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investigation plan

Operative treatment of traumatic anteroinferior shoulder instability in young male patients

The outcome of arthroscopic Bankart vs. open Latarjet stabilization surgery, a randomized controlled trial

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1) INTRODUCTION

Glenohumeral joint is the most mobile joint in the human body. Its bony architecture allows a wide and nearly circumferential range of motion. As a consequence of unrestricted motion, the glenohumeral joint is prone to instability, i.e. the humeral head may dislocate off the scapular glenoid plate especially in the anteroinferior direction (Rockwood et al. 2009, Provencher and Romeo 2012). The most common mechanism of shoulder dislocation is a fall or impact on abducted and externally rotated arm. This is typically a sports related injury and affects especially young males (Lievaag 2011). A primary anteroinferior shoulder dislocation nearly always disrupts the anterior labrum and the anterior inferior glenohumeral ligament (IGHL complex) (Perthes-Bankart laesion), which is considered the primary passive soft-tissue restraint of the glenohumeral joint. There may also be other frequent accompanying laesions, such as an impression fracture of the humeral head (Hill-Sachs), or of the anterior glenoid rim (bony Bankart). The plain x-rays may underestimate this bony pathology in the glenohumeral joint and a computed tomography imaging allows a superior and more careful investigation of the bony morphology. On the other hand magnetic resonance imaging helps to detect the soft tissue injuries. The disruption of passive shoulder restraints and bony architecture may lead to further shoulder instability after the first time dislocation. Among patients below 25 years of age redislocations and residual instability occur in up to 50% of cases after primary dislocation (Hovelius 2008).

The most common operation to treat shoulder instability is arthroscopic capsulolabral repair (Bankart operation). The torn labrum and IGHL are re-attached to the glenoid rim with suture anchors. The results of arthroscopic Bankart repairs are regarded similar to those of open Bankart repairs (Hobby et al. 2007). Recurrence rates of instability after a Bankart repair have been variable ranging from 5% to 35% in 2 to 10 years’ follow-up. Risk factors for failure after arthroscopic Bankart repair have included young age, bony lesions either on humeral or glenoid side, increased laxity of joints (hyperlaxity) and contact sports. Balg and Boileau (2007) found that in young patients under 20 years of age, with glenoid and/or humeral bone defects, and who participated in competitive contact or overhead sports, there is a 70% failure rate after arthroscopic stabilisation surgery. A follow-up study in Oulu University Hospital recognized young age as the most important risk factor for failure after arthroscopic Bankart repair. If the patient’s age at the time of surgery was under 20 years, the failure rate was 44% after arthroscopic Bankart repair during five years follow-up.
up. (Flinkkilä et al. 2010). Accordingly, Castagna et al. (2012) reported a 21% failure rate in 13–18 year-old patients who participated in contact sports. Boileau et al. (2006) reported that 70% of recurrences of instability symptoms take place within two years after the operative intervention. In a previous study from Oulu University Hospital, 75% of the failures took place within two years and 96% within three years after arthroscopic Bankart operation (Flinkkilä et al. 2010).

More robust operative techniques have evolved to achieve greater stability of the glenohumeral joint against eg. sports related recurrences (Roberts et al. 1999). In 1954 Michel Latarjet described an operation in which the coracoid process of the scapulae together with the conjoined tendon (short head of the biceps and coracobrachialis tendon) is detached, transferred through the subscapularis muscle and re-attached to the neck of the glenoid (Latarjet 1954). The stabilizing mechanism of this operation has been reported to be a bone block effect together with a sling effect of the conjoined tendon and inferior part of the subscapularis muscle. The Latarjet operation has gained popularity and is especially advocated in cases with bone defects on the glenoid side. The Latarjet operation (or its modification Bristow-Latarjet) has been reported to yield in high success rates (Matthes 2007). However, there are no studies with comparable groups of patient with Bankart and Latarjet operation. Many orthopaedic surgeons have doubts over Latarjet technique because of its nonanatomic nature. However, in a series by Hovelius et al., the Latarjet operation did not have any more negative long-term effects than open Bankart operation (Hovelius 2011). Only few studies have reported failures after Latarjet–operations and the rates of recurrence of instability have ranged from 0 to 10% (Allain et al. 1998, Hovelius et al. 2004).

