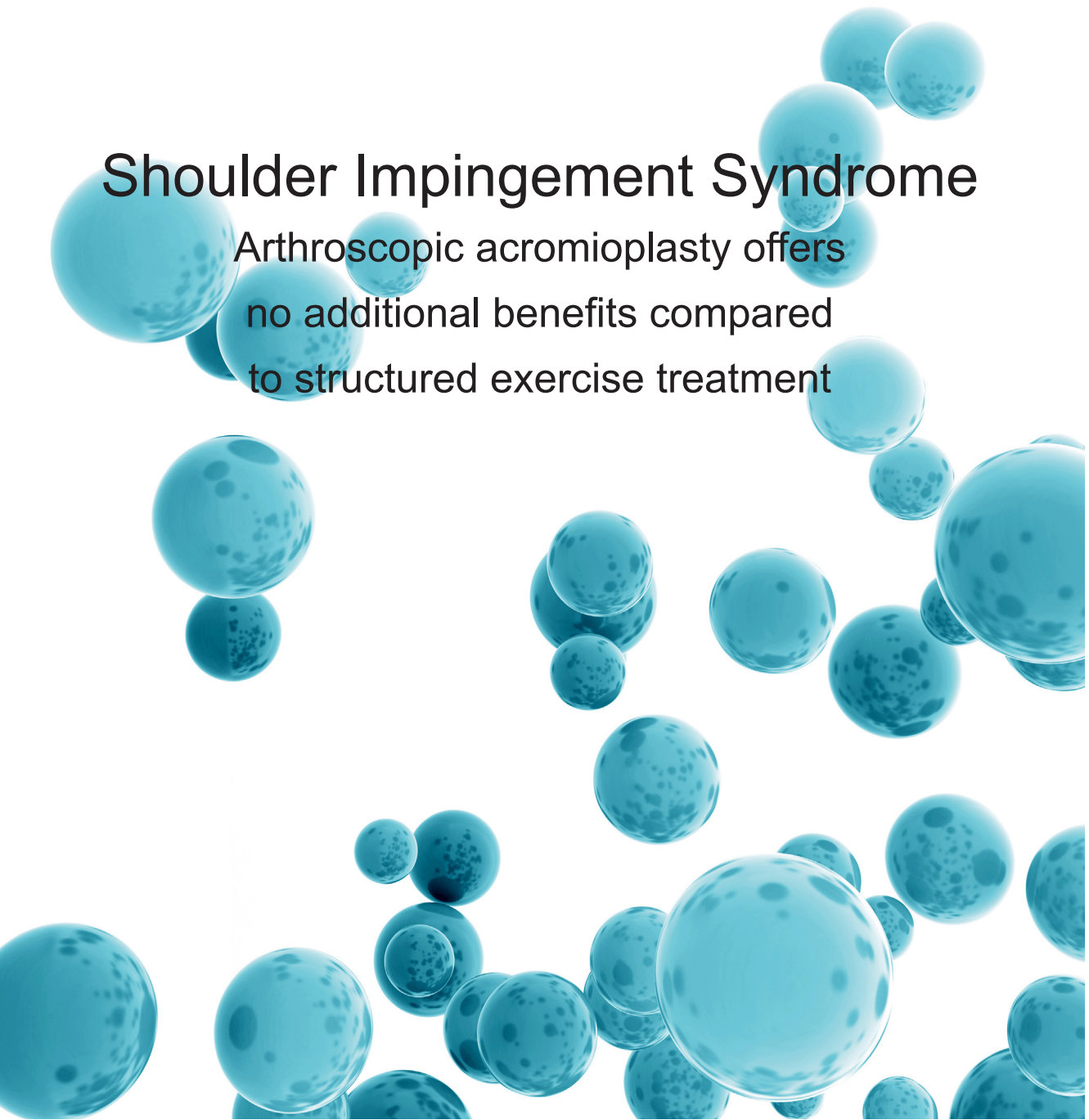


SAARA KETOLA

# Shoulder Impingement Syndrome

Arthroscopic acromioplasty offers  
no additional benefits compared  
to structured exercise treatment





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ACADEMIC DISSERTATION

To be presented, with the permission of  
the Board of the School of Medicine of the University of Tampere,  
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Biokatu 12, Tampere, on 1 April 2016, at 12 o'clock.

UNIVERSITY OF TAMPERE

SAARA KETOLA

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*Acti labores iucundi.*

*To Petra and Lauri*



# ABSTRACT

Shoulder impingement syndrome is a common disorder. However, the treatment algorithm remains controversial. Arthroscopic acromioplasty is a popular procedure, even though its efficacy is unknown. This prospective, randomized, controlled trial examines the efficacy and cost-effectiveness of arthroscopic acromioplasty in the treatment of Stage II shoulder impingement syndrome. In addition, it analyzes prognostic factors to determine which patients would best benefit from the operation. The protectiveness of subacromial decompression from rotator cuff rupture later in life and its effect on the development of rotator cuff muscle volume is also evaluated.

We randomized 140 shoulder impingement patients aged 18–60 years into two groups: a structured exercise treatment group (n=70) and a combined treatment group (n=70). In the latter group, an arthroscopic acromioplasty was performed and then followed by a similar exercise program as used in the other group. Magnetic Resonance Imaging (MRI) of the shoulder was done at baseline and at five years.

The main follow-up points were at two and five years after randomization (134 and 109 patients respectively). The main outcome measure was self-reported pain on a 0–10 Visual Analogue Scale (VAS). Data were examined using an intention-to-treat analysis.

A decrease in the self-reported pain on the VAS was observed between the baseline and the two-year follow-up in both groups: from 6.5 to 2.9 in the exercise group and from 6.4 to 2.5 in the combined treatment group ( $p<0.001$ ). Further improvement continued between two to five years (VAS scores to 2.2 and 1.9, respectively). The same trend was seen in the secondary outcome measures (disability, working ability, pain at night, Shoulder Disability Questionnaire (SDQ) score, and reported painful days). The differences between groups were not statistically significant in any of the outcome measures. The combined treatment was more costly, and operative treatment also creates a possible risk for surgical complications.

Symptom duration, marital status (single), and long periods of sick leave along with a lack of professional education seemed to raise the risk for experiencing pain despite the treatment. Patients with an impingement with radiological acromioclavicular joint degeneration also experienced more pain. The condition of patients who wanted an operation in the exercise group did not improve after the operation.

There were no statistically significant differences in either muscle volume changes or in the amount of perforating ruptures of the supraspinatus tendon at five years. An additional control over ten years after randomization showed no differences between groups in an

intention-to-treat analysis or per protocol (90 patients) in primary or secondary outcome measures.

Arthroscopic acromioplasty does not provide any clinically important effects over a structured and supervised exercise program alone in terms of subjective outcome or cost-effectiveness. This procedure does not seem have any long-term benefits based on radiological findings either. The natural course probably plays a significant role in the results. Arthroscopic acromioplasty cannot be recommended to any specific subgroup of shoulder impingement syndrome patients. Our results suggest that some patients who do not respond to the exercise program do not benefit from acromioplasty either. Further research is needed to identify these patients.

The indications for arthroscopic acromioplasty for working-age patients need to be redefined. Based on the results of this study, it seems that arthroscopic acromioplasty has no good justification as a treatment for shoulder impingement syndrome, and it should therefore be abandoned as the standard treatment. Structured exercise treatment should instead be the basis for treatment. In the future, exercise treatment and programs should also be studied to be able to optimize the treatment effect.



# TIIVISTELMÄ

Olkapään hankausoireyhtymä on yleinen vaiva, jonka hoitolinja ei ole vakiintunut. Hoitomuotoja on monia. Yleisimmin käytetään fysioterapeuttisia hoitoja tai leikkaushoitoa. Olkalisäkkeen avarrusleikkauksia tehdään Suomessa yli 4000 vuodessa. Se on siten Suomen neljänneksi yleisin ortopedinen toimenpide, vaikka sen tehosta ei ole selkeää näyttöä.

Tässä etenevässä satunnaistetussa seurantatutkimuksessa arvioitiin olkalisäkkeen avarrusleikkauksen antamaa hyötyä ja kustannusvaikuttavuutta hankausoireyhtymän hoidossa. Alaryhmäanalyyseillä pyrittiin löytämään leikkauksesta hyötывät potilaat. Samalla selvitettiin, estääkö avarrusleikkaus kiertäjäkalvosimen jännerepeämän syntyä.

Tutkimukseen otettiin 140 olkapään hankausoireyhtymäpotilasta. Heidät satunnaisesti jaettiin kahteen hoitoryhmään. Ei-leikkauksellisen hoidon ryhmässä potilaat saivat toteutettavakseen tarkoin suunnitellun, fysioterapeutin ohjaaman olkapään lihasharjoitteluohjelman. Harjoittelun toteutumista ja edistymistä seurattiin säännöllisillä fysioterapeutin kontrollikäynneillä. Leikkaushoitoryhmässä potilaille tehtiin tähyysteitse olkalisäkkeen avarrusleikkaus, minkä jälkeen he aloittivat täsmälleen samanlaisen fysioterapeuttisen harjoitteluohjelman, kuin vertailuryhmä.

Hoidon tehokkuus arvioitiin mittauksin ja kyselykaavakkein kahden ja viiden vuoden kuluttua satunnaistamisesta. Seurantakäynnillä kävi kahden vuoden kohdalla 134/140 ja viiden vuoden kohdalla 109/140 potilasta. Päättösmuuttuja oli potilaan kokemaa kipua VAS-asteikolla 0–10. Tulokset arvioitiin käyttäen seurannassa lähtöryhmien mukaista analyysiä (intention-to-treat).

Kipu väheni molemmissa hoitoryhmissä verrattaessa lähtötilannetta kahden vuoden tuloksiin: VAS-asteikolla laskua oli ei-leikkauksellisessa hoitoryhmässä 6,5–2,9 ja leikkaushoitoryhmässä 6,4–2,5 ( $p<0,001$ ). Kahden ja viiden vuoden välillä tulokset olivat edelleen jatkaneet paranemistaan (kipu ei-leikkauksellisessa hoitoryhmässä 2,2 ja leikkaushoitoryhmässä 1,9). Myös muissa muuttujissa (potilaan kokemaa haittaa, työkyky, yösrky, SDQ-olkaindeksi ja kipupäivät) todettiin selvä paraneminen. Molemmissa ryhmissä muutokset olivat tilastollisesti merkitseviä. Hoitoryhmien välillä ei todettu tilastollisesti merkitsevää eroa. Kustannukset leikkaushoitoryhmässä olivat kuitenkin selvästi suuremmat. Leikkaushoitoon liittyy myös komplikaatoriskejä. Oirekesto, siviilisäätö (yksinasuvat), pitkä edeltävä sairausloma ja matala koulutustaso näyttivät nostavan kivuliaisuuden riskiä riippumatta hoitoryhmästä. Ei-leikkauksellisessa ryhmässä hoidon tuloksiin tyytymättömät potilaat, jotka myöhemmässä vaiheessa halusivat leikkaushoitoa, eivät hyötывeet toimenpiteestä.

Potilaille tehtiin olkapään magneettikuvaus ennen satunnaistamista. Kuvaus uusittiin viiden vuoden kohdalla. Kiertäjäkalvosimen lihasmassassa ei tällä seurantavälillä havaittu tilastollisesti merkitsevää muutosta. Leikkaus ei myöskään näyttänyt estävän jännerepeämän kehittymistä, vaikka janteen hankausta oli avartavalla toimenpiteellä vähennetty.

Erillinen myöhäisvaiheen arvio tehtiin, kun satunnaistamisesta oli kaikkien potilaiden kohdalla kulunut yli 10 vuotta. Kyselylomakkeeseen vastasi 90 potilasta. Ryhmien välillä ei tutkimuksissa muuttujissa tuolloinkaan ollut tilastollisesti merkitsevää eroa.

Olkalisäkkeen avarrusleikkauksesta ei näytä olevan hyötyä olkanivelen hankausoireyhtymän hoidossa. Yhtäläisiin hoitotuloksiin päästään ohjatulla ja valvotulla fysioterapeuttisella harjoittelulla. Leikkaushoito ei ole kustannustehokasta. Toimenpiteellä ei myöskään todettu olevan suotuisia pitkäaikaisvaikutuksia lihas- ja jännekudoksiin. Taudin luonnollinen kulku vaikuttanee merkittävästi paranemistuloksiin. Tämän tutkimuksen perusteella leikkaushoitoa ei voi suositella millekään erityiselle potilasryhmälle. Aiemmin leikkaushoitoa suositeltiin, jos potilas jäi oireiseksi annetun fysioterapeuttisen hoidon jälkeen. Tässä tutkimuksessa todettiin, että nämä potilaat eivät hyötäneet leikkaushoidosta, mikä on todellinen hoidollinen haaste.

Olkalisäkkeen avarrusleikkauksen käyttöaiheet on määriteltävä uudelleen. Tämän tutkimuksen perusteella olkalisäkkeen avarrusleikkaus ei ole perusteltu eikä ensisijainen hoito olkapään hankausoireyhtymäpotilaille. Ohjattu ja valvottu fysioterapeuttinen harjoittelu on tämän oireyhtymän hoidon perusta. Jatkossa tutkimukset tulisi suunnata fysioterapeuttisen harjoittelun kehittämiseen ja optimointiin, jotta voitaisiin tarjota potilaille mahdollisimman vaikuttavaa hoitoa.

# LIST OF ORIGINAL PUBLICATIONS

- I Ketola S, Lehtinen J, Arnala I, Nissinen M, Westenius H, Sintonen H, Aronen P, Konttinen YT, Malmivaara A, Rousi T. Does arthroscopic acromioplasty provide any additional value in the treatment of shoulder impingement syndrome? A two-year randomised controlled trial. *J Bone Joint Surg Br* 2009 Oct;91(10):1326-1334.
- II Ketola S, Lehtinen J, Rousi T, Nissinen M, Huhtala H, Konttinen YT, Arnala I. No evidence of long-term benefits of arthroscopic acromioplasty in the treatment of shoulder impingement syndrome: Five-year results of a randomised controlled trial. *Bone Joint Res* 2013 Jul 1;2(7):132-139.
- III Ketola S, Lehtinen J, Rousi T, Nissinen M, Huhtala H, Arnala I. Which patients do not recover from shoulder impingement syndrome, either with operative treatment or with nonoperative treatment? *Acta Orthop* 2015 Mar 26:1-6.
- IV Ketola S, Lehtinen J, Elo P, Kortelainen S, Huhtala H, Arnala I. No difference in long-term development of rotator cuff rupture and muscle volumes in impingement patients with or without decompression – A randomized prospective MRI study. *Acta Orthop* 2016 *in press*.
- V Ketola S, Lehtinen J, Arnala I. Nonoperative treatment proven superior to decompression in the treatment of anterolateral shoulder pain. A randomised controlled 12-year follow-up. *Submitted*.

# ABBREVIATIONS

AC	Acromioclavicular
BMI	Body Mass Index
CEAC	Cost-Effectiveness Acceptability Curve
CI	Confidence Interval
CT	Computer Tomography
EMG	Electromyography
HRQoL	Health-Related Quality of Life
ICER	Incremental Cost-Effectiveness Ratio
ITT	Intention-to-treat
MCID	Minimal Clinically Important Difference
MRA	Magnetic Resonance Arthrography
MRI	Magnetic Resonance Imaging
NNT	Number Needed to Treat
NSAID	Non-Steroidal Anti-Inflammatory Drug
OR	Odds Ratio
PP	Per Protocol
SD	Standard Deviation
SDQ	Shoulder Disability Questionnaire
VAS	Visual Analogue Scale

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Tiivistelmä

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# 1 INTRODUCTION

Shoulder pain is very common; it is the second most frequent musculoskeletal disorder (Pope, Croft et al. 1997; Urwin, Symmons et al. 1998; Mäkelä, Heliövaara et al. 1999; Picavet and Schouten 2003), and shoulder impingement is the leading cause of shoulder pain (van der Windt, Koes et al. 1995).

Shoulder impingement has severe effects on the patient's perception of his/her general health. The impingement usually begins gradually, after which it is commonly recurrent or chronic, and it often affects people of working age. In industrial countries, impingement syndrome can be a tremendous burden. As a long-lasting condition, it brings significant economic consequences through treatment costs and productivity losses (van der Windt, Koes et al. 1996; Buckle 1997; Gartsman, Brinker et al. 1998; Urwin, Symmons et al. 1998; Woolf and Åkesson 2001; Tekavec, Jöud et al. 2012).

Shoulder impingement syndrome was introduced in 1972 by Neer, who divided it into three stages: *Stage I*: Edema and hemorrhage, *Stage II*: Fibrosis and tendinitis, *Stage III*: Tears of the rotator cuff, biceps ruptures, and bone changes (Neer 1983). Impingement syndrome was initially described as arising from the mechanical friction of the tendon under the acromion (Neer 1972). However, further studies and treatment trials have not been able to demonstrate a purely mechanical etiology for this syndrome (Soyer, Vaz et al. 2003; Henkus, de Witte et al. 2009). The exact etiology of impingement pain is still unknown, and therefore the current treatment options are controversial (Brox, Staff et al. 1993; Lindh and Norlin 1993; Morrison, Frogameni et al. 1997; Brox, Gjengedal et al. 1999; Spanghel, Hawkins et al. 2002; Husby, Haugstvedt et al. 2003; Haahr, Østergaard et al. 2005; Haahr and Andersen 2006). As diagnosis of shoulder impingement is mainly based on clinical examination, it is somewhat imprecise (Gartsman 1995).

Usually, the first mode of symptomatic treatment is nonoperative: rest, subacromial corticosteroid injections (Buchbinder, Green et al. 2003), and per oral non-steroidal anti-inflammatory drugs (NSAID) (van der Heijden 1999).

Physiotherapy in the treatment of shoulder impingement has been evaluated in many series (Morrison, Frogameni et al. 1997; van der Heijden 1999; Green, Buchbinder et al. 2003; Ludewig and Borstad 2003; Michener, Walsworth et al. 2004; Dickens, Williams et al. 2005; Geraets, Goossens et al. 2005; Haahr, Østergaard et al. 2005; Haahr and Andersen 2006; Lombardi, Magri et al. 2008; Cummins, Sasso et al. 2009; Kuhn 2009; Holmgren, Björnsson Hallgren et al. 2012). Already Neer suggested the use of physiotherapy before surgery is considered (Neer 1983).

In severe cases, arthroscopic decompression and acromioplasty has been used after an apparent failure of all other modes of treatment (Brox, Staff et al. 1993; Brox, Gjengedal et al. 1999; Budoff, Rodin et al. 2005; Haahr, Østergaard et al. 2005; Bengtsson, Lunsjo et al. 2006; Haahr and Andersen 2006; Chin, Sperling et al. 2007; Coghlan, Buchbinder et al. 2008; Henkus, de Witte et al. 2009; Chaudhury, Gwilym et al. 2010; Lunsjo, Bengtsson et al. 2011). Similar results have been obtained by open and arthroscopic acromioplasty (Lindh and Norlin 1993; Spanghel, Hawkins et al. 2002; Husby, Haugstvedt et al. 2003; Barfield and Kuhn 2007).

However, the natural history of the syndrome is still not clear. The recurring nature of the symptoms challenges the faith of the patient in recovery and challenges general practitioners and even shoulder specialists in terms of treatment approach.

Acromial morphology changes with age, but it has been suggested that the presence of a Type 3 acromion does not by itself produce impingement syndrome (Wang and Shapiro 1997). Both asymptomatic and symptomatic cuff tears increase with age (Yamaguchi, Tetro et al. 2001; Nové-Josserand, Walch et al. 2005; Yamamoto, Muraki et al. 2009). The long-term protective effect of acromioplasty on rotator cuff tendons has been suggested (Neer 1972; 1983), but this has not been verified by Magnetic Resonance Imaging (MRI) studies.

Even though the benefits of acromioplasty have been doubted (Brox, Gjengedal et al. 1999; Haahr, Østergaard et al. 2005; Haahr and Andersen 2006), it is still a very common procedure: the incidence has actually risen over the last decade (Yu, Cil et al. 2010). According to a report from the New York area, the incidence of acromioplasty (per 100,000) was 30.0 in 1996, but in 2006 it was already 101.9 (Vitale, Arons et al. 2010). In Finland, the incidence of arthroscopic acromioplasty in 1998 was 75 per 100,000, rising to its highest level of 163 per 100,000 in 2007. Since then, the incidence has started to decline in Finland (Paloneva, Lepola et al. 2015). Table 1 shows the national incidence of arthroscopic acromioplasty in hospitals from four parts of Finland at the start of this study (2002–2003); our study region is Hämeenlinna. There are three-fold differences between some parts of the country.

Table 1. The incidence of acromioplasties in 2002 and 2003 in four different regions of Finland at the onset of this study.

Hospital	2002	2003	2002	2003
	number of procedures	number of procedures	incidence per 100,000	incidence per 100,000
VAASA (West)	204	236	123	142
JOENSUU (East)	164	157	96	92
ROVANIEMI (North)	52	88	43	73
HÄMEENLINNA (South)	53	88	32	53

Clear indications for treatment based on randomized trials have not been defined. The expectations of both surgeons and patients, along with the availability of the operative treatment, affect the choice of treatment.

This randomized, prospective study involves 140 patients with Stage II shoulder impingement. The study's aim is to investigate the possible additional effectiveness of arthroscopic acromioplasty compared to supervised exercise treatment. The two treatment arms of this study are 1) arthroscopic acromioplasty followed by a structured exercise treatment, and 2) a similar structured exercise treatment alone. Thus, the only differentiating factor between these two study groups is the operation. We also analyzed the patients in subgroups. We tried to identify subgroups defined by baseline characteristics in which the response to the intervention differs significantly from the mean. Using MRI data at baseline and at five years, we also tried to discover if surgical decompression would protect the patients from rotator cuff rupture later in life and if it had any effect on the development of muscle volume.

## 2 REVIEW OF THE LITERATURE

### 2.1 Shoulder anatomy

#### 2.1.1 Osseous structures

The bones of the shoulder are the humerus, scapula, and clavicle. The proximal part of the humerus includes the head with greater and lesser tuberosities above the anatomic and surgical neck. The glenoid cavity acts as the site of articulation with the humeral head at the lateral side of the scapula. The subscapular recess is also an extension of the glenohumeral joint. The shoulder joint is composed of four articulations: the glenohumeral, the sternoclavicular, and the acromioclavicular (AC) joint, as well as the scapulothoracic articulation (Spindler, Dovan et al. 2001; Rudez and Zanetti 2008; Cook, Stein et al. 2011). There is no bony junction with the vertebral column. The shoulder girdle articulates with the thoracic cage through the sternoclavicular joint. The upper limb is stabilized to the thorax by the clavicle (Goldstein 2004).

The scapula has two important processes: the acromion and coracoid processes. They both contribute to glenohumeral articulation. The acromion can be divided into three classical types: Type 1: straight or flat, Type 2: curved, and Type 3: hooked. Sometimes, since the creation of the initial description, an additional fourth type is used: a convex upward pointing undersurface (Morrison, Bigliani et al. 1987; Gagey, Ravaud et al. 1993; Natsis, Tsikaras et al. 2007; Balke, Schmidt et al. 2013). The distribution of these types in studies varies to a great extent: 5–68% for Type 1, 24–83% for Type 2, 0–42% for Type 3, and 2–13% for Type 4 (Natsis, Tsikaras et al. 2007). This variation may also reflect the difficulties and inconsistency in classifying the different shapes. It is sometimes difficult to distinguish the non-hooked and hooked acromion, especially if there is an anterior spur (Hirano, Ide et al. 2002). The imaging method is also of importance. In Magnetic Resonance Arthrography (MRA), the type of acromion is more difficult to assign than in plain radiographs (Toivonen, Tuite et al. 1995). Acromion types differ according to age group. Degenerative changes also occur with increasing age among those with normal cuffs. The incidence of Type 1 acromion decreases with increasing age. Of the patients under 50 years of age without impingement, 12% had Type 3 acromions, whereas 36% of patients over 50 years had Type 3 acromions. In the patient group with impingement, the

respective proportions were 10% and 14%. Surprisingly, the incidence of Type 3 acromions in the symptomatic group is lower (Wang and Shapiro 1997).

There are also hypotheses that the morphological changes could be of a degenerative origin rather than congenital (Shah, Bayliss et al. 2001). Bigliani Type 3 acromion is relatively rare in young adults (Schippering, Bailey et al. 1997; Speer, Osbahr et al. 2001; Gill, McIrvin et al. 2002). It is also speculated that Type 3 acromions could be acquired and caused by chronic upward migration of the humeral head, thus forming excrescences on the underside of the anterior acromion (Schippering, Bailey et al. 1997). The proportion of Type 3 acromion seems to increase in line with aging: the prevalence is 16% in individuals aged 30–50 years of age and 31% in those over 50 years (Gill, McIrvin et al. 2002). Scapulas analyzed by the Museum of Natural History showed a 26% prevalence of Type 3 acromions, and again advanced age seemed to correlate with the distribution (Nicholson, Goodman et al. 1996).

The subacromial space consists inferiorly of the humeral head, and superiorly of the AC joint, the under-surface and the anterior edge of the anterior third of the acromion, and the coracoacromial ligament; the latter two are also called the coracoacromial arch (Bigliani and Levine 1997; Umer, Qadir et al. 2012). Within the subacromial space, soft-tissue structures are situated between moving rigid structures. The subacromial arch is considered normal in the sagittal and frontal views in an MRI if it is parallel to the humeral head, in contrast to a situation when there is a narrowing of the subacromial passage (Gagey, Ravaud et al. 1993).

## 2.1.2 Soft tissue structures

The rotator cuff consists of the muscles and tendons of the supraspinatus, infraspinatus, teres minor, and subscapularis. All of these muscles arise from the scapula and attach to the superior part of the humerus. Additionally, the long head of the biceps brachii is structurally and functionally closely associated to the rotator cuff (Curtis, Burbank et al. 2006). The rotator cuff muscles function as dynamic stabilizers and assist in the control of the movements of the other shoulder muscles of the glenohumeral joint, most importantly the deltoid muscle (Gomoll, Katz et al. 2004; Yanagisawa, Okumura et al. 2014). They also contribute to active shoulder movements (Juul-Kristensen, Bojsen-Møller et al. 2000a). The rotator cuff muscles grow in size in accordance with increasing age and reach their morphological maturity at approximately 17 years (Yanagisawa, Okumura et al. 2014). Shoulder abductor muscle volume is again significantly reduced in the elderly (Vidt, Daly et al. 2012). Sarcopenia is an age-associated loss of muscle mass. Muscle force also decreases (Jones, Bishop et al. 2008). The variability in muscle sarcomeres and optimal muscle length has been studied in a cadaveric work (Langenderfer, Jerabek et al. 2004).

The arterial supply to the rotator cuff is derived from the ascending branch of the anterior humeral circumflex artery, the suprascapular and posterior humeral circumflex arteries, and

the acromial branch of the thoracoacromial artery (Chansky and Iannotti 1991). The distal part of the supraspinatus tendon is a zone of relative avascularity, the so-called “critical zone” approximately 1 cm from its insertion. In this area, the effect of subacromial space narrowing is maximized, thus making the site the most common for degenerative rotator cuff tears (Lohr and Uthoff 1990; Tawfik, El-Morsy et al. 2014). However, sometimes this area is also reported to be hypervascularized. This neovascularization is suspected to be secondary to mechanical impingement (Chansky and Iannotti 1991).

The major passive stabilizers of the glenohumeral joint are the inferior, middle, and superior glenohumeral ligaments. They are thick, fibrous bands in the glenohumeral joint capsule. The coracohumeral ligament is part of the shoulder capsule, not a true ligament (Cook, Stein et al. 2011).

Within the shoulder, there are fluid-filled bursae: the subacromial, subcoracoid, subdeltoid, and subscapular, the three first of which are sometimes seen as one continuous bursa. The subacromial bursa works to decrease the friction of the supraspinatus tendon and between the rotator cuff and the deltoid (Rudez and Zanetti 2008; Cook, Stein et al. 2011).

The glenoid labrum is the fibrocartilaginous rim of the glenoid fossa. It increases the depth of the fossa and provides points of attachment for the capsule and glenohumeral ligaments to provide stability to the glenohumeral joint (Juul-Kristensen, Bojsen-Møller et al. 2000a; Cook, Stein et al. 2011; Motamedi, Everist et al. 2014). The pericartilaginous structures, such as the rotator cuff and labrum, come into contact even in stable shoulders (Jobe and Iannotti 1995).

### 2.1.3 Stability and kinematics

The glenohumeral joint has relatively little bone stability (Jobe and Iannotti 1995) because of the size mismatch between the smaller glenoid and larger humeral head (Gomoll, Katz et al. 2004). The glenoid covers at most one-third of the humeral head. This is a functional value, however. The contact area varies by movement, thus making the coverage a measure of an arc rather than an area. By thinking in these terms, the glenoid covers 46–60% of the humeral head depending on the direction of the movement (Jobe and Iannotti 1995). Flexion and abduction are performed in cooperation with the glenohumeral joint and the pectoral girdle. The single action of glenohumeral joint would limit the movement to 90°. Further abduction requires external rotation of the humerus. This adds articular surface. The upper rotation of the glenoid cavity gives a 60° addition to the abduction movement, allowing the translation of the humeral head. External rotation and translation allow the greater and lesser tubercles along with the rotator cuff and subacromial bursa to pass under the acromion and coracoacromial ligament. At the end of the movement, lateral flexion of the trunk provides the last degrees of abduction (Goldstein 2004). As the glenoid cavity gives little support, the coordinated function of the rotator cuff and deltoid muscles is

essential. The rotator cuff muscles act in concert to stabilize the humeral head against the glenoid, especially the teres major, infraspinatus, and subscapularis, thus providing a fulcrum for the supraspinatus and deltoid muscle to work. Along with them, almost 30 muscles in total are required to work in delicate interaction to create the smooth, efficient motion of the shoulder joint (Alpert, Pink et al. 2000; Brox 2003).

Daily activities require free mobility in the shoulder joint combined with an ability to develop forces in all directions. The shoulder has the greatest range of motion compared to any other joint (Juul-Kristensen, Bojsen-Møller et al. 2000a; Brox 2003; Gomoll, Katz et al. 2004). This requires soft tissue structures and neuromuscular control adaptation to the actual demand (Brox 2003). The glenohumeral joint possesses six degrees of freedom, three rotations, and three translations (Michener, McClure et al. 2003). Glenohumeral abduction in the scapular plane, when added to the scapulothoracic motion, is 123°. At this position, external rotation of the shaft is necessary to produce additional humeral cartilage to articulate with the glenoid, thus creating a range of 160° (Jobe and Iannotti 1995).

The prime movers of the glenohumeral joint in abduction are the deltoid and the supraspinatus; in adduction the pectoralis major, the latissimus dorsi, the teres major, and the subscapularis; in flexion the pectoralis major (clavicular head) and the deltoid (anterior fibres); in extension the latissimus dorsi and the deltoid (posterior fibres); in internal rotation the pectoralis major, the latissimus dorsi, the teres major, and the subscapularis; and in external rotation the infraspinatus, the teres minor, and the deltoid (posterior fibres) (Goldstein 2004; Cook, Stein et al. 2011).

The supraspinatus, along with the other rotator cuff muscles (the infraspinatus, the subscapularis, and the teres major), serve to maintain congruent contact between the glenoid fossa and the head of the humerus. In humeral head depression, the forces of the latissimus dorsi and teres major are involved most effectively. The depressor effects of the infraspinatus and subscapularis are also significant (Halder, Zhao et al. 2001; Michener, McClure et al. 2003). These secondary movers are important for the production of the smooth, coordinated movement of glenohumeral elevation. The deltoid muscle is also needed in this function (Alpert, Pink et al. 2000). The latissimus dorsi is measured to be the most effective depressor and the teres major was the second most effective. The supraspinatus is an ineffective depressor (Halder, Zhao et al. 2001). The level of muscle activity in the supraspinatus in electromyography (EMG) is measured to be higher in the first arc of motion, and the deltoid (anterior and middle part) is measured to be higher in the second and third arcs (from 30° to 90° of elevation) (Alpert, Pink et al. 2000).



## 2.2 Shoulder impingement

### 2.2.1 Definition and terminology

Shoulder impingement is the clinical name of a syndrome used to describe symptoms caused by the irritated and perhaps inflamed supraspinatus tendon passing the narrowed subacromial arc. Shoulder disorders are classified by anatomical localization (rotator cuff disease, subacromial pain syndrome), by mechanism (impingement syndrome), by pathological process (tendinitis, tendinosis and rupture), and by etiology (work-related shoulder pain, repetitive strain syndrome) (Brox 2003). It is important, however, to define tendinitis, tendinosis, and tendinopathy systemically. Rotator cuff disease is a complex combination of multifactorial intrinsic or extrinsic causes, and thus the term impingement does not reflect the reality of the pathogenesis (Maffulli, Khan et al. 1998; McFarland, Maffulli et al. 2013).

Impingement syndrome may be the final pathway of diverse conditions of the shoulder. It covers a broad spectrum of entities with different shoulder pathologies and etiologic mechanisms. Subacromial impingement syndrome is commonly used as an umbrella term to cover rotator cuff tendinopathy and partial tears, as well as subacromial bursitis (Greenberg 2014). In addition, the Current Care Guidelines of Finland regarding tendon disorders of the shoulder state that the term subacromial pain can be used to cover a wide variety of conditions in degenerative rotator cuff tendon disease: tendinopathy, impingement, painful arc syndrome, and bursitis ([www.kaypahoito.fi/web/kh/suositus/suositus?id=hoi50099](http://www.kaypahoito.fi/web/kh/suositus/suositus?id=hoi50099)). Impingement syndrome is nowadays a label for a group of diverse conditions with multiple causes and mechanisms but similar clinical presentations and combinations of symptoms. It encompasses a full range of rotator cuff abnormalities and is a non-accurate diagnosis. Accuracy in diagnostics should enable clinicians to replace the non-specific terminology of a combination of findings and symptoms caused by various underlying mechanisms with more accurate terms. Impingement can be considered a descriptive term for a broad spectrum of symptoms rather than a single diagnosis (Barr 2004; Hegedus, Goode et al. 2008; Cools, Cambier et al. 2008; Papadonikolakis, McKenna et al. 2011; de Witte, de Groot et al. 2013).

The terminology also reflects the medical speciality consulted. In orthopaedics, the term impingement is widely used, while radiologists describe the acromion morphology, for example, and in industrial medicine the term “work-related” can be used. Difficulties arise from different diagnostic criteria adopted by therapists and researchers and because of the multiplicity of disorders (Brox 2003; Palmer, Harris et al. 2012). The problems in diagnostics and labeling can lead to different branches of treatment. If motion-related etiology is valued, the patient might be treated with physical therapy. If anatomic etiologies are rated higher, it might easier lead to a surgical treatment. The term impingement should probably be abandoned, as it might limit thinking and instead highlight the new perspective of tendon disorders (Khan, Cook et al. 2002; de Witte, de Groot et al. 2013; McFarland,



Maffulli et al. 2013). It is suggested that the symptoms of this syndrome should, instead of being called impingement pain, be called anterolateral shoulder pain, and the spectrum of rotator cuff abnormalities should be called rotator cuff disease rather than impingement syndrome (McFarland, Maffulli et al. 2013).

### 2.2.2 Incidence and prevalence

Shoulder pain is the second or third most common musculoskeletal complaint. In the top three are low back pain and – depending on the study – either knee pain or neck pain (Chard, Hazleman et al. 1991; Urwin, Symmons et al. 1998; Picavet and Schouten 2003). One to three percent of all visits to physicians annually are estimated to be for shoulder pain (van der Windt, Koes et al. 1995; Bot, van der Waal et al. 2005a; Wofford, Mansfield et al. 2005; Linsell, Dawson et al. 2006; Greving, Dorrestijn et al. 2012). The annual incidence of shoulder disorders is estimated to be about 7% but an incidence of up to 14% has been found in working populations (van der Heijden 1999; Miranda, Viikari-Juntura et al. 2001). Shoulder impingement syndrome is considered to be the most common cause of shoulder pain in primary health care clinical practice (van der Windt, Koes et al. 1995; van der Windt, Koes et al. 1996; Tekavec, Jöud et al. 2012; Greenberg 2014). It accounts for 44–65% of all shoulder complaints (van der Windt, Koes et al. 1995; Vecchio, Kavanagh et al. 1995).

Estimates of shoulder pain prevalences in cross-sectional studies have varied from 7% to 31% and seem to rise in the elderly (Chard, Hazleman et al. 1991; Urwin, Symmons et al. 1998; Luime, Koes et al. 2004; Eltayeb, Staal et al. 2007). The new onset consultation rate seems to peak in women in the 50–59 years age group and in men in the 60–69 years age group (Tekavec, Jöud et al. 2012). In health examination surveys, the prevalence of any shoulder joint impairment was observed in 9% of the subjects, while shoulder pain during the previous month was reported by 30% of the subjects in the Mini-Finland Health Survey (Mäkelä, Heliövaara et al. 1999). In the Finnish Health 2000 Survey population, the prevalence of non-specific shoulder pain was 12%, and the prevalence of clinically diagnosed rotator cuff tendinitis 2% (Miranda, Viikari-Juntura et al. 2005). In the most recent population survey in Finland, *Terveys, toimintakyky ja hyvinvointi Suomessa 2011* (Health, Functional Ability, and Well-being in Finland, 2011), shoulder pain was reported in 13–26 days during the 30 previous days, and it became more common with aging. Difficulties in abducting the upper arm was reported in 5–6% of the answers (<http://urn.fi/URN:ISBN:978-952-245-769-1>).

About half of the population is estimated to have at least one episode of shoulder pain annually and its lifetime prevalence is about 10% (van der Heijden 1999). Approximately 1–2% of adults seek medical attention for shoulder pain every year (Green, Buchbinder et al. 2003; Linsell, Dawson et al. 2006). Nevertheless, perhaps only about 20–50% of

patients with shoulder symptoms ever consult a doctor for their problem (Tekavec, Jöud et al. 2012).

