Treatment of Type II SLAP lesions of the shoulder

PhD Thesis

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*A great person is one who knows and asks.
An average person is one who knows but doesn't ask.
A lesser person is one who doesn't know and doesn't ask.*

"Unknown"

Table of contents

Acknowledgements	4
Summary of the thesis	6
Thesis at a glance	8
List of publications	10
INTRODUCTION	
Anatomy of the superior glenoid labrum	11
What is a SLAP lesion ?	11
Epidemiology	12
Symptoms/Diagnosis	13
Treatment of SLAP lesions:	
Surgical treatment	15
Non-operative treatment	17
EVIDENCE BASED MEDICINE	18
PLACEBO RESEARCH	21
AIMS OF THE RESEARCH	24
METHODS	
Study design	25
Inclusion and exclusion criteria	26
Outcomes	27
Treatment methods	
Study 1, 4 and 5:	
Surgical methods	27
Non-surgical methods	28
Study 2 and 3:	
Surgical methods	28
Non-surgical methods	29
Statistics	30
Ethical considerations	32
RESULTS	
Synopsis of the papers	33
DISCUSSION	
Prospective studies	37
Sham-controlled randomized trial	40
CONCLUSION	
Conclusions and clinical implications	46
Contribution to existing knowledge and further research	47
References	48
Appendix	54
Paper I-IV	

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Summary of the thesis

Background: Discussion of the clinical importance and treatment of type II SLAP lesions has a history spanning more than 25 years. The classification of these lesions in 1990 initiated a decade of attempts to find the optimal surgical treatment of this entity. Retrospective, level IV studies showed promising results, but there was a definite lack of high-level evidence.

Aims: Our first aim was to evaluate the results after isolated type II SLAP repair. As 10% of these patients presented with a paralabral cyst, our second aim was to assess whether the cyst would resolve after isolated labral repair. Our third aim was to evaluate in a high-level study, the efficacy of labral repair, biceps tenodesis and placebo surgery.

Material and methods: In our first study, a cohort of 107 patients with an isolated SLAP II lesion treated with labral repair were followed prospectively for 5 years. Based on the results and discussion of this study, we designed and conducted a randomized controlled trial. Three groups were compared and followed for 2 years; 40 patients in the labral repair group, 39 patients in the tenodesis group and 39 in the sham group. Two cohorts of patients with a SLAP tear and a symptomatic spinoglenoid cyst were also followed. The first study included 42 patients and the second included 47 patients, and all had magnetic resonance imaging postoperatively.

Results and conclusion: The results of the prospective cohort study suggested good long-term results independent of age after SLAP repair. The two cohorts on labral repair in patients with a SLAP lesion and a concomitant symptomatic cyst suggests that labral repair leads to significant pain relief with cyst resolution within 2-3 months in most patients, that secondary muscle pathology (i.e., edema, atrophy and fatty infiltration) is partially or completely reversed, and that bony erosion caused by cyst compression may be remodeled after cyst resolution. Labral repair, biceps tenodesis and sham-surgery for patients with type II SLAP lesions all yield significant improvement both objectively and subjectively. However, surprisingly, there were no

significant differences between the groups in the population studied. The sample was not large enough to perform sub-group analysis, but the fact that surgical treatment was no better than sham treatment, leads us to question the role of operative treatment in this patient group.

THE THESIS AT A GLANCE

	Aim	Method	Results	Conclusions
1	To assess long-term (5-year) results after isolated superior labral repair in a prospective cohort study and to evaluate whether the results were associated with age.	107 consecutive patients with a type II SLAP tear were treated with an isolated labral repair and followed prospectively for 5 years by an independent examiner.	Rowe scores improved from 62.8 (SD 11.4) preoperatively to 92.1 (SD 13.5) at follow-up ($P<.001$). Satisfaction was rated excellent/good for 90 patients (88%) at 5 years. There was no significant difference in the results for patients aged 40 years or older and those under 40 years. Fourteen patients (13.1%) reported difficulty with postoperative stiffness and pain.	Our results suggest that long-term outcomes after isolated labral repair for SLAP lesions are good and independent of age.
2	To design a randomized controlled trial including sham surgery, validated outcomes, and blinded follow-up to evaluate the efficacy of labral repair and biceps tenodesis for type II SLAP lesions.	A double-blind randomized controlled trial planned using 120 patients, aged 18 to 60 years, with a type II SLAP lesion. Primary outcome measures were the clinical Rowe score (1988-version) and the Western Ontario Instability Index (WOSI) at 6 and 24 months.		
3	To evaluate the efficacy of labral repair, biceps tenodesis and sham surgery in patients with a type II SLAP lesion at 6 and 24 months.	A double-blind, sham-controlled trial was conducted with 118 surgical candidates (mean age 40 years) Patients were randomly assigned to either labral repair (n=40), biceps tenodesis (n=39) or sham surgery (n=39) if arthroscopy revealed an isolated SLAP II lesion. Primary outcomes at 6 and 24 months were clinical Rowe score and Western Ontario Shoulder Instability Index (WOSI).	There were no significant between-group differences at any follow-up in any outcome. Between-group differences in Rowe scores at 2 years were: biceps tenodesis versus labral repair: 1.0 (95% CI -5.4 to 7.4), $p=0.76$; biceps tenodesis versus sham surgery: 1.6 (95% CI -5.0 to 8.1), $p=0.64$; and labral repair versus sham surgery: 0.6 (95% CI -5.9 to 7.0), $p=0.86$. Postoperative stiffness was registered in 10 patients: 4 in the tenodesisgroup, 5 in the repair and one in the sham group.	Neither labral repair nor biceps tenodesis had any significant clinical benefit over sham surgery for patients with SLAP II lesions in the population studied.

CONTINUED

	Aim	Method	Results	Conclusions
4	To explore in a prospective cohort study whether labral repair alone would lead to cyst resolution and pain relief.	42 patients with a posterosuperior labral tear and a ganglion cyst at the spinoglenoid notch were treated with isolated labral repair. Magnetic resonance imaging was performed twice; at 15 and 43 months postoperatively. Clinical outcome was assessed with the Rowe score at 43 months for all patients.	In 37 (88%) of the 42 patients, the cyst had resolved completely. The median Rowe score improved from 61.5 points preoperatively to 98.0 points at the time of follow-up. 31 patients assessed the result of the treatment as excellent; 9 as good; and 2 as fair.	This cohort study suggests that most spinoglenoid cysts resolve and patient satisfaction can be expected to be high after labral fixation without cyst decompression.
5	To explore the effect of isolated labral repair on pain relief, cyst resorption, reversal of muscular edema, atrophy, and fatty infiltration, as well as the consequences of glenoid erosion in a prospective cohort study.	47 patients with symptomatic posterosuperior paralabral cysts were treated with isolated labral repair. Magnetic resonance imaging (MRI) was repeated six and twelve weeks postoperatively or until cyst resolution. Preoperatively, 20 patients (43%) presented clinical muscle atrophy and radiological edema, eight had fatty infiltration, and three presented bony scapular erosion caused by cyst compression.	Median time to cyst resolution and regression of muscular edema was 11 weeks (range 3-20, SD 8.8) and 14 weeks (range 3-52, SD 10.6), respectively. Preoperative fatty infiltration grade I and II of the supraspinatus and infraspinatus muscles was reduced in two patients. Bony erosions remodeled after cyst resolution. Mean pain ratings (1-10 scale) improved from 7.7 (SD 1.8) to 1.3 (SD 1.3), ($p < 0.001$, 95% CI of difference: 5.5-6.8).	This cohort study suggests that labral repair leads to significant pain relief with cyst resolution within 2-3 months in most patients, that secondary muscle pathology (i.e., edema, atrophy and fatty infiltration) is partially or completely reversed, and that bony erosion caused by cyst compression may be remodeled after cyst resolution.

LIST OF PUBLICATIONS

Study 1

Long-term results after SLAP repair: A 5-year follow-up study of 107 patients with comparison of patients over and under 40 years.

Cecilie Piene Schrøder, MD., Øystein Skare, P.T., Erling Gjengedal, MD., Gisle Uppheim, MD., Olav Reikerås, MD., PhD, and Jens Ivar Brox, MD., PhD.
Arthroscopy 2012, 11:1601-1607.

Study 2

Efficacy of labral repair, biceps tenodesis, and diagnostic arthroscopy for SLAP lesions of the shoulder: a randomised controlled trial. (Study protocol)

Øystein Skare, Cecilie Piene Schrøder, Olav Reikerås, Petter Mowinckel, Jens Ivar Brox.
BMC Musculoskeletal Disorders 2010. 1111:228

Study 3

Sham surgery versus labral repair or biceps tenodesis for type II SLAP lesions of the shoulder: a three-armed randomised clinical trial.

Cecilie Piene Schrøder, Øystein Skare, Olav Reikerås, Petter Mowinckel, Jens Ivar Brox.
Br J Sports Med, Published Online First, May 11, 2017 as 10.1136/bjsports-2016-097098.

Study 4

Treatment of labral tears with associated spinoglenoid cysts without cyst decompression.

Schrøder CP, Skare Ø, Stiris M, Gjengedal E, Uppheim G, Brox JI. *J Bone Joint Surg Am* 2008, 90:523-530. *J Bone Joint Surg Am* 2008, 90:523-530.

Study 5

Paralabral cysts of the shoulder treated with isolated labral repair: effect on pain and radiological findings.

Cecilie P. Schrøder, MD, Kirsten Lundgreen, MD, PhD, Rune Kvakestad, MD.
J Shoulder Elbow Surg, in press.

SLAP LESIONS – ANATOMY, DEFINITION, DIAGNOSIS AND EPIDEMIOLOGY

Anatomy of the superior glenoid labrum

The labrum continues the long head of the biceps and in the upper quadrants, the periarticular fibers are broadly attached to the neck of the scapula (Figure 1). This has been regarded as stabilizing the joint during external rotation by opposing a tendency of the humeral head to become displaced cranially.¹ The wide superficial insertion of the biceps acts as a tension brace, which opposes the cavity as a buttress against the humeral head and, in this way, transmits pressure over a wide area.¹ Cadaveric studies^{2,3} with a simulation of type II lesions have demonstrated a significantly increased translation in all directions.

Figure 1. Diagrammatic presentation of the periarticular fiber bundles. The long tendons of the biceps and triceps, the glenohumeral ligaments and the glenoid labrum constitute a functional unit: the periarticular fiber system. This produces a basket around the neck of the scapula that acts as a tension brace pressing the cavity like a buttress against the head of the humerus. (Adapted from Huber WP, Putz RV. Periarticular fiber system of the shoulder joint. *Arthroscopy* 1997;13:680-91.)

What is a SLAP lesion?

There are wide variations in the attachment of the superior labrum and the biceps anchor. It may be loosely attached or even detached, and gaps may develop.^{1,4,5} With the possibilities of arthroscopy of the shoulder, this entity was later described as superior labral avulsion.⁴ Snyder et al.⁶ classified this lesion (Figure 2), further described it as a superior labral anterior posterior lesion, and coined the name SLAP tear. The original classification was based on a traumatic initiating episode causing the lesion seen on arthroscopy.

Figure 2. Type I is fraying of the superior labrum, type II is a detachment of the biceps-labrum complex, type III is a bucket-handle lesion of the superior labrum and type IV is a detached labrum combined with a split in the long head of the biceps. (Adapted from Snyder SJ, Karzel RP, Del Pizzo W, et al. SLAP lesions of the shoulder. *Arthroscopy* 1990;6:274-9.)

Type II is the most common⁷⁻¹¹ SLAP lesion and we discuss the treatment of this entity in the thesis.

Epidemiology

The true prevalence and incidence of SLAP lesions are still unknown. Snyder et al.⁷ found in their 1995 study of a non-athletic population based on 2375 arthroscopies, 140 SLAP lesions (6%), and a type II SLAP lesion in 3.3% of the cases. Handelberg et al.¹² reported a prevalence of 6% and Kim et al.¹¹ reported 5.5% of all cases, and most of the lesions were associated with other intra-articular lesions. In specific athletic sports, such as overhead athletes and rugby players, the prevalence among patients undergoing shoulder arthroscopy is higher.¹³ Although the initial classification by Snyder⁶ was based on traumatic cases, in several later reports,¹⁴⁻¹⁶ up to 50% of the patients describe an insidious onset of symptoms. In a young active population, repetitive trauma such as throwing or other overhead activity may lead to a gradual detachment of the superior labrum and thus the patients describe this as an insidious onset. In a middle-aged population, a SLAP tear often represents a normal degenerative process. Schwartzberg et al.¹⁷ found a high prevalence (over 50%) of these lesions diagnosed by MRI in asymptomatic shoulders of middle-aged people (45-60 years) and warn about overtreatment.

We found in our studies that in about 10% of patients with a type II SLAP tear, a symptomatic spinoglenoid cyst is present. The labral tear produces a one-way valve where the intra-articular fluid leaks out and forms a cyst. The cyst may compress the suprascapular nerve and give rise to pain and edema of the infra-/supraspinatus (Figures 3 and 4).¹⁸⁻²²

Figure 3. MRI demonstrating a large spinoglenoid cyst

Figure 4. T2-weighted MRI demonstrating edema of the infraspinatus muscle.

Symptoms/Diagnosis

The main symptom in patients with SLAP II lesions (Figure 5) is pain, typically with overhead activities. Patients also complain of mechanical symptoms of clicking and popping, of bicipital pain at the groove and some have a feeling of instability without subluxation/luxation. A careful patient history and physical examination reveals important information, and together with MRI arthrography describing the labral lesion, result in a tentative diagnosis of a SLAP tear. However, the diagnosis of a SLAP II lesion is controversial; the validity of clinical tests²³ and MRI arthrography is questioned.^{24,25} In a recent systematic review and meta-analysis, the authors conclude that the performance of single physical tests is limited.²⁶ However, when the different tests for SLAP lesions were pooled, they found a statistical significant change in post-test probability indicating an overall statistical validity.²⁶ MRI arthrography has been shown to have a higher sensitivity than MRI without contrast in detecting labral tears. The sensitivity and specificity varies. Amin et al.²⁴ reports a sensitivity of 0.90 and a specificity of 0.50 in detection of SLAP lesions. Holzapfel et al.²⁵ finds sensitivity between 0.86 to 0.90 and specificity ranging from 0.70 to 0.90 with an excellent inter observer agreement (kappa = 0.82)

Figure 5. MRI demonstrating a type II SLAP lesion.

Figure 6. MRI demonstrating compression of the suprascapular nerve with edema of the supraspinatus, infraspinatus, and teres minor muscles.

