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TREATMENT OF PATIENTS WITH ROTATOR CUFF TEARS

Comparative Evidence on the Effectiveness of Tendon Repair and Conservative Treatment for Mainly Supraspinatus Tendon Tears

Anssi Ryösä

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’’It is a riddle, wrapped in a mystery, inside an enigma.’’
Winston Churchill (1939)

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ANSSI RYÖSÄ: Treatment of Patients with Rotator Cuff Tears – Comparative Evidence on the Effectiveness of Tendon Repair and Conservative Treatment for Mainly Supraspinatus Tendon Tears
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ABSTRACT

Rotator cuff tears are a common finding in imaging studies. Tears are usually located at the supraspinatus tendon area, one of the four rotator cuff muscles. The symptoms of tears are frequently reported as shoulder pain and weakness. Physiotherapy, a conservative treatment, can relieve symptoms substantially. However, literature reporting on conservative treatment is scarce. Another well-established treatment modality is rotator cuff repair. According to several observational studies, rotator cuff repair, combined with physiotherapy, yields good to excellent results. Since the introduction of arthroscopic techniques, the incidence of rotator cuff repair has increased substantially despite the lack of clear evidence-based treatment guidelines. Given this, randomized controlled trials are needed to produce low-biased evidence and several randomized controlled trials can be combined in a meta-analysis to provide high-level evidence comparing the effectiveness of different treatment modalities.

In this thesis, a systematic review and meta-analysis was conducted to evaluate evidence on the effectiveness of tendon repair compared with the conservative treatment of rotator cuff tear. Furthermore, we investigated, with a randomized controlled trial, the difference in mid-term outcome between physiotherapy, acromioplasty and tendon repair to treat non-traumatic supraspinatus tendon tears. In addition, we investigated the effectiveness of supervised physiotherapy compared with home exercises alone after supraspinatus tendon repair. Finally, we present a protocol for the Acute Cuff Tear Repair Trial (ACCURATE) to investigate the difference in outcomes between placebo surgery and arthroscopic rotator cuff repair in patients with a supraspinatus tendon tear related to trauma.

According to the meta-analysis and our randomized controlled trial, tendon repair probably does not provide clinically relevant improvement, in 1- to five-years follow-up compared to conservative treatment, in people with mainly supraspinatus tendon tear. After 1-year of supraspinatus tendon repair, no differences were found in the pain or function of the shoulder between postoperative supervised physiotherapy and home exercises only. At three-month follow-up, the supervised physiotherapy group reported less pain than the home-exercise-only group.

KEYWORDS: rotator cuff tear, supraspinatus, repair, surgery, arthroscopy, conservative treatment, physiotherapy, placebo

TURUN YLIOPISTO
Lääketieteellinen tiedekunta
Ortopedia ja traumatologia
ANSSI RYÖSÄ: Kiertäjäkalvosimen repeämien hoito – korjausleikkauksen ja ilman leikkausta toteutetun hoidon vaikuttavuus pääosin ylemmän lapalihaksen jänteen repeämissä
Väitöskirja, 141 s.
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TIIVISTELMÄ

Kiertäjäkalvosimen jännerepeämät ovat yleisiä kuvantamistutkimuksissa näkyviä muutoksia. Yleisimmin repeämä sijaitsee ylemmän lapalihaksen jänteen alueella. Tyypillisiä oireita ovat kipu ja olkavarren nostoheikkous. Repeämien aiheuttamiin oireisiin näyttäisi pelkkä fysioterapia tuovan parannusta, mutta fysioterapian vaikuttavuutta koskevia tutkimuksia on vähäisesti. Korjausleikkaus on yleisesti käytetty hoitomuoto jännerepeämissä ja sillä on useissa havainnoivissa tutkimuksissa saatu hyviä tuloksia. Erityisesti tähystysmenetelmien käyttöönoton myötä leikkausmäärät ovat voimakkaasti nousseet ilman että käytäntö perustuisi näyttöön perustuvaan hoitosuositukseen. Jotta saadaan korkealaatuista tutkimusnäyttöä hoidon vaikuttavuudesta eri hoitovaihtoehtojen välillä, tarvitaan satunnaistettuja kontrolloituja tutkimuksia ja niistä tehtyjä meta-analyysejä tuottamaan mahdollisimman vinoutumatonta tietoa.

Tässä väitöskirjatutkimuksessa selvitettiin ensin systemaattisella kirjallisuuskatsauksella ja meta-analyysillä kiertäjäkalvosimen jännerepeämän korjausleikkauksen vaikuttavuutta verrattuna fysioterapiaan. Tutkimme satunnaistetulla kontrolloidulla tutkimusasetelmalla fysioterapian, olkalisäkkeen avarrusleikkauksen ja jännerepeämän korjausleikkauksen välisiä eroja hoitotuloksissa viiden vuoden kohdalla potilailla, joilla oli ylemmän lapalihaksen jänteen ei-tapaturmainen repeämä. Lisäksi tutkimme ylemmän lapalihaksen jänteen repeämän korjausleikkauksen jälkeisen ohjatun fysioterapian vaikuttavuutta verrattuna ei-ohjattuun fysioterapiaan. Lopuksi esittelemme ylemmän lapalihaksen tapaturmaisen jännerepeämän korjausleikkauksen tehotutkimuksen (ACCURATE) protokollan, jossa verrataan tähystyskorjausleikkauksen tulosta olkanivelen tähystystutkimusleikkaukseen (placebo).

Meta-analyysin ja satunnaistetun kontrolloidun tutkimuksemme perusteella jännerepeämän korjausleikkauksella ei todennäköisesti saavuteta 1–5 vuoden seurannassa kliinisesti merkitsevää parannusta fysioterapiaan verrattuna. Olkapään kivussa tai toiminnassa vuoden kohdalla korjausleikkauksesta ei todettu merkitsevää eroa ohjatun ja ei-ohjatun fysioterapiaryhmän välillä.

AVAINSANAT: kiertäjäkalvosimen jännerepeämä, ylemmän lapalihaksen jänne, korjausleikkaus, kirurgia, tähystysleikkaus, konservatiivinen hoito, fysioterapia, placebo

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Abbreviations

AC	Acromioclavicular
AE	Adverse event
AHI	Acromiohumeral interval
CI	Confidence interval
CROM	Clinician rated outcome measure
CS	Constant score
CT	Computed tomography
CTA	Cuff tear arthropathy
ER	External rotation
FD	Fatty degeneration
GH	Glenohumeral
HE	Home exercise
ISP	Infraspinatus
ITT	Intention to treat
MCID	Minimal clinically important difference
MRA	Magnetic resonance arthroraphy
MRI	Magnetic resonance imaging
OA	Osteoarthrosis
PP	Per protocol
PROM	Patient rated outcome measure
ROM	Range of motion
RC	Rotator cuff
RCT	Randomized controlled trial
SD	Standard deviation
SP	Supervised physiotherapy
SSC	Subscapularis
SSP	Supraspinatus
SSV	Subjective shoulder value
TM	Teres minor
VAS	Visual analog scale
WORC	Western Ontario Rotator Cuff index

List of Original Publications

This dissertation is based on the following original publications, which are referred to in the text by their Roman numerals:

I Ryösä A, Laimi K, Äärimaa V, Lehtimäki K, Kukkonen J, Saltychev M. Surgery or conservative treatment for rotator cuff tear: a meta-analysis. Disabil Rehabil. 2017 Jul;39(14):1357–1363.

II Kukkonen J, Ryösä A, Joukainen A, Lehtinen J, Kauko T, Mattila K, Äärimaa V. Operative versus conservative treatment of small, nontraumatic supraspinatus tears in patients older than 55 years: over 5-year follow-up of a randomized controlled trial. J Shoulder Elbow Surg. 2021 Nov; 30(11):2455–2464.

III Karppi P, Ryösä A, Kukkonen J, Kauko T, Äärimaa V. Effectiveness of supervised physiotherapy after arthroscopic rotator cuff reconstruction: a randomized controlled trial. J Shoulder Elbow Surg. 2020 Sep;29(9):1765–1774.

IV Ryösä A, Kukkonen J, Björnsson Hallgren HC, Moosmayer S, Holmgren T, Ranebo M, Bøe B, Äärimaa V; ACCURATE study group. Acute Cuff Tear Repair Trial (ACCURATE): protocol for a multicentre, randomised, placebo-controlled trial on the efficacy of arthroscopic rotator cuff repair. BMJ Open. 2019 May 19;9(5):1–15.

1 Introduction

Shoulder pain is a common symptom in the general population, being the third most frequent complaint among patients with musculoskeletal disorders (Rekola et al., 1993). The main cause of shoulder pain is considered to be pathology of the rotator cuff (RC), particularly tears (Juel & Natvig, 2014; Vecchio et al., 1995; van der Wind et al., 1995; Östör et al., 2005). Together with shoulder pain, muscle weakness and the inability to move the arm are also normally reported. Tears are usually found at the superior part of the RC, the area of the supraspinatus (SSP) tendon (Jeong et al., 2018; Kim et al., 2010). Age-related tendon degeneration and combined repetitive microtrauma are thought to be the leading cause for the tendon to tear, even without a traumatic event (Nho et al., 2008). Accordingly, full-thickness tears can frequently be found in asymptomatic adult populations. The overall prevalence of full-thickness RC tears is reported to be 22.1 % in the general population, in which every third tear is symptomatic. The prevalence of RC tears clearly increases with age (Minagawa et al., 2013). Although the prevalence of shoulder pain is high, the majority of individuals with shoulder pain do not have a RC tear (Yamamoto et al., 2010).

Surgical reinsertion of the torn tendon back to its insertion area is currently the generally advocated choice of treatment in patients with symptomatic RC tears. The first milestone in the operative treatment of RC tears was already in a 1911 article, by E. A. Codman (Codman, 2011), in which he described a technique for repairing tears of the SSP tendon using transosseous sutures. In later years, the theory of acromion morphology and its assumed association with cuff tears, presented by Neer (Neer, 1972) in 1972, popularized surgical treatment. In the 1990s, operative methods evolved from the early open surgery to arthroscopic assisted 'miniopen' techniques and a few years later to all-arthroscopic reconstruction of the torn tendon (Levy et al., 1990; Snyder, 1993; Thal, 1993). Concurrently, suture materials, configurations and anchors have advanced from transosseous silk sutures to titanium or bioabsorbable anchors with non-absorbable sutures to create single row, double row or suture bridge configurations (Randelli et al., 2015). The outcome of RC repairs is reported to be good to excellent (Aleem & Brophy, 2012) and since the all-arthroscopic era the incidence of RC repairs has substantially increased (Ensor et al., 2013).

Evidence also exists demonstrating that conservative treatment can yield a favourable clinical result, although the tear is not repaired (Kuhn et al., 2013). However, most literature concerning the treatment of patients with an RC tear is observational and mainly addresses the technical aspects of surgical treatment. As such, these studies have a high risk of bias and cannot be regarded as proof that surgery is effective. The first randomized controlled trial (RCT) comparing surgery to physiotherapy in the treatment of small and medium sized RC tears was published in 2010 (Moosmayer et al., 2010), almost 100 years after the seminal article by E.A Codman. According to the ideology of evidence-based medicine, it is desirable not only to investigate new procedures but also established treatments (Sackett et al., 1996). Especially in surgery, there is a risk that operative traditions are adopted generation by generation without questioning their effectiveness.

The aim of this thesis is to investigate the comparative effectiveness of tendon repair versus the conservative treatment of rotator cuff tears. First, it systematically reviews the current literature on short-term evidence comparing operative versus conservative treatments for RC tears. Secondly, it analyses the mid-term clinical and radiological results of an RCT on the treatment of non-traumatic SSP tendon tears. Thirdly, it compares, using an RCT desing, the effectiveness of supervised physiotherapy and home-based exercises after arthroscopic SSP tendon repair. Finally, it designs and presents a protocol for a randomized, placebo-controlled trial on the efficacy of arthroscopic RC repair in patients with a traumatic SSP tendon tear.

2 Review of the Literature

2.1 Anatomy of the rotator cuff

The RC is composed of four scapular muscles including the subscapularis (SSC), the supraspinatus (SSP), the infraspinatus (ISP) and the teres minor (TM) (Figure 1). All of these muscles are attached to the humerus with distal tendinous portions, which seem to fuse with one another at or near the insertion to form a musculotendinous cuff (Clark & Harryman, 1992). The RC, in other words, can be perceived as a unitary as opposed to a separate structure despite each of the RC tendons having its own footprint at the proximal humerus (Curtis et al., 2006).

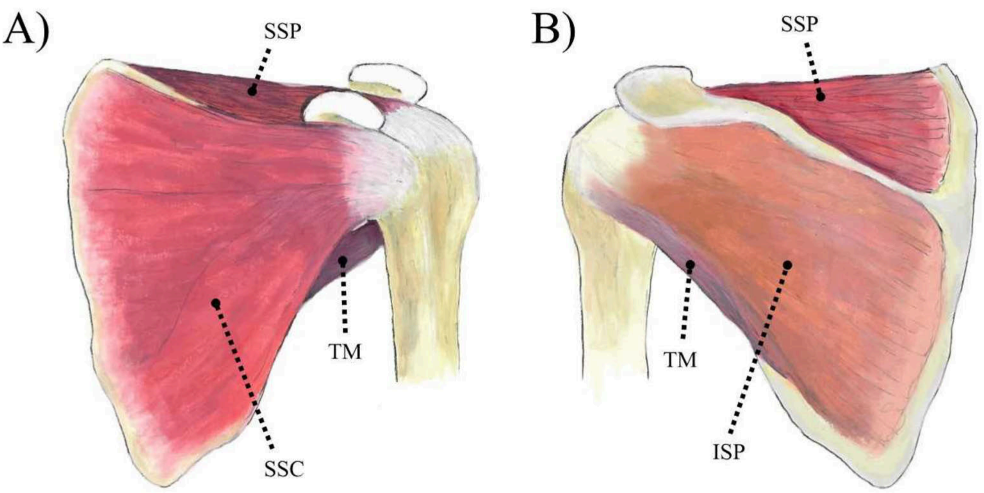


Figure 1. A: Anterior view of the left shoulder. B: Posterior view of the left shoulder. ISP = infraspinatus, SSC = subscapularis, SSP = supraspinatus, TM = teres minor. Illustrations by Essi Takanen (2021).

The SSC muscle arises from the SSC fossa of the scapula and attaches to the lesser tuberosity. The mean cranio-caudal length of insertion is 40 mm (range: 35–55) and medio-lateral width 20 mm (range: 15–25). The most inferior part of the attachment is purely musculocapsular. The distance of insertion from the articular surface is 0 mm superiorly to 18 mm inferiorly (Curtis et al., 2006). The superior part of the tendon's collagen bundles extend laterally to form the floor for the bicipital groove along with interdigitating fibers from the SSP tendon (Clark & Harryman, 1992). The SSC is innervated by the upper and lower subscapular nerves.

The SSP muscle originates from the supraspinous fossa of the scapula and inserts at the greater tuberosity just posterior to the bicipital groove. It is described as having two distinct muscle belly portions, anterior and posterior (Vahlensieck et al., 1994). The muscle of the ISP arises from the medial two-thirds of the ISP fossa of the scapula. Traditionally, as is presented in anatomy books, the SSP and ISP tendons have been thought to have distinct insertions at the greater tuberosity. Minagawa et al. (1998) were the first to demonstrate the overlapping of these two tendons at the footprint by removing the most superficial layer, basically the coracohumeral ligament. The SSP tendon was attached to the superior facet and also the superior half of the middle facet and the ISP tendon to the whole middle facet, covering the posterior half of the SSP tendon from the bursal side. The width of the SSP anteroposterior insertion site was 22.5 ± 3.1 mm (mean ± standard deviation, SD) and 22.8 ± 2.2 mm (mean ± SD) for the ISP. A decade later Mochizuki et al. (2008) noticed the same overlapping of the SSP and ISP tendons but a clear difference in the anteroposterior width of the insertion site, being 12.6 ± 2.0 mm (mean ± SD) for the SSP and 32.7 ± 3.4 mm (mean ± SD) for the ISP. The medial-to-lateral widths were 6.9 ± 1.4 mm (mean ± SD) and 10.2 ± 1.6 (mean ± SD) for the SSP and ISP respectively (Figures 2 and 3).

A slip from the SSP tendon forms a roof over the biceps tendon and is sometimes (in up to 21 % of cases) also inserted into the lesser tuberosity (Clark & Harryman, 1992; Mochizuki et al., 2008). Histologically the tendinous part of the SSP and the ISP are composed of five layers (Clark and Harryman, 1992). Sometimes one can see macroscopically two layers in the SSP or the ISP tendon (Figure 7). The outer layer (bursal sided) is the 'true' tendon and the inner layer (articular sided) is the superior capsule-ligament complex (Pouliart et al., 2007). Both the SSP and ISP are innervated by the suprascapular nerve.

The TM muscle originates from the posterolateral surface of the scapula and inserts at the inferior facet of the greater tuberosity. The mean length of the insertion site is 29 mm (range: 20–40 mm) and width 21 mm (range: 10–33 mm) (Curtis et al., 2006). The most inferior part of the insertion is purely musculocapsular. The TM is innervated by a branch of the axillary nerve.

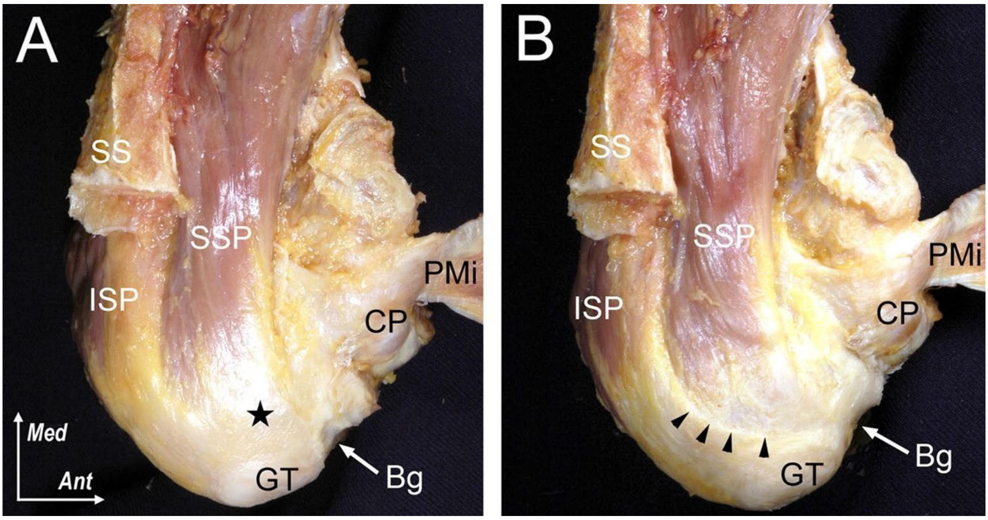


Figure 2. Superior view of the right shoulder (cadaver, acromion has been removed). A: Connective tissue covers the SSP and ISP insertion area (star). B: After removal of the connective tissue, the anterior margin of the ISP (arrowheads) is observed. Bg = bicipital groove, CP = coracoid process, GT = greater tuberosity, ISP = infraspinatus, PMi = pectoralis minor, SS = scapular spine, SSP = supraspinatus, Ant = anterior, Med = medial. Reprinted with permission from Mochizuki et al. (2008).

