

STUDY TITLE (01/11/2025)

Comparative Outcomes of Arthroscopic Surgical Technique in Anterior Shoulder Instability with Glenoid Bone Loss

STUDY INVESTIGATOR

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Academic degree: M.D.

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STUDY SUMMARY

Rationale and Aim

The risk of recurrent anterior shoulder dislocation in young, active patients can reach 70–90%. Anterior shoulder instability is associated with both soft tissue deficiency and bone injury. Bone loss increases the risk of recurrent dislocation.

Dynamic shoulder stabilisation and augmentation of the anterior labrum using the long head of the biceps brachii tendon improve shoulder function without substantially increasing operative time or prolonging rehabilitation. This technique does not require additional implants and provides functional recovery as rapid as that following standard anterior labral reattachment to the glenoid. It represents an alternative to other surgical shoulder stabilisation techniques.

Study Design and Methodology

The study is planned as a prospective longitudinal study involving two patient groups.

Inclusion criteria

- Age of 50 years or younger.
- History of anterior shoulder dislocation or subluxation.
- Persistent anterior shoulder instability.
- Magnetic resonance imaging (MRI) confirmation of an anterior labral lesion and a Hill–Sachs lesion.
- Computed tomography (CT) confirmation of a glenoid bone defect involving 10–20% of the total glenoid articular surface.
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Exclusion criteria

- Age over 50 years.
- Injuries to other structures of the shoulder joint.
- Multidirectional instability.
- Previous surgical procedures.
- Acute infections.
- Blood coagulation disorders.
- Other systemic diseases, including diabetes mellitus, rheumatoid arthritis, gout, and “AI” [abbreviation not defined in the original document].

Patient Allocation and Surgical Treatment

Patients will be allocated to two groups, with 30 participants in each group. Randomisation will be performed using the “Randomizer for Clinical Trial” application.

Patients in the dynamic shoulder stabilisation group, referred to as the “DPS” group in the original protocol, will undergo surgery using the dynamic shoulder stabilisation technique. Their treating surgeon will be Andrejs Finogjevs, the author of the doctoral thesis.

The outcomes of dynamic shoulder stabilisation will be compared with those of patients undergoing Bankart repair, with or without remplissage, performed by Andrejs Finogjevs.

Biological Sampling and Immunohistochemical Assessment

During surgery, bone and long head of the biceps tendon specimens will be collected from patients in the DPS group. These specimens will be used to evaluate the expression of biomarkers that may predict the regenerative capacity of bone and soft tissues. Biomarker expression will be compared with clinical characteristics and surgical outcomes.

Immunohistochemistry will be used to assess the expression of TNF- α , RANKL, ZNF281, FGF-2, and IMP-2.

Follow-up and Outcome Assessment

Patients will undergo repeat clinical assessments at 1 month, 3 months, 6 months, 1 year, and 2 years after surgery. At each visit, clinical outcomes will be assessed using:

- The Constant–Murley Shoulder Score.
- The American Shoulder and Elbow Surgeons (ASES) Score.
- The Oxford Shoulder Instability Score.
- A visual analogue scale (VAS) for pain.

Operative time and additional analgesic administration will also be evaluated. Longer operative time may be associated with greater soft tissue swelling and potentially greater pain.

All patients will follow the same rehabilitation protocol.

Data Management and Statistical Analysis

All collected data were compiled, coded, and anonymised in an Excel database.

Histopathological and clinical parameters were analysed using the chi-square test and the Mann–Whitney U test. Associations between various parameters and the type of surgery will be analysed using Fisher’s exact test.

Associations between immunohistochemical biomarker expression and clinical and histopathological characteristics will be analysed using Pearson’s chi-square test to assess statistical significance.

The association of surgical technique with recurrence and complications will be evaluated using the Kaplan–Meier method and the log-rank test.

Statistical calculations

Categorical and non-parametric data were analyzed using the Chi-square test and the Mann–Whitney U test, respectively. Correlations between the clinical or histopathological variables were evaluated using the Pearson Chi-square (χ^2) test. A p-value of <0.05 was considered statistically significant. The GraphPad Prism 12. version software was used for data analysis.

STUDY PERIOD

Start date: 01 December 2024

End date: 31 August 2029

STUDY SITE

Address: ORTO klīnika SIA., Bukultu iela 1a, Riga, Latvia

Contact person: Andrejs Finogejevs, andrejs.finogejevs@orto.lv

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STUDY PARTICIPANTS

Number of participants, recruitment methodology, and inclusion/exclusion criteria

Inclusion criteria

- Age of 50 years or younger.
- History of anterior shoulder dislocation or subluxation.
- Persistent anterior shoulder instability.
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Exclusion criteria

- Age over 50 years.
- Injuries to other structures of the shoulder joint.
- Multidirectional instability.
- Previous surgical procedures.
- Acute infections.
- Blood coagulation disorders.
- Other systemic diseases, including diabetes mellitus, rheumatoid arthritis, gout, and “AI” [abbreviation requires clarification].

