ASSOCIATION BETWEEN ANTERIOR GLENOHUMERAL INSTABILITY AND GLENOID ANTEVERSION/INCLINATION:

An MRI-based study at the Agha Khan University and Kenyatta National Hospitals

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STUDENTS DECLARATION

I declare that this dissertation is my original work and has not been presented at any other University. All works used from other authors have been accordingly referenced.

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DEDICATION

This book is dedicated to my family for their unwavering support, patience and inspiration.

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ABBREVIATIONS AND ACRONYMS

ACJ	Acromio-clavicular joint
AKUH	Agha Khan University Hospital
AMBRI	A traumatic, Multidirectional, Bilateral, Rehabilitation, Inferior capsular shift
AP	Anteroposterior
CT	Computerised Tomography
IERC	Institutional Ethics and Research Committee
GFL	Glenoid Fossa Line
IGHL	IGHL
KNH	Kenyatta National Hospital
KNH/UON ERC	Kenyatta National Hospital/University of Nairobi Ethics and Research Committee
KEPH	Kenya Essential Package for Health
LHBT	Long Head of the Biceps Tendon
MGHC	MGHL
MRI	Magnetic Resonance Imaging
OPD	Outpatient Department
PACS	Picture Archiving and Communication System
ROC	Radius of Curvature
BL	Scapula Body Line
SCJ	Sterno-clavicular joint
SD	Standard Deviation
SGHL	SGHL
SPSS	Statistical Package for the Social Sciences
TUBS	Traumatic, Unilateral, Bankart lesion, Surgery

ABSTRACT

Background: The shoulder joint complex is made up of several articulations. The main articulation is the glenohumeral joint which works in concert with the acromioclavicular (ACJ), sternoclavicular (SCJ) and the scapulothoracic joints. The glenohumeral articulation has the most mobility in the body and is anatomically classified as a diarthrodial, multiaxial joint (1). The joint stabilizers, both dynamic and static allow for significant mobility of the joint in different planes predisposing the joint to instability and dislocations. Studies have shed more light on the pathological components having a bearing on shoulder instability among them bony and soft tissue contributions, and patient factors. The contribution of glenoid morphology to glenohumeral stability and the biomechanical factors that lead to humeral head impaction has been the subject of research (2). Multiple studies have shown increased glenoid retroversion as a contributor to posterior shoulder instability (2)(3)(4) but few studies report glenoid architecture as a contributing factor to anterior glenohumeral instability, despite it being the most common form of instability in the glenohumeral joint.

Study objective: This study sought to find out the correlation between anterior glenohumeral instability and glenoid anteversion/inclination

Study design: A retrospective, case-control study was carried out.

Study setting: The study was carried out at the departments of radiology and imaging at Agha Khan University (AKUH) and Kenyatta National Hospitals (KNH).

Methodology: Shoulder Magnetic Resonance Imaging (MRI) scans for patients between 18 to 45 years with anterior shoulder instability were used in the study and compared against a control consisting of shoulder MRIs of patients with other shoulder pathologies but having no incidences of dislocation e.g.., frozen shoulder, chronic shoulder pain. A structured data collection tool was used to collect the data

Data processing: Data was analysed with Statistical Package for the Social Sciences (SPSS) version 26 and presented in summary as percentages and frequencies for categorical data, and as median with interquartile range or means with standard deviation for continuous data.

Results: The mean age for the participants was 32.0 (SD 9.0) years. The mean age for the cases was 29.0 (SD 8.7) years, while for the controls was 34.6 (SD 8.5) years. The glenoid was anteverted in 40% and 35.6% of cases and controls respectively ($p = 1.00$) and retroverted in 60% and 64.4% of cases and controls respectively ($p = 0.666$). Most of the glenoids were superiorly inclined (91.1% and 93.3% for cases and controls respectively. The mean glenoid version was 1.04 ^{o} retroversion (range -9.7 ^{o} to 16.3 ^{o}) or for the cases and 2.26 ^{o} retroversion (range -8.5 ^{o} to 21.5 ^{o}) for the controls. The mean inclination on the other hand was 10.51 ^{o} Superior (range -4.6 ^{o} to 29.7 ^{o}) for the cases and 10.80 ^{o} (range -2.6 ^{o} to 29.3 ^{o}) for the controls. The differences in the glenoid version and inclination between the cases and controls were not statistically significant ($p = 0.288$ and $p = 0.489$ for glenoid version and inclination respectively).

Conclusion: Glenoid alignment doesn't seem to be a risk factor for anterior glenohumeral instability.

1.0 CHAPTER ONE: INTRODUCTION

1.1 Shoulder Instability

The shoulder joint complex is made up of several articulations. The main articulation is the glenohumeral joint which works in concert with the ACJ and the SCJ joints in achieving motion in the shoulder joint and maintaining arm position in space. The scapulothoracic joint although not an anatomical joint, is very crucial in shoulder motion as seen in scapulohumeral rhythm. The glenohumeral joint is the most mobile of all joints mainly because of the little congruency of its bony articulating surfaces and it is classified anatomically as a multiaxial, diarthrodial joint (1). This also makes it prone to dislocation and studies have found it to be the most commonly dislocated joint (5)(6). The joints encompassing the shoulder complex due to their innate instability rely on the muscles and ligaments around them for stability and this makes them susceptible to degeneration and injury. The joint stabilizers, both dynamic and static allow for significant mobility of the joint in different planes and the organization of the shoulder complex allows the muscles involved to function efficiently on their length/tension curves.

Glenohumeral instability refers to a shoulder that subluxates or even dislocates from the glenoid fossa due to injury to the bone or soft tissue around the shoulder joint (7) thereby compromising the shoulder function. Patients will typically present with apprehension, recurrent subluxations, and dislocations. This instability interferes with function including overhead motions of the arm and external rotation. Eventually, physical and/or athletic activities are interfered with.

Historically, the acronyms TUBS (Traumatic, Unilateral, Bankart lesion, Surgery) and AMBRI (Atraumatic, Multidirectional, Bilateral, Rehabilitation, Inferior capsular shift) were used by clinicians to classify instability of the shoulder. This classification however didn't help clinicians differentiate between soft tissue hyperlaxity and instability thus it was found to be more useful to classify based on (8):

- The direction of instability (unidirectional or multidirectional)
- Traumatic (unidirectional with a capsulolabral injury) or atraumatic (often with hyperlaxity and multidirectional)
- Presence or absence of hyperlaxity in the soft tissue mainly caused by the patulous laxity of the capsule. This laxity may be congenital or due to major or minortrauma and recurrent instability events.

1.2 Epidemiology

Male patients are affected more (85% - 95%) than females and the mean age for having a shoulder dislocation is 20 years. Acute dislocation events are a surgical emergency demanding immediate relocation, without which, the chances of a successful, stable, closed reduction diminish after twenty hours. Anterior dislocation is the most common type (85%- 95%) (9)(10). It has a reported prevalence of 2% (11) and more than 90% of the cases are trauma-related in patients undergoing anterior shoulder dislocation for the first time (12).

In diseases such as epilepsy characterized by seizures, posterior shoulder dislocation occurs commonly due to excessive muscle contraction (13). The most common mechanism resulting in anterior glenohumeral dislocation with resultant instability is abduction with externalrotation at the shoulder (14) and the dislocation is likely to recur later in life in patients with an anterior dislocation at a young age (11). It has also been noted that there is a shorter interval between the initial injury and recurrence among athletes (11).

1.3 Risk Factors for Glenohumeral Instability

A study focusing on risk factors for anterior glenohumeral dislocation by D. Owens et al (15) found apprehension with accompanying relocation on physical examination as being very key for instability though this could have been associated with earlier/prior incidences of subluxation/dislocation that went unreported. There were also anatomical variables of significance with thin, tall glenoids posing a higher risk of dislocation compared with glenoids that are short and wide. Instability risk also correlated with an increase in the coraco-humeral distance. The same authors had also shown that ligamentous laxity also contributed to glenohumeral instability. Itoi et al (16) found that anterior glenohumeral dislocation with an accompanying glenoid bone loss is a significant risk factor for re- dislocation events.

Younger individuals (17)(18) and men (17)(18)(19) have a higher incidence of glenohumeral dislocation and instability. This has generally been attributed to involvement in high-energy activities and contact sports by these demographics but the risk of dislocation has been shown to decrease with age. Rhee et al similarly noted that anterior shoulder dislocation has a high incidence and recurrence rate among younger patients (20).

