SURGICAL VERSUS NON-SURGICAL TREATMENT FOR FIRST-TIME TRAUMATIC ANTERIOR SHOULDER DISLOCATION WITH A BANKART LESION

10-years Randomised Controlled Clinical Trial

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FINAL DEGREE PROJECT

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En primer lloc, vull agrair molt especialment a la Dra. María José Martínez, per haver-me apropat des del primer dia, al món de la Ortopèdia i la Traumatologia; segurament no m'apassionaria tant sense la seva ajuda. Per haver-me ensenyat tantes coses, haver-me fet sentir com a casa i per la paciència que ha tingut durant el treball.

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A la Teresa Puig, per l'ajuda metodològica donada durant el transcurs del treball.

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I com sempre als de sempre.

A tots ells moltes gràcies

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ABREVIATIONS

OTS Orthopaedics Trauma Service

AAHF American Academy of Health and Fitness

Arto-MRI Magnetic Ressonance Imaging arthrography

LGH Glenohumeral ligaments

x-Ray Radiographs

US Ultrasounds

CT Computed Tomography

MRI Magnetic Resonance Imaging

NS Non-surgical

S Surgical

M Male

F Female

ED Emergency Department

VAS Visual Analogue Scale

ASA American Society of Anaesthesiologists

SD Standard Deviation

RR Relative Risk

ABSTRACT - ENGLISH

Background:

Anterior traumatic dislocation is a common problem faced by orthopaedic surgeons. After a first episode of shoulder dislocation, a combination of lesions can lead to chronic instability or re-dislocations episodes. The management after the first acute anterior shoulder dislocation is controversial. Nowadays, the treatment choose is a conservative management by immobilization, although the available literature supports the early surgical treatment, especially in a close-defined population with a high risk of recurrences (young, male, athletes and/or with a high demanded physical activities).

However, further clinical trials of good quality comparing surgical *versus* non-surgical treatment for well-defined lesions are needed, especially for categories of patients who have a lower risk of recurrence. Our aim is to try to solve this weak point.

Objective:

The aim of this protocol is to compare the effectiveness between the surgical versus non-surgical treatment for the first-time traumatic anterior dislocation of the shoulder with Bankart lesion. The surgery used, will be the arthroscopic Bankart repair.

Design:

Our design will be a randomized, controlled, single-blind and unicentric clinical trial. It will be done in Hospital Universitari Dr. Josep Trueta in Girona with the Orthopaedics and Trauma Surgery (OTS) Department. Patient could be derived from all Girona's province.

Participants:

We include physically active individuals (score of 40-80 in the Physical Activity Index of American Academy of Health and Fitness (AAHF)) with ages between 18 and 30 years old, and with a gender rate of 9 Males : 1 Female. (9M:1F) The lesion should be a first-time episode traumatic anterior dislocation with a Bankart lesion diagnosed by Magnetic Ressonance Imaging arthrography **(**arto-MRI).

Key Words:

Medline

1. (Shoulder dislocation) AND (Bankart)
2. (glenohumeral) AND (joint or instability or unstable)

The Cochrane Library

1. (Shoulder dislocation) AND (acute) AND (treatment) AND (surgical) AND (non-surgical)

RESSENYA – CATALÀ

Antecedents:

La dislocació traumàtica anterior és un problema comú, amb el qual s'encara el cirurgià ortopèdic. Després d'un primer episodi de luxació d'espatlla ens podem trobar amb una gran quantitat de lesions, les quals poden produir una inestabilitat crònica o episodis de re-luxació. El tractament en aquests primers episodis és polèmic. Avui en dia, es fa un tractament conservador a base d'immobilització, tot i que la literatura disponible va a favor d'una cirurgia precoç, especialment en una població ben definida i amb un risc alt de recurrències (jove, home, atleta i/o amb una gran demanda funcional).

De totes maneres, són necessaris nous estudis d'alta qualitat, comparant la cirurgia *versus* el tractament conservador, en lesions ben definides i especialment en aquells amb qui la taxa de recurrència és baixa. El nostre objectiu es base en solucionar aquesta debilitat.

Objectiu:

L'objectiu d'aquest protocol és el del comparar l'efectivitat entre el tractament quirúrgic *versus* el no-quirúrgic, per les dislocacions traumàtiques anteriors d'espatlla, en un primer episodi i amb lesió de Bankart associada. La cirurgia utilitzada serà el procediment de re-anclatge de Bankart artroscòpic.

Disseny:

El nostre disseny és el d'un assaig clínic, randominitzat, controlat, uni-cec i uni-cèntric. L'estudi es farà a l' Hospital Universitari Dr. Josep Trueta a Girona amb el servei de Cirurgia Ortopèdica i Traumatologia. Els pacients poden venir derivats de tota la província.

Participants:

En el nostre estudi inclourem pacients físicament actius (puntuació d'entre 40-80 en el Physical Activity Index of AAHF), amb edats compreses entre 18 i 30 anys i amb una distribució de sexes de 9M:1F. La lesió ha de ser primària, degut a un episodi traumàtic i produint-se una dislocació anterior amb una lesió Bankart associada i diagnosticada amb arto-MRI.

RESEÑA – CASTELLANO

Antecedentes:

La dislocación anterior y traumática es un problema común, con el cual se encuentra el cirujano ortopédico. Después de un primer episodio de luxación de hombro, nos podemos encontrar con una gran cantidad de lesiones asociadas, las cuáles pueden producir una inestabilidad crónica o episodios de re-luxación. El tratamiento de estos primeros episodios es controversial. Hoy en día, es de elección un tratamiento conservador a base de una inmovilización, aunque la literatura disponible va a favor de una cirugia precoz, especialmente en una población bien definida y con alto riesgo de recurrencias (joven, hombre, atleta y/o con gran demanda funcional).

De todas formas son necesarios nuevos estudios de alta calidad, comparando la cirugia *versus* el tratamiento conservador en lesiones bien definidas y especialmente en aquéllos con los que su tasa de recurrencia es baja. Nuestro objetivo es intentar solucionar dichas debilidades.

Objetivo:

El objetivo de nuestro protocolo es el de comparar la efectividad entre el tratamiento quirúrgico *versus* el no-quirúrgico para las luxaciones traumáticas anteriores de hombro, en un primer episodio y con lesión de Bankart asociada. La cirugia utilizada será el del procedimiento artroscópico de re-anclaje de Bankart.

Diseño:

Nuestro diseño es el de un ensayo clínico, randominizado, controlado, uni-ciego y uni-céntrico. El estudio se hará en el Hospital Universitari Dr. Josep Trueta a Girona con el servicio de Cirugia Ortopédica y Traumática. Los pacientes pueden venir derivados de tota la provincia.

Participantes:

En nuestro estudio incluiremos pacientes físicamente activos (puntuación de entre 40-80 en el Physical Activity Index of AAHF), con edades comprendidas entre 18 y 30 años, con una distribución de sexos 9M:1F. La lesión debe ser primaria, causado por a un episodio traumático y produciendo una dislocación anterior con una lesión de Bankart asociada y diagnosticada con arto-MRI.

1. BACKGROUND

1.1 Introduction

Of the large joints, the shoulder is the one most commonly dislocate. The shoulder joint has the greatest range of motion of all the joints in the human body. It is this extreme range of motion that also renders the shoulder the most untestable joint in the body. In glenohumeral joint we can find a spectrum of disorders. Those vary from minor subluxation (partial dislocation) to full dislocation where the articular surfaces of the glenohumeral joint are not longer in contact. Instability may be anterior (forward), posterior (backwards) or multidirectional. Symptomatic episodes may be acute, recurrent or chronic. They most commonly follow a traumatic event but may occur spontaneously, perhaps due to some congenital joint laxity. (1)
There are a variety of shoulder dislocations: anterior, posterior and *luxatio erecta humeri* also known as inferior luxation. (2)

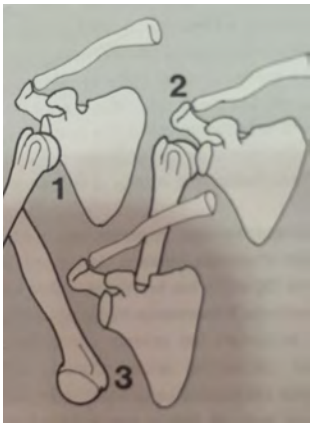

Fig 1: types of dislocation (2)

1: anterior 2: posterior 3: inferior

*1.1.1 Anatomy **(3)***

Bony structures

Clavicle, humerus and scapula are the three bones that take part of the shoulder joint. Sternoclavicular, acromioclavicular and glenohumeral joints connect them.

Muscles

Seven muscles take part of the glenohumeral muscles, four of them take part of the rotator cuff (teres minor, infraspinatus, supraspinatus and subscapularis). The other three are coracobrachialis, deltoid and teres major.

Shoulder joints

The shoulder joint consisted of several articulations. The real ones, glenohumeral, acromioclavicular and sternoclavicular; and the fake ones, suprahumeral and scapulothoracic. Sternoclavicular joint connects the components of shoulder joint to the

axial skeleton. This put a greater demand on the muscles for securing the shoulder girdle on thorax during static and dynamic conditions.

Shoulder joint is a ball and socket type joint so the humeral head is bigger and rounder than the glenoid bone. It is for this reason that the stabilizers are very important during the shoulder movement.

In the static stabilizers are included the negative intraarticular pressure, size, shape and orientation of the glenoid fossa, and the stabilizing presence of the capsulolabral complex (glenoid labrum and glenohumeral ligaments (LGH) as superior glenohumeral, middle glenohumeral, inferior glenohumeral and coracohumeral ligaments). In the dynamic stabilizers are included the rotator cuff's muscles, the long head of biceps tendon and proprioceptive effects. (3-4)

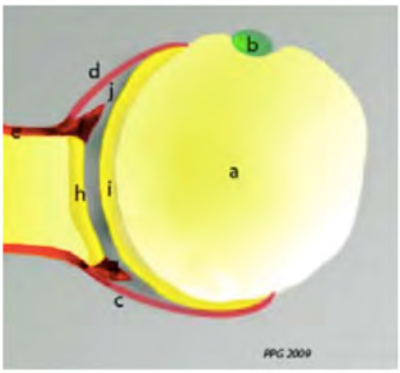

Fig 2: glenoide joint schema (5)
a) humeral head
b) long head biceps tendon
c) posterior capsule
d) anterior capsular complex
e) periosteum
f) anterior labrum
g) posterior labrum
h) cartilage (glenoide)
i) cartilage (humeral)
j) joint space

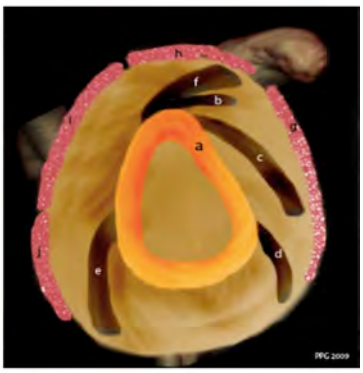

Fig 3: glenoide joint schema (5)
a) laburm
b) superior glenohumeral ligament LGH
c) middle LGH
d-e) inferior LGH
f) long head biceps tendon
g) subescapularis tendon
h) supraspinatus tendon
i) infraspinatus tendon
j) teres minor tendon

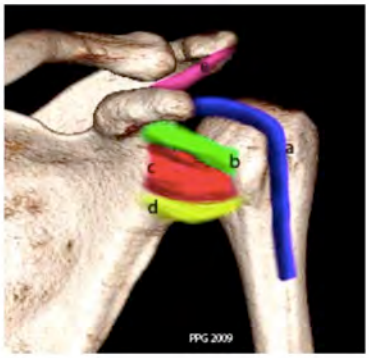

Fig 4: stabilizers of shoulder joint (5)
a) long head biceps tendon
b) superior LGH
c) middle LGH
d) inferior LGH
e) coracoacromial ligament

In the shoulder complex, we can find amount of lesions like partial ruptures, total ruptures, stretching, impingement and calcifications in the subacromial space or other injuries.

After the dislocation, we can find some injuries related to the extreme range movement of the glenohumeral joint, in a short or long-term. They can be:

Bony lesions

Hill-Sachs lesion (cortical depression in the posterolateral head of the humerus. It results from forceful impaction of the humeral head against the anteroinferior glenoid rim when the shoulder is dislocated anteriorly), Bankart bony lesion (is a Bankart lesion that includes

a fracture of the anterior-inferior glenoid cavity of the scapula bone), major tuberosity fracture.

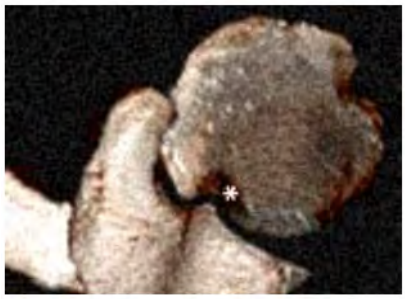

Fig 5: Hill-Sachs Lesion (5)

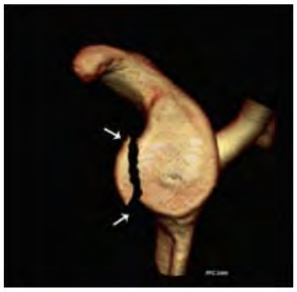

Fig 6: Bony Bankart Lesion (5)

Soft tissue lesions

Bankart lesion (injury of the anterior-inferior glenoid labrum of the shoulder due to anterior shoulder dislocation. When this happens, a pocket at the front of the glenoid it is created. This allows the humeral head to dislocate into it), anterior or posterior glenoid labrum articular disruption (GLAD), inferior glenohumeral ligament tear, superior labral anterior to posterior lesions (SLAP), tenosynovitis, subacromial impingement.

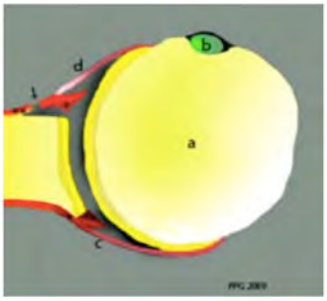

Fig 7: Bankart Lesion: (5)
a) humeral head,
b) biceps tendon,
c) posterior capsule,
d) anterior capsular complex

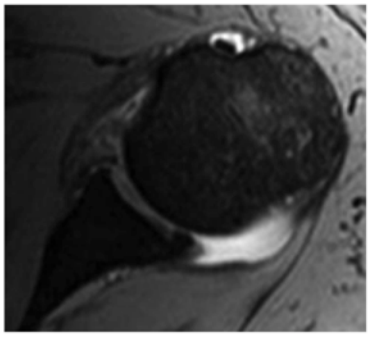

Fig 8: RM (T2) Bankart Lesion (5)

Other

Bennet lesions, multidirectional instability, micro-instability, glenoid labral cysts, intraarticular bodies, arterial lesions (like Hennequin hematoma), nervous lesions (injuries in the circumflex nerve, braquial plexus), complex regional pain syndrome (CRPS), also known as reflex sympathetic dystrophy.

1.1.2 Biomechanics

Shoulder joint is the proximal joint of the superior extremity. The referenced position is vertical, parallel to the axis. It has a large range of movement in all the planes of

movements, so it can do, flexion, extension, abduction, adduction, internal rotation and external rotation. Because of his range of movement and the anatomic condition, the shoulder suffers a weak point, instability. So, shoulder joint has more mobility than stability.

The static stabilizers prevent the dislocation cause by discrepancy of sizes between humeral head and glenoid joint, with a restriction of movement. While dynamic stabilizers prevent the dislocation with the contraction of the muscles. All the stabilizers act in a balanced form.

Because of a traumatic impact, we can damage the stabilizers. When it happens, the biomechanics forces are unbalance and this produce the dislocation of the humeral head or instability.

The instability can be:

- TUBS (*Traumatic aetiology, Unidirectional instability, Bankart lesion is the pathology Surgery is required)*
- AMBRI (*Atraumatic: minor trauma, Multidirectional instability may be present, Bilateral: asymptomatic shoulder is also loose, Rehabilitation is the treatment of choice, Inferior capsular shift: surgery required if conservative measures fail*). (3)

1.2 Epidemiology

The glenohumeral joint is the most common major joint to dislocate, at a rate of 11.2 per 100,000 per year. The glenohumeral dislocation is the 96% of all the shoulder dislocations (6) and more than 90% of them are anterior. (7)

Once a dislocation had occurred, the shoulder is less stable and more susceptible to re-dislocations. This condition has been reported to be as high as 92%. (8) The rate of instability after a first-traumatic shoulder dislocation varies between 26% (9) and 100%. (8)

It has been identified a bimodal distribution, with peaks of shoulder dislocations in the second and sixth decades of life. As result, young and old people have comparable incidence of shoulder primary dislocation. However, the incidence of recurrent dislocation is highly dependent on age and occurs more often in the adolescent population. This difference can be explained by the higher concentration of elastic collagen (type 3) in the adolescences joints. (10)

A population study conducted in Sweden, which examined the prevalence of a history of shoulder dislocation in a random sample of 2092 people in the 18 to 70 years age group, found that 35 patients (1.7%) reported such history. The male and female ratio had been reported, with a rate of 3:1. In adolescence group, or the first peak, the ratio seems to be 9:1. However, in the second peak, older group, the ratio changes to 1:3.

The main cause of primary shoulder dislocation is traumatic, at a rate of 95%, and is derived from a strong collision, landing on an outstretched arm, or by a sudden and violent motion of the shoulder. (11)

1.3 Aetiology and risk factors which predispose a first-time traumatic anterior shoulder dislocations and the evolution to recurrent instability

When a first-time traumatic anterior shoulder dislocation develops into recurrent instability, we can report an emotional and financial cost. On one hand, the patient is afraid of the recurrence and re-dislocation, which produce anxiety. On the other hand, a re-dislocation can produce direct cost as medical ones, and indirect cost related by time off work/school and the impact on family members who care the patient. (12) In addition, every time the shoulder suffers a dislocation the risk of intrinsic lesions increase.

Is for this reason, there is a need to identify modifiable risk factors for the acute anterior shoulder dislocation and also the ones that predispose recurrent instability. We can report that in both conditions, are the same risk factors.

1.3.1 Intrinsic risk factor

Male sex, age (13) and hypermobility (14) seem to be the most important intrinsic risks factors.

May also, the antecedent of a first-time traumatic anterior dislocation shoulder can predispose a recurrence or instability of the joint. The presence of a pathological damage during the dislocation, increase this risk, also. (15-16).

1.3.2 Extrinsic risk factors

Among all the risk factors, cross-sectionals studies reported that the most important are: occupations, which involve using the upper limb above chest height, collisions sport or playing surface and susceptibility to falls. (12)

Table 1: Summary of risk factors and relationship with recurrent instability (12)

Risk factor	Rate of recurrence
Aged 40 years and under	13 times more likely
Men	3 times more likely
Greater tuberosity fracture	7 times more likely
Hyperlaxity	3 times more likely

1.4 Pathophysiology

Dislocations occur more frequently when the arm is forced in a position of abduction and maximal external rotation (10) as a result of an anterior leverage of the humeral head to a position out of the joint.