### 2.2.3 Etiopathology

The shoulder is a complex entity of bones, muscles, tendons, bursae, and nerves from which pain can elicit (Brox 2003; Greenberg 2014). Two main theories have been described to define the etiology of shoulder impingement syndrome: the mechanical (extrinsic) and the degenerative (intrinsic) theory. They are sometimes also called the structural and functional or extratendinous and intratendinous theories. According to Neer, extrinsic impingement of the acromion is the most common cause of shoulder impingement (Neer 1972). Advances in imaging technology and arthroscopy have provided more evidence for pathoanatomy and the intrinsic etiology. The cause is, however, likely to be multifactorial, with contributions from external compression, age-related degeneration, and vascular compromise (Harrison and Flatow 2011). Sometimes the term primary impingement is used, meaning an entity caused by a specific shoulder disorder. The term secondary impingement is used when the disorder is associated with, for example, instability, calcifying tendinitis, and post-traumatic or AC problems (Goldberg and Bigliani 2006).

#### 2.2.3.1 Extrinsic theory

Extrinsic mechanisms can be arranged by dividing shoulder impingement syndrome into anatomical factors (the shape of the acromion and AC degeneration), and biomechanical factors (scapular kinematics, humeral kinematics, the influence of posture such as thoracic spine kyphosis, muscle deficit, and soft tissue tightness) (Seitz, McClure et al. 2011).

##### *Anatomical factors*

Any abnormality that disturbs the subacromial structures and their relationship may lead to impingement (Bigliani and Levine 1997). The differing morphology and anatomical variants of the acromion and AC joint pathologies (spurs and osteophytes) that encroach upon the subacromial space can lead to impingement. The supraspinatus tendon and the subacromial bursa are trapped between the humeral head and the anterior part of the acromion, the coracoacromial ligament, or the AC joint. The subacromial space can also be narrowed because of acute or chronic inflammation of the subacromial bursa, thickening or calcification of the coracoacromial ligament, and proximal humeral fractures (Seitz, McClure et al. 2011; Umer, Qadir et al. 2012).

### *Shape of the acromion*

Neer's extrinsic theory is widely accepted. He states that impingement under the coracoacromial arch causes irritation of the subacromial tissues (Neer 1972). The rotator cuff tendons are mechanically impinged under the inferior surface of the anterior third of the acromion and the AC joint. Many studies have subsequently confirmed this correlation (Morrison, Bigliani et al. 1987; Toivonen, Tuite et al. 1995). Variations in the architecture of the coracoacromial arch can cause symptoms and induce the development of rotator cuff lesions.

Although widely accepted, there is very evidence for and against Neer's theory and acromial morphology being responsible for impingement (Braman, Zhao et al. 2014). In one study, a normal subacromial arch was found in only 6% of patients with clinical impingement, whereas "aggressive" arches were found in 46% (Gagey, Ravaud et al. 1993). According to one study, 50% of patients with rotator cuff tendinitis had Type 1 acromions, and 58% of the patients with full-thickness rotator cuff tears had Type 3 acromions (Gill, McIrvine et al. 2002). In the study group presented by Balke et al., only 2% of the asymptomatic patients had a Type 3 acromion, in contrast to patients with impingement (20%) (Balke, Schmidt et al. 2013). Hirano et al. stated that there is a correlation between acromial shape (Type 3) and rotator cuff tears, but it is not as strong as has been suggested previously. In patients with rotator cuff ruptures, 36% had Type 1 acromions, 24% had Type 2, and 40% had Type 3, and in the latter group the tears were significantly larger (Hirano, Ide et al. 2002). This mechanism has been considered to create a vicious cycle leading to full-thickness tears of the rotator cuff (Ozaki, Fujimoto et al. 1988; Shah, Bayliss et al. 2001). There are reports of a relationship between spurs and enthesophytes and rotator cuff pathology (Farley, Neumann et al. 1994). These changes can also be considered to be not the cause but the result of rotator cuff pathology (Ozaki, Fujimoto et al. 1988; Ogata and Uhthoff 1990; Shah, Bayliss et al. 2001).

Both asymptomatic and symptomatic cuff tears increase with age (Yamamoto, Takagishi et al. 2010). The earlier reported association between cuff rupture and shape of the acromion might be explained by independent increase of both Type 3 acromion and cuff injuries with increasing age. It has also been proposed that the morphology of the acromial arch could have a correlation with the severity of the syndrome (Natsis, Tsikaras et al. 2007).

### *Degeneration of AC joint*

The AC joint has an intra-articular disc that can degenerate due to trauma or age-related factors. This can continue in changes in the surrounding joint surfaces and result in degenerative arthrosis (Chen, Rokito et al. 2003). Neer proposed that degeneration of the AC joint may contribute to subacromial impingement (Neer 1972). The rotator cuff makes contact with the AC joint at 60° of glenohumeral abduction. By 70° of abduction, the greater tuberosity lies directly beneath the AC joint, at which point even minor narrowing

in this space may cause rotator cuff irritation (Cuomo, Kummer et al. 1998). The inferiorly directed osteophytes in the AC joint narrow the AC space, and in addition to subacromial impingement, it has also been associated with cuff tears (Neer 1983; Cuomo, Kummer et al. 1998). Pain of AC etiology is typically quite resistant to impingement (acromioplasty/coplaning) treatments (Chen, Rokito et al. 2003).

### *Coracoacromial ligament*

The coracoacromial ligament can also be a source of impingement. The coracoacromial arch is in contact with the rotator cuff particularly in forward elevation and internal rotation. The relation between the anatomy of the coracoacromial arch and impingement syndrome was introduced already in 1972 by Neer (Neer 1972). It has been noted that coracoacromial ligaments with more than one bundle having a longer lateral border and a larger coracoid insertion appear to show significant association with rotator cuff degeneration. Otherwise, no statistical significance between cuff degeneration and the type of the coracoacromial ligament has been found (Kesmezacar, Akgün et al. 2008).

### *Os acromiale*

An os acromiale is the result of a failed fusion of the epiphysis of the anterior extremity of the acromion (Wright, Heller et al. 2000). It may provoke impingement if it is unstable and as a result of its attachment to the coracoacromial ligament, it tilts anteriorly (Bigliani and Levine 1997). It is quite a rare anatomical condition, or at least it is rarely diagnosed as a single uncomplicated condition (Boehm, Matzer et al. 2003). Its presence in a radiograph is usually an incidental finding (Wright, Heller et al. 2000). According to the literature, the incidence of an os acromiale varies from 1.3% to 15% (Boehm, Matzer et al. 2003). Impingement caused by an unstable os acromiale is much less commonly described than its co-existence with a rotator cuff tear (Wright, Heller et al. 2000; Boehm, Matzer et al. 2003; Boehm, Rolf et al. 2005).

### *Subacromial bursa*

Shoulder impingement syndrome may also involve inflammation of the bursa in the subacromial space. This decreases the volume of the subacromial space. The diagnosis can be confirmed by a selective injection of local anaesthetic (Bigliani and Levine 1997).

### *Coracoid impingement*

Coracoid or subcoracoid impingement is a less common condition and often an unrecognized cause of anterior shoulder pain. In coracoid impingement, the subscapularis or biceps tendon is compressed between the coracoid process and the lesser tuberosity of the humerus (Ferrick 2000). A relationship between anterior shoulder pathologies and narrowed coracohumeral distance or subcoracoid stenosis has been noted (Ferrick 2000; Lo, Parten et al. 2003; Richards, Burkhart et al. 2005). However, there are no clear

conclusions on the diagnostic and therapeutic criteria of the coracoid impingement (Osti, Soldati et al. 2013).

### *Biomechanical factors*

Glenohumeral instability and subluxation may have a role in the development of secondary impingement. It can also be associated with muscle imbalance. Dynamic narrowing may be caused by alterations in scapular or humeral kinematics, postural abnormalities, biomechanical factors, rotator cuff and scapular muscle performance deficits, and tightness of the pectoralis minor, or be a combination of these (Seitz, McClure et al. 2011). By acknowledging this, prevention of microinstability with conservative treatment is advised. This etiology has been thought to explain why throwing athletes and athletes with microinstability have not shown improvement after acromioplasty (Bigliani and Levine 1997; Heyworth and Williams 2009; Page 2011).

The scapula and the thoracic cage form the scapulothoracic articulation. During shoulder elevation the scapula rotates upwardly, rotates externally, and tilts posteriorly, mainly after 90°. During the first degrees of shoulder elevation, downward rotation of the scapula may occur. This is caused by the weight of the limb and the muscular forces that pull downward, thus creating an adequate length-tension relationship for the muscles. In patients with shoulder impingement syndrome, a decreased scapular upward rotation and a decreased posterior tilt can be observed. The altered shoulder kinematics lead to dysfunction of the rotator cuff and scapular muscles, resulting in so-called disturbed scapulothoracic rhythm (Ludewig and Cook 2000; Michener, McClure et al. 2003; Struyf, Nijs et al. 2011).

Glenohumeral movement may also be disturbed by increased posterior capsule tightness and a decreased internal rotation range of motion, thus leading to increased mechanical compression of the subacromial structures and impingement (Tyler, Nicholas et al. 2000; Umer, Qadir et al. 2012).

Impingement can occur as a result of muscle dysfunction or weakness. The rotator cuff muscles can weaken due to tension overload or the natural process of aging, thus leading to a decreased depressor force and the proximal migration of the humeral head (Bigliani and Levine 1997). In addition, poor posture has a significant influence on motion and pain (Bullock, Foster et al. 2005).

### 2.2.3.2 Intrinsic theory

Intrinsic mechanisms include changes that contribute to the tendons themselves. These can arise from alterations in biology, degeneration, aging, diminished blood supply, and alterations in mechanical properties, tensile/shear overload, overuse, or trauma along the morphology. There is increasing evidence to support an intrinsic mechanism behind rotator cuff disease. Intrinsic mechanisms can also be arranged by dividing them into age-related

changes, deficient vascular supply, inhomogenous mechanical properties, tensile tissue overload, and alterations in tendon matrix (Seitz, McClure et al. 2011). In addition, it has been identified that genetic factors play an important role in the development of rotator cuff disease (Harvie, Ostlere et al. 2004).

### *Degenerative tendinopathy*

Histopathologically, tendinopathy includes degenerated and disorganized collagen fibers with increased cellularity and vascularity, but without obvious inflammatory cells present (Khan, Cook et al. 1999). Greater cell death (apoptosis) has been found in patients with chronic rotator cuff symptoms compared to normal tendons in asymptomatic individuals (Tuoheti, Itoi et al. 2005).

Degenerative changes can weaken the supraspinatus and thus diminish its capability to center the humeral head on the glenoid. This leads to superior humeral migration, thus narrowing the subacromial space and leading to impingement (Harrison and Flatow 2011). It has been noticed that the incidence of cuff tears increases with age, while acromial degeneration does not. Based on this, and the fact that the lesions of the cuff are usually not on the surface but within the tendon, intrinsic degenerative tendinopathy has been suspected to be the primary origin of rotator cuff tears rather than pure friction or impingement (Ogata and Uthoff 1990).

Many studies have shown that inflammatory cytokines and growth factors can have an important role in inflammation of the subacromial bursa and in shoulder pain in rotator cuff disease. The association between the release of inflammatory cytokines such as interleukin-1- $\beta$  (Gotoh, Hamada et al. 2001), vascular endothelial growth factor (Yanagisawa, Hamada et al. 2001), tumor necrosis factor- $\alpha$ , transforming growth factor- $\beta$ , basic fibroblast growth factor, and vascular endothelial growth factor (Sakai, Fujita et al. 2001) has been studied. Recognizing and evidently controlling the expression of these cytokines and growth factors might be of importance when treating the syndrome.

### *Overuse of the shoulder*

Subacromial impingement can be caused by inflammation and thickening of the tendons or bursa (Bigliani and Levine 1997). Rotator cuff tendinitis is a generic term that is used to describe acute and chronic inflammatory processes that are connected to irritation, strain, overuse, and poor mechanics (Obaid and Connell 2010; Seitz, McClure et al. 2011). Traditionally, this disorder is considered to be progressive (Seitz, McClure et al. 2011). The subacromial space can be narrowed due to soft tissue inflammatory reactions caused by microtrauma or overuse such as intensive work, heavy loads, or awkward work postures (Miranda, Viikari-Juntura et al. 2001). This can lead to subacromial edema and tendinitis, and the soft tissues extensively occupy the subacromial space and continue to cause friction

and wear against the coracoacromial arch (Bigliani and Levine 1997). Overuse commonly occurs in athletes whose sport involves an overhead motion (Bigliani and Levine 1997). The aging process is also thought to be a contributor (Neviaser, Andarawis-Puri et al. 2012). Inflammatory reactions and failed regeneration processes manifest as pain in and around the tendons (Andres and Murrell 2008).

#### 2.2.3.3 Internal impingement

Internal impingement is a unique mechanism within the biomechanical factors, and it should be clearly differentiated from the classical extrinsic etiologies. It is not related to subacromial narrowing; it is caused by tendon compression between the glenoid and the humeral head (Castagna, Garofalo et al. 2010; Seitz, McClure et al. 2011). Internal impingement often has a multifactorial etiology (Kirchhoff and Imhoff 2010).

Internal impingement is most often associated with throwing or other overhead athletes, and it is provoked especially during distinct phases of motion. It occurs when the arm is repetitively required to be abducted and externally rotated. This condition is characterized by excessive repetitive contact of the greater tuberosity of the humeral head with the posterosuperior aspect of the glenoid. Some even think that it is a normal rather than a pathological condition and that the contact between the posterosuperior glenoid and the rotator cuff could be physiological (Jobe, Iannotti et al. 1995). It can lead to the development of articular-sided rotator cuff fraying or tears and posterosuperior labral lesions (Paley, Jobe et al. 2000; Manske, Grant-Nierman et al. 2013).

Internal impingement can appear as stiffness in warming up or pain while throwing, or be recurrent and chronic (Jobe 1997). The symptoms can be vague, manifesting only in loss of velocity or control during competition, a phenomenon also known as dead arm syndrome (Budoff, Nirschl et al. 2003).

#### 2.2.3.4 Multifactorial etiology

It is a common belief that the etiology of rotator cuff tendinopathy is multifactorial (Seitz, McClure et al. 2011; Neviaser, Andarawis-Puri et al. 2012; Factor and Dale 2014). Rotator cuff disease which at first developed by an intrinsic mechanism can also lead to subacromial space reduction and create an interaction or a combination of extrinsic and intrinsic mechanisms, or it can originally arise from both extrinsic and intrinsic mechanisms (Seitz, McClure et al. 2011). The role of the intrinsic mechanism may be more significant than the extrinsic (Factor and Dale 2014), but the precise etiology, including molecular, mechanical, and structural changes, is not known (Neviaser, Andarawis-Puri et al. 2012), which is a challenge for the examination and treatment protocol.



## 2.2.4 Stages of impingement

Neer has described the staging of impingement syndrome. It ranges from tendinitis through fibrosis and a partial tear to a full-thickness tear. He states that they represent a continuum, and that tears of the rotator cuff are developed secondary to chronic impingement (Neer 1983). Shoulder impingement syndrome may vary from reversible inflammatory changes of the rotator cuff and subacromial bursa to rupture of the rotator cuff with secondary degenerative disease (Michener, McClure et al. 2003).

Stage I impingement is characterized by edema and hemorrhage. This is typically observed in patients under 25 years of age. Stage II impingement represents fibrosis and tendinitis of the rotator cuff caused by repeated inflammatory episodes. This stage is characteristically observed in patients aged between 25 and 40 years. Stage III impingement involves more chronic changes and partial or complete tears of the rotator cuff, and it is usually found only in patients aged over 40 years (Neer 1983).

## 2.2.5 Risk factors

Regardless of the etiology of the impingement syndrome, several risk factors have been identified.

### 2.2.5.1 Age

Age seems to have a greater role in rotator cuff syndrome than shoulder pain in general (Bodin, Ha et al. 2012). Age was also found to be a significant predictor for sclerosis of the medial acromion and the narrowing and degeneration of the AC joint (Bonsell, Pearsall et al. 2000). Higher age increased the risk of incidence of shoulder pain (Buckle 1997; Miranda, Viikari-Juntura et al. 2001; Miranda, Viikari-Juntura et al. 2005; Rechart, Shiri et al. 2010; Roquelaure, Bodin et al. 2011).

The prevalence of rotator cuff tears in the general population (both partial and full-thickness), including those that are asymptomatic, increases with age (Moosmayer and Smith 2005; Nové-Josserand, Walch et al. 2005; Yamaguchi, Ditsios et al. 2006; Yamamoto, Takagishi et al. 2010) and pain can eventually develop in a large percentage of people with asymptomatic tears (Yamaguchi, Tetro et al. 2001). In those under 18 years, glenohumeral instability is the leading cause of shoulder problems (Chang 2004).

Balke et al. and Vähäkari et al. did not find any significant correlation between acromion type and age. Their results suggested that the shape of the acromion does not change with age in individuals without any rotator cuff pathology (Vähäkari, Leppilahti et al. 2010; Balke, Schmidt et al. 2013). It seems that the presence of a Type 3 acromion does not by itself produce impingement syndrome (Wang and Shapiro 1997).



The consultation rates were noted to increase from entering working life and decrease from retirement age (Tekavec, Jöud et al. 2012). Recovery has also been reported to reduce strongly in those of a higher age (Bonde, Mikkelsen et al. 2003).

#### 2.2.5.2 Sex

In general, musculoskeletal complaints in women are reported to be more common than among men, especially neck and shoulder complaints (Wijnhoven, de Vet et al. 2006; Eltayeb, Staal et al. 2007). A female predominance in patients presenting with shoulder pain has been reported (Bot, van der Waal et al. 2005a; Wofford, Mansfield et al. 2005; Linsell, Dawson et al. 2006). This predominance is not explained by age, education, smoking, overweight, physical activity, and pain catastrophizing (Wijnhoven, de Vet et al. 2006). According to the Health 2000 Survey, the lifetime prevalence of shoulder pain was higher for women (51%) than men (43%). Shoulder pain during the preceding month was also reported more frequently in women (23%) than men (18%) ([www.terveys2000.fi/julkaisut](http://www.terveys2000.fi/julkaisut)).

#### 2.2.5.3 Hand dominance

This syndrome more frequently affects the dominant arm (Yamaguchi, Ditsios et al. 2006; Yamamoto, Takagishi et al. 2010). Chronic shoulder syndrome was diagnosed in 5% for the right shoulder and 3% for the left shoulder. The Health 2000 Survey reported an approximately two-fold difference in the prevalence of the syndrome when comparing the right and left arm in the working-age groups, suggesting a link with physical activities ([www.terveys2000.fi/julkaisut](http://www.terveys2000.fi/julkaisut)). There is also evidence that the disorder in one shoulder could be a risk factor for the other shoulder (Silverstein, Viikari-Juntura et al. 2006).

#### 2.2.5.4 Work

Work-related factors associated with rotator cuff syndrome are forceful, highly repetitive manual work, overload at work or prolonged static loading, working with one's hands above shoulder level, work with hand tools especially with elevated arms, exposure to hand-arm vibration, sustained arm elevation, or repeated arm abduction (Buckle 1997; Frost and Andersen 1999; Miranda, Viikari-Juntura et al. 2001; Brox 2003; Roquelaure, Ha et al. 2009; van Rijn, Huisstede et al. 2010; Yamamoto, Takagishi et al. 2010; Roquelaure, Bodin et al. 2011; Bodin, Ha et al. 2012).

Shoulder pain has also been connected to work ergonomics (Tekavec, Jöud et al. 2012). The level of education was associated with chronic rotator cuff tendinitis: the more years of education the subject had, the less pain was suffered (Rechardt, Shiri et al. 2010). Along with

physical work demands, high psychological demands, lack of control, low skill discretion, and low supervisor support also seem to increase the association with upper limb disorders (Brox 2003; Roquelaure, Ha et al. 2009; Bodin, Ha et al. 2012; van Rijn, Huisstede et al. 2010; Bodin, Ha et al. 2014). Shoulder impairment is also connected to previous work stress (Mäkelä, Heliövaara et al. 1999). The perception of high job demands and low social support is associated with a less favorable course of shoulder tendinitis. This might also be a consequence of the shoulder disorder itself (Bonde, Mikkelsen et al. 2003). In the results of the Health 2000 Survey, a clear decrease in chronic shoulder syndrome was noted with increasing years of education both for men and women ([www.terveys2000.fi/julkaisut](http://www.terveys2000.fi/julkaisut)).

#### 2.2.5.5 Psychological and psychosocial factors

Lack of social support has shown an association with upper limb disorders (Buckle 1997). Mental stress also increased the risk of shoulder pain (Miranda, Viikari-Juntura et al. 2001). Psychosocial factors have been noted to be associated with the course and prognosis of chronic shoulder pain (Reilingh, Kuijpers et al. 2008).

The prevalence of shoulder pain in a British cohort study increased in line with lower adult social class. The relationships could be explained by poor adult mental health, psychological distress, adverse life events, and lifestyle factors (Macfarlane, Norrie et al. 2009). In a Dutch cohort study, psychosocial factors came up as predictors of outcome in chronic shoulder pain (Reilingh, Kuijpers et al. 2008). Psychological factors were also reported to predict the outcome in the work of Bot et al. (Bot, van der Waal et al. 2005b).

This association also works in reverse. Patients with non-specific pain often report symptoms of burnout, depression, and alexithymia (Miranda, Viikari-Juntura et al. 2005). Patients with shoulder impingement are found to be significantly lower in all health dimensions of quality of life measures than the normal population (Chipchase, O'Connor et al. 2000).

Pain catastrophizing has an influence on pain perception and clinical outcomes, and psychological factors may interact with the problem. In addition, genetic-, cultural-, experience-, and community-based factors can interact with pain. This must be taken into account when planning and informing the patient to mobilize the painful arm. In the worst case scenario, the patient will avoid any discomfort and relinquish even the necessary movements for rehabilitation. The patient should be encouraged to maintain usual activities despite minor pain (George, Wallace et al. 2008).

#### 2.2.5.6 Obesity

Obesity or high waist circumference have been noted to be associated with an increased risk of shoulder disorders and pain (Miranda, Viikari-Juntura et al. 2001; Luime, Kuiper

et al. 2004; Roquelaure, Ha et al. 2009; Rechartt, Shiri et al. 2010), and also specifically rotator cuff tendinitis (Wendelboe, Hegmann et al. 2004). However, in some studies the association of overweight or high Body Mass Index (BMI) and shoulder pain was not found (Mäkelä, Heliövaara et al. 1999; Macfarlane, Norrie et al. 2009).

#### 2.2.5.7 Other factors

Conditions such as diabetes, stroke, and Parkinson disease are also risk factors for shoulder disorders (Mäkelä, Heliövaara et al. 1999; Miranda, Viikari-Juntura et al. 2005; Roquelaure, Ha et al. 2009; Rechartt, Shiri et al. 2010; Greenberg 2014).

### 2.2.6 Symptoms

Patients with impingement syndrome frequently describe symptoms as a dull ache that has developed insidiously over a period of weeks to months. The pain is localized anterolaterally and can radiate to the lateral mid-humerus. The pain typically worsens at night and can even wake the patient from sleep, especially when lying with the arm overhead or on the affected extremity. Pain on resisted abduction is common. Activities of daily living can be disturbed, such as reaching above one's head, combing one's hair, reaching into one's back pocket, etc. (Gomoll, Katz et al. 2004; Andrews 2005; Umer, Qadir et al. 2012) It has been reported that 89% of patients with subacromial impingement have reported the presence of nocturnal pain (Mulligan, Brunette et al. 2015). The so-called painful arch is a clinical finding denoting pain with arm abduction. Sometimes, a decrease in active range of motion, arm force, and function can also occur (Bigliani and Levine 1997; Koester, George et al. 2005). Stiffness and weakness are sometimes reported, but they are usually secondary to pain (Koester, George et al. 2005). This syndrome is often chronic or produces recurrent pain and dysfunction (Greenberg 2014). Some 40% of patients still report problems a year after the initial consultation (van der Heijden 1999).

### 2.2.7 Diagnostics

An examination begins with the patient telling his/her history. The anamnesis continues with specific, detailed questions about the symptoms and pain. The patient is asked if there is stiffness, weakness, or instability. In addition, the location of the pain, its onset, duration, nature, intensity, and the factors that precipitate or relieve the pain are ascertained. (Goldstein 2004; Schultz 2004.)

The clinical examination includes inspection and palpation as well as testing the range of motion. Deformities, asymmetries, postural abnormalities, scars, atrophy, or erythema are noted. Motion testing is at first performed actively and then passively. The directions

analyzed are forward elevation, abduction, external rotation, internal rotation, and cross-body adduction (Goldstein 2004; Gomoll, Katz et al. 2004; Schultz 2004).

Diagnostics and the evaluation of shoulder dysfunction is challenging and should be performed systematically. It must be kept in mind that these symptoms can also be a manifestation of another serious condition or illness that presents as shoulder pain (Schultz 2004).

There are several clinical tests aimed at establishing the diagnosis. There is still no consensus on the clear diagnostic criteria that would define this syndrome. The accuracy of the tests in clinical practice must be considered in the context of the overall patient assessment. The tests can provoke pain or reveal strength or weakness. Furthermore, the tests can be aimed at identifying impingement *per se* or act to identify the diagnosis of, for example, internal impingement, rotator cuff tears, or labral defects (Alqunae, Galvin et al. 2012; Hanchard, Lenza et al. 2013; Hermans, Luime et al. 2013). A substantial variation in interobserver reliability has also been noted when using tests on the physical examination of the shoulder girdle (Nomden, Slagters et al. 2009). Instead of the sole use of clinical tests that might have limited use in informing diagnosis, an emphasis on dysfunction may be more appropriate, along with functional limitations and muscle imbalance (Kelly, Brittle et al. 2010).

#### 2.2.7.1 Diagnostic testing

##### *Neer's test*

The classic Neer's impingement sign is elicited with the patient's arm is passively elevated by the examiner standing behind a seated patient. Scapular rotation is hindered by pressing down on the acromion and clavicle. The arm lifted in forward flexion forces the greater tuberosity of the humerus underneath the acromion. The supraspinatus tendon is then compressed between the two bony structures and in a positive or pathologic test the reproduction of pain is noted (Neer 1983). It demonstrates contact between the supraspinatus tendon on the greater tuberosity and both the acromion and the coracoacromial ligament. Shoulder pain can further be provoked by maximizing contact pressure with internal rotation (Yamamoto, Muraki et al. 2009). The test can be augmented with an injection of local anaesthetic beneath the anterior acromion (Neer's impingement test). If the pain is due to impingement, it is relieved or abolished (Neer 1983). Neer's test is considered to have a sensitivity of 75–89% (Çalis, Akgün et al. 2000; MacDonald, Clark et al. 2000). The painful arc is a test performed with the patient standing. The patient actively elevates and lowers the arm in abduction. The test is positive if there is pain at 60° and 120° in the upward or downward movement or in both (Hanchard, Lenza et al. 2013; van Kampen, van den Berg et al. 2014).

### *Hawkins–Kennedy test*

In the Hawkins–Kennedy (Hawkins) test, the examiner stands in front of the patient. The arm is placed at 90° of forward flexion. The arm is then internally rotated and lowered. By doing so, the greater tuberosity is driven against the inferior surface of the coracoacromial ligament, thus provoking impingement on the supraspinatus tendon. The endpoint is either when the patient experiences pain or the rotation of the scapula is noticed (Hawkins and Kennedy 1980; Schultz 2004). The Hawkins test is considered to have a sensitivity of 92% (Çalis, Akgün et al. 2000; MacDonald, Clark et al. 2000). In cadaveric shoulders, this manoeuvre seemed to demonstrate contact between the subscapularis tendon on the lesser tuberosity and both the acromion and the coracoacromial ligament. The Hawkins and Neer's test do not present an identical impingement mechanism (Yamamoto, Muraki et al. 2009).

### *Yocum's test*

In this test, the patient is asked to place his/her hand on the opposite shoulder. The examiner then raises the elbow but not the shoulder. Compression in a positive test is similar to that of the Hawkins test (Leroux, Thomas et al. 1995; Schultz 2004).

### *Cross-body adduction*

The arm is lifted at 90° of forward flexion and then adducted toward the opposite shoulder across the body, thus provoking a compression of the AC joint (Schultz 2004).

### *Jobe's test*

This test is also called the empty can test. The patient elevates the arm, elbow fully extended. The arm in full internal rotation thumbs pointing downwards in the scapular plane. Downward pressure is then applied on the upper surface of the arm by the examiner. The test is developed for the evaluation of the supraspinatus tendon and considered positive if weakness or pain occurs during resistance (van Kampen, van den Berg et al. 2014).

### *Codman's sign*

Codman's sign is also known as the drop arm test. In this test, the patient stands with the arm fully abducted. He/she then starts to reverse the motion slowly in the same arc. The test is positive if the arm suddenly drops. The test was developed for the evaluation of the supraspinatus tendon provoking pain or weakness (van Kampen, van den Berg et al. 2014). The specificity of the drop arm test is estimated to be 97% (Çalis, Akgün et al. 2000).

## Other tests

In the infraspinatus drop sign, the patient is seated and the arm is held at a 90° elevation in the scapular plane by the examiner. The arm is kept in external rotation and the elbow at 90° flexion. The sign is positive if the patient is not able to maintain the position (by activating the infraspinatus) (Hertel, Ballmer et al. 1996). Infraspinatus muscle strength is tested with the arm along with the trunk. The elbow is at 90° flexion. The examiner then starts to push the arm in internal rotation and the patient resists. The possible weakness is compared to the other side (van Kampen, van den Berg et al. 2014).

The external rotation lag sign evaluates the integrity of the supraspinatus and infraspinatus. The patient sits with the examiner behind the patient. The elbow is at 90° flexion. The examiner lifts the arm at 20° elevation in the scapular plane, at first also holding the arm in external rotation. The examiner continues to hold the elbow but releases the wrist. The test is positive if the patient is unable to maintain the external rotation and a drop occurs (Hertel, Ballmer et al. 1996).

Gerber's test is also known as the lift-off test. The patient places his/her hand against the back at waist level. The arm is in internal rotation and the elbow at 90° flexion. The examiner starts to pull the arm backwards (5–10 cm) maintaining the arm figure. The patient is then asked to hold this position him/herself. If there is weakness and the arm jerks back forward, slapping against the back, the test is positive, denoting eventual rupture of the subscapularis tendon (Gerber, Hersche et al. 1996).

In Gilcreest's palm-up test, the arm is actively elevated with the palm facing upward and the elbow extended. In a positive test, pain is elicited at the anterior arm when the limb is held against resistance. Strength is not tested. The test reveals pain along the long head of the biceps brachii (Leroux, Thomas et al. 1995).

## Conclusions

Based on a review of the literature, Neer's test, Hawkins test, and the Neer injection test were found to be sensitive but not specific (Papadonikolakis, McKenna et al. 2011), and the painful arc test and the positive external rotation resistance the most accurate for detecting rotator cuff disease (Hermans, Luime et al. 2013). The *Cochrane Database of Systematic Reviews* notes that there is an extreme diversity in the performance and also the interpretation of physical tests for shoulder impingement. The evidence upon which the selection of tests should be based was considered to be insufficient (Hanchard, Lenza et al. 2013). The recommendation is that the diagnosis can only be made using a combination of clinical tests. To determine subacromial impingement, the Hawkins test, the painful arc test, and the infraspinatus muscle strength test are advisable (Park, Yokota et al. 2005; Diercks, Bron et al. 2014).

### 2.2.7.2 Shoulder scores

Standardized measures allow the comparison of patients and treatments in different studies. Many physical measurements to assess the upper extremity have many handicaps in analyzing disabilities and translating measurable impairments (Hudak, Amadio et al. 1996). Measures used for shoulder pain include more concepts of activities than concepts of body functions, and environmental factors are scarcely addressed. ICF (International Classification of Functioning, Disability, and Health) is based on an integrative model that classifies functioning within the components of body functions, body structures, activities and participation, and environmental and personal factors (Roe, Soberg et al. 2013).

Disabilities of the Arm, Shoulder and Hand (DASH) is an outcome measure that has a 30-item questionnaire with a recall period of one week. It includes items relating to the other joints of the upper extremity and how the disability affects general health (Hudak, Amadio et al. 1996; Beaton and Schemitsch 2003).

The Constant score is a functional assessment score that can be used for normal, diseased, and treated shoulders. It has a maximum score of 100 points, of which 65 points are allocated for range of movement and strength (objective), while 35 points are allocated for activities of daily living and pain (subjective). Normal values for age and sex are determined (Constant, Gerber et al. 2008).

The Western Ontario Rotator Cuff (WORC) score measures disease-specific quality of life. It can be used in clinical trials and also in clinical practice, and it is also an appropriate measurement tool for individuals followed over time. The questions in the WORC score include items on physical symptoms, sports and recreation, work, lifestyle, and emotions (Kirkley, Alvarez et al. 2003).

The Shoulder Disability Questionnaire (SDQ) is a pain-related disability questionnaire. It contains items describing common situations in life that are likely to induce symptoms in patients with shoulder disorders. The questions ask whether symptoms have occurred in the preceding 24 hours, and the questions can be responded to with answers of yes/no/not applicable. The final score is calculated as the percentage of “yes” answers. The final score is thus between 0 (no disability) and 100 (all applicable items positive) (van der Windt, van der Heijden et al. 1998; van der Heijden, Leffers et al. 2000).

The Shoulder Pain and Disability Index (SPADI) is a self-administered index divided into two subscales: pain and disability. It consists of thirteen items, and each of item of two Visual Analogue Scale (VAS) scales. This index has been proven useful for both clinical and research purposes, and it captures the patient’s perception of pain interference during daily activities (Engebretsen, Grotle et al. 2010a).

The University of California Los Angeles (UCLA) Shoulder Rating Scale is a functional scoring system that measures pain, motion, function, strength, and patient satisfaction. It was originally described for the evaluation of patients undergoing shoulder arthroplasty (Amstutz, Sew Hoy et al. 1981).



The American Shoulder and Elbow Surgeons Standardized Shoulder Assessment form (ASES) has a physician's assessment and a patient's self-evaluation section. The questions cover pain, instability, activities of daily living, strength, and range of motion. It can be used to measure shoulder function and outcome (Richards, An et al. 1994).

The simple shoulder test (SST) consists of twelve questions about activities of daily living. The questions assess shoulder function and comfort, and the questions are answered yes/no (Lippitt, Harryman et al. 1992).

There are altogether perhaps twenty-two different self-administered shoulder disability questionnaires, of which sixteen are condition-specific questionnaires for the shoulder. A further two have been developed for shoulder instability, one for rotator cuff tears, and one for osteoarthritis. Thus the remaining twelve are for shoulder disorders in general. The above introduced DASH, SPADI, and ASES are the most evaluated scales. DASH has received the best ratings for its clinimetric properties (Bot, Terwee et al. 2004).

### 2.2.7.3 Measures of Quality of Life

Health is a multidimensional concept. Health-Related Quality of Life (HRQoL) encompasses aspects of overall quality of life. It is an indicator of individual physical and mental well-being. The questionnaires can be generic or disease-specific, and they can be used to describe the effects of an illness and give an estimation of health gains produced by clinical interventions. Nowadays, they are an important component of health surveillance and are also considered valid indicators of service needs (Räsänen, Roine et al. 2006).

#### *SF-6D*

Formerly known as Short Form-36 (SF-36), this tool is widely used globally. It has been adopted because of its brevity and comprehensiveness. It is a short-form health survey measuring six domains: physical functioning, role limitations, social functioning, pain, mental health, and vitality. The results are scaled from 0 to 100, where 100 is a good health state. It has been translated and has been (or is being) validated in more than 30 countries (Ware 2000, Brazier, Roberts et al. 2002).

#### *EQ-5D*

This measure was previously referred to as the EuroQOL. This tool was developed to describe and value HRQoL and to generate cross-national comparisons of health status. It has a five-item scale across five dimensions: mobility, self-care, usual activities, pain, and anxiety/depression. The final score is between 0 to 1, where 0 is death and 1 is the best state of health. The questionnaire is simple to use and it is available in at least twenty-



nine languages. It has been applied to musculoskeletal conditions (EuroQol Group 1990; Beaton and Schemitsch 2003; Kopec and Willison 2003).

### *15D*

The 15D quality of life tool consists of questions concerning breathing, mental function, speech, vision, mobility, usual activity, vitality, hearing, eating, excretion, sleeping, distress, discomfort and symptoms, depression, and sexual activity. All the questions have five alternative answers ranging from no problems to extreme problems. The utility score ranges from 0 to 1, with 1 being equivalent to full health and 0 to death (Sintonen 1994; 2001).

### *QWB*

The Quality of Well-Being Scale (QWB) was initially known as the Index of Well-Being. It has scales for three areas: mobility, physical activity, and social activity. A fourth component was added to weigh various symptoms and problems (Kaplan, Bush et al. 1976).

### *HUI*

The previous versions of the Health Utilities Index (HUI) were developed for evaluating outcomes in low-weight infants and the long-term results of childhood cancer. It measures sensory (vision and hearing) and communicational ability (speech), happiness, dexterity, pain or discomfort, learning and school ability, and physical activity (mobility) (Torrance, Feeny et al. 1996; Kopec and Willison 2003).

### *Others*

In addition to the tools mentioned above, Rosser-Kind, Direct valuation, SG (Standard Gamble), TTO (Time Trade-Off), and Rating Scale are also in use (Räsänen, Roine et al. 2006).

### *QALY*

Quality-adjusted life years (QALY) are used for commensurate appraisal of the cost-effectiveness of various health care interventions. QALY can express the effectiveness of the health care as a combination of a change both in the length and quality of life. QALYs are calculated by multiplying the difference in HRQoL scores before and after treatment by life expectancy. Costs per QALY or society's willingness to pay for a QALY can also be counted (Räsänen, Roine et al. 2006). A year of life lived in perfect health is worth 1 QALY and a year of life lived in a state of less than perfect health is worth <1 (Dougherty and Howard 2013a). The use of QALY has been expanded to PPD-QALY (permanent partial

disability-quality of life year). It provides decision makers with, for example, information on the estimated loss of productivity on a cash value basis (Dougherty and Howard 2013b).