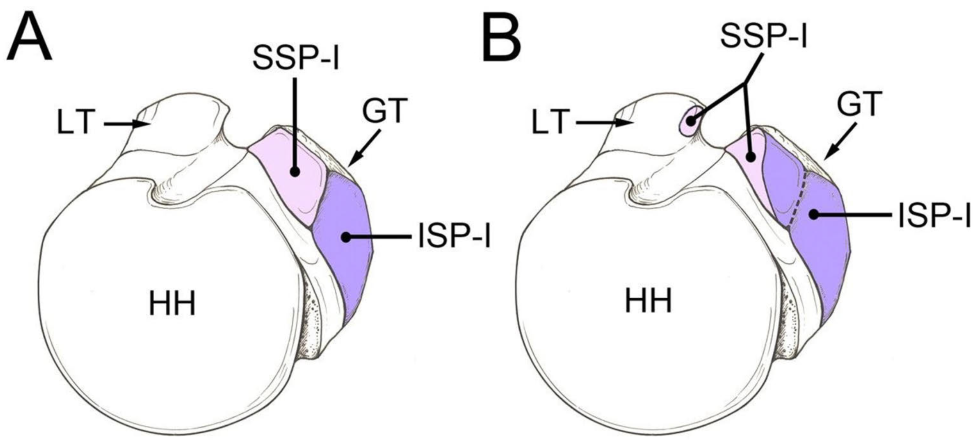


Figure 3. Superior view of the right humeral head showing the insertion areas of the SSP and ISP tendons. A: Traditional concept of the anatomy of humeral insertions. B: An illustration based on latest findings of humeral insertion anatomy. GT = greater tuberosity, HH = humeral head, ISP-I = insertion area of the infraspinatus, LT = lesser tuberosity, SSP-I = insertion area of the supraspinatus. Reprinted with permission from Mochizuki et al. (2008).

2.2 Function of the glenohumeral joint

The glenohumeral (GH) joint, in combination with the acromioclavicular (AC), sternoclavicular and scapulothoracic articulations, provides the greatest range of motion (ROM) of any joint in the human body. Although the glenoid joint surface provides a concavity, with the contribution of cartilage and labrum, it does not provide a constrained osseus socket for the humeral head (Lippitt & Matsen, 1993). In addition to these aforementioned structures, the GH ligaments, with surrounding capsule, form the static stabilizers of the joint. Dynamic stability is achieved primarily by the RC muscles (Lugo et al., 2008). Though, all have their own origin and insertion area, in a healthy shoulder the RC works as a group.

Inman et al. (1996) were the first to introduce the concept of GH force couple in the coronal plane. To establish equilibrium at the GH joint, the cranio-caudal forces must be balanced. Cranial force is generated by the deltoid muscle and caudal forces by the inferior cuff (SSC, ISP and TM). The GH joint is balanced if the line of action of the cuff is inferior to the center of rotation of the humerus, so that it can oppose the counteracting moment created by the deltoid muscle (Inman et al., 1996) (Figure 4B).

Burkhart (1991) extended this originally two-dimensional concept to include a third dimension i.e. the transverse plane. He stated that an equally important force couple in the transverse plane is needed to maintain the fulcrum in equilibrium. The transverse force couple consists of the antagonist muscles of the anterior and posterior cuff. The moment created by the SSC muscle must oppose the moment created by the ISP and TM muscles (Figure 4A). Both force couple concepts are supported by computed tomography (CT) and magnetic resonance imaging (MRI) studies performed on muscle volumes (Bouaicha et al., 2016; Piepers et al., 2014). Strong correlations were found between the anterior (SSC) and the

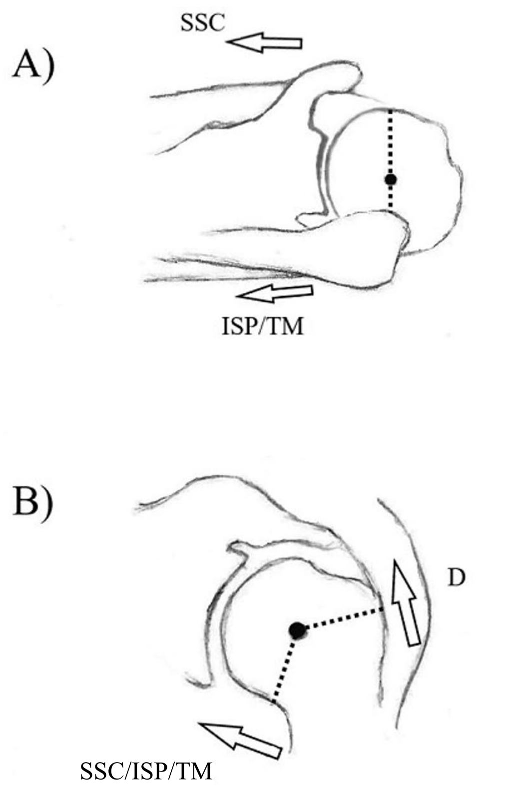


Figure 4. A: Transverse force couple. Superior view of the right shoulder. B: Force couple in the coronal plane. D = deltoid muscle, ISP = infraspinatus, SSC = subscapularis, TM = teres minor. Illustrations by Essi Takanen (2021).

posterior (ISP and TM) part of the transverse force couple muscle volumes and between the superior (deltoid) and inferior (SSC, ISP and TM) part of the coronal force couple. Since the correlation between muscle volume and strength is reported to be strong (Bamman et al., 2000), the forces acting on the GH joint are also assumed to be in balance when the force couple muscles are intact. The SSP muscle is said to be mainly an abductor of the humerus (Inman et al., 1996), but it seems to also have a role as an external rotator (Gerber et al., 2007). It is noteworthy that the SSP muscle has basically no role in the aforementioned force couples. On the other hand, in patients with an isolated SSP tendon tear, the abduction strength decreased 19–33% (Itoi et al., 1997) but according to Ueda et al. (2020) this depends on whether the patient is symptomatic or not. Asymptomatic patients with an SSP tendon tear have greater abduction strength than patients with shoulder symptoms and an SSP tendon tear. Miller et al. (2016) examined patients with shoulder pain and noted that those who had an SSP tear had lower abduction strength compared with those with an intact cuff. It seems that not only the SSP tendon tear but also pain has a role in abduction strength.

In addition, the stability of the GH joint is also affected by the muscles acting away from the shoulder joint itself and the several scapulothoracic muscles, for example, the serratus anterior, latissimus dorsi, pectoralis major, trapezius, levator scapulae and the rhomboids (Lugo et al., 2008). In conclusion, the functional stability and balance of the GH joint is primarily achieved by the neuromuscular control between the scapulathoracic musculature and the RC muscles (Lugo et al., 2008). GH joint balance is achieved when the glenoid fossa encloses the net forces acting on the humeral head (Lippitt & Matsen, 1993).

2.3 Shoulder pain

Shoulder pain is a common symptom in the general population, primary health care and orthopaedic hospital outpatient clinics. It is the third most common reason to visit primary heath care for a musculoskeletal complaint (Rekola et al., 1993). In a systematic review by Luime et al. (2009), the point prevalence of shoulder pain among adults younger than 70 years was 7–27% and for adults older than 70 was 13.2–26%. The 1-month prevalence was 19–31% and the 1-year prevalence was 5–47%. Lifetime prevalence was 7–67%. In another study, the annual cumulative incidence was 2.4 % for adults aged 45–64 years (Djade et al., 2020). The incidence density was estimated to be 17.3, 12.8 and 6.7 per 1,000 person-years for adults in the 45–64 years age group, 65–74 years age group and 75 years and over, respectively.

Even though the majority of shoulder complaints are benign by origin and disappear with time, in a study by Paloneva et al. (2013) only 24% of the patients had recovered at one year after consulting primary health care. RC disorders are thought to be the biggest reason behind the symptom of shoulder pain (Juel & Natvig, 2014; Vecchio et al., 1995; van der Windt et al., 1995; Östör et al., 2005). However, the origin of shoulder pain is still obscure. By ruling out other potential sources of pain (OA, frozen shoulder, pathology of the long head of the biceps, fracture or fracture sequela to mention a few) leaves one with a potential diagnosis of RC tear.

According to a systematic review by Teunis et al. (2014), the overall prevalence of structural abnormalities of the RC increased with age, from 9.7% in patients aged 20 years and younger to 62% in patients aged 80 years and older. The increasing prevalence of these abnormalities were comparable in individuals with or without symptoms in the general population and after shoulder dislocations. The prevalence was so high that they considered RC degeneration (from mild abnormalities to total tears) to be a natural aspect of human aging. In a more recent systematic review, Vincent et al. (2017) noted that the prevalence of self-reported nontraumatic shoulder pain in the general population follows the rising prevalence curve of RC tears, but showed a clear divergence after the age of 65. The prevalence of shoulder pain decreased thereafter, whereas the prevalence of tears continued to increase. With these findings, the authors of the review concluded that degeneration of the cuff should not be considered as the primary source of pain.

2.4 The ethiopathogenesis of rotator cuff tears

The pathogenesis of RC tears is unclear (Dean et al., 2012). Tearing of the RC is considered as beginning at the articular side of the degenerative tendon and evolving from a partial-thickness to a full-thickness tear (already in 1934 by Codman). Classically, ethiopathogenesis is divided into extrinsic (attrition from the surrounding structures) and intrinsic (degeneration within the tendon) theories. However, the ethiopathogenesis of RC tears is complex and seems to be multifactorial with a combination of extrinsic, intrinsic and environmental factors (Lewis, 2009). Furthermore, a traumatic event is often associated with the onset of shoulder symptoms and also the emergence of the tear itself, but many controversies still exist. Here, I present the literature regarding the degenerative changes within the RC tendon and factors that are assumed to predispose to RC tears.

2.4.1 Degenerative changes in rotator cuff tendons

Studies on tendon histopathology have shown that degeneration is involved in tendon tears. Kannus and Jozsa (1991) studied the histopathological patterns of spontaneously torn tendons and found degenerative changes in 97% of cases. The changes included hypoxic degenerative tendinopathy, mucoid degeneration, tendolipomatosis and calcifying tendinopathy, either alone or in combination. Hashimoto et al. (2003) analysed histochemically and morphometrically different-sized cuff tears in 80 patients. Of these, 41% had experienced an obvious traumatic event. Thinning and disorientation of the collagen fibers, myxoid degeneration, and hyaline degeneration were found in all cases. In addition, they identified the degenerative changes chondroid metaplasia, calcification, vascular proliferation and fatty infiltration in 21%, 19%, 34% and 33% of cases, respectively. The first five degenerative changes were thought to be pathological findings in the middle and deep layer of the tendon that existed before the rupture. Vascular proliferation and fatty infiltration, found more on the bursal side, were thought to express reparative changes within the tendon. Heinemeier et al. (2013 & 2018) used innovative carbon-14 bomb pulse method to reveal that human tendon tissue is formed by adolescence and no tissue renewal to healthy tendon is seen after. Tendon tissue turnover after adolescence can happen but the renewed tendon is degenerative.

Reports have highlighted changes in tendon collagen composition. Healthy RC tendons are mainly composed of type I collagen. At the insertion site, the collagen is primarily type II collagen with the ability to resist compressive loads. In torn tendons, the type II collagen levels are decreased and instead, type III collagen levels increased. Type III collagen is associated with tendon healing, and it might be that when type I and II collagen is lacking, the tendon's capacity to withstand loads deteriorates (Nho et al., 2008). In addition, the vascularity of the tendons has been examined and an area of hypoperfusion at the typical SSP tendon tear location has been found (Biberthaler et al., 2003; Levy et al., 2008).

Dean et al. (2012) conducted a systematic review on the histological and molecular changes in RC disease. Across the studies, they observed progressive histological changes and alterations in several molecular biomarkers at the RC tendons. The authors also observed a trend in matrix degeneration, expressed as increased levels of matrix metalloproteinase, and failures in the remodeling of the collagen structure of tendons. In addition, they noted pro-inflammatory changes i.e. high levels of cytokines (for example tumor necrosis factor- α, several members of the interleukin and growth factor family). Several proteins linked with apoptosis were also found in high levels. As increased tendon cell apoptosis affects the tissue homeostasis and compromises the expression of collagen it can eventually predispose the tendon to tear (Maffulli et al., 2011).

Age-related tendon degeneration, alongside chronic microtrauma, may result in partial tendon tears and eventually to full-thickness tears with or without an external traumatic event (Nho et al., 2008). Microtrauma theory is linked to the aforementioned degenerative processes. Repetitive stress focused on the tendon generates small injuries which lack the time to heal before further trauma. As this continues, the tendon weakens and eventually tears with or without a singular external traumatic event (Nho et al., 2008).

2.4.2 Risk factors for rotator cuff tear

In 1972, Neer (Neer, 1972) introduced the chronic impingement syndrome theory whereby the SSP tendon impinges with the acromion and coracoacromial ligament in the forward flexion of the humerus. Eventually, this attrition is presumed to lead to the SSP tendon to tear. In support of this impingment theory, Bigliani et al. (1991) further classified three distinct acromial shapes: type I (flat), type II (curved), type III (hooked) and an association with SSP tears and types II and III acromion. In contrast to these theories, counterarguments have also been published. It might be that age plays a role in the flat acromion developing into a curved and finally hooked shape (Wang & Shapiro, 1997), meaning that an already torn RC increases friction on the acromion eventually shaping it (Maffulli et al., 2011). It has been noted that most partial thickness tears are on the articular side or intratendinous and not on the bursal side where the impingement should have a direct impact (Longo et al., 2011). In line with articular side tearing, an internal impingement theory in turn is proposed (Heyworth & Williams, 2009). A recent systematic review and meta-analysis (Andrade et al., 2019) showed a higher risk (risk ratio, RR = 2.26) for full-thickness RC in patients with a type III acromion but there is no evidence that acromioplasty prevents tear progression (Ranebo et al., 2017). Other bony morphology and morphometry factors, which were moderately associated with full-thickness tears, were a larger critical shoulder angle, higher acromion index and lower lateral acromion angles. Of the studies included, the evidence was limited and many had a high risk of bias.

RC tears are found more often on dominant arms than non-dominant (Yamaguchi et al., 2006); however, up to 36% of those with a tear in the dominant arm also have a tear in the non-dominant arm. On the other hand, according to Harryman et al. (2003) 28% of symptomatic patients have an RC tear in the non-dominant arm only. Furthermore, 70% of full-thickness tears were found in people who performed sedentary work.

Harvie et al. (2004) used a cohort of patients with a full-thickness RC tear to examine the prevalence of cuff tears in siblings and used spouses as controls. The RR of symptomatic full-thickness tears was 4.65 in the siblings versus controls. In support of this, a recent systematic review found preliminary evidence for a link between genetics and a familial predisposition to RC tears (Longo et al., 2019).

A systematic review on the risk factors for RC tears identified five factors that had statistically significant odds ratios (ORs) (Sayampanathan et al., 2017). These factors were age above 60 years (OR = 5.07), dominant hand (OR = 2.3), obesity (OR = 2.35), smoking (OR = 1.74), and hypertension (OR = 1.93). Only the older age and hand dominance were considered by the authors to be associated with RC tears as the number of included studies and subjects were limited. Bishop et al. (2015) conducted a systematic review focusing only on smoking as a risk factor for RC pathology and found smoking to be associated with a higher prevalence of shoulder disabilities, RC degeneration, larger tears and tears at a younger age but mixed results with the overall prevalence of RC tears. After the aforementioned systematic review, one study showed a higher risk for RC tears in patients with depression (Kuo et al., 2019).

A history of shoulder trauma is a risk factor for RC tears according to a large prevalence study (Yamamoto et al., 2010). There is a clear trend of more full-thickness RC tears in patients with pain and difficulties in arm movements after shoulder trauma than is the prevalence of tears in the general population (Figure 5).

2.5 Prevalence and incidence

Screening studies have revealed a high prevalence of full-thickness RC tears, both in asymptomatic and symptomatic people. Two mass screening studies conducted for the residents of a village in Japan (Yamamoto et al., 2010; Minagawa et al., 2013) revealed the true prevalence of a full-thickness RC tear to be 22% in the whole population with a clear increase of prevalence with age (Figure 5). The majority of (65%) were asymptomatic. In the case of detected unilateral RC tears, there is an increased risk of also having a tear in the contralateral shoulder. Of the patients who have a symptomatic RC tear and were scheduled for surgery, 39–67% had an RC tear in their contralateral shoulder with a 16–19% prevalence of a full-thickness tear (Liem et al., 2014; Ro et al., 2015). Yamaguchi et al. (2006) examined patients with unilateral shoulder pain and found 35.5% prevalence of a full-thickness tear on the asymptomatic shoulder. The likelihood of having a bilateral tear after the age of 66 years was 50%.

Because of the relatively high prevalence of asymptomatic tears, the true prevalence or incidence of traumatic RC tear is difficult to study without a reference imaging study. In other words, there is no actual certainty that the RC tear, especially SSP, seen after shoulder trauma is a new finding since the majority of nontraumatic RC tears are located in the SSP tendon 9–17 mm posterior to the long head of the biceps tendon (Jeong et al., 2018; Kim et al., 2010). However, the prevalence of full-thickness RC tears is estimated to be 23% to 32% in patients who have had a normal shoulder radiograph and have been unable to lift their arm normally after having a shoulder trauma (Aagaard et al., 2015; Sørensen et al., 2007) (Figure 5). The annual incidence of full-thickness RC tear after traumatic event is estimated to be 10–16 per

10^5 inhabitants for the population of 18–75 years and 23–25 per 10^5 for the population of 40–75 years (Aagaard et al., 2015; Enger et al., 2018). Liu et al. (2017) did in their study bilateral MRI to patients with unilateral shoulder pain after work-related injury. On average, structural changes on symptomatic shoulders were not worse compared to the asymptomatic shoulders.

