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# Exercise treatment of patients with long-standing subacromial pain

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*To Rafael, Adam, Simon and Ludvig*

*“It is through science that we prove, but through intuition that we discover”*  
- Henri Poincare



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# ABSTRACT

Subacromial pain is the most common problem among patients with shoulder complaints seeking primary care. The recommended treatment for these patients is primarily non-surgical with a focus on exercise treatment. If this treatment fails arthroscopic subacromial decompression (ASD) followed by exercise treatment is recommended. Surgical treatment with ASD has increased substantially in Sweden in recent year even though studies comparing exercise treatment with surgery report equally positive results. Still, there is a need of evidence based pre- and postoperative exercise treatments, standardised and described in detail, to guide treatment of these patients in clinical practice.

The overall aim of this thesis was to evaluate the efficacy of pre- and postoperative exercise strategies on shoulder function and how the preoperative strategy affects the need for surgery in patients with long-standing subacromial pain.

This thesis comprises four papers which are based on two randomised controlled trials. **In study A**, patients were randomised after ASD surgery to either physical therapist (PT) supervised strength-endurance exercises for the rotator cuff and scapula stabilisers or to home-based movement exercises for a period of three months. Shoulder function and pain, health related quality of life and return to work was evaluated for 6 months (*paper I*). **In study B**, patients on the waiting list for ASD surgery were randomised to either specific exercise strategy with strength-endurance exercises for the rotator cuff and the scapula stabilisers or to control exercises with movement exercises for the neck and shoulders for a period of three months. After completing the exercise program and also after 12 months, shoulder function and pain, need for surgery and health related quality of life was evaluated. Baseline shoulder function, rotator cuff status and radiological findings were analysed in relation to the choice of surgery (*paper II, III*). The minimal important change (MIC) of the Constant-Murley (CM) score, used as primary outcome in this thesis, was determined by using a visual anchor-based MIC distribution method (*paper IV*).

Six months after ASD surgery, patients who performed PT-supervised strength-endurance exercises improved significantly more in shoulder function and pain compared to patients who had performed home-based movement exercises (*paper I*). Patients on the waiting list for surgery who performed specific strength-endurance exercises had significantly greater improvements in shoulder function and pain compared to patients performing movement exercises (*paper II*). A significantly lower proportion of those performing specific strength-endurance

exercises chose surgery at the three and 12 months follow-ups (*paper II, paper III*). Low baseline values in shoulder function and pain measured with the CM score and/or having a full thickness rotator cuff rupture were associated with an increased risk of choosing surgery (*paper III*). Regarding the CM score, a change between 17-24 points seems to be clinically important for patients with long-standing subacromial pain (*paper IV*).

Supervised strength-endurance exercises seem to be more effective than home-based movement exercises after ASD surgery. For patients on the waiting list for surgery, the specific strategy of strength-endurance exercises was effective in improving shoulder function and pain and the need of surgery was reduced at 12 months. Low baseline values for shoulder function and pain measured with the CM score and/or having a full thickness rotator cuff tear seem to be predictors for choosing surgery. The CM score is able to detect the MIC in individual patients with long-standing subacromial pain when the rotator cuff is intact. In all patients with long-standing subacromial pain, the MIC value was dependent on the subgroup as well as the choice of statistical analysis.

## LIST OF PUBLICATIONS

This thesis is based on the following papers which are referred to in the text with Roman numerals:

- I. **Theresa Holmgren**, Birgitta Öberg, Irene Sjöberg, Kajsa Johansson. Supervised strengthening exercises versus home-based movement exercises after arthroscopic acromioplasty: a randomized clinical trial. *J Rehabil Med* 2012;44: 12-18.
- II. **Theresa Holmgren**, Hanna Björnsson, Birgitta Öberg, Lars Adolfsson, Kajsa Johansson. Effect of specific exercise strategy on need for surgery in patients with subacromial impingement syndrome: a randomised controlled study. *BMJ* 2012;344:e787
- III. Hanna Björnsson, **Theresa Holmgren**, Birgitta Öberg, Kajsa Johansson, Lars Adolfsson. A specific exercise strategy for patients with subacromial pain significantly reduced the need for surgery: one-year results of a randomised controlled study. *Submitted 2012*
- IV. **Theresa Holmgren**, Birgitta Öberg, Lars Adolfsson, Kajsa Johansson. The minimal important changes in the Constant-Murley score in patients with subacromial pain. *Submitted 2013*

## DESCRIPTION OF CONTRIBUTION

### **Paper I**

Study Design	Holmgren T, Öberg B, Sjöberg I, Johansson K
Data Collection	Holmgren T, Sjöberg I
Data Analysis	Holmgren T, Johansson K
Manuscript Writing	Holmgren T
Manuscript Revision	Holmgren T, Öberg B, Johansson K

### **Paper II**

Study Design	Holmgren T, Öberg B, Björnsson Hallgren H, Adolfsson L, Johansson K
Data Collection	Holmgren T, Björnsson Hallgren H
Data Analysis	Holmgren T, Öberg B, Johansson K
Manuscript Writing	Holmgren T
Manuscript Revision	Holmgren T, Björnsson Hallgren H, Öberg B, Adolfsson L, Johansson K

### **Paper III**

Study Design	Björnsson Hallgren H, Holmgren T, Öberg B, Johansson K, Adolfsson L
Data Collection	Björnsson Hallgren H, Holmgren T
Data Analysis	Björnsson Hallgren H, Holmgren T, Öberg B, Johansson K, Adolfsson L
Manuscript Writing	Björnsson Hallgren H
Manuscript Revision	Björnsson Hallgren H, Holmgren T, Öberg B, Johansson K, Adolfsson L

### **Paper IV**

Study Design	Holmgren T, Öberg B, Johansson K
Data Collection	Holmgren T, Björnsson Hallgren H
Data Analysis	Holmgren T
Manuscript Writing	Holmgren T
Manuscript Revision	Holmgren T, Öberg B, Adolfsson L, Johansson K

# ABBREVIATIONS AND DEFINITIONS

ASD	Arthroscopic Subacromial Decompression
CI	Confidence Interval
CM	Constant-Murley shoulder assessment score. An outcome measure used for evaluation of shoulder function and pain with focus on objective measures of range of motion and strength.
DASH	Disability of the Arm Shoulder and Hand score. An outcome measure used for evaluation of function and pain in the upper extremity with focus on activity and participation.
EMG	Electromyography
EQ-5D	European Quality of Life in 5 Dimensions. An outcome measure used for evaluation of health related quality of life.
Functioning	Refers to body structures and functions as well as activity and participation according to the International Classification of Functioning disability and health (ICF).
HAD	Hospital Anxiety Depression scale.
HRQL	Health Related Quality of Life
ICF	International Classification of Functioning, Disability and Health
MDC	Minimal Detectable Change. Change beyond measurement error.
MIC	Minimal Important Change. The smallest change in score in the construct to be measured which patients perceive as important.
PGIC	Patient's Global Impression of Change
PT	Physical Therapist
RCT	Randomised Controlled Trial
ROC	Receiver Operating Characteristics
SIS	Subacromial Impingement Syndrome
VAS	Visual Analogue Scale



# INTRODUCTION

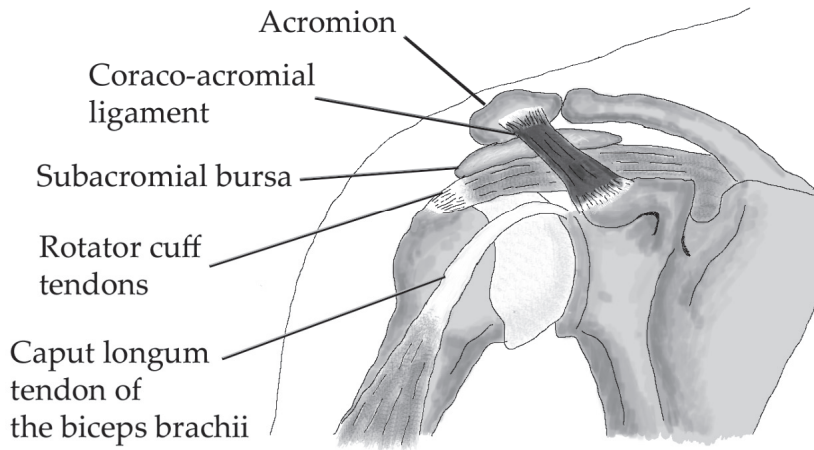
Shoulder pain is the second most common problem among the general population reporting musculoskeletal pain<sup>163</sup>. Values between 6.9 to 26% have been reported for point prevalence and 7 to 67% for lifetime prevalence<sup>133</sup>. The pain is often of long duration and only 50% of patients report recovery after 18 months<sup>50</sup>. The cost for society is high and patients with shoulder disorders account for 20% of all disability payments for musculoskeletal disorders<sup>154</sup>. Of all patients with shoulder pain seeking primary care 44-74% suffer from subacromial pain<sup>161,176,202,203</sup>.

Subacromial pain is the term used in this thesis because it refers to pain arising from the structures located in the subacromial space. Many terms have been used to describe subacromial pain and pathology, including subacromial impingement syndrome, rotator cuff tendinopathy, subacromial bursitis, supraspinatus tendinosis, and rotator cuff syndrome. The variety in diagnostic labels reflects the uncertainty regarding the pathogenesis. The most common source of pain appears to be the subacromial bursa and the rotator cuff with the diagnostic label subacromial impingement syndrome (SIS)<sup>161,166</sup>. SIS is frequently used in the literature and refers to the pain that arises when structures in the subacromial space (primarily the rotator cuff tendons and the subacromial bursa) are impinged between the humeral head and the acromion mainly during arm activity above the horizontal plane<sup>128,144</sup>.

The subacromial space is limited by the coracoacromial arch superiorly and by the humeral head inferiorly. The subacromial bursa and the tendons of the rotator cuff are situated within this space (Figure 1). During elevation of the arm the acromion and humeral head approach each other, narrow the subacromial space and impinge the subacromial structures<sup>24,69</sup>. Rather than being a medical diagnosis, the impingement phenomenon may be either a consequence or a cause of rotator cuff disorders, ranging from rotator cuff tendinopathy to full-thickness rotator cuff rupture.

The recommended treatment for these patients is primarily non-surgical with a focus on exercise treatment<sup>83,124,145</sup>. If non-surgical intervention fails arthroscopic subacromial decompression (ASD) surgery followed by exercise treatment is recommended. Still, there is a need of evidence-based pre- and postoperative exercise treatments that are standardised and described in detail to guide the treatment of these patients in clinical practice.

This thesis will focus on patients with long-standing (>6 months) subacromial pain and the efficacy of pre- and postoperative exercise treatments on shoulder function.



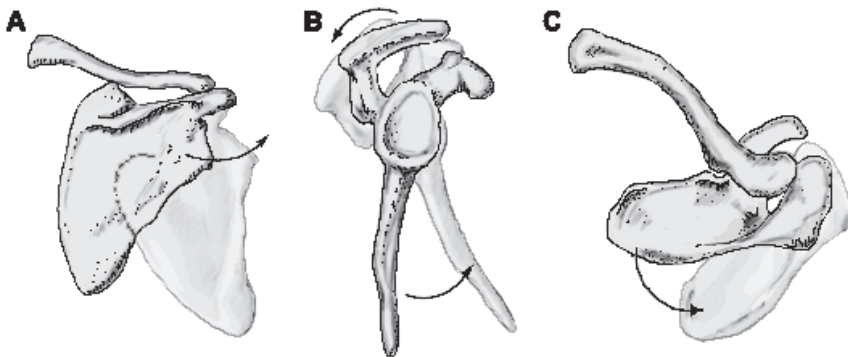
*Figure 1 Anatomy of the shoulder illustrating the subacromial bursa and the rotator cuff tendons in the subacromial space.*

# BACKGROUND

## ANATOMY AND BIOMECHANICS OF THE SHOULDER

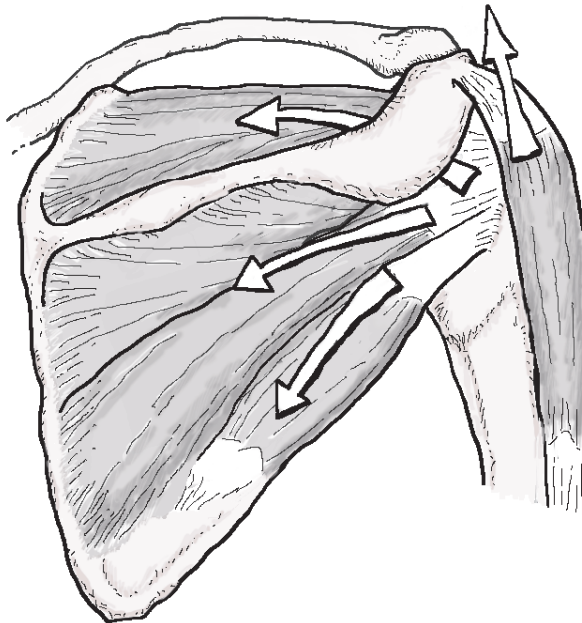
The joints in the shoulder complex result in the largest possible mobility compared to all joints of the human body. Movements of the shoulder girdle joint involve combined motions of the sternoclavicular, acromioclavicular, sternothoracic and glenohumeral articulations<sup>80</sup>.

During normal elevation of the arm the scapula will move in three dimensions: upward rotation with the inferior angle moving laterally and posterior tilt with the inferior angle moving anteriorly; external and internal rotation is less consistent during elevation and depends on the plane of elevation (abduction or flexion). However, in the end range of each of these planes some external rotation occurs<sup>116,144,201</sup> (Figure 2). The scapula serves as a stable base from which the rotator cuff muscles work. Together with the upper and lower trapezius and rhomboid muscles the serratus anterior is considered the main stabiliser of the scapula<sup>118</sup>. When the scapula is stable and appropriately positioned in static and dynamic tasks, the rotator cuff can function at an optimal level.<sup>116</sup>



**Figure 2** Scapular movement. A. Downward and upward rotation around an anterior-posterior axis. B. Scapular anterior and posterior tilting around a medial-lateral axis. C. External and internal rotation around a superior-inferior axis.

The rotator cuff consists of four separate muscles: subscapularis, supraspinatus, infraspinatus and teres minor. These muscles originate from the scapula and their tendons fuse together and form an aponeurotic tendon that surrounds the humeral head and stabilise the glenohumeral joint capsule on the ventral, cranial and dorsal sides <sup>71</sup> (Figure 3). The main function of the rotator cuff is to stabilise the humeral head in to the glenoid fossa and control humeral head translation. Pre-activation of the rotator cuff muscles has been demonstrated in a direction specific manner with anterior and posterior rotator cuff muscles working individually to oppose rotation force and maintain a neutral position <sup>54</sup>. It has also been demonstrated that the rotator cuff uses a specific activation pattern during flexion and extension in the glenohumeral joint. During flexion the supraspinatus and the infraspinatus were significantly more active than the subscapularis; in extension the opposite was the case. These results support the idea that the rotator cuff works in a direction specific way rather than as a block to counterbalance the translation of the caput humeri anteriorly and posteriorly during flexion and extension <sup>209</sup>. These electromyography (EMG) studies on healthy shoulders highlight aspects thought to be important to consider when designing exercise programs for patients with rotator cuff dysfunction, as often seen in patients with subacromial pain <sup>60,150,169</sup>.



*Figure 3 The rotator cuff and the deltoid muscle. Arrows show the direction of force generation.*

## AETIOLOGY AND PATHOGENESIS OF SUBACROMIAL PAIN

Many factors are involved in the pathogenesis of subacromial pain. The shoulder condition has a wide spectrum of severity, ranging from bursitis, rotator cuff tendinitis to rotator cuff tendinopathy, and over time full-thickness rotator cuff tears can develop<sup>153,199</sup>. The rotator cuff tendons and the subacromial bursa are considered the main sources of pain<sup>128,166</sup>.

External and internal impingement are terms used in the literature to describe the location of the impingement phenomenon. External impingement is related to the upper side (bursal side) of the rotator cuff tendons (Figure 1) and internal impingement is related to the underside (articular side). The latter is defined as compression and wear of the rotator cuff tendons at the articular side between the posterior superior glenoid rim and humerus when the arm is in full external rotation, abduction and extension<sup>62</sup>. This impingement phenomenon has been described in overhead athletes<sup>30,117</sup> but also in non-athletes<sup>28,62</sup>. External and internal impingement might interact and internal impingement might lead to external impingement arising from deficient rotator cuff muscle function<sup>128,181</sup>.

Extrinsic and intrinsic factors are described as involved in the pathogenesis of subacromial pain. Extrinsic factors are those causing compression of the structures in the subacromial space while intrinsic factors are those associated with degeneration of the rotator cuff tendons. Despite the controversy regarding the pathogenesis of subacromial pain, evidence indicates that the aetiology is multifactorial and that both intrinsic and extrinsic factors may be involved<sup>128,181</sup>.

### Extrinsic factors involved in subacromial pain

Factors thought to narrow the subacromial space, causing impingement of the structures within this space, are called extrinsic factors. These could be anatomical as well as biomechanical.