#### 2.2.7.4 Radiology

The diagnosis of subacromial impingement is mainly clinical and determined via a combination of physical tests, but radiological examinations are needed to confirm the diagnosis and exclude other reasons for pain. The role of imaging is to identify the extent of the abnormalities in the rotator cuff, subacromial bursa, acromion, and AC joint. Radiological evaluation is suggested after prolonged symptoms (over six weeks) to rule out rotator cuff tears (Sharma, Morrison et al. 2013; Diercks, Bron et al. 2014).

Plain radiographs remain the start of any imaging evaluation for virtually all shoulder pathologies (Willick and Sanders 2004; Sharma, Morrison et al. 2013). Radiographs are taken to evaluate osseous abnormalities of the coracoacromial arch or osteoarthritis (Harrison and Flatow 2011). Routine radiographs include anteroposterior (in external and internal rotation), glenohumeral, axillary, and the scapular Y view (Willick and Sanders 2004; Harrison and Flatow 2011; Sharma, Morrison et al. 2013).

The shape of the acromion is best seen via the outlet view (Willick and Sanders 2004). Measuring the acromiohumeral distance may reflect the clinical status better than the shape of the acromion (Mayerhoefer, Breitenseher et al. 2009). The normal acromiohumeral interval is reported to be 11 mm at 0° of elevation (Flatow, Soslowsky et al. 1994). A diminished acromiohumeral distance of 6–7 mm indicates the presence of a significant rotator cuff tear (McCreesh, Crotty et al. 2015).

The acromial slope, acromial tilt, lateral acromial angle, and acromion index can also be measured. The acromion index is counted by dividing the distance from the glenoid plane to the acromion by the distance from the glenoid plane to the lateral aspect of the humeral head. The extension of the acromion is relative to the acromion index, and the larger the extension of the acromion, the higher the acromion index becomes (Balke, Schmidt et al. 2013). Since there is no clear affiliation of acromial morphology and degenerative rotator cuff tear, the critical shoulder angle has recently been proposed to reveal the most accurate prediction of an individual risk for tear (Moor, Wieser et al. 2014).

Computer tomography (CT) is a fast and efficacious technique in diagnosing bony lesions and dislocations, and it is most commonly used after a trauma. It can also be used as a CT arthrography to evaluate the rotator cuff if a patient is unable to undergo MRA (Willick and Sanders 2004; Sharma, Morrison et al. 2013).

Ultrasound is recommended as the most valuable and cost-effective diagnostic imaging if nonoperative treatment fails (Diercks, Bron et al. 2014). It is highly dependent on the skill of the examiner and requires operator expertise (Willick and Sanders 2004; Sharma, Morrison et al. 2013). It is excellent for viewing superficial muscle and tendon anatomy (Willick and Sanders 2004). One advantage of ultrasound is that it is a dynamic imaging

study (Willick and Sanders 2004). As the examination is performed in real time, the radiologist can receive feedback from the patient. When the arm is abducted during scanning, bursal fluid or bulging can be noticed. In a normal situation, the supraspinatus and bursa glide easily beneath the acromion (Yablon, Bedi et al. 2013). Ultrasound is an excellent method for the evaluation of rotator cuff pathology and actually has an equally high sensitivity and specificity for diagnosing cuff tears as MRI when the examiner is familiar with the sonographic pitfalls (Sharma, Morrison et al. 2013; Yablon, Bedi et al. 2013). The benefit of this examination is also that it can be done to anybody. This modality is not disallowed for patients with metallic implants in their body, patients with claustrophobia, or those who cannot lie flat. It also allows guided percutaneous procedures. The dynamicity also helps in diagnosing problems with the long head of the biceps (Yablon, Bedi et al. 2013). Disadvantages include the limited access to evaluate the labrum, articular surfaces, deep soft tissue structures, and bones. During scanning, the field of view is also limited. Operator dependence can also be counted as a disadvantage (Sharma, Morrison et al. 2013).

When evaluating shoulder derangement, MRI has become the study of choice. It provides accurate images of shoulder anatomy and information about several shoulder pathologic entities. In musculoskeletal imaging, MRI has continued to develop as an important tool in the assessment of the shoulder joint and soft tissues (Willick and Sanders 2004; Chaipat and Palmer 2006; Cook, Stein et al. 2011; Sharma, Morrison et al. 2013). Interpreting MRI scans requires a clear understanding of normal anatomy, anatomic variations in osseous and non-osseous structures, and MRI artefacts (Chaipat and Palmer 2006; Rudez and Zanetti 2008; Cook, Stein et al. 2011; Motamedi, Everist et al. 2014). During the MRI scan, the patient is supine. The arm to be imaged is externally rotated and lies alongside the body (Vahlensieck 2000; Willick and Sanders 2004). Scanning planes most typically include T2-weighted sequences with fat suppression in the oblique sagittal (perpendicular to the course of the supraspinatus), oblique coronal (along the axis of the supraspinatus muscle belly), and axial imaging planes; proton density or gradient-echo sequences in the axial imaging plane; and T1-weighted images in the oblique coronal and oblique sagittal imaging planes. The supraspinatus is best shown on oblique-coronal and axial T1-weighted images (Vahlensieck 2000; Willick and Sanders 2004; Sharma, Morrison et al. 2013). The advantages of MRI include that it is noninvasive, causes no ionizing radiation exposure, has an exquisite capability for soft tissue discrimination (especially muscles and tendons), is able to evaluate multiple pathologies, is multiplanar, and delineates the intricate anatomy of the shoulder well. It can be used with or without contrast administration. When assessing MRI instead of MRA, a further advantage is the lack of contrast exposure (Fitzpatrick and Walz 2010; Motamedi, Everist et al. 2014). MRI has been noted to be superior to ultrasound when assessing bursal effusion or hypertrophy (Ardic, Kahraman et al. 2006). MRI examination may not be feasible if the patient suffers from claustrophobia. In such a situation, an open bore magnet can be considered as an alternative, even though its

resolution lags behind the conventional MRI technique. Other contraindications may be metallic implants in body, aneurysm clips, cochlear implants, and cardiac pacemakers (Willick and Sanders 2004). MRI is currently the examination of choice in most centers. It is significantly more sensitive and specific than ultrasound. It requires the expertise of sub-specialized musculoskeletal radiologists to ensure the best possible diagnostic performance and interpretation (Willick and Sanders 2004; Theodoropoulos, Andreisek et al. 2010).

The accuracy of MRI can be advanced with a contrast solution. Subsequently, it has become the standard of practice to request MRA. It is particularly helpful in evaluating intra-articular bodies and cartilage lesions as well the detection and characterization of labral pathologies. It is also more accurate in finding undersurface tears of the rotator cuff and imaging postoperative patients (Willick and Sanders 2004; La Rocca Vieira, Rybak et al. 2012). MRA is also more sensitive to partial-thickness supraspinatus tears than conventional MRI (Magee, Williams et al. 2004). According to a meta-analysis, the sensitivities and specificities for rotator cuff lesions were reported at between 80–100% (Schulte-Altdorneburg, Gebhard et al. 2003).

Some authors emphasize the influence of acromial morphology on rotator cuff defects. The opposing opinion is that the changes in morphology are not the cause but the result of the degenerative rotator cuff disease (Ozaki, Fujimoto et al. 1988; Nicholson, Goodman et al. 1996; Wang and Shaphiro 1997; Shah, Bayliss et al. 2001). The subacromial arch is in the radiological opinion capable of being an anatomic risk for impingement if there is a narrowing of the subacromial passage or tendinous thinning in that particular area. The arch is presumed normal if it is parallel to the humeral head and if there is a fatty layer interposition between the supraspinatus and the arch. These changes are analyzed in sagittal and frontal views (Gagey, Ravaud et al. 1993). Acromiohumeral distance can be reliably measured on both conventional radiographs and MRI. Tears and fatty muscle degeneration of the cuff have been noted to correlate with reduced acromiohumeral distance (Saupe, Pfirrmann et al. 2006). Normal bursa in the subacromial or subdeltoid space is rarely thicker than 2 mm (White, Schweitzer et al. 2006). Asymptomatic patients can also have changes in radiological assays. Radiological abnormalities should be interpreted in respect to the patient's symptoms (Bonsell, Pearsall et al. 2000).

Earlier muscle geometry was based on cadaveric evaluations. Nowadays, the MRI has been estimated to have high reliability, reproducibility, and validity for measuring muscle volumes. The mean volume has been estimated to be 1.5–1.7-times higher in MRI than in human cadaver specimens, probably partly due to the dehydration effect (Juul-Kristensen, Bojsen-Møller et al. 2000a). MRI has also been compared to ultrasound in estimating muscle volumes. Ultrasound also seems to give satisfactory accuracy, especially when analyzing the supraspinatus (Juul-Kristensen, Bojsen-Møller et al. 2000b). Lehtinen et al. developed a reliable and reproducible method of measuring the muscle volumes of the rotator cuff muscles from shoulder MR images (Lehtinen, Tingart et al. 2003). The interobserver and intraobserver variabilities were less than 4% (Tingart, Apreleva et al.

2003). The average volumes of the supraspinatus are 36–50 mm<sup>3</sup>, the infraspinatus (and teres minor) 96–125 mm<sup>3</sup> (evaluated as one muscle group, because the border is not always clearly visible), and the subscapularis 99–165 mm<sup>3</sup> (Juul-Kristensen, Bojsen-Møller et al. 2000a–b; Lehtinen, Tingart et al. 2003; Holzbaur, Murray et al. 2007; Vidt, Daly et al. 2012) (Table 2). Muscle atrophy of the supraspinatus is diagnosed if the muscle occupies less than half of the area of the fossa. If the superior border of the muscle is below the tangent line (drawn between the spine of the scapula and the coracoids process), atrophy can also be verified. Fatty degeneration can be assessed on MRI T1-weighted images (Tawfik, El-Morsy et al. 2014). It is classified according to Goutallier as low (grade 0 no fat or grade 1 some fatty streaks), moderate (grade 2 muscle > fat), or advanced (grade 3 muscle = fat and grade 4 muscle < fat) (Goutallier, Postel et al. 1994). Fatty degeneration is noted to be one of the factors having an impact on unfavourable results after a rotator cuff repair (Oh, Kim et al. 2010).

## 2.2.8 Treatment

### 2.2.8.1 Nonoperative treatment

Various nonoperative treatment modalities are used to treat shoulder impingement syndrome, including rest, cold, heat, acupuncture, ultrasound, transcutaneous nerve stimulation, stretching, and exercise (Johansson, Oberg et al. 2002). The initial treatment is relative rest of the shoulder. The return to normal activity or temporarily modified work should take place as soon as possible, however (Mitchell, Adebajo et al. 2005). Patient education has a significant role as a part of nonoperative means. The patient should understand the cause behind the shoulder pain and also the goal of the rehabilitation. A therapeutic benefit will not be achieved with a suboptimal rehabilitation program (Morrison, Greenbaum et al. 2000).

Table 2. Muscle volumes of our study patients at baseline and at five years, measurements from previous studies as comparison, which were mainly stated as healthy shoulders.

	M. supraspinatus cm <sup>3</sup>	M. infraspinatus cm <sup>3</sup>	M. subscapularis cm <sup>3</sup>
This study at baseline	49.0	127.3	119.8
This study at five years	45.6	113.8	110.3
Juul-Kristensen, Bojsen-Møller et al. 2000a	48.8	125.1	153.6
Lehtinen, Tingart et al. 2003	36	96	99
Holzbaur, Murray et al. 2007	50.0	118.6	164.5
Vidt, Daly et al. 2012	39.9	101.7	102.5

## *Medication*

In general practice, the first step in treatment often includes rest and analgesic. Oral NSAIDs are found to be more effective than placebo in reducing pain in the short term (van der Windt, van der Heijden et al. 1995; Petri, Huffman et al. 2004). When choosing the medication, the possibility of adverse reactions must be kept in mind (van der Windt, van der Heijden et al. 1995). NSAIDs have also been used as an injection. Subacromial injections have been evaluated to be effective in subacromial impingement and judged not to have the potential side effects of corticosteroids (Min, St Pierre et al. 2013).

Corticosteroid injections may cause an improvement in shoulder impingement and relieve pain (Akgün, Birtane et al. 2004). Earlier improvements in pain and functional disability were seen in the acute or subacute phase when corticosteroid injections were combined with exercise therapy. The additional benefit was no longer seen at three months (Akgün, Birtane et al. 2004; Crawshaw, Helliwell et al. 2010; Penning, de Bie et al. 2012). Higher doses might give greater improvement (Arroll and Goodyear-Smith 2005). The evidence to support the use of corticosteroid injections is yet not clear, and the effect may be small and not well-maintained (Buchbinder, Green et al. 2003; Coombes, Bisset et al. 2010). Tendon ruptures as a complication are rare (Coombes, Bisset et al. 2010). The use of ultrasound-guided injection seems to improve the effect and range of motion (Hsieh, Hsu et al. 2013). The recommendation is to consider corticosteroid injections in acute or subacute tendinitis where the potential benefit appears clearer than in chronic situations (Gaujoux-Viala, Dougados et al. 2009).

Hyaluronate is a normal component of synovial fluid lubricating joints. Promising results have been published about its use in the treatment of rotator cuff disease, but as yet, there is no certainty of its true effect (Chou, Ko et al. 2010; Penning, de Bie et al. 2012; Moghtaderi, Sajadiyeh et al. 2013).

## *Exercise treatment*

Exercise is also probably the most investigated form of shoulder rehabilitation (Michener, Walsworth et al. 2004). Numerous forms of exercise are used in treating rotator cuff disease: range of motion exercises, stretching and flexibility exercises for the anterior and posterior shoulder girdle, scapular stability exercises, and strengthening exercises (isometric and isotonic) with elastic bands, dumbbell weights, wall presses, push-ups, etc. Retraining of the muscle imbalance by muscle relaxation techniques and motor learning is also of importance to normalize dysfunctional patterns (Michener, Walsworth et al. 2004; Senbursa, Baltaci et al. 2007, Kachingwe, Phillips et al. 2008, Bennel, Wee et al. 2010, Østerås, Torstensen et al. 2009).

Exercise treatment is suggested to be the first line management (Kuhn 2009; Holmgren, Björnsson Hallgren et al. 2012). There is currently no consensus on the most appropriate exercise strategy (Holmgren, Björnsson Hallgren et al. 2012).



The choice of treatment is highly dependent on the examiner's field of specialty, first whether it is physiotherapeutic or surgical, and then whether activity modifications or more invasive treatment should be chosen. Clinicians are unsure of the type and duration of the exercises and which muscles should be targeted. There are currently no clear guidelines nor consensus on recommending any ideal or specific treatment schedule (Michener, Walsworth et al. 2004; Kuhn 2009; Hanratty, McVeigh et al. 2012; de Witte, de Groot et al. 2013).

An additional benefit in exercise treatment can be achieved with manual therapy techniques, particularly upper joint mobilization. Improvements in function from minor to significant and a decrease in pain have been reported when combined with therapeutic exercise. Strength has also been reported to improve (Conroy and Hayes 1998; Bang and Deyle 2000; Kromer, De Bie et al. 2013). According to some reports, no additional benefit could be found, when compared to therapeutic exercises alone in reducing pain, decreasing disability, or improving function (Bennell, Wee et al. 2010; Brudvig, Kulkarni et al. 2011).

### *Rationale*

A successful program aims to reestablish normal function. As the shoulder is designed to gain maximum mobility, it relies on the muscles more than any other human joint. The most important stabilizers of the shoulder are the rotator cuff muscles. They center the humeral head on the fossa and coordinate with other muscles performing in a delicate way to allow full range of movement (Ginn, Herbert et al. 1997). Exercise treatment is advocated to restore shoulder and scapular range of motion and stability, reverse muscle imbalances, increase rotator cuff strength, relieve pain, and promote healing (Bang and Deyle 2000; Green, Buchbinder et al. 2003). Isometric and isotonic exercises are therefore designed to strengthen the rotator cuff musculature, thus restoring the ability to counteract the action of the deltoid (Morrison, Greenbaum et al. 2000, Clisby, Bitter et al. 2008, Ludewig and Cook 2000). Tendons act in tensile force transmission and function as a storage of energy which is released during action. The goal of stretching exercises is to reduce tendon stiffness, enhance elasticity, and improve healing (Witvrouw, Mahieu et al. 2007).

In a study by Roe et al., ten rotator cuff tendinopathy patients were treated with supervised exercise treatment for three to six months. EMG and pain during maximal isometric contraction were chosen as outcome measures. Pain at rest was reduced and EMG increased for the trapezius and deltoid muscles in both the afflicted and unaffected arms (Roe, Brox et al. 2000).

### *Scapulothoracic exercises*

Scapulothoracic exercise treatment includes scapular motor control training and stretching (Stuyf, Nijs et al. 2013). Scapular stability exercises are included because EMG studies have

shown increased activity in the upper trapezius, with decreased activity in the serratus anterior and the middle and lower fibers of trapezius, and asynchronous timing deficits in subjects with subacromial impingement syndrome (Ludewig and Cook 2000, Cools, Witvrouw et al. 2004, Cools, Declercq et al. 2007, Moraes, Faria et al. 2008).

Combining exercises for the rotator cuff and scapula stabilizers seems to optimize rehabilitation and lead to a clinically important effect compared to general exercise treatment alone (Holmgren, Björnsson Hallgren et al. 2012; Struyf, Nijs et al. 2013).

### *Eccentric exercises*

During eccentric muscle work, the muscle-tendon unit is lengthened under load compared to concentric and isometric exercises, where the muscle-tendon unit is either shortened or remains constant, respectively (Rees, Wolman et al. 2009). These exercises are noted to decrease pain and increase shoulder function, and they may be one important component in the rehabilitation process (Jonsson, Wahlström et al. 2006; Bernhardsson, Klintberg et al. 2011).

### *Patient education and home training*

Advice and education are part of physiotherapy management. Good posture is taught and it should be maintained during the exercises, including the retracted shoulder position and thoracic spine extension (Holmgren, Björnsson Hallgren et al. 2012).

A functional dialogue is important between professionals, the patient, the patient's family, and the whole support network. The patient is encouraged to be an active participant and should take personal responsibility. This motivates the patient in their situation and as an informed member of the rehabilitation team. Shoulder disorders can in the worst case influence many life domains and may result in far-reaching consequences (Jackins 2004; Nyman, Palenius et al. 2012).

A special additional educational program to prevent the development of inadequate cognitions and maladaptive behaviors in shoulder complaint patients was, however, not found to be cost-effective when compared to usual care (according to Dutch College of General Practitioners guidelines) (De Bruijn, Goossens et al. 2007).

According to several studies, no difference between exercise therapy and home exercises was noted. In addition, a home-based program can effectively reduce symptoms and improve function (Ludewig and Borstad 2003; Walther, Werner et al. 2004).



## *Results of previous studies*

### *Exercise vs. no treatment or placebo*

Exercise treatment is reported to be more effective than no treatment in reducing pain and improving the function of the shoulder joint (Dickens, Williams et al. 2005; Lombardi, Magri et al. 2008). Brox et al. compared therapeutic exercise to placebo treatment. The exercise program in this study was focused on normalizing dysfunctional neuromuscular patterns. They began with antigravity exercises, after which the program aimed at strengthening the rotator cuff and scapular musculature. The exercises were performed partly under physiotherapeutic supervision and partly as a home exercise program. The study results showed significant improvement in favor of the exercise group. Even at 30 months, the therapeutic exercise patients still demonstrated less pain and improved disability than the placebo group (Brox, Staff et al. 1993; Brox, Gjengedal et al. 1999).

In another study, patients were randomized into two groups: one group received progressive resistance training and the other group was informed that they would receive treatment after two months. In training, the maximum number of repetitions with the maximum bearable weight for the muscle was defined and the exercises were performed at 50% and 70% of this amount; the exercise was interrupted if pain was provoked. The study group showed a significant effect in reducing pain and improving function and quality of life compared to those remaining on the waiting list (Lombardi, Magri et al. 2008). In a study by Ludewig et al., a group of construction workers with occupational exposure and shoulder pain was randomized either to the exercise intervention group or to a control group receiving no treatment. The study also included a group of asymptomatic subjects as an additional control group. The patients in the exercise group did progressive strengthening exercises, muscle relaxation exercises, and stretching. Muscle fatigue was permitted, but not an increase in pain. The patients in the active group showed significant improvements in symptoms and shoulder function (Ludewig and Borstad 2003). Therapeutic exercises are recommended over no treatment or placebo as the first treatment option before surgery is considered (Michener, Walsworth et al. 2004).

### *Exercise vs. non-specific physiotherapy or other treatment modalities*

The specific exercise group showed significantly greater improvement in shoulder pain and function compared to patients receiving only non-specific movement exercises for the neck and shoulder (Holmgren, Björnsson Hallgren et al. 2012).

Graded exercise therapy is a behavioral treatment aimed at increasing the levels of daily activity by learning from the consequences of behavior irrespective of the pain experience. It is shown to be more effective in restoring ability in daily activities than usual care. It reduced direct health and non-health care costs. The higher costs of the intervention lifted the total costs significantly higher (Geraets, Goossens et al. 2005; 2006).

Ginn et al. randomized patients into three treatment groups: a corticosteroid injection group; a group receiving a combination of electrophysical modalities, joint mobilization,

and range of motion exercises; and finally the target group. In the actual treatment group, stretching and pain-free strengthening exercises were used to restore normal shoulder muscle function and coordination, dynamic stability, and scapulohumeral rhythm. The exercises were partly supervised and partly performed at home. Each group gained a significant increase in function and reduction in pain. There was no difference between the groups. The authors state that the positive change was greater than could have been anticipated from natural history alone (Ginn and Cohen 2005).

Cloke et al. did not find any significant difference in results when comparing physiotherapy, subacromial steroid injections, and the combination of both (Cloke, Watson et al. 2008).

### *Studies on patients waiting for an operation*

There are many studies that have collected their study group patients from a waiting list for arthroscopic subacromial decompression with the diagnosis of subacromial impingement syndrome.

In one study, 72/97 patients completed a physiotherapist-supervised training program involving strengthening exercises for eight weeks. They did not have a control group. Only ten of the original 97 awaiting surgery were finally operated on (Virta, Mortensen et al. 2009).

In another study, a group of 45 patients was receiving physiotherapy, both with the therapist and in the form of home exercises. The program aimed at reducing pain and inflammation, and the therapists also used electrotherapy modalities. They emphasized the importance of good posture and altering movement patterns. Of the original 45 patients, 42 came to the control visit at six months, and 11 no longer required surgery because of the subjective improvement. These patients were further followed up at one year and none had been operated on (Dickens, Williams et al. 2005).

One study group of 97 patients was randomized into two groups: the actual study group received eccentric exercises for the rotator cuff and a combination of eccentric and concentric exercises for the scapula stabilizers, while the control group received guidance for six active movements for the shoulder and neck without progression. All of these patients previously had unsatisfactory results with exercises in primary care. Thirty of the 97 patients had a cuff tear. The exercise regime reduced the need for surgery: 12/51 of the patients in the actual treatment group went on to surgery, while 29/46 in the control group needed a surgical intervention. The positive short-term results were maintained at a one-year control (Hallgren, Holmgren et al. 2014).

### *Postoperative rehabilitation*

The intention of surgical treatment in shoulder impingement syndrome is to remove the presumed structural pathology. The aim of postoperative rehabilitation is to restore shoulder function and to prevent recurrence (Holmgren, Öberg et al. 2012).

In a study evaluating treatment strategies after arthroscopic acromioplasty, two different rehabilitation regimes were compared. The study group received progressive physiotherapist-supervised rehabilitation and the patients in the control group were advised to do home-based exercises focused on mobility. The patients in the study group concentrated on dynamic strengthening exercises, isometric training of the rotator cuff muscles and the scapula stabilizers, and corrections of posture. There were greater improvements in shoulder function in the physiotherapy group. The authors' opinion was that home exercises are insufficient in reaching optimal shoulder function postoperatively. Strengthening exercises need to be added in the rehabilitation. They also speculate the possible additional effect due to attention and placebo (Holmgren, Öberg et al. 2012).

In an analogous study, no difference was found when comparing physiotherapist-supervised and home exercises. This result was interpreted with the probability of the low intensity of the supervised exercise program. The authors thought, however, that this was an unlikely influence. Patients suffer from pain immediately after surgery. In this study, the strengthening exercises were started six weeks after the operation, while Holmgren et al. began at four weeks (Andersen, Søjbjerg et al. 1999).

### *Conclusions*

In an evidence-based overview of the effectiveness of physiotherapeutic interventions, exercise therapy gave the best results compared to controls or placebo in the midterm in the treatment of subacromial impingement syndrome (Gebremariam, Hay et al. 2011). Diagnostic difficulties include failing to correctly identify the multiple extrinsic diagnoses along with the intrinsic pathology. This complicates the planning of proper treatment (Pyne 2004; Ben Kibler and Sciascia 2008). Rehabilitation should continue as a flow of exercises varying according to the stages of healing (Pyne 2004).

In the treatment of subacromial impingement syndrome, there are many reviews to support the use of exercise treatment including strengthening exercises for the rotator cuff and scapular muscles as well as stretching the soft tissues of the anterior and posterior shoulder. Exercise treatment is efficacious for the patient in decreasing pain and improving function. Specific exercise regimens used in isolation need to be evaluated in the future. The emphasis should be on defining effective exercise programs (Desmeules, Côté et al. 2003; Michener, Walsworth et al. 2004; Kelly, Wrightson et al. 2010).

### *In real life*

In clinical practice, adherence to current recommendations for exercise therapy is, however, found to be insufficient (Ylinen, Vuorenmaa et al. 2013). According to one publication, only one quarter of visits for shoulder pain were referred to physical therapy (Wofford, Mansfield et al. 2005). According to one randomized study of 90 patients, only a minority had received active physiotherapy prior to the enrolment (Haahr, Østergaard et al. 2005;

Haahr and Andersen 2006). In a retrospective interview study of patients who had undergone shoulder arthroscopy and subacromial decompression due to subacromial impingement, the patients' exercise history was analyzed. Preoperatively, 49% of patients had not received shoulder muscle exercises, and 78% had received passive physical therapy including massage, heat, cold, or electrical therapy. Postoperatively, everybody had received mobility exercises, but one-fourth still had no instructions for shoulder strengthening exercises. The implementation of exercise therapy is crucial before deciding on surgery, and it is the responsibility of orthopedic surgeons to ensure that it occurs. If nonoperative treatment was actualized adequately prior to the consideration of surgery, several patients may have avoided surgery (Ylinen, Vuorenmaa et al. 2013).

### *Other nonoperative means*

A laser is a nonionizing, monochromatic light that is believed to have the ability to alter cellular and tissue functions. It has been used as a biostimulator and for analgesic and anti-inflammatory purposes (Santamato, Solfrizzi et al. 2009; Dogan, Ay et al. 2010). In therapy, it can be used at low intensity or high intensity (Dogan, Ay et al. 2010). High-intensity laser use might be more effective than ultrasound in reducing pain (Santamato, Solfrizzi et al. 2009). The results about the efficacy of lasers remain controversial, however. It has not been proven to be effective in shoulder pain when compared to placebo or exercise alone. Laser treatment is not recommended in treatment because it has not demonstrated an additive benefit for improving function or reducing pain (Michener, Walsworth et al. 2004; Dogan, Ay et al. 2010; Çalis, Berberoglu et al. 2011).

Ultrasound can be applied in various intensities and frequencies, thus creating a deep thermal and non-thermal effect in cells and tissues. It has not proven to be effective and its use in the treatment of shoulder impingement patients is not supported (Kurtaiş Gürsel, Ulus et al. 2004; Michener, Walsworth et al. 2004; Çalis, Berberoglu et al. 2011).

It is believed that pulsed electromagnetic fields increase tissue oxygen levels, cause vasodilatation, relieve pain, and change the cell environment. In the treatment of rotator cuff disease, electrical stimulation has not been shown to be more effective than placebo (Aktas, Akgün et al. 2007).

Microwave diathermy converts electromagnetic energy into thermal energy, thus resulting in deep heating. It has not proven to be effective in the treatment of subacromial impingement (Akyol, Ulus et al. 2012).

Massage was found to be effective in reducing pain. Handling of the myofascial trigger points in muscles and soft tissue seemed to improve function and symptoms more effectively than a wait-and-see strategy (Bron, de Gast et al. 2011).

Acupuncture is believed to allow blood or energy to flow more freely through the body. It is thought to override nervous pain signals or release pain relieving chemical compounds (Green, Buchbinder et al. 2005). Its use has been considered as an alternative treatment

for chronic shoulder pain (Guerra de Hoyos, Andrés Martin et al. 2004; Molsberger, Schneider et al. 2010; Johansson, Bergström et al. 2011). Single-point acupuncture used in association with physiotherapy has been reported to improve shoulder function and alleviate pain (Vas, Ortega et al. 2008). Acupuncture has no long-term benefits, however, nor is it perhaps any more effective than placebo. As the evidence of this treatment is conflicted, its use can neither be discouraged nor promoted (Michener, Walsworth et al. 2004; Green, Buchbinder et al. 2005).

Platelet-rich plasma injections have been used as treatment. The autologous concentrated fraction of blood is injected into the subacromial space. This is believed to assist in the repair and regeneration of tissue by growth factors produced by platelets (Moraes, Lenza et al. 2014). Platelet-rich therapy has shown not to be effective in the treatment of subacromial tendinosis, and there is currently no evidence to support its use (Kesikburun, Tan et al. 2013; Rha, Park et al. 2013; Moraes, Lenza et al. 2014).

There are also numerous other treatment modalities used for rotator cuff disease. They include heat/thermotherapies, cold/ice, kinesio taping, transcutaneous electrical stimulation, iontophoresis, phonophoresis, radial extracorporeal shock wave therapy, intravenous therapies, hydrolytic enzymes, dietary interventions (herbal and nutritional supplements), shoulder bracing, and active electrotherapeutical modalities. These treatment modalities are however often stated to be non-significant or ineffective (van der Heijden, van der Windt et al. 1997; Bleakley, McDonough et al. 2004; Engebretsen, Grotle et al. 2009; Szczurko, Cooley et al. 2009; Hanratty, McVeigh et al. 2012; Şimşek, Balki et al. 2013; Merino, Del Carmen Casajuana Briansó et al. 2015). Immobilization should be avoided (Greenberg 2014).

It has been noticed that if there are symptoms in one shoulder, it seems to raise the risk for symptoms in the other shoulder as well. Thus, the importance of prevention must be emphasized in preventing further progress of the disorder (Silverstein, Viikari-Juntura et al. 2006).

#### 2.2.8.2 Surgical treatment

Nonoperative interventions are considered to be successful in most patients. Traditionally, surgical treatment has been suggested for patients with persistent pain who have failed a trial of nonsurgical intervention (Mitchell, Adebajo et al. 2005; Dorrestijn, Stevens et al. 2009; Chaudhury, Gwilym et al. 2010; Harrison and Flatow 2011). There is no evidence that early surgical interference would improve the prognosis (Mitchell, Adebajo et al. 2005).

Surgical treatment was revolutionized by Neer, who advanced the idea of decompressing the acromion and rotator cuff. He identified the contact area to be anterior rather than lateral. Instead of radical resections or a total acromionectomy, which was performed before Neer's advances, he reshaped the acromion, thereby decompressing the rotator cuff.

Surgery aims to increase the subacromial space and thus reduce wear on the rotator cuff. In surgery, the anterior curve of the acromion is reshaped, thus trying to restore anatomical resemblance to the Type 1 acromion. In addition to acromioplasty, the expansion of the coracoacromial arch also includes removal of osteophytes from the anterior region and the AC joint, and resection of the coracoacromial ligament and perhaps the subacromial bursa (Gartsman 1995).

### *Surgical technique*

Traditional acromioplasty was performed through a 9 cm incision from the anterior edge of the acromion lateral to the coracoid. The undersurface of the anterior process was removed with an osteotome. The removed piece of bone included the entire attachment of the coracoacromial ligament. If there were prominences of the AC joint, they were also removed. In cases of a symptomatic or arthritic situation, the distal clavicle was also removed (Neer 1972).

Arthroscopic acromioplasty was pioneered and described by Ellman in 1985. He used anterolateral, posterolateral, and posterior portals. This operation began with debridement of the inflamed bursa with a shaver. The coracoacromial ligament was then released. Acromioplasty was performed with a powered burr. Ellman referred to the procedure as arthroscopic subacromial decompression (Ellman and Kay 1991). The arthroscopic technique permits better visualization of the undersurface of the arch. Arch abrasion and possible sources of impingement may be better detected and managed (Harrison and Flatow 2011).

### *Open or arthroscopic acromioplasty*

There are many studies that have found no difference between the open and the arthroscopic approach. The average pain scores have improved in all groups regardless of technique, and complications were rare (Faber, Kuiper et al. 2006; Barfield and Kuhn 2007; Coghlan, Buchbinder et al. 2008; Davis, Kakar et al. 2010; Donigan and Wolf 2011). In addition, in terms of subjective improvement, satisfaction, and strength, the techniques have been noted to be equivalent (Spanghel, Hawkins et al. 2002).

In an eight-year follow-up, no difference between open and arthroscopic groups were found, either. Even postoperative sick leave was similar. The randomization in this study was done after a diagnostic arthroscopy and the control visits were blinded. The average operation time was shorter in the open group (Husby, Haugstvedt et al. 2003).

Since these procedures have shown to produce equivalent results, the choice of method and the appropriate technique has been left to the surgeon to decide along with the patient's preference (Gartsman 1995; Husby, Haugstvedt et al. 2003). In a prospective cohort study, the arthroscopic method appeared to yield better long-term results than open



acromioplasty, and the results were maintained for twelve years. In this study, a significant number of reoperations were needed: 3/23 revision acromioplasties in the open group and 6/23 in the arthroscopic group (Odenbring, Wagner et al. 2008).

In a prospective randomized and blinded study of 62 patients, the open technique was reported to yield better pain relief and functional improvement (Spanghehl, Hawkins et al. 2002). There seems to be some evidence of earlier improvement in movements in favor of the arthroscopic method (Coghlan, Buchbinder et al. 2008). Since the deltoid is not detached in the arthroscopic technique, active range of motion exercises can be started as soon as tolerated (Gartsman 1998). Open acromioplasty seems to be associated with longer hospital stays. The arthroscopic procedure has fewer inpatient days and can alternatively be performed on an outpatient basis. This has also an economic advantage – especially for the third-party payer – in addition to the patient's convenience (Gartsman 1998; Davis, Kakar et al. 2010; Harrison and Flatow 2011). After arthroscopic acromioplasty, most patients can sooner return to daily activities and work (Lindh and Norlin 1993; Gartsman 1998; Coghlan, Buchbinder et al. 2008; Davis, Kakar et al. 2010; Harrison and Flatow 2011). One advantage of arthroscopic acromioplasty is that the glenohumeral joint can be inspected. Skin incisions are smaller than in the open procedure, giving a better cosmetic result (Gartsman 1998; Husby, Haugstvedt et al. 2003). Arthroscopic subacromial decompression requires good hand-eye coordination. It is more difficult to learn and definitely harder to teach than open acromioplasty (Gartsman 1998).

### *Bursectomy*

In the treatment of subacromial impingement, bursectomy alone seems to provide similar results to bursectomy with acromioplasty (Donigan and Wolf 2011). In a prospective study, patients were randomized to bursectomy or bursectomy with acromioplasty. They had all previously failed nonsurgical management. Both treatments produced good clinical outcomes with no statistical differences between the groups. The authors suspected that the type of acromion and severity of the symptoms would be more predictive than the treatment method (Henkus, de Witte et al. 2009). The opposite opinion was presented by Aydin et al. In their study, no important role of the acromial type in the etiology of impingement syndrome was found. Thus, it was stated that an arthroscopic debridement without acromioplasty is an appropriate treatment (Aydin, Yildiz et al. 2011). Partial-thickness rotator cuff tears have also been treated by arthroscopic debridement alone with 79% excellent or good long-term results (Budoff, Rodin et al. 2005).

### *Results of previous studies*

In an observational study with no comparative group, the efficacy of arthroscopic subacromial decompression was investigated. All the patients had a positive Hawkins test, overhead activity or mid-arc pain, relief of pain after subacromial steroid injection,

radiological evidence of impingement, and had failed a prolonged nonoperative treatment. They achieved good results. They authors state that radiological signs (sclerosis, cysts, or osteophytes of the acromion or greater tuberosity) were indicative of a successful outcome (Magaji, Singh et al. 2012). Disability scores and pain have also been reported to show improvement after arthroscopic subacromial decompression. The reported values were measured at six months and six years. They persisted or had even improved at six years after surgery, and the patients remained satisfied (Bengtsson, Lunsjö et al. 2006; Lunsjö, Bengtsson et al. 2011). In one study, patients expressed a high degree of satisfaction with shoulder function when evaluated 8–11 years after arthroscopic decompression. During activity, 50% of shoulders were pain-free, and 68% were pain-free at rest (Klintberg, Svantesson et al. 2010).

Arthroscopic acromioplasty is associated with a low morbidity rate and low risk for complications. According to one study, the duration of symptoms before surgery was the most significant predictor of outcome. In this study, 75% of patients were satisfied with the outcome after the operation, which still leaves one-fourth outside this figure (Patel, Singh et al. 1999). The results appear to be equivalent whether the patient stayed overnight in hospital after surgery or was treated as an outpatient. The results of arthroscopic acromioplasty were analyzed at 2–5 years after surgery. Of the patients, 50/80 had no pain and 74/80 had mild or no pain, which can be interpreted as a good result (Järvelä, Järvelä et al. 2010). Workers' compensation patients are reported to have a satisfaction rate of 32%, whereas patients not on Workers' compensation had a satisfaction rate of 59% after arthroscopic subacromial decompression (Hawkins, Plancher et al. 2001).

### *Exercise treatment compared to surgery*

In one randomized study with a six- and 12-month follow-up, open acromioplasty was compared to a physiotherapy regime. A total of 42 patients were randomized into these treatment groups. The results showed similar findings in the six-month follow-up, but at one-year, pain reduction was significantly better in those treated surgically. Of the operatively treated patients, also five tendon ruptures were sutured. As many as 13 patients chose surgery after the initial physiotherapy (Rahme, Solem-Bertoft et al. 1998).

