Universitat de Girona
Facultat de Medicina

Operative Versus Non-Operative Treatment in Acromioclavicular Joint Dislocation:

A Randomized Controlled Clinical Trial

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Final Degree project

CONTENT

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ABREVIATIONS

AC: Acromioclavicular

CA: Coracoacromial

CC: Coracoclavicular

CS: Constatn Score

DASH: The Disabilities of the Arm, Shoulder and Hand Score

K-Wire: Kishner Wires

NSAID: NonSteroidal Anti-Inflamatory drugs

OTS: Orthopedic and Trauma Surgery

SST: Simple Shoulder Test

VAS: Visual Analogue scale

1. ABSTRACT

Background:

There is no clear evidence for type III Acromioclavicular (AC) joint dislocations treatment. The clinician should choose the most between non-operative treatment and operative management according to every patient. Past studies are not strong enough to extract clear conclusions. Also, the heterogeneity in the procedures and the existence of new better techniques constitute a lack of current evidence. Functional outcomes seem to see similar on both treatments but complication rates are still unclear.

Objective:

The purpose of this protocol is to show an inferior complication rate after conservative treatment using operative management based on the use of Twin tail TightRope® (by Arthrex) device.

Design:

Randomized, controlled, observer-blind and unicentric clinical trial design will be carried out in Hospital Universitari Dr. Josep Trueta in Girona within the Orthopaedics and Trauma Surgery (OTS) Department department.

Participants:

Patients aged between 18 and 40 years diagnosed of Type III Acromio-Clavicular joint dislocation.

Key Words:

Acriomio-Clavicular joint dislocation, Twin Tail TightRope®, non-operative versus operative treatment.

2. INTRODUCTION.

AC joint **(Image 1)** dislocation is one of the most frequent dislocations in the whole body. Usually affects young people due to sports or road accidents.

For a better understanding about this injury it is necessary a brief explanation about its anatomy and physiology.

2.1. Anatomy and Physiology of the acromioclavicular joint.

AC joint is a plane diarthrosis. It links the acromion of the scapula with the distal portion of the clavicle. It is the main union between axial skeleton and the upper limb, coordinating scapulohumeral motility with clavicular motion (1). The scapular acromion and the distal portion of the clavicle contact by the joint surfaces covered by hyaline cartilage. Sometimes an intraarticular disk is found, its function is still unknown (2,3).

AC joint is stabilized by static and dynamic stabilizers. Static components are:

- Acromioclavicular ligament (2–5): It surrounds the AC joint. Includes superior, inferior, anterior and posterior components. Trapezium and Deltoid muscles insertion in the clavicle add stability to the joint. AC ligament prevents anteroposterior translation of the distal portion of the clavicle **(Image 1 and 2)**.

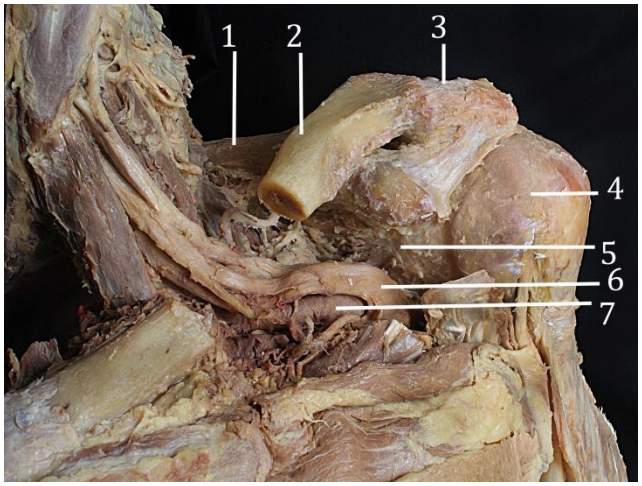

Image 1: Shoulder anatomical dissection anterior view. (own picture) 1) Supraspinatus muscle. 2) Distal portion of the clavicle. 3) AC joint and anterior component of AC ligament. 4) Caput humeri. 5) Subscapularis muscle. 6) Fasciculus medialis of brachial plexus. 7) Axilaris Arteria.

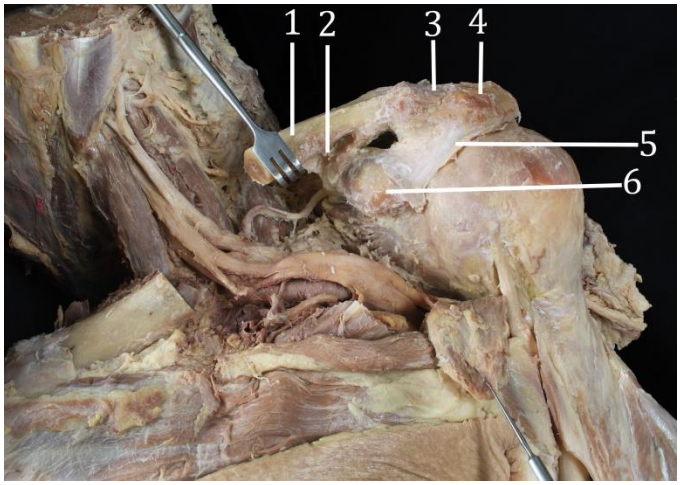

Image 2: Shoulder anatomical dissection anterior view. (own picture) 1) Distal part of the clavicle. 2) CC ligaments. 3) AC joint and anterior component of AC ligament. 4) Acromion. 5) CA ligament. 6) Coracoid process.

- Coracoclavicular ligaments (2–5): it rises from the coracoid process and it gets inserted to the undersurface of the clavicle. Comprises two different components; conoid and trapezoid ligaments. All together prevent superior displacement of the clavicle **(Image 2)**.

    - Conoid ligament (2–5): it arises from the root of the coracoid process and its get inserted to the conoid tubercle of the clavicle. It is the main stabilizer preventing superior displacement of the clavicle. It contributes to restrain anterior translation during small movements and it is the main restrainer during larger displacements **(Image 4)**.

    - Trapezoid ligament (2–5): It arises from the posterior region of the coracoid process and its get inserted to the trapezoid line of the clavicle, lateral to the conoid tubercle. It is the main restraint for lateral movements caused by compressive forces on the joint **(Image 4)**.

- Coracoacromial ligament (2–5): It does not contribute to the AC joint stability. It main function is to avoid anteriosuperior displacement of the head of the humerus on glenohumeral joint **(Image 2)**.

Dynamic stabilizers are deltoid and trapezius muscle. Their insertion into the clavicle contributes to the stabilization of the clavicle itself and the stabilization of the AC joint (2–5).

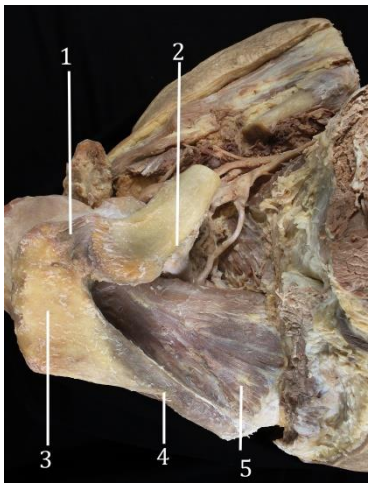

Image 3: shoulder anatomical dissection. Superior view. (Own picture) 1) AC joint. 2) CC ligaments. 3) Acromion. 4) Spine of the scapular. 5) Supraspinatus muscle.

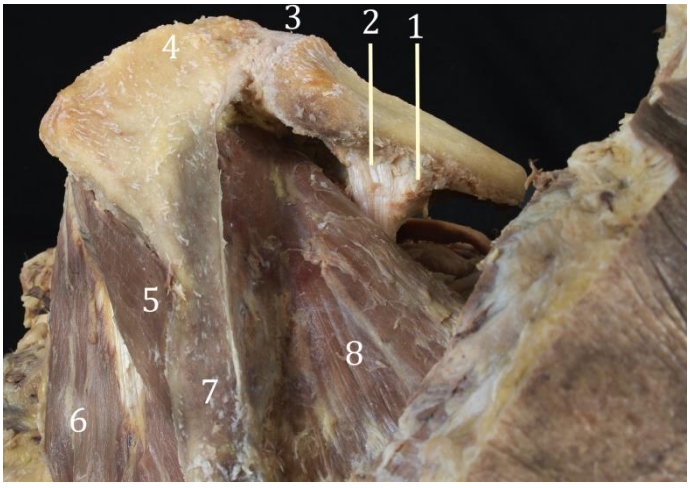

Image 4: shoulder anatomical dissection: Posterior view. (Own picture) 1) Conoid ligament. 2) Trapezium ligament. 1+2) CC ligaments. 3) AC joint. 4) Acromion. 5) Infraspinatus muscle 6) Teres minor muscle. 8) Supraspinatus muscle

		Track	Clavicle's restrained movements	
ESTHATIC STABILIZERS				
AC ligament		Surrounds all AC joint	Anteroposterior displacement Posterior rotation	
CC ligaments	*Conoid ligament*	Coracoid process to conoid tubercle.	Superior displacement	Superior displacement Anterior translation
	Trapezium ligament	Coracoid process to trapezium line of the clavicle.		Lateral displacements
DYNAMIC STABILIZERS				
Deltoid muscle		Insertion along the clavicle and AC joint	Contribution to AC join stabilization and to clavicular motion.	
Trapezius muscle				

Figure 1: AC joint stabilizers (2–5)

AC joint is involved on scapular motion. Normal scapular position and movements are quite complex due to the involvement of several stabilizers. AC joint is the only union between scapular and shoulder griddle so it plays an important role for scapular motion and therefore for shoulder motion (6).

AC tearing increase the clavicular retraction, if tearing of Trapezium ligament is added the internal scapular rotation also increases and, if Coracoid Ligament is also sectioned internal scapular rotation and clavicular retraction are incremented. These injuries modify synchronic motion and it might have clinical consequences such as Scapular Dyskinesis **(2.7. Treatment complications)** causing discomfort, pain or an altered shoulder function (5).

2.2. Epidemiology of the AC joint dislocation.

AC joint dislocations represents above 12% of shoulder griddle injuries (7). Prevalence is higher among young people. The mean age of the consultant patients with AC joint dislocation is 37 years old being most patients between 20 and 39 years old. Frequency is higher in men than in women, ratio 8,5:1. Incidence have been estimated in 1.8/10,000 per year (1,8).

2.3. Etiology of the AC joint dislocation.

Sports and road accidents are the most common causes of AC joint injury (7,8). Contact sports as football, rugby, handball or throwing sports like baseball or athletics are an important source of this kind of injury. Cyclist also are commonly affected (7). AC injury can be the result of a direct or an indirect traumatism.

The most common mechanism of injury is direct trauma. A fall onto the shoulder with the upper limb on adduction position is usually the cause. The impact applies a direct force to the acromion. If there is no clavicle fracture as a result, it results on AC ligament distension (mild sprain). If the force is yet stronger the ligament is strained and broken (moderate sprain). Finally if the ligament cannot resist the force it breaks completely (severe sprain or dislocation) damaging the deltoid and trapezium muscles (9,10).

Indirect mechanism can be produced by an ascendant force on the upper limb (fall onto extended arm and hand) or, less common, by a descendent force produced by traction of upper limb (9,10).

2.4. Classification of the acromioclavicular joint dislocations.

AC joint injuries are classified according to radiological classifications. Tossy et al. (11) proposed in 1963 to classify these injuries into type I, II and III. After that, Rockwood et al. (1,12) added three more types, IV, V, VI, to differentiate different possibilities of total dislocation.

Nowadays Rockwood's classification is the most commonly used. It distinguish the following types of injury (1,12):

- Type I **(Image 6)**: Incomplete injury of AC ligament without CC ligament injury. There is neither radiological evidence nor clinical signs.
- Type II **(Image 5)**: complete injury of AC ligament without CC ligament rupture. A minimal depression of the acromion can be observed on radiographs, distance between acromion and clavicle is less than clavicle thickness (10). Stress views are able to notice this type of injury sometimes.

