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Complete List of Authors:	Malmberg, Catarina; Hvidovre Hospital Sports Orthopedic Research Center Copenhagen, Dept. of Orthopedic Surgery Andreasen, Kristine; Hvidovre Hospital Sports Orthopedic Research Center Copenhagen, Dept. of Orthopedic Surgery Bencke, Jesper; Copenhagen University Hospital, Human Movement Analysis Laboratory Kjær, Birgitte; Institute of Sports Medicine, Department of Physical and Occupational Therapy Hølmich, Per; Hvidovre Hospital Sports Orthopedic Research Center Copenhagen, Dept. of Orthopedic Surgery Barfod, KW; Hvidovre Hospital Sports Orthopedic Research Center Copenhagen, Dept. of Orthopedic Surgery
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The Effect of Arthroscopic Bankart Repair on Shoulder Kinematics and Proprioception in Patients with Traumatic Anterior Shoulder Instability: A Prospective Cohort Study Protocol

Catarina Malmberg[1], MD, Kristine Rask Andreasen[1], MD, Jesper Bencke[2], MSc PhD, Birgitte Hougs Kjær[3], MSc PhD, Per Hölmich[1], MD DMSc, Kristoffer Weisskirchner Barfod[1], MD PhD

[1]Sports Orthopedic Research Center – Copenhagen (SORC-C), Department of Orthopedic Surgery, Copenhagen University Hospital Amager & Hvidovre, Denmark

[2]Human Movement Analysis Laboratory, Department of Orthopedic Surgery, Copenhagen University Hospital Amager & Hvidovre, Denmark

[3]Department of Physical and Occupational Therapy, Institute of Sports Medicine Copenhagen (ISMC), Copenhagen University Hospital Bispebjerg & Frederiksberg

Corresponding author: Catarina Malmberg, Kettegård Allé 30, 2650 Hvidovre, catarina.anna.evelina.malmberg.02@regionh.dk

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Abstract

Introduction: Traumatic shoulder dislocation is a common shoulder injury, especially among the young and active population. More than 95% of dislocations are anterior, in which the humeral head is pushed beyond the anterior glenoid rim. The injury leads to decreased joint stability and recurrence rates are high. There is evidence that the shoulder biomechanics and neuromuscular control change following dislocation, but it remains to be established if these parameters are useful in the clinical setting. The aim of this prospective cohort study is to apply a 360° investigation approach to patients with traumatic anterior shoulder instability undergoing arthroscopic Bankart repair. By conducting the study, we wish to establish if biomechanical and neuromuscular examinations are applicable in the clinical setting to assess shoulder instability and guide surgeons in timely and evidence-based identification of patients that will benefit from surgery.

Methods and analysis: This is a prospective multicenter cohort study with repeated measures of 55 patients undergoing arthroscopic Bankart repair. With carefully selected and completely non-invasive examination methods, we will investigate the effect of arthroscopic Bankart procedure from biomechanical, neuromuscular, clinical, and patient-centered perspectives. The affected shoulders are tested once pre-surgically and twice post-surgically at 6 and 12 months. Patients' contralateral shoulders are investigated once to establish a pre-injury (normal) level.

Ethics and dissemination: The study was approved by the Capital Region Ethics Committee (journal-no: H-21027799) and the Capital Region Knowledge Center for Data Reviews (journal-no: P-2021-842) before patient recruitment began. The study results will be published in international peer-reviewed journals, online and in other relevant media, presented at medical conventions and disseminated to clinicians and patients as appropriate.

Trial registration number: NCT05250388

Keywords: traumatic shoulder instability, anterior shoulder instability, biomechanics, kinematics, proprioception, neuromuscular control, arthroscopic Bankart repair

Strengths and limitations

- This study has a 360° investigation approach from biomechanical, neuromuscular, clinical, and patient-centered perspectives, which has not been previously described.
- The study will contribute with increased understanding of traumatic anterior shoulder instability and might lead to an enlargement of the clinical toolbox to help surgeons in choosing between treatment alternatives.
- All examination methods are non-invasive.
- The study is essentially exploratory, as the literature on biomechanical and neuromuscular changes in patients with traumatic shoulder instability is scarce and the authors cannot refer to any established standard deviations or minimally important difference.

1. Introduction

1.1 Background

Traumatic anterior shoulder dislocation is a common shoulder injury, with a prevalence of 1.7% in a general population aged 18-70 years and incidence rates of 11.2-56.3 per 100'000 person years [1–3]. First-time dislocation incidence rates are highest in the third decade of life for men, while it is most common in women above 50 years of age [3] The injury leads to glenohumeral joint instability and recurrence rates exceed 70% in some reports [4]. Besides disruption and injury to the capsule, labrum and ligaments, bone loss is often seen after the injury [5]. The bone loss can be isolated to the anteroinferior part of the glenoid, referred to as the osseous Bankart lesion, or to the posterolateral aspect of the humeral head, the Hill-Sachs lesion, but can also be seen in combination as bipolar lesions, creating an additive negative effect on the joint stability [6]. Thus, the extent of the structural injury plays a role in development of glenohumeral instability.

Chronic shoulder instability may appear even after the first dislocation and often aggravates with recurrence, which can lead to altered shoulder biomechanics and motion control [5,7–9]. The joint stability is clinically assessed using manual tests including the sulcus sign, load and shift, apprehension test, and relocation test; some of which have high specificity, but are highly patient- and examinator-dependent and none of them provide quantitative data [10]. The instability can be directly inspected and quantified during arthroscopy, which is an invasive procedure, or through medical imaging methods, which might be irradiating and, furthermore, only examines the joint in a static position [6,7,11]. Alternatively, non-invasive and non-irradiating dynamic analysis of the shoulder biomechanics can be performed using motion capture and ultrasound [9,12–14].

Neuromuscular joint control is most often assessed as joint position sense (JPS) or threshold to detection of motion (TTDM). In 2015, a systematic review concluded that patients suffering from traumatic anterior shoulder instability had decreased JPS and increased TTDM, thus impaired

neuromuscular joint control compared to those with stable/healthy shoulders [15]. Both modalities have been criticized for the lack of ecological validity, as they are static and without application of an external force and thereby cannot be generalized to a real-life setting [16]. The shoulder-sway test, developed in 2012, investigates neuromuscular joint control in a loaded static position [17]. Reduced joint control, measured as increased sway-length, has been reported in shoulders with traumatic anterior instability compared to healthy, which supports the theory of impaired neuromuscular control in these patients [18]. Recently, the Copenhagen Assessment of Neuromuscular Control in the Unstable Shoulder (CANCUS) – consisting of the JPS, shoulder-sway and reaction time tests in a dynamic and loaded setting was developed but remains to be tested in patients [unpublished test series].

In treatment of traumatic anterior shoulder instability, the focus is on restoring stability. Surgically, the structural stability is re-established, and the extent of injury determines the type of surgery [6]. Surgery reduces risk of recurrent events but does not always relieve patients of symptoms. Some patients still experience a feeling of instability – apprehension – after surgery and suffer from residual pain and reduced activity level and quality of life [9,19,20]. As the pathologic mechanism of apprehension is complex and probably includes both mechanical and neurological impairments, the effect of surgery might be questioned [21]. More specifically, the effects on biomechanical and neuromuscular properties remain unclear [9,22].

1.2 Research questions

A (biomechanics): Does arthroscopic Bankart repair have a stabilizing effect on the biomechanics in patients with traumatic anterior shoulder instability?

B (neuromuscular control): Does arthroscopic Bankart repair improve neuromuscular control in patients with traumatic anterior shoulder instability?

C (clinical outcomes): What are the clinical outcomes following arthroscopic Bankart repair?

1.3 Aim

We aim to investigate the effect of arthroscopic Bankart repair on biomechanical, neuromuscular, and clinical outcomes (including patient-reported outcome measures) to test the hypothesis that biomechanical and neuromuscular examinations are clinically applicable in assessment of shoulder instability and can be helpful in guiding surgeons in timely and evidence-based identification of those who will benefit from surgery.

1.4 Objectives

1.4.1 Objectives research question A

In patients with traumatic anterior shoulder instability undergoing arthroscopic Bankart repair, to investigate the anterior-posterior glenohumeral translation and the scapular rotations before and six and twelve months after surgery and whether the ranges are restored to the same as the healthy contralateral shoulder.

1.4.2 Objectives research question B

In patients with traumatic anterior shoulder instability undergoing arthroscopic Bankart repair, to investigate the neuromuscular control before and six and twelve months after surgery and whether the neuromuscular control is restored to the same level as the healthy contralateral shoulder.

1.4.3 Objectives research question C

In patients with traumatic anterior shoulder instability undergoing arthroscopic Bankart repair:

1) To determine the recurrence rates in the first 12 months.
2) To investigate the shoulder range of motion (ROM) before and six and twelve months after surgery.
3) To assess the joint instability by manual testing before and six and twelve months after surgery.

4) To quantify potential bone loss before surgery.

5) To investigate patient-reported outcome measures (PROM) before and six and twelve months after surgery.

1.4.4 Other objectives

To investigate if there are correlations between the shoulder biomechanics and a) neuromuscular control, b) PROM, c) ROM, and d) bone loss.

2. Methods and analysis

2.1 Study design

This is a prospective observational cohort study with repeated measures of the patient's affected shoulder pre- and post-intervention. The contralateral shoulder is investigated prior to surgery to establish a pre-injury level representing the normal shoulder.

2.2 Outcomes

The outcomes were designed to investigate the effects of arthroscopic Bankart repair using a 360° approach with biomechanical, neuromuscular, clinical, and patient-centered perspectives (Fig. 1). The change in anterior-posterior glenohumeral translation was chosen as the primary outcome to allow for a statistic sample size calculation (see section 3.1).

2.2.1 Biomechanical outcomes

The primary outcome is the change in anterior-posterior glenohumeral translation six months after surgery as assessed from real-time ultrasound imaging. The examination strictly follows a previously tested protocol in which the joint is tested in two positions: 1) neutral along the body (posterior view) and 2) in abduction and external rotation (anterior view); under three conditions: 1) at rest, 2) during isometric force and 3) with external force applied to the relaxed joint [14,23]. The translation, in millimeters, is calculated by subtracting the distance between the border of the

glenoid (posterior view) or the coracoid process (anterior view), respectively, and the border of the humeral head at rest (condition 1) from the conditions with force applied (conditions 2 and 3). All ultrasound examinations are carried out by the same investigator. The change in the anterior-posterior glenohumeral translation is also evaluated 12 months after surgery (same methods as above).

The scapular upward downward rotations, protraction-retraction and anterior-posterior tilt are analyzed using motion capture technique with a skin-marker based protocol and eight cameras simultaneously collecting data during ROM activities and used to evaluate the effect of Bankart repair six and twelve months following surgery. The motion capture protocol was developed in the Human Movement Analysis Laboratory at Copenhagen University Hospital Hvidovre and has been previously tested in healthy subjects (article in preparation).

2.2.2 Neuromuscular outcomes

The change in neuromuscular control is assessed using the newly developed CANCUS test protocol at six and twelve months after surgery. The test series includes assessment of the shoulder joint reaction time, sway, and joint position sense using motion capture, force platforms and surface electromyography (EMG). The shoulder reaction time test determines the neuromuscular control in a loaded and fast dynamic setting. It was developed and tested in healthy subjects in the Human Movement Analysis Laboratory at Copenhagen University Hospital Hvidovre (article in preparation). The sway test determines the neuromuscular control in a weightbearing and static position, using force platforms to determine the center of pressure in the frontal and sagittal planes. The joint position sense is a slow dynamic, non-weightbearing evaluation of how precisely the patient can reproduce a given position of the joint. It is tested in an external rotational motion with the arm in 90° abduction.

2.2.3 Clinical and patient-reported outcomes

Any recurrent dislocations in the first 12 months are registered during follow-up. Further, the active shoulder ROM (flexion, extension, abduction, internal and external rotation) is evaluated using a handheld goniometer before and six and twelve months after surgery. The clinical instability tests sulcus sign, load and shift, apprehension test and relocation test are performed and evaluated with dichotomous outcomes at all three visits (positive/negative). The manual tests are performed by the same investigator.

All patients undergo a pre-surgical computed tomography (CT) scan to measure potential bone loss. Glenoid bone loss is measured using the PICO-method, which is based on calculating the size of the defect as the percentage of a best-fit circle from the contralateral glenoid [24]. The size (width and depth in millimeters) of Hill-Sachs lesions on the humeral head is also measured and registered [25].

The perceived change in shoulder function is evaluated using the Western Ontario Shoulder Instability (WOSI) index [26]. It consists of 21 items, each scored on a 100 mm Visual Analogue Scale (VAS). Each item falls into one of the domains of physical function, sports/recreation/work, lifestyle, and emotional well-being. Each question is scored between 0-100 points and the sum of all the questions adds up to a final score, ranging from 0 (best) to 2100 (worst).

The perceived change in quality of life is assessed using the EQ-5D questionnaire, which has five components that assess the severity of problems in three functional dimensions (mobility, self-care and usual activities) and two somatic symptom dimensions (pain/discomfort and anxiety/depression) [27]. The response scales consist of a heading and five short statements, each describing a different level of severity.

2.3 Study setting

The patients are screened for eligibility and treated at five centers specialized in treatment of shoulder instability. The centers include the Department of Orthopedic Surgery, Copenhagen University Hospital Amager & Hvidovre, the Department of Orthopedic Surgery, Copenhagen University Hospital Herlev & Gentofte, the Department of Orthopedic Surgery, Zealand University Hospital Køge, Adeas Hospital, Gildhøj Private Hospital. The final enrolment in the study and all study-related investigations are performed at Copenhagen University Hospital Hvidovre. All data collection (collection of informed consent, clinical examination, biomechanical and neuromuscular examinations, CT scan, and collection of PROMs are performed at Copenhagen University Hospital Hvidovre. See Supplement 1 for further general information.

2.4 Study population and eligibility criteria

Fifty-five patients with traumatic anterior shoulder instability undergoing arthroscopic Bankart repair will be recruited from the centers listed above.

Eligibility criteria are age 18-40 years, unilateral traumatic anterior shoulder instability, scheduled for arthroscopic Bankart repair, no pathology in the contralateral shoulder, willingness to adhere to the study protocol, and ability to give informed consent.

Exclusion criteria are other pathology or associated injuries in the affected shoulder (including traumatic rotator cuff/biceps tendon/SLAP lesion, fracture of proximal humerus/scapula/clavicula, dislocation of sternoclavicular or acromioclavicular joint), pregnancy, and severe medical illness (American Society of Anesthesiology physical status (ASA) score ≥3).

All patients must provide written, informed consent prior to any study procedure (Supplement 2). The consent gives the primary investigator and relevant authorities access to the patient's records, including electronic medical records and audit, hereunder internal audit, and quality assessment,

which are mandatory. The right to access the patient's records is in accordance with the Regional Committee on Health Research Ethics law (§ 3, section 3) and promulgation § 4, section 1, and § 10, sections 3 and 5).

Study inclusion does not influence the treatment course, neither does a decision to withdraw from the study at any point. A patient may be excluded from the study based on the investigator's decision, e.g., in the event of post-surgical complications or inability to adhere to the study protocol. Participants may also be excluded if the study sponsor or government or regulatory authorities terminate the study prior to its planned end date. Patients lost to follow-up are not excluded from analysis but will be specifically accounted for in the report.

2.5 Study plan

There are three visits in total: 1) baseline pre-surgical visit; 2) six months post-surgical ±2 weeks; 3) 12 months post-surgical ±2 weeks. All patients undergo arthroscopic Bankart repair at the center from which they are recruited and follow a standardized post-surgical rehabilitation protocol for a minimum of 12 weeks. All study-related activities are carried out according to the study plan presented in Table 1.

Study plan	**Recruitment**	**Inclusion**	**Pre-surgical visit**	**6 months after surgery**	**12 months after surgery**
Setting	Recruiting center	Copenhagen University Hospital Hvidovre			
Eligibility screen	X				
Oral and written study information and enrolment		X			
Written informed consent		X			
Biomechanical outcomes			X	X	X
Neuromuscular outcomes			X	X	X
Clinical outcomes *Computed tomography scan only at pre-surgical visit			X*	X	X
Patient-reported outcome measures			X	X	X

Table 1. Study plan

2.6 Patient involvement

Patients with traumatic anterior shoulder instability have not been involved in formulating the research questions or choosing the outcome measures. However, they were involved in design of the examination methods and protocols used in the study. We carefully assess the burden of all examinations on patients' physical and mental health throughout the study period. The primary findings will be communicated to the participants.