A hugely referenced study of 125 patients compared the effectiveness of supervised exercise treatment, arthroscopic surgery, and placebo in the treatment of shoulder impingement. The patients in the placebo group were told that they would receive a new type of laser treatment. All the included patients had pain resistant to nonoperative attempts prior to the randomization. The follow-up visits were blinded. At six months, both the arthroscopic and exercises groups were better than placebo, but the difference between the arthroscopic and exercise treatment was not statistically significant. The results at 30 months showed only minor changes. The costs of the operative regime were higher. In addition, 25% of the patients in the placebo group reported a satisfactory result at



follow-up, which is likely due to spontaneous recovery. Still both surgery and nonoperative treatment were superior to nontreatment (Brox, Staff et al. 1993; Brox, Gjengedal et al. 1999).

Haahr et al. randomized 90 shoulder impingement patients into two groups: physiotherapy or arthroscopic surgery. The follow-up points were at one year and at 4–8 years. Similar improvements in self-reported outcomes were found in the two treatment groups. The greatest improvement was seen within the first three months. The authors question the indications for operative interventions. They state that patients undergoing surgical treatment take more sick leave without obtaining further benefits in the long run (Haahr, Østergaard et al. 2005; Haahr and Andersen 2006).

There is altogether moderate evidence that operative treatment of shoulder impingement is no more effective than active exercises in reducing pain intensity. There is no evidence to support the superiority of surgery. Operative treatment leads to higher costs and the eventual risk for complications. Based on this knowledge, nonoperative treatment is recommended as a first choice of treatment (Saltychev, Äärimaa et al. 2015).

### *Rotator cuff rupture prevention*

If the pathogenesis of impingement was solely be caused by extrinsic factors, the disease process would come to a halt after surgical decompression. If the symptoms recur, they can be interpreted to be due to intrinsic factors, such as degeneration, or a combination of both intrinsic and extrinsic factors. A study by Hyvönen et al. showed that a rotator cuff tear may appear after open acromioplasty, even though there was no evidence of cuff lesion at the time of operation. The mean follow-up time was nine years (Hyvönen, Lohi et al. 1998).

In a study of arthroscopic subacromial decompressions, 70/183 patients were evaluated with ultrasound fifteen years after the operation. The mean age of the patients was 60 years, and 57/70 had intact tendons, 10/70 partial tears, and 3/70 a full-thickness tear (tears in total: 19%). The authors interpret the results to mean that the procedure lowered the risk for a rotator cuff tear, as the incidence of a degenerative tear at this age group of asymptomatic adults was estimated to be up to 40% (Björnsson, Norlin et al. 2010).

### *The incidence of acromioplasty*

There has been a dramatic increase in the incidence of subacromial decompressive surgery (Judge, Murphy et al. 2014). In Finland, arthroscopic acromioplasty is the fourth most common orthopaedic procedure after arthroscopic menisceal resection of the knee and total knee and hip replacements (Report of the National Institute for Health and Welfare 2010). The reasons for the rising incidence of arthroscopic acromioplasty are multifactorial. This trend may be driven by societal, patient-, surgeon-, technology-, and/or employer-related reasons (Vitale, Arons et al. 2010). In addition, the incidence varies vastly

in different parts of Finland (Table 1). Differences in illness burden, diagnostic practices, and the patient's willingness to undergo surgical intervention explain only a small degree of regional variation in surgery rates. The results probably reflect the different attitudes and beliefs about the indication for surgery (Birkmeyer, Reames et al. 2013).

In the New York area between 1996 and 2006, the population incidence increased from 30 to 102 per 100,000 (Vitale, Arons et al. 2010). Yu and colleagues have also reported an increase in the frequency of anterior acromioplasty and found a dramatic growth over time in Minnesota, USA (Yu, Cil et al. 2010).

In Finland, the incidence of arthroscopic acromioplasty increased between 1998 and 2007 from 75 to 163 per 100,000. Since then, the incidence has declined, the rate being 131/100,000 in 2011. The decrease took place in non-profit hospitals, while conversely in private hospitals it has continued to rise. The authors propose that shoulder surgeons are increasingly practicing evidence-based medicine (Paloneva, Lepola et al. 2015). It has been reported that surgery centers owned by physicians have higher overall operation rates (Birkmeyer, Reames et al. 2013). It must be kept in mind that the consequences of an operation for the patient can be much more serious than those of a prescription or a radiograph.

## *Conclusions*

Firm conclusions about the efficacy or safety of arthroscopic acromioplasty in the treatment of rotator cuff disease cannot be drawn. Current evidence does not support its use over nonoperative treatment (Coghlan, Buchbinder et al. 2008; Papadonikolakis, McKenna et al. 2011; Shi and Edwards 2012).

### 2.2.9 Long-term results

In a recent systematic review and network meta-analysis of available treatment strategies for shoulder impingement syndrome, Dong et al. stated that exercise therapies are the most important treatment options. In chronic situations, operative treatment may be considered, but the decision should be made cautiously (Dong, Goost et al. 2015). Arthroscopic acromioplasty is a common procedure, but few long-term results are available.

Open acromioplasty has been reported to have a good long-term outcome. Chin et al. have reported results at eight and 25 years after operation. The satisfaction rate was 88%, and 72% of the patients had minimal or no pain. They explained the frequency of shoulder pain by aging because the patients also as often had pain in the opposite shoulder (Chin, Sperling et al. 2007).

Lunsjö et al. reported high patient satisfaction that was maintained at least up to six years after arthroscopic acromioplasty (46 patients) (Lunsjö, Bengtsson et al. 2011). According to one review and meta-analysis, exercise is noted to decrease pain and improve function

in short-term follow-ups. They also found strong evidence that improvements in function are maintained in long-term follow-ups (Hanratty, McVeigh et al. 2012). With longer follow-ups, ranging from eight to 20 years, successful/satisfied results after arthroscopic acromioplasty have been reported in 79–84% of patients. In the same studies, revision surgery had been performed on 6–15% of the patients operated on (Stephens, Warren et al. 1998; Klintberg, Svantesson et al. 2010; Jaeger, Berndt et al. 2015). In one patient group, 33% of all patients previously involved in sports were unable to return to overhead and throwing sports due to pain and lack of power after arthroscopic acromioplasty (Stephens, Warren et al. 1998).

In studies comparing operative and exercise treatment, Brox et al. have reported 30-month results and Haahr et al. 4–8-year follow-ups. In Brox et al.'s study group, subjective satisfaction was excellent or good for 68% of the surgical group and 61% in the supervised exercise group. There were 15 (50%) and 11 (22%) patients who had had surgery during the follow-up of the patients randomized to placebo and exercises, respectively. Ten patients randomized to the operative group withdrew from surgery (Brox, Gjengedal et al. 1999). Haahr et al. reported no reoperations. In total, 11/43 patients were operated on in the conservative group (26%). Nine recovered and the condition of two got worse. There were no differences in self-reported outcomes between groups (Haahr and Andersen 2006).

## 2.2.10 Health economics

Comparative effectiveness data is needed for decision-making because health care resources are scarce. Cost-effective analysis can provide essential information to policy-makers so that investments and resources can be allocated in the most cost-effective way (Dougherty and Howard 2013b). Advancing cost-effectiveness and equality in obtaining effective services can be stated as the two main objectives for health care (Malmivaara 2014). Good clinical know-how and skills along with the means for logical decision-making – as well as up-to-date scientific evidence (RCTs and systematic reviews) – are essential for achieving effective patient care. The aim is to produce as much good and as little harm as possible for each patient, with reasonable costs to society. Succeeding in this aim requires a lot, not only from professionals but also from the whole clinical pathway/process. Clinical expertise, scientific evidence, quality improvement (standardized documentation), and benchmarking (learning from best practices, between providers, or over time) have to be ameliorated continuously (Malmivaara 2013).

When analyzing shoulder disorders specifically, it has been noted that they are often chronic and require a significant amount of resources from the health care system. The need for medical care concerns not only new episodes but also individuals who consult

continuously for their disease (Paloneva, Koskela et al. 2013). Cost-effectiveness and QALY values can be found in comparing arthroscopic surgery and open rotator cuff repair (Vitale, Vitale et al. 2007; Carr, Cooper et al. 2015). One study protocol (CSAW Study; Can Shoulder Arthroscopy Work?) has quite recently been published that aims to compare the efficacy and cost-effectiveness of arthroscopic subacromial decompression in patients with subacromial pain. The researchers plan to recruit 100 patients for the operation and 100 for the control group. They also have a placebo intervention planned, which they do not want to call sham surgery, involving arthroscopy only. The procedure contains all components of the standard operation, but without removal of the bony spur (100 patients) (Beard, Rees et al. 2015).

Arthroscopic acromioplasty is reported to lead to a significant improvement in function and quality of life in a cost-effective manner. A total of 83 patients were enrolled and followed up for 15 months. Results in this cost-utility analysis were stated to provide justification for this procedure when performed by an appropriately trained shoulder surgeon in correctly selected patients (Butt, Whiteman et al. 2015).

### 2.2.11 Sick leave and disability pensions

Sick leave due to musculoskeletal disorders – and among them, shoulder disorders – was noted to be associated with older age, sex (women), perceived physical workload, and poorer general health (Lötters and Burdorf 2006). In the forestry industry, the patients with neck and shoulder disorders that had higher proportions of sick leave were more often older workers, blue-collar workers, and those who had been on sick leave in the 60 days preceding the examination. The number of sick leave days was associated with the pain intensity, and trouble working or sleeping (Viikari-Juntura, Takala et al. 2000). Workers' compensation seems to have a negative impact on disability, self-assessed shoulder function, and health status (Viola, Boatright et al. 2000; Holtby and Razmjou 2010).

Patients undergoing operations for rotator cuff disorders, frozen shoulder, and the AC joint are at up to ten times higher risk for disability pension than the background population. This risk is especially high for patients with a low educational level. These blue-collar workers need special support to enable them to return to work (Svendsen, Frost et al. 2012).

According to the Official Statistics of Finland, in 2014, new periods of sickness allowances were 14,528 creating, 644,433 days off work. The total expenditure was 40.6 million euros. There were 730 new retirees due to shoulder disorders (M75, ICD-10). In total, there were 4,531 pension recipients, forming a total pension expenditure of 56.6 million euros (The Social Insurance Institution of Finland and Finnish Centre for Pensions; [www.kela.fi/documents](http://www.kela.fi/documents)).

Part-time sick leave did not exacerbate functional disability; on the contrary, this group's self-rated general health and HRQoL were better (Shiri, Kausto et al. 2013). This supports the claim that improving return-to-work and communication in occupational medicine are worthy and they work in continuity with medical interventions (modified tasks, etc.) (Franché, Baril et al. 2005; Svendsen, Christiansen et al. 2014). Occupational health interventions are found to be very successful for people that consider their health to hinder their ability to work (Taimela, Aronen et al. 2010).

### 3 AIMS OF THE PRESENT STUDY

The main purpose of this study was to investigate the additional benefits of the current treatment strategy, namely arthroscopic acromioplasty for patients with subacromial impingement syndrome.

The specific aims of the studies were as follows (the roman numerals refer to the original publications):

#### **Study I**

To investigate the effectiveness and cost-effectiveness of arthroscopic acromioplasty followed by a structured exercise treatment compared to a similar exercise therapy alone in the treatment of shoulder impingement syndrome. In this study, we not only compared operative and nonoperative treatment, but analyzed the additional value of the operation. The outcome was assessed at two years.

#### **Study II**

To analyze the (additional) effectiveness of arthroscopic acromioplasty and clinical results at five years after randomization and interventions, with primary and secondary outcome measures added to the HRQoL parameters.

#### **Study III**

To analyze prognostic factors at two and five years to find out whether there are subgroups of patients who would genuinely benefit from arthroscopic acromioplasty, and, at the same, to determine whether there is a subgroup in which the procedure should be avoided.

#### **Study IV**

To assess whether arthroscopic acromioplasty to expand the subacromial space protects from rotator cuff rupture later in life, and whether it has any effect on the muscle volume by comparing MRI scans taken at baseline and at five years.

#### **Study V**

To study the long-term (>10 years after randomization) results of combined treatment and structured exercise treatment, and to investigate the natural course of impingement syndrome.

## 4 PATIENTS AND METHODS

The study design was a prospective, controlled, and randomized trial. Stage II shoulder impingement patients aged 18–60 years were collected in the area of Kanta-Häme Health Care District, which had a population of 165,000 at the time of the recruitment. It was decided to recruit 140 patients on the basis of power calculations.

General practitioners in the health care area were encouraged to refer their patients with suspected shoulder impingement syndrome to Kanta-Häme Central Hospital and to Riihimäki Regional Hospital starting from June 2001. Before the study, all the patients had been treated only by general practitioners. None of the patients taken into the study had undergone previous shoulder surgery. Because the symptoms had been resistant to the given treatment, patients were referred to hospital, after which their eligibility for this study was assessed.

The inclusion and exclusion criteria are presented in Table 3. By the end of July 2004, the specialists at these hospitals were able to enroll 140 impingement patients (52 men and 88 women, mean age 47.1 years) who had clinically proven shoulder impingement syndrome that had been symptomatic for at least three months.

Table 3. The inclusion and exclusion criteria.

<b>The inclusion criteria</b>
clinical symptoms of shoulder impingement syndrome
positive Neer's test
symptom duration of at least three months
attempts to treat with: rest, NSAIDs, subacromial corticosteroid injections, and regular physiotherapy
age 18–60 years
no previous operations on the shoulder region
willingness and capacity to comply with the treatment protocol and follow-up visits
written consent
no previous shoulder surgery
<b>The exclusion criteria</b>
glenohumeral osteoarthritis
signs of glenohumeral instability
penetrating rupture of the rotator cuff
cervical radicular syndrome
adhesive capsulitis
neuropathy of the shoulder region

All patients enrolled in this study had been previously treated using one or more modalities of physiotherapy. The physiotherapy had contained various types of nonoperative treatments, including exercises, massage, heat, transcutaneous nerve stimulation, rest, NSAIDs, etc. The common denominator to all of these modes of prior treatment was failure to provide sufficient alleviation of the patients' complaints. The time sequence of administration of these different treatment modalities was not defined in the study protocol and was not recorded, but varied individually between different patients, all of whom were non-responders.

The eligibility of the patients was examined in hospital at baseline by a physician specialized in rehabilitation or orthopaedics. The clinical examination consisted of measuring the range of motion in flexion, abduction, and external and internal rotation. Muscle strength was tested manually and graded normal or decreased, and isometric pain provocations were done. Impingement was tested according to Neer (Neer 1983; Leroux, Thomas et al. 1995, MacDonald, Clark et al. 2000) after 5 ml 1% lidocaine had been injected into the subacromial space.

All patients underwent plain radiographs and an MRI of the symptomatic shoulder (Moeller and Reif 2003). This was done to rule out other shoulder pathologies, including full thickness rotator cuff tears.

Demographic background data and disability values were collected and the patients completed an SDQ form at baseline (van der Windt, van der Heijden et al. 1998; van der Heijden, Leffers et al. 2000; de Winter, van der Heijden et al. 2007).

#### 4.1 Supervised exercise treatment

The patients were at first given information by trained physiotherapists. The exercise program was individually planned for each patient according to the same principles. Physiotherapeutic training was based on home exercises. Later during the long-term follow-up visits, this program was consolidated and modified and systematically evaluated. The exercise regime in the combined treatment group was similar to the one used by the group on the supervised exercise program, thus making the operation the only differing factor between the two groups. We were therefore not comparing the two treatments, but were instead able to evaluate the additional benefits of the surgical treatment.

The aim was to restore painless, normal mobility of the shoulder complex and to increase the dynamic stability of the glenohumeral joint (supra- and infraspinatus, teres minor, and subscapular muscles) and the scapula (trapezoid, rhomboid, serratus anterior, and pectoralis minor muscles) (Böhmer, Staff et al. 1998). Stretch bands and light weights were used in training, which was based in long painless series and repetitions aiming at muscle strengthening. The sessions were performed at least four times per week using nine different exercises with 30–40 repetitions for three series of repetitions. As the self-assessed ability and strength improved, resistance was increased and the repetitions diminished.



Progress was evaluated during control visits, which averaged seven in number and continued until the patient and the therapist considered that the trainee was independently able to maintain the practice level.

## 4.2 Combined treatment

### 4.2.1 Operative procedure

One experienced orthopedic surgeon performed all arthroscopic decompressions at Kanta-Häme Central Hospital. An interscalenic or supraclavicular brachial plexus block was applied for regional anesthesia. Bony landmarks were palpated and marked. Glenohumeral stability and passive range of motion were tested. The arthroscope (Karl Storz GmbH, Tuttlingen, Germany) was introduced into the joint through a standard posterior portal and a systematic recording of the articular cartilage, labrum and ligaments, biceps tendon, and the intra-articular rotator cuff was performed. The same standard portal was used to reach the subacromial space. Debridement and decompression were done through an anterolateral portal with a shaver and/or vaporizer. If the coracoacromial ligament felt tight or thick, it was released. Acromioplasty was performed starting anteriorly and progressing posterolaterally with a burr drill. The range of motion was tested under arthroscopic visualization to check for any local impingement. Unexpected labral lesions were repaired in fourteen procedures. Nine of these were on the upper labrum. The lesions were fixed with either tacks or anchors.

### 4.2.2 Postoperative phase

The patients stayed at the hospital overnight. Postoperatively patient-controlled intravenous oxycodone analgesia or a pain catheter to administer local ropivacaine 2 mg/ml or bupivacaine 2.5 mg/ml 3–5 ml/h to the operation area was used until the first postoperative morning, accompanied and/or followed by oxycodone i.m. and/or p.o. All patients received anti-inflammatory analgesics, usually ibuprofen. A collar cuff was used for a week. Mobilization was allowed with free active movements, starting with gravity-assisted rotating movements. Sutures and tapes were removed after 7–10 days, after which the patients received similar training instructions as were provided for the exercise group. After this, these patients were also subjected to a similar physiotherapeutic treatment and training session schedule described above, and they started their active training progressively. The training program was likewise individually planned and progressive. It was started progressively once the postoperative pain had gradually diminished. As in the supervised exercise treatment group, the progress was evaluated during physiotherapy controls, which averaged six in number.

### 4.3 Adjunct treatment

The use of NSAIDs was allowed in both groups as needed. Subacromial corticosteroid injections were permitted if pain interfered with the execution of the training program.

### 4.4 Outcome measures and resource use

Self-reported pain on a 0–10 VAS at two and five years after randomization was used as the primary outcome measure and was also used in *ad hoc* subgroup analysis. The minimal clinically important difference (MCID) was defined as 2 points on VAS equaling 1 MCID unit (Salaffi, Stancati et al. 2004). Secondary outcome measures were disability, pain at night, and working ability (VAS), SDQ score (Appendix I), the number of painful days during the previous three months, and the proportion of pain-free patients (pain on VAS  $\leq 3$ ) at two and five years from randomization. The same variables were used at three-, six-, and 12-month visits. The follow-up results were analyzed using an intention-to-treat (ITT) approach, but the outcome is later also described based on the actual treatment per protocol (PP). Table 4 gives an overview of the unit costs covering the direct health care

Table 4. Unit costs covering the direct health care and non-health care costs (travel, masseur, naprapath) at the 2004 price level.

Variable description	Unit cost (€)
Operation: arthroscopy and acromioplasty	1,675 <sup>1</sup>
Visits to a physiotherapist	60.40 <sup>2</sup>
Operation: arthroscopy and labral procedure	2,811 <sup>3</sup>
Visits to a physician	82.50 <sup>2</sup>
Travel costs to services	6 <sup>4</sup>
Hospitalization	513 <sup>2</sup>
Visits to a masseur	36 <sup>5</sup>
Operation: arthroscopy and open acromioplasty	1,916 <sup>1</sup>
Travel costs to hospital	30.90 <sup>4</sup>
Medication	– <sup>6</sup>
Visits to a nurse	24.50 <sup>2</sup>
Visits to a naprapath	41 <sup>5</sup>
Mobilization in anesthesia	707 <sup>3</sup>

<sup>1</sup> Benchmarking data on file, National Research and Development Centre for Welfare and Health, Finland

<sup>2</sup> Hujanen T. *Terveystalouden yksikkökustannukset Suomessa vuonna 2001*, National Research and Development Centre for Welfare and Health, Finland, Aiheita 1/2003

<sup>3</sup> Expert opinion

<sup>4</sup> Statistics Finland

<sup>5</sup> Finnish Consumer Agency, <http://www.kuluttajavirasto.fi/>

<sup>6</sup> For 41 different drugs or other therapies, prices taken from Pharmaca Fennica; a pharmaceutical manual used in Finland

and non-health care costs (travel, masseur, naprapath) at the 2004 price level. HRQoL was measured at the five-year visit and at ten years using the 15D questionnaire (Appendix II), and compared to the age-adjusted population values. The baseline characteristics also used in the assessment of prognostic factors were age at baseline, gender, BMI, marital status, basic and professional education, working conditions (requirements at work, loads lifted per day, working with arms raised, and satisfaction at work), symptom duration, sick leave before randomization, Bigliani classification of acromial morphology, and AC joint degeneration as observed radiological examinations.

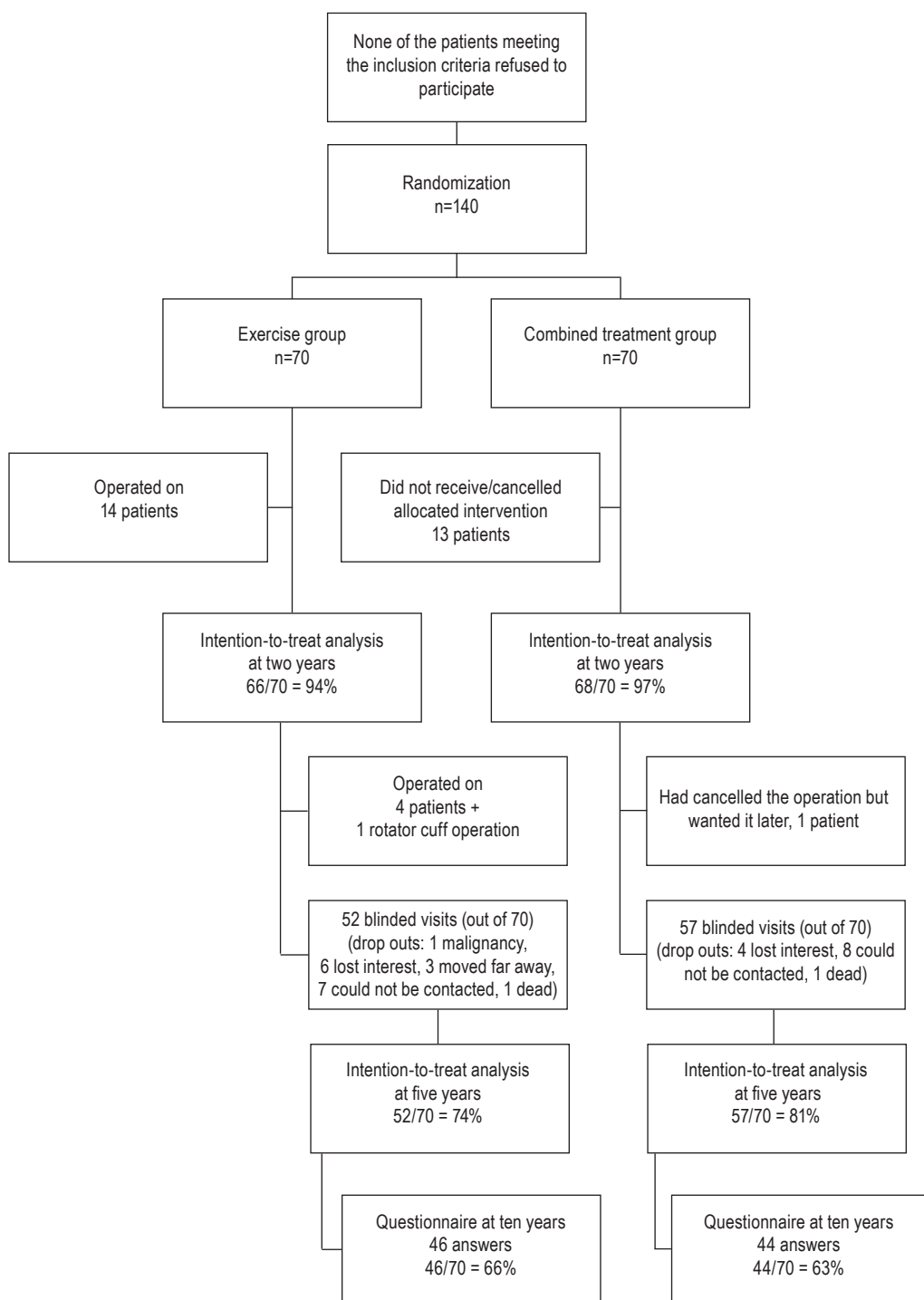
## 4.5 Follow-up

The main follow-up points were at two and five years after randomization. Examinations were also performed at three, six, and 12 months relative to the time of intervention. In addition, baseline and five-year results were compared. One trained physiotherapist, who had not been involved in the treatment prior to evaluations and who was blinded to the mode of treatment, performed all standardized assessments. Patients were instructed not to indicate the type of treatment (exercise or combined) they had received and they wore a T-shirt to cover eventual operation scars. Muscle strength and passive range of motion were assessed and recorded. The Neer's impingement sign was documented, now without lidocaine injections. The patients completed a structured questionnaire including the SDQ (van der Windt, van der Heijden et al. 1998; van der Heijden, Leffers et al. 2000; de Winter, van der Heijden et al. 2007) at each visit (Brauer, Thomsen et al. 2003).

In addition to their health state, questions concerned health care resource use related to the impingement syndrome since the previous follow-ups were collected. These were the use of medication, injections, and sick leave; visits to the doctor, nurse, and/or physiotherapist; massage; and possible hospital treatment. Additionally, the patients were asked whether they had needed another person's help due to shoulder restrictions. HRQoL was measured at the five-year visit using the 15D quality of life questionnaire (Sintonen 2001).

An additional follow-up point was when all the patients had passed the ten-year point since randomization to the whole study group. This was carried out with questionnaires modified from those used in previous visits. The letters were sent only to participants that had attended the five-year visit; those who we had been unable to contact previously, had expressed their willingness to be left out, and those seriously ill or dead were excluded (Flowchart). The information collected included working status and conditions; changes due to shoulder disabilities, retirement, sick leave, medication, and painful days; and incidence of further examinations or procedures performed on the evaluated or opposite shoulder. Pain and disability VAS scores were requested from the patients as well as the SDQ score and 15D. The pain on the contralateral shoulder was also inquired. The questionnaires were first distributed in mid-November 2014 and by mid-January 2015, a reminder letter was sent to non-responders. The patients were asked to complete the questionnaire and return

## Flowchart



it using the enclosed envelope. The completed and returned questionnaires were coded and used in the analysis.

## 4.6 Radiology

All the study patients had an MRI of the shoulder at baseline before randomization. The MRI examinations were performed at two radiological centers belonging to the Hospital District: Kanta-Häme Central Hospital and Forssa Regional Hospital.

At Kanta-Häme Central Hospital, the patients' shoulders were scanned with an MRI at baseline using a Philips Gyroscan Intera T10-NT 1.0 Tesla, and at Forssa Regional Hospital using a Philips Gyroscan T5-NT 0.5 Tesla. The follow-up MRI scans were done at five years after randomization at Kanta-Häme Central Hospital using the 1.0 T MRI system (Philips Gyroscan Intera T10-NT). In each imaging, a dedicated shoulder surface coil was used. The MRI scans were analyzed at Kanta-Häme Central Hospital at a Fuji PACS working station and at Tampere University Hospital Radiological department at a Barco MFGD 2320 working station (Software Impax DS3000 5.2). The sequences are presented in detail in Appendix III.

The MRI examinations were evaluated by two independent experienced musculoskeletal radiologists. They both completed a structured MRI form for each patient blinded of the patient's medical history and treatment group. A separate form was completed for the baseline and the five-year follow-up study. Each patient's studies were evaluated on separate occasions in order to avoid intraobserver bias. The results obtained by the two radiologists were combined and a consensus statement was formed in cases with interobserver disagreement. A consensus statement was based on re-evaluation of the MRI studies in such cases. These consensus values were used in further analyses.

The acromial shape was evaluated according to Bigliani as Type 1: straight or flat; Type 2: curved; or Type 3: hooked (Morrison, Bigliani et al. 1987) on sagittal MRI scans using at least two of the most lateral slices of the acromion (Bright, Torpey et al. 1997; Mayerhoefer, Breitenseher et al. 2009). The tendons were evaluated for tendinosis and possible tears. The muscle volume quantity was estimated using a method developed by Lehtinen et al. in which the muscle volume is calculated based on the area of two T1-weighted sagittal scans. The volume is also estimated by the Tangent sign method (Zanetti, Gerber et al. 1998; Lehtinen, Tingart et al. 2003).

The fatty degeneration of the muscles was graded according to Goutallier method using T1-weighted sagittal MRI slices. The grading of fatty degeneration was divided into five steps: Stage 0 corresponds to a completely normal muscle, without any fatty streaks; in Stage 1 the muscle contains some fatty streaks; in Stage 2 the fatty infiltration is clear but there is still more muscle than fat; in Stage 3 there is as much fat as muscle; and in Stage 4 more fat than muscle is present (Goutallier, Postel et al. 1994).

AC and glenohumeral degeneration were analyzed paying attention to cartilage thinning, joint space, sclerosis, osteophyte formation, subchondral cyst formation, and pathological joint effusion. Based on these findings, degeneration was staged according to the criteria published by Gahunia et al. into three stages: no/mild, moderate, and severe degeneration (Gahunia, Babyn et al. 1995).

## 4.7 Randomization

The eligible and willing patients were randomly assigned into the supervised exercise program group or the combined (arthroscopic acromioplasty with structured exercise regime) treatment group using computer-generated numbers sealed in opaque envelopes prepared by an independent statistician not otherwise involved with the study. The random numbers were allocated using 14 as the block size. The envelope was opened at the hospital by a specialist with the patient present. At that same visit, the referral to the department of physiatry or surgery was made according to the randomized treatment group.

None of the eligible patients refused to participate. There were however two “silent” refusals, one in each group. These two patients neither went through the interventions nor attended any of the control visits after randomization.

## 4.8 Statistical analyses

Sample size calculations were based on the use of self-reported pain (VAS) as the primary outcome measure. Using 1.5 (standard deviation (SD) 2.5) as a clinically important change, the sample size was estimated to 45 patients per group if 5% type I ( $\alpha$ ) and 20% type II ( $\beta$ ) errors were allowed. As the SD of the outcome measure was only a rough estimate, 70 patients were included in both groups.

Data were analyzed using the ITT analysis, and when appropriate, also PP. Descriptive statistics are presented as percentages, frequencies, and means with SD or medians with quartiles. The independent samples t-test was used for group comparisons, paired samples t-test for comparisons within groups over time, and the chi-squared test for equal proportions of pain-free patients between groups.

Fisher’s exact test was used for the comparisons of proportions. The Kruskal–Wallis test was used when VAS scores of the subgroups were compared. The association between patient characteristics and pain were analyzed using binary logistic regression. Univariate and multivariable models were calculated. For the multivariable analyses, only clinically relevant predictors were chosen. Results are given as odds ratios (ORs) followed by 95% confidence intervals (CI). McNemar’s test was used to compare the shape of the acromion before and at five years after the intervention.

The cost-effectiveness analysis is based on data at two years. Self-reported pain on VAS was available for 134 out of 140 patients at two years. There were patients with one missing follow-up; in such cases, the missing cost and effectiveness data were imputed using a two-stage iterative regression approach (Gelman and Hill 2007). After imputation, full data were available for 120 patients (55 patients in the combined treatment group and 65 in the exercise group). Complete data were available for 92 patients who attended all follow-up visits and completed all questionnaires.

To assess uncertainty, one-way (cost variables changed  $\pm 50\%$ ) and probabilistic (bootstrapping with 10,000 replicates) sensitivity analyses were carried out. The latter were performed for both observed and imputed total cost data. Results are given as mean incremental costs and effects with their 95% CI, incremental cost-effectiveness ratios (ICER), cost-effectiveness plane, and cost-effectiveness acceptability curve (CEAC). Due to the short time horizon, no discounting was carried out.

A p-value  $< 0.05$  was considered statistically significant.

Statistical analyses were performed using IBM SPSS Statistics for Windows, Version 19.0 (Armonk, NY: IBM Corp.). For bootstrapping and imputation, R 2.4.1 software was used (Ihaka and Gentleman 1996).

## 4.9 Ethical considerations

Cooperative patients fulfilling the criteria were asked to sign a written consent in which they voluntarily agreed to comply with the randomized treatment protocol and follow-up visits; the patients had the right to withdraw at any time without reason. The patients were given thorough verbal and written information about the study. The risks and benefits of the study arms were discussed.

The study was approved by the Ethics Committee of the Hospital District (Kanta-Häme Central Hospital E9/2001, 11 April 2001).

## 5 RESULTS

### 5.1 Patients and the treatment process

The study groups did not differ at baseline (Table 5). During the follow-up at two years, 14 patients from the exercise group were operated on, one patient after 3–6 months, four after 6–12 months, and nine first after 12–24 months. During the follow-up between two and five years, four additional patients from the exercise group had undergone acromioplasty and one had an operation due to a rotator cuff rupture. The mean time for these five operations was 2.9 years after randomization. Thus, the total number of acromioplasties done in the exercise group was 18. A total of 12 patients originally allocated to the combined treatment group later refused the operation (Flowchart). One patient who had at first cancelled the operation requested it at 2.6 years. All of these patients were also invited to the five-year control visit. The demographic baseline data is presented in Table 6 for the whole group and according to the randomized group. The age limit for inclusion was set at 18–60 years in conformity with the previous studies. Only four patients were younger than 30 years.

Labral lesions were missed in 14 patients in the preoperative MRI, but found and repaired in arthroscopy. In five cases, the labral lesion *per se* was considered the main cause of the symptoms. In nine cases, this occurred together with impingement, and labral repair was combined with acromioplasty. There were no major surgical complications.

In a nationwide comparison, the occupations of the study patients seemed to differ a little from that of the average in Finland. Fewer were technicians and associate professionals. Males in the field of craft and related trades were overrepresented, as were women in the fields of service and care (Figure 1). In the level of occupational education, the lowest degree was overrepresented in women and the highest degree underrepresented among both women and men. A minority of the subjects (15%) had passed the matriculation examination (high school level).

The dominant hand was affected in 65% of the patients.

Anti-inflammatory drugs due to shoulder reasons were used on a mean 37 days during the previous three months before randomization.

When the patients found out their treatment group, 65% of the patients in the combined treatment group and only 28% in the exercise group answered that they believed that full recovery was possible with this randomized treatment.

At two years, 41% of patients said that they had continued doing exercises even after the supervised period. The amount at five years was even higher (64%).



Table 5. Results in the ITT analysis (n=134 at two years, n=90 at five years, n=109 at over ten years)

Variables	Exercise group	Combined treatment group	p
<b>Self-reported pain: VAS (0–10)</b>			
at baseline (mean)	6.5	6.4	0.73
at two years (mean)	2.9	2.5	0.37
at five years (mean)	2.2	1.9	0.44
over ten years (mean)	1.8	2.8	0.12
Change from baseline (mean) zero to two years	-3.7	-3.9	0.65
Change from baseline (mean) zero to five years	-4.1	-4.7	0.35
Change from baseline (mean) zero to over ten years	-4.5	-3.6	0.18
<b>Disability: VAS score (0–10)</b>			
at baseline (mean)	6.5	6.2	0.53
at two years (mean)	2.6	2.0	0.21
at five years (mean)	1.8	1.5	0.57
over ten years (mean)	2.0	2.5	0.41
Change from baseline (mean) zero to two years	-3.8	-4.2	0.47
Change from baseline (mean) zero to five years	-4.4	-4.8	0.46
Change from baseline (mean) zero to over ten years	-4.3	-3.9	0.64
<b>Working ability: VAS (0–10)</b>			
at baseline (mean)	5.9	5.7	0.78
at two years (mean)	8.0	8.0	0.96
at five years (mean)	7.5	7.8	0.41
over ten years (mean)	7.2	7.5	0.57
Change from baseline (mean) zero to two years	+2.0	+2.3	0.53
Change from baseline (mean) zero to five years	+1.6	+2.2	0.23
Change from baseline (mean) zero to over ten years	+1.3	+2.2	0.29

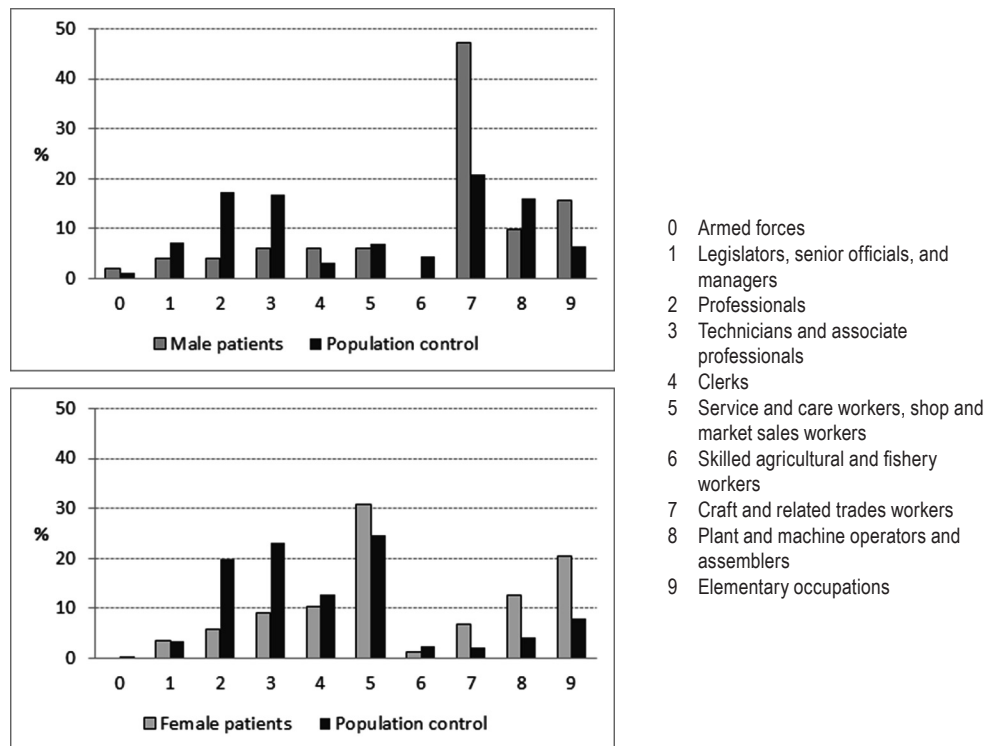
<b>Pain at night: VAS (0–10)</b>			
at baseline (mean)	6.4	6.2	0.60
at two years (mean)	2.6	2.0	0.19
at five years (mean)	1.7	1.7	0.95
over ten years (mean)	1.7	2.5	0.19
Change from baseline (mean) zero to two years	-3.8	-4.2	0.51
Change from baseline (mean) zero to five years	-4.8	-4.8	0.99
Change from baseline (mean) zero to over ten years	-4.9	-4.1	0.30
<b>SDQ score (0 to 100)</b>			
at baseline (mean)	83	78	0.21
at two years (mean)	33	24	0.13
at five years (mean)	22	17	0.33
over ten years (mean)	27	23	0.61
Change from baseline (mean) zero to two years	-50	-53	0.60
Change from baseline (mean) zero to five years	-62	-60	0.84
Change from baseline (mean) zero to over ten years	-56	-55	0.83
<b>Reported painful days</b>			
at baseline (mean)	74	70	0.44
at two years (mean)	20	14	0.22
at five years (mean)	12	12	0.94
over ten years (mean)	12	18	0.32
Change from baseline (mean) zero to two years	-53	-55	0.80
Change from baseline (mean) zero to five years	-59	-61	0.85
Change from baseline (mean) zero to over ten years	-59	-57	0.82
<b>Proportion of pain-free patients</b>			
at baseline (%)	4	12	0.13
at two years (%)	64	65	0.09
at five years (%)	77	75	0.86
over ten years (%)	80	64	0.08

Table 6. Demographic data at baseline.