Image 6: Type I AC joint injury (12)

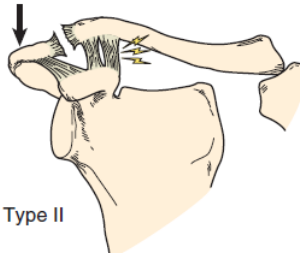

Image 5: Type II AC joint injury (12)

- Type III **(Image 8)**: complete injury of AC ligament and CC ligament. Clavicle is displaced over the acromion with a distance between acromion and clavicle greater than its thickness (10) or a coracoclavicular distance superior to 100% of contralateral distance.

- Type IV **(Image 7)**: complete lesion of both AC and CC ligaments with posterior displacement of the distal portion of the clavicle. Usually there is an injury of the trapezium muscle.

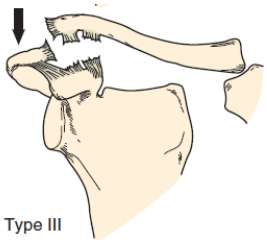

Image 8: Type III AC joint injury (12)

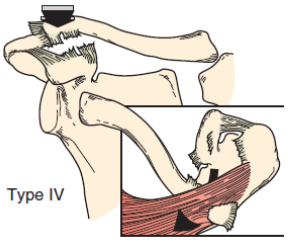

Image 7: Type IV AC joint injury (12)

- Type V **(Image 10)**: complete lesion of both AC and CC ligaments with superior displacement of the distal portion of the clavicle. Distance between the acromion and the clavicle is around 100-300% higher than the contralateral.

- Type VI **(Image 9)**: complete lesion of both AC and CC ligaments with inferior displacement of the distal portion of the clavicle placing under the coracoid process.

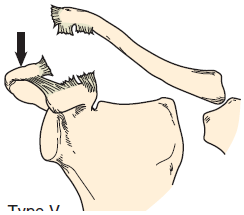

Image 10: Type V AC joint injury (12)

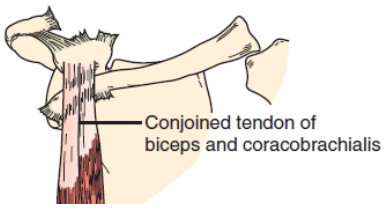

Image 9: Type VI AC joint injury (12)

2.5. Clinical manifestations and diagnosis of AC joint dislocation.

Patients arrive to the Emergency Department with complains of pain in the anterolateral region of the neck or in the anterolateral deltoid zone. Patients usually appears with the affected limb resting in a protective manner supported by the opposite hand and arm braced against the torso and elevating the affected shoulder in order to relieve stress and pain (12).

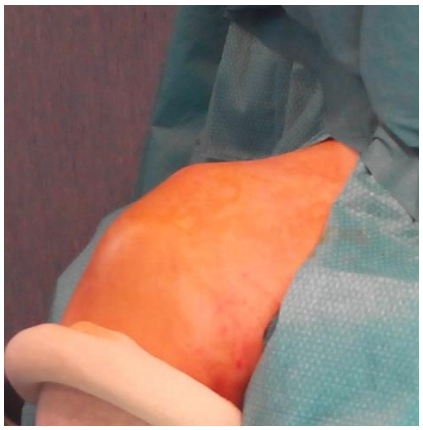

Image 12: Shoulder deformity caused by AC dislocation

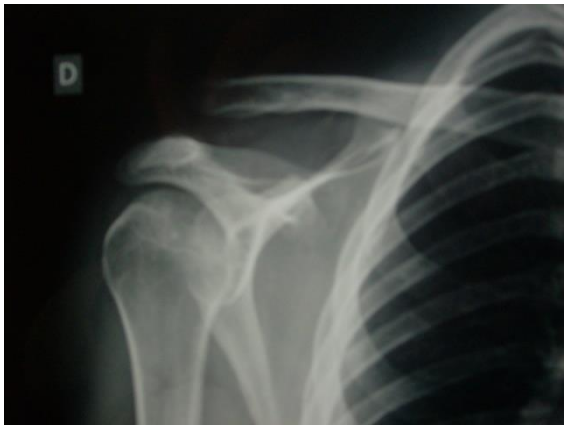

Image 11: Type III AC dislocation. AP view.

Observing the patient a swelling or ecchymosis on the shoulder can be noticed. In complete dislocations the distal portion of the clavicle may be prominent beneath the skin **(Image 12)** and a "positive piano key sign" may be present (1,7,12,13).

Physical examination may be useful in mild injuries (types I and II) where no observable or palpable deformities manifest. Painful cross arm adduction test or visible shoulder prominence when the affected limb is holding weight can be helpful for diagnosis (1).

Active and passive motion does not exacerbate the pain in any direction or degree. Sometimes active motion is limited by shoulder pain but not due to other structural injury (12).

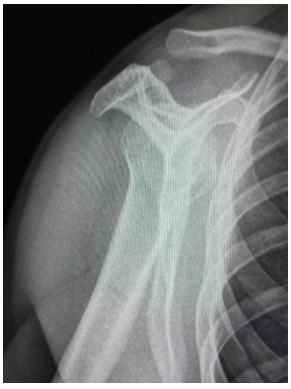

Image 14: type III AC dislocation. Scapular Y view.

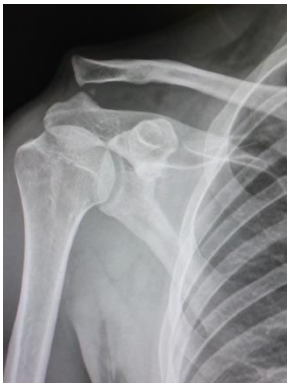

Image 13: Type III AC dislocation. Zanca's view.

If only horizontal instability is found at physical examination type I and II injuries are suspected. If vertical instability is added, type III or higher injury is more probable (12,13).

Imaging will confirm the diagnosis and will classify the type of acromioclavicular dislocation. Anteroposterior view and axial view are necessary to apply Rockwood's classification (7,14). Scapular Y view **(Image 14)** or Zanca's view **(Image 13)** can be helpful to assess the distal portion of the clavicle in uncertain cases (1).

Type	Clinical manifestations	Imaging	Damaged Tissues
I	No deformity, tenderness over AC joint	No alterations	AC: sprain
II	Clavicle horizontal instability	Minimal acromion depresion	AC: torn , CC: sprain
III	AC deformity, horizontal and vertical instability, reducible: "piano key sign".	AC distance 25-100% of contralateral	AC: torn, CC: torn
IV	Tenting on posterior shoulder may be present	Posterior displacement	AC, CC: both torn, Trapezius muscle
V	Subcutaneous prominence of the clavicle, not reducible.	Superior displacement, AC distances 100-300% of contralateral.	AC, CC: both torn, Deltoid muscle
VI	Resulting from severe traumas usually combined with multiple injuries.	Inferior displacement, clavicle under coracoid process	AC, CC: both torn

Figure 2: clinical manifestations and diagnosis of AC injuries (1,7,12–14)

2.6. Treatment of acromioclavicular joint injuries.

There is consensus in the literature for type I and II AC joint injuries to treat them in a non-operative way. For type IV, V and VI operative management is always recommended. For Type III AC joint injuries literature is still debating about which is the most convenient treatment. There is no clear evidence for neither options of management to be better than the other (7,12–15).

Type I injuries are usually treated with the use of a simple sling during 3-10 days, ice, oral nonsteroidal anti-inflammatory drugs as analgesia and early physical therapy to strengthen scapula stabilizers and the rotator cuff. Return to normal daily activity in 2 weeks (7,14–16).

Type II injuries treatment are quite similar to type I except if a significant instability is found (10). The main differences in the treatment are the time of sling, about 2 weeks, and a more progressive reincorporation to daily activities. Carrying weight or back to sports are allowed in 6 weeks (14–16).

There is consensus for operative treatment in type IV, V and VI injuries in all kind of patients if no surgical contraindications are present in order to relieve pain and diminish associated mobility in soft tissues (7,16). It is recommended that surgical techniques include ligament reconstruction or reinforcement and damage muscular fascia reconstruction (14).

Debate is focused on type III treatment. No clear evidence to fully support any treatment is the main reason to design this protocol.

<table>
<tr><th>Type</th><th>Treatment</th><th></th><th>Physical therapy</th></tr>
<tr><td>I</td><td>Non-operative</td><td rowspan="2">Simple Sling + analgesia</td><td rowspan="6"><u>0-4 weeks</u>
Mobilization of elbow, wrist and hand
<u>4-6 weeks</u>
Passive motion
<u>4-8 weeks</u>
Active motion
<u>>8 weeks</u>
Exercises against resistance</td></tr>
<tr><td>II</td><td>Non-operative</td></tr>
<tr><td>III</td><td>Uncertain</td><td>Non-operative/Operative</td></tr>
<tr><td>IV</td><td>Operative</td><td rowspan="3">Operative treatment including deltoid and trapezius fascia reparation</td></tr>
<tr><td>V</td><td>Operative</td></tr>
<tr><td>VI</td><td>Operative</td></tr>
</table>

Figure 3: AC injury treatment (7,12–16)

2.6.1. Treatment of type III AC joint dislocation.

Nowadays there is still a discussion on the proper treatment of type III AC joint dislocation. Prospective studies (17–21), concludes on an absence of enough strong evidence to recommend any option. Systematic reviews (7,16,22,23) and meta-analysis (24) cannot conclude on proper recommendations due to the lack of prospective studies with high statistical power (25). For that reason, the clinician must decide which is the better therapeutic choice regarding the patient's condition. Young patients usually are proposed for operative treatment and for older patients a non-operative management is usually chosen for having a worse outcome with operative treatment (23).

2.6.1.1. Non-operative treatment of type III AC joint injury.

Most spread non-operative treatment is the use of a simple sling during 4 weeks. Ice, NSAID, if needed, as analgesia and physical therapy for recovering motion range and muscle strengthening (7,16,21).

2.6.1.2 Operative treatment of type III AC joint injury.

There are many surgical techniques to treat type III AC joint injury. One of the many existent classifications categorized this techniques according to the fixation of the AC joint, the fixation of the CC ligaments or if there is a ligament reconstruction (14).

- AC joint fixation (7,14):

Kischner Wires (K-wires) AC fixation: there are several techniques using K-wires for AC fixation in order to stabilize the joint in an anatomical position. Joint cerclages or transcortical screws can be combined with k-wire fixation.

Hook plate: One of the most common techniques for AC joint reduction. It consists in the use of a screw fixation plate over the clavicle with a hook in its end to fix it under the acromion to keep the joint in an anatomical position. In 6 weeks the plate must be removed during a second surgery.

- Coracoclavicular Fixation (7,14):

Bosworth screw: Old technique consisting of fixation of the clavicle and the coracoid process using a cannulated screw to restore anatomical position of the joint. The screw must be removed in a second surgery in 8 or 12 weeks due to the high risk of migration.

TighRope® device (by Arthrex): this is an anatomical reconstruction technique of the CC ligaments. First generation of this device consisted in two titanium buttons linked by strands of FiberWire® number 5. One button was placed on the clavicle and the other in the coracoid process. Nowadays second generation is preferred. New devices consist in three buttons, two clavicular components and one coracoid component **(Image 15)**. This device is placed in the same position that the anatomical CC ligaments. (16). Current literature seems to demonstrate better biomechanical results Twin Tail TighRope® (by Arthrex) than using other anatomical reconstructions in acute injuries (26,27).

