# ARTHROSCOPIC BANKART RECONSTRUCTION USING DIFFERENT ABSORBABLE TACKS

Clinical results, radiographic findings and effect on calcaneal bone minera

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### **ABSTRACT**

The aim of the thesis was to explore the clinical and radiographic results after post-traumatic anterior shoulder instability treated with arthroscopic Bankart surgery using absorbable tacks with different compositions. Further aims were to explore possible effects on bone mineral in the heel bone and health-related quality of life after a shoulder-stabilising surgical procedure.

Study I was a clinical long-term study of 81 patients (84 shoulders) operated on using tacks made of PGA (polygluconate B polymer). The majority of patients had good functional results after eight years, although 18% had recurrent instability. Study II was a randomised, controlled study (RCT) using two different tacks, PGA and PLLA (poly-L-lactate acid polymer), with a clinical and radiographic evaluation after seven years. The drill holes after implanting PLLA tacks (18 patients) had healed to a lesser extent (55% unhealed) than those after implanting PGA tacks (17 patients), (0% unhealed), seven years after the operation. There were no differences between the groups regarding radiographic degenerative findings or functional results. Study III (32 patients, 34 shoulders) was a clinical and radiographic two- and eight-year follow-up after reconstruction using PGA implants. As in Study II, the radiographs were classified with regard to the drill-hole appearance and degenerative changes. In Study III, the radiological degenerative changes increased from no changes preoperatively to 24% mild and 18% moderate degenerative changes eight years postoperatively. In Study IV (23 patients), bone mineral was evaluated using Dual-Energy X-ray Absorptiometry (DEXA) combined with laser measurement in the heel bone preoperatively and until five years postoperatively. Activity level was classified according to Tegner activity level and health-related quality of life was classified with the Eurogol 5-dimension (EQ-5D) instrument. The bone mineral had decreased by 6% in the calcaneus five years after the operation. The activity level did not increase, but the EQ-5D increased after the operation.

Keywords: shoulder dislocation, arthroscopic, dislocation arthropathy, BMA

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## SAMMANFATTNING PÅ SVENSKA

Syftet med avhandlingen var att utvärdera det kliniska och radiologiska resultatet efter artroskopisk Bankart rekonstruktion för främre axelledsinstabilitet avseende resorberbara implantat med olika kemiska sammansättningar. Ytterligare syften var att mäta påverkan på bentäthet i hälben och hälsorelaterad livskvalité efter ett axelstabiliserande ingrepp.

Delarbete I var en klinisk långtidsuppföljning av (81 patienter, 84 axlar), opererade med implantat av PGA. Majoriteten av patienterna hade goda funktionella resultat 7 år efter operation även om 18% hade återfall i instabilitet. Delarbete II var en randomiserad kontrollerad studie (RCT) med två olika implantat, PGA och PLLA med klinisk och radiologisk 7-års uppföljning. Borrhålen i PLLA-gruppen (18 patienter) läkte i mindre utsträckning (55% oläkta) än i PGA-gruppen (17 patienter) (0% oläkta) vid röntgenundersökning 7 år efter operationen. Det var ingen skillnad mellan grupperna avseende radiologiska artrosförändringar eller funktionella resultat. Efter 7 år hade 14% återfall i instabilitet. Delarbete III (32 patienter, 34 axlar) var en klinisk och radiologisk 2 och 8 års uppföljning efter operation med PGA implantat. Liksom i delarbete II gjordes radiologisk klassifikation av artrosgrad och utseende på borrhålen i glenoid kanten. I delarbete III ökade förekomsten av radiologiska artrosförändringar från inga före operationen till att 24% av axlarna hade lätta förändringar och 18% hade moderata förändringar efter sju år. I delarbete IV (23 patienter) utfördes bentäthetsmätning med Dual Energy X-ray Absorptiometry (DEXA) kombinerat med lasermätning av mjukdelstjocklek över hälbenet (kalkaneus), klassificering av aktivitetsgrad enligt Tegnerskala samt skattning av hälsorelaterad livskvalitet med Eurogol 5-dimensioner (EQ-5D). Bentätheten sjönk med 6% i bägge hälbenen fem år efter operation. Den hälsorelaterade livskvaliteten mätt med EQ-5D ökade efter operationen.

Artroskopisk Bankart operation med resorberbara implantat ger på medellång/lång sikt goda funktionella resultat även om i dessa studier 14-18% får återfall i instabilitet. Borrhål efter implantation av PLLA tycks läka långsammare än efter implantation av PGA. Artrosförändringar i axelleden ökar med tiden efter operation. Bentätheten i hälbenen minskar mer än den förväntade åldersrelaterade minskningen efter artroskopisk Bankart rekonstruktion och den hälsorelaterade livskvaliteten mätt med EQ-5D ökar.

### LIST OF PAPERS

This thesis is based on the following studies, referred to in the text by their Roman numerals.

 A long-term clinical follow-up study after arthroscopic intra-articular Bankart repair using absorbable tacks

Elmlund A, Kartus C, Sernert N, Hultenheim I, Ejerhed L Knee Surg Sports Traumatol Arthrosc. 2008;16(7):707-12

II. A 7-year prospective, randomized, clinical, and radiographic study after arthroscopic Bankart reconstruction using 2 different types of absorbable tack

Elmlund AO, Kartus J, Rostgård-Christensen L, Sernert N, Magnusson L, Ejerhed L Am J Sports Med. 2009;37(10):1930-7

III. Dislocation arthropathy and drill hole appearance in a mid- to long-term follow-up study after arthroscopic Bankart repair

Elmlund AO, Ejerhed L, Sernert N, Rostgård LC, Kartus J Knee Surg Sports Traumatol Arthrosc. 2012;20(11):2156-62.

IV. Bone mineral decreases in the calcanei after arthroscopic Bankart reconstruction: a prospective study over five years

Elmlund AO, Kartus J, Ejerhed L Manuscript

# Contents

	ABBREVIATIONS	10
	BRIEF DEFINITIONS	11
1	INTRODUCTION	12
2	AIM	20
2.1	Specific aims and hypothesis	20
3	PATIENTS AND METHODS	21
3.1	Patients	21
3.2	Methods	21
3.2.1	Surgical procedures	21
3.2.2	Specification of implants	23
3.2.3	Rehabilitation (Studies I-IV)	24
3.2.4	Clinical examination and scores	24
3.2.5	Radiological examination (Studies II and III)	27
3.2.6	Laboratory examination (Study II)	28
3.2.7	Bone absorptiometry (Study IV)	29
3.2.8	Statistical methods (Studies I-IV)	29
4	RESULTS	30
4.1	Follow-up rates and times (Studies I-IV)	30
4.2	Clinical results (Studies I-III)	31
4.3	Radiographic results in terms of drill holes (Studies II and III)	32
4.4	Radiographic results in terms of dislocation arthropathy (Studies II and III)	32
4.5	C-reactive protein (Study II)	33
4.6	Bone mineral area mass (BMA), (Study IV)	33
4.7	Activity level (Studies I and IV)	34
4.8	Health-related quality of life (Study IV)	34

5	DISCUSSION	35
5.1	On patients	35
5.2	On methods	35
5.3	On follow-up rates and times	37
5.4	On clinical results	37
5.5	On drill-hole appearance and absorbable implants	38
5.6	On dislocation arthropathy	40
5.7	On bone mineral	42
5.8	On activity level	45
5.9	On quality of life	45
6	LIMITATIONS	46
7	CONCLUSIONS	47
8	FUTURE PERSPECTIVES	48
9	ACKNOWLEDGEMENTS	49
10	REFERENCES	50
11	APPENDIX	58
12	PAPERS I-IV	73

## **ABBREVIATIONS**

ACL Anterior Cruciate Ligament

ALPSA Anterior Labroligamentous Periosteal Sleeve Avulsion

**BMA** Bone Mineral Area mass

**BMD** Bone Mineral Density

**CRP** C-Reactive Protein

**CV** Coefficient of Variation

**DEXA** Dual-Energy X-ray Absorptiometry

**DXA** Dual-energy X-ray Absorptiometry

**EQ-5D** European Quality Of Life 5 Dimensions, Europol

**HA** Hydroxy Apatite

**PEEK** Poly Ether Ether Ketone

PGA Poly Glycolic Acid

PLLA Poly-Laevo-Lactic Acid

**ROM** Range of Motion

**SLAP** Superior Labral tear from Anterior to Posterior

**WOSI** Western Ontario Shoulder Instability Index

**β-TCP** β-Tri Calcium Phosphate

## BRIEF DEFINITIONS

**Bankart lesion** Avulsion of the labrum from the antero-inferior rim of the glenoid in the

shoulder (Figure 1A and 2A)

**Bankart reconstruction** Surgical repair of Bankart lesion including capsular shift (Figure 6)

**Bankart repair** Surgical repair of Bankart lesion (Figure 6)

**Bony Bankart lesion** Fracture of antero-inferior rim of the glenoid (Figure 1B and 2B)

Coefficient of Variation The ratio of the standard deviation to the mean, sometimes also called the

relative standard deviation and expressed as a percentage.

**Dislocation** The complete loss of articulation in the shoulder that is between the glenoid

fossa and the humeral head (Figure 1)

Friedman test A non-parametric statistical method for comparing the same group on three

or more different occasions

Hill-Sachs lesion Fracture impaction of the humeral head caused by the impression of the

glenoid rim in a dislocated shoulder (Figure 1C and 2C)

Kappa statistics Or Cohen's kappa. A measurement of agreement between two observers

or two measurements of the same categorical variable

**Mann-Whitney U test** A non-parametric statistical method for comparing two independent groups

regarding a continuous variable

Non-parametric statistics Statistical methods where data are not required to fit a normal distribution

**SLAP lesion** Superior Labrum avulsion from Anterior to Posterior around the biceps ten-

don (Figure 3)

**Spearman's rho**A non-parametric statistical test of correlation between two groups. The

strength of the correlation is expressed in rho, which can vary between 0, which indicates no correlation, and  $\pm 1$ , which indicates perfect positive or

negative correlation.

**Subluxation** Incomplete dislocation

**Suture anchor** An implant with sutures designed to be either drilled or screwed into the bone.

The anchor can be made of metal or an absorbable material. (Figure 5D)

**Tack** An absorbable implant with a slim body and a large head designed to render

both good pull-out strength and good soft-tissue compression (Figure 5C)

Wilcoxon's signed

rank test

A non-parametric statistical method for comparing two related groups, such as one variable relating to the same subjects on two different occasions.

# 01 INTRODUCTION

Shoulder dislocation (Figure 1), subsequent instability and treatment were described back in the Hippocratic collection in 400-200 BC[56] and probably began troubling mankind long before that.

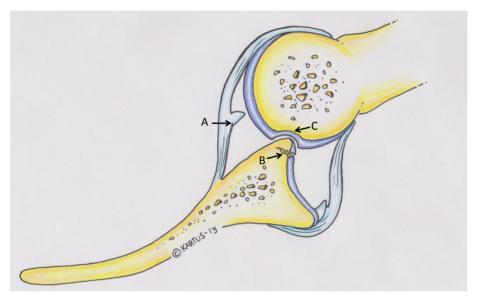


FIGURE 1 Shoulder dislocation with A. Bankart lesion, B. Fracture of the glenoid rim "Bony Bankart" and C. Impaction fracture of the humeral head "Hill-Sachs" or "Hermodsson" lesion

In Sweden, shoulder dislocation has an incidence of almost 2% in adults and approximately three in every four occur in males [58]. The result of a dislocation can be recurrent instability and the risk of this is increased by younger age.

All the patients in this thesis suffer from post-traumatic anterior instability with a patho-anatomical injury, a so-called "Bankart lesion" (Figures 1A and 2A), which is a detachment of the labrum from the anterior glenoid rim. This is a distinct group of patients with instability and should not be confused with other types of instability, such as multidirectional instability with general laxity or posterior instability, which require other treatments[117]. Apart from a Bankart lesion, other patho-anatomical injuries are common in post-traumatically unstable shoulders. The most common are the fractures known as "Hill-Sachs" or "Hermodsson" lesion (Figures 1C and 2C) and "Bony Bankart" lesion (Figures 1B and 2B), both of which, but most commonly the former, can occur simultaneously with the classical soft-tissue Bankart lesion.

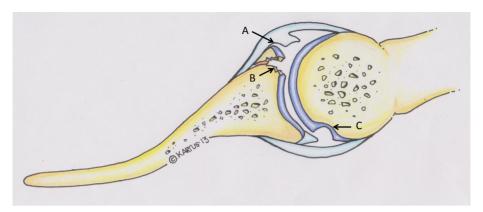


FIGURE 2 A. Bankart lesion, B. Fracture of the glenoid rim "Bony Bankart", C. Impaction fracture of the humeral head "Hill-Sachs" or "Hermodsson" lesion

In this thesis, patients with minor not engaging Hill-Sachs lesions and minor bony Bankart lesions not thought to alter or influence the treatment are included. Apart from the classical Bankart lesion in the anterior to inferior part of the glenoid, the labrum can also detach from other parts of the glenoid rim, resulting in an SLAP lesion in the superior part around the biceps tendon (Figure 3) or posterior labrum lesions, sometimes termed posterior Bankart lesion today.