A traumatic shoulder dislocation involves a complete separation of the joint surfaces and usually produces damage to the soft tissue surrounding the shoulder joint. When this

damage is in a vast area, we usually find injuries patterns such as the classical Bankart lesion (the separation of anterior capsule and labrum from the glenoid rim), the Hill Sachs lesion (compression fracture of the humeral head), and dysfunction of the subscapularis muscle. (1)

After the first episode of shoulder dislocation, a combination of lesions can lead to chronic instability, particularly injuries involving the inferior glenohumeral ligament, which is the most important passive stabilizer of the shoulder. (17) There is not a single pathologic lesion common to all recurrent dislocations. Apart from inferior glenohumeral ligament, we can find lesions that involve capsule, ligaments, glenoid bone, humeral head, muscles or muscles tendons lesions, as a single lesion or a combination of them. (18)

1.5 Diagnostic

In the *acute* moment our diagnose will be based on physical exploration such as on radiographs (X-ray), especially in the cases that the reduction cannot be done in the field.

The typical patient with a shoulder dislocation presents strong pain and the refusal to move the arm in any direction. The muscles that surround the shoulder joint tend to go into spasm, making any movement very painful.

Usually, with anterior dislocations, the arm is held slightly away from the body, and the patient tries to relieve the pain by supporting the weight of the injured arm with the other hand. Often, the shoulder appears squared off since the humeral head has been moved out its normal place in the glenoid fossa. Sometimes, it may be seen or felt as a bulge in front of the shoulder joint.

Related to this pathology, we can find a circumflex nerve (axillar nerve), so it is very important the exploration with a needle on the area affected, the lateral or outside part of the shoulder, also called the deltoid badge area. We may explore for pulses in the wrist and elbow, too.

As other bony injuries, the pain may provoke systemic symptoms, like nausea, vomiting, sweating, light-headedness, and weakness. These occur because of the stimulation of the vague nerve, which blocks the adrenaline response in the body. Occasionally, this may cause the patient to faint or pass out (vasovagal syncope).

When a patient presents a shoulder dislocation, pain control and joint relocation are primary considerations. However, it is still important for the health-care professional to take a careful clinical history, to understand the mechanism of injury and the circumstances surrounding it. Also, it will be important to know if this episode is the first shoulder dislocation or whether the joint has been previously injured. In addition, questions may be asked about medications, allergies, time of the last meal, and past medical history to prepare for a potential anaesthetic administration to help relocate, or reduce, the shoulder dislocation.

Physical examination of the shoulder will begin with inspection. In an anterior dislocation, the shoulder appears to look "squared off," with a loss of the normal rounded appearance of the shoulder caused by the deltoid muscle. In thinner patients, the humeral head may be palpated or felt in front of the joint. Posterior dislocations may be difficult to assess just by looking at the shoulder joint. Pain and muscle spasm accompany dislocated joint.

X-rays may be taken to confirm the diagnosis of shoulder dislocation and to make certain there are no broken bones associated with the dislocation, Hill-Sachs and Bony Bankart fractures. While these may be present, they do not hinder the relocation of the shoulder. Other fractures that we can find are in the humerus and scapula, those may make shoulder reduction more difficult.

In certain circumstances, if a health-care professional is present at the time of injury, an attempt may be made to reduce or relocate the shoulder immediately without X-rays being taken, before the muscles have a chance to go into spasm. Imaging of the injured shoulder (X-ray or MRI) would then be considered at a later time. (2)

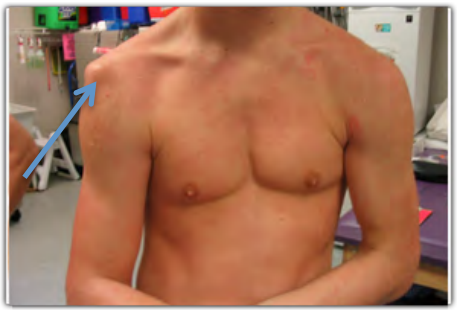

Fig 9: Anterior shoulder dislocation inspection
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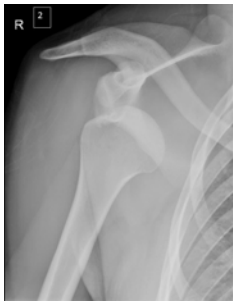

Fig 10: Anterior shoulder dislocation X-ray. AP view
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The *chronic instability examination* should start with non-injured shoulder, to establish a baseline from motion, strength, and stability. Hyperlaxility may be identifies by passive external rotation of the shoulder with the arm at a neutral adduction of greater than 85%. (19).

Fig 11: External rotation of greater than 85° with the arm at the side of the body indicates baseline of shoulder hyperlaxity (19)

The involved shoulder should be examined carefully for range of motion, strength, and positions of apprehension, noting side-to-side differences. Subscapularis dysfunction, contributes to poor out-comes. Excessive passive external rotation or weakens in internal rotation is a harbinger of clinically significant subscapularis injury. (20) Loss of motion suggests capsular contractures and/or subscapularis scarring, which may complicate revision surgery. (21) Weakness in abduction or external rotation raises concern for rotator cuff disorders. (20) A careful neurologic examination helps to detect subtle deficit hat may result from injury-related or iatrogenic injury to the brachial plexus or axillar nerve. (22) The direction and degree of instability should be characterized. Apprehension with posteriorly directed force on the adducted arm is seen with posterior capsulolabral disorders, whereas a positive sulcus sign and/or hyperabduction in excess of 20º compared with the contralateral side occurs with injury of the inferior glenohumeral ligament. (21) Significant glenoid injury or Hill-Sach lesion may manifest as crepitus in positions of apprehension. Concomitant injuries to the biceps anchor and/or tendon as well as the acromioclavicular joint should be assessed because they may require attention at revision surgery. (16-22)

Table 2: Physical Examination: Shoulder instability tests (23,24)

Anterior instability tests	Apprehension test	The examiner stands either behind or at the involved side, grasps the wrist with one hand and passively externally rotates the humerus to end range with the shoulder in 90 degrees of abduction. Forward pressure is then applied to the posterior aspect of the humeral head by the examiner or the table (if the patient is in supine). A positive test for anterior instability is if the patient presents apprehension or if the patient reports pain.
	Fulcrum test	Is the same test that the apprehension test, but in supine position and with the arm out of the examination table.
	Jobe Relocation Test	With the patient supine, the therapist pre-positions the shoulder at 90° of abduction and maximal external rotation. The examiner grasps the subject's wrist and hand with his/her distal hand while applying a posterior force to the humeral head while externally rotating the shoulder
Posterior instability tests	Posterior apprehension test	The patient should be supine or sitting while the examiner elevates the patient's shoulder in the plane of the scapula to 90° while using the other hand to stabilize the scapula. The examiner then applies a force posterior on the patients elbow while horizontally adducting and internally rotating the arm. Apprehension is a positive sign.
Multidirectional instability tests	Sulcus sign	We sit the patient in the examination table. The examiner pulls down the arm with the hand grasping the subject's elbow (20º of shoulder abduction and 90º of elbow flexion). When we see a "step-off deformity" or "sulcus" in the skin during the inferior movement, we can consider a positive test.
	Rockwood test	The patient in supine position, we block the shoulder joint with one

		hand and with the other we try to move the humeral head with an anterior-posterior movement. When it moves more than the common, we consider test positive.
Labrum integrity tests	Clunk test	Patient in supine, examiner hand on the posterior aspect of the shoulder, the other hand holds the humerus above the elbow and abducts the arm over the head. Then pushing anteriorly with the hand under the shoulder and rotating the humerus laterally with the other hand, feel for a grind or clunk which may indicate a tear of the labrum.

After the acute moment will can also do some imaging tests to diagnose instability. Theses tests are important to understand causes of recurrences, as well as, for the development of a preoperative plan.

X-ray

In radiographs we can diagnose osseous anatomy or disorders, or some joint lesions that are produced by the recurrence dislocation of glenohumeral joint.

Ultrasounds or US

In instability, we can diagnose just a few injuries, especially rotator cuff injuries. So, we cannot diagnose lesions in the capsule and labrum. The relationship between the humeral head and the glenoid, the congruity of the articular surfaces, the presence of location of prior implants, and evidence of osteoarthritis should be noted.

Computed tomography CT

CT is useful in the evaluation of the morphology and lesion of the bonny structures, such glenoid defects. When we use with the intraarticular contrast injection, CT arthrography, is comparable with magnetic resonance arthrography. So, we can study soft tissue like capsule, labrum, cartilage lose and ligaments. It has been used to diagnose the bony injuries, glenoides, humeral head, so we can estimate the bony loss during de dislocation. CT is an essential tool for the pre-operative assessment of bone loss to determine the need for a bone grafting procedure.

Magnetic resonance MRI

MRI and the MRI arthrography are the gold-standard tests for diagnose instability. We can diagnose from partial ruptures in the labrum-bicipital, capsulolabral and rotator cuff disorders, to the complete rupture. Also, the subacromial impingement and other disorders can be diagnosed by MRI. (2-5)

Its important to stand out the useful of MRI during the acute moment, normally subsequent the reduction, because in the acute moment we can see a joint effusion, which is synonym of capsular distension, what is needed to evaluate the intraarticular structures that can be injured. (5)

Arthroscopy

An examination of the shoulder under anaesthesia, using arthroscopy, is mandatory to obtain an objective understanding of the direction and degree of instability before starting the procedure. Although, the surgical plan usually is clear before entering in the operating room, arthroscopy can elucidate equivocal cases or show previously unrecognized disorder. (25) Shoulder stability testing may be performed under arthroscopy. The surgeon should incorporate the arthroscopic findings into diagnose and treatment algorithms, and must be prepared to perform an alternative surgery if the preponderance of factors contradict arthroscopic stabilization. (15)

Baker et Al (26) present a classification of the lesions found in the acute shoulder dislocation, based on preliminary study of 45 shoulders.

Table 3: Baker Classification	Description
Group 1	Had capsular tears with no labral lesions: these shoulders were stable under anaesthesia and had no or minimal hemarthrosis
Group 2	Had capsular tears and partial labral detachments: these shoulders were mildly unstable and had mild to moderate hemarthrosis
Group 3	Had capsular tears with labral detachments: these shoulders were grossly unstable and had large hemarthrosis. They had completed capsular/labral detachments

1.6 Interventions background

Shoulder dislocation and its treatment have been recorded since ancient times. Hippocrates revealed the differents types of recurrent dislocations, the seriousness of the lesions and methods of treatment. His treatments included the cauterisation of the deep tissues in front of the shoulder chronic instability. (1)

Nowadays, the management in treatment of young patients after the first acute anterior shoulder dislocation is controversial, conservative (no-surgical) or surgical treatment, are used. Both are generally preceded by reduction of the acute dislocation.

During the acute moment, we can use several methods of reduction. As relaxed is the patient, better are the results of the reduction. Is for this reason that in several times is necessary the use of sedative drugs or muscle relaxants drugs.

The movements during the reduction must be soft, precise and try to reduce the complications after the dislocation.

The reductions' manoeuvres had been recorded since thousands of years, in the ancient Egypt or the ancient Greece.

Ancient Egypt had used the Kocher manoeuvre. It consists on the traction of the forearm in flexion of 90º. After that, we should abduct the arm with an internal rotation until we feel a "clunk" sound.

Fig 12: Kocher Manoeuvre descripted in "Building a Catafalque", Tomb of Ipuy. Ramesses II, The Metropolitan Museum of Art, Manhattan, New York, USA

Hippocrates described a manoeuvre in the ancient Greece. It consists by the traction of the arm in abduction and with the elbow in extension. In the same time, the physician produces a pressure in the armpit or where we can find the humeral head, normally with their leg. Simultaneously, we do movement of abduction or adduction. (3)

Fig 13: Hippocrates Method

http://image.slidesharecdn.com/shoulderdislocationsaseendar-141114052247-conversion-gate01/95/shoulder-dislocation-saseendar-23-638.jpg?cb=1415942831

Both manoeuvres are not longer recommended because of the increment of complications after the reduction.

Nowadays, the manoeuvre recommended is the external rotation method. The patient is in the supine position with the elbow in 90° flexion. The arm is adducted to the side of the chest and the shoulder is placed in 20° forward flexion. The shoulder is externally rotated until the forearm is in the coronal plane. The arm is internally rotated to bring the forearm into the abduction position (27)

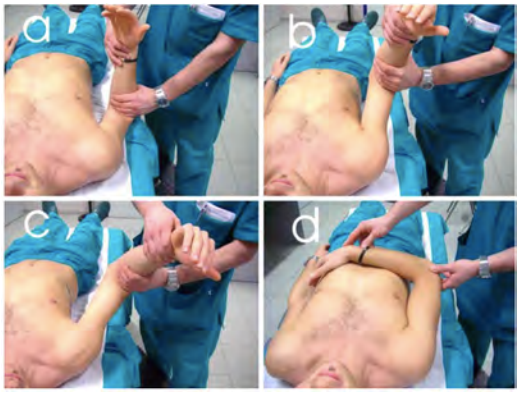


Fig 14: The external rotation method for the reduction of an acute anterior dislocation of the shoulder. (27)
a) The patient is in the supine position with the elbow in 90º flexion
b) The arm is adducted to the side of the chest and the shoulder is placed in 20º forward flexion.
c) The shoulder is externally rotated until the forearm is in the coronal plane.
d) The arm is internally rotated to bring the forearm into the abduction position

1.6.1 Non-surgical treatment

Subsequent conservative management usually comprise a period of rest, activity restriction, generally involving immobilisation of the arm in a sling, for three to six weeks followed by a supervised physiotherapy programme.

There is not statistically significant difference between the immobilization in external or internal rotation, but seems to have less recurrences in external position. (28) The duration of immobilization is also controversial, so we can choice any period between 0 and 6 weeks. (4,29)

A supervised physiotherapy programme usually may consist of several exercises that emphasized strengthening of the adductor and internal rotator muscle of the shoulder. (30)

Traditionally, the eligible option for subsequent treatment was conservative treatment, but it has been reported recurrent rates that reached 100% in skeletally immature patients and 96% in adolescents. (4)

1.6.2 Surgical treatment

On the other side, subsequent surgical intervention for unidirectional shoulder instability has the aim to restore the anatomic position of the labrum and glenohumeral ligaments associated with little damage to other structures of the shoulder.

The type of surgery depends on the pathology of the shoulder. If labrum is affected, the objective of the surgery will be to attach it. If the problem is the capsule, we will repair it with sutures.

Bone loss (Bony Bankart Lesion) - Latarjet-Bristow Procedure

The procedure involves transfer of the coracoid with its attached muscles to the deficient area over the front of the glenoid. This replaces the missing bone and the transferred muscle

also acts as an additional muscular strut preventing further dislocations. The procedure has a high success rate:

- Increase or restore the glenoid contact surface area
- The conjoint tendon stabilises the joint when the arm is abducted and externally rotated, by reinforcing the inferior subscapularis and anteroinferior capsule
- Repair of the capsule.

This procedure is an open-surgery, although nowadays, an arthroscopic approach is investigational. We can considered it like a dynamic and static repair.

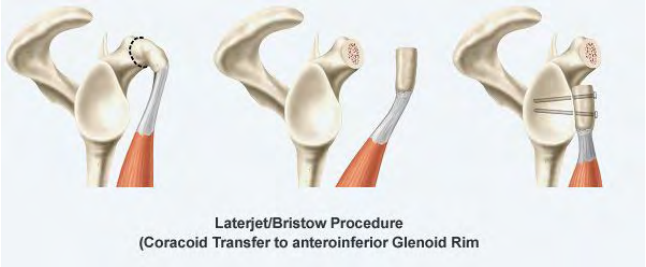


Fig 15. Laterjet-Bristow Procedure
https://s-media-cache-ak0.pinimg.com/736x/d1/d0/09/d1d009e56f9716787e20d6a160e0c8f8.jpg

Anterior capsular distension - Anterior capsular reinforcement or Capsulorraphy

When there is distension in the anterior capsule, the indicated procedure should be capsulorraphy. In this procedure, the surgeon reinforces the capsule by a suture. Also can be arthroscopic or open surgery.

Fig 16. Capsulorraphy procedure
http://www.veteranshealthlibrary.org/spanish/flipbooks/orthopaedics/2211653es_VA.pdf

Labrum tear repair

The procedure used is the Bankart repair. (1,4)

Recently, randomized clinical trials showed lower rates of recurrent instability and better results in young patients treated with surgical stabilization. (4)

Conventional *open Bankart* repair historically was the gold standard for stabilization, because reported the lowest recurrence rates and the highest rates of return to play.

Now, surgeons recommend *arthroscopic Bankart* repair for patients with instability, because seem to have the equivalent results to open repair. (14) Some authors maintain the open repair, as the best procedure for young, high-level athletes as a way to guarantee a low

recurrence rate in those individuals subjected to high training loads. (31) Arthroscopic procedure has been described using a variety of fixation techniques, including transglenoid sutures, staples, and bio-absorbable tacks. (4,15,32)

Arthroscopic approach includes less surgical morbidity, less postoperative pain, the reduced cost of an outpatient setting, improved cosmesis and an easier, if not shorter, rehabilitation. (33)

Arthroscopic Bankart Repair (32)

Morgan and Bodenstab described the arthroscopic procedure. The patient is placed decubitus position with dual traction applied. We use a combination of interscalene and general anaesthesia. The interscalene regional anaesthesia is performed with the patient awaked, thereby providing postoperative analgesia. After the interscalene administration, the patients will be administered a general anaesthesia.

The arm is placed at 30º to 45º of abduction. A sling is placed about the proximal humerus, and overhead traction of 3-4 kg provided a moderate degree of distraction of the humeral head from the glenoid. This improves the visualization of the antero-inferior aspect of the joint, especially the antero-inferior glenohumeral ligament complex.

A standard posterior portal is used for visualization. Two portals, an anteroinferior and an anterosuperior, are used for instrumentation. These portals are made by using an outside-in technique guided by a spinal needle for proper placement. Translucent cannulas are used in both anterior portals to allow easy access to the joint with the instruments, as well as visualization of the tack deployment through the clear plastic.

A systematic diagnostic arthroscopy is performed and the assessment of a Bankart lesion.

After capsulolabral avulsion is identified (Bankart lesion), a motorized shaver is used to debride the clot and frayed tissue along the anterior glenoid. Decortication of the glenoid rim is performed with a mechanical abrader to stimulate healing of the tissue back to the glenoid.

