP	20	91.5	2.7	1.917	0.063 #	
# No Statistical Significance at $p > 0.05$ level							

Table 12: Comparison of CSS scoring done at 3 months between the Groups byUnpaired sample t-test

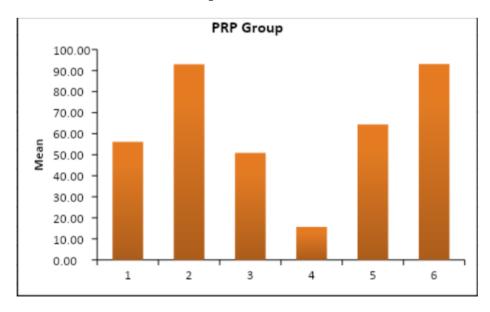


**Graph 9** 

The above table shows comparison of CSS scoring done at 3 months between Groups by Unpaired t-test were t-value (It represented units of standard error) =1.917, *p*-value=0.063>0.05 which shows no statistical significance difference at p > 0.05 level.

PRP		Mean	Ν	SD	t-value	<i>p</i> -value
ASES	At presentation	56.10	20	3.23	16 506	0.0005 **
	At 3 months	93.05	20	1.93	46.596	
DASH	At presentation	50.80	20	3.40	42.747	0.0005 **
DASH	At 3 months	15.71	20	1.56		
CSS	At presentation	64.35	20	2.96	22 457	0.0005 **
CSS	At 3 months	93.15	20	2.78	32.457	
** Highly Statistical Significance at p < 0.01 level						

Table 13: Comparison of ASES Score, DASH Score, CSS scoring done at presentation and at 3 months between the Groups by Unpaired sample t-test in Platelet-Rich Plasma group. which shows highly statistical significance difference at p < 0.01 level.

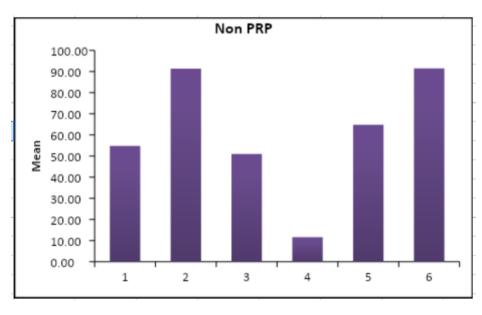


Graph 10

The above table shows comparison of ASES, DASH, CSS score done at presentation and at 3 months between Groups by Unpaired t-test were t-value=46.596 in ASES, t-value=42.747 in DASH score, t-value=32.457 in CSS *p*-value=0.0005<0.01 for all three which shows highly statistical significance difference at p < 0.01 level.

Non-PRP		Mean	Ν	SD	t-value	<i>p</i> -value		
ASES	At	54.80	20	4.05	38.262	0.0005 **		
	presentation							
	At 3 months	91.39	20	2.02				
DASH	At	51.01	20	4.01	42.391	0.0005 **		
	presentation							
	At 3 months	11.60	20	1.54				
CASS	At	64.75	20	2.84	35.835	0.0005 **		
	presentation							
	At 3 months	91.50	20	2.67				
	** Highly Statistical Significance at p < 0.01 level							

Table 14: Comparison of ASES Score, DASH Score, CSS scoring done at presentation and at 3 months between the Groups by Unpaired sample t-test in non-PRP group



Graph 11

The above table shows comparison of ASES, DASH, CSS score done at presentation and at 3 months between Groups by Unpaired t-test were t-value=38.262 in ASES, t-value=42.391 in DASH score, t-value=35.835 in CSS *p*-value=0.0005 < 0.01 for all three which shows highly statistical significance difference at p < 0.01 level.

All the score improved and the difference was statistically significant (p<0.001)

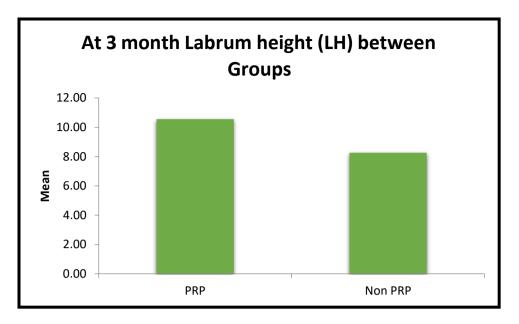
### **Radiological measurements:**

#### 2: Labrum height (LH)

At Overall 3 rd. month minimum and maximum Labrum height (LH) scoring was 13.3 and 4.4 respectively, mean Labrum height (LH) scoring at 3rd month was  $9.4 \pm 4.6$  in Platelet-Rich Plasma group. At 3 rd. month minimum and maximum was 4.4 and 12.3 respectively, mean Labrum height (LH) score at 3rd month was 8.26  $\pm 4.4$  and 12.3 respectively, mean Labrum height (LH) score at 3rd month was 8.26  $\pm 4.4$  and 13.3 respectively, mean Labrum height (LH) score at 3rd month was 8.26  $\pm 4.4$  and 13.3 respectively, mean Labrum height (LH) score at 3rd month minimum and maximum was 5.9 and 13.3 respectively, mean Labrum height (LH) score at 3rd month was 10.55  $\pm 4.18$  in Platelet-Rich Plasma group (Table). Labrum height (LH)done at 3 months between Groups by Unpaired t-test were t-value=3.591, *p*- value=0.001<0.01 which shows highly statistical significance difference at p < 0.01 level.

MRI	Groups	Ν	Mean	SD	t-value	<i>p</i> -value	
At 3 months LH	PRP	20	10.55	2.09	3.591	0.001 **	
	Non- PRP	20	8.26	1.95			
** Highly Statistical Significance at p < 0.01 level							

Table 15: Comparison of Labrum height (LH) done at 3 months between theGroups by Unpaired sample t-test



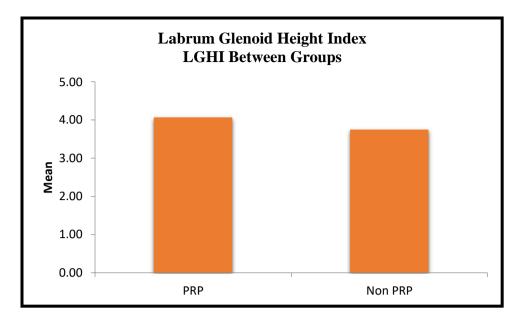


The above table shows comparison of Labrum height (LH) done at 3 months between Groups by Unpaired t-test were t-value=3.591, *p*-value=0.001 < 0.01 which shows highly statistical significance difference at p < 0.01 level.