Image 16: Twin Tail TightRope®

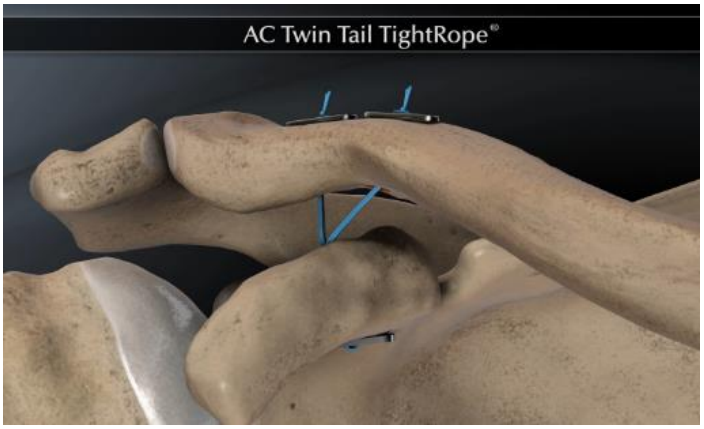

Image 15: Twin Tail TightRope® graphic representation of inserted device (36).

- Ligament's reconstruction (7,10,14):

Waver-Dunn: use of CA ligament for reconstruction of AC ligament injuries.

Modified Waver-Dunn: derived from the previous technique it consists on the excision of the distal clavicle and the transposition of the CA ligament from its acromial insertion to the distal clavicle.

Mazzoca anatomic coracoclavicular reconstruction: this technique consists in the reduction of the AC joint, then, a semitendinsus muscle tendon autologous or homologous graft is passed under the coracoid process and fixed with screws in two drilled holes in the clavicle.

Nowadays Bosworth screw is not recommended due to the requirement of a second surgery to remove it by its high migration or braking risk. Hook plate also is not the first recommendation for the requirement of a second surgery for material removing. Although migration or plate braking risk is inferior than Borsworth screw it may cause other complications like acromion fracture (14).

K-wire fixation it is still widely used due to its technical simplicity and the posterior easy extraction of the material (16).

Actual recommendations are in favor of reconstruction techniques. Ligament reconstruction is preferred to articular fixation. But, if an articular fixation technique is performed ligament reconstruction should be done (14).

Despite the absence of clear evidence to establish optimal time of surgery, early surgery for acute lesions seems to have better outcomes than delayed surgery (16).

2.6.1.3. Physical therapy for type III AC joint injury recovering.

After non-operative and operative treatment's immobilization physical therapy is indicated to regain shoulder function. During shoulder immobilization, mobilization of the elbow, wrist and hand must be done in order to avoid stiffness. Only for doing that exercises simple sling can be removed. At this period ice can be applied as analgesia (28).

Once the immobilization is removed at 4 weeks of the injury, or the surgery, passive assisted or self-assisted mobilizations of the shoulder will be started in order to recover range of motion. At 6 weeks active mobilizations will be started. Firstly slides of the hand over a table will be done and the inclination surface must increase until slide the hand on a wall. Then free active movement will be allowed. At 8 weeks exercises against resistance will be initiated in order to regain strength (28).

2.7. Treatment complications

The incidence of complications due to the treatment is not defined. There is only one prospective study (Joukainen et al (20)) comparing complication's ratio as a secondary objective on both treatments and there were no significant differences. Nor Systematic reviews (7,16,22,23) and meta-analysis (24) analyze this data, Instead they describe complications case by case.

The most frequent remaining symptoms or complications after the conservative treatment are the following:

Most patients suffer a shoulder deformity. The unreduced joint is observable as a prominence and it can cause a subjective disconformity with the applied treatment. This prominence does not affect in any case to the shoulder motion or range of movement (20,21).

Residual pain and weakness are estimated using past studies in a 7-10% of the cases. Patients presenting shoulder pain accompanied or not with shoulder weakness probably will need medical (analgesia) or surgical (distal clavicle excision) treatment (17–19). This is the most frequent late complication (29).

Taft *et al.* (30) estimated a 35% of patients presents post traumatic osteoarthritic changes on radiographs but no relevant for clinical outcomes.

Recently Scapular Dyskinesis is beginning to be considered a consequence of AC joint injuries. It is an alteration of scapular position or motion during scapulohumeral movements. AC injuries, among many other pathological conditions, can be a cause of this clinical condition due to the exposed movement alterations **(2.1. Anatomy and Physiology of the acromioclavicular joint.)**.

Scapular Dyskinesis can produce shoulder pain, exacerbates symptoms already present or can produce a worse outcome for shoulder treatments (31,32). Gumina *et al.* (31) estimated that about 70.6% of patients affected of type III acromioclavicular non-operative treated in a 28 months follow up presented this condition. These patients present significant inferior values for Constant Score (CS) and Simple Shoulder Test (SST) **(8. VARIABLES)** meaning a worst shoulder function respect patients affected of type III AC injury without Scapular Dyskinesis.

Scapular Dyskinesis can be solved with physical therapy. Cabrone *et al.* propose a 6 weeks physical therapy for treating this condition (33).

Operative management has inherent complications to surgical procedures as wound infection, deep tissue infection or scars. Also every surgical technique has its own complications such a distal clavicle fracture on hook plate, broking and migration of K-wires or Bosworth screws on those procedures or breaking of tightrope device or the biological graft (10).

Moreover operative treatment has also complications in common with non-operative treatment like residual pain, limited range of motion or Scapular Dyskinesis (10). This last one has a considerably inferior rate of affected patients, estimated by Murena *et al.* (34) as a 10% of the patients summited to surgery.

2.8. Treatment outcomes

Previous prospective studies (17–21) have tried to compare efficacy of the non-operative treatment versus operative management. Although these are prospective studies they were not statistically strong enough to extract high level evidence based recommendations. Furthermore in each study different treatments, as operative as non-operative, were applied. This fact difficults the extraction of clear evidence in favor or

against both treatments. The results of these prospective studies are synthetized on **Figure 4**.

All studies compared shoulder function after both treatments. No differences were found on recovering of shoulder range of motion. It was similar before and after both interventions. Michael *et al.* (21) observed that in one year of the injury all patients recovered full range of motion.

Clinical recovery was measured by Larsen *et al.* (18) using the Imatani score. Michael *et al*. (21) used the Disabilities of the Arm, Shoulder and Hand (DASH) Score. Both of these scores are patient based; they not include clinician's exploration or observation. The two studies, found that non-operative treatment has a faster recovery in the first three months after the injury. Michael *et al.* (21) also used the Constant Score (CS), an examiner based test; it includes physical examination and observation. It also observed a faster recovery for non-operative treatment. The recover was similar at the 13th month according to Larsen study, and at the 6th month according Michael study. A long time assessment of 18 years was performed by Joukainen *et al.* (20). They didn't fount statistical differences on both group function scores.

Assessment of radiological outcome according to Michael *et al.*(21) in a follow up period of 2 years found significant differences in the number of patient with an anatomical reduction of the AC joint in favor of operative treatment. Joukainen *et al.* (20) found significant differences too at 18 years of follow up. Both studies found no significant differences regarding the presence of osteoarthritis, ostheolysis or CC ligament calcification. Imatani *et al.* (17) Larsen *et al.* (18) and Bannister *et al.* (19) did not analyze radiological outcome but they notice that radiological findings are not correlated with clinical manifestations of the patient.

Complications ratio in each treatment is only statisticaly analized in Joukainen *et al.* (20) study. It found no statistical differences comparing complications ratio of each group of treatment. Other studies only describe the complications case by case with no statistical analysis. It is necessary to clarify that in none of these studies was a variable or objective defined in order to study differences in complications. Furthermore, no study takes into account Scapular Dyskinesis, which, as exposed, may have clinical repercussions. So, there is not enough data to support the optimal treatment even if the present data suggests that non-operative treatment has a lower complication ratio.

Return to work or to normal daily activity is an interesting variable due to the interest of returning to it as soon as possible. Larsen *et al.* (18) observed that the non-operative treated group patients has an early return to work on 6 weeks while operative treated group took 8 weeks for their return to work. Even with this obtained data no statistical differences were found. Bannister *et al.* (19) and Michael *et al.* (21) did find differences. Bannister divided the patients according to its type of job and manual workers on the non-operative management took 4 weeks to return to work against the 11 weeks which took the operative group. Clerical workers were earlier reincorporated too, 1 week for non-operative treatment against 4 in operative management. In the same study also differences were found when the return to sports was compared, 11 weeks for non-operative treatment against 16 on the operative. On Michael's study was described an earlier return to work for the non-operative treatment. At the 3rd month after injury differences in reincorporation still existed and at 1 year of the injury almost all patients in both groups were working again.

Finally cosmetic outcomes were the most difficult variable to assess. For that reason there were only two studies which assess that outcome. Imatani *et al.* (17) only noticed that some patients were more concerned about the esthetics than shoulder function. Joukainen *et al.* (20) did not consider deformity as a complication but it was presented by all the patients on the non-operative group. Michael *et al.* (21) compare the disagreement with the shoulder apparience in both groups and did not found statistical differences at 1 and 2 years of the injury.

STUDY	***IMATANI 1975***	***LARSEN 1986***	***BANNISTER 1989***	***JOUKAINEN 2014***	***MICHAEL 2015***
Non-operative treatment	Velpau bandage immobilization minimum of 3 weeks + physical therapy	Simple sling + bandage binding the arm to the body 2 weeks	simple sling 2 weeks	Kenny howard splint 4 weeks + physical therapy	Simple sling 4 weeks + physical therapy
Operative treatment	Steinman pins AC transfixing/Bosworth Screw + physical therapy	Kischner wires AC transfixing + suture of AC ligament + physical therapy	AC transfixing with AO cancellous or malleolar screw and washer + physical therapy	Kischner wires AC transfixing (removal after 6 weeks)+ suture of AC ligament + physical therapy	Hook plate + sling 4 weeks
randomization	No specified	Yes	Yes	yes	yes
Number of participants	12 ***N-O***/11 ***O***	43 ***N-O***/41***O***	33 ***N-O***/27 ***O***	9 ***N-O***/16 ***O***	43 ***N-O***/40 ***O***
Follow up	12 months	13 months	4 years	18 years	2 years
Clinical outcomes					
Non validated scores	***Imatani Score designed for this trial*** <u>12m:</u> N-O: 6 excellent/1 good O: 4 excellent/5 good	***Evaluation point system designed for this trial*** <u>3m:</u> better N-O (SS) <u>13m:</u> NS diferences	***Imatani Score*** <u>1Y:</u> N-O: 88% good or excellent O: 77% good or excellent <u>4Y:</u> N-O: 59% perfect O: 69% were perfect	------	-----
DASH score (Mean scores)	------	------	------	<u>18Y:</u> NS differences	<u>6w:</u> ***N-O*** 31/ ***O*** 45 (SS) <u>3m:</u> ***N-O*** 16/ ***O*** 29 (SS) <u>6m:</u> ***N-O*** 12/***O*** 14 (NS) <u>1Y:</u> ***N-O*** 9/***O*** 9 (NS) <u>2Y:</u> ***N-O*** 5/ ***O*** 6 (NS)
SST	------	------	------	<u>18Y:</u> NS differences	
CS (Mean scores)	------	------	------	<u>18Y:</u> NS differences	<u>6w:</u> ***N-O*** 51/ ***O*** 75 (SS) <u>3m:</u> ***N-O*** 69/ ***O*** 86 (SS) <u>6m:</u> ***N-O*** 80/***O*** 92 (SS) <u>1Y:</u> ***N-O*** 91/***O*** 91 (NS) <u>2Y:</u> ***N-O*** 94/ ***O*** 91 (NS)

STUDY:	IMATANI	LARSEN	BANNISTER	JOUKAINEN	MICHAEL
Radiological outcome	No radiological outcomes comparison between groups	No radiological outcomes comparison between groups	No radiological outcomes comparison between groups	Wider ACJ space on N-O (SS)	Wider ACJ and CC distance on N-O. (SS) NS diference on osteoarthritic changes
Complications: (No statistical analysis except Joukainen)	***N-O***:------ ***O***: 2 patients had technical failures and they were excluded No statistical analysis	***N-O***: Severe pain: 2 (R) Mild pain: 8 Limited motion: 4 ***O***: Severe pain: 3 (R) Mild pain : 7 Discomfort: 1 (R) Wound infection: 6 (R)	***N-O***: Weakness: 4 (R) Severe pain: 2 (R) Cosmetic: 1 (R) ***O***: Broken screw: 1 (R) Clavicle fracture: 1 (R) Severe pain: 2 (R)	***N-O***: Deformity: all Severe pain: 1 (R) ***O***: Technical failures: 5 (R) Wound infection: 1 (R) NS differences between groups	***N-O:*** Soft tissue complications due to repeat falls after treatment: 2 (R) Heterotopic ossification: 1 ***O:*** Technical failures: 2 (R) Acromial erosion: 2 (R) Clavicular fracture 1 (R) Stiff shoulder: 1 (R) Deep wound infection: 1 (R) Heterotopic ossification: 2
Return to work	------	***N-O***: 6w ***O***: 8w NS diferences	***N-O***: Manual workers: 4w Clerical workers: 1w Back to sports: 7w ***O***: Manual workers: 8w Clerical workers: 4w Back to sports 16w	------	***N-O***: 76% patients returned at 3 months ***O***: 43% patients returned at 3 months (SS) At 1 year almost all patients on both groups returned
Cosmetic outcomes	Some patients complain about cosmetic more than functional outcomes			Present in all ***N-O*** patients	Patients unhappy with the appearance of their shoulder at <u>1Y:</u> ***N-O***: 5/32 ***O***:2/38 <u>At 2Y:</u> ***N-O***:5/23 ***O***: 5/23 NS diferences

Figure 4: Prospective stidues data. (17–21)

3. JUSTIFICATION

The main reason for developing this project is the lack of strong evidence based recommendations for non-operative or operative treatment (22).