Through the anteroinferior portal, the capsulolabral tissue is pierced with a suture and translated superiorly along the glenoid face with the tack drill and guide pin assembly. Occasionally, a soft tissue grasper is inserted through the anterosuperior portal to assist in the translation of the tissue. The guide pin is driven 1.8 cm into the anterior glenoid, followed by the cannulated drill under arthroscopic guidance. The tissue is then secured to the glenoid rim with the bio-absorbable tack. The tissue and the head of the tack are then probed to ensure proper tension and secure fixation.

Additional tacks are then placed superiorly along the face of the glenoid to restore the anatomic position of the labrum tissue as needed. (33-36)

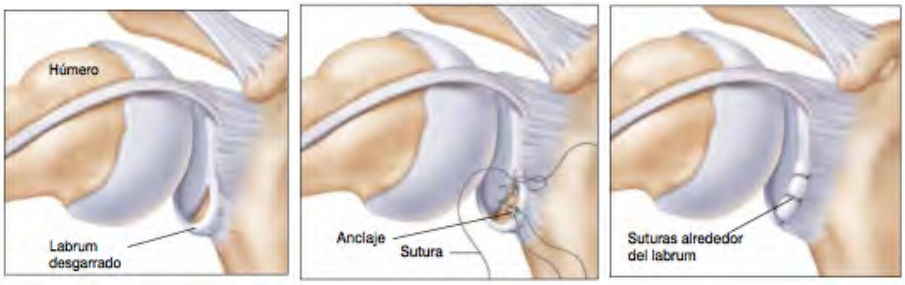


Fig 17. Bankair Repair

http://www.veteranshealthlibrary.org/spanish/flipbooks/orthopaedics/2211653es_VA.pdf

See more on: Annex 1: Bankair Repair Tecnique in Pictures. Annex 2: Bankair Repair Tecnique in Arthoscopic Images (33)

The postoperative regimen consists of a shoulder immobilization in neutral rotation for a minimum of four weeks. At third week or fourth week post surgery, we initiate the physiotherapy programme. The goal is to recover 90% of motion at the twelfth week. For the elite level thrower, establishing full range of motion occurs at eighth weeks to ninth weeks.

The risks of surgery for shoulder instability include, but are not limited to, the followings:

- Infection
- Injury to nerves and blood vessels
- Instability to carry out the planned repair
- Stiffness of the joint
- Tear of the rotator cuff
- Pain
- Persistent instability
- The need additional surgeries
- There are also risks associated with anaesthesia including death.

An experienced shoulder surgery team will use special techniques to minimize these risks but cannot totally eliminate them. (37)

There is a spectrum of treatment ranging from initial immobilisation followed by rehabilitation, to immediate surgical repair in selected cases. The choice of treatment will be influenced by patient aged and previous history of dislocation, occupation, level of activity, general heath, ligamentous laxity and the reliability to carry out a prescribed therapeutic regime. (1)

Generally, arthroscopic Bankart repair has been reported for the treatment of chronic anterior instability but that it is application for the acute, initial episode was investigational.

1.6.3 Physiotherapy programme.

Patients in both groups underwent a therapist-supervised rehabilitation program.

The first week's rehabilitation program consisted of sling immobilization for four weeks with limited active range of motion and isometric muscle contractions were performed with the patient under the supervision of a physical therapist.

Then, lasting four weeks consisted of progressive passive motion exercises followed by active-assisted range of motion exercises without resistance.

The last phase focused on restoration of full active range of motion with progressively greater resistance exercises.

Return to full active duty, contact sports, and activities requiring over- head or heavy lifting were restricted until four months postoperatively.

1.6.4 Treatment outcomes

Previous prospective studies (34-36,38-42) have tried to compare efficacy of the operative management versus non-operative treatment. Although, they are clinical trial studies, they have some limitations. Some of them had methodological problems, such as, they had no blinding asses, not all of them randomise their groups, the examination of the patients is difficult because the examiner can see the scars, the patient know in which group he is,... Also they compare different types of surgeries and they study the results in different moments, and it is known that the re-dislocations follow a decrease and stable progression **Fig 15**, so depends of the moment of the examination, the results can be different but in the same direction. Finally, we find difference in the definition of recurrence, but we try to compare compatible rates.

For this reason, the comparison in the literature is difficult. Even though, we try to synthesized the studies on the next table **(table 4)**.

In conclusion, surgical groups had less recurrence than conservative groups with a statistical difference. In the long-term studies, we become aware, that the rate of re-dislocation draws a characteristic graphic similar to a hyperbole **Fig 15**.

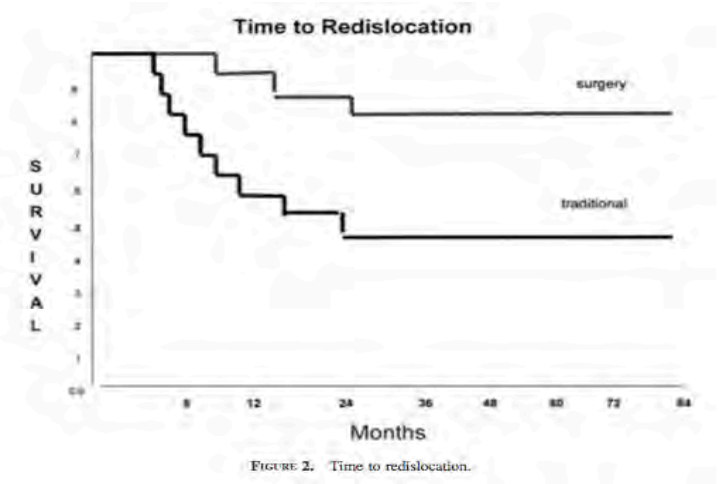
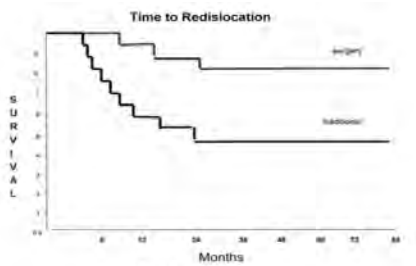
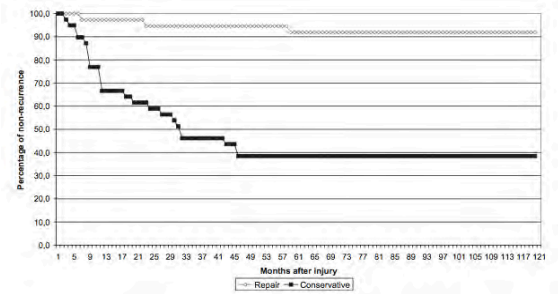


Fig 18: Time-to-event curve for time to redislocation. (38)

Table 4: Summary treatment outcomes	Bottoni 2002 (34)	Arciero 1994 (35)	Kirkley 1999 (36)	Kirkley 2005** (38)
n (gender)	24 (all male) → 14 NS VS 10 S + 3 excluded → 21 follow-up (12 NS – 9 S) + 3 lost	36 → 15 NS + 21 S	40 → 19 NS (19M + 2F) + 19 S (16M + 3F) + 2 lost	Related to Kirkley 1999 study, the patients were re-found by telephone, **31 agreed** to be re-evaluate. →15 NS (14M+1F) + 16 S (13M+3F)
Age (years)	18-26 years old	18 – 24 years old	<30 years old → Stratified by ages <22 years old /23-30 years old	
Population	All military personnel and their families	Cadet athletes	Patients were recruited from the ED and from orthopaedic surgery colleagues in two university centres. Patients of 2) ED university centres	
Method	**Randomization**: Yes, quasi-randomised (Last digit of their social security). **Not blinding** **Loss follow-up**: 3	**Randomization**: No. After the information the patient choose the treatment. **Not blinding**	**Randomization**: Yes → randomized use of a numbered and opaque envelopes that were opened in the operating room by the "circulating" nurse after confirmation that the patient was eligible **Single blinded** → The examination will be done by a research assistant who was unaware of the treatment group the patients had been assigned to. To achieve this, patients wear a t-shirt for all evaluation so the presence or absence of surgical incision could not be detected. **Loss follow-up:** 2 (1999) + 9 (2005)	
Surgical approach	Arthroscopic examination + Bankart repair (10 days after the injury) + Immobilization for 4 weeks in a sling and then rehabilitation.	Arthroscopic examination + Bankart repair (10 days after the injury) + Immobilization for 4 weeks in a sling and then rehabilitation.	Arthroscopic transglenoid suturing technique, Bankart repair (4 weeks after the injury, they were allowed to mobilize the shoulder on their own before the surgery, to reduce the risk of arthofibrosis) + Immobilization for 3 weeks in a sling and then rehabilitation.	
Non surgical approach	Immobilization for 4 weeks in a sling and then rehabilitation. At 4 months after, the patients were allowed to return to full activity	Immobilization for 4 weeks in a sling and then rehabilitation. At 4 months after, the patients were allowed to return to full activity.	Immobilization for 3 weeks, after the rehabilitation.	
Non surgical recurrence rate % *	75%	80%	47%	47% (no additional case reported)
Surgical recurrence rate % *	11.1%	14%	15,9%	15.9% (no additional case reported)
Follow up (months)	16-56 months (average 36m)	15 - 45 months	24 months	51-102 months (average 79m)
Others	Hemarthrosis, Hill-Sachs, Bankart lesions in all patients	They found bony avulsion of the glenohumeral ligament in 27% of the NS patients and 24% of the O patients. Bankart lesions were found in all O patients (Baker group 3). There were three postoperative complications (1 subcutaneous suture abscess (treat by AB)+ 2 transient hypoesthesia of the median nerve (resolute in 3 weeks))	Patient exclusion criteria included associate fracture (excepted Hill-Sachs or Bankart lesions), multidirectional instability or evidences of multidirectional instability of the opposite shoulder, neurovascular compromise of the affected limb, medical conditions that make the patient unfit for surgery. Bankart lesions were found in all the O patients. There was one surgical complication, septic joint (treat by irrigation, debridement and AB). In Kirkley 2005 there was not any new case of recurrence, there were found difference between the rates of quality of life (WOSI questionnaire score) and return to pre-injury level activity. 	

*** (Second dislocation or symptomatic subluxation or instability preventing return to full active duty or necessitating an additional surgical stabilization procedure). ED: emergency department**

Table 4: Summary treatment outcomes	Sandow 1996 (39)	Jakobsen 2007 (40)	Wintzell 1999 (41)	Wintzell 1999 (42)
n (gender)	39 patients → 20 NS +19 S	76 (62 M and 14 F) → 39 NS + 37 S	60 (46 M + 14 F) → 30 NS + 30 S	30 → 15 NS (13 M + 2 F) + 15 S (13 M + 2 F) 3 of the NS group were excluded because they have subsequent instability surgery
Age (years)	14-26 years old	15-39 years old	16-30 years old	18-30 years old
Population	Patients form 2 hospitals (Australia + USA). Probably athletes	Patients of 13 ED hospitals	Patients from 4 ED hospitals, Sweden	Patients from Sweden
Method	**Randomisation**: Yes → not stated but used the double consent randomisation design of Zelen. **Not blinding**. **Loss to follow-up:** none	**Randomisation**: Yes → closed envelopes	**Randomisation**: Yes → closed envelopes, consecutive patients entered into trial. **No blinding** but there was an independent assessor. **Loss to follow up:** none	**Randomisation**: Yes → closed envelopes, consecutive patients entered into trial. **No blinding** but there was an independent assessor. **Loss to follow up:** none
Surgical approach	Arthroscopic Bankart repair with bioabsorbable implant (10 days after the injury) + Immobilization for 4 weeks in a sling and then rehabilitation.	Arthroscopic diagnostic procedure (7 days after the injury) + Open Bankart repair + Immobilization for 2 days in a fixed sling, and 1 week in a non-fixed sling. Then, rehabilitation. At 6 months after, the patients were allowed to return to full activity.	1 week of immobilization in a sling + arthroscopic lavages (10 days after the injury) + Rehabilitation	Optional 1 week of immobilization in a sling + arthroscopic lavages (7 days after the injury) + Rehabilitation
Non surgical approach	Immobilization for 4 weeks in a sling and then rehabilitation.	Arthroscopic diagnostic procedure (7 days after the injury) + Immobilization for 2 days in a fixed sling, and 1 week in a non-fixed sling. Then, rehabilitation. At 6 months after, the patients were allowed to return to full activity.	Immobilization for 2 weeks in a sling and then rehabilitation.	Immobilization for 2 weeks in a sling and then rehabilitation.
Non surgical recurrence rate %	Re-dislocation 75% **Subluxation +Instability + Re-dislocation 85%*** Return to the pre-level of activity 10% Need to a subsequent surgery 50%	56% 62%	43%	60%. They include the 3 patients in the rate, because for the outcome of subsequent surgery do not effect. They are included in the recurrence patients. (9/15)
Surgical recurrence rate %	Re-dislocation 5,2% **Subluxation +Instability + Re-dislocation 15%*** Return to the pre-level of activity 90% Need to a subsequent surgery 50%	3% 9%	13%	20%
Follow up (months)	12-36 months (average 17 m)	24 months 120 months	12 months	24 months
Others	Bony Bankart or rotator cuff tears were excluded.	Bankart lesion → arthroscopic diagnostic → 6,6% Baker 1, 13,2% Baker 2, 80,3% Baker 3 		The entire operative group have Bankart lesion with Baker type 3 capsulolabral detachment, Hill-Sachs lesion and hemarthrosis.
*** We will take this rate to compare to other studies**				

2. JUSTIFICATION

Given the high rate of recurrence or instability after a traumatic first-time anterior shoulder dislocation, a key area of controversy is, its management, and whether surgical treatment of primary dislocation is warranted.

Generally, arthroscopic Bankart repair has been reported for the treatment of chronic anterior instability, but its application for an initial episode is investigational. Immediate surgery stabilisation has been proposed for young physically active adults after a first-time dislocation.

The main of this study is whether a patient within the late adolescent or middle-aged adult category presenting a first-time dislocation should be offered surgical treatment or not.

2.1 Study justification

The reason for developing this project is the lack of strong evidence, based on the latest studies, that recommend one of the two treatments. Theses studies conclude that surgery treatment had less rates of recurrence (second dislocation or symptomatic subluxation or instability preventing return to full active duty or necessitating an additional surgical stabilization procedure) than non-surgical procedure.

Given the characteristic of the populations that had been analysed in the recent studies (young men with high level of fitness and functioning of the shoulder to perform their job or sport activity), we cannot generalise the finding to general population or people with activity levels that differ from those included in the trials. To sum up, this “study population” is not similar to the “usual population”.

The trials recruited patients with high risk of recurrence and further tissue damage. A high rick of recurrence increases the attraction of primary surgery, provided it is shown to be safe and effective in preventing instability and restoring pain-free function.

There are not consents in type of surgery, duration of sling immobilisation and rehabilitation, producing a bias. Therefore, we cannot generalise our hyphothesis to compare “any surgery” versus “any non-surgical” treatment.

Also, we notice there are few articles that study long-term results, so there is not enough evidence in chronic or long-term disorders, like osteoarthritis.

In addition, the studies do not focus in injuries that we usually find after the traumatic dislocation. Some of the published studies exclude patients with bony lesions, because the treatment, in this condition, should be surgical. After a systematic research, we cannot find any study that includes an injury related to the dislocation, in their inclusions criteria.

The conclusions of most of the studies are that patient’s sport, physical examination, age, gender, the period of the season in which the injury occur, extent of shoulder structure

injury and the expectation of the patient in relation to surgery are important factors in choosing a specific method of treatment.

For that reason, our study population will be defined as:

- *Age and Gender:* 18-30 years old (the first peak of shoulder dislocation incidence) with a rate of 9M:1F.
- *Activity*: 40-80 in the Physical Activity Index of the AAHF. **(Annex 3)**
- *Injury found in glenohumeral joint*: arto-MRI should diagnose all patients of Bankart lesion.
- *Treatments choose:* the Bankart lesion will be repair with a non-surgical management (immobilized with a sling) or with a surgical management (arthroscopic Bankart repair surgery).
- *Duration of the study:* Our study will last 10 years (with 5 records moments) to look into if surgery can be related to chronic or long term disorder like osteoarthritis.

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4. HYPOTHESIS

The hypothesis of our study is that **patients with a first episode of a traumatic acute anterior dislocation of the shoulder with Bankart lesion**, **treat by surgical treatment** (arthroscopic Bankart repair *plus* immobilization *plus* rehabilitation protocol), **have better results** (reduce the rate of redislocations, improve disease-specific quality of life, and not decrease range of motion) **than conservative or non- surgical treatment** (immobilization *plus* rehabilitation protocol).

5. OBJECTIVES

5.1 Generals

The aim of this protocol is to compare the effectiveness between the surgical versus non-surgical treatment for the first-time traumatic anterior dislocation of the shoulder with Bankart lesion.

We include physically active individuals (score of 40-80 in the Physical Activity Index) with primary dislocation, with ages between 18 and 30 years old.

5.2 Specifics

To compare short-term and long-term results after a surgical treatment or non-surgical treatment of a traumatic anterior shoulder dislocation, in its first-time, studying the following clinical outcomes:

Primary outcomes:

- Rates of recurrences (second dislocation or symptomatic subluxation or instability preventing return to full active duty and/or necessity of an additional surgical stabilization procedure)

Secondary outcomes:

- Non-return to pre-injury level of activity
- Persistent pain
- Instability (objective or subjective)
- Quality of life (WOSI questionnaire and SF-36 test)
- Range of movements
- Complications of treatment
- Patient dissatisfaction.

6. METHODS

6.1 Types of studies

To obtain high-level evidence, a clinical trial is needed. It will be a controlled, randomized and single blind trial. A research assistant, who was unaware of which "treatment-group" the patient had been assigned to, will do the examinations. To achieve this, patients will wear a black t-shirt for all evaluations, so the presence or absence of surgical incision could not be detected.

The centre of reference will be Hospital Universitari Dr. Josep Trueta. Patients of Hospital Santa Caterina, Hospital de Blanes and Hospital d' Olot, could also be referred to this centre.

The duration of this trial will be approximate of 10 years. The results will be recorded in five moments, at 6 months (after the rehabilitation, either surgical or non surgical group), at 12 months, at 24 months, at 60 months and at 120 months.

If the patient form part of the surgery group, the patient will have an additional appointment with the nursery group of his primary care assistance (extern to our team) for the care of the stiches. If is needed additional appointments with an orthopaedic surgeon (extern to our study) will be done. Those appointments will not be related to our study.

6.2 Outcomes

In order to assess the proposed objectives, study variables are described as:

6.2.1 Independent variable

Type of treatment (*surgical* or *non-surgical* treatment)

6.2.2 Dependent variables

Primary outcomes

- *Re-injury or recurrence* → It will be measured with the incidence of second dislocation, symptomatic subluxation or necessity of an additional surgical stabilization procedure.