Every episode of shoulder instability is likely to induce injury to the joint cartilage and further predispose to osteoarthritis within the glenohumeral joint. It has been reported that there are radiographically visible osteoarthritic changes in at least 20% of the patients 10 years after the primary shoulder dislocation injury (Hovelius 1996). Therefore, surgical intervention, ie. stabilization of the joint to avoid further dislocation episodes, may potentially protect the joint cartilage. However, the surgical treatment may also contribute to the development of osteoarthritis by inducing iatrogenic injury to the joint. Post-traumatic osteoarthritis of the glenohumeral joint may lead to increased disability and morbidity, and should be prevented if possible.
There are no previous prospective randomized studies investigating the difference in outcome between a Bankart and a Latarjet operation.

2) AIMS OF THE INVESTIGATION

1) Study the difference in outcome after arthroscopic Bankart operation compared with open Latarjet operation in the treatment of a residual instability after a traumatic primary dislocation in young males.
   Hypothesis: Open Latarjet operation yields in a significantly lower recurrence rate and a better subjective result.

2) Study the accuracy of plain x-rays on detecting bony lesions of the glenohumeral joint (Hill-Sachs and bony Bankart) compared to computed tomography imaging.
   Hypothesis: Plain X-rays give an inaccurate estimate of the bony lesions.

3) Study the development of osteoarthritic changes within the glenohumeral joint in the study population in 2 to 20 year time interval.
   Hypothesis: The osteoarthritic changes are related to the severity of primary injury and bone lesions.

3) PATIENTS AND METHODS

This randomized controlled study with parallel treatment groups will be conducted according to the revised Declaration of Helsinki by The World Medical Association and the ICH-guidelines for good clinical trial practice. The study will be submitted for approval to the Ethics Committee of the Hospital District of Varsinais-Suomi, Finland. The study will be conducted as a multicentre study in Finland at Turku University Hospital, Helsinki University Hospital, Tampere University Hospital / Tampere Hatanpää hospital, Jyväskylä Central Finland Hospital, Kuopio University Hospital, Oulu University Hospital and Satakunta Central Hospital Pori. Additional recruiting hospitals and researchers maybe included during the trial in case of difficulties in patient recruitment (less than 30 patients during the first 6 months). The study protocol will be registered at clinicaltrials.gov.
Patients with post-traumatic anteroinferior shoulder instability are referred to the participating institutes by local health care providers. All referred patients are called in for clinical and radiological examination by the investigators. If the patient is eligible and willing to participate in the study a written informed consent is obtained. Patients who are eligible, but not willing to participate in the study, are asked for a permission to use their patient records for study purposes.

The recruited patients are informed of study protocol and that a stabilizing shoulder operation will be performed accordingly. The operation is scheduled within 6 weeks after recruitment. Right before the operation the patients are randomized in one of two studied treatment modalities.

Criteria for inclusion:
1. Subluxation or fear of shoulder dislocation after a previous, reduced and primarily conservatively treated (for more than 3 months) traumatic anteroinferior shoulder dislocation.
2. Redislocation after a primary shoulder dislocation.
3. Clinically documented anteroinferior instability (i.e. a positive apprehension and relocation test (Jobe)).
4. X-ray (true ap, 30 degrees oblique ap, Y- and axillary projections), 2- and 3-dimensional computed tomography (2D and 3D CT) and magnetic resonance imaging arthrography (MRA) documentation of the joint.
5. Congruency of the shoulder joint on imaging investigations.
6. Young adult male patient 16-25 years of age (15 years < patient ≤ 26 years).
8. Written informed consent from participating subject.

Criteria for exclusion:
1. Non-congruency of the glenohumeral joint on imaging investigations.
2. Concomitant dislocated fractures (requiring operative treatment) of the humerus or the scapula (other than Hill-Sachs lesion or bony Bankart lesion).
3. Severe grade 2 or above (Samelson et Prieto) osteoarthrosis of the glenohumeral joint detected in X-ray investigation.
4. A humeral avulsion of glenohumeral ligaments (HAGL) detected in MRA investigation.
5. Concomitant ipsilateral plexus or axillary nerve injury affecting motorical function.
6. Life threatening other concomitant injuries (i.e. multitrauma patient).
7. Stiffness of the glenohumeral joint (restricted passive external rotation less than 30 degrees measured in standing position, arm at side).
8. Age under 16 or above 25 years.
9. Open physis with significant growth expectation.
10. Intellectual disability, history of seizures with high risk of recurrence, existing significant malignant, haematological, endocrine, metabolic, or rheumatoid disease.
11. Previous ipsilateral shoulder surgery.
12. Cytostatic or corticosteroid medication.
13. History of alcoholism, drug abuse, psychological or other emotional problems that are likely to invalidate informed consent.
14. Disability to co-operate.
15. Patient’s denial.