As previously mentioned **(2.8. Treatment outcomes)**, both non-operative and operative management have similar functional outcome on those studies. Although current literature tends to recommend non-operative treatment, more prospective studies are needed (20).

Past literature only compared non-anatomical surgical techniques with conservative treatment. As seen **(2.6.1.2 Operative treatment of type III AC joint injury.)** nowadays anatomical procedures are preferred (16). Current literature seems to demonstrate better biomechanical results with triple endobuton devices (Twin Tail TighRope® by Arthrex) than using other anatomical reconstructions in acute injuries (26,27). Twin Tail TightRope® (by Arthrex) is the current method used for treating type III acromioclavicular dislocations in Hospital Universitari Dr. Josep Trueta. So, this study is proposed to increase the evidence of actual techniques regarding non-operative management.

It is also been observed that only one study compares the clinical significant complications ratio between both groups of treatment **(2.8. Treatment outcomes)**, therefore, it is necessary to assess this outcome properly, emphasizing on Scapular Dyskinesis due to its exposed consequences **(2.7. Treatment complications)**, to be able to recommend the safest and the most comfortable treatment for the patient.

To summarize, we want to add high level evidence to the current literature adapted to the new technics in the treatment of acute type III AC dislocation. To reach this objective a randomized controlled clinical trial is proposed.

4. QUESTION

Has operative management (Twin Tail TighRope®, by Arthrex) less complication ratio at short-term and mid-term than non-operative treatment?

5. HYPOTHESIS

Knowing the type of complications and its causes, our hypothesis is that operative management will present an inferior ratio of complications than the non-operative management and it will need less additional treatment.

6. OBJECTIVE

6.1. Main objective

To compare the complication's ratio at 30 months of clinical follow up requiring further treatment presented on operative and non-operative treatment in patients aged between 18 and 40 years old with acute Rockwood's type III acromioclavicular dislocation.

6.2. Secondary objectives

- To compare the clinical outcomes such as pain, shoulder range of motion and strength, joint instability and quality of life of the operative treatment with the non-operative management in patients over eighteen years old with acute Rockwood's type III acromioclavicular dislocation.

- To compare radiological outcomes including distance between the acromion and the clavicle, distance between coracoid process and clavicle, osteoarthritis and soft tissue calcifications of the operative treatment with the non-operative management in patients over eighteen years old with acute Rockwood's type III acromioclavicular dislocation.

- To assess subjective satisfaction with cosmetics outcomes after operative and non-operative management in patients over eighteen years old with acute Rockwood's type III acromioclavicular dislocation.

- To compare time to return to work, sports or daily activities before of the injury after operative and non-operative management in patients over eighteen years old with acute Rockwood's type III acromioclavicular dislocation.

- To compare subjective satisfaction with clinical outcomes in patient of each group of treatment in patients over eighteen years old with acute Rockwood's type III acromioclavicular dislocation.

7. METHODS

7.1. Study design

To obtain high level evidence a clinical trial is needed. This will be a controlled, randomized and observer blind clinical trial. The center of reference will be Hospital Universitari Dr. Josep Trueta. Patients of Hospital Santa Caterina, hospital de Blanes and hospital de Olot also will be referred to the center of reference. The duration of this trial will be 6 years.

7.2. Population of interest

The study population will be all patients aged between 18 and 40 years old who present acute type III acromioclavicular dislocation according to Rockwood's classification **(2.4. Classification of the acromioclavicular joint dislocations.)**.

7.2.1. *Inclusion criteria*

- Patients aged 18-40 years old.
- Type III acromioclavicular dislocation.
- AC joint dislocations < 21 days after injury.
- Closed injury.
- Informed consent.

7.2.2. *Exclusion criteria*

- Patients aged <18 and >40 years old.
- Types I, II, IV, V and VI of acromioclavicular dislocation.
- AC joint dislocations > 21 days after injury.
- Open wound.

- Prior symptoms in the shoulder including Scapular Dyskinesis.
- Ipsilateral shoulder injury.
- Serious concomitant traumatic lesion such as politraumatic patients or severe head injury.
- Past surgeries on injured shoulder.
- Medical contraindication to surgery.
- Medical condition limiting expectancy of life.

Age restrictions are due to the different outcomes observed on past studies on people above 40 years. This group of patients used to have worse outcomes than younger ones. This fact could be a confounding factor for data analysis.

7.2.3Withdrawal criteria

- Final diagnosis of type IV, V, VI AC joint dislocation.
- Difficulty with maintaining follow-up.
- Revocation of information consent to not continue within the study.

7.3. Sample selection

The sample selection will be consecutive and non-probabilistic. Every patient seen on emergency department or referred to us meeting inclusion criteria and not exclusion will be offered to be enrolled in this trial. Interested patients will be informed about the study with an information sheet **(annex 1)**. Afterwards they will be contacted by a trial doctor who will obtain informed consent **(annex 2)**.

7.3.1. *Sample size*

Based on the study of Gumina et al. (27) that approximates incidence of Scapular Dyskinesis on patients with chronic acromioclavicular joint dislocation about 70.6%, Accepting an alpha risk of 0.05 and a beta risk of 0.2 in a two-sided test, 28 exposed subjects to the operative group and 28 in the non-operative are necessary to recognize as statistically significant a relative risk greater than or equal to 0.35. A proportion in the non-exposed group has been estimated to be 0.7.

Incidence of acromioclavicular joint dislocation in Hospital Universitari Dr. Josep Trueta is estimated on 18 cases per year. Therefore two and a half years are needed at least to reach the sample size.

Using past studies data as reference, it has been anticipated a drop-out rate of 20% of patients lost during the follow up.

Sample size has been calculated with GRANMO (35) using the poisson approximation.

7.4. Randomization

Statistician expert will create a database containing ordered codes which will be assigned consecutively to participant patients. There will be as codes as patients estimated on the sample size, 28 for each intervention. These codes will indicate if the patient gets treatment 1 or 2 and main investigators will decide which intervention, A or B, corresponds to 1 or 2. So, the follow up observer and the statistician will not know which intervention is applied to interventions 1 and 2. Randomization will be generated by the SPSS software by the statistician expert.

7.5. Masking techniques

Studies applying surgical techniques have a detection bias due to the impossibility of blinding the surgeon. 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 an external examiner will assess the participants during the follow up. As surgical stigmas are easily noticed, participants will have a bandage on their shoulder and they will be told not to reveal the type of treatment received, so, this study will be an observer blind trial.

Statistical consultant will not know what intervention is assigned for each treatment group. This way detection bias will be reduced.

7.6. Study interventions

The main objective of this study is to compare complications in two different treatment options. One treatment group will receive intervention A: Operative treatment. The other group will receive intervention B: non-operative treatment.

Once the patient is diagnosed it will be asked to take part in our study. An information sheet **(annex 1)** will be given to inform the patient. If the patient agrees, information consent **(annex 2)** will be given and randomization will proceed.

A code will be assigned to each participant **(7.4. Randomization)**. If non-operative treatment is the chosen one, attending doctor will proceed the treatment. However, if operative treatment is chosen, the doctor will inform that surgery will be performed and it will be scheduled after obtaining the surgical procedure consent **(annex 3)**.

Non-operative management will be performed immediately at the emergency room. Operative treatment will be scheduled as soon as possible within the day after the injury and it will be performed at operating room of "Hospital Universitary Dr. Josep Trueta" by the shoulder surgeon's team.

7.6.1. *Intervention A: Operative management*

Preoperative care will consist of anesthesiology assessment before the intervention. General anesthetics and an interescalene brachial plexus block will be performed and intravenous prophylactic antibiotics will be administered.

In this study a triple endobutton device technique has been selected for the reasons exposed before **(2.6.1.2 Operative treatment of type III AC joint injury.)**. The selected device is the Twin Tail TighRope® (by arthrex). This choice has been made because of the technical experience on the surgical team and for the supporting evidence that this is one of the best surgical options.

Surgery should be performed within the day after the injury. The standard surgical approach will consist of the following **(annex 10)**:

1. Skin incision from the acromion to the middle-third of the clavicle
2. Exposition of dislocated AC joint and the coracoid process.
3. Drilling of coracoid hole and insertion of coracoid button.
4. Drilling of two clavicle holes and insertion of clavicle buttons.
5. Reduction of AC joint and fixation of Twin Tail TighRope® (by Arthrex) device.
6. Suture of trapezium and deltoid fascia.
7. Suture of skin incision.
8. Bandage of surgical wound and simple sling immobilization.

Postoperative care will include the use of sling for comfort and inmovilization during 4 weeks. After 4 weeks of the operation physical therapy will be initiated as explained **(2.6.1.3. Physical therapy for type III AC joint injury recovering.)**. Patients could be back to work or to daily activities when clinical manifestations allow a normal shoulder function

7.6.2. *Intervention B: Non-operative management*

A simple sling will be used during 4 weeks. Ice and NSAID can be used as analgesia if needed. Rehabilitation program will start in 4 weeks as explained **(2.6.1.3. Physical therapy for type III AC joint injury recovering.)**. Patients could be back to work or to daily activities when clinical manifestations allow a normal shoulder function.

8. VARIABLES

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

- **Independent variable:**

Being allocated on operative or non-operative treatment will be the independent variable of this study.

- **Dependent variable:**

The main variable of the study will be the incidence of relevant complications occurring during 30 moths of clinical follow up with each intervention. A relevant complication will be defined as the necessity of treatment: medical, surgical or physical therapy, to solve clinical symptoms due to the intervention or derived from the injury.. Information of the patients will be collected in an anonymized table as “need for secondary treatment” and “no need for secondary treatment”.

- **Secondary variables:**

In addition to the main dependent variable, during the follow-up the following items will be assessed and data will be registered on the participant data sheet **(annex 5)**:

- *Pain*: measured with VAS scale in every meeting in the follow-up.

- *Shoulder range of motion*: Degree of motion measured with clinical examination in all movements (flexion, extension, abduction, internal rotation and external rotation).

- *Arm strength*: Measured with Daniel's scale.

- *Joint instability*. Measured with clinical examination. Described as "yes" or "no".