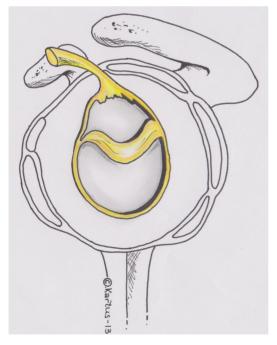
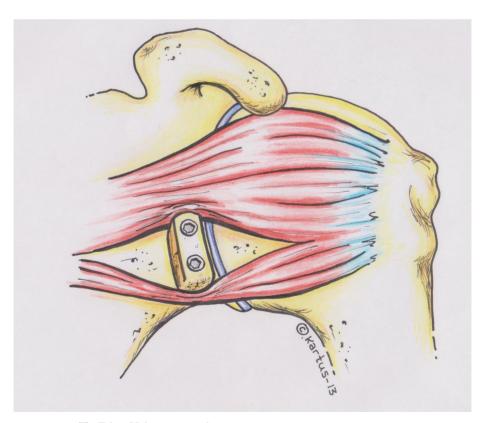


FIGURE 3 SLAP lesion

A related type of soft-tissue injury is the Anterior Labro-ligamentous Periosteal Sleeve Avulsion (ALPSA) lesion, where the labrum has healed in an overly anterior position and this is treated in the same way as the classic Bankart lesion. The most demanding task for the orthopaedic surgeon is often to select the best kind of treatment, whether surgical or not, for each specific patient, but this discussion does not fall within the scope of this thesis.

The goal when treating post-traumatic anterior instability is to restore stability without losing mobility in the gleno-humeral joint. Several treatment techniques for anterior instability have been developed and modified or abandoned over the years. The methods used nowadays or until recently mentioned for reference are the Eden-Hybinette procedure (bone graft attached to the glenoid rim) (Figure 4 A), the Bristow and the Latarjet procedures (coracoid transfer to the glenoid rim) (Figures 4 B and C), the Putti -Platt procedure (shortening of the subscapularis tendon) (Figures 4 D and E) and the Bankart procedure (anatomical repair/reconstruction of the labrum and gleno-humeral ligaments), which has been named the "gold standard" open surgical treatment.



**FIGURE 4 A** The Eden-Hybinette procedure



FIGURE 4 B The Bristow procedure



FIGURE 4 C The Bristow procedure

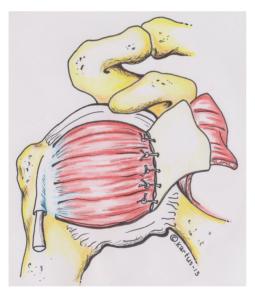


FIGURE 4 D The Putti-Platt procedure

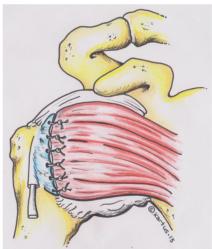


FIGURE 4 E The Putti-Platt procedure

The most recently added surgical procedures are different arthroscopic procedures, which can at least offer improved cosmesis and shorter possibly convalescence, but their results in terms of other aspects are the subject of continuous debate. Most of the arthroscopic techniques are anatomical repairs/reconstructions of the anterior labrum and glenohumeral ligaments and can therefore be called arthroscopic Bankart procedures. We use the term "Bankart repair" for an anatomical repair of the detached labrum and "Bankart reconstruction" when the anatomical repair of the labrum is combined with a more aggressive capsular shift to create an anterior "bumper". Arthroscopic techniques can be intra-articular, when the implants are placed intra-articularly and can be seen with the arthroscope the whole time, and/or extra-articular, when the implants are placed from and remain in the extra-articular compartment. The main difference between the different arthroscopic Bankart procedures is the kind of fixation to the glenoid rim that is used and, in chronological order after their introduction, the main procedures are transglenoid sutures (Figure 5A), staples (Figure 5B), tacks (Figure 5C) and suture anchors (Figure 5D).

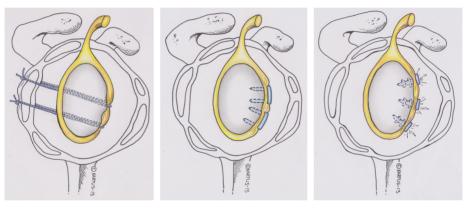


FIGURE 5 A Transglenoid sutures

FIGURE 5 B Staples

FIGURE 5 C Tacks

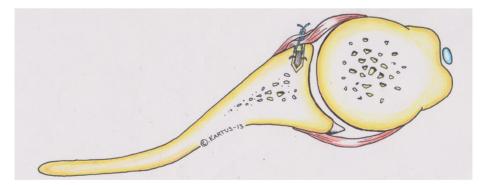


FIGURE 5 D Suture anchor placed extra-articularly

Tacks and most suture anchors are made of absorbable materials. The term "absorbable" gives the impression that the implant will dissolve and be replaced by normal tissue/bone after a while, but short- and mid-term studies have shown that it is at least not necessarily a rapid process[88,97]. The idea when it comes to absorbable implants is that they should provide strong fixation until the tissues are healed and then dissolve quickly without causing any inflammation or other damage. In animal studies, degradation rates for the commonly used absorbable materials, PGA and PLA and mixtures of them, can be measured[89]. However, these results might not be directly applicable to humans. Pure PGA is reported to dissolve more rapidly than pure PLA[89]. There is a lack of long-term studies regarding the behaviour of absorbable materials in humans[88,97].

The comparison of results from different studies is complicated because of different surgical techniques, different implants and the abundance of different outcome measurements.

The most obvious and objective outcome measurement after stabilising surgery is, of course, stability, i.e. re-dislocations or subluxations that happen postoperatively. Other measurements are range of motion (ROM), where the external rotation is of particular interest[107], as it becomes more or less restricted after practically every stabilising procedure. This may also influence the recurrence rate, as free range of motion without symptoms may increase the return to activities, with the risk of a new traumatic dislocation, which might actually not be a real surgical failure. Subluxations might be the real surgical failures, when they occur without adequate trauma. The clinical outcome can be summarised by different scores and, in this thesis, the classical Rowe score and the Constant Shoulder score were used, both of which are observer dependent and the use of independent observers is therefore very important. There are also many modern validated self-administered, patient-reported outcome measurements, such as the shoulder instability-specific Western Ontario Shoulder Instability Index (WOSI)[75], the Oxford Shoulder Score instability questionnaire[34] and the general EQ-5D (which was used in this thesis), to mention just a few.

Arthroscopic Bankart procedures have been regarded as inferior to the open Bankart procedure in terms of stability, where the classical study from 1978 by Rowe et al.[114], for example, showed a recurrence rate of only 3.5%. In the last few years, however, increasing evidence has been presented that the arthroscopic procedure, with the use of suture anchors, can equal the open procedure, even in the aspect of stability, when comparing studies with equal methodology relating to outcome measurements, follow-up rates and follow-up periods. In the Cochrane Review from 2009[104], including three RCTs [20,39,126], no difference was found between arthroscopic and open procedures, but the researchers concluded that more high-quality, randomised studies are needed. Since 2009, only one new randomised comparison can be found[4] in which there was a small statistically significant but not clinically relevant difference in favour of the arthroscopic procedure using metallic suture anchors. The results from a recent meta-analysis by Harris et al.[52], with a minimum of five years of follow-up, are similar, with no significant differences between open Bankart repair and arthroscopic Bankart repair using suture anchors or all arthroscopic techniques (suture anchors, bioabsorbable

tacks and transglenoid sutures) together, although the tacks alone had a significantly higher recurrence rate. It might be that the early results after reconstruction using tacks suffered to some extent from the introduction of a new technique. Inferior results at the beginning of the learning curve have also been reported for other procedures such as knee prostheses[99].

In the radiographic evaluation, special attention was paid to the appearance of drill holes and the development of dislocation arthropathy. Regarding the appearance of drill holes, there are previous studies indicating that drill holes used for implanting polygluconate-B acid polymer (PGA) implants heal in most patients after a period of approximately two years[70,71]. However, there are reports in the literature that these implants might break or cause synovitis in the short term and this might lead to complications and an inferior clinical outcome [15,67,111]. The PLLA implants, on the other hand, do not absorb as quickly as the PGA implants[16,89]. This appears to be beneficial in terms of both a longer period for the tissues to heal before the implants significantly weaken and break and possibly less synovitis[111]. However, there are also reports of reactions several years after PLLA implantation [10,15,45,87,90]. If the period until these implants absorb is very long, they could migrate, break or loosen and might possibly cause rapid chondrolysis in the glenohumeral joint, as has been shown after using metal implants in the anterior shoulder region[45,143]. It has also been proposed that the degradation products can induce foreign-body reactions[87].

The term "dislocation arthropathy" to describe radiographic degenerative changes after shoulder dislocation was coined by Samilson and Prieto[119]. It is still not known whether surgical intervention can prevent the development of dislocation arthropathy, as even a single dislocation can be the cause of dislocation arthropathy[59]. Some researchers argue that surgical intervention can be the cause of dislocation arthropathy[53], which is certainly true if hardware or bone blocks interfere into the joint[124,143]. It has not been shown whether there is a difference between different surgical techniques in terms of the prevention or promotion of dislocation arthropathy, and there is no consensus on the classification of dislocation arthropathy. As dislocation arthropathy evolves slowly, there is a need for long-term studies dealing with this issue.

As many patients undergoing surgery for shoulder instability are young, the implications in the long term are important, as most of the patients are expected to live to experience them. Apart from the slowly evolving dislocation arthropathy, one further aim of this thesis was to investigate possible effects on bone mineral in the calcanei after arthroscopic shoulder surgery. A reduction in bone mineral, expressed as bone mineral density (BMD) or bone mineral area mass (BMA), is a well-known independent risk factor for fractures. Fractures in the lower extremities have been shown to induce a substantial loss of bone mineral both locally and more proximally, in the hip after a tibial fracture, for example [137]. A substantial loss of bone mineral has also been reported after soft-tissue injuries and procedures in the lower extremities [2,8,132]. Following the surgical reconstruction of anterior cruciate ligament (ACL) tears involving the drilling of bone tunnels, the loss of bone mineral has been reported to be more pronounced than after

non-surgical treatment[79]. The loss after ACL reconstruction appears to be irreversible, at least to some extent, despite regained strength after rehabilitation[65,110,142]. Changes in bone mineral appear to be most substantial in trabecular-rich bone, as measured with peripheral Quantitative Computed Tomography (pQCT) and Dual-energy X-ray Absorptiometry (DXA)[41]. Cellular studies have shown that osteocyte death or apoptosis induces bone resorption through a complicated signalling pathway[50,54,73]. Bone drilling has also been shown to induce osteocyte death[43]. This is a mechanism explaining bone loss after injury, apart from disuse and non-weight bearing. Because a significant loss of bone mineral in the contralateral healthy limb, despite early weight bearing and increased activity, has been reported after ACL reconstruction[37], it would be interesting to examine the effects on bone mineral in the lower extremities after surgical intervention in the upper limbs.

# 02 AIM

The general aim of this thesis was to evaluate the mid- and long-term results after arthroscopic Bankart repair/reconstruction using absorbable tacks. The issues to be evaluated were the clinical results, the radiographic results in terms of both the appearance of the drill holes and the development of dislocation arthropathy, the effect on bone mineral in the calcanei and the effect on health-related quality of life.

#### 2.1 SPECIFIC AIMS AND HYPOTHESIS

#### Study I

The aim of the study was to perform an independent, clinical, long-term follow-up study after arthroscopic Bankart repair using absorbable tacks. The hypothesis was that arthroscopic Bankart repair using absorbable tacks results in stable, well-functioning shoulders.

#### Study II

The aim of the study was to compare the early C-reactive protein (CRP) response and the clinical and radiographic long-term results after implanting either PGA or PLLA tacks of similar design during arthroscopic Bankart reconstruction. The hypothesis was that PGA implants would cause less reaction in the bone in terms of less visible drill holes and less development of degenerative changes in the shoulder joint compared with PLLA implants during a follow-up period of seven years.

#### Study III

The aim of the study was to perform a prospective mid- to long-term radiographic and clinical follow-up after arthroscopic Bankart repair using absorbable tacks, with special emphasis on the presence of dislocation arthropathy and the appearance of drill holes. The hypothesis was that the dislocation arthropathy would increase and, at the same time, that the drill holes would disappear (heal) with time.

#### Study IV

The aim of the study was to examine the effect on bone mineral in the calcanei after arthroscopic Bankart reconstruction. The hypothesis of this study was that bone mineral in the calcanei would change more than the expected age-dependent decline after arthroscopic Bankart reconstruction.

# 03 PATIENTS AND METHODS

#### 3.1 PATIENTS

All the patients in the studies suffered from symptomatic post-traumatic recurrent anterior shoulder instability with a Bankart lesion (i.e. avulsion of the antero-inferior labrum from the glenoid rim, Figure 1A and 2A). The number of patients included in the different studies is presented in Table 1.