BASELINE		All n=140	Exercise group n=70	Combined treatment group n=70
Age (mean, years)		47.1	47.8	46.4
Women		%	%	%
Dominant hand affected		63	67	59
BMI, mean		65	64	66
categories				
	underweight	1	0	3
	normal/healthy weight	33	36	31
	overweight	44	40	47
	moderately obese	15	19	12
	severely obese	4	3	4
	very severely obese	3	3	3
Marital status				
	single	7	8	7
	married	67	72	62
	cohabiting	11	10	12
	widow	2	1	3
	divorced	13	9	16
Basic education				
	elementary school	43	43	44
	junior high school	42	40	44
	high school	15	16	13
Professional education				
	none	18	15	22
	occupational course	24	28	20
	trade school	35	33	36
	technical college	19	19	19
	university	4	5	3
Working status				
	currently working	79	84	76
	entrepreneur	8	7	9
	student	1	0	1
	unemployed	10	9	12
	at home	1	0	1
	retired	1	0	1

Requirements/challenges at work							
	low	4	5				4
	quite low	15	13				17
	rather challenging	25	28				22
	quite heavy	35	30				41
	heavy	20	24				16
Loads lifted per work day	(mean total kg)	462	355	568			
	0-20 kg	25	23	27			
	20-100 kg	20	16	24			
	100-500 kg	34	44	24			
	>500 kg	20	16	24			
Working with arms raised	not at all	10	9	10			
	to some extent	68	66	70			
	a lot	23	25	20			
	very good	24	28	21			
Satisfaction at work	quite good	58	56	60			
	neutral	11	13	10			
	quite or very low	7	3	10			
	(mean, years)	2.5	2.6	2.5			
Symptom duration categories	3-6 months	12	8	16			
	6-12 months	33	37	29			
	1-3 years	30	25	35			
	>3 years	25	30	21			
	(mean, days)	16	13	20			
Sick leave prior the randomization (/3 months) categories	none	50	52	47			
	1-7 days	10	9	11			
	8-14 days	11	12	9			
	>14 days	30	27	33			
Self-reported pain (mean, VAS)		6.5	6.5	6.4			
Pain at night (mean, VAS)		6.3	6.4	6.2			
Disability (mean, VAS)		6.4	6.5	6.3			
Working ability (mean, VAS)		5.8	5.9	5.7			
SDQ score (mean)		80.2	82.5	78.0			

Figure 1. The distribution of professions in our study patients compared to age-adjusted population in Finland using the International Standard Classification of Occupations (Brockington 1967).



## 5.2 Effectiveness

The follow-up at two years was attended by 68/70 patients in the combined group and 66/70 in the exercise group (Flowchart). A decrease in self-reported pain exceeding the MCID took place from baseline to two years in both groups: from 6.4 to 2.5 in the combined treatment group and from 6.5 to 2.9 in the exercise group ( $p < 0.001$  in both groups) (Table 5). Differences between the groups were not significant ( $p = 0.65$ ).

The five-year follow-up was attended by 109 patients out of the original 140, 57 patients in the combined treatment group and 52 in the exercise group (Flowchart). A decrease in self-reported pain in VAS clearly took place from baseline to five years in both groups: from 6.4 to 1.9 in the combined treatment group and from 6.5 to 2.2 in the exercise group. The changes over time were statistically significant in both groups ( $p < 0.001$ ), but the differences between the groups were not significant ( $p = 0.35$ ). No statistically significant differences were found in any of the secondary outcome measurements between the groups.

The proportion of pain-free patients (self-reported pain less than 3 in VAS) at two years was 64% in the exercise group and only slightly higher in the combined treatment

group (65%), which raises the number needed to treat (NNT) value up to 100 (Table 5). At five years, the corresponding proportions in the exercise group and the combined group were 77% and 75%, respectively (Table 5). The patients with pain had had more periods of recurrent/worsening pain (31% vs. 7%,  $p<0.01$ ).

At two and five years, both groups reached statistically significantly better values compared to baseline, but there were no differences between the groups. These outcomes were calculated using the ITT principle. Those who fully followed their study assignment were also analyzed separately using the PP principle. The outcome was similar for the two treatment groups. However, the dissatisfied patients in the exercise group who eventually wanted and had an operation still had worse values after surgery compared to the others (Table 7).

Of the five-year control patients ( $n=109$ ), 39 reported that they had had similar symptoms or complaints in the contralateral shoulder region as well. The figures were 21 in the combined treatment group (37%) and 18 in the exercise group (35%). Of the patients experiencing pain, 58% also reported similar symptoms in the other shoulder, while only 29% of those who were pain-free had such symptoms ( $p=0.01$ ).

### 5.3 Cost-effectiveness

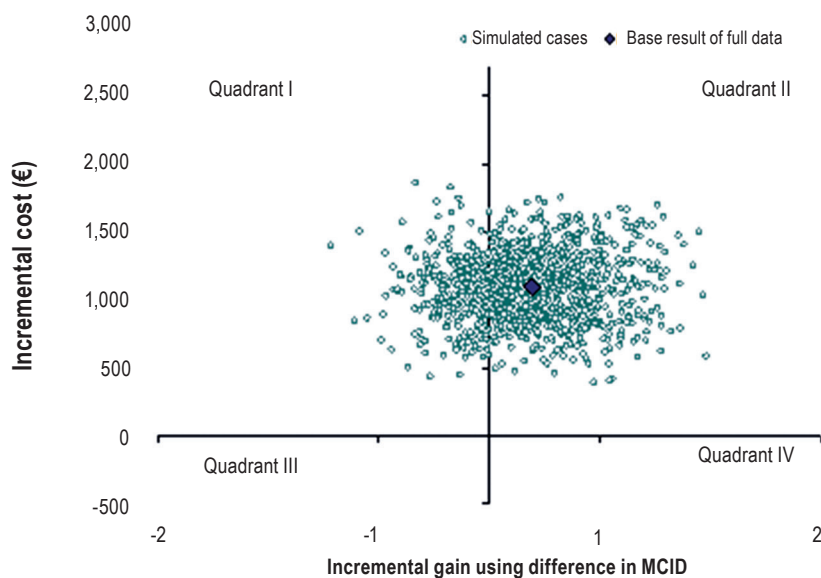
The mean total cost based on the full data was €2,961 in the combined treatment group and €1,864 in the exercise group. Using imputed data, the cost was €3,111 and €1,838, respectively. The incremental cost of combined treatment was €1,097 and the incremental effect 0.19 MCID units, resulting in an ICER of €5,852 per MCID unit. Because there was no significant difference between the results based on the full and imputed data, only the results based on the former are presented.

In one-way sensitivity analyses, the ICER varied from €2,740 to €8,965 per MCID unit. The extreme values were obtained when the unit cost of acromioplasty was varied  $\pm 50\%$ ; the ICER was not sensitive to variation in other cost variables. The probabilistic sensitivity analysis showed that the incremental cost was positive in all simulated cases, while the incremental effectiveness varied from negative to positive values, i.e., from less effective to more effective. The mean incremental cost was €1,092 (95% CI 590–1,590) and the mean incremental effect was 0.20 MCID units (95% CI -0.35–0.73). The cost-effectiveness plane shows that in most cases, the combined treatment was slightly more effective, but clearly more expensive (Figure 2a). Even with the willingness to pay €32,500 for an additional MCID unit, the CEAC suggested that the probability that combined treatment could be acceptable was only 70% (Figure 2b).

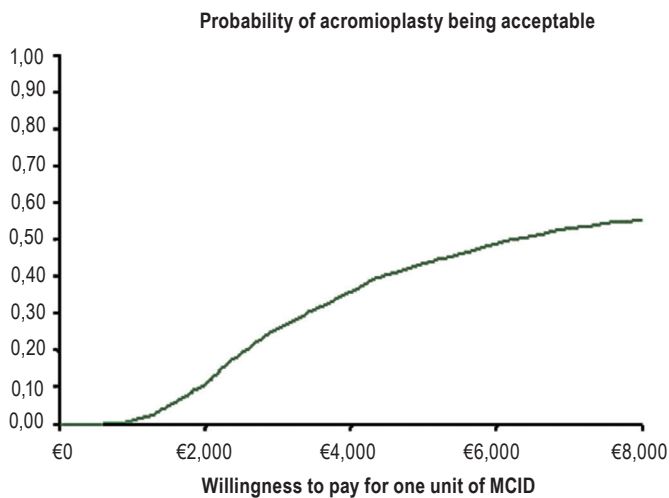
Table 7. Results at five years of the full actualized treatment groups compared to those who were dissatisfied with the nonoperative treatment and were subsequently operated on.

	Full combined treatment group n=43				Full nonoperative treatment group n=43				Wanted operation in nonoperative group n=18				p
	mean	median	Q <sub>1</sub> -Q <sub>3</sub>	mean	median	Q <sub>1</sub> -Q <sub>3</sub>	mean	median	Q <sub>1</sub> -Q <sub>3</sub>	mean	median	Q <sub>1</sub> -Q <sub>3</sub>	
self-reported pain	1.6	0	0-3.0	1.8	1.0	0-3.0	2.6	2.5	1.0-4.0	2.6	2.5	1.0-4.0	0.11
disability	1.2	0	0-2.0	1.3	0	0-1.75	2.1	1.5	0-3.0	2.1	1.5	0-3.0	0.21
working ability	7.8	8.0	7.0-9.0	8.0	8.0	7.0-9.0	7.2	8.0	7.0-8.0	7.2	8.0	7.0-8.0	0.18
pain at night	1.3	0	0-2.0	1.2	0	0-1.0	1.9	1.0	0-3.0	1.9	1.0	0-3.0	0.19
SDQ score	12.0	0	0-11.3	16.7	3.6	0-19.9	25.8	23.4	0-41.4	25.8	23.4	0-41.4	0.06
reported painful days	7.8	0	0-6.0	8.3	0	0-9.0	9.7	1.5	0-6.3	9.7	1.5	0-6.3	0.80

Figure 2. Cost-effectiveness plane and cost-effectiveness acceptability curve.



a) Cost-effectiveness plane. In 75% of cases, combined treatment was more costly and more effective (Quadrant II), and in 25% of cases more costly and less effective (Quadrant I).



b) Cost-effectiveness acceptability curve.



## 5.4 Secondary outcome measures

### 5.4.1 HRQoL

The 15D quality of life index at five years was analyzed in an ITT setting. The groups had similar 15D values. Compared to the age-adjusted general population, the combined treatment group had lower values in the “move”, “sleep”, and “discomfort” parameters ( $p < 0.001$ ,  $p = 0.049$ ,  $p = 0.028$ , respectively) and the exercise treatment group in the “usual activities” and “discomfort” ( $p = 0.040$ ,  $p = 0.037$ , respectively). All these differences exceeded the MCID of 0.02–0.03 (Sintonen 1994; 2001).

### 5.4.2 Work status

Of the whole group, 16 patients were retired at five years (one was already retired at the time of enrolment). In the combined treatment group, five were retired: one had retired due to age and four were on a disability/unemployment pension. However, none had retired due to shoulder-related reasons. In the exercise group, 11 patients were retired: three had retired due to age and eight were on a disability/unemployment pension. Two had retired due to shoulder-related reasons. Two additional patients were semi-retired, one due to shoulder-related reasons (exercise group). Of the patients who were still experiencing pain at five years, 65% were currently working; the corresponding figure for the pain-free patients was 63%.

A total of 58% of the pain-free patients had not had any sick leave during the three-month interval prior to the randomization, whereas only 33% of the patients experiencing pain had not had any sick leave during the corresponding period. Long periods out of work due to shoulder reasons that lasted over two weeks had occurred in 23% of the pain-free patients and in 44% of those patients who were still experiencing pain at five years ( $p = 0.07$ ). These differences between the groups are not statistically significant.

Seven patients in both the exercise and combined treatment groups reported at five years that changes had been made in their working arrangements due to shoulder-related reasons. A total of 22% of the patients still experiencing pain at five years reported that their condition had required special arrangements at work, whereas the corresponding percentage was 11% in patients who were pain-free at five years.

### 5.4.3 Prognostic factors

The following factors seemed to have a significant impact on pain:

Marital status had a significant impact: living alone was associated with still experiencing pain at two years (OR=3.3, 95% CI 1.4–7.8). When dividing the patients into pain sufferers

and the pain-free, those living alone seemed to have more pain ( $p=0.01$  at two years, and  $p=0.03$  at five years).

Lack of professional education was an additional risk factor for those still experiencing pain at two years. At two years, the OR was 3.7 (95% CI 1.2–11) for those with no education and 3.0 (95% CI 0.93–9.5) for those with only occupational education.

Symptom duration prior to the randomization had a positive correlation with pain at two years, especially among those in the exercise group who later wanted an operation ( $p=0.04$ ). In the exercise group, 44% of the pain-free and 40% of those experiencing pain had had symptoms for over one year when analyzed at two years; the corresponding figures in the combined treatment group was 48% for the pain-free and 69% for those experiencing pain. At five years, the symptom duration prior to the randomization was over one year in 56% of the pain-free patients at five years and 57% of the patients experiencing pain. All of those (100%) who wanted operation in the exercise group ( $n=18$ ) had had symptoms for over one year.

Long periods of sick leave also raised the risk of experiencing pain. The patients that had been out of work prior to the randomization due to shoulder-related reasons for over two weeks were more often experiencing pain at two years (OR=2.5) (95% CI 1.10–5.8) and at five years (OR=3.8) (95% CI 1.4–11). This was the only statistically significant predictor in the multivariable logistic regression analysis in which the risk of experiencing pain had an OR of 4.0 (95% CI 1.2–13) if the patient had been out of work due to shoulder reasons for longer than two weeks. Of all the patients who were pain-free at two years, 69% had had no or less than one week of sick leave, but for those experiencing pain, the corresponding proportion was 48%. The incidence of sick leave exceeding two weeks was 21% in the pain-free patients and 44% in the patients experiencing pain (overall  $p=0.02$ ). Conversely, if the sick leave had lasted more than two weeks, more than half of the patients were experiencing pain (54%) at the two-year follow-up.

Satisfaction at work: Of the patients with quite or very low satisfaction at work, 71% were experiencing pain at two years. On the other hand, 68% of the patients experiencing pain at two years had a quite or very low level of satisfaction. Of the patients who were pain-free at two years, 90% were quite or very satisfied, but only 68% of those experiencing pain at two years were quite or very satisfied. Only 3% of the pain-free patients had a quite or very low level of satisfaction at work, whereas 12% of the patients experiencing pain were quite or very satisfied at work (overall  $p=0.01$ ).

Requirements/challenges at work: When requirements/challenges at work were low or quite low, the percentage of pain-free subjects was 88%. Of those who had heavy requirements at work, more than half were experiencing pain at five years (52%). Of the pain-free patients at five years, 13% reported heavy requirements at work, whereas among those experiencing pain, the corresponding figure was 41% (overall  $p=0.01$ ).

Loads lifted per work day: The highest risk (>4-fold odds) of experiencing pain at two years was for those who lifted a moderate amount during a work day compared to those

who lifted lighter or heavier loads. Light lifters formed 31% of the pain-free patients and 16% of those experiencing pain (overall  $p=0.02$ ).

AC degeneration: In the combined treatment group, 96% of the pain-free patients at five years had no or mild AC degeneration, while among those experiencing pain, 75% had moderate or severe degeneration of the AC joint (overall  $p=0.01$ ).

Over the two-year follow-up, there were on average 0.3 and 1.0 recorded corticosteroid injections in the combined and exercise group, respectively. At five years, only five patients had received injections (95% had received none). In addition, at ten years, 5/90 patients had received one or more corticosteroid injections during the preceding year. More patients who received injections were operated on than treated nonoperatively both at five and ten years (4/5).

#### 5.4.4 Radiological results

At enrolment, we conducted 134 MRI scans. Six patients were not examined because of claustrophobia, obesity, or metal implants in their bodies. At the five-year control visit we were able to reach 109 of the patients for clinical examination and a control MRI was done on 90 patients. In total, 15 patients had a perforating rupture of the supraspinatus tendon at five years. Eight of those (53%) had had acromioplasty. Of these patients at the baseline MRI, four had Type 1, nine Type 2, and two Type 3 acromions ( $p=0.73$ ). The muscle volumes of the m. supraspinatus, m. infraspinatus, and m. subscapularis at baseline and at five years are presented in Table 2. All the muscle volumes in this study diminished during follow-up. This change was statistically significant in the m. supraspinatus ( $p=0.004$ ) but not in the m. infraspinatus or subscapularis ( $p=0.31$  and  $0.38$ , respectively).

Table 8 shows the muscle volumes in the different subgroups. We analyzed separately those who fully followed the randomized treatment protocol either in the exercise group or the combined treatment group. The third group comprises those who wanted and had an operation in the exercise group. There were no statistically significant differences in muscle volume changes compared to those continuing in their treatment group. For those following the combined treatment protocol, the volume of the m. supraspinatus diminished by 7%, and for those in the exercise group it diminished by 4% ( $p=0.63$ ). The changes in the m. subscapularis ( $p=0.50$ ) and m. infraspinatus ( $p=0.85$ ) were not statistically different between the groups. The muscle volume of the m. supraspinatus diminished by 10% in patients with a partial tear and 23% in those diagnosed with a total rupture.

The grading of muscle fatty degeneration showed that 65% of the operated patients had at least some fatty streaks compared to 54% in the nonoperative group ( $p=0.31$ ). The shape of the acromion according to Bigliani at baseline was 45% for Type 1, 43% for Type 2, and 11% for Type 3.

Table 8. Muscle volumes in subgroups: those who fully followed their randomized treatment protocol and those not satisfied with the exercise treatment.

Subgroup	Muscle	Muscle volumes	
		Baseline	Five years
		cm <sup>3</sup>	cm <sup>3</sup>
combined treatment group n=43	supraspinatus	45.9	44.7
	subscapularis	107.1	107.6
	infraspinatus	124.2	120.8
exercise group n=43	supraspinatus	47.3	45.5
	subscapularis	128.4	120.7
	infraspinatus	119.9	110.1
wanted an operation in the exercise group	supraspinatus	56.9	51.3
	subscapularis	114.2	99.6
	infraspinatus	128.4	127.4

Effusion in the subacromial bursa was reported to be 0/1. The majority of patients had subacromial bursal effusion at baseline (76%) and also at five years (80%). For those with no bursal irritation, the mean self-reported pain was 6.8 at five years, while the score for those with subacromial bursal fluid was 6.6 ( $p=0.73$ ).

The tangent sign was 0 in 89% of operatively treated patients and 87% of patients who had not had an arthroscopic acromioplasty ( $p=0.75$ ).

The subacromial distance (mean) was 8.2 mm at baseline. Comparing those who had been operated on to those who were not operated on, there was a significant difference (mean 8.2 mm and 7.5 mm respectively;  $p=0.03$ ). It is difficult to judge if this minor difference has any clinical importance because of the existent precision of radiological measurements.

#### 5.4.5 Long-term results

The self-reported pain in VAS as ITT was 2.8 in the combined treatment group and 1.8 in the exercise group. The corresponding PP values were 2.8 in the operated group and 1.8 in the non-operated group. Statistically, there were no significant differences between groups when compared by ITT or PP. There were also no differences in the secondary outcome measures (Table 5 and Figure 3).

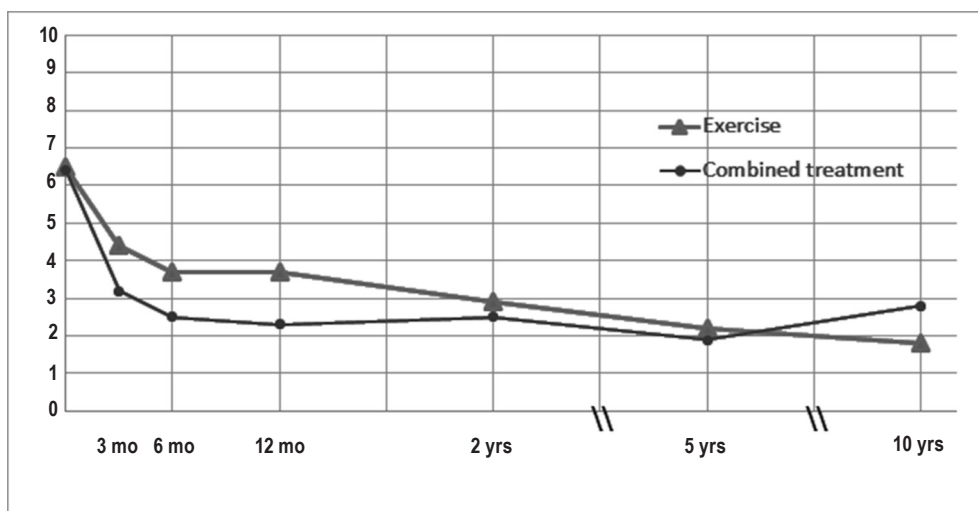
We received 90 answers from the original participants. The final percentage of attendance at this point was 64%. The time point of analysis was on average at 12 years after randomization (range 11–13 years). The answers were analyzed using both the ITT and PP approach.

In the combined treatment group, 22 were retired: 13 because of old age, one for prolonged unemployment, and eight for health reasons. In the exercise group, 26 patients had retired (15+1+10 respectively). Using the PP approach to compare those who were

actually operated on (n=46) to the non-operated (n=44), in both groups 24 patients were retired. The reasons were also alike. In both groups, 14 were retired because of old age, one for prolonged unemployment, and nine due to health reasons. Among those operated on, 1/24 stated that the shoulder was the primary reason for the pension; in the non-operated group the corresponding figure was 4/24. No shoulder operations were reported between the five-year control and this long-term control.

Of all patients, 35% also complained of pain on the contralateral side. The only subgroup where over half of the patients had pain also on the contralateral side were those patients primarily in the exercise group who were not satisfied and eventually wanted an operation. In this group, 9/16 (56%) patients also had pain on the contralateral side at over ten years after the onset of the study.

Figure 3. Self-reported pain in VAS in an ITT. The three-, six-, and 12-month values are only descriptive because they are counted from the onset of treatment and are not alike between groups. The values at two, five, and after ten years are counted individually from the randomization.



## 6 DISCUSSION

### 6.1 Results

The theory that the acromion and coracoacromial ligament are in contact with the supraspinatus and cause pain and tendon disorders has been well established. Currently, the multifactorial theory is widely accepted. The term “impingement syndrome” is used to cover a full range of rotator cuff disorders. It has been suggested that the syndrome should be called rotator cuff disease and the symptoms anterolateral shoulder pain (Papadonikolakis, McKenna et al. 2011; McFarland, Maffulli et al. 2013). At the onset of this study, the term impingement was widely used. Gradually, the role of acromioplasty became questioned and nonoperative choices of treatment more observed. It is essential that researchers and practitioners adopt the tendinopathy paradigm and in such way be able to practice evidence-based medicine. A proper diagnosis is the basis for delivering proper treatment, and the use of more precise language is encouraged whenever possible (Khan, Cook et al. 2002; de Witte, de Groot et al. 2013; McFarland, Maffulli et al. 2013).

There are earlier randomized controlled trials comparing conservative and operative treatment in the treatment of shoulder impingement syndrome (Brox, Staff et al. 1993; Brox, Gjengedal et al. 1999), and data on disability and working capacity (Haahr, Østergaard et al. 2005; Haahr and Andersen 2006). This study is the first to examine whether operative treatment provides any additional value over a structured and supervised exercise program without any surgical intervention. Failure of regular physiotherapy and other nonoperative treatments were criteria for inclusion. According to current standards in clinical practice, this failed nonoperative management would make these patients most likely candidates for surgical intervention.

This study indicates that at two and five years after randomization, an arthroscopic decompression followed by structured exercise treatment is no better in the treatment of shoulder impingement syndrome than structured exercise treatment alone when analyzed using self-reported pain as the primary outcome measure. The two treatment arms did not differ significantly in the secondary outcome measures such as disability, pain at night, SDQ score, number of painful days, and proportion of pain-free patients, either. The SDQ is considered to be a useful questionnaire in assessing functional disability in longitudinal studies (van der Windt, van der Heijden et al. 1998).

The results from the three-, six-, and 12-month visits from the onset of the treatment are merely descriptive and reflect the recovery of individual patients counted from the interventions. It seems that the operative group initially recovers faster in all parameters compared to the nonoperative group when assessed from the start of the treatment.

The primary and secondary outcome measures continued to improve between the two-year and five-year follow-up visits, leading to a highly significant improvement compared to baseline. Yet there were no differences between groups. These results indicate that arthroscopic decompression does not have any additional effect on structured exercise treatment. The non-decompressed, conservatively treated patients did as well as those who underwent operative treatment for the impingement.

Descriptive data in an *ad hoc* PP analysis produced only slightly better results than the ITT analysis. There were no statistically significant differences between the groups in the PP analysis when comparing those who completely followed their treatment protocol, either combined or exercise, when analyzed at five years.

Subgroup analyses are in general important if treatments show statistically similar outcomes but still possible heterogeneity of the individual patients. This may reveal the diversity of the underlying disease pathophysiology and help to create more individualized indications or even contraindications. Subgroup analyses must be predefined and limited to a few clinically important questions (Rothwell 2005). In this prospective and carefully selected patient material, subgroup analysis can be considered justified. We tried to ascertain if the treatment works better in some subgroups than others, acknowledging the risks of statistical problems and misinterpretations. When analyzing the prognostic factors, we focused on differences of the average overall treatment effect and limited the questions to only a few clear and well-defined variables. Participation in an intervention as intended, i.e. analysis according to ITT or PP modes, did not have any significant impact on the results.

The indications for arthroscopic acromioplasty in the treatment of shoulder impingement syndrome should be reconsidered. Based on the current results, it seems that the mere presence of an uncomplicated shoulder impingement syndrome is not *per se* an indication for arthroscopic acromioplasty because nonoperative treatment with a structured exercise program provides equally as good results in the long run. Based on our two-year results, we concluded that acromioplasty is not cost-effective. There are no simple criteria to predict the natural course of the disease in patients suffering from shoulder impingement syndrome. Based on the results, most patients get better. We believe that the natural course of the disease should be better defined to be able to judge the different treatment options.



## 6.2 Costs and absence from work

A large proportion (47%) of the total costs of shoulder pain has been reported to be due to the indirect costs of productivity losses (Kuijpers, van Tulder et al. 2006). Luyckx et al. reported the results of 166 patients who underwent arthroscopic subacromial decompression. The mean duration from operation to full duty was 11.1 weeks, at its shortest being one week (Luyckx, Luyckx et al. 2011). The costs due to sick leave have been reported to contribute up to 84% of the total costs to society. Interventions that would reduce long periods of sick leave are warranted. A reasonable change of healthcare cost has just a minor influence on the total cost (Virta, Joranger et al. 2012).

In this study, patients in the combined treatment group had a mean of 28.1 days' leave of absence due to shoulder-related reasons at the three-month follow-up visit. The patients in the exercise group had a mean 5.3 days' leave of absence ( $p < 0.001$ ). The difference in the total need for sick leave between baseline and five years was not statistically significant between the study groups, but it was still almost double in the combined treatment group (31.2 vs. 16.5), which again raises the overall health care costs (Table 9). The mean total cost was €2,961 in the combined treatment group and €1,864 in the exercise group, i.e., combined treatment was considerably more expensive. The ICER was €5,852 per MCID unit. The cost-effectiveness analysis suggests that the combined treatment is not cost-effective compared to exercise treatment alone. As health care resources are limited, the effectiveness of acromioplasty needs to be higher than that observed in this study to warrant the cost. The effect difference between the treatment arms was small at 24 months in all outcome measures, which simplifies the decision-making to being an issue of cost-minimization.

In this study, we cannot justify the performance of this procedure to any single impingement patient subgroup. Structured exercise treatment should be the treatment of choice for shoulder impingement syndrome at any stage.

Table 9. Leave of absence (days) due to shoulder symptoms.

Control point	exercise group (mean)	combined treatment group (mean)	difference in means p-value
3 months	5.3	28.1	<0.001
6 months	2.4	4.6	0.45
12 months	4.2	4.4	0.94
2 years	3.8	0.1	0.03
5 years	3.2	0.4	0.22
total	16.5	31.2	0.11



## 6.3 Secondary outcome measures

### 6.3.1 HRQoL

It has been reported that patients suffering from chronic shoulder impingement score significantly lower in all health dimensions – including quality of life measures – than the general population (Gartsman, Brinker et al. 1998; Chipchase, O'Connor et al. 2000). Shoulder conditions have an effect on an individual's perception of his/her general health that ranks in severity with five major medical conditions: high blood pressure, cardiac insufficiency, heart attack, diabetes, and depression (Gartsman, Brinker et al. 1998). Quality of life scores in shoulder impingement were, however, higher than in other orthopaedic entities such as osteoarthritis of the knee, fibromyalgia, or osteoporosis (Yilmaz, Sahin et al. 2008). In this study, some parameters of the 15D quality of life index were slightly worse in patients treated for shoulder impingement than in the age-adjusted general population. There were no differences between treatment groups in these HRQoL parameters.

### 6.3.2 Prognostic factors

Despite the treatment, a longer duration of symptoms seems to predict worse results. This probably reflects the possibility that impingement may heal if the condition has lasted less than one year. In this study, after this time point the number of non-responders rose significantly. The same factor probably explains in part the worse results in patients who had longer and more frequent periods of sick leave. Our results are in alignment with previous reports stating that a longer baseline duration of symptoms is a predictor of poor outcome (Bartolozzi, Andreychik et al. 1994; Kuijpers, van der Windt et al. 2004; TaheriAzam, Sadatsafavi et al. 2005; Thomas, van der Windt et al. 2005; Ertan, Ayhan et al. 2015).

Satisfaction at work correlated with the perception of pain negatively. The more demanding the work was according to the patient's own assessment, the worse was the prognosis for recovery. Similarly, lack of higher education associated with poor treatment results. Low education has also previously been noted to be a predictor for shoulder pain (Engebretsen, Grotle et al. 2010b).

Patients living alone had more pain, which might be explained by the lack of disease-related support. There are similar reports of other orthopaedic conditions where psychological factors affect the perception of pain (Wahlman, Häkkinen et al. 2014). If the condition is refractory or the symptoms become bilateral, the overall prognosis is impaired.

Only one radiological feature was significantly connected to pain perception after the treatment. If the patients had AC osteoarthritis, they had more pain than patients with a normal AC joint radiology. If such patients are operated on, a concomitant AC resection is only recommended if there are signs of AC degeneration in the symptomatic joint.

### 6.3.3 Radiological findings

#### 6.3.3.1 Bursal inflammation

Shoulder impingement syndrome involves inflammation of the bursa in the subacromial space (Bigliani and Levine 1997). Bursal effusion has been noted to correlate with shoulder disability and impingement test maneuvers (Ardic, Kahraman et al. 2006). This decreases the volume of the subacromial space. Based on our results, this is a very common finding in these patients and it does not correlate with the symptoms at all.

#### 6.3.3.2 Cuff rupture prevention

Arthroscopic acromioplasty has been supported with the assumption that by enhancing the mechanical situation, the supraspinatus muscle-tendon unit would degenerate more slowly. Thus, the decompression has been thought to prevent tendon ruptures in the long run (Björnsson, Norlin et al. 2010). If solely relying on the extrinsic theory, decompressive acromioplasty should stop the process of this syndrome. However, it has been shown that a tear of the rotator cuff may appear after acromioplasty. Both intrinsic and extrinsic factors are sure to be involved in the pathogenesis (Hyvönen, Lohi et al. 1998).

This study reports the changes in rotator cuff muscle-tendon unit in impingement patients at five years after the onset of the symptoms. We compared operatively and nonoperatively treated patients and found no beneficial differences due to the decompression in the incidence of tendon rupture development at zero to five years. Our results suggest that this procedure probably does not protect from tendon rupture, nor diminish the degeneration of muscle mass. More than half of the patients with a total rupture in the supraspinatus tendon at five years had had an arthroscopic acromioplasty (8/15).

#### 6.3.3.3 The shape of the acromion

The proportion of Type 3 acromions seems to increase with age (Wang and Shapiro 1997; Gill, McIrvin et al. 2002). The influence of acromial morphology on rotator cuff tears has not been clearly proven. The changes in morphology are also suggested to be the result of the degenerative rotator cuff disease rather than the cause (Neer 1983; Ozaki, Fujimoto et al. 1988; Nicholson, Goodman et al. 1996; Shah, Bayliss et al. 2001). According to one study, the majority of patients with Type 3 acromions required surgical intervention. All of the patients in this study with rotator cuff tears were reported to have a Type 3 acromion in plain radiographs (Wang, Horner et al. 2000). In one analysis of postoperative acromial shape, 23 patients still had a Type 3 acromion, while in this study group 29/100 had a

hooked acromion preoperatively. No difference was found in the retear rate with respect to postoperative acromial shape (Koh, Laddha et al. 2012).

In our study, 11% of the patients (15/134) had a Type 3 acromion. Only 2/15 patients of those who had developed a supraspinatus rupture had a Type 3 acromion. Our findings are consistent with the results of Moor et al. regarding the lack of association between the Bigliani type of acromion and cuff tears. However, they considered the critical shoulder angle to be the most accurate prediction of a patient's individual risk for experiencing a rotator cuff tear (Moor, Wieser et al. 2014). In this study, more than one-third of Type 1 acromions degenerated into Type 2 despite the treatment. The re-shaped form is not fully sustained in the Type 2–3 acromions either (Table 10).

#### 6.3.3.4 Muscle volumes

In this study, a reliable and reproducible method of measuring the volumes of the rotator cuff muscles from shoulder MRI images was used (Lehtinen, Tingart et al. 2003; Tingart, Apreleva et al. 2003). The method of measuring the muscle volumes seemed to be valid and comparable (Table 2).

Between baseline and five years, the muscle values measured in this study had slightly diminished. It has been stated before that age has a significant negative effect on muscle volume (Juul-Kristensen, Bojsen-Møller et al. 2000a–b; Vidt, Daly et al. 2012). The changes in values of the supraspinatus, the infraspinatus, and the subscapularis in cm<sup>3</sup> were 49.0–45.6, 119.8–113.8, and 115.0–110.3, respectively. When comparing operatively and nonoperatively treated patients, no beneficial differences were found due to the decompression in the muscle mass development from zero to five years. The method of treatment had no effect on the development of muscle volumes. The procedure seems not to reduce the degeneration of the muscle mass. In actual fact, the muscle volume of

Table 10. The acromial shape according to Bigliani reported PP (operated or non-operated) at baseline and at five years, to compare if the re-shaped acromion was sustained.

		Shape of the acromion at baseline(Bigliani)						
		1		2		3		
	at five years	n	%	n	%	n	%	p-value
Operated on n=49	1	14	63.6	0	0	2	33.3	0.02
	2	8	36.4	19	90.5	3	50.0	
	3	0	0	2	9.5	1	16.7	
	Total	22		21		6		
Non-operated n=41	1	11	57.9	3	16.7	0	0	0.42
	2	7	36.8	13	72.2	3	75.0	
	3	1	5.3	2	11.1	1	25.0	
	Total	19		18		4		

the supraspinatus seems to have decreased a little more in the operated group than in the nonoperative group, but the differences are not statistically significant. We do not have enough statistical power for definitive conclusions.

Of the patients who were not operated on, 46% had a completely normal supraspinatus muscle without any fatty streaks according to Goutallier. The proportion was even smaller in the operative group (35%) but not statistically significant due to small group sizes. Overall, there were no significant differences between the groups regarding fatty degeneration of any grade. The grading of muscle fatty degeneration shows that 65% of the operated patients had at least some fatty streaks compared to 54% in the nonoperative group. This 11% difference is marked but not statistically significant ( $p=0.31$ ). However, because group sizes are so small and due to a lack of power, we cannot draw absolutely secure conclusions.