## **3 LABRUM GLENOID HEIGHT INDEX (LGHI)**

MRI	Groups	Ν	Mean	SD	t-value	<i>p</i> -value	
ІСШ	PRP	20	4.06	0.85	1.027	0.311 #	
LGHI	Non-PRP	20	3.75	1.08			
# No Statistical Significance at p > 0.05 level							

Table 16: Comparison of Labrum Glenoid Height Index (LGHI) between theGroups by Unpaired sample t-test.





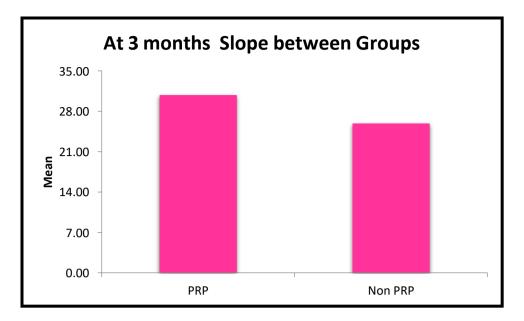
The above table shows comparison of Labrum Glenoid Height IndexLGHI between Groups by Unpaired t-test were t-value=1.027, *p*- value=0.311>0.05 which shows no statistical significance difference at p > 0.05 level.

## 4: Slope angle

At Overall 3 rd. month minimum and maximum Slope angle scoring was 11 and 41 respectively, mean Slope angle at 3rd month was  $28.34 \pm - 12.1$ . At 3 rd.month minimum and maximum was 11 and 33.5 respectively, mean Slope angle at 3rd month was  $25.88 \pm - 15.2$  in non- Platelet-Rich Plasma group (Table). At 3 rd. month minimum and maximum was 23 and 41 respectively, mean Slope angle at 3rd month was  $30.80 \pm - 11.2$  in Platelet-Rich Plasma group (Table). Slope angle done at 3 months between Groups by Unpaired t-test were t-value=2.329, *p*-value=0.025 < 0.05 which shows statistical significance difference at p < 0.05 level.

MRI	Groups	Ν	Mean	SD	t-value	<i>p</i> -value	
At 3	PRP	20	30.80	5.63			
months Slope	Non-PRP	20	25.88	7.59	2.329	0.025 *	
* Statistical Significance at p < 0.05 level							

Table 17: Comparison of Slope angle done at 3 months between the Groups byUnpaired sample t-test





The above table shows comparison of Slope angle done at 3 months between Groups by Unpaired t-test were t-value=2.329, *p*-value=0.025 < 0.05 which shows statistical significance difference at p < 0.05 level.

## DISCUSSION

The use of Platelet-Rich Plasma and other autologous blood products has gradually been on the rise for the treatment of various soft tissue injuries. Although, Platelet-Rich Plasma is being used more commonly for tendon pathology, its potential use for other types of tissues is promising.

To the best knowledge, of author there is no study in the literature that investigates the use of Platelet-Rich Plasma as an adjunct to the operative treatmentfor glenoid labral injury. However, there is only one case report on two individuals who were treated with Platelet-Rich Plasma for labral injury. This case report support the fact that PRP is relative safe and feasibility to use in glenoid labral/capsular injury, but only in two patients. Here, we expand the assessment beyond a case report of two patients and evaluate and compare two groups treated by the same surgeon fora labral tear with arthroscopic labral repair.

In this pilot study, we aimed to assess the feasibility of Platelet-Rich Plasma treatment for patients with glenoid labrum tear toward healing and rated the clinical recovery of patient by the ASES, DASH and CSS score along with improvement in shoulder functional activities. We also assessed the improvement in healing with MRI in follow-up evaluation.

Our results show statistically significant improvement of average ASES, DASH, and CSS scores at 3 months between the two groups. On MRI show the labral height (LH) scoring which shows high statistical significant difference (p < 0.01level) while in glenoid labral height index (GLHI) between Groups shows no statistical significance difference. (p > 0.05 level)

We structured our study to sequentially assess for adverse events on each follow-up visit. During the entirety of our study, no adverse events were reported, with Platelet-Rich Plasma injection. This is consistent with previously publishedstudies of Platelet-Rich Plasma for a variety of soft tissue pathologies. Adverse events related to Platelet-Rich Plasma treatments are uncommon and typically are no different than other needle-based treatments.

Platelet-Rich Plasma is a concentrated supply of blood cells, growth factors, cytokines, and chemokines; nevertheless, there are a few elements that are yet

unknown when it comes to creating the best Platelet-Rich Plasma product. Platelet-Rich Plasma is hypothesized to include biologically active elements that drive tissue development during labral repair and speed up the natural healing process.(58–60)

The effect of Platelet-Rich Plasma gel augmentation on various musculoskeletal tissue types such as arthroscopic rotator cuff repair, osteoarthritic chondrocytes, and open meniscal repair of horizontal tears extending into the avascular zone was effective at mid-term follow-up in young patients, according to different authors. In these case-control studies, the inclusion of Platelet-Rich Plasma improved clinical outcomes marginally.(61)

In a study by Cole *et al*, the role of Platelet-Rich Plasma in meniscal repair is bythe possibility of delivering a local concentration of growth factors as well as other cytokines directly to the repair site.(62)

Platelet-Rich Plasma has anti-inflammatory properties that inhibit inflammatory processes in osteoarthritic chondrocytes.(63) Labral tissue is fibrocartilage and in an animal model meniscal tear, Platelet-Rich Plasma enhanced repair of meniscal fibrocartilage.(64) It has also been shown to play a role in the regeneration of degenerative rotator cuff tears by enhancing proliferation and matrix synthesis of tenocytes.(65)

Autologous blood products, such as platelet-rich plasma and growth factors (single or combined), have recently been utilized to treat ligament injuries with the objective of rapid healing and a quicker return to exercise.(66)

Animal studies have suggested positive effects of Platelet-Rich Plasma augmentation in terms of regenerative effects on meniscal cells *in vitro* with upregulation of meniscal cell viability and synthesis of sulfated glycosaminoglycans compared with controls.(64) Studies addressing the beneficial effects of Platelet-Rich Plasma *in vitro* and *in vivo* have been published in meniscal repair.(62,64,67) But to our knowledge, no study concerning the clinical effects of Platelet-Rich Plasma on glenoid labrum repair have been published to date.