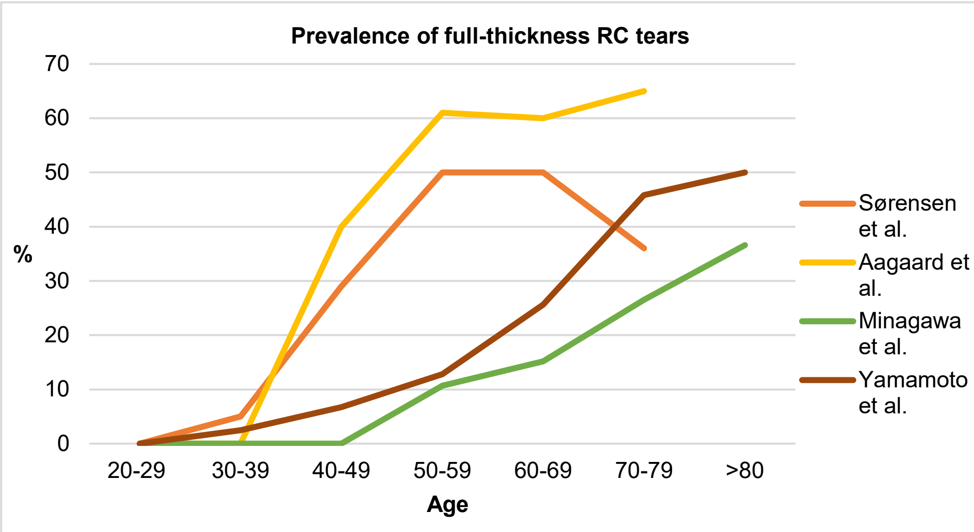


Figure 5. Prevalence of full-thickness RC tears by age in the general population from mass screening studies of Minagawa et al. (n = 664) and Yamamoto et al. (n = 683) and in patients after acute shoulder trauma with pain and limitations in active abduction by studies of Sørensen et al. (n = 104) and Aagaard et al. (n = 259). Own drawing, data derived from the included studies.

In a study by Minagawa et al. (2013), the overall RC tear prevalence of 22% was presented per subject, and there were some patients with bilateral tears. If the prevalence is presented instead per shoulder the overall prevalence rises to 31% and of those tears 45% were single tendon SSP tears and the rest were combined SSP and ISP tears. In contrast, in a study by Aagaard et al. (2015), single tendon SSP tears accounted for only 18% of the traumatic tears in the study. Isolated SSC tears and combined SSP with SSC tears were found in 22% and 23% of cases, respectively. SSP with ISP tears were detected in only 15% of cases.

2.6 Clinical manifestation

The clinical manifestation of a full-thickness RC tear varies widely (Duckworth et al., 1999). The tear can be asymptomatic, the beginning of symptoms may me sudden (usually after a shoulder trauma) or gradual. Even if an RC tear is asymptomatic, it is not usually without objective clinical findings in larger tears. Kim et al. (2009) showed that asymptomatic individuals with an RC tear over 3 cm in width had significantly decreased abduction and ER strength in relation to individuals with an intact cuff, but this might not be the case for smaller tears (Mall et al., 2010). In turn, patients with an asymptomatic SSP tendon tear had a greater shoulder ROM and abduction strength than patients with a symptomatic SSP tendon tear (Ueda et al., 2020).

An RC tear is called chronic degenerative i.e. nontraumatic when there is no previous shoulder trauma that precedes the symptoms. Patients with nontraumatic tears usually experience a gradual onset of shoulder pain (typically in the lateral aspect of the proximal humerus), night pain, shoulder discomfort and weakness, also crepitus on active movements can be present (Matsen, 2008; Yamamoto et al., 2011). Whereas the definion for a nontraumatic RC tear is clear, it is not the case for acute or traumatic tears (Pogorzelski et al., 2021). No universal consensus exists on when to use the term traumatic RC tear. Tears of the RC are usually called traumatic if they are detected after adequate trauma in a previously asymptomatic shoulder with a sudden onset of symptoms of pain and strength.

On clinical examination, atrophy of the SSP and/or ISP can be noticed through inspection. Palpation at the RC insertion site may reveal a defect or a crepitance (Matsen, 2008). Weakness or pain on isometric testing of an individual RC muscle may indicate a tear. When these symptoms are observed in abduction, external rotation, and internal rotation, an SSP, ISP and SSC tear involvement may be suspected, respectively (Matsen, 2008). The size of the RC tear does not correlate with pain (Dunn et al., 2014). On the contrary, factors not related to RC anatomy like mental health, age, sex and comorbidities seem to be associated with pain. The size of an RC tear correlates with shoulder malfunction, at least when the entire tendon is affected. Collin et al. (2014) divided tear patterns into five types according to the involved tendon components: type A: SSP and superior SSC tears; type B: SSP and entire SSC tears; type C: SSP, superior SSC, and ISP tears; type D: SSP and ISP tears; and type E: SSP, ISP, and TM tears (Figure 6). All of the patients with type A tear had a normal active range of anterior elevation and ER. Only 2.9% of patients with a type D tear had pseudoparalysis (an active anterior elevation less than 90^{o} with preserved passive motion), but when also the TM was affected (type E), 33% had a pseudoparalysis. Of patients with a type C, 45% had pseudoparalysis and as much as 80% of the patients with a type B tear.

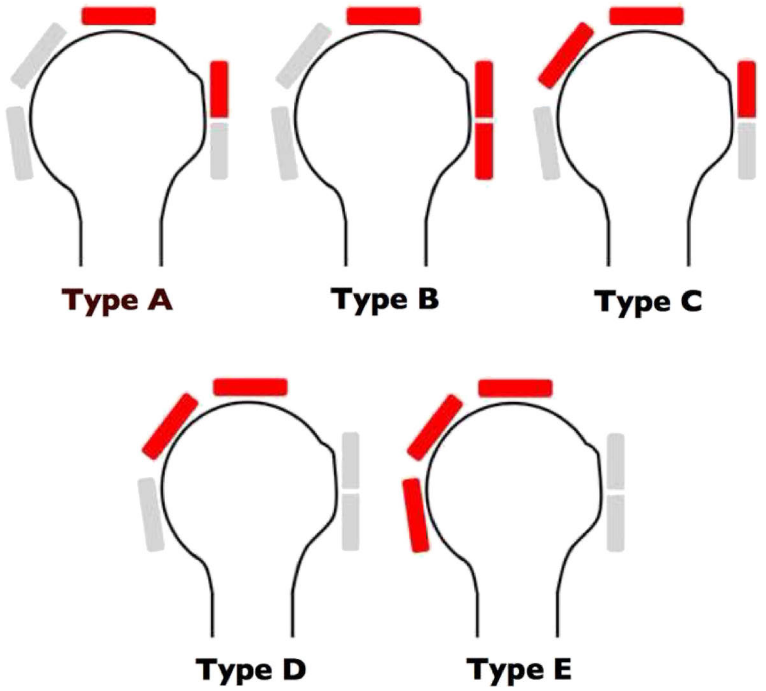


Figure 6. RC tears classified by the involved components: type A, SSP and superior SSC tears; type B, SSP and entire SSC tears; type C, SSP, superior SSC, and ISP tears; type D, SSP and ISP tears; and type E, SSP, ISP, and TM tears. ISP = infraspinatus, SSC = subscapularis, SSP = supraspinatus, TM = teres minor. Reprinted with permission from Collin et al. (2014).

These results emphasize the important role of SSC and TM on shoulder function and also the role of ISP when the SSC is affected, in accordance with the previously described force couple theories.

Gerber et al. (2007) investigated the clinical manifestation of a 'true' acute posterosuperior RC tear. They performed a controlled nerve block of the suprascapular nerve to induce combined SSP and ISP or ISP-only palsy. The results showed that paralysis of the SSP and ISP led to a loss of ER strength of approximately 80% and a loss of abduction strength of approximately 75%, and in a case of ISP alone, a loss of strength of 70% and 45%, respectively. To speculate, in a normal shoulder with an acute SSP and ISP tear the only external rotator left is the TM and it, hereby, generates 20% of the strength of a normal ER. It seems that in an isolated total SSP tear, the abduction strength might decrease by 30%. On the other hand, this loss of power seems to be temporal even if not operated. With time and exercise, the TM muscle will hypertrophy and ER strength increases in patients with combined SSP and ISP tears (Kikukawa et al., 2016). In patients with isolated SSP tears, the abduction strength also increases with only physiotherapy (Kukkonen et al., 2014).

2.7 Diagnosis

Given that RC tears are a common finding in imaging studies in asymptomatic population, it is important that also other methods than imaging are used to diagnose and make clinical decision about treatment. Usually, careful history taking, a meticulous clinical examination and a simple radiograph are enough to advocate treatment. Other conditions must be considered such as tendinosis/tendinitis, shoulder instability, OA of the GH and AC joint, a frozen shoulder, pathology of the long head of the biceps, a tumor, cervical radiculopathy and a fracture or fracture sequela (Brox, 2003). It is noteworthy that the aforementioned conditions do not rule out the existence of an RC tear, but the clinical significance of a concomitant RC tear may be questioned. If the diagnosis is unclear or surgery is considered, more sophisticated imaging modalities such as CT or MRI scans should be carried out.

2.7.1 Clinical tests

More than 180 physical-examination tests of the shoulder are described in the literature (Gismervik et al., 2017). However, here I only report on the tests most commonly used at the upper extremity unit of Turku University Hospital and in the literature. The specific tests for RC muscles evaluate the individual RC muscles by testing their isometric strength and/or ability to maintain a maximum internal or external rotation position (lag sign tests). Strength is always compared to the unaffected contralateral side. The accuracy of a single test is usually expressed as values of sensitivity (the proportion of those patients who have a full-thickness tear, and received a positive result for the test, from the whole group of patients with a full-thickness tear) and specificity (the proportion of those patients who do not have a full-thickness tear, and received a negative result for the test, from the whole group of patients without a full-thickness tear).

Different tests are used to test different RC muscles and they differ in sensitivity and specificity. The Jobe (Jobe & Moynes 1982) or empty can test (SSP test) has obtained the highest diagnostic odds ratio (DOR = 9.24) to detect any full-thickness RC tear with a sensitivity of 74% and specificity of 77% (Gismervik et al., 2017). Shoulders with an isolated SSC tear usually have increased (passive) external rotation and decreased internal rotation strength (Gerber & Krushell, 1991). Several muscles assist internal rotation strength (e.g. the pectoralis major, latissimus dorsi and teres major) of the shoulder. This explains why it is difficult to carry out specific tests to isolate and test the strength of the SSC. The belly press test for SSC tears has a sensitivity of 75–80% and specificity of 88–97%. The lift-off test (Gerber & Krushell, 1991) has a sensitivity of 79 % and specificity of 59% (Itoi et al., 2006). The Internal Rotation Lag Sign (Hertel et al., 1996) has a sensitivity of 100% and specificity of 84%. The ISP and TM are the only external rotators of the shoulder and are usually tested in combination. The Resisted ER/ISP test has a sensitivity of 84 % and specificity of 53% (Itoi et al., 2006). The External Rotation Lag Sign (ER1) (Hertel et al., 1996) for a combined SSP and ISP tear has a sensitivity of 35–46% and specificity of 89–94% (Hegedus et al., 2012). The test for assessing the TM is the Patte or Hornblower's sign which has a sensitivity of 93% and a specificity of 72% (Collin et al., 2015). The most accurate test for the TM seems to be an external rotation lag sign greater than 40^{O} (sensitivity of 100% and specificity of 92%). Because of quality issues in publications, it is not strongly recommended to use a single test to diagnose a full-thickness tear (Hegedus et al., 2012). Instead a combination of tests and other clinical parameters may increase the reliability of diagnosing an RC tear (Lädermann et al., 2021; Hegedus et al., 2015).

Few studies have investigated the value of clinical examination tests in the acute phase of shoulder injury to detect full-thickness RC tears (Bak et al., 2010; Schmidt et al., 2021). According to the results of these studies, the inability to abduct the arm to over 90 ^{o} and decreased abduction and external rotation strengths were reliable methods, not pain assessment. The ability of these tests to identify truly traumatic tears (and not pre-exixting nontraumatic tears) may be questioned because 98% of the tears were located in the SSP.

2.7.2 Imaging

2.7.2.1 Radiographs

A plain radiograph taken in a standing position is a basic examination to rule out other specific GH related conditions, for example OA, a tumor, dislocations, a fracture or fracture sequela. A radiograph can also show calcium deposits, calcific tendinitis or OA of the AC joint. In a radiographically normal shoulder, the proximal humerus is located congruently in regard to the glenoid. Although a simple radiograph only shows the bony structures, it can indirectly reveal an underlying RC tear as incogruency of the GH joint. The cranio-caudal congruency of the GH joint can be analyzed by plain antero-posterior shoulder radiographs according to Hamada et al. (1990). This classification initially comprised 5 grades based on the measurement of the acromiohumeral interval (AHI) and the presence of additional degenerative changes. Since the original classification, more grades have been proposed (Walch et al., 2005): stage 1, an AHI greater than 6 mm; stage 2, an AHI less than 7 mm; stage 3, an AHI less than 7 mm with acetabulization of the acromion; stage 4a, an AHI less than 7 mm with GH arthritis without acetabulization; stage 4b, an AHI less than 7 mm with acetabulization and glenohumeral arthritis; stage 5, an AHI less than 7 mm with osteonecrosis of the humeral head. A Hamada grade 2 or above is specific for the presence of an RC tear (at least the combination of SSP and

ISP) with more advanced fatty degeneration (FD) of the cuff muscles. In addition, there seems to be a negative correlation between the AHI and the size of the RC tear, the smaller the AHI, the larger the tear (Goutallier et al., 2011). Usually changes above Hamada grade 1 are referred as cuff tear arthropathy (CTA).

Samilson et Prieto (1983) graded the severity of GH OA radiologically on the basis of osteophyte size according to three grades. Grade 1 refers to an inferior humeral or glenoid osteophyte, or both, which is less than 3 mm in height. Grade 2: refers to an inferior humeral or glenoid osteophyte, or both, which is between 3 and 7 mm in height, with a slight GH joint irregularity. Grade 3 refers to an inferior humeral or glenoid osteophyte, or both, which are more than 7 mm in height, with a narrowing of the GH joint and sclerosis.

Futile attempts have been made to identify differences in the features of plain radiographs (for example acromion morphology, sclerosis or the greater tuberosity or AHI) between traumatic and nontraumatic MRI verified tears (Loew et al., 2015).

2.7.2.2 Ultrasound

Ultrasound (US) is a non-invasive diagnostic imaging technique with no known adverse events and the capacity to dynamically visualize the RC tendons during shoulder motion (Al-Shawi et al., 2008). Although relatively inexpensive and easily performed at an outpatient clinic, it is very operator dependant and has a long learning curve (Rutten et al., 2006). The sensitivity and specificity of US for detecting full-thickness RC tears is reported to be 92 and 93%, respectively (Lenza et al., 2013).

2.7.2.3 Computed tomography

MRI and MR arthrography are the gold standard for diagnosing suspected RC tears, at least in Scandinavia. In the case of contraindication for MRI, CT arthrography can be used, which is comparable to MRI in terms of sensitivity and specificity when detecting a full-thickness RC tear (Charousset et al., 2015; Omoumi et al., 2012). The FD of the RC muscles, can be evaluated using CT according to Goutallier et al. (1994). They categorized the amount of contrast negative fat in sagittal muscle cuts according to 5 grades: grade 0, normal muscle; grade 1, muscle containing some fatty streaks; grade 2, FD, but still more muscle than fat; grade 3, equal amounts of fat and muscle; grade 4, more fat than muscle is present.

2.7.2.4 MRI and MR arthrography

MRI is a non-invasive imaging method which can produce high resolution static-cut images in multiple planes and directions. However, several factors should be considered pertaining to the MRI. First, the patient must lie still in a tube in a supine position for a period of time which can cause noncompliance. In an attempt to enhance diagnostic accuracy intra-articularly injected contrast agent can be used (magnetic resonance arthrography, MRA). MRI and MRA are also relatively time consuming. Furthermore, some contraindications exist related to the imaging method, for example aneurysm clips, cochlear implants, neurostimulation systems and some pacemakers (Dill, 2008). For full-thickness tears the sensitivity and specificity of MRI and MRA, were 94% and 93%; and 94% and 92%, respectively (Lenza et al., 2013).

The quality of the RC muscles can be assessed using MRI to evaluate the degree of fatty streaks in the muscle. The original classification by Goutallier et al. (1994) was adopted and further developed by Fuchs et al. (1999) to apply to MRI imaging. The evaluation is carried out on the parasagittal plane with a T1-weighted sequence where fatty streaks appear white. On the same plane, the presence or absence of SSP muscle volume atrophy can be identified as a tangent sign (Zanetti et al., 1998).

It is difficult to estimate the acuteness of an RC tear based on any imaging modality (Loew et al., 2015; Teefey et al., 2000), especially when there is no present FD. On the other hand, if imaging studies taken within a short period of time post trauma, show a marked FD of the affected muscle, the tear is usually regarded as old and thus not related to trauma. In a study by Loew et al. (2015) 50 patients with a full-thickness RC tear were investigated to find out specific features in the MRI that could distinguish traumatic and nontraumatic tears. The first group comprised patients who had had a shoulder trauma within 6 weeks and had not experienced shoulder pain previously (traumatic RC tear group). The second group comprised patients with long-standing shoulder pain with no history of trauma (nontraumatic RC tear group). Edema at the musculotendinous junction was more frequently found in the traumatic than nontraumatic group, 38% versus 4% (the sensitivity was 63% and the specificity 96%). Kinking of the lateral part of the affected muscle was found in 64% of traumatic and 32% of nontraumatic cases. Slightly more muscle atrophy and a positive tangent sign were found in the nontraumatic RC group. Between the two groups, no differences were identified in the measurement of tendon retraction, signs of effusion in the subacromial bursa, the occurrence of bone bruises or degenerative features like cysts or cortical sclerosis. In about half of all the cases, a residual tendon stump at the greater tuberosity was observed.

2.8 Classifications of full-thickness tears

Tears of the RC are divided into chronic degenerative (nontraumatic), acute-on-chronic and acute (traumatic). Without a preceding shoulder trauma, the observed RC tear is called nontraumatic. The literature classifying RC tears is inconsistent on which tears should be called traumatic (Loew et al., 2015; Pogorzelski et al., 2021). The proposed criteria relate to the timing of symptoms and the appearance of the tear in imaging studies. As there is a high prevalence of RC tears in the general population, the concept of traumatic tears is challenging; it may be that the detected RC tear is in fact a previously existing asymptomatic tear, and the cause of symptoms is just a simple sprain or contusion irrespective of the tear. On the other hand, it can also be that the underlying asymptomatic tear becomes larger, even due to a minor trauma (e.g. lifting a heavy object) making it symptomatic (acute-on chronic-tear). There is a dire need for RC-tear terminology to be standardized to distinguish traumatic tears from other types of tear. One suggestion is that the word traumatic refers to tears with an adequate traumatic event that initiates the symptoms. These traumatic events may be, for example, falling onto an outstretched arm, attempting to break a fall on a staircase by holding the handrail, or dislocating a shoulder (Pogorzelski et al., 2021).