2.7 Statistics

2.7.1 Sample size calculation

Fifty-five patients will be included in the study, who will each participate with their contralateral shoulder as healthy control. The sample size calculation is based on the primary outcome, set to detect a mean difference in anterior-posterior glenohumeral translation of ≥2.5 mm, with a standard deviation (SD) of 2.3 mm, power of 0.80 (two-sided) and type I error rate of 0.05 for a mixed effects model [9,28]. With six variables in the analysis (sex, height, BMI, dominant/non-dominant side affected, bone loss, clinical score) and an estimated 15% dropout rate, the calculation resulted in 55 patients.

2.7.2 Statistical analysis

Descriptive statistics will be presented as mean (SD), median (range), and percentages with 95% confidence intervals as considered appropriate. Normality of data distribution will be tested, and relevant statistics applied. Results will be evaluated on group level. If data are normally distributed the primary analysis on baseline data will be a linear regression model stratified for sex and height. Correspondingly, the primary analysis including data after intervention will be a mixed effect model with the variables: sex, height, BMI, dominant/non-dominant side affected, bone loss, and clinical

score. If necessary, other relevant statistic models will be chosen according to the characteristics and distribution of the variables.

3. Ethics and dissemination

3.1 Quality

The validity and inter-rater reliability of the motion capture model for analysis of scapular rotations were established by the research group prior to study start. The reliability of the ultrasound technique has a reported test-retest measurement error of 0.2-0.6 mm [29]. For the CANCUS test series, the construct validity and intra-rater reliability of each test is established concurrently during the study. The demographics and clinical examination sheet, as well as PROM questionnaires can be found in Supplement 3 (clinical examination sheet and PROM questionnaires in Danish).

3.2 Risks, side effects and adverse events

The clinical examination and manual tests are clinical practice and not considered to be a risk for the participants. The motion capture model and ultrasound technique are non-invasive and not considered to induce any discomfort during the tests. When removing the skin-mounted markers following motion capture and EMG investigations the patient might experience slight discomfort from the pull on the skin and possible loss of hair, like removal of a band-aid. Some people might have a temporary redness on the skin, which might be eased with normal body lotion. The arm movements included in the experiment does not exceed normal functional use of the upper limb but might induce apprehension of short duration. As for the assessment of neuromuscular control a transient discomfort during the tests is expected with increasing stress on the glenohumeral joint. Before each test, the ROM of the patient is tested and is not exceeded. If the patient cannot achieve the ROM required for the test to be carried out, the patient is excluded from the specific test.

The radiation acquired during a diagnostic shoulder CT scan with the scanners that are currently operating at the Department of Radiology at Copenhagen University Hospital Hvidovre, with an average dose-length product (DLP) of 225 mGy*cm, the effective dose of 2.9 mSv (data acquired from 41 shoulder scans performed January–November 2020) is comparable with approximately one year of background radiation in Denmark (3 mSv). The increased all-time risk of developing cancer is estimated to 0.038% and 0.0618% for 20-year old male and female subjects at one examination, with radiation levels obtained by the planned examination [30]. The variation in risk between the sexes is mainly caused by radiation sensitivity of breast tissue in females.

No severe safety issues are expected. However, there is always a risk of unknown side effects. In this context, adverse events are defined as any unintended, unfavorable finding, symptom or disease that occurs, whether it is related to the study or not. Adverse events are recorded. A critical adverse event is defined as an event or reaction, which causes death, life-threatening situations, hospitalization, or permanent or severe disability. Critical adverse events must be assessed by an investigator to consider whether there is a reasonable possibility that it is caused by any procedure related to the study. The following factors are included in the assessment: consistency in time, consistency with the known effects of participation, and alternative causes. If a critical adverse event is considered to have a causal relationship with the participation, the primary investigator, the clinically responsible and the other investigators will evaluate whether the study should be terminated.

3.3 Education and training

The data collection is conducted by the primary investigator, or experienced staff appointed by the primary investigator. Before commencing data collection, all involved staff is educated and trained in the examination methods and questionnaires to be as calibrated as possible against each other.

There is a Standard Operating Procedures (SOP) file at all recruiting centers. In case a patient, from questionnaires or when examined, shows signs or symptoms of affected mental or physical health the primary investigator is to be informed immediately, and appropriate measures carefully considered (termination of participation, treatment continuation, referral to general practitioner/therapist/psychologist/psychiatrist).

3.4 Ethical considerations

All recruiting centers are specialized in treatment of patients with a wide variety of shoulder pathologies, including traumatic instability. The study methods have been chosen specifically to answer the research questions and for the objectives stated above. From the study results, we expect to contribute to the understanding of the pathophysiology of traumatic anterior shoulder instability and increase awareness of biomechanical and neuromuscular properties. We believe that the potential benefits of using the chosen methods and enabling more efficient diagnostics, monitoring, and treatment exceed the potential inconveniences of the study participants. The study is carried out in accordance with the principles of the Helsinki Declaration and guidelines for Good Clinical Practice (GCP).

3.5 Approvals

The study was approved by the Capital Region Ethics Committee (journal-no: H-21027799) and the Capital Region Knowledge Center for Data Reviews (journal-no: P-2021-842) before patient recruitment began. The primary investigator is responsible of informing the Regional Committee on Health Research Ethics of any critical adverse event and/or major changes of the protocol and files all correspondences.

3.6 Data Management and Confidentiality

The study follows rules on data protection according to the Danish Data Protection Act throughout the complete study period. The primary investigator, supervisors, and other assigned research staff have access to the dataset. The patients are identified by an assigned number. At the completion of the study all identifiable data will be destroyed. The patients receive verbal and written information that data is stored and analyzed digitally, that the patient's anonymity is preserved, and that the data protection legislation is adhered to.

The PROM questionnaires are managed using the software Research Electronic Data Capture (REDCap), a web application for database management originally created at Vanderbilt University.

3.7 Dissemination

The results will be presented in three articles with the preliminary titles:

1. *The effect of arthroscopic Bankart repair on shoulder biomechanics in patients with traumatic anterior instability: A prospective cohort study*
2. *The effect of arthroscopic Bankart repair on neuromuscular control in patients with traumatic anterior shoulder instability: A prospective cohort study*
3. *Clinical outcomes following arthroscopic Bankart repair in patients with traumatic anterior shoulder instability: A prospective cohort study*

The study results will be published in international peer-reviewed journals, online and in other relevant media, presented at medical conventions and disseminated to clinicians and patients as appropriate. Authorship is given based on the Vancouver criteria.

4. Trial status

Patient recruitment began 1 April 2022 and is expected to last for 24 months.

5. Discussion

The shoulder joint is the most mobile of all human joints and consequently the most unstable. The shoulder is in fact the most commonly dislocated joint in the body. The resulting shoulder instability leads to pain, weakness, and loss of shoulder function, and can have life-lasting consequences. Understanding of the complete damage caused by shoulder dislocation is lacking and management of the condition is incomprehensive. There is evidence that biomechanics and neuromuscular control change following shoulder dislocation, but it remains to be established if measurements hereof are applicable in the clinical setting [8,9].

This study is, to our knowledge, the first with a multi-perspective approach focusing on biomechanical and neuromuscular functions to assess the effect of arthroscopic Bankart repair in a group of patients with traumatic shoulder instability. The study methods have been chosen specifically to reach the objectives stated above and have been approved by the regional Ethics Committee. As the literature on biomechanical and neuromuscular changes in patients with traumatic shoulder instability is scarce, the authors cannot refer to any established standard deviations or minimally important difference. Hence, the study is essentially exploratory. Ultimately, the aim is to create grounds for evidence-based decision-making and development of clinical guidelines. The authors believe the study results can contribute to changed management of shoulder instability and optimized health system spending.

6. Data availability statement

No data are currently available for sharing.

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Footnotes:

Contributors: CM and KWB initiated the study. CM, KRA, BHK and JB planned the study and developed the protocol. KWB and PH provided critical feedback about the protocol. Data acquisition is performed by CM and KRA, who will also analyze the data. All authors have read and contributed to the manuscript above, given approval, and agreed to be accountable for all aspects of the work.

Funding: The study is a part of the PhD-project titled "Anterior-posterior glenohumeral translation in traumatic anterior shoulder instability" funded partially by the Department of Orthopedic Surgery, Copenhagen University Hospital Hvidovre (PhD-school, salary, overhead, lab costs). The PhD project has received a grant from the private fund "Familien Hede Nielsens Fond" to cover examination costs, whom did not have any involvement in study design; in the collection, analysis, and interpretation of data; in the writing of the report; nor in the decision to submit the article for publication. Further, the primary investigator has received a grant from the Copenhagen University Hospital Amager & Hvidovre research fund to cover salary.

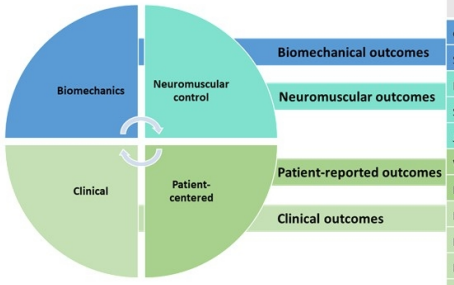
Competing interests: None declared.

Patient involvement: Patients were not involved in formulating the research questions or choosing the outcome measures. Patients were involved in design of the examination methods and protocols used in the study. The primary findings will be communicated to the participants. Further details can be found in section 2.6.

Provenance and peer review: Not commissioned; externally peer reviewed.

Figure legends:

Figure 1. The 360° investigation approach with biomechanical, neuromuscular, patient-centered, and clinical outcomes.



	Pre-operative	6 months after surgery	12 months after surgery
Glenohumeral translations	X	X	X
Scapular rotations	X	X	X
Reaction time	X	X	X
Shoulder sway	X	X	X
Joint position sense	X	X	X
Western Ontario Shoulder Instability Index	X	X	X
EQ-5D questionnaire	X	X	X
Recurrence	X	X	X
Instability tests	X	X	X
Range of motion	X	X	X
3D computed tomography (bone loss)	X		
Ultrasound (soft tissue damage)	X		

205x83mm (150 x 150 DPI)

The Effect of Arthroscopic Bankart Repair on Shoulder Kinematics and Proprioception in Patients with Traumatic Anterior Shoulder Instability: A Prospective Cohort Study Protocol

General information

1. Place of investigation

Sports Orthopedic Research Center – Copenhagen (SORC-C) and Human Movement Analysis Laboratory, Department of Orthopedic Surgery, Copenhagen University Hospital Hvidovre, Kettegård Allé 30, 2650 Hvidovre, Denmark

2. Trial period

Anticipated: 1 April 2022 – 1 April 2025.

3. Trial registration

The study protocol (Version 1.0) was published at Clinical Trials 27 April 2022 (www.clinicaltrials.gov, ID: NCT05250388) according to the World Health Organization Trial Registration Data Set and follows the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) checklist. The study will adhere to the STROBE guidelines for reporting of cohort studies (www.strobe-statement.org). The study has been approved by the Capital Region Ethics Committee (journal-no: H-21027799) and the Capital Region Knowledge Center for Data Reviews (journal-no: P-2021-842).

4. Funding and insurance

The study is a part of the PhD-project titled "Anterior-posterior glenohumeral translation in traumatic anterior shoulder instability" funded partially by the Department of Orthopedic Surgery, Copenhagen University Hospital Hvidovre (PhD-school, salary, overhead, lab costs). The PhD project has received a grant from the private fund "Familien Hede Nielsens Fond" to cover examination costs, whom did not have any involvement in study design; in the collection, analysis, and interpretation of data; in the writing of the report; nor in the decision to submit the article for publication. Further, the primary investigator has received a grant from the Copenhagen University

Hospital Amager & Hvidovre research fund to cover salary. Further fundraising will continuously be carried out through public and private foundations. There are no financial disclosures, from private companies, research funds etc., within the research group that can compromise the integrity of the project.

Study participants will not receive financial compensation. Study participants are covered by the patient insurance of Copenhagen University Hospital Hvidovre.

5. Research group

Primary investigator

Catarina Malmberg (CM) is MD and PhD-student at the Department of Orthopedic Surgery, Copenhagen University Hospital Hvidovre, and is the primary investigator, responsible for planning and conducting the study in all its phases, as well as reporting to all relevant agencies. CM will be first author of the paper on glenohumeral translation.

Address: Sports Orthopedic Research Center – Copenhagen (SORC-C), Department of Orthopedic Surgery, Copenhagen University Hospital Hvidovre, Kettegård Allé 30, 2650 Hvidovre, Denmark
Telephone: +4527519524, Email: catarina.anna.evelina.malmberg.02@regionh.dk

Principal supervisor

Kristoffer Weisskirchner Barfod is MD, PhD, and clinical associate professor at the Department of Orthopedic Surgery, Copenhagen University Hospital Hvidovre. The principal supervisor of the PhD follows requirements from the University of Copenhagen PhD-school throughout the PhD-program. Barfod initiated the study together with CM and contributes to planning of the study and review of the papers.

Co-supervisors

Jesper Bencke is MSc, PhD, and biomechanical laboratory manager at the Department of Orthopedic Surgery, Copenhagen University Hospital Hvidovre. Bencke contributes to planning of the study and review of the papers. Bencke also consults the project with his knowledge in the biomechanical and physiological field and supervise in the biomechanical laboratory.

Per Hölmich is DMSc, professor, and chief surgeon at the Arthroscopic Section, Department of Orthopedic Surgery, Copenhagen University Hospital Hvidovre. Hölmich holds the responsibility to secure that patients participating in the study are treated according to the highest medical standard. Hölmich contributes to planning of the study and review of the papers.

Collaborators

Kristine Rask Andreasen, MD and PhD-student at the Department of Orthopedic Surgery, Copenhagen University Hospital Hvidovre. Andreasen will assist in planning and managing the neuromuscular tests, hereunder experimental work, clinical examinations, and data collection. Andreasen will be first author of the paper on neuromuscular control.

Birgitte Hougs Kjær is MSc, PhD and Postdoc at the Department of Physical and Occupational Therapy, Institute of Sports Medicine Copenhagen (ISMC), Copenhagen University Hospital Bispebjerg & Frederiksberg. Hougs Kjær has specialized experience in musculoskeletal ultrasound imaging and trained the primary investigator in performing the relevant examinations. Hougs Kjær also contributes to planning of the study and review of the paper on glenohumeral translation.

Sanja Bay Hansen is MD at the Centre for Functional and Diagnostic Imaging and Research, Dept. of Radiology, Hvidovre hospital. Hansen is responsible for quantifying bone loss from the computed tomography (CT) scans according to state-of-the-art.

Klaus Bak is MD and senior consultant at the Adeas hospital, Denmark. Bak is associate editor for the medical journal Knee Surgery, Sports Traumatology, Arthroscopy (KSSTA). Bak contributes as external assessor of the project.

Recruiting centers

Department of Orthopedic Surgery, Copenhagen University Hospital Amager & Hvidovre

Department of Orthopedic Surgery, Copenhagen University Hospital Herlev & Gentofte

Department of Orthopedic Surgery, Zealand University Hospital Køge

Adeas Hospitals

Gildhøj Private Hospital

Hvidovre Hospital

SORC-C
Sports Orthopedic Research Center - Copenhagen

Information om forskningsprojektet 'Effekten af kikkertoperation på skulderstabiliteten hos patienter med instabilitet efter traume'

Du er blevet tilset af en ortopædkirurgisk læge, som har konstateret forreste skulderinstabilitet som skal behandles med kikkertoperation.

Vi ved at operation virker godt for langt de fleste, og vi vil med dette forskningsprojekt undersøge hvorfor resultaterne er gode hos mange, men mindre gode hos andre. Vi vil undersøge hvordan operationen påvirker dine ledbånd, dine refleksbuer og din muskulære styring af skulderen. Herved håber vi på sigt at kunne forbedre behandlingen af de patienter som ikke opnår optimale resultater efter operation.

Den projektansvarlige vil efter dette besøg kigge på dine data og kontakte dig via telefon, for at høre om du er interesseret i at høre nærmere om projektet. Hvis det er tilfældet vil vi invitere dig til en samtale, hvor vi gennemgår den skriftlige deltagerinformation og du kan tage endelig stilling til, om du vil være med i projektet.

Forskningsprojektet ændrer ikke på din behandling, men du vil blive indkaldt til 3 ekstra undersøgelser (før operationen, samt hhv. 6 og 12 måneder efter operationen) og du vil få foretaget en udvidet røntgenundersøgelse (3D CT-scanning) af dine skuldre før operationen.

