

STUDY TITLE

ESTABLE: Shoulder Stability Study Using the Latarjet Procedure with Suture Tape Cerclage versus Screw Fixation

Principal Investigator:

Juan Ameztoy Gallego

juan.ameztoy@salud.madrid.org

Department of Orthopaedic Surgery and Traumatology

Hospital Universitario La Paz

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1. Abstract

General Objective

To compare the clinical and radiological outcomes of coracoid bone graft fixation in the Latarjet procedure using high-strength suture tape versus metallic screw fixation in patients with anterior shoulder instability, through a randomized non-inferiority clinical trial.

Study Design and Setting

This is a prospective, single-center, randomized clinical trial with assessor blinding, conducted at Hospital Universitario La Paz.

Randomization will be performed using permuted blocks, stratified by age (<30 years / ≥ 30 years), with a 1:1 allocation ratio.

The experimental group will receive coracoid graft fixation using high-strength suture tape (FiberTape Cerclage).

The control group will receive standard fixation using two metallic screws.

The surgical technique, approach, and rehabilitation protocol will be identical in both groups, standardized and performed by the same surgical team.

Inclusion Criteria

- Patients aged 18 to 50 years
- Diagnosis of anterior shoulder instability
- Indication for Latarjet surgery

Exclusion Criteria

- Surgical contraindication
- Concomitant lesions: rotator cuff pathology or biceps tendon pathology

- Previous surgery on the affected shoulder
- Systemic or neurovascular conditions that may influence outcomes

The calculated sample size is 80 patients, considering a 10% loss to follow-up to detect clinically relevant differences in the functional scale used as the primary endpoint.

2. Background and Rationale

Anterior shoulder instability is a common clinical condition, particularly in young patients, athletes, and individuals with high functional demands. The open Latarjet procedure is a widely used surgical technique for treating anterior shoulder instability, especially in patients with significant glenoid bone loss, with good functional outcomes.

Traditionally, coracoid graft fixation has been performed using two cortical screws, providing rigid fixation and compression at the bone interface. However, in clinical practice, complications related to osteosynthesis hardware have been reported, prompting interest in more biocompatible and versatile alternatives.

Recent studies have documented a significant rate of screw-related complications, including hardware irritation and persistent anterior shoulder pain [1,2], screw loosening particularly when graft union is incomplete [3], stress-induced coracoid graft fractures around screw sites [4], and the need for revision surgery for hardware removal, with some series reporting rates up to 16% [1,2].

These complications may compromise clinical outcomes, delay rehabilitation, increase healthcare costs, and contribute to patient morbidity.

In response to these limitations, Hachem et al. [5] proposed the use of high-strength suture tape (FiberTape, Arthrex) as a fixation alternative without rigid metallic implants. This technique involves passing two interconnected tapes through transverse bone tunnels and tying them under controlled tension, achieving compression without metal hardware.

This approach has been validated at three levels:

1. **Surgical technique:** Hachem et al. [5] described the technique in detail and demonstrated that it maintains axial compression and rotational stability of the graft without screws, while facilitating future arthroscopy or revision procedures by avoiding metallic implants.
2. **Clinical validation:** In a prospective series of more than 30 patients treated with FiberTape, graft union rates exceeded 90%, with no graft fractures or need for hardware removal. Clinical outcomes measured using the WOSI and other functional scales were equivalent or superior to those reported with traditional screws [5].

3. **Biomechanical validation:** In a biomechanical study by Hachem et al. [6], directly comparing FiberTape with bicortical screws, suture tape fixation demonstrated comparable ultimate load to failure, lower stiffness (potentially reducing stress concentration on the graft), and equivalent graft displacement under simulated cyclic loading conditions.

Given the increasing number of complications attributable to screw fixation in the Latarjet procedure, high-strength suture tape fixation represents a biomechanically sound, clinically safe, and potentially superior alternative in terms of biological tolerance and long-term complication profile.

3. Hypothesis and Objectives

Primary Hypothesis

Coracoid graft fixation in the Latarjet procedure using high-strength suture tape (FiberTape Cerclage) is non-inferior to traditional metallic screw fixation in terms of functional recovery at 12 months and may be associated with a lower rate of fixation-related complications.

Primary Objective

To compare functional efficacy between high-strength suture tape fixation and metallic screw fixation in the Latarjet procedure, assessed using the total score of the Western Ontario Shoulder Instability Index (WOSI) at 12 months, in a randomized non-inferiority clinical trial.

Secondary Objectives

1. To evaluate coracoid graft union rate using computed tomography (CT) at 3 and 12 months postoperatively in both groups.
 2. To analyze graft position relative to the glenoid and its angulation in axial and sagittal planes using CT.
 3. To compare postoperative complication rates between groups, including graft fracture, significant bone resorption, graft or fixation malposition, and need for revision surgery.
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4. Study Design

This is a prospective, single-center, randomized clinical trial comparing two methods of coracoid graft fixation in the Latarjet procedure: conventional metallic screw fixation and high-strength suture tape fixation (FiberTape Cerclage).