	Total number of patients included in the studies	Allocation of patients	Dates
Study I	81 patients (84 shoulders)	49 patients were only included in Study I, 32 patients were also included in Study III and of them 7 patients were included in Study II	1993-05-06 until 1999-09-13
Study II	40 patients	7 patients were included in Study I and III	1998-03-03 until 2001-03-06
Study III 32 patients (34 shoulders)		All patients were included in Study I	1993-05-06 until 1999-09-13
Study IV	37 patients originally, 25 males and 12 females, only the males were included in analyses	All patients were only included in Study IV	2004-12-01 until 2007-09-18
Total	151 unique patients		1993 until 2007

 TABLE 1
 Patients included in the studies

The patients in Study I were operated on by one of three different experienced surgeons at two different centres, the patients in Study II were operated on by one of two experienced surgeons at two different centres and the patients in Studies III and IV were all operated on by one experienced surgeon.

#### 3.2 METHODS

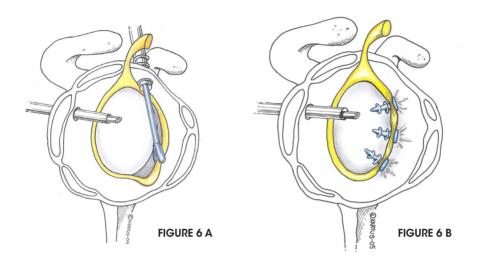
#### 3.2.1 Surgical procedures

#### Arthroscopic Bankart repair (Studies I and III)

An intra-articular technique, described by Warner and Warren[140] and Speer et al.[125], was used. The anterior glenoid was prepared to ensure a clean, bleeding surface and the capsulo-labral complex was mobilised. The anterior glenoid rim was decorticated and troughs were created, usually at the 2-o'clock, 3-o'clock and 5-o'clock positions (in the right shoulder), Figure 6.

#### Arthroscopic Bankart reconstruction (Studies II and IV)

Almost the same technique as described above but modified with a more aggressive capsular shift where the capsulo-labral complex is shifted more laterally to create an anterior "bumper", Figure 6.



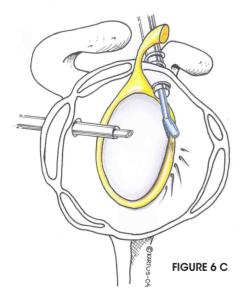


FIGURE 6 Surgical technique arthroscopic Bankart repair/reconstruction

#### 3.2.2 Specification of implants

The implants are similar in design but different in composition (Figure 7) and they are compared in Study II.



FIGURE 7 The PGA implant (to the left) and the PLLA implant (to the right)

#### The PGA implant (Studies I-IV)

The Suretac® device (Smith and Nephew, Andover, USA) (Figure 7) is made of a synthetic co-polymer of polygluconate-B, poly glycolic acid (PGA), identical in composition to Maxon (Davis and Geck, Danbury, USA) absorbable sutures. The co-polymer is made by causing trimethylene carbonate to react with glycolic acid. In vivo testing of this material has shown that it degrades and loses strength at a rate of approximately 25% a week (that is, 1% is left after 16 weeks). The implant is sterilised in ethylene oxide (personal communication from the manufacturer, Smith & Nephew).

#### The PLLA implant (Study II)

The Bionx® Bankart tack device (Linvatec, Largo, USA) (Figure 7) is made of self-reinforced poly-L-lactic acid (PLLA). It is estimated to have a strength retention time of eight to ten months and is gamma radiation sterilised (Linvatec company bioabsorbable implants brochure).

#### 3.2.3 Rehabilitation (Studies I-IV)

Postoperatively, the patients wore a sling for four weeks; however, free flexion and internal rotation were allowed from the first postoperative day. At four weeks, free ROM in all directions was permitted and strengthening exercises were started. At six months, throwing and contact sports were allowed, provided that the patients had regained full functional stability in the operated shoulder.

#### 3.2.4 Clinical examination and scores

#### Independent observers

One of three independent observers (physiotherapists) not involved in the treatment or rehabilitation of the patients performed the clinical examinations in Study I, while one of two independent physiotherapists performed the clinical examinations in Studies II and III. All measurements were recorded in a specified study protocol (Appendix). In Study IV, the Calscan measurements were made by an assistant nurse who also filled in the study protocol (Appendix) on each occasion.

#### Range of motion (ROM)

Measurements of range of motion (ROM) were performed in the sitting position. A hand-held goniometer with an accuracy of 1° was used and the value was approximated to the nearest 5°. The external rotation was measured in 90° of abduction (Figure 8).



**FIGURE 8** Measurement of external rotation in 90° of abduction

#### Apprehension test

Laxity was evaluated using the apprehension test, with the results graded in three categories; normal, discomfort in maximum external rotation without signs of subluxation and signs of subluxation with muscular contraction [67,71]. Patients with signs of subluxation at re-examination, who reported one or more frank dislocations or had a history of a minimum of one episode of "dead arm syndrome" during the follow-up period, were classified as failures in terms of stability/laxity.

#### Strength measurement

Isometric muscular strength was measured at 90° of lateral elevation (i.e. abduction) using the Isobex dynamometer (MDS Medical Device Solutions AG, Burgdorf, Switzerland) (Figure 9), as suggested for the Constant score [6,32,57,78].



FIGURE 9 Strength measurement using the Isobex dynamometer

#### Constant score (Studies I-III)

The Constant score (Appendix) is one of the first shoulder scores. It was developed by Constant and Murley in the 1980s and was first presented in a thesis in 1986 before publication in 1987[32]. It is scored from 0 (minimum/worst) to 100 (maximum/ best), 35 points are allocated for subjective (patient-determined) assessments of pain and ADL and 65 points are allocated to objective (observer-dependent) measurements of movement and strength. The Constant score was not validated when it was first published but has subsequently been evaluated in a systematic review from 2010[115], summarised as follows. The content validity can be questioned, as it is not described in the original publication. Construct convergent validity with strong correlations (>0.7) has been established using the Western Ontario Rotator Cuff index, Simple Shoulder Test, Oxford Shoulder Questionnaire and some other scales, for example. Criterion validity has been regarded a problem for strength measurements with an unsecured spring balance. The Isobex dynamometer, which has shown good reliability [6,57,78], was used in this thesis. In the study by Roy et al. [115], the reliability of the whole score was considered acceptable (0>0.8) and it was considered responsive for detecting improvements after treatment in a variety of shoulder pathologies. Constant and co-workers suggested some modifications in 2008 31, including the optional standardisation to a reference group, but these modifications were not evaluated in the above-mentioned systematic review. The Constant score is regarded as the official outcome measurement after shoulder surgery by the European Shoulder and Elbow Society.

#### Rowe score (Studies I-III)

The Rowe score (Appendix) exists in four versions, from the earliest version published in 1978[114] to the last version published in 1988[113]. The different versions do not give the same results and there is a risk of confusion[63]. The author decided to use the 1988 version, which consists of five domains, pain, stability, function, motion and strength. The score was developed before modern methods of score development were established and it was not tested for reliability or validity. Skare et al.[123] evaluated the 1988 version in 71 patients with instability or SLAP lesions and found acceptable agreement and reliability for the total score in these patients. The agreement and reliability for the different domains were not acceptable and the validity was not acceptable in the evaluation by Skare et al.[123]. The minimal detectable change (MDC) was between 14 and 19 points.

#### Tegner activity scale

The Tegner activity scale score (Appendix) was determined from the patients' answers by the interviewer. The scale has 10 levels from totally sedentary to professional football in the national team. The Tegner activity scale was originally developed for meniscal and ACL injuries of the knee. It was not evaluated for reliability or validity when developed[130], but it has since been evaluated in these terms with good to acceptable results[21,22]. It is widely used in ACL treatment studies.

#### EuroQol 5-dimensions (EQ-5D)

The EQ-5D questionnaire (Appendix) is a generic (non-disease-specific) instrument for measuring health-related quality of life. It consists of five questions relating to five dimensions (mobility, self-care, usual activities, pain/discomfort and anxiety/depression), each with three different answer levels (no problems, moderate problems and severe problems). The resulting 243 possible combinations of responses are then presented as a health profile or computed to a global health index with a weighted total value (the global health index is used in this thesis). The total index is computed using a regional tariff to adjust for cultural differences. Sweden uses the British tariff, which has been shown to be valid for the Swedish population[27]. The resulting index ranges from -0.594 (worse than death) through 0 (worst possible health status) to 1.0 (best possible health status). The EQ-5D questionnaire also includes a vertical VAS scale ranging from 0 (worst possible health status) to 100 (best possible health status). The response from the VAS scale was, however, not used in this thesis. The EQ-5D questionnaire was developed by a group of European researchers and it has been validated and tested for reliability[23,24]. The minimally clinical important difference has been estimated at 0.074[136].

#### 3.2.5 Radiological examination (Studies II and III)

#### Views and examiner

The Stryker notch view, the West point view and the true AP view were taken at all examinations (Figure 10). The same experienced radiologist evaluated all the radiographs. Special attention was paid to the development of arthropathy/degenerative changes with time, as well as to the appearance of the drill holes.





FIGURE 10 Radiological views: the Stryker notch view, the West point view and the true AP view



#### Classification of drill holes

The radiographic classification of the drill holes was rated from 0-III, 0 = invisible, I = hardly visible, II = visible and III = visible with cystic changes[70] (Figure 11). The intra-rater reliability of the radiologist for the classification of drill-hole appearance has been analysed and found to be good, with a kappa value of 0.76[82].

#### Classification of dislocation arthropathy

Arthropathy/degenerative changes were classified as normal (no joint space narrowing, no osteophytes, no sclerosis), minor (slight joint space irregularity, < 1 mm joint space narrowing, slight sclerosis), moderate (narrowing < 2 mm, mild to moderate osteophytes, moderate sclerosis) and severe (severe joint space narrowing, abundant osteophytes, severe sclerosis and cyst formation), as described by Rosenberg et al.[112] (Figure 11). The intra-rater reliability of the radiologist has been analysed and found to be good, with a kappa value of 0.94[82]. Rachbauer et al.[105] tested the inter-rater reliability of the Rosenberg classification and found a kappa value of 0.81.





FIGURE 11 Example from radiographs: Left: Radiograph of a 24-year-old male seven years after the index procedure, where dislocation arthropathy is classified as mild and the drill-hole appearance is classified as visible with cystic changes. Right: Radiograph of a 26-year-old male seven years after the index procedure, where dislocation arthropathy is classified as moderate and the drill-hole appearance is classified as hardly visible

#### 3.2.6 Laboratory examination (Study II)

Blood samples for C-reactive protein (CRP) analysis were collected pre-operatively, on day one and four to six weeks post-operatively. Blood samples were analysed for CRP using an immunoturbidimetric method using a Hitachi 917 (Tokyo, Japan) analysing machine with a lower reference value of < 6 mg/L.

#### 3.2.7 Bone absorptiometry (Study IV)

#### **DXL Calscan**

The DXL Calscan device (development of the DEXA-T device) measures bone mineral area mass by fan beam dual-energy X-ray absorptiometry (DEXA), but, at the same time, it measures heel thickness with a laser scan to create a three-component model (bone mineral, lean soft tissue and fat). The aim is to correct for the inhomogeneous distribution of fat outside and inside the bone, which is a major source of variation in conventional DEXA technology[12-14]. The device automatically finds the region of interest and positioning is not critical. The short-term precision has been investigated and found to be a 0.76% coefficient of variation (CV) short term, 0.73% CV long term in vitro, 1.19% CV in vivo for mixed subjects and 1.09% CV for non-osteoporotic subjects[133]. In another study, the long-term in-vitro precision was 0.5% CV and the in-vivo precision was 1.2% CV[77].

#### 3.2.8 Statistical methods (Studies I-IV)

For ordinal data such as score data, the median (range) is presented and non-parametric methods are used; i.e. for within-group comparisons, the Wilcoxon signed rank test was used and, for between-groups comparisons, the Mann-Whitney U test was used. In Study IV, the Friedman test for repeated measures was used. Correlations involving ordinal data were computed with Spearman's rank correlation (rho).

For continuous data such as BMA values and for the EQ-5D index, the mean ± standard deviation (SD) is presented. Although BMA is a continuous variable, the sample size in Study IV is small and normality cannot be expected and non-parametric methods as mentioned above are therefore also used for analysis relating to BMA.

When there are multiple comparisons, Bonferroni corrected p-values are presented.

A p-value of less than 0.05 is considered significant.

For Studies I-III, the StatView software from SAS institute was used and, for Study IV, the IBM SPSS Statistics 19 software was used, together with Microsoft Office Excel 2007, for graphs.

# 04 RESULTS

### 4.1 FOLLOW-UP RATES AND TIMES (STUDIES I-IV)

In Study I, 76/84 (90%) of the patients (50 males and 23 females) returned for follow-up after 98 (46-129) months, a median of more than eight years after the operation. In Study II, 35/40 patients (88%) returned for follow-up radiographs after a median of 80 (64-96) months, with no significant differences in time to follow-up between the study groups. Five patients were lost to follow-up, three in the PGA group and two in the PLLA group, and one further patient in each group declined to undergo clinical assessment and only had radiographs taken after seven years (Table 2). In Study III, 34/34 (100%) shoulders in 32 patients returned for follow-up II, with a radiographic and clinical examination after 95 (53-129) months. There were 12 females and 20 males (two males underwent bilateral operations). In Study III at follow-up I after 25 (18-42) months, 33 of 34 shoulders underwent radiographic examination and 31 of 34 underwent clinical examination. The follow-up rates and times for Study IV are presented in Table 3. The overall follow-up rate after five years in Study IV was 15/23 (65%).

