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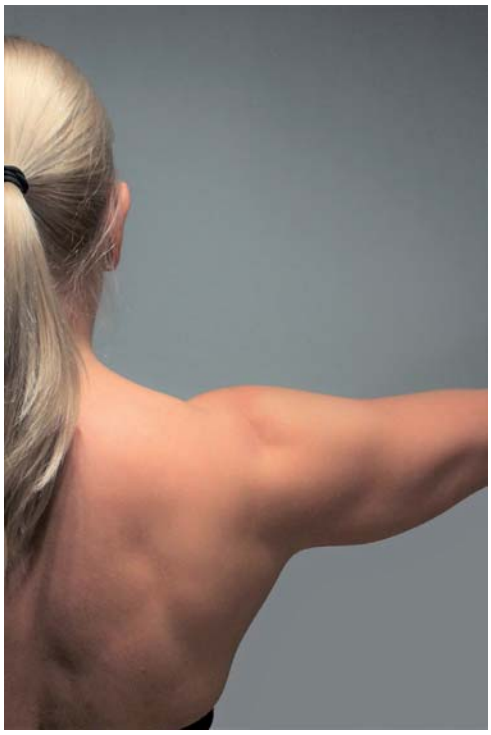
The Effectiveness of 12 Months' Intensive Shoulder Strength Training on Disability, Health-Related Quality of Life and Shoulder Function after Rotator Cuff Repair



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ABSTRACT

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This study examined the effectiveness of intensive shoulder strength training on disability, health-related quality of life (HRQoL) and shoulder function in patients who had undergone rotator cuff repair (RCR). In addition, the self-report section of the American Shoulder and Elbow Surgeons Standardized Assessment Form (ASES) was cross-culturally adapted to the Finnish language and the psychometric properties of the Finnish version were assessed.

Patients with a rotator cuff tear (aged 41-62 years) were randomized into an exercise group (EG, n=35) or a usual care group (UCG, n=32) after RCR. Disability was assessed with ASES questionnaire and quality of life with Short-Form 36 Health Survey (SF-36) preoperatively and at two months, 12 months and three years after surgery. Shoulder function was evaluated by measuring range of motion (ROM) and muscle strength at two and 12 months after surgery. The strength training intervention began two months after surgery and lasted 12 months. The EG were given instructions on a home-based shoulder muscle strengthening programme, while the UCG received ordinary postoperative instructions. The reliability of the ASES questionnaire was assessed.

Preoperatively, the RCR patients with high functional disability of the shoulder demonstrated low HRQoL. After the 12-month intervention, no between-group differences were observed in any of the outcomes. The mean (SD) ASES score improved from 74 (14) by 21 points (95% CI, 16 to 26, $p < 0.001$) in the EG and from 70 (18) by 25 points (95% CI, 20 to 31, $p < 0.001$) in the UCG. Both groups maintained their post-intervention ASES score levels throughout the three-year follow-up. The Finnish version of the ASES proved to be a reliable and valid shoulder-specific measurement tool.

These results suggest that the majority of the patients achieved good recovery during one year. The additional exercise intervention did not benefit patients with a rotator cuff tear.

Keywords: rotator cuff repair, disability, health-related quality of life, muscle strength, range of motion, exercise

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Jyväskylä, February 2017
Kirsi

FIGURES

TABLES

LIST OF ORIGINAL PUBLICATIONS

This thesis is based on the following original publications referred to in the text by Roman numerals I-IV. Some unpublished findings are also presented.

I Piitulainen K, Paloneva J, Ylinen J, Kautiainen H, Häkkinen A. Reliability and validity of the Finnish version of the American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form, patient self-report section. BMC Musculoskeletal Disorders 2014; 15: 272–9. doi: 10.1186/1471-2474-15-272.

II Piitulainen K, Ylinen J, Kautiainen H, Häkkinen A. The relationship between functional disability and health-related quality of life in patients with a rotator cuff tear. Disability & Rehabilitation 2012; 34: 2071–5. doi: 10.3109/09638288.2012.670363.

III Piitulainen K, Häkkinen A, Salo P, Kautiainen H, Ylinen J. Does adding a 12-month exercise programme to usual care after a rotator cuff repair effect disability and quality of life at 12 months? A randomized controlled trial. Clinical Rehabilitation 2015; 29: 447–56. doi: 10.1177/0269215514547598.

IV Piitulainen K, Häkkinen A, Salo P, Kautiainen H, Ylinen J. Effectiveness of 12 months' intensive home training program on shoulder muscle strength and range of motion after rotator cuff repair. Manuscript submitted to Journal of Strength and Conditioning Research

ABBREVIATIONS

AAOS	The American Academy of Orthopaedic Surgeons
ADL	Activities of daily living
ANCOVA	Analysis of covariance
ASES	The American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form
BP	Bodily Pain
CI	Confidence interval
CPM	Continuous passive motion
DASH	Disabilities of the Arm, Shoulder and Hand
EG	Exercise group
GH	General Health
HRQoL	Health-related quality of life
ICC	Intra-class correlation coefficient
IQR	Interquartile ranges
MCS	Mental Component Summary Score
MH	Mental Health
PCS	Physical Component Summary Score
PF	Physical Functioning
RCR	Rotator cuff repair
RCT	Rotator cuff tear
RE	Role Emotional
ROM	Range of motion
RP	Role Physical
SF	Social Functioning
SF-36	The 36-item Short Form Health Survey
SPADI	The Shoulder Pain and Disability Index
SST	Simple Shoulder Test
UCG	Usual care group
UCLA	The University of California, Los Angeles score
VAS	Visual analogue scale
VT	Vitality

CONTENTS

1 INTRODUCTION

Shoulder pain is the third most common musculoskeletal disorder after low back pain and neck pain, and is responsible for a considerable proportion of sick leaves in western countries (Viikari-Juntura 2010, Urwin et al. 1998). One-third of the population over 30 years of age reported shoulder pain during the previous month (Aromaa & Koskinen 2010). Tendinopathy is a concept commonly used to describe different symptoms of subacromial pain. The pathology of subacromial pain has a wide spectrum ranging from acute inflammation through subacromial bursitis to advanced degenerative changes with massive rotator cuff tearing (Umer, Qadir & Azam 2012). It is estimated that symptomatic rotator cuff tears affect between 4% and 32% of the population in the United States (Boykin et al. 2010). Tears become more prevalent with increasing age (Fehringer et al. 2008, Tempelhof, Rupp & Seil 1999), since rotator cuff pathology is mostly related to degenerative changes in the tendons during the aging process (Moosmayer et al. 2009, Yamaguchi et al. 2006). A rotator cuff tear not only causes pain, but over time may lead to a decline in muscle strength, shoulder mobility and quality of life.

Conservative treatment, including self-care, physiotherapy, relative rest, anti-inflammatory medication, and cortisone injections are recommended for small partial tears (Krischak et al. 2013, Krabak, Sugar & McFarland 2003). A rotator cuff repair (RCR) is considered when pain and decline in shoulder movements and muscle strength cause serious functional disability despite conservative treatment (Marx et al. 2009). Borgmästars et al. (2010) reported that pain relief was long-standing in most patients at a long-term follow-up, but the function achieved postoperatively was lost, as ROM and strength decreased to less than preoperative values. Moreover, Gladstone et al. (2007) showed that fatty infiltration and atrophy of the rotator cuff did not improve after RCR. Thus, it is challenging to develop postoperative rehabilitation protocols that promote patients' recovery effectively, so that patients may safely return to their work and recreational activities.

Disease-specific measurement tools link the symptoms and disability to a specific disorder. One of the most frequently used questionnaires pertaining to

the shoulder is the self-report section of the American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form (ASES) (Richards et al. 1994). The ASES has been validated in many languages and is considered to be a reliable, valid, and responsive outcome tool (Celik et al. 2013, Moser et al. 2012, Yahia et al. 2011, Padua et al. 2010, Goldhahn et al. 2008, Kocher et al. 2005, Michener, McClure & Sennett 2002). In Finland, while the ASES questionnaire has been used for several years, it has not been validated in the Finnish.

Currently, a moderate amount of evidence has been accumulated on short-term rehabilitation after RCR, comparing early postoperative rehabilitation with the immobilization period. However, few randomized controlled trials have studied the long-term effectiveness of different postoperative shoulder rehabilitation methods (Hayes et al. 2004, Roddey et al. 2002). Thus, the first purpose of this thesis was to examine the effectiveness of 12 months' intensive shoulder strength training on disability, health-related quality of life (HRQoL) and shoulder function in patients who had undergone RCR. The second purpose was to cross-culturally adapt the self-report section of the ASES to the Finnish language and to assess the psychometric properties of this version.

2 REVIEW OF THE LITERATURE

2.1 Rotator cuff disorders

Shoulder pain is the third leading musculoskeletal complaint after low back pain and neck pain (Viikari-Juntura 2010, Urwin et al. 1998). The rotator cuff allows for control of the arm in space and during overhead activities, and thus, can be a frequent source of pain, especially among the aging population (Oh et al. 2007). Rotator cuff disease is considered the leading cause of prolonged shoulder pain and disability (Mitchell et al. 2005). A full-thickness tear of the rotator cuff may be caused by tendon degeneration. A rotator cuff tear not only causes pain, but over time can lead to a decline in muscle strength and shoulder mobility, symptoms which may have a negative impact on activities of daily living as well as work and leisure activities (Razmjou et al. 2011).

2.1.1 Functional anatomy of the shoulder

The upper extremity is articulated with the shoulder girdle in the glenohumeral joint. The geometrical relationship of the humeral head and the glenoid surface allows for extensive range of motion (ROM) but at the cost of minor inherent skeletal stability (Prescher 2000). The biomechanics of the glenohumeral joint depend on the interaction of static and dynamic stabilizing structures. The static stabilizers of the glenohumeral joint include the bony anatomy, negative intra-articular pressure, the glenoid labrum, and the glenohumeral ligaments of the joint capsule, while the dynamic stabilizing structures consist of the rotator cuff muscles and the other muscles surrounding the shoulder joint (Figure 1). The effect of these stabilizers is to support multiple degrees of motion within the glenohumeral joint (Lugo, Kung & Ma 2008).

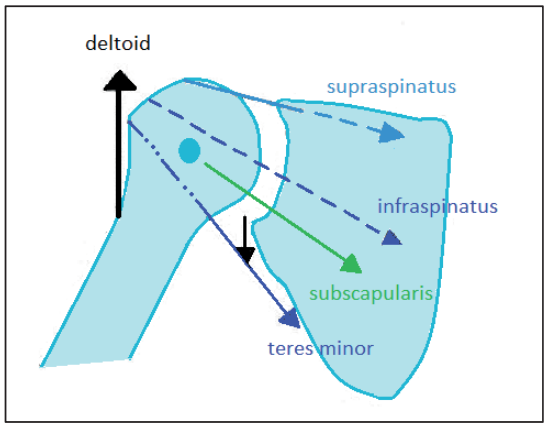


FIGURE 1 Dynamic stability of the rotator cuff. Modified from Huei-Ming Chai (2005).