#### *Anatomical factors*

Neer refined the concept of the subacromial impingement syndrome and highlighted the role of the antero-inferior aspect of the acromion impinging on the rotator cuff tendons thereby causing rotator cuff pathology<sup>153</sup>. Bigliani et al<sup>19</sup> divided the shape of the acromion into (type I), curved (type II) or hooked (type III) and described a higher risk of impingement with a type II or III. The association between acromion shape and the severity of rotator cuff pathology is

well documented<sup>19,72,156</sup>. Morrison et al<sup>148</sup> found that patients with a type I acromion had better outcome after conservative treatment compared to patients with a type II or III acromion. Also large subacromial spurs, thickening or ossification of the attachment of the coracoacromial ligament are associated with bursal sided partial-thickness tears<sup>156</sup>. However, these ideas mainly focusing on anatomical variations have been questioned. Patients with anatomic abnormalities do not necessarily develop rotator cuff pathology,<sup>212</sup> and patients with rotator cuff pathology do not always have acromion abnormalities<sup>72</sup>. A study in rats showed that external compression of the rotator cuff tendons alone was insufficient to cause pathological changes unless overuse activity was added<sup>187</sup>. In summary, these results suggest that anatomical factors alone may not cause but can rather predispose to rotator cuff tendinopathy and are further supported by the fact that symptomatic rotator cuff disease is more commonly seen in the dominant shoulder<sup>214</sup>.

### *Biomechanical factors*

Biomechanical factors that can lead to extrinsic mechanical rotator cuff tendon compression include altered scapular and glenohumeral kinematics including several factors such as: increased thoracic spine flexion, a shortened pectoralis minor muscle, aberrant scapular muscle performance, aberrant rotator cuff muscle performance, and posterior shoulder tightness. Alteration or dysfunction of any of these factors may lead to a functional narrowing of the subacromial space, impinging the subacromial structures.

### **Altered scapular kinematics**

A reduction of scapular upward rotation, scapular external rotation, and posterior tilt during elevation has been identified in patients with subacromial impingement compared to healthy controls<sup>65,131,134,196</sup>. Scapular malpositioning may cause a narrowing of the subacromial space when the acromion fails to move away from the humeral head during elevation of the arm leading to compression of the subacromial structures<sup>131</sup>. To date three studies have attempted to link scapular kinematics alterations with reduction of the subacromial space<sup>109,185,186</sup>, but their results are conflicting. Further studies are needed to determine which scapular kinematic alterations are most related to changes in the subacromial space as well as the magnitude of change needed to affect this space<sup>181</sup>. Several mechanisms are described as being responsible for the alteration in scapular kinematics found in subacromial pain patients including aberrant scapular and rotator cuff muscle performance<sup>131</sup>, posterior capsule tightness<sup>21</sup>, shortening of the pectoralis minor muscle<sup>22,89</sup> and an increase in thoracic spine flexion<sup>131,208</sup>.

A shortened pectoralis minor muscle is associated with a decreased posterior tilt and increased internal scapular rotation during elevation<sup>22</sup>. This relationship has been linked to pain and functional limitations attributed to rotator cuff tendinopathies via scapular kinematic alterations<sup>65,131</sup>. However, to what extent the pectoralis muscle needs to be shortened to affect the size of the subacromial space remains unknown.

Increased thoracic flexion has been linked to alterations in subacromial space<sup>76</sup> and a decrease in scapular posterior tilt and upward rotation during glenohumeral elevation<sup>68,111</sup>. These alterations are the same as those demonstrated in patients with rotator cuff tendinopathy and may hypothetically cause compression of structures in the subacromial space during glenohumeral elevation.

### **Aberrant scapular muscle performance**

Several studies have reported aberrant scapular muscle activities in patients with subacromial pain<sup>43,45-47,60</sup> and some have directly linked it to scapular kinematics<sup>131</sup>. Decreased muscle performance of the serratus anterior has been reported when it comes to force output<sup>47</sup> muscle balance ratios<sup>46</sup> and decreased EMG activity<sup>131</sup>. Alteration in muscle balance ratio with a delay in muscle activation of the lower trapezius muscle<sup>46</sup>, an increased muscle activation of the upper trapezius<sup>43</sup> and alterations in maximal EMG activity in the lower trapezius has also been reported<sup>44,60,131</sup>. Whether the altered scapular kinematics is a cause or a consequence is not fully understood. Proposals for a causative effect include that the aberrant muscle performance results in decreased upward rotation and posterior tilt of the scapula, resulting in impingement of subacromial structures<sup>116</sup>.

### *Altered glenohumeral kinematics*

### **Aberrant rotator cuff muscle performance**

Decreased function in the rotator cuff muscles may contribute to subacromial pain as a result of increased superior migration of the humeral head<sup>95,144,149</sup>, causing extrinsic impingement or intrinsic breakdown of the rotator cuff<sup>34,179</sup>. Patients with rotator cuff tendinopathy have presented greater superior translation of the humeral head compared to healthy subjects<sup>82,215</sup>. Decreased rotator cuff muscle peak torques (isometric, concentric and eccentric) have been identified in patients with rotator cuff tendinopathy compared with asymptomatic controls.<sup>137,197</sup> Also, decreased EMG activity of the infraspinatus and subscapularis has been demonstrated during glenohumeral elevation between 30° and 60°<sup>60,169</sup>. Within this range of motion, the rotator cuff muscles normally provide an inferiorly

directed force to control the humeral translation<sup>81</sup>. In addition, a decreased co-activation of the subscapularis-infraspinatus and supraspinatus-infraspinatus muscles during initiation of elevation has been demonstrated in patients with subacromial impingement. The force couple function plays a vital role in opposing the superior translation force generated by the deltoid muscle early in elevation, when the tendency for the deltoid shearing is highest<sup>150</sup> (Figure 3).

### Posterior shoulder tightness

Posterior shoulder tightness has been demonstrated in patients with rotator cuff tendinopathy compared to healthy subjects<sup>151,198</sup>. This tightness could be the result of capsular tightness and/or muscular contracture. In a cadaver study a decreased posterior capsular length was directly linked to anterior-superior humeral translation during passive glenohumeral flexion<sup>84</sup>. This translation may decrease the subacromial space, enhancing the risk of impingement.

## Intrinsic factors involved in subacromial pain

The hypotheses regarding the intrinsic factors involved in rotator cuff tendinopathy presume that the demand on the tendon cells at some point exceeds the ability to repair structural deficits, which result in degeneration, tearing, and pain usually because of overuse and overload. Several factors are thought to be involved: age, vascularity, tendon biology, mechanical properties, and genetics<sup>181</sup>.

Degeneration has been found not only on the bursal side of the rotator cuff tendons but also on the articular side and intratendinous. These changes are unlikely to be caused by compression from the coracoacromial arch (external impingement). The degenerative changes identified are those of tendon thinning, disorientation of fibres, calcification, fatty infiltration and vascular proliferation<sup>86</sup>.

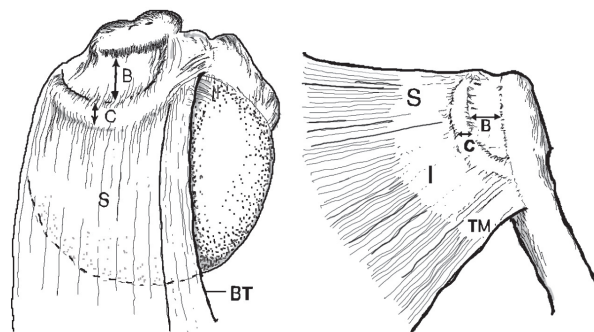
Underuse or stress shielding may play a role in the development of degeneration<sup>6</sup>. The articular-side fibres are reported to be subjected to less strain than the bursal-side fibres. For example, when moving the arm from adduction to full abduction the articular-side fibres of the supraspinatus become elongated while the bursal-side fibers become shortened<sup>92</sup>. This stress shielding may cause atrophic changes as a response to the lack of tensile load. Furthermore, the function of the rotator cable and crescent presented by Burkhart et al<sup>29</sup> (Figure 4), promotes stress shielding. Tendon fibres of the supraspinatus and infraspinatus form a thick bundle of fibers near the insertion of the rotator cuff on the humerus. This suggested rotator cable lies at 90° of the long axis of the supraspinatus fibres. Between the

cable and the humerus is the thinner crescent formed by weaker parts of the rotator cuff tendons. The muscle and tendon fibers medial to the cable may act through the cable to produce movement of the humerus and by doing so stress shield the rotator crescent. Because of the function of the rotator cable, the crescent is exposed to a reduced load which may lead to increased risk of degeneration and tearing<sup>29</sup>.

Age negatively affects tendon properties, and evidence suggests that elasticity decreases with age, as does the overall tensile strength within tendons<sup>181,200,211</sup>. The prevalence of tendon degeneration, often progressing into partial or full thickness tears, is reported to increase with age<sup>147,181,216</sup>. However, no consensus exists on whether the changes in tendons are primarily the result of aging or a consequence of the reduction in mechanical properties making the tendon more fragile<sup>181</sup>.

A deficient vascularisation of the rotator cuff tendons has also been proposed in the pathogenesis of subacromial pain. An increased vascular response has been demonstrated in patients with degenerative changes and small rotator cuff tears in patients with rotator cuff tendinopathies<sup>71,86</sup>. On the other hand, decreased vascularisation has been presented in patients in whom rotator cuff tendinopathies progress to complete tendon tears<sup>140</sup>. The exact role of vascularity in the intrinsic mechanism of rotator cuff tendinopathies is not clear, but it appears to be a factor that influences or that is influenced by the extent and duration of tendon pathology<sup>181</sup>.

Altogether, decreased function in the rotator cuff muscles arising from intrinsic failure may lead to a superior humeral migration with a reduction of the subacromial space, impinging the subacromial structures, but in interaction with extrinsic mechanisms<sup>128,181</sup>.



**Figure 4** Superior and posterior view of the rotator cable and crescent. B = the medio-lateral diameter of the rotator crescent. C = rotator cable. S = Supraspinatus. BT = Biceps tendon. I = Infraspinatus. TM = Teres minor. (Adapted from Burkhart 1993<sup>29</sup>)

## CURRENT CONCEPTS OF EXERCISE TREATMENT IN PATIENTS WITH SUBACROMIAL PAIN

It is a challenge to find the optimal treatment strategy for patients with subacromial pain because the cause is multifactorial. Exercise treatment has been suggested as the first alternative <sup>74,83,124</sup>. Several systematic reviews report that exercise treatment is effective in reducing pain and improving shoulder function in patients with subacromial pain <sup>74,83,123,124,145</sup>. Different exercise strategies have proved to be as effective as surgery at short- and long-term follow-ups <sup>25,61,78</sup> and manual therapy in addition to exercises is more effective than exercises alone <sup>11,37,182</sup>. The components included in these exercise programs vary considerably and are seldom described in detail <sup>113</sup>. Furthermore, the wide variety of exercise programs used and methodological concerns make it difficult to compare and conclude into evidence-based recommendations. Developing such an evidence-based, exercise program to recommend in clinical practice requires several steps. To start with there is a need for well-designed studies evaluating specific strategies described in detail considering content, dosage and progression to guide treatment for patients with subacromial pain <sup>83,113,123</sup>. In the literature endurance and strengthening exercises for the rotator cuff muscles and scapula stabilisers along with flexibility exercises focusing on the posterior shoulder and the pectoralis minor muscle are recommended <sup>42,63,124</sup>. The underlying idea is to improve stabilisation of the caput humeri into the glenoid fossa and normalise the altered scapular kinematics to avoid impingement and allow healing of the subacromial structures. Pre- and postoperative exercise treatments for patients with subacromial pain are based on the same concept of effect mechanisms. However, the postoperative exercise treatments are adjusted when it comes to dosage and progression because of a recent ASD surgery, taking the healing process into account.

### Scapular muscle function and exercise implications

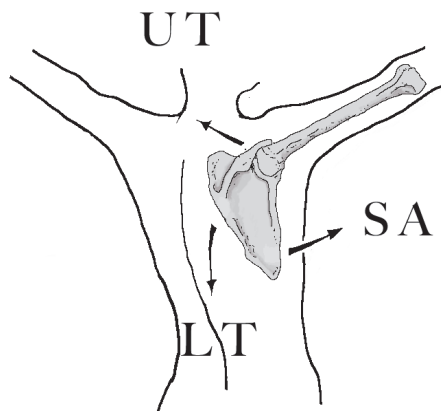
The serratus anterior muscle is together with the upper and lower trapezius muscles and rhomboid muscles considered to be the main stabilisers of the scapula <sup>118</sup>.

The serratus anterior muscle produces scapular upward rotation, posterior tilt, and external rotation while stabilising the medial border and inferior angle, preventing scapular winging <sup>132</sup> (Figure 5). The serratus anterior and pectoralis minor also protract the scapula when working together. In patients with subacromial pain, decreased serratus anterior activity has been demonstrated compared with healthy controls <sup>131</sup>. Cools et al have also reported decreased protraction strength in

patients with subacromial pain compared to healthy controls<sup>47</sup>. Exercises that have shown high to very high EMG activity of the serratus anterior are: push up plus, scapular protraction and retraction exercises, supine upward scapular punch, scaption above 120° in external rotation, and external and internal rotation in 90° of abduction<sup>44,66</sup>.

The main function of the upper portion of the trapezius muscle is scapular upward rotation and elevation for mid-portion scapular retraction and lower-portion depression. The inferio-medial fibres of the lower part of the trapezius also contribute to scapular external rotation and posterior tilt<sup>132</sup>. The lower portion of the trapezius also plays an important role in the last phase in elevation by pulling the upper third of the medial border of the scapula downwards, completing its upward rotation<sup>118</sup> (Figure 5). An abnormal recruitment timing pattern with a delay in muscle activation of the middle and lower trapezius muscle has been demonstrated in patients with subacromial pain compared to healthy controls<sup>46</sup>. Also, increased activity in the upper part of trapezius in relation to the middle and lower parts has been reported<sup>43</sup>. Therefore, exercises to restore scapular stability should emphasise high activity of the middle and lower trapezius in combination with minimal activity in the upper trapezius<sup>44</sup>. Such exercises include: side lying external rotation, low scapular row exercise, and prone extension and horizontal abduction<sup>44,66</sup>.

The rhomboid's function is scapular retraction, downward rotation and elevation. High EMG activity has been demonstrated in the rhomboids during high and low scapular row, standing external rotation in 0° and 90° of abduction, prone rowing and scaption above 120°<sup>66</sup>.



**Figure 5** Scapular rotators. Arrows show the direction of force generation. SA= Serratus Anterior. UT= Upper trapezius. LT= Lower trapezius.

## Rotator cuff muscle function and exercise implications

The rotator cuff muscles act as internal and external rotators of the glenohumeral joint<sup>101,112</sup>. Furthermore, they stabilise the joint by providing a medial and inferior force on the humeral head, keeping it central into the glenoid fossa during shoulder movements<sup>95,183</sup> (Figure 3). Exercises that show high EMG activity in the rotator cuff muscles are: internal and external rotation at 0° and 90° of abduction, side-lying external rotation, standing low scapular row and scaption in “full can” or “empty can”<sup>53,66,173</sup>. The ability to generate force while performing scaption with external rotation (full can) and internal rotation (empty can) has been demonstrated equivalent. However, several reasons remain for choosing the full can exercise. The activity of the deltoid is higher in the “empty can” exercise<sup>173</sup> and the internal rotation in this exercise may cause impingement because of decreased width of the subacromial space<sup>174</sup>. Also, the empty can exercise produces an increased scapular anterior tilt and internal rotation both associated with increased risk of impingement<sup>191</sup>. The side-lying external rotation exercise stimulates high activity of the rotator cuff together with high activity of the lower trapezius muscle and minimises activity in the upper part of the trapezius<sup>44</sup>. This effect is important because one of the purposes of the exercise treatment is to restore the aberrant activation of the scapular muscles.

### *Eccentric exercises of the rotator cuff muscles*

Because intrinsic mechanisms, causing degeneration of the rotator cuff tendons, have been shown to contribute to subacromial pain it is important to address this tendon degeneration when treating subacromial pain patients.

Eccentric exercises have yielded positive clinical results for pain and function<sup>158,184</sup> and in repairing tendon tissue with increased collagen synthesis<sup>125,158</sup> in the treatment of mid-portion Achilles tendinopathies. Because the histological changes seen in the Achilles tendon are similar to those seen in the supraspinatus tendon eccentric exercises might also be effective in patients with subacromial pain<sup>70,107</sup>.

Two pilot studies evaluating the effect of 12 weeks of eccentric exercises for rotator cuff tendinopathies have reported positive results with decreased pain and improved shoulder function<sup>18,106</sup>. Camargo et al<sup>31</sup> recently reported decreased pain and increased shoulder function after six weeks of isokinetic eccentric training of the rotator cuff. A recent randomised trial compared a traditional rotator cuff strengthening exercise program with a strategy that added an eccentric exercise for the supraspinatus muscle to the traditional exercises. The eccentric group showed a

15% higher gain in abduction strength but no significant group differences in shoulder function and pain were reported<sup>139</sup>. However, the study was underpowered to detect differences in shoulder function and pain. Overall the promising results of earlier studies endorse including eccentric exercises as a component in the exercise strategies used for treatment of these patients.

## Posterior shoulder stretching

Increasing the flexibility of the posterior soft tissue structures is recommended in the treatment of patients with subacromial pain<sup>44,63</sup>. The purpose is to restore the shoulder kinematics and to avoid impingement. A common symptom in patients with subacromial pain is decreased internal rotation<sup>41,84,198</sup>. The posterior shoulder stretch (cross body stretch) increases internal rotation<sup>40,141</sup> and a gain in internal rotation has also been correlated with increased shoulder function<sup>142</sup>. Furthermore, increased internal rotation and acromiohumeral distance develop after performing stretching of the posterior capsule for six weeks<sup>138</sup>. In addition a manual technique with dorsal and caudal gliding has been suggested effective in increasing internal rotation in patients with subacromial impingement<sup>40</sup>. However, definitive evidence supporting the use of these techniques is lacking, and this treatment is based mainly on clinical findings.