Du kan læse nærmere om forskningsprojektet i den vedlagte deltagerinformation.
Har du spørgsmål er du velkommen til at kontakte mig via nedenstående mail eller telefonnummer.

Mvh

Catarina Malmberg, læge, PhD-studerende og projektansvarlige
Mail: catarina.anna.evelina.malmberg.02@regionh.dk
Telefonnummer: 2751 9524

En undersøgelse af effekten af kikkertkirurgi på skulderstabiliteten hos patienter med instabilitet efter traume

Vil du deltage i et videnskabeligt forsøg?

Vi vil spørge, om du vil deltage i et sundhedsvidenskabeligt forskningsprojekt, der udføres af Ortopædkirurgisk afdeling på Hvidovre Hospital. Overordnet ansvarlig for forsøget er læge og PhD-studerende Catarina Malmberg.

Før du beslutter, om du vil deltage i forsøget, skal du fuldt ud forstå, hvad forsøget går ud på, og hvorfor vi gennemfører forsøget. Vi vil derfor bede dig om at læse denne deltagerinformation grundigt.
Udover denne pjece, vil du have en samtale med en af projektets forskere om forsøget, hvor deltagerinformationen vil blive uddybet, og hvor du kan stille de spørgsmål, du har om forsøget. Du er velkommen til at have et familiemedlem, en ven eller en bekendt med til samtalen.

Hvis du beslutter dig for at deltage i forsøget, vil vi bede dig om at underskrive en samtykkeerklæring. Husk, at du har ret til betænkningstid, før du beslutter, om du vil underskrive samtykkeerklæringen.
Det er frivilligt at deltage i forsøget. Du kan når som helst og uden at give en grund trække dit samtykke tilbage uden videre konsekvenser.

Formålet med forsøget

Skulderen er det led i kroppen som hyppigst går af led. Skaden medfører en instabilitet i leddet, og hos mange medfører det nedsat funktion, kroniske smerter og forringet livskvalitet. Om de fortsatte problemer skyldes at ledbåndene rives over, at knoglen deformeres, at nervernes refleksbuer ændres, eller en kombination af ovenstående som medfører at af evnen til styre skulderen går tabt, vides endnu ikke.

Typisk vil første behandlingsvalg være fysioterapi og ved manglende effekt kikkertoperation med genskabelse af leddets stabiliserende strukturer. Med dette studie ønsker vi at undersøge operationens effekt, dels på den mekaniske stabilitet og dels på nervernes refleksbuer (den neuromuskulære kontrol), og afklare om disse faktorer kan forklare de symptomer patienter oplever. Vores håb er på sigt at kunne adskille dem, som kan forvente et godt resultat ved fysioterapi fra dem, som vil have gavn af tidlig kirurgisk behandling. Det ville medføre at man tidligt i forløbet vil kunne finde den behandling som fører til bedst mulige slutresultat, og derved bidrage til en mere effektiv og korrekt behandling af skulderinstabilitet.

Studiet udføres på Hvidovre Hospital, hvor alle kontroller vil finde sted. 55 patienter med traumatisk skulderinstabilitet og planlagt kikkertoperation vil blive inviteret til at deltage, med start fra 1. september 2021.

Forsøgets praktiske udførelse

Som deltager i projektet vil du skulle møde til 3 kontroller; før din operation, samt hhv. 6 og 12 måneder efter operationen. Det forventes at hvert besøg vil vare ca. 2 timer. Ved disse besøg skal du møde i Bevægelseslaboratoriet i Ortopædkirurgisk afdeling på Hvidovre hospital, hvor en fagkyndig person vil undersøge dine skuldre med en række forskellige stabilitets- og funktionstests.

Først vil vi lave en almindelig skulderundersøgelse, ligesom den Du tidligere har fået foretaget hos den kirurg som skal operere dig. Det indebærer, at vi vil bede dig om at bevæge armene i det omfang du kan, samt med vores hænder mærke efter om vi kan fremkalde den løshed og gener som du oplever.

Desuden vil vi ved de tre besøg udføre tests i laboratoriet, hvor vi med højteknologiske hjælpemidler analyserer dine skuldres bevægelsesmønster og din evne til at lokalisere arm og skulder i rummet. Disse inkluderer:

- En test hvor du får påklistret en række markører på og omkring din skulder og bliver bedt om at udføre nogle bestemte bevægelser, samtidig med du bliver filmet. Et antal kameraer i laboratoriet opsamler signaler fra markørerne, som føres videre til en computer, og som beregner og analyserer dit bevægelsesmønster.
- En undersøgelse hvor vi placerer din arm i to forskellige positioner, og med ultralyd kigger direkte ind i dit skulderled samtidig med at du er: i hvile, får et let tryk bagfra, eller drejer din arm enten indad eller udad.
- En test af stillingssans hvor du med lukkede øjne bliver bedt om at genfinde en tidligere position, hvor armen var løftet.
- En "svajetest" hvor du ligger i en plankeposition med underkroppen støttet af en briks og, hhv. med ansigtet nedad og til siden, støtter på skiftevist den ene og den anden arm i 30 sekunder.
- En test af reaktionstid, hvor du bærer et armbånd, der via en ledning over en trisse er forbundet til en elektromagnet med en lodret hængende vægt som trækker let i din arm. Pludselig deaktiveres magneten, og håndvægten slipper, hvilket vil få din skulder at bevæge sig i modsat retning. Den tid du bruger på at reagere, og føre hånden tilbage til udgangspositionen, er reaktionstiden.

Du vil desuden få tilsendt 2 elektroniske spørgeskemaer på mail, vedrørende din skulderfunktion- og smerter, som du vil blive bedt om at udfylde i forbindelse med de tre kontroller.

Inden operationen vil vi foretage en udvidet computerassisteret tomografi (3D CT-scanning) af begge dine skuldre for at vurdere størrelsen af et eventuelt knogletab.

Vi vil sammen fastlægge en dato for næste kontrol fra gang til gang, under hensyn til, hvad der er hensigtsmæssigt for dig.

Medicin

Som deltager i projektet vil du ikke skulle tage nogen medicin, og det har ingen indflydelse på medicin som du eventuelt tager i forvejen.

Personlige og journaloplysninger

Ved at skrive under på det informerede samtykke gives forsøgsansvarlige, samt eventuel kontrolmyndighed direkte adgang til at indhente oplysninger i din journal mv., herunder elektronisk journal, med henblik på at se oplysninger om dine helbredsforhold, som er nødvendige som led i gennemførelsen af forskningsprojektet samt i kontroløjemed, herunder egenkontrol, kvalitetskontrol og monitorering, som disse er forpligtet til at udføre. Der henvises til komitelovens § 3, stk. 3 og anmeldelsesbekendtgørelsen § 4, stk. 1, samt § 10, stk. 3 og stk. 5.

De journaloplysninger der er relevante for os er:

1. Dine kontaktoplysninger, som vi anvender til at kontakte dig ud fra.
2. Informationer omhandlende behandling af din skulder, for at sikre at du opfylder kriterierne for deltagelse.
3. Dine billeddiagnostiske undersøgelser (røntgen, CT-scanning), som vi bruger til at undersøge et eventuelt knogletab.

Alle involverede forskere har tavshedspligt og vil behandle dine personlige data strengt fortroligt. Personlige oplysninger vil i gennem hele forsøgets forløb beskyttes ifølge den Danske Databeskyttelsesforordning og Databeskyttelsesloven. Det skal understreges at resultater udelukkende vil blive offentliggjort i anonymiseret form, og hverken navn, CPR- eller deltagernummer vil figurere andre steder end på et sikret, lukket drev. Hvis du vælger at trække dit informerede samtykke tilbage vil ingen nye data blive indsamlet og registreret. Imidlertid tillader lovgivningen, at data indsamlet inden du trækker dit samtykke tilbage stadig indgår i forsøgets datamateriale.

Forsøgets nytte

Som deltager i projektet vil du få en grundig opfølgning af fagpersoner specialiseret i din type skade. Derudover vil du med din deltagelse medvirke til at forbedre undersøgelse og behandling af skulderinstabilitet.

Bivirkninger, risici, og ulemper

Det er en ulempe for dig at skulle møde til de 3 kontroller. Til gengæld får du en grundig opfølgning af din skulder, som potentielt kan bidrage til, at du hurtigere genvinder din oprindelige funktion. Derudover vil din deltagelse i projektet ikke have indflydelse på din behandling.

Den røntgenundersøgelse som vil blive foretaget inden operationen medfører stråling, som potentielt kan øge livstidsrisikoen for kræft. Denne risiko er dog meget lille, og mængden af stråling kan sammenlignes med et års baggrundsstråling i Danmark.

De undersøgelsesmetoder som er inkluderede i projektet i øvrigt er ikke forbundet med kendte sundhedsskadelige risici, men der kan være risici ved forsøget, som vi endnu ikke kender. Under nogle af undersøgelserne vil din skulder være i positioner som kan fremkalde symptomer som smerter, usikkerhed og ubehag. De vil formentlig ligne de symptomer som du i forvejen oplever fra din skulder. Der vil i hele forløbet være en fagkyndig person til stede, med overblik over om undersøgelsen skal pauseres eller afbrydes. Vi beder dig derfor om at fortælle, hvis du oplever problemer med dit helbred, mens forsøget står på. Hvis vi opdager bivirkninger, som vi ikke allerede har fortalt dig om, vil du naturligvis blive orienteret med det samme, og du vil skulle tage stilling til, om du ønsker at fortsætte forsøget.

Udelukkelse fra/afbrydelse af forsøg

Vurderes det, at du ikke følger forsøgsplanen eller oplever bivirkninger som kan påvirke dit fysiske eller psykiske helbred kan du udelukkes fra videre deltagelse i forsøget. Opstår der alvorlige uventede bivirkninger vil forsøget blive afbrudt. Andre årsager til afbrydelse af studiet kan være mangel på deltagere, eller at sufficient datamængde foreligger.

Økonomiske forhold

Der udbetales IKKE vederlag for deltagelse i forsøget. I tilfælde af komplikationer, er deltageren dækket af Hvidovre Hospitals patientforsikring og arbejdsskadeforsikringsloven.

Læge og PhD-studerende Catarina Malmberg og overlæge og klinisk lektor Kristoffer W Barfod har taget initiativ til projektet. Faciliteter i form af undersøgelseslokaler og røntgen stilles til rådighed af Hvidovre Hospital, og projektet finansieres overordnet af Ortopædkirurgisk afdeling. Forsøget har modtaget 20 000 kr. i støtte fra Familien Hede Nielsens Fond. Der søges om yderligere finansiering fra private og offentlige fonde. Hvis yderligere støtte modtages, vil deltagere og Videnskabsetisk Komité blive kontaktet herom. De

involverede forskere har ingen økonomisk udbytte af studiet.

Adgang til forsøgsresultater

Resultaterne vil blive offentliggjort, og udgivet i et internationalt videnskabeligt tidsskrift. Yderligere vil resultaterne blive fremlagt på fagspecifikke kongresser.

Forsøget anses for afsluttet når 55 deltagere har gennemført forsøget. Dette forventes udført inden udgangen af september 2024.

Originaltitel

Forsøgets engelske originaltitel er: 'The effect of arthroscopic Bankart repair on anterior-posterior glenohumeral translation and shoulder proprioception in patients with traumatic anterior shoulder instability: a prospective cohort study'

Det er frivilligt at deltage i forsøget

Vi håber, at du med denne information har fået tilstrækkeligt indblik i, hvad det vil sige at deltage i forsøget, og at du føler dig rustet til at tage beslutningen om din eventuelle deltagelse. Vi beder dig også om at læse det vedlagte materiale "Forsøgspersonens rettigheder i et sundhedsvidenskabeligt forskningsprojekt".

Yderligere oplysninger om forsøget kan fås ved kontakt til projektansvarlig:

Læge, PhD-studerende Catarina Malmberg
Ortopædkirurgisk ambulatorium, afsnit 333, Hvidovre Hospital
Kettegård Allé 30, 2650 Hvidovre
Mail: catarina.anna.evelina.malmberg.02@regionh.dk
Telefon: 27519524 / 38623862

Forsøgspersoners rettigheder i et sundhedsvidenskabeligt forskningsprojekt

Som deltager i et sundhedsvidenskabeligt forskningsprojekt skal du vide, at:

- din deltagelse i forskningsprojektet er helt frivillig og kun kan ske efter, at du har fået både skriftlig og mundtlig information om forskningsprojektet og underskrevet samtykkeerklæringen.
- du til enhver tid mundtligt, skriftligt eller ved anden klar tilkendegivelse kan trække dit samtykke til deltagelse tilbage og udtræde af forskningsprojektet. Såfremt du trækker dit samtykke tilbage påvirker dette ikke din ret til nuværende eller fremtidig behandling eller andre rettigheder, som du måtte have.
- du har ret til at tage et familiemedlem, en ven eller en bekendt med til informationssamtalen.
- du har ret til betænkningstid, før du underskriver samtykkeerklæringen.
- oplysninger om dine helbredsforhold, øvrige rent private forhold og andre fortrolige oplysninger om dig, som fremkommer i forbindelse med forskningsprojektet, er omfattet af tavshedspligt.
- behandling af oplysninger om dig, herunder oplysninger i dine blodprøver og væv, sker efter reglerne i databeskyttelsesforordningen, databeskyttelsesloven samt sundhedsloven. Den dataansvarlige i forsøget skal orientere dig nærmere om dine rettigheder efter databeskyttelsesreglerne.
- der er mulighed for at få aktindsigt i forsøgsprotokoller efter offentlighedslovens bestemmelser. Det vil sige, at du kan få adgang til at se alle papirer vedrørende forsøgets tilrettelæggelse, bortset fra de dele, som indeholder forretningshemmeligheder eller fortrolige oplysninger om andre.
- der er mulighed for at klage og få erstatning efter reglerne i lov om klage- og erstatningsadgang inden for sundhedsvæsenet. Hvis der under forsøget skulle opstå en skade kan du henvende dig til Patienterstatningen, se nærmere på www.patienterstatningen.dk

De Videnskabsetiske Komiteer for Region Hovedstaden (6 komiteer)
Tlf.: +45 38 66 63 95
E-mail: vek@regionh.dk
Hjemmeside: www.regionh.dk/vek

De Videnskabsetiske Komiteer for Region Syddanmark (2 komiteer)
Tlf.: + 45 76 63 82 21
E-mail: komite@rsyd.dk
Hjemmeside: www.regionsyddanmark.dk/komite

Den Videnskabsetiske Komité for Region Nordjylland Tlf.: +45 97 64 84 40
E-mail: vek@rn.dk
Hjemmeside: www.rn.dk/vek

Den Videnskabsetiske Komité for Region Sjælland
Tlf.: +45 93 56 60 00
E-mail: RVK-sjaelland@regionsjaelland.dk
Hjemmeside: https://www.regionsjaelland.dk/sundhed/forskning/forfagfolk/videnskabsetisk-komite/Sider/default.aspx

De Videnskabsetiske Komiteer for Region Midtjylland (2 komiteer)
Tlf.: +45 78 41 01 83 / +45 78 41 01 82 / +45 78 41 01 81
E-mail: komite@rm.dk
Hjemmeside: www.komite.rm.dk

National Videnskabsetisk Komité
Tlf.: +45 72 21 68 55
E-mail: kontakt@nvk.dk
Hjemmeside: www.nvk.dk

Dette tillæg er udarbejdet af det videnskabsetiske komitésystem og kan vedhæftes den skriftlige information om det sundhedsvidenskabelige forskningsprojekt. Spørgsmål til et konkret projekt skal rettes til projektets forsøgsansvarlige. Generelle spørgsmål til forsøgspersoners rettigheder kan rettes til den komité, som har godkendt projektet.

Revideret 11. marts 2019

Hvidovre Hospital

SORC-C Sports Orthopedic Research Center - Copenhagen

Informeret samtykke til deltagelse i videnskabeligt forskningsprojekt

Forskningsprojektets titel:

Effekten af kikkertkirurgi på biomekanik og neuromuskulær kontrol hos patienter med forreste skulderinstabilitet efter traume: Et prospektivt kohortestudie

Erklæring fra forsøgspersonen:

Jeg har fået skriftlig og mundtlig information og jeg ved nok om formål, metode, fordele og ulemper til at sige ja til at deltage.

Jeg ved, at det er frivilligt at deltage, og at jeg altid kan trække mit samtykke tilbage uden videre konsekvenser.

Jeg giver samtykke til, at deltage i forskningsprojektet. Jeg har fået en kopi af dette samtykkeark samt en kopi af den skriftlige information om projektet til eget brug.