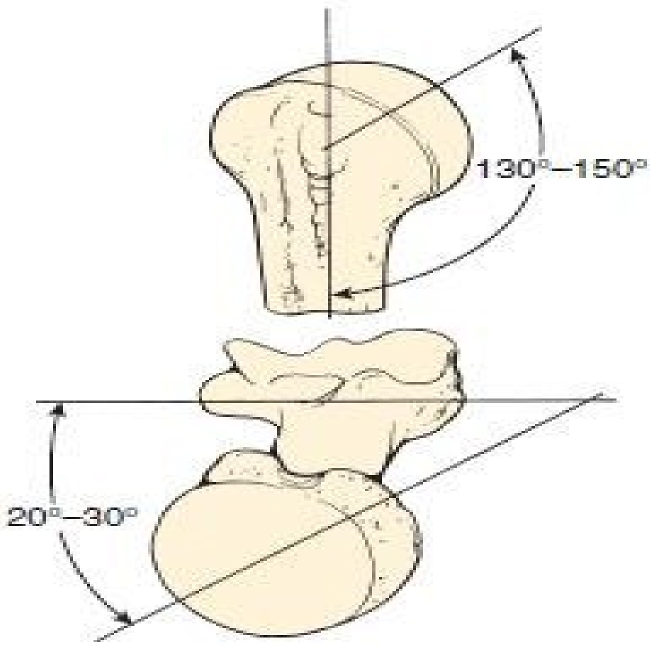
As compared to whites, all other racial categories have demonstrated a protective trend from shoulder instability as was found by Owen et al (17). An interesting finding of people with an advanced degree having a lower occurrence of anterior shoulder instability (21) has been attributed to less vigorous and less physically demanding activities/jobs associated with this demographic. A Previous history of shoulder dislocation places the joint at a higher risk for re-dislocation (22) and it has also been demonstrated that instability in one shoulder is a risk factor for a primary event on the other shoulder.

2.0 CHAPTER TWO: LITERATURE REVIEW

2.1 The Adult Glenohumeral Joint

2.1.1 Bony Anatomy

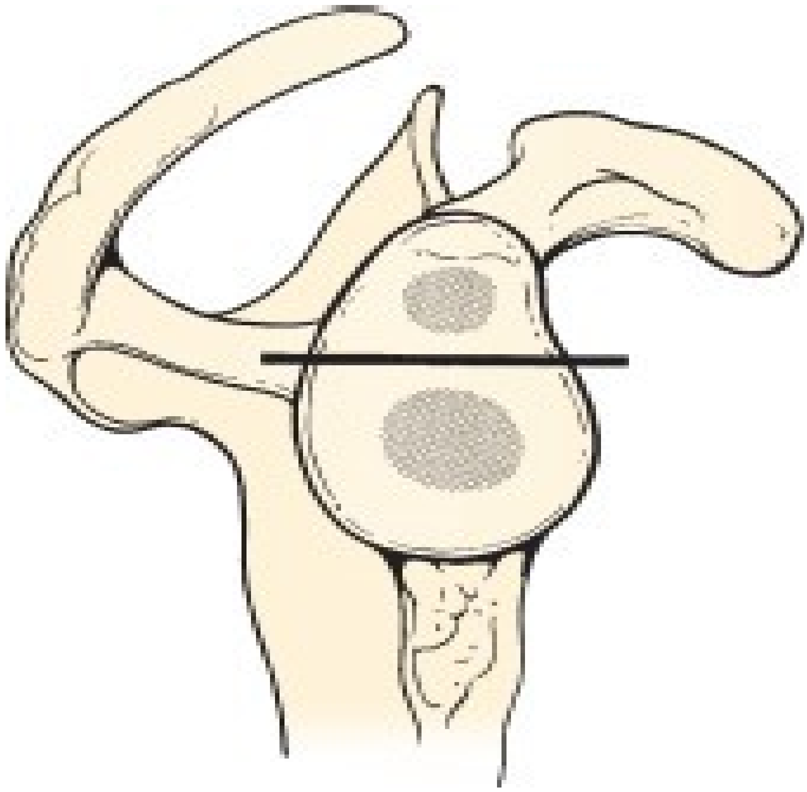
This is an articulation between the glenoid surface and the head of the humerus with their surface areas being in the ratio of 3:1. Their spatial relationship allows for an extreme range of motion. The head of the humerus' articular surface is directed superiorly, medially and posteriorly with an inclination of 130 – 150^0 to the humeral shaft. It forms a third of a sphere (23). The retroversion of the head is however different between different individuals and even in the same individual between sides. Pearl et al, examined 21 shoulders and noted a mean retroversion of 29.8^0 (10^0 - 55^0) (24). The articular portion of the head had an average supero-inferior dimension of 48 mm and an accompanying 25-mm radius of curvature (ROC). The transverse diameter is around 45 mm, and a corresponding ROC of about 22mm (25).



*Adapted from Rockwood and Matsens, 'The Shoulder', 5th Edition.

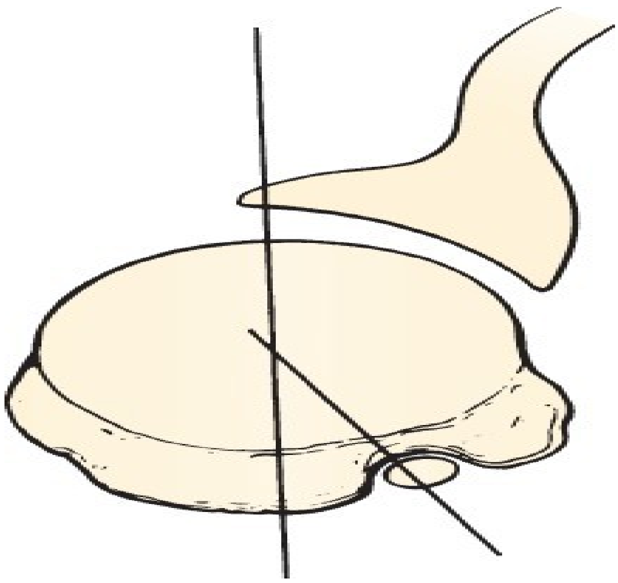
Figure 1: Showing neck-shaft angle and retrotorsion angle of the head and neck of the humerus

The glenoid cavity has a narrow superior portion (tail) and a broader inferior portion. The average height of the glenoid is about 35 mm, while the average anteroposterior diameter is about 25 mm and the glenoid articular surface is more concave from superior to inferior than from anterior to posterior. Therefore, a force in the anteroposterior direction is more likely to dislocate the glenohumeral joint than a force in the supero-inferior direction. The articular surface is covered by hyaline cartilage with thinning in a circular area at the center of the cavity (26). The supra-glenoid and infra-glenoid tubercles occupy the cranial and caudal tips of the glenoid respectively. The bicipital groove is situated 30º medial to a line bisecting the humerus.



*Adapted from Rockwood and Matsens, 'The Shoulder', 5th Edition

Figure 2: Showing glenoid shape



*Adapted from Rockwood and Matsens, ‘The Shoulder’, 5th Edition

Figure 3: Showing the bicipital groove of the humerus

The glenoid labrum has a triangular cross-section and attaches to the glenoid circumferentially. It serves to deepen the glenoid cavity and also increases congruity between the head of the humerus and the glenoid thereby aiding in generating negative intraarticular pressure. It is also attached to the glenohumeral ligaments and fuses superiorly with the long head of biceps tendon (LHBT).

2.1.2 The Glenohumeral Joint Capsule

The capsule is twice the humeral head in terms of surface area with a volume of about 10 to 15 ml. On the outside, the capsule is protected by rotator cuff tendons on all sides except the inferior aspect and the inner aspect of the capsule is lined with synovium. It fuses with supraspinatus and subscapularis muscle tendons near their insertion. It has a wide origin involving the coracoid superiorly and the labrum and neck of the glenoid inferiorly. At its insertion, it forms an extension inferiorly, the axillary recess, while the rest of the capsule attaches to the anatomic neck of the humerus. The posterior joint capsule is quite thin as compared to the anterior and the capsule has two gaps, one for LHBT and the other for the subscapular recess anteriorly.

