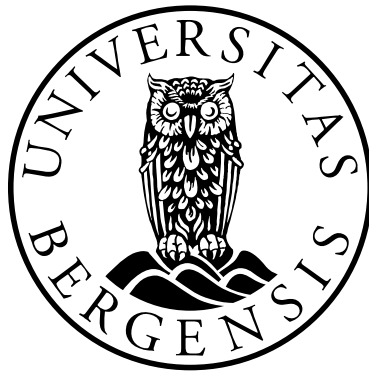# Surgical treatment of shoulder instability in Norway

The Norwegian Shoulder Instability Register

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Dissertation for the degree of philosophiae doctor (PhD)
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In memory of my beloved mother Marianne

Scientific environment

The present PhD project was initiated in 2008 in collaboration with shoulder surgeon colleagues all over Norway, while I was working as a consultant orthopaedic surgeon at Haraldsplass Deaconess Hospital.

Supervision was provided by Professor Leif Ivar Havelin and Professor Eirik Solheim.

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This thesis is part of the PhD programme at the Department of Clinical Medicine, University of Bergen.

Contents

Acknowledgments

The thesis at a glance

	Main findings	**Interpretation**
Paper I	The annual incidence of shoulder stabilisation procedures in Norway is 12/100.000. Anterior instability accounted for 83% of the procedures, followed by posterior (10%) and multi-directional (7%).	Compared to the incidence of traumatic shoulder dislocation, approximately 40% of the patients ended up with a surgical procedure. There were more procedures for posterior and multi-directional instability than anticipated, but it correlated well with published incidence data for traumatic dislocations.
	Arthroscopic labral repair (Bankart) was performed in 88% of patients treated for anterior instability, coracoid transfer (Latarjet) in 10% and only 2% had an open Bankart.	Arthroscopic Bankart was the preferred technique in Norway.
	The register had a national coverage of 54% in the study period.	15% of the procedures included in the register were revisions. This might give an indication of the national revision rate.
Paper II	After an arthroscopic Bankart, there were no differences in functional outcome or recurrence rate after 21 months for patients treated with and without NSAIDs.	The result implies that postoperative use of NSAID in moderate dosages does not affect the outcome of arthroscopic Bankart.
	54% of the outpatients had NSAIDs prescribed post-operatively, compared to 19% of the inpatients.	The use of NSAIDs for postoperative pain management seems to facilitate ambulatory surgery, without any negative effects on the outcome.

Paper III	Recurrence rate for arthroscopic Bankart after 2.7 years was 17%, compared to 7% for open Latarjet. The functional outcome did not differ.	Latarjet yields a better outcome regarding stability, despite a higher proportion of patients with known risk factors for recurrence.
	Revision after a failed arthroscopic Bankart led to an inferior functional outcome compared to primary surgery, also when Latarjet was used for revision.	Due to a demanding procedure with potentially severe complications and no functional difference it is still unclear whether Latarjet can be recommended for patients without bone loss.
	Patients younger than 20 years had a high risk of recurrence after both arthroscopic Bankart and open Latarjet.	Acute arthroscopic Bankart or other treatments need to be considered for the young patient, due to a high rate of recurrence and inferior treatment results in the chronic phase.
	Combined glenoid and humeral bone loss increased the recurrence rate after arthroscopic Bankart.	Patients with a combined bone loss will probably benefit from treatment with a Latarjet procedure.

List of abbreviations

3D	three-dimensional
ALPSA	anterior labroligamentous periosteal sleeve avulsion
CI	confidence interval
CT	computer tomography
GLAD	glenolabral articular disruption
IGHL	inferior glenohumeral ligament
ISIS	instability severity index score
MCID	minimal clinical important difference
MDI	multidirectional instability
MGHL	middle glenohumeral ligament
MRI	magnetic resonance imaging
NOMESCO	Nordic Medico-Statistical Committee
NPR	Norwegian patient register
NSAID	non-steroid anti-inflammatory drug
OR	odds ratio
p	probability value
RCT	randomised controlled trial
PROMs	patient reported outcome measures
SGHL	superior glenohumeral ligament
SLAP	superior labrum anterior posterior lesion
WOSI	Western Ontario shoulder instability index

Abstract

Shoulder dislocation affects approximately 1300 person per year in Norway. The dislocation is normally caused by a fall on the outstretched arm. Many of the patients develop chronic recurrent instability, where the shoulder joint re-dislocates during sport activity or daily living. Other patients experience habitual chronic instability without an initial trauma.

The current thesis has evaluated the surgical treatment of shoulder instability using data from the Norwegian Shoulder Instability Register that was established as a part of the project. The results are published in three papers.

In Paper I we reported that the annual incidence rate of shoulder stabilisation surgery was 12 per 100.000 inhabitants. Compared to the annual incidence of shoulder dislocations approximately 40% of the patient with a primary dislocation underwent surgery. Anterior instability accounted for 83% of the procedures whereas posterior and multi-directional instability constituted 10% and 7% respectively. An arthroscopic labral repair (Bankart) was performed in 88% of the patients with primary anterior instability. In revision cases an open technique was used for 50% of the patients and coracoid transfer (Latarjet) was the dominating technique performed with an open approach. There was a significant improvement of the functional score for all patient groups. Primary anterior Bankart had a 1-year outcome of 75% on the WOSI score and a recurrence rate of 10%. Patients with posterior instability had a slightly worse WOSI score at follow-up (63%), and a recurrence rate of 16%.

In Paper II we investigated if postoperative prescription of non-steroid anti-inflammatory drugs, NSAIDs, had any effect on the outcome after arthroscopic Bankart. In total only one third of the patients were treated with NSAIDs in the postoperative phase. The outcome for patients treated with and without NSAIDs did not differ after a mean follow up of 21 months. WOSI score was 75% and recurrence rate 12% for patient with NSAID treatment. For the control group the corresponding figures were 74 and 14%. Reoperation rates were 5% in both groups. 43% of the patients treated with an arthroscopic Bankart had an ambulatory procedure. 54% of the outpatients had non-

steroid anti-inflammatory drugs, NSAIDs, prescribed post-operatively, compared to 19% of the inpatients. The result implies that postoperative use of NSAID in moderate dosages does not affect the outcome of arthroscopic Bankart and that it may facilitate ambulatory surgery.

In paper III the outcomes of arthroscopic Bankart and open Latarjet were compared. After a mean 2.7 years follow-up we found a significantly higher recurrence rate of 17% after arthroscopic Bankart, compared to 7% after open Latarjet. There was a significant improvement but no difference between the treatment groups in the functional outcome, with a WOSI score of 74% for arthroscopic Bankart and 75% for Latarjet. Patients with recurrence of instability did not improve their score. Item analysis of the WOSI score indicated that patient with a Latarjet felt more secure on the stability of their shoulder, but had a lower score on mobility.

In multiple logistic regression analysis the risk of recurrence after arthroscopic Bankart was further emphasised, with an odds ratio (OR) of 12.8 (CI 95%: 1.45-113, p=0.002). Age below 20 years at time of surgery was a risk factor for recurrence after both procedures (OR 2.24, CI 95%: 1.36-3.69, p=0.002). A combination of glenoid bone loss and an engaging Hill Sachs lesion was a risk factor for recurrence after arthroscopic Bankart (OR 12.6, CI 95%: 1.61-98, p=0.014), but not after a Latarjet procedure.

WOSI for revision patients was 67% for arthroscopic Bankart and 65% for Latarjet at follow-up, with recurrence rates of 24 vs. 17%. WOSI-score was significantly lower for revisions compared to primary procedures (p<0.05), but there was no statistical significant difference between the two techniques.

This thesis supports previous studies that have shown a high recurrence rate after arthroscopic Bankart. The Latarjet procedure had significantly fewer recurrence events, despite a higher proportion of patients with bone loss. Still, there was no difference in the functional outcome, indicating that there may be other drawbacks with this treatment. Patients with bone loss, especially when present on both the humerus and glenoid, seem to profit on treatment with a Latarjet procedure. Patient below 20 years of age has a poor prognosis for both treatment options.

Norsk sammendrag (Summary in Norwegian)

Skulderluksasjon rammer ca. 1300 personer i Norge årlig. Luksasjonen forårsakes vanligvis av et fall på utstrakt arm. Mange av pasientene utvikler kronisk instabilitet der skulderleddet går ut av ledd på ny ved idrett eller daglig aktivitet. Et mindretall pasienter rammes av kronisk instabilitet uten forutgående traume.

For å studere forekomst og effekt av kirurgisk behandling for skulderinstabilitet, etablerte studiegruppen i 2008 Norsk Register for skulderinstabilitetskirurgi. Resultater fra dette registeret er publisert i tre delarbeider:

Delarbeid I fant en årlig insidens for skulderstabiliserende kirurgi på 12 per 100.000 innbyggere. Sammenlignet med antall pasienter med primær skulderluksasjon tyder dette på at ca. 40% av pasienter med skulderluksasjon blir operert i skulderen. Fremre instabilitet var årsak til 83% av operasjonene, mens bakre og multidireksjonal instabilitet var årsak til henholdsvis 10 og 7%. For fremre instabilitet ble artroskopisk reparasjon av labrum utført hos 88% av pasienter uten tidligere kirurgi i skulderen og 10% ble operert med Latarjets prosedyre. Ved revisjoner ble omtrent halvparten operert med åpen kirurgi, der Latarjets prosedyre var den dominerende metoden. Funksjonsskår ble signifikant forbedret for alle behandlingsgrupper sammenlignet med utgangspunktet. Pasienter som hadde fått operasjon med primær artroskopisk labrumreparasjon hadde 1 år postoperativt en WOSI-skår på 75% og en residivfrekvens på 10%. Pasienter med bakre instabilitet hadde en noe lavere WOSI-skår (63%), og en residivfrekvens på 16%,

I delarbeid II studerte en effekt av postoperativ behandling med antiinflammatorisk medisin, NSAIDs, etter skulderstabiliserende operasjon med artroskopisk reparasjon av labrum. En tredjedel av pasientene fikk resept på NSAIDs for postoperativ smertebehandling. Pasientene ble i gjennomsnitt fulgt i 21 måneder postoperativt. En fant da at WOSI-skår var 75% og residivfrekvens 12% for pasienter behandlet med NSAID. Tilsvarende tall for kontrollgruppen var 74 og 14%. Reoperasjonsfrekvensen var 5% i begge grupper. Resultatmessig var det ikke forskjell mellom pasienter med og uten NSAID-behandling på oppfølgingstidspunktet. En fant videre at 43% av pasientene som

ble behandlet med artroskopisk labrumreparasjon ble operert dagkirurgisk. 54% av de dagkirurgiske pasientene fikk resept på NSAIDs, postoperativ, mens bare 19% av inneliggende pasienter fikk resept på NSAIDs. Dette tyder på at NSAIDs gitt i moderate doser postoperativt ikke påvirker resultatet ved artroskopisk labrumreparasjon, og at behandling med NSAIDs kan forenkle dagkirurgisk behandling.

I delarbeid III ble behandlingsresultatene for artroskopisk labrumkirurgi og åpen Latarjet sammenlignet. På oppfølgingstidspunktet etter i gjennomsnitt 2.7 år ble det påvist en signifikant høyere residivfrekvens (17%) etter artroskopisk labrumreparasjon sammenlignet med 7% etter åpen Latarjet. I begge behandlingsgruppene ble det påvist en signifikant funksjonsforbedring, med en WOSI-skår på 74% for artroskopisk labrumreparasjon og 75% for Latarjet. Det var ingen statistisk signifikant forskjell mellom gruppene. Pasienter med residiv av instabilitet opplevde ingen forbedring av sin funksjonsskår. Analyse av elementene i WOSI-skjemaet påviste at pasienter med Latarjet i større grad stolte på skulderstabiliteten, men hadde en lavere skår på bevegelighet.

Ved multippel regresjonsanalyse ble residivrisikoen etter artroskopisk labrumreparasjon ytterligere forsterket, med en odds-ratio (OR) på 12.8 (CI 95%: 1.45-113, p=0.002) i forhold til Latarjets operasjon. Alder under 20 år på operasjonstidspunktet var en risikofaktor etter begge operasjonstypene (OR 2.24, CI 95%: 1.36-3.69, p=0.002). Kombinasjon av erosjon av glenoidkanten og en engasjerende Hill Sachs-lesjon medførte forhøyet residivrisiko etter artroskopisk labrumreparasjon (OR 12.6, CI 95%: 1.61-98, p=0.014), men ikke etter Latarjet.

For revisjonspasienter var WOSI på oppfølgingstidspunktet 67% for artroskopisk labrumreparasjon og 65% for Latarjet, med residivfrekvens på 24 respektive 17%. WOSI-skår for revisjonspasienter var statistisk signifikant lavere enn for primæroperasjoner (p<0.05), men forskjellen mellom de to operasjonsmetodene var ikke statistisk signifikant.

Avhandlingen støtter tidligere publiserte artikler som har vist en høy residivfrekvens etter artroskopisk labrumreparasjon. Latarjet medførte signifikant færre residiv til tross

for en høyere andel pasienter med beintap. Likevel var der ikke noen forskjell i funksjonsskår, noe som kan tyde på at denne behandlingen har andre ulemper. Pasienter med beintap, spesielt ved samtidig forekomst på glenoid og humerus, ser ut til å ha nytte av Latarjets operasjon. Pasienter yngre enn 20 år på operajsonstidspunktet hadde dårlig prognose i begge behandlingsgruppene.

List of publications

The thesis is based on the following papers, referred to in the text by their Roman numerals:

I   Blomquist J, Solheim E, Liavaag S, Schroder CP, Espehaug B, Havelin LI. **Shoulder instability surgery in Norway: the first report from a multicenter register, with 1-year follow-up.** Acta Orthop. 2012 Apr;83(2):165-70.

II   Blomquist J, Solheim E, Liavaag S, Baste V, Havelin LI. **Do nonsteroidal anti-inflammatory drugs affect the outcome of arthroscopic Bankart repair?** Scand J Med Sci Sports. 2014 Dec;24(6):e510-514.

III   Blomquist J, Solheim E, Liavaag S, Havelin LI. **Arthroscopic Bankart versus Latarjet for anterior shoulder instability.** Manuscript submitted.

1 Introduction and background

The human shoulder is distinguished from the other joints of the body by its high range of motion, which is a prerequisite for a normal use of the upper extremity. The high mobility is achieved at the expense of stability and the shoulder is therefore the most common site of joint dislocations (Yang et al. 2011). At the primary dislocation the constraining soft tissue of the shoulder is permanently damaged. This leads to a decreased stability and a risk of *recurrent* dislocations, in the same direction as the original dislocation. In many cases recurrent dislocations occurs during light daily activity – and in some cases even at night during sleep – and and can be very disabling for the patient.

Several surgical techniques have been developed to improve shoulder stability for patients with recurrent dislocations. To be successful, the procedure need to either durably restore the anatomy of the joint to its original form or construct an alternative mechanism of stability. Today, reattachment of the soft tissue, done by a minimal invasive endoscopic approach, is the dominating procedure (Zhang et al. 2014). The method is appealing as it restores the original anatomy, but has limitations considering long term stability (Castagna et al. 2010; Bessière et al. 2014).

An alternative technique is to transfer the coracoid, the bony origin of the conjoined tendon of the biceps and coracobrachialis muscles, to the glenoid fossa. This method prevents dislocations by creating a sling effect between the tendon and the subscapularis muscle in addition to the increased width of the glenoid surface, which gives a higher long-term stability. Being a more technically demanding procedure with a reported complication rate of 30% (Griesser et al. 2013), the technique is often reserved for patients with damages to the bone or contact sport athletes with a high risk of recurrence.

1.1 Anatomy of the shoulder

The shoulder complex consists of the humeral, scapular and clavicular bones. The connection between the upper extremity and the axial skeleton is conveyed through

three anatomic joints; the glenohumeral, the acromioclavicular and the sternoclavicular joints. Colloquially the glenohumeral joint is often referred to as the shoulder joint. In addition to the three joints, the scapulothoracic articulation constitutes a functional connection between the thorax and the scapula. This is formed by the convex surface of the posterior thoracic cage and the concave surface of the anterior scapula, where muscular stabilisation of the scapula maintain a stable base and allow a dynamic positioning of the glenoid fossa during glenohumeral elevation (Williams et al. 1999). The clavicula works as a lever for the scapula against the axial skeleton and all movements in the acromio- and sternoclavicular joints are a direct result of an altered position of the scapula (Kibler and Sciascia 2010). Active motion in the glenohumeral joint is achieved by the rotator cuff, the deltoid, the pectoralis, the teres major and the latissimus dorsi muscles.

The scapula is oriented 30° anteriorly on the chest wall, with a 5-7° mean retroversion of the glenoid. Together with a physiological 25-30° retroversion of the humeral head and a relative wide joint capsule this allows for the exaggerated range of motion of the shoulder compared to other joints (Randelli and Gambrioli 1986; Williams et al. 1999; McCluskey and Getz 2000) (Figure 1).
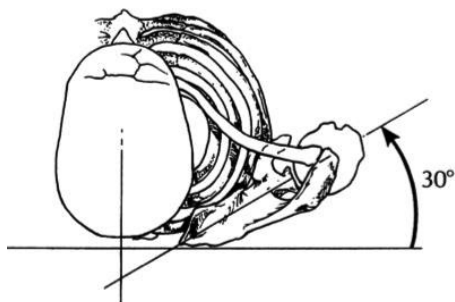
Figure 1a: Orientation of the scapula on the chest wall.
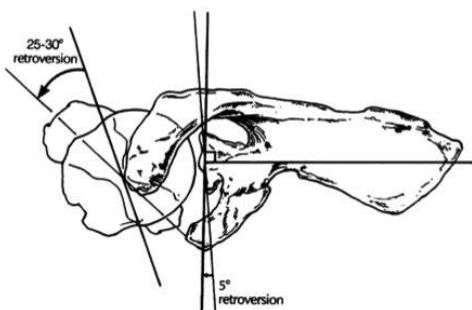
Figure 1b: Retroversion of the glenoid and the humeral head.

Reprinted with permission, McCluskey and Getz: Pathophysiology of anterior shoulder instability. *J Athl Train.* 2000;35(3):268–272.

The glenohumeral joint is a ball and socket joint, where the socket consists of the disk shaped glenoid fossa of the scapula and the ball is the humeral head. The bony radius of the humeral head and the glenoid fossa differs, but due to an increasing cartilage thickness in the periphery the joint surfaces are congruent in normal position (Soslowsky et al. 1992a) (Figure2a). With increasing abduction there is however a mismatch in radius, allowing translation of the head (Zumstein et al. 2014). There is a large difference in the area of the joint surfaces and only one-third of the humeral head is covered by the glenoid at any time (Soslowsky et al. 1992b) (Figure 2b).
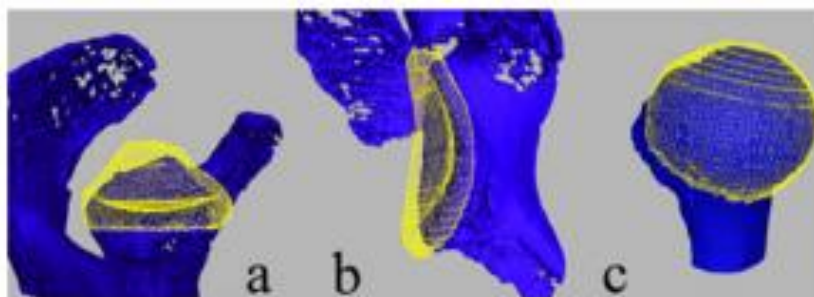
Figure 2a: Visualisation of the cartilaginous (yellow) and osseous structure (blue) in (a) infero-superior (b) anteroposterior view of the glenoid and (c) frontal view of the humeral head.

Reprinted, creative commons, Zumstein et al.: The glenohumeral joint - a mismatching system? A morphological analysis of the cartilaginous and osseous curvature of the humeral head and the glenoid cavity. *J Orthop Surg Res*. 2014;9:34
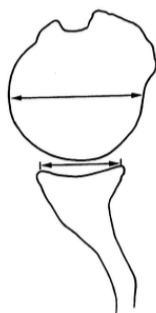
Figure 2b: Only one-third of the humeral head is covered by the glenoid at any time. The stabilising mechanisms of the shoulder keep the humeral head centered in the glenoid fossa during rotation and abduction.

Reprinted with permission, McCluskey and Getz.: Pathophysiology of anterior shoulder instability. *J Athl Train*. 2000;35(3):268–272.

The shoulder depends on both passive and active stabilising mechanisms to maintain stability. Passive stability is mainly achieved by the restraining structures of capsule, glenohumeral ligaments and glenoid labrum. A suction effect caused by a negative intracarticular pressure and the cohesion and adhesion forces of the joint fluid also contribute to the stability, although probably only significantly at low load (Gibb et al. 1991; Pagnani and Warren 1994; Warner et al. 1999).