Diagnostic arthroscopy has been considered the gold standard, but studies indicate disagreement among observers,²⁷ even though a recent study found that experienced shoulder surgeons have high agreement on the classification of the SLAP lesion.²⁸

For patients with a spinoglenoid cyst, MRI and clinical examination will lead to this diagnosis. When the suprascapular nerve is affected, the patient describes posterior pain, pain and/or weakness with external rotation and may present clinical atrophy of the infra and/or supraspinatus muscle. The suprascapular nerve is a mixed peripheral nerve.²⁹ The motor unit supplies the supra and infraspinatus muscle, and in some cases it may innervate the teres minor muscle (Figure 6). German anatomists described this alternative innervation in 1959.³⁰ This seems to be forgotten knowledge, but we registered edema and atrophy of both the infraspinatus and the teres minor muscle in one patient in study 4 and in 3 patients in study 5. Therefore, it is reasonable to suggest that, although rare, this alternative innervation does exist. The sensory unit supplies the acromio-clavicular joint and the posterior capsule. In 3.5% to 14.7% of individuals, the nerve has a cutaneous branch innervating the skin at the upper, lateral shoulder region.^{31, 32} The cyst may affect only the sensory branches and thus induces pain without any muscular changes. This was the case in 24 of the 47 patients in our 5th study.²⁰ If the motor unit of the nerve is affected, the T2-weighted images may show edema of the affected muscles (Figures 4 and 6).¹⁸⁻²¹

TREATMENT OF TYPE II SLAP LESIONS

Surgical treatment

Despite the lack of high-level evidence, arthroscopic labral repair has been the dominant treatment in patients with type II SLAP lesions for the last two to three decades.

In a systematic review from 2010, Gorantla et al.³³ present the outcome of arthroscopic repair of type II SLAP lesions in order to assess the effectiveness of current methods of treatment. The authors found no good (level I or II) evidence for outcomes of SLAP repair. Except for two prospective studies, the rest were retrospective case series. Seven of the 12 studies consisted of athletes (age ≤ 34 years).³⁴⁻⁴⁰ Regarding the general outcome, the percentage of good and excellent results ranged from 40% to 94%, and the return to previous level of performance ranged from 20% to 94%. Five studies reported on the return to previous level of activity for overhead athletes, and the rate ranged from 22% to 64% for baseball players.

The results of SLAP repairs vary widely depending on the study population. In contrast to the poor results regarding return to prior level of activity in overhead athletes, Funk and colleagues reported excellent results and 95% return to previous level of activity after SLAP repair in rugby players.¹³

The discussion regarding whether the age of the patient matters is inconclusive. In a recent prospective study of 179 SLAP repairs, Provencher et al.¹⁶ assessed the outcomes and factors associated with success and failure in a young active military population. They concluded that a reliable return to previous activity level is limited; 37% of patients had failure, with a 28% revision rate. Age greater than 36 years was associated with a higher revision rate ($p < .001$). Denard et al.⁴¹ reported a tendency for inferior results among patients over 40 years of age, but this did not reach statistical significance. Other studies found no difference in results for patients over and under 40 years.^{15,42}

Along with reports of a large increase in the number of SLAP repairs performed, studies documenting poor results and complications were published.⁴³⁻⁴⁵ Consequently, biceps tenodesis was introduced as an alternative to labral repair. Recent studies show a decrease in the numbers of SLAP repairs performed and in the age of the patients undergoing these

repairs, and an increase in the number of biceps tenodesis performed.⁴⁶⁻⁴⁷ Although Huri et al.⁴⁸ conclude in their review from 2014 that biceps tenodesis may be a viable treatment option for SLAP repair, others report that the evidence for this recommendation is weak.⁴⁹ In a recent paper from Chalmers et al.,⁵⁰ biceps tenodesis in baseball players resulted in an average 35% return rate to their prior level of play. However, pitchers had only a 17% rate of return to play, whereas position players had 80%.⁴⁸ Snyder et al.⁵¹ advocate a role for labral repair combined with a biceps tenodesis in select patients because an unstable labrum can theoretically continue to cause pain, even after biceps detachment. The main conclusion in the review papers is the need for high-level evidence to evaluate the best treatment for patients with type II SLAP lesions.^{33,48}

Historically, the treatment of SLAP II with a symptomatic cyst has varied from ultrasound-guided aspiration to open treatment and variations of arthroscopic procedures.^{32,52-59} The results after ultrasound guided aspiration is effective in decompressing the cyst, but does not address the underlying etiology. Without labral repair, cyst formation often recurs.^{54,57} When we initiated our first study (Study 4) of the treatment of these patients in 1998, different arthroscopic methods, all including decompression of the cyst, were reported.⁵²⁻⁵⁹ Although there were no reports on injury to the suprascapular nerve, we feared that the use of a motorized shaver to decompress the cyst could potentially harm the nerve. None of the prior studies included pre- and postoperative MRI and we hypothesized that just repairing the labral lesion would close the one-way valve and lead to cyst resorption. All patients were followed with MRI controls and 88% of the cysts were resorbed.^{18,20} Youm et al.²¹ have reported similar cyst resolution and high patient satisfaction after labral repair without cyst decompression for patients with a SLAP tear and a symptomatic spinoglenoid cyst. There is still an ongoing discussion of whether or not to decompress the cyst in addition to labral repair. Kim et al.¹⁹ performed a randomised study comparing labral repair and cyst decompression with isolated labral repair and found no significant difference between the two groups. In a recent systematic review, the authors conclude that the results do not show any advantages from performing cyst decompression.²²

Non-operative treatment

The reports on conservative treatment of SLAP lesions are few and have not received much attention. A retrospective (level IV) study by Edwards et al.⁶⁰ reported that half of their patients (19/39) treated non-operatively had a successful outcome. Pain relief, ASES score, and Euro-QoL improved significantly. Mean age in this group was 34 years and there were nine competitive and 10 recreational athletes. Ten of 15 (67%) overhead athletes returned to the same level of activity. The published return-to-play rates for athletes who have undergone surgical repair of SLAP tears vary widely and are generally accepted to be lower in the subset of competitive throwers.

Fedoriw et al.⁶¹ have assessed the efficacy of nonsurgical treatment for baseball players. Sixty-eight patients had failed one attempt at rehabilitation but had continued with supervised physical therapy focusing on the correction of scapular dyskinesia and posterior capsular contracture with gleno-humeral internal rotational deficit (GIRD), followed by pain-free return to throwing. Those who failed two cycles of nonsurgical treatment were treated surgically. The rate of return after surgical treatment was low for pitchers, and higher for positional players. They concluded that nonsurgical treatment had a reasonable success rate and should be considered for professional baseball players.

Jang et al.⁶² have retrospectively evaluated predictive factors associated with failure of non-operative treatment for isolated SLAP lesions in 63 patients with a mean age of 38 years. Of the 63 patients, 45 (71.4%) had a successful outcome and 18 (28.5%) were either dissatisfied or had arthroscopic surgery and were considered failures. Those who did not succeed with non-operative treatment more often had history of trauma, mechanical symptoms and participation in overhead activities. Shin et al.⁶³ reported a success rate of 85% in a prospective study of 46 patients with a mean age of 39 years. They concluded that non-operative management using combined intra-articular corticosteroid injection with rotator cuff and periscapular strengthening exercises could be applied as primary treatment for patients with a symptomatic SLAP lesion at a recreational level of sports. Most of the studies on non-operative treatment are small and have methodological weaknesses.

EVIDENCE - BASED MEDICINE

Evidence Based Medicine (or health care) sees clinical expertise as the ability to integrate patient circumstances, research evidence, and patient preferences to help patients arrive at optimal diagnostic and treatment decisions.⁶⁴ The evidence-based or evidence-informed practice emphasizes the importance of research-based evidence in decision making.⁶⁵

A randomized controlled trial (RCT) is the gold standard for evaluating health care interventions in clinical research.⁶⁵ Systematic reviews of randomized trials are considered the highest level of evidence. In a controlled study, the individuals are randomly allocated to receive a placebo, standard practice, or no intervention. The study participants are allocated to the intervention groups at random, in order to reduce confounding by minimizing systematic differences between the groups.⁶⁶ This ensures that subjects with different known and unknown prognostic factors are randomly distributed between or among interventions.

The use of placebo and blinding in controlled trials of surgical interventions further reduces the biases related to expectation, both allocation and observer bias, in assessing the effects of surgery.⁶⁷

Blinding means withholding information on allocation group from participants, the clinicians/caregivers, and the assessors, and is recommended whenever possible to prevent bias. Blinding has also been shown to improve patient retention in trials and to reduce the likelihood of patients in the control group not following the assigned treatment.⁶⁷ To avoid an imbalance in group size between the interventions blocked randomization is used.

Case-control and cohort studies are observational studies. They have a weaker design compared with RCT`s, but are analytical studies, whereas case reports and case-series define descriptive studies. Although these studies are more explorative, they can provide evidence if conducted appropriately and they are important for the formulation of new hypotheses to be tested in RCT`s.⁶⁸

A cohort study can be retro- or prospective, but prospective studies are more common. The study follows these participants for a defined period to assess by example the proportion that develops the outcome/disease of interest. Therefore, cohort studies are good for assessing prognosis, risk factors and harm.⁶⁵ In addition, the generalizability in RCT`s are often limited by more strict inclusion criteria and lower sample sizes compared with cohort studies.

RCTs can be difficult to conduct for surgical interventions. Well-designed observational studies therefore play a role in deriving evidence in surgery. Results from observational studies are often criticized for being vulnerable to influences by unpredictable confounding factors. But these studies complement RCTs in hypothesis generation, establishing questions for future RCTs, and defining clinical conditions.⁶⁸

The term “evidence based research” was coined in 2009 to indicate the approach that is needed to identify and refer to earlier research when justifying, designing, or discussing new research. Several authors emphasize the importance and lack of systematic reviews of existing relevant evidence in clinical trials.⁶⁹⁻⁷¹ The evidence based approach is needed to avoid the tendency for medical researchers to selectively cite studies based primarily on preferences and strategic considerations.⁷¹ The lack of an evidence base approach is in their opinion an

important source of research waste and risks unnecessary harm for patients and study participants. For scientific, ethical, and economic reasons, current high quality systematic reviews need to be considered as an essential component of decisions about whether future studies are justified, the design of new studies, and the interpretation of new study results.⁶⁹⁻⁷¹

On the other hand, systematic reviews are not always justified to be on the top of the evidence pyramid.⁷² The Grading of Recommendations Assessment and Evaluation (GRADE) Working Group developed a framework in which the certainty in evidence was based on numerous factors and not solely on study design, which challenges the pyramid concept.⁷³ Murad et al.⁷² claim that study design alone appears to be insufficient as a RCTs surrogate for risk of bias. By example, they describe a meta-analysis of RCTs where allocation and blinding was not adequate in most of the trials included. Consequently, they conclude that despite having five RCTs, the quality of this evidence must be rated down due to the methodological limitations of the trials and imprecision of the findings (wide CI that reflect the statistical uncertainty, sample size and heterogeneity of patients included). The same authors also state that the quality of evidence can be rated up. The benefits of hip replacement are used as an example. Even though not tested in RCTs, we are quite certain that this is an effective treatment for patients with disabling hip osteoarthritis. Therefore, the quality of evidence may be rated up despite the weaker study design (non-randomized observational studies). Murad et al. also challenge the placement of systematic reviews on top of the evidence pyramid based on the different studies included in a meta-analysis. A meta-analysis of observational studies at higher risk of bias cannot be equated with a meta-analysis of well-conducted RCTs.⁷²

The CONSORT statement is an evidence-based reporting guideline that aims to improve research transparency and reduce waste.⁷⁴ In 2008, the CONSORT group developed an extension to the original statement that addressed methodological issues specific to trials of non-pharmacological treatments (NPTs), such as surgery, rehabilitation, or psychotherapy. Changes to the statement extension for NPT trials address whether and how adherence of participants to interventions is assessed or enhanced, description of any attempts to limit bias if blinding is not possible, and specification of the delay between randomization and initiation of the intervention.⁷⁴

To reduce the tendency to publish positive findings more often than negative ones (publication bias) and to minimize the problem of unpublished trials, ClinicalTrials.gov was

launched in February 2000, and in 2007 the database was expanded to include registration of additional types of trials.⁷⁵

Last, but not least, medical research involving human subjects must follow the ethical principles of the Declaration of Helsinki.⁷⁶

PLACEBO RESEARCH

Placebo effects are a cornerstone in medical research. No new drugs will be approved without evidence that they outperform a placebo control group. The exact placebo mechanisms have been hard to identify and historically doctors and researchers have doubted the validity of the placebo effect. Even when placebos gained acceptance and established an important role in clinical trials, they were considered an annoyance to be taken into account, but not a phenomenon in their own right. This changed in 1955 with a meta-analysis by Beecher⁷⁷ combining the data from the placebo groups of 15 studies on pain, seasickness, cough and anxiety. He calculated that the placebo effect contributed to 35% improvement in symptoms, which led him to argue that the placebo effect was powerful and worthy of study. His methodology was later criticized, but his research sparked great interest in the placebo's potential power to heal.⁷⁸ Subsequent studies of the placebo effect have been conducted on pain, depression, anxiety, insomnia, immunosuppression, ADHD, Parkinson's disease, and irritable bowel syndrome.^{78,79}

Kaptchuk and Miller⁸⁰ describe placebo effects as improvements in patients' symptoms that are attributable to their participation in a therapeutic encounter, with its rituals, symbols, and interactions. The placebo effect relies on complex neurobiological mechanisms involving neurotransmitters (e.g. endorphins, cannabinoids, and dopamine) and activation of specific, quantifiable, and relevant areas of the brain. Many common medications also act through these pathways. In addition, genetic signatures of patients who are likely to respond to placebos have been identified.⁷⁸ Such basic knowledge has greatly enhanced the credibility of placebo effects. Recent clinical research has provided compelling evidence that these effects are genuine biopsychological phenomena that represent more than simple spontaneous remission, normal symptom fluctuations, and regression to the mean.⁸⁰

There is evidence that placebo effects modulate active treatment outcomes, can be just as effective as real surgery, may occur even without deception, and are not always beneficial.⁸⁰ Benedetti et al.⁸¹ compared the effect of open versus hidden administration of active treatments across four different conditions (pain, anxiety, Parkinson's disease and cardiovascular disease). Across each treatment, they found that open treatment led to significantly larger improvement than the same hidden dose. This provided unambiguous evidence that the placebo effect was not confined to inert agents and that many active treatments involve a placebo component that substantially contributes to the overall treatment response, demonstrating the importance of considering the placebo effect in any treatment setting.⁸²

Surgery is believed to have an enhanced placebo effect. Invasive procedures have an enhanced placebo effect compared to non-invasive methods, just as injections have stronger placebo effects than pills.⁸¹ In addition, a convincing and decisive surgeon and rituals involved in surgery may enhance expectations and produce a strong placebo effect.⁸³ A systematic review of placebo-controlled studies in surgery evaluated 53 trials and found that the effect of placebo in 51% of the trials did not differ from that of surgery.⁸⁴ The magnitude of the placebo component in these studies could not be estimated, as they did not include an observational control arm. However, it is worth noting that there is a risk of inducing a nocebo effect if the patients receiving no treatment in an observational arm experience this as negative.