Randomization:
The randomization is divided into two main lists (each containing four separate lists for each risk profile) according to participating hospitals to keep the groups better balanced between the institutions (main list 1 = Turku, Helsinki, Pori and Tampere institutes, and main list 2 = Kuopio, Jyväskylä and Oulu institutes). Turku University Hospital serves as a randomization center for the study. A stratified randomization is used to control the equal distribution of two major previously reported risk factors for failure between the groups. There are thus 4 possible combinations of risk factors (0+0, 1+0, 0+1, 1+1), and within each risk profile block randomization with randomly selected block sizes of 2 to 4 is used. SAS statistical software is used to generate the randomization lists up to 60 patients for each risk profile within each main list. After informed consent the individual study center will contact Turku study nurse by phone and informs about the eligible patient and the scheduled operation day, and whether there is: 1) a significant glenoid bone defect/bony Bankart-lesion or not, and 2) a significant humeral impression (Hill-Sachs) or not, according to APPENDIX 1. The study nurse will then activate the electronic follow-up registry for the patient. At two weeks before the planned operation the pre-operative measurements are performed by a
physiotherapist according to APPENDIX 7. The individual study center will then contact the study nurse who then performs and controls the randomization and informs the clinical investigator of the study group 2 days before the planned operation (on Friday if the operation is planned to take place on Monday) by sending an email and SMS-message to the operating surgeon and entering the randomized treatment group into the electronic patient registry. The clinical investigators are blinded from the randomization procedure. Recruitment and randomization is continued until 120 patients are enrolled in the study.

Following anamnestic patient characteristics are recorded:
age at primary injury, mechanism of primary injury, number of dislocation episodes, degree of instability (dislocations at sleep, during daily activities, at sports, no dislocations), level (elite, competitive, recreational, none) and intensity (times per week) to perform sports activities (type of sport), pain at rest, subjective visual analogue estimation of the shoulder condition, smoking habits, other diseases, type and ability to work, handedness, and subjective satisfaction on the treatment outcome on a 5-point Likert scale.

Following clinical patient characteristics are recorded:
clinical glenohumeral stability (jerk test, apprehension and relocation tests), clinical signs of hyperlaxity (external rotation range over 90° in 0° abduction position, and/or positive sulcus sign in the inferior drawer test, and/or a positive Gagey test (over 100°), and/or significantly increased translation in the anteroposterior drawer test).

Following shoulder scores are recorded:
Constant score, Western Ontario Shoulder Instability index (WOSI), Oxford Instability Score (Oxford score), Subjective Shoulder Value (SSV) and instability severity index score (ISIS). (Constant and Murley 1987, Kirkley et al. 1998, Balg and Boileau 2007, Gilbart and Gerber 2007).
A blinded physiotherapist performs all scorings with patient wearing a shirt (covering the scars around the shoulder).
APPENDIX 2-5.

Following imaging investigation is performed:
X-ray (true ap, 30 degrees oblique ap, Y-, and axillary projections) APPENDIX 6, 2D and 3D CT, and MRA. All the imaging data will be sent and stored in the Turku University Hospital’s picture archive PACS. Computed tomography will be taken of both shoulders (affected and unaffected side).

The timing and method of the data gathering is presented in APPENDIX 7.

Treatment groups:

1) Bankart operation

An arthroscopic Bankart operation is performed in general anaesthesia according to current practise (Provencher 2010). The intra-articular findings are recorded and the anteroinferior labrum and the IGHL are mobilized until subscapular muscle fibers can be seen. The IGHL complex is then re-attached to the freshened neck of the glenoid with 2 to 3 suture anchors according to surgeons preference to re-create labral bumber and capsular tension. In case of a significant Hill-Sachs defect an additional remplisage procedure may be performed according to surgeons’ decision by inserting 1 to 2 more suture anchors, according to surgeon’s preference into the deepest portion of the Hill-Sachs defect and tying the infraspinatus tendon down to fill the bony defect.