## 6.4 Failed nonoperative treatment

Arthroscopic subacromial decompression has been considered to have good outcome and to be an excellent surgical treatment for primary impingement syndrome that is resistant to nonoperative interventions (Nicholson 2003). Brox and Rahme compared physiotherapeutic and surgical treatments. Brox et al.'s study results showed the treatments were equal, while in Rahme's material, the operated-on patients had a little less pain at six months (Brox, Staff et al. 1993; Rahme, Solem-Bertoft et al. 1998; Brox, Gjengedal et al. 1999). In a review, these findings were synthesized as an indication for surgery for patients who have failed exercise or injection (Michener, Walsworth et al. 2004). Chaudhury et al. also share the opinion that if nonoperative strategies fail, surgery might be considered. They emphasize the importance of a clear diagnosis and state that the proportion of patients with shoulder pain requiring surgery is small (Chaudhury, Gwilym et al. 2010).

In our study group, there were 18 patients who were not pleased with the results of the exercise treatment alone and were therefore operated on later on. However, these patients did not improve after the operation either; they had worse results in the outcome measures than patients treated in the combined or exercise treatment groups. If there were an equal group of patients in the combined treatment group as well who were not responding to the treatment, it would make almost one-third of all patients with this diagnosis non-responders to any sort of treatment. The remaining two-thirds would get better regardless of the nature of the treatment. The natural course might well contribute significantly to the improvement of those impingement syndrome patients who are "healed" after treatment in the five-year follow-up.

It seems that some patients who do not get better by nonoperative means do not get better with operative treatment either. There may be several reasons for this and it may also in part depend on the duration of the symptoms prior to the initiation of the treatment. This is after all a real challenge to the previous guidelines of offering an operation to patients

who “fail” nonoperative treatment. Longer follow-up periods of patients with shoulder impingement syndrome are needed to learn more about the natural course of the disease.

## 6.5 Evidence-based medicine vs. real life

A clinician should constantly evaluate information to be able to find out the optimal way to treat patients. This requires time and skill. When following the guidelines of evidence-based medicine, the decisions of managing patients and overall health care should be based on the best available evidence and performance should be constantly evaluated rather than just following habits or protocols (Davidoff, Haynes et al. 1995). Unfortunately, when analyzing specific therapies and the available scientific evidence for their efficacy, there was little congruence and a weak association with the primary care clinicians’ trust in these treatments (Johansson, Oberg et al. 2002). It is difficult to draw up new guidelines, especially in highly professional organizations, to ensure that they reach all parts of the health service. Practice changes are better led by the professionals themselves rather than imposed from outside (Ferlie, Wood et al. 1999).

Neer considered acromioplasty indicated if a patient had had persistent disability for one year (Neer 1983). In a review by Kromer et al., it is stated that patients should not undergo surgery before having been treated nonoperatively. Exercise treatment seemed to incur fewer costs than surgery. Surgery should be handled with care, and clear indications for its application need to be established (Kromer, Tautenhahn et al. 2009). However, when interviewing patients who had undergone subacromial decompression due to shoulder impingement and analyzing the implementation of physiotherapy, this has not been actualized. Before surgery, half of the patients had not received advice for shoulder muscle exercises. Postoperatively, all patients had received mobility exercises, but one quarter still had no instructions for strengthening exercises (Ylinen, Vuorenmaa et al. 2013).

Subacromial impingement syndrome is a multifactor problem and there are inherent concerns of which clinicians should be aware of when interpreting studies of this condition (Sauers 2005). Understanding sternoclavicular and AC joint interactions, muscle function, and potential mechanisms of movement abnormalities in impingement patients can assist the therapists in targeting treatment interventions to specific movement problems (Ludewig and Braman 2011). Orthopedic surgeons should ensure the implementation of exercise therapy before deciding on surgery. If nonoperative treatment is being done adequately prior to an operation being considered, it is highly probable that several patients will avoid surgery (Ylinen, Vuorenmaa et al. 2013).

## 6.6 Strengths and weaknesses of the study

This was a prospective, randomized study. The selection bias was low at the actual entrance to the study because at baseline all eligible consecutive 140 patients were willing to participate, although two lost interest immediately after the randomization. The unusual willingness to participate may be due to the thorough information that had already been given during the basic health care and continued at the hospital.

The dropout bias was relatively small since it was possible to analyze 134/140 randomized patients at two years and 109/140 at five years. Even at the late control, we received 90 answers. Compared to previous studies, this is good. In a retrospective study at eight years, Ertan et al. could not reach half of the patients, and in addition to that more than half of those meeting the inclusion criteria were unwilling to participate (Ertan, Ayhan et al. 2015).

The treatment groups were similar at baseline, reflecting successful randomization. Although there were patients in the exercise group who wanted to be operated on or refused the operation in the combined treatment group still attending the follow-up visits, their low numbers did not compromise the results. This reflects the real-life situation.

The follow-up examinations were done by an independent and blinded assessor (physiotherapist) who did not otherwise participate in the study. The patients wore T-shirts so the possible scars were not visible and would not compromise the blinding. This blinded arrangement minimizes the bias caused by the tendency of the operated patients (or of the evaluating physiotherapist) to please the surgeon.

A strength of the study is also that all arthroscopic acromioplasties were performed by one experienced surgeon considered to have reached the top of the learning curve. This contributes to the uniform quality of the operative care. There were, fortunately, no significant surgical complications.

As the study was conducted in an ordinary provincial hospital setting, not in a highly specialized shoulder center, the external validity is relatively good. However, in real life patients do not always follow the guidance given: it is their health and also their decision.

The waiting time for the operation was longer than for the primary visit for the exercise treatment, 8.3 months and 1.2 months, respectively. This may have influenced the results in favour of the exercise group. Nevertheless, the waiting time was short compared to the duration of the complaints before randomization (mean 2.5 years), which suggests this possibility is unlikely.

The accurate diagnosis of impingement syndrome requires a thorough patient history and a careful clinical examination to exclude other conditions that may mimic impingement symptoms. To avoid such pitfalls, all patients in this study were examined with Neer's impingement test (Neer 1983). An MRI of the shoulder was taken at baseline and controlled at five years after randomization.

The radiological evaluations were done using MRI scans, including the Bigliani classification. Usually plain radiographs are used, but the MRI method is shown to be

accurate when using a combination of two MRI slices (Mayerhoefer, Breitenseher et al. 2009). We had two radiologists who separately evaluated the scans and their consensus report was used in this study. According to the literature, the sensitivity in detecting rotator cuff tears can be further increased using MRA compared to MRI alone. This is especially true with partial-thickness tears (Vahlensieck 2000). At the onset time of this study, MRA was not yet in routine use and this may to some extent affect the incidence of minor cuff tears detected and explain the non-diagnosed labral lesions. However, the method was equal in both study groups and thus the results between the groups are comparable. A similar proportion of labral lesions/findings can be assumed to exist in the exercise treatment group. In five patients out of 14, the labral lesion itself was considered the main cause of the symptoms. In nine patients this occurred together with impingement, and the labral fixation was combined with acromioplasty.

In this study, self-reported pain was used as a primary outcome measure. The previous findings in the literature imply that retrospective reports on pain intensity are sufficiently reliable. Pain has been used in analysis, especially in epidemiologic studies of work-related musculoskeletal disorders. It has been suggested that patients are able to recall the severity of their pain for a period of three months (Brauer, Thomsen et al. 2003). In this study, the MCID was defined as 2 points on VAS. The value has later been up-dated and estimated to be 1.4 in VAS measuring pain in patients treated for rotator cuff disease (Tashjian, Deloach et al. 2009).

VAS functions best for measuring present pain intensity (Breivik, Borchgrevink et al. 2008). Different forms of VAS have also long been used to measure health outcomes. It is simple and quick to use. The context bias must be acknowledged as the reports of VAS were, in addition to self-reported pain, also used for disability, working ability, and pain at night. End aversion is also a bias that can affect the use of a VAS; the respondents may be reluctant to use the extreme categories near the ends of the scale (Torrance, Feeny et al. 2001). In our study, the same patients answered the same questions in every control visit, so this might diminish the bias, or at least changes in values can be recognized.

O'Holleran et al. have pointed that patient satisfaction should be an essential part of shoulder assessment. They included impingement patients in their cohort study along with patients with rotator cuff tears (311 patients) and followed them up for one year. The strongest relationship with satisfaction lay in subjective measures of symptoms and function, whereas demographic variables seemed not to reveal significant differences (O'Holleran, Kocher et al. 2005).

Due to multiple variables, the subgroup sizes became relatively small, which increases the risk for type II error and does not provide enough statistical strength. In addition, the fact that all factors are not independent has to be taken into account.

Additionally, there are no reports or common consensus on how shoulder impingement syndrome evolves over time. There may always be some patients who recover spontaneously and others who are not cured despite the treatment given.



Using a prospective, randomized, trial enabled us to evaluate the effect of subacromial decompression on all main radiological features of the shoulder impingement syndrome compared to nonoperative intervention. We were able to have 90 control MRI studies at the five-year follow-up compared to 134 at baseline. The scans were analyzed separately by two experienced musculoskeletal radiologists and their consensus statement was used in the analyses.

In this study setting, we did not have a sham operation group. Though our patients were suffering from chronic severe pain, when faced with a crucial question at randomization between the possibilities of operative or nonoperative treatment, the compliance was excellent. The patients' belief in the healing capability of an operation was higher compared to those randomized in the exercise group. Less than one-third of the patients thought they would be completely healed without the operation. Even though the combined treatment group had a stronger belief and the power of placebo effect of surgery with them, the exercise group reached similar or even better results. One might even consider the real effect of acromioplasty to be negative.

Major problems have been met in performing randomized studies between operative and nonoperative treatments, especially concerning lumbar disc herniation in the previous literature (Weinstein, Tosteson et al. 2006). The psychosocial background of low back pain may be the explanation. In our research population, such problems did not arise. The patients reported high satisfaction with work. Despite of their severe pain, the mean self-reported ability to work was also reported as good. At the beginning, the patients were willing to commit to the randomized treatment, which was preceded by thorough information about both options. They were allowed to change treatment groups during the study, as in normal health care practice. Despite this, the groups remained quite stable. The excellent compliance found in this study may also reflect on the reliance on the health care system in Finland. The execution of this study is an encouragement to perform randomized, controlled studies between nonoperative and operative treatments in musculoskeletal conditions.

## 6.7 Future

In the future, clinical and experimental efforts should be directed toward establishing the pathophysiology of rotator cuff disease, its natural history, the source of pain, and its effective treatments (McFarland, Maffulli et al. 2013). Future studies on exercise therapy should concentrate on the long-term effect of different exercise protocols, including the intensity, duration, frequency, and load of the exercises (Gebremariam, Hay et al. 2014). In addition, longer follow-up periods are needed to learn more about the natural course of the disease and the long-term effects of the treatments.



## 7 CONCLUSIONS

### *Study I*

There was a significant decrease in mean self-reported pain in both treatment groups, but there was no statistically significant difference between groups. The additional effect of arthroscopic acromioplasty does not seem to be significant in the treatment of shoulder impingement syndrome compared to structured exercise treatment alone when evaluated at two years. It is also very improbable that acromioplasty is cost-effective.

### *Study II*

Arthroscopic acromioplasty did not give any additional effect on top of the structured exercise treatment when evaluated at five years. Three-fourths of the patients recovered well and the rest continued to have discomfort despite the treatment. Some parameters of the 15D quality of life index were slightly worse in this study group than in the age-adjusted general population, but there were no differences between the treatment groups.

### *Study III*

Based on the study results of the prognostic factors, arthroscopic acromioplasty cannot be recommended to any specific subgroup of shoulder impingement syndrome. This condition behaves somewhat differently from usual in some patient subgroups, which can be explained by the nature of the condition rather than the demographic properties of the patients. If the patients do not recover by nonoperative means, it appears that there is a considerable risk that they will not benefit from the arthroscopic acromioplasty either, due to unknown causes.

### *Study IV*

This study shows that arthroscopic acromioplasty probably has no long-term benefits based on radiological findings. It has no effect on the development of rotator cuff tendon ruptures, nor on muscle volumes.

### *Study V*

Both treatment groups reached a statistically significant change compared to baseline, but there were no differences between the groups. Even though the patients operated on had a stronger belief in their recovery, the exercise group reached similar or even better results. The interpretation of the long-term effects is not straightforward as the natural history of the condition is unknown.

The indications for arthroscopic acromioplasty should be redefined in the treatment of shoulder impingement syndrome. Structured exercise treatment should be the basis for treatment. This study suggests that arthroscopic acromioplasty is inefficient in preserving the rotator cuff. Based on our results, we do not recommend arthroscopic acromioplasty as the treatment for shoulder impingement syndrome for working-age patients.

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Tampere, February 2016

A handwritten signature in black ink, appearing to read 'Saara Ketola'. The signature is fluid and cursive, with a large initial 'S' and a long horizontal stroke at the end.

Saara Ketola

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# APPENDICES



## Appendix I

<i>Shoulder Disability Questionnaire</i>	Yes	<i>Not applicable</i>	No
I wake up at night because of shoulder pain.			
My shoulder hurts when I lie on it.			
Because of pain in my shoulder, it is difficult to put on a coat or a sweater.			
My shoulder hurts during my usual activities.			
My shoulder hurts when I lean on my elbow or hand.			
My shoulder hurts when I move my arm.			
My shoulder hurts when I write or type.			
My shoulder is painful when I hold the steering wheel of my car or handlebars of my bike.			
When I lift and carry something, my shoulder hurts.			
When reaching and grasping above shoulder level, my shoulder hurts.			
My shoulder is painful when I open or close a door.			
My shoulder is painful when I bring my hand to the back of my head.			
My shoulder is painful when I bring my hand to my buttock.			
My shoulder is painful when I bring my hand to my low back.			
I rub my painful shoulder more than once during the day.			
Because of my shoulder pain, I am more irritable and bad-tempered with people than usual.			

(van der Windt, van der Heijden et al. 1998; van der Heijden, Leffers et al. 2000; de Winter, van der Heijden et al. 2007)

## Appendix II

### QUALITY OF LIFE QUESTIONNAIRE (15D©)

Please read through all the alternative responses to each question before placing a cross (x) against the alternative which best describes **your present health status**. Continue through all 15 questions in this manner, giving only **one** answer to each.

#### QUESTION 1. MOBILITY

- 1 ☐ I am able to walk normally (without difficulty) indoors, outdoors and on stairs.
- 2 ☐ I am able to walk without difficulty indoors, but outdoors and/or on stairs I have slight difficulties.
- 3 ☐ I am able to walk without help indoors (with or without an appliance), but outdoors and/or on stairs only with considerable difficulty or with help from others.
- 4 ☐ I am able to walk indoors only with help from others.
- 5 ☐ I am completely bed-ridden and unable to move about.

#### QUESTION 2. VISION

- 1 ☐ I see normally, i.e. I can read newspapers and TV text without difficulty (with or without glasses).
- 2 ☐ I can read papers and/or TV text with slight difficulty (with or without glasses).
- 3 ☐ I can read papers and/or TV text with considerable difficulty (with or without glasses).
- 4 ☐ I cannot read papers or TV text either with glasses or without, but I can see enough to walk about without guidance.
- 5 ☐ I cannot see enough to walk about without a guide, i.e. I am almost or completely blind.

#### QUESTION 3. HEARING

- 1 ☐ I can hear normally, i.e. normal speech (with or without a hearing aid).
- 2 ☐ I hear normal speech with a little difficulty.
- 3 ☐ I hear normal speech with considerable difficulty; in conversation I need voices to be louder than normal.
- 4 ☐ I hear even loud voices poorly; I am almost deaf.
- 5 ☐ I am completely deaf.

#### QUESTION 4. BREATHING

- 1 ☐ I am able to breathe normally, i.e. with no shortness of breath or other breathing difficulty.
- 2 ☐ I have shortness of breath during heavy work or sports, or when walking briskly on flat ground or slightly uphill.
- 3 ☐ I have shortness of breath when walking on flat ground at the same speed as others my age.
- 4 ☐ I get shortness of breath even after light activity, e.g. washing or dressing myself.
- 5 ☐ I have breathing difficulties almost all the time, even when resting.

### **QUESTION 5. SLEEPING**

- 1 ☐ I am able to sleep normally, i.e. I have no problems with sleeping.
- 2 ☐ I have slight problems with sleeping, e.g. difficulty in falling asleep, or sometimes waking at night.
- 3 ☐ I have moderate problems with sleeping, e.g. disturbed sleep, or the feeling I have not slept enough.
- 4 ☐ I have great problems with sleeping, e.g. having to use sleeping pills often or routinely, or usually waking at night and/or too early in the morning.
- 5 ☐ I suffer severe sleeplessness, e.g. sleep is almost impossible even with full use of sleeping pills, or staying awake most of the night.

### **QUESTION 6. EATING**

- 1 ☐ I am able to eat normally, i.e. with no help from others.
- 2 ☐ I am able to eat by myself with minor difficulty (e.g. slowly, clumsily, shakily, or with special appliances).
- 3 ☐ I need some help from another person in eating.
- 4 ☐ I am unable to eat by myself at all, so I must be fed by another person.
- 5 ☐ I am unable to eat at all, so I am fed either by tube or intravenously.

### **QUESTION 7. SPEECH**

- 1 ☐ I am able to speak normally, i.e. clearly, audibly and fluently.
- 2 ☐ I have slight speech difficulties, e.g. occasional fumbling for words, mumbling, or changes of pitch.
- 3 ☐ I can make myself understood, but my speech is e.g. disjointed, faltering, stuttering or stammering.
- 4 ☐ Most people have great difficulty understanding my speech.
- 5 ☐ I can only make myself understood by gestures.

### **QUESTION 8. EXCRETION**

- 1 ☐ My bladder and bowel work normally and without problems.
- 2 ☐ I have slight problems with my bladder and/or bowel function, e.g. difficulties with urination, or loose or hard bowels.
- 3 ☐ I have marked problems with my bladder and/or bowel function, e.g. occasional 'accidents', or severe constipation or diarrhea.
- 4 ☐ I have serious problems with my bladder and/or bowel function, e.g. routine 'accidents', or need of catheterization or enemas.
- 5 ☐ I have no control over my bladder and/or bowel function.

### QUESTION 9. USUAL ACTIVITIES

- 1 ☐ I am able to perform my usual activities (e.g. employment, studying, housework, free-time activities) without difficulty.
- 2 ☐ I am able to perform my usual activities slightly less effectively or with minor difficulty.
- 3 ☐ I am able to perform my usual activities much less effectively, with considerable difficulty, or not completely.
- 4 ☐ I can only manage a small proportion of my previously usual activities.
- 5 ☐ I am unable to manage any of my previously usual activities.

### QUESTION 10. MENTAL FUNCTION

- 1 ☐ I am able to think clearly and logically, and my memory functions well.
- 2 ☐ I have slight difficulties in thinking clearly and logically, or my memory sometimes fails me.
- 3 ☐ I have marked difficulties in thinking clearly and logically, or my memory is somewhat impaired.
- 4 ☐ I have great difficulties in thinking clearly and logically, or my memory is seriously impaired.
- 5 ☐ I am permanently confused and disoriented in place and time.

### QUESTION 11. DISCOMFORT AND SYMPTOMS

- 1 ☐ I have no physical discomfort or symptoms, e.g. pain, ache, nausea, itching etc.
- 2 ☐ I have mild physical discomfort or symptoms, e.g. pain, ache, nausea, itching etc.
- 3 ☐ I have marked physical discomfort or symptoms, e.g. pain, ache, nausea, itching etc.
- 4 ☐ I have severe physical discomfort or symptoms, e.g. pain, ache, nausea, itching etc.
- 5 ☐ I have unbearable physical discomfort or symptoms, e.g. pain, ache, nausea, itching etc.

### QUESTION 12. DEPRESSION

- 1 ☐ I do not feel at all sad, melancholic or depressed.
- 2 ☐ I feel slightly sad, melancholic or depressed.
- 3 ☐ I feel moderately sad, melancholic or depressed.
- 4 ☐ I feel very sad, melancholic or depressed.
- 5 ☐ I feel extremely sad, melancholic or depressed.

### QUESTION 13. DISTRESS

- 1 ☐ I do not feel at all anxious, stressed or nervous.
- 2 ☐ I feel slightly anxious, stressed or nervous.
- 3 ☐ I feel moderately anxious, stressed or nervous.
- 4 ☐ I feel very anxious, stressed or nervous.
- 5 ☐ I feel extremely anxious, stressed or nervous.

### QUESTION 14. VITALITY

- 1 ☐ I feel healthy and energetic.
- 2 ☐ I feel slightly weary, tired or feeble.
- 3 ☐ I feel moderately weary, tired or feeble.
- 4 ☐ I feel very weary, tired or feeble, almost exhausted.
- 5 ☐ I feel extremely weary, tired or feeble, totally exhausted.

**QUESTION 15. SEXUAL ACTIVITY**

- 1 ☐ My state of health has no adverse effect on my sexual activity.
- 2 ☐ My state of health has a slight effect on my sexual activity.
- 3 ☐ My state of health has a considerable effect on my sexual activity.
- 4 ☐ My state of health makes sexual activity almost impossible.
- 5 ☐ My state of health makes sexual activity impossible.

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## Appendix III

### *Abbreviations:*

FOV	Field of View
PD	Proton Density
SPIR	Spectral Presaturation with Inversion Recovery
TE	Echo Time
TR	Repetition Time
TSE	Sagittal Turbo Spin Echo

### **The sequences used in Kanta-Häme Central Hospital at baseline:**

Axial T1 sagittal turbo spin echo (TSE), repetition time in msec (TR) 575/echo time in msec (TE) 11, matrix 179/256, field-of-view (FOV) 18, slice thickness 4 mm/0.4mm, axial T2 spectral presaturation with inversion recovery (SPIR) (TR3934/TE70, matrix 179/256, FOV 18, 3 mm/0.3 mm), coronal oblique T1 TSE (TR575/TE11, matrix 215/512, FOV 18, 4 mm/0.4 mm), coronal oblique T2 TSE (TR2200/TE90, matrix 228/512, FOV 18, 4 mm/0.4 mm), coronal oblique T2 SPIR (TR2887/TE70, matrix 229/512, FOV 18, 4 mm/0.4 mm), sagittal oblique T1 TSE (TR666/TE12, matrix 179/512, FOV 24, 3.5mm/0.4 mm).

### **The sequences used in Forssa Regional Hospital at baseline:**

Axial T1 TSE (TR 615/TE 18, matrix 179/256, FOV 19, slice thickness 4 mm/0.4 mm), axial T2 TSE (TR 3078/TE 90, FOV 19, matrix 179/256, 4 mm/0.4 mm), coronal oblique T1 SE (TR557/TE16, FOV 22, matrix 179/256, 4 mm/0.4 mm), coronal oblique T2 SPIR (TR2092/TE14, matrix 179/256, FOV 22, 4 mm/0.4 mm), coronal oblique T2 TSE (TR3090/TE90, matrix 179/256, FOV 22, 4 mm/0.4 mm), sagittal oblique T1 SE (TR557/TE16, matrix 179/256, FOV 22, 4 mm/0.4 mm).

### **At five years, the sequences applied at Kanta-Häme Central Hospital were:**

Axial T1 TSE (TR500/TE18, matrix 256/512, FOV 180, 3.5 mm/0.35 mm), axial T2 SPIR (TR3769/TE70, matrix 256/512, FOV 180, 3.5 mm/0.35 mm), axial PD SPIR (TR2388/TE25, matrix 256/256, FOV 180, 3.5 mm/0.35 mm), coronal oblique T1 TSE (TR500/TE18, matrix 304/512, FOV 180, 3.5 mm/0.35 mm), coronal oblique T2 SPIR (TR3772/TE70, matrix 256/512, FOV 180, 3.5 mm/0.35 mm), sagittal oblique T1 TSE (TR500/TE18, matrix 304/512, FOV 180, 3.5 mm/0.35 mm), sagittal oblique T2 SPIR (TR3772/TE70, matrix 256/512, FOV 180, 3.5 mm/0.35 mm).

## ORIGINAL PUBLICATIONS



This is the unedited, pre-publication version of the manuscript published in The Journal of Bone and Joint Surgery (Br.)

Reproduced with permission and copyright © of the British Editorial Society of Bone and Joint Surgery. [Ketola S, Lehtinen J, Arnala I, et al. Does arthroscopic acromioplasty provide any additional value in the treatment of shoulder impingement syndrome? A two-year randomised controlled trial. J Bone Joint Surg [Br] 2009;91-B:1326-1334.]

## Does arthroscopic acromioplasty provide any additional value in the treatment of shoulder impingement syndrome? A two-year randomised controlled trial.

Ketola S., Lehtinen J., Arnala I., Nissinen M., Westenius H., Sintonen H., Aronen P.,  
Konttinen Y.T., Malmivaara A., Rousi T.

This is a randomised controlled trial to examine the effectiveness and cost-effectiveness of arthroscopic acromioplasty in the treatment of stage II shoulder impingement syndrome.

140 patients were randomly divided into two groups: supervised exercise programme (n = 70, exercise group) and arthroscopic acromioplasty, followed by a similar exercise programme (n = 70, combined treatment group). The main outcome measure was self-reported pain on a 0–10 Visual Analogue Scale at 24 months measured on the 134 patients (66 in the exercise group and 68 in the combined treatment group) on whom end-point data were available.

An intention-to-treat analysis disclosed an improvement in both groups. Differences in outcomes between the groups were not statistically significant. The combined treatment was considerably more costly.

Arthroscopic acromioplasty does not provide any clinically important effects over structured and supervised exercise programme alone in terms of subjective outcome or cost-effectiveness. Structured exercise treatment should be the basis for treatment of shoulder impingement syndrome. Operative treatment should be offered judiciously.

Shoulder pain is even the second most common musculoskeletal disorder<sup>1-4</sup> and it severely affects patients' perception of their general health<sup>5</sup>. Impingement syndrome is the most frequent singular cause of shoulder pain<sup>6,7</sup>. This syndrome was introduced by Neer<sup>8</sup>, who defined its three stages<sup>8</sup>. As its diagnosis is purely clinical, it is somewhat imprecise<sup>9</sup>. Chronicity and recurrence are common features<sup>10</sup>. In addition to rest, its symptomatic treatment consists of subacromial glucocorticosteroid injections<sup>11</sup> and per oral non-steroidal anti-inflammatory drugs<sup>12</sup>. In severe cases physiotherapy<sup>12-16</sup> and eventually arthroscopic decompression and acromioplasty<sup>17-22</sup> are used. The syndrome has significant economic consequences through its treatment costs and productivity losses due to absence from work. One pioneering head-to-head comparison of physiotherapy to arthroscopic acromioplasty has been published<sup>17,18</sup>.

We designed a novel type of study to investigate the eventual additional effectiveness and cost-effectiveness of arthroscopic decompression with acromioplasty followed by a structured exercise treatment compared to a similar exercise therapy alone in the treatment of stage II impingement syndrome<sup>8</sup>. Thus the remaining intervention contrast was surgery vs. no surgery estimated at 24 months time point counted from randomisation.

## PATIENTS AND METHODS

The study design was a prospective, controlled, and randomised trial.

The patients with suspected shoulder impingement syndrome were referred to Kanta-Häme Central Hospital and to Riihimäki Regional Hospital by general practitioners in the area of Kanta-Häme Health Care District (population 165000) starting in June 2001 because of longstanding pain not relieved by conservative treatment. By the end of July 2004 140 patients, 52 men and 88 women (mean age 47.1 years) had been recruited to the study by the specialists in these hospitals.

The study was approved by the Ethics Committee of the Hospital District.

The eligibility of the patients was examined at baseline by a physician in the hospital. The patients were given an information brochure and the risks and benefits of the study arms were discussed. The range of motion in flexion, abduction, and external and internal rotation were measured with goniometer. Muscle strength was tested manually and graded normal or decreased and isometric pain provocations were done. Impingement was tested according to

Neer<sup>8,23,24</sup> after 5 ml 1 % lidocain had been injected into the subacromial space. All patients underwent an X-ray and MRI of the shoulder<sup>25</sup>. The inclusion criteria were a positive Neer's test, shoulder pain resistant to rest, anti-inflammatory drugs, subacromial glucocorticosteroid injections, in addition to various modalities of physiotherapy and symptom duration for at least three months.

All patients enrolled in this study had been treated using one or more modalities of physiotherapy. This treatment was not part of the current study protocol, but was administered in the primary health care and was individually designed to comprise exercise programmes, massage, and physical therapy treatments like heat and transcutaneous nervous stimulation. The patients had used non steroidal anti-inflammatory drugs for a mean of 37 days (SD 32.0) during the previous 3 months before randomisation. During this 3-month period 67 % of the patients had been treated with subacromial cortisone injections, the mean number of injections being 1.6 (SD 1.5).

These previous treatments had failed to provide sufficient alleviation of pain. None of the patients had been treated by specialists/in special centres before recruitment.

The mean duration of symptoms in the study population was 2.5 years (SD 3.0). During this time the patients had been treated with subacromial cortisone injections, various modalities of physiotherapy, rest and NSAIDs. Some patients had obtained more than one treatment period. The time when patients had obtained these treatments was not recorded. None of the patients got any substantial relief of their symptoms, and all were still disabled and painful when entering the current trial. Because the symptoms were resistant to the given treatment the patient were sent to Central hospital after which their eligibility to this study was assessed. Before randomisation the mean disability for the whole study group was 6.4 (SD 2.1), self-reported pain 6.5 (SD 1.9) and pain at night 6.3 (SD 2.6) all in 0-10 Visual Analogue Scale (VAS). They considered their working ability to be 5.8 in VAS 10 being the best (SD 2.6).

Patients aged 18-60 years were accepted, if they indicated their willingness to comply with the randomised treatment protocol and follow-up visits and gave their full verbal and written consents.

The exclusion criteria were glenohumeral or acromioclavicular osteoarthritis, signs of glenohumeral instability, a penetrating rupture of the rotator cuff, cervical radicular syndrome, adhesive capsulitis, or neuropathy of the shoulder region. None

of the patients taken to the study had undergone any previous shoulder surgery. Demographic information was collected and the patients filled a structured Shoulder Disability Questionnaire (SDQ)<sup>26,27</sup>.

After checking through the inclusion and exclusion criteria the eligible patients were randomly assigned to the treatment groups using computer-generated numbers sealed in opaque envelopes prepared by an independent statistician not otherwise involved with the study. The random numbers were allocated using 14 as the block size. None of the eligible patients referred to the two centres refused to participate. There were though two "silent" refusals, one in each group. These two patients neither went through the interventions nor any of the the control visits after randomisation.

### Supervised exercise treatment

Information was first given by a trained physiotherapist. Home programme was individually planned for each patient according to the same principles. The aim was to restore painless and normal mobility of the shoulder complex and to increase the dynamic stability of the glenohumeral joint (supra- and infraspinat, teres minor, and subscapular muscles) and the scapula (trapezoid, rhomboid, serratus anterior, and pectoralis minor muscles)<sup>28</sup>. Stretch bands and light weights were used in training, which was based on long painless series and repetitions aiming at tendon strengthening. The sessions were performed at least 4 times a week using nine different exercises with 30–40 repetitions 3 times. As the self-assessed ability and strength improved, resistance was increased and repetitions diminished. The progress was evaluated during control visits, which averaged 7 in number and continued until the patient and the therapist considered that the trainee was independently able to maintain the practise level.

### Combined treatment

#### *Operative procedure*

One experienced orthopedic surgeon (HW) performed all arthroscopic decompressions in Kanta-Häme Central Hospital. Interscalenic or supraclavicular brachial plexus block was applied for regional anaesthesia. Bony landmarks were palpated and marked. Glenohumeral stability and passive range of motion were tested. The arthroscope (Karl Storz GmbH, Tuttlingen, Germany) was introduced into the joint through a standard posterior portal and a systematic recording of the articular cartilage, labrum and ligaments, biceps tendon, and the intra-articular rotator cuff was performed. The same standard

portal was used to reach the subacromial space. Debridement and decompression were done through an anterolateral portal by shaver and/or vaporisator. If the coracoacromial ligament felt tight or thick, it was released. Acromioplasty was then performed starting anteriorly and progressing posterolaterally with a burr drill. The range of motion was tested under arthroscopic visualization to check for any local impingement.

#### *Post operative phase*

The patients stayed in the hospital overnight. Post-operatively patient-controlled intravenous oxycodone analgesia or a pain catheter to administer local ropivacain 2 mg/ml or bupivacain 2.5 mg/ml 3–5 ml/h to the operation area was used until the first post-operative morning, accompanied and/or followed by oxycodone i.m. and/or p.o. All patients received anti-inflammatory analgetics, usually ibuprofen. Collar cuff was used for a week. Mobilisation was allowed with free active movements, starting with gravity-assisted rotating movements. Sutures and tapes were removed after 7–10 days after which the patients received similar training instructions as were provided for the exercise group. The training programme was likewise individually planned and progressive. It was started progressively once the post operative pain had gradually diminished. Like in the other group, the progress was evaluated during physiotherapy controls, which averaged 6 in number.

#### *Adjunct treatment*

In both groups the use non-steroidal anti-inflammatory drugs was allowed as needed. Subacromial corticosteroid injections were permitted, if pain interfered with the execution of the training programme.

#### *Follow-up*

The main follow-up point was at 24 months after randomisation. Examinations were also performed at 3, 6 and 12 months relative to the time of intervention. One trained physiotherapist from outside the surgical department and therefore neutral to both the institution and patients, and who had not been involved with the patients prior to evaluations and who was blinded to the mode of treatment, performed all standardised assessments. Patients were instructed not to indicate the type of treatment (exercise or combined) they had received and they wore a T-shirt to cover eventual operation scars. Muscle strength and passive range of motion were assessed and recorded. The Neer's

impingement test was performed, but now without lidocain injections. The patients filled in a structured questionnaire (including the SDQ<sup>26,27</sup>) at each visit<sup>29</sup>. In addition to their health state the questions also concerned the health care resource use related to the impingement syndrome since the previous follow-up.

### Outcome measures and resource use

Self-reported pain on a 0–10 VAS at 24 months after randomisation was used as the primary health outcome measure. The minimal clinically important difference (MCID) was defined as 2 points on VAS equalling 1 MCID unit<sup>30</sup>. Additional outcome measures were disability, pain at night, and working ability (VAS), SDQ score, the number of painful days during previous 3 months, and the proportion of pain-free patients (pain on VAS  $\leq 3$ ) at 24 months from randomisation. The same variables were used at 3, 6 and 12 month visits. Table 1 gives an overview of the resource use, unit costs, and mean costs by resource items. The costs cover the direct health care and non-health care costs (travel, masseur, naprapath) at 2004 price level.

### Statistical analyses

Analyses were performed based on the intention-to-treat principle. Power calculations were performed using self-reported pain (VAS) at 24 months as the outcome measure. Using 1.5 (SD 2.5) as a clinically important change, the sample size was estimated to be 45 patients per group, if 5% type I (alpha) and 20% type II (beta) errors were allowed. As the standard deviation of the outcome measure was only a rough estimate, 70 patients were included in both groups.

Statistical analyses were performed using SPSS 14.0 software (SPSS Inc, Chicago, Illinois). Independent samples t-test was used for group comparisons (with Levene's test to check, whether t-test for equal or non-equal variances is applicable), paired samples t-test for comparisons within groups over time and Chi-squared test for equal proportions of pain free patients between groups. In order to adjust for spuriously significant results that might arise from multiple testing, the significance level was set at 0.01 and 99% confidence intervals reported. For bootstrapping and imputation R 2.4.1 software was used<sup>31</sup>.

Complete data were available from 92 patients, who attended all follow-up visits and filled in all questionnaires. Since end-point outcome data were available from 134 patients we decided to use imputation for 28 patients with only one missing

follow-up either at 3, 6 or 12 months. Only the cost for the missing follow-up was imputed. Cost data were imputed using a two-stage iterative regression approach<sup>32</sup>. With imputation the sample size was increased from 92 with complete information to 120 patients (55 patients in combined treatment and 65 in exercise group).

To assess uncertainty, one-way (cost variables changed  $\nabla 50\%$ ) and probabilistic sensitivity analyses with 10,000 bootstrapped resamples were carried out. The latter were performed for both observed and imputed total cost data. Results are given as mean incremental costs and effects with their 99 % confidence intervals (CI), incremental cost-effectiveness ratios (ICER), cost-effectiveness plane and cost-effectiveness acceptability curve (CEAC). Due to the short time horizon no discounting was carried out.

## RESULTS

### Patient and treatment process

The groups were similar at baseline (table 2). During the follow-up 14 patients from the exercise group were operated, one patient after 3–6 months, four after 6–12 months, and nine first after 12–24 months. Twelve patients, who were allocated to the combined treatment group, refused later the operation, but attended the follow-up visits (Flowchart).

There were no major surgical complications. Labral lesions were not diagnosed in 14 patients in the preoperative MRI, though found and repaired in arthroscopy. In five cases the labral lesion per se was considered the main cause of the symptoms. In nine cases this occurred together with impingement, and labral repair was combined with acromioplasty. Over the two-year follow-up, there were on average 0.3 and 1.0 recorded corticosteroid injections in the combined and exercise group, respectively.

### Effectiveness

The follow-up at 24 months was attended by 68/70 patients in the combined and 66/70 in the exercise group. Decrease in self-reported pain exceeding the MCID took place from baseline to 24 months in both groups: from a mean of 6.4 to 2.5 in the combined treatment and from a mean of 6.5 to 2.9 in the exercise group. The changes were statistically significant in both groups. Differences between the mean changes in the groups over time were not statistically significant. The proportion of pain-free patients at 24 months was

64% in the exercise group and only slightly higher in the combined treatment group, 65%, the difference was not statistically significant (table 3). The primary outcome measure and some of the additional outcome measures suggest that the recovery would have been faster in the combined treatment group (table 4).

### Cost-effectiveness

Table 5 shows the base case cost-effectiveness results. The ICER of combined treatment versus exercise treatment is € 5431 per incremental MCID unit for 92 patients with complete data, and €5734 for 120 patients with partially imputed cost data. Because there was no statistically significant difference between the cost-effectiveness results based on complete and imputed data, i.e. mean incremental costs and effects from imputed data were within the 99% confidence intervals of complete case data, only results based on the former are presented.