The rotator cuff muscles actively stabilises the glenohumeral joint by compressing the humeral head against the concave glenoid surface, allowing concentric rotation of the humeral head on the glenoid. Through this mechanism, termed concavity-compression, the rotator cuff may be the primary stabiliser of the glenohumeral joint during mid range of motion, where the capsuloligamentous structures are lax. In end-range positions, shoulder muscle activity protects the capsuloligamentous structures by limiting the joint's range of motion and by decreasing strain in these structures (Lippitt and Matsen 1993; Warner et al. 1999; Labriola et al. 2005).

Labrum

The labrum is a fibrocartilaginous structure with a triangular cross-sectional profile. The superior part of the labrum has a distinctly different morphology compared with the inferior part. The superior and anterosuperior portions are loosely attached to the glenoid with thin connective tissue that stretches easily. The macro-anatomy of those portions is similar to that of the meniscus of the knee. The superior labrum and the biceps tendon have a close association both grossly and histologically. At the twelve o'clock position the labrum inserts directly into the biceps tendon distal to the insertion of the tendon to the supraglenoid tubercle, and the collagen fibers of the labrum and biceps tendon are intermingled in this area. Inferiorly the labrum is firmly attached to the glenoid rim and appears as a fibrous extension of the articular cartilage (Cooper et al. 1992).

The labrum increases the depth of the glenoid by approximately 50% and increase the articulating area of the glenoid cavity (Howell and Galinat 1989) (Figure 3). The articular cartilage also increases the depth of the glenoid because it is thicker in the periphery than in the central area and together the labrum and the cartilage make the articulating glenoid surface more congruent to the humeral head, which is a prerequisite for the concavity-compression stabilising mechanism of the joint (Soslowsky et al. 1992a; McCluskey and Getz 2000).
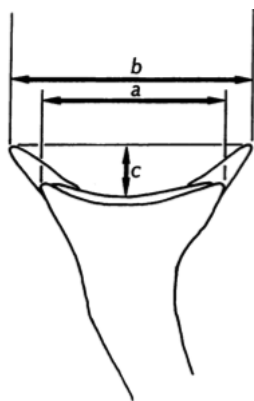
Figure 3: The effect of labrum on the depth of the glenoid. The glenoid articular surface (line a) is relatively flat and small compared with the humeral head surface. Line b is the total width of the glenoid labrum. The glenoid labrum increases the glenoid depth (line c) and increases the glenoid cavity surface area.

Reprinted with permission, McCluskey et al.: Pathophysiology of anterior shoulder instability. *J Athl Train*. 2000;35(3):268–272.

Capsule

The joint capsule is voluminous and stretchable to allow for the large range of motion in the glenohumeral joint. It is a thin collagen structure encircling the glenohumeral joint and attaches to the labrum on the glenoid edge and to the humeral head directly medial to the rotator cuff. The capsule contains more rigid reinforcements, the glenohumeral ligaments, which are mainly located in the anterior and inferior part and constrain the range of motion and provide stability at end-range. The posterior capsule is the thinnest part of the capsule, with no direct posterior ligamentous structures.

The existence of a reflex arc from the glenohumeral capsule to several muscles crossing the shoulder joint was found in an animal model (Guanche et al. 1995). This implies that the capsule plays a proprioceptive role and extends the concept of synergism between the passive (ligaments) and active (muscles) restraints of the glenohumeral joint. This was further investigating by Jerosh et al., who found a higher grade of anteroposterior translation in the shoulders of healthy volunteers after intraarticular injection of lidocaine (Jerosch et al. 1993).

Glenohumeral ligaments

The three glenohumeral ligaments extend from the glenoid labrum and are attached to the humerus (Figure 4). The anatomy and the stabilising effect of the glenohumeral ligaments were investigated by Turkel et al. in a dissection study with sequential cutting (Turkel et al. 1981).
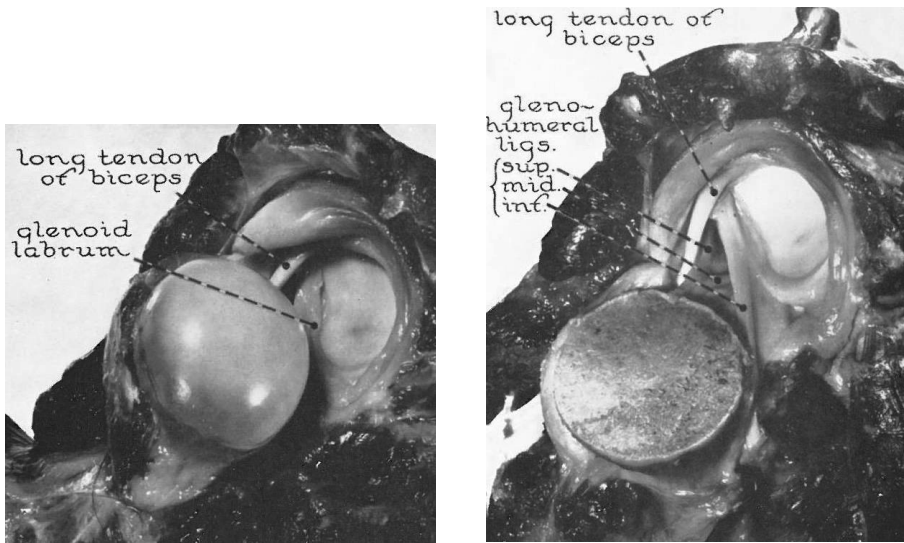
Figure 4: Posterolateral view of the shoulder with the glenohumeral ligaments and the labrum. Humeral head is resected in the right image for better visualisation of the ligaments.

Reprinted with permission, Recurrent dislocation of the shoulder by H.F. Moseley, 1961, E&S Livingstone publisher.

The superior glenohumeral ligament (SGHL) originates from the anterosuperior part of the glenoid and labrum and inserts on the top of the lesser tuberosity. It provides static restraint to inferior translation of the adducted shoulder and together with the subscapularis muscle it restricts external rotation in the shoulder at 0° of abduction.

The middle glenohumeral ligament (MGHL) originates from the upper third and middle part of the glenoid and anterior labrum. It crosses the subscapularis tendon before it attaches to the lesser tuberosity. At 45° of abduction the middle glenohumeral ligament, together with the subscapularis muscle, restricts external rotation.

The inferior glenohumeral ligament (IGHL) consists of a thick anterior band and a thin and less prominent posterior band with a thin capsule pouch between these bands inferiorly. The anterior band extends from the anteroinferior labrum and glenoid rim to the humeral neck and the lesser tuberosity. At 90° of abduction the IGHL and especially its anterior rim prevents anterior dislocation and the subscapularis muscle is no longer effective in supporting the restraining ligaments, as it is positioned too high to cover the inferior part of the humeral head. The anterior portion of the inferior glenohumeral

ligament is the most important factor for stability, but MGHL and the subscapularis muscle provides support. The role of the inferior glenohumeral ligament as the primary stabilising structure of the shoulder is confirmed by other studies and it is shown that it follows the humeral head in rotation and provide a dynamic stabilising effect (O'Brien et al. 1990; O'Connell et al. 1990; Warner et al. 1993) (Figure 5).
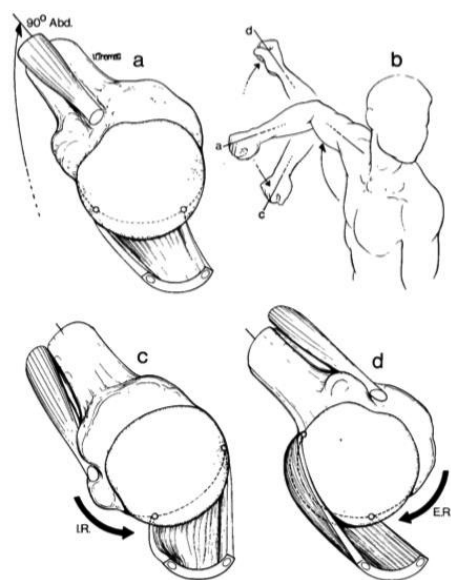
Figure 5: The dynamic stabilising properties of the inferior glenohumeral ligament complex during rotation.

Reprinted with permission, O'Brien et al.: The anatomy and histology of the inferior glenohumeral ligament complex of the shoulder, Am J Sports Med. 1990;18(5):449–456.

Active stabilisers of the shoulder joint

Activation of the rotator cuff muscles and the long head of the biceps compresses the humeral head into the glenolabral socket, thereby stabilising the shoulder by the concavity-compression mechanism. Further, the rotator cuff balance the humeral head by force-couple between the muscles traversing the shoulder joint as response to activation of stretch receptors in the capsule (Guanche et al. 1995; Hsu et al. 1997). Lephart et al. studied proprioception in patients before and after stabilising surgery compared to healthy controls. They found that the proprioception was significantly reduced in unstable shoulders and returned to almost normal in surgically repaired shoulders (Lephart et al. 1994). This indicates that the glenohumeral ligaments provide neurologic feedback that mediates joint position sensibility and muscular reflex stabilisation of the joint.

Active scapula positioning is important for the shoulder joint stability, and is of special importance in throwing athletes and in patients with atraumatic shoulder instability (Burkhart et al. 2003; Eisenhart-Rothe et al. 2005). Scapular dyskinesia alters normal shoulder biomechanics and joint stability by altering the scapular positions to an increased anterior tilt, increased internal rotation, decreased upward rotation, and increased protraction. These positions have the effect of increasing the glenohumeral angle beyond the "safe zone". The result is increased anterior shear, with increased tensile loads on the anterior band of the IGHL. The scapular protraction also decreases maximum rotator cuff activation, thereby decreasing the concavity-compression mechanism that provides dynamic stability (Cooper et al. 1992; Kibler and Sciascia 2015).

1.2 Pathoanatomy of the unstable shoulder joint

The most common cause of a shoulder dislocation is an indirect trauma where the arm is forced in abduction and external rotation (Tanaka et al. 2012) until the stress on the anteroinferior capsulolabral comples exceeds its tensile strength (Bigliani et al. 1992). The stabilising soft-tissue of the capsulolabral complex is ruptured, normally as an avulsion of the insertion at the glenoid rim (Baker et al. 1990; Hintermann and Gächter 1995; Liavaag et al. 2011a) (Figure 6) and the humeral head is forced out of the joint socket. The joint capsule is stretched and sometimes avulsed from the humerus.
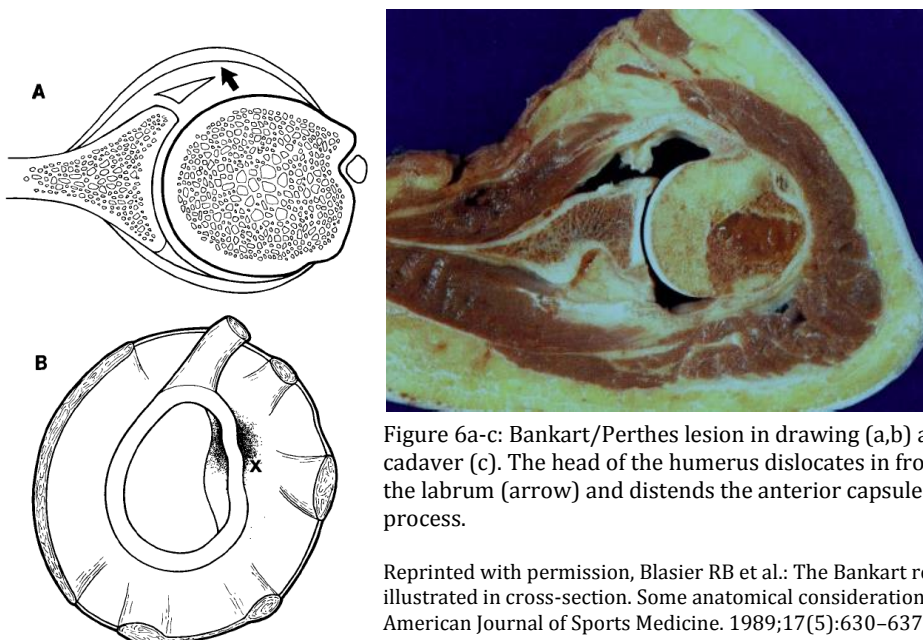
Figure 6a-c: Bankart/Perthes lesion in drawing (a,b) and cadaver (c). The head of the humerus dislocates in front of the labrum (arrow) and distends the anterior capsule in the process.

Reprinted with permission, Blasier RB et al.: The Bankart repair illustrated in cross-section. Some anatomical considerations. The American Journal of Sports Medicine. 1989;17(5):630–637.

In all but a few cases the morphological appearance of the capsule normalises during the first 4 weeks after the dislocation (Liavaag et al. 2011a), although there is an elongation of the ligaments affecting their tensile properties (Urayama et al. 2003). The labrum do normally not heal in its anatomic position, but either fails to reattach to bone, referred to as a Bankart or Perthes lesion (Broca and Hartmann 1890; Perthes 1906; Bankart 1923) (Figure 6), or adheres too medial on the scapular neck, known as an ALPSA-lesion (Neviaser 1993a).

Associated bone defects

In many cases of shoulder dislocation there is an associated bony injury in form of an indentation of the posterosuperior part of the humeral head. The indentation is made when the hard anterior rim of the glenoid meets the softer cancellous bone of the humerus. It was first described by Malgaigne in 1855, but is normally referred to as a Hill-Sachs lesions after the article by Hill and Sachs in 1940 (Malgaigne 1855; Hill and Sachs 1940) (Figure 7).

Figure 7: A dislocated shoulder with a Hill Sachs-lesion of the humeral head, viewed from posterior on a 3D CT-scan.

Reprinted with permission, M J Fuller, www.wikiradiography.net

A dislocation may also lead to fractures of the glenoid, either as an avulsion of a tiny fragment of the rim at the insertion of the labrum (Bankart fracture), or as a larger fragment that contains part of the joint surface, a glenoid fracture. There are several classifications of glenoid fractures. Ideberg´s classification is the most commonly used (Ideberg et al. 1995). In patients with chronic instability there is often a

defect of the anteroinferior glenoid where the bone is resorbed, termed glenoid erosion. If the erosion is extensive the lesion is called "inverted pear" due to the appearance of the glenoid on parasagittal CT views, first used by Burkhart and de Beer (Burkhart and De Beer 2000)(Figure 8).

Figure 8.
A: Normal glenoid
B: Bankart fracture
C: "Inverted pear"
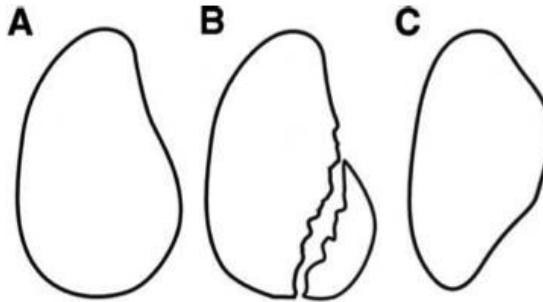
Due to extensive erosion of the anteroinferior part, the normally pear-shaped glenoid resembles a pear standing on the top.

Reprinted with permission, Burkhart and De Beer: Traumatic glenohumeral bone defects and their relationship to failure of arthroscopic Bankart repairs. Arthroscopy, 2000;16(7):677–694.

Biomechanical cause of instability

The incomplete healing of the labrum precludes several of the mechanisms that contributes to shoulder stability; first, the suction effect between the humeral head and the glenoid is revoked as the labrum no longer provides a seal between the joint surfaces. Second, the concavity-compression mechanism will not work properly, as the labrum will be unstable in the direction of the injury and not able to contain the humeral head at higher shearing forces (Lazarus et al. 1996). Third, the humeral head will be displaced towards the injury even when unloaded (Fehringer et al. 2003) and this might affect proprioception and the dynamic stabilisation by the rotator cuff.

Traditionally the anteroinferior labrum avulsion has been regarded as the essential lesion of anterior traumatic shoulder dislocations, but it is not pathognomonic. Although the lesion is very often present after traumatic instability the reported percentage of Bankart lesions in patients with anterior instability varies between 83 and 100% (Baker et al. 1990; Norlin 1993; Taylor and Arciero 1997; Yiannakopoulos et al. 2007). Further, experimental studies have shown that the shoulder will not dislocate solely by the creation of a Bankart lesion (Speer et al. 1994; Pouliart et al. 2006). The

pathomechanism behind posttraumatic chronic instability is therefore thought to be a combination of several factors, where elongation or changes in tensile properties of the capsule is the most important (Bigliani et al. 1992; Urayama et al. 2003; Browe et al. 2013).

A defect in the glenoid rim or a large Hill-Sachs lesion aggravates the instability by diminishing the retaining concavity-compression force when the arm is positioned in abduction and external rotation (Burkhart and De Beer 2000; Bushnell et al. 2008; Olds et al. 2015). Avulsion of the capsule on the humeral side (HAGL-lesion) is a rare cause of recurrent instability. Without an attachment to the humeral head the glenohumeral ligament will not tighten in abduction and external rotation and the joint will dislocate (Wolf et al. 1995). Rupture of the rotator cuff, especially the subscapularis tendon, at the primary dislocation is associated with recurrence of instability in older patients (Itoi and Tabata 1992; Neviaser and Neviaser 1995). In addition, hyperlaxity (Olds et al. 2015), congenital deficiency of the normal glenoid concavity (Moroder et al. 2015) or abberant version of the glenoid (Gottschalk et al. 2015) are inherent factors that are predisposing factors of instability.

1.3 Classification of shoulder instability

Glenohumeral joint instability is a common disorder, yet the definition and classification of instability remains unclear without an unanimous agreement on how to classify the condition. Classification must take into account the degree and direction of instability, associated soft-tissue and bony lesions and the cause of instability, for example trauma (Kuhn 2010).

Degree of instability

Shoulder dislocation is defined as a complete separation of the joint surfaces of the humeral head and the glenoid fossa. Normally a forced reduction or at least a repositioning of the arm is required to reduce the joint and a dislocation is normally accompanied by irreversible structural damage to the capsulolabral complex and often bone.

Subluxation is a partial dislocation, where the humeral head retain some contact with the joint socket. The humeral head regains its position immediately and no repositioning manoeuvre is required, but the patient feels an acute discomfort and may have a feeling of the joint being out of position. If a subluxation is provoked during a medical examination it can be perceived by the examiner as a twitch when the humeral head regains its natural position. Structural damage to the joint is less pronounced than for dislocations, but is normally present.

Apprehension refers to a discomfort and feeling that the shoulder is about to pop out when the shoulder is positioned in a way that put stress on dysfunctional stabilising structures of the shoulder. A slight displacement of the humeral head is present, but there is no twitch when it returns to its normal position. The condition cannot be verified objectively, but is normally very consistent and reproducible and a good indication of an underlying true instability.

The term shoulder instability includes all degrees of instability from dislocations to apprehension. It must be distinguished from hyperlaxity, which refers to a congenital condition with abnormally large range-of-motion due to a wide joint capsule, but without instability symptoms. Hyperlaxity predisposes for, and can coexist with instability, but it is common to have one condition and not the other (Merolla et al. 2015).

Precipitating cause
Shoulder instability is normally induced by trauma, but for patients with hyperlaxity it can appear without a defined traumatic event, often with a gradual onset in the teen years or early 20s. Patients with atraumatic instability normally have no or only discrete structural damage to the capsulolabral insertion, as the wider joint capsule allows instability without detachment of the constraining soft tissue. In cases with true dislocations there are however intra-articular findings also in this group of patients (Werner et al. 2004).

<u>Direction</u>

The instability can be directed anterior, posterior or as a combination where the shoulder is unstable in one or both of these directions as well as inferiorly. One direction usually dominates, with only subluxations for the other directions. The terms bi- or multidirectional instability is used for shoulder instability in more than one direction and it is associated with hyperlaxity and atraumatic instability.

1.4 Epidemiology of shoulder instability

The reported overall incidence of first-time glenohumeral dislocation varies depending on the study population and definition, but is in the general population reported from 11 to 26 per 100.000 person-years in different countries (Liavaag et al. 2011b; Olds et al. 2015). The exact incidence of both primary and recurrent dislocation in the population remains unknown. The main reason for this is that many patients do not seek medical attention and Hovelius et al. reported in a nationwide prevalence study in Sweden in 1982 that nearly 50 % of the people with primary dislocations did not visit hospital or a physician (Hovelius 1982). For subluxation, the figure is most likely even higher. The same study estimated the prevalence of shoulder instability to be 1.7% in the grown-up population.