## SURGICAL INTERVENTION AND POSTOPERATIVE TREATMENT FOR PATIENT WITH SUBACROMIAL PAIN

Clinical guidelines in Sweden suggest that patients who have had subacromial pain for at least six months and failed non-surgical treatment at three to six months should be considered for surgery. The most used technique is ASD. During this procedure, the surgeon removes part of the subacromial bursa, performs an acromion bone resection, and resects the attachment for the coraco-acromial ligament<sup>64</sup>.

Coghlan et al concluded that little evidence supports or refutes the effect of surgery in patients with subacromial pain<sup>36</sup>. Two studies<sup>25,78</sup> have compared ASD surgery with a standardised exercise program described by Böhmer et al for patients with subacromial pain<sup>20</sup>. No significant differences between the two groups were reported at the one and two-and-a-half-year follow-ups<sup>25,78</sup>. Regardless, the number of ASD procedures has increased substantially in recent

years in Sweden (figures from the Swedish board of Health and Welfare 2013) and also in the USA <sup>206</sup>.

Studies are lacking to date that present predictors of a poor result from exercise treatment indicating the need for surgery. Even though the need for surgery in these patients is questioned, several studies have reported excellent success rates after ASD with reduced pain and increased shoulder function <sup>64,100,136,155,168</sup>. However, postoperative exercise treatment is seldom evaluated or described. At the time study A was designed, the usual practice was home-based range of motion exercises. Today, rehabilitation after surgery with graded strengthening exercises is common. Nevertheless, evaluation of different postoperative rehabilitation programs is scarce. General programs have been described in the literature recommending active assisted exercises directly after surgery and then gradual loading and strengthening of the rotator cuff muscles and scapula stabilisers <sup>99</sup>. Klintberg et al compared two programs after ASD: early activation versus a more protective regime. No differences were found between the two groups and the authors concluded that the more progressive active program was safe to implement <sup>94</sup>. Andersen et al <sup>8</sup> compared home training versus physical therapist (PT) supervised exercises after ASD surgery and concluded that home exercises are as effective as supervised exercises. However, they did not describe the exercises, dosage and progression in their study making it difficult to interpret and implement their results in clinical practice.

Because the intention of a surgical procedure with ASD is to remove the presumed structural pathology and the aim of the exercise program is to restore shoulder function and prevent recurrence, both aspects are considered important for a successful outcome. Further studies evaluating the effect of different postoperative exercise treatments are needed to be able to recommend one exercise treatment or another.

## **ASSESSMENT OF FUNCTIONING IN PATIENTS WITH SUBACROMIAL PAIN**

Patients with subacromial pain have limitations such as loss of muscle endurance and strength <sup>137</sup> and reduction in range of motion is observed, particularly in internal rotation <sup>41,198</sup>. These limitations are often associated with limitations in leisure time activities and difficulties working with weights above their heads as well as being unable to work full time <sup>35</sup>. Disturbed sleep and a reduction in quality of life are also reported <sup>35,137</sup>. Östör et al <sup>161</sup> presented baseline values of shoulder function, using both shoulder-specific and generic instruments in patients with

shoulder pain, mainly with the diagnosis of rotator cuff tendinopathy (85%). They reported a significantly reduced shoulder function, increased pain intensity and reduction in health-related quality of life compared to normative data.

Functioning is a broad term and refers to body structures and functions as well as activity and participation according to the international classification of functioning disability and health (ICF) <sup>213</sup>. To assess all of these aspects, both generic and disease-specific instruments are accessible. Several disease-specific instruments measuring shoulder function and pain are available and used in clinical practice <sup>9</sup> but there is no consensus on a gold-standard instrument for measuring shoulder function and pain in patients with subacromial pain. However, the Constant-Murley score (CM score) is recommended by the European Society for Surgery of the Shoulder and Elbow for use in all research involving patients with shoulder disorders <sup>38</sup>. This specific shoulder instrument focuses on body structures and body functions while other instruments frequently used in shoulder research such as the Disability of the Arm Shoulder and Hand (DASH) score focus more on aspects of activity and participation. In addition health-related quality of life (HRQL) is affected in patients with subacromial pain. Piitulainen et al <sup>164</sup> reported that patients with rotator cuff disease having the most difficulties in shoulder function also had the lowest HRQL. Therefore a combination of shoulder specific and generic instruments is recommended in the evaluation of patients with shoulder pain to obtain an overall picture of the patient's individual situation <sup>13,14,59,164</sup>.

Instruments that are used for evaluating treatment effects need to be sensitive to detect changes. Furthermore, the relevance of an observed change needs to be interpreted in the light of clinical importance because the statistical significance is partially a matter of sample size <sup>57</sup>. In large randomised clinical trials even small changes may be statistically significant, but the interesting question is, are these changes of clinical relevance for the patients? <sup>56</sup>. One way of evaluating and interpreting changes in scores is to use the minimal important change (MIC) which relates the change to what the patients and clinicians think is important. It is defined as “the smallest change in score in the construct to be measured which patients perceive as important” <sup>56</sup>. Still many outcome measures for assessment of shoulder function and pain lack this reference value.

## THE RATIONALE OF THE THESIS

There is a need of standardised pre- and postoperative exercise programs based on the latest evidence with a thorough description of content, dosage and progression to guide the treatment of patients with subacromial pain in clinical practice.

Surgical treatment with ASD has increased substantially in Sweden in recent years (Figures from the Swedish board of Health and Welfare 2013) as well as in the USA<sup>206</sup>, even though studies comparing exercise treatment with surgery report equally positive results at the one and two-and-a-half-year follow-ups<sup>25,78</sup>. If a standardised exercise program based on latest evidence designed to enable implementation into clinical practice could be proved effective, the need for surgery might decrease.

Factors that predict outcome and treatment modifiers classifying a possible “responder” from a “non-responder” to exercise treatment need to be identified to further decide on the best treatment alternative for subgroups of patients with subacromial pain.

The intention of the surgical procedure with ASD is to remove the presumed structural pathology, while the aim of the exercise program is to restore shoulder function and to prevent recurrence. Therefore, both are important but how the postoperative exercise strategy should be performed is less evaluated and needs to be further studied because it is considered important for the outcome.

The minimal important change of the CM score has not been reported. To interpret changes in outcome measures for shoulder function and pain as a result of exercise treatment, the importance of the change for the patient needs to be considered. This value would add useful knowledge and ease the interpretation of the relevance of the change in research and clinical practice.

# AIMS OF THE THESIS

## GENERAL AIM

The overall aim of this thesis was to evaluate the efficacy of pre- and postoperative exercise strategies on shoulder function and how the preoperative strategy affects the need for surgery in patients with long-standing subacromial pain.

## SPECIFIC AIMS

- to evaluate and compare the efficacy of two postoperative exercise programs regarding shoulder function, pain and health-related quality of life
- to evaluate the efficacy of a specific exercise strategy regarding shoulder function, pain, health-related quality of life and the need for surgery
- to analyse if the rotator cuff status, baseline shoulder function and radiological findings influenced the choice of surgery
- to develop recommendations concerning minimal important changes in the Constant-Murley score for patients with long-standing subacromial pain

# MATERIALS AND METHODS

## DESIGN

The thesis is based on two studies:

**Study A - a clinical randomised study** that evaluated and compared the efficacy of two postoperative exercise programs (*paper I*).

**Study B - a clinical randomised study** that evaluated the efficacy of a specific exercise strategy and the need for surgery (*papers II-IV*).

## OVERVIEW OF THE STUDIES

### Study A

Patients with long-standing subacromial pain who had undergone ASD surgery were randomised to either physical therapist (PT)-supervised exercise treatment including progressive strength-endurance exercises for the rotator cuff and scapula stabilisers (PT-group) or to home-based movement exercises (H-group), the current practice in participating clinics at the time of the study design. Shoulder function, pain and health-related quality of life were evaluated after 1 week and, 1, 2, 3 and 6 months. These results are presented in **paper I**.

### Study B

Patients with long-standing subacromial pain on the waiting list for surgery were randomised to either a specific exercise strategy including strength-endurance exercises for the rotator cuff and scapula stabilisers (specific exercise group) or to control exercises including mobility exercises for the neck and shoulders (control exercise group). Shoulder function, pain, health-related quality of life and the patient's own choice about surgery were assessed after completing the interventions at three months and 12 months after inclusion. The three month results are presented in **paper II**. Associations between rotator cuff status, baseline

shoulder function, radiological findings and the patient's choice of surgery (yes/no) were analysed with logistic regressions. These results along with the 12 month follow-up results are presented in **paper III**.

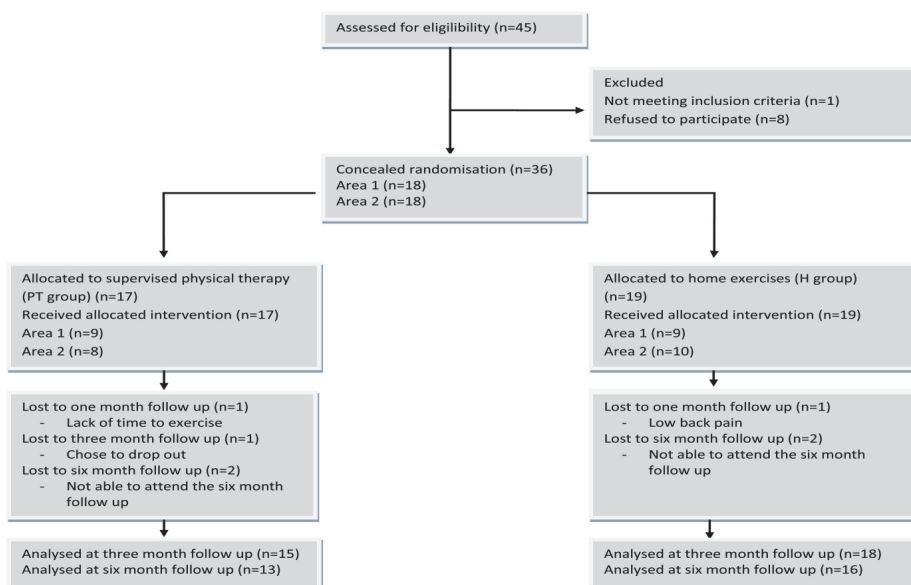
A visual anchor-based MIC distribution method was used to determine the MIC in the primary outcome in this study (CM score). Those results are presented in **paper IV**.

## **PATIENTS**

The patient population were those with long-standing subacromial pain (>6 months duration) who were on the waiting list for surgery (study B) and patients operated with ASD (study A). Before entering the studies all patients had received verbal and written information about the study and had given their written informed consent. The regional board of ethics in Linköping approved the studies (study A dnr: 02-37 and study B dnr: M124-07).

### **Study A**

Patients were recruited between 2003 and 2006 from the orthopaedic departments of a university hospital and a local hospital located in two geographical areas of Sweden. Patients who were scheduled for ASD, ranging in age from 30 to 65 years, were recruited. An orthopedic surgeon set the following standardised criteria for surgery: a positive impingement test by Neer (local anaesthetic, 10 mL prilocaine in the subacromial bursa), a minimum of six months duration of pain, no results or unsatisfactory results after at least three months of physical therapy, and typical pain location (C5 dermatome). Inclusion and exclusion criteria are presented in Table 1 and 2. Thirty-six patients were randomly assigned using a concealed allocation procedure; 33 fulfilled the exercise treatment, 29 of whom completed all required follow-ups. Two patients dropped out because of lack of time, and one had low back pain and could not continue after four weeks. Another four patients did not attend the six-month follow-up, and gave no reasons (Figure 6).



**Figure 6** Flow chart of the participants in study A (paper I).

## Study B

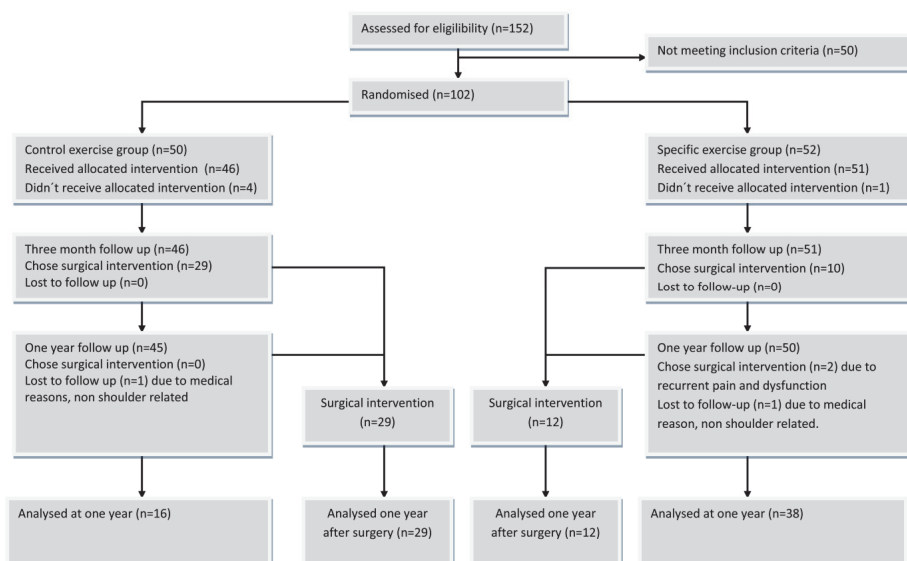
Patients, who were scheduled for ASD surgery ranging in ages from 30 to 65 years, were recruited between 2008 and 2010 from the orthopedic department of a university hospital in Sweden. An orthopedic surgeon set the following standardised criteria for surgery: a positive impingement test by Neer (injection of 1 mL of 20mg/mL triamcinolone mixed with 6 mL of 10 mg/mL of 10mg/mL mepivacain), a minimum of six months duration of pain, no results or unsatisfactory results after at least three months of physical therapy including exercise treatment, and typical pain location (C5 dermatome). Inclusion and exclusion criteria are presented in Table 1 and 2. A total of 102 met the inclusion criteria and were randomly assigned using a concealed allocation procedure. Three weeks after inclusion, five patients were excluded: two patients developed a frozen shoulder diagnosed by the PT three weeks after inclusion and three patients changed their mind about participating and declined participation at the first PT visit because of a lack of time (Figure 7). Ninety seven patients were compliant until the three-month follow-up and included in the analysis. Two patients, one in each group, could not attend the one-year follow-up because of medical reasons, non-shoulder related.

**Table 1** Inclusion criteria for studies A and B. Differences shown in italics.

Study A	Study B
<ul style="list-style-type: none"> <li>• Age 30-65 years</li> <li>• Duration of pain &gt;6 months</li> <li>• Unsatisfactory results &gt; 3 months of conservative treatment</li> <li>• <i>ASD surgery</i></li> </ul> <p>- Positive impingement test by Neer</p> <p>- At least 3 positive test results of the following:</p> <ul style="list-style-type: none"> <li>• Neer impingement sign</li> <li>• Hawkins Kennedy impingement sign</li> <li>• Jobe supraspinatus test</li> <li>• <i>Painful arch</i></li> </ul>	<ul style="list-style-type: none"> <li>• Age 30-65 years</li> <li>• Duration of pain &gt;6 months</li> <li>• Unsatisfactory results &gt; 3 months of conservative treatment</li> <li>• <i>Scheduled for ASD</i></li> </ul> <p>- Positive impingement test by Neer</p> <p>- At least 3 positive test results of the following:</p> <ul style="list-style-type: none"> <li>• Neer impingement sign</li> <li>• Hawkins Kennedy impingement sign</li> <li>• Jobe supraspinatus test</li> <li>• <i>Patte's manoeuvre</i></li> </ul>

**Table 2** Exclusion criteria for studies A and B. Differences shown in italics.

Study A	Study B
<ul style="list-style-type: none"> <li>• <b>Clinically verified:</b></li> </ul> <ul style="list-style-type: none"> <li>- shoulder instability</li> <li>- symptoms from the cervical spine</li> <li>- fibromyalgia</li> <li>- frozen shoulder</li> <li>- suspected polyarthritis</li> <li>- rheumatoid arthritis</li> <li>- <i>general neck and shoulder pain</i></li> </ul> <ul style="list-style-type: none"> <li>• <b>Radiologically verified:</b></li> </ul> <ul style="list-style-type: none"> <li>- malignancies</li> <li>- osteoarthritis of the glenohumeral joint</li> <li>- previous fracture or surgery in the shoulder complex on the affected side</li> </ul>	<ul style="list-style-type: none"> <li>• <b>Clinically verified:</b></li> </ul> <ul style="list-style-type: none"> <li>- shoulder instability</li> <li>- symptoms from the cervical spine</li> <li>- fibromyalgia</li> <li>- frozen shoulder</li> <li>- suspected polyarthritis</li> <li>- rheumatoid arthritis</li> <li>- <i>pseudoparalysis</i></li> <li>- <i>received a corticosteroid injection for the last three months for the current problem</i></li> </ul> <ul style="list-style-type: none"> <li>• <b>Radiologically verified:</b></li> </ul> <ul style="list-style-type: none"> <li>- malignancies</li> <li>- osteoarthritis of the glenohumeral joint</li> <li>- previous fracture or surgery in the shoulder complex on the affected side</li> <li>- <i>os acromiale</i></li> <li>- <i>acromioclavicular arthritis</i></li> </ul>



**Figure 7** Flow chart of participants in study B (paper II, III)

## CLINICAL ASSESSMENT

A standardised questionnaire was used to collect background data and expectations of treatment effect were requested (choices were: completely restored, quite improved, and not improved but some relief of the symptoms or no expectations of being restored). Furthermore, patients rated their work load on a four-item scale dichotomised into two categories: light to moderate (not working with arms above the shoulders) and moderate to heavy (working with arms above the shoulders). All questions and outcome measures used in studies A and B are presented in Table 3 (page 35).