Elevation of the arm can be observed in three planes: the frontal plane (abduction), sagittal plane (flexion), and plane of the scapula (scaption). The rotator cuff consists of four muscles and tendons: the subscapularis, supraspinatus, infraspinatus, and teres minor. These muscles originate on the scapula and their tendons blend in and strengthen the glenohumeral joint capsule on the ventral, cranial and dorsal sides, and insert at the greater and lesser tuberosities of the humeral head (Table 1). The rotator cuff stabilizes the glenohumeral joint, neutralizes the antagonistic effects of undesirable actions, and controls humeral head translations. It also participates to the movements in lifting and rotational movements (Escamilla et al. 2009). The rotator cuff muscles control the scapulohumeral rhythm of the shoulder with the muscles moving the scapula: the serratus anterior, trapezius, rhomboids, and levator scapulae (Escamilla et al. 2009).

TABLE 1 Summary of the attachments and functions of the rotator cuff muscles. Modified from Peter Ronai (2005).

Muscle	Attachments	Nerve	Action(s)
Supraspinatus	Supraspinous fossa of the scapula Upper facet of greater tuberosity of the humerus	Suprascapular nerve	Abduction Compression and depression of humeral head during elevation
Infraspinatus	Infraspinous fossa of the scapula Middle facet of the greater tuberosity of the humerus	Suprascapular nerve	External rotation Compression and depression of humeral head during elevation
Teres minor	Inferior medial border of the scapula Lower facet of the greater tuberosity of the humerus	Posterior branch of the axillar nerve	External rotation Compression and depression of humeral head during elevation
Subscapularis	Subscapular fossa of the scapula Lesser tuberosity of the humerus	Subscapular nerves	Internal rotation Compression and depression of humeral head during elevation

The subscapularis muscle is the largest and most powerful of the rotator cuff muscles. It rotates the humerus inwards and stabilizes the humeral head in the glenoid cavity by resisting anterior, posterior and inferior displacement. Weakness or injury of the subscapularis may lead to increased impingement and/or anterior instability during humeral elevation, abduction, and external rotation (Pennock et al. 2011).

The supraspinatus muscle is active in any movement involving elevation of the arm and it is important in stabilizing the glenohumeral joint. It compresses,

abducts and provides a small external rotation torque to the glenohumeral joint. In abduction of the humerus, the vertical force of the deltoid is low and the head-depressing force of the supraspinatus is lost, but the abduction and compression forces remain. The infraspinatus and subscapularis muscles provide further depression force on the humeral head (Escamilla et al. 2009). In their electromyographic study, Hawkes et al. (2012) found that the deltoid, adductor, and rotator cuff muscles all contribute to the stability of the glenohumeral joint during daily activities.

The infraspinatus muscle is the main external rotator of the humerus, and it depresses and stabilizes the humeral head in the glenohumeral joint with the other rotator cuff muscles, and works against posterior dislocation. *The teres minor muscle* is the other external rotator of the humerus, and it also works with the other rotator cuff muscles to stabilize the glenohumeral joint (Figure 2) (Prescher 2000).

The rotator cuff is poorly vascularized near its insertion zone due to mechanical conditions. This area is a commonly degenerated zone (Yang et al. 2012, Prescher 2000).

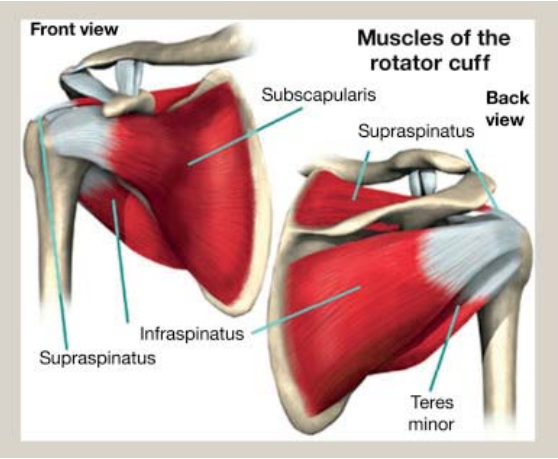


FIGURE 2 Rotator cuff muscles. Reproduced with Vollans & Ali (2016) with permission of Elsevier.

Contact between the glenoid fossa and the head of the humerus is minimal, and consequently the shoulder joint predominantly depends for stability on the ligamentous and muscular structure. The rotator cuff muscles act in co-operation with their respective force-couple antagonists (deltoids, trapezius muscles, latissimus dorsi, teres major, pectoralis major, rhomboids, levator scapula, biceps

brachi, coracobrachialis) to guide and maintain the head dynamically in the glenoid fossa (Anders et al. 2004, Terry & Chopp 2000).

Force couples are two equal forces that act in opposite but parallel directions to produce rotatory motion. The force couple of the glenohumeral joint consists of the deltoid and supraspinatus muscles which act as elevators. The deltoid muscle pulls the humeral head upwards toward the subacromial arch, and the supraspinatus muscle pulls medially toward the glenoid fossa during abduction. Inferior components of the rotator cuff muscles (subscapularis, infraspinatus and teres minor) assist the supraspinatus by compressing and depressing the humeral head. Consequently, when the rotator cuff muscles are loaded simultaneously the humeral head is stabilized in the superior-inferior direction and in the anterior-posterior direction. These actions prevent compression of the humeral head against the coracoacromial arch and allow greater motion during overhead activities (Parsons et al. 2002, Halder, Itoi & An 2000). The force couple of the scapulothoracic joint is the upper and lower trapezius with serratus anterior that contribute to scapular upward rotation during glenohumeral abduction and posterior tilt during glenohumeral flexion. The pectoralis minor, levator scapula, and rhomboid muscles produce downward scapular rotation that accompanies glenohumeral adduction, and the anterior scapular tilt that accompanies glenohumeral extension (Myers & Lephart 2000, Culham & Peat 1993). More details of force couples and motions are given in Table 2.

TABLE 2 Glenohumeral and scapular force couples and motions. Modified from Peter Ronai (2005).

Glenohumeral motion	**Glenohumeral muscles**	**Scapular motion**	**Periscapular muscles**
Abduction	Deltoid/supraspinatus Initiate abduction Subscapularis, infraspinatus, and teres minor compress and depress humeral head	Upward rotation	Upper and lower trapezius and serratus anterior
Adduction	Latissimus dorsi Teres major Pectoralis major Subscapularis, infraspinatus, and teres minor stabilize humeral head	Downward rotation Depression	Pectoralis minor Rhomboideus major and minor Levator scapula Lower trapezius
Flexion	Anterior/medial deltoid Clavicular pectoralis Supraspinatus Long head of biceps brachi Coracobrachialis Infraspinatus, teres minor, and subscapularis stabilize humeral head	Posterior tilt	Serratus anterior Upper and lower trapezius
Extension	Latissimus dorsi Teres major Sternal pectoralis Long head of triceps brachi Posterior deltoid Infraspinatus, teres minor, and subscapularis stabilize humeral head	Anterior tilt Downward rotation Depression	Pectoralis minor Pectoralis minor Rhomboideus major and minor Levator scapula Pectoralis minor Lower trapezius Serratus anterior
Horizontal flexion Internal rotation	Pectoralis major Subscapularis	Protraction	Serratus anterior
Horizontal extension External rotation	Posterior deltoid, infraspinatus, teres minor Infraspinatus, teres minor	Retraction	Mid trapezius Rhomboideus major and minor

Sangwan et al. (2015), in their recent systematic review, reported that stabilization role of the rotator cuff muscles is to limit translation in a direction-specific manner. During shoulder abduction, relatively high force from the rotator cuff

neutralizes the superior directed force generated by the deltoid muscles at lower abduction angles.

2.1.2 Rotator cuff tendon disease

Degenerative rotator cuff tendon disease (tendinopathy) is the most common disorder of the shoulder. Tendinopathy is concept commonly used to descript for different symptoms of subacromial pain (impingement syndrome, subacromial bursitis, supraspinatus tendinitis or tendinosis, painful arc syndrome and rotator cuff syndrome). The pathology of subacromial pain has a wide spectrum, ranging from acute inflammation through subacromial bursitis to advanced degenerative changes with massive rotator cuff tearing (Umer, Qadir & Azam 2012). The theory that the rotator cuff tendons make contact with the acromion and coracoacromial ligament, resulting in pain and finally tearing of the tendon, has been challenged, with recent evidence suggesting that this theory does not explain aging-related change in the rotator cuff tendons. Instead, tendinopathy associated with aging may be a predominant factor in the development of rotator cuff degeneration (McFarland et al. 2013). The prevalence of rotator cuff abnormalities ranges from 9.7% in patients aged 20 years and younger and 62% in patients aged 80 years and older (Teunis et al. 2014). Calcific tendinitis, which mostly appears in the supraspinatus tendon may cause shoulder pain, but it can also be asymptomatic (Suzuki et al. 2014).

2.1.3 Rotator cuff tear

Rotator cuff tear may be caused by an acute trauma in the absence of previous shoulder pathology. In a tear caused by a trauma, an intact tendon ruptures, resulting in a high-energetic injury. A trauma may also cause tearing in a degenerated tendon or an enlargement of a previous tear (Fukuda 2000). Alternatively, chronic tendinopathy may proceed tendon tear owing to several factors such as overuse and degeneration (Seitz et al. 2011) (Figure 3). A tendon disorder may be connected to hyperlaxity, especially in young people (Johnson & Robinson 2010). Rotator cuff tears also may occur after shoulder dislocations, whether in young athletes or older people with age-related tendon degeneration (Gombera & Sekiya 2014).

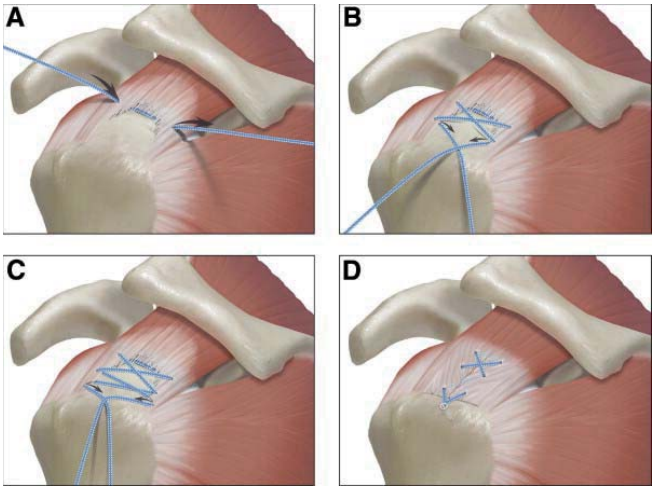


FIGURE 3 Repair of a supraspinatus tendon tear. Reproduced with van der Zwaal et al. (2012) with permission of Elsevier.