Bergeson *et al.* found comparable outcomes with Platelet-Rich Plasma fibrin matrix (PRFM) in at-risk rotator cuff injuries.(54) This might be due to a variety of variables, including changes in Platelet-Rich Plasma preparation products. Unlike injectable liquid Platelet-Rich Plasma preparations, these investigations employed a

semisolid implant material that had to be given using an arthroscope cannula. This implant was left near the bone-tendon contact, which may have caused a space-occupying effect as well as an adverse biological environment with elevated inflammatory mediators.

In a laboratory model, human Platelet-Rich Plasma has been shown to stimulate migration and chondrogenic differentiation of human subchondral progenitor cells.(68) Glenohumeral intra-articular injection of Platelet-Rich Plasma to stabilize fibrocartilage and hyaline cartilage lesions has evolved after safety and efficacy results of studies with good short-term results in osteoarthritis of the hip and knee joints.(50) In the past few years there has been interest in mesenchymal pluripotent stem cells (MSC) in the regeneration of cartilage and tendon disorders.

Wang *et al.* carried out a well-designed randomized controlled trial. A total of 60 patients underwent arthroscopic double-row supraspinatus tendon repair. After randomization, half the patients received 2 ultrasound-guided injections of PRP to the repair site at postoperative days 7 and 14. After surgery it helped healing and early functional recovery.

*Charousset et al.* conducted case-control research to see if there were any functional or anatomical differences between patients who had double-row rotator cuff repairs with Platelet-Rich Plasma injections and those who didn't.(48) There wereno variations in rotator cuff healing between the two groups as measured by MRI. The Platelet-Rich Plasma group had a 35.5 % retear rate, whereas the control group had a 40% retear rate.(48) However, in the group of patients who got Platelet-Rich Plasma, the size of the recurring tears was reduced.(48)

Patients who had arthroscopic rotator cuff surgery of big to severe rips and received Platelet-Rich Plasma had better structural results, according to a randomized controlled experiment done by *Jo et al.*(47) Patients who got Platelet-Rich Plasma had a considerably reduced retear rate (3.0 percent) than those who did not (20.0 percent).(47) Patients who received Platelet-Rich Plasma also had substantially bigger supraspinatus cross-sectional areas, prompting the authors to infer that Platelet-Rich Plasma treatment improves postoperative tendon healing quality.(47)

Randelli et al. discovered decreased postoperative pain and faster healing rates in individuals with non-massive rotator cuff rupture when Platelet-Rich Plasma was utilized in separate randomized controlled research.(45) There was a total of 53patients in the study. At 3 months postoperatively, the UCLA, SST, Constant scores, and strength in the external rotation was considerably greater in the Platelet-Rich Plasma group; however, these differences were not obvious at 6, 12, or 24 months. (28)

Because the outcomes of the studies exploring Platelet-Rich Plasma in the setting of rotator cuff repair have been inconsistent, multiple authors have undertaken meta-analyses of the data.(69,70)

*Warth et al.* looked at 11 studies that were either level 1 or level 2.(70) According to the findings of the meta-analysis, there were no significant differences in clinical outcomes between patients who got Platelet-Rich Plasma and those who didn't.(70) The total improvement in the Constant score was higher when Platelet- Rich Plasma was placed at the tendon-bone interface rather than over the surface of the healed tendon, according to meta-regression.(70) Platelet-Rich Plasma administration resulted in considerably decreased retear rates in patients who had double-row surgeries for major (> 3 cm) rotator cuff injuries, according to subgroup analysis.(70) This conclusion is particularly intriguing since retear rates in huge rotator cuff tears are significantly greater than in smaller tears, making large and massive rips the primary target for adjuncts to promote healing.

Based on 13 published research, *Vavken et al.* performed a meta-analysis and cost-effectiveness analysis of Platelet-Rich Plasma usage.(69) In contrast to Warth et al findings' the authors discovered that Platelet-Rich Plasma helped lower retear rates in the arthroscopic repair of minor and medium-sized rotator cuff tears, but there was no indication that retear rates for big and major injuries reduced.(70) The usage of Platelet-Rich Plasma is presently not cost-effective, according to the cost- effectiveness study.(70) With the current cost of Platelet-Rich Plasma (PRP), the cost-effectiveness analysis indicated that the use of Platelet-Rich Plasma is currently not cost-effective.(52) The decreases in retear rates for small and medium-sized rotator cuff injuries are consistent with a trend identified by Chahal et al. in a systematic study.(71) While the effect of Platelet-Rich Plasma injections on retear rates varied depending on tear size in the two meta-analyses, the findings imply that Platelet-Rich Plasma may play a role in rotator cuff repair recovery.(69)

Follow-up MRI evaluation in our study revealed an improvement in Labral height (p<0.05), labral slope (p<0.05), and Labral glenoid height index (p>0.05). the improvement was statistically significant in labral height and labral slope. Labral glenoid height index (LGHI) improved in absolute value but this difference was not statistically significant.

Regarding the clinical benefit of PRP injection, we noticed at significant improvement in ASES, CSS and DASH in both the group.

In follow-up group I had higher scores on comparing the follow-up scores between 2 group with statistically significant difference achieved in ASES and DASH.

Our results show a clear radiological and clinical benefit of PRP infection in Labral repair cases.