Forsøgspersonens navn: _____

Dato: _____ Underskrift: _____

Ønsker du at blive informeret om forskningsprojektets resultat samt eventuelle konsekvenser?:

Ja _____ (sæt x) Nej _____ (sæt x)

Ønsker du at blive informeret om væsentlige oplysninger om din egen helbredstilstand?:

Ja _____ (sæt x) Nej _____ (sæt x)

Erklæring fra den, der afgiver informationen:

Jeg erklærer, at forsøgspersonen har modtaget mundtlig og skriftlig information om forsøget og har haft mulighed for at stille spørgsmål.

Efter min overbevisning er der givet tilstrækkelig information til, at der kan træffes beslutning om deltagelse i forsøget.

Navnet på den, der har afgivet informationen:_____

Dato: _____ Underskrift: _____

Baseline Demographics

Form Status	
Subject ID	_____
Gender	◯ Male ◯ Female ◯ Other
Weight, kg w. 1 decimal	_____ (Vægt i kg, med 1 decimal)
Height, cm	_____ (Højde i cm)
BMI	_____ (BMI: vægt/(højde*højde) kg og cm)
Dominant side	◯ right ◯ left ◯ both ◯ other
If other, explain	_____
Injured shoulder, side	◯ Right ◯ Left (Beskadiget skulder, side)
Primary injury mechanism	◯ Fell on outstretched arm ◯ Fell directly on shoulder ◯ Arm was pulled ◯ External force to shoulder ◯ Other (Skadesmekanisme)
If 5) other, explain:	_____ (Hvis anden skadesmekanisme, da uddyb)

No. dislocations of injured shoulder	◯ 0 ◯ 1 ◯ 2 ◯ 3 ◯ 4 ◯ 5 ◯ 6-10 ◯ 11-15 ◯ 16-20 ◯ >20 ◯ Only subluxation(s) (Antal luksationer)
Previous treatment(s) of shoulder instability	☐ Home-based exercise ☐ Supervised exercise (physiotherapy) ☐ Passive treatment (manipulation, massage, acupuncture) ☐ Chiropractor ☐ Pain relievers ☐ Other medicines ☐ Other (TIdl. forsøgt behandling(er))
If either: smertestillende medicin anden medicinsk behandling anden behandling, explain:	_____ (Uddyb medicinsk behandling/anden behandling)
Pre-injury activity level. (ADL: bathing, dressing, toileting, transferring (moving to and from a bed or a chair), eating, and continence).	◯ Limited ADL ◯ Unlimitied ADL ◯ Physical activity w. affected limb 1-3/w. ◯ Physical activity w. affected limb >3/w. (Fysisk aktivitet før skade)
Post-injury activity level. (ADL: bathing, dressing, toileting, transferring (moving to and from a bed or a chair), eating, and continence).	◯ Limited ADL ◯ Unlimitied ADL ◯ Physical activity w. affected limb 1-3/w. ◯ Physical activity w. affected limb >3/w. (Fysisk aktivitet efter skade)

KLINISK SKULDERUNDERSØGELSE - Bankart

Marker dominant side	HØ	VE
Inspektion		
Palpation		
Flexion		
Extension		
Abduktion		
IR		
ER		
Hawkins		
Empty can scaption +force **Jobe's**		
Adduction +thumbs up/down **O'Brien's**		
Sulcus test		
Load and shift		
Apprehension		
Relocation		

Denmark Danish Eq5d5l Redcap Self Complete Web

Venligst udfyld spørgeskema nedenunder.

Tak og mvh

Catarina Malmberg, læge og PhD-studerende

Du bedes klikke med musen i DEN kasse, der bedst beskriver dit helbred I DAG.

BEVÆGELIGHED

◯ Jeg har ingen problemer med at gå omkring
◯ Jeg har lidt problemer med at gå omkring
◯ Jeg har moderate problemer med at gå omkring
◯ Jeg har store problemer med at gå omkring
◯ Jeg kan ikke gå omkring

Du bedes klikke med musen i DEN kasse, der bedst beskriver dit helbred I DAG.

PERSONLIG PLEJE

◯ Jeg har ingen problemer med at vaske mig eller klæde mig på
◯ Jeg har lidt problemer med at vaske mig eller klæde mig på
◯ Jeg har moderate problemer med at vaske mig eller klæde mig på
◯ Jeg har store problemer med at vaske mig eller klæde mig på
◯ Jeg kan ikke vaske mig eller klæde mig på

Du bedes klikke med musen i DEN kasse, der bedst beskriver dit helbred I DAG.

SÆDVANLIGE AKTIVITETER (fx. arbejde, studie, husarbejde, familie- eller fritidsaktiviteter)

◯ Jeg har ingen problemer med at udføre mine sædvanlige aktiviteter
◯ Jeg har lidt problemer med at udføre mine sædvanlige aktiviteter
◯ Jeg har moderate problemer med at udføre mine sædvanlige aktiviteter
◯ Jeg har store problemer med at udføre mine sædvanlige aktiviteter
◯ Jeg kan ikke udføre mine sædvanlige aktiviteter

Du bedes klikke med musen i DEN kasse, der bedst beskriver dit helbred I DAG.

SMERTER / UBEHAG

◯ Jeg har ingen smerter eller ubehag
◯ Jeg har lidt smerter eller ubehag
◯ Jeg har moderate smerter eller ubehag
◯ Jeg har stærke smerter eller ubehag
◯ Jeg har ekstreme smerter eller ubehag

Du bedes klikke med musen i DEN kasse, der bedst beskriver dit helbred I DAG.

5) ANGST / DEPRESSION

◯ Jeg er ikke ængstelig eller deprimeret
◯ Jeg er lidt ængstelig eller deprimeret
◯ Jeg er moderat ængstelig eller deprimeret
◯ Jeg er meget ængstelig eller deprimeret
◯ Jeg er ekstremt ængstelig eller deprimeret

6) Vi vil gerne vide, hvor godt eller dårligt dit helbred er I DAG.

Denne skala er nummereret fra 0 til 100.

100 svarer til det bedste helbred, du kan forestille dig.
0 svarer til det dårligste helbred, du kan forestille dig.
Klik med musen på det sted på skalaen, der viser, hvordan dit helbred er I DAG.

0 - Det dårligste helbred, du kan forestille dig

50

100 - Det bedste helbred, du kan forestille dig

(Place a mark on the scale above)

Spørgeskema om skulderfunktion (WOSI)

Kære deltager

Du bedes venligst at udfylde dette spørgeskema. Det er desværre ikke muligt at gemme undervejs, men hele spørgeskemaet må besvares når du er startet (du kan til gengælg starte forfra, hvis du er nødt til at afbryde).

Tak for din deltagelse! Mvh projektansvarlige

Sektion A: De følgende spørgsmål drejer sig om de fysiske symptomer, du har på grund af dit skulderproblem. Ved hvert spørgsmål skal du på linjen markere omfanget af dine symptomer indenfor den seneste uge.

1) Hvor ondt gør det i din skulder, når du arbejder med armen over hovedet?
Ingen smerte — Ekstrem smerte
(Place a mark on the scale above)

2) Hvor meget murren eller ømhed har du i skulderen?
Ingen Murren/ømhed — Ekstrem murren/ømhed
(Place a mark on the scale above)

3) Hvor plaget er du af kraftnedsættelse eller manglende styrke i din skulder?
Ingen kraftnedsættelse — Ekstrem kraftnedsættelse
(Place a mark on the scale above)

4) Hvor plaget er du af udtrætning eller manglende udholdenhed i din skulder?
Ingen udtrætning — Ekstrem udtrætning
(Place a mark on the scale above)

5) Hvor generet er du af klikken, knasen eller smæld i skulderen?
Ingen klikken — Ekstrem klikken
(Place a mark on the scale above)

6) Hvor generet er du af stivhed i skulderen?
Ingen stivhed — Ekstrem stivhed
(Place a mark on the scale above)

7) Hvor meget ubehag har du i dine nakkemuskler som en følge af dit skulderproblem?
Intet ubehag — Ekstremt ubehag
(Place a mark on the scale above)

8) Hvor ustabil eller løs er din skulder?
Ingen løshed — Ekstrem løshed
(Place a mark on the scale above)

9) Hvor meget kompenserer du for din skulder med brug af andre muskler?
Slet ikke — Ekstremt
(Place a mark on the scale above)

10) Hvor meget har du mistet af din bevægelighed i skulderen?
Intet tab — Ekstremt tab
(Place a mark on the scale above)

Sektion B: Følgende afsnit handler om, hvor meget dit skulderproblem har påvirket dit arbejde, dine sports- og fritidsaktiviteter indenfor den seneste uge. Du skal igen til hvert spørgsmål markere omfanget af dine symptomer på linjen

11) Hvor meget har dit skulderproblem begrænset dig i at deltage i sport eller fritidsaktiviteter?

Ikke begrænset — Begrænset ekstremt

(Place a mark on the scale above)

12) Hvor meget har skulderen indvirket på din evne til at udføre specifikke færdigheder, som er nødvendige i din sport eller dit arbejde? (Hvis skulderen generer både ved arbejde og sport skal du angive det i forhold til der hvor den generer mest)

Ingen indvirkning — Ekstrem indvirkning

(Place a mark on the scale above)

13) Hvor stort et behov har du for at beskytte din arm under aktivitet?

Slet ikke — Ekstremt

(Place a mark on the scale above)

14) Hvor svært er det at løfte tunge ting under skulderens niveau?

Ikke svært — Ekstremt svært

(Place a mark on the scale above)

Sektion C: Følgende afsnit handler om, i hvor høj grad dit skulder problem har påvirket eller ændret din livsstil. Du skal igen til hvert spørgsmål markere omfanget af dine symptomer på linjen

15) Hvor meget frygter du at falde på din skulder?

Ingen frygt — Ekstrem frygt

(Place a mark on the scale above)

16) I hvilken grad forhindrer dit skulderproblem dig i at holde dig i form?

Slet ikke — Ekstrem grad

(Place a mark on the scale above)

17) Hvor svært har du ved løssluppen aktivitet, så som brydning og slåskamp med familie og venner?

Ingen besvær — Ekstremt besvær

(Place a mark on the scale above)

18) Hvor meget søvnbesvær har du på grund af din skulder?

Ingen besvær — Ekstremt besvær

(Place a mark on the scale above)

Sektion D: De følgende spørgsmål handler om, hvordan du har følt det den sidste uge med hensyn til dit skulderproblem. Marker omfanget på linjen

19) Hvor bevidst er du om din skulder?

Ikke bevidst — Ekstrem bevidst

(Place a mark on the scale above)

20) Hvor bekymret er du for at dit skulderproblem forværres?

Ikke bekymret — Ekstremt bekymret

(Place a mark on the scale above)

21) Hvor frustreret er du over din skulder?

Ikke frustreret — Ekstremt frustreret

(Place a mark on the scale above)

Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SPIRITreporting guidelines, and cite them as:

Chan A-W, Tetzlaff JM, Gøtzsche PC, Altman DG, Mann H, Berlin J, Dickersin K, Hróbjartsson A, Schulz KF, Parulekar WR, Krleža-Jerić K, Laupacis A, Moher D. SPIRIT 2013 Explanation and Elaboration: Guidance for protocols of clinical trials. BMJ. 2013;346:e7586

		Reporting Item	Page Number
Administrative information			
Title	#1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1 (manuscript).
Trial registration	#2a	Trial identifier and registry name. If not yet registered,	1 (suppl 1)

		name of intended registry	
Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	1 (suppl 1)
Protocol version	#3	Date and version identifier	1 (suppl 1)
Funding	#4	Sources and types of financial, material, and other support	23 (manuscript), 1-2 (suppl 1)
Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	2-4 (suppl 1)
Roles and responsibilities: sponsor contact information	#5b	Name and contact information for the trial sponsor	2 (suppl 1)
Roles and responsibilities: sponsor and funder	#5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	23 (manuscript), 1-2 (suppl 1)
Roles and responsibilities: committees	#5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and	n/a

		other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	
Introduction			
Background and rationale	#6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4-6 (manuscript)
Background and rationale: choice of comparators	#6b	Explanation for choice of comparators	7 (manuscript)
Objectives	#7	Specific objectives or hypotheses	6-7 (manuscript)
Trial design	#8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)	7 (manuscript)
Methods: Participants, interventions, and outcomes			
Study setting	#9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data	10 (manuscript), 4

		will be collected. Reference to where list of study sites can be obtained	(suppl 1)
Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	10-11 (manuscript)
Interventions: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	7-12 (manuscript)
Interventions: modifications	#11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving / worsening disease)	11, 13-15 (manuscript)
Interventions: adherance	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	n/a
Interventions: concomitant care	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	11 (manuscript)
Outcomes	#12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen	7-12 (manuscript)

		efficacy and harm outcomes is strongly recommended	
Participant timeline	#13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	12 (manuscript)
Sample size	#14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	12-13 (manuscript)
Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	10 (manuscript)
Methods: Assignment of interventions (for controlled trials)			
Allocation: sequence generation	#16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	n/a
Allocation	#16b	Mechanism of implementing the allocation sequence	n/a

concealment mechanism		(eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	n/a
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	n/a
Blinding (masking): emergency unblinding	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	n/a
Methods: Data collection, management, and analysis			
Data collection plan	#18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	13-16 (manuscript)

Data collection plan: retention	#18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	11 (manuscript)
Data management	#19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	15-16 (manuscript)
Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	13 (manuscript)
Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	n/a
Statistics: analysis population and missing data	#20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	11 (manuscript)
Methods: Monitoring			
Data monitoring: formal committee	#21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement	n/a

		of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	
Data monitoring: interim analysis	#21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	n/a
Harms	#22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	14-15 (manuscript), 2 (suppl 1)
Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	11 (manuscript)
Ethics and dissemination			
Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	16,18 (manuscript), 1 (suppl 1)
Protocol amendments	#25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg,	2 (suppl 1)

		investigators, REC / IRBs, trial participants, trial registries, journals, regulators)	
Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	10 (manuscript), 2-3 (suppl 1)
Consent or assent: ancillary studies	#26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	n/a
Confidentiality	#27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	16 (manuscript)
Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	23 (manuscript), 1-2 (suppl 1)
Data access	#29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	11, 16 (manuscript)
Ancillary and post trial care	#30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	2 (suppl 1)
Dissemination policy: trial results	#31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals,	16-17 (manuscript)

		the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	
Dissemination policy: authorship	#31b	Authorship eligibility guidelines and any intended use of professional writers	17 (manuscript)
Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	18 (manuscript)
Appendices			
Informed consent materials	#32	Model consent form and other related documentation given to participants and authorised surrogates	suppl 2
Biological specimens	#33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	n/a

Notes:

- 1: 1 (manuscript)
- 2a: 1 (suppl 1)
- 2b: 1 (suppl 1)
- 3: 1 (suppl 1)
- 4: 23 (manuscript), 1-2 (suppl 1)

- 5a: 2-4 (suppl 1)
- 5b: 2 (suppl 1)
- 5c: 23 (manuscript), 1-2 (suppl 1)
- 6a: 4-6 (manuscript)
- 6b: 7 (manuscript)
- 7: 6-7 (manuscript)
- 8: 7 (manuscript)
- 9: 10 (manuscript), 4 (suppl 1)
- 10: 10-11 (manuscript)
- 11a: 7-12 (manuscript)
- 11b: 11, 13-15 (manuscript)
- 11d: 11 (manuscript)
- 12: 7-12 (manuscript)
- 13: 12 (manuscript)
- 14: 12-13 (manuscript)
- 15: 10 (manuscript)
- 18a: 13-16 (manuscript)
- 18b: 11 (manuscript)
- 19: 15-16 (manuscript)

- 20a: 13 (manuscript)
- 20c: 11 (manuscript)
- 22: 14-15 (manuscript), 2 (suppl 1)
- 23: 11 (manuscript)
- 24: 16,18 (manuscript), 1 (suppl 1)
- 25: 2 (suppl 1)
- 26a: 10 (manuscript), 2-3 (suppl 1)
- 27: 16 (manuscript)
- 28: 23 (manuscript), 1-2 (suppl 1)
- 29: 11, 16 (manuscript)
- 30: 2 (suppl 1)
- 31a: 16-17 (manuscript)
- 31b: 17 (manuscript)
- 31c: 18 (manuscript) The SPIRIT Explanation and Elaboration paper is distributed under the terms of the Creative Commons Attribution License CC-BY-NC. This checklist was completed on 20. July 2023 using https://www.goodreports.org/, a tool made by the EQUATOR Network in collaboration with Penelope.ai

BMJ Open

Biomechanical and Neuromuscular Characteristics in Patients with Traumatic Anterior Shoulder Instability Undergoing Arthroscopic Bankart Repair: A Clinical Prospective Cohort Study Protocol

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Biomechanical and Neuromuscular Characteristics in Patients with Traumatic Anterior Shoulder Instability Undergoing Arthroscopic Bankart Repair: A Clinical Prospective Cohort Study Protocol

Catarina Malmberg[1], MD, Kristine Rask Andreasen[1], MD, Jesper Bencke[2], MSc PhD, Birgitte Hougs Kjær[3], MSc PhD, Per Hölmich[1], MD DMSc, Kristoffer Weisskirchner Barfod[1], MD PhD

[1]Sports Orthopedic Research Center – Copenhagen (SORC-C), Department of Orthopedic Surgery, Copenhagen University Hospital Amager & Hvidovre, Denmark

[2]Human Movement Analysis Laboratory, Department of Orthopedic Surgery, Copenhagen University Hospital Amager & Hvidovre, Denmark

[3]Department of Physical and Occupational Therapy, Institute of Sports Medicine Copenhagen (ISMC), Copenhagen University Hospital Bispebjerg & Frederiksberg

Corresponding author: Catarina Malmberg, Kettegård Allé 30, 2650 Hvidovre, catarina.anna.evelina.malmberg.02@regionh.dk

Competing interests: None

Word count abstract: 250

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Abstract

Introduction: Traumatic shoulder dislocation is a common shoulder injury, especially among the young and active population. More than 95% of dislocations are anterior, in which the humeral head is forced beyond the anterior glenoid rim. The injury leads to increased joint laxity and recurrence rates are high. There is evidence that the shoulder biomechanics and neuromuscular control change following dislocation, but the existing literature is scarce, and it remains to be established if and how these parameters are useful in the clinical setting. The aim of this exploratory prospective cohort study is to investigate biomechanical and neuromuscular outcomes in patients with traumatic anterior shoulder instability undergoing arthroscopic Bankart repair, to test the hypothesis that examinations of these characteristics are applicable in the clinical setting to assess shoulder instability.

