COMPARISON OF CORACOCLAVICULAR FIXATION WITH VERSUS WITHOUT ACROMIOCLAVICULAR STABILIZATION FOR REPAIR OF ACUTE ACROMIOCLAVICULAR JOINT DISLOCATIONS: A RANDOMIZED CONTROLLED CLINICAL TRIAL, DOUBLE-BLIND TEST.

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THEORETICAL FRAME

The upper extremity is completely attached by the axial skeleton, especially through the clavicle and the acromioclavicular articulation (AC)(1). The previously mentioned articulation is a diarthrodial joint. The stability of this articulation is caused by coracoclavicular ligaments in the vertical plane and the acromioclavicular ligaments in the horizontal plane(2). The AC luxation is a common pathology in youth and athletes who participate in contact sports which has a 9,2 per 1000 incidence between inhabitants every year represented between 30% to 50% from shoulder injuries in young athlete, it is most common in men than women with a ratio of 8:1(3). It's main injury mechanism is direct trauma while the shoulder is adducted and less frequently is the indirect mechanism of dropping the arm in an extended motion(4). In the year 1963, Tossy et al(5) for the first time described and classified some of the patterns of luxation AC, which was then extended to 6 AC luxation degrees and published by Rockwood in the year 1984 becoming the first most accepted and used till this day(6). There have many techniques of conservative treatment and surgery management as a treatment for all time of laxation AC (Rockwood grades I-VI) written as time passed by, although literature suggests and supports the conservative treatment for grades I and II and the surgical management for grades IV-V-VI, the optimal treatment for grade III injuries is still controversial(7). In regards to these type of injuries, taking into account the importance of medial stability an agreement was taken by the committee of the upper extremity of the International Society of Arthroscopy, Knee Surgery and Orthopedic Sports Medicine (ISAKOS), which suggests that a subdivision of the III grade of Rockwood in IIIA when the AC articulation is stable and the IIIB when the AC articulation is unstable(8), helping to differentiate and identify the patients with grade III Rockwood in a better manner who will be benefited from a surgical treatment.

To evaluate the correct AC luxation ligaments, the radiological evaluation must include a projection of bilateral, axillary Zanca and Alexander (also known as Basmania). This last projection has increased its relevance in the past couple of years since it can help us to differentiate whether there's a presence or an absence of medial instability in the case of Rockwood III AC luxation(9). Till this day there are no actual standardized measurements that guide the correct manner of treating it with a good variability, Zumstein et al(10) proposed 2 new quantitative parameters to evaluate the vertical and horizontal instability

and based on the Alexander view. To evaluate the vertical stability the use of the vertical distance between the center of the acromion and the midpoint of the lateral clavicle (AC-DC) and to evaluate the horizontal stability he used the distance of the center of the glenoid and lateral clavicle (GC-PC). Both parameters were shown to be trusted sources with excellent validity, which helped guide the treatment for some AC luxation, especially for Rockwood grade II and III injuries.

Despite the numerous described surgical techniques, currently more than 160, do not show evidence of superiority of one in specific and there is no agreement whether it is necessary to stabilize only the AC articulation in the vertical, horizontal or both planes(11). In this case more attention is focused on the complex AC ligament standing out the superior AC band as its main horizontal stabilizer(12), which does have an injury and in the process of insufficiently healing and repairing it can contribute up to 50% of horizontal instability in the AC articulation(13). Many studies demonstrate that the horizontal instability can have an important clinical relevance associated with the worst functional postsurgical results(14–16) which during the past couple of years has increased the interest of conducting many surgical techniques to better the horizontal stability and so the functional results after surgery(17). Al though there have been many advances in surgical techniques during the time, the percentage of complications are still considerable, with up to 14% of inoperable complications, 21% reduction loss and 10% remains in revision surgery(4). With the result of minimizing complications and obtaining better functional results arises the idea of conducting the randomized clinical trial.

INVESTIGATION QUESTIONING

"In patients with an acute and unstable acromioclavicular luxation, the coracoclavicular fixation with stabilized acromioclavicular has a clinical impact to decrease of complications and better its functionality?"

OBJECTIVES

General objectives

- To observe the clinical impact of the fixed coracoclavicular with acromioclavicular stabilization and compare it with the isolated coracoclavicular stabilization in the management of the unstable acromioclavicular luxation.