- *Shoulder function*: DASH score **(annex 6)** will be used to assess symptoms and function of the entire upper extremity in a patient-based way. Simple Shoulder Test (SST) **(annex 8)** will be used to assess shoulder function in a patient-based way. Finally, Constant Score (CS) **(annex 7)** will be used to assess shoulder function in an examinator-based way.

- *Quality of life*: measured with SF-36 test **(annex 9)**.

- *Radiological outcomes*: Distance between acromion and clavicle, and distance to coracoid process to the clavicle will be measured in millimeters on AP view. Presence of osteoarthritis and CC ligaments calcification will be registered as "presence" or "absence".

- *Subjective satisfaction on cosmetics outcome*: Patients will be asked if they are in accordance the applied treatment and data will be registered as "yes" or "no".

- *Subjective satisfaction on clinical outcomes*: Patients will be asked if they are in accordance the clinical outcomes and data will be registered as "yes" or "no".

- **<u>Covariates:</u>**

- Age.
- Gender.
- BMI.
- Physical activity.
- Type of work.
- Physical therapy incompliance.
- Back to work or sports before solving clinical symptoms .

9. DATA COLLECTION

- First visit – Emergency Department – intervention B: Non-operative treatment:

Patients diagnosed of acromioclavicular dislocation on the emergency room will be explored and questioned about age, sex, profession, physical activity and mechanism of injury in order to obtain ordinary clinical history.

After anamnesis, radiological examination will be done to define type of dislocation according to Rockwood's classification. An anteroposterior view and an axillary view will be performed for primary assessment. Scapular Y or Zanca's views can also be performed if there is any doubt on the primary images **(2.5. Clinical manifestations and diagnosis of AC joint dislocation.)**.

If the patients meet the inclusion criteria but not exclusion it will be proposed to participate in the study. If the patient agrees, it will be necessary to sign an information sheet **(annex 1)** and written informed consent **(annex 2)**. After consent is given, a code will be assign to each patient for decide which treatment will be applied **(7.4. Randomization)**. A new Participant data sheet **(annex 5)** must be filled with patients' data.

Once randomization assigns one management for the patient, if non-operative management **(7.6.2. *Intervention B: Non-operative management*)** is chosen, the patient will be treated in the emergency room, and it will be referred to Physical therapy **(2.6.1.3. Physical therapy for type III AC joint injury recovering.)** for 10 weeks and to the follow-up with a blind examiner doctor. If operative management is the chosen one, the patient will be hospitalized in order to perform the surgery next day of the injury.

- Hospital admission – intervention A

Patient will be admitted on OTS unit after being evaluated on emergency department. Nursery team will check vital signs before the hospitalization and the patient must fast 6h before the intervention. Proceeding surgeons will explore and asses the patient during the hospitalization before the intervention.

- Preoperative – Intervention A

Anesthesiologists will assess the patient before the intervention during the patient's hospitalization. ASA score will be used for surgical risk.

- Intervention A: operative treatment

All members of the shoulder surgical team know the procedure. The procedure will be done by two shoulder team surgeons and one OTS resident doctor, usual instrumentalist nurses on trauma surgery and one anesthesiologist.

Intervention **(7.6.1. *Intervention A: Operative management*)** will be performed in the operating room and X-ray equipment will be needed for final assessment.

Time of surgery, from first skin incision to skin bandage, and any complication during the procedure must be registered.

Patients will use a simple sling for comfort and immobilization during 4 weeks. After that it will be referred at physical therapy **(2.6.1.3. Physical therapy for type III AC joint injury recovering.)** for 10 weeks.

- Postoperative assessments:

Patients will stay in the post-surgical unit until they recover from anesthesia. It is expected that this period will last about five hours. After their recovery patient will be returned at OTS unit for one more day. Nursery team will register all the incidences during the hospitalization and an OTS doctor will discharge the patient. The follow up and one additional visit for suture removal will be scheduled at the patient's leaving.

- Follow up:

Primary objective of this study is the assessment of complications in 30 months of follow up. This objective, and the secondary ones, will be evaluated during the follow up visits in the outpatient service at 4, 8, and 12 weeks and at 6, 12, 24 and 30 months. For procedure A, one additional visit on the first week after the surgery has to be scheduled to remove the wound sutures. This visit will not be performed by a follow up examiner, it will be done by the proceeding surgeon instead. The information will be collected in the Participant Data Sheet **(annex 5)**.

If any complication appears after the intervention the patient is informed to come back as soon as possible.

The follow up examiner will be performed a physical examination measuring degree of motion, strength, joint instability and VAS pain score. Also DASH score, SST and CS will be assessed in all meetings. Radiological assessment will be done at 4, 8 and 12 weeks, and at 12 and 30 months. SF-36 test about QoL will be done at 8 weeks and 12, 30 months meetings.

All the steps are synthetized on section **9.2. Schedule of assessment**.

9.2. Schedule of assessment

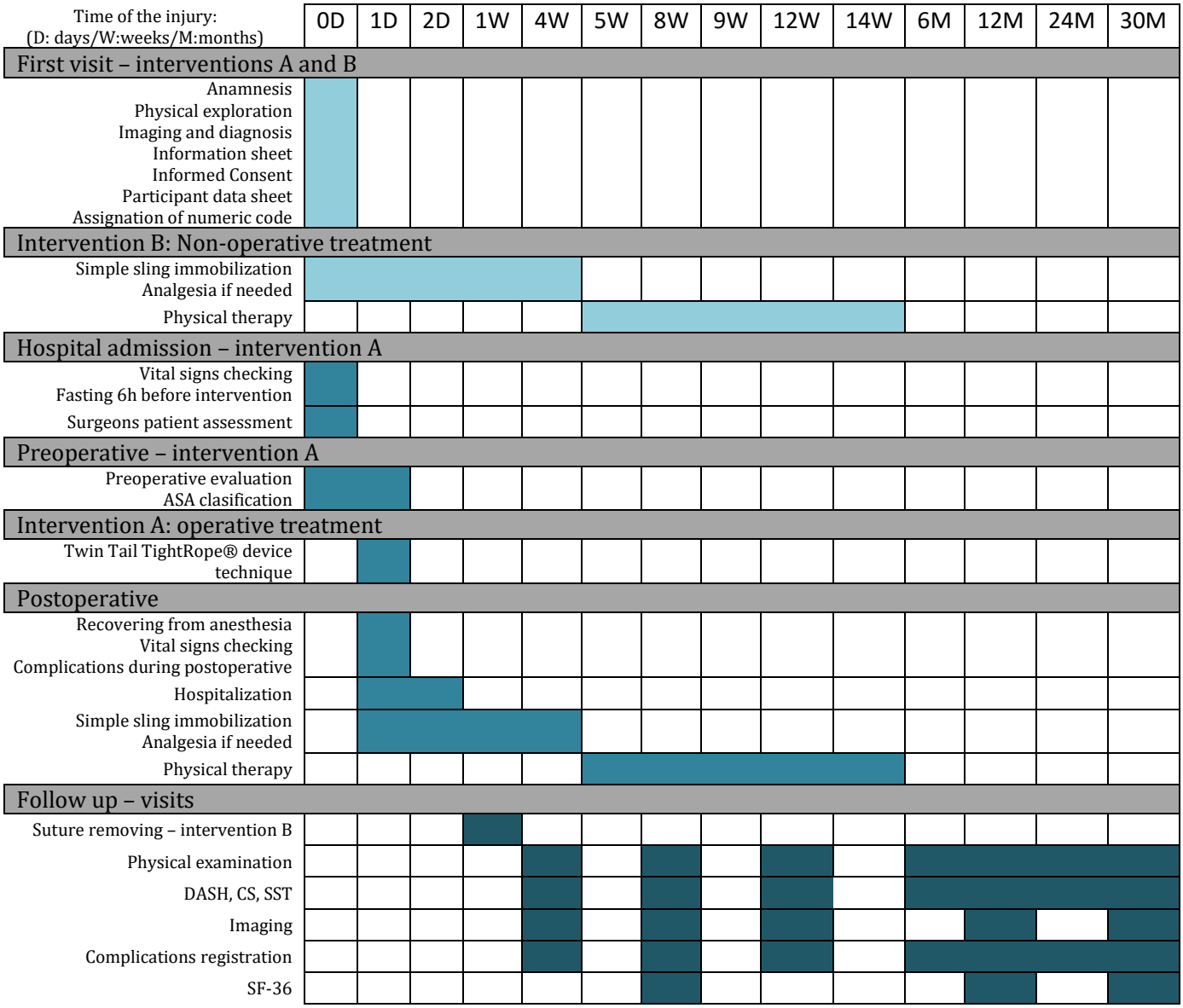

Figure 5: Schedule of assessment

10. STATYSTICAL ANALISIS

Statistical analysis will be done with Statistical Package for the Social Science (SPSS) software for Windows®. Sample size calculation has been defined in Methods section **(7.3.1. *Sample size*)**.

- **Univariate:**

Quantitative variables will be represented as mean and standard deviation (if a normal distribution can be assumed) or median, first and third quartile (if a normal distribution cannot be assumed). For categorical variables the results will be presented as percentages.

- **Bivariate:**

The Relative Risk (RR) with a confidence interval of 95% will be calculated for each group to analyze our primary objective.

To compare pain, shoulder range of motion and strength, radiological outcomes and quality of life of the operative treatment with the non-operative management a T-student test will be performed if a normal distribution can be assumed. If not, U-Mann-Withney test will be performed.

To analyze joint instability, presence of osteoarthritis, presence of ligament calcification, cosmetic outcomes and subjective satisfaction of each intervention a χ^2 (Chi Square) test will be necessary.

- **Multivariate:**

Furthermore, multivariate logistic regression analysis will be performed to see possible contribution of the described covariates or possible confusion variables such as physical activity or type of work on the obtained results. A confidence interval of 95% will be assumed and P-value <0.05 to consider statistical significant differences.

11. WORK PLAN

Researchers: Dra. María José Martínez (MJM), Javier Arenas (JA)

Collaborators: Shoulder surgeon 2 (SS-2), OTS Doctor 1 (OTS-1), OTS Resident Doctor (OTS-R), collaborating hospitals representant (CR), Nursing Staff (NS), Statistician (ST).

- Phase 0: Preparation – 1 month
    - Conducted by: MJM, JA

Protocol must be accepted by the Ethics Committee of Clinical Research.

- Phase 1: Coordination – 1 month
    - Conducted by: MJM, JA, SS-2, OTS-1, OTS-2, OTS-R, CR, NS, ST

First step will be setting up the chronogram and description of each researcher activities phase by phase. The protocol will be detailed to all members, explaining how the patient recruitment and the data collection will work. CR will assist the meetings to be able to inform and to refer to the center of reference potential candidates.

- Phase 2: Field Work – 66 months
    - Conducted by: : MJM, JA, SS-2, OTS-1, OTS-2, OTS-R, CR, NS, ST

Recruitment will take 3 years approximately and it will take place on Emergency Room Department. Patients will be included if they meet inclusion criteria but no exclusion criteria. A code will be assigned **(7.4. Randomization)** for every participant and randomization will be done.

MJM, SS-2, OTS-R will treat non-operatively and operatively. NS will instrument the intervention. NS working at OTS service will attend the patients during its hospitalization and OTS surgeons will visit them for discharge them to home.

Follow up will be done by OTS-1 as blind investigators. It will last 30 months from the first visit after treatment. Control visits will be programed at at 4, 8, and 12 weeks and at 6, 12, 24 and 30 months after treatment.

- Phase 3: Data collection – 66 months
    - Conducted by: OTS-1, ST

All data will be registered during the course of the study in a created database and reviewed every 3 months by a Clinical Research Associate to control that protocol it is being followed and all data is properly registered.

- Phase 4: Data analysis – 1 month
    - Conducted by: ST

Data collected will be analyzed using the exposed statistical test **(10. STATYSTICAL ANALISIS)**.