Secondary outcomes

- *Non-return to pre-injury level of activity (sports or work).* → The examination will be done using the Physical Activity Index of the AAHF. **(Annex 3)** The data will be recorded as "yes" or "not" comparing to the initial level of activity.
- *Persistent pain* → Patients will be asked if they have residual pain. The data will be registered with the visual analogue scale (VAS). **(Annex 4)**
- *Objective instability: re-dislocation or subluxation* → Measured with clinical examination

- *Positive apprehension test* → the data will be registered as "positive" or "negative" test.
- *Instability ROWE shoulder score* **(Annex 5)**

- *Subjective instability* → patients will be asked if they feel instability of the shoulder joints. The data will be registered as "yes" or "not".
- *Quality of life* → We will use these scores:
  - *WOSI questionnaire: Disease - Specific quality of life (instability)* **(Annex 6)**
  - *SF-36 test* **(Annex 7)**
- *Range of movement: % of normal side.* → Degree of motion measured with clinical examination in all range of movement (flexion, extension, abduction, internal rotation and external rotation). It will be compared to the no affected arm to establish the baseline. It will be measured as percentages.
- *Complications* →It will be measured with the incidence of sensory deficit, infection, osteoarthritis or other complications
- *Patient dissatisfaction.* → patients will be asked if they are satisfied with the treatment results. The data will be registered as "yes" or "not".

6.3 Population of interest

The study population will be patients aged between 18 and 30 years old who present a first-time traumatic anterior dislocation of the shoulder that meet the following criteria:

6.3.1 Inclusion criteria

- Diagnose in the acute moment of the luxation by an emergency physician, and or, by an orthopaedic surgeon.
- The anterior dislocation is the initial episode.
- The dislocation requires a manual reduction by physician or trained health professional. If the on-field reduction was unsuccessful, pre-reduction radiographs will be obtained, and the reduction will be performing under intravenous sedation.
- An Anteroposterior and West Point radiographs will be obtained in all patients after the reduction, taking care there is no exclude criteria.
- Also we will obtain an artro-MRI image of the shoulder joint, in the acute moment. The result of the artro-MRI should be distension of glenoide capsule with a concomitant Bankart lesion.
- We should demonstrate a pre-injury activity level of 40-80 in the Physical Activity Index of the AAHF. **(Annex 3)** If we are not sure, the patient we will be excluded.

6.3.2 Exclusion criteria

- Degenerate shoulder dislocation.
- The patient has concomitant neurologic injury (e.g. axillar compression).
- The patient has concomitant lesions, such Hill-Sachs, fractures or other concomitant damage, in exception of Bankart lesion.
- The patient had history of subluxation or impingement, possibly suggesting occult subluxation.
- Cannot be participants, the patients who take part in an elite sport team or practice high-level competition activities. Also, the ones who work in high-physically-demands jobs.
- Rheumatic or other traumatic injuries in the shoulder before the dislocation.
- The presence of rheumatic systemic illness, such fibromyalgia or arthritis rheumatoid.
- Past surgeries in the injured shoulder.
- Concomitant lesions or conditions that can difficult the exploration and treatment.
- The presence of contradictions to the surgery.
- Medical conditions limiting expectancy of life

6.4 Sample selection

The sample selection will be consecutive and non-probabilistic. All patients who came in the Emergency Department (ED) of Hospital Universitari Josep Trueta of Girona, Spain or referred to us, from Hospital Santa Caterina, Hospital de Blanes and Hospital d' Olot, Girona, Spain, and complain the inclusions and not the exclusions criteria will be offered to be enrolled in this trial. Interested patients will be informed about the study with an information sheet. **(Annex 8)** Afterwards, they should sing an inform consent. **(Annex 9)** If the patient, during the study, wants to revoke this consent should sign the revocation. **(Annex 10)**

6.4.1 Sample size

The calculation of the sample size has been done by the Institut Municipal d'Investigació Mèdica (IMIM) calculator program. We calculated it, base on our principal outcome, the rate of recurrence.

Based on the studies of Bottoni 2002 (34), Arciero 1994 (35), Kirkley 1999 (36), Kirkley 2005 (38), Sandow 1996 (39), Jakobsen 2007 (40) the approximate incidence of recurrence dislocations is about 12% in surgical group and 65% in non-surgical group. Accepting an alpha risk of 0.05 and a beta risk of 0.2% in a bilateral contrast, and with a 10% rate of lost

patients during the follow-up, 13 subjects in the surgical group and 13 in the non-surgical group are necessary to recognize statically significance.

To be similar to the real population, the gender rate will be 9M:1F. So, in each group shall be composed of 12 males and 1 female.

Incidence of shoulder dislocations in Girona is estimate on 11 cases per year (considering Goss TP (6) study's data and the population of the city of Girona). Therefore, two years and a half are needed at less to reach the sample size. Considering that Hospital Universitari Dr. Josep Trueta can assume patients of the entire province of Girona, therefore, we think than with two years or less, we can reach the sample size.

6.5 Randomization

After patient had accepted to entry in the study signing the informed consent **(Annex 8**) and the subsequent diagnose of Bankart lesion by artro-MRI is done, the patient will be subscribed to the database program, created by a statistician.

A statistician expert will create a database containing ordered codes, which will be assigned consecutively to each participant. There are going to be as codes as patients estimated on the sample size, 26 patients in total. A statistical program will randomize the codes, which will indicate if the patient gets treatment S or NS (surgical or no-surgical). The randomization codes will take into account the sex of the patients, so in each group will be 12 males and 1 female.

6.6 Masking techniques

Studies applying surgical techniques have a detection bias, due to be impossible of blinding the surgery. In this study, patients will not be able to be "blind" either, because they will know the treatment applied.

To minimize this type of bias, the examination will be done by a research assistant who was unaware of which treatment group the patients had been assigned to. To achieve this, the patients will wear a black t-shirt for all evaluations, so the presence or absence of surgical incision could not be detected. So, this study will be an examiner blind trial.

Statistical consultant will not know which intervention is assigned to each patient, when he collects the data. Patient's name and treatment will not appear in examination records. By this way, the detection bias will be reduced.

6.7 Study intervention

The aim of this study is to compare the efficacy in the two different treatments options, basically the subsequent re-dislocate rate. One group will be describing as *S: Surgical treatment*. The other group will be *NS: non-surgical treatment*.

Patients with a traumatic acute anterior dislocation of the shoulder in their first episode, diagnosed by a physician or orthopaedic surgeon, that meet the inclusion criteria and no

exclusion criteria, comprised our study population. Radiographs will be done after reduction manoeuvres. If bony lesions are present, the patient is not longer in our study.

Once the patient is diagnosed, he will be asked to take part in our study. An information sheet **(Annex 8)** will be given to inform him about our study and both treatments. Emphasizing that, although conservative treatment is now the suggested one, arthroscopic Bankart repair has been reported for the treatment of chronic anterior instability, but the application for an initial episode, is investigational.

If the patient agrees the information consent, **(Annex 9)** we will do a subsequent artro-MRI request, in an urgent form. The imaging test will be done searching for Bankart lesion. The patients, who had Bankart lesion and not other ones, will continue in our study.

After the confirmation that the patient takes part of the study, randomization will proceed **(6.5 Randomization)**.

The next appointment will be in one week or less, and during the week, all patients will wear a sling. In this appointment, the artro-MRI and the randomization will be done, so the treatment will be informed.

If the patient takes part of the *non-surgical treatment*, it will be performed immediately (keeping the sling three more weeks).

If the patient takes part of the *surgical treatment*, the doctor will inform the surgery procedure. The surgery will be programmed at the operating room of "Hospital Universitari Dr. Josep Trueta" with the shoulder surgeon team's program within four weeks, after obtaining the surgical consent. **(Annex 11)**

6.7.1 Intervention NS: Non-surgical treatment

The patients will be immobilized for three weeks more, with a Gill-Chirst ® sling. During this time, they were allowed to remove it for bathing and mobilizing the elbow and wrist. They will start a physiotherapy program to rehabilitate the shoulder. **(Annex 12)**.

6.7.2 Intervention S: Surgical treatment

Surgery was performed within four weeks of the acute dislocation in all patients in this group. The patient should have been immobilized the shoulder one week (during the diagnose and randomization). The patients were allowed to mobilize the shoulder (controlling extremes movements) on their own, before the surgery, to ensure that none of the patients entering surgery had a stiff shoulder, which, in theory, would increase the risk of arthrofibrosis.

The surgery is an arthroscopic Bankart repair, described in *1.6.2 Surgical treatment*.

After the surgery the patients should be immobilized for three weeks more, with a Gill-Chirst ® sling. During this time, they were allowed to remove it for bathing and mobilizing

the elbow and wrist, and they will start a physiotherapy program to rehabilitate their shoulder. **(Annex 12)**

The patient will be scheduled to the nursery group of his primary care assistance (extern to our team), for the care of the suture and stiches. If is needed additional appointments with an orthopaedics surgeon (extern to our study) will be done. Those appointments will not be related to our study.

6.8 Data collection

First Visit – ED

A patient, diagnosed of glenohumeral dislocation on emergency room, requires a manual reduction by physician or trained health professional. If the on-field reduction was unsuccessful, pre-reduction radiographs will be obtained, and the reduction will be performing under intravenous sedation.

After reduction manoeuvres, patient will be explored and questioned about age, sex, profession, physical activity, mechanism of injury and number of glenohumeral dislocation in other to obtain ordinary clinical history.

After anamnesis, radiological examination (antero-posterior and west point radiographs) will be done.

If the patients meet the inclusion criteria but not exclusion, they will be proposed to participate in the study. We will give them the trial's information sheet, **(Annex 8)** and will be necessary to sign the informed consent. **(Annex 9)** After given his consent, we will program an artro-MRI, as quickly as possible. If the artro-MRI's diagnose is Bankart lesion, a code will be assigned to each patient for decide with treatment will be applied. **(6.5 Randomization)**

After a week of the acute dislocation, the patient will be scheduled to the Orthopaedic Service. All patients will wear a sling during this week.

Second visit – Orthopaedics Service

In this appointment, a week after, we will fill in the Participant Data Sheet **(Annex 13)** with patient's data and the code of the patient. Statistical program and the code, will give us the information of treatment group the patient take part in.

- If the patient take part in the *non-operative group*, *(6.7.1 Intervention NS: Non-surgical treatment)* will be treat in the orthopaedic service, with immobilizing the shoulder three weeks more and will be referred to Physical therapy following the protocol **(Annex 12)**
- If the patient takes part in the *operative group*, the patient will sign the surgery consent **(Annex 11)** and will be programed to the surgery within four weeks. *(6.7.2 Intervention S: Surgical treatment)*

Third visit –Intervention S

Hospital admission

Patient will be admitted on OTS unit the day programmed. Nursery team will check vital signs before the hospitalization. Proceeding surgeons will explore and assess the patient during the hospitalization before the intervention.

Preoperative assessment

Anaesthesiologist will assess the patient before the intervention during the patient's hospitalization. American Society of Anaesthesiologists (ASA) Physical Status Classification System score will be use for surgical risk. **(Annex 14)**

Operative assessment

All members of the shoulder surgical team know the procedure and they will be trained before the trial starts. The procedure will be done by a shoulder surgeon, one OTS resident doctor, the usual instrumentalist nurse on trauma surgery and an anaesthesiologist.

Intervention *(1.6.2 Surgical treatment)* will be performed in the operating room. Time of surgery, from the skin incision to the skin bandage, is less than 60 minutes. Any complication during the procedure must be registered. Patients will use a simple Gill-Christ ® sling, during three weeks. After that, they will be referred at Physical therapy following the protocol. **(Annex 12)**

Postoperative assessment

Patients will stay in the post-surgical unit until recovering from anaesthesia. After their recovery, patient will return at OTS unit until the next morning. Nursery team will register all the incidences during the hospitalization and OTS doctor will discharge the patient.

The follow-up visits and the additional visit for the suture remove will be scheduled at the patient's leaving, with the nursery group of his primary care assistance (extern to our team).

Follow-up

The duration of this trial will be approximate of 10 years. The results will be recorded in five moments, at 6 months (after the rehabilitation, either surgical or non surgical group), at 12 months, at 24 months, at 60 months and at 120 months.

A research assistant will do all the trial's visits, the examination and the collection of the information to the Participant Data Sheet. **(Annex 13)** During the examination, the patient should wear black t-shirts to prevent the detection of surgical incisions.

If any complication appears after the intervention the patient should come back as soon as possible.

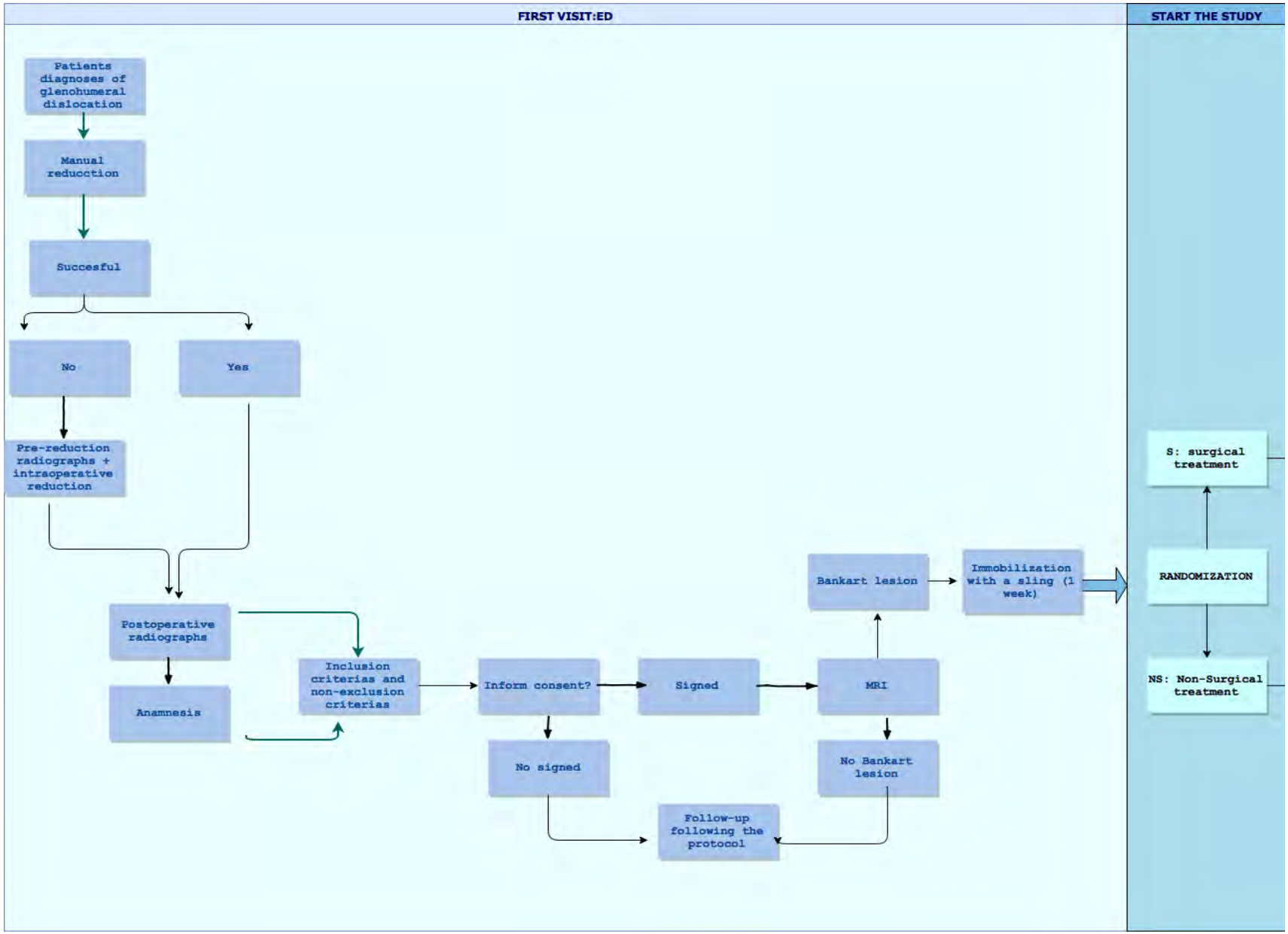
The follow-up examination will record the result of these items **(6.2 Outcomes)**:

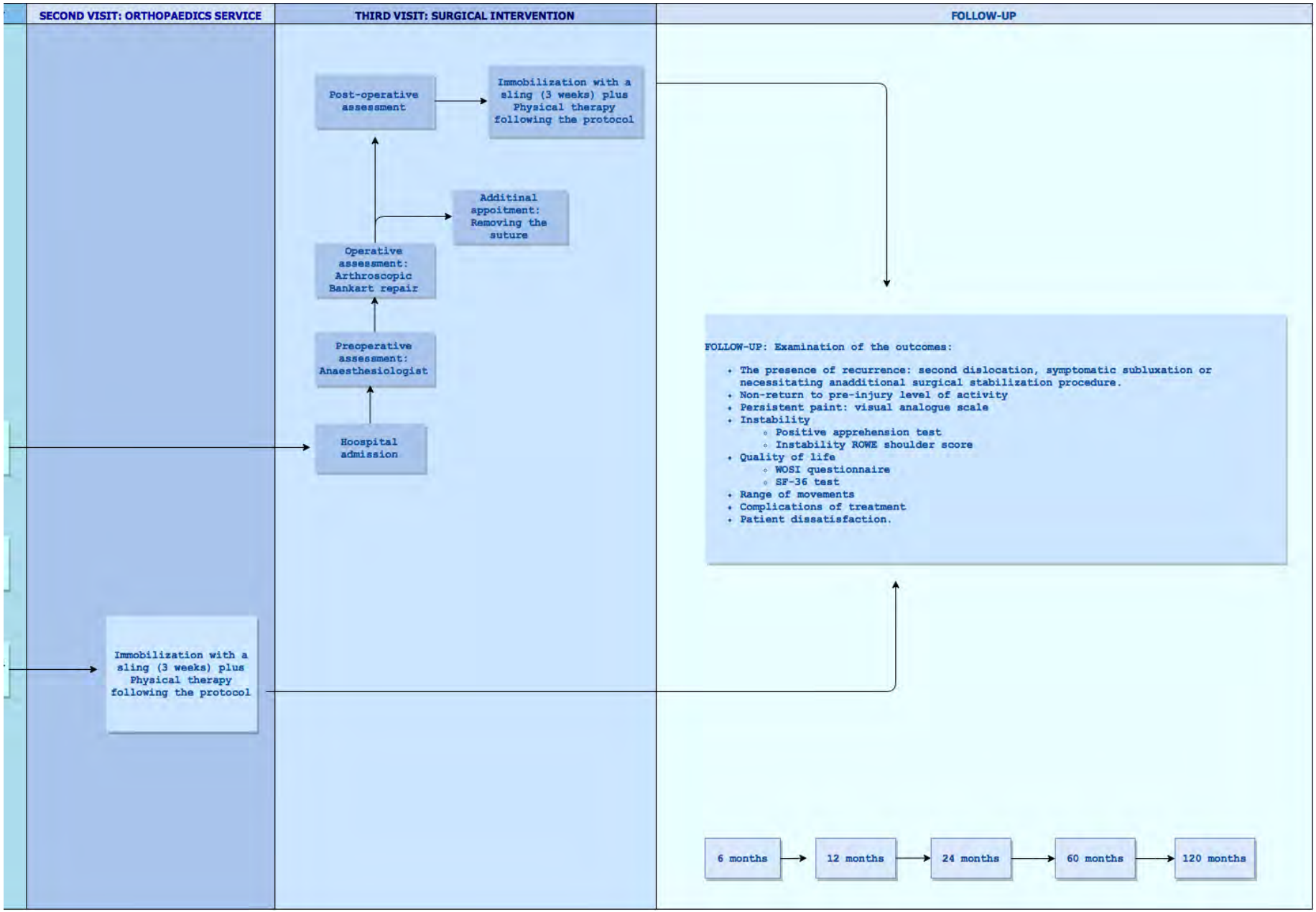
- The presence of recurrence:

    - Second dislocation, symptomatic subluxation or necessity of an additional surgical stabilization procedure.