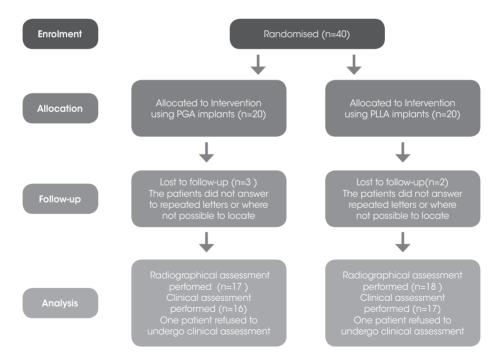


 TABLE 2
 Flowchart study II

Time	Preoperative	6 months	18 months	36 months	60 months
Total number	23	19	15	15	15
Number attending all previous follow-ups	23	19	15	15	11
Did not attend		4	4	4	
Lost to follow-up			4		4

 TABLE 3
 Follow-ups in Study IV

### 4.2 CLINICAL RESULTS (STUDIES I-III)

In Study I, the total failure rate in terms of stability was 14/76 (18%), 8/76 suffered at least one re-dislocation and a further 6/76 had experienced or had clinical signs of subluxation. In Study II, the total known failure rate was 5/36 (14%), with no significant differences between the groups (p=0.58). The failure rate after two years was 2/40 (5%), published in a previous study[83]. In Study III, the failure rate in terms of stability was 6/34 (18%), 3/34 due to re-dislocation and 3/34 shoulders had clinical signs of subluxation.

The clinical results in terms of ROM, strength measurements and Constant and Rowe scores for 114 patients in Studies I-III are presented in Table 4.

In Study II, there were no significant differences between the study groups regarding the clinical results in terms of ROM, strength measurements and Constant and Rowe scores.

Number (from start= 117 shoulders)		102/117 (87%)
Time to follow-up	(months)	93 (46-129)
External rotation in 90° abduction: I (injured side)	(degrees)	90° (50°-125°)
External rotation in 90° abduction: C (contralateral side)	(degrees)	100° (50°-130°)
Isobex strength measurement in 90° abduction: I	(kilograms)	8.2 (0,4-16)kg
sobex strength measurement in 90° abduction: C	(kilograms)	8.1 (2,4-21,3)kg
Constant score: I	(points)	89 (25-100)
Constant score: C	(points)	93 (69-100)
Rowe score: I	(points)	90 (27-98)
otal known amount of failure in terms of instability (re-dislocati	17 (10+7)(17%)	

**TABLE 4** Clinical results for 114 patients in Studies I-III

## 4.3 RADIOGRAPHIC RESULTS IN TERMS OF DRILL HOLES (STUDIES II AND III)

The development of the drill holes in Studies II and III is presented in Table 5. In Study II, the radiographic visibility of the drill holes after seven years was significantly (p=0.0001) greater in the patients in the PLLA group than in those in the PGA group. In the whole study group, no correlation was found between the appearance of the drill holes and the degenerative changes (rho=0.25, n.s.).

Nor in Study III was there any correlation between the visibility of the drill holes and arthropathy/degenerative changes at follow-up II (rho=0.2, n.s).

	Study II		Study II		Study III		Study II + III	
	PLLA 2 years	PLLA 7 years					All PGA 2 years	All PGA 7 years
Invisible	2	2	2	12	7	13	9	25
Hardly visible	3	6	11	5	8	7	19	12
Visible	5	5	4	0	9	6	13	6
Visible with cystic changes	10	5	1	0	2	1	3	1
Missing		2	2	3	1		3	3
Visible+ Visible with cystic changes (Percent)	15/20 (75%)	10/18 (56%)	5/18 (28%)	0/17 (0%)	11/26 (42%)	7/27 (26%)	16/44 (36%)	7/44 (16%)

**TABLE 5** Development of drill-hole appearance for 67 patients in Studies II and III (two year results in Study II from Magnusson et al [83])

# 4.4 RADIOGRAPHIC RESULTS IN TERMS OF DISLOCATION ARTHROPATHY (STUDIES II AND III)

The development of dislocation arthropathy in Studies II and III is presented in Table 6. In Study II, radiographic examinations after seven years revealed a significant increase in degenerative changes during the follow-up period in the PLLA group (p=0.045) but no significant increase in the PGA group (p=0.076). After analysing all the patients together, there was a significant increase in radiographic degenerative findings (p=0.008) during the follow-up period.

In Study III preoperatively, none of the shoulders had any arthropathy/degenerative changes, while, at follow-up I, 10/33 (30%) had minor changes and none had moderate or severe arthropathy/degenerative changes (p=0.03). At follow-up II, 8/34 (24%) had minor changes, 6/34 (18%) had moderate changes and none had severe arthropathy/degenerative changes; p=0.005 versus preoperative and p=0.005 versus follow-up I. There was a significant correlation between the age at the index operation and arthropathy/degenerative changes at follow-up II (rho 0.4; p=0.01). There was no correla-

tion between time to operation and arthropathy/degenerative changes at follow-up II (rho 0.2; n.s,) or between the clinical results and arthropathy/degenerative changes at follow-up II (rho<0.2; n.s,).

Time	Preoperative	2 years	7 years	
None	59	45	34	
Mild	1	18	20	
Moderate		1	8	
Severe				
Missing	7	3	5	

 TABLE 6
 Development of dislocation arthropathy for 67 patients in Studies II and III (corrected)

#### 4.5 C-REACTIVE PROTEIN (STUDY II)

The CRP values pre-operatively, on day 1 and four to six weeks post-operatively showed median values of less than ten on all occasions in both groups, with no significant differences between the groups. In the whole study cohort, the highest measured CRP on day 1 was 20 units and, correspondingly, the highest measured CRP four to six weeks post-operatively was 23 units.

### 4.6 BONE MINERAL AREA MASS (BMA), (STUDY IV)

BMA values (g/cm2) in the left and right calcaneus were compared over time. Ten patients who underwent all five evaluations (preoperatively, six, 18, 36 and 60 months after the reconstruction) were included in the analysis of BMA. The decrease in BMA over time was significant both in the left (p=0.007) and in the right calcaneus (p=0.0001). Correspondingly, after 60 months, the BMA had decreased significantly compared with the preoperative values both in the left (p=0.02) and in the right calcaneus (p=0.002) for those patients who underwent all five evaluations.

A subgroup analysis of 11 non-smokers after 60 months revealed a significant decrease in the BMA in both the left (p=0.03) and the right (p=0.007) calcaneus compared with the preoperative values.

The mean change in per cent after 60 months was 6% in the left and 6% in the right calcaneus for the whole study group, as well as for the non-smokers.

#### 4.7 ACTIVITY LEVEL (STUDIES I AND IV)

In Study IV, the activity level as measured using the Tegner activity score decreased significantly between the preinjury assessment and the preoperative assessment (p=0.005, n=22). There was no significant difference in the Tegner activity level across time after the reconstruction (preoperatively, six, 18, 36 and 60 months).

There is a significant correlation between the preinjury-reported Tegner activity level and BMA at the preoperative assessment (rho=0.71, p<0.0005) and the Tegner activity level and BMA at 18 months (rho=0.69, p=0.008), at 36 months (rho=0.7, p=0.006) and at 60 months (rho=0.78, p=0.001).

In Study I, the cause of the first dislocation/subluxation was contact sports in 28/76 shoulders, non-contact sports in 24/76, work-related activities in 6/76, activities of daily living in 7/76, other activities in 10/76, while data were missing for one patient. At follow-up, 40/70 (57%) of the patients were actively involved in overhead or contact sports, 21/70(30%) were actively involved in sports without overhead activity and 9/70 (13%) were sedentary (six shoulders with missing data).

### 4.8 HEALTH-RELATED QUALITY OF LIFE (STUDY IV)

Health-related quality of life was measured using the EQ-5D index score. There was a significant difference in the EQ-5D index score across the five time points (preoperative, six, 18, 36 and 60 months), (p=0.003). There was a significant improvement between preoperatively and six months (p=0.01, n=20), preoperatively and 18 months (p=0.02, n=15), preoperatively and 36 months (p=0.02, n=15) and preoperatively and 60 months (p=0.03, n=15).

# 05 DISCUSSION

#### **5.1 ON PATIENTS**

All in all, 151 unique patients were included in these four studies (Table 1). They underwent surgery between 1993 and 2007. From the Swedish national patient registry with data from 2005 (Table 7), it can be seen that half the patients undergoing surgery in the region (Västra Götaland Region) in 2005 and one third of the patients undergoing surgery in 2006 were included in Study IV. It is worth noting that an increasing number of arthroscopic shoulder stabilisations are being performed annually in Sweden. The percentage of women is approximately the same (roughly 25%) in this thesis and at Swedish national level (Table 7), which is similar to the recently started Norwegian register of shoulder-stabilising procedures[11]. The male dominance (equal to the male dominance in the incidence of shoulder dislocation) is the explanation for the difficulty involved in including enough women in Study IV, where we were finally forced to exclude the twelve women who were originally included, as they were too few to analyse.

NBH 71 Region	Year Gender	2005	2006	2007	2008	2009	2010	2011
Sweden, total	Males	78	92	179	360	373	450	493
Sweden, total	Females	29	26	72	101	122	163	180
Sweden, total	All	107	118	251	461	495	613	673
Sweden, Västra Götaland county	Males	19	27	60	104	64	96	119
Sweden, Västra Götaland county	Females	7	7	28	38	25	44	40
Sweden, Västra Götaland county	All	26	34	88	142	89	140	159
Included in study IV	All	13	14	9				

Number of surgical procedures coded with NBH71 (Arthroscopic surgery for recurrent instability in shoulder), all ages http://www.socialstyrelsen.se/statistik/statistik/databas/dagkirurgi 2013-04-23

 TABLE 7
 Data from the Swedish national patient register 2005–2011

#### 5.2 ON METHODS

#### Clinical scores

The scores we have used (Rowe score and Constant score) are well established and are needed for comparisons with previous studies. When Studies I and III were planned, these were the scores to use. Since then, there has been a shift towards patient-reported outcome measurements and there are now several modern, self-administered, validated

and reliability-tested shoulder scores and even instability-specific scores that can be used, such as the Western Ontario Shoulder Instability score (WOSI)[75] and the Oxford Shoulder Score instability questionnaire[34], the first of which is available in a validated Swedish translation[118].

#### Radiologic classification of degenerative findings/dislocation arthropathy

There is no consensus on how to classify dislocation arthropathy or other kinds of osteoarthrosis in the shoulder. The choice of the classification by Rosenberg et al.[112] was based on the fact that it includes all the classical signs of osteoarthrosis (joint space narrowing, osteophytes, subchondral sclerosis and cysts). The reliability of the widely used Samilson and Prieto[119] classification, which only takes account of the size of the humeral osteophyte in a single view, has been questioned[62,105]. The most recent classification (to the author's knowledge) by Rachbauer et al.[105] is similar to the Rosenberg classification and the authors have demonstrated good reproducibility between these two classifications, with a kappa value of 0.85. They also report poor agreement between their own rating system and the Samilson and Prieto system. According to Ogawa et al.[93], the Samilson and Prieto classification of plain radiographs has low sensitivity compared with computerised scans. The inconsistency in classifications makes comparisons between studies more difficult.

#### DXA/Calscan

The "gold standard" for measuring bone mineral and diagnosing osteoporosis is Dual-Energy X-ray Absorptiometry (DEXA/DXA) in the hip and spine [120]. The role of peripheral devices such as the DXL Calscan for diagnosing osteoporosis is under continuous evaluation. Theoretically, the calcaneus should be more sensitive to changes in bone mineral than the hip or spine, as it mainly consists of metabolically active trabecular bone [116,121]. The DXL Calscan uses DXA technology with the addition of a laser scan of heel thickness to create a three-component model [77,116,133] and it is thus designed to compensate for inhomogeneities in fat and soft-tissue content, which is a major source of variation [12-14,51]. The result of a DEXA measurement is given in g/cm2 and is thus termed bone mineral area mass (BMA), although other studies use the term bone mineral density (BMD) even for DEXA results. BMD is best measured with three-dimensional quantitative computed tomography (QCT), which is a sensitive technique, but it also involves higher radiation doses, which limits its use[41]. When diagnosing osteoporosis using DEXA, the BMA result is correlated to a reference population which should be device, ethnicity, region and gender specific and the result is then given in standard deviation (SD) units as a T-score (compared with peak bone mass from a young reference population value) or Z-score (compared with an age-matched reference value) 120 |. T-score and Z-score results in SD units are therefore highly dependent on the reference population that is used[33,116].

In Study IV, only the analyses of BMA measurements were reported.