The most common type of RC tear is the disruption of the lateral tendon stump. The tendon can also avulse with a bone chip at the insertion site. This can be seen on imaging studies as a fracture of the lesser tuberosity (avulsion of the SSC) or a fracture of the greater tuberosity (avulsion of the SSP, ISP and TM). Another rare tear type is a lesion at the musculotendinous junction, which is predominantly seen in the ISP region (Walch et al., 2009). There are six main classification systems for RC tears (Kuhn et al., 2007; Lädermann et al., 2017): according to size, shape, configuration, the number of tendons involved, the extent and topography in the sagittal and frontal planes. The size of the tear can generally be classified as small (<1 cm), medium (1–3 cm), large (3–5 cm) and massive (>5 cm) (DeOrio & Cofield, 1984). A massive RC tear can also be classified as a tear with two or more tendons involved (Cofiel, 1982; Gerber et al., 2000). The pattern of a posterosuperior (SSP and ISP) tear can be classified as cresent, L- and reverse L-shape, and U-shape tears (Davidson & Burkhart, 2010). The unique tear characteristics of SSC have been described by Lafosse et al. (2007) Tendon retraction can be staged according to Patte (1990) based on the level of the lateral tendon edge: stage 1, little retraction; stage 2, at the level of the humeral head; stage 3, at the level of the glenoid.

After RC repair, the integrity of the repaired tendon can be classified using MRI (T2-weighted sequence) according to Sugaya et al. (2005) using 5 categories: type I, sufficient thickness with homogenously low intensity; type II, sufficient thickness with partial high intensity; type III, insufficient thickness without discontinuity; type IV, presence of a minor discontinuity in only 1 or 2 slices on both oblique coronal and sagittal images, suggesting a small full-thickness tear; type V, presence of a major discontinuity (observed in more than 2 slices on both oblique coronal and sagittal images) suggesting a medium or large full-thickness tear.

2.9 Treatment of rotator cuff tears

2.9.1 Conservative treatment

The conservative, i.e. non-surgical, treatment for full-thickness RC tears includes a variety of treatment options. These are analgesics, NSAIDs, corticosteroid injections, education, manual therapy and exercise therapy (Boudreault et al., 2014; Gialanella & Prometti, 2011; Page et al., 2016). Usually, a combination of therapies with or without medication are referred to as conservative treatment or physiotherapy. The aim of therapy is to diminish pain and disability, promote healing, strengthen the periscapular musculature and improve the stabilizing function of the rotator cuff (Brantingham et al., 2011; Littlewood et al., 2012). Most studies regarding physiotherapy for subacromial pain have excluded patients with RC tears, but it seems that these patients can be managed using the same principles: education and individualized, progressive exercise therapy (Boland et al., 2021; Jeanfavre et al., 2018).

A Cochrane review (Page et al., 2016) evaluated the effectiveness of manual therapy and exercise, alone or in combination, for RC disease and concluded that no clinical benefit exists over placebo or other interventions. However, evidence from a recent systematic review (Jeanfavre et al., 2018) moderately supported the use of exercise therapy in the management of full-thickness RC tears. The review included 35 studies from which the exercise and rehabilitation programmes varied substantially. The components of the therapy programmes that were included in over 50% of the studies were strengthening (97% of studies), ROM (79% of studies), stretching/flexibility (61% of studies) and education (57% of studies). The conclusion of this study can be questioned since only 9 out of 35 studies were RCTs and they looked only the change of outcome within the nonoperative groups. A recent RCT questioned the need for progressive exercise (up to 6 physiotherapy sessions) in patients with rotator cuff disorder (Hopewell et al., 2021).

2.9.2 Rotator cuff repair

Alexander Monro is noted as the first to have described RC tears in his 1788 book "A Description of All the Bursal Mucosae of the Human Body" (Randelli et al., 2015). The first re-attachment of torn rotator cuff tendons to the humeral diafysis after humeral head resection in a case of chronic dislocation was performed by Karl

Hüter in 1870, and in 1898 Wilhelm Müller repaired torn tendons on the humeral head during an operation for shoulder stabilization. A milestone for RC surgery was Codman's 1911 presentation of operative treatment on a torn SSP tendon using transosseous sutures (Codman, 2011). Five years before Codman, a German surgeon, George Perthes, published a series of three RC repairs in which he used suture anchors. After the introduction of X-rays in 1895, the identification of fractures, dislocations and calcifications could be done non-invasively. Until the introduction of contrast medium arthrography, the suspicion of a cuff tear was based on the clinical assessment only.

The second milestone in rotator cuff surgery after Codman was the 1972 article by Charles Neer (Neer, 1972) in which he reported the results of RC repair combined with anterior acromioplasty. The torn tendon was identified and released from its adhesions. After preparation of the insertion area, the tendon was fixed into place with sutures through bone tunnels or by suture anchors.

After the development of arthroscopy, Levy et al. (1990) described an arthroscopic-assisted technique for RC repair. Via arthroscopy, the surgeon could inspect the structures (Figure 7), release the torn tendon and perform the acromioplasty. The lateral portal could be extended and RC repair done using a mini-open approach without detaching the deltoid. The beginning of the 1990s witnessed the era of all-arthroscopic RC repair (Snyder, 1993; Thal, 1993).

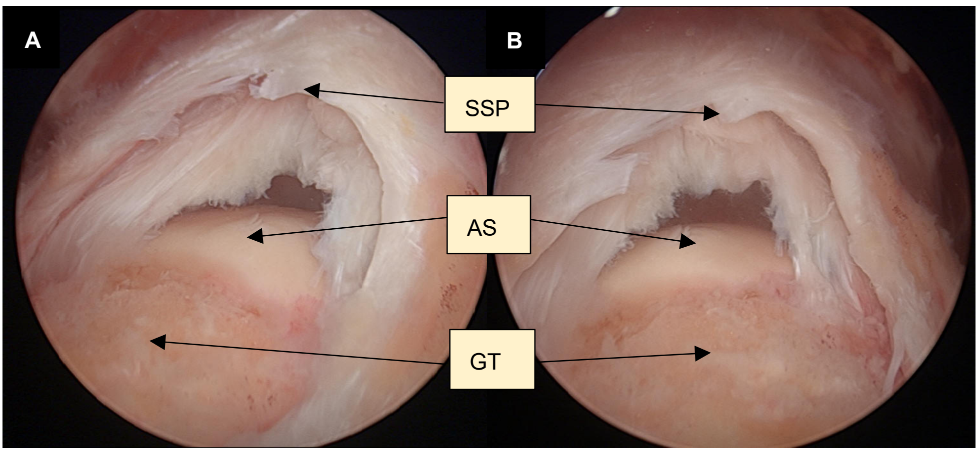


Figure 7. Arthroscopy view of a torn SSP tendon of the left shoulder. **A**. View from the postero-lateral portal. **B**. View from the lateral portal. AS = articular surface of the humeral head, GT = greater tuberosity, SSP = supraspinatus. Own collection.

In an arthroscopic RC operation, the patient is either in a beach-chair or a lateral decubitus position, and a traction is usually applied to the operating arm. A standard posterior portal is used to visualize the GH and subacromial space. To visualize the tear pattern and to protect the repaired tendon, a bursectomy and acromioplasty are commonly carried out, but the need for acromioplasty as a concomitant procedure is questionable (Sayampanathan et al., 2021). If necessary, the torn tendon is mobilized, and the footprint area of the involved tendon is prepared. The first published series were reconstructions of SSP tendons, which were re-attached using one or two anchors placed a few millimeters lateral to the footprint (Tauro, 1998). Both single and mattress suture configurations were used, referred to as a single row repair (Figure 8A.). In this technique, the suture anchor is placed into the bone at an over 45° angle to restrict the pullout strengths (Burkhart, 1995). To cover the whole footprint area and potentially enhance the biomechanical healing properties, a double row technique was developed (Figute 8B.) (Lo & Burkhart, 2003). In this technique, the first row of anchors is placed medially on the footprint, near the articular surface, and mattress type of sutures are passed through the tendon. A second row is placed more laterally and passed through the part of the tendon and tied in a simple suture fashion. Numerous repair methods have been used since. One modification of the double-row configuration is the ’’suture bridge’’ or ’’transosseous-equivalent’’ technique (Figute 8C.) (Park et al., 2006). In this technique, the medial row of anchors and mattress sutures are done in a similiar fashion as in the double row technique. The knots are tied, but the sutures are not cut. The free suture limbs are then attached to the bone lateral to the footprint to create suture bridges over the tendon.

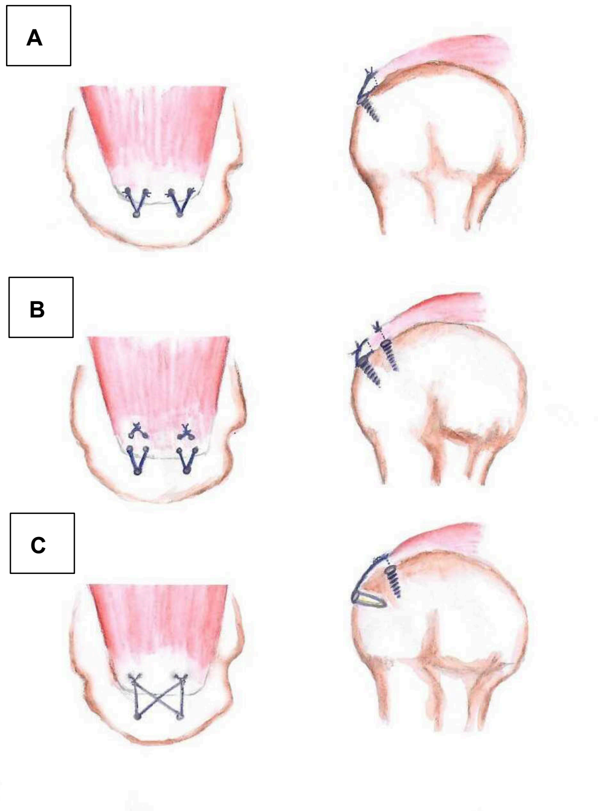


Figure 8. Examples of tendon repair methods. **A**. Single row. **B**. Double row. **C**. Suture bridge or transosseus equivalent. Illustrations by Essi Takanen (2021).

In the case of a retracted RC tear that cannot be reattached to the anatomical footprint, especially in large tears, a partial repair can be implemented. The father of this concept, Stephen Burkhart, introduced the theory and published a patient series in which restored transverse force couple (SSC and ISP) led to decreased pain and improved the ROM of the shoulder (Burkhart 1994 & 1997; Burkhart et al., 1994).

During the last few decades, the incidence of RC repair, especially arthroscopic RC repair, to treat patients with RC tears has increased significantly in Europe and the United States (Colvin et al., 2012; Ensor et al., 2013; Judge et al., 2014).

2.9.2.1 Postoperative rehabilitation

The usual aftercare of RC repair includes sling immobilisation, passive ROM exercises and gradual progressive active exercises (Jung et al., 2018). Due to a lack of high- quality studies, no consensus exists regarding the duration for arm immobilization, the type of physiotherapy and the need for supervision. The reason for immobilization in the first weeks is to protect the tendon during the healing process while avoiding prolonged immobilization, which can lead to shoulder stiffness. According to the current literature, the need for sling immobilization is questionable, and early active motion is encouraged in patients with small to medium sized tears, with no difference in outcomes in the short term between no sling and sling immobilization up to 6 weeks (Mazuquin et al., 2018; Sheps et al., 2019; Tirefort et al., 2019). Traditionally, a postoperative rehabilitation programme is carried out based on several guidance and control visits, so-called supervised physiotherapy. However, the optimal extent and benefits of supervision are not known (Longo et al., 2020).

2.9.3 Alternative surgical procedures

The RC tear may be irreparable if the lateral edge of the torn tendon cannot be securely fixed to its native footprint. Some chronic non-traumatic tears can be repaired. However, if there is extensive FD and atrophy of the cuff muscles there is a risk that the repaired tendon will not heal or regain function (Jeong et al., 2018). The term functionally irreparable rotator cuff tear (FIRCT) was introduced to characterise patients fitting this clinical scenario (Burnier et al., 2019).

There are numerous techniques to treat patients with FIRCT surgically. After tenotomy of the long head of the biceps tendon, patients report better function (Walch et al., 2005) but it is unclear if this is related to the tenotomy itself. There are currently no RCTs to support or refute this hypothesis. In addition, acromioplasty is hypothesized to relieve the symptom state (Zvijac et al., 1994), but as the results of study II showed, no difference was observed when compared to physiotherapy. A biodegradable balloon spacer has been developed to treat patients with FIRCT. It is implanted to the subacromial space and inflated to a balloon to resist the cranial forces of the humeral head and thus minimize subacromial attrition (Senekovic et al., 2013). However, the results are conflicting and relatively high complication rates have been observed in some series (Viswanath & Drew, 2021). Some innovative methods have been introduced to reconstruct the cuff defect. Interposition grafting with human acellular dermal matrix allograft is a possible technique to fix the RC tendon remnant to the greater tuberosity (Bond et al., 2008). Mihata et al. (2013) introduced superior capsular reconstruction. In this technique, the superior capsule is reconstructed using a fascia lata autograft, fixed medially to the glenoid and laterally to the greater tuberosity, to oppose the superior migration of the humerus and its friction with the acromion. Eventually mobility is enhanced and pain decreases. Since then, techniques using a dermal allograft to reconstruct the superior capsule have been published (Denard et al., 2018). These techniques have been studied only in observational studies thus the benefits are completely unknown (Haque & Modi, 2021).

Tendon transfers is an alternative for young and active patients with FIRCT. The idea is that by restoring the force couples around the shoulder, function improves. The muscles and tendons have been used for transfers are the latissimus dorsi, teres major, lower trapezius and pectoralis major (Adam et al., 2021). The true value for these aforementioned joint-preserving surgical innovations is unknown since the improvement noticed rely on observational studies only (Burnier et al., 2019). For older people with irreparable RC tears, reverse shoulder arthroplasty is a solution to restore function and diminish pain, but evidence on its effectiveness is lacking (Sevivas et al., 2017).

2.10 Outcome measures

In orthopaedics the outcome or effectiveness of a treatment were for a long time based on purely so called objective outcomes, known as clinician reported outcome measures (CROMs). These can be divided into performance-based, like strength and ROM; the clinician reported status of the patient, for example poor, good or excellent; or radiological outcome, for example re-tear rate. Although performance-based measures are part of a treatment outcome, they fail to fully account for the patient's perspective. In response to this, subjective measures were developed i.e. patient-rated outcome measures (PROMs). These can be divided into generic health-related quality of life instruments-, and limb-, joint- and disease-specific outcome instruments. The most recent development is to additionally measure the patients' experience throughout the episode of care (patient-reported experience measure, PREM) (Bull et al., 20219).

In the literature concerning RC tears, shoulder- and disease specific instruments are mainly used. To assess the results of a study, knowledge of the properties of a specific instrument is necessary. The most important properties of an outcome instrument are validity, reliability and responsiveness (Mokkink et al., 2010). An instrument is considered valid if it measures what it was intended to measure. Reliabity is the extent to which an instrument yields the same results on repeated measurements in patients with a stable status for the condition in question. Responsiveness is the ability of an instrument to detect change over time. An important feature of an instrument's interpretability is the concept of minimal clinically important difference (MCID) (Jaeschke et al., 1989). This refers to the smallest change in a score that the patient would consider clinically meaningful or important.

The most often used limb-specific outcome instrument is the Disabilities of the Arm, Shoulder and Hand (DASH) (Hudak et al., 1996) which consists of 30 items and a score range from 0 to 100. The MCID for DASH is reported to be 10.2 (Hao et al., 2019).

The Constant score (CS) (Constant & Murley, 1987) is the most widely used shoulder-specific outcome instrument in Europe, despite its limitations (Constant et al., 2008; Henseler et al., 2015; Kirkley et al., 2003). The CS is a 100-point scoring scale including both subjective and objective measurements and is divided into 4 domains (pain, 15 points; activities of daily living, 20 points; ROM, 40 points; and strength, 25 points). The reported MCID for CS in patients with a full-thickness RC tear is between 10.4 and 15 points (Holmgren et al., 2014; Kukkonen et al., 2013b). Other shoulder-specific instruments used in the literature are, for example, the American Shoulder and Elbow Society Score (ASES), the University of California-Los Angeles End-Result Score (UCLA), the Oxford Shoulder Score (OSS), the Shoulder Pain and Disability Index (SPADI), the Subjective Shoulder Value (SSV) and the Simple Shoulder Test. The most commonly used disease-specific outcome instrument for rotator cuff disease is the Western Ontario Rotator Cuff (WORC) Index (Kirkley et al., 2003). It consists of 21 visual analogue scale (VAS) items in five domains: physical symptoms (six items), sports/ recreation (four items), work (four items), lifestyle (four items) and emotions (three items). Each item has a possible score from 0 to 100 (100 mm VAS), and these scores are added to give a total score from 0 to 2100. A score of 0 implies no reduction in the status of the shoulder, and a score of 2100 is the worst score possible. The data can be converted to a percent score by inverting the raw score and then converting it to a score out of 100 (2100 – 'patient WORC raw score'/21). WORC was considered to have the highest ratings in psychometric properties among all shoulder instruments in a systematic review (Huang et al., 2015). The minimally clinically important change (MCIC) for WORC is reported to be 275 points or 12.8% (Ekeberg et al., 2010).

2.11 Treatment outcome in observational studies

2.11.1 Conservative treatment

The majority of RC-tear outcome studies concern surgical interventions. However, studies on the outcome of conservatively treated full-thickness RC tears are scarce (Ainsworth et al., 2007). Traditionally, RC tears are treated conservatively if they are deemed irreparable, or if the patient is not considered a good candidate for surgery, or refuses to undergo an operation. Often, these tears are large to massive in size and the patients are older than in the operative series. In a review of exercise therapy in the non-operative treatment of full-thickness RC tears, 78% of the non-operatively treated cohorts reported an improvement in pain, 81% in ROM, 85% in strength and 84% in functional outcomes (Jeanfavre et al., 2018). Furthermore, 15% of patients were unsatisfied and chose surgery later on. Well over half of the reviewed papers were retrospective studies. Many papers included patients with irreparable tears, rendering it difficult to conclude the effectiveness of initial conservative treatment. According to a few prospective studies, which offered initial conservative treatment to patients with repairable tears, the majority of patients recovered, at least in the short term, and about 1 out of 4 did not recover and chose to undergo surgery (Boorman et al., 2014; Kuhn et al., 2013).

2.11.2 Rotator cuff repair

McElvany et al. (2015) conducted a systematic review and meta-analysis of articles on RC repair published between 1980 and 2012. The weighted mean postoperative score was 85% (presented as a percentage of the best possible score). The follow-up per study ranged from 12 to 119 months. They also noticed an almost exponential rise in the published literature concerning RC repair and an increasing proportion of intact RCs after repair. Interestingly, the postoperative score or percentage of possible improvement did not change over the study period. According to a few long-term outcome studies, the clinical outcome after the repair of SSPs or massive RC tears remains satisfactory after 20-years of follow-up (Collin et al., 2020).