All patients had a radiological examination to secure inclusion. In study B also signs of subacromial calcification and subacromial degeneration were recorded. Subacromial degeneration was considered present with one or more than one of the following findings; sclerosis, cysts and spur formations on the greater humeral tuberosity and/or under the acromion. In study B, ultrasound also was performed between inclusion and the three-month follow-up to investigate the status of the rotator cuff (intact, partial-tear, or full-thickness tear). A partial tear was defined as a localised absence of the tendon as seen in two orthogonal imaging planes as a mixed hyperechogenic and hypoechogenic region on the bursal side, joint side, or in the intratendinous region that did not penetrate the entire tendon. A full

thickness tear was defined as non-visualisation of the tendon throughout its thickness.

## Clinical tests

Clinical tests along with the information from the standardised questionnaire were used to clinically diagnose subacromial pain in patients included in studies A and B. The tests used can broadly be classified as impingement tests and rotator cuff strength/provocation tests. Impingement tests are reported to reproduce pain by reducing the subacromial space compressing the greater tuberosity against the acromion impinging the subacromial structures<sup>102,152,200</sup>. In addition, the rotator cuff strength/provocation tests that apply tension to the rotator cuff tendons are used to assess the function of the individual rotator cuff tendons, and the response could be either weakness or pain or a combination of both. These clinical tests are reported to be sensitive but less specific; and therefore combining the results of several tests is recommended<sup>146,162</sup>. Michener et al<sup>146</sup> reported that three or more positive tests out of five (those presented below) can confirm the diagnosis of subacromial pain while fewer than three positive out of five rules out subacromial pain.

The Neer impingement test was compulsory for inclusion in both studies. Further, three positive tests out of four was used as a criterion in study A (not including the Patte's test) and three out of four (not including painful arch) in study B to confirm the diagnosis of subacromial pain.

### *Neer impingement sign*



**Figure 8** *Neer impingement sign*

To elicit this sign, the examiner internally rotates the sitting patient's shoulder and then forcibly elevates the arm while scapular movement is prevented by the other hand, which applies a downward force at the acromion<sup>152</sup>. This test is considered positive if pain is present during the procedure. A sensitivity of 72–89% and a specificity of 30–60% have been reported<sup>15,90</sup>.

### *Neer impingement test*

The Neer impingement test is positive for having subacromial pain if patients having a positive Neer impingement sign become free from symptoms after receiving an injection of local anaesthetic in the subacromial space<sup>152</sup>. Pain relief with injection of local anaesthetic in combination with steroids preoperatively has proved to be a prognostic factor for a successful outcome after ASD surgery<sup>129</sup>. In study B, a combination of local anaesthetics and steroids was used. This test has been reported to have a high sensitivity of 75–89% but a low specificity of 30–40%<sup>15</sup>.

### *Hawkins-Kennedy impingement test*



The examiner positions the patient's arm at approximately 90° of forward flexion and forces the arm into internal rotation while the other hand fixates the scapula by a depressive force<sup>87</sup>. This test is considered positive if pain is present during the procedure. The sensitivity has been reported to be high at 80–92% while the specificity is lower at 25–56%<sup>15,90</sup>.

**Figure 9** *Hawkins-Kennedy impingement test*

### *Painful arc of abduction*

The patient performs an active abduction with the arm externally rotated. The test is positive if pain is present in the range between 60–120° of abduction<sup>114</sup>. This test has been reported to have a sensitivity of 75% and a specificity of 67%<sup>146</sup>.

*Jobe supraspinatus test*

The examiner elevates the shoulder to 90° in the scapular plane and then places the shoulder in internal rotation (thumb facing downward). The patient is instructed to maintain this position while the examiner applies a downward force aiming to



**Figure 10** *Jobe supraspinatus test*

break through the patient's resistance. The test is considered positive if weakness or pain appears<sup>103</sup>. A sensitivity of 77–95% and a specificity of 65–68% have been reported when weakness is used to define a positive test. When pain exacerbation was used to define a positive test, the sensitivity (66%) and the specificity (55%) were lower<sup>15</sup>.

*Patte's test (infraspinatus and teres minor)*

The examiner places the patient's arm in 90° of flexion in the glenohumeral joint with the elbow in 90° of flexion and internally rotates the arm by lowering the forearm. The examiner supports the patient's arm at the elbow and fixates the



**Figure 11** *Patte's test (infraspinatus and teres minor)*

scapula by a depressive force. Then the patient is instructed to perform external rotation while the examiner applies a downward force at the wrist, resisting the movement. The patient is instructed to hold against the resistance. The test is positive if pain or weakness is reproduced<sup>126</sup>. A sensitivity of 76–79% and a specificity of 57–67% have been reported<sup>15</sup>.

## OUTCOME MEASURES

### Constant–Murley score

The Constant-Murley (CM) score (Appendix 1) was used as the primary outcome for evaluation of shoulder function and pain in studies A and B. This score is a shoulder-specific assessment tool containing objective measures (range of movement and shoulder strength) and subjective measures (activity of daily living and pain). The maximum is 100 points and indicates excellent shoulder function.

The CM score has four subscales: pain (15 points; p); activities of daily living (20p); range of motion (40p); and strength (25p). Questions and measurements were standardised according to the original description by Constant and Murley and further developed and presented in a later publication<sup>38,39</sup>. Strength in abduction was measured with a handheld myometer (Nottingham Mecmesin Myometer<sup>®</sup>) with the patient in a standing position with the arm in the scapular plane and 90° of elevation, with hand and forearm pronated. The measurement should be pain-free and the highest value out of three is used. This procedure, using the handheld myometer when measuring strength instead of the spring balance used in the original version, has been validated by Johansson et al<sup>104</sup>. The intra-tester reliability of the CM score has been reported to be high while the inter-tester reliability is weaker<sup>175,177</sup>. Responsiveness to treatment in patients with subacromial pain has been shown to be excellent in the CM score<sup>9</sup>. Construct convergent validity has been established between CM score and other shoulder specific questionnaires such as the Western Ontario Rotator Cuff index and Oxford shoulder questionnaire and strong correlations (>0.70) have been reported<sup>177</sup>. MIC values in the CM score are presented in paper IV and established a range of 17-24 points.

### Disability of the Arm, Shoulder and Hand

The Disability of the Arm, Shoulder and Hand (DASH) score, used in studies A and B, is a self-administered region specific outcome instrument assessing symptoms and function of the entire upper extremity, developed by the American Academy of Orthopedic Surgeons<sup>93</sup>. The main instrument consists of a 30-item disability/symptom scale asking about the degree of difficulty in performing different physical activities (21 items) and the severity of the pain symptoms, such as activity-related pain, tingling, weakness, and stiffness (5 items), as well as the effect of these problems on social activities, work, and sleep, and psychological

impact (4 items). Each item has five response alternatives from “no difficulty” to “unable to perform activity”. The score for all items is then used to calculate a scale score ranging from 0 (no disability) to 100 (severe disability). High correlation with shoulder-specific scores as well with generic instruments such as the EQ-5D has been reported<sup>9,10,12</sup>. MIC has been established at 10 points in patients with shoulder disorders<sup>180</sup>.

## Pain perception

The visual analogue scale (VAS; 0–100) first presented by Huskisson<sup>98</sup> was used in both studies to assess the patient’s perceived pain intensity at rest, during arm activity and at night during the previous 24 hours at each follow-up. An ungraded 100 mm horizontal line with vertical bars at each end, with no pain at one end and with worst imaginable pain at the other, was presented for the patients. The patients moved a vertical marker on a plastic VAS ruler to the point on the horizontal line that represented their perceived pain. A review evaluating different aspects of reliability and validity in three different pain rating scales (VAS, pain rating scale, the verbal rating scale) concluded that all three are reliable and valid and appropriate for use in clinical practice. Further, the VAS was statistically the most robust because it can present ratio interval data. However, VAS was also considered as the most difficult of the three scales to use in clinical practice and has the highest failure rate<sup>210</sup>. Responsiveness has been reported to be good using the VAS in patients with long-standing pain<sup>135</sup>. The MIC for VAS measurements in patients treated with rotator cuff disease has been reported to be 14 mm<sup>190</sup>. Farrar et al<sup>67</sup> defined a clinically important change in pain as “much improved” or “very much improved” using the Global Rating Scale, and that related to a 30% reduction in pain.

## Health related quality of life

The Euroqol (EQ-5D)<sup>1,167</sup> was used in studies A and B for evaluation of health-related quality of life. The EQ-5D is a self-administered questionnaire that includes two parts. The first part contains five items covering five dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. These dimensions can be graded on three levels: 1, no problems; 2, moderate problems; and 3, extreme problems. The combinations of the levelled responses to the five dimensions are then transformed into a five-item index score defining the patient’s health state. There were 243 possible health states and each had a preference value attached to it with values that ranged from -0.57 to 1.0 where 1.0 was optimal

health state. The second part consists of a VAS designed as a thermometer valuing the current health state, measured on a 20-cm 10-point interval scale. The worst imaginable health state is scored as 0 and best imaginable health state scored as 100. Psychometric properties such as construct validity, criterion validity, face validity, and test-retest reliability have been tested and found acceptable in patients with musculoskeletal disorders<sup>97,167</sup>.

## Hospital Anxiety and Depression Scale

The Hospital Anxiety and Depression (HAD) scale was used in study B as a screening tool for mental distress because anxiety and depression symptoms have been reported to influence the outcome after treatment in patients with shoulder pain<sup>23</sup>. The HAD is a self-administered instrument with a total of 14 statements, seven about anxiety and seven about depression. The patients then rate their experience in the context of these statements by choosing one of four graded alternatives. The different graded alternatives to each question are then transformed into a score range, and cut-off values are presented for having no symptoms (0–6 points), mild symptoms (7–10 points), or likely having anxiety or a depression diagnosis (>10 points)<sup>217</sup>. The HAD has been reported to be valid and reliable in detecting anxiety and depression in patients visiting a hospital outpatient clinic<sup>217</sup>.

## Patient Global Change Questionnaire

A patient self-report global change questionnaire, the patient's global impression of change (PGIC)<sup>96</sup> was used in study B to evaluate the degree of change arising from treatment according to the patient's perspective. The question being asked was, "Since the beginning of the treatment, how would you describe your change (if any) in activity limitations, symptoms, and overall quality of life related to your painful shoulder condition?" The patients registered the change on a five-point numerical scale: 1, recovered; 2, large improvement; 3, small improvement; 4, unchanged; or 5, worse. Global assessment scales are commonly used but have been questioned because they seldom are sufficiently investigated when it comes to validity and reliability<sup>51,108</sup>. However, global assessment scales have proved to be sensitive to change in several patient populations<sup>79</sup> and to provide clinically relevant information about the treatment effect in an individual patient<sup>96</sup>. In paper IV, the MIC in the CM score was determined, and the PGIC was used as an external criterion (anchor) and compared to the patients' individual changes in the CM score.

**Table 3** Overview of questions, outcome measures and screening tools used in this thesis

Variable	Studies
Age	A,B
Sex	A,B
Dominant side affected	A,B
Affected side left/right	A,B
Duration of symptoms	A,B
Pain location	A,B
Sick leave at start	A,B
Sick leave after treatment	A
Drugs	B
Earlier treatment	B
Corticosteroid injections yes/no	B
Occupation	A,B
Work load (1-4)	A,B
Expectation of treatment (1-4)	B
CM score	A,B
DASH score	A,B
Pain intensity (VAS mm)	A,B
EQ-5D	A,B
EQ-VAS	B
HAD	B
PGIC	B
Yes or no to surgery	B
Ultrasound (rotator cuff status)	B
Radiographic	A,B

*CM score=Constant Murley score, DASH=Disabilities of the Arm Shoulder and Hand, VAS=Visual Analogue Scale, EQ-5D=Euroqol, HAD=Hospital Anxiety and Depression scale, PGIC=Patients Global Impression of Change.*

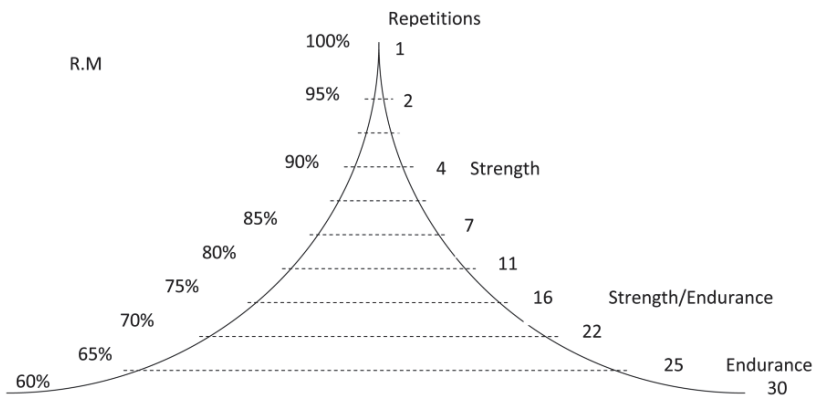
## INTERVENTIONS

All patients in study B received a subacromial corticosteroid injection from the orthopaedic surgeon at the inclusion visit, which is in line with usual procedure. The exercises were introduced two weeks after the injection. In studies A and B, all patients in both groups received thorough information about their shoulder condition, ergonomic practices, and correction of their posture.

## Exercise strategies

### *Specific exercise strategy*

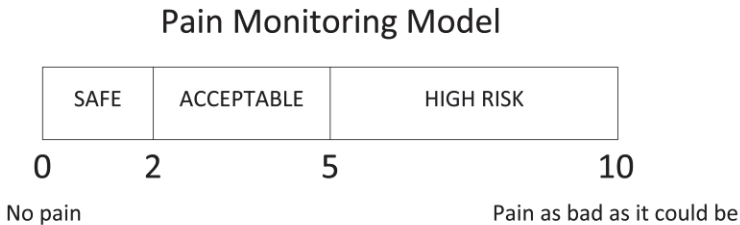
The specific exercise strategy used in study B focused on strength–endurance with eccentric exercises for the rotator cuff muscles and concentric/eccentric exercises for the scapula stabilisers and a posterior shoulder stretch (Appendix 2). The program was recommended to be performed twice daily for the first eight weeks and after that once a day for another four weeks. The patients were offered a total of six to seven PT visits during these 12 weeks. The program consisted of a total of six exercises, and progression was made with increased load and increases in exercise complexity. The exercises were standardised and the same for all patients but the load was individually adjusted. To find the proper load the Oddvar Holten diagram was used<sup>75</sup> (Figure 12). A resistance was selected at which the patient could barely perform 20 repetitions. This resistance was used to fulfil 15 repetitions in three sets. The pain monitoring model was used to control for pain (Figure 13)<sup>194</sup>. The patients were not to exceed 5 on a scale between 0–10. If they did, the resistance was decreased. Manual mobilisation including stretching of the pectoralis minor<sup>42</sup> and a manual technique with dorsal gliding of caput humeri<sup>40</sup> was additionally performed if the patient had a limited range of motion or flexibility in the shoulder. The progression of exercises and load was done during these supervised sessions. An exercise diary was used to monitor adherence.



**Figure 12** *Oddvar Holten diagram*<sup>75</sup>. R.M = *Repetition maximum*

### *Pain monitoring model*

The pain monitoring model was first described by Thomeé<sup>194</sup> who used this model to control pain during exercises in patients with patella-femoral pain syndrome. Patients rated their pain experience just after performing the exercise on a VAS from 0 (no pain) to 10 (pain as bad as it could be) with safe, acceptable, and high-risk pain zones indicated (Figure 13). This model was used to control pain during the exercises in study B. Patients were allowed to experience VAS pain levels of 5 while performing an exercise. If this level was exceeded the load was decreased. Pain after the exercise program was completed was tolerated up to a VAS level of 5, but all pain triggered by the exercises was to have subsided within the next 12 hours. The pain monitoring model has been successfully used in areas of pain monitoring in the treatment of Achilles tendinopathy and rotator cuff tendinopathies<sup>18,139,184</sup>.



**Figure 13** *Pain monitoring model (Thomee 1997<sup>194</sup>)*

### *Range of motion exercises*

The control exercise program (Appendix 3) used in study B consisted of six non-specific range of motion exercises with no progression aiming at restoring shoulder motion. Each movement exercise was repeated 10 times, and each stretching exercise 30 seconds times three, twice a day for 12 weeks. Support and guidance for the exercises was achieved at the supervised PT session (a total of six to seven PT visits were offered during 12 weeks). The home-based movement exercise program used in study A was the current practice in participating clinics at the time of the study design. This program consisted of six exercises with active and active supported exercises to restore shoulder motion (Appendix 4). Each exercise was repeated 10 times and performed at home twice a day for 12 weeks without progression and supervision.

### *Postoperative exercise program*

In study A, the PT supervised strength-endurance exercise program consisted of four phases after the first week of home exercises with pendulum and active supportive and active movements (Appendix 5). This program was also performed post operatively by the patients in study B who chose surgery. The program focused on strength–endurance exercises for the rotator cuff muscles and the scapula stabilisers. The patients were instructed to perform the program twice a day at home and under PT supervision with progression through the phases twice a week for eight weeks. During the last four weeks only home exercises were performed. Each exercise was to be repeated 10–15 times in three sets.

In **Phase 1** (*week 2*), the patients focused on correction of posture and active movement exercises of the shoulder to restore shoulder motion.

In **Phase 2** (*week 3*), isometric strengthening exercises of the rotator cuff muscles and scapula stabilisers with the shoulder in a neutral position were performed, as was dynamic external rotation while lying on the side through the range of motion against gravity.