Control Group

The control group consists of patients who meet the same inclusion criteria and have undergone labral reattachment with or without remplissage. All groups will follow the same rehabilitation protocol.

Patients will be allocated to two groups, with 30 participants in each group.

INFORMED CONSENT

Does the study involve any of the following participant groups?

Participant group	Yes	No
Minors		X
Emergency care patients		X
Psychiatric patients		X
Individuals with intellectual disabilities		X
Prisoners		X
Pregnant women		X
Breastfeeding women		X

Consent procedure	Yes	No
Will participants sign an informed consent form?	X	
Will participants provide oral informed consent without signing an informed consent form?		X

Procedure for Obtaining Informed Consent

The study investigator will obtain written informed consent during outpatient consultations from patients who meet the inclusion criteria.

Justification for Not Obtaining Informed Consent

Not applicable.

VII. ANALYSIS OF STUDY RISKS AND BENEFITS

What are the potential physical and psychological risks to participants (pain, stress, discomfort, etc.)?

Patients may experience postoperative pain lasting several days or weeks. Pain may range from moderate to severe, depending on the individual response and the complexity of the surgery. There is a risk of infection during surgery and the postoperative period, associated with the surgical incision and the use of implants. Possible complications include implant failure, nerve injury, joint stiffness, and recurrent shoulder instability. Allergic reactions to anaesthetic agents or other medications administered during surgery may also occur.

What measures will be taken to minimise risks and protect participants?

Patients will undergo thorough screening and selection according to the inclusion and exclusion criteria to identify suitable candidates for the study.

Patients will receive comprehensive information about the study procedures, potential risks, and benefits so that they can make an informed decision about participation. An effective pain management strategy using multimodal analgesia, including appropriate pharmacological treatment, will be developed and implemented. Sterile conditions will be maintained during surgery, and appropriate aseptic care will be provided postoperatively. Regular monitoring and clinical assessments will enable prompt identification and management of potential complications.

What benefits to society are expected from the study?

The study is expected to improve treatment methods for anterior shoulder instability by supporting more effective surgical and rehabilitation approaches. Improved treatment protocols may help patients recover movement and function more quickly and effectively, reduce the risk of long-term complications, and improve quality of life.

The study findings may contribute to the standardisation of rehabilitation protocols, providing a consistent and effective approach to rehabilitation following shoulder surgery. Reducing the number of complications may also reduce healthcare costs.

What benefits to participants are expected from the study?

Participants are expected to benefit from improved health and shoulder function through more effective treatment methods. Potential benefits include reduced pain and discomfort and access to new surgical and rehabilitation approaches.

Detailed monitoring and regular clinical assessments will provide a high standard of medical care, while an individualised approach and psychological support will help address stress and anxiety. Participants will receive information about their condition and prognosis, helping them better understand the strategies needed to manage their health.

Participation will also provide access to experienced specialists and may reduce treatment-related costs. Participants will contribute to the advancement of medical science by helping improve treatment methods for future patients.

Overall, participants may experience health, psychological, and financial benefits that contribute to their well-being and quality of life.

Financing and Other Support

All costs associated with the study are covered by ORTO Clinic. No external funding is requested or anticipated.

Collaboration with Other Scientists or Research Institutions

There are no formal collaborations with other scientists or research institutions for this project.

Participant Information and Consent Form (01/11/2025)

Dear Madam / Sir,

We invite you to participate in the clinical research study titled:
“Comparison of Arthroscopic Treatment Methods in Relation to Bone Deficiency in Anterior Shoulder Joint Instability”,
conducted by **Dr. Andrejs Finogejevs**.

This document provides detailed information about the purpose, procedures, potential benefits, and possible risks of the study.

Please read this document carefully before signing.

You have the right to ask any questions about the study and to receive clear answers before giving consent.

1. Purpose of the Study

The purpose of this study is to evaluate whether **anterior labrum augmentation using the long head of the biceps brachii tendon** improves shoulder functionality in patients with anterior shoulder instability associated with bone deficiency.

This technique is hypothesized to:

- Improve functional outcomes without significantly increasing operative time or rehabilitation duration.
- Avoid the need for additional implants.
- Achieve functional recovery comparable to standard anterior labrum refixation at the glenoid.

This method may represent a **viable alternative** to other surgical stabilization techniques for the shoulder joint.