Rotator cuff tears are classified starting from partial tears to rotator cuff arthropathy (Table 3). Tears become more prevalent with increasing age (Yamamoto et al. 2010, Fehringer et al. 2008, Tempelhof, Rupp & Seil 1999), since rotator cuff pathology is mostly related to degenerative changes in the tendons during the aging process (Moosmayer et al. 2009, Yamaguchi et al. 2006). Age, gender, rotator cuff tear size, and medical and social comorbidities are associated with worse shoulder function (painful arc, restriction of active ROM and strength) and quality of life in patients with rotator cuff tear (Tashjian et al. 2004, Harryman et al. 2003). Rotator cuff tears are frequently associated with loss of strength and stability of the shoulder. Muscle atrophy and fatty infiltration are also associated with rotator cuff tears, and both are related to increasing age (Geary & Elfar 2015, Barry et al. 2012, Melis et al. 2010).

TABLE 3 Classification of rotator cuff tears. Modified from Lepola et al. (2015).

Partial tear	A tear that does not extend through the whole tendon. It may occur on the upper surface or underneath of the tendon.
Full-thickness tear	A tear that extends through the whole tendon, and compounds the synovial cavity and subacromial space.
Total tear	A tear that extends across the whole mounting substrate of the tendon.
Massive tear	A tear that extends across the whole mounting substrate of at least two rotator cuff tendons.
Rotator cuff arthropathy	A massive rotator cuff tear, superior migration of the humerus against the underneath of the glenoid, and diminished subacromial space.

2.1.4 Epidemiology of rotator cuff disorders

One-sixth of males and nearly a quarter of females have had a shoulder disorder (Viikari-Juntura, Nykyri & Takala 2007). In Finland, every fifth adult has reported shoulder pain during the past month, and on physical examination the prevalence of chronic shoulder syndrome is estimated at 5.3% in the right and 3.2% in the left shoulder (Kaila-Kangas 2007).

The point prevalence (proportion of a population that has the condition at a specific point in time) estimates of shoulder pain in the general population range from 7% to 26% (Luime et al. 2004). In Sweden, annual consultation prevalence for shoulder pain conditions was 103/10000 in women and 98/10000 in men. Two-thirds of patients consulted a doctor only once (Tekavec et al. 2012). However, only 24% of patients who had consulted a doctor in primary care because of a shoulder problem had recovered one year later (Paloneva et al. 2013).

Rotator cuff tears are the most common non-traumatic upper-limb cause of disability affecting the musculoskeletal system in people over 50 years of age. However, in Sweden, Aagaard et al. (2015) found a high incidence of acute full-thickness rotator cuff tears: the estimated annual incidence of acute full-thickness rotator cuff tears was 16/10000 inhabitants for the population aged 18–75 years and 25/10000 inhabitants for the population aged 40–75 years. It has been estimated that symptomatic rotator cuff tears affect between 4% and 32% of the population in the United States (Boykin et al. 2010). Full-thickness rotator cuff tears were present in approximately 25% of individuals in their 60s and 50% of individuals in their 80s (Tashjian 2012). In one-third of asymptomatic individuals, a rotator cuff tear has been identified by magnetic resonance imaging (Sher et al. 1995). It has also been reported that patients with rotator cuff tears have a significantly higher risk for having a tear on the contralateral shoulder and deficits in their shoulder function even if the tear is asymptomatic

(Liem et al. 2014). Nakajima et al. (2012) evaluated the effects of rotator cuff tears on ADLs in the general population. The results showed that ADLs were restricted in participants who had asymptomatic rotator cuff tears compared to those who had no rotator cuff tears. Participants with tears experienced night pain in the shoulder and muscle weakness during shoulder elevation, thus causing restrictions in ADL.

The role of central pain sensitization in rotator cuff disease has been an object of interest in recent years. In rotator cuff disease, the nervous system may be altered from the peripheral receptors to the brain and from the brain to the neuromuscular junction (Bachasson et al. 2015). Sensory abnormalities involving central mechanisms have been observed in the noninjured as well as injured side of patients with rotator cuff disease (Hidalgo-Lozano et al. 2010). Furthermore, worse clinical outcomes have been observed in cuff tear patients with signs of central sensitization than those without signs of central sensitization (Gwilym et al. 2011).

2.1.5 Etiology

The causes of rotator cuff tendinopathy can be divided into extrinsic and intrinsic mechanisms (Figure 4) (Seitz et al. 2011). Extrinsic factors pertaining to the subacromial space and bursal side compression of the rotator cuff tendons comprise anatomical alterations in the acromion, in scapular or humeral kinematics, rotator cuff and scapular muscle performance deficits, decreased extensibility of pectoralis minor or posterior shoulder, and postural abnormalities, e.g. kyphotic thoracic spine. The other extrinsic mechanism is internal impingement, where compression of the posterior articular surface of the tendons between the humeral head and glenoid occurs, and thus is not related to narrowing of the subacromial space. Intrinsic factors that originate within tendons contribute to rotator cuff tendon degeneration through tensile or shear overload, alterations in biology, vascularity, mechanical properties and morphology. Extrinsic and intrinsic mechanisms may also co-occur (Seitz et al. 2011).

Highly repetitive work, forceful exertion in work, awkward postures, and high psychosocial job demand are associated with the appearance of subacromial impingement syndrome (van Rijn et al. 2010). The etiology of rotator cuff tears is multifactorial and likely a combination of age-related degenerative changes and micro/macro trauma (Tashjian 2012). Diabetes and thyroid disease have been reported to associate with rotator cuff lesions (Oliva et al. 2014), and smoking, hypercholesterolemia, and genetics have been shown to predispose individuals to rotator cuff tearing (Tashjian 2012, Baumgarten et al. 2010). In addition, modification of the vascular background appears to influence the severity and prevalence of tears (Djerbi et al. 2015).

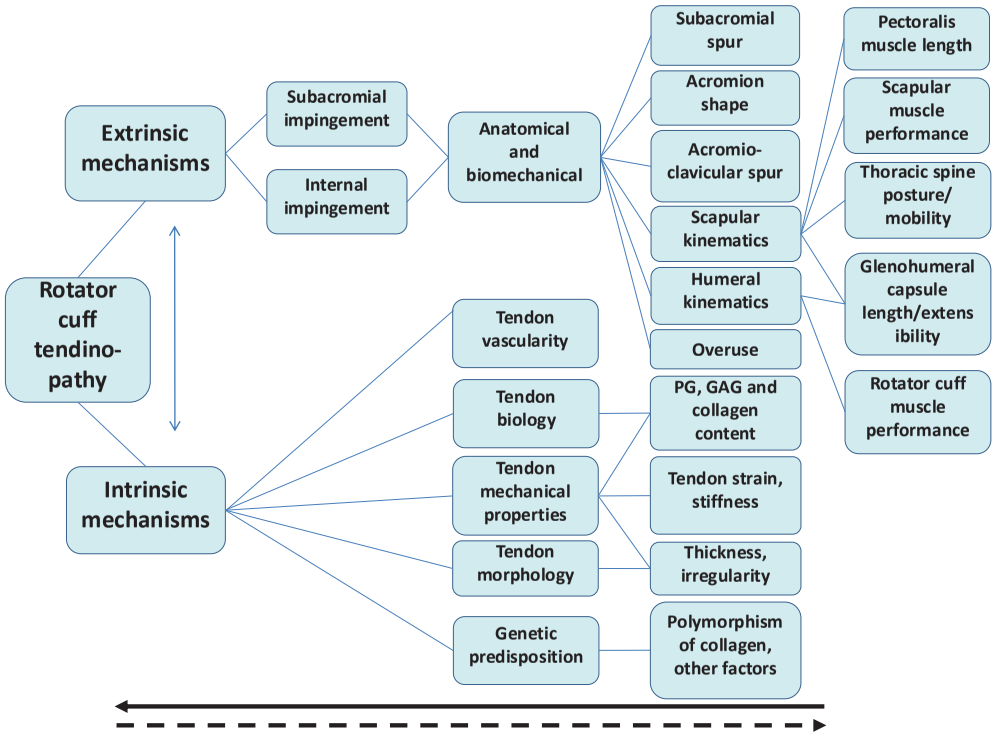


FIGURE 4 The extrinsic and intrinsic mechanisms of rotator cuff tendinopathy. Modified from Seitz et al. (2011). PG, Proteoglycan; GAG, glycosaminoglycan.

2.2 Treatment of rotator cuff disorders

While conservative treatment for symptomatic degenerative tendinopathy of the shoulder has been widely recommended (Toliopoulos et al. 2014, Ketola et al. 2013, Coghlan et al. 2008), a similar concensus has yet to be established for the treatment of rotator cuff tears (van der Meijden et al. 2012). If initial conservative treatment of a rotator cuff tendopathy or tear fails, surgical repair is often the next recourse.

2.2.1 Conservative treatment of rotator cuff tendinopathy

The current guidelines, e.g. the Current Care Guidelines of Finland (http://www.kaypahoito.fi/web/kh/suositukset/suositus?id=hoi50099) and the guidelines produced by the Dutch Orthopedic Association recommend conservative treatment of symptomatic degenerative tendinopathy in primary health care. Diagnoses should be made with a combination of clinical tests (Michener et al. 2009, Park et al. 2005, Murrell & Walton 2001). In diagnosing tendinopathy, a combination of the Hawkins-Kennedy test, the painful arc test, and the infraspinatus muscle strength test should be used. To determine a rotator cuff tear, use of the drop-arm test and the infraspinatus and supraspinatus muscle strength tests are recommended (Michener et al. 2009, Park et al. 2005, Murrell & Walton 2001). Treatment of rotator cuff disorders is mainly self-care in the inial phase, if no red flags are detected. Red flags include systemic symptoms (i.e. fever), intense radiant pain, wide sensor or motor deficiency, decreased strength and/or abduction less than 60° with or without marked trauma. In the treatment of shoulder diseases, self-care guidance has effect on pain and functional ability (Krischak et al. 2013), including optimal control of loading, ergonomics, exercise therapy and correction of posture, cold and heat treatments, and analgesics. Acute pain should be treated with analgesics for one to two weeks, if necessary (Petri et al. 2004). Corticosteroid injections can be used for severe pain in the first eight weeks (Gaujoux-Viala, Dougados & Gossec 2009, Buchbinder, Green & Youd 2003).