#### Tegner activity scale

The Tegner activity scale might not be ideal for use in this thesis, but, to the author's knowledge, an activity scale to measure bone-stimulating activities has not been developed. In any case, the Tegner activity scale scores high-impact sports such as soccer and jumping sports high, swimming, even in the competitive setting, low and skiing, for example, in between, which would be appropriate for scoring bone-stimulating activities. Other single-item global activity scales are the UCLA activity rating scale, VAS for patients and VAS for clinicians, all of which were developed for evaluating patients after joint replacement [131]. There is also a validated shoulder specific activity level score[25,26] but the purpose in study IV was to measure activity in relation to possible stimulation of bone mineral. Other alternatives are the use of a pedometer or accelerometer, but they have to be validated and reliability tested as well and there are issues relating to time periods and compliance with wearing them that need to be resolved. Accelerometers are otherwise attractive for the purpose of quantifying activity in relation to bone mineral stimulation, as it has been suggested that high-impact exercise is the most important stimulatory factor [135]. There are also some more detailed multi-item instruments, such as the Baecke questionnaire, the Short Questionnaire to Assess physical activity (SQASH) and the International Physical Activity Questionnaire (IPAQ) short form, all of which measure the frequency, duration and intensity of activities, making them more informative but also more demanding for the patients to fill in.

#### 5.3 ON FOLLOW-UP RATES AND TIMES

In Studies I, II and III, the follow-up rates are between 88% and 100% after such long periods as a median of seven and eight years, which must be considered very good. The median follow-up times of seven to eight years are quite long, but there is a wide range in the follow-up times in all the studies. In Study I, the follow-up period was 46-129 months and, in Study III, 53-129 months, which means less than four years to almost eleven years and perhaps the correct generalisation should be a follow-up time of more than four years, which is the minimum value, instead of eight years, which is the median value. In Study II, the range was 64-96 months, which means more than five to eight years. In Study IV, the follow-up times have a narrower range (Table 3), but the follow-up rates are instead considerably lower.

#### **5.4 ON CLINICAL RESULTS**

In Studies I and III, the total failure rate in terms of stability after a mean of eight years was 18% (14/76 and 6/34). In Study II, there is a total failure rate in terms of stability (re-dislocations and subluxations) of 5/36 (14%) after a mean of seven years. The failure rate in the same study cohort was 2/40 (5%) after two years, as previously reported by Magnusson et al.[83], which could be regarded as low. This illustrates the importance

of sufficient follow-up times when comparing different surgical techniques. It may also indicate that it takes some time for the patients to regain confidence in their shoulder and engage in more demanding activities with a risk of new dislocations[127]. In the meta-analysis by Harris et al., the mean time to recurrence for the different arthroscopic techniques varied between 1.2 and 3.1 years and, in the case of the open procedure, the mean time was 3.7 years. In the same study, the cause of re-dislocation was a new trauma in 24-60% of cases. In a large community-based study of 5,904 primary stabilising procedures (68.9% arthroscopic) in Ontario, Canada, the re-dislocation rate after five years was 6.9%, while it was only 3.8% after two years[141]. In a systematic review by Randelli et al.[108], the patient-related risk factors for recurrence after arthroscopic Bankart reconstruction with suture anchors was young age (<20 years), male gender, involvement in competitive sports and possibly a large number of preoperative dislocations. The patho-anatomical risk factors were large bone defects on either the glenoid or the humeral head (engaging Hill-Sachs defects) and the technical risk factors were incorrectly placed or too few anchors.

The results in terms of stability in this thesis can be compared with those in other studies. In a recent meta-analysis with a minimum of five years' follow-up, Harris et al. 52 found a recurrence rate after arthroscopic Bankart repair using absorbable tacks of 34/199 (17%) re-dislocation and 14/199 (7%) subluxations after a mean of 11.5 years' follow-up based on five studies [72,84,95,103], as well as Study III from this thesis [38]. In the same meta-analysis, the recurrence rate after arthroscopic Bankart repair using suture anchors was 17/200 (8.5%) re-dislocations and 7/200 (4%) subluxations after a mean of 7.3 years' follow-up with data from five studies [30,42,74,102,109]. Data from five studies with a mean of 8.5 years' follow-up after arthroscopic Bankart repair using transglenoid sutures showed a recurrence rate of 14/185 (8%) re-dislocations and 6/185 (3%) subluxations. After open Bankart repair (15 studies), the recurrence rate in the same meta-analysis was 55/731 (7%) re-dislocations and 40/731 (4%) subluxations after a mean of 13.1 years' follow-up. There were no significant differences in terms of a recurrence of instability, clinical score results or a return to sports between the arthroscopic Bankart procedures analysed together and the open Bankart procedure in this meta-analysis [52].

#### 5.5 ON DRILL-HOLE APPEARANCE AND ABSORBABLE IMPLANTS

The main finding in Study II was that the drill holes were significantly less well healed in the PLLA group, where 10/18 (56%) of the shoulders had drill holes that were visible or visible with cystic changes. This can be compared with the PGA group, where none (0/17) of the shoulders had drill holes that were visible or visible with cystic changes after a median of seven years. These results are not fully confirmed by the results of Study III, where all the patients underwent surgery with PGA implants and, in 8/34 (24%) of the shoulders, the drill holes were still visible or visible with cystic changes after a median of eight years. In the study by Privitera et al.[103], with a minimum of 10 years'

follow-up after arthroscopic Bankart repair using the same PGA absorbable tacks as in this thesis, the drill holes were classified as invisible or hardly visible in 11/20 (55%) and visible or visible with cystic changes in 9/20 (45%) cases.

This illustrates the importance of a sufficient sample size, but it does not diminish the issue of the many unknown aspects of the long-term behaviour of absorbable materials implanted in human bone. Although tacks have been replaced to a large extent by suture anchors, this discussion can apply to them as well, as they are implanted in a similar manner and are of similar size and materials. The succession of suture anchors after tacks also illustrates the rapid introduction of new implants for orthopaedic surgery without previous long-term investigations in humans. The designation of "absorbable" or "biodegradable implants" gives the impression that the material will disappear, leaving a normalised bone structure after a while, but this is obviously not the case, at least in the mid-term perspective[35]. Other possible advantages of absorbable implants are that they do not generate artefacts on MRI and that they might not damage the joint cartilage as much as metal implants if they break or loosen.

One possible limitation is if the implant dissolves before the tissues have healed, but, in this thesis, there were no early re-dislocations, which indicates that both types of absorbable implant had sufficient strength during the early period until capsular labrum healing occurred.

Other known limitations are several reports of adverse tissue reactions following the implantation of absorbable materials in bone. The reactions have been characterised as a foreign-body reaction, synovitis if inside a joint or as osteolytic lesions [9,10,15,17-19,36,45,46,66,87,88,90,92,97,111,139]. The mechanism for these reactions is not fully understood, however [19,88,111]. In Study II, we used two absorbable implants of similar design but different composition – a synthetic co-polymer of polygluconate (PGA), also used in Studies I, III and IV, and a polymer of self-reinforced poly-L-lactic acid (PLLA). The degradation of both these polymers is known to take place mainly through hydrolysis but also through enzymatic action. PGA is known to degrade more rapidly than PLLA[16]. Reactions after the rapidly degradable PGA material appear to start at an early stage (weeks) and then resolve within approximately a year 15-17,139. When used for fracture stabilisation, the reaction does not appear to influence the fracture healing [17]. Reactions after the more long-lasting PLLA material appear to start and become apparent at a later stage (months to years)[9,10,45] and then persist for years [18,90]. In Study II, seven patients (four in the PGA and three in the PLLA group) had symptoms that might reflect early synovitis, but this could not be confirmed in the laboratory examinations in terms of increased CRP values. However, CRP might not be sensitive enough to capture possible reactions and the samples were collected preoperatively, on day one and four to six weeks postoperatively, allowing for changes between these times that could not be detected. The nature of the radiographically visible osteolytic lesions in Studies II and III cannot be further analysed, as we have not performed any histological analyses. In a case report by Nusselt 92, MRI and histology examinations revealed a large intraosseous foreign-body granuloma after using a PLLA

anchor. McCarty et al. [87] found 44 cases of late synovitis, where biopsies showed polarising crystalline material in all cases and in most cases giant cell granuloma after implanting PLLA anchors for either labral or rotator cuff repair. Moreover, interference screws made of PLLA used in ACL reconstruction surgery have been shown to produce pretibial cysts, where histological analysis has shown foreign-body reaction[47]. Since the introduction of bio-absorbable materials, implants made of pure PGA, pure PLLA (or other isomers of poly-lactic acid PLA, PDLLA), mixtures of PGA/PLLA, different mixtures with  $\beta$ -tricalcium phosphate ( $\beta$ -TCP) and mixtures of hydroxyapatite (HA) and PLLA have been introduced[1,7,87]. One of the latest non-metallic materials in implants is poly-ether-ether-ketone (PEEK), a non-absorbable semicrystalline thermoplastic material mentioned for reference. The true long-term effects of absorbable implants in humans are yet to be established[15,88], but mixtures with HA appear to have better bio-compatibility and heal more rapidly, at least in animal models[1]. Neither in Study II nor in Study III is there a correlation between the visibility of drill holes and the development of degenerative findings/dislocation arthropathy.

The clinical relevance of drill-hole appearance has been questioned by Stein et al.[128], as they found no correlation between clinical results and drill-hole appearance on MRI scans. Neither in this thesis was there any correlation with clinical results, but it is the opinion of the author of this thesis that the incomplete healing of drill holes without any other adverse reactions is a matter of concern only if revision surgery of any kind is needed. The concerns relating to the incomplete healing of the drill holes after implanting PLLA tacks in Study II are partly confirmed by the development of new materials such as HA/PLLA composite implants with improved bio-compatibility and more rapid healing, at least in rabbits and dogs[1].

#### 5.6 ON DISLOCATION ARTHROPATHY

The term "dislocation arthropathy" was coined by Samilson and Prieto in 1983, but the phenomenon had been described by others long before this[55]. The mechanism of dislocation arthropathy is not known, but it has been suggested that the initial trauma is the most important factor, supported by the natural course, as described by Hovelius and Saeboe[59]. This opinion is also supported by other studies[85,86]. Other factors that increase the risk of dislocation arthropathy are the number and frequency of dislocations[28,59,93], whereas younger age appears to have a protective effect[59,60]. The question has been raised as to whether surgical intervention is the cause of dislocation arthropathy, like capsulorraphy-induced arthropathy proposed by Hawkins and Angelo[53], who suggested that the anterior capsular shift increases the risk of subsequent osteoarthritis due to an increase in posterior joint load. This mechanism has been questioned, however. For example, Matsoukis et al.[86] selected patients with prior dislocations from a large cohort comprising shoulder arthroplasties and analysed the glenoid morphology using computed tomographic scans and they were not able to find any differences in terms of the localisation of the osteoarthri-

tis between previously-operated or non-operated dislocations [86]. The suggestion of capsulorraphy-induced arthropathy[53] can also be debated, as the loss of external rotation can also be a symptom of osteoarthritis and retrospective studies are not able to clarify this [28]. Other prospective studies have shown no correlation between the presence of restricted external rotation and subsequent dislocation arthropathy [59,106,138]. Recurrent shoulder dislocations treated conservatively will also cause osteoarthritis in the long term[53,112,119]. Protruding hardware or bone blocks are, quite obviously, a risk factor for subsequent osteoarthrosis[143] or even rapid chondrolysis[124]. The study by Buscaryet et al. [28] showed a significant association between the number of anchors (metal and absorbable) and arthropathy findings. The study by Hovelius and Saeboe[59] indicates that surgical intervention, irrespective of technique, can be protective, as those who underwent surgery had less dislocation arthropathy than those with recurrent instability. In a study by Kreuger et al. [76] comparing revision arthroscopic Bankart repair with primary Bankart repair, there were more patients with arthropathy findings in the revision group after a minimum of two years, although the difference was not significant. The studies in this thesis are too limited with regard to cohort size to permit subgroup analysis. Conclusions on the aetiology of arthropathy cannot be drawn, although there is a significant yet weak correlation in Study III between higher age at surgery and more arthropathy/degenerative changes. The same finding has also been reported by other researchers [28,29,42].

There is a mismatch between Study II, where the majority of patients were already reported to have mild degenerative findings on the preoperative radiographs in contrast to none in Study III. This led to a second evaluation and the inconsistency was found to be a shift in classification when the radiologist's evaluation of Study II was transferred to the study protocol, so that normal became mild, mild became moderate and moderate became severe (there were actually no severe changes in Study II or in Study III) (Table 6). Correcting the results relating to dislocation arthropathy in Study II makes them very similar to the results in Study III and the main finding that dislocation arthropathy increases with time remains unchanged.