2) Latarjet operation

A diagnostic arthroscopy is performed before the Latarjet operation in general anaesthesia. The intra-articular findings are recorded and in case of a significant Hill-Sachs defect an additional remplisage procedure may be performed according to surgeons’ decision by inserting 1 to 2 more suture anchors according to surgeon’s preference into the deepest portion of the Hill-Sachs defect and tying the infraspinatus tendon down to fill the bony defect. Thereafter an open Latarjet operation is performed using standard techniques described by Walch or de Beer (de Beer et al. 2010, Young and Walch 2012). A deltopectoral incision is used. The coracoid process is osteotomized and, depending on the technique used, the ventral (Walch) or medial side (de Beer congruent arc modification) is prepared to bleeding bone. The coracoid process is then transferred through the middle of the subscapularis and re-attached on to the freshened neck of the glenoid, just medial to the joint line with two screws and washers, according to the surgeon’s preference.
Postoperatively all the patients receive an 8-week sick leave and recipe of painkillers (paracetamol + codein 1x4 and ibuprofen 600mg 1x3) to be used if needed. The patient’s arm is immobilized with a simple sling for three weeks. At three weeks the patient is called for physiotherapy and the patient is given guidance to painless free passive range of motion exercises. At six weeks active strengthening program is begun. Thereafter patient is asked to report any incidents regarding the studied shoulder by phone to study nurse. Participation in contact sports is forbidden for all patients until six months after the operative treatment. The patient is called in for a doctor’s control visit at three months, six months, one year, two years, five years, ten years and twenty years postoperatively. In case of re-dislocation or signs of instability occurs the patient is called for and urgent clinical examination. If symptomatic and clinically documented residual instability exists the treatment is considered a failure and the further treatment is planned individually.

4) ETHICS AND SAFETY

This study is conducted according to ethics principles of Helsinki declaration. Both treatments used in this study are well established and considered safe, and used in current clinical practise. All observed or volunteered adverse events regardless of suspected relationship to the study will be recorded. The investigator assesses the likelihood of the adverse event to be caused by the study treatment on a six-grade causality scale (none, unlikely, possible, probable, definite, cannot be classified).

The patients are urged to report any adverse events immediately after appearance to the research nurse and research doctor (SE). The severity of all adverse events is assessed on a three-grade scale (mild, moderate, severe). All adverse events are dealt with in a symptomatically adequate manner and the patients are hospitalized if needed.

A blinded interim (coded groups) analysis of the available outcome data is performed after 60 patients have been recruited and operated on to confirm safety and ethical considerations of the study. In case either technique results in unacceptably high rate of recurrence of instability or other complications, premature discontinuation of the study is considered.
Ethics committee will be informed in case of study discontinuation.

5) PREMATURE DISCONTINUATION

A patient may withdraw consent and discontinue the study prematurely at any time if he or she so wishes.

6) DATA HANDLING

All data for this study is collected from patient files and hospitals’ electronic patient registry (Artux, BCB Medical, Finland). All data is stored and secured in a specific electronic study subject register. Patient data is accessible to investigators only.

7) ASSESSMENTS AND OUTCOME MEASURES

1) The recurrence of instability (re-dislocation, subluxation, positive apprehension) is used as a primary outcome measure together with WOSI score two and five years postoperatively. Secondary outcome measures include: level and intensity to perform sports activities, subjective visual analogue estimation of the shoulder condition, Constant score, Oxford score, and SSV.

2) The pre-operative X-ray and MRA findings are compared with pre-operative CT imaging. The sensitivity and specificity to detect bony pathology in X-ray and MRA imaging is evaluated. All the acquired images are analysed by two separate radiologists at Turku University Hospital. The correlation of bone pathology detected in CT imaging with treatment outcome is further analysed.