No studies to date have examined the clinical and radiological consequences of Platelet-Rich Plasma augmentation in isolated labrum tear repairs.

There are some limitations of this pilot study, and therefore, a full determination of treatment efficacy needs to be examined on a larger scale,

- The sample size was smaller and it yielded a small population for analysis. With the small sample size, there was the risk that one patient's results had the potential to drastically alter the average ASES DASH, CSS scores; however, no major outliers in our group were noted
- 2. A longer follow-up could help identify further improvements, or lack of, in function and possibly healing on imaging, as well as questions regardingadverse events that might not be answered with just a 3-month follow-up period. Although we observed no untoward event /complication at short term follow-up.

Despite these limitations of our study, the findings indicate that there is an appreciable difference in terms of labrum healing and functional outcomes to labral repair when Platelet-Rich Plasma is used. Future prospective randomized studies with an appropriate sample size to detect a difference will help better elucidate the use of Platelet-Rich Plasma in labral healing after arthroscopic bankart labral repair.

We strongly encourage more extensive studies with a larger study population with comparative control group and randomization, as well as the use of a reliable Platelet-Rich Plasma kit similar to ours that produces leukocyte-rich Platelet-Rich Plasma. Including a more structured approach to glenoid labrum morphology (i.e., with serial MRI, ultrasound imaging) would also strengthen future studies. The resultsof this study successfully demonstrate that treatment of glenoid labral tears with Platelet-Rich Plasma. can be done safely, is well-tolerated, and improved function in patients with MRI-documented labral tears compared to those who have not used Platelet-Rich Plasma during arthroscopic bankart repair.

## CONCLUSION

This is the first case-control study to investigate the effect of Platelet-Rich Plasma gel on the healing of labrum following arthroscopic bankart repair with a favorable outcome. This study offers evidence that Platelet-Rich Plasma use during surgical procedures in glenoid labral tears will improve clinical outcomes.

In this study, the inclusion of Platelet-Rich Plasma injection during arthroscopic bankart repair increased ROM, function, and overall satisfaction when compared to conventional repair at any time point. Rather, at 3 months following surgery, the Platelet-Rich Plasma group's recovery of several measures, such as ASES, DASH, and CSS functional scores, was better than the conventional groups. Furthermore, with the numbers available, our study shows a statistically significant difference in functional outcomes between patients with and without Platelet-Rich Plasma. No previous study has evaluated the clinical results of labrum repair with and without Platelet-Rich Plasma augmentation. There was a trend towards increased functional scores in patients treated with Platelet-Rich Plasma as compared to thenon- Platelet-Rich Plasma group.

In addition, given the absence of adverse events, this suggests that Platelet- Rich Plasma is a potentially safe treatment option in these regards. Overall, Platelet- Rich Plasma injection, in conjunction with proper rehabilitation, may exaggeratehealing and improve function, optimizing the quality of life by enabling patients to resume the activities they enjoy. A larger, randomized controlled study of Platelet- Rich Plasma for glenoid labral tears is now warranted to further investigate and validate this promising,

# SUMMARY AND RESEARCH RESULTS:

- The Age distribution where 18-20 years is 15.0%, 21-25 years is 40.0%, 26-30 years is 20.0%, 31-35 years is 15.0%, >35 years is 10.0%.
- The Gender distribution where Female is 10.0%, Male is 90.0%.
- The Site distribution where Right is 62.5%, Left is 37.5%.
- The Age distribution between Groups by Pearson's Chi-Square test was <sup>2</sup>=2.917, p=0.572>0.05 which shows no statistical significance between Age distribution and Groups.
- The Gender distribution between Groups by Pearson's Chi-Square test was □2=1.111, p=0.605>0.05 which shows no statistical significance between Gender distribution and Groups.
- The Site distribution between Groups by Pearson's Chi-Square test was <sup>2</sup>=0.107, p=1.000>0.05 which shows no statistical significance between Site distribution and Groups.
- The ASES scoring done at 3 months between Groups by Unpaired t-test was t-value=2.660, p-value=0.011<0.05 which shows statistical significance difference at p < 0.05 level.</li>
- The DASH scoring done at 3 months between Groups by Unpaired t-test was t-value=8.370, *p*-value=0.0005<0.01 which shows highly statistical significance difference at p < 0.01 level.</li>
- The CSS scoring done at 3 months between Groups by Unpaired t-test were t-value=1.917, *p*-value=0.063>0.05 which shows no statistical significance difference at p > 0.05 level.
- The LH scoring done at 3 months between Groups by Unpaired t-test was t-value=3.591, *p*-value=0.001<0.01 which shows highly statistical significance difference at p < 0.01 level.</li>
- The LGHI between Groups by Unpaired t-test were t-value=1.027, p-value=0.311>0.05 which shows no statistical significance difference at p > 0.05 level.

• The Slope scoring done at 3 months between Groups by Unpaired t-test was t-value=2.329, *p*-value=0.025<0.05 which shows statistical significance difference at p < 0.05 level.

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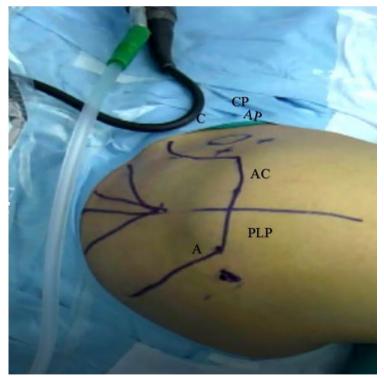
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# **ATLAS OF IMAGES**



## Figure 9

Patient positioned in the left lateral decubitus position for a left shoulder arthroscopy before preparation and draping. Ten to 15 pounds of traction is placed on the operative (right) extremity expose to the joint space



## Figure 10

Superior view of a right shoulder identifying the surface landmarks of the shoulder, acromioclavicular joint (AC), the coracoid (C), and the posterior border of the acromion (A). anterior portals (AP), postero-lateral portal.