When surgical treatments are compared with placebo treatments, the biased estimates of treatment effects are reduced.⁸⁵ This is considered especially important when outcome measures are subjective and reflect satisfaction with the treatment when it comes to pain, function and quality of life. In addition, studies comparing surgery and sham surgery are important when it comes to reducing costs to patients and health services due to ineffective treatments.⁸⁵

On the other hand, there are reports claiming that the placebo effect can be largely influenced by inadequate research methods producing artefacts and that analysis of confounding factors show that they could influence the reliability of the surgical placebo effects. Such factors include among others: lack of homogeneity among inclusion and exclusion criteria, false double blinding, statistical power of the study, and patients lost to follow-up.⁸⁶

The ethics of placebo-controlled clinical trials is widely discussed.⁸⁶⁻⁹⁰ Savulescu et al.⁸⁸ argue that placebo controls for surgery are necessary in the same way as for medicine, but that there are important differences, which both increase justification and limit application for surgical studies. One of the main arguments against placebo-controlled studies is that they are not in accordance with the recommendations about clinical research defined by the Helsinki Declaration. However, several studies have shown that in sham-controlled trials the adverse effects are less common in the sham group than the active treatment group.⁹¹ Moreover, it is argued that the focus should be on the patient and not the research.⁸⁹ However, looking closely at the Helsinki Declaration,⁷⁶ the use of placebo is specifically allowed in situations: “Where for compelling and scientifically sound methodological reasons the use of placebo is necessary to determine the efficacy or safety of an intervention and the patients who receive placebo or no treatment will not be subject to any risk of serious or irreversible harm.”

In their ethical analysis and guidelines, Savulescu et al.⁸⁸ propose that surgical randomized placebo-controlled trials are ethical if certain conditions are fulfilled: “ 1) the presence of equipoise, defined as lack of unbiased evidence for efficacy of an intervention; 2) clinically important research question; 3) the risk to patients is minimized and reasonable; 4) there is uncertainty about treatment allocation rather than deception; 5) there is preliminary evidence for efficacy, which justifies a placebo-controlled designed; and 6) ideally the placebo procedure should have some direct benefit to the patient, for example as a diagnostic tool.” We believe that these conditions are fulfilled in our trial.

AIMS OF THE RESEARCH

The overall aim of this thesis was to assess current treatments of type II SLAP lesions.

Specific aims of the five studies:

Aim 1:

To assess in a prospective cohort study the long-term (5-year) results after isolated superior labral repair, and to evaluate whether the results were associated with age.

Aim 2:

To design a randomized controlled trial including sham surgery, validated outcomes, and blinded follow-up to evaluate the efficacy of labral repair and biceps tenodesis for type II SLAP lesions.

Aim 3:

To evaluate the efficacy of labral repair, biceps tenodesis and sham surgery on clinical (Rowe score) and patient related outcome (WOSI) in patients with a type II SLAP lesion at 6 and 24 months.

Aim 4:

To explore in a prospective cohort study whether labral repair alone would be followed by cyst resolution and pain relief.

Aim 5:

To explore in a prospective cohort study whether isolated labral repair would be followed by pain relief, cyst resorption, and reversal of muscular edema. We also studied muscle atrophy, and fatty infiltration, as well as the consequences of glenoid erosion.

METHODS

Study design

The thesis consists of three prospective cohort studies, a study protocol and a randomized blinded sham-controlled trial (Table 1).

Table 1. Study design, sample size, and timeline

	Study design	Number of patients	Years
Study 1	Prospective cohort	107	1998-2002
Study 2	Protocol	120	2004-2008
Study 3	Randomized sham – controlled	118	2008-2016
Study 4	Prospective cohort	42*	1998- 2006
Study 5	Prospective cohort	47	2009-2014

*11 patients were also included in study 1

Table 2. Follow-up and design characteristics

	Follow-up time	Randomized	Blinded evaluation	Blinded statistician	Follow-up rate (%)
Study 1	5 years		X		95.3
Study 2	6 and 24 months	X	X		
Study 3	6 and 24 months	X	X	X	96.6
Study 4	4 years		X		100
Study 5	6 and 12 weeks, or until cyst resolution				100

Inclusion and exclusion criteria

The inclusion and exclusion criteria for each of the five studies are summarized in Tables 3 and 4.

Table 3. Inclusion criteria

<i>Inclusion criteria</i>	Study 1	Study 2	Study 3	Study 4	Study 5
Patient history	X	X	X	X	
Positive result on at least one of the following tests: -O'Brien -Apprehension -Crank		X	X		
MRI	X			X	X
MRI arthrography		X	X		
Arthroscopy	X	X	X	X	X

Table 4. Exclusion criteria

<i>Exclusion criteria</i>	Study 1	Study 2	Study 3	Study 4	Study 5
Bankart lesion	X	X	X	X	
Large posterior tear		X	X		
Bucket handle tear		X	X		
Spinoglenoid cyst		X	X		
Rotator cuff/biceps tear	X	X	X	X	
AC arthritis*	X	X	X		
GH arthritis**	X	X	X		
Not willing to accept one of the treatments		X	X		
Not able to understand Norwegian	X	X	X	X	X

*Acromio-clavicular joint

**Glenohumeral joint

Outcomes

The outcomes used in each study are summarized in Table 5.

Table 5. Outcome measures

<i>Outcomes</i>	Study 1	Study 2	Study 3	Study 4	Study 5
Rowe score	X	X	X		
WOSI (Western Ontario Shoulder Index)		X	X		
OISS (Oxford Instability Shoulder Score)		X	X		
Postoperative stiffness	X	X	X	X	X
Patient satisfaction	X	X	X	X	X
Return to pre-injury activity level, return to work, time of sick leave	X	X	X		
EQ- 5D 3 response categories		X	X		
Cyst resolution (MRI)				X	X
Reversal of edema and fatty infiltration (MRI)				X	X
Bone remodeling (CT)					X

In study 1, two different examiners evaluated the patient and performed the Rowe score.

In study 3, one blinded examiner examined the patients before and after surgery.

In study 4 and 5, neither the clinical or radiological examinations were blinded.

Treatment methods

Studies 1, 4 and 5

Surgical methods

The surgical treatment was performed by 5 different orthopedic surgeons. The labral tears were treated with arthroscopic debridement of the glenoid rim and fixation of the labrum with

absorbable tacks (Suretac; Acufex, Mansfield, MA) or suture anchors (Study 5). Patients with a concomitant spinoglenoid cyst were treated according to the same protocol.

Non-surgical methods

All patients wore a sling for 5 weeks, except for those in Study 5 who only wore a sling for 3 weeks, and all were instructed to perform passive range-of-motion and pendulum exercises. At 3 weeks, physical exercises were started and patients performed active-assisted range-of-motion exercises. Achieving a normal global range of motion was the goal of the rehabilitation protocol during this period. At 6 weeks, patients started muscle-strengthening exercises; active biceps exercises were not performed until 12 weeks postoperatively. Overhead activity, such as throwing, was restricted until 6 months postoperatively. All patients received physiotherapy for 4 to 6 months.

Study 2 and 3

Surgical methods

Arthroscopic examination was performed in all patients under general anaesthesia with the use of standard posterior and anterior portals. The surgeon evaluated both the subacromial space and the glenohumeral joint and noted the intra-articular findings. A video of the surgery was also created for each patient. During the labral repair, the superior glenoid rim was debrided with a motorized shaver, followed by a percutaneous placement of a drill guide and suture anchors through the myotendinous junction of the supraspinatus. All anchors were placed posterior to the biceps root and single circular sutures were used. The biceps tenodesis was done with a mini-open technique. Under arthroscopic vision, a spinal needle was placed as laterally as possible and at a 90° angle into the biceps tendon and a tenotomy was performed at the biceps insertion. With a skin incision of less than 2 cm (to mimic the scars in the two other groups), the spinal needle was followed down to the biceps pulley, the pulley was split and the biceps tendon was lifted out. The groove was debrided, a double loaded metal anchor was placed in the inferior part of the groove, and the tendon secured with two sutures, each passing twice through the tendon. The proximal part of the tendon was excised and the wound closed. For the sham surgery, standard diagnostic shoulder arthroscopy was performed. In addition, a 5 mm skin incision was made to mimic labral repair. The patient was kept in the operating theater for the amount of time required to perform an actual

arthroscopic index shoulder surgery. All patients received a sling before they left the operating room, and standard postoperative care and instruction were provided.

Non-surgical methods

Patients in all three groups had a standardized, but individually adjusted rehabilitation. Elbow, wrist, and finger mobilization and gentle pendulum exercises were conducted, starting on the first day. A sling was used for 3 weeks. Local physiotherapists, blinded to the allocation of the patient, provided treatment after discharge from the hospital. Passive techniques, such as massage and stretching, core stability exercises and general physical training, were used during the first 3 weeks. Exercises to improve the scapula-humeral rhythm, coordination and mobility were performed using sling exercise therapy.⁹² Gradual biceps loading was started at 12 weeks. Exercises to improve functional stability and scapula muscles were progressively emphasized after 6 weeks. Sports and job-specific rehabilitation were provided on an individual basis, usually starting 3 months postoperatively. Rehabilitation was continued for 3-6 months and included 12-16 sessions with a therapist and 20 self-administered exercises.

Statistics

The statistical approach used in each of the five studies is summarized in Table 6.

Table 6. Statistical methods used in each of the five studies.

<i>Statistical method</i>	Study 1	Study 2	Study 3	Study 4	Study 5
Wilcoxon signed-rank test	X			X	
Paired t-test	X				X
χ^2-test	X				
Multiple linear regression	X				
Logistic regression	X				
Non-parametric Spearman <i>R</i>	X				
Independent t-test				X	
Multivariate regression				X	
Sample size estimation		X	X		
Mixed models^a		X	X		
Adjustment for covariates, by multiple regression		X	X		
Post hoc analysis		X	X		
Imputation^b		X	X		

^a ANCOVA was originally planned, but a mixed model was later determined to be a better approach.

^b Loss to follow-up was less than 10%, but we still did imputation.

Study 1

Registry data for this study were collected and stored by use of an institution-approved, secure data-collection instrument. Continuous data were described with the use of means and medians, standard deviations, or ranges, and mean differences with 95% confidence intervals. A paired-sample *t* test was used to assess the difference between preoperative and 5-year Rowe scores. Categorical variables were described in terms of the number and proportions of patients. χ^2 statistics were used to test for significant group differences in categorical variables. A multiple linear regression model including age, gender, preoperative Rowe score, and preoperative subacromial pain score was used to evaluate prognostic factors for the 5-year Rowe score. A logistic regression model, including the same variables, was used to assess predictors of patient satisfaction at 5 years. The non-parametric Spearman *R* was used to

evaluate the correlation between a categorized Rowe score and patient satisfaction. All p values are 2-sided with a significance level of 5%. Analyses were carried out with SPSS version 16.1 (IBM Corp., Armonk, NY).

Study 2 and 3

The study was designed to detect a clinically important difference of 10 points in mean Rowe score between the three treatment groups. To detect this difference ($SD = 15$, $\alpha = 0.05$, $\beta = 0.80$, one-way analysis of variance), the study required 36 patients in each group. Assuming 10% dropout, we planned to include 40 patients in each group. In a later study by Skare et al.,⁹³⁻⁹⁵ we found the minimal clinically important change for Rowe to be 17. At 6 months, there were no cross-overs, and the results were analyzed and interpreted blindly, as recommended by Järvinen et al.⁹⁶ Continuous variables were presented as mean values with 95% CI and categorical values as numbers and percentages. We used a mixed model approach to analyze the effect of the interventions on primary and secondary variables at 6 and 24 months. For each model, we included a core set of adjustment variables as covariates: age, sex, time and frequency of physical activity, manual labor and dominant arm. In addition, the baseline measurement was included as a covariate to account for regression towards the mean for the estimated changes over time of the different treatments and for pairwise comparisons. The final model was tested for confounding with the covariates not included in the final main effects model. Confounding was defined as a change in the estimate of at least 25% when a term was added to a model. Finally, we tested for interactions between covariates and all outcomes at the 0.05 level only. If a significant difference was found, we applied Tukey's test for multiple comparisons. The assumptions were explored using Cook's distance, covariance ratio and trace statistics to assess the validity of the model. To ascertain the robustness of findings, we performed a bootstrap regression analysis with 1000 replications, adjusting for the baseline values and the variables mentioned above. Likewise, we performed multiple imputation using the Markov chain Monte Carlo method. The analysis was performed with the missing data as is and with the imputed values. For categorical variables, we applied the mixed models with multinomial distribution. For sensitivity analysis, we performed per protocol analysis comparing results in those who adhered to the protocol. Post hoc analysis was used to compare primary outcome scores at 6 months in those who crossed over from sham surgery with scores in a similar number of patients with the most inferior scores of patients randomized to biceps tenodesis and labral repair. The analyses were performed using Statistical Analysis System (SAS) software Version 9.4 and R software Version 3.11.

Study 4

Measurements were expressed as the median with the range. Preoperative and postoperative differences were evaluated with the non-parametric Wilcoxon signed-rank test because of the relatively low sample size and because outcome was not normally distributed. Categorical variables were expressed as frequencies. Results from the last follow-up evaluation before additional surgery were used if patients had a later second operation. The six patients who had an additional acromioplasty at the time of the primary operation were included, but an evaluation was also done with these patients excluded. Age, gender, duration of follow-up, and preoperative subacromial pain were evaluated in a multivariate regression model. Independent *t* tests were used both to investigate whether patients with preoperative muscle atrophy had different cyst sizes than the patients without atrophy and to test whether the mean duration of preoperative symptoms was different in the patients with muscle atrophy on MRI compared to those without atrophy.

Study 5

Descriptive statistics (mean, median, standard deviation [SD], and frequencies) were used to summarize patient outcomes. Paired sample *t*-tests were used to compare pre- and postoperative VAS ratings of pain. Data were analyzed using SPSS for Windows Version 24.0 (IBM Corp., Armonk, NY).

Ethical considerations

Ethical approval was received from the Ethics Committee Health Region Southeast, Oslo, Norway. The study was conducted in accordance with the Declaration of Helsinki and registered at ClinicalTrials.gov. **NCT 00586724.**

All patients provided written informed consent. In Study 3, they were informed that they might undergo sham surgery and that their group assignment could be unblinded after 6 months if they were not satisfied with their shoulder function. All patients received information about group allocation after the 2-year follow-up, and received a copy of the published article.

RESULTS

Synopsis of the papers

Paper 1

Long-term results after SLAP repair: A 5-year follow up study of 107 patients with comparison of patients over and under 40 years.

Aim: To assess in a prospective cohort study the long-term (5-year) results after isolated superior labral repair, and to evaluate whether the results were associated with age.

Material and methods: From 1998 to 2002, we included 107 consecutive patients with an isolated SLAP lesion. The mean age was 43.8 years (range: 20 – 68). They were treated with a labral repair. 58% of the patients were aged 40 years or older. An independent examiner performed all follow-up exams in our outpatient clinic. At the 5-year follow-up, 102 patients (95.3%) were examined.

Results: The preoperative Rowe score was 62.8 (SD 11.4) and the 5-year score was 92.2 (SD 13.5), which was a significant improvement ($p < .001$). 90 (88%) of the patients rated their shoulder as excellent/good at 5 years, and we found no significant difference between those aged over 40 years and those under 40 years.