Men have almost 3 times higher incidence than women and males between 20 and 35 years dominate. There is a second hump on the incidence curve consisting of women above 75 years in the study to Zacchilli and Owens (2010) (Figure 8). Liavaag et al. (2011b) confirmed the dominance of young males, but found an equal gender distribution among the older patients.
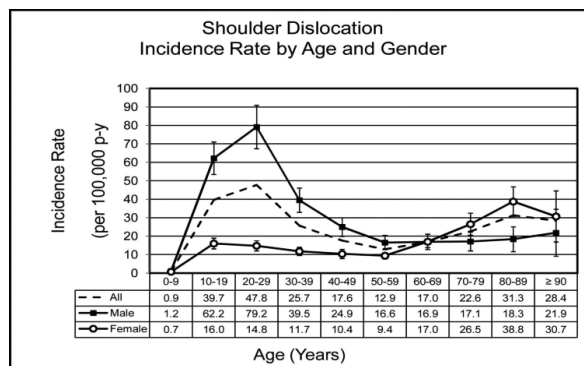
Figure 8: Incidence curve for shoulder dislocation related to age and gender.

Reprinted with permission, Zacchilli and Owens: Epidemiology of Shoulder Dislocations Presenting to Emergency Departments in the United States. J Bone Joint Surg Am. 2010;92(3):542–549.

The annual incidence of first time shoulder instability episodes in a young, athletic military population is reported to be 1.8%, with 80% anterior instability and only 21% of the patients presents with a complete dislocation after the initial trauma (Owens et al. 2007). Hovelius found that 8% of active elite ice hockey players in Sweden had a history of shoulder dislocation (Hovelius 1978).

1.5 Conservative treatment of shoulder dislocations

Reduction

The first description of shoulder instability dates back to ca. 1200 BC, where a wall painting in the tomb of Ipuy, Egypt, probably demonstrates the reduction of a dislocated shoulder (Figure 9). The reduction technique resembles the technique Kocher described 3070 years later (Cunningham 2011).
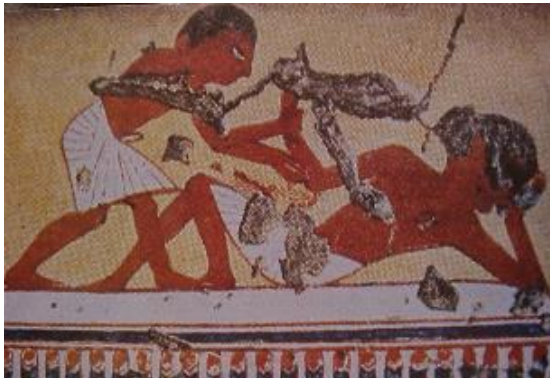
Figure 9a: Detail of wall painting from the tomb of Ipuy, Luxor, Egypt, 1200 BC

Figure 9b: Schematic drawing depicting the same scene of a patient and a man manipulating a dislocated shoulder with the technique of Kocher.

Reproduced with permission and copyright © of the British Editorial Society of Bone and Joint Surgery, Hussein: Kocher's method is 3,000 years old. J Bone Joint Surg Br. 1968;50(3):669–671. Republished from: Davies, N. de Garis. *Two Ramesside Tombs at Thebes.* Robb de Peyster Tytus Memorial Series, Volume V. 1927. New York, The Metropolitan Museum of Art. (Plate XXXVIII)

Hippocrates (460-377 BC) described several techniques to reduce a dislocated shoulder all based upon traction of the injured arm, but with the use of different methods of counter-traction (Hippocrates 1989) (Figure 10). Modified versions of his techniques of shoulder reduction are in worldwide use to this day.

Figure 10: A woodcut of the reduction of a dislocated shoulder with a Hippocratic device. *Artist: Francesco de Rossi (1510-1563)*

Reprinted with permission, Surgery: An Illustrated History by Ira M. Rutkow, 1993, Mosby-Year Book Incorporated publisher.

Immobilisation

From the era of Hippocrates and until today reduction of the dislocated shoulder followed by a period of immobilisation of the arm in a sling and swathe and thereafter rehabilitation have remained the basic principle for treatment of acute primary shoulder dislocation. Rowe reported however already in 1956 on his results of 500 dislocations, where he found that immobilisation only reduced the rate of recurrence by 10 to 15 % and he found no association between the length of the immobilisation period and the rate of recurrence (Rowe 1956). This was one of the first studies questioning the benefit of immobilising the shoulder after a dislocation. Later studies, summarised in the systematic review by Paterson et al. evaluating 2083 published studies, have confirmed that immobilisation for a longer time period than one week probably has little or no benefit following a dislocation (Paterson et al. 2010). Unfortunately, in a survey of the daily practice in the United Kingdom made by Chong et al in 2006, more than 90% of trauma clinicians still treated shoulder dislocations with initial immobilisation in internal rotation for an average of 4.8 weeks (Chong et al. 2006).

Immobilisation in external rotation was proposed by Itoi et al. to decrease the recurrence rate. The rationale for this was an MRI study where external rotation showed better coaptation between the labrum and the glenoid in patients with an acute traumatic Bankart lesion (Itoi et al. 2001). Itoi hypothesised that retaining the arm in this position would lead to a more anatomic healing of the labrum and thus a lower risk of recurrence. In a randomised controlled trial of 198 patients with 25 months of follow-up, he found that patients treated with immobilisation in external rotation had 26% recurrence compared to 42% in the group with internal reduction (Itoi 2007). Later randomised studies have tried to reproduce his results, but have not found any benefits of external rotation (Finestone et al. 2009; Liavaag et al. 2011c; Vavken et al. 2014).

1.6 The natural course after a primary shoulder dislocation

There are numerous studies concerning the natural history and recurrence rates after a primary traumatic shoulder dislocation. Olds et al. found in their systematic review 1195 articles regarding risk factors for recurrence of instability (Olds et al. 2015). Due to differences in patient populations, length and control of follow-up and definitions of recurrence, i.e. if only frank dislocations or also subluxations are included, the recurrence rate varies considerable, from 8.5% to 100% (McLaughlin and Cavallaro 1950; Rowe 1956; Kazár and Relovszky 1969; Henry and Genung 1982; Simonet and Cofield 1984; Hovelius et al. 1996).

Subjective complaints of instability or reduced shoulder function are to a variable degree mentioned in the literature and fear of participating in activities is normally only recognised for athletes withdrawing from their pre-injury level. In more recent studies subjective shoulder function is taken into account by the means of standardised questionnaires filled out by the patient, Patient Reported Outcome Measures (PROMs).

Studies including mostly young and physically active patients with long-term follow-up tends to have a very high rate of recurrence ranging from 70 to 100% (Henry and Genung 1982; Marans et al. 1992; Hovelius et al. 1996; Postacchini et al. 2000; Lampert et al. 2003; te Slaa et al. 2004; Robinson 2006; Roberts et al. 2015). For the older population recurrence rate is much lower; McLaughlin and Cavallaro reported 10% and

Gumina and Postacchini 22% (McLaughlin and Cavallaro 1950; Gumina and Postacchini 1997). On the other hand, tears of the rotator cuff was very common, 61% in Guminas´ paper. Further, 9% of the patients had an axillary nerve injury. Neviaser and Neviaser reports a 100% prevalence of cuff tears in 12 older patients with a mean age of 63 years and recurrent instability (Neviaser and Neviaser 1995).

Most patients that develop recurrence after a primary traumatic dislocation have their first recurrence event within 2 years of the first dislocation. However, both Robinson and Hovelius found however that an additional 10% of the patients developed recurrent instability between 2 and 5 years of follow-up (Hovelius 1987; Hovelius et al. 1996; Robinson 2006).

1.6.1 Prognostic factors for developing recurrent instability
<u>Age</u>

Age at the time of the primary dislocation has been found to be the dominating risk factor for recurrence in almost all studies of the subject and Olds et al. in their systematic review from 2015 found a combined rate of recurrence of 44% for patients aged 40 years or less and 11% for those older than 40 years (Rowe 1956; Simonet and Cofield 1984; Vermeiren et al. 1993; Hovelius 1999; Robinson 2006; Paterson et al. 2010; Olds et al. 2015). Adolescents aged 14 to 20 years of age have the highest risk in most studies. The risk declines somewhat, but is till high, between 20 and 30 years. After 30 years the risk declines more rapidly, but from forty years of age associated injuries like rotator cuff tears, nerve injuries and fractures are more common.

Interestingly, in the studies from Lampert et al. and Leroux et al., the recurrence rate for children younger than 14 years was very low, compared not only to the older children but also to adults (Lampert et al. 2003; Leroux et al. 2015).

<u>Gender</u>

There is conflicting evidence on gender as a risk factor for recurrence. Simonet and Cofield found in their material of 116 primary dislocations a 41 % mean recurrence for males versus 12% for females. The majority of the females in this study was however

aged 40 years or more and the authors concluded that for age-matched males and females there were no difference in recurrence rate (Simonet and Cofield 1984). This is in accordance with the distribution of age in relation to gender in other studies, where women in general are older at the time of dislocation. Hovelius and Robinson both studied the natural course in teenagers and young adults. Hovelius found no difference in recurrence rate between male and female patients at 2 and 5 years follow-up with adjustment for age (Hovelius 1987). Robinson et al. on the other hand reported a significantly lower risk of recurrent instability, including both recurrent dislocations and subluxations, for female patients compared to men, with a lower risk in all age groups from 15 to 35 years (Robinson 2006). In their meta-analysis Olds et al. found that male had an odds ratio of 3.18 (CI 1.28-7.89) to develop recurrent instability compared to women (Olds et al. 2015).

Hand dominance

No studies were found that supported any association between hand dominance and the rate of recurrence. Olds et al. found five studies reporting on hand dominance, none of them with a side difference in recurrence rate (Simonet and Cofield 1984; Hoelen et al. 1990; Vermeiren et al. 1993; Sachs et al. 2007; Salomonsson et al. 2009b).

Hyperlaxity

The studies by Robinson et al. and Salomonsson et al. both found that people with hyperlaxity are at risk of recurrence. In the meta-analysis by Olds et al. it is estimated that hyperlax individuals have a 2.68 increased risk of recurrent instability compared to people with normal mobility (Olds et al. 2015).

Concomitant bony lesions

Several studies have found that the presence of a greater tubercle fracture decreases the risk of recurrence, with an odds ratio of 0.13 in the meta-analysis done by Olds et al. (Hoelen et al. 1990; Hovelius et al. 1996; Kralinger et al. 2002; Slaa et al. 2004; Robinson 2006; Salomonsson et al. 2009b; Olds et al. 2015).

The effect of a Bankart fracture is more complex. The presence of a smaller avulsion fracture had a protective effect against recurrence in the study by Salomonsson et al., while the studies by Vermeiren et al. and Hoeland et al. were undecided but with a trend towards better results with a fracture (Hoelen et al. 1990; Vermeiren et al. 1993; Salomonsson et al. 2009b). Rim defects larger than 20% of the glenoid diameter are associated with an increased risk of instability, both in biomechanical tests (Yamamoto et al. 2009) and after arthroscopic Bankart (Burkhart and De Beer 2000; Boileau et al. 2006). Many authors therefore advocate acute surgical fixation of larger (>5mm) glenoid rim fractures with a displacement of more than 4-5 mm (Spiegl et al. 2013; van Oostveen et al. 2014). However, in the study by Maquieira et al., who choose to treat also large defects conservatively as long as the humeral head were centred after reduction, the long-term results of non-operative treatment were excellent (Maquieira et al. 2007).

Porcellini et al. had better results after arthroscopic reattachment of acute Bankart fractures compared to chronic cases (Porcellini et al. 2007). This is however not surprising as you must assume that many of the patients in the group of acutely treated patients would have done well also without surgical treatment.

Hill-Sachs lesions are reported to increase the risk of recurrence in the study by Hovelius et al (Hovelius et al. 1996). In the studies by Salomonsson et al. and Hoelen et al., no significant association were found (Hoelen et al. 1990; Salomonsson et al. 2009b). By combining the available data in their meta-analysis, Olds et al. found a 1.55 times increased likelihood of recurrent instability in the presence of a Hill Sachs lesions, but the result was not statistically significant (Olds et al. 2015).

In studies of risk factors for recurrence after arthroscopic Bankart, large Hill-Sachs defects have a clear association with failure (Boileau et al. 2006). Burkhart and De Beer used the term ''engaging Hill-Sachs lesion'' to describe a compression fracture of the humeral head that is large enough for the edge of the humeral head to drop over the glenoid rim as the arm is abducted and externally rotated (Burkhart and De Beer 2000). These lesions are thought to drastically increase the risk of recurrence.

Mechanism of injury at the primary dislocation and return to sports

It is controversial whether the mechanism of injury at the primary dislocation or participation in sports activity is associated with a higher risk for recurrent dislocations. Many studies have low quality on the data regarding the mechanism of injury and the reason for not participating in sports after the initial dislocation.

Hovelius et al. reported in their article with 10 years follow-up that the prognosis was similar for patients with a trivial trauma at the primary dislocation compared to those who had a substantial injury, based on the description of the activity causing the injury (Hovelius et al. 1996). Olds et al. concluded that a meta-analysis was not possible due to large variation in the definition of mechanism of injury.

Simonet and Cofield found that young athletes had a higher risk of recurrence compared to non-athletes of similar age and that an athletic re-injury was the cause of redislocation in 77% of the patients less than 30 years old (Simonet and Cofield 1984). Robinson et al. found that participation in sports, level of sports, return to contact sports within the first year after injury, return to full activity or work at six weeks all had a significant effect on re-dislocation rate in univariate analysis (Robinson 2006). With multivariate analysis however, only age and gender had any influence on the recurrence rate. In the study by Sachs et al. patients participating in contact or collision sports had an adjusted odds ratio of 7.8 for experiencing a new dislocation, although not statistically significant (Sachs et al. 2007). Neither Kralinger et al. nor Slaa et al. found any difference in recurrence rate between patients who were active in sports and those who were not (Kralinger et al. 2002; Slaa et al. 2004). Rhee et al. found a higher recurrence rate among athletes. However, the athletes were younger than the non-athletes at the time of the first dislocation, which can explain this difference (Rhee et al. 2009).

For recurrence after surgery there are more data on the effect of return to play. Balg and Boileau (2007) found that performing contact or forced over-head sports preoperatively or returning on a competitive level was associated with a significantly increased risk of recurrence after arthroscopic Bankart. There was a trend, but not statistically

significant, that returning to contact sports on all levels was associated with an increased recurrence rate. In the recent study by Yamamoto et al., contact sports athletes had a 14% recurrence rate 17 months after an arthroscopic Bankart, compared to 4% for non-contact athletes (Yamamoto 2015). The difference was however not statistically significant due to a small study population. In both groups only 50% of the patients returned to pre-injury level of performance and 25% quit sports completely. There were described that none of the patients quit due to inability to perform sports.

One must assume that some patients choose not to return to sports because they do not want to risk further damage to their shoulder. Their prognosis is presumably above average as many recurrent dislocations are caused by a new trauma. Others may have a subjective instability or poor shoulder function as their reason for not returning to their previous level of activity. Those patients can be expected to have an inferior functional outcome. It is difficult to discriminate between these to groups, as there might be a mix of factors that explain why the patient chooses not to return to sports. Different sports have different risk of sustaining new traumatic events in the shoulder. Some authors separate between contact and collision athletes, where collision athletes are thought to be more at risk of dislocation.

Due to the heterogeneous study populations it is difficult to find statistically significant differences,, but it is reasonable to believe that participating in contact sports both increases the risk to obtain a primary dislocation and the risk of recurrence. Hovelius found a very high prevalence of shoulder instability, 8%, among elite ice hockey players, which would support this view (Hovelius 1978).

Occupation

Sachs et al. found that people working at or above chest level had an odds ratio for new instability episodes of 5.8 (p=0.006) compared to those that did not (Sachs et al. 2007). Also Vermeiren found a trend towards increased risk for manual labourers, but not as pronounced (Vermeiren et al. 1993).

1.7 Surgical treatment of recurrent instability

1.7.1 Historic perspective

Surgical treatment for recurrent instability is first mentioned in the literature by Hippocrates, who describes cauterisation of the subcutaneous tissue in the arm pit to stabilise the shoulder in patients with frequent dislocations (Hippocrates 1989). The first recorded surgical treatment in modern history was performed in the 1800s by the Czech surgeon, Eduard Albert, who performed a shoulder arthrodesis on a patient with recurrent shoulder dislocation (Iqbal et al. 2013).

In the 1890s, Broca and Hartman were the first to describe avulsion of the glenohumeral ligament complex and its association with chronic instability of the shoulder (Broca and Hartmann 1890). Perthes described in 1906 the avulsion of the anteroinferior labrum as the cause of recurrence and that surgical reattachment of the labrum stabilised the joint (Perthes 1906). His operative technique, using bone clips and transglenoidal stitches is with some modification still in use. In 1923 Bankart described a lesion where the labrum were separated both from the glenoid and the capsule and a technique where the glenoid is abraded to facilitate the reattachment of the labrum and suturing of the capsule to the labrum. Fixation of the labrum to the glenoid was not performed in the original paper, but added to his procedure later (Bankart 1923).

In 1961, Herbert Moseley published a well-illustrated and highly referenced work on recurrent dislocation (Moseley 1961). The book describes in detail the anatomy and pathology of various types of dislocations and he recommends the use of an extra-articular vitallium plate fixated on the front of the glenoid as a buttress an anchor for capsule sutures.

During the 20th century many different operative techniques were being presented to correct instability of the shoulder, with over a hundred methods for correction of anterior dislocation alone. In addition to the method of anatomic reattachment of the labrum described by Bankart, other methods focused on tightening of the anterior capsule or subscapularis to prevent dislocation. Two examples are the Putti-Platt procedure, where

the subscapularis is shorted and the inferior capsular shift described by Neer for multidirectional instability (Osmond-Clarke 1948; Neer and Foster 1980).

1.7.2 Modern treatment

<u>Development of arthroscopic techniques</u>

To be able to repair the intraarticular Bankart lesion without the trauma caused to the subscapularis muscle and capsule by the open approach, there was a drive towards being able to perform the procedure with an arthroscopic technique. Less risk of infection and a better cosmetic result were other benefits of arthroscopy, and there was a rapid development of equipment and surgical skills from the middle of the eighties and onwards. Arthroscopic Bankart repair using transglenoidal sutures was first described in 1987 by Morgan and Bodenstab and was later modified to be performed with suture anchors (Wolf et al. 1991) or bioabsorbable implants (Altchek 1993). Arthroscopic stabilisation with suture anchors has since gained popularity due to its nature of a minimal invasive procedure with few complications for an experienced arthroscopic surgeon using modern equipment. It is now the most commonly used surgical method in the treatment of recurrent anterior shoulder instability in most countries (Malhotra et al. 2012; Zhang et al. 2014; Berendes et al. 2015).

<u>Long-term outcome of arthroscopic treatment</u>

However, medium- to long-term reports on the outcome after arthroscopic Bankart have raised concerns that the arthroscopic Bankart has a much higher recurrence rate than the open technique, especially in young male patients (Mohtadi et al. 2014; Chen et al. 2015). This risk is severely increased in patients with glenoid erosion (Burkhart and De Beer 2000) and patients returning to competitive and contact sports (Balg and Boileau 2007). There is a pattern of many late recurrences for arthroscopic Bankart (Castagna et al. 2010). Most studies with a long follow-up describe a recurrence rate after Bankart in young active patients between 10-30% (Chen et al. 2015).

The coracoid transfer technique by Latarjet (1954) has gained in popularity during recent years (Zhang et al. 2014), as this method seems to give better stability (Bessière et al. 2014). This method is however technically demanding, has a more severe

complication spectre with a reported complication rate of 30% (Griesser et al. 2013) and it is more difficult to revise.

Treatment alternatives

There seems to be two alternative shoulder instability treatment strategies; either to use an arthroscopic Bankart with few acute complications but a higher recurrence rate, or to use a more invasive non-anatomic technique with more acute complications but fewer failures. Several papers report on risk factors for recurrence after arthroscopic Bankart. Bone loss, young age, hyperlaxity and return to contact sports are considered to be the main risk factors (Burkhart and De Beer 2000; Boileau et al. 2006; Randelli et al. 2012; Shibata et al. 2014). Balg and Boileau has published a treatment algorithm, the ISIS-score, to guide the surgeon in the choice of treatment for the individual patient (Balg and Boileau 2007).

Further, it is of interest to know not only the outcomes of the two treatments, but also to what extent a previous failed procedure will affect the outcome of revision surgery. This will lead to a better understanding of the long-term results for the two strategies.