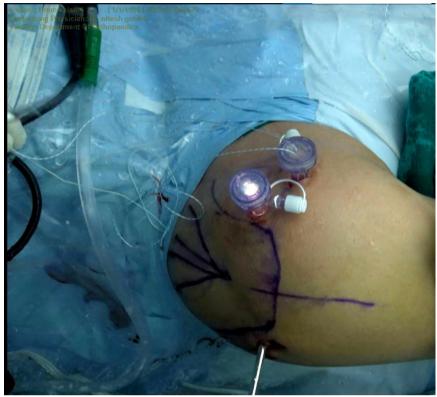


Figure 11 A). anterior portals (AP), antero-lateral portal.

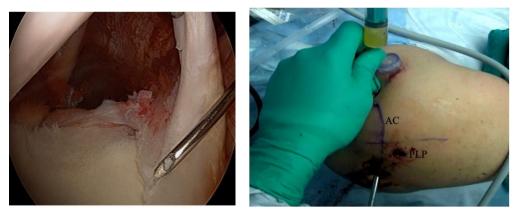


Figure 12 Injections of Platelet-Rich Plasma in the shoulder during arthroscopic labral repair



Figure 13

A Platelet-Rich Plasma globule threaded onto the suture anchor suture was delivered to the repair site.

#### **ANNEXURE I:**

#### ETHICAL CLEARANCE CERTIFICATE



अखिल भारतीय आयुर्विज्ञान संस्थान, जोधपुर All India Institute of Medical Sciences, Jodhpur संस्थागत नैतिकता समिति Institutional Ethics Committee

No. AIIMS/IEC/2020/2045

Date: 01/01/2020

#### ETHICAL CLEARANCE CERTIFICATE

Certificate Reference Number: AIIMS/IEC/2019-20/975

Project title: "Effect of platelet rich plasma on healing of labrum following arthroscopic bankert repair"

Nature of Project:	Research Project
Submitted as:	M.S. Dissertation
Student Name:	Dr.Sheikh Azharuddin
Guide:	Dr.Nitesh Gahlot
Co-Guide:	Dr.Abhay Elhence, Dr.Pawan Garg & Dr.Saptarshi Mandal

This is to inform that members of Institutional Ethics Committee (Annexure attached) met on 23-12-2019 and after through consideration accorded its approval on above project. Further, should any other methodology be used, would require separate authorization.

The investigator may therefore commence the research from the date of this certificate, using the reference number indicated above.

Please note that the AIIMS IEC must be informed immediately of:

- Any material change in the conditions or undertakings mentioned in the document.
- Any material breaches of ethical undertakings or events that impact upon the ethical conduct of the research.

The Principal Investigator must report to the AIIMS IEC in the prescribed format, where applicable, bi-annually, and at the end of the project, in respect of ethical compliance.

AIIMS IEC retains the right to withdraw or amend this if:

- · Any unethical principle or practices are revealed or suspected
- · Relevant information has been withheld or misrepresented

AIIMS IEC shall have an access to any information or data at any time during the course or after completion of the project.

On behalf of Ethics Committee, I wish you success in your research.

eo uend Enclose: 07 02 + 1. Annexure 1

AllMS, Jodhpur

Page 1 of 2

Basni Phase-2, Jodhpur, Rajasthan-342005, Website: www.aiimsjodhpur.edu.in, Phone: 0291-2740741 Extn. 3109 Email: ethicscommittee@aiimsjodhpur.edu.in

#### **ANNEXURE II**

## ETHICAL JUSTIFICATION

According to the guideline set up by ICMR (2000) and Helsinki declaration modified (2008) the the following will be adhered to in all patients/volunteers involved in the study.

- 1. All the possible treatment options will be given and none will be withheld.
- 2. Patients will be enrolled in the study with their knowledge and the study will be done by utilizing known investigation modalities, regarding which proper information will be provided to the patients.
- 3. Patients will be informed about all the major and minor risk factors and the remedies thereof and a refusal to participate in this study will not interfere with the patientdoctor relationship.
- 4. Patients will be given the option of quitting the study at any point during the study if he or she so desires and no element of compulsion will be exerted.
- 5. Confidentially of data collected from contribution sources or individuals will be maintained.
- 6. Written informed consent will be obtained from all the patients included in the study after informing them about the aims and method of the study and the institutional affiliation of the researcher.
- 7. In the cases where the patients are legally incompetent, minors, or are not eligible for giving consent due to poor neurological status, consent of the close relative available will be taken.
- 8. The study will not lead to extra expenditure on the part of the patient. The subject will be free to withdraw from the study at any time of their choice. Participation or withdrawal from this study would have no bearing on the treatment being offered to patients.
- 9. All the patients will be treated by the standard protocol of the Department of Orthopedics, AIIMS Jodhpur in the best interest of the patient. All efforts will be made to ensure that no extra visits are required for the study.
- 10. In the publication of the results of this study all efforts would be made to preserve the accuracy of both the positive and negative results of this study.
- 11. After the study every patient entered into this study will be assured of access to the best proven diagnostic and therapeutic methods identified by this study.

#### **ANNEXURE III**

## **DOCUMENTATION OF INFORMED CONSENT:**

I, ...., have read the information in thisform (or it has been read to me). I was free to participate in the study. I am over 18 years of age and, exercising my free power of choice, hereby give my consent to be included as a participant in

EFFECT OF PLATELET-RICH PLASMA ON HEALING OF LABRUM FOLLOWING ARTHROSCOPIC BANKART REPAIR

- 1. I have read and understood this consent form and the information provided to me.
- 2. I have had the consent document explained to me.
- 3. I have been explained about the nature of the study.
- 4. My rights and responsibilities have been explained to me by the investigator.
- 5. I have been advised about the risks associated with my participation in the study.
- 6. I have informed the investigator of all the treatments I am taking or have taken in the past.... months including any desi (alternative) treatments.
- 7. I agree to cooperate with the investigator and I will inform him/her immediately if I suffer unusual symptoms.
- 8. I have not participated in any research study within the past ......month(s).
- I am aware of the fact that I can opt out of the study at any time without having to give any reason and this will not affect my future treatment in the hospital.
- 10. I am also aware that the investigators may terminate my participation in the study at any time, for any reason, without my consent.
- 11. I hereby permit the investigators to release the information obtained from me as a result of participation in this study to the sponsors, regulatory authorities, government agencies, and ethics committee. I understand that they may inspect my original records.
- 12. My identity will be kept confidential if my data are publicly presented.
- 13. If, despite following the instructions, I am physically harmed because of any substance or any procedure as stipulated in the study plan, [my treatment will be carried out free at the investigational site / the sponsor will bear all the

expenses], if they are not covered by my insurance agency or by a government program or any third party.