In **Phase 3** (*weeks 4 and 5*), dynamic strength–endurance exercises of the rotator cuff muscles and the scapula stabilisers (eccentric as well as concentric) with the shoulder in a neutral position, using rubber bands and weights, was conducted. In addition, movement exercises in full range of motion were performed

In **Phase 4** (*weeks 6–8*), dynamic strength-endurance of the rotator cuff and the scapular muscles continued but was performed in different positions (shoulder in 45° of abduction and progression with 90° of abduction), while gradually increasing the load. At the end of this phase (*week 9–12*) progression of exercises was conducted with increased load and more complex exercises individually designed for patients, considering work situation and leisure time activities.

## VISUAL ANCHOR-BASED MIC DISTRIBUTION METHOD (PAPER IV)

The analysis in paper IV was based on 93 patients because 2 of the 97 patients included in study B lacked complete data on the CM change score and the PGIC. Furthermore, two patients were excluded because of deterioration, which is in line with earlier studies<sup>160,165</sup>. The anchor-based distribution method was used to determine the MIC, which integrates anchor- and distribution-based approaches. The PGIC was used as an anchor. This scale was dichotomized, and patients who indicated that they were unchanged or had a small improvement were labelled as “not importantly changed”, and patients who indicated that they had a large

improvement or that they were recovered were labeled “importantly improved”. The individual changes in the CM score (baseline to three months) was compared to the PGIC categories in all the included patients. This method is further described under data analysis (page 41).

## STATISTICAL METHODS

### *Paper I*

To compare independent variables between the two groups at baseline, the Student’s *t*-test was used for continuous data and the  $\chi^2$  test for categorical data. Changes in continuous dependent variables over time were assessed by repeated measures analysis of variance (ANOVA). Four separate analyses were performed (CM score, the DASH score, the EQ-5D, and the VAS); the within-subjects factor was time and the between-subject factor was treatment for all four analysis. Paired *t*-tests with Bonferroni correction were used for post-hoc analysis. Statistical significance was defined as  $p < 0.05$  for all tests. A change of 10 points in the CM score as previously suggested was considered to be clinically relevant between groups<sup>8</sup>.

### *Paper II*

A sample size calculation was performed based on the CM score. The calculation estimated that a total of 82 patients would be required to detect a 10 point mean group difference with a variability of 16 points ( $\beta = 0.80$ ,  $\alpha = 0.05$  two-sided). To compensate for drop outs an additional 20 patients were recruited. To compare independent variables between the two groups at baseline, the Student’s *t*-test was used for continuous data and the  $\chi^2$  test for categorical data. One-way ANOVA was used for group differences at the three-month follow-up in primary and secondary outcomes using continuous scales; the dependent variable was adjustment for baseline levels of outcomes using group differences in mean change from baseline to the three-month follow-up. The patient’s global impression of change in symptoms because of treatment was dichotomised into large improvement (large improvement or recovered) or unimproved (slightly recovered, unchanged, or worse). Pearson’s  $\chi^2$  test was used to compare changes between groups, as well as the proportion of patients who still wanted or thought they needed surgery in the respective groups at the three-month follow-up. We compared the percentage of successful outcomes between groups by calculating the odds ratios and their 95% confidence intervals (CIs) with logistic regression.

### *Paper III*

The patients were the same as in paper II. Parametric and non-parametric tests were used for comparison of baseline variables. For within-group comparisons, paired *t*-tests were used to calculate differences in total scores (primary and secondary outcome measures) from the three-month to one-year follow-ups. The number of patients choosing surgery in each group was calculated and compared with Pearson's  $\chi^2$  test. The proportions of radiologic and ultrasound findings were examined using Fisher's exact test. Any associations among radiologic and ultrasound findings, baseline CM score, and the patient's choice of surgery (yes/no) were analysed with logistic regressions. In the logistic regression analysis, the CM score at baseline was divided into quartiles (25% of the values in each quartile, 0–35, 36–44, 45–58, and 59–100 points). Subacromial degeneration findings were dichotomized into two categories: yes (one or more signs) and no (zero signs). Gender was adjusted for. A  $p < 0.05$  was considered significant in papers I–III.

### *Paper IV*

The patients were the same as in paper II and III. Two values for MIC were calculated: the optimal cut-off point of the receiver operator characteristic curve (ROC) ( $MIC_{ROC}$ ) and the 95% limit cut-off point ( $MIC_{95\% \text{ limit}}$ ). The study population was considered as a cohort, ignoring the two different treatment groups. The correlation between the changes in the CM score and the anchor (PGIC) was analysed using Spearman's rho to determine if the choice of the anchor was adequate. A correlation coefficient of at least 0.5 has been recommended<sup>66</sup>. The individual changes in the CM score (baseline to three months) were compared to the PGIC categories in all of the included patients. The anchor function of PGIC was to discriminate between patients who experienced that they had undergone a clinically important change from those who did not. The  $MIC_{ROC}$  considered the CM score as a diagnostic test to distinguish between "importantly improved" and "not importantly changed" patients. The ROC cut-off point for each change in the CM score was determined by calculating the sensitivity and specificity. The sensitivity is the proportion of patients correctly classified as "importantly improved" by the CM score. The specificity is the proportion of patients correctly classified as "not importantly changed" by the CM score. The  $MIC_{ROC}$  is the value found at the point closest to the upper left corner on the ROC curve (Figure 16). This value corresponds to where the sum of the percentages of misclassified patients is lowest. The  $MIC_{95\% \text{ limit}}$  was calculated by using mean  $\text{change} + 1.645 * SD_{\text{change}}$  of the "not importantly changed" group<sup>56</sup>. A subgroup analysis using the same methods as described above was done in patients with and without rotator cuff ruptures. Patients were divided into two groups: those with an intact rotator cuff and those with partial and full-thickness rotator cuff tears.

# RESULTS

## STUDY A – PAPER I

The patients were comparable at baseline for background variables and outcome measures except that the PT-group had a higher percentage of dominant affected shoulders compared with the H-group (Table 4 and 5). Patients from the two hospitals were equally distributed in the two treatment groups. All patients in the PT-group were regarded as compliant with the study protocol and had a minimum of 12 supervised exercise visits.

**Table 4** Background variables presented for the supervised physical therapy group (PT-group) and for the home exercise group (H-group) respectively. All in numbers if not stated otherwise.

	PT-group (n=15)	H-group (n=18)	Statistical Analysis
Sex, male/female	7/8	10/8	NS, Pearson Chi-square
Age in years, mean (SD)	51 (10)	55 (7)	NS, Student's t- test
Duration of shoulder pain before surgery in months, mean (SD)	38 (35)	23 (25)	NS, Student's t- test
Dominant shoulder affected, n (%)	14 (86)	7 (44)	p=0.001, Fischer's exact
Sick-leave before surgery, (yes/no)	9/6	11/7	NS, Fischer's exact
Duration of sick leave in months, mean (SD)	18 (33)	17 (11)	NS, Student's t-test

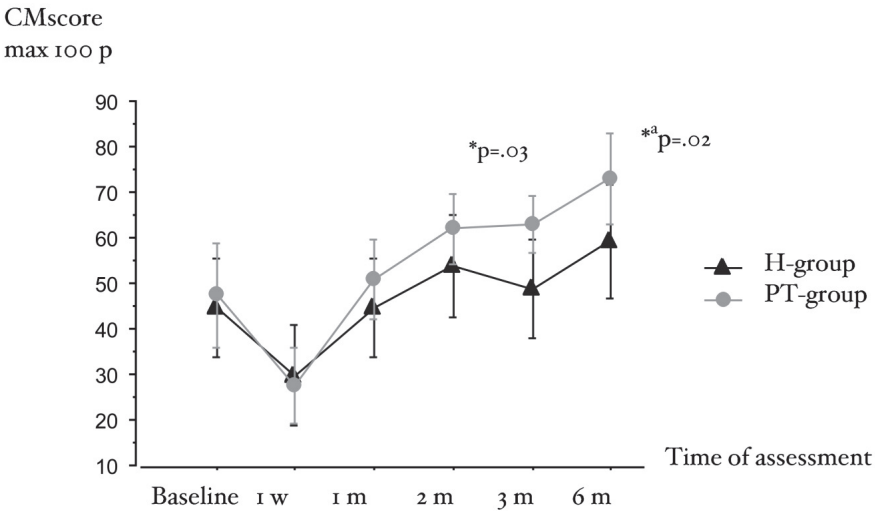
NS=non-significant

## Six-month follow-up

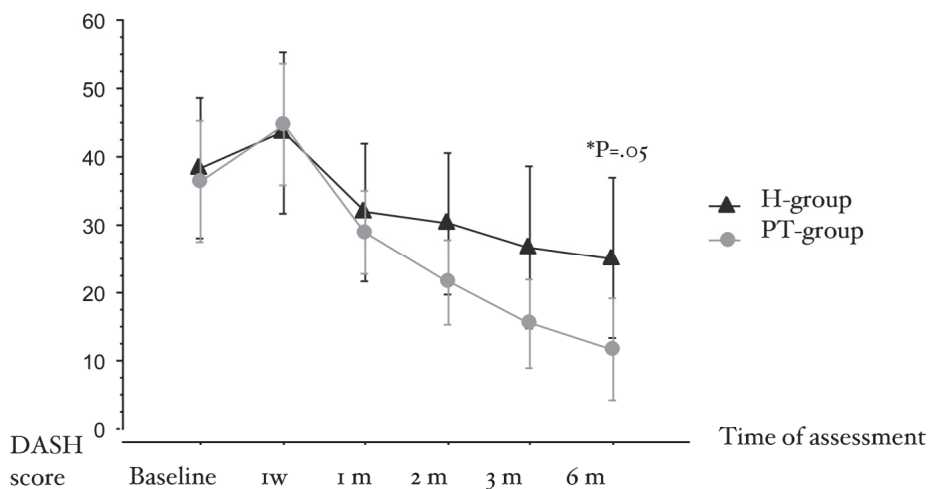
The PT-group had a significantly larger improvement over time in shoulder function and pain as measured with the CM score ( $p = 0.02$ ), presented in Figure 14. They improved from 47.4 points at baseline (preoperatively) to 72.8 points at the six-month follow-up, compared with the H-group, which improved from 46.0 to 59.1 (Table 5). After completion of the treatment period, the between-groups mean

difference in CM score was 14.2 p and the PT-group had a significantly larger improvement ( $p = 0.03$ ) (Figure 14).

The PT-group also had a significantly larger improvement over time in the DASH score ( $p = 0.05$ ) compared to the H-group, as presented in Figure 15. They improved from 36 points at baseline (preoperatively) down to 12 points at the six-month follow-up, compared with the H-group which improved from 38 points to 25 points (Table 5). At the six-month follow-up the between-group mean difference in the DASH score was 13.4 points and the PT-group had a significantly larger improvement ( $p = 0.05$ ).



**Figure 14.** The mean CM score presented with 95 % CI at each follow-up, baseline (preoperative), 1 week and 1, 2, 3 and 6 months after surgery in both groups respectively. Higher score, better shoulder function. \*Significant at three-month endpoint. \*\*Significant over time (ANOVA analysis).



**Figure 15** The mean DASH score presented with 95% CI at each follow-up, baseline (preoperative), 1 week and 1, 2, 3 and 6 months after surgery in both groups respectively. Lower score, better shoulder function. \*Significant at six-month endpoint and significant over time (ANOVA analysis).

There was no statistical difference in EQ-5D between the groups over time ( $p = 0.20$ ), although both improved (Table 5).

Both groups reported significantly decreased pain over time (VAS) during rest ( $p < 0.001$ ), arm activity ( $p < 0.001$ ), and at night ( $p < 0.05$ ), but there was no significant difference between the two groups (Table 5).

After three months, 10 out of 15 patients in the PT-group had returned to full-time work, compared with 6 out of 18 patients in the H-group. At the time of the six-month follow-up, one additional patient in each group had returned to work.

**Table 5** Outcome measurements in the physical therapy (PT) group and the home exercise (H) group. Mean (SD) for both groups at all follow-ups and mean differences between groups (95%CI)

	Baseline		1 week		1 month		2 months		3 months		6 months	
	PT n=15	H n=18	PT n=15	H n=18	PT n=15	H n=18	PT n=15	H n=18	PT n=15	H n=18	PT n=13	H n=16
<i>Outcome measurements</i>												
CM score	47 (19)	45 (20)	28 (14)	30 (21)	51 (15)	45 (21)	62 (13)	54 (21)	63 (11)	49 (20)	73 (16)	59 (23)
DASH score	36 (14)	38 (19)	45 (14)	44 (22)	29 (10)	32 (19)	22 (10)	30 (20)	16 (10)	27 (22)	12 (11)	25 (22)
EQ-5D	0.63	0.52	0.55	0.56	0.71	0.61	0.69	0.65	0.82	0.63	0.84	0.74
	(0.26)	(0.26)	(0.21)	(0.26)	(0.20)	(0.24)	(0.16)	(0.26)	(0.14)	(0.28)	(0.19)	(0.26)
VAS rest	22 (20)	29 (27)	14 (16)	17 (19)	13 (17)	9 (14)	3 (6)	6 (14)	5 (10)	3 (6)	5.5 (9) <sup>a</sup>	5.4 (10) <sup>a</sup>
VAS activity	57 (23)	54 (26)	42 (23)	42 (22)	28 (22)	28 (22)	21 (21)	25 (19)	13 (22)	19 (18)	3.1 (9) <sup>a</sup>	19 (21) <sup>a</sup>
VAS night	47 (23)	37 (31)	26 (25)	26 (31)	26 (24)	19 (27)	14 (21)	12 (18)	10 (17)	16 (26)	2.6 (5.6) <sup>a</sup>	19 (34) <sup>a</sup>
<i>Differences between groups</i>												
CM score	2.9 (-12 to 18)		2.2 (-15 to 11)		6.0 (-7 to 19)		8.1 (-5 to 21)		14.2 (2 to 26)		13.7 (-2 to 28)	
DASH score	1.8 (-15 to 11)		-1.2 (-13 to 15)		-3.0 (-8 to 14)		-8.6 (-3 to 20)		-11.1 (-2 to 24)		-13.4 (0.1 to 27)	
EQ-5D	0.1 (-0.1 to 0.32)		0.01 (-0.19 to 0.17)		0.1 (-0.06 to 0.27)		0.04 (-0.13 to 0.20)		0.19 (0.02 to 0.35)		0.1 (-0.07 to 0.28)	
VAS rest	7.1 (-24 to 10)		3.2 (-16 to 9)		3.2 (-8 to 14)		3.7 (-11 to 4)		3.0 (-4 to 8)		0.19 (-9 to 9) <sup>a</sup>	
VAS activity	2.8 (-15 to 20)		0.4 (-16 to 15)		0.01 (-16 to 16)		4.3 (-19 to 10)		5.3 (-20 to 9)		16 (-29 to -3.5) <sup>a</sup>	
VAS night	10 (-10 to 30)		0.4 (-20 to 19)		6.8 (-11 to 25)		7.0 (-12 to 17)		7.6 (-21 to 9)		2.5 (-9 to 14) <sup>a</sup>	

<sup>a</sup>VAS assessed at the 6-month follow-up: H-group n = 14 and PT-group n = 11.

CM score: Constant Murley Shoulder Assessment score 0–100 in which 100 is the best shoulder function; DASH score: Disabilities of the Arm Shoulder and Hand score 0–100 in which 0 is the best shoulder function. EQ-5D index 1–(-0.59), in which -0.59 is the lowest health-related quality of life. Pain VAS (visual analogue scale) 0–100 mm, in which 100 is the worst imaginable pain.

## STUDY B — PAPERS II AND III

There were no statistical differences in the background variables at baseline, except for there being more men in the specific exercise group. Both groups had a low mean score in the HAD, indicating limited mental distress (Table 6). The groups did not differ statistically in any of the outcome measures at baseline (Table 7).

Most of the patients in each group (80%) attended five to six PT visits (six to seven were offered) during the 12-week exercise period. In the specific exercise group, 45 of the 51 (88%) patients completed their exercise diaries, and 44 of them missed fewer than 15 days of exercise out of 84. A total of 41 patients out of the 46 (89%) in the control exercise group fulfilled their exercise diaries, and 40 of them missed fewer than 15 days of exercise out of 84.

**Table 6** Baseline variables for the two groups of patients with subacromial pain according to the treatment allocation. Values are numbers (percentages) unless stated otherwise.

Groups	Specific exercises (n=51)	Control exercises (n=46)
Male	37*	24
Age (years) mean (range)	52 (33-65)	52 (37-65)
Duration of pain (months), median (range)	24 (6-120)	12 (6-156)
Dominant side affected	30 (59)	22 (48)
Affected shoulder (right:left)	32:18	22:24
<b>Occupation</b>		
Heavy load	22 (43)	21 (46)
Light load	29 (57)	25 (55)
On sick leave at start	9 (18)	9 (20)
<b>Rotator cuff status<sup>a</sup></b>		
<i>affected shoulder</i>		
Intact cuff	33 (65)	34 (74)
Partial tear	15 (29)	6 (13)
Full-thickness tear	3 (6)	6 (13)
<i>contralateral shoulder</i>		
Intact	42 (88)	39 (87)
Partial-tear	5 (10)	3 (7)
Full-thickness tear	1 (2)	3 (7)
<b>Radiology</b>		
Subacromial calcification	9 (18)	11 (24)
Subacromial degeneration	7 (14)	9 (18)
<b>HAD<sup>b</sup> (0-21)</b>		
Anxiety, mean (SD)	3.3 (3.1)	3.9 (3.0)
Depression, mean (SD)	2.2 (2.3)	2.5 (2.6)

\* Significantly more men ( $p = 0.04$ ), <sup>a</sup> Ultrasonographic examination <sup>b</sup> HAD, Hospital Anxiety Depression Scale

## Three-month follow-up (paper II)

At the three-month follow-up the specific exercise group had significantly greater improvement (from baseline to three months) than the control exercise group in shoulder function and pain, measured with the CM score. The mean difference between groups was 15 points (95% CI 8.5 to 20.6). The mean change was 24 points (95% CI 19 to 28) in the specific exercise group and 9 points (95% CI 5 to 13) in the control exercise group (Table 7).