2.1.3 The Glenohumeral Ligaments

The glenohumeral joint is stabilized by several ligaments. The coraco-humeral ligament runs transversely across the glenohumeral joint to the greater tuberosity. It takes origin from the coracoid process and serves as a primary restraint to the LHBT. The transverse ligament of the humerus bridges the bicipital groove at its proximal end and acts as the retinaculum for the LHBT. The superior glenohumeral ligament (SGHL) is constant in presence although it varies in its origin and size variable in size and origin although constant in presence. It originates from the anterior labrum although it sometimes has a wide origin involving the LHBT superiorly and the middle glenohumeral ligament (MGHL) inferiorly or in between.
The MGHL has the largest variation in diameter. Its origin is the anterior labrum or neck of the glenoid and it mingles with the subscapularis tendon before inserting into the lesser tuberosity. The inferior glenohumeral ligament (IGHL) is the thickest part of the capsule and shows variation in attachment site and size. It has two main parts, the anterior and posterior bands which sandwich the axillary pouch between them. Its insertion is into the anatomic neck of the humerus.

2.2 Stability and Biomechanics of the Shoulder Joint

The stability of the glenohumeral joint is achieved via several biomechanical and anatomical factors. As noted earlier, effective stabilization of this joint is paramount as the great range of motion it offers comes at a cost in terms of instability. The glenohumeral joint's static stability is realized through different structures including; the labrum, ligaments, articular congruity, negative intra-articular pressure and version while its dynamic stability is maintained by rotator cuff muscles, rotator interval, LHBT, and periscapular muscles. These dynamic stabilizers come into play during movement to coordinate and synchronize the glenohumeral joint. The majority of the constraints to the extreme movement of this joint come from the glenohumeral ligaments and the capsule although the concavity of the glenoid, albeit shallow, also offers a semblance of stability (1).

2.2.1 Glenohumeral Stability: The 'Soft Tissue Factors'

The contributions to glenohumeral stability by the different stabilizing structures have been widely studied. With the arm at rest, a negative intraarticular pressure, which is usually about -30 mm hg, is generated and this acts as the main static stabilizer preventing inferior dislocation (27)(28). This is facilitated by congruence between the articulating surfaces with an intact labrum playing a crucial role. Stability is added by the LHBT (29) acting as a 'rein', the capsule of rotator interval, and the coracohumeral ligament (30) both situated antero-superiorly.

After initiation of movement, the role played by the negative intraarticular pressure, maintained by the rotator interval capsule, diminishes (31) and the cuff muscles actively compress the humeral head onto the glenoid a phenomenon termed concavity compression. (32). This is assisted partially by the midportion of the deltoid muscle. The capsule at this range is lax and doesn't contribute to stability.

At the end range of motion, the glenohumeral ligaments are now involved (33) and in concert with the capsule, act as the main stabilizers. In abduction and external rotation of the arm, the IGHL (anterior band) and the anterior capsule are taut and prevent an anterior glenohumeral joint dislocation. The MGHL serves a similar role at around 45^{o} of abduction and external rotation and the SGHL prevents inferior dislocation with the arm in adduction and external rotation. Lastly, posterior dislocation is prevented by the IGHL (posterior band) in internal rotation and flexion (3).

2.2.3 Glenohumeral Stability: The 'Bony Factors'

The glenoid is twice as deep supero-inferiorly as compared to antero-posteriorly (34) therefore pointing to the fact that its stability is better supero-inferiorly. Studies have also shown thatthe translation force needed to dislocate the joint supero-inferiorly is twice that needed to dislocate it antero-posteriorly. This was studied by Lippitt et al, whose work formed the basis of the 'stability ratio' concept described as the amount of translation force that can be present per compressive force without causing a dislocation in the joint (32). The study noted a stability ratio of 64% in the cranial-caudal plane and 33-35% in the anteroposterior plane. This means that the glenoid is nearly twice as stable supero-inferiorly compared to antero-posteriorly. This was directly related to the larger glenoid concavity from supero- inferior (translating to a greater depth) than anteroposterior.

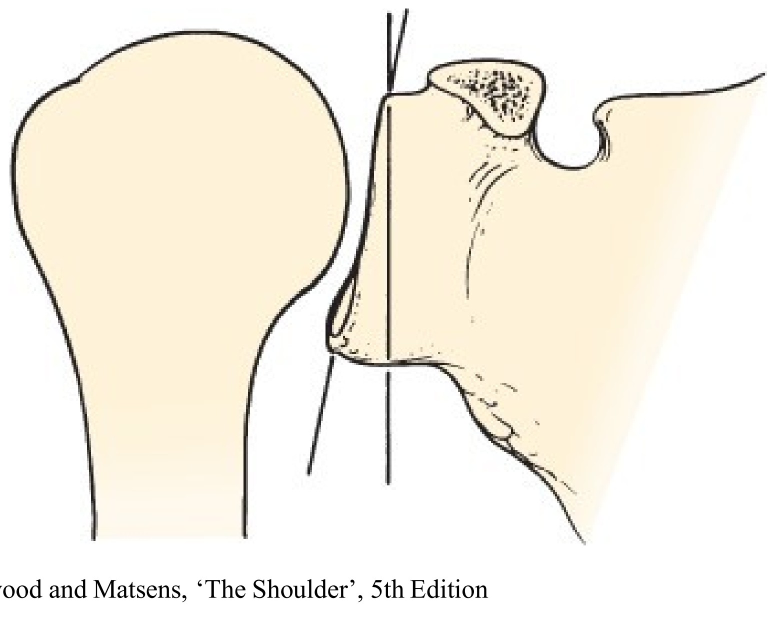
Moroder et al (35)(36), did a study on the clinical implication of pathology-related loss of bone concavity. Peltz et al (37), did a similar study and the findings of both studies showed there was a connection between loss of glenoid concavity and instability with the glenoid being flatter in both trauma and non-trauma related shoulder instability. This may explain the high occurrence of instability in the anteroposterior direction.

2.2.3.1 Glenoid Version and Inclination

Glenoid version has been defined as the spatial orientation of the glenoid relative to the scapular body axis. When the glenoid version is altered as seen in glenoid dysplasia, studies have found that the stability of the shoulder in the anteroposterior direction is affected predisposing the glenohumeral joint to dislocation either anteriorly or posteriorly depending on the direction of the version. This has been found to be significant with anteversion approaching 10 degrees and with 15 degrees of retroversion (2).

Saha did several studies on the shoulder and found that the glenoid is either anteriorly facing (anteverted) or posteriorly facing (retroverted) in relation to the scapula plane (38)(39). From his studies, 75% of the shoulders were retroverted (average 7.4 degrees) while about 25% were anteverted (2-10 degrees).

The glenoid isn't neutral to the scapula plane but is inclined about 15 degrees medially. This creates a relationship with the humeral head whereby the head seems to seat on the glenoid surface conferring even better stability to this articulation.



*Adapted from Rockwood and Matsens, 'The Shoulder', 5th Edition

Figure 4: Showing glenoid inclination

Saha also studied the glenohumeral relationship further and in a study involving twenty shoulders, he studied the nature of glenohumeral articulation and came up with three types of articulations which he based on the contact surfaces. In the first type (type A), he noted that the glenoid contact area was limited to a small area in the middle of the glenoid and the humeral head had a smaller ROC than the glenoid. In type B articulations, there was congruity in the glenohumeral articulation with the articulating surfaces having similar ROC. The contact area was therefore uniform and circular. In the last type (type C), the contact area was ring-shaped and limited to the periphery of the glenoid with a bigger ROC in the humeral head.

Soslowsky et al, examined 32 cadavers. Their study was more precise as they used stereophotogrammetry in studying the shoulders. The study noted that all the glenohumeral articulations were highly congruent and fell into type B category. The instability noted in shoulders, according to this study, was caused by the mismatch in the glenoid and humeral head articulating surfaces and not due to an incongruent or shallow glenoid. Humeral head to glenoid ratios were 3.12:1 in males and 2.9:1 in females (40).

2.2.3.2 Scapulohumeral Rhythm

Glenohumeral and scapulothoracic motion occur concurrently and are intertwined and have been viewed to occur at a ratio of 2:1. This positions the glenoid for maximum shoulder stability and preserves the length-tension relationships of the glenohumeral muscles. It also prevents impingement in the subacromial space.