Specific objectives

- Evaluate the functionality levels and postoperative pain of the surgically managed acromioclavicular luxation.
- Evaluate the variation of the post-operational radiological parameters (coracoclavicular distance) in the surgical management of the luxation of acromioclavicular ligaments.

- Evaluate the incidence of postoperative complications in surgical management of luxated acromioclavicular joints.

METHOD

The unstable acromioclavicular luxation evaluated and diagnosed patients will be admitted by on duty Traumatologists at the urgency services of Hospital Dr. Hernán Henríquez Aravena de Temuco. The unstable acromioclavicular luxation that are surgically managed according to the instability criteria found in international literature (Rockwood IIIb, IV, V and VI).

The length of the study will be of at least 1 year with the option of continuing it for 2 years. The coracoclavicular fixation with and without acromioclavicular stabilization will be compared making up two investigation groups.

The patients that fulfill the requirements and criteria for inclusion will be invited to form part of the study where they will need to evaluate and sign an informed consent form.

It will be randomized by block using a computer system. The documents will be printed and into sealed envelopes. Before the surgery one of the envelopes will be chosen, this envelope will contain one of the 2 techniques from which the surgeon will use in the procedure. Postoperative evaluations will be done, the patients will be controlled by a surgeon from a different team, which will not know the surgical protocol. The first control will be done at 3 weeks postoperative, then on the 3, 6, 12, and 24 months. During the controls the clinical functionality will be evaluated with 3 scores (ASES, Nottingham and Constant) and the eventual clinical or radiological complications using an x-ray with Bilateral Zanca view. Lastly, the need of analgesia will be consulted, and the presence of complications will be evaluated.

Statistically there will be 0.05 alpha used and there will be protocol analysis, as well as, by intent to treat for calculation of RR, RRR, RAR, NNT, NNH. Finally, there will be analysis done by subgroups of ages 15-40 and 40-65 years, sex, and acromioclavicular luxation grade according to Rockwood, affected side and preoperative evolution time. Lastly, the need of analgesia will be consulted, and the presence of complications will be evaluated.

ELECTION OF DESIGN

Our question is about therapy, from which is the best kind that will give us an estimate to the truth is through a randomized clinical trial so that we decrease biases. The 2 surgical techniques are currently valid alternatives, and they are done in the Hospital Dr. Hernán Henríquez Aravena on a routinary basis, so there are no ethical dilemmas in regard to added adverse events.

INCLUSION CRITERIA

- Rockwood IIIB, V, and VI acromioclavicular luxation
- Less than 14 días of progression time since the lesion
- Patient over the age of 15
- Possibility of clinical monitoring
- Informed and validated consent by the ethics committee

EXCLUSION CRITERIA

- Surgery previously done on the clavicle and/or ipsilateral acromioclavicular, contralateral and/or bilateral articulation.
- Neuropathy of motor or mixed upper extremities.
- Exposure of an acromioclavicular injury.
- Fractures associated with clavicles, scapula and/or ipsilateral humerus.
- Function alterations concerning the previously mentioned extremity.
- Functional alterations of the contralateral extremity.
- Disease that can evolve with neuropathy during the study period (Multiple Sclerosis, Vasculitis, badly controlled Diabetes with progressed damage, etc.)

PRIMARY OUTCOME

- The clinical impact of the daily strength, proprioception, range of movement and decrease of pain (functional Score)
- Complication rates (fail of the implant, loss of the reduction, clavicular or coracoid fracture, pain associated with the implant, infections, etc.)

SECONDARY OUTCOME

- Evolution of adduction force according to the postoperative period.
- Evolution of mobility rate according to the postoperative period.
- Results of the radiological variable according to the postoperative evolution time.
- Need of postoperative analgesic.
- Revision surgery rate according to the postoperative evolution.
- Presence of side effects.