If self-care in the initial phase does not relieve the symptoms, the next most important treatment modality is therapeutic exercise (Kromer, de Bie & Bastiaenen 2014, Hanratty et al. 2012). The basic principles of therapeutic exercise are the individual tailoring and regularity of exercises, and a training period of at least three months (Kromer, de Bie & Bastiaenen 2014, Holmgren et al. 2012). Therapeutic exercise includes active therapy modalities, aiming to improve control of the scapula and restore shoulder ROM and muscle strength. In therapeutic exercise, combining concentric and eccentric training, paying attention to posture and relaxation is recommended (Camargo, Alburquerque-Sendin & Salvini 2014, Holmgren et al. 2012). Manual joint mobilization techniques have shown no added benefit compared to active exercises in reducing pain and improving shoulder function (Kromer, de Bie & Bastiaenen 2014, Chen,

Ginn & Herbert 2009, Kachingwe et al. 2008). In treatment of acute pain, cold therapy relieves pain and decreases swelling and inflammation of the tissue (Kuo et al. 2013, Hubbard & Denegar 2004). Physical modalities (ultrasound, laser) have not been shown to have any notable benefits in relieving pain or increasing functional ability in the treatment of rotator cuff disorders (Gebremariam et al. 2014, Calis, Berberoglu & Calis 2011). High-energy extracorporeal shockwave therapy (ESWT) reduces pain and improves shoulder function in patients with calcifying tendinitis (Ioppolo et al. 2012, Hsu et al. 2008).

2.2.2 Conservative treatment of rotator cuff tear

The current evidence supports physical therapy as the initial treatment for atraumatic full-thickness rotator cuff tears (Ryösä et al. 2016, Kuhn et al. 2013, Itoi 2013). As in the treatment of tendinopathy, exercise therapy is the most essential component of conservative treatment aiming to restore or improve the ROM and strength of the rotator cuff and scapular stabilizing muscles. The initial phase of exercise (1-2 weeks) includes daily ROM exercises (postural exercises, passive, active-assisted ROM, active scapular movements and active ROM), isometric external and internal rotation exercises. The second phase of exercise (2-3 weeks) includes daily flexibility (anterior and posterior shoulder stretching) and strengthening exercises 3 times a week, e.g. with elastic resistance (rotator cuff and scapula exercises). The third phase (4-6 weeks) includes progression of flexibility and strengthening exercises (e.g. lateral pull down, scapular retraction, pectoral press, deltoid raises, closed kinetic chain protraction with rhythmic stabilization) and ADL or sport-specific activities (Miller et al. 2015, Kuhn et al. 2013).

Cold therapy is recommended for pain management and reducing swelling of the tissue (Kuo et al. 2013, Hubbard & Denegar 2004).

2.2.3 Operative treatment

According to the Current Care Guidelines of Finland, surgical treatment is indicated in full-thickness rotator cuff tears, especially after traumatic onset, and also in degenerative rotator cuff tears in working-aged patients, unless proper conservative treatment has not yielded the desired results. Surgery is clearly indicated in the case of a physically active patient with a traumatic rotator cuff tear and consequently notable strength deficit. Rotator cuff repair is not indicated in the case of arthritis or a clearly narrowed subacromial space verified by X-ray examination.

Rotator cuff repair can be performed with shoulder arthroscopy or with an open (or mini-open) incision. The patient is placed in the beach chair position or in the lateral decubitus position and under general or regional anaesthesia. The torn tendon is mobilized and fixed with tendon-to-bone suture anchors. Acromioplasty, tenotomy or tenodesis of the long head of the biceps may be includ-

ed in the operation (MacDonald et al. 2011). Acromioplasty does not give any additional benefit in rotator cuff repair (MacDonald et al. 2011, Milano et al. 2007, Gartsman & O'connor 2004).

There is no convincing evidence that surgical treatment for tendinopathy is more effective than conservative management (Ketola et al. 2015, Ketola et al. 2013, Kromer et al. 2009, Haahr & Andersen 2006). During a 14-year period (from 1998 to 2011), the incidence of rotator cuff repairs in Finland increased by 204% (Paloneva et al. 2015). No convincing evidence has been adduced that operative treatment is more effective than non-operative management in degenerative rotator cuff tears (Kukkonen et al. 2014, Kuhn et al. 2013). In contrast, operative treatment is often indispensable for traumatic rotator cuff tears (Petersen SA, Murphy TP 2011, Björnsson HC, Norlin R, Johansson K 2011).

Reported healing rates for rotator cuff repairs vary from 91% for small tears to 6% for large and/or massive tears in some series (Frank et al. 2008, Lafosse et al. 2007, Boileau et al. 2005, Galatz et al. 2004). Older age, larger tear size, worse muscle quality, greater muscle-tendon unit retraction, smoking, osteoporosis, diabetes and hypercholesterolemia are patient-related factors that have been shown to impair tendon healing. Surgeon-related factors that may impair tendon healing are repair construct (single vs double row), rehabilitation, and biologics, including platelet rich plasma and mesenchymal stem cells (Abtahi, Granger & Tashjian 2015).

The tendon healing process is a continuum of constantly changing events. These events can be divided into three phases: inflammation, proliferation (fibroplastic), and remodeling (maturation). Tendon healing process has to be considered precisely in postoperative treatment and rehabilitation. In tendon healing, the inflammation phase is completed during the first week, when collagen synthesis is initiated with the placing of new collagen fibers in a random and disorganized way. In the proliferation phase, at three weeks, significant revascularization occurs and the endotenon provides notable fibroplast proliferation in the operated area. At four weeks, collagen is fully oriented in line with the tendon's long axis. The remodeling phase starts at two months, when the new collagen is mature and realigned along the tendon's axis. At around four months, fibroblasts have reverted to tenocytes, type I collagen has replaced type III collagen, and maturation is completed. Tendon strength is 85-95% of normal at one year (Diegelmann & Evans 2004).

2.2.4 The effectiveness of conservative compared to operative treatment

Several studies have investigated whether rotator cuff repair is more effective than conservative treatment in the treatment of full-thickness small and medium-sized tears. Moosmayer et al. (2010) compared surgery with physiotherapy in 103 patients over one year. They reported that surgery had significantly better results on the functional ability of the shoulder, pain-free abduction and reduction in pain. At the five-year follow-up, the results from surgery were superior to those from physiotherapy plus secondary repair (24% of patients in the

physiotherapy group had secondary tendon repair) in reduction in pain and disability, and patient satisfaction. However, the between-group differences were small and their clinical importance might have been low (Moosmayer et al. 2014). Kukkonen et al. (2014) compared 1) physiotherapy, 2) acromioplasty and physiotherapy, and 3) rotator cuff repair, acromioplasty and physiotherapy in a randomized controlled trial of 173 patients over 55 years of age with non-traumatic full-thickness small and medium-sized rotator cuff tears. They found that the effect of operative treatment was not better than that of conservative treatment on pain and disability of the shoulder after one year. Similarly, at the two-year follow-up, no between-group differences in clinical outcome were observed. The researchers stated that conservative treatment is a reasonable option for the primary initial treatment of isolated, symptomatic, nontraumatic, supraspinatus tears in older patients (Kukkonen et al. 2015).

Lambers Heerspink et al. (2015) compared the outcomes of 56 conservatively and surgically treated patients with a degenerative full-thickness rotator cuff tear. At 12 months, there were no between-group differences in disability, whereas VAS pain and VAS disability were significantly lower in the surgery group than conservative group. Training frequency and possible complications due to the training were not reported. In summary, there seems to be good evidence that conservative treatment should be considered as the primary method of treatment with regard to isolated, symptomatic, and non-traumatic supraspinatus tears.

Based on these previous randomized controlled trials, a recent meta-analysis (Ryösä et al. 2016) stated that no clinically significant difference has been observed at 1-year follow-up between surgery and active physiotherapy in functional ability or pain reduction caused by small and medium-sized, full-thickness rotator cuff tears. This, admittedly limited, evidence indicates that surgery is not more effective than conservative treatment alone in treating rotator cuff tears. In general, conservative treatment can be considered an appropriate initial treatment modality for rotator cuff tears.

2.3 Shoulder function and outcome measures

Outcome measures are an important aspect of research and clinical decision making in guiding treatment interventions and management strategies, and, to a certain extent, in predicting outcome. The methods for assessing functioning have to be reliable and valid. A number of condition-specific and generic measures are available for making these assessments, including standardized clinical examination methods, patient-reported questionnaires and composite scores (Roe et al. 2013, Üstün et al. 2010). Patient reported outcomes (PROs) are often the outcomes of the greatest importance for the patients, as they concern to the direct benefit of treatment rather than disease or survival. Objectively measured outcomes may include assessment by a health professional and may

focus on a specific joint or disease process, or on general health (Smith et al. 2012).

2.3.1 Shoulder-spesific outcome measures

The self-report section of the American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form (ASES) (Richards et al. 1994) is one of the most widely used and cited disease-specific measurement instruments that connect symptoms and disability to a specific disorder (Roe 2013). It has been translated and cross-culturally adapted in several languages. An outcome instrument is reliable if it produces consistent results regardless of different testers or repeated tests under similar circumstances. It is valid when it measures what it claims to measure. Validity includes many considerations (construct, content and criterion validity), and therefore the validity of an instrument is based on a body of evidence rather than on a single test (Smith et al. 2012). Several studies have assessed the psychometric properties of the self-report section of the ASES, which has been considered to be a reliable and valid outcome tool (Table 4) (Celik et al. 2013, Moser et al. 2012, Yahia et al. 2011, Padua et al. 2010, Goldhahn et al. 2008, Kocher et al. 2005, Michener, McClure & Sennett 2002). In the previous studies, the number of subjects has varied from 63 to 1 066, and the sample age from 18 to 95 years. The interval between the first and the second measurement has varied from one day to four weeks. The mean reproducibility ICC of the ASES has varied from 0.75 to 0.96. Internal consistency, using Cronbach's alpha, has been reported to vary from 0.61 to 0.96. For convergent validity, which is one component of construct validity, correlations, e.g. between the ASES and the SPADI (the Shoulder Pain and Disability Index), have ranged from -0.82 to 0.92, between the ASES and the DASH from -0.92 to 0.84, between the ASES and the Physical Component of the SF-36 from 0.02 to 0.64, and between the ASES and the Mental Component of the SF-36 from -0.02 to 0.66. There seems to be a strong correlation between the ASES and other shoulder-specific questionnaires, and a variable correlation between the ASES and a generic questionnaire.

The minimal clinically important difference refers to the minimum change in a score that indicates a change in disability (Smith et al. 2012). The study by Michener et al. (2002) included operated and non-operated patients aged from 20 to 81 years, across a wide range of shoulder disorders, such as impingement syndrome and humeral fracture. The minimal clinically important difference was 6.4 ASES points and the estimated minimal detectable change was 9.7 ASES points (Michener, McClure & Sennett 2002). The minimal detectable change is an estimate of the smallest amount of change that corresponds to a noticeable change in disability that is detectable by a measure. According to another estimate, a change of between 12 and 17 ASES points indicates a minimal clinically important difference after conservative treatment in patients with rotator cuff disease (Tashjian et al. 2010). In addition, outcome measures may have floor or ceiling effects, meaning that the outcome measure is unable to assess deterioration (floor) or improvement (ceiling) (Smith et al. 2012).