Participants will be assigned in a 1:1 ratio using permuted block randomization, stratified by age group (<30 years and ≥ 30 years) to ensure sample homogeneity.

Surgeons performing the procedure will be aware of the fixation technique, as intraoperative blinding is not feasible. However, clinical and radiological outcome assessors will be blinded to group allocation to minimize assessment bias.

Both groups will follow a standardized surgical protocol and identical postoperative rehabilitation regimen. A minimum follow-up of 12 months will be conducted for all patients.

The study will be conducted at a single hospital center, Hospital Universitario La Paz, with experience in shoulder surgery, and will include consecutive patient recruitment until the calculated sample size is reached.

5. Study Population

All patients diagnosed with anterior shoulder instability who freely agree to participate will be consecutively included until the estimated sample size is achieved.

Inclusion Criteria

Participants must meet all of the following criteria:

1. Age between 18 and 50 years
2. Diagnosis of anterior shoulder instability
3. Indication for surgical treatment with the Latarjet procedure
4. Provision of written informed consent

Exclusion Criteria

Participants will be excluded if any of the following are present:

1. Multidirectional or posterior shoulder instability
2. Previous surgery on the affected shoulder

3. Concomitant associated pathology: rotator cuff tear, glenohumeral osteoarthritis, long head of the biceps lesions, etc.
4. Upper limb conditions unrelated to the current episode that may influence study outcomes (fractures, motor paralysis due to systemic or neurovascular diseases, etc.)

6. Study Variables

The following variables will be collected:

1. Demographic Variables

Age, sex, affected side, limb dominance, type of instability, age at first dislocation episode, number of dislocation episodes, number of subluxation episodes, hyperlaxity, range of motion, sports activity, type of sport, occupational activity.

2. Radiological Variables

At study inclusion, computed tomography (CT) will be used to assess:

- Glenoid bone loss
- Humeral Hill-Sachs lesion
- Glenoid track

At 3 months and 12 months postoperatively, CT scans will evaluate:

- Graft union
- Alpha angle to determine graft position
- Graft height
- Degenerative changes
- Complications

3. Early and Late Postoperative Complications

Complications related to surgery will be recorded and classified as early or late events.

4. Clinical and Functional Assessment

Clinical and functional outcomes will be evaluated at 3 months, 12 months, and, if applicable, 24 months after surgery.

Objective data will be collected regarding:

- Functional status
- Range of motion

- Muscle strength of the operated limb

Return to work and return to sport will be assessed.
Shoulder mobility will be measured using a goniometer.

Clinical, functional, and quality-of-life outcomes will be assessed using validated scales routinely used in the Department of Orthopaedic Surgery at Hospital Universitario La Paz:

- a. **WOSI (Western Ontario Shoulder Instability Index)** – Appendix I
 - b. **Subjective Shoulder Value (SSV)** – Appendix II
 - c. **ROWE Score** – Appendix III
 - d. **Visual Analog Scale (VAS) for pain** – Appendix IV
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7. Data Source

Data collection will be performed using the patient's electronic medical record within the HCIS system of Hospital Universitario La Paz.

Data will be pseudonymized by assigning each participant a study reference number. Data will be stored in Microsoft Excel databases and secured on the servers of Hospital Universitario La Paz for subsequent analysis.

Data will be retained for the duration of the study and for a maximum period of 10 years thereafter to comply with potential legal obligations arising from the study.

8. Statistical Analysis Plan

Data collected through clinical case report forms and patient consultations will be entered into databases for subsequent analysis.

Sample Size Calculation

The sample size was calculated to detect a minimal clinically important difference (MCID) of 210 points on the WOSI scale (10% of the total score), assuming a standard deviation of 450 points, a one-sided alpha error of 0.025, and a statistical power of 80% ($\beta = 0.2$).

This resulted in a required sample of 72 patients (36 per group). Considering a potential 10% loss to follow-up, the final sample size was set at 80 patients (40 per group).

Baseline Analysis

Prior to the primary analysis, baseline characteristics of both groups will be described to assess homogeneity following randomization.

- Continuous variables will be expressed as mean \pm standard deviation or median and interquartile range if non-normally distributed.
- Categorical variables will be expressed as absolute frequencies and percentages.

Statistical Tests

The following tests will be applied according to data type and distribution:

- Kolmogorov–Smirnov test to assess normality
- Independent Student's t-test or Mann–Whitney U test for comparison of continuous variables between groups
- Chi-square test or Fisher's exact test for categorical variables

Primary Analysis

The primary analysis will compare total WOSI score at 12 months postoperatively between the two groups.

The primary hypothesis is that high-strength suture tape fixation is non-inferior to metallic screw fixation.

A non-inferiority analysis for independent means will be performed using a one-sided t-test with a predefined non-inferiority margin of 210 WOSI points (10% of total score).

Both intention-to-treat and per-protocol analyses will be conducted in accordance with recommendations for non-inferiority trials.

A one-sided 95% confidence interval for the difference between groups will be calculated.