3) The degenerative changes on x-rays two and five years post-operatively are graded according to Samilson and Prieto. APPENDIX 8. The differences between and within the study groups are analysed and compared with clinical findings and subjective patient satisfaction. All the acquired images are analysed by two separate radiologists at Turku University Hospital.
8) STATISTICS

The data will be analyzed using methods suitable for clinical trials regarding comparison of parallel treatment groups with repeated measurements. The primary technique will be the analysis of variance of repeated measurements together with generalized linear mixed models for longitudinal data and Cox regression models for survival data. These analytical tools cover methods for analysing different kinds of outcome variables, and are applicable although there is missing data in the measurements during the follow-up. The primary statistical software, to be used is the latest release of SAS system for windows, SAS Institute Inc., Cary, NC, USA.

9) SAMPLE SIZE AND POWER ANALYSES

The amount of residual instability after the operative stabilization is estimated to be 10% in the Latarjet group and 35% in the Bankart group. 90% of all redislocations are expected to occur within the first two years. This makes the possible number of redislocators 4 in the Latarjet group and 14 in the Bankart group at two years follow-up. If the mean WOSI score difference is 10 between the groups (estimated SD 17) and if α is set at 0.05 and power (1-β) at 80 %, a total of 47 patients per group is needed. To have enough statistical power in subgroup analysis, and to compensate for the possible drop-outs (estimate 15 %), a total of 120 patients are recruited into the study.

10) STUDY REGISTRATION

Study is registered in an electronic registry of medical studies at the website ClinicalTrials.gov.

11) AMENDMENT TO THE PROTOCOL

No deviation should be made from the protocol without an amendment. An amendment must be agreed to in writing and signed by the investigator and approved by the ethics committee before its implementation. An amendment, if it is of administrative nature only without affecting the treatment of the patients, may be implemented without ethics committee approval, but the investigator must submit the amendment to the ethics committee for information.
12) PUBLICATION OF THE RESULTS

The study groups are coded, and only after the one-year follow-up is completed for all patients the results are analyzed, the blinding is decoded, and a manuscript is prepared for publication. The investigators are free and willing to publish the results of this study in peer-reviewed journals. The results of this investigation are also published as part of MD Sami Elamo’s thesis on operative treatment of anteroinferior shoulder instability.

13) STUDY CENTERS AND COLLABORATORS

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14) PICOS

| **P** Patients | 120 young (16-25 year old) male patients with clinically documented anteroinferior shoulder instability requiring operative intervention. |
| **I** Intervention | Open Latarjet procedure (n=60) |
| **C** Comparator | Arthroscopic Bankart procedure (n=60) |
| **O** Outcome | Primary outcome measures: recurrence of instability (re-dislocation, subluxation, positive apprehension) and WOSI score. |
| **S** Study design | Randomized controlled study with parallel treatment groups. |
| **S** Study design | Secondary outcome measures: level and intensity to perform sports activities, subjective visual analogue estimation of the shoulder condition, Constant score, Oxford score, and SSV. |
16) TIMETABLE

The study protocol is submitted the Ethics Committee and after the approval the recruitment of participants is commenced. The estimated time of recruitment is two years until the end of year 2015. Thereafter the follow-up will take up to 5 years and the study will be completed by year 2021.

17) FUNDING

At the beginning all participating hospitals will take care of their own patients, imaging and treatment expenses as part of normal patient care. The study nurse and the PhD student are partially employed by the principal investigator and are at use for all clinical researchers for the purpose of this study. Extra funding is applied for the follow-up imaging studies and other cost relating to this study.
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Wellmann M, de Ferrari H, Smith T, Petersen W, Siebert CH, Agneskirchner JD, Hurschler C
Biomechanical investigation of the stabilization principle of the Latarjet procedure.

Yamamoto N, Muraki T, Sperling JW, Steinmann SP, Cofield RH, Itoi E, An KN
Stabilizing mechanism in bone-grafting of a large glenoid defect.

Young AA, Walch G

Zhu YM, Lu Y, Zhang J, Shen JW, Jiang CY
Arthroscopic Bankart repair combined with remplissage technique for the treatment of anterior shoulder instability with engaging Hill-Sachs lesion: a report of 49 cases with a minimum 2-year follow-up.
APPENDIXES

APPENDIX 1

1) The glenoid bone defect is considered significant when the tangential length of the defect is equal or more than 50% of the maximal width of the glenoid surface on a two dimensional en face CT view (Gerber 2002).