Other measurements used to assess shoulder disability are the Disabilities of the Arm, Shoulder, and Hand questionnaire (DASH) (Hudak, Amadio & Bombardier 1996), the QuickDASH (Beaton et al. 2005), the Constant Score (CS) (Constant & Murley 1987), the Shoulder Pain and Disability Index (SPADI) (Roach et al. 1991), and the Simple Shoulder Test (SST) (Lippitt, Harryman & Matsen FA 1993).

TABLE 4 Summary of translation, cultural adaptation and validation studies of the ASES.

	Number of subjects (age range, years)	**Shoulder disorders**	**Interval between the first and the second measurement**	**Reproducibility ICC (95% CI)**	**Internal consistency (Cronbach's alpha)**	**Convergent validity ASES and other questionnaire**	**Convergent validity ASES and SF-36 PCS**	**Convergent validity ASES and SF-36 MCS**
Celik et al. 2013 Turkish	n=63 (18-74)	Operated and non-operated; RCdisorders, frozen shoulder, Bankart surgery, RCR	3-7 days	0.94	0.88	SPADI r=-0.82 p<0.001	r=0.02 p=0.82	r=0.53 p<0.001
Moser et al. 2012 Portuguese	n=50 (39±13)	Shoulder dysfunction	7 days (n=38)	0.75	0.79	DASH ρ=-0.69 p<0.001	PF ρ=0.50 p<0.001 BP ρ=0.60 p<0.001 RP ρ=0.43 p=0.002	VT, SF, RE, and MH ns
Yahia et al. 2011 Arabic	n=80 (21-75)	Periarticular shoulder disabilities	1-3 days (n=30)	0.96 (0.92 to 0.98)	0.81	SPADI r=-0.80 p<0.001 DASH r=-0.86 p<0.001	-	-
Padua et al. 2010 Italian	n=50 (33-78)	Impingement syndrome, glenohumeral arthritis, adhesive capsulitis	7 days (n=20)	0.91	0.85	DASH r=-0.92 p<0.02 OSQ r=0.78 p<0.02	r=0.48 p<0.01	r=-0.20 ns

Goldhahn et al. 2008 German	n=118 (33-89)	All patients had undergone total shoulder arthroplasty due to osteoarthritis, rheumatoid arthritis or other conditions	7 days	0.93 (9.90 to 0.95)	0.96	SPADI r=0.92 DASH r=0.84	r=0.64	Overall SF-36 r=0.66
Kocher et al. 2005 English	n=1066 (13-95)	Shoulder instability, rotator cuff disease, glenohumeral arthritis	4 weeks	0.94 (n=56) age range 15-78 years	0.61 instability, 0.64 rotator cuff disease, 0.62 arthritis	-	SF-12 r=0.32-0.58 p<0.001-0.002	SF-12 r=0.09-0.11 p=0.27-0.67
Michener et al. 2002 English	n=63 (20-81)	Operated and non-operated; RCdisorders, adhesive capsulitis, humerus fracture, instability	24 to 72 hours, and after 3 to 4 weeks	0.84 (0.75 to 0.91)	0.86	Penn Score r=0.78 p<0.01	r=0.40 p=0.001	r=0.15 p=0.25

ASES, American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form; ICC, intra-class correlation coefficient; CI, Confidence interval; SST Simple Shoulder Test; SPADI, Shoulder Pain and Disability Index; DASH, Disability of Arm, Shoulder and Hand questionnaire; OSQ, Oxford Shoulder Questionnaire; Penn Score, the University of Pennsylvania Shoulder Score; SF-36, Short Form 36 Health Survey; PCS, Physical Component Summary; MCS, Mental Component Summary; RC, Rotator cuff; RCR, Rotator cuff repair; SF-12, Short Form 12 Health Survey.

2.3.2 Assessment of health-related quality of life

Quality of life has been defined "as a perception of individuals of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns" (The World Health Organization quality of life assessment 1995). HRQoL instruments are increasingly being used to describe and evaluate functioning and health in clinical trials and clinical practice, as well as various other fields of research. The main purpose of HRQoL instruments is to describe the burden of disease of the population studied, focusing on activities and types of participation that are considered to be the most relevant to patients and society, and that are relevant to all health conditions. Such instruments enable functioning and health to be compared across health conditions, populations, and interventions (Cieza & Stucki 2005). Several generic questionnaires assessing general health, overall disability, and quality of life are available, including the World Health Organization Quality of Life (WHOQOL), EuroQol (the EuroQol Group 1990), and the Short-Form 36 Health Survey (SF-36) (Ware JE, Kosinski M, Keller SD 1994).

The SF-36 evaluates a patient's state of health on eight scales: Physical Functioning, Role Physical, Bodily Pain, General Health, Vitality, Social Functioning, Role Emotional, and Mental Health. Scores range from 0 to 100, with a higher score indicating better health. The eight Short-Form 36 Health Survey scales were subsequently aggregated into two summary measurements: a physical component summary score and a mental component summary score.

2.3.3 Measurement of shoulder muscle strength and range of motion

Rotator cuff tears have been associated with weaker muscle strength and decreased active range of motion (ROM) (Yamamoto et al. 2010). Impaired rotator cuff muscle strength and decreased ROM may lead to increases in adverse loading and functional limitations (Kolber & Hanney 2012, Ludewig & Reynolds 2009). Thus, objective shoulder strength and ROM measurements are indispensable both in the clinical assessment of the patient's status and progress, and in the research domain (Cools et al. 2014, Kolber & Hanney 2012).

Shoulder muscle strength measurements are most commonly performed with isometric and isokinetic devices. In a study of isometric shoulder muscle strength measurements, intra-rater reliability (ICC 0.93-0.99) and inter-rater reliability (ICC 0.94-0.99) were excellent for internal and external rotation regardless of the shoulder position or equipment used (Cools et al. 2014).

Clinical measurement of shoulder ROM has most commonly been performed with a goniometer (Hayes et al. 2001). The study by Mullaney et al. (2010) compared the reliability of a goniometer to a digital level. The results indicated that reliability between the digital level and the goniometer was similar, but that, owing to systematic error, glenohumeral rotation was 3°-5° larger for the digital level than goniometer. Thus, these two methods may not be used

interchangeably. Assuming the average intratester 95% limits of agreement (LOA) for the goniometer and the digital level, a change of 6°-11° is needed to be sure that a true change has occurred (Mullaney et al. 2010).

Normal age- and sex-related benchmarks for shoulder muscle strength and ROM are lacking in the literature. Murray et al. (1985) measured the maximal isometric strength (torque) and active shoulder ROM of several shoulder muscle groups (in flexion, extension, internal and external rotation) in normal healthy men (n=20) and women (n=20) in two age groups: 25-36 and 55-66 years. The strength of the women was 45% to 66% of that in men, and strength of the older subjects was 66% to 93% of that in the younger subjects. The strength of the second attempt at contraction was greater than that of the first attempt. Arm dominance did not significantly affect the strength values. The values for shoulder ROM were similar for the two age and sex groups. In the study by Roy et al. (2009), isometric rotational strength and rotational ROM was measured in 294 subjects with unaffected shoulders. The subjects were divided into three subgroups by age and sex: 18-39, 40-59, and over 60 years. The results showed that, among the men, the 40-59 age group showed the highest strength values, while among the women the highest values were found in the 18-39 age group. The strength of the dominant arm in women was 46% that of men in internal rotation and 51% that of men in external rotation. The strength of the older subjects was significantly lower in external rotation than that of the younger subjects. Women had a significantly higher ROM than men for external rotation on the non-dominant side in the 40-59 age group. In addition, men over 60 years of age showed lower strength. Moreover, all the subjects over 60 years of age had lower ROM.

2.4 Postoperative rehabilitation after rotator cuff repair

2.4.1 Therapeutic exercise of the shoulder

Therapeutic exercise is a subcategory of physical activity that includes all bodily movements produced by skeletal muscle contraction that result in energy expenditure (Howley 2001, Caspersen, Powell & Christenson 1985). The prime goal of therapeutic exercise is to achieve symptomless capacity to meet the physical load of work and other activities in everyday life. This individually tailored training should be based on knowledge of the effects of specific exercises, functional capacity status, the potential rate of recovery, complications, precautions, and contraindications (Mälkiä & Kannus 1996).

Faulty scapular positioning is associated with various shoulder disorders (Ludewig & Reynolds 2009). In cases of shoulder tendinopathy, the kinematics of the scapula may alter when, especially during shoulder flexion, the posterior tilt, upwards rotation and external rotation of the scapular may be abnormal (Struyf et al. 2013). In conservative treatment of the shoulder, the objective of therapeutic exercise is to contribute to the healing process of soft tissues, to re-

lieve pain and inflammation, and to restore the posture and control of the shoulder, scapula and trunk. An additional goal of therapeutic exercise is to increase ROM and shoulder strength (Kromer, de Bie & Bastiaenen 2014, Kuhn 2009, Lombardi et al. 2008, Walther et al. 2004). Based on randomized controlled trials, the researchers recommend ROM and stretching exercises be performed once or twice a day, 10 seconds at a time and repeated two or three times. It is recommended that ROM exercises begin with postural exercise such as shrugs and shoulder retraction. Glenohumeral motion should begin with pendulum exercises, progressing through active assisted motion to active motion. Patients may use a cane, pulleys, or the unaffected arm, when performing active assisted exercises. Active motions can be performed in front of a mirror. Stretching exercises include, e.g. anterior and posterior shoulder stretching. Strengthening exercises should be performed three times a week, in 2 to 3 sets and with 10 to 15 repetitions. They include rotator cuff internal and external rotation exercises with resistance bands. Scapular strengthening should include chair press, push-up, and upright row exercises with resistance bands (Kuhn 2009). According to Kjaer et al. (2009), progressive shoulder training stimulates the re-conditioning process and improves the capacity of the rotator cuff to withstand greater load and stress. Therapeutic exercise relieves shoulder pain in the short term (six to 12 weeks), and improves shoulder function in patients with rotator cuff disease in the short and long term (more than 12 weeks) (Hanratty et al. 2012). The effectiveness of therapeutic exercise is likely to improve when a specified strength training protocol, including eccentric exercises for for the rotator cuff and consentric/eccentric exercises for the scapula stabilizers, is followed (Camargo, Alburquerque-Sendin & Salvini 2014, Holmgren et al. 2012).

Successful exercise therapy in the treatment of small full-thickness rotator cuff tears results in improved glenohumeral joint kinematics and patient-reported outcomes (i.e. ASES, DASH, WORK) by significantly increasing rotator cuff muscle strength and joint stability (Miller et al. 2015).

