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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

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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 multicentre cohort study with repeated measures of 30 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 presurgically and twice post surgically at 6 and 12 months. Patients' contralateral shoulders are investigated once to establish a preinjury 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.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This study has a broad investigation approach including biomechanical, neuromuscular, clinical and patient-centred 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 SD or minimally important difference.

INTRODUCTION

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 dependent

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 with those with stable shoulders.[15] Both modalities have been criticised for the lack of ecological validity, as they are static and without application of an external force and thereby cannot be generalised 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 with 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 pathological 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]

Research questions

A (biomechanics): Does arthroscopic Bankart repair have a stabilising 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?

Aim

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

Objectives and hypotheses

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 6 and 12 months after surgery and whether the ranges are restored to the same as the non-injured contralateral shoulder.

Hypotheses research question A

1. Arthroscopic Bankart repair results in a ≥2.5 mm decrease in anterior–posterior glenohumeral translation, remaining both 6 and 12 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 6 and 12 months after surgery.
4. Scapular rotations and tilt remain unchanged after arthroscopic Bankart repair.

Objectives research question B

In patients with traumatic anterior shoulder instability undergoing arthroscopic Bankart repair, to investigate the neuromuscular control before and 6 and 12 months after surgery and whether the neuromuscular control is restored to the same level as the non-injured contralateral shoulder.

Hypotheses research question B

1. Arthroscopic Bankart repair improves neuromuscular control, remaining both 6 and 12 months after surgery.
2. Arthroscopic Bankart repair improves neuromuscular control to the same range as the non-injured shoulder.

Other objectives

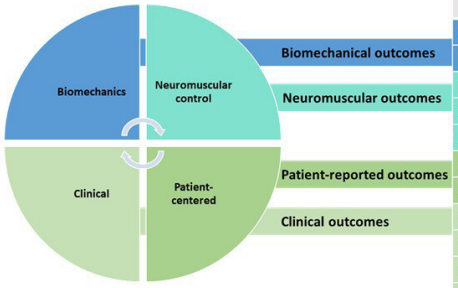
In patients with traumatic anterior shoulder instability undergoing arthroscopic Bankart repair:

1. To investigate patient-reported outcome measures (PROM) before and 6 and 12 months after surgery.
2. To determine the recurrence rates (radiographically confirmed or manually reduced dislocation) in the first 12 months after surgery.
3. To investigate the shoulder range of motion (ROM) before and 6 and 12 months after surgery.
4. To assess the joint instability by manual testing before and 6 and 12 months after surgery.
5. To quantify potential bone loss before 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.

METHODS AND ANALYSIS

Study design

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



	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		

Figure 1 The investigation approach with biomechanical, neuromuscular, patient-centred and clinical outcomes. EQ-5D: EuroQol-5 Domain questionnaire.

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-centred outcomes (figure 1).

Biomechanical outcomes

The primary outcome for research question A is the change in anterior–posterior glenohumeral translation 6 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 millimetres, 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 intrarater and inter-rater 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 intrarater and inter-rater 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 12 months after surgery (the same methods as above).

The scapular upward-downward rotations, protraction–retraction and anterior–posterior tilt, are analysed 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 6 and 12 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 inter-rater reliability (ICC (2.1) >0.5) for the tested motion tasks in subjects without shoulder complaints (article in preparation).

Neuromuscular outcomes

The primary outcome for research question B is the reaction time six months after surgery. The change in neuromuscular control is assessed using the newly developed Copenhagen Assessment of Neuromuscular Control in the Unstable Shoulder (CANCUS) test protocol at 6 and 12 months after surgery. The test series includes assessment of the shoulder joint reaction time, sway and JPS 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 centre of pressure in the frontal and sagittal planes. The JPS 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.

Clinical and patient-reported outcomes

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

The perceived change in shoulder function is evaluated using the Western Ontario Shoulder Instability index.[25] It consists of 21 items, each scored on a 100 mm Visual Analogue Scale. 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

and 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 EuroQol-5 domain (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).[26] The response scales consist of a heading and five short statements, each describing a different level of severity.

Any radiographically confirmed or manually reduced 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 6 and 12 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 with the contralateral as the upper arm is anteriorly translated. The apprehension test and relocation test are performed with the patient lying supine and the shoulder positioned in 90° 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 presurgical 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.[27] The size (the largest height, width and depth in millimetres) of Hill-Sachs lesions on the humeral head is also measured and registered, but not the specific location.[28]

Study setting

The patients are screened for eligibility and treated at five centres specialised in treatment of shoulder instability. The centres 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 online supplemental file 2 for further general information.

Study population and eligibility criteria

Thirty patients with traumatic anterior shoulder instability undergoing arthroscopic Bankart repair will be recruited from the centres 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/superior labrum anterior posterior (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 score≥3).