In one-way sensitivity analyses the ICER varied from € 2740 to € 8965 per MCID unit. The extreme values were obtained, when the unit cost of acromioplasty was varied  $\pm 50\%$ ; the ICER was not sensitive to variation in other cost variables. The probabilistic sensitivity analysis showed that the incremental cost was positive in all simulated cases, while the incremental effectiveness varied from negative to positive values, i.e., from less effective to more effective. The bootstrapped mean incremental cost was € 1092 (99 % CI 590–1590) and the bootstrapped mean incremental effect 0.20 MCID units (99 % CI -0.35–0.73). The cost-effectiveness plane shows that in most cases (75%) the combined treatment was more effective, but also more costly (quadrant II in figure 1A). With the willingness to pay (WTP) of € 8000 for an additional MCID unit the probability that combined treatment would be acceptable was 56% (figure 1B).

### DISCUSSION

Our study indicates that at 24 months arthroscopic decompression with acromioplasty followed by a structured exercise treatment (combined treatment) did not differ significantly from supervised exercise programme (exercise group) in mean self-reported pain on VAS, or in secondary outcome measures of disability, pain at night, SDQ score, number of painful days, and proportion of pain-free patients. The mean total cost based complete data was € 2961 in the combined treatment group and € 1864 in the exercise group, i.e., combined treatment was considerably

more costly on average. The incremental cost-effectiveness ratio was € 5431 per MCID unit. At any level of WTP the probability of combined treatment being cost-effective was 75 %. The results from 3, 6 and 12 months visits from onset of the treatment reflect the recovery of individual patients counted from the interventions (differing from the 24 month visits that were counted from the randomisation in all), since the natural history of the disease is unknown. However, it seems that the operative group initially recovers faster in all parameters when assessed from the start of the treatment, combined or conservative (table 4).

The first trial comparing operative treatment with physiotherapy was published in 1993 (and 1999)<sup>17,18</sup>. Haahr and co-workers extended this work by publishing a comparative study focusing on disability and working capacity<sup>19,22</sup>. The present study, conducted and clinically finalised between June 2001 and October 2006, is the first one to examine, whether operative treatment provides any additional value over a structured and supervised exercise programme, without any surgical intervention. This not only compares the two treatments moreover evaluates surgery vs. no surgery. In contrast to the previous studies, failure of regular physiotherapy and other conservative treatments were criteria for inclusion. 67 % of the patients had been treated with subacromial cortisone injections during the 3 months long pre-randomisation period (mean 1.6, median 2 injections) and the mean duration of their symptoms before enrolment into the current study was 2.5 years. Therefore, practically all patients had at least once been treated with cortisone injection during the course of the disease.

According to current standards in clinical practise this failed non-operative management would make these patients most likely candidates for surgical intervention.

As our patients were evaluated by a blinded, independent assessor at the control visits, the results are not biased by the tendency of the operated patients to please the surgeon. The unusual willingness to participate may be due to the thorough information given already in the basic healthcare, where most of the patients were recruited. The selection bias was minor as all patients fulfilling the inclusion criteria were willing to participate, although two lost their interest right after the randomisation. In addition dropout bias was small since the dropout was only 4%.

All operations were performed by one experienced senior arthroscopist which is one of the strengths of this study. The similarity of the groups at baseline



was achieved by successful randomisation. Although a minority of patients from the exercise group wanted to be operated or refused operation (but not follow-up) in the combined treatment group, this may not compromise the results. This reflects the real-life situation.

The accurate diagnosis of the impingement syndrome requires a thorough patient history and a careful clinical examination to exclude other conditions, which may mimic impingement symptoms. To avoid such pitfalls, all patients in the present study were examined with Neer's impingement test<sup>8</sup> and MRI, without contrast, which might explain the non-diagnosed labral lesions. These patients were included in the intention-to-treat analysis, as a similar proportion of lesions can be assumed to exist in the exercise treatment group.

The age limits for inclusion were set at 18-60 years in conformity with the previous studies. In the younger age groups glenohumeral instability is the leading cause of shoulder problems<sup>33</sup>, but the frequency of rotator cuff tears increases with age<sup>34,35</sup>. In this study, only four patients were younger than 30 years.

The waiting time to the operation was longer than to the primary visit in the exercise treatment, 8.3 months and 1.2 months, respectively. This may have affected in favour of the exercise group. Still, the waiting time was short compared to the duration of the complaints before randomisation (mean 2.5 years, median 1.5 years), which argues against this possibility.

Cost-effectiveness analysis suggests that the combined treatment is not cost-effective compared to exercise treatment. As health care resources are limited, the effectiveness of acromioplasty needs to be higher than that observed in this study. Further research is essential to find the patients gaining the most and recovering fast from the operative treatment, i.e. to utilize the strength of the arthroscopic operation. The effect difference between the treatment arms was small at 24 months in all outcome measures, which simplifies the decision making close to a cost-minimisation problem. Longer follow-up periods are needed to learn more of the natural course of the disease in addition to long-term effects of the treatments.

## CONCLUSIONS

Acromioplasty seems not be an effective additional treatment over supervised exercise for shoulder impingement syndrome when evaluated at 2 years and

the costs are much higher when compared to exercise therapy alone. It is most improbable that acromioplasty would be cost-effective. The interpretation of the long-term effects is not straightforward as the natural history of the condition is unknown. The decision whether to operate should be based on clear indications favouring operative treatment, which are yet to be determined.

## CONTRIBUTORS

All authors participated in the conception and conduct of the study and contributed to the final manuscript.

## CONFLICT OF INTEREST STATEMENT

We declare that we have no conflict of interest.

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Table 1. The items of resource use, their unit costs, amount of resource use and associated mean costs in euros at 2004 price level (standard deviations in parentheses).

Variable description	Unit cost (€)	Total use, based on complete data i.e. patients attending all follow-up visits		Mean costs (€), based on complete data i.e. patients attending all follow-up visits	
		Combined treatment group n=39	Exercise group n=53	Combined treatment group n=39	Exercise group n=53
Operation: arthroscopy and acromioplasty	1675 <sup>1</sup>	36	12	1546 (593)	379 (708)
Visits at physiotherapist	60.4 <sup>2</sup>	466	744	723 (592)	847 (464)
Operation: arthroscopy and labral procedure	2811 <sup>3</sup>	3	1	216 (759)	53 (386)
Visits at physician	82.5 <sup>2</sup>	47	94	99 (126)	146 (245)
Travel costs to services	6 <sup>4</sup>	616	1054	95 (71)	120 (77)
Hospitalisation	513 <sup>2</sup>	7	10	92 (330)	97 (303)
Visits at masseur	36 <sup>5</sup>	94	166	85 (235)	113 ( 221)
Operation: arthroscopy and open acromioplasty	1916 <sup>1</sup>	1	0	49 (307)	0 (0)
Travel costs to hospital	30.9 <sup>4</sup>	47	26	37 (24)	15 (28)
Medication	.. <sup>6</sup>	455 <sup>7</sup>	1366 <sup>7</sup>	12 (25)	26 (43)
Visits at nurse	24.5 <sup>2</sup>	8	38	5 (15)	18 (43)
Visits at naprapath	41 <sup>5</sup>	1	13	1 (7)	10 (40)
Mobilisation in anaesthesia	707 <sup>3</sup>	0	3	0 (0)	40 (165)
Mean health care costs				2961	1864
Total health care costs				115474	98773

1 Benchmarking data on file, National Research and Development Centre for Welfare and Health, Finland

2 Hujanen T. Terveysthuollon yksikkökustannukset Suomessa vuonna 2001, National Research and Development Centre for Welfare and Health, Finland, Aiheita 1/2003

3 Expert opinion

4 Statistics Finland

5 Finnish Consumer Agency, <http://www.kuluttajavirasto.fi/>

6 41 different drugs or other therapies, prices taken from Pharmaca Fennica; a pharmaceutical manual used in Finland

7 Total use in euros by group

Table 2. The treatment groups compared at baseline

	Exercise group (n = 70)	Combined treatment group (n = 70)
Women – n (%)	47 (67)	41 (59)
Age – years		
Mean	47.8	46.4
Median	49.0	46.9
Range	26.8–59.2	23.3–60.0
Body Mass Index (kg/cm <sup>2</sup> )		
Mean	27.4	27.0
Median	27.1	26.5
Range	19.5–46.3	15.2–41.2
Dominant hand affected (%)	66	64
Marital status (%)		
single	8	7
married	72	62
cohabitation	10	12
widow	1	3
divorced	9	16
Working status (%)		
currently working	84	76
entrepreneur	7	9
student	0	1
unemployed	9	12
at home	0	1
retired	0	1
Duration of symptoms – years		
Mean	2.6	2.5
Median	1.2	1.8
Range	0.25–20.0	0.25–17.0
Self-reported pain – VAS 0–10		
Mean	6.5	6.4
Median	7.0	7.0
Range	1.0–10.0	2.0–10.0
Pain at night – VAS 0–10		
Mean	6.4	6.2
Median	7.0	7.0
Range	0–10.0	0–10.0
Disability – VAS 0–10		
Mean	6.5	6.3
Median	7.0	7.0
Range	0–10.0	1.0–10.0
Working ability – VAS 0–10		
Mean	5.9	5.7
Median	6.0	6.0
Range	0–9.0	0–9.0
SDQ score (0–100)		
Mean	82.5	78.0
Median	85.7	84.6
Range	0–100	0–100

Table 3. Results in the intention-to-treat analysis (134 patients at baseline and at 24 months after randomisation)

Variables	Exercise group (n = 66 at 24 months)	Combined treatment group (n = 68 at 24 months)	99% CI of the difference in means*
Self-reported pain – VAS 0–10			
at baseline (mean)	6.5	6.4	-1.01 to 0.77
at 24 months (mean)	2.9	2.5	-1.60 to 0.78
Change from baseline (mean)	-3.7	-3.9	-1.61 to 1.14
Disability – VAS 0–10			
at baseline (mean)	6.4	6.2	-1.13 to 0.75
at 24 months (mean)	2.6	2.0	-1.81 to 0.62
Change from baseline (mean)	-3.8	-4.2	-1.76 to 1.00
Working ability – VAS 0–10			
at baseline (mean)	6.0	5.7	-1.42 to 0.85
at 24 months (mean)	8.0	8.0	-0.82 to 0.85
Change from baseline (mean)	+2.0	+2.3	-0.93 to 1.52
Pain at night – VAS 0–10			
at baseline (mean)	6.5	6.2	-1.46 to 0.93
at 24 months (mean)	2.6	2.0	-1.95 to 0.65
Change from baseline (mean)	-3.8	-4.2	-2.00 to 1.17
SDQ score (0–100)			
at baseline (mean)	82.6	77.7	-14.14 to 4.47
at 24 months (mean)	32.9	24.2	-23.34 to 6.10
Change from baseline (mean)	-50.0	-53.1	-19.11 to 12.75
Reported painful days			
at baseline (mean)	73.0	69.8	-16.14 to 9.64
at 24 months (mean)	19.7	13.9	-18.16 to 6.52
Change from baseline (mean)	-53.3	-55.0	-19.68 to 16.22
Proportion of pain-free patients			
at baseline	0.05	0.12	-0.197 to 0.055
at 24 months	0.64	0.65	-0.224 to 0.203

\*) Levene's test was used to check, whether t-test for equal or non-equal variances is applicable.

Table 4. Descriptive data from the 3, 6 and 12 months control points counted from intervention (intention-to-treat)

Variables	Exercise group	Combined treatment group	99% CI of the difference in means*
Self-reported pain – VAS 0–10			
at 3 months (mean)	4.4	3.2	-2.45 to -0.02
at 6 months (mean)	3.7	2.5	-2.40 to -0.01
at 12 months (mean)	3.7	2.3	-2.63 to -0.13
Disability – VAS 0–10			
at 3 months (mean)	4.2	3.1	-2.48 to 0.32
at 6 months (mean)	3.0	2.2	-2.10 to 0.59
at 12 months (mean)	3.2	1.8	-2.76 to -0.12
Working ability – VAS 0–10			
at 3 months (mean)	7.0	7.0	-1.21 to 1.12
at 6 months (mean)	7.6	7.8	-0.72 to 1.15
at 12 months (mean)	7.4	8.0	-0.41 to 1.46
Pain at night – VAS 0–10			
at 3 months (mean)	3.8	2.7	-2.53 to 0.44
at 6 months (mean)	3.2	2.2	-2.54 to 0.42
at 12 months (mean)	3.2	1.7	-2.83 to -0.07
SDQ score (0–100)			
at 3 months (mean)	55.6	37.4	-34.01 to -2.45
at 6 months (mean)	43.7	26.6	-32.53 to -1.67
at 12 months (mean)	41.7	24.8	-32.53 to -1.19
Reported painful days*			
at 3 months (mean)	49.1	33.0	-33.06 to 0.90
at 6 months (mean)	31.1	18.8	-28.28 to 3.73
at 12 months (mean)	25.4	13.5	-26.35 to 2.63
Proportion of pain-free patients			
at 3 months	0.35	0.65	-0.569 to -0.032
at 6 months	0.57	0.73	-0.399 to 0.087
at 12 months	0.55	0.71	-0.389 to 0.074
	Exercise group	Combined treatment group	
at 3 months	n=57	n=43	
at 6 months	n=56	n=44	
at 12 months	n=62	n=51	

\* Levene's test was used to check, whether t-test for equal or non-equal variances is applicable.

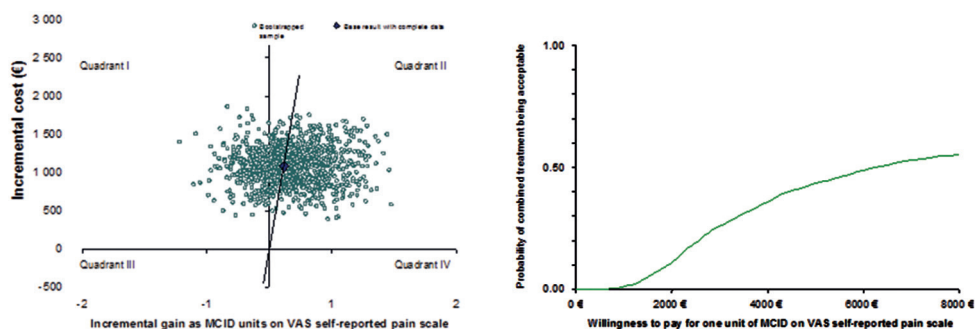
Table 5. The base case cost-effectiveness results.

Treatment group	Mean cost (€) <sup>1</sup>	Mean incremental cost (ΔC)	Mean self-reported pain on VAS (in MCID-unit) <sup>2</sup>	Mean incremental effectiveness (-ΔE)	ICER (ΔC/-ΔE)
Based on patients with complete data (n=92)					
Exercise (n = 53)	1864		1.439		
Combined (n = 39)	2961	1097	1.238	0.201	5431
Based on partially imputed cost data (n=120)					
Exercise (n = 65)	1838		1.431		
Combined (n = 55)	3111	1273	1.209	0.222	5734

<sup>1</sup> see Table 1 for complete data results

<sup>2</sup> see Table 3

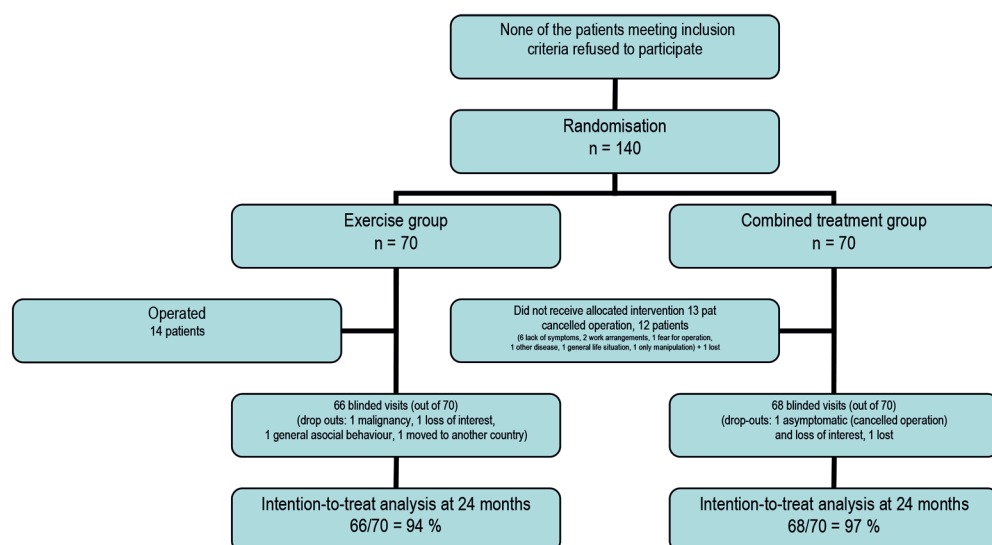
Fig 1. Cost-effectiveness plane and cost-effectiveness acceptability curve



A) Cost-effectiveness plane. The diamond represents the base case result, where  $\Delta E$  is plotted on the x axis and  $\Delta C$  is plotted on y axis (see table 5). The ICER is the slope joining the origin and point  $(\Delta E, \Delta C)$ . Since each of the bootstrapped resamples was drawn from the original data with replacement, they have different ICERs at the cost-effectiveness plane. If a point falls at quadrant I then combined treatment is more costly and less effective than exercise, at quadrant II it is more costly and more effective, at quadrant III less costly and less effective, and at quadrant IV less costly and more effective. In 75 % of simulated cases the ICER falls at quadrant II, and in 25 % of cases at quadrant I.

B) Cost-effectiveness acceptability curve. If the willingness to pay (WTP) for an additional MCID unit is the same as the base case result (ICER = 5431€), then approximately 50 % of the bootstrapped resamples fall on the right side of the line ("threshold line") at the plane. With different values of WTP we can calculate the proportion of resamples, which fall on the right side of the corresponding threshold line and thus are said to be cost-effective (acceptable). This proportion is then interpreted as a probability of combined treatment being acceptable.

## CONSORT FLOWCHART





## ■ UPPER LIMB

# No evidence of long-term benefits of arthroscopic acromioplasty in the treatment of shoulder impingement syndrome

## FIVE-YEAR RESULTS OF A RANDOMISED CONTROLLED TRIAL

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### Objectives

To report the five-year results of a randomised controlled trial examining the effectiveness of arthroscopic acromioplasty in the treatment of stage II shoulder impingement syndrome.

### Methods

A total of 140 patients were randomly divided into two groups: 1) supervised exercise programme (n = 70, exercise group); and 2) arthroscopic acromioplasty followed by a similar exercise programme (n = 70, combined treatment group).

### Results

The main outcome measure was self-reported pain as measured on a visual analogue scale. At the five-year assessment a total of 109 patients were examined (52 in the exercise group and 57 in the combined treatment group). There was a significant decrease in mean self-reported pain on the VAS between baseline and the five-year follow-up in both the exercise group (from 6.5 (1 to 10) to 2.2 (0 to 8);  $p < 0.001$ ) and the combined treatment group (from 6.4 (2 to 10) to 1.9 (0 to 8);  $p < 0.001$ ). The same trend was seen in the secondary outcome measures (disability, working ability, pain at night, Shoulder Disability Questionnaire and reported painful days). An intention-to-treat analysis showed statistically significant improvements in both groups at five years compared with baseline. Further, improvement continued between the two- and five-year timepoints. No statistically significant differences were found in the patient-centred primary and secondary parameters between the two treatment groups.

### Conclusions

Differences in the patient-centred primary and secondary parameters between the two treatment groups were not statistically significant, suggesting that acromioplasty is not cost-effective. Structured exercise treatment seems to be the treatment of choice for shoulder impingement syndrome.

**Keywords:** Shoulder impingement, Syndrome, Operation, Physiotherapy, Arthroscopic, Acromioplasty

### Article focus

- The effectiveness of acromioplasty in shoulder impingement syndrome

### Key messages

- Structured exercise treatment is the treatment of choice for shoulder impingement syndrome

### Strengths and limitations of this study

- A randomised controlled trial
- Results may in part reflect the natural course of shoulder impingement syndrome

### Introduction

Shoulder pain is a common complaint, sometimes described as the second most common musculoskeletal disorder after low back pain.<sup>1–4</sup> Impingement is often cited as the leading cause of pain in the shoulder,<sup>5</sup> which was initially thought to arise from the mechanical friction of the tendon under the acromion.<sup>6</sup> However, further studies and treatment trials have not been able to demonstrate a pure mechanical aetiology for this syndrome,<sup>7,8</sup> and therefore current treatment options remain controversial.<sup>9–16</sup>



Impingement of the shoulder has a severe and long-lasting effect on the patient, with costs of treatment and absence from work causing economic consequences.

The syndrome is traditionally divided into three stages: Stage I, oedema and haemorrhage; Stage II, fibrosis and tendinitis; and Stage III, tears of the rotator cuff, biceps ruptures and bone changes.<sup>17</sup> The condition usually begins gradually and then over time becomes continuous.<sup>18</sup> Its diagnosis is based on clinical examination, which makes its nature somewhat imprecise. The first mode of treatment is non-operative, involving rest, subacromial corticosteroid injections,<sup>19</sup> oral non-steroidal anti-inflammatory drugs<sup>20</sup> and physiotherapy.<sup>9,20-23</sup> Although surgical treatment has not been conclusively shown to be superior to conservative treatment,<sup>13-16,24</sup> arthroscopic acromioplasty is still a popular procedure with a rising incidence over the last decade.<sup>25,26</sup>

Clear indications for different modes of treatment based on randomised clinical trials have not yet been defined. It seems that the expectations of both the surgeons and the patients and the availability of the arthroscopic technology affect the demand.

We designed a randomised clinical trial to investigate the eventual additional effect of arthroscopic decompression with acromioplasty on a supervised exercise program.<sup>24</sup> We now report the five-year results.

## Patients and Methods

The study design was a prospective, controlled and randomised trial. Patients were recruited from the area of Kanta-Häme Health Care District (population 165 000) between June 2001 and July 2004. The full exclusion and inclusion criteria are provided in Table I. The eligibility of the patients was examined at baseline by a physician (a specialist in rehabilitation or orthopaedics). Impingement was tested with Neer's method<sup>17</sup> by assessing whether lidocain injected into the subacromial space relieved the pain. All patients had a plain radiograph and MRI of the symptomatic shoulder.<sup>27</sup> The risks and benefits of both treatments were discussed and the patients were also given written information. Included patients were asked to sign a written consent in which they voluntarily agreed to comply with the randomised treatment protocol and follow-up visits, with the right to withdraw at any time without giving reason for it.

A total of 140 patients (52 men and 88 women) with a mean age of 47.1 years (23 to 60) were recruited to the study, which was approved by the Ethics Committee of the Hospital District. Patients were randomly assigned to the treatment groups using computer-generated numbers sealed in envelopes prepared by an independent statistician not otherwise involved with the study.

Demographic data and disability-values and a structured Shoulder Disability Questionnaire (SDQ)<sup>28,29</sup> were collected at baseline. The SDQ contains common situations referring to the preceding 24 hours (yes/no/not

**Table I.** Inclusion and exclusion criteria (NSAIDs, non-steroidal anti-inflammatory drugs)

Criteria
<b>Inclusion criteria</b>
Clinical symptoms of shoulder impingement syndrome
A positive Neer's test
Symptom duration of at least three months
Attempts to treat with: rest, NSAIDs, subacromial corticosteroid injections and regular physiotherapy
Age between 18 and 60 years
No previous operations on shoulder region
Willingness and capacity to comply with the treatment protocol and follow-up visits
<b>Exclusion criteria</b>
Osteoarthritis
Signs of glenohumeral instability
A penetrating rupture of the rotator cuff
Cervical radicular syndrome
Adhesive capsulitis
Neuropathy of the shoulder region

applicable (i.e. not occurred)). The score is calculated by dividing the number of positive scores to the total number of applicable items subsequently multiplied by 100 (0 no disability, 100 all applicable items positive). All patients had received various types of physiotherapy including massage, heat, transcutaneous nerve stimulation and exercises, but had not been treated by a specialised physician before entering the study.

The control visit assessment, including SDQ-score and the clinical measurements, were performed by an independent, blinded investigator (physiotherapist), not otherwise involved in the study or rehabilitation, at three and six months and at one, two and five years. The health-related quality of life was measured at the five-year visit using the 15D quality of life tool.<sup>30</sup>

**Supervised exercise.** Physiotherapeutic training was based on home exercises, for which the patients received individual guidance and general information during an average of seven visits to an independent physiotherapist.

The aim of the supervised exercise treatment was to restore painless, normal mobility of the shoulder complex and to increase the dynamic stability of the glenohumeral joint and the scapula.<sup>31</sup> Series of long painless movement with repetition were undertaken with the aim of strengthening the tendons. Patients were instructed to do nine different exercises at least four times a week, with three courses of 30 to 40 repetitions. As the self-assessed ability and strength improved, resistance was increased and repetitions diminished. The progress was evaluated at control visits (mean of seven) and continued until the patient and the therapist considered that the trainee was independently able to maintain the practise level.

**Combined treatment: surgery.** One independent experienced orthopaedic surgeon performed all the

arthroscopic decompressions under regional anaesthesia at Kanta-Häme Central Hospital, Hämeenlinna, Finland. Debridement and decompression were performed with a shaver and/or a vaporisator. Acromioplasty was undertaken with a burr drill (Arthroscope Karl Storz GmbH, Tuttlingen, Germany). A standard posterior portal was used to analyse the structures of the glenohumeral joint and to reach the subacromial space. An anterolateral portal was used to perform debridement and decompression. The range of movement was tested under arthroscopic visualisation to check for any local impingement.

The use of a collar cuff sling was recommended for one week, after which mobilisation was allowed with free active movements, starting with pendular motion. In the rehabilitation period patients in the combined treatment group received similar training instructions from a physiotherapist as were provided for the exercise group with the same kind of follow-up schedule. The training programme was individually planned and progressive. It started progressing once the post-operative pain had started to diminish. Like in the supervised exercise treatment group, the progress was evaluated at the visits to the physiotherapist (mean of six visits).

**Follow-up.** At five years one trained independent physiotherapist, who had not been involved with the patients before evaluation and who was blinded to the mode of treatment, performed all standardised assessments. Patients were instructed not to indicate their treatment group and they wore a T-shirt to cover eventual operation scars.

**Outcome measures.** Self-reported shoulder pain, as the primary outcome measure, was assessed on a visual analogue scale (VAS) ranging from 0 (no pain) to 10 (extreme pain). Secondary outcome measures included disability (measured on a VAS from 0 (no disability) to 10 (total disability)), working ability (VAS from 0 (totally unable to work) to 10 (no restriction on work)), pain at night (VAS from 0 (no pain) to 10 (extreme pain)), SDQ score, number of painful days during the previous three months and the proportion of pain-free patients (defined as a VAS for pain  $\leq 3$ ). The health related quality of life was measured at the five-year visit using the 15-D tool and compared with the age-adjusted population values.<sup>30</sup>

**Statistical analysis.** Power calculations were performed based on the use of self-reported pain (VAS) as the primary outcome measure. Using 1.5 (SD 2.5) as a clinically important change,<sup>32</sup> the sample size was estimated to 45 patients per group, if 5% type I ( $\alpha$ ) and 20% type II ( $\beta$ ) errors were allowed. As the standard deviation of the outcome measure was only a rough estimate, a total of 70 patients were included in both groups.

Statistical analyses were performed using IBM SPSS Statistics for Windows v19.0 (IBM Corp., Armonk, New York). Descriptive statistics are presented as percentages, frequencies, and means. The independent samples *t*-test was used for group comparisons, paired

samples *t*-test for comparisons within groups over time and the chi-squared test for equal proportions of pain-free patients between groups. A *p*-value  $< 0.05$  was considered to represent statistical significance.

## Results

The study groups did not differ at baseline in any pre-operative measure (Table II). During the follow-up between two and five years, a total of four patients in the exercise group had undergone acromioplasty and one patient had undergone operation of a rotator cuff rupture. The mean time after randomisation until these five operations were performed was 2.9 years (2.6 to 3.3). Additionally, a total of 12 patients originally allocated to the combined treatment group refused operation; one of whom went on to undergo surgery at a follow-up of 2.6 years. The total number of operated patients in the exercise group was 18. All these patients were invited to and attended the five-year control visit. The follow-up results were analysed using an intention-to-treat approach, but the outcome is also described based on the actual treatment using a per protocol approach.

The five-year follow-up was attended by 109 (77.9%) of the original 140 patients recruited; 52 patients (74.3%) in the exercise group and 57 (81.4%) in the combined group. A statistically significant decrease in the mean self-reported pain was observed from baseline to the five-year follow-up in both groups: from 6.5 (1 to 10) to 2.2 (0 to 8) in the exercise group and from 6.4 (2 to 10) to 1.9 (0 to 8) in the combined treatment group (both  $p < 0.001$ , *t*-test). There was no difference in self-reported pain between the groups at the five-year follow-up ( $p = 0.44$ , independent-samples *t*-test).

At five years, there was no statistically significant difference between the two groups in terms of self-reported disability ( $p = 0.57$ ), working ability ( $p = 0.41$ ), night pain ( $p = 0.95$ ) or SDQ ( $p = 0.33$ , independent-samples *t*-tests) (Table II). The proportion of pain-free patients at two years was similar in the two groups, with 64% (42 of 66) of the exercise group and 65% (44 of 68) of the combined treatment group pain-free ( $p = 0.89$ , chi-squared test). These proportions increased to 77% (40 of 52) of the exercise group and 73% (43 of 57) of the combined treatment group at five years ( $p = 0.86$ , chi-squared test) (Table II). Of the 109 patients who attended the five-year follow-up, 39 (36%) reported that they had had similar symptoms or complaints in the contralateral shoulder: 18 (35%) in the exercise group (35%) and 21 (37%) in the combined treatment group.

The 15D quality of life index was analysed in an intention-to-treat setting. Figure 1 displays the mean scores for each parameter for the two groups and also the age-adjusted general population.<sup>30</sup> The groups had similar 15D values for total score ( $p = 0.82$ ) and also by each domain (mobility,  $p = 0.13$ ; vision,  $p = 0.91$ ; hearing,  $p = 0.95$ ; breathing,  $p = 0.67$ ; sleeping,  $p = 0.81$ ; eating,

**Table II.** Results in the intention-to treat analysis (CI, confidence interval)

Mean outcome (range)*	Exercise	Combined treatment	Mean difference (99% CI)	p-value†
Number of patients				
At baseline (n = 140)	70	70		
At two years (n = 134)	66	68		
At five years (n = 109)	52	57		
<b>Self-reported pain VAS</b>				
Baseline	6.5 (1 to 10)	6.4 (2 to 10)	-0.1 (-1.01 to 0.77)	0.73
Two years	2.9 (0 to 9)	2.5 (0 to 10)	-0.4 (-1.60 to 0.78)	0.37
Five years	2.2 (0 to 8)	1.9 (0 to 8)	-0.3 (-1.54 to 0.84)	0.44
Mean change from baseline				
At two years	-3.7	-3.9	-0.2 (-1.61 to 1.14)	0.65
At five years	-4.1	-4.7	-0.6 (-2.13 to 1.01)	0.35
p-value (baseline vs five-year)	< 0.001‡	< 0.001‡		
<b>Disability VAS</b>				
Baseline	6.5 (2 to 10)	6.2 (1 to 10)	-0.3 (-1.13 to 0.75)	0.23
Two years	2.6 (0 to 9)	2.0 (0 to 10)	-0.6 (-1.81 to 0.62)	0.21
Five years	1.8 (0 to 9)	1.5 (0 to 8)	-0.3 (-1.45 to 0.93)	0.57
Mean change from baseline				
At two years	-3.8	-4.2	-0.4 (-1.76 to 1.00)	0.47
At five years	-4.4	-4.8	-0.4 (-2.07 to 1.16)	0.46
<b>Working ability VAS</b>				
Baseline	5.9 (0 to 9)	5.7 (0 to 9)	-0.2 (-1.42 to 0.85)	0.78
Two years	8.0 (1 to 10)	8.0 (0 to 10)	0.0 (-0.82 to 0.85)	0.96
Five years	7.5 (2 to 10)	7.8 (1 to 10)	+0.3 (-0.66 to 1.27)	0.41
Mean change from baseline				
At two years	+2.0	+2.3	+0.3 (-0.93 to 1.52)	0.47
At five years	+1.6	+2.2	+0.6 (-0.81 to 2.18)	0.23
<b>Night pain VAS</b>				
Baseline	6.4 (0 to 10)	6.2 (0 to 10)	-0.2 (-1.46 to 0.93)	0.60
Two years	2.6 (0 to 9)	2.0 (0 to 8)	-0.6 (-1.95 to 0.65)	0.19
Five years	1.7 (0 to 8)	1.7 (0 to 9)	0.0 (-1.19 to 1.25)	0.95
Mean change from baseline				
At two years	-3.8	-4.2	-0.4 (-2.00 to 1.17)	0.51
At five years	-4.8	-4.8	0.0 (-1.75 to 1.73)	0.99
<b>SDQ score</b>				
Baseline	82.5 (0 to 100)	78.1 (0 to 100)	-4.4 (-14.4 to 4.47)	0.21
Two years	32.8 (0 to 100)	24.2 (0 to 100)	-8.6 (-23.34 to 6.10)	0.13
Five years	22.2 (0 to 100)	16.9 (0 to 100)	-5.3 (-19.54 to 8.90)	0.33
Mean change from baseline				
At two years	-50.0	-53.2	-3.2 (-19.11 to 12.75)	0.6
At five years	-61.7	-60.4	+1.3 (-15.74 to 18.34)	0.84
<b>Reported painful days in preceding three months (n)</b>				
Baseline	73.8 (5 to 90)	70.1 (0 to 90)	-3.7 (-16.28 to 8.86)	0.44
Two years	19.7 (0 to 90)	13.9 (0 to 90)	-5.8 (-18.16 to 6.52)	0.22
Five years	11.8 (0 to 90)	12.2 (0 to 90)	+0.4 (-12.52 to 13.32)	0.94
Mean change from baseline				
At two years	-53.3	-55.0	-1.7 (-19.68 to 16.22)	0.80
At five years	-59.4	-60.8	-1.4 (-20.57 to 17.83)	0.85
<b>Patients pain-free (%)</b>				
Baseline	4% (3 of 70)	11% (8 of 70)	+7% (-0.197 to 0.055)	0.21§
Two years	64% (42 of 66)	65% (44 of 68)	+1% (-0.224 to 0.203)	0.89§
Five years	77% (40 of 52)	75% (43 of 57)	-2% (-0.219 to 0.195)	0.86§

\* VAS, visual analogue scale: pain/night pain (0 = no pain, 10 = extreme pain), disability (0 = no disability, 10 = total disability), working ability (0 = totally unable to work, 10 = no restriction on work); SDQ, Shoulder Disability Questionnaire (from 0 to 100, with 0 denoting no functional impairment)

† independent samples *t*-test, unless otherwise stated

‡ paired samples *t*-test, unless otherwise stated

§ chi-squared test

p = 0.30; speech, p = 0.95; elimination, p = 0.01; usual activities, p = 0.49; mental function, p = 0.45; discomfort and symptoms, p = 0.81; depression, p = 0.99; distress,

p = 0.57; vitality, p = 0.45; and sexual activity, p = 0.61; all independent samples Mann–Whitney U test). In comparison with the age-adjusted general population the

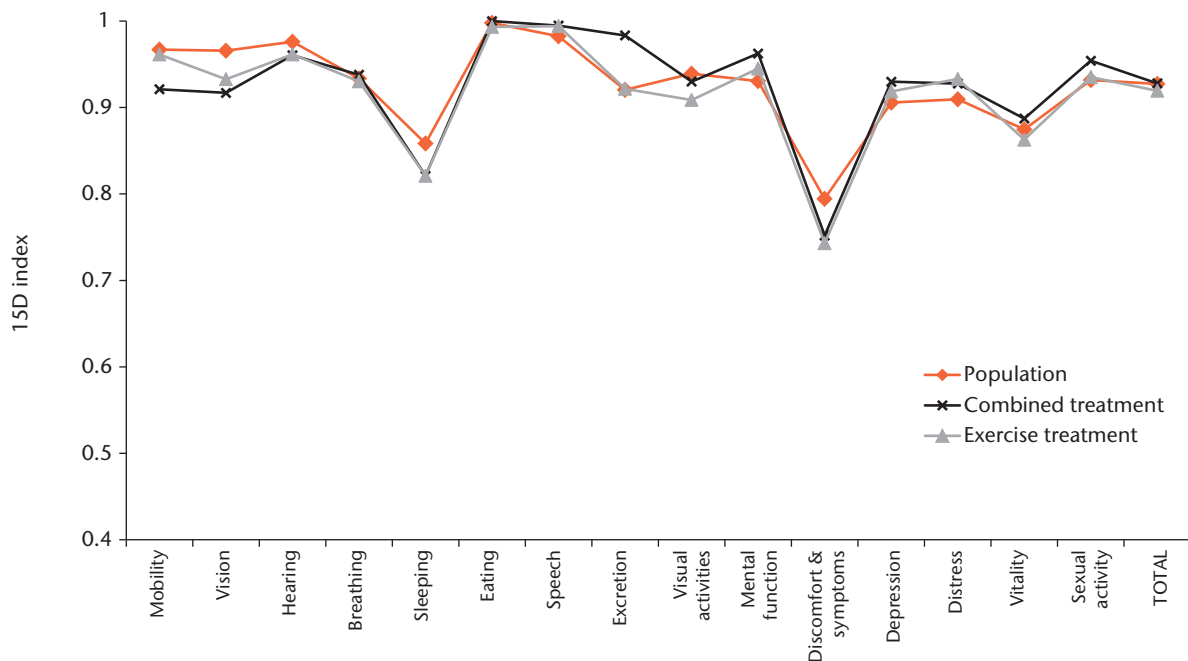


Fig. 1

Graph showing the 15D Quality of Life index in the combined and exercise treatment groups and in comparison with age-adjusted standard population at five years.

exercise treatment group had lower values in the 'usual activities' and 'discomfort' dimensions ( $p = 0.040$  and  $p = 0.037$ , respectively), and the combined treatment group had lower values in the 'mobility', 'sleeping' and 'discomfort' parameters ( $p < 0.001$ ,  $p = 0.049$  and  $p = 0.028$ , respectively; all independent samples Mann-Whitney U test). All these differences exceeded the minimally clinically important difference (MCID) of between 0.02 and 0.03<sup>33</sup> (Fig. 1).