In the statistical methods in the article (study 1) we stated that a multiple linear regression model included age, gender and preoperative Rowe score. We found that the preoperative Rowe score explained very little of the 5 year Rowe score, $< 5\%$ of the variance (R^2 0.048), but it was significant ($p=0.33$) Together with age and gender it explained 0.084, but age and gender were not significant predictors, ($p=0.221$ and 0.164) The multiple linear regression analysis also included preoperative subacromial pain. With regard to Rowe score at 5 years, the subacromial pain, age and gender explained 13% of the variance. Preoperative subacromial pain was significantly associated with Rowe score ($p=0.01$), ($B=7.8$, $t=2.6$) and patient satisfaction ($p=0.046$), (Odds Ratio 0.12, 95% CI 0.001 to 0.98) at final follow-up. The correlation between Rowe score at five years and patient satisfaction was 0.62. None of the factors mentioned above were significantly associated with patient satisfaction. We reported only the results for patients > 40 years and < 40 years in the text with no table showing the statistics from regression analysis. Postoperative stiffness and pain were reported in 14 (13.1%) patients.

Conclusion: Our results suggest that long-term outcomes after isolated labral repair for SLAP lesions are good and independent of age.

Paper 2

Efficacy of labral repair, biceps tenodesis, and diagnostic arthroscopy for SLAP lesions of the shoulder: a randomized controlled trial. (Study protocol)

Aim: To design a randomized controlled trial including sham surgery, validated outcomes, and blinded follow-up to evaluate the efficacy of labral repair and biceps tenodesis for type II SLAP lesions.

The lack of high-quality evidence for the efficacy of surgical treatment of SLAP lesions motivated us to design a participant and observer-blinded randomized placebo-controlled trial. We aimed to compare the efficacy of labral repair, biceps tenodesis and placebo (diagnostic arthroscopy), with the regard to both the short-term (6 months) and long-term results (2 years). All patients were to follow the same postoperative rehabilitation protocol. We planned to include 120 patients between the ages of 18 and 60 years. The inclusion criteria were a patient history, a preoperative MRI-documented SLAP lesion and clinical signs suggesting a type II SLAP lesion. The final inclusion criteria was an isolated SLAP II lesion diagnosed under arthroscopy. The exclusion criteria were former shoulder surgery, recurrent dislocations and pathology of the cuff or long head of the biceps. The primary outcome measures were Rowe score and Western Ontario Instability Index (WOSI) at 6 and 24 months. Shoulder Instability Questionnaire, the generic EQ-5D and EQ-VAS, return to work and sports, complications and reoperations were the secondary outcome measures. The study was designed to evaluate the effect of two important aspects of elective surgery: the surgery itself and the patient's expectation to the operation. The trial was registered at **ClinicalTrials.gov NCT 00586724**.

Paper 3

Sham surgery versus labral repair or biceps tenodesis for type II SLAP lesions of the shoulder: a three-armed randomized clinical trial.

Aim: To evaluate the efficacy of labral repair, biceps tenodesis and sham surgery on clinical (Rowe score) and patient related outcome (WOSI) in patients with a type II SLAP lesion at 6 and 24 months.

Material and methods: From 2008 to 2014 we included 118 patients with a mean age of 40 years in a double-blind, sham-controlled trial. They all had a patient history, clinical

symptoms and a MRI indicating a SLAP II lesion. The final inclusion was done when a diagnostic arthroscopy revealed an isolated SLAP II. After randomization, 40 patients were assigned to labral repair, 39 to biceps tenodesis, and 39 to the sham group. Our primary outcomes were clinical Rowe score ranging from 0 to 100 (best possible) and WOSI ranging from 0 (best possible) to 2100 at 6 and 24 months. Oxford Instability Shoulder Score (OISS), change in main symptoms, EQ-5D, EQ-VAS, patient satisfaction and complications were registered as secondary outcomes.

Results: We did not find any significant between-group differences in any of our outcome measures at any follow-up. At 2-year follow-up, the between-group differences for Rowe scores were: biceps tenodesis versus labral repair: 1.0 (95% CI -5.4 to 7.4), $p = 0.76$; biceps tenodesis versus sham surgery: 1.6 (95% CI -5.0 to 8.1), $p = 0.64$; and labral repair versus sham surgery: 0.6 (95% CI -5.9 to 7.0), $p = 0.86$. For the WOSI scores, the results were similar, with no differences between the groups. Four patients in the tenodesis group, five in the labral repair group, and one in the sham group were diagnosed with postoperative stiffness.

Conclusion: Neither labral repair nor biceps tenodesis had any significant clinical benefit over sham surgery for patients with SLAP II lesions in the population studied.

Paper 4

Treatment of labral tears with associated spinoglenoid cysts without cyst decompression.

Aim: To explore in a prospective cohort study whether labral repair alone would be followed by cyst resolution and pain relief.

Material and methods: We prospectively followed 42 patients with a postero-superior labral tear and a spinoglenoid cyst. They all had an arthroscopic isolated labral repair performed after debridement of the glenoid rim. The fixation was either done with a resorbable tack or a suture anchor. The patients ranged from 23 to 68 years in age. MRI was performed twice on all patients, the first one at a mean of 15 months and the last at a mean of 43 months postoperatively. Clinical and radiologic atrophy of the infraspinatus muscle was registered in 7 patients, one had these changes both in the infraspinatus and the teres minor muscles, while two had isolated atrophy of the teres minor muscle.

Results: The cyst had resolved completely in 37 (88%) of the patients. Five patients still had a cyst, but with a clear reduction in size. All five were pain free and reported normal shoulder function. Of the 10 patients with muscular atrophy, the three patients without fatty changes

regained normal appearing muscles. The seven with preoperative fatty infiltration, continued to demonstrate this postoperatively. At final follow-up, the median Rowe score had improved from 61.5 to 98.0. Of the 42 patients, 31 (74%) rated the treatment as excellent, nine (21%) as good, and two (5%) as fair.

Conclusion: This cohort study suggests that most spinoglenoid cysts resolve and patient satisfaction can be expected to be high after labral fixation without cyst decompression.

Paper 5

Paralabral cysts of the shoulder treated with isolated labral repair: effect on pain and radiologic findings.

Aim: To explore in a prospective cohort study whether isolated labral repair would be followed by pain relief, cyst resorption, and reversal of muscular edema. We also studied muscle atrophy, and fatty infiltration, as well as the consequences of glenoid erosion.

Material and methods: Forty-seven patients were included in the study. They all had a symptomatic posterosuperior cyst and were treated with isolated labral repair. MRI was performed at 2 and 12 weeks postoperatively or until cyst resolution. Fifteen patients had an MRI performed the day before surgery and on the first postoperative day, in addition to the MRIs at 2, 6 and 12 weeks. The median cyst size was 6.8 cm³ (range 2.1-88.8, SD 18.3). Twenty patients (43%) presented edema and muscle atrophy on MRI, eight patients (17%) had fatty changes of the affected muscles and in three patients (6%), the cyst had caused a bony erosion of the scapula.

Results: The mean time to cyst resolution was 11 weeks (range 3-20, SD 8.8) and the median time to regression of the muscular edema was 14 weeks (range 3-25, SD 10.6). The two patients with preoperative fatty infiltration grade I and II, respectively, presented reduced fatty infiltration at the final MRI. In the patients with bony erosions of the scapula, the bone remodeled after resolution of the cyst. At the last follow-up, the pain ratings on a 1-10 scale were reduced from 7.7 (SD 1.8) preoperatively to 1.3 (SD 1.3) ($p < .001$, 95% CI of difference: 5.5-6.8).

Conclusion: This cohort study suggests that labral repair leads to significant pain relief with cyst resolution within 2-3 months in most patients, that secondary muscle pathology (i.e., edema, atrophy and fatty infiltration) is partially or completely reversed, and that bony erosion caused by cyst compression may be remodeled after cyst resolution.

DISCUSSION

This thesis is a demonstration of how potentially interesting questions may arise from thorough clinical follow-up of patients. With the possibilities of arthroscopy of the shoulder, labral lesions were identified and classified in the early 1990s.⁶ The incidence and clinical importance of these lesions were not clear; neither was how they were best treated. Labral repair was introduced as a treatment option, and through the next decade, several low-level studies reported promising results. Given the general discussion at that time about whether to treat these lesions surgically or not, we decided that we had to follow our patients prospectively if we were to treat them operatively.

Prospective studies

Thus, in 1998 we designed a prospective study including 107 consecutive patients treated with an isolated labral repair. An independent observer followed the patients through 2 and 5 years. Results after 5 years are reported. As there was a significant improvement in Rowe score and high patient satisfaction, the results suggested that labral repair was a good treatment for patients with shoulder pain, dysfunction and a type II SLAP lesion. We found no difference in results between patients over and under 40 years of age. However, we were concerned about the postoperative stiffness that 13% of the patients experienced. The non-randomized design and lack of a control group were important limitations, and postoperative rehabilitation, patient characteristics, placebo, the natural course and regression to the mean may have contributed to the outcomes. However, this was a prospective study with a high-follow-up rate (95.3%) and it was important in terms of establishing questions for further research and hypothesis generation.⁶⁷

At that time, other shoulder surgeons were also concerned about the long-term results, and many promoted biceps tenodesis as an alternative treatment for these patients, but no studies documented its efficacy compared with isolated labral repair. We got the impression that there was a genuine clinical equipoise in the shoulder surgeon community as to the superiority of one treatment over the other. At this point, there were no other prospective studies or review papers in this field. Brockmeier et al.¹⁴ published a prospective study in 2009 and a systematic review by Gorantla et al.³¹ was published in 2010. Labral repairs were performed worldwide

and the lack of high quality studies prompted our design of a randomized controlled study including patients with isolated SLAP II lesions.

In the first prospective study of 107 patients with a SLAP tear, we found that about 10% (n=11) of the patients with a postero-superior labral tear also presented a concomitant spinoglenoid cyst affecting the suprascapular nerve. These patients had clinical signs of neuropathy and were treated with an isolated labral repair; MRI postoperatively demonstrated cyst resolution and high patient satisfaction. As this represented a novel and less invasive treatment of this group of patients, we decided to include these 11 patients in a separate prospective study of patients with spinoglenoid cysts treated with isolated repair (Study 4). The knowledge gained from this study led us to address the clinical signs, patient symptoms and radiological features of these cysts in a third prospective study (study 5). In total, we have prospectively evaluated almost a hundred patients with labral tears and symptomatic cysts and we are the first to demonstrate our results with MRI. Other studies have corroborated our statement that decompression of the cyst is unnecessary, but this statement rely on non-randomized pragmatic clinical studies, and high quality scientific studies are lacking.^{19,21,22}

Studies 1, 4 and 5 are true prospective cohorts, a protocol was written for each study, and the patients were scored preoperatively and followed by an independent examiner. Study 4 may be considered a pioneer study, and it is often cited. This pragmatic clinical cohort study explored the outcome after labral repair only in patients with labral cysts while the recommended method was to both repair the labrum and decompress the cyst. The observed outcome was good, but the study had a hypothesis generating design and should have been followed by a randomized study. Results from observational studies are criticized for being vulnerable to influences by unpredictable confounding factors. Still they are important to complement RCTs in hypothesis generation, establishing questions for future RCTs, and defining clinical conditions.⁶⁸

All three cohort studies are prone to bias and confounding, but a control group would to a lesser extent also be subject to this unless the patients were randomized. In fact, the results from the first prospective study led us to design such a study. The patients in study 1 were followed with a clinical examination and Rowe score at 2 and 5 years. In study 1, the 5-year outcome was 92/100 points on the Rowe score and 88% reported that the result was good/excellent. The patients in study 1 were followed with a clinical examination and Rowe

score at 2 and 5 years. Because 9 in 10 patients had good results at 5 years and the study sample consisted of about 100 patients, it is difficult to identify baseline factors associated with a negative outcome. In the sham-controlled trial a mixed model was applied and outcome was poorer, particularly at 6 and 12 months. Not surprisingly, outcome was associated with lower baseline score. Because the results improved from 12 to 24 months in the sham-controlled trial we might hypothesize better results at 5 years, but a long-term follow-up has not been performed. In study 1 we found that the preoperative Rowe score explained very little of the 5 year Rowe score, only $< 5\%$ (R^2 0.048), but it was significant ($p=0.033$). Together with age and gender it explains 0.084, but age and gender were not significant, ($p=0.221$ and 0.164). The multiple linear regression analysis also included preoperative subacromial pain. With regard to Rowe score at 5 years, the subacromial pain, age and gender explained 13% of the variance. Preoperative subacromial pain was significantly associated with Rowe score ($p=0.01$), ($B=7.8$, $t=2.6$) and patient satisfaction ($p=0.046$), (Odds Ratio 0.12, 95% CI 0.001 to 0.98) at final follow-up. The correlation between Rowe score at five years and patient satisfaction was 0.62. As stated in the results, only the results for patients > 40 years and < 40 years were reported, with no table showing the statistics from regression analysis.

In study 4, we included 11 patients from study 1. The reason was that MRI control revealed cyst resolution after isolated labral repair. There was no consensus on the treatment of these patients at this point. We wanted to assess whether isolated repair without decompression of the cyst would in fact lead to cyst resolution and pain relief. We decided to follow patients with this a labral tear and a symptomatic cyst and thus designed a prospective study. Although the evaluation of these patients should be considered as a pilot study that made us write a protocol for a larger prospective study. As these 11 patients were all scored and followed prospectively with clinical and MRI examinations, we found it appropriate to include them. The study was at that time the largest study and the only with MRI control of all patients. In 88% of the patients, the cyst was completely resolved. We were criticized for not decompressing the cyst and it was suggested that we probably decompressed the cyst during debridement of the glenoid rim. Meanwhile, a small (28 patients) non-randomized case-control study by Kim et al.¹⁸ had shown no difference between labral repair combined with cyst decompression and labral repair alone. A recent review concluded that results did not show any advantage from performing decompression.²²

Study 5 was designed on the basis of the results and critiques of study 4. We included patients with a labral tear and a cyst $\geq 1.0 \text{ cm}^3$ in a prospective cohort study. The protocol included preoperative MRI the day before surgery and on the first postoperative day, to assess whether the cyst was unintentionally decompressed under debridement. The results showed that this was not the case. The protocol also included MRI to assess the time to cyst resolution, regression of muscular edema and atrophy, and remodeling after bone resorption caused by cyst compression. Both study 4 and 5 are pragmatic clinical prospective cohort studies with limitations in diagnostics, outcome measures and study design. In retrospect, considering the non-randomized design and the small sample size in the study by Kim et al. and the design of study 5, a randomized design would have been preferable. In addition, the use of EMG and muscle strength testing would have improved the quality of the study.

The use of Suretac anchors has been criticized because it has been reported that this causes radiographic arthropathic changes. Elmlund et al.,⁹⁷ found that 24% of the patients had minor and 18% had moderate degenerative changes in a mid-to long-term follow-up after Bankart repair with Suretac. Castagna et al.⁹⁸ found 29% mild and 10 % moderate changes at 10 years after stabilization with metallic anchors. Long-term follow-up of other methods of stabilization, both open and arthroscopic, all report degenerative changes at long-term follow-up.^{97,99,100,101} However, no or only a weak correlation between clinical outcome measures and radiographic changes is reported, and the changes are likely due to the initial trauma and instability.⁹⁷⁻¹⁰¹

Sham-controlled randomized trial.

