# 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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# INFORMED CONSENT

Title

Comparison of coracoclavicular fixation with versus without acromioclavicular stabilization for repair of acute acromioclavicular joint dislocations: a randomized controlled clinical trial, double-blind test.

Sponsor

None

Study Center

Servicio de Traumatología y Ortopedia de Hospital Hernán Henríquez Aravena, Temuco, IX Región. Universidad de la Frontera.

Research coordinator

Dr. Felipe Gómez Lagos

Principal Investigator

Dr. Martin Zecher Magni

Informed consent team

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

Contact

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You have been asked to participate in a research study in patients undergoing surgery for unstable acromioclavicular dislocation, with plate, screws and high-strength sutures.

Please read this consent form carefully. Take the time to ask as many questions as you want. If there is anything you don't understand, the studio staff will be happy to explain it to you.

**INTRODUCTION**

Currently there are more than 160 surgical techniques for the repair of unstable acromioclavicular dislocations, despite this, the percentage of complications is still considerable with an average of approximately 30%, with no evidence showing an advantage of one technique over the other.

There is also no consensus on whether it is necessary to stabilize the acromioclavicular joint only in the vertical plane, horizontal plane or in both planes. In this sense, more and more attention is paid to the acromioclavicular ligament complex, which can contribute up to 50% of the horizontal stability of the joint. Several studies have shown that horizontal instability has important clinical relevance, being associated with worse post-surgical functional results, which has generated in recent years a greater interest in performing various surgical techniques to improve horizontal stability and thus the results after surgery.
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To date, there is no information that allows us to widely recommend this technique (coracoclavicular fixation with acromioclavicular stabilization) in all these surgeries, however, the technique itself does not present complications for the patient.

**PROCEDURE OF RESEARCH**

If you decide to participate in this study, you will be randomized to conventional treatment (coracoclavicular fixation) or new surgical procedures (coracoclavicular fixation and acromioclavicular stabilization).

In addition, information will be obtained from the clinical record about their medical history and laboratory tests, which will be known only by the researchers.

**BENEFITS.**

Your participation in this study could be indirectly beneficial for you and other patients, since it will allow you to evaluate the real usefulness of this surgical technique and eventually make it the standard technique for this type of surgery.

**RISKS AND DISCOMFORTS**

**There are no additional adverse risks to those found in any surgery of this type,** since all the surgical techniques to be used are currently accepted.

In untrained surgeons, the acromioclavicular stabilization technique could imply a significant increase in surgical time, but in our study the procedure was carried out by the Shoulder team of the Traumatology and Orthopedics Service of the Hernán Henríquez Aravena Hospital, so there would be no significant differences.

There are no studies showing variations in response to pain treatment between these procedures, but there should be no differences in this regard.

The risk of irradiation is minimal for you, since only the usual radiographic controls will be carried out.

**COSTS**

The procedure and supplies used are at no cost to you.

**CONFIDENTIALITY**

Your participation in this research is completely voluntary. You have the right not to agree to participate or to withdraw your consent and withdraw (or withdraw your son/daughter, relative or representative) from this research at the time you deem appropriate. By doing so, you (or your son/daughter, family member or representative) do not lose any right that assists you as a patient of this institution and the quality of medical care you deserve will not be affected.

If you withdraw your consent, your tests and data will be deleted and the information obtained will not be used.

The presentation of medical information will be made in strict compliance with the rules of professional confidentiality. They will be known only by the research team and your treating physician. They may be published in medical journals, but their confidentiality will be respected and names will not be used in any reports.

Once you have read, accepted and signed this consent, you will receive a signed copy.

## QUESTIONS

If you have questions about this medical research you can contact or call Dr. Felipe Gómez Lagos or Dr. Martin Zecher Magni. Responsible Researcher of the study, by phone 045-2556615.

If you have questions about your rights as a participant in medical research, you can call Dr. Patricio Valdés García, President of the Scientific Ethics Evaluation Committee, Araucanía Sur Health Service, at 045 557064, or at the committee's address, Andres Bello 636, 2nd floor, Temuco.

# INFORMED CONSENT

I have been informed that my participation in this project is entirely voluntary and that if I choose not to do so, there will be no consequences to my current or future care provided by the medical team.

I have read the content of this consent form and have listened to the explanation given by the researcher. I have been given the opportunity to ask questions about this project and they have been answered to my satisfaction.

If at any time I wish to obtain additional information about this project, I can contact Dr. Martin Zecher Magni, via email (mzecher@gmail.com) or by phone (045-2556615).

This project was reviewed by the ethics committee of the Universidad de la Frontera and, if required, I can contact Dr. Patricio Valdés García, President of the Scientific Ethics Evaluation Committee, Araucanía Sur Health Service, at 045 557064, or at the address of the committee, Andres Bello 636, 2nd floor, Temuco.

**Name of patient**_____Date:_____

Signature_____

**Patient representative**_____Date:_____

Signature_____

Investigator's signature: “I have detailed the content of this sheet with the above signatories. I have explained the potential risks and benefits of the study.”

**Investigator**_____Date:_____

**Signature**_____

**Director of the Hospital or his legal representative**_____Date:_____

**Signature _____**