- Non-return to pre-injury level of activity
- Persistent pain: VAS
- Instability
    - Positive apprehension test
    - Instability ROWE shoulder score
- Quality of life
    - WOSI questionnaire
    - SF-36 test
- Range of movements
- Complications of treatment
- Patient dissatisfaction.

6.8.1 Algorithm of assessment




SECOND VISIT: ORTHOPAEDICS SERVICE
THIRD VISIT: SURGICAL INTERVENTION
FOLLOW-UP
Post-operative assessment
Immobilization with a sling (3 weeks) plus Physical therapy following the protocol
Additinal appoitment: Removing the suture
Operative assessment: Arthroscopic Bankart repair
Preoperative assessment: Anaesthesiologist
Hoospital admission
Immobilization with a sling (3 weeks) plus Physical therapy following the protocol
FOLLOW-UP: Examination of the outcomes:
The presence of recurrence: second dislocation, symptomatic subluxation or necessitating anadditional surgical stabilization procedure.
Non-return to pre-injury level of activity
Persistent paint: visual analogue scale
Instability
Positive apprehension test
Instability ROWE shoulder score
Quality of life
WOSI questionnaire
SF-36 test
Range of movements
Complications of treatment
Patient dissatisfaction.
6 months
12 months
24 months
60 months
120 months

6.9 Statistical analysis

The calculation of the sample sizes has been done by the Institut Municipal d'Investigació Mèdica (IMIM) calculator program. We calculate it, based on our principal outcome, the rate of recurrence. *(6.4.1 Sample size)*

For the statistical analysis, we will use the Statistical Package for the Social Science software (SPSS), 20.0 Windows ®'s version.

6.9.1 Univariate analysis

The results will be expressed as **percentages** for *categorical variables*.

For *quantitative variables*, we will use the **mean +/- standard deviation** (SD) or **median** for *continuous variables*, depending on whether or not, they are normally distributed, respectively.

6.9.2 Bivariate analysis

The **Relative Risk (RR)** with a confidence interval of 95% will be calculated for each group, to analyse our *primary outcome (rate of recurrences).*

$$\frac{Rate\ of\ patients\ with\ recurrence\ in\ the\ surgical\ group}{Rate\ of\ patients\ with\ recurrence\ in\ the\ non-surgical\ group}$$

With a RR <1 surgery prevents of recurrence episodes after the intervention. With a RR>1 surgery treatment increases the risk of recurrence episodes. RR=1 means no statically significant differences.

To *compare secondary outcomes* (Non-return to pre-injury level of activity, pain, range of movements, joint instability (Rowe score), quality of life, patient's dissatisfaction) between both treatments will be use the **T-student or U-Mann-Withney test**, whether or not they are normally distributed, respectively.

To *compare outcomes based on frequencies* (joint instability, complication) of each **intervention a χ^2 (chi Square) test** will be used.

6.9.3 Multivariate analysis

We define strongly our population to avoid confusion variables.

Even though, if during our study, we find possible confusion variables, we will use **multivariate logistic regression analyses** to see possible contribution of them. A confidence interval of 95% will be assumed and P-value <0.05 to consider statically significant differences.

7. WORK PLAN

Researchers: Dra. María José Martínez (**MJM**), Laia Boadas i Gironès (**LBG**)

Collaborators: Emergency department physician (**ED-P**), Shoulder surgeon team (**SST**) (MJM + shoulder surgeon 2), Resident doctor (**OTS-R**), Surgery Nursing Staff (**SNS**), OTS Doctor (**OTS-D**), OTS Nursing Staff (**OTS-NS**), Health Care Nursing Staff (**HC-NS**) Statiscian (**ST**)

7.0.1 Phase 0: Preparation – 1 month

MJM, LBG. Protocol must be accepted by the Ethics Committee of Clinial Research.

7.0.2 Phase 1: Coordination - 2 month

The protocol will be detailed to all the members, explaining the patients' recruitment, the data collection and the role of all the collaborators. We will revise the procedure with the surgeons.

7.0.3 Phase 2: Field work – 24 months

Recruitment will take 2 years approximately and it will be took place on Emergency Room Department (**ED-P**). Patients, who meet our inclusion but not exclusion criteria, will be our participants.

Potential participants, who want to take part into the trial, will be scheduled to a second visit with the **SST** within a week. During this week all participants will be immobilized with a sling (by **ED-P**) and an arto-MRI will be done.

If the patient had Bankart lesion will be included in our study and a code will be assigned for every patient and the **ST** will do randomization.

In the second appointment with the **SST**, the patient will know if they are candidate to our protocol and which treatment they will receive.

- Non-surgical group: the immobilization will continue until the fourth week from the acute moment.
- Surgical group: will be assigned to the surgery team within three weeks (four from the acute moment).
    - **SST** and **OTS-R** will do the surgery
    - **SNS** will instrument the intervention
    - **OTS-NS** will take care of the patient during the hospitalization and the **SST** will visit them for discharge them to home.
    - **HC-NS** will take off the suture within 15-20 days from the surgery

7.0.4 Phase 3: Follow-up – 120 months

The follow-up will be done by an external examiner **OTS-D** as blind investigator. It will last 120 month. Control visits will be programed at 6 months, 12 months, 24 months, 60 months and 120 months from the acute episode.

In the surgical group, if is needed additional appointments with an orthopaedics surgeon (extern to our study), will be done. Those appointments will not be related to our study.

7.0.5 Phase 4: Data collection – 120 months

During the follow-up the **OTS-D** will registered the examination to a database. (**Annex 13: Participant Data Sheet**). Every 3 months a **Clinical Research Associate** will control that protocol it is being followed and all data is properly registered.

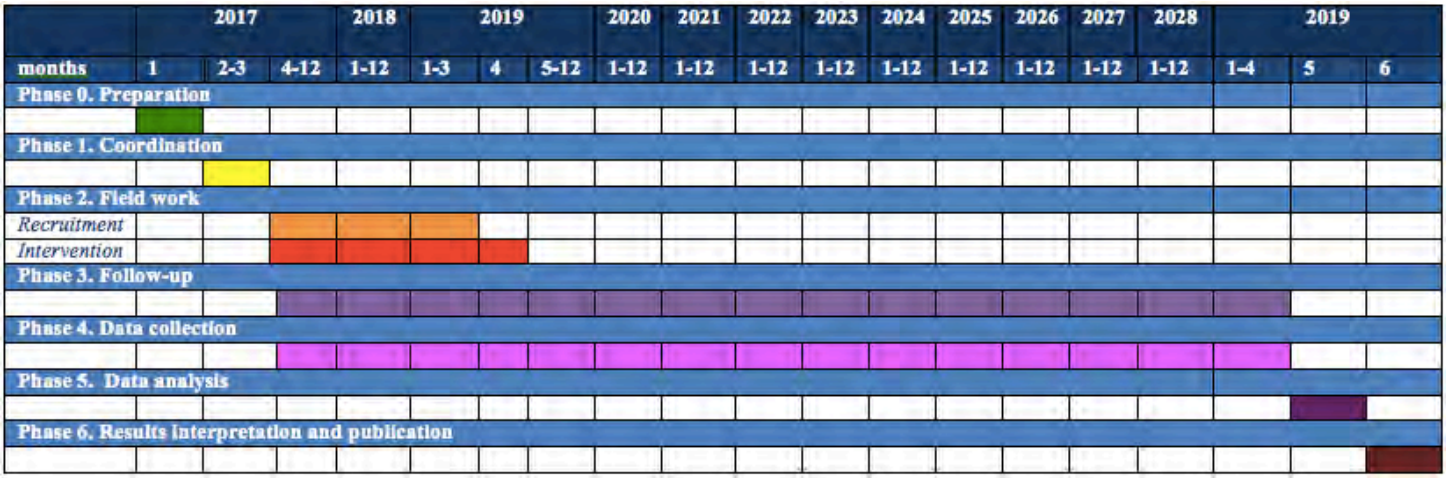
7.0.6 Phase 5: Data analysis- 1 month

The **ST** will analyse the data collected using the exposed statistical test. (**6.9 Statistical analysis**).

7.0.7 Phase 6: Results interpretation and publication - 1 month

Once statistical analysis is performed, principal investigators **MJM** and **LBG** will interpret the results and write down the conclusions in a scientific paper. Articles will be sent to different journals for its publication.

7.1 Chronogram



Phase 0: **MJM, LBG**.
Phase 1: **MJM**, **LBG, SST**, **OTS-R**, **ED-P**, **SNS**, **OTS-D**, **OTS-NS**, **HC-NS**, **ST**.
Phase 2 recruitment: **ED-P**, **SST**. Phase 2 intervention: **SST**, **OTS-R**, **SNS** , **OTS-NS**, **HC-NS**.
Phase 3: **OTS-D**.
Phase 4: **OTS-D (*plus* Clinical Research Associate)**.
Phase 5: **ST**. Phase 6: **MJM, LBG**.

8. DISSEMINATION PLAN

Our study is about the treatment of the traumatic shoulder dislocation. Nowadays, surgical treatment is indicated to recurrence dislocation or residual instability. So, if the results approve our hypothesis, the results should be diffuse to explain the treatments innovations in this field.

We want to diffuse our study in medical journals with the highest impact factors, meetings, training sessions, reports and other documents. “Sociedad Española de Cirurgía Ortopédica y Traumatología” (SECOT) congress could be a good location to start to diffuse the results.

9. STRENGTHS AND LIMITATIONS

The consecutive recruitment proposed in this study want to obtain a representative population. We try to include in our study population, the same gender amount than the general population, to have the necessary external validity to extrapolate the results.

Inclusion and exclusion criteria are design to try to diminish the possible confusing factors, so no covariates are found. This study will not include high-active people, because in this small population, we know that surgery is better than conservative management. Also, including this people in our study can confuse the results because of their shoulders’ high demands.

The available literature supports early surgical treatment, especially in a close-defined population with a high risk of recurrences (young, male, athletes and/or with a high demanded physical activities). However, further clinical trials of good quality comparing surgical *versus* non-surgical treatment for well-defined lesions are needed, especially for categories of patients who have a lower risk of recurrence. Our aim is to try to solve this weak point.

This study will not include patients younger than eighteen. This exclusion criterion is because of difference in the histology composition of their joints. Also, older than thirty had difference in the histology and also they have worse outcome with operative treatment, in past studies. These exposed facts may cause a selection bias.

A low rate of recruitment, high rate of loses and withdrawals during the follow up can also cause a selection bias. A low rate of recruitment can be solved with high trained personal explaining well our study to the patient and with a good information sheet. **(Annex 8)** If there is a high rate of recruitment, a survey form will be gave to the patients to know the reason of the denial to the recruitment. Loses will be quantified, to avoid that loses affect the study, sample size is already calculated with expectations of future loses. Withdrawals will be registered in the study and described in the results. Finally, we know that in a long-term study, we may have a higher loses. But, for our main goal, long period results were

necessary. For that reason, we had increased the rates of losing in following-up comparing to the references, when we measured the sample (10%).

Operative management will be performed by different surgeons, which may cause a procedure bias. Meetings with the most experienced shoulder surgeons in orthopaedic service, detailing the intervention to standardize the technique, before starting the study, will try to diminish procedure bias.

The main strength of this protocol is the experimental randomized blinded design, regarding other projects with similar hypothesis.

Difficulties on designing a triple blind study when surgical techniques are performed may cause a detection bias. Examiners who assess patients during the follow-up will be blind and patients will wear a black t-shirt for all evaluations so, the presence or absence of surgical incision could not be detected. Also, the statistician will be blind when analysing the obtained data. “Patient’s” blind cannot be controlled because the patient will know which treatment he received and this can produce a limitation.

Randomization will help to distribute systemically the patients (keeping in mind the sex proportion) in both groups, to be able to extrapolate the future results on general population between 18 and 30 year old.

Sample size and methods are designed to studying the main objective (re-dislocation rate) and it is not consider to the secondary variables, but they will be studied too. The results of the secondary outcomes could not have sufficient validity, to be extrapolated. So, if these results seem to have significant differences between both treatments, could contribute as valuable data for further studies.

We focus in uni-centric study to be aware to have the less losing follow-up and high consistency, possible in our study. Even though, a multi-centric study may increase the statically power and reduce time of recruiting. For that reason, the patients derivate from other hospitals from Girona’s province can be accepted.

Clinical outcomes will be assessed with validated scales and the result could be compared to other studies. It will contribute as valuable dada if further meta-analysis will do.

10. FEASIBILITY

Experience of the research team

In order to put this project into action we will form a suitable medical team and a multiprofessional team. The main investigators will be María Jose Martínez, OTS surgeon at Hospital Universitary Dr. Josep Trueta and Laia Boadas i Gironès, Medical Student at Universitat de Girona..

This clinical trial is composed by an interdisciplinary team. The surgeons, who will do the procedure, will be the ones with such experience in arthroscopies, like the Shoulder Surgeon Team in OTS of Hospital Universitari Dr. Josep Trueta. The nursing staff will be the usual workers on our OTS service used to handle trauma and orthopaedic surgeries and its post surgeries. As we do not have specialized professionals in statistics, we will hire an external statistician to do the statistical analysis. The examiners also will be external to the OTS service. The National Health System will hire all workers, in exception of the statistician.

Availability of Resources:

The operation room will be the orthopaedic operating room. As the arthroscopic Bankair repair is already doing in Hospital Universitari Dr. Josep Trueta, with another indication, all the resources are in stock. Also, there is in stock Gill-Chirst® sling on the Emergency Department for non-operative treatment.

Patients in surgical group will be hospitalized until the next day after the intervention, on COT service, so the bed must be available.

Material non-operative treatment: Gill-Chirst ® immobiliser

Material operative treatment: Shoulder arthroscopic surgery box, Fiber-Wire suture, BioComposite™ PushLock® 3,5x19,5mm tacks, arthroscopic equipment, sterile gloves and sterile gowns, sterile compresses, suture, sterile bandages, Gill-Chirst ® immobiliser

Sample feasibility:

It is estimated that, in the Hospital Universitari de Girona Doctor Josep Trueta, more than 11 patients per year will be diagnosed of a traumatic anterior acute shoulder dislocation with Bankair lesion, and will be candidates for our study.

In addition, Hospital Dr. Trueta could assume patients from the entire province (Salt, Blanes, Olot), so the rate of diagnose could increase.

To find the main hypotheses relevant, it is estimated that the sample size should be 26 patients, so we expected than in two years of data collection, we would meet our goal.

11. IMPACT OF THE PROJECT

There is no consensus for the treatment in first-time anterior traumatic shoulder dislocation, so with this study it is expect to provide significant data to choose the optimal treatment. Generally, arthroscopic Bankart repair has been reported for the treatment of chronic anterior instability but its application for the initial episode was investigational.

Operative treatment may seem risky in comparison with the conservative but, if our hypothesis is correct, with this surgery, after the initial episode of dislocation, we can reduce the rate of recurrence (second dislocation, symptomatic subluxation or necessity of an additional surgical stabilization procedure).

The high risk of recurrence after a shoulder dislocation can produce healthy problems like an increment of complications after news re-dislocations, pain, shoulder instability, fear to re-dislocation, anxiety, no-return to previous activity level or economical problems (day off work, immobilization, rehabilitation…). So, operative treatment can get better the quality of life of our patients.

It is expected also, if the hypothesis is not confirmed or we find new relationships between the outcomes, to encourage other research teams performing new studies about this item.

12. BUDGET AND ASSISTANCE REQUEST JUSTIFICATION

Research team personnel are employees of Hospital Universitari Dr. Josep Trueta or other National Health System services. For this reason, it is no necessary that any worker earns additional money.

It is necessary external staff like a statistical expert for data analysis. It is calculated a need of 48 h in the preliminary study (randomization program), and 16 h more after the data collection (statistical analysis) (64h). Also, is needed an external skilled staff to carry out the data monitoring, quality control data and regular submissions to the Spanish Medicine Agency. We calculated 3h of work par 3 weeks, for 10 years of study (520h).

	Category	Cost/time	Time	Cost
STAFF	***Statistical expert for data analysis***	35€/h	64h	2.240€
	Clinical Research Associate	30€/h	520h	15.600€
TOTAL				**17.840€**

The National Health System provides non-operative treatment materials, as well as, surgical material, because are already used as election when both treatments are applied out of the study. Patients treat with surgery will be hospitalized 2 days, the habitual procedure in these surgeries. It is not include on our budget, because it is already charge on the National Health System.

Printing and papers (information sheets, information consent sheets and participant data sheet) is nearly 50€.

	Category		Cost
MATERIAL	***Surgery material***	*Provided by the National Health System*	-
	Gill-Christ ® sling	*Provided by the National Health System*	-
	Printing and papers		50€
TOTAL			**50€**

In addition, patient will be insured for any possible damage during the intervention. The insurance policy cost is 6000€.

Once the study is finished, it is necessary to diffuse our conclusions to the scientific community. We want to publish them in scientific journals, and also presenting the project to the SECOT congress. Finally, we include a consignment of travel, accommodation and food, for the two investigators during the diffuse phase.

	Category		Cost
OTHERS	***Insurance policy***		6.000€
	Article Publication		1.500€
	Inscription to SECOT congress		700€
	Travel, accommodation and food allowances	*2 people - 400€/p*	800€
TOTAL			**9.000€**

The total budget is 26.890 €.

TOTAL	**26.890€**

13. ETHICAL AND LEGAL ASPECTS

Our ethical code and our good clinical practice will be based in the World Medical Association Declaration of Helsinki and the Col·legi de Metges de Catalunya, and will be developed following their criteria.

This trial and its methods will be present to Clinical Research Ethics Committee (CEIC) of the Hospital Universitari Dr. Josep Trueta for its approbation and registration in ClinicalTrials.gov and in EudraCT as regulated in the law 14/2007 of the 3rd of July about biomedical investigation.