The mean change in the DASH score was significantly higher in the specific exercise group than in the control exercise group, with a mean difference between groups of 8 points (95% CI 2.3 to 13.7) (Table 7).

The mean change in VAS was significantly greater in the specific exercise group than in the control exercise group during the night, with a mean difference between groups of 20 points (95% CI -30.9 to -7.2). No significant differences in VAS between the groups for the mean change in pain during activity or at rest were found (Table 7).

Health related quality of life, measured with the EQ-5D, was significantly higher ( $p < 0.001$ ) in the specific exercise group than in the control exercise group at the three-month follow-up, but no significant group difference was found in mean change from baseline to the three-month follow-up (Table 7).

Significantly more patients in the specific exercise group reported a large improvement or that they were recovered according to the PGIC due to treatment (69% (35/51) *v* 24% (11/45); odds ratio 7.6; 95% CI 3.1 to 18.9;  $p < 0.001$ ). A significantly lower proportion of patients in the specific exercise group subsequently chose surgery (20% (10/51) *v* 63% (29/46); odds ratio 7.7; 95% CI 3.1 to 19.4;  $p < 0.001$ ).

**Table 7** Mean (SD) of groups, mean change within groups (95% confidence interval), and mean differences (95% confidence interval) between groups

Groups*	Baseline		At 3 months		Mean change within groups (baseline to 3 months)		Mean differences between groups (baseline to 3 months)
	Specific (n=51)	Control (n=46)	Specific (n=51)	Control (n=46)	Specific (n=51)	Control (n=46)	
CM score	48.5 (15)	43.5 (15)	72.5 (19)	52.5 (23)	24 (19 to 28)	9 (5-13)	15 (8.5 to 20.6)
DASH score	30 (14)	35 (19)†	16 (15)	29 (19)†	14 (11 to 18)	6 (2 to 11)†	8 (2.3 to 13.7)
EQ-5D	0.67 (0.23)	0.62 (0.23)†	0.82 (0.14)	0.69 (0.24)†	0.16 (0.09 to 0.22)	0.07(-0.14 to 0.01)	0.09 (-0.07 to 0.18)
EQ VAS	68 (15)	62 (20)	75 (20)§	69 (21)‡	6.6 (0.4 to 13)	6.1 (-0.7 to 13)‡	0.5 (-8.7 to 9.8)
VAS rest	15 (19)	20 (21)	10 (14)	20 (25)	4.1 (-0.7 to 11)	-5 (-6.5 to 6.5)	-5.4 (-14.1 to 3.4)
VAS activity	61 (22)	66 (20)	25 (26)	41 (27)	36 (27 to 46)	25 (16 to 35)	-10.6 (-23.6 to 2.4)

\*Groups: CM score = Constant-Murley shoulder assessment score, 0-100 (100 = maximum shoulder function); DASH score = Disabilities of Arm, Shoulder, and Hand score, 0-100 (0 = maximum shoulder function); EQ-5D index, 1 to -0.59 (-0.59 = lowest health-related quality of life); EQ-VAS, 0-100 (0 = lowest health status); VAS = visual analogue scale, 0-100 (0 = no pain).

†n=44.

‡n=42.

§n=49.

## One-year follow-up (paper III)

At the one-year follow-up the three-month results were maintained and a significantly lower proportion of patients in the specific exercise group had chosen surgery, 12 out of 51 (24%) compared to 29 out of 46 (63%), ( $p < 0.0001$ ) in the control exercise group.

Patients from both groups improved significantly in the CM score (Table 8) as well as in all secondary outcomes (DASH, VAS at rest, activity and night, EQ-5D, and EQ VAS) ( $p < 0.05$  for all secondary outcomes) from the three month follow-up to the one year follow-up. All patients treated with exercises only, 39 from the specific group and 17 from the control exercise group, had significantly higher CM score than patients treated with ASD surgery, ( $p = 0.002$ ). A significantly larger proportion of patients with radiographic signs of subacromial degeneration also had a full-thickness tear ( $p = 0.03$ ). The presence of subacromial calcification or degeneration did not independently influence the choice of surgery.

**Table 8** Mean (SD) values in Constant-Murley score, the original two groups at baseline and three-month follow-up and the four groups appearing after the choice of surgery at three-month and one-year follow-up.

Groups	Baseline CM score	3-month CM score	Groups	3-month CM score	1-year CM score
Specific (n=51)	48 (15)	72 (19)	Specific Non-surgery (n=39)	78 (13) <sup>1</sup>	84 (14)
			Specific Surgery (n=12 <sup>3</sup> )	53 (22) <sup>2</sup>	79 (12)
Control (n=46)	43 (15)	52 (23)	Control Non-surgery (n=17)	75 (14)	85 (13)
			Control Surgery (n=29)	40 (16)	72 (18)

*In the period from three-month to one-year follow-up two additional patients in the specific exercise group chose surgery<sup>1)</sup> n = 41<sup>2)</sup> n = 10*

Patients presenting baseline CM scores at the lower quartile (0–35 points) had a higher risk of choosing surgery, independently of treatment group, sex, and rotator cuff status compared to the patients in the highest quartile (odds ratio 7.7; 95% CI 1.67 to 33.3;  $p = 0.007$ ). Also, patients having a full-thickness tear had an increased risk of choosing surgery compared to those with intact tendons (odds ratio 5.5; 95% CI 1.1 to 29;  $p = 0.04$ ). No increased risk for choosing surgery was seen in patients with a partial tear (Table 9).

**Table 9** The influence of rotator cuff status in relation to the patient's choice of surgery (yes/no) during the follow-up period analysed with logistic regression. The reference group was patients with an intact rotator cuff.

N	Rotator cuff status	Odds Ratio	95% Confidence interval	p-value
67	Intact	1	–	–
21	PTT	1	0.4 to 2.7	0.95
9	FTT	5.5	1.1 to 28.6	0.04

PTT = partial-thickness tear, FTT = full-thickness tear. Statistical level of significance  $p < 0.05$

## STUDY B – PAPER IV

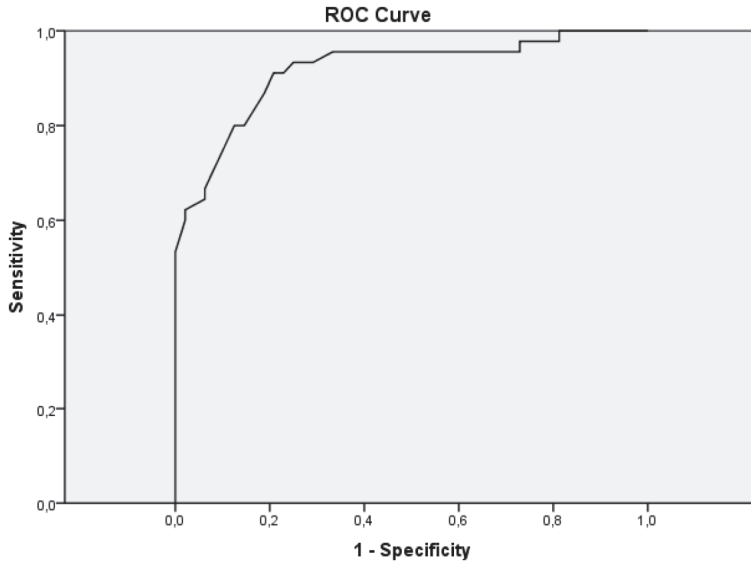
The mean changes in the CM score for each PGIC category are presented in Table 10. Spearman's rho between the changes in the CM score and the PGIC categories was 0.72. The sensitivity and specificity for various changes in the CM scores are presented in Figure 16. The  $MIC_{ROC}$  was found at a mean change of 17 points in the CM score, which corresponds to a sensitivity of 91% and a specificity of 79% which resulted in 30% of misclassified patients. The  $MIC_{95\% \text{ limit}}$  was found at a mean change of 24 points in the CM score (Figure 17). The distribution of the “not importantly changed” and the “importantly improved” patients, with the  $MIC_{ROC}$  and the  $MIC_{95\% \text{ limit}}$  cut-off points indicated, are presented in Figure 17. The ROC cut-off point for  $MIC_{\text{percentage}}$  from baseline to three months was 22%, which corresponds to a sensitivity of 71% and a specificity of 90% and 39% misclassified patients.

**Table 10** Mean score (SD) at baseline and after three months in the Constant-Murley score for the different categories in the Patients global impression of change due to treatment (PGIC).

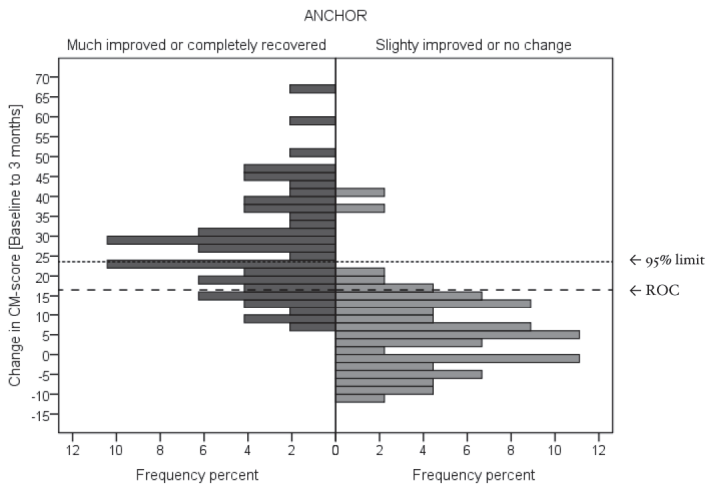
Categories of PGIC	Constant-Murley score		
	Baseline	3 month	Mean change
*Completely recovered (n=9)	58.6 (19.6)	93.9 (5)	35.3 (11.8)
*Much improved (n=40)	50.2 (10.9)	76.5 (10.5)	26.3 (11.8)
†Small improvement( n=19)	44.0 (14.8)	54.8 (18.0)	10.8 (12.2)
†Unchanged( n=26)	38.4(13.2)	40.3(17.6)	1.9 (8.2)

\*Categories “completely recovered” and “much improved” were considered importantly improved.

†Categories “small improvement” and “unchanged” were considered not importantly changed.



**Figure 16** Receiver operating characteristic (ROC) curve for different cut off points for changes in the Constant-Murley score, including specificity, sensitivity and sum of percentages of misclassification (n=93).



**Figure 17** Distribution of changes in the CM score for patients (n=93) who reported that they were "importantly improved" (much improved or completely recovered) and those who reported that they were "not importantly changed" (slightly improved or had no change). Presented with the optimal ROC- and 95% limit cut-off points.

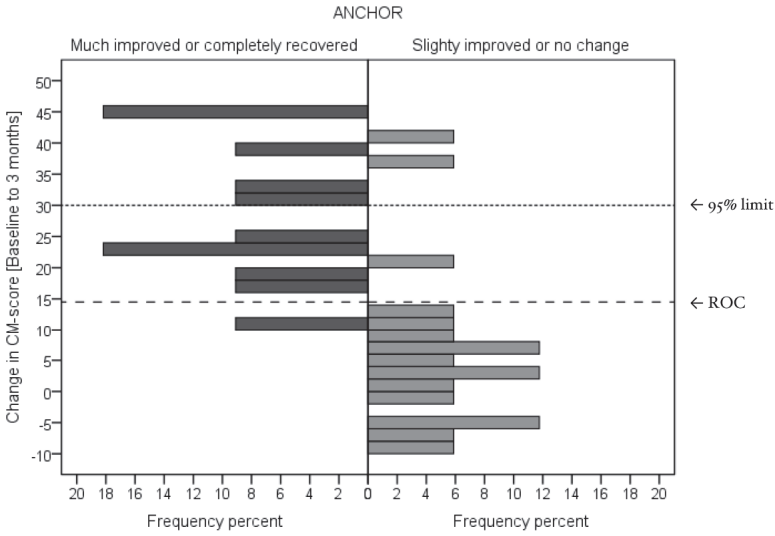
A sub-group analysis was made in patients who had rotator cuff ruptures (n=28) and patients who had an intact rotator cuff (n=65). The mean changes in the CM score for the PGIC categories in both subgroups are presented in Table 11. Spearman's rho between the changes in the CM score and the PGIC categories was 0.65 in the group of patients with rotator cuff ruptures and 0.75 for patients with an intact rotator cuff. The  $MIC_{ROC}$  was 15 points for the group with rotator cuff ruptures which corresponds to a sensitivity of 82% and a specificity of 91%. The group with an intact rotator cuff had a  $MIC_{ROC}$  of 19 points which corresponds to a sensitivity of 100% and a specificity of 70%. In both subgroups, the corresponding misclassification rate was 27%. The  $MIC_{95\%limit}$  was 18 points in the group with an intact rotator cuff and 30 points in the group of patients with rotator cuff ruptures. The distribution of the "not importantly changed" relative to the "importantly improved" patients with rotator cuff rupture is presented in Figure 18 with  $MIC_{ROC}$  and  $MIC_{95\%limit}$  cut-off points indicated. The same data are presented in Figure 19 for patients that had an intact rotator cuff.

**Table 11** Mean score (SD) at baseline and after three months in the Constant-Murley score for the different categories in the Patients global impression of change (PGIC) due to treatment in patients with and without ruptures.

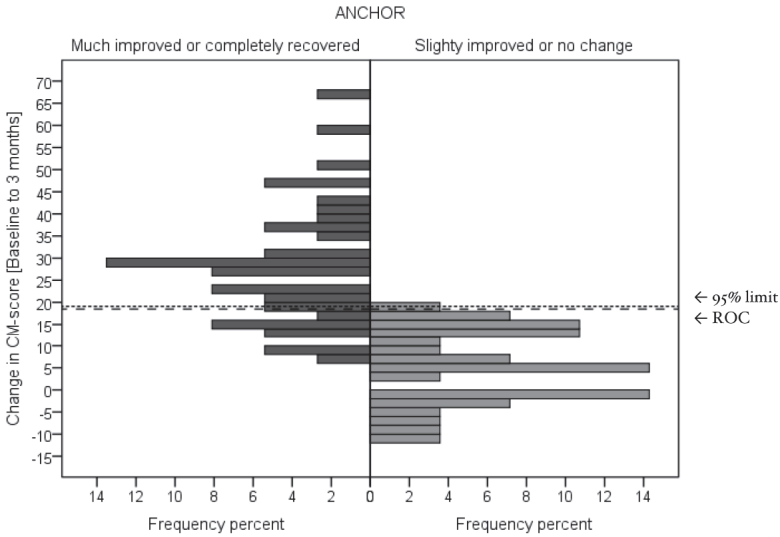
Categories of PGIC	Constant-Murley score		
	Baseline	3 month	Mean change
†Not importantly changed No cuff rupture( n=28)	42.9 (15.4)	47.8 (20.0)	4.9 (8.6)
†Not importantly changed Cuff rupture( n=17)	37.4 (10.9)	44.2 (17.6)	6.9 (14.0)
*Importantly improved No cuff rupture( n=37)	52.6 (14.1)	80.6 (12.1)	28.0 (14.1)
*Importantly improved Cuff rupture (n=11)	48.7 (8.9)	76.8 (11.2)	28.1 (11.4)

† The categories "small improvement" and "unchanged" were considered as not importantly changed.

\* The categories "completely recovered" and "much improved" were considered importantly improved.



**Figure 18** Distribution of changes in the CM score for patients who had rotator cuff ruptures (n=28) who reported that they were “importantly improved” (much improved or completely recovered) and those who were “not importantly changed” (reported slightly improved or no change). Presented with the optimal ROC - and 95% cut-off limits.



**Figure 19** Distribution of changes in the CM score for patients who had an intact rotator cuff (n=65) who reported that they were “importantly improved” (much improved or completely recovered) and those who were “not importantly changed” (slightly improved or no change). Presented with the optimal ROC - and 95% cut-off limit.

# GENERAL DISCUSSION

## MAIN FINDINGS

The main findings in this thesis are the positive effect of the pre- and postoperative supervised strength-endurance exercise programs with improved shoulder function in patients with long-standing subacromial pain. After having ASD surgery, rehabilitation with a focus on strength-endurance with exercises for the rotator cuff and scapula stabilisers seems to be more effective than a home-based movement exercise program. The positive effect of the specific exercise strategy significantly reduced the need for surgery in patients on the waiting list for ASD surgery despite the fact that all patients were “failures” of at least three months of exercise treatment and had at least a six-month symptom duration before entering the study. Low baseline values in shoulder function and pain measured with the CM score and/or the presence of a full-thickness tear were factors associated with an increased risk of choosing surgery. Even though these results should be interpreted with caution because of the small sample, they are similar to those reported in the limited number of previous studies of predictors. The clinical importance of a change in an outcome after treatment is of value when interpreting treatment results in clinical practice. In the CM score, a range of 17-24 points of change is considered a clinically important change for patients with subacromial pain after 3 months of guided exercise treatment.