We designed the prospective randomized trial in 2007 and 2008 after a thorough discussion of the ethical issues involved. In our application to the ethical committee, we described the genuine disagreement in the shoulder community about the treatment of SLAP II lesions, and the lack of high quality studies regarding the efficacy of the surgical methods. In addition, we reported the very low rate of adverse effects in connection with diagnostic arthroscopy. In our first prospective cohort study (Study 1), none of the 107 patients experienced any anaesthesiologic complications or infection. A diagnostic arthroscopy represented the sham/placebo arm and this procedure is what we would currently offer many of these patients in our ordinary diagnostic practice at that time. The observation that 65 of the 183 patients

who underwent arthroscopy were excluded preoperatively because we did not confirm an isolated SLAP II lesion reflects the diagnostic purpose. These patients were treated according to the arthroscopic findings, results not reported.

We informed the patients about the lack of evidence regarding which of the three treatment options was the best and that they would not be included in the study unless we confirmed an isolated SLAP II lesion at arthroscopy. They were assured that if they were not allocated in the trial because of other findings at arthroscopy, they would receive treatment according to the arthroscopic findings. The patients signed the consent for participation after being provided with oral and written information, which included the possibility of being allocated to the sham group. They were informed that, according to the Helsinki declaration, they could drop out from the study at any time without giving any reason. At the same time, they were informed that recovery was often slow and that we preferred to wait until the 6-month follow-up to unblind their treatment allocation, which could be performed if they were not satisfied with their shoulder after surgery.

The study has a gold standard design: double-blinded and randomized with a placebo arm. The attrition rate was less than 2% at 6 months and less than 4% at 2 years. The study group assignments were concealed from the patients as well as from those collecting and analyzing outcomes and increased the methodological rigor of the study. Our statistician was independent and blinded. One may discuss whether imputation was necessary with so few missing data. Likewise, the adjustment for baseline factors possibly affecting the result may not be necessary in a randomized study. The trial was conducted as a single-center study. While a multicenter study has an advantage from a scientific perspective (higher external validity), it is a disadvantage organizationally and operationally. We would never have had the same control of the monitoring of the patients, the quality of the data and the analysis. In the multicenter placebo-controlled study (CSAW) by Beard et al., they report that a major study limit was the level of non-compliance to treatment allocation.¹⁰²

The outcome measures for the same group of patients were validated particularly for the present study.⁹³⁻⁹⁵ Our group ran parallel studies validating the Rowe score, the Western Ontario Shoulder Index, and the Oxford Instability Shoulder Score. The ideal situation would have been to have the minimal clinical important difference (MCID) calculated before designing the study. On the other hand, MCID is not a universal estimate and depend both on

the characteristics of the patients and the treatment given, we consider that the MCID in the present population is an advantage of the study. We estimated that the clinical relevant change that the trial should detect to be 10 on the 0-100 Rowe score. The validation by Skare et al.⁹³ calculated it to be 17, suggesting our choice of 10 was at least not too large. The two different primary outcomes yielded consistent results and included both patient and examiner reported outcomes. Neither secondary outcomes revealed any differences between interventions. Although our study was not large enough to perform subgroup analysis, the sample size was adequate to detect a clinically relevant difference between the three groups on primary outcomes.

The diagnostics are difficult and maybe we overemphasized the patho-anatomical changes, as a later study revealed that many may have the same lesion without symptoms.¹⁷ It is likely that more strict inclusion criteria with more than one positive test, as described in a recent study by Gismervik et al.,²⁶ would have been preferable. However, as all patients had diagnostic arthroscopy performed, only patients with an isolated SLAP II lesion were included. By this, the patho-anatomical heterogeneity was reduced and thus the internal validity increased. The fact that 313 patients were excluded for several reasons, including additional shoulder diagnoses detected at clinical examination (248) or at arthroscopy (65), reflects the diagnostic difficulties.

A true treatment effect is impossible to distinguish from the nonspecific (placebo) effect without a sham comparison group, especially when the end points are subjective, as in our study. The act of performing surgery may have a profound placebo effect in itself. All three groups went through the same rituals surrounding the procedure and follow-up, and 73% of the patients in the sham group believed they received the active treatment. Thus, it seems reasonable to assume that the treatment expectations and thus the placebo effects were comparable in all three groups. As we had no control arm receiving no treatment, the magnitude of the placebo effect is unknown.

The results were almost identical for all three groups at all time points. Both intention-to-treat and per-protocol analysis were performed and we found no statistical differences between the three groups. We are aware of the discussion regarding possible bias and underestimation of potential benefit of a treatment using intention-to-treat analysis in studies with only one-way cross-over.¹⁰³ In such studies, only the patients in the sham-group have the possibility for cross-over, and it is claimed that a patient with more severe symptoms is more likely to cross

over from sham treatment than a patient with less severe symptoms and that this represents a possible bias.

We cannot claim that this is not the case in our study as 14/39 (35.9%) patients in the sham group were re-operated. However, the mean Rowe and WOSI scores at 6 months (before cross-over) in these 14 patients were not significantly different from the 14 patients with the lowest scores in the labral repair and biceps tenodesis groups. This comparison suggests that the threshold for reoperation was lower in the sham group and the higher rate of re-operation in the sham group was related to the unblinding procedure rather than to differences in treatment failure.

At final follow up, the mean Rowe and WOSI scores in the crossover group were significantly lower than for the three original groups. This is a small group and meaningful analysis is not possible. We can only report the scores after re-operation as in a cohort study. We observed a mean improvement in all groups over time and it is not possible to discriminate the effect of the re-operation from improvement over time. Nevertheless, eight of the 14 crossover patients had a satisfactory result with a Rowe score above 80 and rated their shoulder function as good or excellent. Robinson et al.¹⁰⁴ discuss in their editorial the challenges of translating the results of randomized controlled trials in orthopedic surgery into clinical practice. They claim that the results of a pragmatic trial are most relevant to the applicability of a treatment to clinical practice. When no treatment effect is seen in such a trial, they hypothesize that this may reflect that the treatment is effective in certain subgroups of patients only. In this way, they underestimate the results from a well-designed RCT. We do not know the results in subgroups and there is no scientific evidence to warn against extrapolating negative results from pragmatic RCTs to all patients.

Regarding the indication for operative treatment, age and activity level of patients with SLAP lesions are widely discussed.^{33,42,44,45,50} The same goes for whether the lesion is traumatic or degenerative. The average age in our study, (Study 3) was 40 years and thus the results can be applied to a middle-aged population. In study 1, age did not influence results. A large, prospective study by Provencher¹⁶ reports that age over 36 years is a poor prognostic factor. In contrast, many studies of labral repair in young and active patients show a low success rate and low return to play, suggesting that these patients do not benefit from labral surgery.^{44,45,49-}

⁵¹ The current opinion among those who are involved in the treatment of overhead athletes,

especially throwers, is that a good result is not achieved with labral repair. The prognostic influence of age and trauma have been examined in many, mostly small studies, but other factors such as psychosocial factors have not been evaluated.

In their editorial, Cools and Borm¹⁰⁵ ask whether the patient's perception of having undergone a surgical intervention is critical to success. In addition, they ask whether the results in the sham surgery group and the other surgical groups are based on a well-designed rehabilitation program, rather than repair, placebo, natural healing and spontaneous recovery. These are important questions, but our study design does not allow us to discriminate between these factors. An advantage of the present study is that patients in all groups had the same rehabilitation program and that the influence of other factors than placebo were randomly distributed between groups except that more patients in the sham group had a re-operation as discussed previously.

Possible limitations of the sham controlled RCT are clinical diagnostics, sample size, the sham and surgical procedure, post-operative rehabilitation, outcomes, statistics, lack of no treatment group and blinding. This has been outlined in the original paper. A distinction between the efficacy of diagnostic arthroscopy and skin incision was not the topic of this trial. We had no hypothesis that diagnostic arthroscopy would be more effective than skin incision. There was neither any hypothesis in the international shoulder surgical community that diagnostic arthroscopy could replace biceps tenodesis or labral repair as an effective surgical intervention. The discussion of the eventual therapeutic effect of the diagnostic arthroscopy has no clinical relevance but in theory a physiological effect different from placebo cannot be ruled out. The use of mini-open technique was identified neither by the blinded single assessor nor the patient. The patient wore a t-shirt at follow-up and none of them had been told that the scar could be different according to the procedure. The postoperative procedure was principally similar for all patients and all physiotherapists and manual therapists involved in the study got similar information from the experienced study manual therapist (ØS). Because patients differ in many aspects and because rehabilitation is not just an exercise program, the patients had not exactly the same treatment. The rehabilitation followed the same principles in terms of progression. The rationale for the choice of different outcomes in patients are given in paper I as we in this study missed patient reported outcome (PROM). Sickness absence was recorded from the National Register and has been submitted for publication but has not been included in this thesis. The statistical analysis described in paper

3 is principally the same as outlined in the protocol. ANCOVA and multiple linear regression are principally similar methods and the use of mixed models allow for estimation of differences at different time points. Because of the randomized design and the high rate of follow-up the adjustment for covariates and the use of imputation is strictly not necessary, but we it is our opinion that it strengthened the analyses. We presumed that it would be difficult to handle four different intervention groups and to include an additional no treatment group. We presumed that because they knew that they were allocated to no treatment, they were in a way the unlucky ones. This may have triggered a nocebo effect and negatively influenced outcome. In our opinion the outcome of a control group, wait and see or no treatment, may be difficult to interpret.

We found no difference between sham surgery and commonly used surgical repair methods. This should be communicated to patients and the treatment decision should be shared between the physician and the patients. Scientifically, our results imply that the patients should be recommended sham surgery because the risk of complications is lower. Ethically, the use of sham surgery is controversial and not openly recommended by surgeons today and the stakeholders would probably not have reimbursed such treatment. Pragmatically most would recommend a rehabilitation program, but scientifically we do not know the effectiveness of this as compared to information alone. What the trial indicates is that the labral repair and biceps tenodesis are no better than sham surgery.

Conclusions and clinical implications

Study 1. The results from our first cohort study suggested that long-term outcomes after isolated labral repair for SLAP lesions were good and independent of age. Postoperative stiffness was registered in 13.1% of the patients. The labral repair, placebo, the postoperative rehabilitation program and the natural course, or a combination of these, could all have contributed to the results. *Clinical implication:* there was a need for a placebo-controlled randomized study.

Study 2. Thus, we designed a randomized controlled trial to compare labral repair and biceps tenodesis with sham surgery, using validated outcomes and blinded follow-up.

Study 3. The results of our randomized controlled trial indicate that neither labral repair nor biceps tenodesis has a significant clinical benefit over sham surgery for patients with SLAP II lesions in the population studied. Although there is a need for corroboration by other high-quality studies, the results is important and should influence decision making related to the treatment of SLAP lesions. *Clinical implication:* the results question the efficacy of and the indication for labral repair and biceps tenodesis in patients with a SLAP II lesion.

Studies 4 and 5. In the two cohort studies regarding SLAP tears with associated spinoglenoid cysts, the results suggest that isolated labral repair is an efficient treatment and that decompression of the cyst is unnecessary. Most spinoglenoid cysts resolve and patient satisfaction is high. Labral repair led to cyst resolution within 2-3 months in most patients. Secondary muscle pathology (i.e., edema, atrophy and fatty infiltration) may be completely reversed and bony erosion caused by cyst compression may be remodeled after cyst resolution. *Clinical implications:* The results indicate that patients with a labral cyst can safely be treated with labral repair. The efficacy of this procedure as compared with labral repair and decompression of the cyst should preferably be evaluated in a randomized trial.

Contribution to existing knowledge and further research

The lack of high-level evidence studies regarding the treatment of SLAP lesions is evident. The majority of studies have been retrospective, only a few prospective studies have been performed and review papers are scarce. We conducted a prospective study with proper follow-up by an independent observer and our conclusion was that a randomized controlled study was needed to gain evidence of higher quality. Snyder et al.⁵¹ stated in 2011, with over 25 years of experience, that each case of a suspected SLAP lesion must be evaluated on its own merits and that high-level research involving prospective, randomized data is necessary to further elucidate this issue. Our study is a first step in this direction. We found no differences between our three treatment groups. The study though, was not designed to analyze subgroups that may benefit from SLAP-repair or biceps tenodesis and studies designed to explore this are needed. As stated in the editorial in British Journal of Sports Medicine,¹⁰⁶ the burden of responsibility is now with the proponents of SLAP surgery to perform good quality trials to document indications where surgery is justified.

Regarding our studies on SLAP lesions with concomitant paralabral cysts, in contrast to others, we have prospectively followed all our patients with MRI. In addition, the numbers of patients included in both our studies are by far the largest.²² The lack of control group and randomized trials together with better evaluation of morphological findings and neuromuscular function means that there is a need for high quality future studies.

A new scientific truth does not triumph by convincing its opponents and making them see the light, but rather because the opponents eventually die, and a new generation grows up that is familiar with it.

Max Plank (1858-1947)

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STUDY PROTOCOL

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Efficacy of labral repair, biceps tenodesis, and diagnostic arthroscopy for SLAP Lesions of the shoulder: a randomised controlled trial

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Abstract

Background: Surgery for type II SLAP (superior labral anterior posterior) lesions of the shoulder is a promising but unproven treatment. The procedures include labral repair or biceps tenodesis. Retrospective cohort studies have suggested that the benefits of tenodesis include pain relief and improved function, and higher patient satisfaction, which was reported in a prospective non-randomised study. There have been no completed randomised controlled trials of surgery for type II SLAP lesions. The aims of this participant and observer blinded randomised placebo-controlled trial are to compare the short-term (6 months) and long-term (2 years) efficacy of labral repair, biceps tenodesis, and placebo (diagnostic arthroscopy) for alleviating pain and improving function for type II SLAP lesions.

Methods/Design: A double-blind randomised controlled trial are performed using 120 patients, aged 18 to 60 years, with a history for type II SLAP lesions and clinical signs suggesting type II SLAP lesion, which were documented by MR arthrography and arthroscopy. Exclusion criteria include patients who have previously undergone operations for SLAP lesions or recurrent shoulder dislocations, and ruptures of the rotator cuff or biceps tendon. Outcomes will be assessed at baseline, three, six, 12, and 24 months. Primary outcome measures will be the clinical Rowe Score (1988-version) and the Western Ontario Instability Index (WOSI) at six and 24 months. Secondary outcome measures will include the Shoulder Instability Questionnaire (SIQ), the generic EuroQol (EQ-5 D and EQ-VAS), return to work and previous sports activity, complications, and the number of reoperations.

Discussion: The results of this trial will be of international importance and the results will be translatable into clinical practice.

Trial Registration: [ClinicalTrials.gov NCT00586742]

Background

The glenoid labrum contributes to stability by increasing joint concavity and depth of the glenohumeral joint socket. The superior glenoid labrum of the shoulder joint is a common site of injury and degeneration^{1,2}. Because it is related to the intraarticular insertion of the long head of the biceps tendon, injuries are common in throwing athletes. These lesions are often associated with other shoulder injuries such as rotator cuff tears, glenohumeral instability or impingement, but they also may be due to an isolated injury. Snyder et al. used the

term SLAP (superior labrum anterior posterior) to describe these lesions, and they classified the lesions into four categories¹. Type II SLAP lesions, which occur most frequently, are characterised by the combined detachment of the superior labrum and biceps tendon from the peripheral edge of the glenoid. Surgical treatment includes reattachment of the labrum with the use of staples, metal screws, bioabsorbable tacks, and bioabsorbable anchors. Alternatively, tenodesis of the biceps tendon is performed, by inserting the tendon in the bicipital groove of the humeral head, either with suture anchors or interference screws.