- Phase 5: Results interpretation and publication – 1 month
    - Conducted by: MJM, JA

Once statistical analysis is performed, principal investigators MJM and JA will interpret the results and will draw conclusions. Finally all the work will be reflected on a scientific paper. Written articles will be sent to different journal for its publication. This phase will last 1 month.

11.1. Chronogram

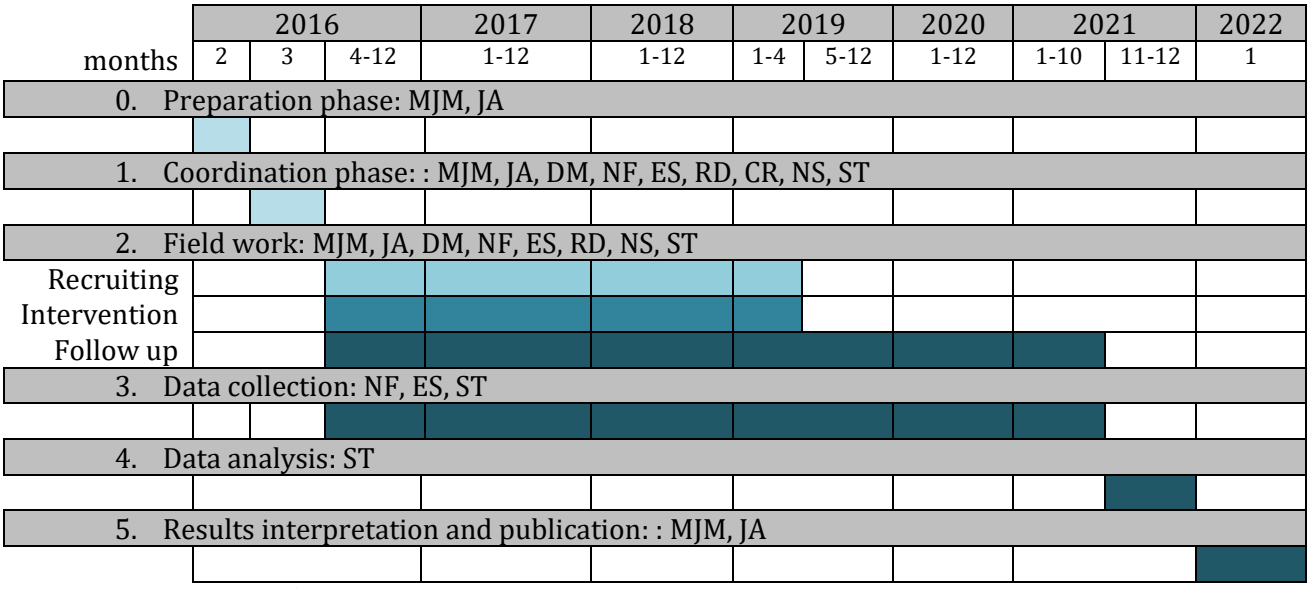

Figure 6: chronogram

12. ETHICAL AND LEGAL ASPECTS

Our ethical code and our good clinical practice are reflected on the great respect about all basic ethic principles according to the World Medical Association Declaration of Helsinki (2013) which also rules the principles of human experimentation.

It is necessary to properly inform all participants about the interventions and the clinical trial with an information sheet **(annex 1)**. Also, all participants must read, understand and sign one informed consent **(annex 2)** for entry in the study, and, in the case of going under operation treatment, another specific informed consent for the procedure **(annex 3)**.This way, principle of autonomy will be respected

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; personal data protection must be guaranteed.

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.

Clinical Research Ethics Committee (CEIC) of the Hopital Universitary Dr. Josep Trueta will have to approve this trial and register it in ClinicalTrials.gov and in EudraCT as regulated in the law 14/2007 of the 3rd of July about biomedical investigation.

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 few existing trials comparing operative and non-operative treatment have not compared the ratio of complications. Nowadays literature admits that Scapular Dyskinesis may occur as consequence of non-operative management and it may require additional physical therapy. This data, in addition with other potential complications of this type of management, supports our hypothesis that we will be apply the best treatment option and should not have many ethical dilemmas.

A conflict is found if treatment efficiencies are compared, no studies have shown statistical differences. So, surgery may be questionable 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. In any case participants will not be summited to a worst intervention therefore any ethical aspects will be violated.

Selection of participants between 18 and 40 years old can be contradictory to the ethical principle of justice and beneficence since not all the population might be benefited by a potential better treatment. But, as exposed, it seems that patients older than 40 years presents worse outcomes with operative treatment so there is no ethical dilemmas.

The remaining exclusion criteria can be contradictory to the principle of justice and beneficence too. This study is not about an experimental treatment, non-included patients will be treated with the more appropriate treatment (operative or non-operative) for their clinical situation to avoid further complications if operative treatment is applied.

13. STRENGHTS AND LIMITATIONS

The consecutive recruitment proposed in this study may not obtain a representative population due to the high prevalence among young males. A low number of female participants are expected.

Inclusion and exclusion criteria are design to try to diminish the possible confusing factors. This study will not include patients older than forty years old as they have worse outcomes with operative treatment in past studies. This excludes them of the main study population.

These exposed facts may cause a selection bias. Loses and withdrawals during the follow up can also cause a selection bias. 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.

Operative management is detailed but it will be performed by different surgeons, which may cause a procedure bias. Meetings in coordination phase detailing the intervention to standardize the technique and proceeding by the most experienced shoulder surgeons in OTS service will try to diminish procedure bias.

Difficulties on designing a triple blind study when surgical techniques are performed may cause a detection bias. As a triple blind design is no possible in this study, a simple blind design has been proposed in order diminish this bias. Doctors who assess patients during the follow up will be blind and patients will be told to not reveal the procedure performed. Also, the statistician will be blind when analyzing the obtained data.

Randomization will help to distribute symmetrically the covariates on both groups to be able to extrapolate the future results on general population between 18 and 40 years despite, as mentioned, low female participants are expected.

Sample size and methods are designed to studying the main objective so the proposed secondary variables will not have a definitive result. Therefore it would be interesting to create new protocols to be able to extract conclusions of the collected data.

It would be interesting in a future to create a multicentric study in order to increase sample size for increasing statistical power and reduce time of recruiting. Also, long term follow up should be considered in future studies.

Main strength of this protocol is the experimental randomized blinded design. There is a lack of this type of study in the bibliography, nor studies evaluating the main objective, so it would be interesting to be able to extract conclusions once performed.

Clinical outcomes will be assessed with validated scales and the results could be compared with other studies. It will contribute as valuable data if further meta-analysis are done.

Apply a contemporary surgical technique is another of the strengths of this study considering that there is no data comparing non-operative treatment with new surgical procedures.

Finally, the study of Scapular Dyskinesis after both treatments will be a new updated data at current literature.

14. FEASIBILITY

Medical team:

This clinical trial is composed by an interdisciplinary team. The main investigators will be María Jose Martínez, OTS surgeon at Hospital Universitary Dr. Josep Trueta and Javier Arenas, Medical Student at Universitat de Girona. Nursing staff will be the usual workers on OTS service used to handle trauma and orthopedic surgeries and its post operations. The surgical team has not enough knowledge for doing an extensive statistical analysis. So, hiring an external statistician will be necessary. All workers will be hired by the National Health System.

Available Resources:

The operation room will be the delayed trauma operating room. So, it will be available once other emergent surgeries are finished during the next day after consulting on emergency department. There is a stock of simple sling and bandages on emergency department for non-operative treatment and at the operation room storehouse for operative treatment. As Twin Tail TightRope® (by Arthrex) device is usually demanded for treating selected patients, the hospital must have an available stock for this trial. Patient will be hospitalized one day after the intervention on COT service so a bed must be available.

Material required for non-operative treatment is: a simple sling, bandages to hide the shoulder on the follow up visits.

Material required for operative treatment is: Shoulder open surgery box, Twin Tail TightRope® (by Arthrex) device, sterile gloves and gowns, electric scalpel, aspirator, gauzes, compresses, sterile carvings.

Patients:

Assumed sample size is estimated to be complete at 3 yeas approximately. Recruiting is though about 20 patients per year counting on patients consulting on the center of reference and patients referred by collaborating hospitals. Follow up will last 30 months. So, 66 months will be necessary for the recruitment and for assess complications treatment.

15. BUDGET

Research team and personnel are employed by Hospital Universitary Dr. Josep Trueta and it is no necessary to hide any worker for our function. So, no additional cost for staff will be included in the budget.

It is necessary a statistical expert for data analysis due to the lack of knowledge on this area in the team. It is calculated a need of 160h of work payed at 35€/h. total costs are 5,600€. Also, a skilled staff to carry out the data monitoring, quality control data and regular submissions to the Spanish Medicine Agency is required. 1h of work per week is needed. So, 264h of work at 30€/h, needed budget is 7,920€.

Non-operative treatment material and surgical material **(14. FEASIBILITY)** are provided by the National Health System. Twint Tail TightRope® (by Arthrex) is also included because is already used as election when operative treatment is applied out of the study.

Patients treated with operative management will be hospitalized 2 days, the habitual procedure on these surgeries, so, as any additional hospitalization is needed it is not included on the budget and it is in charge of the National Health System.

As exposed **(12. ETHICAL AND LEGAL ASPECTS)** patients will be insured for any possible damage due to the intervention. The insurance policy costs are budgeted on 6,000€.

50€ are for printing information sheets, information consent sheets and participant data sheet.

Once the study is finished it will be disseminated to scientific community. All collected data will be reflected on a scientific paper for the purpose of publish it in scientific journals with open access. Publication costs are budgeted on 2,500€.

Diffusion of the trial will be made at the "Sociedad Española de Cirugía Ortopédica y Traumatología" (SECOT). Duration and location of the congres is still unknown. So, it has been estimated a registration price of 700€, and 400€ for travel, accommodation and food allowances.

	Quantity	Price	Cost
A) Services and material			
Statistical expert for data analysis	160h	35€/h	5,600€
Clinical Research Associate	264h	30€/h	7,920€
Printing and papers	1	50€	50€
Insurance policy	1	6,000€	6,000€
B) Publication and presentation costs			
Publication fees	1	2,500€	2,500€
Inscription to "Sociedad Española de Cirugía Ortopédica y Traumatología" (SECOT) congress	2	700€	1,400€
Travel, accommodation and food allowances	2	400€	800€
Total: 24,270€			

Figure 7: Budget

16. IMPACT

There is no consensus for acute type III AC joint dislocation so with this study it is expect to provide significant data to choose the optimal treatment.

Operative treatment may seem too aggressive but if our hypothesis is confirmed, patients will have fewer complications after the injury and they will be able to get back to previous activities with no clinical manifestations. This would be an improvement for patients since they will not need more treatment after the physical therapy.

It is expected also, if the hypothesis is not confirmed, to encourage other research teams to perform new studies comparing economic cost of all the applied resources on both treatments from the injury until the total recovery, including complications' treatment.

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ANNEXES

ANNEX 1. INFORMATION SHEET

TITLE: NON-OPERATIVE VERSUS OPERATIVE TREATMENT IN ACROMIO-CLAVICULAR JOINT DISLOCATIONS: A RANDOMIZED CONTROLLED CLINICAL TRIAL.

INVESTIGATORS: María José Martínez, Javier Arenas
LOCATION: Hospital Universitari Dr. Josep Trueta

We are writing to you to provide information about a research that is being carried out in our center which you are invited to participate. We would like you to consider this research study and then decide whether or not you wish to take part in it. Please read carefully the following information before decide whether or not to take part.

DESCRIPTION OF THE STUDY: the main objective of this study is to compare the complications ratio on operative treatment or non-operative treatment. Half of the patients will be operated using a Twin Tail TightRope® device which includes being hospitalized during one day after consulting on emergency department. The other half of the patients will be treated on emergency department with a simple sling and analgesia if needed. Both treatments will require 8 weeks of physical therapy to recover shoulder function.