## Interpretation of the results in study A

In study A, there was a significant difference between groups with greater improvements in shoulder function and pain in the group performing PT supervised strengthening-endurance exercises. Although the results should be interpreted with some caution because of the small sample size, the current study in combination with existing research suggests that performing strength-endurance exercises for the rotator cuff and scapula stabilisers is superior to instructions for home-based movement exercises and could be safely implemented into clinical practice. There are, however, some methodological considerations. Because attention is one factor that might affect treatment outcome<sup>121</sup> the lesser attention given to the patients in the home exercise group needs to be considered. However, there were many follow-ups during which patients in the home exercise group had

the opportunity to ask questions of an independent PT about their exercise program and shoulder condition, which was thought to compensate for this.

In addition adherence to treatment is important for a positive effect<sup>58</sup>. Patients in the PT supervised group were adherent to the study protocol and attended 12 PT supervised exercise sessions. The patients in the home-exercise group received a phone call to stimulate adherence, but because we did not use an exercise diary, the adherence was not monitored and remains unknown. However, this design was according to clinical practice at the time the study started.

Both groups reached significantly decreased pain intensity as assessed with VAS in activity and at rest at the one-month follow-up compared to baseline values. This decrease was probably an effect of the surgical procedure, removing structural pathology. Shoulder function and pain measured with CM score and the DASH score was back to preoperative levels after one month and continued to improve after this point. This initial improvement was also similar in both groups and probably a response to the surgical treatment. Starting at three months after surgery, the PT-supervised group began to show significantly greater improvement in functional status compared with the home-exercise group, and this effect may have been the result of PT-supervised strength-endurance exercises. The latter response and improvement in shoulder function is in line with the results from other studies<sup>16,49</sup>.

In summary, the positive results observed with the PT-supervised strength-endurance exercise treatment are likely attributable to a combination of placebo, attention, and the specific treatment effect.

## Interpretation of the results in study B

The significant improvement in shoulder function and pain seen in the specific exercise group was likely a response to the treatment. Little is known about natural recovery in patients with subacromial pain and because a third group with no treatment was not included, the influence of natural recovery cannot be evaluated. The patients included had long-standing symptoms (>6 months) with high disability at baseline, which has been associated with a poorer prognosis<sup>193</sup>. Therefore, natural recovery is unlikely to explain the whole treatment effect, which is further supported by the differences between groups.

The total treatment effect is also influenced by other factors such as attention<sup>121</sup> and expectations about treatment<sup>52</sup>. Positive expectations have been associated with a more successful outcome<sup>91,192</sup>. Because the patients were blinded to

treatment assignment and had the same number of individual sessions, including support and attention by the PT, this expectation could not explain the superior effect of the specific exercise strategy. In addition, all patients expected a moderate to large effect of the exercise treatment, and no differences between the groups can explain the significantly greater results of the specific exercise strategy. However, only one PT, not blinded to group assignment treated patients in both groups. This might increase the risk of bias and also affect external validity. Nevertheless, because all patients had tried exercise treatment prior to inclusion and had a long duration of pain it is not likely that the patients would decline surgery solely because of a convincing PT.

After one year, patients treated with exercises alone achieved significantly better results in the CM score compared to the patients who chose ASD surgery, regardless of whether they were initially in the specific or control exercise group. However, 70% of the non-operated patients had performed the specific exercise strategy. Some patients in the control exercise group (n = 17) were satisfied and did not choose surgery. This result was not unexpected because all patients, independent of randomisation, received a corticosteroid injection and thorough information about the condition, ergonomic practices, and posture correction. Corticosteroid injections have proved effective in reducing pain in patients with subacromial pain in the short-term<sup>27,48,73</sup> and a combination of corticosteroids and exercise treatment has proved more effective compared to exercise treatment alone at short-term follow-ups<sup>49,85</sup>. Shoulder pain inhibits rotator cuff muscle function and effective pain relief improves rotator cuff function<sup>26</sup>. Reduced pain might enhance arm activity with improved shoulder kinematics which may be sufficient in reducing symptoms of impingement in subgroups of patients with subacromial pain. In addition the attention and hands-on guidance from the PT might have contributed to the positive results<sup>121</sup>. Dickens et al<sup>204</sup> had a similar study design but included true controls, who were requested to wait for surgery and continue with normal activity. They reported that all patients in the control group still wanted surgery.

Significantly fewer patients chose surgery in the specific exercise group (12 out of 51) than in the control exercise group (29 out of 46) at the one-year follow-up. The patient's choice of surgery may be influenced by other factors. It may be affected by earlier experience of treatment or the information given by the orthopaedic surgeon, as well as the demands the patient places on their shoulders. Therefore, the orthopaedic surgeon was blinded for group assignment, and the information about surgery was standardised. Because the groups did not differ in self-reported work load or sick leave, the patient's own choice of surgery was thought to be related to a positive response to specific exercises. This conclusion is further supported by the fact that patients with a large improvement in CM score did choose surgery to a lesser extent.

## Generalisability of results

The inclusion criteria used in studies A and B are similar to those recommended in earlier studies that included patients with subacromial pain<sup>25,78,162</sup>. To confirm the subacromial pain diagnosis a combination of several positive clinical tests was used in both studies as recommended in recent systematic reviews<sup>7,146</sup>. The inclusion criteria together with the strict criteria for exclusion were believed to identify a rather homogeneous group of patients having long-standing subacromial pain.

One important factor that affects generalisability is sample size. The generalisability of study A is limited in this context, but to some extent, the external validity was improved because the patients were recruited from two hospitals in different geographical areas and several blinded PTs were involved in the follow-ups as well as in supervision of the postoperative exercise treatment.

In study B, the patients were recruited from the surgical waiting list of one orthopaedic clinic, which might have affected the external validity. However, patients referred to an orthopaedic specialist for surgery from a primary care physician in the region of Östergötland (population 427 106, Central Bureau of Statistics 2009) are thought to be representative of the studied population. Because all included patients were on the waiting list for surgery, this factor might have affected the generalisability of the results to the subacromial pain population in primary care. Patients in primary care are thought to be more heterogeneous, with a larger proportion reporting a shorter duration of symptoms<sup>105</sup>. Because shorter duration of symptoms is associated with a greater treatment response<sup>193</sup> the specific exercise strategy could be effective also in this population.

## Content in the preoperative specific exercise strategy

The content of the specific exercise strategy in study B was based on the current concepts in the treatment of patients with subacromial pain<sup>44,63,66,124</sup> in combination with clinical experience and was standardised for content, dosage and progression. This standardisation along with the pragmatic design of the program, with few exercises and relatively few PT supervised sessions, enables implementation into every day practice. Few of the exercise programs presented in the literature to date are well described when it comes to content, load, dosage and progression<sup>83,113,123</sup>. Consequently, implementation of these earlier programs into clinical practice is difficult. However, the majority of the programs presented in these studies focus on strength-endurance exercises for the rotator cuff and scapula stabilisers, as recommended in the literature<sup>44,63,124</sup>.

The specific exercise group reported positive results despite the fact that all patients were “failures” of at least three months of conservative treatment (including exercises) and had experienced a pain duration of at least 6 months before entering the study. These factors imply that the specific exercise strategy is better than the current clinical practice. In addition to the thorough description, the content in the specific exercise strategy also differs from other traditional programs<sup>25,32,78,115,130,205</sup> regarding two major aspects: eccentric exercises for the rotator cuff were included and pain during exercise was accepted to a certain extent, monitored and controlled using the pain monitoring model. These two components could be the reason why these patients had a superior result compared to earlier treatment. Still, questions remain regarding whether another dosage and progression could produce even larger effects.

In earlier studies, eccentric exercises for the rotator cuff have yielded positive results in terms of decreasing pain and improving shoulder function<sup>18,31,106</sup>, suggesting that this component could be important to include in exercise strategies for patients with subacromial pain. The effect mechanism of eccentric exercises in the treatment of tendinopathies is not fully understood although several hypotheses have been presented. A reduction of neovessels and nerve ingrowth in the affected tendon along with decreased pain has been demonstrated after an eccentric exercise program in patients with midportion Achilles tendinopathies<sup>3,5,157</sup>. Neovascularisation has also been associated with subacromial pain<sup>33</sup> and sclerosing treatment aiming for a reduction of pathological nerve endings and vessels has significantly reduced shoulder pain<sup>4</sup>. These findings suggest increased vascularity and sensory nerve endings as contributing to the subacromial pain and thus being a possible site of action for eccentric exercises.

An increased collagen synthesis together with reduced pain has been demonstrated after eccentric exercises in patients with Achilles tendinopathies<sup>125,158</sup>. During eccentric exercises, the tendon is subjected to greater force than during concentric exercises, thus inducing a greater remodelling stimulus<sup>188</sup>. This might stimulate tenocytes and restart the halted healing process seen in patients with tendinopathies<sup>171</sup>. EMG studies comparing eccentric and concentric contractions have demonstrated greater fluctuations in force in eccentric exercises. These fluctuations have also been suggested to constitute a greater remodeling stimulus of tendons and as the reason for successful results with eccentric exercises<sup>170</sup>. Tendon loading seems to be the key factor and type of loading might be of secondary importance<sup>119</sup>.

Controlled, graded, tendon reloading exercise programs together with pain management are recommended in the management of rotator cuff tendinopathies<sup>127</sup>. In study B guided eccentric loading of the rotator cuff was performed and pain

was controlled and monitored by using the pain monitoring model. Conclusions considering the sole effect of the eccentric component could not be drawn but our results suggest that this component might contribute to the positive effects.

Strength-endurance exercises for the rotator cuff and scapula stabilisers were the key feature in both of the strengthening exercise programs used in studies A and B. These exercises are aimed at restoring the altered scapular and glenohumeral kinematics observed<sup>44,46,47,131,143</sup> to prevent further impingement. However, structured evaluation of the scapular or glenohumeral kinematics was not conducted, although objective measurements of strength and range of motion are included in the CM score and was significantly increased. To date, two studies could be found that evaluated scapular kinematics before and after an exercise program in patients with subacromial pain<sup>55,142</sup>. Both studies reported improved shoulder function and pain after treatment but the results considering alteration in scapular kinematics differed. McClure et al<sup>142</sup> did not find any differences while De Mey et al<sup>55</sup> identified a difference in scapular muscle activation levels before and after exercises although the onset timing in muscles was unchanged. However, these studies lacked a control group, and randomised studies evaluating the effect of specific exercises on changes in muscular patterns and scapular kinematics are needed to further explain the effect mechanism of these exercises.

In study B, manual therapy targeting increased flexibility of the posterior capsule was added if patients had decreased range of motion. This approach was standardised as described in the literature<sup>40,42</sup> and a pragmatic choice reflecting the treatment in clinical practice, as further supported by studies reporting superior results when adding manual mobilisation<sup>11,37,182</sup>. Approximately 10 % of the patients had this additional treatment at a limited number of PT sessions. However, the possible additional effect of manual treatments remains unknown. A pragmatic approach is recommended in the treatment of patients with subacromial pain<sup>16,122</sup>. However, the balance between standardisation and individualisation is challenging and highlights the importance of a detailed description of the specific exercise strategy to guide PTs in clinical practice.

In summary, the specific exercise strategy focusing on strength–endurance with eccentric exercises for the rotator cuff and concentric/eccentric exercises for the scapula stabilisers includes several components thought to be important for a positive effect. Consequently, it is impossible to draw conclusions about any specific effect of each component. However, because the aetiology of subacromial pain is multifactorial<sup>128,181</sup> all of these factors were considered important during the design of the specific exercise strategy to achieve an optimal effect.

## Content in the postoperative exercise strategy

The aim of the postoperative exercise program is to restore shoulder function and prevent recurrence. Even if the surgical procedure removes the structural pathology, the function of the rotator cuff muscles and scapula stabilisers needs to be restored for an optimal shoulder function. Therefore, the key content in the postoperative exercise program is similar to the preoperative programs for patients with subacromial pain but is adjusted because the patients are newly postoperative. In study A, the content in the program was based on the existing recommendations by Jackins et al.<sup>99</sup> but involved a more progressive approach with early activation of the rotator cuff (after 4 weeks) thought to hasten recovery and promote an earlier return to work compared to the ordinary postoperative program used. Klintberg et al.<sup>94</sup> featured a rehabilitation program with a similar design and progression to supervised rehabilitation. They also reported that patients tolerated the progression, further supporting early postoperative activation of the rotator cuff. The design of study A makes conclusions impossible regarding supervision as a key component for success. However, some reports emphasise the importance of guidance and support for patients during their rehabilitation<sup>195</sup>. Because a correct starting position and qualitative performance of the exercises are important for optimal treatment effect guidance from a PT is thought to be essential. Additionally, PT supervision may facilitate good adherence<sup>58</sup>.

## Measurement of shoulder function and clinically relevant changes

The CM score was used as primary outcome and the DASH as the secondary outcome for evaluation of shoulder function and pain in both studies. The combination of these instruments was used to obtain a broader overall picture of functioning according to the ICF definition<sup>213</sup>. DASH includes more questions concerning activity of daily living and also questions regarding the ability to participate in different activities. The correlation between CM score and DASH is weaker (0.3-0.7) than those between CM score and other shoulder-specific instruments indicating that DASH captures other aspects<sup>177</sup>. However, because DASH is a purely self-assessed instrument developed to evaluate upper extremity function it is not as sensitive as the CM score when it comes to evaluation of change arising from treatment in shoulder patients<sup>177</sup>.

The European Society for Surgery of the Shoulder and Elbow recommends using the CM score in shoulder research<sup>38</sup> and its common use thus makes comparison of research results possible. Furthermore, responsiveness to change in patients with

subacromial pain has been shown to be excellent in the CM score. In addition the ability to distinguish between patient's self-assessment of being slightly better from being much better on a global assessment score has been shown in patients with subacromial pain <sup>9</sup>. The CM score incorporates objective measures of range of motion and strength, which is useful when quantifying improvements after shoulder exercises. However, as described earlier in the methodological section, the CM score also has been criticised for low inter-rater reliability. The poor descriptions of how to use the score in the original version in combination with lack of standardisation are contributing factors <sup>175</sup>.

To secure reliability in studies A and B we used the same assessor, the same equipment, and a standardised protocol from the original version of the CM score <sup>39</sup>. Age and sex have also been reported to influence the CM score at a specific time point, with higher scores in men and decreasing scores after the age of 50 <sup>110,207</sup>. The mean baseline score in the control group in study B was 5 points lower than in the specific exercise group because of significantly more women in the control exercise group. Adjustment for baseline levels of outcomes was done by using the mean change from baseline to the three-month follow-up as a dependent variable in group differences. Therefore, this sex-based difference was not expected to affect the results.

To evaluate the importance of the change from a patient's perspective a global assessment scale, the PGIC, was used in study B. Global assessment scales are thought to capture the importance of a change from the patient's perspective <sup>108</sup>. These scales have been questioned, however, because they seldom are adequately evaluated for validity and reliability <sup>108</sup>. It has been debated whether patients can recall their previous status, and these scales are influenced more by recent events and the patient's current mood state rather than the change arising from treatment <sup>51</sup>. However, such scales have also proved to be sensitive to change <sup>79</sup> and to provide clinically relevant information about the treatment effect in an individual patient <sup>96</sup>.

The estimated MIC could be used as an indication for relevant individual changes in a score to guide the clinician in interpreting response to a specific treatment. Furthermore, using the MIC as a benchmark for clinically important changes may also improve results interpretation in future studies <sup>56</sup>. Instead of relying solely on significant statistical differences when comparing the effect of treatments in RCT studies, the use and interpretation of MIC values in clinical trials at a group level has been presented <sup>77</sup>. One method is to determine the proportion of patients who show larger changes than the MIC in each treatment group and then to compare these proportions.

Distribution-based and anchor-based approaches are used to determine the MIC<sup>51</sup>. Distribution-based approaches rely on the distributional characteristics of a sample and express the change in the outcome measure relative to a parameter of measurement error. Anchor-based approaches use an external criterion (anchor) to determine what patients or clinicians consider as important improvement or deterioration. A combination of both approaches that was used and presented in paper IV is recommended in the literature<sup>51,57</sup>.

A MIC range of 17-24 points was presented in paper IV as being a clinically relevant change in the CM score in patients with long-standing subacromial pain. Because different methods will result in different MIC values, some argue for a range instead of single value<sup>88,120,159</sup>. In study B, the specific exercise group had a mean change of 24 points (95% CI 19-28) in the CM score after completing the exercise treatment compared to the control exercise group that had a change of 9 points (95% CI 5-13). Hereby, the specific exercise group not only reached significantly greater improvement but also the changes in this group were clinically important for the patients.

Comparison with postoperative results in relation to MIC is also interesting; however with some caution since the MIC values are related to the population studied and performed treatment. In study A, the change was 26 points (95% CI 16-35) in patients with postoperative strength-endurance exercises while patients with home-based movement exercise changed 14 points (95% CI 7-23). Those results indicate that the latter did not reach the lower limit for a clinical important improvement due to calculated MIC for the CM score. The important changes in both studies were also comparable with earlier reported results one year after ASD surgery followed by postoperative exercise treatment<sup>78</sup>.

The MIC in the DASH score has been established at 10 points in a heterogeneous shoulder population with non-surgical treatment<sup>178</sup>. In study B, the specific exercise group reached above this value but the control group did not. In study A, both groups reached this MIC level, however the PT-supervised group reached significantly higher.

Since the MIC value refers to the patient's individual change presenting proportions of patients reaching MIC is another way to report clinical relevant changes. For example in study B 63% of the patients in the specific exercise group reached the MIC compared to 25% in the control exercise group. Still, specific clinical results and MIC needs to be interpreted in the light of economical as well as safety perspectives<sup>160</sup>.

## Predictors of treatment outcome

Studies evaluating factors that influence treatment effect are scarce. Low baseline values and a long duration of pain have been reported as the strongest predictors for failing conservative treatment in a general shoulder population in primary care<sup>172,193</sup>. This finding is in line with the results presented in paper III in which low baseline CM scores were associated with increased risk of choosing surgery after three months of exercises independently of sex, rotator cuff status, or treatment group.