Systematic reviews have analysed the value of diagnostic tests for SLAP-lesions³⁻⁵. Recently, a systematic review summarised the current evidence about the outcome of

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type II SLAP repair5]. Twelve studies, including 10 to 50 patients each, with at least 2-years of follow-up, were included; two studies compared two different surgical methods, two studies were prospective, while ten were retrospective cohort studies. There were no randomised trials. The percentage of patients classified as good to excellent varied from 40 to 94%. A return to their previous level of sports activity varied from 20 to 94%. Despite these unpredictable results and a lack of evidence from properly designed studies, shoulder surgeons worldwide perform type II SLAP repairs.

The aforementioned systematic review recommended that future studies should be prospective in nature and they should at least use a longitudinal prospective cohort design. Because uncontrolled studies have the potential to provide a distorted view of treatment results, and non-randomised trials are liable to produce biased results, we designed a prospective, randomised, double-blind, sham-controlled trial.

Aims

There are two aims of this randomised placebo-controlled trial:

- 1) Compare the short-term (6 months) efficacy of labral repair, biceps tenodesis, and placebo (diagnostic arthroscopy), for alleviating pain and improving function for type II SLAP lesions.
- 2) Compare the long-term (2 years) efficacy including the number of reoperations.

Methods/Design

Trial design

This is a participant and observer blinded randomised placebo-controlled trial with a 2-year follow-up (Figure 1).

Ethics

Ethics approval for this study has been received from the Ethics Committee Health Region Southeast, Oslo, Norway.

Participants

Participants will be recruited from general practitioners, physiotherapists, manual therapists, and from departments of orthopaedic surgery or physical medicine and rehabilitation. To increase the awareness of the trial, health care providers will be invited to attend lectures on shoulder complaints with a focus on the current study.

All potential participants will be screened to determine their eligibility according to the following inclusion and exclusion criteria. For inclusion, participants should be aged 18 to 60 years and have a history of type II

SLAP lesions or clinical signs suggesting the presence of a type II SLAP lesion, and an MR arthrography that documents the type II SLAP lesion6-]. Finally, the diagnosis should be verified at arthroscopy. One experienced shoulder surgeon and one experienced manual therapist will perform clinical examinations of the patients. Patients should have at least one positive sign of a SLAP lesion (positive O'Brien test], positive Crank test], or painful apprehension test9]).

A thorough clinical examination will be performed to exclude possible candidates with differential diagnoses. The clinical examination will include tests for impingement10-], pain or weakness on isometric tests of abduction and external rotation], tests for apprehension and relocation], scapular dyskinesis], and arthritis of the acromioclavicular joint15]. Possible candidates will have an MR arthrography evaluated by a radiologist experienced in shoulder imaging. In addition, conventional x-rays including outlet view will be conducted to exclude patients with major acromioclavicular or acromial spurs.

Exclusion criteria include previous surgery for SLAP lesions, SLAP lesions with concomitant labral cysts16,], previous surgery for recurrent shoulder dislocation or SLAP lesions, clinical and radiological signs of arthritis of the acromioclavicular15,] or the glenohumeral joints, ruptures of the rotator cuff or biceps tendon11], synovial chondromatosis, fibromyalgia, major somatic or psychiatric disease, and patients that are not able to understand Norwegian or unwilling to accept one of the treatment alternatives.

Randomisation

Participants who fulfil the inclusion criteria, and consent to take part in the trial after they have received the oral and written information, will be randomised to receive labral repair, biceps tenodesis, or placebo (diagnostic arthroscopy) treatment. An independent statistician will use the method of permuted blocks for random allocation after the final inclusion criteria are met. Treatment allocation will be organised by an independent secretary who distributes sealed opaque numbered envelopes to the nurse manager in the operation theatre. A nurse will open the envelope only when a peroperative diagnostic evaluation has documented a type II SLAP lesion.

Interventions

The patient will be positioned in the lateral decubitus position with lateral traction and under general anaesthesia. A standard posterior portal will be created and a diagnostic evaluation will be performed. Prior to entering the glenohumeral joint the subacromial space will be inspected and evaluated. The subacromial and the glenohumeral evaluations will be documented in a video created for each patient. An anterior working portal will

Figure 1 Diagram of Recruitment and Participation Process. Placebo is sham surgery (diagnostic arthroscopy). All groups had standard postoperative rehabilitation.

be established in the rotator interval with a spinal needle for accurate placement. This portal will be used to probe the superior labrum for documentation of a type-II SLAP lesion. Arthroscopic diagnostic evaluations and treatments will be performed by a single experienced shoulder surgeon.

Following confirmation of a type II SLAP lesion, the patient will be included in the randomisation procedure. All patients will receive 20 to 40 ml of a 0.5% local anaesthetic (Marcaine) at the end of the procedure, partly to serve as a suprascapular nerve block and partly to serve as an intraarticular injection. A collar and cuff

slings will be placed before the patient leaves the operating room.

Placebo (diagnostic arthroscopy)

Patients randomised to diagnostic arthroscopy and postoperative rehabilitation will comprise the placebo group.

Labral repair

Debridement of the superior glenoid rim will be performed with a motorized shaver from the anterior portal. The bioabsorbable suture anchor will be placed percutaneously, guided by a spinal needle through the myotendinous junction of the supraspinatus. From the percutaneous portal two suture anchors will be placed

in the glenoid posterior to the insertion of the biceps tendon. Sutures will then be made with the use of a shuttling device from the anterior portal. Fixation will be secured with a sliding knot and three half-hitches in alternating directions. Eventually, an anterior anchor will be placed through the anterior portal. No other procedures will be performed.

Biceps tenodesis

Although other arthroscopic methods are described, we routinely use a mini-open technique for biceps tenodesis (14). For exact positioning of the biceps tendon, a spinal needle will be placed under arthroscopic vision, as far laterally and central as possible in the biceps tendon. A tenotomy will be performed at the biceps labrum junction. The rest of the procedure will be performed mini-open with a 2 cm skin incision with the spinal needle in the centre. In order to identify and open the biceps pulley the deltoid will be split along the muscle fibers. The biceps tendon will be identified and lifted outside of the bicipital groove. The groove will be debrided, and a metal double suture anchor with needles will be placed in the groove. One of the limbs of each suture will be placed as a simple stitch to secure sliding of the knot, and the second limb will be passed two times to secure the fixation. Approximately 2 cm of the tendon will be excised and the pulley and skin will be closed. No other procedures will be performed.

Post-operative rehabilitation

Patients in all three groups will have standardised, but individually adjusted rehabilitation. Elbow, wrist, and finger mobilisation and gentle pendulum exercises will be conducted, starting on the first postoperative day. A sling will be used for three weeks. Local physiotherapists or manual therapists, who are given a written detailed description of the methods and progression, will provide treatment to patients when they are discharged from the hospital. Passive techniques like massage and stretching along with core stability exercises and general physical training will be used during the first three weeks. Exercises to normalise the gleno-humeral rhythm and improve coordination and mobility will be given using sling exercise therapy [17]. Exercises to improve functional stability and muscle strength of the rotator cuff and scapular stabilising muscles will be progressively emphasised after six weeks. Sports- or job-specific rehabilitation will be given on an individual basis, usually starting three months post-operatively. Rehabilitation will continue for three to six months and will include 12-16 sessions with a therapist and about 20 sessions of self-administered exercises.

Outcome assessment

Baseline data will include gender, age, smoking, previous treatment, duration of symptoms, MR arthrography and

conventional x-rays including outlet view, and primary and secondary outcome measures.

The same blinded observer will assess all participants after the procedure at three, six, 12 and 24 months. Pain, health related quality of life, complications, and a return to sports and work will be assessed at each time point. Blinding will be evaluated by asking the patients about which treatment they perceive to have received.

Pain during activity and pain at rest (over the last week) will be measured on a 0-100 visual analogue scale (VAS), comprising a horizontal line labelled no pain at one end and worst imaginable pain at the other end.

A range of standardised, generic and specific self-report health-related quality of life measures and the clinical Rowe Score will be used. To our knowledge outcome measures have not been particularly evaluated for patients with SLAP lesions. The primary outcome measures in the present trial will be the 1988 version of the Rowe Score [18], and the Western Ontario Instability Index (WOSI) [19]. The latter has been professionally translated to Norwegian.

The Rowe Score was first described in 1978 for use in patients after they were administered the Bankart procedure for anterior shoulder dislocation [20]. Four different versions exist. We will use the 1988 version. The observer will question the patient about function and pain, and assess their stability, muscle strength, and range of motion. The Rowe Score can be weighted using either pain or stability as the main problem. Because pain is the main complaint in patients with type II SLAP lesions, we will weight pain as 25 points. Pain has five levels ranging from severe (0 points) to none (25). Stability has five levels ranging from recurrent dislocation (0) to normal shoulder stability, which includes a negative apprehension test (15). Function has five response alternatives from total disability (0) to normal function with no limitation in daily living, sports, or work (25). Range of motion is evaluated for abduction/forward flexion, internal rotation and external rotation, and it is categorised from a full range of motion (25) to less than 30° of motion (0). Muscle strength will be measured by a spring gauge, and results will be compared to the opposite shoulder and categorised from normal (10) to poor (0). The best achievable score is 100. Results are commonly classified into four categories: poor (39 points or less), fair (40 to 69 points), good (70 to 89 points), and excellent (90 to 100 points).

The WOSI is a disease-specific health related quality of life instrument developed and validated for use in patients with shoulder instability. It comprises 21 items representing four domains. The first domain covers physical symptoms and contains 10 items. The remaining domains are sports, recreation, and work (four items), lifestyle (four items), and emotions (three items). Each

question is scored from 0 (best possible) to 100 on a visual analogue scale. The worst score possible is 2100. This signifies that the patient has an extreme decrease in shoulder-related health-related quality of life.

The Shoulder Instability Questionnaire (SIQ) is a disease-specific health related quality of life instrument validated for use in patients with shoulder instability[21]. It includes 12 questions (1-5 points each) with possible scores from 12 (best function) to 60 (worst function).

The EuroQuol (EQ-5 D and EQ-VAS) is a standard generic health-related quality of life instrument[22]. The EQ-5 D measures five domains (Mobility, Self-Care, Usual Activities, Pain/Discomfort, and Anxiety/Depression); each has three levels, ranging in severity from no problem, to some problem, or an extreme problem. Responses are transformed to an index and then classified into 243 (3^5) health states, with the best imaginable state (1.0) representing the highest level of functionality.

Sickness absence data will be collected from the National Social Security Institution.

Sample size

The main end-points are six and 24 months[12]. From clinical experience we estimated that the smallest clinically important detectable difference is 10 points on the 100 points Rowe Score. Assuming that the largest difference between treatments will be 10 units, we simulated multiple scenarios and estimated the standard deviation between means to be 14.6 units. To detect this difference between treatment groups ($SD = 15$, $\alpha = 0.05$, $\beta = 0.80$, One-Way ANOVA) our study will require 36 patients in each group. Assuming some patients drop-out, we plan to include 40 patients in each group.

Planned statistical analysis

Treatment groups will be examined for comparability at baseline with respect to demographic and prognostic factors. All eligible patients, regardless of their compliance with protocol (analysis by intention-to-treat) will be included in the main analyses. To assess the effect of the interventions on the endpoints (six and 24 months), analysis of covariance (ANCOVA) will be performed using the baseline values as one of the covariates. Standard regression assumptions will be assessed using diagnostic plots, Jackknife residuals, Cook's distances, and Variance inflation Factor (VIF). We will adjust for an eventual imbalance at the baseline. Corresponding post-hoc tests (Tukey's test) will be performed. To evaluate the time-course at three, six, 12, and 24 months, repeated measures will be analyzed using linear mixed models. If the number of missing values exceeds 10% in one of the groups, multiple imputations will be used to estimate the missing values. To assess the robustness of

our findings the analysis will be performed with and without the imputed values.

Discussion and conclusion

Surgery for type II SLAP lesions are performed worldwide, but published reports suggest that outcome is difficult to predict. Interventions that effectively reduce pain, improve function, and allow patients to return to sports and work are lacking. Promising results are published for both biceps tenodesis and labral repair[5,23], but the lack of a randomised design, standardised inclusion and exclusion criteria, and small study sizes, may bias these conclusions.

Few clinical trials in orthopaedic surgery include sham or placebo treatments. Two trials compared vertebroplasty[24-] with placebo in patients with osteoporotic vertebral compression fractures, and one trial compared arthroscopic lavage, debridement, and placebo in patients with osteoarthritis of the knee[26]. Neither of these trials found that the surgical procedure was effective compared with the placebo. These trials emphasise the importance of including a placebo intervention in a randomised trial in order to improve present knowledge about mechanisms for pain reduction after surgical procedures.

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Authors' contributions

ØS participated in the design of the study, drafted the manuscript, and evaluated patients for inclusion and follow-up exams. CPS participated in the design of the study, operated on all patients included in the study, and helped to draft the manuscript. OR participated in the design of the study and contributed to monitoring the trial. PM participated in the design of the study, and planned and performed the statistical analyses. JIB participated in the design of the study, drafted the manuscript, and monitored the trial. All authors read and approved the final manuscript.

Competing interests

The authors declare that they have no competing interests.

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Sham surgery versus labral repair or biceps tenodesis for type II SLAP lesions of the shoulder: a three-armed randomised clinical trial

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ABSTRACT

Background Labral repair and biceps tenodesis are routine operations for superior labrum anterior posterior (SLAP) lesion of the shoulder, but evidence of their efficacy is lacking. We evaluated the effect of labral repair, biceps tenodesis and sham surgery on SLAP lesions.

Methods A double-blind, sham-controlled trial was conducted with 118 surgical candidates (mean age 40 years), with patient history, clinical symptoms and MRI arthrography indicating an isolated type II SLAP lesion. Patients were randomly assigned to either labral repair (n=40), biceps tenodesis (n=39) or sham surgery (n=39) if arthroscopy revealed an isolated SLAP II lesion. Primary outcomes at 6 and 24 months were clinical Rowe score ranging from 0 to 100 (best possible) and Western Ontario Shoulder Instability Index (WOSI) ranging from 0 (best possible) to 2100. Secondary outcomes were Oxford Instability Shoulder Score, change in main symptoms, EuroQol (EQ-5D and EQ-VAS), patient satisfaction and complications.

Results There were no significant between-group differences at any follow-up in any outcome. Between-group differences in Rowe scores at 2 years were: biceps tenodesis versus labral repair: 1.0 (95% CI -5.4 to 7.4), p=0.76; biceps tenodesis versus sham surgery: 1.6 (95% CI -5.0 to 8.1), p=0.64; and labral repair versus sham surgery: 0.6 (95% CI -5.9 to 7.0), p=0.86. Similar results—no differences between groups—were found for WOSI scores. Postoperative stiffness occurred in five patients after labral repair and in four patients after tenodesis.