The effect of anti-inflammatory drugs

Although a minimal invasive procedure, post-operative pain control after shoulder surgery can be difficult to achieve, even with the use of an interscalene nerve block (Fredrickson et al. 2010). Nonsteroidal anti-inflammatory drugs (NSAIDs) have been proven effective against post-orthopedic surgery pain (Heidrich et al. 1985; Alexander et al. 2002; Malan et al. 2003; Axelsson et al. 2008), but experimental studies in animal models have raised concerns that these drugs may have a negative effect on tendon and tendon-to-bone healing in the early proliferative phase (Dimmen et al. 2009a; 2009b; Chen and Dragoo 2012). NSAIDs have an inhibitory effect on bone healing in animal studies (Sudmann 1975; Rø et al. 1976) and have been shown to affect the clinical outcome of long bone fractures (Burd et al. 2003) and spinal fusion (Li et al. 2011). No studies have been found that investigate the effects of NSAIDs on the clinical outcome after arthroscopic Bankart or other procedures that involve healing between soft tissue and bone in humans.

1.7.3. Rationale for a treatment register

Based on only a few randomised trials with low statistical power that found no difference in short-term (2 year) outcome, there was a major transition from open to arthroscopic procedures for shoulder instability in the mid 2000 world-wide (Sperber et al. 2001; Fabbriciani et al. 2004; Bottoni et al. 2006; Malhotra et al. 2012). This change of practice occurred despite the report by Kartus et al. in 2007, that revealed an unexpected high number of patients with recurrence of instability (38%) after arthroscopic stabilisation with bio-absorbable tacks (Kartus et al. 2007). The authors found that most instability episodes after the arthroscopic stabilisation occurred after more than two years, and concluded that it is important to follow patients over time to identify the true recurrence rate. As a result of the report the technique for fixation of labrum was changed and soon absorbable tacks was replaced by suture anchors. Still, the arthroscopic technique continued to spread without convincing long-term results. Further, most studies are done by experienced surgeons at high volume clinics. It is not evident that the use of a novel technique that requires advanced skills in arthroscopy will yield the same results for younger surgeons in a less specialised environment. On this background, the study group decided to establish a nationwide register on shoulder stability operations.

2 Aims of the thesis

The overall objective of this thesis was to collect data on epidemiology and the results of different surgical procedures for shoulder instability, including prognostic factors associated with good and poor outcome.

The specific aims of the three papers included in the thesis were:

I   To describe the Norwegian Shoulder Instability Register, describe epidemiology and short-term results of shoulder instability surgery in Norway and evaluate the completeness of the register.

II   To evaluate if the use of anti-inflammatory drugs in the postoperative phase affects the outcome after arthroscopic Bankart for anterior shoulder instability.

III   To evaluate the mid-term results of the most common surgical methods for treatment of anterior shoulder instability, and identify prognostic factors for the outcome.

3 Methods

3.1 Collection of data

Based on the experience from a pilot study performed in 2006 at 12 hospitals and involving 107 patients (Liavaag et al. 2007), a working group was set up to plan the establishment of a Norwegian shoulder instability register. The first registration started in January 2008. 39 hospitals performing shoulder stabilisation surgery were identified in the Norwegian Patient Register (NPR; www.npr.no) and these hospitals were invited to participate in the register. Eligible for inclusion in the register are Norwegian-speaking residents of Norway undergoing primary or revision surgery for shoulder instability. All directions of instability and both dislocation and subluxation are accepted for inclusion in the register.

The patients are asked to complete the Western Ontario Shoulder Instability Score (WOSI) (Kirkley et al. 1998) (Appendix 1) and to provide information about their profession and their level of sports activity (Appendix 2). The WOSI score consists of 21 items divided into 4 domains, to be answered using visual analogue scales. The total score is presented as a number between 0 (best) and 2100 (worst), or transformed to a score where 100% equals normal shoulder function and 0% is the worst possible outcome. We use a Norwegian version of the WOSI score that has been translated and validated according to the guidelines presented by Guillemin et al. (Guillemin et al. 1993; Skare et al. 2013).

At 1, 2, and 5 years after the primary or revision surgery, the patients are asked to complete the same questionnaire. Furthermore, they are asked if they have experienced any new episodes of shoulder dislocation, if they have had additional surgery in the same shoulder and if they participate in sports. If additional surgery has been performed to the same shoulder, consent is obtained to retrieve hospital records regarding the surgery.

Based on the experiences from the pilot study, a registration form was designed (Appendix 3 and 4). The aims were to define the type of instability, to describe the surgical treatment, and to identify patient characteristics that might influence the risk of

recurrent instability and the functional outcome. Previous shoulder surgery, pathology in the opposite shoulder, history of injury, direction and degree of instability, duration of symptoms, minimum activity level to trigger instability symptoms, and number of dislocations were recorded. Any glenoid bone defects and injuries to the labrum and/or capsule were marked on a schematic drawing of the shoulder. Humeral head defects, tendon injuries, or other findings were recorded. The surgical procedures were described schematically, including descriptions of the types of implants used and their positions. To obtain correct information for the implants used, the surgeons were encouraged to provide the identification stickers supplied by the manufacturer.

To estimate the national coverage of the register, the data were compared to those in the NPR. The NPR contains a modified NOMESCO Classification of Surgical Procedures (NOMESCO 2009) for all procedures performed in public or private hospitals that are funded by the Norwegian public social security. The NPR contains information on surgical procedures performed and patient age and gender, but no information regarding laterality and outcome.

3.2 Classification of instability and treatment

To be included in the register the patient should have experienced at least one episode of slipping in the shoulder with the feeling of malposition of the humeral head in relation to the glenoid fossa. This inclusion criteria aimed to include patients with dislocations and subluxations, but not isolated SLAP- or GLAD-lesions where pain normally is the predominating symptom (Snyder et al. 1990; Neviaser 1993b). The surgeon was asked to define whether the patient had experienced any dislocations or only subluxations. A radiological evidence of dislocation was not a prerequisite for inclusion, but if there was pathognomonic findings this was noted in the surgeon´s report. History of injury, duration of symptoms, the number of dislocations, if any, and the minimum activity level that triggered instability symptoms were noted, together with history of previous shoulder surgery and any pathology in the opposite shoulder.

The instability was classified according to direction by the treating surgeon as anterior, posterior or multidirectional (MDI). The multidirectional category included true

multidirectional instability as well as bi-directional instability with an anterior or posterior predominance.

Any glenoid bone defects and injuries to the labrum and/or capsule were marked on a schematic drawing of the shoulder. Humeral head defects, tendon and nerve injuries, or other findings were noted in the surgeon´s report. The surgeon reported schematically on treatment details like implant placement, number and type of suture anchors, bony procedures, perioperative positioning of the patients, outpatients status and the use of NSAIDs in the postoperative phase (Appendix 3 and 4).

Using the surgeons' report, the instability was classified as anterior/posterior/multidirectional, the approach as open/arthroscopic and the type of procedure as Bankart/Latarjet/other procedure.

3.3 Methodological and statistical considerations

Outcome measures

Revision surgery with stabilisation of the joint was defined as the hard endpoint of the register, whereas soft endpoints were patient-reported recurrence of instability and WOSI score at follow-up. Follow-up from the original procedure was stopped for patients that underwent revision surgery. The functional outcome could however be followed-up on questionnaires sent to the patients after the revision procedures had been performed, thus allowing an intention-to-treat analysis.

The WOSI score was considered to be the most sensitive measure of treatment outcome and the first that could find significant differences between the treatment groups (Kirkley et al. 1998; Kirkley et al. 2003; Kemp et al. 2012). It is validated in several languages and is in universal use (Salomonsson et al. 2009a; Skare et al. 2013; Gaudelli et al. 2014; van der Linde et al. 2014). The score can be distributed by mail, a prerequisite to be used in a national register, and in addition to the proven responsiveness and validity the score is a continuous variable that permits linear statistical methods.

Due to the difficulties for the patient to define dislocation versus subluxation and for statistical reasons, we opted to treat all cases of subjective feeling of the shoulder "popping out" postoperatively as recurrence, opposed to stable shoulders. Likewise, the patient-reported reoperation rate included both revision stabilisation and other surgical procedures in the same shoulder, for example hardware removal.

Statistics

To evaluate the subjective change in shoulder function we used a paired t-test of the pre- and postoperative WOSI score. To compare the functional outcome between treatment groups we used an unpaired t-test of the postoperative WOSI score. For categorical variables the chi-square test was used to evaluate group differences and the Kruskal–Wallis was used for comparison of medians.

Both the subjective change and the absolute postoperative score can be used as the main outcome measures of shoulder function. As most studies present their data as an absolute outcome score, we opted to follow this convention. In paper II the WOSI score was adjusted for age using univariate analysis of variance. In paper III possible confounding predictors of outcome such as age at surgery, gender, traumatic debut, duration of symptoms, number of dislocations, level of activity at recurrence, glenoid and/or humeral bone loss were analysed using multiple logistic regression and presented as odds ratios (OR), with 95% confidence interval where applicable.

4 Summary of papers I-III

Paper I

Blomquist J, Solheim E, Liavaag S, Schroder CP, Espehaug B, Havelin LI.
Shoulder instability surgery in Norway: the first report from a multicenter register, with 1-year follow-up. Acta Orthop. 2012 Apr;83(2):165-70.

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Background: In January 2008, we established the Norwegian shoulder instability register. We report on the establishment, the baseline data, and the results at 1-year follow-up.

Methods: Primary and revision shoulder stabilisation procedures are reported by the surgeon on a 1-page paper form containing the patient's history of shoulder injury, clinical findings, and perioperative findings. The WOSI questionnaire for self-assessment of shoulder function is completed by the patient at baseline and at follow-up after 1, 2, and 5 years. To evaluate the completeness of registration, we compared our data with those in the Norwegian Patient Registry (NPR).

Results: During the period from January 2008 to December 2009, 464 stabilisation procedures were recorded at 20 hospitals, with a mean patient age of 29.7 years, ranging from 10-74. 404 of the treatments were primary procedures and 59 were revisions after previous failed surgical stabilisation. Arthroscopic Bankart was used in 88% of the patients treated for primary anterior instability and open Latarjet in 10% of such patients. No open Bankart or arthroscopic bony procedures were recorded. 83% of the patients had an anterior instability, 10% a posterior instability and 7% a multidirectional instability. 89% of the primary anterior dislocations had a traumatic debut. 60% of the injuries were related to sports, 18% of cases were caused by a fall during daily non-athletic activities and 7% were caused by road traffic accidents, including bicycling. The details of the patient characteristics are presented in Paper I, Table 2.

We found a statistically significant improvement in shoulder function after 1 year for primary instability in all directions. For revisions, there was a significant improvement of the WOSI score at follow-up for anterior instability, while there were too few patients with revision of posterior and multidirectional instability to allow a statistical analysis. The mean WOSI score after a primary Bankart was 75% at the 1-year follow-up. Patients treated with primary open Latarjet had a WOSI score of 80%, whereas arthroscopic posterior and multidirectional instability had a postoperative WOSI of 63% and 76% respectively. 10% of the patients who were treated with arthroscopic anterior Bankart and 16% of those treated with arthroscopic posterior Bankart reported having experienced a recurrent dislocation at the time of follow-up. There were no statistically significant differences between the groups regarding change in WOSI score, rate of recurrence, or rate of reoperation.

587 patients from 39 different hospitals were entered into the Norwegian Patient Register during 2009. In 2009, 315 stabilisation procedures from 20 hospitals were included in the shoulder instability register, which represented 54% of the number reported to NPR.

Conclusion: Arthroscopic Bankart is the dominating technique in Norway for anterior shoulder instability. The functional results are in accordance with those in previous studies. However, the incidence of recurrent instability one year after arthroscopic Bankart was higher than expected.

Paper II

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Background: To achieve pain control after arthroscopic shoulder surgery, nonsteroidal anti-inflammatory drugs (NSAIDs) are a complement to other analgesics. However, experimental studies have raised concerns that these drugs may have a detrimental effect on soft tissue-to-bone healing and, thus, have a negative effect on the outcome. We wanted to investigate if there were any differences in the clinical outcome after the arthroscopic Bankart procedure for patients who received NSAIDs prescription compared with those who did not.

Methods: 477 patients with a primary arthroscopic Bankart procedure were identified in the Norwegian shoulder instability register and included in the study. 32.5% received prescription of NSAIDs postoperatively. 370 (78%) of the patients answered a follow-up questionnaire containing the Western Ontario Shoulder Instability index (WOSI). Mean follow-up was 21 months.

Results: Patients in the NSAID group were significantly younger, had a shorter duration of symptoms and were more likely to be treated ambulatory. Patients treated with NSAIDs post-operatively had an unadjusted mean WOSI score at follow-up of 75%, compared with 74% for the control group. Recurrence rate was 12% in the NSAID and 14% in the control group, while reoperation rates were 5% in both groups. The increase in WOSI score from baseline to follow-up was 24% (CI 95% 20.2–28.1, P < 0.001) for the NSAID group and 22% (CI 95%18.9–24.7, P < 0.001) for the control group. None of the differences between the groups was statistically significant.

18% of the patients in the NSAID group and 25% of the patients in the control group did not answer the follow-up questionnaire. Males were overrepresented among the non-

responders, however evenly distributed between the two treatment groups. No other significant differences were found compared with the patients that answered the follow-up questionnaire.

Conclusion: There were no statistically significant differences between the groups. Prescription of short-term NSAID treatment in the postoperative period did not influence on the functional outcome after arthroscopic Bankart procedures.

Paper III

Blomquist J, Solheim E, Liavaag S, Eide GE, Havelin LI.
Arthroscopic Bankart versus Latarjet for anterior shoulder instability.
Submitted

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Background: Arthroscopic Bankart has to a large extent replaced open procedures. Due to a presumed lower risk of recurrence with the Latarjet procedure, many surgeons prefer this procedure in young and active patients. By using the Norwegian shoulder instability register, we compared the outcome after the two procedures used in primary and revision surgery.

Methods: 760 primary arthroscopic Bankart and 93 primary open Latarjet procedures were identified, with a mean 2.7-year follow-up in 613 patients (72%). Further, 124 revisions after previous arthroscopic Bankart were registered; 50 revised with a new arthroscopic Bankart and 74 with an open Latarjet procedure.

Results: There were no significant differences in age or gender between any of the groups, but the revision arthroscopic Bankart group had significantly shorter symptom duration compared to the primary arthroscopic Bankart group (p=0.001). The occurrence of glenoid bone loss were 7 times higher in the primary Latarjet group compared to the primary Bankart group (p<0.001) and engaging Hill-Sachs lesions were 4 times more common (p=0.002). Still, 69% of the patients with bony defects were treated with an arthroscopic Bankart.

Patients with a primary arthroscopic Bankart had a mean WOSI score at follow up of 74%, compared to 75% for the primary Latarjet group. There was a highly significant improvement for both groups (p<0.001), but no difference between treatment modalities (p=0.81). Recurrence rate was 16.9% in the primary Bankart and 6.7% in the primary Latarjet group (p=0.038), while reoperation rates were 6.2% and 6.7% respectively (p=0.89).

An analysis of the WOSI score items revealed a better score of mobility (element 10) after Bankart (p=0.039) whereas Latarjet patients had less fear of falling on their injured shoulder (element 15, p=0.003). No other systematic differences in WOSI items were found between the groups. Revision led to a significant lower WOSI score compared to primary procedures, regardless of treatment modality (Bankart: p=0.027, Latarjet: p=0.046) (Paper III, Table 2). However, due to a lower baseline score in the revision patients compared to the primary cases , the improvement in WOSI score did not differ (Bankart: p=0.27, Latarjet: p=0.33). Recurrence rate was 24.4% for revision Bankart and 17.4% for revision Latarjet, with a reoperation rate of 9.8% and 21.7%. There were no significant differences between the two revision techniques. Revision Latarjet had a significantly higher reoperation rate than the corresponding primary procedure (p=0.026).

Using multiple logistic regression, we found an increased risk of recurrence in patients below 20 years of age, both for arthroscopic Bankart and open Latarjet (Paper III, Table 4). After a primary arthroscopic Bankart there was an increased risk of recurrence for patients with a combination of glenoid bone loss and en engaging Hill Sachs lesion. For the Latarjet, glenoid bone loss had a protective effect. There was no significant correlation between outcome and symptom duration, number of dislocations, traumatic debut or unipolar bone loss. There was a high correlation between reported recurrence and a low WOSI score at follow-up, with a difference in WOSI score of 23% compared to the patients with stable shoulders (p<0.001).

Twenty-seven per cent of the patient in the arthroscopic Bankart group and 33% of the patients in the Latarjet group did not answer the follow-up questionnaire. A non-responder analysis was made (Paper III, Table 5). Young males were overrepresented among the non-responders. There were no significant differences between non-responders and the responders for bone loss, symptom duration, trauma at first dislocation or preoperative WOSI score. We compared high and low volume hospitals. Hospitals reporting less than 10 procedures per year did not differ significantly on either WOSI score or recurrence rate from the hospitals with more than 10 procedures per year.

Conclusion: The recurrence rate was higher for the arthroscopic Bankart than for the Latarjet procedure. Both procedures had inferior results in the young and combined glenoid and humeral bone loss increased the recurrence rate after arthroscopic Bankart. There were no differences in the outcome on WOSI for the two procedures, neither for primary operations nor revisions.

5 Results and general discussion

5.1 Methodology

5.1.1 Register studies as a method

Randomised controlled clinical trials, RCTs, constitute the gold standard for comparing the effectiveness of different types of healthcare. However, despite their strengths, they have some limitations. It has been shown that randomised controlled trials may risk a poor external validity, as patients included in studies tend to have less comorbidity than the general population under treatment (Wennberg et al. 1998). Further, the surgeons and hospitals performing RCTs might not be representative for the average surgeon or hospital. With a prevalence of primary surgical intervention for anterior shoulder instability of less than 1/10.000 individuals per year, it would take a long time to include enough patients in a RCT to gain sufficient statistical power. For surgical treatments there is always a performance bias, as different surgeons have different skills and expertise in the different procedures. Further, if the procedures leave different scars it is difficult to blind the patient and health care workers. In combination this leads to few RCTs being undertaken and there is a risk of introducing weaknesses in the design. For shoulder instability, the problem is further emphasised by the fact that the outcome very likely is affected by age, postoperative level of activity and concomitant bone lesions, but to a different degree for the different procedures. The selection of inclusion criteria of a trial would therefore influence the outcome of the study to a large extent.

Observational studies are relatively inexpensive and feasible complements or alternatives to randomised trials. Normally, a national register can include much larger numbers of patients than RCTs, and during a shorter time. Further, register studies have a good external validity as their results represent the average surgeon in average hospitals. Their main drawback is the risk of misinterpreting treatment effects due to an uneven distribution of confounding factors in the treatment groups due to a preconceived opinion on treatment choices among practitioners and patients. It is shown that well-designed observational studies (with either a cohort or a case–control

design) do not systematically overestimate the magnitude of the effects of treatment compared with those in randomised, controlled trials (Concato et al. 2000).

In Scandinavia, national quality registers have been used for many years to monitor outcome, thus making it possible to pinpoint inferior treatment methods (Herberts and Malchau 2000; Irgens 2000; Pahlman et al. 2005). There are nationwide registers for joint replacement and hip fractures in several countries, and cruciate ligament registers have been established in Sweden, Denmark, and Norway (Granan et al. 2009). In some of the registers, the patients are also asked to complete an outcome questionnaire (Gjertsen et al. 2008; Granan et al. 2008; Rasmussen et al. 2014). To our knowledge, no other national quality registers for shoulder instability surgery have yet been reported (Pulavarti et al. 2009; Chen et al. 2015).

5.1.2 Completeness and quality of register data

The number of patients reported to the shoulder register was 54% of the number of presumed shoulder stabilisation operations found in the NPR. However, as the NPR in 2009 did not contain data such as the patients' I.D. coupling was not possible. It is therefore not possible to assess how many of the patients reported to the shoulder instability register that had been reported to the NPR, with a correct code, and vice versa. Further, the completeness and accuracy of the NPR data for shoulder instability is debatable, as the NOMESCO classification—which is used in the NPR—has no specific codes for different stabilisation techniques, revision surgery, or SLAP repair. Thus, SLAP repairs might have been reported to the NPR as stabilisations, while some stabilisation procedures might have been registered with other codes. Validation studies of both NPR data and shoulder register data are warranted to determine the true incidence of shoulder stabilisation surgery in Norway. The register is therefore dependent on the patient response or individual coupling against the NPR to detect revision procedures.

For the Norwegian Hip Fracture Register, the registration completeness after 2 years of inclusion was 79% (Gjertsen et al. 2008). Compliance rates for the Nordic cruciate ligament registers after the start-up phase were reported to be 85% for Denmark, 97% for Norway, and approximately 70% for Sweden (Granan et al. 2009). For the Norwegian Arthroplasty Register, the registration completeness is 97% (Espehaug et al.