After the treatment you will be visited by a Orthopedics and Trauma Surgeon for 30 months. Visits will be scheduled in the weeks 1 (for operative treatment), 4, 8, 12 and in the months 6, 12, 24, 30 after the treatments. If you need extra visits due to any complication an appointment can be scheduled at any time.

WHY HAVE YOU BEEN INVITED?: You have been diagnosed of type III acute acromio-clavicular dislocation meeting the inclusion criteria and no the exclusion ones

VOLUNTEER PARTICIPATION: Your participation in the study is totally voluntary. You are free to decide whether to participate or not and you are able to withdraw the study at any time without any reason. The decision will not affect the treatment or healthcare assistance you recive. If you decide to take part you will be asked to sign information consent.

You should also being informed that you can be excluded from the study if investigators or the sponsor of the study considers it necessary if you are not complying with the established procedures. In any case you will receive a proper explanation why have you been withdraw from the study.

BENEFITS AND RISKS OF PARTICIPATION ON THE STUDY: Your condition of acute acromio-clavicular dislocation should be treated. Non-operative and operative are to proper managements to recover shoulder functions so it will be healed. Operation treatment group will require one day of hospitalization and going under a surgery but you can benefit from better results with less complication after treatment.

The adverse side effects from operative management can be: wound infection, soft tissue infection, technical failure, bleeding, and pain. For Non-operative management can be: pain, limited shoulder motion, Scapular Dyskinesis and it could require further medical, surgical or physical interventions.

RESPONSIBILITY AND INSURANCE: All patients are insured for any damage you may suffer as a result of your participation on this trial, in accordance with the law.

CONFIDENTIALITY: All patient data is recorded on a password protected computer database. The information will be keeped as confidential according to the Spanish Organic law (15/1999) on personal data protection.

Data collected during the study will be identified by a numeric code and only the researchers and collaborators will be able to access this information. Your personal identification will not be disclosed.

ECONOMIC COMPENSATION: Your participation in the study will not include any additional cost and you will not pay the treatments received during this study.

CONTACT: If any doubt or problem during the trial occurring during period please contact the researchers:

Dra. Maria josé Martínez and Javier Arenas
T: 972940200
Hospital Universitari Dr. Josep Trueta
Av/ de França, s/n. 17007 – Girona

Thank you for reading this. Try to keep this information sheet until your participation in the study is finished.

Any queries, questions or doubts do not hesitate to ask us.

If you agree to participate in the study, sign the consent below.

ANNEX 2. INFORMED CONSENT

INFORMED CONSENT TO PARTICIPATE IN THE CLINICAL TRIAL: OPERATIVE VERSUS NON-OPERATIVE TREATMENT IN ACUTE ACROMIO-CLAVICULAR JOINT DISLOCATION.

I have been informed by the investigator about the purpose of the study

- I have read and understood the information sheet
- I have had time to think and consider this information
- I have had the opportunity to ask any questions and be answered
- I understand that my participation is entirely voluntary and I can withdraw this study any moment I wish, for any reason and without any consequences for the healthcare I receive.
- I give permission to collect my data and analyze it. I have been informed that all my data will be kept confidential.
- Finally, I agree to participate in this study:

Name of the participant	Name of Doctor taking consent
_____	_____
ID	ID
_____	_____
Signature	Signature

Girona, _____(month)_____(day) of 20___

ANNEX 3. INFORMED CONSENT TO SURGICAL PROCEDURE:

I,_____have read the information sheet that Dr. _____ has given to me. I have understood everything he/she has explained to me and he/she has answered all my questions. I aslo understand that, at any time and with no need of explanation, I can withdraw the consent that I'm giving now. That is why I confirm that I feel comfortable with the information that I have received and I understand the nature and risk that can happen during the surgical procedure and also the specific risks that can appear that are:

_____
_____
_____
_____

In these conditions I give my consent to have the following procedure:

_____
_____

Girona,_____(month)_____(day) of 20___

Signature of the patient

Signature of the Doctor

DNI:

Graduate Number:

ANNEX 4. RESEARCHER COMMITMENT:

Dr./Mr._____

Service:

Center:

Exposes:

I have evaluated the protocol of this clinical trial titled:

OPERATIVE VERSUS NON-OPERATIVE TREATMENT IN ACUTE ACROMIO-CLAVICULAR JOINT DISLOCATION.

Referring to these aspects:

- The clinical trial respects the ethical rules relevant to these kind of studies, according to good clinical practice recommendations, in Helsinki, Declaration of World Health Organization (15 January of 2001), and to the legal normative applicable.
- I agree to participate as the main researcher in this clinical trial.
- I have all the material and human resources necessary to carry on the clinical trial without affecting the performance of other studies or my usual duties.
- I compromise to treat and control every patient according to CEIC protocol and authorized by the "Agencia Española de Medicamentos y Productos Sanitarios" (AEMPS)

Signed,

Girona, ___/_____/20___

ANNEX 5. PARTICIPANT DATA SHEET:

PARTICIPANT'S CODE:

DATE OF BIRTH:

TELEPHONE:

EMAIL:

ADDRESS:

SEX: ***M*** ***F***

DAY OF TREATMENT:

CLINICAL HISTORY
ALLERGIES:
AFFECTED SIDE: LEFT / RIGHT
MEDICAL AND SURGICAL HISTORY:
MEDICATION:
MECHANISMS OF INJURY:
PROFESSION:
PHYSICAL ACTIVITY/SPORTS:

PREOPERATIVE INFORMATION: ASA = I II III IV V

INTERVENTION A AND B: follow up data sheet

	4W	8W	12W	6M	12M	24M	30M
FISICAL EXPLORATION							
VAS PAIN SCORE (1-10)							
RANGE OF MOTION (DEGREES)							
FLEXION							
EXTENSION							
ABDUCTION							
INTERNAL ROTATION							
EXTERNAL ROTATION							
CLINICAL OUTCOMES (QUESTIONARES SCORES)							
DASH SCORE							
SST							
CS							
RADIOLOGICAL OUTCOMES							
AC DISTANCE (mm)							
CC DISTANCE (mm)							
OSTEOARTRITIS							
CALCIFICATIONS							
QUALITY OF LIFE							
SF-36 TEST							

PRESENCE OF COMPLICATIONS		**TREATMENT REQUIRED**
4W		
8W		
12W		
6M		
12M		
24M		
30M		

ANNEX 6. THE DISABILITIES OF THE ARM, SHOULDER AND HAND SCORE (DASH SCORE) – SPANISH VALIDATED VERSION:

Por favor puntúe su habilidad o capacidad para realizar las siguientes actividades durante la última semana. Para ello marque con un círculo el número apropiado para cada respuesta.

	Ninguna dificultad	Dificultad leve	Dificultad moderada	Mucha dificultad	Imposible de realizar
1. -Abrir un bote de cristal nuevo	1	2	3	4	5
2.-Escribir	1	2	3	4	5
3.- Girar una llave	1	2	3	4	5
4.- Preparar la comida	1	2	3	4	5
5.-Empujar y abrir una puerta pesada	1	2	3	4	5
6.-Colocar un objeto en una estantería situadas por encima de su cabeza.	1	2	3	4	5
7.-Realizar tareas duras de la casa (p. ej. fregar el piso, limpiar paredes, etc.	1	2	3	4	5
8.-Arreglar el jardín	1	2	3	4	5
9.-Hacer la cama	1	2	3	4	5
10.-Cargar una bolsa del supermercado o un maletín.	1	2	3	4	5
11.-Cargar con un objeto pesado (más de 5 Kilos)	1	2	3	4	5
12.-Cambiar una bombilla del techo o situada más alta que su cabeza.	1	2	3	4	5
13.-Lavarse o secarse el pelo	1	2	3	4	5
14.-Lavarse la espalda	1	2	3	4	5
15.- Ponerse un jersey o un suéter	1	2	3	4	5
16.-Usar un cuchillo para cortar la comida	1	2	3	4	5

17.-Actividades de entretenimiento que requieren poco esfuerzo (p. ej. jugar a las cartas, hacer punto, etc.)	1	2	3	4	5
18.-Actividades de entretenimiento que requieren algo de esfuerzo o impacto para su brazo, hombro o mano (p. ej. golf, martillear, tenis o a la petanca)	1	2	3	4	5
19.-Actividades de entretenimiento en las que se mueva libremente su brazo (p. ej. jugar al platillo "frisbee", badminton, nadar, etc.)	1	2	3	4	5
20.- Conducir o manejar sus necesidades de transporte (ir de un lugar a otro)	1	2	3	4	5
21.- Actividad sexual	1	2	3	4	5
	No, para nada	Un poco	Regular	Bastante	Mucho
22.- Durante la última semana, ¿ su problema en el hombro, brazo o mano ha interferido con sus actividades sociales normales con la familia, sus amigos, vecinos o grupos?	1	2	3	4	5

	No para nada	Un poco	Regular	Bastante limitado	Imposible de realizar
23.- Durante la última semana, ¿ha tenido usted dificultad para realizar su trabajo u otras actividades cotidianas debido a su problema en el brazo, hombro o mano?	1	2	3	4	5

Por favor ponga puntuación a la gravedad o severidad de los siguientes síntomas

	Ninguno	Leve	Moderado	Grave	Muy grave
24.-Dolor en el brazo, hombro o mano.	1	2	3	4	5
25.- Dolor en el brazo, hombro o mano cuando realiza cualquier actividad específica.	1	2	3	4	5
26.-Sensación de calambres (hormigueos y alfilerazos) en su brazo hombro o mano.	1	2	3	4	5
27.-Debilidad o falta de fuerza en el brazo, hombro, o mano.	1	2	3	4	5
28.-Rigidez o falta de movilidad en el brazo, hombro o mano.	1	2	3	4	5

	No	Leve	Moderada	Grave	Dificultad extrema que me impedía dormir
29.- Durante la última semana, ¿cuanta dificultad ha tenido para dormir debido a dolor en el brazo, hombro o mano?.	1	2	3	4	5

	Totalmente falso	Falso	No lo sé	Cierto	Totalmente cierto
30.- Me siento menos capaz, confiado o útil debido a mi problema en el brazo, hombro, o mano	1	2	3	4	5

Módulo de Trabajo (Opcional)

Las siguientes preguntas se refieren al impacto que tiene su problema del brazo, hombro o mano en su capacidad para trabajar (incluyendo las tareas de la casa si ese es su trabajo principal)

Por favor, indique cuál es su trabajo/ocupación: _____

Yo no trabajo (usted puede pasar por alto esta sección) .

Marque con un círculo el número que describa mejor su capacidad física en la semana pasada. **¿Tuvo usted alguna dificultad...**

	Ninguna dificultad	Dificultad leve	Dificultad moderada	Mucha dificultad	Imposible
1. para usar su técnica habitual para su trabajo?	1	2	3	4	5
2. para hacer su trabajo habitual debido al dolor del hombro, brazo o mano?	1	2	3	4	5
3. para realizar su trabajo tan bien como le gustaría?	1	2	3	4	5
4. para emplear la cantidad habitual de tiempo en su trabajo?	1	2	3	4	5

Actividades especiales deportes/músicos (Opcional)

Las preguntas siguientes hacen referencia al impacto que tiene su problema en el brazo, hombro o mano para tocar su instrumento musical, practicar su deporte, o ambos. Si usted practica más de un deporte o toca más de un instrumento (o hace ambas cosas), por favor conteste con respecto a la actividad que sea más importante para usted. Por favor, indique el deporte o instrumento que sea más importante para usted.