2. Study Procedures

The study will be conducted over a period of **at least two years**.

The first stage involves **patient recruitment, eligibility screening, and necessary diagnostic assessments**.

All examinations and procedures will take place at a medical institution specializing in the treatment of anterior shoulder joint instability. Participants will undergo:

- Clinical assessments
- Magnetic Resonance Imaging (MRI)
- Computed Tomography (CT)
- Other diagnostic tests as needed

Following screening, eligible participants will be randomly assigned to one of two groups:

- **Study Group** – receiving the experimental surgical technique
- **Control Group** – receiving standard arthroscopic treatment

All participants will undergo **arthroscopic shoulder surgery**. Randomization will occur prior to surgery to ensure objectivity and comparability between the groups, under the supervision of medical personnel.

Participants will be asked to complete questionnaires regarding pain, shoulder function, and medication use to assess recovery and treatment efficacy.

If biological samples (e.g., blood) are collected, volumes will be minimal and limited to what is necessary for laboratory analyses. During surgery, **small fragments (3–5 mm) of bone and tendon tissue** may be collected as part of standard procedures, without increasing surgical risk or duration.

All participants and their treating physicians will have access to **individual study-related results** to ensure optimal treatment and follow-up.

Participation will last **at least three years**, though long-term follow-up may continue to evaluate durability and long-term effects of the treatment.

3. Potential Benefits

Participation in this study may lead to:

- Improved shoulder function and reduced pain due to a more effective surgical approach
- Access to innovative surgical and rehabilitation techniques
- Comprehensive medical monitoring and regular clinical evaluations
- Individualized care and psychological support to manage stress or anxiety
- Increased understanding of your own health condition and treatment strategies
- Access to experienced medical professionals and potentially reduced treatment costs

Additionally, participation will contribute to **medical research and the advancement of future treatment methods**.

Overall, participants may experience **health, psychological, and practical benefits**, leading to improved quality of life and well-being.

4. Possible Risks and Discomforts

Potential risks associated with participation include:

- Postoperative pain (mild to severe), lasting several days or weeks depending on individual recovery and surgical complexity
- Risk of infection related to surgical incisions or implant use
- Potential complications such as implant rejection, nerve injury, joint stiffness, or recurrent shoulder instability
- Possible allergic reactions to anesthesia or other medications used during surgery

To minimize risks:

- Only suitable candidates will be enrolled, following strict inclusion and exclusion criteria
- Comprehensive preoperative assessment and patient education will be provided
- Multimodal pain management and appropriate medication will be implemented
- Sterile technique will be strictly maintained during and after surgery
- Regular postoperative follow-up and monitoring will be conducted to detect and manage any complications promptly

5. Confidentiality and Data Protection

All personal data will be processed in accordance with the **Personal Data Processing Law**. Your data will be stored securely within the clinic's IT system, protected by passwords and user authentication.

Collected data may include:

- Gender
- Age
- Patient medical record number

The responsible person for data protection is the principal investigator, **Dr. Andrejs Finogejevs**.

If you have any questions or complaints regarding data processing or storage, please contact:

Dr. Andrejs Finogejevs

Phone: +371 29951841

Email: andrejs.finogejevs@orto.lv

6. Voluntary Participation and Right to Withdraw

Your participation in this study is **entirely voluntary**.

You have the right to refuse participation or withdraw from the study at any time, without providing a reason.

Your decision to withdraw will **not affect the quality of your medical care or treatment** in any way.

You will be informed of any new information that may influence your willingness to continue participation.

This document is prepared in **two copies** — one retained by the investigator and one by the participant.

For any questions regarding the study, please contact:

Dr. Andrejs Finogejevs

Phone: +371 29951841

Email: andrejs.finogejevs@orto.lv

7. Ethical Approval

This study has been reviewed and approved by the Rīga Stradiņš University Ethics Committee on 29 November 2024, approval number 2-PĒK-4/694/2024.

Ethics Committee contact details: RSU central building, Dzirciema iela 16, Rīga, Latvija, LV1007. E-mail: pek@rsu.lv

8. Participant Consent Statement

I hereby confirm that (please mark each box as appropriate):

Statement	Agree	Disagree
1. I have been provided with all information relevant to the study.	☐	☐
2. I have had the opportunity to ask questions about the study and my role in it.	☐	☐
3. I voluntarily agree to participate in the study.	☐	☐
4. I consent to the collection and storage of my data for research purposes (audio or video recording, if applicable).	☐	☐

Signatures

Participant (Interviewee)

Name and Surname: _____

Signature: _____

Date: _____

Researcher (Interviewer)

Name and Surname: _____

Signature: _____

Date: _____

Contact Person:

Dr. Andrejs Finogejevs

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