- 14. I have had my questions answered to my satisfaction.
- 15. I have decided to be in the research study.

I am aware, that if I have any questions during this study, I should contact at one of the addresses listed above. By signing this consent form, I attest that the information given in this document.

I will be given a copy of this consent document.

Date:

Place:

Name of the participant:

Complete postal Address:

Participant's initials

Place:

Signature of principal investigator: Date:

This is to certify that the above consent has been obtained in my presence.

Witness Signature

Name:

Address:

Investigator Name: Dr. SHEIKH AZHARUDDIN Mobile No.: +91 8448916358 Guides Name: DR. NITESH GAHLOT Mobile no.: +91 9116096665

## ANNEXURE IV

सू ित सहभतत का दस्तावेजः

सू ित सहभतत का दस्तावेजः

(5) भुझे इस अध्ममन की प्रकृतत के फाये भें सू ित कमा गमा है, जहाो नय प्रतबा गता को कोई नुकसान नहीं होगा तमों क अध्ममन गैय-आक्राभक औय वशुद्ध उद्देश्म है। (6) भुझे उन राबों के फाये भें फतामा गमा है जो क एखतबागी यों के रए मा सभुदाम मा दस्त्रनुसरोधान के नरयणाभ के रून भें उ ित उम-भीद कमे जा सकते हैं।

(7) अन्वेषक द्वाया भुझे भेये अधकाय औय ग्जम्भेदारयमों को सभझामा गमा है।

(9) भने नछरे ... .. भहीने/ सार के बीतय कसी बी शोध अध्ममन भें दहस्सा नहीं। रमा है। (10) भैं इस तथ्म से अवगत हूों क भैं कसी बी सभम बफना कसी कायण के अध्ममन से फाहय तनकर सकता है औय मह इस अस्नतार भें भेये ब वष्म के उन्तिाय को प्रबा वत नहीं। कयेगा।

(11) भैं मह बी जानता हूों क जाोि कता भेयी सहभतत के त्रफना, कसी बी कायण, कसी बी सभम अध्ममन भें भेये वाडम की बागी दायी को सभाप्त कय सकते हैं।
(12) प्रामोज कों, वतनमाभक प्रा धकारयमों, सयकायी एजें समों औय नैततकता स भतत को इस अध्ममन भें बाग रेने

के ज़रयणाभ स्वरूज़,भने इनके द्वाया प्राप्त जानकायी को जायी कयने के रए जोिकतामओं को

<sup>(8)</sup> भुझे भेये उत्त िाय के फाये भें सबी रूनये खाओं के अन्वेषक द्वाया सू ित कमा गमा है।

अन**ुभात द**ी है।भैं सभझता हूो क वे भेये भ अ बरेखों का ानयीं ण कय सकते हैं। (1) अगय भेये डरूा को स**ावजानक रून स**े एस**्त**ुत कमा गमा है तो भेयी नह**िान क**ो गोननीम यखा जाएगा।

(2) मदद तनदेशों का न**ारन कयने के फ**ावजूद, भुझे शायीरयक रून से न**ुकस**ान नह**ुो िामा जाता है तम**ों कअध्ममन मोजना भें तनधासयत कसी

ब ी प्र क्रमा के कायण, भेया इराज जाोि स्थर

```
तय भुफ़्त भें कमा जाएगा/ग्रामोजक सबी खािोिंको सहन कयेंगे], मदद वे भेयी फीभा
एजेंसीमा
कसी सयकायी कामक्रभ मा कसी तीसये नं द्वाया कवय नहीं। कमा जाता है
(3) अनुसरोधान र्ीभों औय नतेऔय पोन नॉफय वारे सॉनकम व्मक्ततमों की
नहिान भुझे अनुसरोधान से सॉफो धत प्रश्नों के रए मा नैततक सद्धाोतों औय भानवा
धकायों के उल्रोघन केखरापअनीर कयने के रए दी गई है।
(4) भेये सवारों के भेयी सरोतुक्ष्र् के अनुसाय उत्तय द्वए गए हैं।
(5) भने शोध अध्ममन भें शा भर होने रमाहै।
का तनणात्म्दनाक:
```

प्रतत्व**ागा** क्य हस**़त**ांय: जगह:

प्रतबागी का नाभः

न ा डाक नताः

प्रभ**ुख अन्व**ेषक के हस**्त**ा'य: तत थ: जगह:

मह प्रभा णत कयना है क उनय**ोतत सहभतत भेयी उनक्स**्थतत भे**ं प्र**ाप**्त क**ी गई है। गवाह के हस्ता'य

नाभः नताः Department of Orthopaedics All India Institute of Medical Sciences, Jodhpur

## ANNEXURE V

## PATIENT INFORMATION SHEET

# TITLE: EFFECT OF PLATELET RICH PLASMA ON HEALING OF LABRUM FOLLOWING ARTHROSCOPIC BANKART REPAIR

This study requires detailed musculoskeletal examination as well as examination of the shoulder and upper limb by Physical Examination; MRI with the pure intention of your health benefit. The MRI used for the examination which will not cause any harm to your health. The expected duration of your stay in OPD, Department of Orthopaedics, AIIMS, Jodhpur will be about 1 hour. You are expected to attend to all the questions put in front of you in the form of Questionnaire depending on the mutual comfort of you and the investigator. There are no obvious expected or known adverse effects on the patient due to this study.