Of the whole group, 16 patients were retired at five years (one already at enrolment). In the combined treatment group five were retired, one due to old age and four on a disability/unemployment pension unrelated to shoulder symptoms. In the exercise group 11 patients were retired, three due to old age and eight were on a disability/unemployment pension, two of which were due to shoulder-related reasons. Two additional patients were part-time retired, one due to shoulder-related reasons (exercise group).

Seven patients in each group reported that changes had been made in their working arrangements due to shoulder-related reasons.

## Discussion

The current study suggests that treatment with arthroscopic decompression combined with structured exercise treatment did not provide better results at five years compared with structured exercise alone, when assessed by self-reported pain. The same pattern was

seen in the secondary outcome measures of disability, pain at night, SDQ score, number of painful days and the proportion of pain-free patients.

The improvements seen in both groups at the two-year follow-up continued to the five-year follow-up, resulting in highly significant improvements compared with the baseline values. However, there were no statistically significant differences between the groups. These five-year results indicate that arthroscopic decompression does not have any additional effect on conservative structured exercise. Furthermore, based on the current results, arthroscopic decompression does not have any prophylactic effect from a five-year perspective because the non-decompressed conservatively treated patients did as well as those who underwent operative release of the impingement.

Some parameters of the 15D quality of life index were slightly worse in patients treated for shoulder impingement than in the age-adjusted general population, but there were no differences between the treatment groups in these health-related quality of life parameters.

There have been randomised controlled trials comparing conservative and operative treatment of shoulder impingement syndrome<sup>13,14</sup> and others have investigated the effect of the treatment on disability and working capacity.<sup>15,16</sup> In these earlier studies, failure to respond to regular physiotherapy and other conservative treatment was used as an inclusion criterion. In contrast, the present study aimed to examine whether operative treatment

**Table III.** Leave of absence from work due to shoulder-related symptoms during the three months preceding the control visit, except at five years when the year preceding the visit was used

Control point	Mean absence from work (days) (range)		p-value*
	Exercise	Combined treatment	
3 months	5.3 (0 to 60)	28.1 (0 to 90)	< 0.001
6 months	2.4 (0 to 65)	4.6 (0 to 90)	0.45
12 months	4.2 (0 to 58)	4.4 (0 to 90)	0.94
2 years	3.8 (0 to 65)	0.1 (0 to 4)	0.03
5 years	3.2 (0 to 110)	0.4 (0 to 10)	0.22
Total	16.5	31.2	0.11

\* t-test

provided any additional value to a conservative structured exercise treatment. At all follow-up visits the patients were evaluated by a blinded, independent assessor, thus minimising any bias. Selection and drop-out biases were minor as all eligible consecutive 140 patients volunteered to the study and the drop-out rate even at five years was relatively small (six of 140 at two years and 31 of 140 at five years).

As the study was conducted in an ordinary provincial hospital setting, not in a highly specialised shoulder centre, the external validity is relatively good. All operations were performed by one experienced orthopaedic surgeon and without any significant surgical complications. Although it concerns patients' health and their decision, in reality patients do not always follow the given guidance. The similarity of the groups at baseline confirms a successful randomisation. Therefore, the adherence to the treatment was probably rather similar in both study groups.

The diagnosis of the impingement syndrome requires a thorough patient history and a careful clinical examination to exclude other conditions that may mimic impingement. All patients were examined also with MRI at baseline, in order to exclude conditions such as penetrating ruptures of the rotator cuff.

The age limits for inclusion were set at 18 and 60 years in conformity with previous studies.<sup>13-16</sup> In patients aged < 18 years, glenohumeral instability is the leading cause of shoulder problems.<sup>34</sup> However, our study included only four patients aged < 30 years. The frequency of rotator cuff tears is higher in patients aged > 60 years,<sup>35-37</sup> hence their exclusion from our study.

Luyckx et al<sup>38</sup> described 166 patients who underwent arthroscopic subacromial decompression, and reported a mean time between operation and full activity of 11.1 weeks (with a minimum of one week). In the present study, patients in the combined treatment group reported a mean of 28.1 days leave of absence due to shoulder-related reasons at the month follow-up visit and additional 4.6 days between the three- and six-month follow-up visits due to surgical procedure (Table III). The use of sick leave was minimal between the two- and five-year follow-up

**Table IV.** Results in the per protocol analysis at five years (SDQ, Shoulder Disability Questionnaire)

Mean outcome	Full exercise treatment group (n = 43)	Full combined treatment group (n = 43)
Self-reported pain		
2 years	2.5	2.4
5 years	1.8	1.6
Disability		
2 years	2.1	2.0
5 years	1.3	1.2
Working ability		
2 years	8.5	8.0
5 years	8.0	7.8
Night pain		
2 years	2.1	2.1
5 years	1.2	1.3
SDQ score		
2 years	26.9	22.1
5 years	16.7	12.0
Painful days		
2 years	13.6	13.9
5 years	8.3	7.8

visits. Values were slightly higher in the exercise group, probably due to shifts in the group and operations performed between the two- and five-year visits. The difference in the total number of sick leave days was not statistically significant between the study groups ( $p = 0.11$ ), but still almost double in the combined treatment group, which raises the overall health care costs.

Use of descriptive data in an *ad hoc* per protocol analysis (43 patients in the exercise group and 43 patients in the combined treatment group) produced only slightly better results (Table IV) than the intention-to-treat analysis (Table II). There were no statistically significant differences between the groups in the per protocol analysis.

The reasons for the rising incidence of arthroscopic acromioplasty are complex. This trend may be driven by patient, surgeon, technology, society and/or employer related reasons. At present, expenses and best evidence must also be taken into consideration. Based on our



two-year results we concluded that acromioplasty is not cost-effective.<sup>24</sup> Structured exercise treatment should be the treatment of choice for shoulder impingement syndrome. Operative treatment should be offered with discernment. In 2010 the Finnish National Institute for Health and Welfare reported that the combined incidence of open and arthroscopic acromioplasties was 91.6/100 000 in Finland.<sup>39</sup> In the New York area the incidence was 101.9/100 000 in 2006 and has risen vastly in the previous decade.<sup>25</sup> The indications for arthroscopic acromioplasty should also be thoroughly discussed. We believe that the natural course of the disease should be better defined to improve the judgement of different treatment options.

The indications for arthroscopic acromioplasty in the treatment of shoulder impingement syndrome should be reconsidered. Based on our results, it seems that the mere presence of an uncomplicated shoulder impingement syndrome is not an indication for arthroscopic acromioplasty *per se*, as conservative treatment with a structured exercise program provides as good results at five years at a lower cost.

**Conclusions.** The additional effect of acromioplasty on top of structured exercise is not significant in the treatment of shoulder impingement syndrome when evaluated at two and five years. Approximately 75% of patients recover well and the rest continue to have discomfort despite the treatment. The effects of the arthroscopic acromioplasty may have been overestimated due to regression to the mean and the natural long-term course of the shoulder impingement syndrome.

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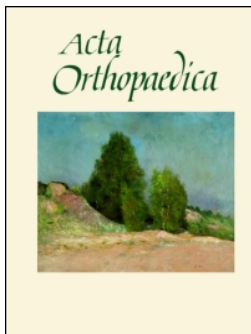
- S. Ketola: Planning of the study (overall planning), Substantive intellectual contribution, Seeking permits from the ethical committee, Seeking permits from the hospitals, Recruitment of the patients, Organisation of the study, Collection and organisation of the data, Statistical analysis, Literature review, Writing the draft, Critical commenting and improvement of the manuscript
- J. Lehtinen: Recruitment of the patients, Organisation of the study, Thesis supervision, Clinical analysis of the data, Literature review, Writing the draft, Critical commenting and improvement of the manuscript
- T. Rousi: Planning of the study (overall and especially physiotherapeutic aspects), Seeking permits from the ethical committee, Seeking permits from the hospitals, Clinical analysis of the data, Critical commenting and improvement of the manuscript

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**ICMJE Conflict of Interest:**

- None declared

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# Which patients do not recover from shoulder impingement syndrome, either with operative treatment or with nonoperative treatment?

Saara Ketola, Janne Lehtinen, Timo Rousi, Maunu Nissinen, Heini Huhtala & Ilkka Arnala

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# Which patients do not recover from shoulder impingement syndrome, either with operative treatment or with nonoperative treatment?

## Subgroup analysis involving 140 patients at 2 and 5 years in a randomized study

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**Background and purpose** — Shoulder impingement syndrome is common, but treatment is controversial. Arthroscopic acromioplasty is popular even though its efficacy is unknown. In this study, we analyzed stage-II shoulder impingement patients in subgroups to identify those who would benefit from the operation.

**Patients and methods** — In a previous randomized study, 140 patients were either treated with a supervised exercise program or with arthroscopic acromioplasty followed by a similar exercise program. The patients were followed up at 2 and 5 years after randomization. Self-reported pain was used as the primary outcome measure.

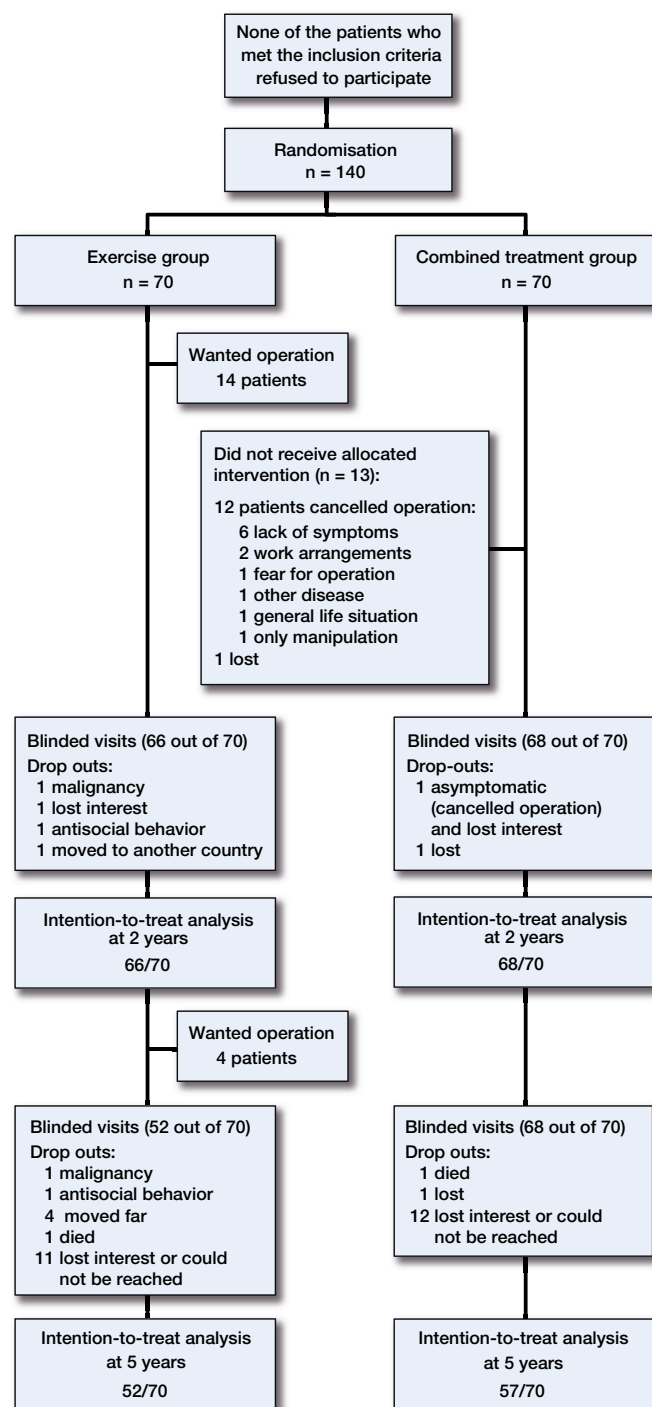
**Results** — Both treatment groups had less pain at 2 and 5 years, and this was similar in both groups. Duration of symptoms, marital status (single), long periods of sick leave, and lack of professional education appeared to increase the risk of persistent pain despite the treatment. Patients with impingement with radiological acromioclavicular (AC) joint degeneration also had more pain. The patients in the exercise group who later wanted operative treatment and had it did not get better after the operation.

**Interpretation** — The natural course probably plays a substantial role in the outcome. Based on our findings, it is difficult to recommend arthroscopic acromioplasty for any specific subgroup. Regarding operative treatment, however, a concomitant AC joint resection might be recommended if there are signs of AC joint degeneration. Even more challenging for the development of a treatment algorithm is the finding that patients who do not recover after nonoperative treatment should not be operated either.

divided into 3 progressive stages: (1) edema and hemorrhage (stage I), (2) fibrosis and tendinitis (stage II), and (3) tears of the rotator cuff, biceps ruptures, and bone changes (stage III) (Neer 1983). Nowadays, the term impingement syndrome is used to refer to a full range of rotator cuff abnormalities, being still a diagnosis based on physical examination (Papadonikolakis et al. 2011). Diercks et al. (2014) highlighted the need for a combination of clinical tests in the diagnosis, and suggested the use of an imaging test after prolonged symptoms (of more than 6 weeks) to rule out rotator cuff tears. Shoulder impingement is a common cause of shoulder pain (van der Windt et al. 1995, Urwin et al. 1998). Tendinopathy is considered to have a multifarious etiology: intrinsic mechanisms may be more important than extrinsic mechanisms (Factor and Dale 2014).

Both nonoperative treatment and operative treatment have been used to treat this syndrome (Coghlan et al. 2008, Dorrestijn et al. 2009, Kromer et al. 2009, Chaudhury et al. 2010). It has been shown that arthroscopic acromioplasty is not superior to a supervised exercise program (Ketola et al. 2009, 2013, Papadonikolakis et al. 2011, Diercks et al. 2014, Saltychev et al. 2015). However, arthroscopic acromioplasty has been increasingly used during the last decade (Paloneva et al. 2015). Similar results have been obtained with open and arthroscopic acromioplasty (Davis et al. 2010). It is unclear whether a specific subgroup of patients who would benefit from arthroscopic acromioplasty can be identified. In most studies, the inclusion criterion has simply been failure of nonoperative treatment (Brox et al. 1999, Henkus et al. 2009). We have already done a cost-effectiveness study that suggested that arthroscopic acromioplasty followed by a structural exercise program is less cost-effective than exercise treatment

Shoulder impingement syndrome has traditionally been



Study design

alone (Ketola et al. 2009), and this was confirmed by Saltychev et al. (2015). We have now analyzed the 140 impingement patients from our previous study (Ketola et al. 2009) in subgroups to find out whether there is a subgroup of patients who would really benefit from arthroscopic acromioplasty. Secondly, we wanted to determine whether there is a subgroup in which the procedure should be avoided.

## Patients and methods

The original study design was a controlled randomized trial. 140 patients (18–60 years old) were included in the study if history and clinical tests indicated impingement syndrome (52 men and 88 women, mean age 47 years). All patients were collected from the Kanta-Häme Health Care District in Finland, which at the time of the inclusion had a population of 165,000. The study started in June 2001, and by the end of July 2004 we had recruited 140 patients—as planned from a power calculation. The dropout rate was 6 of 140 at 2 years and 31 of 140 at 5 years. It was therefore possible to analyze 134 of the 140 randomized patients at 2 years and 109 of the 140 at 5 years (Figure). MRI of the shoulder was performed before randomization, as a supplementary tool to exclude other shoulder pathologies such as full-thickness rotator cuff lesions. All the radiographs were evaluated by 2 independent radiologists and their consensus values were used in the analyses. For inclusion, the symptoms had to be resistant to previous attempts to treat them nonoperatively during the previous 3 months. None of the patients had had previous shoulder surgery. The inclusion and exclusion criteria and the precise study protocol are described in the report of the 2-year results (Ketola et al. 2009).

The 2 treatment groups were (1) arthroscopic acromioplasty followed by a supervised and structured exercise treatment program (the combined treatment group), and (2) a similarly supervised and structured exercise treatment program alone without any surgery (the exercise treatment group). The only difference between treatments in these 2 study groups was the operation. For those patients who were randomized to the combined treatment group, an arthroscopic decompression was first performed. All the operations were performed under regional anesthesia by the same experienced orthopedic surgeon. After the diagnostic part of the procedure, debridement and decompression were done by shaver and/or vaporizer. If the coracoacromial ligament felt tight or thick, it was released. Acromioplasty was then performed with a burr drill. After that, these patients were also given a similar schedule of physiotherapy and training sessions.

The main follow-up points were at 2 and 5 years after randomization. A physiotherapist, who was blind regarding which patients were in the treatment group, performed all the assessments (with the patients in T-shirts) and was not otherwise involved in the study, treatment, or rehabilitation.

Self-reported pain on a 0–10 visual analog scale (VAS) was used as the primary health outcome measure, and values at 2 and 5 years were also used in this ad hoc subgroup analysis. The proportion of pain-free patients was also used, with patients being considered free of pain if they reported pain at a level between 0 and 3 on VAS.

Secondary outcome measures were disability, working ability, pain at night (VAS values), shoulder disability questionnaire (SDQ) score, and reported painful days during the 3

Table 2. Results for the treatment groups at 5 years compared to those who were dissatisfied with conservative treatment and operated

	Combined treatment group n = 43			Exercise treatment group n = 43			Wanted operation in conservative group n = 18			p-value
	Mean	Median	Q1–Q3	Mean	Median	Q1–Q3	Mean	Median	Q1–Q3	
Self-reported pain	1.6	0	0–3.0	1.8	1.0	0–3.0	2.6	2.5	1.0–4.0	0.1
Disability	1.2	0	0–2.0	1.3	0	0–1.8	2.1	1.5	0–3.0	0.2
Working ability	7.8	8.0	7.0–9.0	8.0	8.0	7.0–9.0	7.2	8.0	7.0–8.0	0.2
Pain at night	1.3	0	0–2.0	1.2	0	0–1.0	1.9	1.0	0–3.0	0.2
SDQ score	12.0	0	0–11	17	3.6	0–20	26	23	0–41	0.06
Reported days with pain	7.8	0	0–6.0	8.3	0	0–9.0	9.7	1.5	0–6.3	0.8

months preceding the follow-up visit. For baseline characteristics used in this subgroup analysis, see Supplementary data, Table 1.

Statistics

Fisher’s exact test was used for the comparisons of proportions. Kruskal-Wallis test was used when VAS scales of the subgroups were compared. The association between patient characteristics and pain was tested using binary logistic regression analysis. Results are given as odds ratios (ORs) with 95% confidence intervals (CIs). Any p-value less than 0.05 was considered statistically significant. Statistical analyses were performed using IBM SPSS Statistics for Windows, version 19.0.

Ethics

The study was approved by the ethics committee of the hospital district (Kanta-Häme Central Hospital; entry no. E9/2001, April 11, 2001).

Registration

The study has been registered at ClinicalTrials.gov, identifier NCT00349648.

Results

At 2 and 5 years, both groups reached statistically significantly better values in the outcome measures compared to baseline, which were similar between the groups. These outcomes were calculated using the intention-to-treat (ITT) principle. Those who fully followed their study assignment were also analyzed separately using the per-protocol (PP) principle. Outcome was similar between the 2 treatment groups. However, the dissatisfied patients in the exercise group who eventually wanted and had an operation still had worse values after surgery than the others (Table 2).

Pain

At 5 years 82/109 of the patients were pain-free (self-reported

pain less than 3 in the visual analog scale). Over 2 weeks long out of work periods due to shoulder reasons had occurred in 18/77 of the pain-free patients and in 12/27 of those patients who were painful at 5 years (p = 0.07). (Table 4, see Supplementary data).

The following factors had a statistically significant impact on pain (see Supplementary data, Tables 3 and 4).

**Marital status.** Living alone was associated with a higher risk of having pain at 2 years (OR = 3.3, CI: 1.4–7.8). When we divided the patients into those who experienced pain and those who were pain-free, those living alone appeared to have more pain at 2 years (p = 0.01) and at 5 years (p = 0.03).

**Lack of professional education.** At 2 years, the OR was 3.7 (CI: 1.2–11) for those with no education and 3.0 (CI: 0.93–9.5) for those who had gone through an occupational course.

**Duration of symptoms** prior to the randomization had a positive correlation with pain at 2 years, especially in those in the exercise group who later wanted an operation (p = 0.04). In the exercise group, 11/25 of the pain-free patients and 4/10 of the patients with pain had had symptoms over 1 year. In the combined treatment group, 12/25 of the pain-free patients and 9/13 of the patients with pain had had symptoms over 1 year. All of the 18 patients in the exercise group who wanted surgery had had symptoms over 1 year.

**Long periods of sick leave** was also associated with an increased risk of having pain. If a patient had been out of work before the randomization—for more than 2 weeks—for shoulder-related reasons, the risk of having pain was high at 2 years (OR = 2.5, CI: 1.1–5.8) and at 5 years (OR = 3.8, CI: 1.4–11).

**Satisfaction at work.** 5/7 of patients with a quite low or very low level of satisfaction experienced pain at 2 years. At 2 years, 72/80 of the pain-free patients were quite satisfied or very satisfied but only 28/41 of those with pain were quite satisfied or very satisfied. Only 2/80 of the pain-free patients had a quite low or very low level of satisfaction, whereas 5/41 of the patients with pain had a quite low or very low level of satisfaction (overall p = 0.01).

**Requirements/challenges at work.** In patients whose requirements/challenges at work were low or quite low, the fraction of pain-free subjects was 21/24. Of those who had

heavy commitments at work, more than half had pain at 5 years. Of the pain-free patients at 5 years, 10/80 reported having heavy commitments at work, whereas in patients with pain the corresponding proportion was 11/27 (overall  $p = 0.01$ ).

**Loads lifted per workday.** The highest risk ( $> 4$ -fold risk) of having pain at 2 years was in those who lifted a moderate amount during a workday, compared to those who lifted lighter or heavier loads. Of the patients who were pain-free, those who lifted light loads constituted 20/64 of the total. Of the patients with pain, those who lifted light loads accounted for 7/37 of the total (overall  $p = 0.02$ ).

**AC joint degeneration.** In the combined treatment group, 21/22 of the pain-free patients had no or only mild AC joint degeneration at 5 years. In those with pain, 3/4 had moderate or severe degeneration of the AC joint (overall  $p = 0.01$ ).

## Discussion

Operative treatment is commonly used for shoulder impingement syndrome, even though its effectiveness has not been proven in the literature (Papadonikolakis et al 2011, Diercks et al 2014, Saltychev et al. 2015). The fact that the diagnosis is merely clinical also makes comparison of different studies difficult. In a recent review and meta-analysis, the evidence on effectiveness of operative or nonoperative treatment was found to be limited (Saltychev et al. 2015). This is in keeping with the Cochrane Collaboration report (Coghlan et al. 2008) and 2 previous reviews (Dorrestijn et al. 2009, Gebremariam et al. 2011).

Subgroup analyses are important if treatments with statistically similar outcomes show extensive heterogeneity of the treatment effect in individual patients (perhaps related to the diversity of the pathophysiology of the underlying disease). This may help to create more individualized indications and contraindications for the treatments of interest. Subgroup analyses must be predefined, carefully justified, and limited to a few clinically important questions (Rothwell 2005), because otherwise they could be misleading. We feel that the prospective nature of this carefully selected patient material justified a subgroup analysis.

In this study, we tried to determine whether the treatment works better in some subgroups than in others, acknowledging the risks of statistical problems and misinterpretations. In the subgroup analyses, we focused on differences from the average overall treatment effect and limited the questions to only a few clear and well-defined variables. Participation in intervention as intended, i.e. analysis according to the ITT principle or the PP principle, did not have any statistically significant effect on the results. Our study indicates that using self-reported pain (by VAS) or secondary outcome measures at 2 or 5 years for analysis, the effects of combined treatment did not differ significantly from the effects of treatment with supervised exercise alone. In this study we did not compare the overall effects

of these 2 modes of treatment, but specifically analyzed the eventual additional value provided by the operation over and beyond the effect obtained using a structured and supervised exercise program alone (Ketola et al. 2009 and 2013).

## Strengths and weaknesses

The dropout rate was small; it was possible to analyze 134 of the 140 randomized patients at 2 years and 109 of them at 5 years. The selection bias was low at the actual entry to the study, because at baseline all suitable subjects were willing to participate in the study. However, it is possible that some patients living in the hospital catchment area with similar pain-related complaints did not come to the hospital outpatient department, thus creating potential bias. The groups were similar at baseline. All arthroscopic acromioplasties were performed by one experienced surgeon who was considered to have reached the top of the learning curve, which contributed to the uniform quality of the operative care. Control visits/follow-up examinations were done by an independent and blinded physiotherapist who did not otherwise participate in the study. Due to multiple variables, the subgroup sizes became small, which would increase the risk of type-II error. In addition, there have been no reports and there is no common consensus on how shoulder impingement syndrome evolves over a long time. There may always be some patients who recover spontaneously and some others who are not cured despite the treatment given.

## The natural course of the treated disease

The results at 2 and 5 years were similar between treatment groups and they seemed to continue to improve in a similar way in both groups after the first 2 years (to the 5-year follow-up). The effects of both procedures appeared to be long-lasting and to continue to improve over time (Ketola et al. 2013). Do these good results reflect the therapeutic intervention, or the natural long-term course of this syndrome?

The age limits for this study were 18 and 60 years. It has been shown that there are changes in acromial morphology with age. Both asymptomatic and symptomatic cuff tears increase with age (Yamamoto et al. 2010).

18 patients were not pleased with the results of the exercise treatment alone, and they were therefore operated later on. However, these patients did not do any better after the operation. We believe that there was a similar group of patients in the combined group as well, who would not respond to surgery either. So it appears that almost one-third of all patients with this diagnosis do not respond to any sort of treatment. The remaining two-thirds will get better irrespective of the nature of the treatment. It might well be that the natural course of the shoulder impingement syndrome contributes substantially to the improvement of those patients who are "healed" after treatment, during the 5-year follow-up.

It appears that patients who do not get better with nonoperative treatment do not get better with operative treatment



either, although this may also partly depend on the duration of the symptoms before initiation of the treatment. This in any case challenges the previous guidelines of offering surgery to patients who “fail” with nonoperative treatment. Longer follow-up periods in patients with shoulder impingement syndrome are needed to learn more about the natural course of the disease.

### Factors affecting the results of the treatment

A longer duration of symptoms appeared to be predictive of worse results in both groups. This probably reflects the possibility that impingement heals spontaneously if the condition has lasted less than 1 year. In this study, after this checkpoint the number of non-responders increased substantially. The same consideration probably explains the worse results in patients who had longer and more frequent periods of sick leave, which is in line with previous studies (Bot et al. 2005, Thomas et al. 2005, Reilingh et al. 2008).

There was a negative correlation between satisfaction at work and the perception of pain. The more demanding the work was, according to the patient’s own assessment, the worse was the prognosis for recovery. Similarly, lack of a higher education was associated with poor treatment results. Patients living alone had more pain, which might be explained by the lack of disease-related support. There are similar reports involving other orthopedic conditions where psychological factors have affected the perception of pain (Wahlman et al. 2014). Also, in shoulder complaints several psychological factors have been related to outcome (Bot et al. 2005). If the condition is refractory or the symptoms become bilateral, the overall prognosis is negatively affected. This is probably explained by the previously mentioned third of the patients who have a more difficult disease. This is the group that does not recover from the initial symptoms, which appears to happen to most of the patients who are treated more than 1 year after the onset of symptoms.

Only 1 radiological feature was significantly associated with pain perception after the treatment. If the patients had AC osteoarthritis, they had more pain than patients with normal AC joint radiology. The incidence of arthroscopic acromioplasty has been increasing, but has probably now reached a plateau (Vitale et al. 2010, Yu et al. 2010). Based on this material, we cannot justify the performance of this procedure to any single subgroup of impingement patients. However, if the patient is to be operated, a concomitant AC resection is only recommended if there are signs of AC joint degeneration.

### Conclusions

There are no simple criteria to predict the natural course of the disease in patients suffering from shoulder impingement syndrome. This condition behaves somewhat differently from usual in some patient subgroups, which can be explained by the nature of the condition rather than the demographic properties of the patients. Regardless of the treatment chosen, most

of the patients get better. If the patients do not recover by non-operative means, it appears that they do not benefit from the operative treatment either.

### Supplementary data

Tables 1, 3, and 4, are available at Acta’s website ([www.actaorthop.org](http://www.actaorthop.org)), identification number 8071.

All the authors participated in the conception and conduction of the study, and contributed to the final manuscript. SK, TR, MN, and IA: (overall) planning of the study (TR especially the physiotherapy aspects, IA especially the operative aspects). SK: substantial intellectual contribution. SK and TR: seeking permission from the ethical committee. SK, TR, MN, and IA: seeking permission from the hospitals. SK, JL, and MN: recruitment of the patients. SK, JL, and IA: organization of the study. SK: collection and organization of the data. SK and HH: statistics. JL, TR, and IA: clinical analysis of the data. SK and JL: literature review. SK and JL: writing of the draft. SK, JL, TR, MN, HH, and IA: critical commenting on and improvement of the manuscript.

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## Supplementary article data

# Which patients do not recover from shoulder impingement syndrome, either with operative treatment or with nonoperative treatment?

Subgroup analysis involving 140 patients at 2 and 5 years in a randomized study

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Table 1. Baseline characteristics of the study participants

	All n = 140	Combined treatment group n = 70	Exercise treatment group n = 70		All n = 140	Combined treatment group n = 70	Exercise treatment group n = 70
Age, years, mean (SD)	47 (7.8)	46 (8.1)	48 (7.6)	Loads (kg) lifted per workday, mean total (SD)	568 (1117)	355 (633)	462 (913)
Self-reported pain (VAS), mean (SD)	6.5 (1.9)	6.4 (2.0)	6.5 (1.9)	0–20 kg	31	17	14
Pain at night (VAS), mean (SD)	6.3 (2.6)	6.2 (2.6)	6.4 (2.6)	20–100 kg	25	15	10
Disability (VAS), mean (SD)	6.4 (2.1)	6.3 (2.1)	6.5 (2.0)	100–500 kg	42	15	27
Working ability (VAS), mean (SD)	5.8 (2.5)	5.7 (2.6)	5.9 (2.3)	> 500 kg	25	15	10
SDQ score, mean (SD)	80 (20)	78 (22)	82 (18)	Working arms raised, n			
Female gender	88	41	47	not at all	13	7	6
Body Mass Index, mean (SD)	27 (5.0)	27 (4.9)	27 (5.2)	to some extent	92	48	44
Weight categories, n				a lot	31	14	17
underweight	2	2	0	Satisfaction at work, n			
normal/healthy weight	46	21	25	very good	30	13	17
overweight	60	32	28	quite good	71	37	34
moderately obese	21	8	13	neutral	14	6	8
severely obese	5	3	2	quite or very low	8	6	2
very severely obese	4	2	2	Symptom duration, mean (SD) years	2.5 (3.0)	2.5 (2.8)	2.6 (3.2)
Marital status, n				Duration categories, n			
single	10	5	5	3–6 months	15	10	5
married	91	43	48	6–12 months	40	18	22
cohabiting	15	8	7	1–3 years	37	22	15
widow	3	2	1	> 3 years	31	13	18
divorced	17	11	6	Sick leave prior randomization (/3 months), mean (SD) days	16 (26)	20 (30)	13 (22)
Basic education, n				Sick leave categories			
elementary school	59	30	29	none	66	31	35
junior high school	57	30	27	1–7 days	13	7	6
high school	20	9	11	8–14 days	14	6	8
Professional education, n				>14 days	40	22	18
none	25	15	10	Classification of acromion (Bigliani)			
occupational course	33	14	19	1	48	24	24
trade school	47	25	22	2	46	26	20
technical college	26	13	13	3	12	5	7
university	5	2	3	AC degeneration compressing supraspinatus tendon, yes	42	22	20
Working status, n				AC degeneration (visual score)			
currently working	108	52	56	none or mild	75	35	40
entrepreneur	11	6	5	moderate	21	13	8
student	1	1	0	severe	10	7	3
unemployed	14	8	6				
at home	1	1	0				
retired	1	1	0				
Requirements/challenges at work, n							
low	6	3	3				
quite low	21	12	9				
rather challenging	34	15	19				
quite heavy	48	28	20				
heavy	27	11	16				



Table 3. Univariate odds ratios (ORs) and multivariable model of various baseline characteristics for the outcome at 2 and 5 years

	2 years				5 years	
	Univariate OR	95% CI	Multivariable OR	95% CI	Univariate OR	95% CI
Group						
combined treatment	1				1	
exercise	1.05	0.52–2.12			0.92	0.38–2.23
Age at baseline, years	1.02	0.97–1.06			0.98	0.93–1.04
Gender						
male	1				1	
female	1.44	0.68–3.04			1.13	0.45–2.83
Body Mass Index	1.02	0.95–1.10			1.05	0.97–1.14
Marital status						
living with a partner	1		1		1	
living alone	3.29	1.39–7.78	3.29	0.98–11.0	2.77	1.02–7.55
Basic education						
elementary school	1				1	
junior high school	3.88	1.02–14.8			1.07	0.42–2.73
high school	2.74	0.71–10.6			0.45	0.09–2.26
Professional education						
technical college/university	1				1	
trade school	1.41	0.36–5.55			1.98	0.48–8.13
occupational course	2.98	0.93–9.52			0.68	0.15–3.10
none	3.67	1.20–11.2			1.95	0.53–7.16
Requirements/challenges at work						
low	1				1	
quite low	1.18	0.11–13.1			0.47	0.03–6.57
rather challenging	3.25	0.34–31.1			1.00	0.09–11.0
quite heavy	2.93	0.32–27.2			1.10	0.11–11.3
heavy	3.67	0.37–36.0			3.64	0.35–38.2
Loads lifted per workday						
0–20 kg	1		1		1	
20–100 kg	4.36	1.38–13.8	5.10	1.05–24.7	3.29	0.71–15.3
100–500 kg	2.53	0.89–7.24	4.10	0.97–17.4	4.53	1.13–18.1
> 500 kg	0.86	0.24–3.12	0.76	0.14–4.11	1.53	0.27–8.63
Working arms raised						
not at all	1				1	
to some extent	7.29	0.91–58.6			3.09	0.37–25.9
a lot	7.33	0.83–64.4			6.00	0.66–55.0
Satisfaction at work						
very good	1		1		1	
quite good	0.41	0.16–1.04	0.34	0.11–1.07	0.85	0.28–2.57
neutral	1.89	0.52–6.87	2.28	0.42–12.5	2.40	0.48–12.0
quite or very low	3.54	0.59–21.40	1.20	0.12–11.8	1.00	0.09–11.5
Symptom duration						
3–6 mo	1				1	
6–12 mo	1.41	0.37–5.39			1.06	0.23–4.97
1–3 y	1.27	0.33–4.96			0.53	0.10–2.82
> 3 y	1.13	0.28–4.57			1.67	0.36–7.81
Sick leave periods prior to randomization (/3 months)						
none	1		1		1	
1–7 days	0.18	0.02–1.47	0.14	0.13–1.49	1.44	0.26–8.04
8–14 days	0.95	0.26–3.45	1.76	0.38–8.03	3.83	0.88–16.7
> 14 days	2.52	1.10–5.77	3.99	1.22–13.0	3.83	1.35–10.9
Classification of acromion (Bigliani)						
1	1				1	
2	1.07	0.45–2.50			0.96	0.33–2.81
3	2.80	0.77–10.22			3.63	0.84–15.7
AC degeneration compressing supraspinatus tendon						
no	1				1	
yes	1.10	0.49–2.45			1.05	0.40–2.80
Acromio-clavicular degeneration (visual score)						
none or mild	1				1	
moderate	1.82	0.68–4.85			2.71	0.87–8.43
severe	1.33	0.35–5.16			3.71	0.86–16.1

Table 4. All study participants divided into pain-free patients and patients with pain, and sorted by baseline characteristics at 2 and 5 years

	2 years		p-value	5 years		p-value
	Pain-free group n = 86	Pain group n = 48		Pain-free group n = 82	Pain group n = 27	
Age at baseline, years			0.5			1.0
< 30	2	2		2	1	
30–44	34	13		28	9	
45–54	35	24		36	13	
55–60	15	9		16	4	
Gender			0.4			0.8
male	34	15		31	9	
female	52	33		51	18	
Body Mass Index			0.6			0.3
underweight/normal weight	33	15		30	7	
overweight	37	21		36	14	
moderately obese	11	7		11	2	
severely or very severely obese	4	5		4	4	
Marital status			0.01			0.03
living alone	12	16		12	10	
living with a partner	74	30		68	17	
Basic education			0.1			0.6
elementary school	33	24		37	14	
junior high school	37	19		30	11	
high school	16	3		13	2	
Professional education			0.7			0.2
none	16	9		15	7	
occupational course	19	12		25	4	
trade school	28	17		23	12	
technical college/university	23	8		17	4	
Requirements/challenges at work			0.1			0.01
low or quite low	22	5		21	3	
rather challenging/ quite heavy	49	30		49	13	
heavy	15	11		10	11	
Loads lifted per workday			0.02			0.08
0–20 kg	24	7		23	3	
20–100 kg	11	14		13	7	
100–500 kg	23	17		22	13	
> 500 kg	20	5		15	3	
Working with arms raised			0.09			0.2
not at all	12	1		10	1	
to some extent	56	34		55	17	
a lot	18	11		15	9	
Satisfaction at work			0.01			0.3
very good	17	12		18	6	
quite good	55	16		46	13	
neutral	6	8		5	4	
quite or very low	2	5		2	2	
Symptom duration			1.0			0.6
3–6 months	9	4		10	3	
6–12 months	24	15		22	7	
1–3 years	23	13		24	5	
> 3 years	20	10		16	8	
Sick leave prior to randomization (/3 months)			0.02			0.07
none	45	21		45	9	
1–7 days	12	1		8	2	
8–14 days	9	4		6	4	
> 14 days	17	20		18	12	
Classification of acromion (Bigliani)			0.3			0.2
1	32	16		29	8	
2	30	16		34	9	
3	5	7		5	5	
AC degeneration compressing supraspinatus tendon			0.8			1.0
no	41	23		41	13	
yes	26	16		27	9	
AC degeneration (visual score)			0.4			0.08
none or mild	50	25		31	11	
moderate	11	10		22	4	
severe	6	4		9	3	