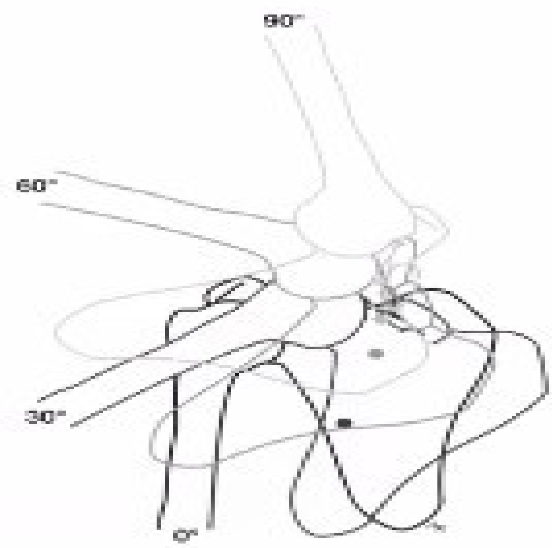


Figure 5:Showing scapulothoracic rhythm.

2.3 Methods of Measuring Glenoid Version

Different methods have been used to study glenoid version in cadavers and patients. Among them is the use of a simple protractor (41), computerized tomography (CT) scan and MRI. The modalities have been compared by Parada et al (42) whereby they did a review on patients with shoulder instability using pre-operative CT and MRI imaging. In the study, measurements of glenoid version with available scapular width were performed. The study didn't find any significant differences between the two modalities.

Aygun et al (43), demonstrated that MRI imaging was as accurate as CT imaging in assessing glenoid version in anterior instability. Fifty-five patients with a history of one non-surgically treated unilateral anterior glenohumeral dislocation and who had both CT and MRI images were sampled. The glenoid version was then measured on CT scan and MRI. After analysis of their data, the study concluded that either MRI or CT scan can be used in evaluating glenoid version.

Different studies report different glenoid version values with literature reporting a range of 2+ to 7.5- in non-pathological shoulders (44). These version values differ depending on the study itself and the method used. in measuring the version as depicted in the table below

Table 1:Showing variability in version measurements depending on the methods used

Reference	Mean version	Method
Budge	-3.3	CT
Hurley	-7.5	X-ray
Lewis	4.9	skiagram
Randelli	2	CT
Seltzer	-4	CT
Brewer	-1	MRI
Inui	-4	CT
Hill	-2	CT
Graichen	-10.4	CT
Cyprien	0.1	CT

Other different methods have been used to measure glenoid Version in unstable shoulders (45)(46), yielding a range of mean version angles. This has varied from 17 degrees of retroversion (46) to 9 degrees of anteversion (47). Patients with excessively retroverted glenoids were found to suffer from Posterior shoulder instability (48)(49).

2.4 Glenoid Version and Inclination Vs. Glenohumeral Instability

Bone plays a critical role in maintaining glenohumeral stability. Giovanni et al (33), looked at this concept in a literature search and concluded that the abnormality in bony structures in glenohumeral instability whether acquired or congenital can both predispose to instability and lead to inferior results after surgery if not correctly diagnosed and addressed. This is particularly true in traumatic shoulder dislocation, whether anterior or posterior when evaluating bone loss.

Numerous studies on the intricate relationship between shoulder instability and glenoid version have been done for over five decades and yielded conflicting results. Some studies have shown an association between the two phenomena (39)(50)(2) while others have failed to find any correlation. Among the latter are two studies one radiographic (51) and the other CT scan-based (48). The relationship between posterior glenohumeral instability and retroversion has been studied extensively and a definite association determined in many studies. Studies on anterior instability are however fewer and far between (3)(4).

Umit et al, in a CT scan-based study, demonstrated more anteversion in shoulders with established anterior instability compared with controls (52). The glenoid version angles were significantly more anteverted on the side of the shoulder with established dislocation in the affected group than those measured in both the non-dominant and dominant shoulders in the control. This finding was supported by Hohmann et al, who studied patients under 40 years who had undergone shoulder stabilization arthroscopically (study group). The study also recruited a control group of patients who had undergone MRI imaging of their shoulders for dislocation unrelated causes. The two groups were compared. The anterior dislocation group had 1.7° of retroversion and 1.6° of inferior inclination as compared to 5.8° and 4.0° of retroversion and superior inclination respectively. This demonstrated that the patients with glenohumeral instability had greater glenoid anteversion and inclination than the control (50).

Dowdy et al, in their study, noted increased anteversion with increasing frequency of dislocations in 128 patients followed up postoperatively at a mean of 9 years. This analysis, however, relied on axial radiographs and was not an assessment of the state of the glenoid before possible degenerative changes had set in. It also did not allow for the assessment of the cartilage thickness (53)

Privitera et al studied the shoulders of patients with either anterior or posterior glenohumeral instability or those with labral tears. MRI images were used in measuring the glenoid version after the study participants were grouped into three groups thus; those with anterior instability/labral tears, those with posterior instability/labral tears and a control group. Using the Friedman method, the study found that the group with posterior dislocation pathology had more retroversion (−9°) than the control (−4°) and the group with anterior dislocation pathology (−5°). No difference was noted between the glenoid version angles of the control and the group with anterior instability. The study summarised the findings that in posterior instability, there was more retroversion but in anterior dislocation, the anteversion was not significantly increased (3).

Abnormalities in version contribute prominently to the instability of the glenohumeral joint (46) with increased glenoid anteversion being an important risk factor in recurrent anterior glenohumeral instability (50)(39).

2.4.1 Cadaveric Studies

Eichinger et al did a study on ten cadavers and demonstrated that significantly less force was required to cause either an anterior or posterior dislocation with anteversion or retroversion respectively (2). A dislocation device was used to test the cadaveric shoulders with the arm at 90 degrees abduction and external rotation. The glenoid version was then adjusted in 5º increments for six version angles (-10º, -5º, 0º 5º, 10º, 15º). The energy and force needed to dislocate were recorded. The study found that the amount of force required to dislocate the joint varied with varying glenoid version angles. It further noted that a Hill-Sachs lesion was less likely in an anteroinferior glenohumeral dislocation than in a direct anterior dislocation. The former also required less energy to dislocate. The study also proposed that glenoid version is important and should be considered when choosing a surgical treatment for glenohumeral instability.

Another cadaveric study by Kazuma et al (54) involved nine fresh-frozen cadaveric shoulders. They measured the translation force produced by a compressive load of 50 N in the 3, 6,9 and 12 o'clock positions and using a tilt of 0º, 5º, 10º, 15º and 20º. The glenoid was then inclined/tilted in a given direction and the translation force produced measured both in the direction of inclination/tilt of the glenoid and in the other direction. The study concluded that the posterior glenohumeral stability increased when the anterior tilt (version) was more than 5º and the inferior glenohumeral stability increased with a superior inclination of 10º. Anterior glenohumeral stability decreased with an anteversion of 5º and the posterior glenohumeral stability decreased with a posterior tilt of 15º.

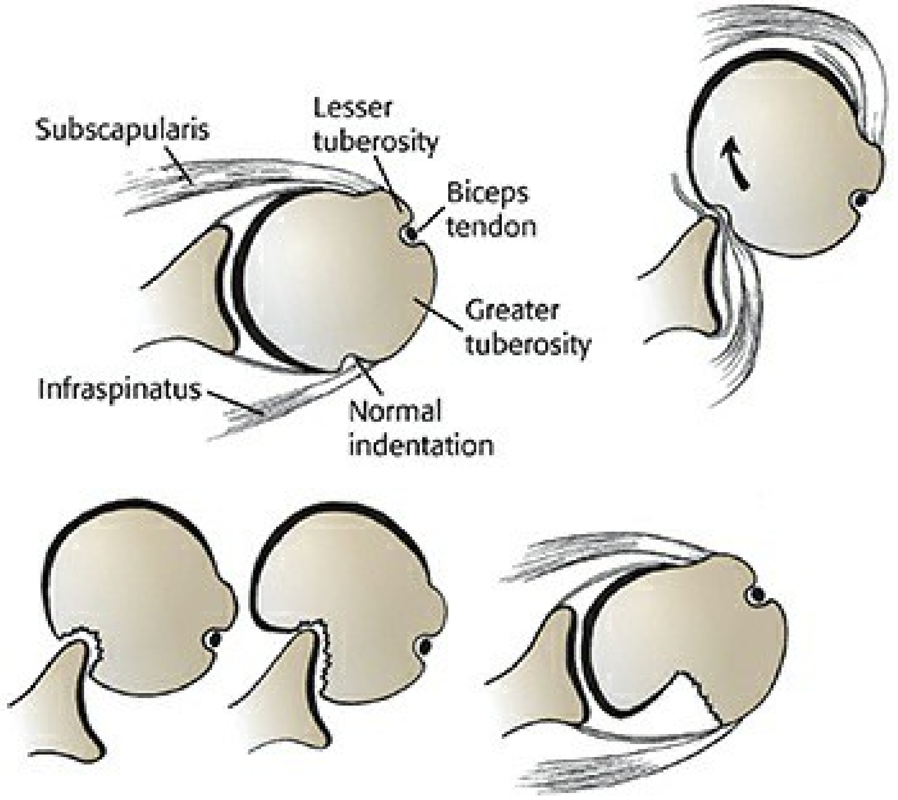
2.5 Other Common Factors Associated With Anterior Glenohumeral Instability

2.5.1 Bankart's and Hillsachs Lesions

During an episode of anterior shoulder dislocation, as the humeral head slides over the glenoid rim and relocates in the glenoid cavity, shear forces and compression of the relatively softer head against the glenoid can produce osseous lesions of the posterosuperior humeral head and anteroinferior glenoid (55) The two lesions (Hill-Sachs and Bankart lesions respectively) are commonly associated with anterior shoulder dislocations. A Bankart lesionis seen in up to 85% of dislocations while a Hill-Sachs lesion is noted in 30–40% of primary anterior dislocations and up to 80% of recurrent dislocations (56-57).