Principle of autonomy will be respected, for this reason information sheet **(Annex 8)** will be present to our patients, which will explain our study, the treatments and all what the patient may know. The trial process also will be explained in the information sheet. Patient should read, understand and sign the inform consent **(Annex 9)** before be included to this study. In the case of going under operation treatment, another specific informed consent for the procedure. **(Annex 11)**

The aim of this trial is to find which treatment is the most effective of this pathology, first-time anterior shoulder dislocation with Bankart lesion. This knowledge can get only with human investigation. The existing trials comparing operative and non-operative treatment had limitations, but even thought the results are that surgery had less re-dislocations rates and better results, in general, than conservative management. We should remember than re-dislocations produce psychology problems (fear to another re-dislocation), economics problems (work off, medical products, physiotherapy…), subsequent surgeries, complications in the re-dislocation, or other.

Surgery treatments may be questionable conflicted because of summiting participants under an aggressive way of treatment. This research team believes that operative treatment is better to recover functionality and to avoid complication rates, than the non-operative management. In any case, participants will not be summited to a worst intervention therefore any ethical aspects will be violated.

The surgeons will be instructed and revise the surgery procedure, before the trial, to try to increase the treatment efficacy. The rest of investigators also will be instructed on their work. The previous instruction is very important to offer security, responsibility and efficiency of our scientific investigation.

Participant data will be handled respecting Spanish organic law 15/1999 of the 13th of December about data protection; confidentiality and protection of personal data and RD 1720/2007 of the 21st about of December on personal data protection must be guaranteed (personal identity, medical history, and results); during this study. In case of results publications, personal identity must not consist.

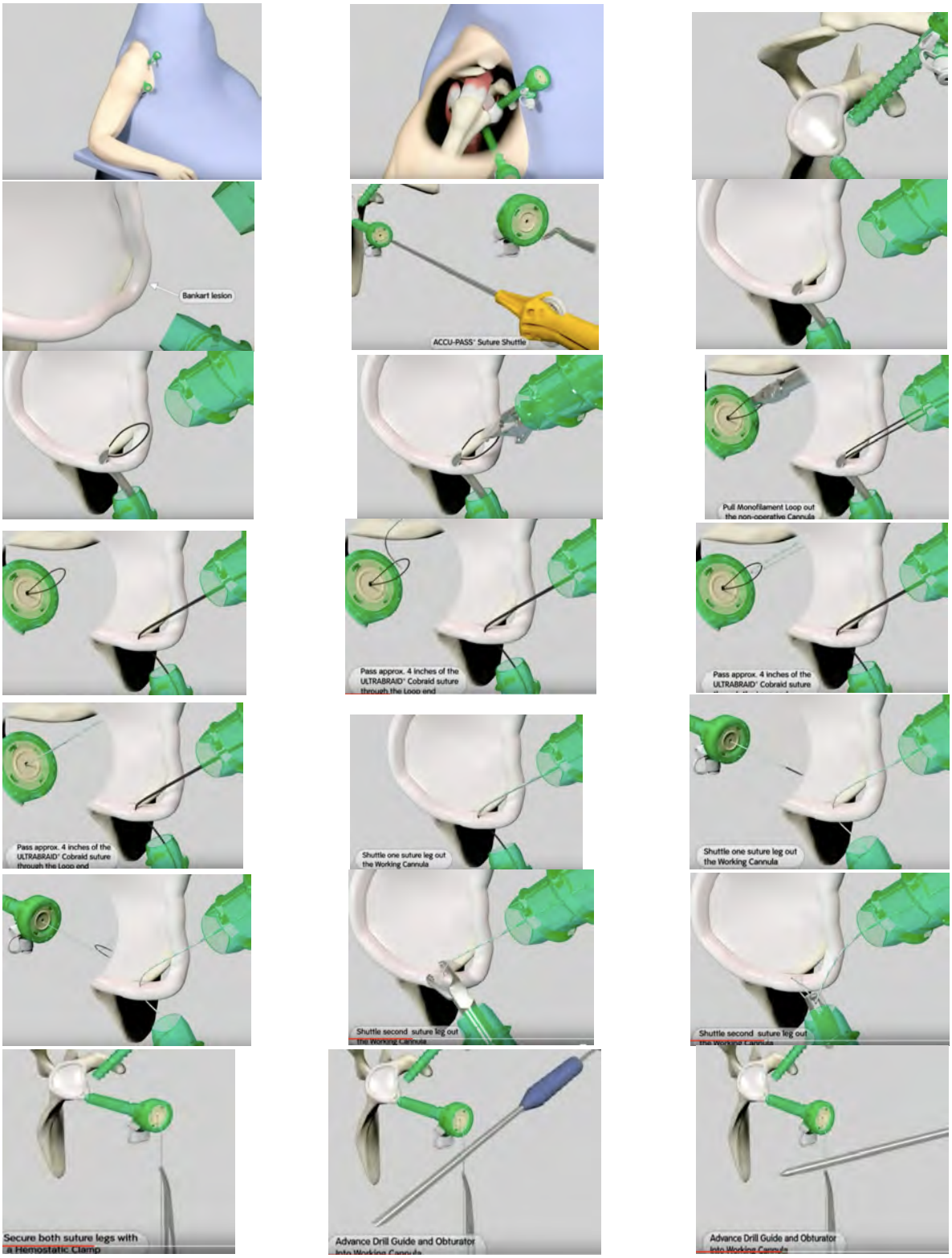
Stated in the Spanish Constitution of 1978, article 43, the right of health protection is preserved on this trial. All participants will be insured if any damage is caused.

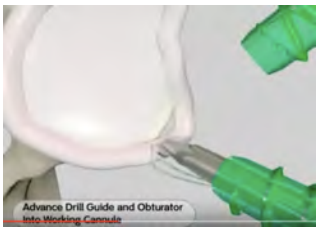
This trial will follow Spanish laws RD 1591/2009 of the 16th of October on drugs and health products and RD 1616/2009 of the 26th of October on research using health products.

The remaining exclusion criteria can be contradictory to the principle of justice and beneficence, too. But, we should remind that non-included patients would be treated with the more appropriate treatment (operative or non-operative) for their clinical situation.

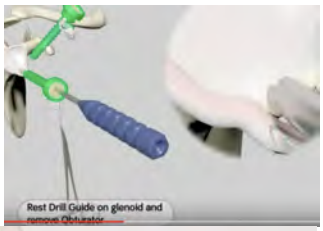
14. ANNEXES

Annex 1 - Bankair Repair Technique in Pictures.



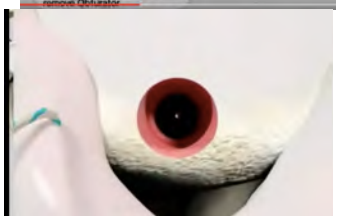

Advance Drill Guide and Obturator
into Working Cannula

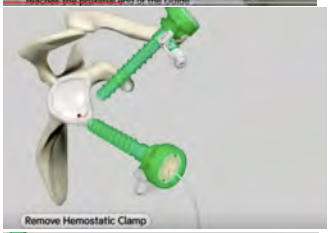

Rest Drill Guide on glenoid and
remove Obturator


Rest Drill Guide on glenoid and
remove Obturator

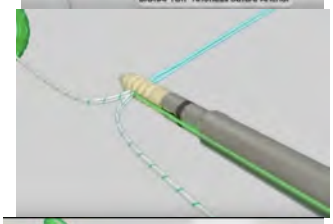

Advance Drill Bit until the Drill Stop
reaches the proximal end of the Guide

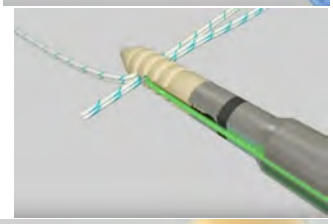

Advance Drill Bit until the Drill Stop
reaches the proximal end of the Guide

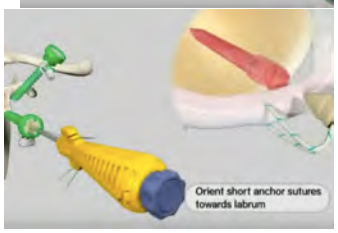


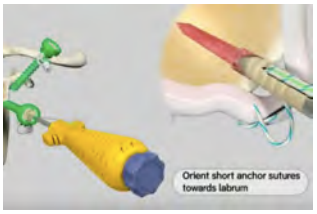

Remove Hemostatic Clamp

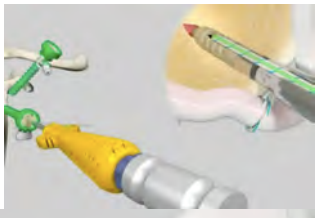

BIORAPTOR® Knotless Suture Anchor

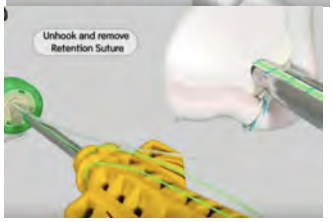


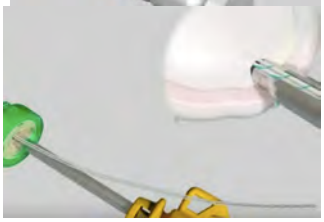


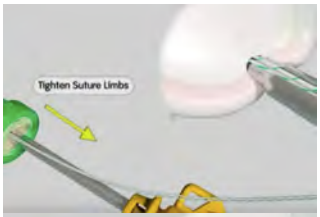

Orient short anchor sutures
towards labrum


Orient short anchor sutures
towards labrum

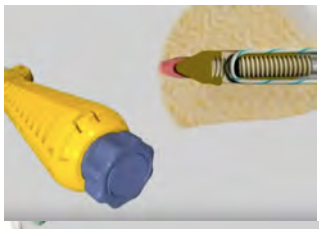


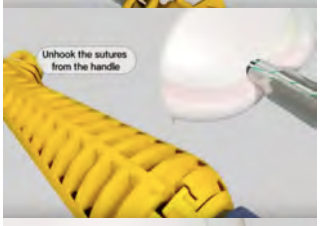

Unhook and remove
Retention Suture

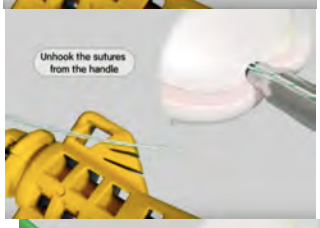


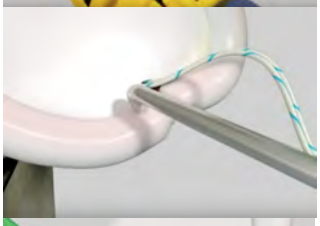

Tighten Suture Limbs

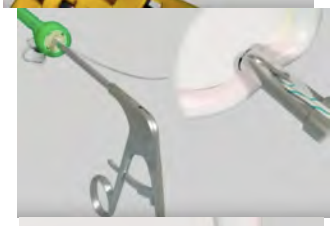

Lock sutures on the handle

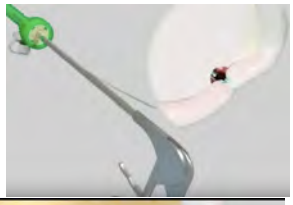


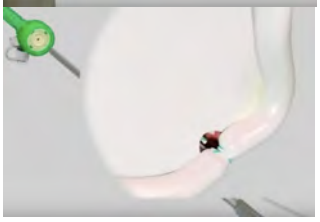

Unhook the sutures
from the handle

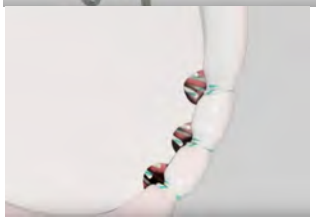

Unhook the sutures
from the handle

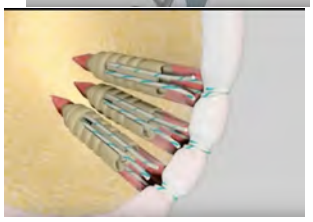












Annex 2 - Bankair Repair Technique in Arthroscopic Images

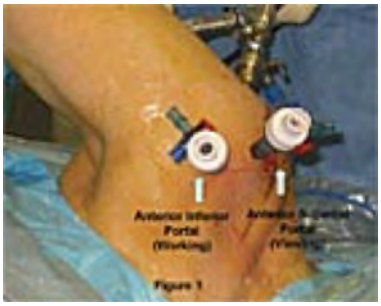


Fig 1: exterior view of dual anterior portal placement.

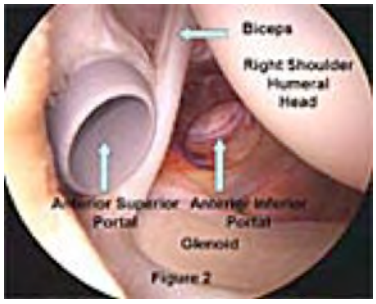


Fig 2: intraarticular view of dual anterior portals straddling the biceps tendon.

Fig 3: intrarticular view of posterior portal placement above the glenoid rim to facilitate instrumentation.

Fig 4: Visualization of the inferior GHL from the anterior superior portal

Fig 5: Bankart lesion seen from the anterior superior portal

Fig 6: In-substance capsular tear, which can lead to capsular lengthening compounding the instability of the Bankart lesion.

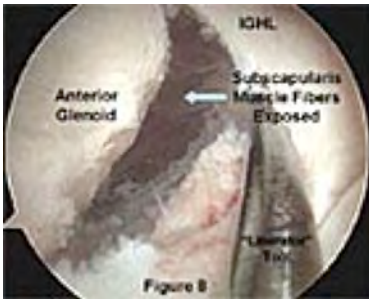


Fig 7: Subscapularis muscle fibers visible after the GHL is liberated from the glenoid. Appropriate tensioning of the ligament cannot be accomplished unless the inferior GHL is mobilized

Fig 8: Anterior ligamentous periosteal sleeve avulsion (ALPSA) with medial and inferior scarring on medial neck of the glenoid of a right shoulder seen from anterior superior portal.

Fig 9: Appearance after thorough mobilization of ALPSA lesion.

Fig 10: Grasping device used to evaluate inferior to superior tissue shift.

Fig 11: Placement of initial anchor at he 7 o'clock position (left shoulder); anchor insert 2 mm to 3 mm onto the glenoid face).

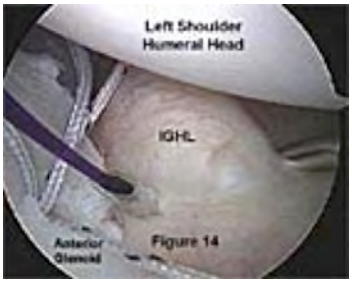


Fig 12: Suture hook loaded with No. 1 PDS (polydioxanone) passing inferior to anchor such that the tissue is shifted inferior. To superior in addition closing the Bankart defect

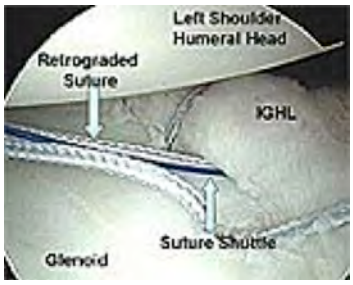


Fig 13: Permanent suture being retrograde through the inferior GHL using the PDS as a suture shuttling device.

Fig 14: Knot pusher delivers knot down the suture limb, which has passed through the labrum. Labral height is re-established.

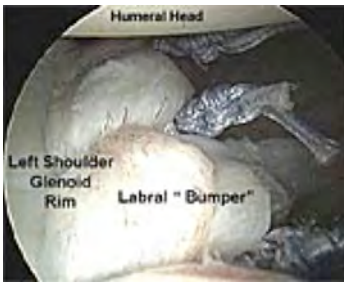


Fig 15: Completed repair with restored labral attachment, seen form the anterior superior portal

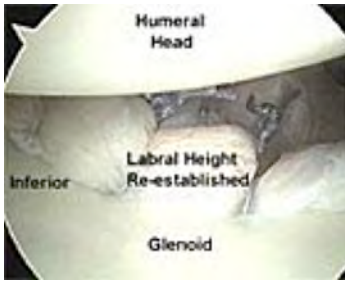


Fig 16: Completed repair from posterior portal

Annex 3 – Physical Activity Index of the AAHF

PHYSICAL ACTIVITY INDEX

Evaluate your current exercise program by selecting your score for each category.

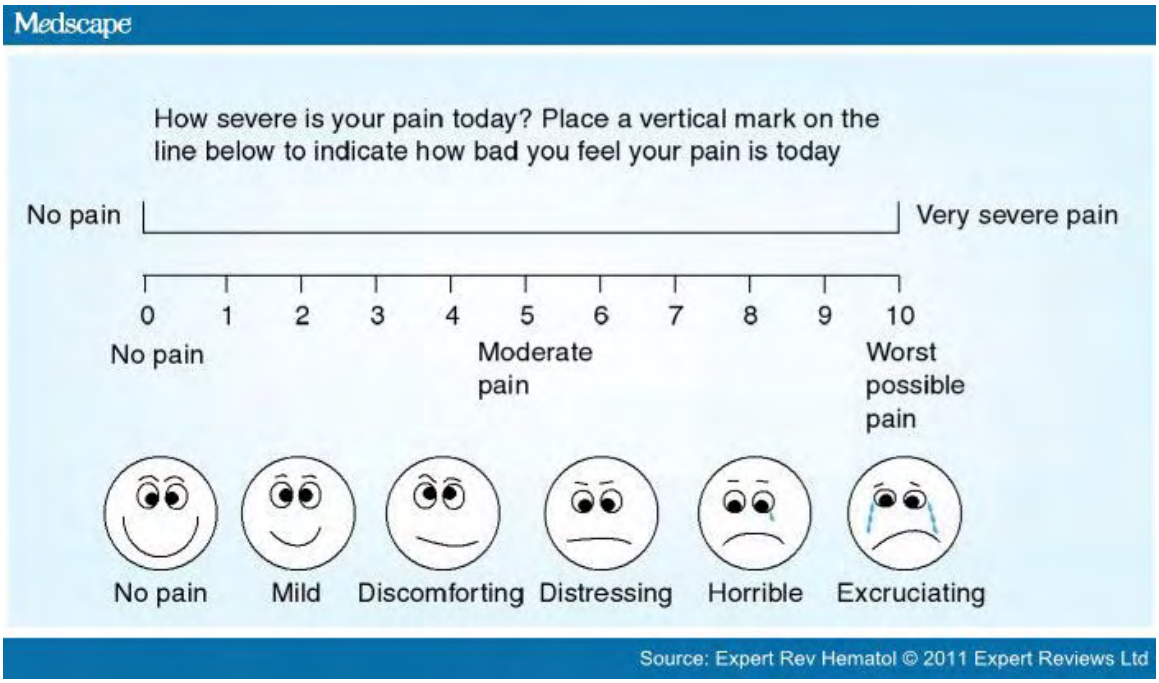
	Score	Activity
Intensity		
	5	Sustained heavy breathing and perspiration
	4	Intermittent heavy breathing and perspiration, as in tennis
	3	Moderately heavy, as in cycling and other recreational sports
	2	Moderate, as in volleyball, softball
	1	Light, as in fishing
Duration		
	4	Over 30 minutes
	3	20 to 30 minutes
	2	10 to 20 minutes
	1	Less than 10 minutes
Frequency		
	5	6 to 7 times per week
	4	3 to 5 times per week
	3	1 to 2 times per week
	2	A few times per month
	1	Less than once a month

Intensity X Duration X Frequency = Score Total

Your Score: _____ x _____ x _____ = _____

Evaluation of Activity Score		
Score	**Evaluation**	**Activity Category**
81 to 100	Very active lifestyle	High
60 to 80	Active and healthy	Very good
40 to 59	Acceptable but could be better	Fair
20 to 39	Not good enough	Poor
Under 20	Sedentary	

Annex 4 - Visual Analogue Scale



Annex 5 – Instability ROWE shoulder score 1981

There are several Rowe scores, 1978, 1981, 1982, 1988. Each Rowe score version is an updated version of the previous version, the latest Rowe score version (1988) should consequently be used; however, it has never been published in a scientific journal, and significant differences appeared between experienced examiners using the categorical classification of the total score

An argument for the 1978 Rowe score, however, is that it is the only score, which clearly documents re-dislocation, also refers to this score as the ‘‘original’’ Rowe score.