You have been invited to take part in a study, which will help us in better understanding the post- operative effect of PLATELET-RICH PLASMA in rate of labrum healing for future use of platelet rich therapies for providing early clinical recovery and healing. You are free to withdraw from the study at any time and this will not have any negative implication on your future treatment in the hospital.

Contact Person for further queries. DR SHEIKH AZHARUDDIN +91 08448916358

#### **ANNEXURE VI**

## आथोने डतस वबाग

ऑर इो डमा इोक्स्र्र्ट्मूर् ऑप भै डकर साईं सस, जोधनुय

स नानः

TITLE: अथय**ोस**्को नक फैन**्कार**्म रयनेमय भे**ं प**्र**ेर**्रे रय**िप**्राज्भा के उनमोग स**े ग रनोइड** 

रैब्रभ के ही **रग** ज़य प्रब**ाव** 

इस अध्ममन के रए आनके स्वास्थ्म राब के शुद्ध इयादों के साथ शायीरयक नयींा औय एभ.आय.आई स**्कै न द**्वाया घ**ुर**्ने के अल्स्थ फोध की ल्स्थात की नय**ींा के स**ाथ साथ नयींा की आवश्मकता है।एभ.आय.आई स**्कै न का इस्तिभार नय**ींा के रए कमा जाता है जोआन के

स**्वास**्थ्म क**ो क**ोई स**ान नहीं नह**ुॊि िाएगा।ओ.न**ी.डी भ**ेंआनके ठहयने की ब**ी नक उम**्भीद की

अव ध,ऑथोने डतस वबाग,एम्स,जोधनुय भें 1 घोर्ा होगा।आनको प्रश्नोत्तयी के रून भेंआनके साभने यखे गए प्रश्नों के अन्वेषक को जवाफ देने होंगे।इसअध्ममन के कायण योगी नय क**ोई** स**्नष**्र**्,अने ंत मा ाात फ़्रतकू र प्रब**ाव नहीं। हैं।आनकोइसअध्ममन भें बाग रोने केरएआभोबत्त्त कमा गमा हैं, जो हभें ऑनयेशन से नहरे औयऑनयेशन के फाद कन्धा के अन्स्थिषोध की न्स्थित्त को फेहतय सभझने भें सहामता कयेगाऔयकनधा के अन्स्थ फोध का

ऑनयेशन कयवाने वारे बायतीमजनसॊख्मा के रए एक प्रोर्ोकॉर फनाने औय सल्जकर ियण

भे**ं भ**ौजूदा प्रोर्ोकॉर भे**ं तरयवतन र**ाने भे**ं भदद कय**ेगा।आन कसी ब**ी** सभमअध्ममन को छ**ोड़ने** 

के रए स**्वतोत्र है**ंऔयअस्नतार भें आनके ब वष्म के उन्त**िाय नय** इसका कोई

87

नक**ायात**्भक प्रब**ाव नहीं। होगा।** 

अ धक प्रश्नों के रए व्मग्तत से सॊऩकम कयें

डॉ शख अज़हर**ु**ढ़**ीन** 

08448916358

## **ANNEXURE VII:**

## PATIENT PROFORMA

## **BASIC INFORMATION OF PATIENT**

- 1. Name:
- 2. Age:
- 3. Sex:
- 4. Address:
- 5. Ip no / reg no:
- 6. History:

Duration of symptoms

- Any h/o trauma
- Any other co morbidities
- Any treatment taken earlier for the same complaints
- 6. Date and time patient seen in our hospital:
- 7. Any form of conservative treatment given in our hospital:
- 8. Local examination:
- 1. Limb involved
- 2. Swelling
- 3. Deformity
- 4. Tenderness
- 5. Local rise in temperature
- 6. Vascular status: Peripheral circulation -radial artery.
- 7. Range of motion
- 8. Investigations:
- A. Grading of labrum tear based on pre-op mri
- B preoperative hemoglobin
- 9. Surgery:
- 1. Type of surgery
- 2. Date of surgery
- 3. Category of surgery:
  - A. Use of PLATELET-RICH PLASMA intraoperatively
  - B. Without the use of PLATELET-RICH PLASMA intraoperatively
  - 4. Anesthesia –
- 10. Post operative assessment:
- 11 Durations of hospital stay
- 12 post operative complications (if any)
- 13 MRI scan after 6 months

## **ANNEXURE VIII**

## ASES SCORE

# orthotoolkit \*

ASES Score Summary	
1. Usual work? No response	2. Usual sport/leisure activity? No response
3. Do you have shoulder pain at night? No	4. Do you take pain killers such as paracetamol (acetaminophen diclofenac, or ibuprofen? No
5. Do you take strong pain killers such as codeine, tramadol, or morphine? No	<ol> <li>How many pills do you take on an average day? No response</li> </ol>
7. Intensity of pain? Intensity of pain: 0	(10 point
8. Put on a coat Putting on a coat is not difficult	(3 point
<ol> <li>Sleep on the affected side</li> <li>Sleeping on the affected side is not difficult</li> </ol>	(3 point
<ol> <li>Wash your back/do up bra Washing my back/doing up my bra is not difficult</li> </ol>	(3 point
11. Manage toiletting Managing toiletting is not difficult	(3 point
12. Comb your hair Combing my hair is not difficult	(3 point
<ol> <li>Reach high shelf Reaching a high shelf is not difficult</li> </ol>	(3 point
<ol> <li>Lift 10lbs. (4.5kg) above your shoulder Lifting 10lbs. (4.5kg) above my shoulder is not diff.</li> </ol>	Geult (3 point
15. Throw a ball overhand Throwing a ball overhand is not difficult	(3 point
<ol> <li>Do your usual work</li> <li>Doing my usual work is not difficult</li> </ol>	(3 point
17. Do your usual sport/leisure activity Doing my usual sport/leisure activity is not difficult	r (3 point
Pertinent Negative Pertinent Positive	Pertinent Positive
ASES Score: 100 points	
Graphical ASES Score	

The tools listed on this website do not substitute for the informed opinion of a licensed physician or other health care provider. All scores should be re-checked. Please see our full Terms of Use.