Methods and analysis: This is a prospective multicenter cohort study with repeated measures of 55 patients undergoing arthroscopic Bankart repair. With carefully selected and completely non-invasive examination methods, we will investigate biomechanical and neuromuscular outcomes in the affected shoulders once pre-surgically and twice post-surgically at six and twelve months. Patients' contralateral shoulders are investigated once to establish a pre-injury level.

Ethics and dissemination: The study was approved by the Capital Region Ethics Committee (journal-no: H-21027799) and the Capital Region Knowledge Center for Data Reviews (journal-no: P-2021-842) before patient recruitment began. The study results will be published in international peer-reviewed journals, online and in other relevant media, presented at medical conventions and disseminated to clinicians and patients as appropriate.

Trial registration number: NCT05250388

Keywords: traumatic shoulder instability, anterior shoulder instability, biomechanics, kinematics, proprioception, neuromuscular control, arthroscopic Bankart repair

Strengths and limitations

- This study has a broad investigation approach including biomechanical, neuromuscular, clinical, and patient-centered examinations and outcomes.
- All examination methods are non-invasive.
- The study is essentially exploratory, as the literature on biomechanical and neuromuscular changes in patients with traumatic shoulder instability is scarce and the authors cannot refer to any established standard deviations or minimally important difference.

1. Introduction

1.1 Background

Traumatic anterior shoulder dislocation is a common shoulder injury, with a reported point prevalence of 1.7% in a general population aged 18-70 years and incidence rates of 11.2-56.3 per 100'000 person years [1–3]. First-time dislocation incidence rates are highest in the third decade of life for men, while it is most common in women above 50 years of age [3] The injury causes an increased glenohumeral joint laxity and recurrence rates exceed 70% in some reports [4]. Besides disruption and injury to the capsule, labrum and ligaments, bone loss is often seen after the injury [5]. The bone loss can be isolated to the anteroinferior part of the glenoid, referred to either as the osseous Bankart lesion or a glenoid rim erosion, or to the posterolateral aspect of the humeral head, the Hill-Sachs lesion, but can also be seen in combination as bipolar lesions, creating an additive negative effect on the joint laxity [6]. Thus, the extent of the structural injury plays a role in development of glenohumeral instability.

Chronic shoulder instability may appear even after the first dislocation and often aggravates with recurrence, which can lead to altered shoulder biomechanics and motion control [5,7–9]. The joint stability is clinically assessed using manual tests including the sulcus sign, load and shift, apprehension test, and relocation test; some of which have high specificity, but are highly patient- and examinator-dependent and none of them provide quantitative data [10]. The laxity can be directly inspected and quantified during arthroscopy, which is an invasive procedure, or through medical imaging methods, which might be irradiating and, furthermore, only examines the joint in a static position [6,7,11]. Alternatively, non-invasive and non-irradiating dynamic analysis of the shoulder biomechanics can be performed using motion capture and ultrasound [9,12–14].

Neuromuscular joint control is most often assessed as joint position sense (JPS) or threshold to detection of motion (TTDM). In 2015, a systematic review concluded that patients suffering from

traumatic anterior shoulder instability had decreased JPS and increased TTDM, thus impaired neuromuscular joint control compared to those with stable shoulders [15]. Both modalities have been criticized for the lack of ecological validity, as they are static and without application of an external force and thereby cannot be generalized to a real-life setting [16]. The shoulder-sway test, developed in 2012, investigates neuromuscular joint control in a loaded static position [17]. Reduced joint control, measured as increased sway-length, has been reported in shoulders with traumatic anterior instability compared to stable, which supports the theory of impaired neuromuscular control in these patients [18].

In treatment of traumatic anterior shoulder instability, the focus is on restoring stability. Surgically, the structural stability is re-established, and the extent of injury determines the type of surgery [6]. Surgery reduces risk of recurrent events but does not always relieve patients of symptoms. Some patients still experience a feeling of instability – apprehension – after surgery and suffer from residual pain and reduced activity level and quality of life [9,19,20]. As the pathologic mechanism of apprehension is complex and probably includes both mechanical and neurological impairments, the effect of surgery might be questioned [21]. More specifically, the effects on biomechanical and neuromuscular characteristics remain unclear [9,22].

1.2 Research questions

A (biomechanics): Does arthroscopic Bankart repair have a stabilizing effect on the biomechanics in patients with traumatic anterior shoulder instability?

B (neuromuscular control): Does arthroscopic Bankart repair improve neuromuscular control in patients with traumatic anterior shoulder instability?

1.3 Aim

To investigate the effect of arthroscopic Bankart repair on shoulder biomechanics and neuromuscular control and increase understanding of traumatic anterior shoulder instability.

1.4 Objectives and hypotheses

1.4.1 Objectives research question A

In patients with traumatic anterior shoulder instability undergoing arthroscopic Bankart repair, to investigate the anterior-posterior glenohumeral translation and the scapular rotations before and six and twelve months after surgery and whether the ranges are restored to the same as the non-injured contralateral shoulder.

1.4.2 Hypotheses research question A

1) Arthroscopic Bankart repair results in a ≥2.5 mm decrease in anterior-posterior glenohumeral translation, remaining both six and twelve months after surgery.
2) Arthroscopic Bankart repair reduces anterior-posterior glenohumeral translation to the same range as measured in the non-injured shoulder (±2.5 mm).
3) Arthroscopic Bankart repair reduces superior-inferior glenohumeral translation significantly, as measured six and twelve months after surgery.
4) Scapular rotations and tilt remain unchanged after arthroscopic Bankart repair.

1.4.3 Objectives research question B

In patients with traumatic anterior shoulder instability undergoing arthroscopic Bankart repair, to investigate the neuromuscular control before and six and twelve months after surgery and whether the neuromuscular control is restored to the same level as the non-injured contralateral shoulder.

1.4.4 Hypotheses research question B

1) Arthroscopic Bankart repair improves neuromuscular control, remaining both six and twelve months after surgery.
2) Arthroscopic Bankart repair improves neuromuscular control to the same range as the non-injured shoulder.

1.4.5 Other objectives

In patients with traumatic anterior shoulder instability undergoing arthroscopic Bankart repair:

1) To determine the recurrence rates (radiographically confirmed or manually reduced dislocation) in the first twelve months after surgery.
2) To investigate the shoulder range of motion (ROM) before and six and twelve months after surgery.
3) To assess the joint instability by manual testing before and six and twelve months after surgery.
4) To quantify potential bone loss before surgery.
5) To investigate patient-reported outcome measures (PROM) before and six and twelve months after surgery.
6) To investigate if there are correlations between a) the shoulder biomechanics and b) the neuromuscular control, and PROM, ROM, and bone loss, respectively.

2. Methods and analysis

2.1 Study design

This is a prospective observational cohort study with repeated measures of the patient's affected shoulder pre- and post-intervention. The contralateral shoulder is investigated prior to surgery to establish a pre-injury level representing the non-injured shoulder.

2.2 Outcomes

The outcomes were designed to investigate the effects of arthroscopic Bankart repair on biomechanical and neuromuscular characteristics and, further, to investigate correlations with clinical and patient-centered outcomes (Fig. 1). The change in anterior-posterior glenohumeral translation was chosen as the primary outcome to allow for a statistic sample size calculation (see section 3.1).

2.2.1 Biomechanical outcomes

The primary outcome is the change in anterior-posterior glenohumeral translation six months after surgery as assessed from real-time ultrasound imaging. The examination strictly follows a previously tested protocol in which the joint is tested in two positions: 1) neutral along the body (posterior view) and 2) in abduction and external rotation (anterior view); under three conditions: 1) at rest, 2) during isometric force and 3) with external force applied to the relaxed joint [14,23]. The translation, in millimeters, is calculated by subtracting the distance between the border of the glenoid (posterior view) or the coracoid process (anterior view), respectively, and the border of the humeral head at rest (condition 1) from the conditions with force applied (conditions 2 and 3). The intra- and interrater reliability of the ultrasound assessment has previously been shown good to excellent in the abducted position from an anterior view (ICC 0.95-0.96 and 0.72-0.8, respectively) and posterior view (ICC 0.98 and 0.77-0.85, respectively) [24]. The intra- and interrater reliability with the shoulder in neutral position has also previously been shown to be moderate to excellent (ICC 0.85-0.98 and 0.5-0.75, respectively) [14]. All ultrasound examinations are carried out by the same investigator. The change in the anterior-posterior glenohumeral translation is also evaluated twelve months after surgery (same methods as above).

The scapular upward downward rotations, protraction-retraction and anterior-posterior tilt are analyzed using motion capture technique with a skin-marker based protocol and eight cameras

simultaneously collecting data during ROM activities and used to evaluate the effect of Bankart repair six and twelve months following surgery. The motion capture protocol was developed in the Human Movement Analysis Laboratory at Copenhagen University Hospital Hvidovre and has been previously found to have a mean error of <7° in all scapular rotations and at least moderate interrater reliability (ICC(2,1) >0,5) for the tested motion tasks in subjects without shoulder complaints (article in preparation).

2.2.2 Neuromuscular outcomes

The change in neuromuscular control is assessed using the newly developed CANCUS test protocol at six and twelve months after surgery. The test series includes assessment of the shoulder joint reaction time, sway, and joint position sense using motion capture, force platforms and surface electromyography (EMG). The shoulder reaction time test determines the neuromuscular control in a loaded and fast dynamic setting. It was developed at the Human Movement Analysis Laboratory at Copenhagen University Hospital Hvidovre and is currently being tested in subjects without shoulder complaints and in subjects with unilateral recurrent anterior shoulder instability. The sway test determines the neuromuscular control in a weightbearing and static position, using force platforms to determine the center of pressure in the frontal and sagittal planes. The joint position sense is a slow dynamic, non-weightbearing evaluation of how precisely the patient can reproduce a given position of the joint. It is tested in an external rotational motion with the arm in 90° abduction.

2.2.3 Clinical and patient-reported outcomes

Demographic parameters including age, gender, height, weight, limb dominance, pre-injury and current physical activity level, the initial mechanism of injury, number of dislocations and previous non-surgical treatment will be collected (Supplement 1).

Any radiographically confirmed or manually reduced dislocations in the first twelve months are registered during follow-up. Further, the active shoulder ROM (flexion, extension, abduction, internal and external rotation) is evaluated using a handheld goniometer before and six and twelve months after surgery. The clinical instability tests sulcus sign, load and shift, apprehension test and relocation test are performed and evaluated with dichotomous outcomes at all three visits (positive/negative). The sulcus sign is considered positive if a sulcus (>1 cm) appears in the subacromial region when manual inferior traction to a neutral shoulder is applied. The load and shift test is considered positive when there is increased anterior-posterior laxity with a sensation of subluxation of the humeral head anteriorly AND there is a clear asymmetry compared to the contralateral as the upper arm is anteriorly translated. The apprehension test and relocation test is performed with the patient lying supine and the shoulder positioned in 90 degrees abduction and externally rotated, and considered positive if an anteriorly directed pressure to the upper arm leads to a sensation of discomfort or instability which is relieved when the arm is pushed posteriorly. The manual tests are performed by the same investigator.

All patients undergo a pre-surgical computed tomography (CT) scan to measure potential bone loss. Glenoid bone loss is measured using the PICO-method, which is based on calculating the size of the defect as the percentage of a best-fit circle from the contralateral glenoid [25]. The size (the largest height, width and depth in millimeters) of Hill-Sachs lesions on the humeral head is also measured and registered, but not the specific location [26].

The perceived change in shoulder function is evaluated using the Western Ontario Shoulder Instability (WOSI) index [27]. It consists of 21 items, each scored on a 100 mm Visual Analogue Scale (VAS). Each item falls into one of the domains of physical function, sports/recreation/work, lifestyle, and emotional well-being. Each question is scored between 0-100 points and the sum of all the questions adds up to a final score, ranging from 0 (best) to 2100 (worst).

The perceived change in quality of life is assessed using the EQ-5D questionnaire, which has five components that assess the severity of problems in three functional dimensions (mobility, self-care and usual activities) and two somatic symptom dimensions (pain/discomfort and anxiety/depression) [28]. The response scales consist of a heading and five short statements, each describing a different level of severity.

2.3 Study setting

The patients are screened for eligibility and treated at five centers specialized in treatment of shoulder instability. The centers include the Department of Orthopedic Surgery, Copenhagen University Hospital Amager & Hvidovre, the Department of Orthopedic Surgery, Copenhagen University Hospital Herlev & Gentofte, the Department of Orthopedic Surgery, Zealand University Hospital Køge, Adeas Hospital, Gildhøj Private Hospital. The final enrolment in the study and all study-related investigations are performed at Copenhagen University Hospital Hvidovre. All data collection (collection of informed consent, clinical examination, biomechanical and neuromuscular examinations, CT scan, and collection of PROMs are performed at Copenhagen University Hospital Hvidovre. See Supplement 2 for further general information.

2.4 Study population and eligibility criteria

Fifty-five patients with traumatic anterior shoulder instability undergoing arthroscopic Bankart repair will be recruited from the centers listed above.

Eligibility criteria are age 18-40 years, unilateral traumatic anterior shoulder instability following radiographically confirmed or manually reduced dislocation (first-time or recurrent), scheduled for arthroscopic Bankart repair, no pathology in the contralateral shoulder, willingness to adhere to the study protocol, and ability to give informed consent.

Exclusion criteria are other present or previous traumatic pathology or associated injuries in the affected shoulder (including rotator cuff/biceps tendon/SLAP lesion, fracture of proximal humerus/scapula/clavicula, dislocation of sternoclavicular or acromioclavicular joint confirmed by medical imaging), atraumatic pathologies (frozen shoulder, symptomatic osteoarthritis of the shoulder or acromioclavicular joints, acute calcific tendinitis, degenerative rotator cuff tear or neurological disorders), pregnancy, and severe medical illness (American Society of Anesthesiology physical status (ASA) score ≥3).

All patients must provide written, informed consent prior to any study procedure (Supplement 3). The consent gives the primary investigator and relevant authorities access to the patient's records, including electronic medical records and audit, hereunder internal audit, and quality assessment, which are mandatory. The right to access the patient's records is in accordance with the Regional Committee on Health Research Ethics law (§ 3, section 3) and promulgation § 4, section 1, and § 10, sections 3 and 5).