2006). The shoulder instability register was initiated by a network of shoulder surgeons and not by the Norwegian Orthopedic Association, as were the other Norwegian registers, and this might explain a lower rate of hospital recruitment in the shoulder instability register. The higher proportion of eligible procedures performed at private day surgery units for this register than for the other orthopedic registers, might also explain the lower completeness.

The register is dependent on the accuracy of the registration of history, perioperative findings and treatment details. A validation against hospital records and radiological examinations has not been performed. Especially perioperative details, like bone deficiency, can either have been missed or omitted by the reporting surgeon. Although there is no reason to believe that there are large or systematic errors in the recording, the lack of validation is a weakness that affects all three papers.

Another weakness of the register is the high proportion of patients lost to follow-up (28%). Further, missing data at one of the follow-up points for many patients may bias the survival rate analysis and reduce the observational time. For Paper II and III a dropout analysis were made. No systematic characteristics of the non-responders were found, except for male gender and young age. Thus, the comparisons between the groups are most likely valid, but the non-responders could affect the absolute functional score and recurrence rate.

5.1.3 Outcome measures

It is controversial whether the rate of recurrence or a subjective functional score is the best outcome for evaluating shoulder instability. Many patients have a normal shoulder function between their recurrence episodes, only limited by their fear of contracting a new dislocation. Others may have pain and severe limitations in daily living and sports activity. A surgical procedure may restrict the mobility or cause other side effects that could actually reduce the function despite a stabilising effect on the joint. It is generally accepted that patient reported scores are easier to undertake and less prone to bias than scoring by the health professional in charge of the treatment (Lieberman et al. 1996; Dawson et al. 2010). The score system must be validated to measure the condition under treatment and universally accepted to allow comparison between different health

care facilities. Disease specific patient related outcome measures, PROMs, are therefore accepted as the most important outcome measure after surgery supposed to improve the patients' quality of life, where changes in survival or other undisputable endpoints cannot be expected.

WOSI is generally accepted as a primary outcome measure for the treatment of shoulder instability (Kirkley et al. 2003). We observed a relatively strong correlation between the individual pre- and postoperative scores; and that women have a lower mean average score than men both pre- and postoperatively. This is considered to reflect a bias in how the score is filled out, rather than a true difference in shoulder function. Thus, the preoperative score levels and the gender distribution must be taken into account when the results are analysed.

Recurrence rates differ considerably between different studies. There is no single established defined way of how to phrase the question regarding recurrence episodes. Clearly, studies only considering frank dislocations as recurrence underestimate the rate of recurrence while our definition, where the patient define at least one episode of the shoulder "popping out", may exaggerate the incidence.

The lack of postoperative radiological and clinical shoulder examination is a weakness of our project. Examination of range of motion and apprehension test would add valuable information regarding the outcome. A postoperative x-ray would reveal if the bone block is correctly placed and fused after a Latarjet and thus help explain the reason of failure for patients with a poor outcome. A clinical and radiological follow-up is however not possible to achieve in the register in its current form and we must rely on the patient reported outcome.

5.1.4 Selection bias and confounders

In Paper II the patients in the group treated with NSAIDs were younger. Young age is associated with a higher risk of recurrence both in this material and other studies, but even with adjustment for age there were no significant differences between the groups. In paper III there was, as expected, a higher frequency of bone deficiency among the patients treated with Latarjet. Most surgeons reserve the Latarjet procedure for patients

with bone deficiency and/or planned return to sports with a high risk of new shoulder trauma, and these are factors that probably will affect the outcome (Laboute et al. 2012). The heterogeneity of the material therefore makes a direct comparison between the groups difficult.

A randomised trial is the preferred method to avoid selection bias between treatment groups. To study the effect of anti-inflammatory drugs would be methodological straightforward, as the indication for surgery is not affected by NSAID use. To compare the Bankart and Latarjet procedures would be more difficult, as the two methods have strengths and weaknesses that depend on patient characteristics and if postoperative PROMs score or absence of recurrence is used as outcome measure. Choice of inclusion criteria and endpoint would probably favour one method or the other.

The indications for use of NSAIDs and choice of treatment differ between the participating surgeons and there could be a performance bias depending on the surgical skills that could affect the outcome of the groups. Due to a high volume of surgeons and hospital this is however not probable.

5.1.5 Statistical power and validity

The papers are underpowered to detect an increase in recurrence rate. For Paper II, it is unlikely that an increased recurrence rate after NSAID administration has been overlooked, as we found a slightly lower recurrence rate at 2 years in the NSAID group. Studies have shown a linear recurrence incidence over time after arthroscopic Bankart (Castagna et al. 2010). Longer follow-up and a larger patient population are needed to better understand the recurrence risk after different procedures and to identify patient groups at risk.

The register analyses the outcome in a prospective cohort with participants from both large and small hospitals in all parts of Norway, and we can anticipate that the sample population is representative for the general population who are treated with instability. The population is older with a lower proportion of athletes than in many other studies.

5.2 Results

5.2.1 Epidemiological findings

With 4.8 million residents in Norway 2009 and 587 procedures (according to the NPR), the annual incidence of shoulder stabilisation surgery in 2009 was 12 per 10.000 inhabitants. The male-to-female ratio for surgery was 2.2 to 1. The corresponding incidence for Sweden, according to the NOMESCO classification, was practically the same, with a 2.9-times higher rate for men than for women (Socialstyrelsen). The annual number of procedures coded as shoulder stabilisation in the NPR increased from 486 in 2007 to 587 in 2009. The trend was the same in Sweden, with an increased incidence of shoulder stabilization of 37% between 2006 and 2008 (Socialstyrelsen). Zhang et al. reported a 20% increase in the same time period and a 92% increase from 2004 to 2009 and a transition from open to arthroscopic procedures (Zhang et al. 2014). We have not found incidence Figures regarding instability surgery from other countries than Norway, Sweden and the United States.

We can compare the incidence of surgical procedures with the incidence of shoulder dislocations published by Liavaag et al. (Liavaag et al. 2011b), who found the incidence of primary dislocations to be 26.2 per 100.000 in the Oslo region. According to the prevalence study by Hovelius et al. from 1982, half of the patients with a primary shoulder dislocation did not seek medical attention (Hovelius 1982). It is likely that a higher percentage of the patients seek medical attention today, but some patients with acute dislocations and many with subluxations are most likely not diagnosed at the primary instability episode even today. Combining the findings of Liavaag et al on incidence of shoulder dislocation and our incidence rate on surgery, we can assume that somewhere between 25% and 40% of the patients with a shoulder dislocation are treated with a surgical procedure. In the longitudinal follow-up from 1996 by Hovelius et al. of patients younger than 40 years with a shoulder dislocation (Hovelius et al. 1996), 24% of the patients had already undergone a surgical procedure or had been scheduled for surgery 10 years after the initial dislocation. These patients had a high risk of recurrence due to their young age, but the indication for surgery has very likely changed since then and it is reasonable to believe that a higher percentage would have received surgery if they had experienced their dislocations today.

Of the 404 primary procedures registered, 83% of the patients had an anterior instability, 10% had a posterior instability, and 7% had multidirectional instability. The distribution of type of procedures in our register is in accordance with the incidence of shoulder instability reported by others. Owens et al. (2007) found that anterior instability comprised 80% of the instability cases. For primary anterior stabilisation, arthroscopic Bankart predominated and were performed in 88% of the cases, while an open Latarjet procedure was performed in 10% of cases. For MDI and posterior instability, only soft tissue techniques were used. Zhang et al. (2014) found an increasing trend of arthroscopic soft tissue procedures from 2004 to 2009, with 89% arthroscopic procedures in 2009. At the same time, the incidence of open Latarjet more than doubled, but they still accounted for only 2% of the stabilising shoulder procedures in 2009.

5.2.2 Treatment results

As the WOSI score is widely used, comparison with other contemporary papers is possible. Older papers often use the rating sheet for Bankart repair presented by Rowe et al. (1978) and have a different definition of recurrence, which makes a direct comparison difficult. The need for physical examination excluded the use of the Rowe score in our register study. Unfortunately, we have not included the ISIS-score in our preoperative assessment and we can therefore not validate that score on our material (Rouleau et al. 2013).

Our functional results as expressed by the WOSI score for arthroscopic anterior stabilization are in accordance with those in the studies of Bottoni et al. and Mologne et al. (Bottoni et al. 2006; Mologne et al. 2007). However, other more recent studies have reported 5-10% better functional outcome (Sachs et al. 2007; Kemp et al. 2012; Mohtadi et al. 2014). We observed that we in our register had a slightly lower WOSI score than in other studies also after the Latarjet procedure (Hovelius et al. 2011; Flinkkilä and Sirniö 2015). We found no difference in outcome for high- and low-volume hospitals in our material. A reason for the difference in WOSI score may be that reporting to a register by mail instead of directly to the treating hospital can make the patients more willing to report an inferior result, but real differences in outcome related to patient selection,

surgical methodology, rehabilitation and rate of return to sports are other possible explanations.

In our material, we had a patient-reported recurrence rate for arthroscopic Bankart 2.7 years after surgery of 17%, in comparison with 15% reported 3 years postoperatively in a study by Boileau et al. (2006). Castagna et al. (2010) report a 23% recurrence rate 10 years after surgery, with half of the recurrence episodes occurring more than 6 years after surgery. By combining the reported recurrence in paper I-III, there is an increase in recurrence over time (Figure 11). We must therefore expect an even higher recurrence rate with a longer follow-up. 12% of the stabilising procedures included in Paper III were revisions. This might give an indication on the magnitude of revision surgery, but we need to follow the primary procedures over a longer time period to be able to make any conclusions.

Recurrence rate vs. time of follow-up
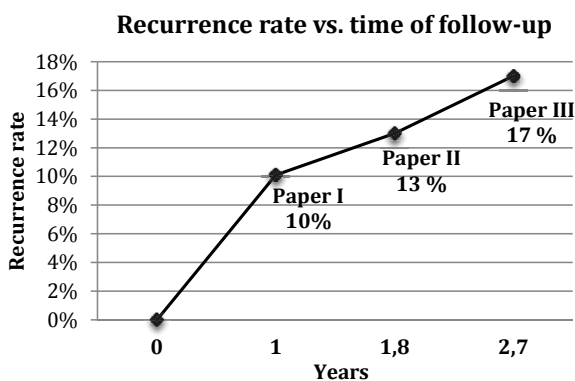
Figure 11. Recurrence rate for arthroscopic Bankart in Paper I-III in relation to time of follow-up.

5.2.3 The effect of anti-inflammatory drugs

The use of NSAIDs after procedures dependent on bone and collagen healing is controversial in the orthopaedic environment. Healing of labral lesions involve an inflammatory response (Abe et al. 2012) and could theoretically be inhibited by anti-inflammatory drugs. The scepticism is reflected by the fact that only one third of the patients in Paper II were prescribed NSAIDs postoperatively. Although other side effects, mainly gastrointestinal (Thiéfin et al. 2010), may account for some restraint, one may speculate that the concern regarding the long-term surgical result is the main reason for the limited use in this young patient population.

In Paper II, we found that 43% of the patients treated with arthroscopic Bankart had an ambulatory procedure. 54% of the outpatients had NSAIDs prescribed post-operatively, compared to 19% of the inpatients. This finding may imply that the more extent use of NSAIDs for ambulatory patients reflects the need for proper pain control without the facilities for inter-scalene block or parenteral analgesics, but we have no definitive information on this. As there is no difference in the outcome between the groups, this study support the view that short-term NSAIDs in moderate dosages can be safely administered after arthroscopic Bankart in respect of possible negative effects on healing, thus facilitating a more cost-effective ambulatory treatment regime.

5.2.4 Outcome after Bankart and Latarjet procedures

The findings in Paper III is in accordance with previous published studies where the long-term recurrence rate is found to be at least twice as high for arthroscopic Bankart as for open Latarjet (Boileau et al. 2006; Bessiere et al. 2013; Mizuno et al. 2014). The absolute rate of recurrence varies considerably between studies and is dependent on time of observation and definition of recurrence. In our study we believe to have a relatively low threshold to define a recurrence episode, as we defined any patient-reported dislocation or subluxation, with and without a new traumatic event, as recurrence of instability.

Despite the difference in recurrence rate between the two treatments, there was no difference in the functional outcome measured by the WOSI score. A previous study has shown that a single postoperative subluxation lowers the WOSI score by 10% and a frank dislocation results in a 20% decrease (Kemp et al. 2012). In the current study, we found that patients that reported recurrence of instability did not improve their WOSI score compared to baseline. The item-analysis of the WOSI score implies that the lack of difference between the groups might be related to a lower postoperative mobility after open Latarjet than after arthroscopic Bankart. One review reported a mean loss of external rotation after open Latarjet to be 12° (Griesser et al. 2013), while another study reported less restriction after open Latarjet than after open Bankart (Hovelius et al. 2011). Several studies report no or only marginal differences in mobility after open and arthroscopic Bankart (Bottoni et al. 2006; Godin and Sekiya 2011; Mohtadi et al. 2014). Previous literature is therefore undecided and there might be methodological differences in how the procedures were performed.

5.2.5 Predictors of outcome after surgical treatment

Young age has been found to be a risk factor for inferior outcome after shoulder stabilisation in several studies (Balg and Boileau 2007; Voos et al. 2010; Bessiere et al. 2013; Mohtadi et al. 2014; Waterman et al. 2014). In Paper III, we demonstrated a relationship between age below 20 and recurrence. The effect of young age on the recurrence rate was not only present for the arthroscopic Bankart procedure but also for the Latarjet procedure in our material. This corresponds to the findings of Bessiere et al. who found that young age, but not bone loss or competitive sports, was a risk factor for recurrence after both arthroscopic Bankart and Latarjet procedures (Bessiere et al. 2013). The age element of the ISIS score, where age below 20 years increases the indication for a Latarjet procedure, might therefore be questioned (Balg and Boileau 2007). As Bessiere et al., we did not find a relationship between gender and recurrence. The finding is contrary to that of Mohtadi et al. (Mohtadi et al. 2014).

There was an increased risk of recurrence after arthroscopic Bankart for patients with a combination of glenoid bone loss and engaging Hill Sachs lesions. This factor was present despite the fact that bone loss was taken into account by the surgeon, as these patients were overrepresented in the Latarjet group. Di Giacomo et al. presents the concept of bipolar bone loss where stability depends on the combined bone loss of glenoid and humerus (Di Giacomo et al. 2014). The findings in Paper III support their view that the combined bone loss increases the recurrence rate more than unipolar lesions. A majority of these patients will probably profit from a Latarjet procedure, but remplissage may be an alternative if the glenoid lesion is small. In the Latarjet group glenoid bone loss seemed to have a protective effect. A possible explanation might be that the Latarjet procedure works less well in patients with other risk factors of recurrence not accounted for in this study, for example hyperlaxity.

A previous arthroscopic Bankart procedure affects the functional outcome, not only of a revision Bankart, but also of a Latarjet procedure. A series of revision cases will always include problematic cases resulting in a selection bias that might account for the observed difference. On the other hand, according to the Norwegian surgical tradition, primary Latarjet procedure is to a large extent reserved for the patients where a high recurrence rate is anticipated due to a high ISIS-score or bone loss. The difference in

outcome in the WOSI score between primary and revision procedures is therefore somewhat surprising. It may be an argument not to choose a strategy were you treat most patients with a Bankart and revise those that fails with a Latarjet. Flinkkilä and Sirniö (2015) show good functional results for Latarjet after a failed arthroscopic Bankart procedure, but have a 14% recurrence rate after 1.5 years.

6 Interpretations and conclusions

Anterior traumatic instability is the dominating indication for instability surgery in the shoulder. Procedures for treating posterior and multidirectional instability are however more common than expected and constitute 17% of the primary procedures. This proportion corresponds with epidemiological studies were not only dislocations, but also subluxations of the shoulder joint is included.

Arthroscopic Bankart is by far the most common technique for treating shoulder instability, accounting for 88% of the primary anterior procedures and almost all procedures for posterior and multidirectional instability. In revision surgery and for patients with bone loss, the open Latarjet procedure is used in a large proportion of the cases.

12% of the registered procedures are revisions, indicating a relatively large proportion of failures in the stabilisation procedures.

The use of anti-inflammatory drugs in the postoperative phase seems not to affect the outcome of arthroscopic Bankart. Ambulatory patients had a higher prescription of these drugs that may facilitate same-day surgical care.

Arthroscopic Bankart had a higher recurrence rate than open Latarjet, but there was no difference in the functional outcome. The recurrence rate for arthroscopic Bankart increased with time of follow-up. Patients with recurrence had a significant lower functional score than patients with stable shoulders, without any improvement from baseline. Item-analysis of the WOSI score implies that the lack of functional difference between the two procedures may be due to a lower mobility in the Latarjet group.

Age below 20 years at time of surgery was a risk factor for recurrence both for arthroscopic Bankart and open Latarjet. For arthroscopic Bankart, the presence of combined bony lesions in the glenoid rim and the humeral head increased the risk of recurrence.

7 Future research

Further use of a register for shoulder instability surgery seems to be justified to better understand the risk factors for an inferior outcome and how to choose the right procedure for a particular patient. With a better coverage and preferable a higher response rate from the patients the conclusions will be more accurate. The future use of web-based questionnaires and integration in hospital systems may facilitate this.

A randomised trial would prevent selection bias and could better answer the question of which procedure gives the best outcome: Bankart or Latarjet, open or arthroscopic. It could however be hard to define what the best outcome is, as the recurrence rate might be lower in one group and the functional outcome better in the other. Athletes dependent on throwing capability might give a different answer than athletes using their arms below shoulder height but with a high risk of new shoulder traumas. The inclusion criteria would affect the outcome and reduce the external validity of a trial. A randomised trial conducted by a register would facilitate the execution of a study and increase the external validity, as large numbers of patients could be included, and the patients would be operated at average hospitals by average shoulder surgeons.

PROMs and recurrence rate only gives an indication of the shoulder function, and long-term clinical and radiological evaluation should preferably be performed, at least for selected patients. In addition to measurement of range of motion and the prevalence of osteoarthritis, isokinetic test of muscular strength and endurance would add knowledge to the functional outcome for the different procedures.

It seems appropriate to conclude as Professor Perthes did in 1906: *"The surgical treatment of recurrent shoulder dislocation is still not a closed chapter of surgery...we wish not only to prevent recurrent dislocations with our surgery, but also restore the function of the shoulder joint as far as possible."*

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Appendix 1 Western Ontario Shoulder Instabiliy Index (WOSI)

INSTRUCTIONS TO PATIENTS

In Sections A, B, C, and D you will be asked to answer questions in the following format and you should give your answer by putting a slash "**/**" across the horizontal line.

NOTE:

1. If you put a slash "**/**" at the left end of the line i.e.

no
pain
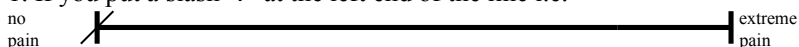
extreme
pain

then you are indicating that you have no pain.

2. If your put your slash "**/**" at the right end of the line i.e.

no
pain
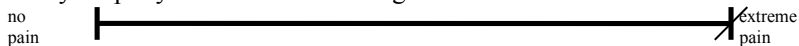
extreme
pain

then you are indicating that your pain is extreme.

3. Please note:
a) that the further to the right you put your slash "**/**" , the
more you experience that symptom.

b) that the further to the left you put your slash "**/**", the **less** you experience that symptom.

c) please do not place your slash "/" outside the end markers

You are asked to indicate on this questionnaire, the amount of a symptom you have experienced in the past week as related to your problematic shoulder. If you are unsure about the shoulder that is involved or you have any other questions, please ask before filling out the questionnaire.

If for some reason you do not understand a question, please refer to the explanations that can be found at the end of the questionnaire. You can then place your slash "**/**" across the horizontal line at the appropriate place. **If an item does not pertain to you or you have not experienced it in the past week, please make your "best guess" as to which response would be the most accurate.**

Section A:
Physical Symptoms

INSTRUCTIONS TO PATIENTS

The following questions concern the physical symptoms you have experienced due to your shoulder problem. In all cases, please enter the amount of the symptom you have experienced in the last week. (Please answer with a slash "/" across the horizontal line.)