![Glenoid Bone Defect CT View](image1)

2) The humeral defect is considered significant when the maximal width of the Hill-Sachs defect is equal or more than 40% of the diameter of the humeral head on a two dimensional axial CT view (Cho 2011, Kaar 2010).

![Humeral Defect CT View](image2)
APPENDIX 2

Constant score

<table>
<thead>
<tr>
<th>OUT-PATIENT CLINIC</th>
<th>SHOULDER UNIT</th>
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<tbody>
<tr>
<td><strong>CONSTANT SCORE</strong></td>
<td></td>
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<tr>
<td>Operation/Diagnosis:</td>
<td>Date:</td>
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<tr>
<td>Examination:</td>
<td>Side: R L</td>
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<tr>
<td>Pre-op</td>
<td>3 months</td>
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<tr>
<td>1 year</td>
<td>2 years</td>
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</table>

**A - Pain (15): Average (1+2)**
- Do you have pain in your shoulder (normal activities)?
  - No = 15 pt.
  - Mild pain = 10 pt.
  - Moderate = 5 pt.
  - Severe or permanent = 0.

  2. Linear scale:
  - If “0” means no pain and “15” is the maximum pain you can experience, please circle where is the level of pain.
  - Points given are inverse to the scale. E.g. level 5 in the scale means 9 points.

  **Level of pain:**
  - Points: 15 14 13 12 11 10 9 8 7 6 5 4 3 2 1 0

**B - Activities of daily living (20)**
- Total (1+2+3+4)

  1. Is your occupation or daily living limited by your shoulder?
  - No = 4.
  - Moderate limitation = 2.
  - Severe limitation = 0.

  2. Are your leisure and recreational activities limited by your shoulder?
  - No = 4.
  - Moderate limitation = 2.
  - Severe limitation = 0.

  3. Is your night sleep disturbed by your shoulder?
  - No = 2.
  - Sometimes = 1.
  - Yes = 0.

  4. Stain to what level you can use your arm for painless, meaningful activities.
  - Waist = 2.
  - Shoulder (shoulder): 4.
  - Neck = 6.
  - Head = 8.
  - Above head = 10

**C - Range of movement** (leave this for the doctor or physiotherapist) (10):
- Total (1+2+3+4)

  1. Forward Flexion:
     - 0 to 30 = 0 pt.
     - 31 to 60 = 2 pt.
     - 61 to 90 = 4 pt.
     - 91 to 120 = 6 pt.
     - 121 to 150 = 8 pt.
     - > 150 = 10 pt.

  2. Abduction:
     - 0 to 30 = 0 pt.
     - 31 to 60 = 2 pt.
     - 61 to 90 = 4 pt.
     - 91 to 120 = 6 pt.
     - 121 to 150 = 8 pt.
     - > 150 = 10 pt.

  3. External Rotation:
     - 0 to 90 = 0 pt.
     - > 90 = 4 pt.
     - > 120 = 8 pt.

  4. Internal Rotation:
     - 0 to 90 = 0 pt.
     - > 90 = 4 pt.
     - > 120 = 8 pt.

**D - Power (25): Points: average (kg) x 2**
- First pull: Second pull: Third pull: Fourth pull: Fifth pull: Average pull:

**TOTAL (100): A + B + C + D**
APPENDIX 3

WOSI Western Ontario Shoulder Instability Index

<table>
<thead>
<tr>
<th>SECTION A: Physical Symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>INSTRUCTIONS TO PATIENTS</td>
</tr>
<tr>
<td>The following questions concern the physical symptoms you have experienced due to your shoulder problem. In all cases, please rate the amount of the symptom you have experienced in the last week. (Please answer with an “X” on the horizontal line.)</td>
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<tr>
<td>1. How much pain do you experience in your shoulder with overhead activities?</td>
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<td>2. How much aching or throbbing do you experience in your shoulder?</td>
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<td>3. How much weakness or lack of strength do you experience in your shoulder?</td>
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<tr>
<td>4. How much fatigue or lack of stamina do you experience in your shoulder?</td>
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<tr>
<td>5. How much clicking, craking or snapping do you experience in your shoulder?</td>
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<tr>
<td>6. How much stiffness do you experience in your shoulder?</td>
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<table>
<thead>
<tr>
<th>SECTION B: Sports/Recreation/Work</th>
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<tbody>
<tr>
<td>INSTRUCTIONS TO PATIENTS</td>
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<tr>
<td>The following section concerns how your shoulder problem has affected your work, sports or recreational activities in the past week. For each question, please indicate the amount of the symptom you have experienced in the last week. (Please answer with an “X” on the horizontal line.)</td>
</tr>
<tr>
<td>11. How much has your shoulder limited the amount you can participate in sports or recreational activities?</td>
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<tr>
<td>12. How much has your shoulder affected your ability to perform the specific skills required for your sport or work?</td>
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</table>