Study inclusion does not influence the treatment course, neither does a decision to withdraw from the study at any point. Some patients will have a pre-surgical magnetic resonance imaging (MRI) scan as part of the local practice, which is not required for study inclusion and the results from such a scan will not be used in the study. A patient may be excluded from the study based on the investigator's decision, e.g., in the event of post-surgical complications (infection, nerve injury, recurrent event, or revision surgery), as these might influence the post-surgical treatment course and outcomes, or inability to adhere to the study protocol. Participants may also be excluded if the study sponsor or government or regulatory authorities terminate the study prior to its planned end date. Patients lost to follow-up are not excluded from analysis but will be specifically accounted for in the report.

2.5 Study plan

There are three visits in total: 1) baseline pre-surgical visit; 2) six months post-surgical ±2 weeks; 3) 12 months post-surgical ±2 weeks. All patients undergo arthroscopic Bankart repair at the center from which they are recruited by an orthopedic surgeon specialized in arthroscopic shoulder surgery. The procedure is done through a posterior viewing portal and a low antero-lateral portal for instrumentation. The labrum is released from the glenoid and the bone is scarified. No standard capsular shift is performed unless deemed necessary by the operating surgeon. Three to four anchors of the preference of the operating surgeon are placed at the glenoid rim and the labrum is sutured with simple circular sutures. Surgical details are registered using a standardized form including the position and extent of the lesion, number and position of anchors used, and whether a capsular shift was performed is filled out by the surgeon. All patients follow a standardized post-surgical rehabilitation protocol for a minimum of twelve weeks. All study-related activities are carried out according to the study plan presented in Table 1.

Study plan	**Recruitment**	**Inclusion**	**Pre-surgical visit**	**6 months after surgery**	**12 months after surgery**
Setting	Recruiting center	Copenhagen University Hospital Hvidovre			
Eligibility screen	X				
Oral and written study information and enrolment		X			
Written informed consent		X			
Biomechanical outcomes			X	X	X
Neuromuscular outcomes			X	X	X
Clinical and patient-reported outcomes *Computed tomography scan only at pre-surgical visit			X*	X	X

Table 1. Study plan

2.6 Patient and public involvement

Patients with traumatic anterior shoulder instability have not been involved in formulating the research questions or choosing the outcome measures. However, they were involved in design of

the examination methods and protocols used in the study. We carefully assess the burden of all examinations on patients' physical and mental health throughout the study period. The primary findings will be communicated to the participants.

2.7 Statistics

2.7.1 Sample size calculation

Fifty-five patients will be included in the study, who will each participate with their contralateral shoulder as non-injured control. The sample size calculation is based on the primary outcome, set to detect a mean difference in anterior-posterior glenohumeral translation of ≥2.5 mm, with a standard deviation (SD) of 2.3 mm, power of 0.80 (two-sided) and type I error rate of 0.05 for a mixed effects model [9,29]. With six variables in the analysis (sex, height, BMI, dominant/non-dominant side affected, bone loss, clinical score) and an estimated 15% dropout rate, the calculation resulted in 55 patients.

2.7.2 Statistical analysis

Descriptive statistics will be presented as mean (SD), median (range), and percentages with 95% confidence intervals as considered appropriate. Normality of data distribution will be tested, and relevant statistics applied. Results will be evaluated on group level (injured/non-injured shoulder). If data are normally distributed the primary analysis on baseline data will be a linear regression model stratified for sex and height. Correspondingly, the primary analysis including data after intervention will be a mixed effect model with the variables: sex, height, BMI, dominant/non-dominant side affected, bone loss, and clinical score. If necessary, other relevant statistic models will be chosen according to the characteristics and distribution of the variables. Patients lost to follow up are not excluded from the analysis. Prior to any analysis, missing data pattern will be investigated and reasons for missing data obtained and summarized where possible. The primary

analysis will be conducted as an intention-to-treat analysis, which includes all participants with missing outcome data, unless there is clear evidence that its underlying assumption is inappropriate. The main comparisons planned for the biomechanical, neuromuscular, clinical, and patient-centered outcomes are shown in Table 2.

Outcome	**Comparisons**
Biomechanical	1. Change in anterior-posterior glenohumeral translation from baseline to six months (**primary outcome**), and twelve months. 2. Change in superior-inferior glenohumeral translation from baseline to six and twelve months. 3. Change in scapular upward downward rotations, protraction-retraction and anterior-posterior tilt from baseline to six and twelve months. 4. Side to side difference between the injured and the non-injured shoulder in anterior-posterior glenohumeral translation at baseline, and six and twelve months. 5. Side to side difference between the injured and the non-injured shoulder in scapular upward downward rotations, protraction-retraction and anterior-posterior tilt at baseline, and six and twelve months.
Neuromuscular *(the analyses are considered exploratory with no hierarchy between the outcomes)*	1. Change in reaction time from baseline to six and twelve months. 2. Change in sway length from baseline to six and twelve months. 3. Change in joint position sense from baseline to six and twelve months. 4. Side to side difference between the injured and the non-injured shoulder in reaction time, sway, and joint position sense at baseline, and six and twelve months.
Clinical and patient reported outcomes *(the analyses are considered exploratory with no hierarchy between the outcomes)*	1. Correlations with biomechanical and neuromuscular outcomes 2. Change in WOSI index from baseline to six and twelve months. 3. Change in EQ-5D questionnaire from baseline to six and twelve months. 4. Change in range of motion from baseline to six and twelve months. 5. Correlations between bone-loss and WOSI index, EQ-5D questionnaire, re-dislocation, and range of motion.

Table 2. Main comparisons for the biomechanical, neuromuscular, clinical, and patient-centered outcomes. WOSI: Western Ontario Shoulder Instability index.

3. Ethics and dissemination

3.1 Quality

The validity and inter-rater reliability of the motion capture model for analysis of scapular rotations were established by the research group prior to study start. The reliability of the ultrasound technique has a reported test-retest measurement error of 0.2-0.6 mm [30]. For the CANCUS test series, the construct validity and intra-rater reliability of each test is established concurrently during the study. The demographics and clinical examination sheet, as well as PROM questionnaires can be found in Supplement 1 (clinical examination sheet and PROM questionnaires in Danish).

3.2 Risks, side effects and adverse events

The clinical examination and manual tests are clinical practice and not considered to be a risk for the participants. The motion capture model and ultrasound technique are non-invasive and not considered to induce any discomfort during the tests. When removing the skin-mounted markers following motion capture and EMG investigations the patient might experience slight discomfort from the pull on the skin and possible loss of hair, like removal of a band-aid. Some people might have a temporary redness on the skin, which might be eased with normal body lotion. The arm movements included in the experiment does not exceed normal functional use of the upper limb but might induce apprehension of short duration. As for the assessment of neuromuscular control a transient discomfort during the tests is expected with increasing stress on the glenohumeral joint. Before each test, the ROM of the patient is tested and is not exceeded. If the patient cannot achieve the ROM required for the test to be carried out, the patient is excluded from the specific test.

The radiation acquired during a diagnostic shoulder CT scan with the scanners that are currently operating at the Department of Radiology at Copenhagen University Hospital Hvidovre, with an average dose-length product (DLP) of 225 mGy*cm, the effective dose of 2.9 mSv (data acquired from 41 shoulder scans performed January–November 2020) is comparable with approximately one

year of background radiation in Denmark (3 mSv). The increased all-time risk of developing cancer is estimated to 0.038% and 0.0618% for 20-year old male and female subjects at one examination, with radiation levels obtained by the planned examination [31]. The variation in risk between the sexes is mainly caused by radiation sensitivity of breast tissue in females.

No severe safety issues are expected. However, there is always a risk of unknown side effects. In this context, adverse events are defined as any unintended, unfavorable finding, symptom or disease that occurs, whether it is related to the study or not. Adverse events are recorded. A critical adverse event is defined as an event or reaction, which causes death, life-threatening situations, hospitalization, or permanent or severe disability. Critical adverse events must be assessed by an investigator to consider whether there is a reasonable possibility that it is caused by any procedure related to the study. The following factors are included in the assessment: consistency in time, consistency with the known effects of participation, and alternative causes. If a critical adverse event is considered to have a causal relationship with the participation, the primary investigator, the clinically responsible and the other investigators will evaluate whether the study should be terminated.

3.3 Education and training

The data collection is conducted by the primary investigator, or experienced staff appointed by the primary investigator. Before commencing data collection, all involved staff is educated and trained in the examination methods and questionnaires to be as calibrated as possible against each other. There is a Standard Operating Procedures (SOP) file at all recruiting centers. In case a patient, from questionnaires or when examined, shows signs or symptoms of affected mental or physical health the primary investigator is to be informed immediately, and appropriate measures carefully

considered (termination of participation, treatment continuation, referral to general practitioner/therapist/psychologist/psychiatrist).

3.4 Ethical considerations

All recruiting centers are specialized in treatment of patients with a wide variety of shoulder pathologies, including traumatic instability. The study methods have been chosen specifically to answer the research questions and for the objectives stated above. From the study results, we expect to contribute to the understanding of the pathophysiology of traumatic anterior shoulder instability and increase awareness of biomechanical and neuromuscular characteristics. We believe that the potential benefits of using the chosen methods and enabling more efficient diagnostics, monitoring, and treatment exceed the potential inconveniences of the study participants. The study is carried out in accordance with the principles of the Helsinki Declaration and guidelines for Good Clinical Practice (GCP).

3.5 Approvals

The study was approved by the Capital Region Ethics Committee (journal-no: H-21027799) and the Capital Region Knowledge Center for Data Reviews (journal-no: P-2021-842) before patient recruitment began. The primary investigator is responsible of informing the Regional Committee on Health Research Ethics of any critical adverse event and/or major changes of the protocol and files all correspondences.

3.6 Data Management and Confidentiality

The study follows rules on data protection according to the Danish Data Protection Act throughout the complete study period. The primary investigator, supervisors, and other assigned research staff have access to the dataset. The patients are identified by an assigned number. At the completion of the study all identifiable data will be destroyed. The patients receive verbal and written information

that data is stored and analyzed digitally, that the patient's anonymity is preserved, and that the data protection legislation is adhered to.

Data (demographics, clinical examinations, both PROM questionnaires and ultrasound measurements) are managed using the software Research Electronic Data Capture (REDCap), a web application for database management originally created at Vanderbilt University.

3.7 Dissemination

The results will be presented in three articles with the preliminary titles:

1. *The effect of arthroscopic Bankart repair on shoulder biomechanics in patients with traumatic anterior instability: A prospective cohort study*
2. *The effect of arthroscopic Bankart repair on neuromuscular control in patients with traumatic anterior shoulder instability: A prospective cohort study*
3. *Clinical outcomes following arthroscopic Bankart repair in patients with traumatic anterior shoulder instability: A prospective cohort study*

The study results will be published in international peer-reviewed journals, online and in other relevant media, presented at medical conventions and disseminated to clinicians and patients as appropriate. Authorship is given based on the Vancouver criteria.

4. Trial status

Patient recruitment began 1 April 2022 and is expected to last for 36 months.

5. Discussion

The shoulder joint is the most mobile of all human joints and consequently the most unstable. The shoulder is in fact the most commonly dislocated joint in the body. The resulting shoulder instability leads to pain, weakness, and loss of shoulder function, and can have life-lasting consequences. Understanding of the complete damage caused by shoulder dislocation is lacking and

management of the condition is incomprehensive. There is evidence that biomechanics and neuromuscular control change following shoulder dislocation, but it remains to be established if measurements hereof are applicable in the clinical setting [8,9].

This study is, to our knowledge, the first with a multi-perspective approach focusing on biomechanical and neuromuscular functions to assess the effect of arthroscopic Bankart repair in a group of patients with traumatic shoulder instability. The study methods have been chosen specifically to reach the objectives stated above and have been approved by the regional Ethics Committee. As the literature on biomechanical and neuromuscular changes in patients with traumatic shoulder instability is scarce, the authors cannot refer to any established standard deviations or minimally important difference. Hence, the study is essentially exploratory. Ultimately, the aim is to create grounds for evidence-based decision-making and development of clinical guidelines. The authors believe the study results can contribute to changed management of shoulder instability and optimized health system spending.

6. Data availability statement

No data are currently available for sharing.

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Footnotes:

Contributors: CM and KWB initiated the study. CM, KRA, BHK and JB planned the study and developed the protocol. KWB and PH provided critical feedback about the protocol. Data acquisition is performed by CM and KRA, who will also analyze the data. All authors have read and contributed to the manuscript above, given approval, and agreed to be accountable for all aspects of the work.

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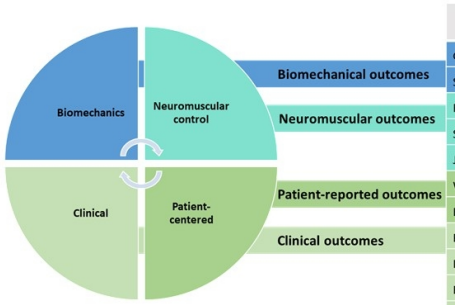
Competing interests: None declared.

Provenance and peer review: Not commissioned; externally peer reviewed.

Figure legends:

Figure 1. The investigation approach with biomechanical, neuromuscular, patient-centered, and clinical outcomes.



	Pre-operative	6 months after surgery	12 months after surgery
Glenohumeral translations	X	X	X
Scapular rotations	X	X	X
Reaction time	X	X	X
Shoulder sway	X	X	X
Joint position sense	X	X	X
Western Ontario Shoulder Instability Index	X	X	X
EQ-5D questionnaire	X	X	X
Recurrence	X	X	X
Instability tests	X	X	X
Range of motion	X	X	X
3D computed tomography (bone loss)	X		
Ultrasound (soft tissue damage)	X		

205x83mm (150 x 150 DPI)

Baseline Demographics

Form Status	
Subject ID	_____
Gender	◯ Male ◯ Female ◯ Other
Weight, kg w. 1 decimal	_____ (Vægt i kg, med 1 decimal)
Height, cm	_____ (Højde i cm)
BMI	_____ (BMI: vægt/(højde*højde) kg og cm)
Dominant side	◯ right ◯ left ◯ both ◯ other
If other, explain	_____
Injured shoulder, side	◯ Right ◯ Left (Beskadiget skulder, side)
Primary injury mechanism	◯ Fell on outstretched arm ◯ Fell directly on shoulder ◯ Arm was pulled ◯ External force to shoulder ◯ Other (Skadesmekanisme)
If 5) other, explain:	_____ (Hvis anden skadesmekanisme, da uddyb)

No. dislocations of injured shoulder	◯ 0 ◯ 1 ◯ 2 ◯ 3 ◯ 4 ◯ 5 ◯ 6-10 ◯ 11-15 ◯ 16-20 ◯ >20 ◯ Only subluxation(s) (Antal luksationer)
Previous treatment(s) of shoulder instability	☐ Home-based exercise ☐ Supervised exercise (physiotherapy) ☐ Passive treatment (manipulation, massage, acupuncture) ☐ Chiropractor ☐ Pain relievers ☐ Other medicines ☐ Other (TIdl. forsøgt behandling(er))
If either: smertestillende medicin anden medicinsk behandling anden behandling, explain:	_____ (Uddyb medicinsk behandling/anden behandling)
Pre-injury activity level. (ADL: bathing, dressing, toileting, transferring (moving to and from a bed or a chair), eating, and continence).	◯ Limited ADL ◯ Unlimitied ADL ◯ Physical activity w. affected limb 1-3/w. ◯ Physical activity w. affected limb >3/w. (Fysisk aktivitet før skade)
Post-injury activity level. (ADL: bathing, dressing, toileting, transferring (moving to and from a bed or a chair), eating, and continence).	◯ Limited ADL ◯ Unlimitied ADL ◯ Physical activity w. affected limb 1-3/w. ◯ Physical activity w. affected limb >3/w. (Fysisk aktivitet efter skade)

KLINISK SKULDERUNDERSØGELSE - Bankart

Marker dominant side	HØ	VE
Inspektion		
Palpation		
Flexion		
Extension		
Abduktion		
IR		
ER		
Hawkins		
Empty can scaption +force **Jobe's**		
Adduction +thumbs up/down **O'Brien's**		
Sulcus test		
Load and shift		
Apprehension		
Relocation		

Denmark Danish Eq5d5l Redcap Self Complete Web

Venligst udfyld spørgeskema nedenunder.

Tak og mvh

Catarina Malmberg, læge og PhD-studerende

Du bedes klikke med musen i DEN kasse, der bedst beskriver dit helbred I DAG.

BEVÆGELIGHED

◯ Jeg har ingen problemer med at gå omkring
◯ Jeg har lidt problemer med at gå omkring
◯ Jeg har moderate problemer med at gå omkring
◯ Jeg har store problemer med at gå omkring
◯ Jeg kan ikke gå omkring

Du bedes klikke med musen i DEN kasse, der bedst beskriver dit helbred I DAG.