Comparisons with other studies are difficult, due to the inconsistency in classifications[96]. However, in the study by Privitera et al.[103] of twenty patients, the Rosenberg classification was also used. After a minimum follow-up of 10 years, an average of 13.5 years after arthroscopic Bankart repair using absorbable PGA tacks, they found no arthropathy changes in 4/20, mild changes in 8/20, moderate changes in 5/20 and severe changes in 3/20. Other recent studies after arthroscopic procedures have used the Samilson and Prieto classification or a slight modification of it for the classification of dislocation arthropathy. One study reported arthropathy rates of 9% after 3.3 years[28], another reported 29% mild and 10% moderate dislocation arthropathy after 10 years[30] and a third study reported 4% mild, 7% moderate and 11% severe changes after a minimum of five and an average of eight years[42]. Using a classification similar to the one in this thesis, Rachbauer et al. found 50% moderate/severe and another 30% mild changes 15 years after the Eden-Hybinette open procedure[105]. Other studies with a variety of classifications, surgical techniques, follow-up rates and times have reported figures of

radiographic arthropathy changes between 13% and 88%[5,40,55,60,106,112,138]. In a recent meta-analysis by Harris et al. [52] also including Study III, the incidence of dislocation arthropathy of all grades after different arthroscopic Bankart repairs analysed together was 39%, after a mean of 10 years using either the Samilson and Prieto or the Rosenberg classification in 344 shoulders. After open Bankart repair, the corresponding numbers were 33% after a mean of 14 years using the Samilson and Prieto classification in 329 shoulders.

The clinical relevance of radiographic dislocation arthropathy can be debated, as there is no or only a weak correlation between radiographic findings and clinical outcome measurements in the present studies and in other studies as well[5,30,55,59,106]. Follow-up periods of at least 15 years are probably necessary to demonstrate the need for future shoulder arthroplasty due to dislocation arthropathy. In a study of 19 patients treated with shoulder arthroplasty due to symptomatic osteoarthritis after surgery for shoulder instability, a mean age at instability surgery of 31 (19-46) years and a mean age at shoulder arthroplasty surgery of 45 (32-69) years was reported, which is a much younger age than the average patient requiring a shoulder arthroplasty due to primary osteoarthritis[49]. In a retrospective follow-up of 30 patients a mean of 29 years after the initial open Bankart repair, five patients had undergone a shoulder arthroplasty a mean of 26 years after the initial surgery[98]. In the multi-centre study by Matsoukis et al.[86] of 1,542 shoulder arthroplasties, only 55 (4%) were due to dislocation arthropathy. Neer reported in 1982[91] that 7% of his shoulder arthroplasties had a history of instability surgery.

In this thesis comprising 151 patients, only one male patient in Study II had signs of symptomatic arthropathy with severe restrictions of ROM and a poor result, with a Constant score of 29 points at the seven-year follow-up. Radiographically and arthroscopically, he had developed moderate dislocation arthropathy.

#### 5.7 ON BONE MINERAL

Study IV opens a new question of whether a limited surgical trauma, such as an arthroscopic Bankart reconstruction in the shoulder, can be related to a negative development in bone mineral in the calcaneus. Bone mineral increases from childhood to the so-called peak bone mass (PBM) in early adulthood and then decreases slowly throughout life. In women, there is an accelerated decrease around menopause (Figure 12).

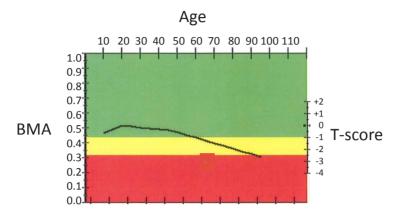


FIGURE 12 Normal curve for BMA in women from the Calscan reference population

Many other factors, apart from age and gender, influence bone mineral as well; they include heredity and ethnicity, previous fracture, chronic inflammation, certain medication, such as long-term cortisone treatment, smoking and the vitamin D level, which is partly associated with sunlight exposure[120]. Bone mineral metabolism is very complex, especially in women. The limited sample size and the complexity of the female group of patients explain why no analysis of the results from the twelve women originally included in Study IV could be performed. Bone mineral and osteoporosis are deeply connected and osteoporosis might be a "silent ticking bomb", which only becomes apparent to the patient after a trauma causing a fracture. Osteoporotic fractures are a major problem and have a high incidence in the Scandinavian countries[120].

The decrease in the BMA in male calcanei of a mean of 6% after five years in Study IV is more than the expected age-dependent decrease for men. The cumulative bone loss in the calcanei in men between 25 and 45 years of age is expected to be only 0.7% during a 20-year period and then 0.5% per year after the age of 50 when measured with the DXL Calscan[77]. For some individuals in the study, the decrease was 15% or more during the five-year study period.

The regulation of bone remodelling in bone multicellular units is very complex, but it is interesting to correlate biological findings to clinical findings. Osteocytes have been shown to have an inhibitory effect on bone resorption by osteoclasts and osteocyte death and apoptosis then increase osteoclast activity through the release of the inhibitory effect, as has been shown in cellular in-vitro and in-vivo studies[50,54,73]. The signalling pathway for this is not fully understood, but it is believed to be local, which is in line with clinical findings of local decreases in bone mineral after fractures and bone manipulating surgery[68]. Bone drilling has been reported to cause osteocyte death[43,44]. Several studies have found a long-standing decrease in bone mineral in the hip after lower leg fractures and surgery, a decrease which is not only local[68,132]. In a study by Ejerhed et al.[37], the decrease in BMA was almost as substantial in the

opposite calcaneus as in the affected limb two years after ACL reconstruction, despite an increase in activity level and immediately permitted weight-bearing. Moreover, in the study by Therbo et al.[132], there was a significant loss of bone mineral in the contralateral proximal tibia, as well as the ipsilateral hip and tibia, measured prospectively during one year after Achilles tendon rupture that was treated surgically. There are few studies of bone mineral after upper extremity surgery and fractures. Kannus et al.[64] reported a significant decrease in the affected humerus but not in the opposite humerus, in both femurs or the spine, nine years after rotator cuff rupture treated surgically, but no preoperative measurements were made. Two studies of adhesive capsulitis or frozen shoulder[80,94] showed a local decrease in BMA in the affected humerus.

It is the opinion of the author of this thesis that bone drilling has a systemic effect that results in a reduction in bone mineral in all bones, but, as the effect is small, it has so far only been shown in the calcaneus, which mainly consists of metabolically active trabecular bone.

Another explanation is the reduction in activity level. In Study IV, a significant reduction in the Tegner activity level from preinjury to the preoperative assessment was registered, although the reported preinjury level could suffer from recall bias. The preinjury activity level was not regained postoperatively and there is no significant improvement in activity level postoperatively in Study IV, as measured with the Tegner activity scale. There are not many studies with longitudinal measurements of bone mineral after a moderate reduction in activity level, as in Study IV, which therefore cannot be compared with studies after total bed rest or weightlessness, where there is a substantial decrease in bone mineral, even after a short time [3]. The calcaneus appears to be one of the more sensitive bones in response to stimulation by activity and not much exercise is needed to have an impact on its amount of bone mineral [48,135], although it is difficult to compare activity levels measured with different methods. Otherwise, it appears to be difficult to increase the amount of bone mineral by increasing physical activity in adulthood[61,122]. Interventions to increase peak bone mass (PBM) have to be implemented before puberty[69,81,134]. Differences in bone mineral in childhood appear to persist into early adulthood at the very least [69,134]. In a cross-sectional study of jumpers, swimmers and sedentary activities, there was a significant difference between the groups in terms of bone mineral in the heel bone, with jumpers having the highest amount after approximately ten years of training from the age of fourteen [129]. In Study IV, there was, however, a moderately strong correlation between the preinjury Tegner activity level and the preoperative BMA, as well as between the BMA and the Tegner activity level on the different postoperative follow-up occasions. As mentioned before, many other factors also influence bone mineral and we have collected data on some of them - smoking, intake of dairy products to calculate the daily intake of calcium, previous fracture, medication and so on. To examine the possible effects of these factors, a much larger study group would have been needed to allow for a multiple regression analysis. However, as Study IV compares the same subjects in a longitudinal manner, only factors that change during the study or factors that influence the individual slope of the natural age-dependent decrease in bone mineral would influence the results. Smoking is a known risk factor for osteoporosis, but the way this occurs is not known. The results in Study IV are also presented for the non-smokers alone and this shows that the decrease is similar in the non-smoking group and in the whole study group. When it comes to the possible bone-stimulating or bone-inhibitory effect of bioabsorbable materials, Pihlajamäki et al. did not find any such effect compared with stainless steel implants for either PGA or PLLA implants in cancellous or cortical bone[100,101].

#### 5.8 ON ACTIVITY LEVEL

In Study IV, the patients' activity level had declined significantly from preinjury (although this is a recollected value that could suffer from recall bias) to preoperatively, but no significant change after the operation was found. The Tegner activity scale might not be sensitive enough to detect a change, however. No activity score was used in the other studies. However, in Study I, the patients were asked to classify their level of activity as overhead activity, contact sports and sports without overhead activity or sedentary activity, but the frequency of activity was not recorded.

The activity level is an important factor when looking at the return to previous activity, which indicates a very good functional result. Return to demanding activity could also increase the risk of new dislocations both due to a new and significant trauma and due to repetitive and demanding use. There is a validated shoulder activity level scale that is useful for this purpose[25,26], but it is probably not appropriate for the purpose of Study IV regarding the stimulation or maintenance of bone mineral.

#### 5.9 ON QUALITY OF LIFE

The EQ-5D or Euroqol is a widely used generic health related quality of life measurement score that has probably not previously been used after arthroscopic Bankart reconstruction. The philosophical question is of course "What is quality of life?". This is far beyond the scope of this thesis and the discussion is therefore limited to the results relating to what is measured with the EQ-5D. In Study IV, the EQ-5D index was  $0.64 \pm 0.26$  preoperatively and  $0.87 \pm 0.21$  after five years (p=0.003, (n=23)). This can be compared with the results after other orthopaedic procedures in Sweden, such as ACL reconstruction, where the EQ-5D index was 0.69 preoperatively and 0.8-0.83 1-5 years postoperatively, as seen in the Swedish ACL Register annual report from 2011 (http://www.artroclinic.se/info/rapport2011.pdf), and total hip replacement, where the EQ-5D index was 0.40 preoperatively and 0.76 after one year (data from 73,395 and 66,145 patients respectively) in the Swedish Hip Replacement Register annual report from 2010 (http://www.shpr.se/Libraries/Documents/AnnualReport-2010-3. sflb.ashx). These changes should also be correlated to the minimally clinical important difference, which has been estimated at 0.074 136 l. The EQ-5D index in the Swedish general population was reported to be 0.88 in the 30-39 year age group and 0.86 in the 40-49 year age group[27].

### 06 LIMITATIONS

The common main limitation for all studies is the small sample size, although the sample sizes have been large enough to answer the hypotheses. For Studies II and III, another limitation is the lack of radiographs of the contralateral shoulder, which could have served as a control for each individual. Taking repeated radiographs of a healthy shoulder might be an ethical problem, however. In Study IV, there was considerable non-attendance at the follow-ups, despite large-scale efforts to track all patients. It is also possible to argue that the analysis of BMA could have been accompanied by an analysis of bone turnover with blood markers, for example. It would also have been interesting to have had a control group in Study IV, such as a group of patients with first-time shoulder dislocation and a purely soft-tissue surgical group, such as patients undergoing surgery for appendicitis or a similar procedure. Control groups of this kind would make it possible to clarify whether bone drilling is important in relation to the reduction in BMA.

## 07 conclusions

Arthroscopic Bankart reconstruction with absorbable tacks results in stable, well-functioning shoulders in the majority of patients, although 17% of the shoulders had a recurrence of instability.

Drill holes after implanting absorbable tacks are radiographically visible for a longer time, i.e. heal more slowly, after implanting PLLA compared with PGA tacks.

Dislocation arthropathy increases with time.

Bone mineral in the calcaneus decreases after arthroscopic Bankart surgery with limited bone drilling in the shoulder.

The activity level as measured by the Tegner activity scale decreases from preinjury to preoperatively and does not increase significantly after the operation.

Health-related quality of life as measured with the EQ-5D index increases significantly after arthroscopic Bankart reconstruction.

## PERSPECTIVES

Long-term studies of the behaviour of new implants in humans are important. The standardisation of outcome measurements would make comparisons between different studies easier. Longitudinal studies of bone mineral after surgical procedures and moderately reduced physical activity are needed. In future studies, it would be interesting to include analyses of bone turnover with blood markers or biopsies, for example. As there is a lack of knowledge, the author recommends that rehabilitation programmes after surgical procedures involving bone should also include information and exercises to prevent bone mineral loss and that the effect of this should be evaluated.