1. How much pain do you experience in your shoulder with overhead activities?

no   extreme
pain   pain

2. How much aching or throbbing do you experience in your shoulder?

no   extreme
aching/   aching/
throbbing   throbbing

3. How much weakness or lack of strength do you experience in your shoulder?

no   extreme
weakness   weakness

4. How much fatigue or lack of stamina do you experience in your shoulder?

no   extreme
fatigue   fatigue

5. How much clicking, cracking or snapping do you experience in your shoulder?

no   extreme
clicking   clicking

Section A: Cont'd

6.   How much stiffness do you experience in your shoulder?

no   extreme
stiffness   stiffness
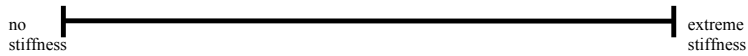
7.   How much discomfort do you experience in your neck muscles as a result of your
        shoulder?

no   extreme
discomfort   discomfort

8.   How much feeling of instability or looseness do you experience in your
        shoulder?

no   extreme
instability   instability
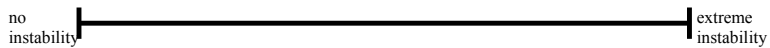
9.   How much do you compensate for your shoulder with other muscles?

not   extreme
at all
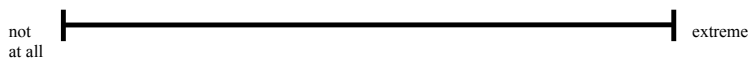
10.   How much loss of range of motion do you have in your shoulder?

no   extreme
loss   loss

SECTION B: Sports/Recreation/Work

INSTRUCTIONS TO PATIENTS

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 with a slash "/" across the horizontal line.

11. How much has your shoulder limited the amount you can participate in sports or recreational activities?

not
limited |————————————————————————————————| extremely
limited

12. How much has your shoulder affected your ability to perform the specific skills required for your sport or work? (If your shoulder affects both sports and work, consider the area that is most affected.)

not
affected |————————————————————————————————| extremely
affected

13. How much do you feel the need to protect your arm during activities?

not at
all |————————————————————————————————| extreme

14. How much difficulty do you experience lifting heavy objects below shoulder level?

no
difficulty |————————————————————————————————| extreme
difficulty

SECTION C: Lifestyle

INSTRUCTIONS TO PATIENTS

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 a slash "/" across the horizontal line.

15.   How much fear do you have of falling on your shoulder?

no   extreme
fear   fear

16.   How much difficulty do you experience maintaining your desired level of fitness?

no   extreme
difficulty   difficulty

17.   How much difficulty do you have "roughhousing or horsing around" with family or friends?

no   extreme
difficulty   difficulty

18.   How much difficulty do you have sleeping because of your shoulder?

no   extreme
difficulty   difficulty

SECTION D: Emotions

INSTRUCTIONS TO PATIENTS

The following questions relate to how you have felt in the past week with regard to your shoulder problem. Please indicate your answer with a slash "/" across the horizontal line.

19.   How conscious are you of your shoulder?

not
conscious |————————————————————| extremely
conscious

20.   How concerned are you about your shoulder becoming worse?

no
concern |————————————————————| extremely
concerned

21.   How much frustration do you feel because of your shoulder?

no
frustration |————————————————————| extremely
frustrated

_____

THANK YOU FOR COMPLETING THE QUESTIONNAIRE

Appendix 2 Patient questionnaire with WOSI (Norwegian)

Register for skulderstabiliserende kirurgi
- *et forskningsprosjekt ved Universitet i Bergen i samarbeid med norske sykehus som behandler skulderinstabilitet*

Kontaktadresse:
Overlege Jesper Blomquist
Haraldsplass Diakonale Sykehus,
Pb 6165, 5892 Bergen
Tlf: (+ 47) 5597 8710
E-post: jesper.blomquist@haraldsplass.no

SPØRRESKJEMA FØR OPERASJON

Fødselsnr: _____ _____

Navn: _____

Adresse: _____

Postadresse: _____

FORESPØRSEL OM DELTAGELSE I OPERASJONSREGISTER FOR SKULDERKIRURGI

I forbindelse med din skulderoperasjon ber vi om tillatelse til å lagre opplysninger vedrørende operasjonen og at du besvarer spørsmål om hvordan din skulder fungerer. Ytterligere informasjon gis i vedlagt samtykkeerklæring. Alle svar behandles konfidensielt. Dersom du aksepterer deltakelse kommer du få tilsendt spørsmål 2 og 5 år etter operasjonen for å følge skulderfunksjonen over tid. Vi ber om at alle spørsmålene besvares og at du markerer <u>et</u> svarsalternativ per spørsmål (det som samsvarer best).

Dato for utfylling: ____.____.____

E-post (for oppfølging, skriv tydelig): _____

Mobilnr (for oppfølging): _____

Kryss av for riktig skulder (den som nå skal opereres)
    Høyre   Venstre

Var det en skade som forårsaket at skulderen gikk ut av ledd første gang?
    Ja   Nei, den gikk ut av seg selv   Usikker   Har aldri gått ut av ledd
Dersom ja, hvilken idrett eller annen aktivitet var det som forårsaket skaden? _____

Hvor lenge siden er det skulderen gikk ut av ledd for første gang?
    Mindre enn 3 mnd   3-12 mnd   1-2 år   2-5 år   Mer enn 5 år   Har aldri gått ut av ledd

Hvor mange ganger har skulderen gått ut av ledd totalt?
    Ingen   1 gang   2-5 ganger   6-10 ganger   11-20 ganger   Mer enn 20 ganger

Hva er den laveste aktivitetsnivå som har ført til at skulderen har gått ut av ledd?
    Fall på armen   Idrett   Daglig aktivitet/arbeid   Spontant/i søvne   Går ikke ut av ledd

Bruker du tobakksprodukter?
    Nei   Røyker 5 sigaretter daglig eller mer   Røyker mindre enn 5 sigaretter daglig   Snuser

<u>Før operasjonen:</u> Bedriver du regelmessig idrett med store krav til skulderfunksjon?
(for eksempel håndball, fotball, rugby, kampsport, kajakk, ski, snowboard, klatring, kasteidretter)

    Nei, ikke aktuelt for meg uavhengig av skulderfunksjon

    Nei, jeg er utrygg på armen og vil ikke risikere ny skade

    Nei, skulderfunksjonen tillater ikke dette per i dag

    Ja, mosjonistnivå

    Ja, elitenivå   Dersom ja, angi idrett med størst skulderbelastning: _____ _____

<u>Før operasjonen:</u> Påvirker skulderen din evne til å utføre ditt arbeid?

    Nei. (Hvis du ikke er i arbeid av andre grunner svarer du nei)

    Ja, det påvirker meg i arbeidssituasjoner, men jeg har vært i arbeid <u>siste uken før operasjonen.</u>

    Ja, det påvirker meg uttalt i arbeid og jeg var helt eller delvis sykemeldt <u>siste uken før operasjonen.</u>

Veiledning for besvarelse av spørreskjemaet:
I spørreskjemaet under blir du bedt om å svare på spørsmålene på følgende måte: Ved å markere med en strek **/** på den vannrette (horisontale) linjen viser du hvordan du opplever din situasjon:

Eksempel:
1. Om du setter en strek **/** lengst til venstre på linjen viser du at du ikke har smerte i det hele tatt dvs. ingen**.**

Ingen smerte ────────────────────────────────── Ekstrem smerte
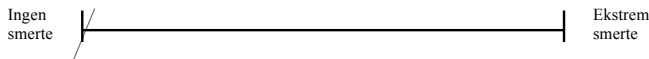
2. Om du setter en strek **/** lengst til høyre på linjen viser du att du har ekstremt mye smerte.

Ingen smerte ────────────────────────────────── Ekstrem smerte
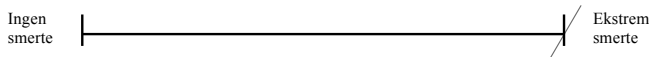
Vennligst vær klar over at:
a) Jo lengre til **høyre** du setter streken din **/** desto **mer** opplever du angitte symptom.
b) Jo lengre til **venstre** du setter streken din **/** desto **mindre** opplever du symptomet.
c) Du må ikke sette streken **/** utenfor endemarkeringene**.**

I dette spørreskjemaet blir du bedt om angi **graden** av symptomer, det vil si plager som du har opplevd på grunn av skulderen din, i løpet av den **siste uken**.
Alle spørsmål skal besvares. Dersom du ikke har utført den aktivitet som spørsmålet omhandler, vennligst prøv å anslå hvor mye plager aktiviteten hadde forårsaket.

Del A: Fysiske symptomer

De følgende spørsmålene angår de fysiske symptomer som du har opplevd på grunn av ditt skulderproblem. Ved alle spørsmål, var vennlig å angi graden av symptomer du har hatt den siste uken. Vennligst marker hvert svar med en strek på den vannrette linjen.

1. Hvor mye smerter har du i skulderen ved aktiviteter over hodehøyde?

├─────────────────────────────────────┤

Ingen smerte   Ekstrem smerte
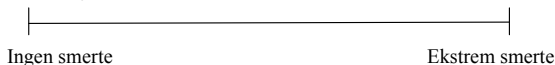
2. Hvor mye verking eller bankende smerte har du i skulderen?

├─────────────────────────────────────┤

Ingen   Ekstremt mye
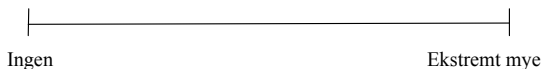
3. Hvor mye er skulderen svekket eller hvor mye styrke mangler du?

├─────────────────────────────────────┤

Ikke svekket   Ekstremt svekket
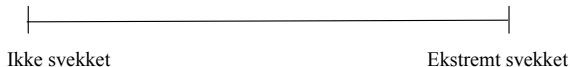
4. Hvor mye tretthet eller mangel på utholdenhet har du i skulderen?

├─────────────────────────────────────┤

Ingen tretthet   Ekstrem tretthet

5. Hvor mye klikking, knaking eller knepping har du i skulderen?

├─────────────────────────────────────┤

Ingen klikking   Ekstrem klikking
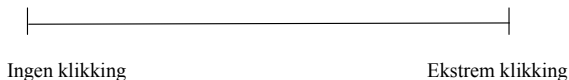
6. Hvor stiv føler du deg i skulderen?

├─────────────────────────────────────┤

Ikke stiv   Ekstremt stiv

7. Hvor mye ubehag føler du i nakkemusklene som følge av skulderproblemene?

├─────────────────────────────────────┤

Ikke noe ubehag   Ekstremt mye ubehag

8. Hvor ustabil eller lealaus føler du at skulderen er?

├─────────────────────────────────────┤

Ikke ustabil   Ekstremt ustabil

9. Hvor mye kompenserer du for skulderen ved å bruke andre muskler?

├─────────────────────────────────────┤

Ikke i det hele tatt   Ekstremt mye

10. Hvor mye er bevegeligheten i skulderen redusert?

├─────────────────────────────────────┤

Ikke i det hele tatt   Ekstremt mye

Del B: Sport / fritid / arbeid

Den følgende delen omhandler hvordan ditt skulderproblem har påvirket dine sports- fritids- og arbeidsaktiviteter <u>den siste uken</u>. Vennligst marker hvert svar med en strek på den vannrette linjen.

11. Hvor mye har skulderen hemmet deg i å kunne delta i sport og fritidsaktiviteter?

├─────────────────────────────────────┤

Ikke hemmet   Ekstremt hemmet

12. Hvor mye har skulderen innvirket på spesielle ferdigheter som du trenger i sport

eller arbeid? (Hvis skulderen har innvirket på begge aktiviteter, ta da den mest rammede i

betraktning.)

├─────────────────────────────────────┤

Ikke i det hele tatt   Ekstremt mye

13. I hvor stor grad føler du at du må beskytte armen under aktivitet?

├─────────────────────────────────────┤

Ikke i det hele tatt   Ekstremt mye

14. Hvor store vanskeligheter har du med å løfte tunge gjenstander under skulderhøyde?

├─────────────────────────────────────┤

Ingen vanskeligheter   Ekstreme vanskeligheter

Del C: Livsstil

Den følgende delen omhandler hvordan ditt skulderproblem har påvirket eller forandret din livsstil. Igjen, vennligst marker graden av påvirkning den siste uken med en strek på den vannrette linjen.

15.   Hvor redd er du for å falle på skulderen?

Ikke redd   Ekstremt redd

16.   Hvor vanskelig synes du det er å holde seg i form som du ønsker?

Ikke vanskelig   Ekstremt vanskelig

17.   Hvor vanskelig synes du det er å delta i fysisk lek og moro sammen med familie og venner?

Ikke i det hele tatt   Ekstremt mye

18.   Hvor store vanskeligheter har du med å sove på grunn av skulderen?

Ingen vanskeligheter   Ekstreme vanskeligheter

Del D: Følelser

Veiledning til pasienten:

De følgende spørsmålene handler om hvordan du har følt deg den siste uken i forhold til ditt skulderproblem. Vennligst marker hvert svar med en strek på den vannrette linjen.

19.   Hvor opptatt av/obs på skulderen er du?

Ikke opptatt av   Ekstremt opptatt

20.   Hvor bekymret er du for at skulderen skal bli verre?

Ikke bekymret   Ekstremt bekymret

21.   Hvor mye frustrasjon føler du på grunn av skulderen?

Ingen frustrasjon   Ekstrem frustrasjon

Takk for at du tok deg tid til å besvare spørreskjemaet! Se gjerne gjennom skjemaet før du sender det inn og kontroller at alle spørsmålene er besvart.

Appendix 3 Surgeon´s form (English translation)

Register of shoulder instability surgery
- a cooperative project at Norwegian hospitals treating shoulder instability

Contact address:
Dr Jesper Blomquist
Haraldsplass Deaconal Hospital,
Pb 6165, 5892 Bergen, NORWAY
Tlf: (+47) 5597 8500

Patietn ID and date of birth:(11digits)

Name:

Hospital:

SHOULD INSTABILITY SURGERY – SURGEON`S FORM

❑ **STABILIZATION PROCEDURES IN THE SHOULDER**
❑ **ALL REVISION PROCEDURES AFTER STABILIZATION PROCEDURS**

INDEX SIDE ☐ Høyre ☐ Venstre
(bilateral surgery=2 forms)

OPPOSITE SHOULDER ☐ Normal ☐ Instability
☐ Other pathology

PREVIOUS SURGERY IN INDEX SHOULDER
☐ No surgery or diagnostic arthroscopy
☐ Stabilization (specify type):
☐ Other surgery, specify:

CLASSIFICATIION OF SHOULDER INSTABILITY
Direction ☐ Anterior ☐ Posterior ☐ MDIl
Grade ☐ Dislocation ☐ Subluxation ☐ Uncertain
X-ray verified dislocation? ☐ Yes ☐ No

TIME OF FIRST DISLOCATION (mm.yy): ____.____
(First subluxation for patients without dislocation)

INJURY CAUSING FIRST DISLOCATION?
(first postoperative dislocation for revision cases)
☐ Yes ☐ No ☐ Uncertain

ACTIVITY THAT LEAD TO INJURY (if plausible)
☐ _____

ACTIVITY NEEDED TO CAUSE REDISLOCATIONS
☐ Injury ☐ Sports ☐ Daily activity ☐ Spontaneous

NUMBER OF DISLOCATION BEFORE SURGERY
(Only dislocations, not subluxations)

☐ 0 ☐ 1 ☐ 2-5 ☐ 6-10 ☐ 11-20 ☐ >20
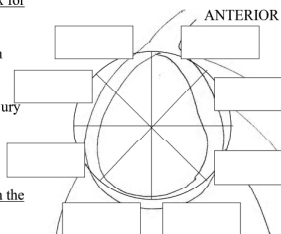
PREOPERATIVE FINDINGS
Normal variants
☐ Sublabral foramen ☐ Buford complex ☐ _____

Injuries in labrum capsule and glenoid + implants
State injuries in the box for
each sector

ANTERIOR

1. Degenerative labrum
2. Avulsion of labrum
3. Rupture in labrum
4. Capsule/ligament injury
5. HAGL
6. Glenoid resorption
7. Glenoid fracture

Mark implants direct in the
figure with "X"

Size of intraarticular bone defects
☐ Reverse pear glenoid (>25% loss of diameter)
Hill-Sachs lesion: ☐ "engaging" ☐ "not engaging"

Other injuries (SLAP is marked in the figure)
No other injuries: ☐
Biceps pathology ☐
Suprapspinatus rupture ☐ Total ☐ Partial
Infraspinatus rupture ☐ Total ☐ Partial
Subscapularis rupture ☐ Total ☐ Partial
Clinical nerve injury ☐ Axillaris ☐ Plexus
☐ Other findings, specify:

PROSEDURES (mark all that apply)
Fixation of labrum (mark in the figure)
Debridement of labrum ☐ Anterior ☐ Posterior ☐ Superior
Capsular shift ☐ Anterior ☐ Posterior
Plication of capsule ☐ Anterior ☐ Posterior ☐ Inferior
Closure rotator interval ☐
Bone block procedure ☐ Latarjet
☐ Other, specify:
Biceps tendon ☐ Tenodesis ☐ Tenotomy
Synevektomy ☐ Total ☐ Partial
Cuff suture ☐
Removal of: ☐ Loose bodies ☐ Implants
Capsulotomy ☐ 360º ☐ Other
MUA ☐
Lavage due to infection ☐
☐ other procedure, specify:

IMPLANTAT FOR LABRUM REATTACHMENT
(identifying labels on the other side)
☐ Direct sutures through bone without implants
☐ No implants used
☐ No id labels (state implant on the other side)

DATE OF SURGERY (dd.mm.yy): ____.____.____

APPROACH ☐ Open ☐ Arthroscopic ☐ Combined

POSISTION ☐ Beach chair ☐ Lateral

OUTPATIENT SURGERY ☐ Yes ☐ No

PER OPERATIVE COMPLICATIONS ☐ Yes ☐ No
Which: _____

DURATION OF SURGERY (skin to skin): _____min

SYSTEMIC ANTIBIOTIC PROPHYLAXIS ☐ Yes ☐ No

NSAID ☐ No ☐ Yes(name, days):_____

POSTOP. RESTRICTION Weeks of immobilization: ____

☐ Int.rotation ☐ Neutral pos. ☐ Ext. rotation

SURGEON: (for questions, not registered in database):

Appendix 4 Surgeon´s form (Norwegian)

Register for skulderstabiliserende kirurgi
– et forskningsprosjekt ved Universitet i Bergen i samarbeid
med norske sykehus som behandler skulderinstabilitet

Kontaktadresse:
Overlege Jesper Blomquist
Haraldsplass Diakonale Sykehus,
Pb 6165, 5892 Bergen
Tlf: (+47) 5597 8500 Faks: (+47) 5597 8718
E-post: jesper.blomquist@haraldsplass.no

Fnr.:(11 Sifre) _____

Navn: _____
(Skriv tydelig, ev pasientklistrelapp)

Sykehus:

OPERASJON FOR SKULDER SOM GÅR UT AV LEDD - KIRURGI

☐ **STABILISERENDE OPERASJONER I SKULDER**
☐ **ALLE REOPERASJONER DER DET TIDLIGERE ER UTFØRT STABILISERENDE KIRURGI**

AKTUELL SIDE   ☐ Høyre   ☐ Venstre

MOTSATT SKULDER   Normal | Instabil
                                     Annen patologi

TIDLIGERE OPERASJON I AKTUELL SKULDER
☐ Ingen operasjon, eller ren diagnostisk artroskopi
☐ Stabilisering (angi type):
☐ Annen operasjon, spesifiser:

KLASSIFISERING AV SKULDERINSTABILITETEN
Retning | Fremre | Bakre | | Multidireksjonal
Grad   ☐ Luksasjon ☐ Subluks ☐ Usikker
Rtg-verifisert luksasjon? ☐ Ja   ☐ Nei

DATO FOR FØRSTE LUKSASJON (mm.åå): _____._____
(Første subluksasjon for dem som ikke har totalluksasjoner)

TRAUME VED FØRSTE LUKSASJON/SUBLUKS
(Ved første postoperative reluksasjon hvis skulderen er stabilitetsop.
tidligere)   ☐ Ja   ☐ Nei   ☐ Usikker

VED TRAUME, AKTIVITET SOM FØRTE TIL SKADEN
☐ _____

NØDVENDIG KRAFT FOR RELUKSASJON/SUBLUKS
☐ Traume ☐ Idrett ☐ Daglig aktivitet ☐ Spontan/nattlig

ANTALL LUKSASJONER FØR DENNE OPERASJON
(Subluksasjoner skal ikke inkluderes, kun fullstendige luksasjoner)

☐ 0   ☐ 1   ☐ 2-5   ☐ 6-10   ☐ 11-20   ☐ >20

OPERASJONSFUNN
Normalvarianter
☐ Sublabralt **foramen** ☐ Bufordkompleks ☐ _____

Skader på labrum, kapsel og glenoid + implantatplassering
Angi skader med tallkode i
boks for aktuelle sektor   ANTERIOR