At the time of glenohumeral dislocation, the IGL is put under traction and this force is transmitted to the labrum. This may lead to a partial or complete labral tear with detachment from the glenoid rim. Avulsion of the labrum is called a Bankart lesion, which is the classic pathoanatomic hallmark of anterior instability as described by Bankart (58). This lesion occurs at the anteroinferior labrum (IGL attachment site) and is the most common labral injury following primary traumatic dislocation (59). Bony Bankart lesions are present in 5 % of patients, while soft tissue Bankart lesions occur in approximately 90 % of patients less than 30 years old with an anterior shoulder dislocation (60-61).

Compared with the hard, wedge-shaped cortex of the anterior glenoid rim, the flat contour and softer trabecular bone of the humeral head make it susceptible to Hill-Sachs fracture. Whereas Hill-Sachs defect is the more common imaging finding following dislocation, glenoid rim fracture has the greater prognostic significance. The risk for recurrent dislocation and chronic instability increases with the size of the glenoid bone defect (62).



*Adapted From Handbook of Fractures

Figure 6: Showing Hill-Sachs lesion

The prevalence of Hills-Sachs defects increases from 25% in first-time dislocators to 40%–90% in repeat dislocators (63-64). The defects enlarge in size with increasing numbers of dislocations, eventually taking the signature hatchet morphology (65). Hill-Sachs defects rarely require surgical treatment unless they are large enough to cause mechanical symptoms or engage the glenoid rim (65-66). Functional assessment based on clinical criteria, not imaging criteria, differentiates the engaging lesion from the nonengaging lesion.

Bankart lesions may be identified with the special view radiograph called West Point Axillary View. Hill-Sachs lesions may be identified with an anteroposterior (AP) X-ray with the arm in internal rotation or Stryker Notch view. However, these special views can only detect the osseous part of the lesions and further MRI investigation is necessary to detect the non-osseous part, such as the avulsion of the joint capsule, labral part of Bankart lesion and the chondral compression injury of Hill-Sachs lesion.

2.6 Conceptual Framework

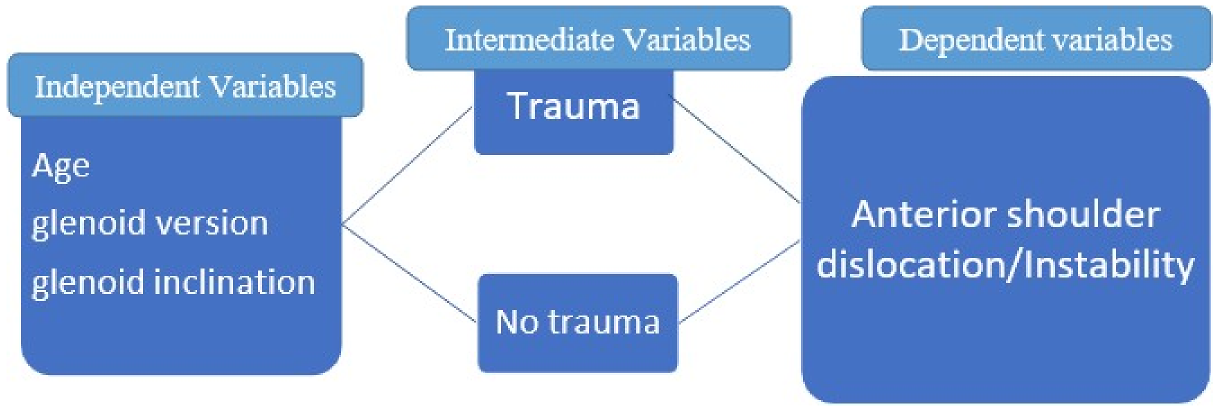


Figure 7:Conceptual framework

2.7 Study Justification

The very high prevalence of anterior glenohumeral dislocation (95%) as compared to posterior dislocations (9)(10) and the findings in relevant studies on the subject that bony factors play a critical role in glenohumeral stability (35)(36) raise critical questions, among them, whether glenoid anteversion has a role to play in this phenomenon. The redislocation rate after arthroscopic stabilization surgery has been unusually high. This finding has been made by several studies which have mostly focused on the young people who bear the burden of shoulder instability.

Studies by Kramer et al (66) and Castagna et al (67), reported a shoulder redislocation rate of 25% and 21% respectively following arthroscopic stabilization among patients with anterior glenohumeral instability. These procedures usually manipulate the soft tissues and the high recurrence rates raise questions, among them, whether the bony component which is often not addressed could be contributing to these dislocations.

If it is demonstrated that increased anteversion is rampant in patients with anterior glenohumeral instability it may herald a paradigm shift in the management of primary and recurrent anterior glenohumeral instability with greater emphasis on bony procedures rather than soft tissue repair which may reduce the re-dislocation rates post shoulder stabilization surgery. This would also significantly reduce the cost of surgery as bony procedures are globally less costly compared to other soft tissue procedures.

The impact of the findings of this study if any, on the design of shoulder arthroplasty implants would also be an interesting angle to look forward to. This study, therefore, sets out to find out whether there is any correlation between glenoid morphology (anteversion and inclination) and anterior glenohumeral dislocation.

2.8 Research Question

Is there any correlation between anterior glenohumeral instability and glenoid anteversion and inclination?

2.9 Objectives

2.9.1 General Objective

To find out the correlation between anterior glenohumeral instability and glenoid anteversion/inclination

2.9.2 Specific Objectives

i. To measure glenoid version from shoulder MRI images of study and control groups.
ii. To measure glenoid inclination from shoulder MRI images of study and control groups.
iii. To assess for any association between glenoid anteversion, inclination and anterior glenohumeral instability.

3.0 CHAPTER THREE: MATERIALS AND METHODS

3.1 Study Design

This is a retrospective, case-control study. It involved the evaluation of shoulder MRIs from patients being managed for recurrent anterior shoulder dislocations and measurements involving the glenoid version and inclination were taken. A control group of shoulder MRIs of patients being managed for conditions other than shoulder dislocation was evaluated and the data analysed.

3.2 Study Location

The study was conducted at KNH and AKUH. Kenyatta National Hospital is a Kenya Essential Package for Health (KEPH) Level 6 national referral hospital, while AKUH is a KEPH Level 5, private hospital and both are in Nairobi County. Both institutions are tertiary referral facilities with specialized radiologic and orthopaedic services and staff. The study was carried out in the Radiology departments of both hospitals where MRI Image repositories are found.

3.3 Study Population

The study used digital records of MRI images stored in the picture archiving and communication system (PACS) at AKUH and MRI images of patients with anterior glenohumeral instability at KNH. The images studied consisted of 45 images from the cases and 45 images from the control group.

- Case: A shoulder MRI image of a patient who has had two or more anterior shoulder dislocations and who met the inclusion criteria
- Control: A shoulder MRI image of a patient taken for shoulder pathologies like rotator cuff lesions, frozen shoulder, chronic shoulder pain, etc. but who had not had incidences of glenohumeral instability.