A few postoperative rehabilitation protocols have been recommended after RCR (Thigpen et al. 2016, Koo & Burkhart 2010, Conti et al. 2009). The aim of these protocols is to restore maximal postoperative shoulder function and simultaneously minimize stress in the repaired tendons (Lee, Cho & Rhee 2012, Du Plessis et al. 2011, Brislin, Field & Savoie 2007); however, no agreement has yet been reached on what rehabilitation exercises best achieve both the healing and functional goals (Murphy et al. 2013). In a recent concensus statement, Thigpen et al. (2016) described a postoperative rehabilitation framework that lies between early passive mobilization and strict immobilization, and includes a two-week period of immobilization followed by protected passive ROM exercises for two to six weeks, after which active ROM exercises and, finally, beginning at 12 weeks postoperatively, progressive strengthening exercises are performed.

2.4.2 Effectiveness of postoperative exercise

To review the literature on rehabilitation after rotator cuff repair, a systematic literature search of English language articles using several databases (PubMed,

Embase, Cochrane, and PEDro) was conducted in January 2016. A total of 121 original articles were found using "rotator cuff" and "repair" or "reconstruction" or "surgery" and "rehabilitation" or "exercise*" or "training" or "physiotherap*" or "physical therapies" as search words. The date of publication was not delimited. Finally, after examining the full text of these articles, 15 randomized controlled studies were selected for the review (Table 5). All the references included in the selected studies were perused to identify any additional papers that may have been overlooked or were not indexed in the electronic databases.

A number of the systematic reviews and meta-analyses comparing early postoperative rehabilitation with an immobilization period of four to six weeks were very recent. Kluczynski et al. (2015b) recommended that immediate passive ROM exercises should be started in the case of small (≤3 cm) tears, but that, to maximize tendon healing in large (≥5 cm) tears, delayed passive ROM exercises should be considered. These authors also stated that, regardless of the method of repair, starting early active ROM exercises less than six weeks after surgery seemed to be harmful to the healing process for both small and large tears. Thus delaying active ROM exercises by at least six weeks was recommended (Kluczynski et al. 2015a). In cases of small to medium-sized tears shoulder ROM increased significantly more in the early rehabilitation groups than immobilization groups up to three months after rotator cuff repair. However, no between-group differences in disability were found (Chang et al. 2015, Chan et al. 2014, Riboh & Garrigues 2014). Early ROM exercise had a positive effect on postoperative stiffness but it tended to cause a higher rate of recurrent tendon tears, and thus caused improper tendon healing in shoulders with large-sized tears. Chen et al. (2015) found that early motion after arthroscopic rotator cuff repair resulted in a significantly greater recovery of external rotation at three, six, and 12 months postoperatively, and forward elevation at six months postoperatively ($p<0.05$), from the pre-operative values, as compared to when motion was delayed.

Of the 15 randomized controlled trials, 13 compared early postoperative rehabilitation with immobilization (Table 5A). Three studies found no between-group differences in shoulder pain or disability (Lee, Cho & Rhee 2012, Kim et al. 2012, Klintberg et al. 2009). In the study by Koh et al. (2014) two different immobilization periods (four weeks versus eight weeks) were compared, and the results suggested that more than four weeks' immobilization seems to lead to more stiffness without additional positive effects. There were no between-group differences in disability. Four studies reported significantly better outcomes in active flexion and external rotation in favour of early rehabilitation up to 3 months after the operation. Thereafter, the between-group differences disappeared (Keener et al. 2014, Arndt et al. 2012, Cuff & Pupello 2012, Duzgun, Baltaci & Atay 2011). The other studies on this issue reported no addional benefits to shoulder ROM (Lee, Cho & Rhee 2012, Kim et al. 2012, Klintberg et al. 2009). Passive self-assisted ROM exercises associated with the use of continuous passive motion (CPM) has led to better ROM values than passive self-

assisted exercises alone (Garofalo et al. 2010, Raab et al. 1996). These authors also reported significant pain relief in the CPM group (Table 5A).

Only two randomized controlled trials were found in which the effectiveness of different postoperative shoulder rehabilitation methods were investigated in the long term (Table 5B) (Hayes et al. 2004, Roddey et al. 2002). Hayes et al. (2004) compared the effectiveness of individualized supervised physiotherapy and standardized home exercise on functional ability of the shoulder. Individualized physiotherapy started in the second postoperative week and consisted of any combination of exercises, manual therapy techniques, physical modalities of ice and moist heat, and home exercise advice. Subjects in the individualized physiotherapy group received 16±11 treatments over 17±9 weeks. No between-group differences were found in shoulder function, as measured by the Shoulder Service Questionnaire after six months of training. Roddey et al. (2002) reported that two different instructional approaches aiming to improve shoulder function (one using videotaped instructions and the other using personal instructions from a physiotherapist) led to equal improvements in pain and in functional ability of the shoulder at 12 months, as measured by the Shoulder Pain and Disability Index (Table 5B).

Clearly, there is a lack of research assessing the effectiveness of long-lasting progressive postoperative strength training on shoulder disability, HRQoL and shoulder function in a randomized controlled study design.

TABLE 5 Randomized controlled trials comparing postoperative rehabilitation.

Study	Patients	Interventions	Main outcome and Length of follow-up	Main results
A. Early postoperative rehabilitation				
Sheps et al. 2015	n=165; F=68, M=97 G1: n=80, G2: n=85 mean age 55 y	G1: Early mobilization G2: Immobilization for six weeks	Pain Disability Constant score HRQoL WORC Abduction strength ROM 24 months	No between-group differences were found in any of the outcomes. It is suggested that the patient and the treating surgeon make the decision on rehabilitation following the RCR.
De Roo et al. 2015	n=130; F=41, M=38 G1: n=79, G2: n=51 mean age 65 y	G1: Immediate passive mobilization exercises G2: Immobilization in a brace for four weeks except for the pendulum exercises	Disability SST SPADI Constant Score UCLA Muscle strength ROM 4 months	No between-group differences were found in any of the outcomes at four months. Both the early passive mobilization protocol and delayed mobilization protocol seemed applicable and safe.
Keener et al. 2014	n=124; F=51, M=73 G1: n=65, G2: n=59 mean age 55 y	G1: Traditional rehabilitation program with early range of motion G2: Immobilization with delayed range of motion for six weeks	Pain Disability ASES SST Muscle strength 24 months	Active elevation and external rotation were better in the traditional rehabilitation group at 3 months. No between-group differences were studied in active motion, functional scores, or shoulder strength at the later time points.

Koh et al. 2014	n=88; F=44, M=44 G1: n=40, G2: n=48 mean age 60 y	G1: 4-week immobilization without passive or active motion exercises G2: 8-week immobilization without passive or active motion exercises	Disability Constant Score ASES ROM 24 months	More than 4 weeks of immobilization seemed to lead to more stiffness without additional positive effects. No between-group differences in disability or ROM.
Klintberg et al. 2009	n=14; F=5, M=9 G1: n=7, G2: n=7 mean age 55 y	G1: Early progressive muscle activation and passive ROM from the first day after surgery G2: Immobilization for 6 weeks and passive ROM from the first day after surgery	Pain Disability Constant Score Muscle strength ROM 24 months	No between-group differences in any outcomes. The progressive protocol produced no adverse effects compared with the traditional protocol.
Kim et al. 2012	n=105; F=61, M=44 G1: n=56, G2: n=49 mean age 60 y	G1: Early passive motion exercises 3 to 4 times a day during the abduction brace-wearing period G2: No passive motion during the abduction brace-wearing period	Pain Disability Constant Score SST ASES ROM 12 months	Early passive motion exercise after arthroscopic cuff repair did not guarantee early gain in ROM or pain relief but also did not negatively affect cuff healing.

Lee et al. 2012	n=64; F=23, M=41 G1: n=30, G2: n=34 mean age 55 y	G1: Aggressive early passive rehabilitation (manual therapy 2 times a day from 1 day post-operatively and unlimited self–passive stretching exercise) G2: Limited early passive rehabilitation (limited continuous passive motion and limited self–passive exercise)	Pain Disability UCLA Muscle strength ROM 6-12 months	Pain, ROM, muscle strength, and function improved significantly, regardless of the early postoperative rehabilitation protocol. A gentle rehabilitation protocol with limits on ROM and exercise times would be better for tendon healing.
Arndt et al. 2012	n=92, F=58, M=34 G1: n=49, G2=43 mean age 55 y	G1: Early ROM, commencing day 2 postoperatively, CPM without ROM limitations, pendular exercises G2: Immobilization, maintenance of sling immobilization for 6 weeks, pendular exercises	Disability Constant Score 12 months (mean 15 mo)	Statistically significant difference in favour of early group, not regarded as clinically important.
Düzgün et al. 2011	n=29; F=26, M=3 G1: n=13, G2: n=16 mean age 56 y	G1: Accelerated rehabilitation G2: Slow rehabilitation	Disability DASH 24 weeks	Statistically significant between-group differences in favour of accelerated rehabilitation at 8, 12 and 16 weeks, but not significant difference at 24 weeks.
Cuff & Pupello 2012	n=68; F=30, M=38 G1: n=33, G2: n=35 mean age 63 y	G1: Early passive range of motion G2: Immobilization	Disability ASES SST ROM 12 months	At 6 months, the early range of motion group demonstrated significantly greater forward elevation compared with the delayed range of motion group. No between-group dif-ferences were studied in any outcomes at 12 months. Both groups showed simi-lar improvements in disability.

Garofalo et al. 2010	n=100; F=53, M=47 G1: n=46, G2: n=54 mean age N/A	G1: Passive self-assisted range of motion exercise G2: Passive self-assisted range of motion exercise associated with use of CPM	Pain ROM 12 months	Passive self-assisted exercises associated with 2-h CPM a day provided a significant advantage in terms of ROM improvement and pain relief when compared to passive self-assisted exercise alone.
Lastayo et al. 1998	n=31; F=17, M=14 G1: n=17, G2: n=15 mean age 63 y	G1: Continuous passive motion (CPM) for the first 4 weeks G2: Manual passive ROM for the first 4 weeks	Pain Disability SPADI Muscle strength ROM Mean 22 months	No between-group differences in disability, pain, ROM or strength.
Raab et al. 1996	n=26; F=8, M=18 G1: n=12, G2: n=14 mean age 56 y	G1: Physiotherapy only G2: Continuous passive motion (CPM) and physiotherapy (PT)	An author-generated patient-reported shoulder score (function, pain, muscle strength, ROM) 3 months	No between-group differences in shoulder score. However, CPM had an effect on ROM for all patients, and on pain relief in female patients and patients over 60 years of age.
B. Interventions started about 2 months after the operation				
Hayes et al. 2004	n=58; F=18, M=40 G1: n=26, G2: n=32, mean age 60 y (range 41 to 83)	G1: Individualized physiotherapy sessions for 17±9 weeks in addition to the standardized home exercise regime. G2: Standardized home exercise regime	Disability Shoulder Service Questionnaire Manual muscle test Visual estimation of passive ROM 6 months	No between-group differences in disability, ROM or strength.