We recommend indicate the Rowe score version used, always. If the 1981, 1982, and 1988 Rowe scores are used, it should be documented if the patient experienced re-dislocation.

We will use Rowe 1981

FUNCTION	
No limitation in sports or work; able to throw baseball and football; can swim crawl-stroke	50
No limitation in work; slight limitation in throwing baseball, serving forcefully in tennis, or swimming crawl-stroke; can throw football normally	35
Moderate limitation in overhead work, throwing baseball and swimming crawl-stroke, or serving in tennis football,	20
Marked limitation in throwing in all sports; unable to work with arm overhead	0
PAIN	
None	10
Moderate	5
Severe	0
STABILITY	
Negative apprehension test, no subluxation	30
Negative apprehension test, but discomfort with arm in position abduction and external rotation	15
Positive apprehension test and sense of subluxation	0
MOTION	
Full range of motion	5
As much as 25 % loss of motion in any plane	4
More than 25 % loss of motion in any plane	3
TOTAALSCORE	

ROWE - SCORE

Excellent	90 - 100 points	Fair	40 - 69 points
Good	70 - 89 points	Poor	30 or fewer points

Annex 6 - WOSI questionnaire: Disease - Specific quality of life (instability)

APPENDIX‡

SECTION A:
Physical Symptoms

INSTRUCTIONS TO PATIENTS

The following questions concern the physical symptoms you have experienced due to your shoulder problem. In all cases, please enter the amount of the symptom you have experienced in the last week. (Please answer with an "X" on the horizontal line.)

1. How much pain do you experience in your shoulder with overhead activities?
   no pain — extreme pain
2. How much aching or throbbing do you experience in your shoulder?
   no aching/throbbing — extreme aching/throbbing
3. How much weakness or lack of strength do you experience in your shoulder?
   no weakness — extreme weakness
4. How much fatigue or lack of stamina do you experience in your shoulder?
   no fatigue — extreme fatigue
5. How much clicking, cracking or snapping do you experience in your shoulder?
   no clicking — extreme clicking
6. How much stiffness do you experience in your shoulder?
   no stiffness — extreme stiffness
7. How much discomfort do you experience in your neck muscles as a result of your shoulder?
   no discomfort — extreme discomfort
8. How much feeling of instability or looseness do you experience in your shoulder?
   no instability — extreme instability
9. How much do you compensate for your shoulder with other muscles?
   not at all — extreme
10. How much loss of range of motion do you have in your shoulder?
    no loss — extreme loss

‡ On the actual form the lines are 100-mm long. This form is reproduced by permission of the Fowler - Kennedy Sports Medicine Clinic.

SECTION B:
Sports/Recreation/Work

INSTRUCTIONS TO PATIENTS

The following section concerns how your shoulder problem has affected your work, sports or recreational activities in the past week. For each question, please indicate the amount with an "X" on the horizontal line.

11. How much has your shoulder limited the amount you can participate in sports or recreational activities?
    not limited — extremely limited
12. How much has your shoulder affected your ability to perform the specific skills required for your sport or work? (If your shoulder affects both sports and work, consider the area that is most affected.)
    not affected — extremely affected

13. How much do you feel the need to protect your arm during activities?

|—————————————————————|
not at all — extreme

14. How much difficulty do you experience lifting heavy objects below shoulder level?

|—————————————————————|
no difficulty — extreme difficulty

SECTION C:
Lifestyle

INSTRUCTIONS TO PATIENTS

The following section concerns the amount that your shoulder problem has affected or changed your lifestyle. Again, please indicate the appropriate amount for the past week with an "X" on the horizontal line.

15. How much fear do you have of falling on your shoulder?

|—————————————————————|
no fear — extreme fear

16. How much difficulty do you experience maintaining your desired level of fitness?

|—————————————————————|
no difficulty — extreme difficulty

17. How much difficulty do you have "roughhousing or horsing around" with family or friends?

|—————————————————————|
no difficulty — extreme difficulty

18. How much difficulty do you have sleeping because of your shoulder?

|—————————————————————|
no difficulty — extreme difficulty

SECTION D:
Emotions

INSTRUCTIONS TO PATIENTS

The following questions relate to how you have felt in the past week with regard to your shoulder problem. Please indicate your answer with an "X" on the horizontal line.

19. How conscious are you of your shoulder?

|—————————————————————|
not conscious — extremely conscious

20. How concerned are you about your shoulder becoming worse?

|—————————————————————|
no concern — extremely concerned

21. How much frustration do you feel because of your shoulder?

|—————————————————————|
no frustration — extremely frustrated

Disease-specific quality of life was measured using the Western Ontario Shoulder Instability (WOSI) index. This index consists of 4 domains: physical symptoms and pain; sport, recreation, and work function; lifestyle and social functioning; and emotional well-being.

There are a total of 21 items, each with a 100-mm visual analogue scale response. A perfect score on the measurement tool is 0 and the worst possible score is 2,100. This is the only tool that we are aware of that has been validated specifically for use in a population of patients with shoulder instability.

We will use an online form that will be easier to answer: http://www.orthopaedicscore.com/scorepages/oxford_wosi_score.html

Annex 7 - SF-36 test

Su Salud y Bienestar

Por favor conteste las siguientes preguntas. Algunas preguntas pueden parecerse a otras pero cada una es diferente.

Tómese el tiempo necesario para leer cada pregunta, y marque con una la casilla que mejor describa su respuesta.

¡Gracias por contestar a estas preguntas!

1. En general, usted diría que su salud es:

Excelente	Muy buena	Buena	Regular	Mala
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

2. ¿Cómo diría usted que es su salud actual, comparada con la de hace un año?:

Mucho mejor ahora que hace un año	Algo mejor ahora que hace un año	Más o menos igual que hace un año	Algo peor ahora que hace un año	Mucho peor ahora que hace un año
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

3. Las siguientes preguntas se refieren a actividades o cosas que usted podría hacer en un día normal. Su salud actual, ¿le limita para hacer esas actividades o cosas? Si es así, ¿cuánto?

	Sí, me limita mucho	Sí, me limita un poco	No, no me limita nada
a Esfuerzos intensos, tales como correr, levantar objetos pesados, o participar en deportes agotadores.	☐ 1	☐ 2	☐ 3
b Esfuerzos moderados, como mover una mesa, pasar la aspiradora, jugar a los bolos o caminar más de 1 hora.	☐ 1	☐ 2	☐ 3
c Coger o llevar la bolsa de la compra.	☐ 1	☐ 2	☐ 3
d Subir varios pisos por la escalera.	☐ 1	☐ 2	☐ 3
e Subir un sólo piso por la escalera.	☐ 1	☐ 2	☐ 3
f Agacharse o arrodillarse.	☐ 1	☐ 2	☐ 3
g Caminar un kilómetro o más	☐ 1	☐ 2	☐ 3
h Caminar varios centenares de metros.	☐ 1	☐ 2	☐ 3
i Caminar unos 100 metros.	☐ 1	☐ 2	☐ 3
j Bañarse o vestirse por sí mismo.	☐ 1	☐ 2	☐ 3

4. Durante las 4 últimas semanas, ¿con qué frecuencia ha tenido alguno de los siguientes problemas en su trabajo o en sus actividades cotidianas, a causa de su salud física?

	Siempre	Casi siempre	Algunas veces	Sólo alguna vez	Nunca
a ¿Tuvo que reducir el tiempo dedicado al trabajo o a sus actividades cotidianas?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b ¿Hizo menos de lo que hubiera querido hacer?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c ¿Tuvo que dejar de hacer algunas tareas en su trabajo o en sus actividades cotidianas?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
d ¿Tuvo dificultad para hacer su trabajo o sus actividades cotidianas (por ejemplo, le costó más de lo normal)?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

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5. Durante las 4 últimas semanas, ¿con qué frecuencia ha tenido alguno de los siguientes problemas en su trabajo o en sus actividades cotidianas, a causa de algún problema emocional (como estar triste, deprimido o nervioso)?

	Siempre	Casi siempre	Algunas veces	Sólo alguna vez	Nunca
a ¿Tuvo que reducir el tiempo dedicado al trabajo o a sus actividades cotidianas por algún problema emocional?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b ¿Hizo menos de lo que hubiera querido hacer por algún problema emocional?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c ¿Hizo su trabajo o sus actividades cotidianas menos cuidadosamente que de costumbre, por algún problema emocional?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

6. Durante las 4 últimas semanas, ¿hasta qué punto su salud física o los problemas emocionales han dificultado sus actividades sociales habituales con la familia, los amigos, los vecinos u otras personas?

Nada	Un poco	Regular	Bastante	Mucho
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

7. ¿Tuvo dolor en alguna parte del cuerpo durante las 4 últimas semanas?

No, ninguno	Sí, muy poco	Sí, un poco	Sí, moderado	Sí, mucho	Sí, muchísimo
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6

8. Durante las 4 últimas semanas, ¿hasta qué punto el dolor le ha dificultado su trabajo habitual (incluido el trabajo fuera de casa y las tareas domésticas)?

Nada	Un poco	Regular	Bastante	Mucho
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

9. Las preguntas que siguen se refieren a cómo se ha sentido y cómo le han ido las cosas durante las 4 últimas semanas. En cada pregunta responda lo que se parezca más a cómo se ha sentido usted. Durante las últimas 4 semanas ¿con qué frecuencia...

	Siempre	Casi siempre	Algunas veces	Sólo alguna vez	Nunca
a se sintió lleno de vitalidad?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b estuvo muy nervioso?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c se sintió tan bajo de moral que nada podía animarle?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
d se sintió calmado y tranquilo?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
e tuvo mucha energía?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
f se sintió desanimado y deprimido?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
g se sintió agotado?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
h se sintió feliz?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
i se sintió cansado?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

10. Durante las 4 últimas semanas, ¿con qué frecuencia la salud física o los problemas emocionales le han dificultado sus actividades sociales (como visitar a los amigos o familiares)?

Siempre	Casi siempre	Algunas veces	Sólo alguna vez	Nunca
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

11. Por favor diga si le parece CIERTA o FALSA cada una de las siguientes frases:

	Totalmente cierta	Bastante cierta	No lo sé	Bastante falsa	Totalmente falsa
a Creo que me pongo enfermo más facilmente que otras personas	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b Estoy tan sano como cualquiera	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c Creo que mi salud va a empeorar	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
d Mi salud es excelente	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Annex 8 – Information sheet – Català

FULL D'INFORMACIÓ AL PACIENT

Títol de l'estudi: **SURGICAL VERSUS NON-SURGICAL TREATMENT FOR FIRST-TIME TRAUMATIC ANTERIOR SHOULDER DISLOCATION WITH A BANKART LESION.**

Investigadors: Dra. Maria José Martínez, Laia Boadas i Gironès

Informació general:

Abans de que accedeixi a participar en aquest estudi, es important que llegeixi i comprengui la informació que exposarem a continuació. Si tingués alguna pregunta sobre l'estudi o dels seus drets com a participant, no dubti en posar-se en contacte abans de prendre una decisió.

En aquest document es descriu l'objectiu, procediments, beneficis, riscs i precaucions que suposa l'estudi.

És essencial que sigui totalment sincer en els seus antecedents, si no fos així podria haver-hi resultats no esperats durant la intervenció.

Participació voluntària:

La participació en aquest estudi és completament voluntària, i es pot negar a formar-ne part o retirar-se de l'estudi en el moment en el que ho desitgi, sense que per això alteri la relació amb el seu metge, ni es produeixi cap perjudici en el seu tractament.

El metge que el tracti o el promotor de l'estudi podrien retirar-lo sense necessitat de consentiment, per qualsevol raó que considerin apropiada, ja sigui per motius de seguretat o perquè considerin que no està complint amb els procediments establerts. En qualsevol dels casos, vostè rebrà una explicació adequada del motiu que ha ocasionat la seva retirada de l'estudi.

A continuació se li exposarà informació més detallada. És important que llegeixi el document de consentiment informat i que comprengui el seu contingut.

Descripció de l'estudi:

Se l'ha invitat a participar en aquest estudi d'investigació clínica perquè vostè ha patit un primer episodi de luxació aguda i traumàtica d'espatlla.

La luxació d'espatlla és una patologia en la que després d'un procés traumàtic, el cap del seu húmer ha sortit de la seva glenoides. Vostè sol o amb l'ajuda d'un professional sanitari, hem aconseguit deixar l'articulació en una posició anatòmica normal. Però durant aquest moviment anormal, ha de saber que és probable que la seva articulació glenohumeral hagi quedat malmesa. Com a seqüeles podem trobar alteracions òssies tant en la glenoides com a l'húmer, lesions toves del labrum, lligaments de la càpsula, entre altres.

En el nostre estudi ens interessen les lesions de Bankart. Aquestes són lesions de la zona antero-inferior del labrum de la glenoides. Quan aquesta lesió es produeix, hi ha un forat o més aviat una "butxaqueta" en la zona que protegeix l'articulació i que la manté estable. Quan aquesta "butxaqueta" apareix, ens trobem en un lloc per a on a mínims traumes o moviments del cap de l'húmer, aquest no es troba contingent i pot escapar-se i produir re-luxacions.

Cal que sàpiga que aquesta condició es pot diagnosticar de manera factible amb una ressonància, i que ara, en moment agut i en el transcurs dels pròxims dies pot ser fàcil de diagnosticar, per la distensió aguda que ha patit la seva espatlla.

Com pot imaginar, si vostè té aquesta complicació, la possibilitat d'una recurrència en un futur o d'una inestabilitat de l'espatlla és alta. I en cada recurrència la possibilitat de dany a l'articulació és major.

Actualment, els tractaments estan en aquest punt:

- Si és un primer episodi, es tracta amb un cabestrell immobilitzat durant unes 4 setmanes i la iniciació d'un programa de rehabilitació per tal d'incrementar la massa muscular que es troba al voltant de la lesió. Ha de saber que aquesta distensió o "butxaqueta" no s'arregla sola, i que sempre la tindrà, pel que l'objectiu de la rehabilitació és incrementar la massa muscular per tal de que suplir la funció del labrum afectat. Ara bé, com que la patologia no s'arregla, el risc de recidiva és alt. Si hi ha disminució de la massa muscular després de la rehabilitació, el risc encara és més alt. Fins ara, aquest és el protocol de tractament davant la seva condició.
- Si és un primer episodi i vostè és un esportista d'elit o té una gran demanda funcional de la seva articulació d'espatlla, és probable que el seu traumatòleg li ofereixi un tractament quirúrgic per arreglar la lesió, que tal com hem dit, no s'arregla de manera espontània. Seguirà d'un tractament d'immobilització i rehabilitació per incrementar l'eficàcia del tractament.
- Si vostè tingués moltes recurrències de luxacions o inestabilitat, també se l'indicarà un tractament quirúrgic per tal de solventar la lesió, seguit d'un tractament d'immobilització i rehabilitació com en el cas anterior.

El nostre objectiu d'estudi és investigar si fent una cirurgia en el moment en el que vostè es troba, després del primer episodi de luxació, pot millorar la seva condició. Per tant, volem evitar un dolor, patiment, recurrències, inestabilitat i uns danys afegits a l'articulació; acabant en una cirurgia, la qual es podria haver fet en un primer moment.

La cirurgia que farem es tracta d'una cirurgia artroscòpia en la qual amb 2 o 3 petites incisions (1-2 cm), entrarem mitjançant una càmera dins de l'articulació i l'instrumental especialitzat. S'insertarà el labrum al seu lloc anatòmic amb arpons biodegradables, fent desaparèixer aquesta "butxaqueta" per la que el seu húmer pot sortir.

Al ser un assaig clínic, si vostè vol entrar en aquest estudi, pot rebre un tractament conservador o quirúrgic, de manera aleatòria. D'altre manera si vostè decideix no entrar, se'l tractarà seguint els protocols.

El període de duració de l'estudi serà de 10 anys, en els quals vostè haurà de venir al nostre hospital a fer-se les revisions pertinents. Les revisions de l'estudi en seran cinc, als 6 mesos, als 12 mesos, als 24 mesos, als 60 mesos i als 120 mesos. Si vostè necessita qualsevol cita addicional, no dubti en demanar-la.

En el cas que vostè li toqui en el grup quirúrgic, se'l citarà una vegada addicional, pel grup d'infermeria del seu centre d'assistència, per treure les sutures de la cirurgia i per començar el següent procés de rehabilitació.

En les revisions se li passaran uns qüestionaris i s'analitzarà la funció de la seva articulació segons els protocols d'aquest estudi. En cap cas hi haurà cap procediment invasiu.

Beneficis i riscs derivats de la seva participació en l'estudi:

La seva condició d'haver patit una luxació d'espatlla ha de ser tractada. Tant de manera conservadora com quirúrgica, hauria de recuperar la seva total funcionalitat. El grup quirúrgic necessitarà un dia d'hospitalització (l'endemà de la cirurgia serà donat d'alta), serà sotmès a una cirurgia amb anestèsia general, però el benefici podria ser millor i amb menys complicacions i recurrències després del tractament.

Les complicacions de la cirurgia que, amb baixa probabilitat, però que podrien sorgir serien: infecció, lesions a nervis i vasos, inestabilitat que no es solventa, rigidesa a l'articulació, lesions als músculs del manegot dels rotadors, dolor, necessitat de pròximes operacions, i riscos associats a l'anestèsia.

En cas de patir algun dels efectes adversos, vostè ho haurà de comunicar al seu metge.