1. Oppflosset labrum
2. Labrumavulsjon
3. Ruptur i labrum
4. Kapsel/ligamentskade
5. HAGL
6. Glenoidresorpsjon
7. Glenoidfraktur

Markere hvert implantat
som settes direkte på figur
med "X"
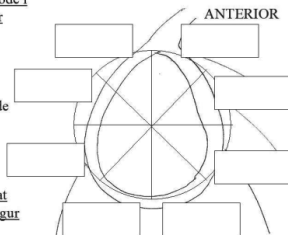
Størrelse på beinete intraartikulare skader
☐ Omvendt pæreform av Glenoid (tap av >25% diameter)
Hill-Sachs lesjon: ☐ "engaging"   ☐ "not engaging"

Andre skader (SLAP registreres i figur nede til ve)
Ingen andre skader påvist: ☐
Bicepssenepatologi   ☐
Suprapspinatusruptur   ☐ Total   ☐ Partiell
Infraspinatusruptur   ☐ Total   ☐ Partiell
Subscapularisruptur   ☐ Total   ☐ Partiell
Nerveskade   ☐ Axillaris ☐ Plexus
☐ Andre funn, spesifiser:

UTFØRTE PROSEDYRER (ev flere kryss)
Fiksasjon av labrum   (marker i figuren)
Debridement av labrum ☐ Fremre ☐ Bakre ☐ Øvre
Kapselskift nedfra-opp ☐ Fremre ☐ Bakre
Plikering av kapsel   ☐ Fremre ☐ Bakre ☐ Inferior
Lukke rotatorintervall   ☐
Beinblokkprosedyre   ☐ Latarjet
                                      ☐ Annen, spesifiser:
Bicepssene   ☐ Tenodese   ☐ Tenotomi
Synevektomi   ☐ Total   ☐ Partiell
Cuffsutur   ☐
Fjerning av: ☐ Fritt legeme   ☐ Implantat
Capsulotomi   ☐ 360°   ☐ Annen
Mobilisering i narkose ☐
Lavage pga infeksjon   ☐
☐ Annen prosedyre, spesifiser:

IMPLANTAT FOR FORANKRING AV LABRUM
(merkelapper festes på baksiden)
☐ Direkte sutur til bein uten implantat
☐ Utført prosedyre krever ikke implantat
☐ Merkelapper mangler (angi brukt implantat på baksiden):

OPERASJONSDATO (dd.mm.åå): _____._____._____

TILGANG   ☐ Åpen   ☐ Endoskopisk   ☐ Kombinert

LEIE   ☐ Beach chair   ☐ Sideleie

DAGKIRURGISK OPERASJON   ☐ Ja   ☐ Nei

PEROPERATIVE KOMPLIKASJONER   ☐ Ja   ☐ Nei
Hvilke(n): _____

OPERASJONSTID (hud til hud): _____min

SYSTEMISK ANTIBIOTIKAPROFYLAKSE ☐ Ja   ☐ Nei

NSAID ☐ Nei ☐ Ja (preparat, antall dager):_____

POSTOP. REGIME Antall uker immobilisering: _____

☐ Innadrotert   ☐ Nøytralstilt   ☐ Utadrotert

UTFYLLENDE KIRURG (ved spørsmål, registreres i ikke):
_____

Shoulder instability surgery in Norway

The first report from a multicenter register, with 1-year follow-up

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Background and purpose In January 2008, we established the Norwegian Register for Shoulder Instability Surgery. We report on the establishment, the baseline data, and the results at 1-year follow-up.

Methods Primary and revision shoulder stabilization is reported by the surgeon on a 1-page paper form containing the patient's history of shoulder injury, clinical findings, and perioperative findings. The WOSI questionnaire for self-assessment of shoulder function is completed at baseline and at follow-up after 1, 2, and 5 years. To evaluate the completeness of registration, we compared our data with those in the Norwegian Patient Registry (NPR).

Results The NPR reported 39 hospitals performing shoulder stabilizations. 20 of these started to report to our register during 2009, and 464 procedures (404 primary, 59 revisions) were included up to December 31, 2009, which represented 54% of the procedures reported to NPR. Of the 404 primary procedures, 83% were operations due to anterior instability, 10% were operations due to posterior instability, and 7% were operations due to multidirectional instability. Arthroscopic soft tissue techniques were used in 88% of the patients treated for primary anterior instability and open coracoid transfer was used in 10% of such patients. At 1-year follow-up of 213 patients, we found a statistically significantly improved WOSI score in all types of instability. 10% of the patients treated with arthroscopic anterior labral repair and 16% treated with arthroscopic posterior labral repair reported recurrent instability. No statistically significant difference in functional improvement or rate of recurrence was found between these groups.

Interpretation The functional results are in accordance with those in previous studies. However, the incidence of recurrent instability 1 year after arthroscopic labral repair is higher than expected.

In Scandinavia, national quality registers have been used for many years to monitor outcome, thus making it possible to pinpoint inferior treatment methods (Herberts and Malchau 2000, Irgens 2000, Pahlman et al. 2005).

There are nationwide registers for joint replacement in several countries, and cruciate ligament registers have been established in Sweden, Denmark, and Norway (Granan et al. 2009). Most orthopedic registers are based on a simple reporting system whereby the surgeon completes a registration form, which is transferred to a secretariat either electronically or by post. In the Scandinavian cruciate ligament and hip fracture registers, the patients are also asked to complete an outcome questionnaire (Gjertsen et al. 2008, Granan et al. 2009). The reporting systems are simple to use and fast to fill in, and in return the hospitals are provided with feedback on the outcome of their patients, which are easily compared to that of the average outcome. The simplicity of use and the feedback provided are of benefit to each hospital, which may explain the high compliance rate (Espehaug et al. 2006).

To our knowledge, no national quality registers for shoulder instability surgery have been reported yet (Pulavarti et al. 2009). The experience from other orthopedic registers and the reported disparity concerning the results of surgery for shoulder instability was the background for establishment of a shoulder instability register. During the last decade, arthroscopic stabilization techniques have replaced open surgery to a large extent, as in some studies the short- and medium-term results of the former techniques have been found to be similar to those of open Bankart repair (Sperber et al. 2001, Bottoni et al. 2006, Fabbriciani et al. 2004). However, some other studies with medium-term or long-term follow-up have shown less satisfactory results after arthroscopic Bankart repair, with recurrent instability in 15.3–23% of patients (Boileau et al. 2006, Castagna et al. 2010). Thus, non-anatomical methods

such as the Latarjet procedure have been proposed for use in patients with concomitant risk factors of recurrence (Boileau et al. 2006, Burkhart et al. 2007).

The aims of our recently established Register for Shoulder Instability Surgery are to collect epidemiological data, to evaluate the results of different treatment methods, to identify prognostic factors associated with good and poor outcome, and to facilitate improved treatment through direct feedback to the participating hospitals. In this article we describe the register, the methods used, the baseline data of the patients included, and our experience during the first 2 years of operation of the register. We also give the preliminary results of shoulder instability surgery, based on 1-year follow-up data.

Patients and methods

Based on the experience from a pilot study performed in 2006 at 12 hospitals and involving 107 patients (Liavaag et al. 2007), a working group was set up to plan the establishment of a Norwegian shoulder instability register. The first registration started in January 2008. 39 hospitals performing shoulder stabilization surgery were identified in the Norwegian Patient Register (NPR; www.npr.no) and they were invited to participate in the register.

Eligible for inclusion in the register were Norwegian-speaking residents of Norway undergoing primary or revision surgery for shoulder instability. All directions of instability and both dislocation and subluxation are accepted for inclusion in the register. The patients are asked to complete the Western Ontario Shoulder Instability Score (WOSI) (Kirkley et al. 1998) and to provide information about their profession and their level of sports activity.

The WOSI score consists of 21 items divided into 4 domains, to be answered using visual analog scales. The total score is presented as a number between 0 (best) and 2,100 (worst), or transformed to a score where 100% equals normal shoulder function and 0% is the worst possible outcome. We use a Norwegian version of the WOSI score that has been translated and validated according to the guidelines presented by Guillemin et al. (1993). At 1, 2, and 5 years after the primary or revision surgery, the patients are asked to complete the same questionnaire. Furthermore, they are asked if they have experienced any new episodes of shoulder dislocation or if they have had additional surgery in the same shoulder. If additional surgery has been performed to the same shoulder, consent is obtained to retrieve hospital records regarding the surgery.

Based on the experience of the pilot study, a registration form was designed (Appendix 1). The aims were to define the type of instability, to describe the surgical treatment, and to identify patient characteristics that might influence the risk of recurrent instability and functional outcome. Previous shoulder surgery, pathology in the opposite shoulder, history of injury, direction and degree of instability, duration of symp-

toms, minimum activity level to trigger instability symptoms, and number of dislocations were recorded. Any glenoid bone defects and injuries to the labrum and/or capsule were marked on a schematic drawing of the shoulder. Humeral head defects, tendon injuries, or other findings were recorded. The surgical procedures were described schematically, including descriptions of the types of implants used and their positioning. To obtain correct information for the implants used, the surgeons were encouraged to provide the identification stickers supplied by the manufacturer.

Revision stabilization is defined as the hard endpoint of the register, whereas soft endpoints are patient-reported recurrences of instability and WOSI score at follow-up.

To estimate the national coverage of the register, the data were compared to those in the Norwegian Patient Register (NPR). The NPR contains a modified NOMESCO Classification of Surgical Procedures (NOMESCO 2009) for all procedures performed in public or private hospitals that are funded by the Norwegian public social security. The NPR contains information on surgical procedures performed and patient age, gender, and co-morbidity, but no information regarding outcome.

Statistics

Mean substitution was used for replacing missing data. Distribution, with floor and ceiling effects, were analyzed. Subscores of 0–1% or 99–100% were considered to be extreme values, representing a floor or ceiling effect. Mean changes in WOSI score when comparing preoperative and 1-year results are given with 95% confidence intervals (CIs), and they were evaluated with paired t-test. Rates of recurrence in the different groups were compared with the chi-square test. Values of $p < 0.05$ were considered to be statistically significant. SPSS statistical software version 18.0 was used for the analyses.

Ethics

The register was designed to comply with the ethical standards of the revised Helsinki Declaration of 2000. Participation is voluntary, and confidentiality is ensured for the patient and for the surgeons. The patients are informed about the aim of the study and about the kinds of data that are collected. They are also informed that they may withdraw from the register and have their personal data deleted at any time. The register was approved by the Regional Ethics Committee (Rek-vest 245.07). The collection and storage of data was approved by the Norwegian Data Inspectorate (NSD 1791).

Results

The registration started in 8 hospitals in January, 2008. During 2008, 10 more hospitals joined the register, and 2 more started registration in the spring of 2009. During the period from January 2008 to December 2009, 464 stabilization procedures

Table 1. Distribution of surgical procedures

	Primary	Revision	Total
Anterior stabilization			
Arthroscopy			
Bankart	294	25	322
Capsular plication	6	3	6
Sum	300	28	329
Open			
Latarjet	35	26	60
Capsular shift	1	1	2
Sum	36	27	62
Total	336	55	391
Posterior stabilization			
Arthroscopy			
Bankart	31	1	32
Capsular plication	8	0	8
Sum	39	1	40
Open			
Bony	0	0	0
Capsular shift	1	0	1
Sum	1	0	1
Total	40	1	41
Multidirectional stabilization			
Arthroscopy			
Bankart	14	1	15
Capsular plication	14 [a]	1	15
Sum	28	2	30
Open			
Bony	0	0	0
Capsular shift	0	1	1
Sum	0	1	1
Total	28	3	31

[a] 3 with rotator interval closure

Table 2. Patient characteristics for primary stabilization

	Anterior (n = 336)	Posterior (n = 40)	Multidirectional (n = 28)
Sex (%male)	68	73	61
Age (median, range)	25 (13–74)	28 (14–56)	25 (10–45)
Instability in contralateral shoulder, n (%)	34 (10)	5	12
Traumatic debut, n (%)			
definitive	299 (89)	20	11
uncertain	20 (6)	9	4
Month of symptoms, median (range)	28 (0–489)	34 (4–234)	60
Most common activities at injury (n)	Daily activity (55) Ski (43) Soccer (24) Handball (20) Snowboard (17) Epilepsy (10) Assault (10) MC (8) Volleyball (8) Car (7) Weight lifting (7)	Daily activity (6) Handball (5)	Soccer (2) Ski (2)
Prophylactic antibiotics, n (%)	223 (69)	27	17
NSAID, n (%)	97 (31)	11	9
Day surgery, n (%)	133 (41)	8	9
Surgery position (beach), n (%) [a]	86 (30)	3	3
Operating time (median, range)	70 (18–200)	86	84
Concomitant SLAP lesion, n (%) [a]	70 (23)	12	6
Glenoid fracture, n (%)	21 (6)	0	0
Glenoid resorption, n (%)	28 (8)	1	0
HAGL (anterior or posterior)	0	1	1
Number of suture anchors (mean) [a]	2.61	2.38	2.39

[a] in arthroscopic procedures

Table 3. Preoperative WOSI, percent of maximum score: mean (SD)

	Primary anterior (n=314)	Revision anterior (n=50)	Primary posterior (n=39)	Primary multidirectional. (n=28)
WOSI total score	51 (18)	44 (18)	45 (14)	42 (16)
Physical symptoms and pain	59 (20)	52 (21)	48 (14)	45 (20)
Sport, recreation and work	40 (21)	34 (20)	41 (19)	38 (19)
Lifestyle and social functions	53 (23)	44 (23)	51 (21)	46 (20)
Emotions	36 (24)	30 (24)	36 (21)	31 (21)

were recorded (Table 1). No open labral repair or arthroscopic bony procedures were recorded.

Patient characteristics

89% of the primary anterior dislocations had a traumatic debut. 60% of the injuries were related to sports. Winter sports (20%) and ball games (17%)—including soccer and team handball—were the most common causative activities. 18% of cases were caused by a fall during daily non-athletic activities and 7% were caused by road traffic accidents, including bicycling (Table 2).

Preoperative functional score

Of the 464 patients who were included, 435 (94%) completed the preoperative WOSI form. Of these 435 WOSI forms containing a total of 9,135 items, data were missing for 85 items (0.9%) (Table 3). We found a normal distribution for the total score and all subscores, except for the emotional subscore for primary and revision anterior stabilization. In these groups, we found a positive skew, with a floor effect of 3% for primary cases and 8% for revision cases.

Table 4. Results at 1-year follow up after stabilization procedures

	Arthroscopy primary anterior (n=141[a])	Arthroscopy revision anterior (n=13)	Open primary anterior (n=10)	Open revision anterior (n=10)	Arthroscopy primary posterior (n=25)	Arthroscopy primary multidirectional (n=13)
Preop WOSI%, mean (SD)	51 (19)	48 (16)	55 (17)	48 (18)	45 (15)	42 (19)
1-year WOSI%, mean (SD)	75 (19)	64 (18)	80 (16)	69 (18)	63 (28)	76 (19)
Change in WOSI%, mean (CI 95%)	24 (20–27)	16 (3–30)	26 (13–38)	21 (14–28)	17 (8–26)	34 (24–45)
p-value	p<0.001	p=0.02	p=0.001	p<0.001	p=0.001	p<0.001
Recurrent instability(n)	14	0	0	0	4	0
Reoperation (n)	6	0	1	0	2	1

[a] n=138 for rate of recurrence and reoperation

One-year follow-up

213 of 296 patients who were included until June 2009 completed the follow-up WOSI index and 210 also reported on recurrence of instability and additional surgery (Table 4). For all groups with primary stabilization and with anterior revision stabilization, we found a statistically significant improvement in shoulder function after 1 year. 10% of the patients who were treated with arthroscopic anterior labral repair and 16% of those treated with arthroscopic posterior labral repair reported having experienced at least 1 recurrent dislocation at the time of follow-up. There were no statistically significant differences between the groups regarding change in WOSI score, rate of recurrence, or rate of reoperation.

National coverage of the register

In 2009, 315 stabilization procedures were included in the shoulder instability register. 587 patients were entered into the Norwegian Patient Register during the same period.

Discussion

With 4.8 million residents in Norway and 587 procedures (according to the NPR), the annual incidence of shoulder stabilization surgery in 2009 was 12 per 105 inhabitants. The male-to-female ratio for surgery was 2.2 to 1. The corresponding figure for Sweden, when the NOMESCO classification is used, was the same, with a 2.9-times higher rate for men than for women (Socialstyrelsen 2008). The annual number of procedures coded as shoulder stabilization in the NPR increased from 486 in 2007 to 587 in 2009. The trend was the same in Sweden, with an increased incidence of shoulder stabilization of 37% between 2006 and 2008 (Socialstyrelsen 2008). We have not found any other incidence figures regarding instability surgery in other countries.

Based on the information provided by the NPR, we estimate that about 54% of all stabilization procedures performed in 2009 were included in the register. For the Norwegian Hip Fracture Register, the registration completeness after 2 years of operation was 79% (Gjertsen et al. 2008). Compliance rates for the Nordic cruciate registers after the start-up phase were reported to be 85% for Denmark, 97% for Norway, and approximately 70% for Sweden (Granan et al. 2009). For the Norwegian Arthroplasty Register, the registration completeness is 97% (Espehaug et al. 2006). However, the completeness and accuracy of the NPR data are debatable, as the NOMESCO classification—which is used in the NPR—has no specific codes for different stabilization techniques, revision surgery, or SLAP repair. Thus, SLAP repairs might have been reported to the NPR as stabilizations, while some stabilization procedures might have been registered under other codes. Validation studies of both NPR data and shoulder register data are warranted to determine the true incidence of shoulder stabilization surgery in Norway. The shoulder instability register was started through a network of shoulder surgeons and not by the Norwegian Orthopedic Association, as were the other registers, which might explain a lower rate of hospital recruitment. A higher proportion of eligible procedures are performed at private day surgery units for this register than for the other orthopedic registers. For other orthopedic registers in Norway, the completeness rate increased over time and we believe that the same will be the case for this register.

Of the 404 primary procedures registered, 83% of the patients had anterior instability, 10% had posterior instability, and 7% had multidirectional instability. The distribution of type of procedures in our register is in accordance with the incidence of shoulder instability reported by others. For example, Owens et al. (2007) found that anterior instability comprised 80% of the instability cases. For primary anterior stabilization, arthroscopic soft tissue techniques predominated and were performed in 88% of the cases, while a coracoid transfer procedure was performed in 10% of cases. For MDI and posterior instability, only soft tissue techniques were used. We have not found any population-based studies in the literature that describe the frequency of the different techniques used.

The functional results as expressed by the WOSI score for arthroscopic anterior stabilization are in accordance with those in other studies (Bottoni et al. 2006, Mologne et al. 2007). The WOSI score is less used than the rating sheet for Bankart repair presented by Rowe et al. (1978). Direct comparison

with many other studies is therefore difficult. The WOSI score was considered to be the most appropriate functional outcome score for the register, as it is validated, internationally acknowledged, and can be administered by post. Validation studies have shown a high effect size, allowing detection of clinical change in individual patients and groups (Salomonsson et al. 2009). Clinician-based outcome measures have historically had widespread use, but the use of patient-reported outcomes has increased. The need for physical examination excluded the use of the Rowe score in our register study.

In our material, we had a patient-reported recurrence incidence 1 year after surgery of 10%, in comparison with a figure of 15.3% 3 years postoperatively reported by Boileau et al. (2006) and 23% reported by Castagna et al. (2010). These articles describe an even rate of recurrence episodes during the follow-up period. We must therefore expect a higher degree of recurrence in our material over time. Of 463 procedures recorded in the register, 58 were revisions (13%). We need to follow the patients over a longer time period before we can make any conclusions about the true revision and re-revision rates.

The main aim of the register is to identify prognostic factors for the clinical outcome after surgery, by way of patient characterics, perioperative findings, and procedures performed. The selection of items for the registration form was based on literature review, clinical experience, and experience from the pilot study. The register is for presently underpowered for analysis of prognostic factors, and further data collection is needed to answer such questions.