Secondary Analyses

- **Pain (VAS) and ROWE score at 12 months:** comparison using repeated-measures ANOVA or non-parametric equivalent where appropriate.
- **Time to return to sport:** comparison of means between groups.
- **Surgical complications:** comparison of proportions using Chi-square or Fisher's exact test.

- **Graft union rate:** comparison using parametric or non-parametric tests as appropriate.

A sensitivity analysis will be performed to assess the impact of missing data or loss to follow-up.

In the intention-to-treat analysis, missing data will be imputed using the last observation carried forward method or multiple imputation if losses exceed 5%.

All statistical analyses will be conducted using SPSS version 18.0 (IBM Inc., Armonk, NY, USA).

Statistical significance will be set at:

- $\alpha = 0.025$ (one-sided) for the non-inferiority analysis
 - $\alpha = 0.05$ (two-sided) for exploratory and secondary analyses
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9. Ethical Considerations

9.1 General and Specific Investigator Responsibilities

Investigators will strictly adhere to the provisions of this protocol and will fully complete all case report forms.

The study will be conducted in accordance with:

- Good Clinical Practice (GCP)
- The ethical principles of the Declaration of Helsinki (75th WMA General Assembly, Helsinki, Finland, October 2024)
- Spanish Law 14/2007 of July 3 on Biomedical Research

The processing, communication, and transfer of personal data of all participating patients will comply with:

- Regulation (EU) 2016/679 (General Data Protection Regulation – GDPR)
 - Spanish Organic Law 3/2018 on Personal Data Protection and Guarantee of Digital Rights
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9.2 Benefit–Risk Assessment

Participants may not directly benefit from participation in this study. However, the results are expected to contribute to improved knowledge regarding outcomes in patients with anterior shoulder instability undergoing the Latarjet procedure and may help prevent complications associated with screw fixation.

Participants will not be exposed to any additional or extraordinary risks, as no extra procedures beyond routine clinical practice are planned and the treatment is well supported by current scientific literature.

9.3 Informed Consent

The informed consent document is attached separately to this protocol.

9.4 Data Security and Confidentiality Measures

Investigators will strictly adhere to this protocol and to Good Clinical Practice guidelines.

In accordance with clinical trial regulations, the study will be reviewed and approved by the Research Ethics Committee with Medicines (CEIm) of Hospital La Paz.

Only investigators will have access to identifying patient data (initials and medical record number). These identifiers will be kept separate from the main study database and will not be entered into study datasets.

Each participant will be identified by a numerical code to ensure confidentiality in compliance with Regulation (EU) 2016/679 (GDPR).

10. Data Management

10.1 Compliance with European/National Legislation

The sponsor/principal investigator and collaborating team will comply with applicable data protection regulations:

- Regulation (EU) 2016/679 (GDPR)
- Spanish Organic Law 3/2018 and related implementing regulations

10.2 Privacy Protection

All collected information will be treated with strict confidentiality in accordance with applicable legislation.

Data will be pseudonymized, ensuring technical and functional separation between:

- The research team
- Personnel responsible for pseudonymization and re-identification key storage

Pseudonymized data will be accessible to the research team only after signing confidentiality agreements and committing not to attempt re-identification.

Re-identification may only occur if necessary to protect the safety or health of an individual or group, or to ensure appropriate medical care.

The list linking identification codes to patient identity will be stored confidentially at the healthcare institution.

Access to identifiable data will be restricted to:

- Study investigators and collaborators
- Health authorities (Spanish Agency of Medicines and Medical Devices and relevant international authorities)
- Research Ethics Committee (CEIm)
- Inspectors for GCP compliance

All access will be subject to strict confidentiality obligations.

10.3 Data Access and Use Limitations

The sponsor/principal investigator will share data only with co-investigators involved in the study and reported to the Research Ethics Committee.

11. Biological Sample Management

Not applicable.

12. Detection, Collection, and Reporting of Adverse Drug Reactions (ADR)

Not applicable.

13. Timeline

Months 1–3: Study design and coordination of the working protocol. Submission for approval to the Research Ethics Committee with Medicines (CEIm) of Hospital Universitario La Paz.

Months 4–12: Patient recruitment and collection of related study variables. Clinical-functional and radiological assessment scales will be completed.

Months 13–24: Analysis of clinical and radiological data.

Months 24–26: Preparation of a manuscript for publication reporting the study results.

14. Publication and Transparency

Publication of clinical trial results must meet requirements that ensure transparency, integrity, and accessibility of the data obtained.

14.1 Registration

Not applicable.

14.2 Publication of Results

After completion of the 12-month follow-up period, data analysis will be performed and a manuscript will be prepared for publication presenting the study results. This analysis and manuscript preparation is expected to take approximately 2 months prior to submission to a scientific journal.

14.3 Data Transparency Policy

Data will be stored in databases for subsequent evaluation. Data will be retained during the conduct of the study and thereafter for a maximum period of 10 years in order to comply with any legal obligations that may arise.

14.4 Communication of Results to Patients and Society

Results will be published in a high-impact scientific journal accessible to patients and to the wider public.

15. Funding

This study does not receive funding from any public or private entity.

16. Conflict of Interest

The study investigators declare no conflicts of interest related to the study described.