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<tr>
<th>SECTION C: Lifestyle</th>
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</thead>
<tbody>
<tr>
<td>INSTRUCTIONS TO PATIENTS</td>
</tr>
<tr>
<td>The following section concerns the amount that your shoulder problem has affected or changed your lifestyle. Again, please indicate the appropriate amount for the past week with an “X” on the horizontal line.</td>
</tr>
<tr>
<td>13. How much do you feel the need to protect your arm during activities?</td>
</tr>
<tr>
<td>14. How much difficulty do you experience lifting heavy objects below shoulder level?</td>
</tr>
<tr>
<td>15. How much fear do you have of falling on your shoulder?</td>
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<tr>
<td>16. How much difficulty do you experience maintaining your desired level of fitness?</td>
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<table>
<thead>
<tr>
<th>SECTION D: Emotions</th>
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</thead>
<tbody>
<tr>
<td>INSTRUCTIONS TO PATIENTS</td>
</tr>
<tr>
<td>The following questions relate to how you have felt in the past week with regard to your shoulder problem. Please indicate your answer with an “X” on the horizontal line.</td>
</tr>
<tr>
<td>17. How much difficulty do you have “roughhousing or having around” with family or friends?</td>
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<tr>
<td>18. How much difficulty do you have sleeping because of your shoulder?</td>
</tr>
<tr>
<td>19. How anxious are you of your shoulder?</td>
</tr>
<tr>
<td>20. How connected are you about your shoulder becoming worse?</td>
</tr>
<tr>
<td>21. How much frustration do you feel because of your shoulder?</td>
</tr>
</tbody>
</table>
APPENDIX 4

Oxford Instability Score

OXFORD SHOULDER INSTABILITY SCORE

Problems with your shoulder

1. During the last 6 months...
   - how many times has your shoulder slipped out of joint (or dislocated)?
     - Never
     - 1 or 2 times
     - 3 or 4 times
     - More often than 3 or 4 times

2. During the last 3 months...
   - have you had any trouble (or worry) with putting on a T-shirt or pullover because of your shoulder?
     - Trouble / no trouble
     - Slight trouble / worry
     - Moderate trouble / worry
     - Extreme difficulty
     - Impossible to do

3. During the last 3 months...
   - how would you describe the worst pain you have had from your shoulder?
     - None
     - Mild
     - Moderate
     - Severe
     - Unbearable

4. During the last 3 months...
   - how much has the problem with your shoulder interfered with your usual work?
     - Not at all
     - A little bit
     - Moderately
     - Greatly
     - Totally

5. During the last 3 months...
   - have you avoided any activities due to worry about your shoulder – feared that it might slip out of joint?
     - No
     - Yes
       - Occasionally
       - Some days
       - Most days or more
       - Every day or every activity

6. During the last 3 months...
   - has the problem with your shoulder prevented you from doing things that are important to you?
     - No
     - Yes
       - Occasionally
       - Some days
       - Most days or more
       - Every day or many activities

Oxford Instability Shoulder Score

7. During the last 3 months...
   - how much has the problem with your shoulder interfered with your social life?
     - Not at all
     - Occasionally
     - Some days
     - Most days
     - Every day

8. During the last 4 weeks...
   - how much has the problem with your shoulder interfered with your sporting activities or hobbies?
     - Not at all
     - Occasionally
     - Some of the time
     - Most of the time
     - All of the time

9. During the last 4 weeks...
   - how often has your shoulder been ‘on your mind’ – how often have you thought about it?
     - Never or only if someone asks
     - Occasionally
     - Some days
     - Most days
     - Every day