PERSONLIG PLEJE

◯ Jeg har ingen problemer med at vaske mig eller klæde mig på
◯ Jeg har lidt problemer med at vaske mig eller klæde mig på
◯ Jeg har moderate problemer med at vaske mig eller klæde mig på
◯ Jeg har store problemer med at vaske mig eller klæde mig på
◯ Jeg kan ikke vaske mig eller klæde mig på

Du bedes klikke med musen i DEN kasse, der bedst beskriver dit helbred I DAG.

SÆDVANLIGE AKTIVITETER (fx. arbejde, studie, husarbejde, familie- eller fritidsaktiviteter)

◯ Jeg har ingen problemer med at udføre mine sædvanlige aktiviteter
◯ Jeg har lidt problemer med at udføre mine sædvanlige aktiviteter
◯ Jeg har moderate problemer med at udføre mine sædvanlige aktiviteter
◯ Jeg har store problemer med at udføre mine sædvanlige aktiviteter
◯ Jeg kan ikke udføre mine sædvanlige aktiviteter

Du bedes klikke med musen i DEN kasse, der bedst beskriver dit helbred I DAG.

SMERTER / UBEHAG

◯ Jeg har ingen smerter eller ubehag
◯ Jeg har lidt smerter eller ubehag
◯ Jeg har moderate smerter eller ubehag
◯ Jeg har stærke smerter eller ubehag
◯ Jeg har ekstreme smerter eller ubehag

Du bedes klikke med musen i DEN kasse, der bedst beskriver dit helbred I DAG.

5) ANGST / DEPRESSION

◯ Jeg er ikke ængstelig eller deprimeret
◯ Jeg er lidt ængstelig eller deprimeret
◯ Jeg er moderat ængstelig eller deprimeret
◯ Jeg er meget ængstelig eller deprimeret
◯ Jeg er ekstremt ængstelig eller deprimeret

6) Vi vil gerne vide, hvor godt eller dårligt dit helbred er I DAG.

Denne skala er nummereret fra 0 til 100.

100 svarer til det bedste helbred, du kan forestille dig.
0 svarer til det dårligste helbred, du kan forestille dig.
Klik med musen på det sted på skalaen, der viser, hvordan dit helbred er I DAG.

0 - Det dårligste helbred, du kan forestille dig

50

100 - Det bedste helbred, du kan forestille dig

(Place a mark on the scale above)

Spørgeskema om skulderfunktion (WOSI)

Kære deltager

Du bedes venligst at udfylde dette spørgeskema. Det er desværre ikke muligt at gemme undervejs, men hele spørgeskemaet må besvares når du er startet (du kan til gengælg starte forfra, hvis du er nødt til at afbryde).

Tak for din deltagelse! Mvh projektansvarlige

Sektion A: De følgende spørgsmål drejer sig om de fysiske symptomer, du har på grund af dit skulderproblem. Ved hvert spørgsmål skal du på linjen markere omfanget af dine symptomer indenfor den seneste uge.

1) Hvor ondt gør det i din skulder, når du arbejder med armen over hovedet?
Ingen smerte — Ekstrem smerte
(Place a mark on the scale above)

2) Hvor meget murren eller ømhed har du i skulderen?
Ingen Murren/ømhed — Ekstrem murren/ømhed
(Place a mark on the scale above)

3) Hvor plaget er du af kraftnedsættelse eller manglende styrke i din skulder?
Ingen kraftnedsættelse — Ekstrem kraftnedsættelse
(Place a mark on the scale above)

4) Hvor plaget er du af udtrætning eller manglende udholdenhed i din skulder?
Ingen udtrætning — Ekstrem udtrætning
(Place a mark on the scale above)

5) Hvor generet er du af klikken, knasen eller smæld i skulderen?
Ingen klikken — Ekstrem klikken
(Place a mark on the scale above)

6) Hvor generet er du af stivhed i skulderen?
Ingen stivhed — Ekstrem stivhed
(Place a mark on the scale above)

7) Hvor meget ubehag har du i dine nakkemuskler som en følge af dit skulderproblem?
Intet ubehag — Ekstremt ubehag
(Place a mark on the scale above)

8) Hvor ustabil eller løs er din skulder?
Ingen løshed — Ekstrem løshed
(Place a mark on the scale above)

9) Hvor meget kompenserer du for din skulder med brug af andre muskler?
Slet ikke — Ekstremt
(Place a mark on the scale above)

10) Hvor meget har du mistet af din bevægelighed i skulderen?
Intet tab — Ekstremt tab
(Place a mark on the scale above)

Sektion B: Følgende afsnit handler om, hvor meget dit skulderproblem har påvirket dit arbejde, dine sports- og fritidsaktiviteter indenfor den seneste uge. Du skal igen til hvert spørgsmål markere omfanget af dine symptomer på linjen

11) Hvor meget har dit skulderproblem begrænset dig i at deltage i sport eller fritidsaktiviteter?

Ikke begrænset — Begrænset ekstremt

(Place a mark on the scale above)

12) Hvor meget har skulderen indvirket på din evne til at udføre specifikke færdigheder, som er nødvendige i din sport eller dit arbejde? (Hvis skulderen generer både ved arbejde og sport skal du angive det i forhold til der hvor den generer mest)

Ingen indvirkning — Ekstrem indvirkning

(Place a mark on the scale above)

13) Hvor stort et behov har du for at beskytte din arm under aktivitet?

Slet ikke — Ekstremt

(Place a mark on the scale above)

14) Hvor svært er det at løfte tunge ting under skulderens niveau?

Ikke svært — Ekstremt svært

(Place a mark on the scale above)

Sektion C: Følgende afsnit handler om, i hvor høj grad dit skulder problem har påvirket eller ændret din livsstil. Du skal igen til hvert spørgsmål markere omfanget af dine symptomer på linjen

15) Hvor meget frygter du at falde på din skulder?

Ingen frygt — Ekstrem frygt

(Place a mark on the scale above)

16) I hvilken grad forhindrer dit skulderproblem dig i at holde dig i form?

Slet ikke — Ekstrem grad

(Place a mark on the scale above)

17) Hvor svært har du ved løssluppen aktivitet, så som brydning og slåskamp med familie og venner?

Ingen besvær — Ekstremt besvær

(Place a mark on the scale above)

18) Hvor meget søvnbesvær har du på grund af din skulder?

Ingen besvær — Ekstremt besvær

(Place a mark on the scale above)

Sektion D: De følgende spørgsmål handler om, hvordan du har følt det den sidste uge med hensyn til dit skulderproblem. Marker omfanget på linjen

19) Hvor bevidst er du om din skulder?

Ikke bevidst — Ekstrem bevidst

(Place a mark on the scale above)

20) Hvor bekymret er du for at dit skulderproblem forværres?

Ikke bekymret — Ekstremt bekymret

(Place a mark on the scale above)

21) Hvor frustreret er du over din skulder?

Ikke frustreret — Ekstremt frustreret

(Place a mark on the scale above)

Biomechanical and Neuromuscular Characteristics in Patients with Traumatic Anterior Shoulder Instability Undergoing Arthroscopic Bankart Repair: A Clinical Prospective Cohort Study Protocol

General information

1. Place of investigation

Sports Orthopedic Research Center – Copenhagen (SORC-C) and Human Movement Analysis Laboratory, Department of Orthopedic Surgery, Copenhagen University Hospital Hvidovre, Kettegård Allé 30, 2650 Hvidovre, Denmark

2. Trial period

Anticipated: 1 April 2022 – 31 March 2026.

3. Trial registration

The study protocol (Version 1.0) was published at Clinical Trials 27 April 2022 (www.clinicaltrials.gov, ID: NCT05250388) according to the World Health Organization Trial Registration Data Set and follows the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) checklist. The study will adhere to the STROBE guidelines for reporting of cohort studies (www.strobe-statement.org). The study has been approved by the Capital Region Ethics Committee (journal-no: H-21027799) and the Capital Region Knowledge Center for Data Reviews (journal-no: P-2021-842).

4. Funding and insurance

The study is a part of the PhD-project titled “Anterior-posterior glenohumeral translation in traumatic anterior shoulder instability” funded partially by the Department of Orthopedic Surgery, Copenhagen University Hospital Hvidovre (PhD-school, salary, overhead, lab costs). The PhD project has received a grant from the private fund “Familien Hede Nielsens Fond” to cover examination costs, whom did not have any involvement in study design; in the collection, analysis, and interpretation of data; in the writing of the report; nor in the decision to submit the article for publication. Further, the primary investigator has received a grant from the Copenhagen University

Hospital Amager & Hvidovre research fund to cover salary. Further fundraising will continuously be carried out through public and private foundations. There are no financial disclosures, from private companies, research funds etc., within the research group that can compromise the integrity of the project.

Study participants will not receive financial compensation. Study participants are covered by the patient insurance of Copenhagen University Hospital Hvidovre.

5. Research group

Primary investigator

Catarina Malmberg (CM) is MD and PhD-student at the Department of Orthopedic Surgery, Copenhagen University Hospital Hvidovre, and is the primary investigator, responsible for planning and conducting the study in all its phases, as well as reporting to all relevant agencies. CM will be first author of the paper on glenohumeral translation.

Address: Sports Orthopedic Research Center – Copenhagen (SORC-C), Department of Orthopedic Surgery, Copenhagen University Hospital Hvidovre, Kettegård Allé 30, 2650 Hvidovre, Denmark
Telephone: +4527519524, Email: catarina.anna.evelina.malmberg.02@regionh.dk

Principal supervisor

Kristoffer Weisskirchner Barfod is MD, PhD, and clinical associate professor at the Department of Orthopedic Surgery, Copenhagen University Hospital Hvidovre. The principal supervisor of the PhD follows requirements from the University of Copenhagen PhD-school throughout the PhD-program. Barfod initiated the study together with CM and contributes to planning of the study and review of the papers.

Co-supervisors

Jesper Bencke is MSc, PhD, and biomechanical laboratory manager at the Department of Orthopedic Surgery, Copenhagen University Hospital Hvidovre. Bencke contributes to planning of the study and review of the papers. Bencke also consults the project with his knowledge in the biomechanical and physiological field and supervise in the biomechanical laboratory.

Per Hölmich is DMSc, professor, and chief surgeon at the Arthroscopic Section, Department of Orthopedic Surgery, Copenhagen University Hospital Hvidovre. Hölmich holds the responsibility to secure that patients participating in the study are treated according to the highest medical standard. Hölmich contributes to planning of the study and review of the papers.

Collaborators

Kristine Rask Andreasen, MD and PhD-student at the Department of Orthopedic Surgery, Copenhagen University Hospital Hvidovre. Andreasen will assist in planning and managing the neuromuscular tests, hereunder experimental work, clinical examinations, and data collection. Andreasen will be first author of the paper on neuromuscular control.

Birgitte Hougs Kjær is MSc, PhD and Postdoc at the Department of Physical and Occupational Therapy, Institute of Sports Medicine Copenhagen (ISMC), Copenhagen University Hospital Bispebjerg & Frederiksberg. Hougs Kjær has specialized experience in musculoskeletal ultrasound imaging and trained the primary investigator in performing the relevant examinations. Hougs Kjær also contributes to planning of the study and review of the paper on glenohumeral translation.

Sanja Bay Hansen is MD at the Centre for Functional and Diagnostic Imaging and Research, Dept. of Radiology, Hvidovre hospital. Hansen is responsible for quantifying bone loss from the computed tomography (CT) scans according to state-of-the-art.

Klaus Bak is MD and senior consultant at the Adeas hospital, Denmark. Bak is associate editor for the medical journal Knee Surgery, Sports Traumatology, Arthroscopy (KSSTA). Bak contributes as external assessor of the project.

Recruiting centers

Department of Orthopedic Surgery, Copenhagen University Hospital Amager & Hvidovre

Department of Orthopedic Surgery, Copenhagen University Hospital Herlev & Gentofte

Department of Orthopedic Surgery, Zealand University Hospital Køge

Adeas Hospitals

Gildhøj Private Hospital

Hvidovre Hospital

SORC-C
Sports Orthopedic Research Center - Copenhagen

Information om forskningsprojektet 'Effekten af kikkertoperation på skulderstabiliteten hos patienter med instabilitet efter traume'

Du er blevet tilset af en ortopædkirurgisk læge, som har konstateret forreste skulderinstabilitet som skal behandles med kikkertoperation.

Vi ved at operation virker godt for langt de fleste, og vi vil med dette forskningsprojekt undersøge hvorfor resultaterne er gode hos mange, men mindre gode hos andre. Vi vil undersøge hvordan operationen påvirker dine ledbånd, dine refleksbuer og din muskulære styring af skulderen. Herved håber vi på sigt at kunne forbedre behandlingen af de patienter som ikke opnår optimale resultater efter operation.

Den projektansvarlige vil efter dette besøg kigge på dine data og kontakte dig via telefon, for at høre om du er interesseret i at høre nærmere om projektet. Hvis det er tilfældet vil vi invitere dig til en samtale, hvor vi gennemgår den skriftlige deltagerinformation og du kan tage endelig stilling til, om du vil være med i projektet.

Forskningsprojektet ændrer ikke på din behandling, men du vil blive indkaldt til 3 ekstra undersøgelser (før operationen, samt hhv. 6 og 12 måneder efter operationen) og du vil få foretaget en udvidet røntgenundersøgelse (3D CT-scanning) af dine skuldre før operationen.

Du kan læse nærmere om forskningsprojektet i den vedlagte deltagerinformation.
Har du spørgsmål er du velkommen til at kontakte mig via nedenstående mail eller telefonnummer.

Mvh

Catarina Malmberg, læge, PhD-studerende og projektansvarlige
Mail: catarina.anna.evelina.malmberg.02@regionh.dk
Telefonnummer: 2751 9524

En undersøgelse af effekten af kikkertkirurgi på skulderstabiliteten hos patienter med instabilitet efter traume

Vil du deltage i et videnskabeligt forsøg?

Vi vil spørge, om du vil deltage i et sundhedsvidenskabeligt forskningsprojekt, der udføres af Ortopædkirurgisk afdeling på Hvidovre Hospital. Overordnet ansvarlig for forsøget er læge og PhD-studerende Catarina Malmberg.

Før du beslutter, om du vil deltage i forsøget, skal du fuldt ud forstå, hvad forsøget går ud på, og hvorfor vi gennemfører forsøget. Vi vil derfor bede dig om at læse denne deltagerinformation grundigt.
Udover denne pjece, vil du have en samtale med en af projektets forskere om forsøget, hvor deltagerinformationen vil blive uddybet, og hvor du kan stille de spørgsmål, du har om forsøget. Du er velkommen til at have et familiemedlem, en ven eller en bekendt med til samtalen.

Hvis du beslutter dig for at deltage i forsøget, vil vi bede dig om at underskrive en samtykkeerklæring. Husk, at du har ret til betænkningstid, før du beslutter, om du vil underskrive samtykkeerklæringen.
Det er frivilligt at deltage i forsøget. Du kan når som helst og uden at give en grund trække dit samtykke tilbage uden videre konsekvenser.

Formålet med forsøget

Skulderen er det led i kroppen som hyppigst går af led. Skaden medfører en instabilitet i leddet, og hos mange medfører det nedsat funktion, kroniske smerter og forringet livskvalitet. Om de fortsatte problemer skyldes at ledbåndene rives over, at knoglen deformeres, at nervernes refleksbuer ændres, eller en kombination af ovenstående som medfører at af evnen til styre skulderen går tabt, vides endnu ikke.

Typisk vil første behandlingsvalg være fysioterapi og ved manglende effekt kikkertoperation med genskabelse af leddets stabiliserende strukturer. Med dette studie ønsker vi at undersøge operationens effekt, dels på den mekaniske stabilitet og dels på nervernes refleksbuer (den neuromuskulære kontrol), og afklare om disse faktorer kan forklare de symptomer patienter oplever. Vores håb er på sigt at kunne adskille dem, som kan forvente et godt resultat ved fysioterapi fra dem, som vil have gavn af tidlig kirurgisk behandling. Det ville medføre at man tidligt i forløbet vil kunne finde den behandling som fører til bedst mulige slutresultat, og derved bidrage til en mere effektiv og korrekt behandling af skulderinstabilitet.

Studiet udføres på Hvidovre Hospital, hvor alle kontroller vil finde sted. 55 patienter med traumatisk skulderinstabilitet og planlagt kikkertoperation vil blive inviteret til at deltage, med start fra 1. september 2021.