3.4 Inclusion Criteria

Patients with recurrent anterior shoulder instability and having shoulder MRI scans

3.5 Exclusion Criteria

i. Patients with recurrent anterior shoulder instability but lacking a shoulder MRI scan as part of the investigations done.

ii. Patients with multidirectional shoulder instability as a pre-imagingclinical diagnosis.

iii. Patients above 45 years

3.6 Sample Size

The sample size was calculated as follows using Cochran's formula (70). The sample population was random thus the population standard deviation was estimated by the confidence interval. The z figure (standard normal deviation) was obtained from the z tables.

Cochran's formula: $n = \frac{z2pq}{e2}$

n = sample size

e = Desired level of precision (margin error)

p = estimated proportion of the population which has the attribute in question q = 1-p

CI=95%, z = 1.96, P= the estimated population proportion to be reached during the research period is 86.5%, thus P = 0.865, q = 0.135. Therefore, n0 is:

$n_0 = \frac{1.96^\wedge 2(0.865*0.135)}{0.1^\wedge 2}$ n_0= 44.86. As such, the minimum sample size was 45 participants.

3.7 Sampling Technique

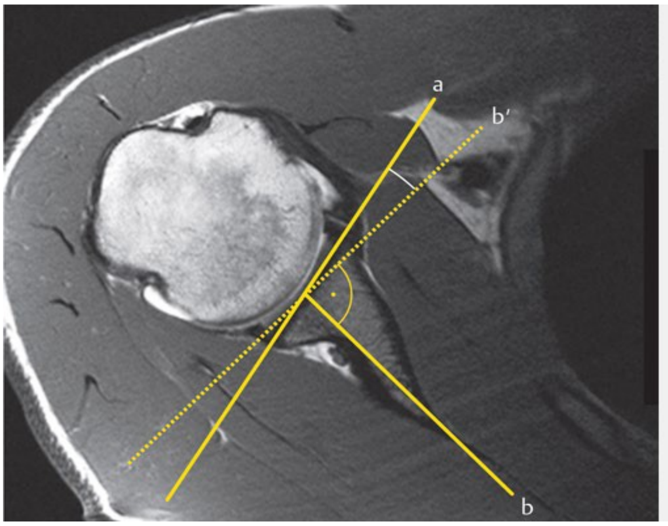
Consecutive sampling of all shoulder MRI images of patients who meet the inclusion criteriawas done until the sample size was achieved.

3.8 Data Collection Procedures

A structured data collection tool was used to collect the data. Demographic information was obtained from the patients' medical records. The shoulder MRI images were obtained from the PACS system, printed MRI images or any other storage forms including DVD copies. At AKUH, the MRI images had been taken with a 1.5 T GE or a 3T Philips MR scanner. At KNH, the MRI images were taken with a 3T MR. Forty-five images from patients with anterior shoulder instability were studied against a control group of 45 patients with shoulder MRIs for other unrelated shoulder pathologies. A third of the images were obtained from KNH and the rest from the AKUH repository. The shoulder MRI images were reviewed by the primary investigator and the necessary measurements were done as shown below.

3.8.1 Measuring Glenoid Version (Friedman Method) Friedman Et al

Two lines drawn on an axial MRI image of the shoulder are used for this technique. The first line connects the anterior glenoid to the posterior margin. The second line connects the midpoint of the glenoid fossa to the medial end of the image of the scapula. The glenoid version angle is the angle between the first line and the line perpendicular to the second line gotten by subtracting 90 degrees from the angle measured. A negative angle denotes retroversion, a positive angle denotes anteversion.



*Adapted from *Radiologykey.com*

Figure 8: Showing a shoulder MRI image demonstrating the measurement of glenoid version

3.8.2 Measuring Glenoid Inclination

Inclination can be determined on MRI or CT scans. Maurer et al suggested a method for measuring glenoid inclination that was used in this study. The coronal image which displays the supraspinatus fossa at its deepest point is displayed, and the scapula body line (SBL) is drawn along this point. The glenoid fossa line (GFL) is drawn connecting the most superior and most inferior points on the glenoid. The angle of inclination is obtained by subtracting 90 from the angle formed at the intersection of GFL and SBL. An inferior inclination is denoted by a positive angle and a superior inclination by a negative angle.

*Adapted from Hohmann et al.

Figure 9: Showing a shoulder MRI image demonstrating measurement of glenoid inclination

3.9 Quality Assurance

For optimal minimization of errors and biases, the researcher carried out a pilot study at the KNH Radiology Department with the use of the data extraction tool.

3.10 Ethical Considerations

The study was conducted after approval by the AKUH and KNH IERC. Application for waiver of written informed consent was done to the Ethics Review Boards (KNH ERC and AKUH ERC). All the information obtained from the study was held in utmost confidence during and after the study. The name, religion and ethnicity of the patient were not documented.Patients were identified by MRI number only to safeguard confidentiality. No additional cost was incurred by the patient for participating in the study.

3.11 Data Analysis and Presentation

The data was analyzed with the use of the Statistical Package for Social Sciences version 26. Demographic and clinical characteristics of the patients were presented as frequencies and percentages for categorical data, as means with standard deviations for continuous data or as median with interquartile range. The range of glenoid version was analyzed and presented as mean with standard deviation, minimum and maximum values.

The range of glenoid inclination was also reported as a mean with standard deviation as well as minimum and maximum values. The relationship between glenoid anteversion and inclination and anterior glenohumeral instability was analyzed with the use of an independent samples t-test. All statistical tests were considered significant where $p < 0.05$.

3.12 Data Dissemination

Results from the study were disseminated to the UON-Department of Orthopaedic Surgery and the University of Nairobi Library.

4.0 CHAPTER FOUR: RESULTS

Ninety shoulder MRI scans were studied in this study half of them being cases and the rest controls. For the cases, 9 were females and 36 males while the controls had 15 females and 30 males.

4.1 Demographic Characteristics

The mean age of the participants was 32.0 (SD 9.0) years, where the youngest was 15.0 years and the oldest 45.0 years. The median age was 32.0 (IQR 24.5 – 40.0) years. The mean age for the cases was 29.0 (SD 8.7) years, where the youngest patient was 17.0 years and the oldest 45.0 years. The median age was 29.0 (IQR 22.0– 34.0) years. The mean age for the controls was 34.6 (SD 8.5) years, with the youngest being 15.0 years and the oldest 45.0 years. The median age was 36.0 (IQR 30.0– 41.0) years.

Table 2: Demographic Characteristics

	Cases	Controls	p-value
Age, *n (%)*			
15 – 20	10 (22.2)	4 (8.9)	**0.044**
21 – 25	7 (15.6)	4 (8.9)	
26 – 30	10 (22.2)	4 (8.9)	
31 – 35	8 (17.8)	10 (22.2)	
36 – 40	4 (8.9)	8 (17.8)	
41 – 45	6 (13.3)	15 (33.3)	
Gender, *n (%)*			
Male	36 (80.0)	31 (68.9)	0.227
Female	9 (20.0)	14 (31.1)	

Most of the cases fell in the 15 – 20 and 26 – 30 age brackets each with 22.2% of the cases. This contrasts with the 36 – 40 and 41 – 45 age brackets which had 8.9% and 13.3% of the cases respectively. For the controls, the opposite was noted with very few patients between 15 – 30 years (26.1%) while 34.8% of the cases fell in the 41 – 45 age bracket.

Most of the cases had a superior glenoid inclination (91.1%) which also correlated with the controls although a bit higher (93.3%). Very few of the shoulders for both cases and controls had an inferiorly facing glenoid with cases having 8.9% and controls 6.7%. The glenoid was anteverted in 40% and 35.6% of cases and controls respectively (p = 1.00) and retroverted in 60% and 64.4% of cases and controls respectively (p =0.666). These differences weren't statistically significant.

Table 3:Cases and controls distribution Table 3: Showing the distribution of cases and controls

	Cases	Controls	p-value
Inclination, *n (%)*			
Inferior	4 (8.9)	3 (6.7)	1.000
Superior	41 (91.1)	42 (93.3)	
Version, *n (%)*			
Anteversion	18 (40.0)	16 (35.6)	0.666
Retroversion	27 (60.0)	29 (64.4)	

4.2 Glenoid Inclination

Both cases and controls displayed relatively similar degrees of glenoid inclination. The mean superior inclination was 11.8 ^{o} and 11.7 ^{o} for cases and controls while the mean inferior inclination was 2.5 ^{o} and 1.8 ^{o} for cases and controls respectively.