In summary, the Norwegian shoulder surgeons have opted to use modern arthroscopic techniques. No arthroscopic bony techniques and very few open soft tissue stabilizations are reported, while open coracoid transfers are performed regularly. The functional result is in accordance with previous studies. We found that the incidence of recurrent instability after arthroscopic labral repair was higher than expected one year after surgery. Longer follow-up and larger numbers of patients are needed before we can assess the effects of different prognostic factors on the results.
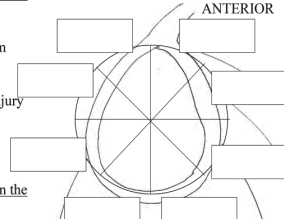
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Appendix: Surgeon's form

Register of shoulder instability surgery – a project at Norwegian hospitals treating shoulder instability	Patient ID and date of birth:
Contact address: *Dr Jesper Blomquist* *Haraldsplass Deaconal Hospital,* *Pb 6165, 5892 Bergen, NORWAY* *Tlf: (+47) 5597 8500*	Name: Hospital:

SHOULDER INSTABILITY SURGERY – SURGEON'S FORM

❑   **STABILIZATION PROCEDURES IN THE SHOULDER**
❑   **ALL REVISION PROCEDURES AFTER STABILIZATION**

INDEX SIDE   Right   Left
(bilateral surgery=2 forms)

OPPOSITE SHOULDER   Normal   Instability
                          Other pathology

PREVIOUS SURGERY IN INDEX SHOULDER
  No surgery or diagnostic arthroscopy
  Stabilization (specify type):
  Other surgery, specify:

CLASSIFICATION OF SHOULDER INSTABILITY
Direction   Anterior   Posterior   MDI
Grade   Dislocation   Subluxation   Uncertain
X-ray verified dislocation? Yes   No

TIME OF FIRST DISLOCATION (mm.yy): ____.____
(First subluxation for patients without dislocation)

INJURY CAUSING FIRST DISLOCATION?
(first postoperative dislocation for revision cases)
  Yes   No   Uncertain

ACTIVITY THAT LEAD TO INJURY (if plausible)
  _____

ACTIVITY NEEDED TO CAUSE REDISLOCATIONS
  Injury   Sports   Daily activity   Spontaneous

NUMBER OF DISLOCATION BEFORE SURGERY
(Only dislocations, not subluxations)

  0   1   2-5   6-10   11-20   >20

PREOPERATIVE FINDINGS
Normal variants
  Sublabral foramen   Buford complex   _____

Injuries in labrum capsule and glenoid + implants
State injuries in the box for
each sector   ANTERIOR

1. Degenerative labrum
2. Avulsion of labrum
3. Rupture in labrum
4. Capsule/ligament injury
5. HAGL
6. Glenoid resorption
7. Glenoid fracture

Mark implants direct in the
figure with "X"

Size of intraarticular bone defects
  Reverse pear glenoid (>25% loss of diameter)
Hill-Sachs lesion: "engaging"   "not engaging"

Other injuries (SLAP is marked in the figure)
No other injuries:
Biceps pathology
Supraspinatus rupture   Total   Partial
Infraspinatus rupture   Total   Partial
Subscapularis rupture   Total   Partial
Clinical nerve injury   Axillary Plexus
  Other findings, specify:

PROCEDURES (mark all that apply)
Fixation of labrum   (mark in the figure)
Debridement of labrum   Anterior Posterior   Superior
Capsular shift   Anterior Posterior
Plication of capsule   Anterior Posterior   Inferior
Closure of rotator interval
Bone block procedure   Latarjet
                             Other, specify:
Biceps tendon   Tenodesis   Tenotomy
Synevectomy   Total   Partial
Cuff suture
Removal of: Loose bodies   Implants
Capsulotomy   360º   Other
MUA
Lavage due to infection
  other procedure, specify:

IMPLANT FOR LABRUM REATTACHMENT
(identifying labels on the other side)
  Direct sutures through bone without implants
  No implants used
  No id labels (state implant on the other side)

DATE OF SURGERY (dd.mm.yy):_____._____._____

APPROACH   Open   Arthroscopic   Combined

POSITION   Beach chair   Lateral

OUTPATIENT SURGERY Yes   No

PERIOPERATIVE COMPLICATIONS   Yes   No

Description:_____

DURATION OF SURGERY (skin to skin):_____ min

SYSTEMIC ANTIBIOTIC PROPHYLAXIS   Yes   No

NSAID No   Yes (name, days):_____

POSTOP. RESTRICTIONS Weeks of immobilization: _____
  Int. rotation   Neutral pos.   Ext. rotation

SURGEON: (for questions, not registered in database):

II

Do nonsteroidal anti-inflammatory drugs affect the outcome of arthroscopic Bankart repair?

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To achieve pain control after arthroscopic shoulder surgery, nonsteroidal anti-inflammatory drugs (NSAIDs) are a complement to other analgesics. However, experimental studies have raised concerns that these drugs may have a detrimental effect on soft tissue-to-bone healing and, thus, have a negative effect on the outcome. We wanted to investigate if there are any differences in the clinical outcome after the arthroscopic Bankart procedure for patients who received NSAIDs prescription compared with those who did not. 477 patients with a primary arthroscopic Bankart procedure were identified in the Norwegian shoulder instability register and included in the study. 32.5% received prescription of NSAIDs post-operatively. 370 (78%) of the patients answered a follow-up questionnaire containing the Western Ontario Shoulder Instability index (WOSI). Mean follow-up was 21 months. WOSI at follow-up were 75% in the NSAID group and 74% in the control group. 12% of the patients in the NSAID group and 14% in the control group reported recurrence of instability. The reoperation rate was 5% in both groups. There were no statistically significant differences between the groups. Prescription of short-term post-operative NSAID treatment in the post-operative period did not influence on the functional outcome after arthroscopic Bankart procedures.

Shoulder instability is a common problem, with an overall incidence of acute glenohumeral dislocation in the general population reported from 11 to 56 per 100 000 person-years in different countries (Liavaag et al., 2011). The peak incidence occurs during the third decade of life, with a male dominance (Zacchilli & Owens, 2010) and anterior instability as the predominant direction (Owens et al., 2007). Young age predicts a high risk of recurrence and 67% of the patients below 35 years of age develop chronic instability, with new dislocations within 5 years of the primary dislocation (Robinson, 2006). With an annual incidence of shoulder stabilization procedures of 12 per 100 000 inhabitants in Norway (Blomquist et al., 2012) it is estimated that about one fourth of the patients in Norway with a traumatic dislocation end up with a surgical procedure to stabilize the shoulder joint, with a much higher proportion in the young patients.

The arthroscopic Bankart procedure is widely used in the treatment of recurrent anterior shoulder instability

(Owens et al., 2011). Although a minimal invasive procedure, post-operative pain control after shoulder surgery can be difficult to achieve, even with the use of an interscalene nerve block (Fredrickson et al., 2010). Nonsteroidal anti-inflammatory drugs (NSAIDs) have been proven effective against post-orthopedic surgery pain (Heidrich et al., 1985; Alexander et al., 2002; Silvanto et al., 2002; Malan et al., 2003; Axelsson et al., 2008), but experimental studies in animal models have raised concerns that these drugs may have a negative effect on tendon and tendon-to-bone healing in the early proliferative phase (Dimmen et al., 2009a,b; Chen & Dragoo, 2012). NSAIDs have an inhibitory effect on fracture healing in animal studies (Bo et al., 1976) and have been shown to affect the clinical outcome of long bone fractures (Burd et al., 2003) and spinal fusion (Li et al., 2011). However, we have not found any studies that investigate the effects of NSAIDs on the clinical outcome after arthroscopic Bankart repair or other procedures that involve healing between soft tissue and bone in humans.

On this background, we wanted to investigate if there are any differences in the clinical outcome for patients that received NSAIDs in the post-operative phase compared with those who did not.

Materials and methods

The present study was based on the Norwegian shoulder instability register (Blomquist et al., 2012) that was established in 2008. The register includes 54% of the patients who had surgery for glenohumeral instability in Norway 1 year after start-up. The surgeon completed a form at the time of surgery specifying the type of surgical procedure, any previous surgery and shoulder history, including duration of symptoms, number of dislocations and the peroperative bone and soft tissue conditions. If NSAID was prescribed for post-operative administration, medicament name and duration of treatment was recorded. The patient completed a questionnaire with the Western Ontario Shoulder Instability Index (WOSI; Kirkley et al., 1998) pre-operatively. A questionnaire including the same items was answered by mail 1 and 2 years post-operatively. In addition, the patients were asked if they had experienced instability events or had been treated operatively for instability in the same shoulder after the primary operation. Revision surgery was linked to the original procedure in the register by the patient's social security number. The WOSI score is a disease-specific, quality of life measurement tool for patients with shoulder instability. It is built up of 21 visual analog scales in four domains, reflecting physical symptoms, disability in sport/recreation/work and impact on lifestyle and emotions. The score is presented either as an absolute number, ranging from 0 (best) to 2100 (worst), or as a percentage score were 100% represent the best possible result. The instrument is validated in several languages, including Norwegian, and is found to have a high validity, reliability, and responsiveness for shoulder instability patients. (Skare et al., 2013) A 10.4 percentage point difference in WOSI score is considered to reflect a clinically relevant difference in shoulder function, both for the individual patient over time and for comparison between groups. (Kirkley et al., 1998, 2005)

525 patients who underwent an arthroscopic Bankart procedure during the period from February 2008 to August 2011, without prior surgery in the same shoulder, were identified in the register and assessed for eligibility. Twenty-four patients that had no data on NSAID administration and 24 patients without both pre- and post-operative WOSI score were excluded from further analysis. Of the 477 included patients, 463 (97%) had completed the preoperative questionnaire. 348 (73%) answered the 1-year follow-up questionnaire and 283 (59%) answered at 2 years post-operatively. 370 patients (78%) responded at either 1 or 2 years post-operatively and the last response was carried forward with a mean follow-up of 21.2 months. Dropout analysis were performed to evaluate if there were any systematic differences between the responders and the nonresponders.

322 (68%) of the patient did not receive NSAID in the post-operative period and was applied as control group. 78 (16%) had NSAID prescribed for 1–3 days, 63 (13%) for 4–7 days and 14 (3%)

for more than 7 days. All patients treated with NSAIDs post-operatively were pooled in one group for the statistical analysis.

WOSI score and recurrence rate were both considered to be adequate as outcome variables that would reflect a true change in shoulder function. The statistical power to detect a 10.4 percentage point difference in WOSI score was calculated to be 99%, based on a significance level at 0.05 and a sample size of 200 and 100 in the respective groups. However, rate of recurrence was rejected as primary outcome variable, as the statistical power was low, estimated to 0.26, calculation based on sample size of 200 and 100, a 50% increase in recurrence rate from 10% to 15% and a significance level at 0.05.

The primary outcome variable was absolute WOSI score at follow-up. The null hypothesis was that there is no difference in outcome between the group treated with NSAIDs post-operatively and the control group. We also evaluated change in shoulder function compared with baseline, recurrence rate and reoperation rate for both groups. Possible confounders such as differences in baseline WOSI score, age at surgery, traumatic debut, duration of symptoms, number of dislocations, number of suture anchors used, post-operative immobilization, ambulatory or in-house surgery, duration of surgery and follow-up time were analyzed.

Statistics

Descriptive statistics were presented as mean values for normal distributed continuous variables, median for variables with a skewed distribution and ratios for categorical variables. t-tests were used to test differences in mean values and were presented with 95% confidence interval (CI), Kruskal–Wallis test for comparison of medians and chi-square test for categorical variables. Adjustments were done for possible confounding variables with uneven distribution in the two groups using univariate analysis of variance. SPSS Statistics 20 (IBM, New York, USA) software was used for the statistical evaluation.

Ethics

The study was evaluated by the local ethics committee and considered not to need an ethical approval. The data collection was authorized by the Norwegian Data Protection Authority.

Results

The mean age of the included patients was 28.8 years, ranging from 12 to 74 years. The patients in the NSAID group were significantly younger, had a shorter duration of symptoms and were more likely to be treated ambulatory (Table 1).

Table 1. Baseline characteristic of patients having a primary arthroscopic Bankart procedure divided by those receiving NSAIDs and the control group (not receiving NSAIDs)

Baseline characteristic	NSAID				Control group				P-value
	n	%	Mean (95% CI)	Median (range)	n	%	Mean (95% CI)	Median (range)	
WOSI%	125		51 (48–54)		231		52 (49–54)		0.63
Sex, male	127	66			243	68			0.79
Age at surgery	127			24 (58)	243			27 (62)	0.04
Trauma at first dislocation	125	92			236	90			0.50
Symptom duration (months)	116			28 (387)	218			37 (489)	0.02
Patients with > 5 dislocations	122	36			234	36			0.98
Number of suture anchors	118		2.6 (2.5–2.8)		228		2.6 (2.5–2.8)		0.90
Duration of surgery (minutes)	124		70 (64–75)		236		76 (72–79)		0.08
Ambulatory surgery	124	68			240	30			< 0.01
Weeks of immobilization	123		4.7 (4.4–5.0)		225		4.5 (4.3–4.7)		0.16

Patients treated with NSAIDs post-operatively had an unadjusted mean WOSI score at follow-up of 75%, compared with 74% for the control group. Recurrence rate was 12% in the NSAID and 14% in the control group, while reoperation rates were 5% in both groups. None of these differences were statistically significant. Age correlated with symptom duration with a P-value < 0.001 and the outcome score were therefore only adjusted for age and ambulatory surgery. The adjusted WOSI score at follow-up was 74% for the NSAID group and 71% for the control group, the difference between the groups were statistically nonsignificant (Table 2).

The increase in WOSI score from baseline to follow-up was 24 percentage points (95% CI 20.2–28.1, $P < 0.001$), from 51% to 75% for the NSAID group. The control group had an improvement of 22 percentage points (95% CI 18.9–24.7, $P < 0.001$), from 52% at baseline to 74% at follow-up. The difference between the groups was not statistically significant.

18% of the patients in the NSAID group and 25% of the patients in the control group did not answer the follow-up questionnaire. Males were overrepresented among the nonresponders, however evenly distributed between the two treatment groups. No other significant differences were found compared with the patients that answered the follow-up questionnaire (Table 3). None of the participating hospitals had an outcome that differed statistical significant from the mean.

Discussion

We found no effect of NSAIDs on the outcome after an arthroscopic Bankart procedure. This is in accordance with previously published articles where there is insufficient evidence of a detrimental effect on tissue healing, when using either NSAIDs or COX-2 inhibitors at standard doses for less than 2 weeks (Chen & Dragoo, 2012).

Anti-inflammatory drugs were prescribed to only one third of the patients included in the study despite documented effect on post-operative pain as part of a multimodal pain therapy (Marret et al., 2005). Although other side effects, mainly gastrointestinal (Thiéfin et al., 2010), may account for some restraint, the risk of affecting the long-term surgical result is probably the main reason for the limited use in this young patient population with supposedly few concomitant diseases. The use of NSAIDs for the treatment of post-operative pain is controversial for procedures involving healing between bone and tendon as it is shown that NSAIDs and COX2-inhibitors affect the tendon-to-bone healing in experimental animal models (Cohen et al., 2006; Dimmen et al., 2009b). Healing of labral lesions involve an inflammatory response (Abe et al., 2012) and could theoretically be inhibited by anti-inflammatory drugs, but there are no published data that support the theory that treatment with short-term NSAID in therapeutic doses has a negative effect on the outcome after

Table 2. Post-operative evaluation of patients having a primary arthroscopic Bankart procedure by those receiving NSAIDs and the control group (not receiving NSAIDs)

	NSAID			Control group			*P*-value
	n	%	Mean (95% CI)	*n*	%	Mean (95% CI)	
WOSI% at last follow-up	127		75 (72–78)	243		74 (71–77)	0.60
Adjusted* WOSI% at last follow-up	127		74 (70–78)	243		71 (68–75)	0.27
1-year WOSI%	119		76 (73–79)	229		74 (71–77)	0.42
2-year WOSI%	98		76 (72–79)	185		75 (72–78)	0.77
Recurrence rate at last follow-up	127	12		243	14		0.56
Reoperation rate at last follow-up	127	5		243	5		0.80

*Adjusted for age and ambulatory surgery.

Table 3. Nonresponder's analysis of baseline characteristics among patients that underwent a primary arthroscopic Bankart procedure

Baseline characteristic	Responders				Nonresponders				*P*-value
	n	%	Mean (95% CI)	Median (range)	*n*	%	Mean (95% CI)	Median (range)	
WOSI%	356		52 (50–53)		107		50 (46–53)		0.32
Sex, male	370	67			107	84			< 0.01
Age at surgery	370			27 (62)	107			25 (47)	0.13
Trauma at first dislocation	361	91			107	88			0.41
Symptom duration (months)	334			32 (489)	99			32 (322)	0.94
Patients with > 5 dislocations	356	36			104	43			0.18
Number of suture anchors	346		2.6 (2.5–2.7)		104		2.7 (2.5–2.9)		0.58
Duration of surgery (minutes)	360		74 (71–77)		106		74 (68–79)		0.97
Ambulatory surgery	364	43			106	47			0.46
Weeks of immobilization	348		4.6 (4.4–4.7)		103		4.5 (4.2–4.8)		0.71

arthroscopic shoulder surgery. It has been found in earlier clinical studies (Li et al., 2011) that any negative effect of NSAIDs on healing is dose-dependent. A majority of the patients in this study had NSAIDs prescribed for 7 days or less. A longer administration of anti-inflammatory drugs may have a clinical effect not investigated in the present study. Our data on NSAID use is obtained from the surgeons planned prescription at the time of surgery. We have no control on patient compliance and one must assume occurrence of crossover between the groups during the post-operative period, not accounted for in the study. This would dilute a potential effect of NSAID on the outcome. The study is well powered to detect changes in WOSI score and can tolerate a moderate amount of crossover, but the lack of compliance monitoring is a weakness.

The WOSI score is a well-established instrument to evaluate outcome after shoulder instability surgery. It is considered to reflect the change in the patients subjective shoulder function and quality of life and the groups have a very similar functional outcome. This was a prospective cohort study with participants from hospitals in all parts of Norway and we can anticipate that the sample population is representative for the general population who needs instability surgery and should therefore be valid for this group of patients. The groups differed in age, with a significantly lower age and a higher proportion of patients below 20 years in the NSAID group. Young age is found to be a risk factor for inferior outcome after arthroscopic stabilization (Boileau et al., 2006) and adjustment for age further strengthen the finding that NSAIDs have no negative influence on the outcome.

The study is underpowered to detect an increase in recurrence rate and one might therefore argue that a moderate increased recurrence rate cannot be ruled out, even though we found a slightly lower recurrence rate at 2 years in the NSAID group. Studies have shown a linear recurrence incidence over time after arthroscopic Bankart procedures (Castagna et al., 2010), and a weakened bone-labrum interface due to post-operative NSAID administration could theoretical affect the recurrence rate several years after the surgery. Long follow-up and a large patient population are needed to answer this question. An arthro-CT evaluation of the joint could assess attachment of labrum to bone after a certain post-operative time interval. It is however difficult to draw conclusions regarding risk of recurrence based on healing on MRI or CT, as studies have shown that Bankart lesion could be radiological well adapted, but without correlation with recurrence rate (Liavaag et al., 2009; Liavaag, 2011). Post-operative arthroCT also raise ethical questions and was not part of this register study.

The lack of randomization is a weakness to the study. The use of NSAIDs or not is usually consistent for each participating surgeon and there could be a performance bias between the groups that could mask an effect of NSAID administration. The finding that NSAIDs are more commonly used in ambulatory surgery might imply a higher experience level for the surgeons in this group. Based on knowledge of the participating hospitals and the national funding structure for health care, we see that the use of in-house or ambulatory surgery to a large extent is based on local routines and facilities and is more prone to follow hospital and region than the surgeon. We believe that the more extent use of NSAIDs for ambulatory patients reflects the need for proper pain control without the facilities for inter-scalene block or parenteral analgesics, but we have no information on this. The high number of participating hospitals would normally dilute a surgeon effect and none of the participating hospitals have a statistical significant below par outcome that would affect the result.

Perspectives

To achieve adequate and predictable pain control after shoulder surgery, a multimodal approach is normally used, where inter-scalene nerve block, opioid analgesics, and NSAIDs are the main components (Fredrickson et al., 2010). Single-injection inter-scalene block gives excellent immediate pain control, but because of its short and unpredictable duration, there is a high risk that the patient experience severe and uncontrollable pain the first night after surgery (Boezaart & Tighe, 2010). Continuous nerve block gives a better pain control but is more technically and logistically demanding (Boezaart, 2002). As the severity and duration of pain after shoulder surgery has a high inter-individual variation, it is challenging to safely administer an adequate dosage of opiate analgesics, especially after single-injection inter-scalene block and for ambulatory patients without professional post-operative monitoring. It is our experience that NSAIDs, in combination with other modalities, is a very valuable component to achieve post-operative pain control. In this registry study, we found that only one third of the patients received anti-inflammatory drugs in the post-operative phase and less than half were treated ambulatory. A randomized study would be the best tool to test if there is a difference in outcome between the group treated with NSAIDs post-operatively and the control group. So far, this cohort study support the view that short-term NSAIDs in moderate dosages can be safely administered after arthroscopic Bankart repair, without any affect on the outcome.

Acknowledgements

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