Responsabilitat i assegurança:

El promotor de l'estudi ha subscrit una pòlissa d'assegurança que cobreix els danys que vostè pogués patir com a conseqüència de la seva participació en aquest assaig, d'acord amb la legislació vigent.

Confidencialitat:

Totes les dades de caràcter personal i informació recollida o generada durant l'estudi quedarà protegida segons la Llei Orgànica 15/1999 de "Protecció de Dades de Caràcter Personal".

Les dades recollides durant l'estudi estaran identificades mitjançant un codi numèric i només el seu metge de l'estudi i els col·laboradors podran relacionar aquestes dades amb vostè i amb la seva historia clínica. Per tant, la seva identitat no serà revelada.

Compensació econòmica:

La seva participació en l'estudi no li suposarà cap cost addicional, ni rebrà cap compensació econòmica.

Altra informació rellevant:

Qualsevol nova informació referent al tractament serà comunicada pel seu metge el més aviat possible.

Persones de contacte:

Davant de qualsevol dubte o problema que succeeixi durant la realització de l'estudi, vostè podrà posar-se en contacte amb els responsables de l'estudi:

Laia Boadas i Gironès, i Dra. Maria José Martínez

Telèfon: 972 94 02 00
Hospital Dr. Josep Trueta. Departament de Traumatologia i Cirurgia Ortopèdica

Av/ de França, s/n. 17007 - Girona.

Moltes gràcies per la seva atenció

Si us plau, no dubti en fer més preguntes al seu metge, si alguna cosa no li ha quedat clara. Si decideix entrar a l'estudi, signi el consentiment informat que se li adjunta.

Annex 9 – Inform consent – Català

FULL DE CONSENTIMENT INFORMAT

Títol de l'estudi: **SURGICAL VERSUS NON-SURGICAL TREATMENT FOR FIRST-TIME TRAUMATIC ANTERIOR SHOULDER DISLOCATION WITH A BANKART LESION.**

Investigadors: Dra. Maria José Martínez, Laia Boadas i Gironès,

Aquest document ha de ser complimentat a mà pel propi pacient.

Jo, (nom i cognoms) .....

amb DNI……..……

- ✓ He llegit el full d'informació que se m'ha entregat.
- ✓ He pogut fer preguntes sobre l'estudi.
- ✓ He rebut respostes satisfactòries a les meves preguntes.
- ✓ He rebut suficient informació de l'estudi i la he entès.
- ✓ He parlat amb (nom i cognoms del investigador) .....
- ✓ Comprenc que la meva participació es voluntària.
- ✓ Comprenc que puc retirar-me de l'estudi quan vulgui.
- ✓ Dono la meva conformitat a participar en l'estudi i rebré una copia d'aquest document.

..... (data) ..... (data)

....

(signatura del pacient) (signatura del investigador)

Telèfon de contacte: ……

Annex 10 – Revocation consent – Català

FULL DE REVOCACIÓ

Títol de l'estudi: **SURGICAL VERSUS NON-SURGICAL TREATMENT FOR FIRST-TIME TRAUMATIC ANTERIOR SHOULDER DISLOCATION WITH A BANKART LESION.**

Investigadors: Dra. Maria José Martínez, Laia Boadas i Gironès,

Aquest document ha de ser complimentat a mà pel propi pacient.

Sr/Sra.: (Nom i Cognoms)....., amb domicili a ....., i DNI: .....

REVOCO el consentiment informat el dia..... i desitjo acabar la meva participació a l'estudi a data d'avui.

..... (data) ..... (data)

....

(signatura del pacient) (signatura del investigador)

Annex 11 – Surgical consent – Català

Títol de l'estudi: **SURGICAL VERSUS NON-SURGICAL TREATMENT FOR FIRST-TIME TRAUMATIC ANTERIOR SHOULDER DISLOCATION WITH A BANKART LESION.**

Investigadors: Dra. Maria José Martínez, Laia Boadas i Gironès

Aquest document ha de ser complimentat a mà pel propi pacient.

Jo, …….. amb el DNI ……he llegit el full d'informació de l'estudi ≪**SURGICAL VERSUS NON-SURGICAL TREATMENT FOR FIRST-TIME TRAUMATIC ANTERIOR SHOULDER DISLOCATION WITH A BANKART LESION**≫ dels investigadors Laia Boadas i Gironès i Dra. Maria José Martínez que m'han donat. He entès tot el que m'han explicat i m'han solventat tots els dubtes que tenia. També he entès, que qualsevol moment puc sortir de l'estudi sense donar cap motiu.

Es pel motiu que firmo que estic d'acord amb la informació que m'han donat sobre la cirurgia que em practiran: *ARTROSCÒPIA D'ESPATLLA AMB LA TÈCNICA DE "REPARACIÓ DE BANKART" UTILITZANT ANCLATGES BIODEGRADABLES.* Entenc la natura i els riscos que poden sorgir durant el procediment quirúrgic i els específic:

- Infecció
- Lesions a nervis i vasos
- Instabilitat que no es solventa
- Rigidesa a l'rticulació
- Lesions als músculs del manegot dels rotadors
- Dolor
- Necessitat de pròximes operacions
- _____
- _____

Girona,_____(dia)_____(mes) del 20___

DNI: Nº de col·legiat:

Signatura del pacient Signatura del metge

Annex 12 - Physiotherapy program to rehabilitate the shoulder

Table 4: Physiotherapy programme after a first-time traumatic anterior shoulder dislocation with a Bankart lesion.

Time	Focus	Recommended Exercises	Precautions
Phase 1 **0-4 Weeks**	• Tissue Healing • Decrease Pain and Inflammation • Start Early Passive ROM with Attention to Restrictions	• **Passive/Active ROM** o Pendulums o Scapular Retraction o Shoulder Shrugs o Passive External Rotation o Passive Flexion o Passive Internal Rotation (at 2 weeks post-surgery) • **Strengthening** o Submaximal Isometric ER/IR o Ball Squeeze	• Sling 0-4 Weeks or per MD Instruction • Limit ROM Especially ER • No Excessive Shoulder Extension • No Active ER, Extension,
Phase 2 **4-8 Weeks**	• Improve ROM with Careful Progression of IR/ER • Slow Transition to Strengthening after MD Follow Up	• **Passive ROM** o Continue PROM Exercises • **Active Assisted ROM** o Supine/Standing Flexion o Crossbody Adduction (6-8 weeks) • **Active ROM Against Gravity (6-8 weeks)** o Sideling ER o Standing Scaption o Prone Row o Prone Extension o Prone Horizontal o Abduction Prone o Scaption • **Strengthening (6-8 weeks)** o T-Band IR/ER (in 0º Abd) • **Dynamic Progressions (6-8 weeks)** o Gentle Rhythmic Stabilization and Proprioceptive Drills	• No Resisted Activity/Lifting • Avoid Repetitive Motion Overhead and in Rotation Away from Body • Must have good Scapular Control with Active ROM and Strengthening • Never Force ROM especially ER
Phase 3 **8-12 Weeks**	• Progressive Strengthening • Continued Attention to ROM if Still Deficient • Establish Proper Scapulohumeral Rhythm • Enhance Proprioception	• **Passive ROM** o Continue as Needed • **Active Assisted/Active ROM and Stretching** o Continue Phase 2 Exercises o Wall Slide o Sideling IR (“Sleeper”) Progressive Abd Angle with ER o Supine/Standing Cross Body • **Strengthening (Dumbell/T-band)** o Row o Prone Extension o Prone Horizontal Abduction o Standing/Prone Scaption o Internal Rotation o External Rotation “W”(Row/ER) o Bicep Curl • **Dynamic Progressions** o Rhythmic Stabilization	• No Heavy or Repetitive Overhead Lifting/Reaching • Limited Return to Gym Lifting Late in Phase 3 per MD Discretion • Dynamic Progressions if Pain Free/Full ROM with all ROM and Strengthening Exercises • Never Force ROM especially ER

		○ Proprioceptive Drills	
Phase 4 **12-24 Weeks**	• Progress strengthening • Regain use of arm for all daily activities. • Prepare for Return to Sport and Physical Activity	• **Active Assisted/Active/Stretch** ○ Continue Phase 3 As Needed • **Strengthening** ○ Continue T-band and Dumbbell ○ Progressions from Phase 3 ○ Progress to Diagonal Patterns IR/ER at 90º Abd ○ May Begin Limited Weight Training • **Dynamic Progressions** ○ Push up Progression ○ Continue Proprioceptive Drills ○ Plyometrics/Rebounder ○ Progress to Overhead ○ Rhythmic Stabilization ○ Manual Resistance Patterns	• Progress Gym Lifting per MD Discretion • Avoid Activities that Cause Shoulder Pain • Begin Progressive Return to Sports and Physical Activity Program After MD Evaluation

Source: Bankair Repair Protocol. South Shore Hospital Orthopaedic, Spine and Sports Therapy in Clinical Collaboration with South Shore Orthopaedics

Annex 13 - Participant Data Sheet

Study's Tittle: **SURGICAL VERSUS NON-SURGICAL TREATMENT FOR FIRST-TIME TRAUMATIC ANTERIOR SHOULDER DISLOCATION WITH A BANKART LESION.**

Researchers: Laia Boadas i Gironès, Dra. Maria José Martínez

This Sample should be answered the first day (after the acute moment), by the physician, and delivered to the researcher group.

PARTICIPANT

NAME:

DNI:

DATE OF BIRTH:

TELEPHONE:

EMAIL:

ADDRESS:

SEX: M F

THE CONSENT FORM IS SIGNED? Yes No

Check the inclusion criteria (✓) and the exclusions criteria (✗)

INCLUSION CRITERIA

- ☐ Diagnose in the acute moment of the luxation by an emergency physician, and or, by an orthopaedic surgeon.
- ☐ The anterior dislocation is the initial episode.
- ☐ The dislocation requires a manual reduction by physician or trained health professional. If the on-field reduction was unsuccessful, pre-reduction radiographs will be obtained, and the reduction will be performing under intravenous sedation.
- ☐ An Anteroposterior and West Point radiographs will be obtained in all patients after the reduction, taking care there is no exclude criteria.
- ☐ Also we will obtain a MRI image of the shoulder joint, in the acute moment. The result of the MRI should be distension of glenoide capsule with a concomitant Bankart lesion
- ☐ We should demonstrate a pre-injury activity level of 40-80 in the Physical Activity Index of the AAHF. If we cannot be sure, the patient we will be excluded.

EXCLUSION CRITERIA

- ☐ Degenerate shoulder dislocation
- ☐ The patient has concomitant neurologic injury (ex. axillar compression).
- ☐ The patient has concomitant lesions, such Hill-Sachs, fractures or other concomitant damage, in exception of Bankart lesion.
- ☐ The patient had history of subluxation or impingement, possibly suggesting occult subluxation.

- ☐ Cannot be participants, the patients who take part in an elite sport team or practice high-level competition activities. Also, the ones who work in high-physically-demands jobs, such carpenters or construction workers.
- ☐ Rheumatic or other traumatic injuries in the shoulder before the dislocation.
- ☐ The presence of rheumatic systemic illness, such fibromyalgia or arthritis rheumatoid.
- ☐ Past surgeries in the injured shoulder.
- ☐ Concomitant lesions or conditions that can difficulty the exploration and treatment.
- ☐ The presence of contradictions to the surgery.
- ☐ Medical conditions limiting expectancy of life

CLINICAL HISTORY

ALLERGIES:

MEDICAL AND SURGICAL HISTORY:

MECHANISMS OF INJURY:

PHYSICAL ACTIVITY/SPORTS:
(Physical Activity Index of the AAHF)

AFFECTED SIDE: **LEFT / RIGHT**

MEDICATION:

PROFESSION:

This part will be fill before the second visit, with the MRI results and the acceptance of the patient to our study

MRI DIAGNOSES BANKART LESION: **Yes** **No**

OTHER FINDINGS:

The stadistical program gives the patient's code number: _____

Study's Tittle: **SURGICAL VERSUS NON-SURGICAL TREATMENT FOR FIRST-TIME TRAUMATIC ANTERIOR SHOULDER DISLOCATION WITH A BANKART LESION.**

Researchers: Dra. Maria José Martínez i Laia Boadas i Gironès

This Sample should be answered by the researcher assistant during the following up. In no time, the researcher will know the patient treatment.

The name of the patient will not writte down in this sample.

PARTICIPANT

PATIENT Nº CODE:

FIRST EXAMINATION: 6 months
DATE:
AFFECTED SIDE:

AVALUATION:

OUTCOME	METHOD			
Re-injury or recurrence rate:	Incidence of second dislocation, symptomatic subluxation or necessity of an additional surgical stabilization			
Non-return to pre-injury level of activity	AAHF level			
Persistent pain	Visual analogue scale			
Instability (objective or subjective)	Positive apprehension test			
	Instability ROW shoulder score			
Quality of life	WOSI questionnaire			
	SF-36 test			
Range of movement %			**Right**	**Left**
	ACTIVE	**FLEXION**		
		EXTENSION		
		ABDUCTION		
		ADDUCTION		
		EXTERNAL ROTATION		
		INTERNAL ROTATION		
	PASSIVE	**FLEXION**		
		EXTENSION		
		ABDUCTION		
		ADDUCTION		
		EXTERNAL ROTATION		
		INTERNAL ROTATION		
Complications of treatment	Name any complication			
Patient dissatisfaction.	Yes/No			

SECOND EXAMINATION: 12 months
DATE:

AVALUATION:

OUTCOME	METHOD			
Re-injury or recurrence rate:	Incidence of second dislocation, symptomatic subluxation or necessity of an additional surgical stabilization			
Non-return to pre-injury level of activity	AAHF level			
Persistent pain	VAS			
Instability (objective or subjective)	Positive apprehension test			
	Instability ROWE shoulder score			
Quality of life	WOSI questionnaire			
	SF-36 test			
Range of movement %			**Right**	**Left**
	ACTIVE	**FLEXION**		
		EXTENSION		
		ABDUCTION		
		ADDUCTION		
		EXTERNAL ROTATION		
		INTERNAL ROTATION		
	PASSIVE	**FLEXION**		
		EXTENSION		
		ABDUCTION		
		ADDUCTION		
		EXTERNAL ROTATION		
		INTERNAL ROTATION		
Complications of treatment	Name any complication			
Patient dissatisfaction.	Yes/No			

THIRD EXAMINATION: 24 months
DATE:

AVALUATION:

OUTCOME	METHOD
Re-injury or recurrence rate:	Incidence of second dislocation, symptomatic subluxation or necessity of an additional surgical stabilization
Non-return to pre-injury level of activity	AAHF level
Persistent pain	VAS
Instability (objective or subjective)	Positive apprehension test
	Instability ROWE shoulder score
Quality of life	WOSI questionnaire

	SF-36 test			
Range of movement %			**Right**	**Left**
	ACTIVE	**FLEXION**		
		EXTENSION		
		ABDUCTION		
		ADDUCTION		
		EXTERNAL ROTATION		
		INTERNAL ROTATION		
	PASSIVE	**FLEXION**		
		EXTENSION		
		ABDUCTION		
		ADDUCTION		
		EXTERNAL ROTATION		
		INTERNAL ROTATION		
Complications of treatment	Name any complication			
Patient dissatisfaction.	Yes/No			

FOURTH EXAMINATION: 60 months
DATE:

AVALUATION:

OUTCOME	**METHOD**			
Re-injury or recurrence rate:	Incidence of second dislocation, symptomatic subluxation or necessity of an additional surgical stabilization			
Non-return to pre-injury level of activity	AAHF level			
Persistent pain	VAS			
Instability (objective or subjective)	Positive apprehension test			
	Instability ROWE shoulder score			
Quality of life	WOSI questionnaire			
	SF-36 test			
Range of movement %			**Right**	**Left**
	ACTIVE	**FLEXION**		
		EXTENSION		
		ABDUCTION		
		ADDUCTION		
		EXTERNAL ROTATION		
		INTERNAL ROTATION		
	PASSIVE	**FLEXION**		
		EXTENSION		
		ABDUCTION		
		ADDUCTION		
		EXTERNAL ROTATION		
		INTERNAL		

		ROTATION		
Complications of treatment	Name any complication			
Patient dissatisfaction.	Yes/No			

FIFTH EXAMINATION: 120 months
DATE:

AVALUATION:

OUTCOME	**METHOD**			
Re-injury or recurrence rate:	Incidence of second dislocation, symptomatic subluxation or necessity of an additional surgical stabilization			
Non-return to pre-injury level of activity	AAHF level			
Persistent pain	VAS			
Instability (objective or subjective)	Positive apprehension test			
	Instability ROWE shoulder score			
Quality of life	WOSI questionnaire			
	SF-36 test			
Range of movement %			**Right**	**Left**
	ACTIVE	**FLEXION**		
		EXTENSION		
		ABDUCTION		
		ADDUCTION		
		EXTERNAL ROTATION		
		INTERNAL ROTATION		
	PASSIVE	**FLEXION**		
		EXTENSION		
		ABDUCTION		
		ADDUCTION		
		EXTERNAL ROTATION		
		INTERNAL ROTATION		
Complications of treatment	Name any complication			
Patient dissatisfaction.	Yes/No			

Annex 14 - ASA Physical Status Classification System

ASA PS Classification	Definition	Examples, including, but not limited to:
ASA I	A normal healthy patient	Healthy, non-smoking, no or minimal alcohol use
ASA II	A patient with mild systemic disease	Mild diseases only without substantive functional limitations. Examples include (but not limited to): current smoker, social alcohol drinker, pregnancy, obesity (30 < BMI < 40), well-controlled DM/HTN, mild lung disease
ASA III	A patient with severe systemic disease	Substantive functional limitations; One or more moderate to severe diseases. Examples include (but not limited to): poorly controlled DM or HTN, COPD, morbid obesity (BMI ≥40), active hepatitis, alcohol dependence or abuse, implanted pacemaker, moderate reduction of ejection fraction, ESRD undergoing regularly scheduled dialysis, premature infant PCA < 60 weeks, history (>3 months) of MI, CVA, TIA, or CAD/stents.
ASA IV	A patient with severe systemic disease that is a constant threat to life	Examples include (but not limited to): recent (< 3 months) MI, CVA, TIA, or CAD/stents, ongoing cardiac ischemia or severe valve dysfunction, severe reduction of ejection fraction, sepsis, DIC, ARD or ESRD not undergoing regularly scheduled dialysis
ASA V	A moribund patient who is not expected to survive without the operation	Examples include (but not limited to): ruptured abdominal/thoracic aneurysm, massive trauma, intracranial bleed with mass effect, ischemic bowel in the face of significant cardiac pathology or multiple organ/system dysfunction
ASA VI	A declared brain-dead patient whose organs are being removed for donor purposes	

*The addition of "E" denotes Emergency surgery: (An emergency is defined as existing when delay in treatment of the patient would lead to a significant increase in the threat to life or body part)