Forsøgets praktiske udførelse

Som deltager i projektet vil du skulle møde til 3 kontroller; før din operation, samt hhv. 6 og 12 måneder efter operationen. Det forventes at hvert besøg vil vare ca. 2 timer. Ved disse besøg skal du møde i Bevægelseslaboratoriet i Ortopædkirurgisk afdeling på Hvidovre hospital, hvor en fagkyndig person vil undersøge dine skuldre med en række forskellige stabilitets- og funktionstests.

Først vil vi lave en almindelig skulderundersøgelse, ligesom den Du tidligere har fået foretaget hos den kirurg som skal operere dig. Det indebærer, at vi vil bede dig om at bevæge armene i det omfang du kan, samt med vores hænder mærke efter om vi kan fremkalde den løshed og gener som du oplever.

Desuden vil vi ved de tre besøg udføre tests i laboratoriet, hvor vi med højteknologiske hjælpemidler analyserer dine skuldres bevægelsesmønster og din evne til at lokalisere arm og skulder i rummet. Disse inkluderer:

- En test hvor du får påklistret en række markører på og omkring din skulder og bliver bedt om at udføre nogle bestemte bevægelser, samtidig med du bliver filmet. Et antal kameraer i laboratoriet opsamler signaler fra markørerne, som føres videre til en computer, og som beregner og analyserer dit bevægelsesmønster.
- En undersøgelse hvor vi placerer din arm i to forskellige positioner, og med ultralyd kigger direkte ind i dit skulderled samtidig med at du er: i hvile, får et let tryk bagfra, eller drejer din arm enten indad eller udad.
- En test af stillingssans hvor du med lukkede øjne bliver bedt om at genfinde en tidligere position, hvor armen var løftet.
- En "svajetest" hvor du ligger i en plankeposition med underkroppen støttet af en briks og, hhv. med ansigtet nedad og til siden, støtter på skiftevist den ene og den anden arm i 30 sekunder.
- En test af reaktionstid, hvor du bærer et armbånd, der via en ledning over en trisse er forbundet til en elektromagnet med en lodret hængende vægt som trækker let i din arm. Pludselig deaktiveres magneten, og håndvægten slipper, hvilket vil få din skulder at bevæge sig i modsat retning. Den tid du bruger på at reagere, og føre hånden tilbage til udgangspositionen, er reaktionstiden.

Du vil desuden få tilsendt 2 elektroniske spørgeskemaer på mail, vedrørende din skulderfunktion- og smerter, som du vil blive bedt om at udfylde i forbindelse med de tre kontroller.

Inden operationen vil vi foretage en udvidet computerassisteret tomografi (3D CT-scanning) af begge dine skuldre for at vurdere størrelsen af et eventuelt knogletab.

Vi vil sammen fastlægge en dato for næste kontrol fra gang til gang, under hensyn til, hvad der er hensigtsmæssigt for dig.

Medicin

Som deltager i projektet vil du ikke skulle tage nogen medicin, og det har ingen indflydelse på medicin som du eventuelt tager i forvejen.

Personlige og journaloplysninger

Ved at skrive under på det informerede samtykke gives forsøgsansvarlige, samt eventuel kontrolmyndighed direkte adgang til at indhente oplysninger i din journal mv., herunder elektronisk journal, med henblik på at se oplysninger om dine helbredsforhold, som er nødvendige som led i gennemførelsen af forskningsprojektet samt i kontroløjemed, herunder egenkontrol, kvalitetskontrol og monitorering, som disse er forpligtet til at udføre. Der henvises til komitelovens § 3, stk. 3 og anmeldelsesbekendtgørelsen § 4, stk. 1, samt § 10, stk. 3 og stk. 5.

De journaloplysninger der er relevante for os er:

1. Dine kontaktoplysninger, som vi anvender til at kontakte dig ud fra.
2. Informationer omhandlende behandling af din skulder, for at sikre at du opfylder kriterierne for deltagelse.
3. Dine billeddiagnostiske undersøgelser (røntgen, CT-scanning), som vi bruger til at undersøge et eventuelt knogletab.

Alle involverede forskere har tavshedspligt og vil behandle dine personlige data strengt fortroligt. Personlige oplysninger vil i gennem hele forsøgets forløb beskyttes ifølge den Danske Databeskyttelsesforordning og Databeskyttelsesloven. Det skal understreges at resultater udelukkende vil blive offentliggjort i anonymiseret form, og hverken navn, CPR- eller deltagernummer vil figurere andre steder end på et sikret, lukket drev. Hvis du vælger at trække dit informerede samtykke tilbage vil ingen nye data blive indsamlet og registreret. Imidlertid tillader lovgivningen, at data indsamlet inden du trækker dit samtykke tilbage stadig indgår i forsøgets datamateriale.

Forsøgets nytte

Som deltager i projektet vil du få en grundig opfølgning af fagpersoner specialiseret i din type skade. Derudover vil du med din deltagelse medvirke til at forbedre undersøgelse og behandling af skulderinstabilitet.

Bivirkninger, risici, og ulemper

Det er en ulempe for dig at skulle møde til de 3 kontroller. Til gengæld får du en grundig opfølgning af din skulder, som potentielt kan bidrage til, at du hurtigere genvinder din oprindelige funktion. Derudover vil din deltagelse i projektet ikke have indflydelse på din behandling.

Den røntgenundersøgelse som vil blive foretaget inden operationen medfører stråling, som potentielt kan øge livstidsrisikoen for kræft. Denne risiko er dog meget lille, og mængden af stråling kan sammenlignes med et års baggrundsstråling i Danmark.

De undersøgelsesmetoder som er inkluderede i projektet i øvrigt er ikke forbundet med kendte sundhedsskadelige risici, men der kan være risici ved forsøget, som vi endnu ikke kender. Under nogle af undersøgelserne vil din skulder være i positioner som kan fremkalde symptomer som smerter, usikkerhed og ubehag. De vil formentlig ligne de symptomer som du i forvejen oplever fra din skulder. Der vil i hele forløbet være en fagkyndig person til stede, med overblik over om undersøgelsen skal pauseres eller afbrydes. Vi beder dig derfor om at fortælle, hvis du oplever problemer med dit helbred, mens forsøget står på. Hvis vi opdager bivirkninger, som vi ikke allerede har fortalt dig om, vil du naturligvis blive orienteret med det samme, og du vil skulle tage stilling til, om du ønsker at fortsætte forsøget.

Udelukkelse fra/afbrydelse af forsøg

Vurderes det, at du ikke følger forsøgsplanen eller oplever bivirkninger som kan påvirke dit fysiske eller psykiske helbred kan du udelukkes fra videre deltagelse i forsøget. Opstår der alvorlige uventede bivirkninger vil forsøget blive afbrudt. Andre årsager til afbrydelse af studiet kan være mangel på deltagere, eller at sufficient datamængde foreligger.

Økonomiske forhold

Der udbetales IKKE vederlag for deltagelse i forsøget. I tilfælde af komplikationer, er deltageren dækket af Hvidovre Hospitals patientforsikring og arbejdsskadeforsikringsloven.

Læge og PhD-studerende Catarina Malmberg og overlæge og klinisk lektor Kristoffer W Barfod har taget initiativ til projektet. Faciliteter i form af undersøgelseslokaler og røntgen stilles til rådighed af Hvidovre Hospital, og projektet finansieres overordnet af Ortopædkirurgisk afdeling. Forsøget har modtaget 20 000 kr. i støtte fra Familien Hede Nielsens Fond. Der søges om yderligere finansiering fra private og offentlige fonde. Hvis yderligere støtte modtages, vil deltagere og Videnskabsetisk Komité blive kontaktet herom. De

involverede forskere har ingen økonomisk udbytte af studiet.

Adgang til forsøgsresultater

Resultaterne vil blive offentliggjort, og udgivet i et internationalt videnskabeligt tidsskrift. Yderligere vil resultaterne blive fremlagt på fagspecifikke kongresser.

Forsøget anses for afsluttet når 55 deltagere har gennemført forsøget. Dette forventes udført inden udgangen af september 2024.

Originaltitel

Forsøgets engelske originaltitel er: 'The effect of arthroscopic Bankart repair on anterior-posterior glenohumeral translation and shoulder proprioception in patients with traumatic anterior shoulder instability: a prospective cohort study'

Det er frivilligt at deltage i forsøget

Vi håber, at du med denne information har fået tilstrækkeligt indblik i, hvad det vil sige at deltage i forsøget, og at du føler dig rustet til at tage beslutningen om din eventuelle deltagelse. Vi beder dig også om at læse det vedlagte materiale "Forsøgspersonens rettigheder i et sundhedsvidenskabeligt forskningsprojekt".

Yderligere oplysninger om forsøget kan fås ved kontakt til projektansvarlig:

Læge, PhD-studerende Catarina Malmberg
Ortopædkirurgisk ambulatorium, afsnit 333, Hvidovre Hospital
Kettegård Allé 30, 2650 Hvidovre
Mail: catarina.anna.evelina.malmberg.02@regionh.dk
Telefon: 27519524 / 38623862

Forsøgspersoners rettigheder i et sundhedsvidenskabeligt forskningsprojekt

Som deltager i et sundhedsvidenskabeligt forskningsprojekt skal du vide, at:

- din deltagelse i forskningsprojektet er helt frivillig og kun kan ske efter, at du har fået både skriftlig og mundtlig information om forskningsprojektet og underskrevet samtykkeerklæringen.
- du til enhver tid mundtligt, skriftligt eller ved anden klar tilkendegivelse kan trække dit samtykke til deltagelse tilbage og udtræde af forskningsprojektet. Såfremt du trækker dit samtykke tilbage påvirker dette ikke din ret til nuværende eller fremtidig behandling eller andre rettigheder, som du måtte have.
- du har ret til at tage et familiemedlem, en ven eller en bekendt med til informationssamtalen.
- du har ret til betænkningstid, før du underskriver samtykkeerklæringen.
- oplysninger om dine helbredsforhold, øvrige rent private forhold og andre fortrolige oplysninger om dig, som fremkommer i forbindelse med forskningsprojektet, er omfattet af tavshedspligt.
- behandling af oplysninger om dig, herunder oplysninger i dine blodprøver og væv, sker efter reglerne i databeskyttelsesforordningen, databeskyttelsesloven samt sundhedsloven. Den dataansvarlige i forsøget skal orientere dig nærmere om dine rettigheder efter databeskyttelsesreglerne.
- der er mulighed for at få aktindsigt i forsøgsprotokoller efter offentlighedslovens bestemmelser. Det vil sige, at du kan få adgang til at se alle papirer vedrørende forsøgets tilrettelæggelse, bortset fra de dele, som indeholder forretningshemmeligheder eller fortrolige oplysninger om andre.
- der er mulighed for at klage og få erstatning efter reglerne i lov om klage- og erstatningsadgang inden for sundhedsvæsenet. Hvis der under forsøget skulle opstå en skade kan du henvende dig til Patienterstatningen, se nærmere på www.patienterstatningen.dk

De Videnskabsetiske Komiteer for Region Hovedstaden (6 komiteer)
Tlf.: +45 38 66 63 95
E-mail: vek@regionh.dk
Hjemmeside: www.regionh.dk/vek

De Videnskabsetiske Komiteer for Region Syddanmark (2 komiteer)
Tlf.: + 45 76 63 82 21
E-mail: komite@rsyd.dk
Hjemmeside: www.regionsyddanmark.dk/komite

Den Videnskabsetiske Komité for Region Nordjylland Tlf.: +45 97 64 84 40
E-mail: vek@rn.dk
Hjemmeside: www.rn.dk/vek

Den Videnskabsetiske Komité for Region Sjælland
Tlf.: +45 93 56 60 00
E-mail: RVK-sjaelland@regionsjaelland.dk
Hjemmeside: https://www.regionsjaelland.dk/sundhed/forskning/forfagfolk/videnskabsetisk-komite/Sider/default.aspx

De Videnskabsetiske Komiteer for Region Midtjylland (2 komiteer)
Tlf.: +45 78 41 01 83 / +45 78 41 01 82 / +45 78 41 01 81
E-mail: komite@rm.dk
Hjemmeside: www.komite.rm.dk

National Videnskabsetisk Komité
Tlf.: +45 72 21 68 55
E-mail: kontakt@nvk.dk
Hjemmeside: www.nvk.dk

Dette tillæg er udarbejdet af det videnskabsetiske komitésystem og kan vedhæftes den skriftlige information om det sundhedsvidenskabelige forskningsprojekt. Spørgsmål til et konkret projekt skal rettes til projektets forsøgsansvarlige. Generelle spørgsmål til forsøgspersoners rettigheder kan rettes til den komité, som har godkendt projektet.

Revideret 11. marts 2019

Hvidovre Hospital

SORC-C Sports Orthopedic Research Center - Copenhagen

Informeret samtykke til deltagelse i videnskabeligt forskningsprojekt

Forskningsprojektets titel:

Effekten af kikkertkirurgi på biomekanik og neuromuskulær kontrol hos patienter med forreste skulderinstabilitet efter traume: Et prospektivt kohortestudie

Erklæring fra forsøgspersonen:

Jeg har fået skriftlig og mundtlig information og jeg ved nok om formål, metode, fordele og ulemper til at sige ja til at deltage.

Jeg ved, at det er frivilligt at deltage, og at jeg altid kan trække mit samtykke tilbage uden videre konsekvenser.

Jeg giver samtykke til, at deltage i forskningsprojektet. Jeg har fået en kopi af dette samtykkeark samt en kopi af den skriftlige information om projektet til eget brug.

Forsøgspersonens navn: _____

Dato: _____ Underskrift: _____

Ønsker du at blive informeret om forskningsprojektets resultat samt eventuelle konsekvenser?:

Ja _____ (sæt x) Nej _____ (sæt x)

Ønsker du at blive informeret om væsentlige oplysninger om din egen helbredstilstand?:

Ja _____ (sæt x) Nej _____ (sæt x)

Erklæring fra den, der afgiver informationen:

Jeg erklærer, at forsøgspersonen har modtaget mundtlig og skriftlig information om forsøget og har haft mulighed for at stille spørgsmål.

Efter min overbevisning er der givet tilstrækkelig information til, at der kan træffes beslutning om deltagelse i forsøget.

Navnet på den, der har afgivet informationen:_____

Dato: _____ Underskrift: _____

STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No.	Recommendation	Page No.	Relevant text from manuscript
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	*Page 1*	*Line #1-3*
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	*Page 2*	*Line #17-39*
Introduction				
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	*Page 4-5*	*Line #48-87*
Objectives	3	State specific objectives, including any prespecified hypotheses	*Page 6-7*	*Line #96-130*
Methods				
Study design	4	Present key elements of study design early in the paper	*Page 7*	*Line #132-135*
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	*Page 11* *Page 13*	*Line #213-221* *Line #253-254, #262-264*
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	*Page 11-12*	*Line #223-251*
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case	*N/A*	*N/A*
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	*Page 7-11*	*Line #137-211*
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	*Page 7-11*	*Line #137-211*
Bias	9	Describe any efforts to address potential sources of bias	*Page 17*	*Line #338-345*
Study size	10	Explain how the study size was arrived at	*Page 14*	*Line #274-280*

Continued on next page

Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	*Page 14-15*	*Line #279-291*
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	*Page 14-15*	*Line #272-297*
		(*b*) Describe any methods used to examine subgroups and interactions	*N/A*	*N/A*
		(*c*) Explain how missing data were addressed	*Page 15-16*	*Line #289-293*
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy	*Page 15-16*	*Line #289-293*
		(*e*) Describe any sensitivity analyses		*N/A*
Results				
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed		*N/A*
		(b) Give reasons for non-participation at each stage	*N/A*	*N/A*
		(c) Consider use of a flow diagram	*N/A*	*N/A*
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	*N/A*	*N/A*
		(b) Indicate number of participants with missing data for each variable of interest	*N/A*	*N/A*
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	*N/A*	*N/A*
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	*N/A*	*N/A*
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	*N/A*	*N/A*
		Cross-sectional study—Report numbers of outcome events or summary measures	*N/A*	*N/A*
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	*N/A*	*N/A*
		(*b*) Report category boundaries when continuous variables were categorized	*N/A*	*N/A*
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	*N/A*	*N/A*

Continued on next page

Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	*N/A*	*N/A*
Discussion				
Key results	18	Summarise key results with reference to study objectives	*N/A*	*N/A*
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	*N/A*	*N/A*
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	*N/A*	*N/A*
Generalisability	21	Discuss the generalisability (external validity) of the study results	*N/A*	*N/A*
Other information				
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	Appl. 1, p. 2	Line #17-27

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.