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## APPENDIX

Maria			No		
Name	O.C. and O. and a	1	140		
Sex	female male	Impl	ant		
Age at index procedure		Borrhål 8	4.		
Injuried side	left right	Artros 8			
Dominant side	left right				
Contralateral side normal	yes no				
Cause of injury	ontact sport	none contact sport O	ADL work	other	
Previous surgery	Bristow ar		omeoplasty romeoplasty		
Date of index procedure		Number of dislocations			
Type of operation	acute more than 2 more revision surgery			ter onset after onset after index proc	edure
Findings at index procedure	Bankart bony Bankart Andrew lesion	SLAP Hermodsson, Hill-Sac	cartila	cuff othe	
Index procedure	open Bankart open capsular sh arthro Bankart	arthro acromeoplas ift open acromeoplas SLAP repair		nesis	
Hospital stay	day/s	Sickleave	days after index	c procedure	
Post-operative problems	none delayed wound he wound infection	trombosis aling deep infection neurological co	mplications	ROM prob	lems
Fp I months post-oper	ative	Fp II months	post-operative		
Active standing ROM	ext flex	add 90° abd	ext rot 0°	ext rot 90°	vertebral int rot
Preop					
Diff contralateral side					
FpI					
Diff contralateral side					
Fp II					
Diff contralateral side					

Preop OK painful sublux dislocation  Posterior jerk test  Precp OK painful sublux dislocation  Precp Fp I OK painful sublux dislocation  Fp II OK painful sublux dislocation  Fp II OK painful sublux dislocation  Preop Fp I OK painful sublux Fp II OK painful  Preop Fp I OK painful Sublux Fp II OK painful  Preop Fp I OK painful Preop Fp I OK painful Preop Fp I OK painful Preop Fp I OK painful Preop Fp I OK painful Preop Preop Fp I OK painful Preop Preop Preop Preop Painful Preop Pr	Jobe to Preop OK pair of No. Palm Preop OK pair of No. Preop O 1+ 2+ Lift off Preop nom	est  ful arc 70-1  ful arc 70-1  ful ful arc 70-1  ful ful arc 70-1	OK painful OK painful	Fp II OK painful  Fp II OK painful  Fp II OK painful  Fp II OK painful		
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painful sublux dislocation dislocation dislocation  mpingement test (int rot 90° abd)  Preop Fp I Fp II OK painful Painful  Crossbody test  Preop Fp I Fp II OK painful  Crossbody test  Preop Fp I Fp II OK painful  Crossbody test  Preop Fp I Fp II OK OK DK  Preop Fp I Fp II OK OK OK	Pain Preop OK pair  Sulcus Preop 0 1+ 2+  Lift off Preop nom	oful arc 70-1  oful sign  f test	painful  OK painful  DI  OK painful	Fp II OK painful  Fp II 0 1+		
sublux dislocation sublux dislocation dislocation  mpingement test (int rot 90° abd)  Preop Fp1 Fp II OK painful  Preop Fp1 OK painful  Preop Fp1 Fp II OK painful  Crossbody test  Preop Fp1 Fp II OK painful  Crossbody test  Preop Fp1 Fp II Fp II OK OK OK OK OK	Pain Preop OK pair  Sulcus Preop 0 1+ 2+  Lift off Preop nom	oful arc 70-1	DI OK painful	Fp II OK painful  Fp II 0 1+		
dislocation dislocation dislocation  mpingement test (int rot 90° abd)  Preop Fp I OK Painful Painful  alm up test  Preop Fp I OK Painful  Crossbody test  Preop Fp I Fp II OK Painful  Crossbody test  Preop Fp I Fp II OK Painful  Crossbody test  Preop Fp I Fp II OK Painful  Crossbody test  Preop Fp I Fp II OK Painful	Pain Preop OK pair  Sulcus Preop 0 1+ 2+  Lift off Preop nom	sign Fr	OK painful	OK painful		
npingement test (int rot 90° abd)  Preop	Pain Preop OK pair  Sulcus Preop 0 1+ 2+  Lift off Preop nom	sign Fr	OK painful	OK painful		
Preop	Sulcus Preop 0 1+ 2+ Lift off	sign Fr	OK painful	OK painful		
Preop	Sulcus Preop 0 1+ 2+ Lift off	sign Fr	OK painful	OK painful		
OK OK OK Painful OK Painful  Preop Fp I Fp II OK Painful  Crossbody test  Preop Fp I Fp II Painful  Crossbody test  Preop Fp I Fp II Fp II Fp II OK OK OK OK OK	Sulcus Preop 0 1+ 2+ Lift off	sign Fr	OK painful	OK painful		
painful painful painful  calm up test  Preop Fp I OK OK painful  Crossbody test  Preop Fp I Fp II  Crossbody test  Preop Fp I Fp II  OK OK OK	Sulcus Preop 0 1+ 2+ Lift off	sign Fr	painful pl 0	painful  Fp II  0  1+		
Preop Fp I Fp II OK OK painful  Crossbody test  Preop Fp I Fp II OK OK OK OK	Sulcus Preop 0 1+ 2+  Lift off	sign Fr	p1 0 0	Fp II 0 0 1+		
Preop         Fp I         Fp II           OK         OK         OK           painful         Painful    Crossbody test  Preop  Fp I  OK  OK  OK	Preop 0 1+ 2+ Lift off Preop nom	Fr C	0	0 0 1+		
Preop         Fp I         Fp II           OK         OK         OK           painful         Painful    Crossbody test  Preop  Fp I  OK  OK  OK	Preop 0 1+ 2+ Lift off Preop nom	Fr C	0	0 0 1+		
OK OK OK Painful OK Painful  Crossbody test  Preop Fp I Fp II OK OK OK	Lift off	f test	0	0 0 1+		
painful         painful         painful           Crossbody test         Preop         Fp I         Fp II           OK         OK         OK	Lift off	f test	1+	○1+		
Crossbody test           Preop         Fp I         Fp II           ○ OK         ○ OK         ○ OK	Lift off	f test				
Preop         Fp I         Fp II           OK         OK         OK	Lift off	f test	2+	O2+		
Preop         Fp I         Fp II           OK         OK         OK	Preop					
OK OK OK	nom					
OK OK OK	nom	Er	p I	FpII		
0 011			normal	normal		
pannui	weal		weak	weak		
			impossible	impossible		
	,p	Jane 1	impossiore	- Impossion		
K-ray findings Preop Fp I		F	Fp II			
none none		_ 17	none			
Hermodsson, Hill-Sachs Hermods	sson, Hill-Sachs	□ F	Hermodsson,	Hill-Sachs		
bony Bankart bony Ba	nkart	_ b				
GH Arthrosis GH Arth	nrosis		GH Arthrosis			
unhealed drill holes unhealed	d drill holes		inhealed dril			
healed drill holes healed d	rill holes	1	healed drill h	oles		
acromeon I acromeo	n I	2	acromeon I			
acromeon II acromeo	n II	2	acromeon II			
acromeon III acromeo	on III	8	acromeon III			
cranial migration cranial n	migration	0	cranial migra	tion		
caudal sublux caudal s			caudal sublux			
AC arthrosis AC arthr			AC arthrosis			
other other		Lane of the land o	other			

pprehension Preop			Relocation test		
OK	Fp I OK	FpII	Preop	FpI	FpII
painful	0.000	OK.	○ OK	○ OK	OK
	painful	painful	painful	painful	painful
sublux	sublux	sublux			
dislocation	dislocation	dislocation			
osterior jerk	test		Jobe test		
Preop	FpI	FpII	Preop	FpI	Fp II
OK	OK	OOK	OOK	OK	○ OK
painful	painful	painful	painful	painful	painful
sublux	sublux	sublux			
dislocation	dislocation	dislocation			
		- b-d)	Painful arc	70.4000	
	est (int rot 90°				
Preop	FpI	FpII	Preop	FpI	Fp II
OK	OK	OK	○ OK	○ OK	OK OK
painful	O painful	opainful painful	o painful	o painful	painful
alm up test			Sulcus sign		
Preop	FpI	FpII	Preop	FpI	Fp II
○ OK	○ OK	○ OK	00	00	0
painful	painful	O painful	0 1+ 0 2+	○1+ ○2+	0 1+ 0 2+
Crossbody t	est		Lift off test		
Preop	FpI	Fp II	Preop	FpI	Fp II
○ OK	OK.	OK	normal	normal	normal
O painful	painful	painful	weak	○ weak	O weak
			impossible	impossible	impossible
(-ray findings		FpI		Fp II	
none		none		none	
Hermodsson	, Hill-Sachs	Hermodsson,	Hill-Sachs	Hermodsson,	Hill-Sachs
bony Bankar	t	bony Bankart		bony Bankart	
GH Arthrosi	s	GH Arthrosis		GH Arthrosis	
unhealed dri	ll holes	unhealed dril	l holes	unhealed drill	holes
healed drill	holes	healed drill h	oles	healed drill he	oles
acromeon I		acromeon I		acromeon I	
acromeon II		acromeon II		acromeon II	
acromeon II		acromeon III		acromeon III	
cranial migr		cranial migra	tion	cranial migrat	ion
caudal sublu		caudal sublu		caudal sublux	
AC arthrosis		AC arthrosis		AC arthrosis	
other		other		other	

	nead activity ct sport s without o.h. activity ttary activity		IB	Fp I overhead activity contact sport sports without o.h. activity sedentary activity			y	Fp      overhead activity   contact sport   sports without o.h. activit			tivity
we score				injure	d side			non-inj	ured side	e	
Stability	subsco	re	Preor	F	pΙ	Fp II	Pr	eop	FpI	Fp II	
Pain su	bscore										
Total											
1000											
nstant sc	ore	Т.		1	_						
bex											
Preop	ext rot	int rot	abd	Fp I	ext rot	int rot	abd	Fp II	ext rot	int rot	abd
I				I				I			
NI				NI				NI			
I/NI				I/NI				I/NI			
nor RO		i		problem	-	njury [	other				
		H					Ŧ				
	valuation	at 2 year	rs	Poor	○ Fair	Good	○Ex	cellent			
Patients e		v at 2 ves	rs	Poor	○ Fair	○ Good	○ Ex	cellent			
Patients e		, ,				00	OF	cellent			
	cpectansy		irs	Poor	O Fair	Good	OF	ecement.			
Patients ex	cpectansy		irs	Poor	○ Fair	O G000	O Ex	cenem			
Patients ex	cpectansy		irs	Poor	○ Fair	Good		cenem			
Patients ex	evaluatio	n at 2 yea		Poor	○ Fair	Good	, CEX	cenent			

Functional Co	onstant'	s sco	re				
	Righ	Right shoulder Let			ft shoulder		
	Preop	Fp I	Fp II	Preop	Fp I	Fp II	
Pain: 15 points/100							
None: 15 p Mild: 10 p Moderate: 5 p Severe: 0 p						$\vdash$	
Activities of daily living: 20 points/100							
Professional handicap (0 to 4 points)							
Severe handicap: 0 p, full work: 4 p							
Recreational handicap (0 to 4 points)							
Sleep (0 to 2 points)							
Affected sleep: 0 p, unaffected sleep: 2 p							
Level of wee of hands (10 points)						$\vdash$	
Level of use of hands (10 points) Waist Xiphoid Neck Top of head Above head							
2 p 4 p 6 p 8 p 10 p							
Subtotal/35 points							
Painless active mobility: 40 points/100							
Forward elevation							
0-30° 30-60° 60-90° 90-120° 120-150° 150-180°							
0 p 2 p 4 p 6 p 8 p 10 p							
Lateral elevation							
0-30° 30-60° 60-90° 90-120° 120-150° 150-180°							
0р 2р 4р 6р 8р 10р							
External rotation						$\vdash$	
Hand behind head with elbow held forward 2 p							
Hand behind head with elbow held back 2 p							
Hand on top of head with elbow held forward 2 p							
Hand on top of head with elbow held back 2 p Full elevation from top of head 2 p							
Full elevation from top of head 2 p							
Internal rotation: Dorsum of hand to:							
Tight Buttock Sacrum L <sub>3</sub> Th <sub>12</sub> Th <sub>7</sub>							
0 p 2 p 4 p 6 p 8 p 10 p							
Power 25 points/100							
Measured in 90° abduction in scapular plane using							
a dynamometer							
Subtotal/65 points							
Total/100 points							

#### Rowe rating method for shoulder evaluation

		Patie	ore I	
Pain	Points	Preop	Fp I	Fp II
None	15			
Mild	12			
Moderate	6			
Marked	3			
Disabled	0			

Motion		Patient's score			
Add & Fwd					
(ROM)	Points	Preop	Fp I	Fp II	
151-170°	15				
120-150°	12				
91-119°	6				
61-90°	3				
<30°	0				

Motion Int. Rot.		Patient's score			
(ROM)	Points	Preop	Fp I	Fp II	
Thumb to scapula	5				
Thumb to sacrum	3				
Thumb to trochanter	2				
< trochanter	0				

Motion		Patient's score				
Ext. Rot. (ROM)	Points	Preop	Fp I	Fp II	Norm. side	
80°	5					
60°	3					
30°	2					
<30°	0					

Muscle		Patient's score			
strength	Points	Preop	Fp I	Fp II	
Normal	10				
Good	8				
Fair	6				
Poor	4				
Trace	2				
Zero	0				

		Patient's score		
Stability	Points	Preop	Fp I	Fp II
Normal	25			
Apprehension	20			
Rare sublux	10			
Recurr sublux	5			
Recurr disloc	1			
Fixed disloc	0			

		Patient's score			
Function	Points	Preop	Fp I	Fp II	
Normal	25				
Mild	20				
limitation					
Moderate	10				
limitation					
Severe	5				
limitation					
Complete	0				
disability					

Overall		Patio	ent's sc	ore
Rowe rating	Points	Preop	Fp I	Fp II
Excellent	100-85			
Good	84-70			
Fair	69-50			
Poor	<49			