Table 4: Glenoid inclination (superior and inferior)range

		n	Mean (SD)	Min	Max	Median (IQR)
Cases	Superior	41	11.8 ^{o} (6.5)	1.0 ^{o}	29.7 ^{o}	11.5 (6.7 – 15.5)
	Inferior	4	2.5 ^{o} (1.6)	0.9 ^{o}	4.6 ^{o}	2.2 (1.4 – 3.6)
Control	Superior	42	11.7 ^{o} (6.0)	1.3 ^{o}	29.3 ^{o}	12.2 (7.5 – 15.9)
	Inferior	3	1.8 ^{o} (0.7)	1.2 ^{o}	2.6 ^{o}	1.7 (1.5 – 2.2)

4.3 Glenoid Version

The mean retroversion and anteversion in the cases were 4.3 ^{o} and 3.8 ^{o} respectively while the controls had a mean retroversion and anteversion of 5.2 ^{o} and 3.0 ^{o} respectively. The highest value for retroversion noted amongst the cases was 16.3 ^{o} while 21.5^{o} was the highest for the controls.

Table 5:Glenoid version range

		n	Mean (SD)	Min	Max	Median (IQR)
Cases	Retroversion	27	4.3 ^{o} (3.4)	0.4 ^{o}	16.3 ^{o}	3.8 (1.8 – 5.7)
	Anteversion	18	3.8 ^{o} (3.2)	0.3 ^{o}	9.7 ^{o}	2.3 (1.1 – 7.1)
Control	Retroversion	29	5.2 ^{o} (4.6)	0.1 ^{o}	21.5 ^{o}	4.1 (2.4 – 6.2)
	Anteversion	16	3.0 ^{o} (2.5)	0.1 ^{o}	8.5 ^{o}	2.7 (0.8 – 4.9)

Distinction between males and females was made and from the analysis in the table below, no statistically significant differences were noted between the cases and controls for both males and females.

Table 6: Means for males and females

	Cases	Controls	p-value
Inclination			
Superior			
Male	11.9±6.9	11.9±6.5	0.957
Female	11.2±6.9	11.4±6.5	0.919
Inferior			
Male	2.5±1.6	1.8±0.7	0.562
Female*	-	-	-
Version			
Retroversion			
Male	4.1±3.5	5.4±3.6	0.260
Female	4.9±3.3	4.8±6.6	0.946
Anteversion			
Male	3.6±2.9	3.3±2.7	0.749
Female	5.4±6.1	2.4±2.1	0.335

*No female with inferior

Table 7: Combined means for males and females

	Cases	Controls	p-value
Inclination			
Male	10.9±7.2	10.9±6.8	0.996
Female	11.2±5.1	11.4±5.2	0.919
Version			
Male	3.9±3.2	4.6±3.4	0.364
Female	5.0±3.6	3.9±5.4	0.592

4.4 Relationship Between Glenoid Anteversion and /Inclination and Anterior Glenohumeral Instability

An independent samples t-test was used to determine if there were statistical differences in the means for inclination and also for version between the cases and the controls. For inclination, the means for superior as well as those for inferior between the cases and controls were found not to be statistically significant. As for version, the means for retroversion as well as those for anteversion between the cases and controls were also found not to be statistically significant. The results are as shown in Table 8 below.

Table 8:Glenoid version and inclination Means and p values

	Cases	Controls	p-value
Inclination			
Superior	11.8±6.5	11.7±6.0	0.956
Inferior	2.5±1.6	1.8±0.7	0.562
Version			
Retroversion	4.3±3.4	5.2±4.6	0.425
Anteversion	3.8±3.2	3.0±2.5	0.416

The data was analysed further and means were calculated for both version and inclination for cases and controls. The cases had a mean version of 1.04 ^{o} while the controls' mean glenoid version was 2.27 ^{o}. For glenoid inclination, the means were 10.5 ^{o} and 10.8 ^{o} for cases and controls respectively.

Table 9:Combined version means

Patient category		Statistic
Cases	Mean	1.0444
	Std. Deviation	5.19692
	Minimum	-9.70
	Maximum	16.30
Controls	Mean	2.2622
	Std. Deviation	5.60480
	Minimum	-8.50
	Maximum	21.50

Table 10: Combined inclination means

Patient category		Statistic
Cases	Mean	10.5089
	Std. Deviation	7.44162
	Minimum	-4.60
	Maximum	29.70
Controls	Mean	10.7956
	Std. Deviation	6.73640
	Minimum	-2.60
	Maximum	29.30

5.0 CHAPTER FIVE: DISCUSSION, CONCLUSION AND RECCOMENDATIONS

5.1 Discussion

This study was undertaken since anterior glenohumeral instability accounts for the majority of the patients who present with glenohumeral instability and very few studies have been done to assess the contribution of bony factors to this instability. Of the studies done, very few have been conclusive. Posterior glenohumeral instability has been better studied and a direct correlation drawn between the instability and glenoid retroversion. None of these studies has been done on an indigenous African population to the best of our knowledge and this was the first of such. Most of the surgeries for anterior glenohumeral instability address the soft tissues arthroscopically and if a direct association between glenoid morphology and the instability can be drawn, focusing on bony procedures, which are cheaper for the patient, would be a gamechanger.

From this study, it was clear that most of the cases were of a younger population while the controls were mostly in their fourth and fifth decades. There were generally more males than females among the cases and controls. This finding mirrors that noted by Hohmann et al (50) in their case-control study where the mean age was 24.5 years and 30.9 years for the cases and controls respectively.

5.1.1 Glenoid Version

Glenoid morphology didn't vary significantly between the cases and the controls with version and inclination parameters being almost similar between the two groups. The range of glenoid version for the controls was 8.5° anteversion to 21.5° retroversion while that for the cases was 9.7° to 16.3°. Further analysis of the glenoid data revealed a mean glenoid version of 2.26° and 1.04° for controls and cases respectively and the difference wasn't statistically significant ($p=0.288$). These findings compare with that of Friedman et al(44) who studied Shoulder CT scans of 63 patients with no shoulder pathology and found a version range of 14° anteversion to 12° retroversion. Das et al(71) did a study on 50 dry scapulae and found that 30 of them had retroverted glenoids ranging from 2° to 12° while 20 had anteverted glenoids ranging from 2° to 10°. No mean was given but later analysis of the original data revealed a mean version of 1.1° of retroversion. Another study by Churchill et al(41) also found a mean version of 1.23° which is also strikingly consistent with this study's finding. Hohmann et al (50) in their MRI-based study (case-control) found a mean a version of 1.7° (retroversion) for cases and 5.8°

(retroversion) for controls and the difference was statistically significant. A CT scan-based study by Matsumura et al (72) on 410 3D reformatted shoulder CT scans of healthy individuals found a mean glenoid retroversion of 1 ± 3 ° ranging from 9 ° anteversion to 13 ° retroversion. Some studies like Welsch et al (73) have however had different findings on mean glenoid version. They reconstructed 12 3D scapula models and found no difference between left and right sides or male and female. On the left, the mean version was 9.02 ± 3.89 ° (retroversion) while on the right it was 8.26 ± 3.72 ° (retroversion). No measurements for inclination were made.

Saha in one of his studies on 50 healthy (no shoulder pathology) patients using axillary radiographs and humerus in 120 ° of abduction noted that 73.5% had an average retroversion of 7.4° and 26.5% had anteversion from 2° to 10°. No mean for the entire group or range for the retroversion group was reported.

Another study by Cyprien et al (51) which was x-ray based studied 50 healthy patients. The average glenoid was determined to be retroverted approximately 7° to 8°. The study went further to compare this value with that obtained for 15 shoulders in patients with a history of recurrent anterior dislocation and no statistical difference between the groups was found which is consistent with this study's findings.

Because of concerns over the accuracy and reproducibility of standard x-ray films, CT -based studies have gained prominence and Randelli et al (48) published their CT evaluation of 50 patients without a history of glenohumeral arthritis or instability. Their technique involved measuring the version at 3 separate glenoid locations, upper, middle, and lower. Although no mean values were given for the group, the "preponderance of cases" measured 5°, 2°, and 7° of retroversion for the upper, middle, and lower glenoid locations, respectively. They too found no difference in glenoid version between healthy patients and those with a history of recurrent anterior dislocation.