Roddey et al. 2002	n=108; F=N/A, M=N/A G1: n=54, G2: n=54, mean age 58 y	G1: Videotape-based home exercise instruction G2: Personal instructions from a physiotherapist	Pain Disability Shoulder Pain Disability Index 12 months	No between-group differences.

G, Group; ROM, Range of motion; ASES, the American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form; SST, the Simple Shoulder Test; UCLA, the University of California, Los Angeles score; DASH, Disabilities of the Arm, Shoulder and Hand; N/A, Not available; CPM, Continuous passive motion; SPADI, the Shoulder Pain and Disability Index.

3 AIMS OF THE STUDY

The primary aim of this study was to investigate the effectiveness of a long-lasting progressive shoulder muscle strength training program after rotator cuff repair. Therefore, the first step was to validate a shoulder-specific measurement tool for disability translated and cross-culturally adapted to the Finnish language. The specific aims and hypotheses of the present studies were as follows:

1. To assess the reliability and validity of the ASES questionnaire translated into the Finnish language in patients with different shoulder disorders (I).

2. To investigate the relationship between shoulder disability and health-related quality of life (HRQoL) in patients with rotator cuff tear (II).

3. To examine the effectiveness of an intensive 12-month home-based shoulder training program on shoulder disability and HRQoL after rotator cuff repair (III).

4. To compare a 12-month shoulder training program with usual care for shoulder muscle strength and range of motion (ROM) after rotator cuff repair (IV).

4 MATERIAL AND METHODS

4.1 Subjects

4.1.1 Patients in the validation study (I)

For the validation study (I) 105 subjects, who had been clinically diagnosed with a shoulder disorder and referred for a specialized care in the outpatient clinics of the Departments of Orthopedics and Traumatology and Physical Medicine and Rehabilitation in Central Finland Hospital, were recruited. The inclusion criteria were age over 18 years, shoulder symptoms, and the ability to communicate in the written Finnish language. The exclusion criterion was previous surgery in the affected shoulder less than one year previously.

The self-report section of the ASES questionnaire was administered twice. On the first occasion, the questionnaire was mailed to the patients, who completed it 2 weeks before arriving at the outpatient clinic. At the clinic, the patients were contacted personally by a physiotherapist and asked to complete the questionnaire for the second time. On this occasion, the questionnaire included the following item asking the patients to assess their shoulder symptoms: "Have your shoulder symptoms 1) Remained the same, 2) Improved, or 3) Worsened?"

4.1.2 Patients in the intervention study (III-IV)

In the intervention study (III-IV) comparing progressive home-based postoperative rehabilitation and usual care following rotator cuff repair, 67 subjects were recruited from the outpatient clinic of the Department of Orthopedics and Traumatology in Central Finland Central Hospital between May 2006 and December 2009. The inclusion criteria were age 18 to 65 years with a <5-cm symptomatic rotator cuff tear (anterior-to-posterior dimension) in the supraspinatus and/or infraspinatus tendons. The following exclusion criteria were applied: previous surgery on the affected shoulder, cervical intervertebral disc prolapse,

previous operations on the cervical spine, stenosis of the spinal canal, signs of marked osteoarthritis, rheumatoid arthritis, fibromyalgia, pregnancy, serious mental illness or social problems, and severe cardiac disease or neurological disorders.

Pre-study calculation of sample size was not applied; instead, our target was to collect 50 participants per group (Altman 1999) (ClinicalTrials.gov database: NCT00624117). At baseline (two months after the operation), the study participants were stratified by gender and their preoperative ASES indices (dichotomized as < or >50 points). To ensure that the intervention groups were equivalent in terms of disability, an ASES index of 50 points, which is the median of the maximal ASES index, was chosen as the cut-off point for randomization. The participants were randomized consecutively into an exercise group (EG, n=35) or a usual care group (UCG, n=32), using a computer-generated randomization list by Medstat (Wulff & Schlichting P). The study was approved by the regional health ethics board of the Central Finland Health Care District, and a written informed consent was obtained from all patients.

4.2 Study design

Study I was a translation and cross-cultural adaptation study. Study II was a cross-sectional study carried out to assess the relationship between shoulder function and HRQoL. Studies III and IV evaluated the effectiveness of a 12-month training intervention on shoulder disability, HRQoL, and physical functioning (randomized controlled trial) (Figure 5).

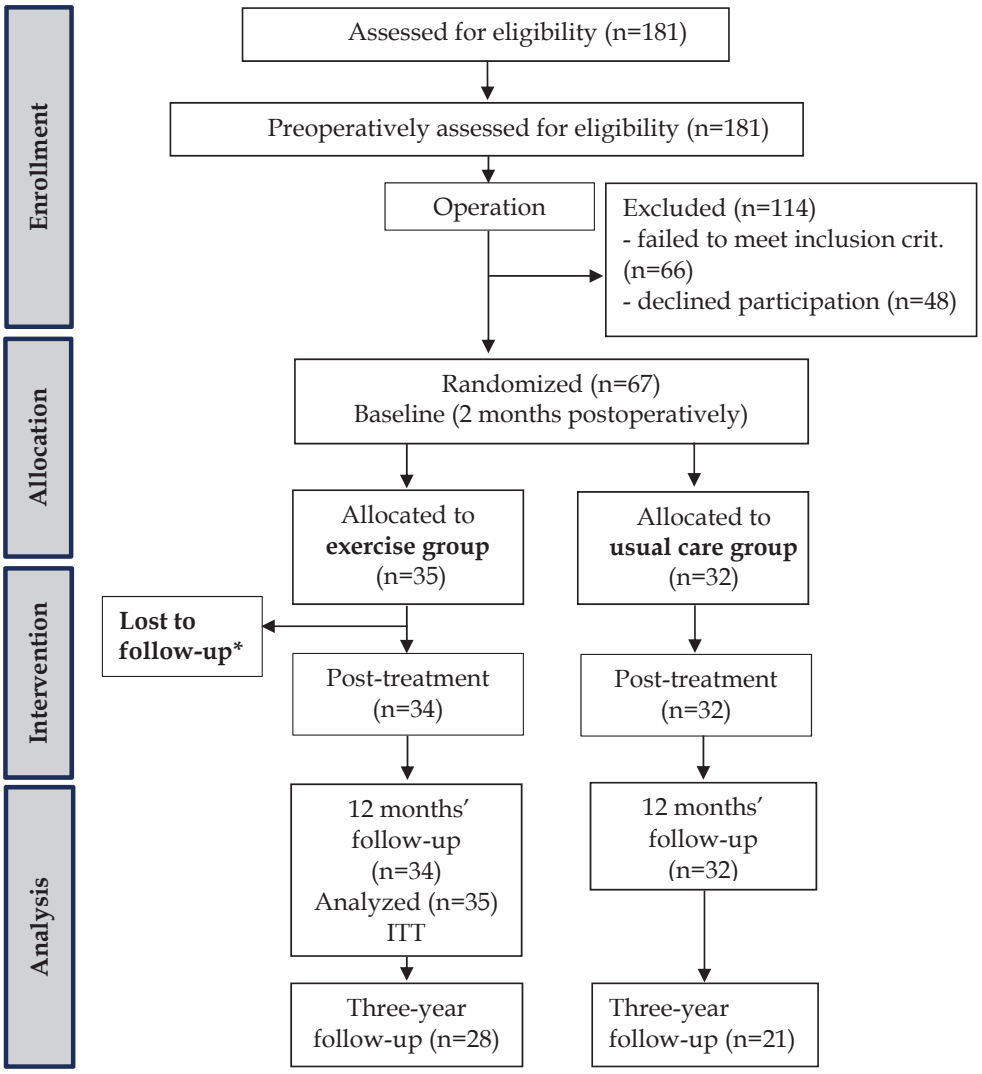


FIGURE 5 CONSORT diagram summarizing the flow of the study.
*Interrupted the training (n=1), but was analyzed (ITT).

The patients completed questionnaires on their demographic and clinical characteristics preoperatively. They also completed the ASES and the SF-36 questions preoperatively, at the baseline of the postoperative intervention (two months after the operation), at the end of the 12-month intervention and three years thereafter. The three-year follow-up was initiated by mailing the ASES questionnaire to all participants; those who answered the questionnaire were

included in the analysis. Before the baseline measurements, block randomization (size of 4) was performed by gender and preoperative ASES scores (dichotomized as < or >50 points), and patients randomized into an exercise group (EG) (n = 35) or a usual care group (UCG) (n = 32). The randomization was done by a person who was not working with the patients. The CONSORT Statement was used in designing and reporting this intervention study. The study is registered in the ClinicalTrials.gov database: NCT00624117.

4.2.1 Surgery and the early postoperative rehabilitation

The rotator cuff repairs were performed in a standard manner, using either an arthroscopic (n = 3) or mini-open (n = 64) approach. All operations were performed with the patient placed in the beach chair position with general or interscalene block regional anaesthesia. Single-row suture anchors were used for the tendon-to-bone repair. Acromioplasty was included in the procedure in 33 (94%) of the EG patients and 30 (94%) of the UCG patients. In addition, tenotomy or tenodesis of the long head of the biceps was performed in three cases (9%) in the EG and six cases (19%) in the UCG.

After the operations, all individuals underwent the same early postoperative rehabilitation protocol. The upper arm was maintained beside the body in an immobilizing sling for three weeks, although the patients were allowed to perform light domestic work without wearing the sling. Patients were advised to perform a set of postoperative home exercises (active elbow and finger flexion and extension, shoulder and scapula retraction, pendulum exercises, passive/ assisted shoulder flexion, external rotation 60°, functional internal rotation), according to instructions, three times a day. The exercises were started on the first postoperative day. Two weeks after the operation, each patient met with a physiotherapist for a normal control visit at the outpatient clinic. Light isometric contractions of the shoulder muscles in flexion, extension, internal and external rotation, three times a day, were added to the exercise program. At six weeks, each patient visited the outpatient clinic again and was instructed to start dynamic ROM and strength exercises with a light resistance, using yellow resistance bands (Thera-Band®, The Hygenic Corporation Akron Ohio 44310 USA). The ROM exercises were to be performed once a day and strength exercises two to three times a week. At two months, each patient visited a physiotherapist. If the patients fulfilled the study criteria, they were recruited into the study and randomized into an EG or a UCG.

4.2.2 Description of the intervention study arms (III, IV)

The subjects were randomized into two groups: an exercise group (EG, n=35) and a usual care group (UCG, n=32) (Figure 6).