Total patient's Rowe score

Preop	
Fp I	
Fp II	

#### **BONE MINERAL EVALUATION PROTOCOL**

NU-SJUKVÄRDEN, NÄL, TROLLHÄTTAN, UDDEVALLA SJUKHUS, UDDEVALLA FYRBODALINSTITUTET, UDDEVALLA SWEDEN

First name Family name Date of birth Address Postal code			Age	number		
Post address						
Housing	OOwn	O Servic	e O Institution	O Other	Housing com	ments
Date index						
Follow up after index (	(months)	FpI	Fp II	Fp III	Fp IV	Fp V
Age at index procedu	re	Stud	O Abdomini O Distortion	, knee surgery, dist rad osis	00	Shoulder Gonarthrosis Distal radius fracture Other
	Study	comment	s			
Ostoporotic risk	factors	TATE		1 - 10	71.1	I. Water
Gender	O female	Omale		H	eridity comment	s
Heredity	number of	fractures,	Mother F	ather		
Ethnic group	O white	O black	Oasien Oot	her comm	ments	
Menarche	index		Menopaus		umber mensesye	
Bodywheight (kg)		FpI	Fp II	FpIII FpI	IV Fp V	
Bodywheight (kg) Height (m)			Fp II	FpIII FpI	IV FpV	
	index				IV FpV	
Height (m)		Heigh Fp I	20 years		IV FpV	nments
Height (m) BMI Diet	index	Height Fp I	20 years	Fp III Fp	IV FpV	
Height (m) BMI Diet Daily intake milk (ml)	index  O Norma	Height Fp I	Fp II	Fp III Fp ovegetarian O cheese Fp II	Other com  Daily intake C	a (mg) index
Height (m)	index  O Norma	Fp I  Vege Daily in	Fp II tarian O Lakte	Fp III Fp ovegetarian O cheese Fp II I), A	IV Fp V Other com	a (mg) index
Height (m)  BMI  Diet  Daily intake milk (ml)  Daily intake Ca comm	index O Norma ents Num beer	Height  Fp I  Vege  Daily in  ber of glas (500 ml), d	Fp II tarian O Lakte take slices of Fp I of wine (200 m	Fp III Fp ovegetarian O cheese Fp II I), A 0 ml)/week	Other com Daily intake C Fp III Fp I Icohol comment	a (mg) index

	iry		
Injured s	side Oleft Oright		
Dominant :	01-0 0-1-11		
Contralateral side nor	rmal Oyes Ono		
Date of in	jury		
Date of opera	tion		
Current injury comme	ents		
Current disease			
No Chronic Liver Disea Hypercortisolism Diabetes Mellitus Malabsorption Chronic Pulmonary Chronic Inflammato Parkinson's Diseas Rheumatoid Arthriti	Obstructive Disease ry Intestinal Disease e or mother Movement Disorders	☐ Urolithiasis ☐ Dementia ☐ Cerebrovascular disorder ☐ Breast Cancer ☐ Lung Cancer ☐ Lymphoma ☐ Other Cancer	
Currently use of d			
	☐ Antiarrythmics	☐ Vitamin D supplementation	
□No			
☐ Anticonvulsants ☐ Thyroid Hormones ☐ Glucocorticoids ☐ Antidepressants ☐ Benzodiazepines	Antihypertensives Oral Anticoagulants/Heparin Insulins/Oral Hypoglycaemics Hormone replacement therap Calcium	NSAID	
☐ Thyroid Hormones ☐ Glucocorticoids ☐ Antidepressants	Antihypertensives Oral Anticoagulants/Heparin Insulins/Oral Hypoglycaemics Hormone replacement therap Calcium	NSAID	
☐ Thyroid Hormones☐ Glucocorticoids☐ Antidepressants☐ Benzodiazepines	Antihypertensives Oral Anticoagulants/Heparin Insulins/Oral Hypoglycaemics Hormone replacement therap Calcium	NSAID	
☐ Thyroid Hormones☐ Glucocorticoids☐ Antidepressants☐ Benzodiazepines	Antihypertensives Oral Anticoaguiants/Heparin Insulins/Oral Hypoglycaemics Hormone replacement therap Calcium	NSAID	
☐ Thyroid Hormones ☐ Glucocorticoids ☐ Antidepressants ☐ Benzodiazepines	Antihypertensives	NSAID	
☐ Thyroid Hormones ☐ Glucocorticoids ☐ Antidepressants ☐ Benzodiazepines  Currently use of drugs  Former use of dru ☐ No ☐ Anticonvulsants ☐ Thyroid Hormones ☐ Glukcocorticoids	☐ Antihypertensives ☐ Oral Anticoagulants/Heparin ☐ Insulins/Oral Hypoglycaemics ☐ Hormone replacement therap ☐ Calcium  s comments ☐ Benzodiazepines ☐ Antiarrythmics ☐ Antihepertensives ☐ Oral Anticoagulants/Heparin ☐ Insulins/Oral Hypoglycaemics	□ NSAID  □ Hormone replacement therapi □ Calcium □ Vitamin D supplementation	

BONE MINERAL EVALUATION PROTOCOL NJ quidolifenTyrbodalineRitutel 02-909-1000-0832/81005 Lais Ejerhed

sid 2

#### TEGNER ACTIVITY SCALE

Competitive sports

soccer - national or international level

Competitive sports soccer - lower divisions

icehockey

wrestling gymnastics

Competitive sports

bandy squash or badminton

athletics (jumping etc) downhill skiing

Competitive sports athletics (running)

motocross or speedway tennis

handball or basketball

Recreational sports soccer

bandy or icehockey

squash

squasii athletics (jumping) cross-country track findings (orienteering) both recreational and copmpetitive

Recreational sports

tennis or badminton handball or basketball downhill skiing

jogging at least 5 times weekly

Work

heavy labour (eg building, forestry)

Competitive sports

cycling cross-country skiing

Recreational sports jogging on uneven ground at least twice weekly

Work

moderately heavy work (eg lorry-driving, charring)

Recreational sports

cycling cross-country skiing

jogging on even ground at least twice weekly

Work

light work (eg nursing)

Competitive and recreational sports swimming

walking in rough forrest terrain

2 Work

light work walking on uneven ground

Work

sedentary work

walking on even ground

Sickleave or disability pension because of kneeproblems

Sickleave, disability pension comments

Performed level pre injury

Fp II Fp III

Fp V Fp IV

Daily physical activity in km (walking, cycling, skiing, swimming etc.) O -1 km O 1-2 km O 2-4 km O -5 km

Fp I

Daily physical activity km comments

Daily physical activity in minutes O -10 min O 10-30 min O 30-60 min O 60- min

Daily physical activity min comments

sid 3

#### Prior fracture and surgery Prior fracture O Yes O No Skull wrist knee neck vertebra other ladvicle pelvis lower leg thoracic vertebra lumbar vertebra forcarm femur foot sternum,ribs Fracture location Fracture location comments Fracture side Oright Oleft Fracture side comments Date of fracture Date of fracture comments Fracture type O high energy (traffic accident, fall exceeding 3m) O other O low energy (fall in the same level) Fracture type comments Fracture treatment O conservative (plaster, brace) O surgery O other racture treatment comments Fracture complications No deep infection thrombosis other wound infection mechanical failure non union Fracture complications comments Number of fractures Number of fractures comments Prior surgery O Yes O No Head Gynaecological Laparascopy Neck Upper extremity Other Thorax Lower extremity Abdominal Arthroscopy Surgery location comments Surgery side O Right O Left Surgery side comments Date of surgery comments Date of surgery Surgery complication No Thrombosis Reoperation Deep infection Other Surgery complication comments Number of operations Number of operations comments BONE MINERAL EVALUATION PROTOCOL NUI-sunsintentifytodalnatuset 05009/0000 0522/061006 Lars Ejethed sid4

67

EuroQOL LIVSK	VALITE	SKALA				
Markera, genom att kryssa	i en muta i sar	ia nadanestand	anunn vilket ni	istående som		
bäst beskriver Ditt hälsotill		je neuanstaenu	e grupp, viikee pe	istacinae som		
Rörlighet						
Jag går utan svårigheter Jag kan gå men med viss sv	ariahat E					
Jag är sängliggande	arigiet	-				
Hygien						
Jag behöver ingen hjälp me			ller påklädning	H		
Jag har vissa problem att tv Jag kan inte tvätta och klä r		nig sjalv		Н		
Huvudsakliga aktiviteter		studier, hushā	llssyssior,			
familje- och fritidsaktivite Jag klarar min huvudsaklig		ng	П			
Jag har vissa problem med	att klara av n					
huvudsakliga sysselsättning Jag klarar inte av min huvu		alettraina				
	donninga oyoo	ersantining.	П			
Smärtor/besvär Jag har varken smärtor elle	e hande					
Jag har måttliga smärtor oc			Н			
Jag har svåra smärtor och besvär						
Rädsla/nedstämdhet						
Jag är inte orolig eller neds		landar.				
Jag är orolig och nedstämd Jag är i högsta grad orolig o						
Rörlighet index	FpI	FpII	Fp III	Fp IV	Fp V	
Hyglen index	FpI	FpII	Fp III	FpIV	FpV	
Huvusaklig aktivitet index	FpI	FpII	FpIII	FpIV	FpV	
Smärtor/besvär index	Fpl	FpII		FpIV		
Rädsla/nedstämdhet index	FpI		Fp III	FpIV	Fp V	
Total index	FpI	Fp II	Fp III		Fp V	
			Fp III	Fp IV	Fp V	
varande hälsotillstånd index	FpI	Fp II	Fp III	Fp IV	Fp V	

BONE MINERAL EVALUATION PROTOCOL NU-survivident/Pytocal/retis/art 06-acyanoso 0622/061006 Lans Elemed

#### BMA/BMD, T-score, Z-score Calcaneus

Left side		
BMA index	Tscore index	Zscore index
BMA Fp I	Tscore FpI	Zscore Fp I
BMA Fp II	Tscore Fp II	Zscore Fp II
BMA Fp III	Tscore Fp III	Zscore Fp III
BMA Fp IV	Tscore Fp IV	Zscore Fp IV
BMA Fp V	Tscore Fp V	Zscore Fp V
Right side		
BMA index	Tscore index	Zscore index
BMA Fp I	Tscore FP I	Zscore Fp I
BMA Fp II	Tscore Fp II	Zscore Fp II
BMA Fp III	Tscore Fp III	Zscore Fp III
BMA Fp IV	Tscore Fp IV	Zscore Fp IV
BMA Fp V	Tscore Fp V	Zscore Fp V

#### BMA/BMD, T-score, Z-score, Spine

BMD L	_1 BMD L2	- F	BMD L3	BMD L4
index	index	index	index	
FpI	FpI	Fp I	Fp I	
Fp II	Fp II	Fp II	Fp II	
Fp III	Fp III	Fp III	Fp III	
Fp IV	Fp IV	Fp IV	Fp IV	
FpV	Fp V	FpV	Fp V	
-1				
BMD L1-L4	T-score L1-L4		Z-score L1-L4	
index	index		index	
pl	FpI		Fp I	
p II	Fp II		Fp II	
Fp III	Fp III		Fp III	
Fp IV	Fp IV		Fp IV	
Fp V	Fp V		Fp V	

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0620/91000 0622/061005 Lars Ejerhed sid6

#### BMA/BMD, T-score, Z-score, Femur neck

	T-score	Z-score
index Fp I Fp II Fp III Fp IV Fp V	index Fp I Fp II Fp III Fp IIV Fp V	index Fp I Fp II Fp III Fp IV Fp V
Right side	T-score	Z-score
Index Fp I Fp II Fp III Fp IV Fp V	Index Fp I Fp II Fp II Fp IV Fp IV	index Fp I Fp II Fp III Fp IV Fp V

#### BMA/BMD, T-score, Z-score, Femur total

Left side		
BMD	T-score	Z-score
index Fp I Fp II Fp IV Fp V	Index Fp I Fp II Fp III Fp IV Fp V	index Fp I Fp II Fp IV Fp V
Right side	T-score	Z-score
index Fp I Fp II Fp III Fp IIV Fp IV	Index Fp I Fp II Fp III Fp IV Fp V	index Fp I Fp II Fp III Fp IV Fp V

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0520/91000 0522/261005 Lars Ejerhed

# 15 PAPERS I-IV



### PAPER I

A long-term clinical follow-up study after arthroscopic intra-articular Bankart repair using absorbable tacks

Elmlund A, Kartus C, Sernert N, Hultenheim I, Ejerhed L

Knee Surg Sports Traumatol Arthrosc. 2008; 16(7):707-12



### PAPER II

A 7-year prospective, randomized, clinical, and radiographic study after arthroscopic Bankart reconstruction using 2 different types of absorbable tack

Elmlund AO, Kartus J, Rostgård-Christensen L, Sernert N, Magnusson L, Ejerhed L

Am J Sports Med. 2009 :37(10):1930-7



### PAPER III

Dislocation arthropathy and drill hole appearance in a mid- to long-term follow-up study after arthroscopic Bankart repair

Elmlund AO, Ejerhed L, Sernert N, Rostgård LC, Kartus J

Knee Surg Sports Iraumatol Arthrosc. 2012 ;20(11):2156-62



### PAPER IV

Bone mineral decreases in the calcanei after arthroscopic Bankart reconstruction: a prospective study over five years

Elmlund AO, Kartus J, Ejerhed L

Manuscript