Repair techniques may not have a great impact on patient outcomes (Hurley et al., 2019; Mascarenhas et al., 2014) and there seems to be no clinically significant differences in PROMs, pain or ROM between arthroscopic and open or mini-open RC repairs (Ide et al., 2005; Nazari et al., 2019).

2.12 Risks and complications of conservative treatment

There are only limited risks related to conservative treatment because of its non-invasiveness. These are mainly related to the progression of the unrepaired tear, retraction and finally irreversible FD of the RC muscles. In observational studies, 38–61% of asymptomatic full-thickness tears became enlarged and 44% of partial-thickness tears progressed to full-thickness tears in a 3-year period (Keener et al., 2015b; Keener et al., 2015a; Moosmayer et al., 2013; Yamaguchi et al., 2001). Since the onset of tearing is not known, the actual chronology of tear progression is also obscure. A dominant extremity and degeneration of the SSP muscle have been proposed to be risk factors for tear enlargement (Keener et al., 2015a). Of asymptomatic individuals with an RC tear, 23–51 % became symptomatic in a 1.5- to 3-year period and were more likely to have tear enlargement compared to those who remained asymptomatic (Keener et al., 2015a; Moosmayer et al., 2013). However, these previous studies also showed that 37–77% of individuals who became symptomatic did not develop tear enlargement. A recent systematic review reported the rate of tear progression to be 41 % in asymptomatic individuals at 47 months (Kwong et al., 2019).

Maman et al. (2009) studied patients with a symptomatic full-thickness RC tear treated nonoperatively and found that 51% of the tears increased in size and the remainder did not change or even decrease in size. Similar findings were also noted by Safran et al. (2011) in patients 60 years of age or younger. Of their cohort, 50% reported a trauma before the symptoms started, but this did not correlate with the progression of tear size. For symptomatic full-thickness tears, 34% progressed during a mean follow-up period of 38 months in a systematic review and meta-analyses of 8 studies (Kwong et al., 2019). The follow-up duration, diabetes mellitus and ISP muscle atrophy were independent risk factors for the tear size progression in the antero-posterior plane. A higher critical shoulder angle and SSP and ISP muscle atrophy were risk factors associated with medio-lateral tear progression (Jung et al., 2020). Of patients with a full-thickness RC tear treated conservatively, 35% had a progression in the muscle FD in a 6-year follow-up period (Hebert-Davies et al., 2017). This occurred more frequently in shoulders where the tears had enlarged. Older age and larger tear size at baseline were risk factors for FD.

2.13 Risks and complications of tendon repair

A lack of consensus on surgical complications, and which adverse events (AEs) should be documented and reported in clinical trials, leads to inaccurate and inconsistent reporting (Audigé et al., 2015; Goldhahn et al., 2009). Recently, a core set of AEs associated with arthroscopic RC repair was defined by a Delphi consensus process (Audigé et al., 2016). Based on this, Felsch et al. (2021) performed a registry study on complications within 6 months after arthroscopic RC repair. The cumulative risk for AEs within 6 months was 18.5%. Intraoperative device-related events occurred in 2.2% of patients, i.e. anchor pullout and breakage. Of all patients, 1.7% had a peripheral neurologic injury and 0.8% an infection. Shoulder stiffness was the most common AE, with a risk of 7.6%. The AE rates of arthroscopic RC repair have been reported to be significantly lower than for open mini-open RC repair (Kelly et al., 2019). The relative risk of complications for arthroscopic RC repair was 0.71 compared with open RC repair.

A well recognized risk for RC repair is re-tear. The rate of unhealed or re-torn RCs after repair is reported to be as high as 13 to 94% (Haque & Pal Singh, 2018). The majority of retears seem to occur in the first 6-to-26 weeks after surgery (Iannotti et al., 2013). Interestingly, a meta-analysis by Russel et al. (2014) showed that re-tears do not have a clinically significant effect on function or pain in an average of 30.1 months of follow-up. Patients with intact RCs had increased strength by 2.4 kilograms when elevating the arm and a trend toward increased strength in the ER of the arm. Since there are no MCID values for strength in different planes of motion, the clinical relevance of this finding is unclear. Despite an early structural failure, the clinical outcomes seem stable in long-term follow-ups (Jost et al., 2006; Paxton et al., 2013).

There seems to be slightly more re-tears with single row repairs compared to double row, at least in tears larger than 3 cm (Hurley et al., 2019; Mascarenhas et al., 2014). Some preliminary evidence from a meta-analysis showed that the suture bridge technique can lead to higher repair integrity and function compared to single and double row configurations (Xu et al., 2019).

2.14 Prognostic factors of outcome

There are only a few prognostic studies on conservatively-treated patients with rotator cuff tears. Bartolozzi et al. (1994) found that rotator cuff tears > 1 cm^2, a history of symptoms over one year and shoulder weakness at the initial presentation were associated with an unfavorable clinical outcome. Goldberg et al. (2001) concluded that patients who improved were more likely to have a cuff tear on the dominant extremity, had a lower initial Simple Shoulder Test score and had more difficulty tucking their shirt behind their back. Jain et al. (2018) concluded that positive marriage status, having at least a college education, a shorter duration of symptoms, light or manual labor in daily work, alcohol use of 1 to 2 times per week or more, a partial-thickness tear and the absence of FD of the rotator cuff were predictors of a better outcome for the non-operative treatment.

There are five published systematic reviews on the prognostic factors for outcome after rotator cuff repair (Fermont et al., 2014; Lambers Heerspink et al., 2014; McElvany et al., 2015; Raman et al., 2017; Saccomanno et al., 2016). Lambers Heerspink et al. (2014), Fermont et al. (2014) and Saccomanno et al. (2016) did not perform a meta-analysis because of the diversity in the outcome measures, heterogeneity and a lack of statistical rigor among the included studies. Lambers Heerspink et al. (2014) concluded that a worker’s compensation status and additional AC procedure have a negative influence on functional outcome after rotator cuff repair. Fermont et al. (2014) identified twelve prognostic factors associated with a better recovery: younger age, male sex, higher bone mineral density, the absence of diabetes mellitus, a higher level of sports activity, a greater preoperative shoulder range of motion, the absence of obesity, a smaller sagittal size for the cuff lesion, less retraction of the cuff, less FD, no multiple tendon involvement, and no concomitant biceps or AC joint procedures although the evidence was scarce. McElvany et al. (2015) found that studies with higher values for the mean FD, a higher proportion of women, higher proportion of nonsmokers and longer mean times until the initiation of active exercise were associated with worse clinical outcomes. They only included articles reporting both anatomic and clinical outcomes and excluded articles that did not report cuff integrity. A recent systematic review by Raman et al. (2017) found 18 studies that were sufficiently reported to conduct a meta-analysis. Among these, only 3 were graded as high-quality studies. They found that a worker’s compensation status, low preoperative muscle strength and larger tear size are predictors of poor function in patients after rotator cuff repair. The effects of these variables were considered moderate.

Naimark et al. (2019) looked at muscle quality on magnetic resonance imaging and the outcome in operatively and non-operatively treated patients. A positive supraspinatus tangent sign was the only variable that was significantly associated with a worse outcome in operatively treated patients. This association could not be detected in non-operatively treated patients. Kijowski et al. (2019) on the other hand, did not find an association between muscle atrophy and outcome after surgery, but in turn they found a significant positive association between the tear size, retraction and tendon degeneration. The psychosocial factors for patients may also have a role in recovery, and especially in patient expectations and outcomes after rotator cuff surgery (Coronado et al., 2018; Kennedy et al., 2019). After the aforementioned systematic reviews, few prognostic studies have been published. Fermont et al. (2014) found that in patients with rotator cuff repair, FD and the level of tendon retraction were prognostic factors for the health-related quality of life instrument RAND-36 and shoulder hindrance, but they did not influence the WORC index or CM score. A study by Jenssen et al. (2018) also looked at prognostic factors for functional outcome after rotator cuff repair. The preoperative WORC and CM score in the contralateral shoulder were the best prognostic factors of outcome measured as WORC at 2-year follow-up.

3 Aims

1. To evaluate evidence on the effectiveness of tendon repair in reducing pain and improving the function of the shoulder when compared with conservative treatment for rotator cuff tears (I).
2. To investigate the difference in mid-term clinical and radiological outcomes between physiotherapy only, acromioplasty + physiotherapy and tendon repair + acromioplasty + physiotherapy in the treatment of symptomatic, non-traumatic supraspinatus tendon tears (II).
3. To investigate the effectiveness of supervised physiotherapy compared with home exercises alone following supraspinatus tendon repair (III).
4. To design and present a protocol of the Acute Cuff Tear Repair Trial (ACCURATE) to investigate the difference in the outcomes between placebo surgery and arthroscopic rotator cuff repair in patients with an acute supraspinatus tendon tear related to trauma (IV).

4 Materials and Methods

4.1 Systematic review and meta-analysis (study I)

Cochrane Controlled Trials Register (CENTRAL), MEDLINE, EMBASE, CINAHL, Web of Science and PhysiotherapyEvidence (Pedro) databases were searched in June 2015 unrestricted by date.

The criteria for considering studies for this review were based on the PICO (Population, Intervention, Comparison and Outcome) framework as follows:

- Population: Adults with rotator cuff tear; types of studies –RCTs; papers published in English.
- Intervention: Surgical repair of the tendon tear.
- Comparison: Placebo, sham or other conservative treatment.
- Outcome: Pain, function, quality of life and mobility of the shoulder.

Titles and abstracts were screened by two independent reviewers, full texts of potentially relevant trials were assessed, and finally the risk of bias of included trials was rated using risk of bias tool v 1.0 (Higgins et al. 2011): (1) selection bias (randomised sequence generation and allocation concealment); (2) performance bias (blinding of participants and personnel); (3) detection bias (blinding of outcome assessment); (4) attrition bias (incomplete outcome data e.g. due to dropouts); (5) reporting bias (selective reporting); (6) other sources of bias. The risk of bias were graded as low, high or unclear risk. The overall level of evidence was considered ‘‘strong’’ if there were consistent findings among several high quality RCTs, and‘‘moderate’’ if findings were consistent among several low-quality RCTs and/or one high-quality RCT. The level of evidence was ‘‘conflicting’’ if findings were inconsistent across the studies, and ‘‘no evidence from trials’’, if there were no RCTs. Disagreements between the two reviewers were resolved by consensus or by the third reviewer. Data needed for the meta-analysis were extracted from the included trials using a standardised form based on recommendations by the Cochrane Handbook for Systematic Reviews of Interventions 5.1.0 Edition, Chapter 7.6.9 Cochrane Collaboration.

We used a random effects meta-analysis to quantify the effect size of included studies as a more natural choice than fixed effects in the context of making clinical decisions. The test for heterogeneity was conducted using the Q^2, T^2 and I^2 statistics. According to the Cochrane Handbook of Systematic Reviews, an I^2 of 0–40% was considered as indicating unimportant heterogeneity; 30–60% moderate; 50–90% substantial; and 75–100% considerable heterogeneity. The estimates of changes in outcome measures were compared with published MCIDs. At least one of three SDs (baseline, follow-up and change) were not reported by the included studies. By having access to the unpublished raw data of the study by Kukkonen et al. (2014), the pre-/post-correlation coefficient of change in total CS was calculated using the raw data from that study. The results were accompanied by two-tailed p values and 95% confidence intervals (95% CIs).

4.2 Randomized controlled trials (study II, III and IV)

4.2.1 Study II

Study II was a superiority RCT with three parallel treatment arms conducted in three hospitals: Turku University Hospital, Kuopio University Hospital and Tampere Hatanpää Hospital between October 2007 and December 2012. Patients with isolated and symptomatic full-thickness SSP tears, referred for surgery in the participating centers, were screened. The inclusion and exclusion criteria are listed in Table I. Eligible patients were recruited and informed consent was obtained. The study nurse randomized the patients into one of the three treatment groups, physiotherapy; acromioplasty and physiotherapy; and rotator cuff repair, acromioplasty and physiotherapy, using sequentially numbered, opaque, sealed envelopes. The randomization was stratified according to the participating hospital into three blocks. After randomization the patient and the treating physician were openly informed of the treatment group. The treatment was initiated within one month after the randomization. Patients were informed of the possibility of crossing over to the RC repair group if adequate relief of symptoms was not achieved at 6 months after the acromioplasty or physiotherapy.

Table I. Study II inclusion and exclusion criteria. Modified from Kukkonen et al. (2021).

	Description
Inclusion criteria	Age > 55 years
	Symptomatic nontraumatic SSP tendon tear comprising < 75% of the width of the tendon insertion and documented with MRI
	Full ROM of the shoulder
	Written informed consent
Exclusion criteria	Age < 55 years
	History of trauma relating to the onset of symptoms
	A massive tendon tear involving the whole SSP tendon and/or combined tear of two to three tendons, i.e., SSP with ISP or SSC tendon tear
	Stiffness of the GH joint (passive external rotation < 30° ± elevation < 120°)
	OA of the GH joint with present osteophytes in radiographs
	Systemic corticosteroid or antimetabolite medication
	Significant malignant, hematological, endocrine, metabolic, rheumatoid or gastrointestinal disease
	History of alcoholism, drug abuse, psychological or other emotional problems that are likely to invalidate informed consent
	Previous ipsilateral shoulder surgery
	Patient denial

Treatment arms were as follows:

Physiotherapy (group 1)

Patients received written and guided information by a physiotherapist on how to perform a standardized exercise protocol at home. In the first six weeks, the aim was to improve GH motion and active scapular retraction, after which static and dynamic exercises to improve scapular and GH muscle function were gradually increased until twelve weeks. After this, ascending resistance and strength training was carried out up to six months. Patients were referred for ten sessions of physiotherapy at an outpatient health-care facility where the progress was monitored.

Acromioplasty and physiotherapy (group 2)

All operations (groups 2 and 3) were performed arthroscopically in a standardized manner by 4 experienced shoulder surgeons. In group 2, all patients received acromioplasty. A biceps tenotomy was performed if the long head of the biceps tendon was frayed or unstable. AC resection was performed if palpation of the AC joint elicited pain preoperatively and severe radiographic OA changes were present. Postoperatively the same standardized exercise protocol was used as in group 1.

Rotator cuff repair, acromioplasty and physiotherapy (group 3)

The SSP tendon was repaired anatomically with titanium suture anchors according to the preferences of the surgeons. A single-row technique was used when the anteroposterior tear width was ≤ 10 mm, whereas for larger tears, the repair was performed in a double-row fashion. Acromioplasty, and when appropriate, biceps tenotomy and AC joint resection were performed as in group II. Postoperatively, the arm was immobilized in a sling for 3 weeks, after which passive mobilization was begun. Active shoulder motion was allowed after 6 weeks, and thereafter, the exercise protocol was the same as that in group 1 and 2.

The change in total CS was used as the primary outcome measure. Patients who exceeded the MCID value of CS were considered responders. Secondary outcome measures were pain VAS, subjective satisfaction with the treatment outcome and OA and CTA changes on plain radiographs. The power calculations were based on the assumed changes in the CS. The mean score at baseline was assumed to be 50 (SD, 10). The score in the worst treatment group was assumed to be 60 at follow-up and in the best treatment group 70. The correlation between the measurements during follow-up was assumed to be 0.40–0.50 (SD, 20). On analysis-of-variance testing with $\alpha = 0.05$ and power = 85%, a mean difference exceeding 10 points was expected to be statistically significant if the number of subjects per group was 51. The number of patients per group was set at 60 to account for a dropout rate of 15%. The outcomes were analyzed on an intention-to-treat (ITT) basis. The main outcomes were analyzed with analysis of covariance controlling for baseline values. The distributions of continuous variables were investigated with the Shapiro-Wilk test of normality. The differences between categorical variables were calculated with the Pearson χ^2 test. The numeric values of the VAS pain score were log transformed to attain normality. Post-hoc pairwise comparisons were adjusted for multiplicity using a simulation-based method, yielding corrected p-values and 95% CIs. Model fit was verified using Pearson residuals.

4.2.2 Study III

Study III was a single-center RCT with 2 parallel treatment arms to compare supervised physiotherapy (SP) and home-exercise (HE) alone in patients after arthroscopic RC repair. Patients with arthroscopically verified and repaired full-thickness supraspinatus tendon tear at Turku University Hospital between 2010 and 2015 were screened. The inclusion and exclusion criteria are listed in Table II.

Table II. Study III inclusion and exclusion criteria. Modified from Karppi et al. (2020).

	Description
Inclusion criteria	Age between 30 to 65 years
	Arthroscopically reinserted isolated full-thickness SSP tendon tear
	Written informed consent
Exclusion criteria	Age <30 years or > 65 years
	Existing significant malignant, hematologic, endocrine, metabolic, rheumatoid, or gastrointestinal disease
	OA of the GH joint grade III or above (radiographic evaluation with present osteophytes according to Kellgren-Lawrence classification)
	Cytostatic or corticosteroid medication
	History of alcoholism, drug abuse, or psychological or other emotional problems that are likely to invalidate informed consent
	Previous ipsilateral shoulder surgery
	Massive tendon tear involving > 1 tendon and/or combined tear of 2 tendons, i.e., SSP with ISP or SSC tendon tear
	Patient denial

Patients were operated on in a lateral decubitus position under general anesthesia and regional nerve block. The torn SSP tendon was anatomically repaired with a titanium suture anchor. Postoperatively, after full recovery from general anesthesia, patients were asked to participate in the trial. Eligible patients were randomly assigned using sealed envelopes to 1 of 2 treatment groups. Both groups received the same progressive exercise instructions delivered by a shoulder-specialized physiotherapist. Sling immobilization was 2 weeks in both groups. The instructions included model pictures of training for ROM and movement and a recommended timetable for training. All patients were advised not to return to heavy work or activity earlier than 3 months after the operation. Patients were allowed to call the physiotherapist if they encountered unexpected difficulties with the exercises or if they had extra questions about the recovery process.

The patients in the SP group returned to the hospital for a total of 5 SP sessions between 2 and 10 weeks after the operation. The physiotherapist went through the exercises and supervised the patients' practice during sessions. In contrast, patients in the HE group were given postoperatively both oral and written detailed instructions alone on how and when to perform the exercises at home for 3 months after the operation. The ROM, strength and the CS were recorded by a separate, independent physiotherapist at 3 months and at 1 year after the operation. If a patient had severe pain and/or recovery was delayed at 3 months, as judged by the physiotherapist at follow-up, an additional SP was scheduled with 2-week intervals at a primary care or occupational health care facility.

The primary outcome measure was the between group difference in CS at 1-year follow-up. The secondary outcomes were CS, VAS for pain and subjective shoulder value (SSV) at 3-month follow up and VAS for pain and SSV at 12-month follow-up.