All patients must provide written, informed consent prior to any study procedure (online supplemental file 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 presurgical 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, for example, in the event of postsurgical complications (infection, nerve injury, recurrent event or revision surgery), as these might influence the postsurgical 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.

Study plan

There are three visits in total: (1) baseline presurgical visit; (2) 6-month postsurgical ±2 weeks; (3) 12 months post surgical ±2 weeks. All patients undergo arthroscopic Bankart repair at the centre from which they are recruited

Table 1 Study plan

Study plan	Recruitment	Inclusion	Presurgical visit	6 months after surgery	12 months after surgery
Setting	Recruiting centre	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			X*	X	X

*CT scan only at presurgical visit.

by an orthopaedic surgeon specialised in arthroscopic shoulder surgery. The procedure is done through a posterior viewing portal and a low anterolateral 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 standardised 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 standardised postsurgical rehabilitation protocol for a minimum of 12 weeks. All study-related activities are carried out according to the study plan presented in table 1.

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.

Statistics

Sample size calculation

The sample size calculation is made to allow for assessment of the primary outcomes within each category of outcomes; For research question A concerning biomechanics, the study is powered to detect a mean change in anterior-posterior glenohumeral translation of ≥2.5 mm with a standard deviation (SD) of 2.3 mm.[29] For research question B concerning neuromuscular control, the study is powered to detect an effect size of 0.8 for change in reaction time. For the clinical and patient-reported outcomes, the study is powered to detect an effect size of 0.8 for the WOSI score.

For power of 90% and type I error rate of 0.017 (0.05/3), correcting for three tests, sample size for a one-sample t-test is 15, 24 and 24 for anterior-posterior glenohumeral translation, reaction time and WOSI score, respectively. As such, the largest sample size of 24 will be used. To account for expected dropout rate of 25% a total of 30 patients will be included.

Originally, the study was powered to detect a between group difference in anterior-posterior glenohumeral translation of ≥2.5 mm with a standard deviation (SD) of 2.3 mm, and a power of 80%. 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. During the writing of this protocol article, it was realized that since the same shoulders are compared pre and post intervention no between groups analysis is performed and hence the setup controls for the six mentioned variables in itself. The sample size was thus re-calculated as stated above.

Statistical analysis

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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. Change in outcomes will be analyzed by one-sample t-test, comparison between injured and non-injured side will be done by paired t-test. If data cannot be assumed to be normally distributed, Wilcoxon rank-sum or signed-rank test will be used instead.

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.

Table 2 Main comparisons for the biomechanical, neuromuscular, clinical and patient-centred outcomes

Outcome	Comparisons
Biomechanical	► Change in anterior–posterior glenohumeral translation from baseline to 6 months (*primary outcome*), and 12 months. ► Change in superior–inferior glenohumeral translation from baseline to 6 and 12 months. ► Change in scapular upward-downward rotations, protraction–retraction and anterior–posterior tilt from baseline to 6 and 12 months. ► Side to side difference in anterior-posterior glenohumeral translation between the injured shoulder at 6 and 12 months and the non-injured shoulder at baseline. ► Side to side difference in scapular upward-downward rotations, protraction-retraction and anterior-posterior tilt between the injured shoulder at 6 and 12 months and the non-injured shoulder at baseline.
Neuromuscular (*the analyses are considered exploratory with no hierarchy between the outcomes*)	► Change in reaction time from baseline to 6 and 12 months. ► Change in sway length from baseline to 6 and 12 months. ► Change in joint position sense from baseline to 6 and 12 months. ► Side-to-side difference in neuromuscular outcomes between the injured shoulder at 6 and 12 months and the non-injured shoulder at baseline.
Clinical and patient reported outcomes (*the analyses are considered exploratory with no hierarchy between the outcomes*)	► Correlations with biomechanical and neuromuscular outcomes ► Change in WOSI index from baseline to 6 and 12 months. ► Change in EQ-5D questionnaire from baseline to 6 and 12 months. ► Change in range of motion from baseline to 6 and 12 months. ► Correlations between bone-loss and WOSI index, EQ-5D questionnaire, redislocation, and range of motion.

WOSI, Western Ontario Shoulder Instability index.

The main comparisons planned for the biomechanical, neuromuscular, clinical and patient-centred outcomes are shown in table 2.

ETHICS AND DISSEMINATION

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 online supplemental file 1 (clinical examination sheet and PROM questionnaires in Danish).

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 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 1 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, unfavourable 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,

hospitalisation, 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.

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 file at all recruiting centres. 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).

Ethical considerations

All recruiting centres are specialised in the 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.

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.

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 are stored and analysed 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, a web application for database management originally created at Vanderbilt University.

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. *Patient-reported 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.

Trial status

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

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 multiperspective 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 SD

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 that the study results can contribute to changed management of shoulder instability and optimised health system spending.

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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 analyse 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.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

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