SURGICAL TECHNIQUE

The procedure will be done with combined anesthesia, using general and locoregional anesthesia with an interscalene block. The patient will be placed in supine position on top of an orthopedic bed and an interscapular cushion. Using the gel pads, all of the bone

prominences are protected. The head needs to be reassured that it is in a secure and correct position. The arm that will not be intervened must remain in a neutral position while the other is prepared to be sterile manner and positioned along with the adducted body. Finally, it is covered with standard sterile drapes.
Once the patient is in the correct position, the relevant bone prominences of the shoulder are palpated and identified (clavicle, acromion, and the coracoid process) and the initial incision is marked using a surgical pen, starting on the Langer lines to create a more aesthetic scar. With a number 15 scalpel we create an incision in the bretel "continue the line of the strap of the brassiere" and we continue to dissect the subcutaneous tissue in the same direction until exposing the deltotrapezial fascia, which is opened using Metzenbaum scissors parallel to the clavicle, achieving a flap that when it's raised towards the inside we are able to see the upper and lower clavicle and coracoid process. As we palpitate we can identify the subcoracoid space and using a subcoracoid suture passer we pass a guiding suture maintaining it with mosquito forceps. With a surgical ruler over the top face of the clavicle we mark a 1 cm of the most lateral part of the clavicle to do the first tunnel with a 2,5mm drill from the top to the bottom, then we stabilize a 3-hole third plate with 3 holes and a screw in the previously done hole. Continuing with the subcoracoid of 1 Fiberwire double number 2 and a thread of Fibertape using a guide suture. Both of the remaining holes of the 3-hole third plate are drilled in the direction of the coracoclavicular ligaments so that the double Fiberwire and the thread of Fibertape with Nitinol can pass through in a retrograde manner. Using the Fiberwire we do a knot over the 3-hole third plate, then using fluoroscopy we visualize the adequate coracoclavicular reduction continuing to tie the Fibertape with a knot. It's important not to cut the remaining suture so that it is set aside for the next step. Guided by fluoroscopy, we made an 8mm incision in the lateral edge of the acromion, to perform an anterior and posterior clavicular tunnel using an anterior cruciate ligament guidewire. Using the first tunnel that goes through the Polyglactin stitch, fetching back the thread from the previous one, we go back in the same retrograde manner using the Fiberwire threads and the Fibertape that were previously mentioned. Finally, both the remaining Fiberwire and Fibertape are tied using a surgical knot achieving AC fixation.

POSTOPERATION

After the surgical stabilization on the AC articulation, we indicate that the immobilization of the shoulder with a sling for 2 weeks, which is the moment where the patients will be able to begin to move passively under shoulder level with the assistance by physical therapist. Strengthening is allowed once the patient can fully complete the movement, which is generally around the 6^{th} to 8^{th} week. Generally, we allow the patient to retake sports 4 to 6 months after surgery.

RISK OF ADVERSE EVENTS

There are no additional adverse risks in any surgery of this kind. As mentioned previously, the 2 accepted techniques are accepted and utilized by our service currently, therefore,

there will be no action that will increase the risk of the surgery in comparison to a common surgical procedure.

There are no studies that show variations in regard to the pain response of the treatment between the two procedures, but there should not be any differences in that aspect. Either way, every case will be monitored regarding the response of the analgesia, and it will be adjusted according to the patients' necessities.
The irradiation from the x-ray taken of the extremities is equivalent to 0.001 mSv of effective radiation (19). Since the x-ray control used in this procedure will be normal, there will only be 4 x-rays taken, without exceptions, which results in an insignificant additional increase in the risk of patient developing cancer due to the test.

In any case, the complications will be detected in an early manner during the evaluations done by the investigation team, where these will be handled and monitored, and additional controls will be done if necessary.

CONSCENT PROCESS

The responsible investigator and their collaborators are in charge of receiving the consent form given by the patient. This will be solicited in a private premises where the patient and their family members will be informed about the nature of the investigation, taking the necessary time to answer all questions.

The patient will be able to take the document of consent and after its signature, later a copy of the document will be provided. If the patient needs to further analyze the document with more detail or in case that they do not want to participate they are free to take a copy to inspect and analyze.

The patient may withdraw from the study whenever they wish.

RESPONSIBLE OF RECEPTION OF CONSCENT FORM
(Hospital Hernán Henríquez Aravena)

- Dr. Felipe Gómez Lagos
- Dr. Martin Zecher Magni
- Dr. Andrés Sánchez Garcia
- Dr. Enrique Pávez Uribe

FINANCING SOURCING

The study does not count with any sponsors, the financing is run by the investigation team.

CONFLICTS OF INTERESTS

The authors declare that there are no conflicts related to any type of economic interests.

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