¿Tuvo alguna dificultad.:

	Ninguna dificultad	Dificultad leve	Dificultad moderada	Mucha dificultad	Imposible
para usar su técnica habitual al tocar su instrumento o practicar su deporte?	1	2	3	4	5
para tocar su instrumento habitual o practicar su deporte debido a dolor en el brazo, hombro o mano ?	1	2	3	4	5
para tocar su instrumento o practicar su deporte tan bien como le gustaría?	1	2	3	4	5
para emplear la cantidad de tiempo habitual para tocar su instrumento o practicar su deporte?	1	2	3	4	5

ANNEX 7. CONSTANT SCORE (CS) – SPANISH VALIDATED TEST:

CONSULTAS EXTERNAS **UNIDAD DE HOMBRO**

CONSTANT SCORE

NHC y Nombre del Paciente

Operación/Diagnostico: **Fecha:**

Lateralidad: R L

Examen: Pre-op

3 meses 6 meses

1 año 2 años ___ años

A.- Dolor (/15): media (1 + 2/2) ☐ **A**

1. ¿Cuànto dolor tiene dolor en el hombro en sus actividades de la vida diaria?
   No =15 pts, Mild pain = 10 pts, Moderate = 5 pts, Severe or permanent = 0 pts. ___

2. Escala lineal:
   Si "0" significa no tener dolor y "15" el mayor dolor que pueda sentir, haga un circulo sobre el nivel de dolor de su hombr
   La puntuación es inversamente proporcional a la la escala de dolor (Por ejemplo, un nivel de 5 son 10 puntos)

Nivel de dolor: 0 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15

Puntos: 15 14 13 12 11 10 9 8 7 6 5 4 3 2 1 0 ___

B.- Actividades de la vida diaria (/20) **Total (1 + 2 + 3 + 4)** ☐ **B**

1. ¿Esta limitada tu vida diaria por tu hombro?
   No = 4, Limitacio moderada = 2, Limitacion severa = 0 ___
2. ¿Esta limitada tu actividad deportiva por tu hombro?
   No = 4, Limitacio moderada = 2, Limitacion severa = 0 ___
3. ¿Te despiertas por el dolor de hombro?
   No = 2, A veces = 1, Si = 0 ___
4. ¿Hasta que altura puedes elevar tu brazo para coger un objeto (pe. un vaso)?
   Cintura = 2, Xiphoides (esternon) = 4, Cuello = 6, Cabeza = 8, Sobre cabeza = 10 ___

C.- Balance articular (/40): **Total (1 + 2 + 3 + 4)** ☐ **C**

1.- Flexion anterior:

0 - 3	0 pts
31 -60	2 pts
61 - 90	4 pts
91 - 120	6 pts
121- 150	8 pts
> 150	10 pts

___

2.- Abduccion:

0 - 30
31 - 60
61 - 90
91 - 120
121 - 150
> 150

___

3.- Rotracion externa: ___

Mano nuca	0 pts
Mano detras de la cabeza y codos delante	2 pts
Mano detras de la cabeza y codos detras	4 pts
Mano sobre la cabeza y codos delante	6 pts
Mano sobre la cabeza y codos detras	8 pts
Elevacion completa del brazo	10 pts

4.- Rotacion interna: (Pulgar hasta) ___

Muslo
Nalga
Artic. SI
Cintura
T12
Entre las escapulas

D.- Fuerza (/25): Puntos: media (kg) x 2 = ☐ **D**

Primera medicion: Segunda medicion: Tercera medicion: Cuarta medicion: Quinta medicion:
Average pulls:

TOTAL (/100): A + B + C+ D ☐

ANNEX 8. SIMPLE SHOULDER TEST (SST):

SIMPLE SHOUDER TEST

NHC y Nombre del Paciente	**Operación/Diagnóstico**	**Fecha:**
		Lateralidad: R L
	Examen: Pre-op	
	3 meses	6 meses
	1 año	2 años ___ años

1. ¿Está cómodo cuando descansa sobre el brazo del lado afecto?	**Sí**	**No**
2. ¿Le permite su hombro dormir confortablemente?	**Sí**	**No**
3. ¿ Puede alcanzar la parte baja de su espalda para meterse la camisa?	**Sí**	**No**
4. ¿Puede colocar la mano por detrás de la cabeza con el codo hacia fuera?	**Sí**	**No**
5. ¿Puede colocar una moneda en una estantería a la altura de su hombro sin doblar el codo?	**Sí**	**No**
6. ¿Puede levantar medio kilo hasta la altura del hombro sin doblar el codo?	**Sí**	**No**
7. ¿Puede levantar 3,5 kg hasta la altura del hombro sin doblar el codo?	**Sí**	**No**
8. ¿Puede transportar 9 kg utilizando la extremidad afecta?	**Sí**	**No**
9. ¿Cree que puede alcanzar una pelota (de tenis) por debajo del hombro unos 9 metros con la extremidad afecta?	**Sí**	**No**
10. ¿Cree que usted puede lanzar una pelota (de tenis) por encima de la cabeza unos 18 metros con la extremidad afecta?	**Sí**	**No**
11. ¿Se puede lavar la parte posterior de su hombro contrario con la extremidad afecta?	**Sí**	**No**
12. ¿Su hombro le permita trabajar a tiempo completo en su trabajo diario?	**Sí**	**No**

ANNEX 9. SF-36 TEST ABOUT QUALITY OF LIFE – SPANISH VALIDATED VERSION:

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:

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

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

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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

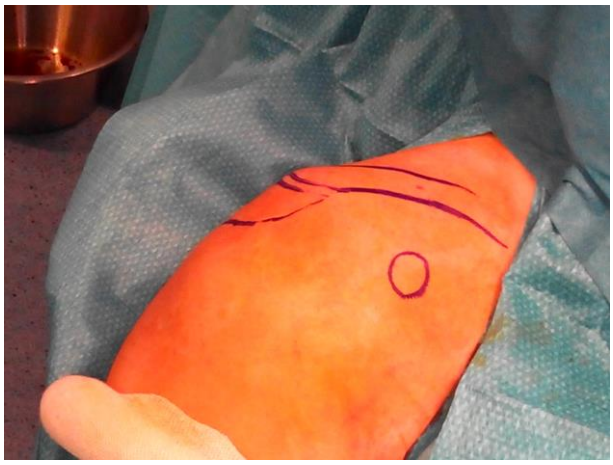
11. Por favor diga si le parece CIERTA o FALSA cada una de las siguientes frases:

	Totalmente cierta	Bastante cierta	No lo sé	Bastante falsa	Totalmente falsa
a Creo que me pongo enfermo más fácilmente 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

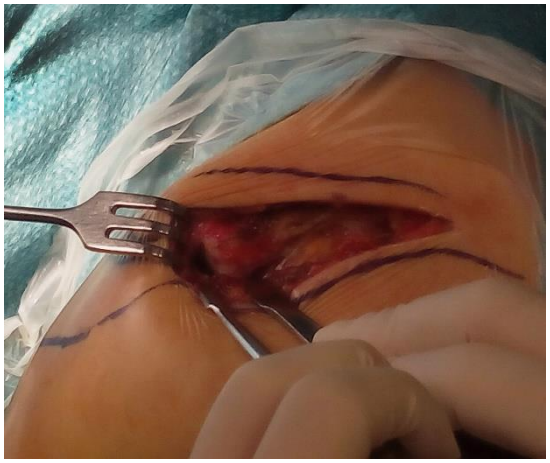
Gracias por contestar a estas preguntas

ANNEX 10: OPERATIVE PROCEDURE:

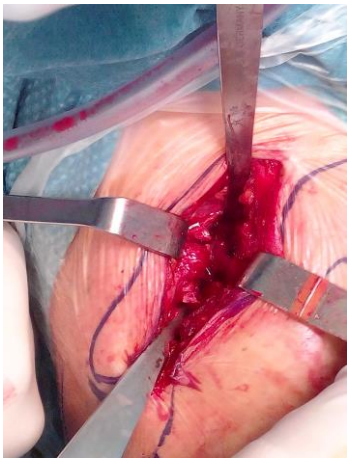
1. Identification of the main anatomic structures: clavicle, acromion and coracoid process.



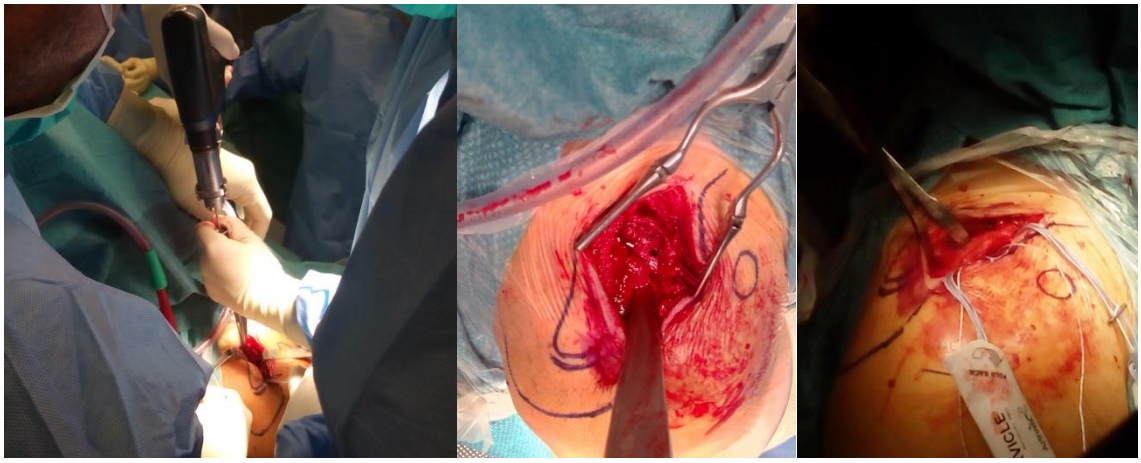
2. Skin incision from the acromion to the middle third of the clavicle. Exposiotion of the dislocated AC joint.



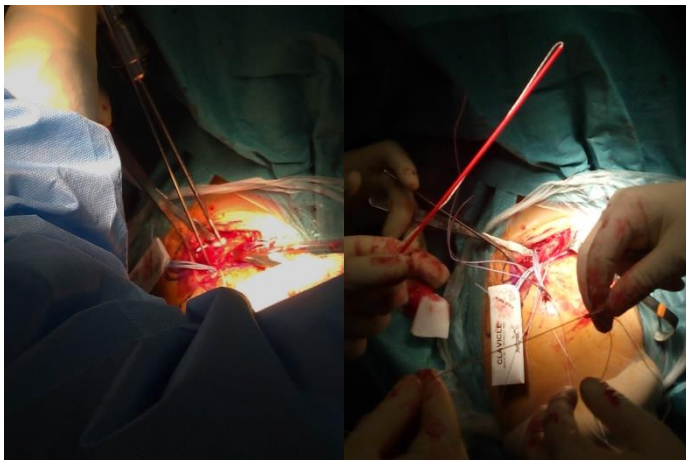
3. Identification of the coracoid process and the teared CC ligaments.



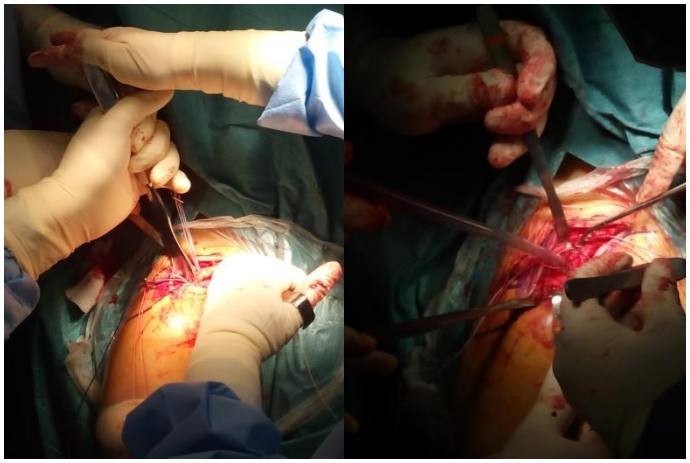
4. drilling of the coracoid process hole and inserction of the Twin Tail TightRope's® coracoid button



6. Drilling of the two clavicle holes and inserction of the Twin Tail TightRope's® clavicle buttons.



7. Reduction of the AC joint and fiation of the Twin Tail TightRope®.



8. Wound suture by planes and bandaging.