The knowledge of the influence of the rotator cuff structural status on treatment effect is limited. Patients with a full thickness tear have been reported to have less satisfactory results after exercise treatment<sup>189</sup> and also after ASD surgery<sup>17</sup>. This finding is in line with that from paper III in which having a full thickness rotator cuff rupture was significantly associated with failure of exercises treatment and choosing surgery. However, some of the patients with full thickness rotator cuff rupture were responding to exercise treatment which might be explained by the location of the rupture and that none of the ruptured supraspinatus tendon extended into the infraspinatus tendon. A patient with an intact rotator cable might have a rotator cuff that is biomechanically functioning despite having a rupture<sup>29</sup>.

The results of the effect of conservative treatment including exercise treatment for patients with full-thickness tears vary and success rates between 33-88% are reported<sup>2,189</sup>. This variability may reflect the lack of standardised inclusion criteria, treatment and methods of evaluation. In a study by Tanaka et al, who investigated factors predicting a successful outcome of conservative treatment in patients with full thickness tears, an intact intramuscular tendon of the supraspinatus, no or little atrophy, negative impingement signs and preserved motion in external rotation predicted a successful outcome of conservative treatment. This outcome is not, however, in line with the result in paper III in which the signs of radiographic subacromial degeneration did not influence the choice of surgery. However, a significantly larger proportion of patients with radiographic signs of subacromial degeneration had a full-thickness tear. The results of the logistic regression analysis in paper III should be interpreted with caution because of the small number of included patients with rotator cuff ruptures.

## CONCLUSIONS

Postoperative treatment with PT-supervised strength-endurance exercises, focusing on the rotator cuff and scapula stabilisers, seems to be more effective than home-based movement exercises after ASD surgery.

The progressive approach with early activation of the rotator cuff muscles, used in the PT-supervised strength-endurance exercises after ASD surgery, seems to be well tolerated because no adverse effects were reported.

The specific exercise strategy, focusing on strength-endurance for the rotator cuff and scapula stabilisers, is effective in improving shoulder function and pain in patients with long-standing subacromial pain. This approach reduces the need for ASD surgery at three months.

Pain while performing the specific exercises can be accepted since no adverse effects were reported.

The positive three month results with improved shoulder function and pain after a specific exercise strategy were maintained at one year and significantly reduced the need of ASD surgery at 12 months.

Low baseline values in shoulder function and pain as measured with the Constant-Murley score and/or having a full-thickness rotator cuff tear seem to be predictors for choosing surgery.

The CM score is able to detect the minimal important change in individual patients with long-standing subacromial pain when the rotator cuff is intact. In all patients with long-standing subacromial pain, the MIC value was dependent on the subgroup as well as the choice of statistical analysis.

## CLINICAL IMPLICATIONS

The conclusions of this thesis results in the following clinical implications from preoperative treatments to postoperative treatment:

The standardised exercise protocol used in the specific exercise strategy provides guidance about content, dosage, and progression, which enables implementation into clinical practice. This strategy could be recommended for patients with long-standing subacromial pain also those with a non-acute rotator cuff rupture. Non-responders to this strategy might be those who need surgery for a more satisfactory outcome.

Supervision by a PT with hands on guidance seems to be important and may improve the quality of performance of the exercises. Supervision along with few exercises performed in a rather short time may also facilitate good adherence. Because good adherence is essential for a positive treatment result it is important to consider this aspect when treating patients with subacromial pain in clinical practice.

ASD surgery followed by a progressive strength-endurance exercise treatment seems to be better than home-based movement exercises. These results indicate that the surgical procedure followed by home-based movement exercises is not enough. To restore shoulder function specific exercises, aiming to restore muscle performance, seem important. Furthermore, the progressive approach with early activation of the rotator cuff muscles was well tolerated and could be safely implemented into clinical practice.

## FUTURE RESEARCH

A randomised study evaluating the effects of the specific exercise strategy in a primary care setting has already started. Because patients with subacromial pain who seek primary care are a more heterogeneous population than the one in the current study the positive results need to be repeated in this context before implementation of this strategy could be done early in the rehabilitation process. A secondary purpose with this study is to identify predictors for being a “responder” or a “non-responder” to the specific exercise strategy. Identifying such factors could enable classification of subgroups to further guide the initial choice of treatment.

Experimental studies evaluating the effect of specific exercises in changing muscular patterns and shoulder kinematics are needed to further understand the effect mechanism of the recommended exercise treatments available in the literature. Also, studies evaluating the effect of each component included in the specific exercise strategy are needed to further understand the contribution of each component.

It would be of interest to further explore the effect of eccentric exercises on the structural status of the rotator cuff tendons. Such research would add information about the underlying effect mechanism of eccentric exercises in the treatment of tendinopathies.

Little is known about dosage and response in exercise treatment in patients with subacromial pain. The dose and progression used are based on clinical experience rather than on evidence. Studies evaluating the effect of standardised exercises with different doses are needed to develop recommendations for optimal dosage and progression.

## SUMMARY IN SWEDISH

Subacromial smärta är det vanligast förekommande problemet bland patienter som söker för skulderbesvär i primärvården. Icke kirurgisk behandling rekommenderas primärt och innefattar oftast sjukgymnastiska träningsprogram. Om denna behandling inte når önskad effekt så rekommenderas kirurgi med artroskopisk subacromial dekompression (ASD) med efterföljande träning. Antalet ASD-operationer har ökat kraftigt senaste åren i Sverige trots att studier har rapporterat likvärdiga resultat vid jämförelse av träning och ASD-operation. Det finns fortfarande ett behov av evidensbaserade pre- och postoperativa träningsprogram som är standardiserade och detaljerat beskrivna för att vägleda behandlingen av dessa patienter.

Det övergripande syftet med avhandlingen var att utvärdera effekterna av pre- och postoperativa träningsprogram med avseende på skulderfunktion och smärta samt hur det preoperativa programmet påverkar behovet av kirurgi för patienter med långvarig subacromial smärta.

Avhandlingen är baserad på två randomiserade kliniska studier som redovisas i fyra artiklar. I **studie A** randomiserades patienterna efter ASD-kirurgi till antingen styrke-uthållighetsträning med fokus på rotatorkuff- och skapulamuskulatur övervakad av sjukgymnast eller till hemträning med fokus på rörlighetsträning för skuldran. Skulderfunktion, smärta och hälsorelaterad livskvalitet samt återgång till arbetet utvärderades upp till 6 månader (*artikel I*). I **studie B** randomiserades patienter som stod på väntelista för ASD-kirurgi till antingen en specifik träningsstrategi med styrke-uthållighetsträning med fokus på rotatorkuffen och skapulamuskulaturen eller till generell rörlighetsträning för skuldran. Skulderfunktion, smärta och hälsorelaterad livskvalitet och behov av kirurgi utvärderades efter avslutad träningsperiod vid 3 månader (*artikel II*) och även efter 12 månader (*artikel III*). Vidare undersöktes sambandet mellan skulderfunktion vid inklusion, rotatorkuffstatus och röntgenfynd i relation till val av kirurgi (*artikel III*). Den kliniskt relevanta skillnaden i det primära utfallsmåttet, Constant-Murley score (CM-score), fastställdes med hjälp av en metod som tog hänsyn till både patientens perspektiv och statistisk signifikans (*artikel IV*).

Efter kirurgi hade patienterna som genomförde styrke-uthållighetsträning övervakad av sjukgymnast signifikant större förbättring i skulderfunktion och smärta jämfört med gruppen som utförde rörelseträning i hemmet. Patienterna på väntelistan för kirurgi som utförde den specifika träningsstrategin hade en signifikant större förbättring i skulderfunktion och smärta jämfört med gruppen

som genomförde rörelseträning. Signifikant färre patienter i den specifika träningsgruppen valde kirurgi efter tre månader. Detta resultat kvarstod vid 12 månader. Låga värden i skulderfunktion vid inklusion samt förekomst av en genomgående rotatorckuffruptur var faktorer som ökade risken att välja kirurgi. Den kliniskt relevanta förändringen i CM-score för patienter med långvarig subacromial smärta ligger mellan 17-24 poäng.

Efter kirurgi verkar styrke-uthållighetsträning för rotatorckuff- och skapulamuskulaturen vara mer effektiv än hembaserad rörelseträning. För patienter på väntelistan för kirurgi var styrke-uthållighetsträning av rotatorckuffen och skapulamuskulaturen effektiv för att förbättra skulderfunktion och minska behovet av kirurgi upp till 12 månader. Patienter med störst funktionsnedsättning vid inklusion samt de med genomgående rotatorckuffruptur valde i större utsträckning kirurgi. CM-score kan detektera kliniskt relevanta skillnader hos individuella patienter med subacromial smärta med en intakt rotatorckuff. I hela patientgruppen med subacromial smärta berodde det kliniskt relevanta värdet på vilken undergrupp som studerades samt val av statistisk analys.

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## APPENDICES (1-5)

**Appendix 1** *The Constant-Murley shoulder assessment score (Swedish version). Used in studies A and B.*

			hö	Vä				Hö	Vä	
<b>smärta</b>	svår	0			<b>Utåttrot</b>	nacke/ armb fram	2+			
	måttl	5				nacke/ armb ut	2+			
	lindrig	10				huvud/ armb fram	2+			
	ingen	15				huvud/ armb ut	2+			
<b>ADL</b>	opåv sömn	2+				full elev	2			
	opåv arb	4+			<b>Flex</b>	0-30	0			
	opåv fritid	4				31-60	2			
	midjan	2				61-90	4			
	xiphod	4				91-120	6			
	nacke	6				121-150	8			
	på huv.	8				151-180	10			
	över huv	10			<b>Abd</b>	0-30	0			
	<b>Inåttrot</b>	låret	0				31-60	2		
		glutealt	2				61-90	4		
lumbo- s		4				91-120	6			
L3		6				121-150	8			
Th12		8			151-180	10				
	Th7	10			<b>Kraft</b>	0,5kg/p	max 25			
<b>SUMMA</b>						max 100p				

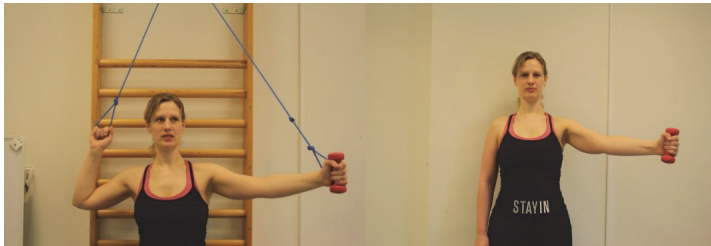
**Appendix 2** *The specific exercise strategy used in study B*

**Specific exercise program**

To perform twice a day for the first 8 weeks then once a day for the last 4 weeks



**Exercise 1:** Week 1-12 - Shoulder retraction, low scapular row 15 repetitions x 3



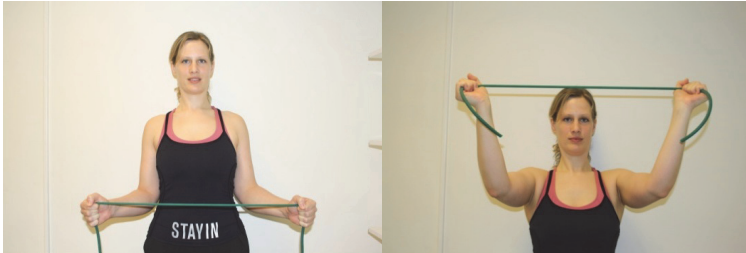
**Exercise 2:** Week 1-8 - Full can eccentric exercise in the scapular plane for m. supraspinatus, 15 repetitions x 3  
Week 9-12 - Full can concentric/eccentric exercise for m. supraspinatus, 10 repetitions x 3 → 15 repetitions x 3



**Exercise 3:** Week 1-8 - Eccentric exercise for m. infraspinatus and m. teres minor, 15 repetitions x 3  
Week 9-12 - Concentric/eccentric exercise, 10 repetitions x 3 → 15 repetitions x 3



**Exercise 4:** Week 1-8 - Concentric/eccentric exercise for m. serratus anterior, 15 repetitions x 3  
Week 9-12 - Push up plus exercise, 10 repetitions x 3 → 15 repetitions x 3



**Exercise 5:** Week 5-8 - Bilateral external rotation; a combined exercise for the rotator cuff and the scapula stabilizers, 10 repetitions x 3 → 15 repetitions x 3  
Week 9-12 - Elevation with bilateral external rotation, 10 repetitions x 3



**Exercise 6:** Week 1-12 - Posterior shoulder stretch, 30-45 seconds x 3

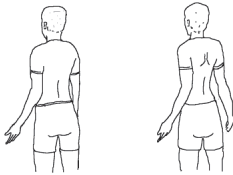
**Link to the video of specific exercise strategy:**

<http://www.imh.liu.se/sjukgymnastik/forskning/the-specific-exercise-program-theresa-holmgren?l=sy>

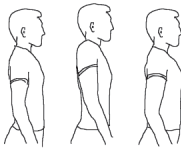
**Appendix 3** *Control exercises used in study B. The program was performed twice daily.*



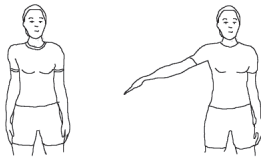
**Exercise 1** Retraction of the neck.  
10 repetitions.



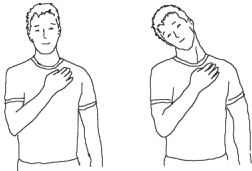
**Exercise 2** Retraction of shoulders.  
10 repetitions.



**Exercise 3** Shoulder elevation.  
10 repetitions.



**Exercise 4** Shoulder abduction  
10 repetitions.



**Exercise 5** Stretch of the trapezius  
muscle. 30-45 seconds x 3.



**Exercise 6** Stretch of the pectoralis  
muscles. 30-45 seconds x 3.

**Appendix 4** *Mobility exercises used in the home exercise group in study A.  
This program was performed at home twice daily.*

**Exercises for the H-group**

- Active assisted/active bilateral abduction with a stick 5-10 repetitions x 2.
- Active assisted/active bilateral flexion with a stick 5-10 repetitions x 2.
- Active assisted unilateral external rotation with a stick 5-10 repetitions x 2.
- Active bilateral external rotation 5-10 repetitions x 2.
- Active scapula retraction 5-10 repetitions x 2.

Exercises (retraction and depression of shoulders) for correct posture in front of a mirror.

## Appendix 5 Strength-endurance exercises used in the PT-supervised group in study A.

### Exercises for the PT supervised group

#### Week 1

- Active assisted/active bilateral abduction with a stick in the frontal plane 5-10 repetitions x 2.
- Active assisted/active bilateral flexion with a stick 5-10 repetitions x 2.
- Active assisted external rotation with a stick 5-10 repetitions x 2.
- Active bilateral external rotation 5-10 repetitions x 2.
- Active scapula retraction 5-10 repetitions x 2.
- Exercises (retraction and depression of shoulders) for correct posture in front of a mirror.

#### Phase 1 (Week 2)

- Continue with active assisted /active exercises from week 1.
- PT assisted passive range of motion in flexion, abduction and external rotation.
- Active external rotation lying on the side, 5-10 repetitions x 3, 3 times daily.
- Exercises for correct posture, scapula retraction with straight arms 5-10 repetitions x 3, 3 times daily.  
The exercises were performed at the PT practice 2 times a week combined with home exercises twice daily.  
Some of the exercises above were carried out three times a day.

#### Phase 2 (Week 3)

- Active exercises bilateral in shoulder flexion, scaption, extension, external/internal rotation 5-10 repetitions x3.
- Active external rotation lying on the side 10-15 repetitions x 3.
- Manually resisted isometric external rotation, internal rotation, abduction, flexion and extension 5-10 repetitions x 3.
- Active bilateral flexion in sitting focusing on depression of the shoulders 10 repetition x 3.
- Posterior shoulder stretch 30 seconds x 3.  
The exercises were performed at the PT practice 2 times a week combined with home exercises twice daily.

#### Phase 3 (Week 4-5)

- Active exercises bilateral in shoulder flexion, scaption, extension, external/internal rotation 5-10 repetitions x2.
- Dynamic strengthening exercises of the rotator cuff and scapula stabilizers with a elastic rubber band in standing with shoulder in neutral position (0° of abduction) in external rotation, internal rotation, scaption 0-45°, shoulder. extension and scapula retraction with straight arms 10-15 repetitions x 3.
- Press up (protraction and retraction) with straight arm and a weight in your hand, lying on the back 10-15 repetitions x 3.
- Posterior shoulder stretch 30 seconds x 3.  
The exercises were performed at the PT practice 2 times a week combined with home exercises twice daily.

#### Phase 4 (Week 6-8)

- Dynamic strengthening exercises concentric and eccentric of the rotator cuff and scapula stabilizers with a elastic rubber band in standing with shoulder in different positions of elevation (30°, 45°, 90°) external rotation, internal rotation. Scaption 0-90° and scapula retraction with rows in sitting 10-15 repetitions\*3.
- Unilateral exercises, upright row with weight 10-15 repetitions x 3.
- Push-ups against wall and progression on the floor with push-up plus 10-15 repetitions x 3.
- Posterior shoulder stretch 30 seconds x 3.  
The exercises were performed at the PT practice 2 times a week combined with home exercises twice daily.

#### (Week 9-12)

- Progression of exercises in phase 4 with increased load and more complex coordination for the rotator cuff and scapula stabilizers individually designed for patients considering work situation and leisure time activities.  
The exercises were performed as home exercises twice daily.