The power calculations were based on the assumed behavior of the CS. The mean score at baseline was assumed to be 50, with a SD of 15. The score of the best treatment group after follow-up was assumed to be 80 and the score of the worst treatment group, 70, with a SD of 15. The correlation between measurements during follow-up was estimated to be 0.50, and the SD of the change, 15. Using a 2-sided 2-sample t test with $\alpha = 0.05$ and 80% power, we could expect the findings (difference in change between groups) to be statistically significant if the number of subjects in each group was 37. Because of possible dropouts, the number of subjects per group was set at 40. The groups were compared using repeated measures analysis of variance. Studentized residuals were checked to confirm model fit to the data. The statistical significance was determined based on the p-values; a significance level of 0.05 was chosen. All analyses were conducted using R (version 3.5.2 [2018]; R Core Team, Vienna, Austria)

4.2.3 Study IV

4.2.3.1 Objective

Study IV is a protocol for an ongoing randomized, placebo controlled, multicenter efficacy trial, with two parallel (1:1) treatment arms. The objective of the Acute Cuff Tear Repair Trial (ACCURATE) is to investigate the difference in outcome between placebo surgery and arthroscopic RC repair in patients aged 45–70 years with an acute full-thickness SSP tear related to trauma. Our hypothesis is that arthroscopic RC repair yields superior results compared to placebo surgery.

4.2.3.2 Eligibility criteria

Being an efficacy trial, ACCURATE is designed to estimate the benefits and harms of arthroscopic RC repair under ideal and controlled circumstances. Patients with a full-thickness SSP tear, detected after a traumatic event, are screened. A traumatic event is defined as any kind of sudden stretch, pull, fall, or impact, on the upper extremity that is associated with the onset of symptoms. Any kind of planned or controlled movement like throwing a ball or lifting an object is not defined as a sudden traumatic event. The traumatic event must happen quickly and without warning, for example falling down on an outstretched arm. Symptoms have to be typical of cuff tear (pain laterally on the shoulder and/or painful motion arc during abduction or flexion). The inclusion and exclusion criteria are listed in Table III.

Table III. Study IV inclusion and exclusion criteria. Modified from Ryösä et al. (2019).

	Description
Inclusion criteria	Aged between 45 years and 70 years at the time of injury.
	Acute onset of shoulder symptoms after a traumatic event (any kind of sudden stretch, pull, fall or impact, on the shoulder that is associated with the onset of symptoms)
	Shoulder symptoms relating to rotator cuff tear = pain laterally on the shoulder and/or painful motion arc during abduction or flexion.
	MRI-documented full-thickness SSP tear
Exclusion criteria	Traumatic event of the shoulder due to a criminal act of violence with legal consequences
	A delay of more than 4 months after the onset of symptoms of trauma to the day of intervention.
	Arthroscopically documented partial thickness RC tear only.
	A large MRI documented full-thickness RC tear, sagittal tear size at the level of footprint larger than 3 cm.
	MRI or arthroscopically documented total width of ISP or SSC tear
	MRI or arthroscopically documented fully dislocated biceps tendon (biceps out of the groove) with concomitant SSC tear
	Positive clinical rotatory lag sign (ER1 lag (>10°), lift off lag (involuntary drop against the back) and horn blower lag (involuntary internal rotation of the forearm in supported elevated position).
	Marked FD in any of the cuff muscles (more than Fuchs/Goutallier grade 2)
	Radiographically or MRI-documented concomitant fracture line of the involved extremity or bony avulsion of the torn tendon or dislocation of the humeral head or the AC joint
	Concomitant clinically detectable motor nerve injury affecting the shoulder
	Radiographically documented severe OA of the GH joint, Samilson-Prieto 2 or above
	Non-congruency of the GH joint in radiographs (Hamada stage 2 or above).
	Clinical stiffness of the GH joint (severely limited passive range of motion: GH external rotation <60°).
	Previous surgery of the affected shoulder (affecting clavicle, scapula or upper third of the humerus)
	Earlier sonographic or MRI finding of a RC tear
	Previous symptoms of the ipsilateral shoulder requiring conservative treatment (glucocorticosteroid injections and/or physiotherapy) delivered by healthcare professionals during the last 5 years.
	Systemic glucocorticosteroid or antimetabolite medication during the last 5 years.
	Ongoing treatment for malignancy.
	American Socety of Anesthesiologist (ASA) classification 3 or 4.
	Patient’s inability to understand written and spoken Finnish, Norwegian or Swedish.
	History of alcoholism, drug abuse, psychological or other emotional problems likely to jeopardise informed consent.
	Patients with a contraindication/non-compliance for MRI examination or use of electrocautery devices.
	Previous randomisation of the contralateral shoulder into the ACCURATE trial.
	Patient’s denial for operative treatment and/or participation in the trial.

4.2.3.3 Interventions

Eligible patients are asked to participate in the trial, and a written informed consent is obtained. The operation is commenced within four months after the traumatic event.

All patients receive regional nerve block and/or general anesthesia, and a prophylactic antibiotic is administered. These are not standardized, but delivered as a routine practice for each hospital. The arthroscope is introduced to the glenohumeral joint, and thereafter a thorough diagnostic arthroscopy is performed as well as a global assessment of the joint surfaces according to the Outerbridge classification (Outerbridge & Dunlop, 1975).

The presence of a full-thickness cuff tear is verified by introducing a probe/switching stick through the subacromial space into the joint. The patient is excluded from the trial and treated according to local routine if the diagnostic arthroscopy reveals a partial-thickness cuff tear only, a total width of infraspinatus or subscapularis tear or a fully dislocated long head of the biceps tendon with concomitant subscapularis tear. After the diagnostic arthroscopy and confirmation of the eligibility criteria, the patient is randomly assigned to arthroscopic RC repair or placebo surgery, and treated accordingly.

Rotator cuff repair

A biceps tenotomy or tenodesis may be performed according to the surgeon’s preference if the biceps tendon is noted to be frayed, unstable or inflamed. An additional acromioplasty can be performed according to the surgeon’s preference if there are signs of mechanical tightness (fraying on the undersurface and close contact to the cuff structures). The rotator cuff insertion is prepared and the cuff tear is repaired to its anatomic location using suture anchors based on the surgeon’spreference. No additional procedures are performed.

Placebo surgery

Only the joint space is evaluated, no subacromial scoping is performed. Nothing is to be removed or excised and the use of any electrocautery or shaver device is not allowed. Altogether 3 to 5 small skin stab incisions are made in typical locations resembling locations of a typical RC repair. The time spent in the operating theatre with patients in the placebo surgery group should resemble the time spent with patients in the RC repair group and hence give the impression of an RC repair.

Postoperative physiotherapy

Postoperative care and rehabilitation are identical in both groups. The patients in both groups are immobilized in a sling for 4 weeks and during this time the exercise program is standardized. After 4 weeks, the rehabilitation program consists of three phases. Phase one consist of active assisted ROM exercises, phase 2 of active unloaded exercises and phase 3 of dynamic strengthening exercises. The patients have approximately 15 guided-exercise sessions with a physiotherapist during a 5-month period. In between these guided exercise sessions, patients perform home-exercises according to the different phases.

All patients receive a prescription for analgetics according to the local routine to be used if needed. The patients receive sick leave for up to 12 weeks, which can be extended if needed.

4.2.3.4 Outcomes

The primary outcome measure is the change in WORC at 2-year follow-up compared to baseline. The secondary outcomes are CS, the Numerical Rating Scale for pain, the 15D and subjective patient satisfaction. Signs of OA or CTA are analyzed in the radiographs, and muscle FD and tear progression or re-tears are analysed in the MRI. Radiographs and MRI studies will be done for both groups at 2, 5 and 10 year follow-ups.

4.2.3.5 Allocation and blinding

We use the computerized internet-based online randomization software application (https://www.randomize.net/). Randomization is done in the operation theatre after the diagnostic arthroscopy when the final confirmation of the eligibility criteria is ascertained. The randomization is stratified, according to the participating hospital (X), gender (2), and baseline WORC index (3 separate lists: <20%, 20–40%, >40%), into (Xx2x3) 6X randomization lists respectively (with variable block size known only by the trial statistician). At recruitment, different treatment modalities are explained to patients. Thereafter, the patients, the hospital staff and outcome assessors are blind to the treatment allocation. Only the operating doctor and operating-theatre personnel are aware of the allocated treatment group but are not allowed to share this further.

The participants may be unblinded if there is a serious AE, treatment failure (serious persisting symptoms six months after the treatment) or discontinuation. A blinding index is used to evaluate the success and maintainence of blinding for to 2 years. The success of blinding is assessed by asking the participant to guess (by 5 point Likert scale) which treatment they received.

4.2.3.6 Declined cohort

The patients who are otherwise eligible but do not want an operation and/or do not want to participate, are asked to participate in a follow-up cohort. An informed consent is obtained from these patients also. The patient receives the treatment they desire after counseling. The baseline demographics, together with treatment modality, WORC outcome measure at baseline, 1 and 2 year follow-up are collected.

4.2.3.7 Sample size

The power calculation is based on the assumed behavior of the WORC score. The mean score value at baseline is assumed to be 40% (Ekeberg et al., 2008; Sugaya et al. 2005). The mean score of the best treatment group at follow-up is assumed to be 85% (Bang et al., 2004). The SD is assumed to be 18% (Sugaya et al., 2005). The trial is set out to reliably detect the reported MCID of WORC, i.e. 273 points (13% of the total 2100 points) (Ekeberg et al., 2008). Therefore, the score for the most inefficient treatment group is assumed to be less than 73%. The correlation between measurements during the follow-up is estimated to be about 0.40 to 0.50. In an analysis of variance (ANOVA) test using an alpha of 0.05 and a power of 95%, we can expect the findings to be statistically significant if the number of subjects in each group is 72. Due to potential drop-outs, the minimum number of subjects per group is set at 90.

4.2.3.8 Statistical methods

The ITT dataset will include all enrolled patients and who have at least one post-baseline primary-outcome measurement available. The per-protocol dataset is a subset of the ITT dataset excluding patients or measurements for a given patient with major protocol violation(s) expected to alter the outcome to treatment. The primary outcome measures will be analysed using both the ITT (primary analysis) and the per protocol dataset. In addition to absolute values, changes relative to the baseline values will be compareded, if feasible. All of the outcome measure analysis will be done using the generalised linear mixed models. All between group differences will be presented with 95% CIs. A two-sided significance level of 0.05 will be used. Subjects attaining a change in WORC and CS greater than the MCID are considered as responders to the treatment. The evaluation of reaching the MCID is done at each timepoint individually, and the responder status is carried over to all adjacent timepoints once attained. The responder analysis will be carried out with generalised logistic regression model using responder/non-responder as an outcome. All secondary analyses are designed to be supportive of the primary endpoint and/or exploratory, and each analysis will be undertaken at the two-sided 5% level of significance.

5 Results

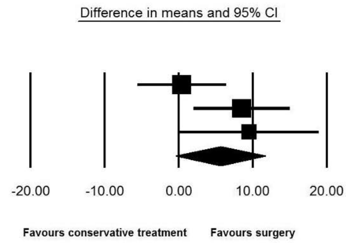
5.1 Short-term comparative evidence on operative versus conservative treatment of rotator cuff tears – a systematic review and meta-analysis (Study I)

We screened a total of 319 abstracts. After exclusions, the initial search resulted in two RCTs (Kukkonen et al., 2014; Moosmayer et al., 2010). One trial (Lambers Heerspink et al., 2015) was published shortly after the initial search and was added to the final set. All three trials were relevant for both the qualitative and quantitative analyses. Published data from two trials (Lambers Heerspink et al., 2015; Moosmayer et al., 2010) were used for analysis but as the trial by Kukkonen et al. (2014) reported results by shoulder, we used unpublished data to access the results by patient. As the aim was to compare tendon repair with conservative treatment, we excluded patients who underwent acromionplasty without tendon repair in the study by Kukkonen et al. (2014) from the meta-analyses. The three RCTs involved altogether 252 participants (123 in the tendon repair group and 129 in the conservative treatment group). The treatment protocol in the tendon repair group were comparable, although two trials used an open or mini-open approach and one all-arthroscopic. Acromioplasty was used in all patients with repair. Tenotomy and/or tenodesis of the long head of the biceps tendon were used in two trials (Kukkonen et al., 2014; Moosmayer et al., 2010) and AC resection in one trial (Kukkonen et al., 2014) on a''when needed'' basis. The conservative treatment consisted of various exercises. These were standardized in two trials (Kukkonen et al., 2014; Lambers Heerspink et al., 2015), while in one (Moosmayer et al., 2010) they were implemented depending on an individual patient's clinical status. In the standardised conservative treatment groups, passive GH and active scapulothoracic motion exercises were allowed for the first 4 to 6 weeks followed by guided active exercises. In a trial by Lambers Heerspink et al. (2015), patients received subacomial corticosteroid injections. The total risk of bias was considered low in all three RCTs.

The three RCTs reported several outcomes in the different follow-up time points. The meta-analysis was conducted on two outcomes in one follow-up time point (the only outcomes reported by all three RCTs within a similar timeframe): change in pain VAS and total CS at 1-year follow-up. The pooled mean difference in the change of CS was 5.6 (95% CI -0.41 to 11.62), being statistically and clinically insignificant (Figure 9). The pooled mean difference in change of pain level was -0.93 (95% CI -1.65 to -0.21) being statistically but not clinically significant (Figure 10). It is noteworthy that the CI estimates, in both outcomes, does not exclude clinical significance. Because of the small pooled sample size, we suggest that the level of evidence should be defined as ''limited''.

Statistics for each study

Study name	Difference in means	Lower limit	Upper limit	Standard error	Variance	Z-Value	p-Value
Kukkonen 2014	0.400	-5.549	6.349	3.035	9.212	0.132	0.895
Moosmayer 2014	8.500	2.028	14.972	3.302	10.902	2.574	0.010
Lambers Heerspink 2015	9.500	0.141	18.859	4.775	22.802	1.989	0.047
	5.604	-0.409	11.617	3.068	9.412	1.827	0.068

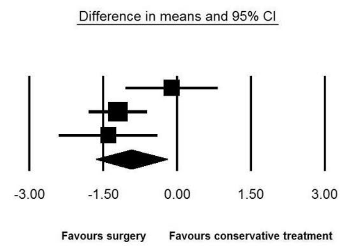


Follow-up 1 year

Figure 9. Forest plot of change in total CS in 1-year follow-up.

Statistics for each study

Study name	Difference in means	Standard error	Variance	Lower limit	Upper limit	Z-Value	p-Value
Kukkonen 2014	-0.110	0.474	0.225	-1.039	0.819	-0.232	0.816
Moosmayer 2014	-1.200	0.302	0.091	-1.793	-0.607	-3.967	0.000
Lambers Heerspink 2015	-1.400	0.511	0.261	-2.401	-0.399	-2.741	0.006
	-0.929	0.369	0.136	-1.652	-0.206	-2.519	0.012



Follow-up 1 year

Figure 10. Forest plot of change in pain level on a visual analoque scale from 0 to 10 points in 1-year follow-up.

5.2 Mid-term clinical and radiological outcomes of operatively versus conservatively treated non-traumatic supraspinatus tendon tears – a randomized controlled trial

In total, 150 shoulders (51 in group 1, 50 in group 2 and 49 in group 3) were available for analysis at a mean of 6.2 years (drop-out rate 17%). There were no significant differences in the patient demographics between the groups. The mean age of patients was 65 and the mean anteroposterior tear size 9 mm in MRI at baseline.

Primary outcome

The mean CS at final follow-up was 75.6 (95% CI, 71.5 to 79.8) for group 1, 76.3 (95% CI, 72 to 80.5) for group 2 and 78.7 (95% CI, 74.4 to 83) for group 3. There were no statistically or clinically significant differences between the mean CS at the final follow-up or the mean change of CS (Table IV, V and Figure 11).

Table IV Between group differences at final follow-up.

	Group 1 – Group 2	Group 1 – Group 3	Group 2 – Group 3
Mean CS at final follow-up (95% CI)	-0.6 (-7.7–6.5) 0.98	-3.0 (-10.2–4.1) 0.58	-2.4 (-9.6–4.8) 0.71
Mean change of CS (95% CI)	0.6 (-7.7–8.9) 0.98	-1.4 (-9.8–6.9) 0.91	-2.0 (-10.4–6.3) 0.84
Mean pain VAS at final follow-up (95% CI)	0.8 (0.0–1.6) 0.04	0.8 (0.0–1.6) 0.04	0.0 (-0.8–0.8) 0.99
Mean change of pain VAS (95% CI)	0.4 (-0.9–1.8) 0.7248	0.3 (-1.1–1.7) 0.8619	-0.1 (-1.5–1.2) 0.9684
Proportion of satisfied to treatment outcome (RR, 95% CI)	0.96 (0.84–1.09) 0.74	0.96 (0.84–1.09) 0.74	1.00 (0.89–1.13) 1.00
Proportion of responders (RR, 95% CI)	0.95 (0.73–1.23) 0.83	0.89 (0.70–1.13) 0.38	0.93 (0.74–1.18) 0.65

CI = confidence interval, CS = Constant score, RR = risk ratio, VAS = visual analog scale.

Secondary outcomes

The mean pain VAS at the final follow-up was 1.4 (95% CI, 1 to 1.9) for group 1, 0.6 (95% CI, 0.2 to 1.1) for group 2 and 0.6 (95% CI, 0.2 to 1.1) for group 3. The between group difference was statistically ($p = 0.02$) but not clinically significant in favor of group 2 and 3. The between group mean difference in the change of pain VAS on the other hand was neither statistically or clinically significant (Table IV, V and Figure 12).

The satisfaction (yes/no) showed high rate of satisfaction in all three groups. There were no treatment-related complications in any of the groups. Eight shoulders in Group 1 and two shoulders in Group 2 crossed over to RC repair during the follow-up. Data on the cross-overs is presented in Table VI. The mean sagittal size of the SSP tendon tear was at baseline 10.1 mm (95% CI 8.6–11.6) in Group 1, 9.6 mm (95% CI 8.1–11.1) in Group 2 and 8.5 mm (95% CI 7.0–10.0) in Group 3, ($p=0.33$)

Table V. Outcomes at final follow up. Modified from Kukkonen et al. (2021)

	Group 1	Group 2	Group 3	p-value
Mean baseline of CS (95 % CI)	57.1 (53.1–61.1)	58.2 (54.1 – 62.2)	58.7 (54.7–62.8)	0.85
Mean CS at final follow-up (95% CI)	75.6 (71.5–79.8)	76.3 (72–80.5)	78.7 (74.4–83)	0.58
Mean change of CS (95% CI)	18.5 (13.6–23.4)	17.9 (13–22.9)	20 (15–24.9)	0.84
Mean baseline of pain VAS (95% CI)	2.9 (2.2–3.7)	2.6 (1.9–3.4)	2.5 (1.7–3.2)	0.69
Mean pain VAS at final follow-up (95% CI)	1.4 (1–1.9)	0.6 (0.2–1.1)	0.6 (0.2–1.1)	0.02
Mean change of pain VAS (95% CI)	-1.6 (-2.4–-0.8)	-2 (-2.8–-1.2)	-1.9 (-2.7–-1)	0.74
Proportion of satisfied to treatment outcome	88%	92%	92%	0.83
Proportion of responders	68%	71%	76%	0.71

CI = confidence interval, CS = Constant score, VAS = visual analog scale.