## ANNEXURE IX

## CONSTANT SHOULDER SCORE

www.orthopaedicscores.com		Date of completio December 30, 202			
Constant Shoulder Score					
Clinician's name (or ref)		Patient's name (or re			
Answer all questions, selecting just one unless otherwise stated					
During the past 4 weeks					
1. Pain	2. Activity Level (che	eck all that apply)			
O Severe	O yes O no Unaffected	Sleep			
O Moderate	Ves Full Recreation/Sport				
O Mild	O yes O no Full Work				
O None					
3. Arm Positioning	4. Strength of Abduc	tion [Pounds]			
O Up to Waist	00	0 13-15			
O Up to Xiphoid	O 1-3	0 15-18			
O Up to Neck	O 4-6	0 19-21			
O Up to Top of Head	0 7-9	0 22-24			
O Above Head	O 10-12	○ >24			
RANGE OF MOTION					
5. Forward Flexion	6. Lateral Elevation				
O 31-60 degrees	O 31-60 degrees				
O 61-90 degrees	O 61-90 degrees				
O 91-120 degrees	O 91-120 degrees				
O 121-150 degrees	121-150 degrees				
O 151-180 degrees	O 151-180 degrees				
7. External Rotation	8. Internal Rotation				
O Hand behind Head, Elbow forward	O Lateral Thigh				
O Hand behind Head, Elbow back	O Buttock				
O Hand to top of Head, Elbow forward	O Lumbosacral Junction				
O Hand to top of Head, Elbow back -	O Waist (L3)				
O Full Elevation	O T12 Vertebra				
	O Interscapular (T7)	5			
Print page Close Window	Reset	The Constant Shoulder Score is			
To save this data please print or Save As	CSV	0			
Grading the Cons	tant Shoulder Score				
(Difference between no					
>30 Poor 21-30 Fair	11-20 Good	<11 Excellent			

## ANNEXURE X

## DASH SCORE

12/30/21, 11:05 AM

#### The Disabilities of the Arm, Shoulder and Hand (DASH) Score - Orthopaedic Scores

#### www.orthopaedicscores.com

Date of completion December 30, 2021

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

Clinician's name (or ref)

Patient's name (or ref

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

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

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

https://www.orthopaedicscore.com/scorepages/disabilities\_of\_arm\_shoulder\_hand\_score\_dash.html?textfield=&textfield=JTENDRA&one=1&two=2&t... 1/2

## ANNEXURE XI

## Master chart

PERSONAL		clinical scoring pre			inical scoring post operati			MRI	scoring post operative				
	Α	SE	SIT	PRE	PRE	PRE	POST	POST	POST	POST	POST	LH/G	POST
SEQ	G	Х	Е	ASES	DASH	CSS	ASES	DASH	CSS	GH	LH	н	SLOP
1	25	1	2	54	47.5	63	95	14.2	92	2.8	8.1	3.85	28
2	25	1		57	49	67	96	15	91	2.4	8.8	3.67	28
3	21	1	2	61	51	71	96	16	93	3.3	13.2	4	32
4	32	1		55	51.5	69	95	14.8	92	2.6	5.9	2.26	23
5	20	1	2	59	49	67	94	16.4	94	2.1		3.85	26
6	36	1	1	53	57.5	62	90	18.3	94	2.1		5.47	33
7	27	1	1	51	53	61	93	16.7	90	2.3	7	3.04	26
8	37	1	1	57	49.5	63	95	17.5	98	2.6	13.4	5.15	38
9	22	1	1	53	47	61	92	17	90	2.7	10.9	4.03	33
10	18	1	2	56	48	68		19	89	2.6		4.26	41
11	25	1	1	55	48	62	92	14.2	93	3.2		3.4	29
12	- 34	1	1	55	51	63		15	90	2.8		3.96	40
13	22	2	1	50	49	62	92	14	93	3.2		3.75	36
14	24	1		60	55	61	90	16	90	2.2		4.04	26
15	21	1	2	61	58	63	91	14	97	2.5	12	4.8	28
16	20	1	1	55	49	67	93	13	98	2.5		4.56	27
17	24	2	1	54	47	66	94	15	95	2.7	10.5	3.88	26
18	30	2	1	58		64	95	17	93	2.6		3.19	41
19	32	1		57	- 51			16	94	2.8		Pade	
20	- 34	1		61	<b>5</b> 6	62	- 93	15	97	2.2		6.04	- 29
21	27	1	2	51	57	67	94	14	93	2.3		4.65	33
22	- 39	1	1	49	47	61	88.3	8.9	83	2.8		1.6	0
23	29	1		53	48	63	89.9	12.9	88	1.4	5.6	4	19
- 24	28	1	2	63	51.7	68	91.6	11.2	94	2.7		3.03	32
25	22	1	1	55	49.5	63	91.6	11	92	2.1		4.52	24
26	22	1	1	59	51	61	93.3	11.2	90	2.8		3.42	31
27	21	1		51	57.5	68	94.9	9.5	90	1.9		3.84	20
28	20	2	2	56	51.5	67	93.3	10.3	90	1.8		4.66	26
29	36	1	_	53	46.5	69	89.9	10.9	92	2.5		3.72	33.5
30	30	1		56	47	63	88.3	13.3	92	1.8		2.44	17
31	_	1		57	49	68	91.6	14.2	94	1.8		6.83	29
32	21	1			49.5	63	89.5	12	92	2.6		3.73	26
- 33		1		49	48	67	91.5	12.5	93	2.1		4.3	28
34	21	1		61	53.5	65	91	11.2	94	2.3		3.7	27
35	27	1	2	53	54.5	67	94	10.3	92	1.9		4.68	31
36	20	1		57	59	64	90	13.3	90	2.7	9.5	3.5	28
37	21	1	2	53	46	59	88.5	9.5	94	2.2		3.5	26
38	27	1	-	60	56	66		11	90	2.3	7.6	3.3	27
39	31	1		51	47	62	91	11.5	93	2.6	7.2	2.77	28
40		1	- 1	58	51	64		13.3	94	2.0		2.76	32