Conclusion Neither labral repair nor biceps tenodesis had any significant clinical benefit over sham surgery for patients with SLAP II lesions in the population studied.

Trial registration number ClinicalTrials.gov identifier: NCT00586742

Labral repair is the most common procedure to treat labral tears, but because of high rates of complications and poor outcomes,^{10–17} it has been suggested that indications should be narrowed.^{10–17} Recent reports show a decrease in the number of labral tears performed and a decrease in the age of the patients undergoing these operations.^{18–19} Release of the biceps tendon (tenodesis or tenotomy) is increasingly used as an alternative^{13–22} to SLAP repairs in select patients, but the evidence for it is weak.^{13–20–22} One non-controlled study reported better results after tenodesis compared with labral repair,¹³ but no randomised trials have compared these procedures. Very little evidence about non-operative treatment for type II SLAP lesions was available when the present study was designed. Recent non-controlled studies suggest that non-operative treatment including graded exercise therapy is beneficial, and the postoperative rehabilitation in the present study followed those rehabilitation principles.^{23–25}

Our aim was to conduct a randomised, double-blind, sham-controlled trial to assess the clinical effectiveness of labral repair and biceps tenodesis in patients with a type II SLAP lesion.

MATERIALS AND METHODS

Design

This blinded, three-armed randomised, sham-controlled study with a 2-year follow-up was conducted at Lovisenberg Diaconal Hospital, Oslo, Norway, from January 2008 to January 2014. The study protocol has been published previously.²⁶ The patients, the treating physiotherapists/manual therapists and the persons collecting and analysing the data were blinded to the study group assignments. The first author was not blinded to group assignment, but had no role in the follow-up of the patients.

Participants

We enrolled patients 18–60 years of age who had shoulder pain (>3 months) that was unresponsive to conventional non-operative treatment (physiotherapy, non-steroidal anti-inflammatory drugs and/or corticosteroid injections) and had a history, clinical findings and MRI arthrography indicating a SLAP lesion. Patients were informed that final study inclusion and randomisation would be performed during arthroscopy if an isolated type II SLAP lesion was confirmed. Exclusion criteria included previous shoulder surgery, SLAP lesions with concomitant

INTRODUCTION

The superior glenoid labrum of the shoulder is a common site of injury and degeneration, which can cause both pain and disability.^{1,2} Snyder *et al*¹ used the term SLAP (superior labrum anterior posterior) to describe a combined detachment of the long head of biceps tendon and the superior labrum from the glenoid rim (figure 1). The diagnosis is controversial; the validity of clinical tests,³ and even arthroscopy and MRI arthrography is questioned.^{4–8} In addition, a high prevalence of SLAP lesions has been reported in a middle-aged asymptomatic population.⁹

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Original article

labral cysts,²⁷ clinical and radiological signs of arthritis of the acromioclavicular (AC) or glenohumeral joint,²⁸ and tears of the rotator cuff or the long head of the biceps tendon. Detailed criteria are described in the published study protocol.²⁶

Diagnostic arthroscopy

Arthroscopic examination of the shoulder was performed in all patients under general anaesthesia, with the use of standard posterior and anterior portals. The orthopaedic surgeon (CPS) evaluated both the subacromial space and the glenohumeral joint and noted the intra-articular findings (figure 1), and a video was created for each patient.

Randomisation

Participants who fulfilled the inclusion criteria and consented to take part in the trial were randomised to receive either (1) labral repair, (2) biceps tenodesis or (3) sham surgery. An independent statistician used the permuted block method of randomisation. Concealed allocation was organised by an independent secretary who distributed sealed opaque-numbered

envelopes to the head nurse in the operating room. The nurse opened the envelope when a patient was confirmed to be eligible by arthroscopic diagnostic evaluation. Following confirmation of an isolated type II SLAP lesion, the patient was included in the randomisation procedure.

Interventions

A detailed description of each intervention is provided in the published protocol.²⁶ A single experienced shoulder surgeon performed all arthroscopic evaluations and treatments.

Operative and postoperative procedures

During the labral repair, the superior glenoid rim was debrided with a motorised shaver, followed by a percutaneous placement of a drill guide and anchors through the myotendinous junction of the supraspinatus. All anchors were placed posterior to the biceps root, and single circular sutures were used.

The biceps tenodesis was done with a mini-open technique. Under arthroscopic vision, a spinal needle was placed as laterally as possible and with a 90° angle central in the biceps

Figure 1 CONSORT (Consolidated Standards of Reporting Trials) flow chart. AC, acromioclavicular; SLAP, superior labrum anterior posterior.

Table 1 Baseline characteristics of the patients according to study group

Characteristic	Biceps tenodesis (n=39)	Sham surgery (n=39)	Labral repair (n=40)
Age (years), median (range)	40 (18 to 64)	40 (23 to 60)	42 (22 to 57)
Female sex, n (%)	15 (38.5)	17 (42.5)	15 (37.5)
Body mass index [†]	27.6 (5.6)	26.1 (3.8)	26.4 (4.3)
University education, n (%)	18 (48.6)	23 (59.0)	22 (56.4)
Manual labour, n (%) [‡]	19 (48.7)	11 (28.2)	17 (42.5)
Physical activity, n (%) [§]	18 (47.2)	21 (56.4)	28 (70.0)
No training	22 (55.0)	17 (42.5)	12 (30.0)
Frequent physical activity	17 (42.5)	17 (42.5)	27 (67.5)
Competitive	1 (2.5)	5 (12.5)	1 (2.5)
Taking analgesics daily or weekly, n (%)	7 (17.9)	5 (12.8)	6 (15.0)
Duration of pain, month median (IQR)	24 (59)	26 (61)	24 (47)
Dominant shoulder involved, n (%)	28 (71.8)	33 (84.6)	28 (70.0)
Positive O'Brien test, n (%)	37 (94.9)	33 (86.8)	36 (90.0)

*Plus-minus values are means±SD.

[†]The body mass index is the weight in kilograms divided by the square of the height in metres.[‡]Manual labour was reported if the patient was engaged in daily manual work.[§]Physical activity was reported if the patient had no regular training, frequent if the patient was training two times or more in a week on a regular basis, and competitive if the patient was competing on a national level.^{||}The O'Brien test is positive if the patient has pain when resisting force from an examiner, with the arm in 90° of flexion, 20° adduction and supinated, and less pain with the arm otherwise in the same position but with pronation.

tendon and a tenotomy was performed at the biceps insertion. With less than 2 cm skin incision (to mimic the scars in the other two groups), the spinal needle was followed down to the biceps pulley, the pulley was split and the biceps tendon was lifted out. The groove was debrided, a double-loaded metal anchor was placed in the inferior part of the groove, and the tendon secured with two sutures, each passing twice through the tendon. The proximal part of the tendon was excised and the wound closed.

For the sham surgery, standard diagnostic shoulder arthroscopy was performed. In addition, a 5 mm skin incision was made to mimic a labral repair. The patient was kept in the operation theatre for the amount of time required to perform an actual arthroscopic index shoulder surgery.

All operative procedures were recorded on video. For all patients, a sling was placed before they left the operating room, and standard postoperative care and instructions were provided.

Postoperative rehabilitation

Patients in all three groups had a standardised, but individually adjusted rehabilitation. Elbow, wrist, and finger mobilisation and gentle pendulum exercises were conducted, starting on the first day. A sling was used for 3 weeks. Local physiotherapists, blinded to the allocation of the patient, provided treatment after discharge from the hospital. Passive techniques, such as massage and stretching, core stability exercises and general physical training, were used during the first 3 weeks. Exercises to improve the scapula-humeral rhythm, coordination and mobility were performed using sling exercise therapy.²⁹ Gradual biceps loading was started at 12 weeks. Exercises to improve functional stability and scapula muscles were progressively emphasised after 6 weeks. Sports

and job-specific rehabilitation were provided on an individual basis, usually starting 3 months postoperatively. Rehabilitation was continued for 3–6 months and included 12–16 sessions with a therapist and 20 self-administered exercises.

Outcome measures

The two primary outcome measures were the Rowe score³⁰ and the Western Ontario Shoulder Instability Index (WOSI)³¹ at 6 and 24 months after surgery. The 1988 version of the Rowe score and the WOSI were validated for use in the present study.^{32–34} As recommended by Rowe, patient satisfaction was assessed separately using a self-reported question with response alternatives of poor, fair, good and excellent.³⁵

Secondary outcomes were: WOSI and Rowe at 3 and 12 months, the Oxford Instability Shoulder Score (OISS),³⁶ the EuroQol (EQ-5D, EQ-VAS) for generic health-related quality of life³⁷ and change of the main symptom (pain) from baseline to all follow-ups.³⁸ The EuroQol and OISS are validated for use in patients with SLAP lesions.^{33 34}

A single-blinded observer assessed all participants and administered questionnaires at baseline and all postoperative follow-ups. Patient characteristics were assessed at baseline and included self-reported manual labour (yes/no); physical activity (1=competitive sports/2= frequent physical activity (three to four times a week)/3=occasional or none); dominant shoulder (yes/no); Apprehension test (positive/negative); Crank test (positive/negative); and O'Brien test (positive/negative). Blinding was evaluated by a question asking the patients if they thought they were operated or had sham surgery. Adverse events were classified as serious if the patient needed prolonged inpatient hospital care, hospitalisation or death, and considerable if the patient had painful shoulder stiffness (capsulitis) with external rotation and forward flexion <30° and abduction <90°.³⁹

Sample size and statistical analysis

The study was designed to detect a clinically important detectable difference of 10 points in mean Rowe score. To detect this difference among treatment groups (SD=15, $\alpha=0.05$, $\beta=0.80$, one-way analysis of variance), the study required 36 patients in each group. Assuming 10% dropout, we planned to include 40 patients in each group. In a later study,³² we found the minimal clinically important change for Rowe score to be 17. At 6 months there were no crossovers and the results were analysed and interpreted blindly, as recommended by Järvinen *et al.*⁴⁰

Continuous variables are presented as mean values with 95% CI and categorical values as numbers and percentages. We used a mixed models approach to analyse the effect of the interventions on primary and secondary variables at 6 and 24 months. For each model, we included a core set of adjustment variables as covariates: age, sex, time, frequency of physical activity, manual labour and dominant arm. In addition, the baseline measurement was included as a covariate to eliminate regression towards the mean for the estimated changes over time of the different treatments and for pairwise comparisons. The final model was tested for confounding with the covariates not included in the final main effects model. Confounding was defined as a change in the estimate of at least 25% when a term was added to a model. Finally, we tested for interactions between covariates and all outcomes at the 0.05 level only. If a significant difference was found, we applied Tukey's test for multiple comparisons. The assumptions were explored

Original article

Figure 2 Rowe scores (with error bars) for each group at baseline and at 3, 6, 12 and 24 months.

using Cook's distance, covariance ratio and trace statistics to assess the validity of the model. To ascertain the robustness of findings, we performed a bootstrap regression analysis with 1000 replications, adjusting for the baseline values and the variables mentioned above. Likewise, we performed multiple imputation using the Markov chain Monte Carlo method. The analysis was performed with the missing data as is and with the imputed values. For categorical variables, we applied the mixed models with a multinomial distribution. For sensitivity analysis, we performed per protocol analysis comparing results in those who adhered to the protocol. Post hoc analyses were used to compare primary outcome scores at 6 months in those who crossed over from sham surgery with scores in a similar number of patients with the most inferior scores of patients randomised to biceps tenodesis and labral repair. The analyses were performed in Statistical Analysis System (SAS, V.9.4) and R V.3.1.1.

Ethics and registration

Ethics approval (IRB00001870) was received from the Ethics Committee Health Region Southeast, Oslo, Norway. The study was conducted in accordance with the Declaration of Helsinki. All patients provided written informed consent. They were informed that they might undergo sham surgery and that their group assignment could be unblinded after 6 months if they were not satisfied with their shoulder function. The study was also registered with ClinicalTrials.gov (NCT00586742).

RESULTS

Patient characteristics

Of the 445 patients eligible for inclusion, 262 were excluded before arthroscopy. Of the 183 patients who had arthroscopy, 65 were excluded peroperatively (figure 1). A total of 118 patients were randomised; 39 were assigned to sham surgery, 39 to biceps tenodesis and 40 to labral repair. The mean age was 40 years, ranging from 18 to 64. One patient aged 64 years was mistakenly included. The baseline characteristics are described in table 1.

Four patients were lost to follow-up at 2 years; two in the sham group and one in each of the other two groups.

Primary outcomes

There was a significant improvement from baseline to 6 and 24 months for all three study groups (figure 2 and table 2). Age, sex, trauma, manual work, frequency of physical activity, duration of pain and dominant shoulder were not significantly associated with primary outcomes at follow-up. The only significant covariates were the baseline Rowe ($p<0.001$) and WOSI ($p<0.002$) scores.

There were no significant between-group differences in the change from baseline to 6 or 24 months in any primary outcome, neither for the adjusted nor for the unadjusted results (table 3). Unadjusted results were marginally different and imputation did not materially change between-group differences.