Pre-operatively there was no or mild radiographic OA (Samilson-Prieto 0–1) in 36 (97%), 31 (89%), and 33 (89%), and moderate or severe OA (Samilson-Prieto 2–3) in 1 (3%), 4 (11%), and 4 (11%) shoulders in Groups 1, 2, and 3 respectively (p=0.352). At follow-up, moderate or severe OA was detected in 7 (19%), 14 (40%), and 13 (35%) shoulders in Groups 1, 2, and 3 respectively (p=0.124). Despite non-significant between group differences, there was a statistically significant mean progression of 0.33 steps in the Samilson-Prieto grading from baseline to follow-up in the trial population (p=0.0045). Pre-operatively the humeral head was radiographically cranio-caudally centered in 30 (81%), 30 (88%), and 34 (92%), and at follow up in 26 (59%), 23 (56%), and 24 (62%) shoulders in Groups 1, 2, and 3 respectively (p=0.0003). There were no statistically significant between group differences in the radiographic Hamada or Samilson-Prieto classifications (Table VII and VIII). There was a mild but statistically significant negative correlation between the radiographic Hamada classification and CS at follow-up (r=-0.27, p=0.0026).

Table VI. Data of 10 crossovers at final follow-up. Modified from Kukkonen et al. (2021).

	Group 1	Group 2
Shoulders, n (%)	8 (16)	2 (4)
Mean CS at baseline (SD)	55.6 (13.7)	45 (11.3)
Mean time of reoperation, months (SD)	20.3 (17.4)	15 (8.3)
Mean CS before reoperation (SD)	63.6 (9.7)	40.5 (9.2)
Mean pain VAS at follow-up (SD)	0.3 (0.5)	1.2 (1.2)
Mean CS at follow-up (SD)	78.9 (2.9)	68 (0)
Satisfied patients, %	100	100

CS = Constant score, SD = standard deviation, VAS = visual analog scale.

Table VII. Radiographic Hamada classification. Modified from Kukkonen et al. (2021).

Hamada grade	Group 1 at BL (%)	Group 1 at FU (%)	Group 2 at BL (%)	Group 2 at FU (%)	Group 3 at BL (%)	Group 3 at FU (%)
1	81	62	88	64	92	71
2	19	38	12	28	8	21
3	0	0	0	8	0	6
4	0	0	0	0	0	3

BL = baseline, FU = follow-up.

Table VIII. Radiographic Samilson-Prieto classification. Adopted from Kukkonen et al. (2021).

S-P grade	Group 1 at BL (%)	Group 1 at FU (%)	Group 2 at BL (%)	Group 2 at FU (%)	Group 3 at BL (%)	Group 3 at FU (%)
0–1	97	81	89	60	89	65
2–3	3	19	11	40	11	35

BL = baseline, FU = follow-up.

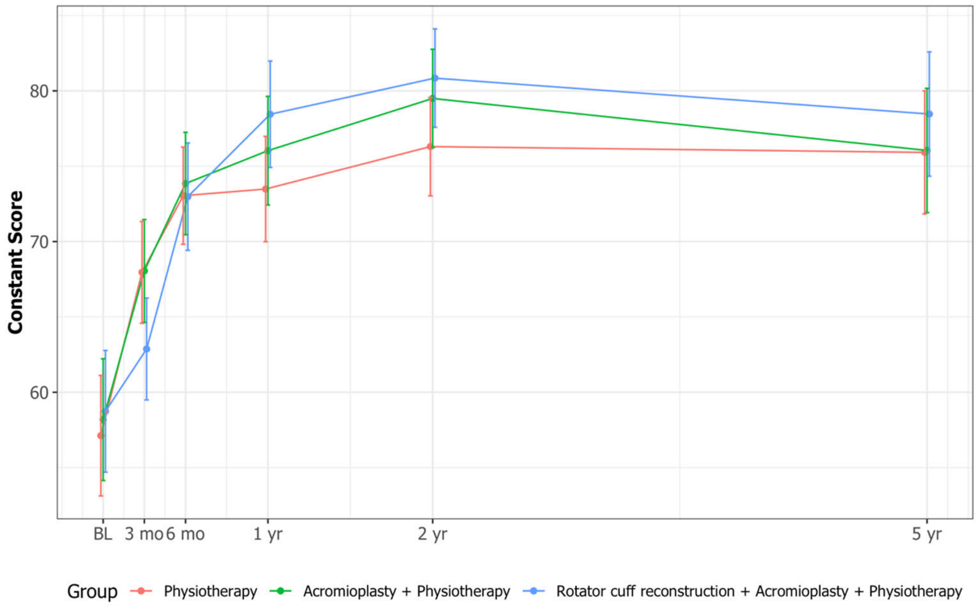


Figure 11. Behavior of Constant score. BL = baseline. Reprinted with a permission from Kukkonen et al. (2021).

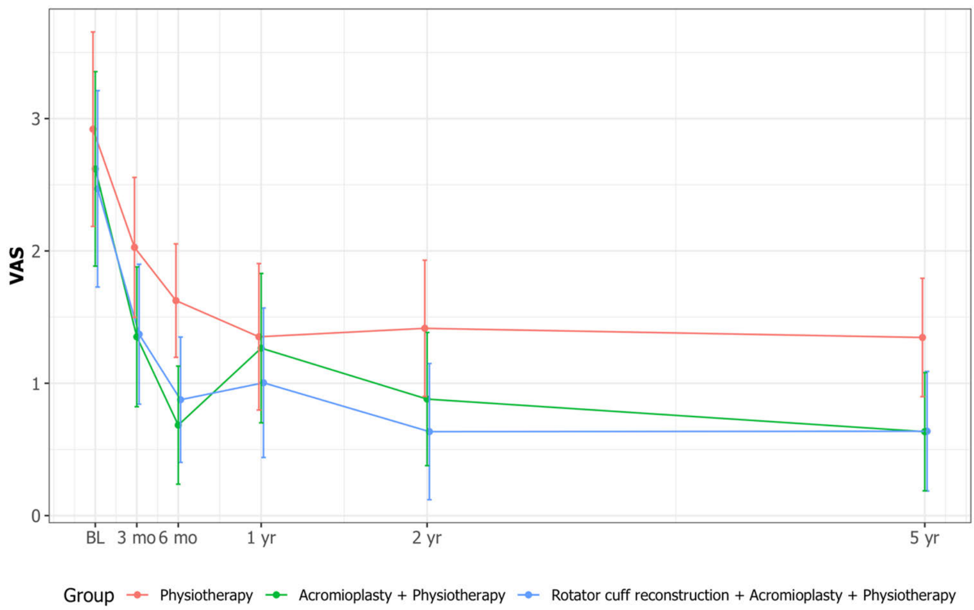


Figure 12. Behavior of pain VAS score. BL = baseline, VAS = visual analog scale. Reprinted with a permission from Kukkonen et al. (2021).

5.3 Effectiveness of supervised physiotherapy after arthroscopic rotator cuff reconstruction – a randomized controlled trial

A total of 80 patients were allocated (1:1) into two groups. The mean age of the patients in the SP group was 54 (SD, 6.9) years and 56 (SD, 6.2) years in the HE group at baseline. In the SP and HE groups, 67% and 70% were males, respectively. The mean size of the SSP tear in the SP group was 12 (SD, 7.6) mm and 14 (SD, 6.5) mm in the HE group.

Altogether, 76 participants were available for follow-up at 3 months (dropout rate, 5%), and 70 patients, at 1 year (dropout rate, 12.5%). There were no reported treatment-related complications. In the HE group, 10 patients (25%) contacted the physiotherapist by phone to receive counseling and self-treatment instructions and none in the SP group. Additional physiotherapy, after 3 months, was administered in 8 patients in the SP and 3 in the HE group.

The results of the outcome measures are presented in Table IX. The behavior of the CS and pain VAS are presented in Figures 13 and 14. No statistically significant difference in the CS was found between the groups at any time point. A statistically significant difference in the VAS pain score was observed between the groups at 3 months' follow-up but not at the baseline or at the 1-year follow-up.

Table IX. Outcome measures. Modified from Karppi et al. (2020).

	SP group	HE group	p-value
Mean total CS (SD)			
Baseline	48 (17.5)	54 (17.3)	0.2
3 month	59 (18.6)	55 (20.3)	0.06
1 year	83 (9.7)	82 (10.5)	0.42
Mean pain VAS (SD)			
Baseline	3.4 (2.9)	3.8 (2.6)	0.53
3 month	1.0 (1.3)	2.4 (2.2)	0.005
1 year	0.3 (0.6)	0.5 (0.5)	0.35
Mean SSV			
Baseline	4.6 (2.2)	4.2 (1.7)	0.58
3 month	6.8 (2.3)	6.9 (1.8)	0.87
1 year	9.0 (1.9)	8.7 (2.0)	0.71

CS = Constant score, HE = home exercise SD = standard deviation, SSV = subjective shoulder value, SP = supervised physiotherapy, VAS = visual analog scale.

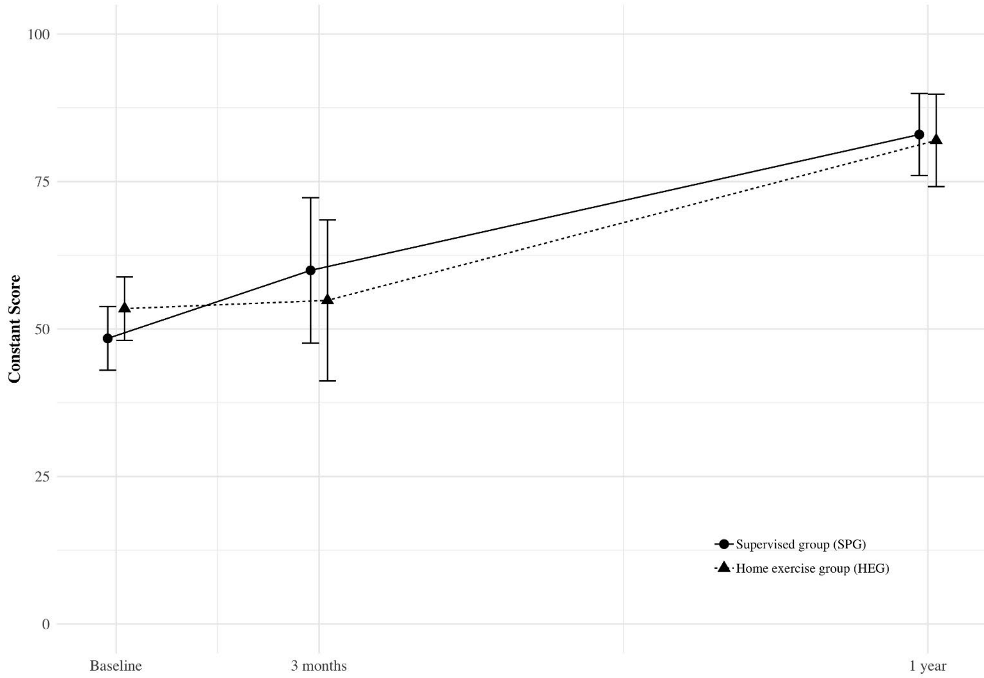


Figure 13. Graph showing total CS in both treatment groups. Whiskers indicate 95% Cis. Reprinted with permission from Karppi et al. (2020).

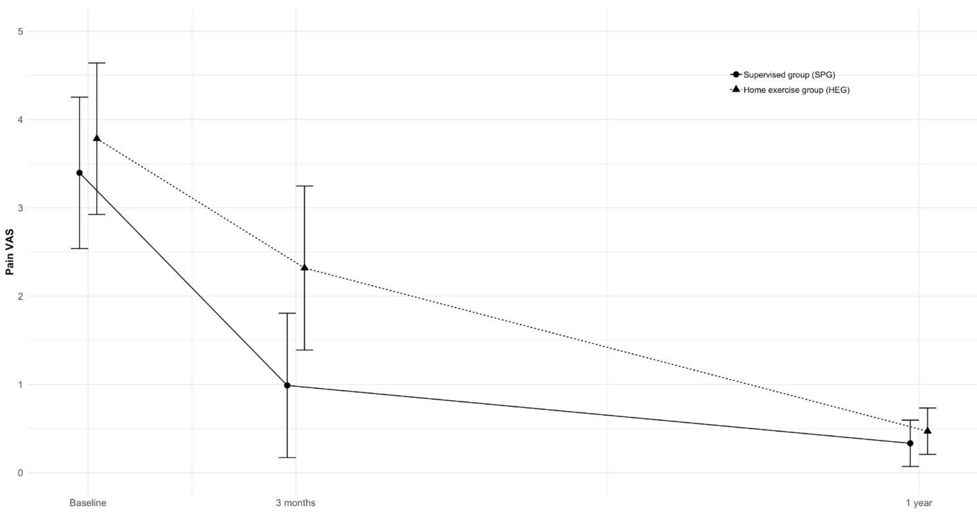


Figure 14. Graph showing score of the pain VAS in both treatment groups. Whiskers indicate 95% CIs. Reprinted with permission from Karppi et al. (2020).

6 Discussion

6.1 Comparison of repair and conservative treatment in patients with symptomatic full-thickness supraspinatus tendon tear (study I–II)

Our meta-analysis indicated that at one-year follow-up there were no clinically important differences in function (assessed by Constant Score), or pain (assessed by pain VAS), between patients with full-thickness mainly SSP tendon tear, treated surgically or conservatively. At one year the pooled mean difference in the change of Constant score and pain favored surgery, but the differences were clinically unimportant, although a statistical significance for pain VAS was noted. However, the CIs overlapped with MCID value both in pain and CS indicating that clinically important benefits should not be excluded based on the meta-analysis. After a mean follow-up of 6.2 years, our RCT found no statistically or clinically significant differences between the outcomes of conservative treatment, acromioplasty or RC repair in patients with nontraumatic SSP tendon tear. A subtle GH joint wear was detected in the whole cohort; however, cuff repair did not seem to protect from progression of OA.

In addition to the one-year results, which were included in our meta-analysis, Moosmayer et al. (2014 & 2019) have published 5- and 10-year results for the same RCT cohort. They randomized 103 patients with small to medium-sized RC tears (not exceeding 3 cm) to either open/mini-open repair or physiotherapy. Both, physiotherapy and tendon repair, groups improved their Constant scores and pain levels decreased significantly. At 2-year and 10-year follow-up, the outcomes remained stable in the repair group but had deteriorated in the physiotherapy group, to the extent that the 1.8 cm (95% CI 1.1 to 2.6) difference on a 10 cm pain VAS scale was statistically and clinically significant at 10-year follow-up. A 9.6-point (95% CI 3.6 to 15.7) difference in Constant score was statistically significant and near the level of clinical significance, in favor of tendon repair. It is noteworthy that Moosmayer et al. also included trauma-related tears and tears involving ISP and SSC.

Lambers Heerspink et al. (2015) randomized 56 patients with full-thickness nontraumatic RC tears to RC repair or conservative treatment. At 1-year follow-up, no significant differences were observed in the total CS between groups, but a statistically and a clinically significant between-group difference was observed when analysed by the change of pain VAS. The significance of the results of this trial can be questioned, as inclusion was prematurely terminated, due to difficulties in recruiting. They also included other tears than only SSP.

Our meta-analysis of three RCTs was the first conducted on RCTs comparing tendon repair and physiotherapy in the treatment of RC tears. A similar kind of meta-analysis on the same RCTs has been done since and the results are in line with ours, as too is the latest Cochrane systematic review on the subject (Karjalainen et al., 2019; Longo et al., 2021; Piper et al., 2018; Schemitsch et al., 2019).

The study by Ranebo et al. (2020) was the first to include only traumatic tears. They allocated 58 patients with trauma-related SSP tendon tears to mini-open tendon repair or physiotherapy. They found no significant difference between any outcome measures at 1-year follow-up.

Cederqvist et al. (2020) did a pragmatic RCT on patients with RC disease. Patients who were still symptomatic after 3-month controlled physiotherapy were allocated to either surgery or to continue with conservative treatment. Patients with a full-thickness RC tear allocated to RC repair were statistically better in terms of function and pain than patients in the conservative group at two-year follow-up. The between-group difference in function (7.0; 95% CI 1.8 to 12.2) did not reached the MCID value for CS but the difference in pain reduction (13; 95% CI 5 to 22) was near clinical significance in favor of repair. The RCTs comparing tendon repair and conservative treatment in patients with full-thickness RC tears are listed in Table X.

A recent systematic review (Brindisino et al., 2021) pooled all the aforementioned RCTs in a meta-analysis to compare tendon repair with conservative treatment. At 6, 12 and 24 months there were statistically significant differences in pain (pain VAS) favoring tendon repair, -0.59, 95% CI -0.84 to -0.33; -0.41, 95% CI -0.7 to -0.12; -0.92, 95% CI -1.31 to -0.52, respectively. A similar kind of trend was observed with function (CS) at 12 and 24 months, 5.25, 95% CI 1.55 to 8.95; 5.57, 95% CI 1.86 to 9.29, respectively. Nonetheless, the clinical significance remains unclear since the pooled mean differences did not reach the minimal clinically important differences for pain or function at any time point.