10. During the last 4 weeks...
    - how much has the problem with your shoulder interfered with your ability – or willingness – to lift heavy objects?
      - Not at all
      - Occasionally
      - Some days
      - Most days
      - Every day

11. During the last 4 weeks...
    - how would you describe the pain you usually had from your shoulder?
      - None
      - Very mild
      - Mild
      - Moderate
      - Severe

12. During the last 4 weeks...
    - have you avoided lying in certain positions, in bed at night, because of your shoulder?
      - No nights
      - Only 1 or 2 nights
      - Some nights
      - Most nights
      - Every night
APPENDIX 5

ISIS score

<table>
<thead>
<tr>
<th>Prognostic factors</th>
<th>Points</th>
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<tr>
<td>Age at Surgery (yrs)</td>
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<tr>
<td>≤ 20</td>
<td>2</td>
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<tr>
<td>&gt; 20</td>
<td>0</td>
</tr>
<tr>
<td>Degree of sport participation (pre-operative)</td>
<td></td>
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<tr>
<td>Competitive</td>
<td>2</td>
</tr>
<tr>
<td>Recreational or none</td>
<td>0</td>
</tr>
<tr>
<td>Type of Sport (pre-operative)</td>
<td></td>
</tr>
<tr>
<td>Contact or forced overhead</td>
<td>1</td>
</tr>
<tr>
<td>Other</td>
<td>0</td>
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<tr>
<td>Shoulder Hyperlaxity*</td>
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<tr>
<td>Hyperlaxity (anterior/inferior)</td>
<td>1</td>
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<tr>
<td>Normal</td>
<td>0</td>
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<tr>
<td>Hill-Sachs lesion on AP radiograph</td>
<td></td>
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<tr>
<td>Visible on external rotation</td>
<td>2</td>
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<tr>
<td>Not visible on external rotation</td>
<td>0</td>
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<tr>
<td>Glenoid loss of contour on AP radiograph</td>
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<tr>
<td>Loss of contour</td>
<td>2</td>
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<td>No lesion</td>
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<tr>
<td>Total (points)</td>
<td>10</td>
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APPENDIX 6

Required X-ray projections
APPENDIX 7

**Preoperative eligibility criteria include:** assessment of clinical glenohumeral stability (apprehension and relocation tests, jerk test, clinical signs of hyperlaxity (positive sulcus sign or Gagey test)), and inclusion and exclusion criteria. **Clinical scoring includes:** Constant score and pre- or postoperative anamnestic characteristics.

1) **Preoperative anamnestic characteristics include:** age at primary injury, mechanism of primary injury, number of dislocation episodes, degree of instability (dislocations at sleep, during daily activities, at sports, no dislocations), level (elite, competitive, recreational, none) and intensity (times per week) to perform sports activities (type of sport), pain at rest, subjective visual analogue estimation of the shoulder condition, smoking habits, other diseases, type and ability to work, handedness.

2) **Postoperative anamnestic characteristics include:** number of dislocation episodes, degree of instability (dislocations at sleep, during daily activities, at sports, no dislocations), level and intensity to perform sports activities, pain at rest, subjective visual analogue estimation of the shoulder condition, and ability to work, and subjective satisfaction on the treatment outcome on a 5-point Likert scale.

**Electronic scoring includes:** Western Ontario Shoulder Instability index (WOSI), Oxford Instability Score (Oxford score), Subjective Shoulder Value (SSV).

**Clinical postoperative examination includes:** clinical glenohumeral stability (apprehension and relocation tests).

**Assessment**

<table>
<thead>
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<th>Assessment</th>
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D = doctor

P = physiotherapist

E = electronic
APPENDIX 8

Classification of osteoarthritic changes by Samilson et Prieto.

Fig. 60. Radiological classification of dislocation arthropathy: a) Mild arthrosis evidence on the anteroposterior radiograph of an inferior humeral or glenoid exostosis, or both, measuring <3 mm. b) Moderate arthrosis evidence on the anteroposterior radiograph of an inferior humeral or glenoid exostosis, or both, measuring between 3 and 7 mm, with slight glenohumeraljoint irregularity. c) Severe arthrosis evidence on the anteroposterior radiograph of an inferior humeral or glenoid osteosis, or both, measuring >8 mm, with glenohumeral narrowing and sclerosis. (From [117])