Table 2 Primary and secondary outcomes at baseline and at 3, 6, 12 and 24 months after arthroscopy*

Outcome	Biceps tenodesis (n=39)	Sham surgery (n=39)	Labral repair (n=40)
<i>Primary outcome, mean (95% CI)</i>			
Rowe score (0 to 100) [†]			
Baseline	60.3 (57.0 to 64.0)	63.2 (59.8 to 66.7)	62.7 (59.6 to 65.8)
3 Months	62.4 (57.1 to 67.7)	68.9 (63.5 to 74.3)	63.8 (58.6 to 69.0)
6 Months	76.0 (70.7 to 81.1)	76.3 (71.1 to 81.6)	76.1 (71.0 to 81.3)
12 Months	83.3 (78.4 to 88.1)	81.4 (76.4 to 86.5)	83.5 (78.6 to 88.4)
24 Months	86.8 (82.2 to 91.4)	85.3 (80.6 to 89.9)	85.8 (81.3 to 90.4)
WOSI (0 to 2100) [‡]			
Baseline	1155 (1026 to 1283)	1062 (940 to 1183)	1044 (941 to 1146)
3 Months	1115 (829 to 1401)	833 (528 to 1138)	788 (506 to 1070)
6 Months	689 (548 to 829)	560 (420 to 701)	552 (414 to 691)
12 Months	490 (353 to 627)	475 (335 to 614)	429 (294 to 565)
24 Months	436 (313 to 559)	458 (334 to 582)	340 (219 to 461)
<i>Secondary outcome, mean (95% CI)</i>			
OISS (12 to 60) [§]			
Baseline	38.6 (36.1 to 41.1)	36.9 (34.3 to 39.6)	36.7 (34.8 to 38.6)
3 Months	37.8 (35.3 to 40.4)	36.0 (33.4 to 38.6)	36.0 (33.6 to 38.5)
6 Months	29.7 (27.0 to 32.4)	28.6 (25.9 to 31.3)	27.4 (24.7 to 30.6)
12 Months	24.1 (21.1 to 27.1)	25.9 (22.8 to 28.9)	23.3 (20.3 to 26.2)
24 Months	21.7 (18.5 to 24.8)	23.3 (20.1 to 26.5)	22.7 (19.6 to 25.8)
EQ-5D (0.59 to 1.00) [¶]			
Baseline	0.6 (0.5 to 0.7)	0.7 (0.6 to 0.7)	0.7 (0.6 to 0.7)
3 Months	0.6 (0.6 to 0.7)	0.7 (0.7 to 0.8)	0.7 (0.6 to 0.8)
6 Months	0.7 (0.7 to 0.8)	0.8 (0.8 to 0.9)	0.8 (0.7 to 0.9)
12 Months	0.8 (0.8 to 0.9)	0.8 (0.7 to 0.9)	0.8 (0.8 to 0.9)
24 Months	0.8 (0.8 to 0.9)	0.9 (0.8 to 0.9)	0.9 (0.8 to 0.9)
EQ-VAS (0 to 100) [¶]			
Baseline	67.9 (63.3 to 73.4)	66.7 (62.2 to 73.1)	68.4 (62.9 to 73.8)
3 Months	67.1 (60.7 to 73.5)	67.7 (61.6 to 74.3)	72.9 (66.6 to 79.3)
6 Months	73.9 (68.3 to 79.4)	76.9 (71.3 to 82.4)	81.3 (75.8 to 86.7)
12 Months	78.3 (72.5 to 84.1)	79.4 (73.5 to 85.3)	79.2 (73.5 to 85.0)
24 Months	79.6 (74.0 to 85.2)	76.8 (71.2 to 82.5)	81.7 (76.1 to 87.2)
Change of main complaint (−9 to +9)			
3 Months	3.0 (1.5 to 4.5)	2.3 (0.8 to 3.9)	3.2 (1.7 to 4.6)
6 Months	3.8 (2.2 to 5.4)	2.8 (1.2 to 4.4)	3.7 (2.1 to 5.3)
12 Months	5.3 (3.9 to 6.6)	4.5 (3.1 to 5.9)	5.5 (4.2 to 7.0)
24 Months	5.7 (4.6 to 6.9)	5.5 (4.3 to 6.7)	5.3 (4.3 to 6.9)

*Unadjusted values are given.

†Higher scores indicating better shoulder function.

‡Western Ontario Shoulder Instability Index, lower scores indicating better shoulder function.

§Oxford Instability Shoulder Score, lower scores indicating better shoulder function.

¶EuroQol (EQ-5D and EQ-VAS), higher scores indicating better health-related quality of life.

OISS, Oxford Instability Shoulder Score; WOSI, Western Ontario Shoulder Instability Index.

Secondary and other outcomes

All three groups improved on the secondary outcomes from baseline to 6 and 24 months (table 2), and there were no significant differences among the groups (table 3). In the sham group, 31/37 (84%) patients reported excellent or good results at 1-year follow-up, in the labral repair and biceps tenodesis groups the numbers were 29/35 (83%) and 34/38 (89%), respectively. The first 25 patients did not receive the blinding question. After sham surgery, 19/26 (73%) patients believed they were repaired, in comparison to 31/32 (97%) after biceps tenodesis and 31/35 (89%) after labral repair.

There were no serious adverse events, infections or nerve injuries. Ten patients experienced prolonged postoperative stiffness (capsulitis); five after labral repair, four after biceps tenodesis

and one after sham surgery (due to trauma 3 weeks postoperatively).

Per protocol analysis

There were no significant differences in the changes between groups for any primary or secondary outcomes in the per protocol analysis. At 6 and 24 months, respectively, the mean Rowe scores for the three groups were: biceps tenodesis 76.1 and 87.0; labral repair 76.2 and 85.9; sham surgery 81.4 and 89.0. The mean WOSI scores were: biceps tenodesis 690 and 437; labral repair 552 and 339; sham surgery 428 and 338.

Original article

Table 3 Adjusted between-group differences at 3, 6, 12 and 24 months after arthroscopy*

Outcome	Biceps tenodesis versus labral repair	p Value	Biceps tenodesis versus sham surgery	p Value	Labral repair versus sham surgery	p Value
<i>Primary outcomes</i>						
Rowe score (0 to 100) [†]						
3 Months	−1.3 (−8.7 to 6.0)	.76	−6.5 (−14.0 to 1.1)	.09	−5.1 (−12.6 to 2.4)	.18
6 Months	−0.2 (−7.5 to 7.1)	.96	−0.2 (−7.8 to 7.0)	.92	−0.2 (−7.5 to 7.1)	.95
12 Months	−0.2 (−7.1 to 6.6)	.95	1.8 (−5.2 to 8.8)	.61	2.1 (−5.9 to 9.0)	.56
24 Months	1.0 (−5.4 to 7.4)	.76	1.6 (−5.0 to 8.1)	.64	0.6 (−5.9 to 7.0)	.86
WOSI (0 to 2100) [‡]						
3 Months	−327 (−728 to 75)	.11	−282 (−700 to 137)	.19	45 (−370 to 461)	.83
6 Months	−137 (−335 to 61)	.17	−128 (−328 to 71)	.20	8 (−189 to 205)	.93
12 Months	−60 (−254 to 133)	.53	−15 (−211 to 181)	.88	45 (−149 to 240)	.64
24 Months	−96 (−269 to 77)	.27	22 (−152 to 196)	.80	118 (−54 to 291)	.18
<i>Secondary outcomes</i>						
OISS (12 to 60) [§]						
3 Months	−1.8 (−5.4 to 1.8)	.32	−1.8 (−5.4 to 1.8)	.32	0.0 (−3.6 to 3.6)	.99
6 Months	−2.3 (6.1 to 1.5)	.56	−1.1 (−5.0 to 2.7)	.22	1.2 (−5.0 to 2.6)	.53
12 Months	−0.8 (−5.4 to 5.0)	.41	1.8 (−2.3 to 6.5)	.41	2.6 (−1.6 to 6.9)	.23
24 Months	1.0 (−5.5 to 3.5)	.65	1.6 (−2.9 to 2.3)	.65	0.6 (−3.9 to 5.1)	.79
EQ-5D (−0.59 to 1.00)						
3 Months	−0.1 (−0.2 to 0.0)	.18	−0.1 (−0.2 to 0.0)	.03	−0.1 (−0.1 to 0.1)	.41
6 Months	−0.1 (−0.1 to 0.0)	.19	−0.1 (−0.2 to 0.0)	.08	0.0 (−0.1 to 0.1)	.65
12 Months	0.0 (−0.1 to 0.1)	.85	0.0 (0.0 to 0.1)	.37	0.0 (−0.1 to 0.1)	.47
24 Months	0.0 (−0.1 to 0.1)	.50	0.0 (−0.1 to 0.1)	.56	0.0 (−0.1 to 0.0)	.93
EQ-VAS (0 to 100)						
3 Months	−5.8 (−14.8 to 3.2)	.20	−0.6 (−9.8 to 8.5)	.90	5.2 (−4.0 to 14.4)	.26
6 Months	−7.4 (−15.2 to 0.4)	.06	−3.1 (−10.9 to 4.8)	.44	4.4 (−3.4 to −12.1)	.27
12 Months	−1.0 (−9.2 to 7.2)	.82	−1.1 (−9.4 to 7.1)	.79	−0.2 (−8.4 to 8.1)	.97
24 Months	−2.1 (−10.0 to 5.8)	.50	2.8 (−5.5 to 10.7)	.49	4.9 (−3.0 to −12.8)	.23
Main complaint (−9 to +9)						
3 Months	−0.2 (−2.3 to 1.9)	.87	0.6 (−1.5 to 2.8)	.55	0.8 (−1.3 to 2.9)	.44
6 Months	0.1 (−2.2 to 2.4)	.93	1.0 (−1.3 to 3.3)	.40	0.9 (−1.4 to 3.1)	.44
12 Months	−0.1 (−2.0 to 1.8)	.90	0.8 (−1.1 to 2.8)	.41	1.0 (−0.9 to 2.9)	.34
24 Months	−0.1 (−2.0 to 1.8)	.95	0.2 (−1.4 to 1.9)	.80	0.3 (−1.4 to 1.3)	.75

The values are expressed as mean (95% CI).

*Adjusted for age, sex, baseline score, time, manual labour, physical activity and dominant shoulder. Between-group differences were not significant for any outcome. Time and baseline score significantly predicted outcome.

†Higher Rowe scores indicating better shoulder function.

‡Western Ontario Shoulder Instability Index, lower scores indicating better shoulder function.

§Oxford Instability Shoulder Score, lower score indicating better shoulder function.

||EuroQol (EQ-5D and EQ-VAS), higher scores indicating better health-related quality of life.

OISS, Oxford Instability Shoulder Score; WOSI, Western Ontario Shoulder Instability Index.

Crossovers

Fourteen patients in the sham group were reoperated between the 6 and 24 months of follow-up, 12 with labral repair and 2 with a biceps tenodesis. Six patients in the biceps tenodesis and four in the labral repair group were reoperated; two patients had capsular release, three had a labral repair and one patient had an AC joint resection in the tenodesis group, while three biceps tenodesis and one AC joint resection were performed in the labral repair group. The mean Rowe and WOSI scores at 6 and 24 months in the 14 patients who crossed over from the sham group were not significantly different from the 14 patients with the lowest scores in the labral repair and biceps tenodesis groups. At 24 months of follow-up, 8 of the 14 patients in the crossover group had a Rowe score over 80 and 7 of them rated the shoulder as good or excellent.

DISCUSSION

In this three-armed randomised, double-blind, sham-controlled trial comparing labral repair, biceps tenodesis and sham surgery for symptomatic, isolated SLAP II lesions of the shoulder, we found a significant improvement in objective and subjective shoulder scores for all three groups, but no significant group differences at either the 6 or 24 months of follow-up. As there is no previous sham-controlled trial of the clinical effectiveness of shoulder surgery, we discuss the results of the present sham surgical trial in the context of sham surgical trials in knee patients with knee pain.^{41 42}

Clinically relevant outcome measures

The choice of outcome measures is an important issue. The scores used in this study were validated for use on patients with a SLAP lesion^{32–34} and capture the most important aspects of shoulder function.⁴³ Both the clinician-based and the patient-based scores showed comparable results and differences

between groups were much smaller than the different scores are able to detect.

Potential limitations

Issues related to sample size, blinding, the population studied and external validity are possible limitations of the present study. This is a small study, but the CIs of the observed between-group differences indicate that the study was adequately powered to detect clinically relevant differences between the three groups. For Rowe scores, the CIs did not include 10, which the trial was designed to detect. That only 73% of patients in the sham group believed that they had been repaired may have biased the results. Unfortunately, data did not provide enough information to calculate a blinding index.⁴⁴ The primary follow-up time of 6 months was selected mainly for ethical reasons. Given that the patients were referred for surgery and that we hypothesised better results after surgical repair compared with sham surgery, it was our opinion that it would be unethical to maintain patient blinding much beyond 6 months. Therefore, we advised patients that it would take time to recover from surgery and informed them that it was our aim to maintain the blinding as long as possible. However, if they were not satisfied by 6 months, their group assignment could be unblinded.

Our results at 2 years confirm the 6-month results with no statistically significant differences between the three groups. In addition, the comparison of crossovers with a similar number of patients with inferior results in the biceps tenodesis and labral repair groups suggests that the threshold for reoperation was lower in the sham group. However, it cannot be ruled out that the higher rate of reoperation in the sham group was related to unblinding rather than to differences in treatment failure. Even though there was no significant difference in mean Rowe score in the crossover group after reoperation, it is worth noting that 8 of the 14 patients had a Rowe score over 80.

We assessed 445 patients and included 118 according to strict inclusion criteria. This introduces a risk of selection bias but improves the internal validity of the study in order to assess isolated SLAP II lesions. Both athletes and patients with work-related injuries were included. Results were adjusted for frequency of physical activity and manual labour, but do not apply to a specific population. Future studies should compare non-operative and operative treatments in athletes, including return to sports in addition to the validated outcomes applied in the present study.

The choice of method regarding the biceps tenodesis may be questioned. Surgeons currently use several methods, both arthroscopic and open, with a variety of fixation devices.^{45 46} The point of fixation of the biceps tendon may be in the bicipital groove, subpectoral humeral fixation or transferred to the conjoint tendon. We fixed the biceps with a mini-open technique using a suture anchor low in the bicipital groove. Systematic reviews and randomised studies comparing different tenodesis techniques have not shown any differences in outcome.^{45 46}

Strengths of this study

The study has several strengths: randomisation; inclusion of a sham surgery control; blinded assessments, analysis and interpretation of results; validated outcome measures; no crossovers at 6 months; and minimal loss to follow-up. Strict inclusion criteria were applied to increase the internal validity for evaluating the efficacy of the surgical procedures. The use of locally available physiotherapists and manual therapists for the post-operative exercise programme of these patients enhances the external validity of the study.

The physiotherapy provided to all groups (the sole treatment in the sham group) followed current guidelines.⁴⁷ However, the study does not provide information about the effectiveness of physiotherapy with supervised exercises without diagnostic arthroscopy. Ideally, the study should have included an arm with patients not receiving any treatment (natural course), or an arm with physiotherapy without placebo surgery. We discussed this and decided that the inclusion of a fourth group would be too difficult to implement. Although physiotherapy might have contributed to the results in all groups, the impact of placebo, the natural course and regression to the mean should not be underestimated.

Clinical implications

The results of our trial extend previous reports^{12 19} of possible overtreatment of SLAP lesions and indicate a need to narrow indications. Patient age is debated and authors advocate that SLAP repair should be reserved for the young and active patient.^{11 48} There were no significant differences in function, patient satisfaction or complications by age in this study, but the groups are too small to perform subgroup analysis and identify factors associated with failures. The present study does not support either labral repair or biceps tenodesis for type II SLAP lesions in this population, as we found no significant difference between treatments in any outcome. Considering the lack of high-quality trials in this field, the results of this study should be interpreted with caution.

Based on this study, we believe future patients should be informed about the long recovery and possible complications after surgery, and that non-operative treatment has a good probability of success. Future studies should evaluate non-operative treatments and predictors of success.

We conclude that at 6 and 24 months of follow-up, there were no significant differences between labral repair, biceps tenodesis and sham surgery for patients with a type II SLAP lesion in the population studied.

What are the findings?

Labral repair, biceps tenodesis and sham surgery for patients with an isolated SLAP II lesion all led to significant improvement in both objective and subjective scores. There was no significant difference among (1) labral repair, (2) biceps tenodesis and (3) sham surgery in the population studied.

How might it impact on clinical practice in the future?

Patients should be told that non-operative treatment has a good probability of success, but further studies are needed to establish what treatment is the best for the young active patient.

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Contributors CPS, OR and JIB conceived and designed the study. ØS and PM participated in setting up of the study. ØS participated in patient recruitment and data collection. PM conducted the analysis and, together with JIB, ØS, OR and CPS, interpretation. CPS and JIB drafted the first version of the manuscript. All authors helped revise the manuscript and gave their final approval of the submitted version.

Competing interests None declared.

Original article

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Sham surgery versus labral repair or biceps tenodesis for type II SLAP lesions of the shoulder: a three-armed randomised clinical trial

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