Table X. The RCTs comparing tendon repair and conservative treatment in patients with full-thickness RC tears

Author (year), country	Number of patients	Age (mean)	Trauma related tears (%)	Tear size (mean)	SSP tears (%)	SSP+ISP tears (%)	SSC+ SSP tears (%)	Crossovers (%)	Dropout (%)	Primary outcome (mean)	Secondary outcome
Moosmayer et al. (2010) Norway	103	60	57	15 mm in US	74.8	23.3	1.9	17.6	1	CS at 1 year Repair: 76.8 Conservative: 66.8	VAS pain at 1 year Repair: 0.5 Conservative: 1.6
Moosmayer et al. (2014) Norway								23.5	2	CS at 5 years Repair: 79.8 Conservative: 74.2	VAS pain at 5 year Repair: 0.6 Conservative: 1.6
Moosmayer et al. (2019) Norway								27.4	11.7	CS at 10 years Repair: 80.5 Conservative: 71.8	VAS pain at 10 year Repair: 0.6 Conservative: 2.3
Kukkonen et al. (2014) Finland	180	65	0	9.1 mm in MRI	100	-	-	6.9 (from conservative to repair) and 1.7 (from acromioplasty to repair)	5.5	CS at 1 year Repair: 77.9 Conservative: 74.1 Acromioplasty: 77.2	VAS pain at 1 year Repair: 0.9 Conservative: 1.2 Acromioplasty: 1.1
Kukkonen et al. (2015) Finland								12.1 (from conservative to repair) and 1.7 (from acromioplasty to repair)	7	CS at 2 year Repair: 80.6 Conservative: 76.0 Acromioplasty: 80.2	VAS pain at 2 year Repair: 0.6 Conservative: 1.4 Acromioplasty: 0.8
Kukkonen et al. (2021) Finland								13.8 (from conservative to repair) and 3.4 (from acromioplasty to repair)	17	CS at 6.2 year Repair: 78.7 Conservative: 75.6 Acromioplasty: 76.3	VAS pain at 6.2 year Repair: 0.6 Conservative: 1.4 Acromioplasty:0.6
Lambers Heerspink et al. (2015) Netherlands	56	60.6	0	NA	89.3	1.8	8.9	0	12.5	CS at 1 year Repair: 81.9 Conservative: 73.7	VAS pain at 1 year Repair: 2.2 Conservative: 3.2

Ranebo et al. (2020) Sweden	58	59.7	0	9.7 mm in MRI	100	0	0	3	0	CS at 1 year Repair: 83 Conservative: 78	
Cederqvist* et al. (2020) Finland	98	56**	17***	NA	89.8	NA	NA	13****	16*****	The mean between group difference in VAS pain was 13 in favor of repair	The mean between group difference in CS was 7 in favor of repair

*Trial included patients with and without full-thickness RTCTs. In here are listed the numbers available from the full-thickness RTCT cohort.

**The number is for the whole trial.

**The number is for the whole trial. Percentage for the full-thickness RTCT cohort was not presented.

****The number is for the whole non-surgery group. Percentage for the conservative full-thickness RTCT cohort was not presented.

*****The number is for the whole trial that included also participants with no full-thickness tear

6.2 Comparison of repair and subacromial decompression in patients with symptomatic full-thickness supraspinatus tendon tear (study II)

There are a few trials similar to ours that compare, in a RCT setting, tendon repair with subacromial decompression, but these trials lack a conservative treatment arm. Dezaly et al. (2011) randomized patients over 60 years of age with a full-thickness RC tear to either RC repair (with acromioplasty and biceps tenotomy) or acromioplasty and tenotomy. At 1-year follow-up, the mean CS in the repair group was 75.8 and in the acromioplasty with biceps tenotomy group 68.8, being statistically but not clinically significant. A 5 point between-group difference was reported by Flurin et al. (2013) in favor of repair in patients over 70-years. The difference was also statistically but not clinically significant. Bidwai et al. (2016) did not find any differences in the CS between repair and acromioplasty in short- to long-term follow-up. A meta-analysis has also been conducted on these four RCTs, and it also showed a statistically significant difference of 5.8 (95% CI 2.58 to 9.03) points in CS at 1-year follow-up (Schemitsch et al., 2019). Again, this is below the reported MCID.

6.3 Comparison of supervised physiotherapy and home exercise only following rotator cuff repair (study III)

Based on the results of our RCT, supervised physiotherapy (SP) was not superior when compared to home-exercise (HE) only following arthroscopic RC repair at 1-year follow-up. The difference in the primary outcome CS did not reach statistical significance at any time point. Interestingly, the SP-group experienced less pain than the HE-only group at 3-month follow-up. The difference reached the established MCID value for pain VAS (1.4), but at 1-year was again non-significant. The reason for this difference in pain at the 3-month time point is unclear. One explanation is that the human contact, reassurance and guidance of the physiotherapist are related to this phenomenom.

Two systematic reviews have recently been conducted on the subject (Dickinson et al., 2017; Longo et al., 2020). Dickinson et al. (2017) found five RCTs which were all limited by methodological problems for example no sample size calculations, differences in the definition of supervision and no supervision. As a result, they were unable to conclude whether SP leads to improved outcomes over less expensive nonsupervised physiotherapy. Longo et al. (2020) found the same five RCTs but excluded one because a group doing exercises at home in the trial received instructions via videotapes. They were able to perform a meta-analysis on the pain

VAS and discovered no important between group differences. Both reviews raised concerns about the higher costs of SP considering that it did not provide additional benefits in terms of function or pain.

6.4 Ethics of using a placebo arm in RCT of trauma-related RC tears (study IV)

The outcomes of a surgical procedure are said to be comprised of three main effects in a cumulative manner: the effect of a critical surgical element, placebo effect and other non-specific effects (Ernst & Resch, 1995; Tenery et al., 2002; Wartolowska et al., 2014). The critical surgical element in study IV is the repairing of the torn SSP tendon which is believed to produce the therapeutic effect of the procedure. The change observed after placebo surgery is not a placebo effect, but rather a placebo response including also other non-specific effects. The true placebo effect is the result of psychological factors including the patient's beliefs, expectations and interaction with the healthcare professionals (Colagiuri et al., 2015; Ernst & Resch, 1995). The non-specific effects relate to the natural course of the RC tear, regression to the mean, fluctuations in symptom severity and the reaction of patients to being observed and assessed (Savulescu et al., 2016). The function of the diagnostic shoulder arthroscopy as a placebo procedure is just to simulate the RC repair procedure, as it has no real therapeutic effect. With a placebo as comparator in the controlled setup of study IV, both the true placebo effect and non-specific effects are comparable, and the bias is minimised when investigating the true efficacy of the arthroscopic SSP tendon repair (Figure 15).

Placebo-controlled trials are widely used in other fields of medicine, especially in pharmacological trials. In surgical trials, a placebo-arm is used less frequently. The reasons might be the challenges related to design and implementation, as well as ethical issues that may arise. Recent literature has focused on the methods, ethical analysis and guidelines related to placebo-controlled surgical trials (Beard et al., 2020; Savelescu et al., 2016). To ensure a placebo-controlled surgical trial is ethical, Savulescu et al. (2016) have suggested that six criteria are fulfilled. Here I reflect the criteria outlined by Savulescu et al. (2016) onto the ACCURATE trial.

The presence of equipoise is number one. Clinical equipoise means that in the expert medical community there must be a genuine uncertainty about the preferred

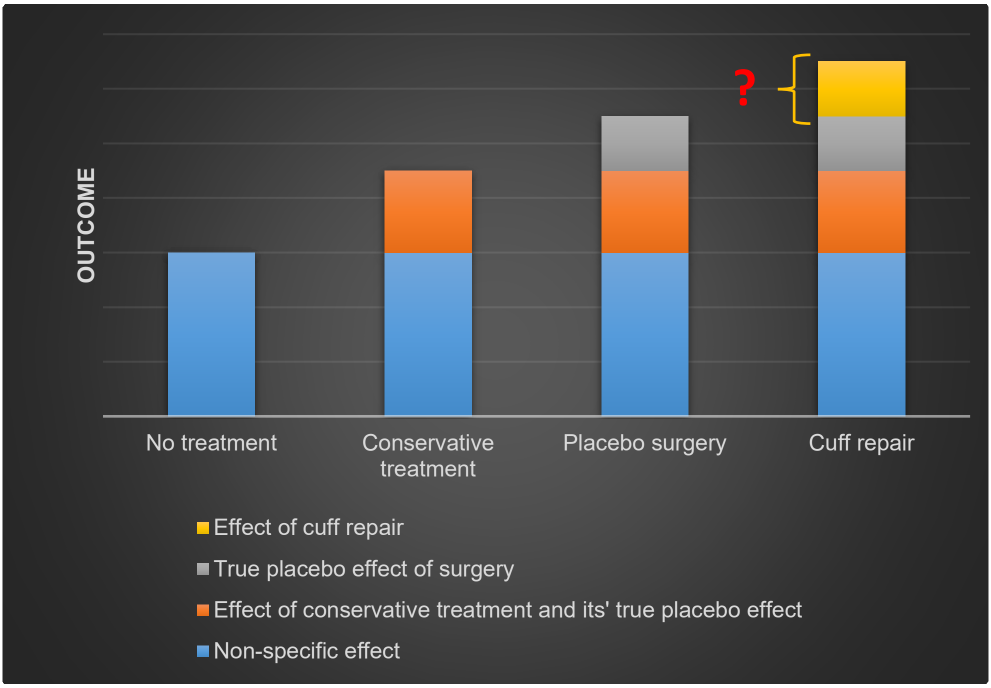


Figure 15. Elements of a treatment in a cumulative manner. The propotions of different elements are imaginary since they are not (yet) known. Own drawing.

treatment. That is, the uncertainty either regarding the efficacy of the investigated procedure or the lack of unbiased evidence for the efficacy of the intervention. If there is an equipoise, the requirement of the Declaration of Helsinki that all patients receive the best proven available treatment, is not violated (Savulescu et al., 2016). At the time of designing the ACCURATE trial, no RCTs had been done on trauma-related RC tears. As mentioned earlier, there is now one RCT on trauma-related SSP tears, which showed no difference at the one-year follow-up. One can hereby state that there is a clinical equipoise.

The second criteria is preliminary evidence for the efficacy of the procedure. There are many open-label studies on the operative treatment of SSP tears with good to excellent results (McElvany et al., 2015). These studies, however, are highly biased because of the study design itself; not controlling the true placebo effect and non-specific effects.

Minimising the risks for patients in the placebo arm is the third criteria. The risks of AEs in the surgical trial, and especially in the placebo arm, should be minimised and unnecessary harm should be avoided. The risk profile should be reflected onto other trials with similar patients and the active treatment delivered. The natural course of the disease should also be accounted for. The placebo arm in the ACCURATE trial includes a diagnostic arthroscopy and supervised physiotherapy.

The potential risks are associated with the diagnostic arthroscopy procedure and other interventions in the peri- and post-operative phase. These potential risks are: side effects to pre-, peri- and post-operative medications, nerve or vascular injury related to plexus or regional anaesthesia and possible complications related to the diagnostic arthroscopy procedure itself. Medications can cause side effects, but the overall risk is estimated to be low. Surgery always comes with a risk of AEs. The AEs associated with RC repairs are listed in chapter 2.13. AEs related to diagnostic arthroscopy are not reported on in the literature. Considering that it only involves the insertion of an arthroscopic camera into the shoulder joint and not any additional procedures, it is much less traumatic than the active treatment arm. In addition, no foreign materials are left in the shoulder (on the contrary to RC repair, after which the suture anchor and suture materials are left). We assume that the risks for AEs in the diagnostic arthroscopy group will be smaller than the risks for AEs reported for arthroscopic RC repair. One concern is also that in the placebo arm the RC tear remains unrepaired. Consequently, the tear may become larger over time, may retract and the scapular musculature may be accompanied by irreversible fatty degeneration. There are no high-quality studies on the natural course of an acute cuff tear. According to the results of the RCT by Ranebo et al. (2020) and a study on patients with trauma-related SSP tears who refused operative treatment, significant short-term tear-size progression is unlikely. Also, the development of CTA or GH OA is not faster if the SSP is left repaired, as seen in study II.

The fourth criteria is avoiding deception. Patients have to know why the trial is conducted and what is known and unknown about the subject under investigation. Basically, this refers to the equipoise discussed previously. Patients are informed of the meaning of the placebo design in the trial. They receive oral and written information concerning the trial, and written informed consent is obtained. The operating doctor and staff do not meet with the patient after the operation to avoid compromising the blinding. The follow-up visits are done by a physiotherapist and a doctor, who are blinded to the allocation.

According to the fifth criteria, there should be a significant change in clinical practice. The results should substantially improve the health of future patients. The results of the ACCURATE trial will affect the decision-making process worldwide. If the results show that RC repair with additional physiotherapy is clinically superior to placebo surgery with additional physiotherapy, this verifies that tendon repair has an important effect in the treatment of an acute cuff tear. However, if the placebo surgery group is superior or the difference between the groups is not clinically important, there is no justification for a tendon repair in the treatment of a trauma-related SSP tear.

The sixth and last criteria is the benefits to the patients in the placebo group. All patients in the placebo arm in the ACCURATE trial receive additional physiotherapy, like the patients in the RC repair group. According to the RCT by Ranebo et al., conservative treatment yields a clinically significant improvement in patients with trauma-related SSP tears. Second, the patients in the placebo arm will probably experience a positive meaning response due to the trial design. Third, the patients in the placebo arm may benefit from undergoing a diagnostic arthroscopy prior to randomisation. Their GH joint is evaluated, and any encountered pathology is documented, and if, for example, a total subscapularis or infraspinatus tear or a partial-thickness tear only is noticed, the patient is excluded and treated accordingly. In addition, patients in clinical trials have many potential benefits over standard care (including additional imaging, clinic visits and interviews) which would likely hold value (Stock, 2003). Furthermore, after a placebo intervention, patients report a significant improvement for a prolonged period of time, and the response on subjective outcomes does not seem to change significantly with time (Wartalowska et al., 2017). It is noteworthy that the improvement investigated in that study was the placebo response (there were no trials with no-treatment arm) and thus the true placebo effect of surgery is unknown. If at the end of our trial the placebo group is equal or superior to the tendon repair group, the patients in the placebo group will presumably have benefitted because they received a smaller operation with a smaller risk for AEs, and no foreign material left in their shoulder.

6.5 Clinical implications

According to the findings of this thesis, and reflecting on the pre-existing literature, middle-aged and elderly patients with mainly nontraumatic SSP tendon tears can initially be treated conservatively. The higher short-term risk profile for harms (i.e. infection and stiffness) and greater direct costs related to operative treatment should be acknowledged in shared clinical decision making. However, the true efficacy of tendon repair remains unknown, and hopefully ACCURATE trial will be clarify this. In conclusion, it seems that according to the best evidence, the benefits of operative treatment, in the short- to medium-term timeframe may not outweigh the potential harm and effort involved. However, the clinical decision process should always account for the patient and their values and preferences when discussing the uncertainties of risks and benefits related to different treatment alternatives in the short- and long-term.

It is noteworthy that these results should not be extrapolated directly to trauma-related RC tears or to tears involving the SSC or ISP tendons. Also, the comparative evidence between tendon repair and conservative treatment in younger patients, particularly under 55 years, is lacking.

6.6 Strengths and limitations of the study

6.6.1 Strengths

A comprehensive search of six major databases and standardized methods in assessing methodological quality are the strengths of study I. There are several factors that strengthen the internal validity of the studies: use of RCT setting (studies II–IV), high follow-up rate (studies II and III), an online computer-based randomizing system (study IV), the blinding of patients and outcome assessors (study IV) and an adequate sample size based on a power calculation (studie II–IV). The use of additional radiological analysis in study II is a clear strength that increses our knowledge about the mid-term radiological changes related to different treatments. The strict inclusion and exclusion criteria in study IV can be perceived both as a strength but also as a limitation. The strength part is that an eligible patient in study IV is assumably an ideal candidate for RC repair. If this population does not benefit, then likely no one does. In addition, the multicenter setup (study II and IV) and the three countries included (study IV) strengthen the external validity and finally, make the results more generalizable.

6.6.2 Limitations

It is important to note that meta-analysis is always an approximation of the average treatment effect, and limitations are usually related to the included trials. Study I included RCTs with trauma and non-trauma-related tears. This might have an impact on the functional results, at least in operatively-treated patients (Braune et al., 2003), but the literature is controversial (Kukkonen et al., 2013a; Paul et al., 2021). One trial included only patients with SSP tears (Kukkonen et al., 2014) and the other two had patients with ISP and SSC tears also (Lambers Heerspink et al., 2015; Moosmayer et al., 2010). Surgical techniques also varied slightly among the included trials in study I. Moosmayer et al. (2010) and Lambers Heerspink et al. (2015) used a mini-open approach while Kukkonen et al. (2014) arthroscopic technique. However, the outcome is reported to be comparable between these approaches (Nazari et al., 2019).

The non-blinding of patients in study II and III can be a source of bias, but the impact of blinding might not be of great importance (Moustgaard et al., 2020). We did not use any imaging studies to see the possible tear progressions and re-tear rate in study II, as was done at the 2-year follow-up. Instead, we used plain radiographs to identify the possible development of OA and CTA, which can be seen as the end stage of cuff tear enlargement. It can also be argued that the re-tear is just a surrogate endpoint (Russell et al., 2014), at least in the area of SSP.

Not-controlling the repair technique in study IV can be seen as a limitation. However, the latest meta-analyses showed no sound evidence on the difference in clinical outcome or re-tear rates between single and double row repair in small to medium sized (<3 cm) tears. The limitation related to the strict inclusion and exclusion criteria in study IV manifests as difficulties in finding eligible patients to the trial during the screening of patients and eventually the risk of the prolonged recruitment period.

Although the CS is a widely used shoulder-specific outcome score, it has problems with psychometric properties (Vrotsou et al., 2018), for example combining both subjective and objective outcomes in one single score which heavily emphasizes the objective outcomes; range of motion (40%) and strength (25%). The results for determining the minimal detectable change (MDC) of CS raises concern about interpretability in regard to the MCID value. The MDC for CS is reported to be 18 for RC tears (Henseler et al., 2015). As observed changes below the MDC might be the result of a measurement error, the true clinical interpretation for the reported MCID value of 10.4–15 is questionable. Nevertheless, the correlation with subjective oucomes is reported to be good (Vrotsou et al., 2018).

6.7 Future aspects

A strong controversy exists between the structural changes in the RC and shoulder symptoms. What causes pain in a shoulder with an RC tear? Is the tear, especially in the area of the SSP, only an incidental lesion, a part of the normal spectrum of degeneration? What is the role of trauma in the changes perceived in the RC? A sudden loss of ER or a marked weakness in the SSC strength after trauma and corresponding to the non-old-looking tear of the ISP and/or SSC may perhaps be called an acute tear related to trauma.

There is still a dire need for studies with longer follow-ups to monitor how the accomplished outcome and the global GH joint degeneration behave after 5-years in patients with an RC tear treated operatively or conservatively.

As the RCTs give an estimate of the population under investigation and how the outcome score behaves average, the treatment effect might, in theory, differ from one individual to another. Quests to investigate these possible individual interactions would be tempting.

7 Conclusions

Based on this thesis, the following conlusions are drawn:

1. Our meta-analysis indicated that in the short-term follow-up there was no clinically meaningful improvement in function, assessed by Constant score, or decrease in pain, assessed by pain VAS, between patients with full-thickness mainly supraspinatus tendon tear, treated conservatively or with tendon repair.
2. We detected no differences between the clinical or radiological outcomes in mid-term follow-up after conservative treatment, acromioplasty or rotator cuff repair with acromioplasty in patients with nontraumatic supraspinatus tendon tear.
3. When analysed at 1-year postoperatively, supervised physiotherapy after arthroscopic rotator cuff repair does not contribute to additional benefits compared with home exercises only. At 3-month follow-up, patients with supervised physiotherapy experienced less pain.
4. The ACCURATE trial protocol was designed and patient recruitment is ongoing.

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Anssi Ryösä

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