5.1.2 Glenoid Inclination

The mean glenoid inclination for this study was 10.5° (superior) and 10.8° (superior) for cases and controls respectively. This finding differs from that of Hohmann et al (50) who also did a case/control study and found glenoid inclination means of 1.6 ° (inferior) and 4.0 ° (superior) for case and controls respectively. Two cadaveric studies were found in the literature which had studied both glenoid inclination and version. The first by Mathews et al (74) was CT scan based and found a mean glenoid inclination (male and female) of 13.0° ± 7° and a mean glenoid version of 1.0° ± 4° (retroverted). The other study by Sandra W.L et al (75) involving a hundred and fifty scapulae from the osteological collection at the National Museums of Kenya, found a mean glenoid inclination of 6° (interquartile range 6° to 7°). The study further noted that the average glenoid version was retroverted (3.5° and 3.0° for male and female males and females respectively).

5.1.3 Relationship Between Glenoid Version/Inclination and Anterior Glenohumeral Instability

From the data analysis results displayed above, there was no statistically significant difference between the cases and controls for the glenoid version and inclination parameters. Between-group differences were not significant for either version (p=0.288) or inclination (p= 0.849). This study, therefore, adds weight to studies by Cyprien et al(51) and Randelli et al (48) which found no difference between glenoid inclination and version between patients with a recurrent anterior shoulder dislocation and a group of controls. This finding, however, is in contrast to that of Hohmann et al (50) who found between-group (cases vs controls) differences that were significant for version (P =0.00001) and inclination (P = 0.00001).

5.2 Conclusion

The results of this study revealed that glenoid version and inclination in patients with established anterior shoulder instability do not differ significantly compared with a matched control group of patients with no history of anterior glenohumeral instability. Therefore, glenoid alignment isn't a risk factor for anterior shoulder dislocation.

5.3 Recommendations

This study didn’t find any correlation between glenoid version/inclination and anterior glenohumeral instability so no practice-changing observations were made. A follow-up study involving history taking on the cause of the dislocation and mechanism of injury and clinical examination of both cases and controls is recommended to shed more light on the subject.

5.4 Study Limitations

The study had several limitations. No bilateral shoulder MRIs were available to compare glenoid morphology bilaterally. The age distribution was skewed towards the young for the cases while the controls were from an older age group and this may have impacted the results for lack of absolute case and control matching.

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APPENDICES

Appendix I: Data Collection Tool

Case ☐ **Control** ☐

Unique MRI Study ID: ____________________

Date of Data Collection: ____________________

PART A: Demographic Data

	Variable	**Measurement**	
1	Age of patient (Years)		
2	Sex of patient	Female	Male

PART B: Quantitative Measurements

	Variable	**Unit of measurement**	**Units**		
1	Glenoid version	degrees	Anteversion	Neutral	Retroversion
2	Glenoid inclination	degrees	Superior	Neutral	Inferior

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RESEARCH LICENSE

This is to Certify that Dr. JOSEPH THIONG'O WACHIRA of University of Nairobi, has been licensed to conduct research in Nairobi on the topic: ASSOCIATION BETWEEN ANTERIOR GLENOHUMERAL INSTABILITY AND GLENOID ANTEVERSION/INCLINATION: An MRI-based study at the Agha Khan University and Kenyatta National Hospitals. for the period ending : 19/May/2023.

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THE AGA KHAN UNIVERSITY

Faculty of Health Sciences
Medical College

Ref: 2022/ISERC-43 (v1)
June 2, 2022

Dr. Mordicai Atinga –AKU Supervisor
Dr. Wachira J. Thiong'o MBChB (Moi)
MMed. Orthopedic Surgery student
University of Nairobi; Faculty of Health Sciences
P. O. Box 19676 - 00202, Nairobi, Kenya

Dear Dr. Mordecai Atinga, Dr. Wachira J. Thiong'o and team

Re: CORRELATION BETWEEN ANTERIOR GLENOHUMERAL INSTABILITY AND GLENOID ANTEVERSION/INCLINATION: AN MRI-BASED STUDY AT THE AGHA KHAN UNIVERSITY AND KENYATTA NATIONAL HOSPITALS

The Aga Khan University, Nairobi Institutional Scientific Ethics Review Committee (ISERC), is in receipt of your protocol resubmitted to the Research Office (RO) on April 15, 2022. The ISERC has reviewed and approved this project *{as per attached official stamped protocol and attachments - version Ref: 2022/ISERC-43 (v1).*

You are authorized to conduct this study from **June 2, 2022**. This approval is valid until **June 1, 2023** and is subject to compliance with the following requirements;

1. The conduct of the study shall be governed at all times by all applicable national and international laws, rules and regulations. ISERC guidelines and Aga Khan University Hospital policies shall also apply, and you should notify the committee of any changes that may affect your research project (amendments, deviations and violations)
2. Researchers desiring to initiate research activities during COVID-19 pandemic must comply with the COVID-19 SOPs for Research as well as submit to the Research Office a Request Form to Initiate, Reinstate or Continue Research During COVID-19 Pandemic.
3. **Prior** to human subjects enrolment you must obtain a research license from the National Commission for Science, Technology and Innovation (NACOSTI), *where applicable*, site approvals from the targeted external site(s) and file the copies with the RO.
4. *As applicable*, **prior** to export of biological specimens/data, ensure a Material Transfer Agreement (MTA)/Data Transfer Agreement (DTA), is in place as well as seek shipment authority/permit from the relevant government ministry. Copies of these approvals, should be submitted to the RO for records purpose.
5. All Serious Adverse Events and the interventions undertaken must be reported to the ISERC as soon as they occur but not later than 48 hours. The SAE shall also be reported through the AKUHN quality monitoring mechanism(s) at Client Relations Department of the Chief of Staff's Office.
6. All consent forms must be filed in the study binder and where applicable, patient hospital record.
7. Further, you must provide an interim Progress Report Form **60 days before expiration** of the validity of this approval and request extension if additional time is required for study completion; as well as submit the completed Self-Assessment Tool -Monitoring Ethical Compliance in Research. You must advise the ISERC when this study is complete or discontinued and a final report submitted to the Research Office for record purposes.
8. The Aga Khan University Hospital management should be notified of manuscripts emanating from this work.

If you have any questions, please contact Research Office at AKUKenya.ResearchOffice@aku.edu or 020-366 2148/1136.

With best wishes,

Dr. Christopher Opio,
Chair – Institutional Scientific and Ethics Review Committee (ISERC)
Aga Khan University, (Kenya)
Copy: Co-Investigators

Appendix IV: KNH/UoN-ERC Letter of Approval

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Ref: KNH-ERC/A/171

10th May, 2022

Dr. Joseph Thiong'o Wachira
Reg. No. H58/7091/2017
Dept. of Orthopaedic Surgery
Faculty of Health Sciences
University of Nairobi

Dear Dr. Wachira,

RESEARCH PROPOSAL: CORRELATION BETWEEN ANTERIOR GLENOHUMERAL INSTABILITY AND GLENOID ANTEVERSION/ INCLINATION; AN MRI-BASED STUDY AT THE AGA KHAN UNIVERSITY AND KENYATTA NATIONAL HOSPITALS (P52/02/2022)

This is to inform you that KNH-UoN ERC has reviewed and approved your above research proposal. Your application approval number is **P52/02/2022.** The approval period is 10th May 2022– 9th May 2023.

- This approval is subject to compliance with the following requirements;
  - i. Only approved documents including (informed consents, study instruments, MTA) will be used.
  - ii. All changes including (amendments, deviations, and violations) are submitted for review and approval by KNH-UoN ERC.
  - iii. Death and life threatening problems and serious adverse events or unexpected adverse events whether related or unrelated to the study must be reported to KNH-UoN ERC 72 hours of notification.
  - iv. Any changes, anticipated or otherwise that may increase the risks or affected safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH-UoN ERC within 72 hours.
  - v. Clearance for export of biological specimens must be obtained from relevant institutions.
  - vi. Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. Attach a comprehensive progress report to support the renewal.
  - vii. Submission of an executive summary report within 90 days upon completion of the study to KNH-UoN ERC.

Protect to discover

Prior to commencing your study, you will be expected to obtain a research license from National Commission for Science, Technology and Innovation (NACOSTI) https://research-portal.nacosti.go.ke and also obtain other clearances needed.

Yours sincerely,

DR. BEATRICE K.M. AMUGUNE
SECRETARY, KNH-UoN ERC

c.c. The Dean, Faculty of Health Sciences, UoN
The Senior Director, CS, KNH
The Chairperson, KNH- UoN ERC
The Assistant Director, Health Information, KNH
The Chair, Dept. of Orthopaedic Surgery, UoN
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Glenoid proposal

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