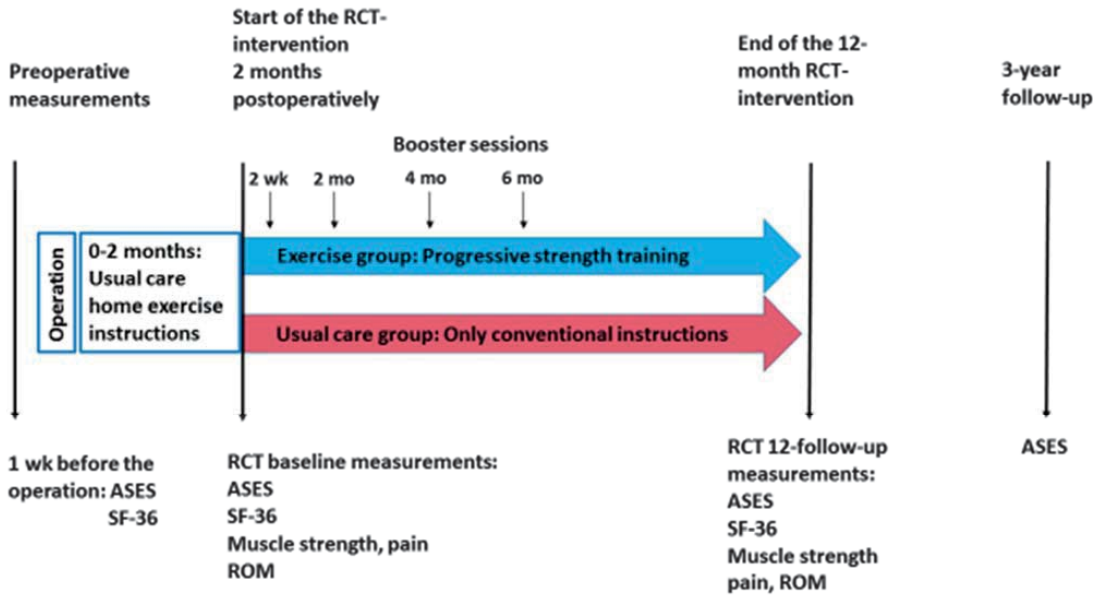


FIGURE 6 Description of the 12-month strength training intervention.

The home-based training intervention started two months after the rotator cuff repair. The patients in the EG were instructed to perform the muscle strength exercises three times a week. The training began ten-repetition dumbbell exercises with individual load, after which the number of repetitions was gradually increased to 15. When the patients were able to perform 15 repetitions, they were advised to increase the load by ½ to 1 kg. Males were allowed increase the load up to 18 kg and females up to 11 kg, which were the highest possible loads for the adjustable dumbbells used. The strength exercises consisted of wall push-ups, one-arm dumbbell rows, shoulder adductions with black rubber Thera-Bands®, internal and external shoulder rotations with a dumbbell (lying on the side), one-arm dumbbell shoulder presses (in the supine position), dumbbell front raises with short lever arm (standing), bicep curls, abdominal crunches (in the supine position) and back extensions (in the prone position). The shoulder mobility movements consisted of ROM and stretching exercises instructed to be performed daily.

Two months after the initial exercise instructions, the patients in the EG had a second individual session focused on exercise progression. Shoulder elevation in scapular plane with a dumbbell, military push-ups and dumbbell triceps kickback exercises were added to the training program (Training program: Appendix 1). Most of these exercises aim at strengthening the rotator cuff and scapular muscles. Closed-chain exercises, e.g. push-ups, improve shoulder stability, proprioception and sensorimotor control (Kibler 2000). External rotation exercises open the subacromial space and prevent compression of the greater tubercle against the subacromial surface (Smith et al. 2002). Shoulder elevation exercises in the scapular plane strengthen the supraspinatus muscle and increase the subacromial space, reduce stress in capsuloligamentous tissues and tendons, and contribute to normal scapulohumeral rhythm (Williams & Kelley 2000). The core muscle exercises were added to the exercise program, as core stabilization provides a firm base from which the scapula can work.

Two weeks, 2 months, 4 months, and 6 months after starting the training, the patients in the EG had booster sessions, when the physiotherapist checked the training progression by assessing isometric strength and checking the training diaries in which the patients recorded the frequency with which they performed the strength and stretching exercises. Training progression was individually based on shoulder symptoms, ROM restrictions and strength. If the patients had shoulder pain during the training, they were advised to use cold therapy, check the training technique, and/or lighten the training regimen, until the pain was relieved.

The patients in the UCG did not receive any advice beyond the standardized usual care, which included ROM and light strength (without dumbbells) exercises, which the patients in both groups received six weeks after their operations. The UCG patients did not meet with a physiotherapist after six weeks.

4.3 Measurements

Subjective, objective, clinical and sociodemocraphic data were measured preoperatively, at baseline and at 12 months. The patients in the exercise group kept training diaries.

In the reliability and validity study (I) and in the intervention study (II-IV) the patients filled in a questionnaire eliciting sociodemographic and clinical information: body weight, body height, education, working status, duration of shoulder pain, possible shoulder injuries and medical history.

4.3.1 The American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form (ASES) (I-III)

The score of the self-report section of the ASES questionnaire was used to evaluate pain and condition-specific disability. The pain score was calculated on the visual analogue scale (0-100 mm), with a higher score indicating greater pain, in the ASES score, and the function score was the sum of the 10 questions addressing function. The pain and function composite scores were equally weighted (50 points each) and were combined to form a possible total score of 100 points, with a higher score indicating better functional ability. The ASES score is equal to 5 ([100 - ASES pain VAS]/10 + ASES Cumulative ADL score/3) (Richards et al. 1994). The ASES questionnaire is considered to be a reliable, valid, and responsive outcome tool (Michener, McClure & Sennett 2002).

The translation and cross-cultural adaptation were performed based on the guidelines proposed by Beaton et al. (2000). The first stage was an independent translation (English to Finnish) of the self-report section of the ASES by two professionals (each with Finnish as their first language). In the second stage, a synthesis of the two translations was performed. In the third stage, a person not working in the field of medicine, whose first language is English, and who has mastery of the linguistic and cultural aspects of the Finnish language, backtranslated (Finnish to English) the synthesized version blinded to the purpose of the instrument. In the fourth stage, the translation of the Finnish version of the ASES was accepted by an expert committee. The questionnaire was finally tested in a population of 128 patients with various shoulder disorders (Paloneva et al. 2013).

In the reliability and validity study of the self-report section of the ASES, the Simple Shoulder Test (SST), the single disability question "How severe was your shoulder disability during the last week" (expressed on a visual analogue scale), and the SF-36 were used to assess the contruct validity of the questionnaire. The SST consists of 12 items; two items deal with function related to pain, seven with function/strength, and three with ROM (Lippitt, Harryman & Matsen FA 1993). The SST has proven to be a valid and reliable tool for assessment of functional disability of the shoulder (Godfrey et al. 2007), although the Finnish version has not been validated.

4.3.2 The 36-item Short Form Health Survey (SF-36) (II-III)

The Short-Form 36 Health Survey was used to measure quality of life (Garratt et al. 2002) and indicates a patient's state of health as evaluated on eight scales: Physical Functioning (PF), Role Physical (RP), Bodily Pain (BP), General Health (GH), Vitality (VT), Social Functioning (SF), Role Emotional (RE) and Mental Health (MH). Scores range from 0 to 100, with a higher score indicating better health. The eight Short-Form 36 Health Survey scales were aggregated into two distinct summary measurements: the physical component summary score, which comprises PF, RP, BP, GH, and the mental component summary score, which comprises VT, SF, RE and MH (Ware JE, Kosinski M, Keller SD 1994). The PCS and the MCS are finally standardized using a mean of fifty and a standard deviation of ten.

4.3.3 Strength measurements (IV)

All measurements were performed by an assessor who was familiarized with the procedures beforehand. The operated and non-operated side was measured. Visual analogue scale (VAS scale from 0 to 100 mm) was used to assess shoulder pain during the ROM and strength measurements (Dixon & Bird 1981). The measurements were performed at baseline (two months after the operation) and at 12 months thereafter.

Isometric shoulder strength measurements were carried out with a dynamometer (Ds Europe, Mod. 546QTD strain gauge, Milano, Italy) (Figure 7) and analyzed with Protacon software (Jyväskylä, Finland). During the measurement of internal and external rotation of the shoulder, the patient was sitting in an upright position, with a sturdy barbell between the body and upper arm to prevent use of the body during the measurement. The shoulder was in 20° flexion and elbow in 90° flexion. The measurement sensor was placed above the wrist at the level of the processus styloideus. During the isometric shoulder flexion strength measurement, the patient was sitting with the upper arm in 90° flexion, 30° horizontal abduction, and the elbow straight. The measurement sensor was placed at the level of the processus styloideus. Two warm-up contractions were performed prior to the maximal tests. Three maximal trials were performed in each measurement direction with a one-minute rest period between each trial. If the third trial showed an improvement of more than 5 % of the best result of the previous two trials, additional trials were performed. The best result of each measurement was used in the final analysis. Grip strength was measured with a Saehan dynamometer (Model SH5001, Masan, Korea). Pain during the strength measurements was assessed by visual analogue scale (VAS scale from 0 to 100 mm) (Dixon & Bird 1981).

FIGURE 7 Isometric shoulder flexion measurement with a dynamometer.

4.3.4 Range of motion measurements (IV)

ROM measurements included shoulder flexion, abduction, and internal and external rotation performed using a digital inclinometer to within an accuracy of 1° (800-98-JTECH, North American Fork, Utah), and functional internal rotation and horizontal adduction measured with a tape measure. During the measurement of active and passive shoulder flexion, the patient was standing with the trunk supported on a bar to prevent bending of the body backwards. Active abduction was measured and simultaneously the painful arch sign was recorded. Active external rotation was measured in a supine position with the arm beside the body and the elbow in 90° flexion. The inclinometer was attached to an alignment rail and tied on the radial side of the elbow. Passive external and internal rotation was measured in a supine position with the arm in 90° abduction and the elbow in 90° flexion with a wedge under the elbow. During the former measure, the inclinometer with the alignment rail was tied on the palmar side of the elbow and in the latter measurement on the dorsal side of the elbow. Functional active internal rotation was performed in a standing position and the distance between the thumb and the upper edge of the spinosus Th1 was measured. Passive horizontal adduction was performed in a sitting position and the distance between the epicondylus lateralis and the opposite acromion was measured. The painful arc test from 60 to 120 degrees was measured in a standing position.

4.4 Statistical methods

The results are expressed as means with standard deviation (SD) or with 95% confidence intervals (95% CIs), medians with interquartile ranges (IQR), as

counts with percentages, or as frequency distributions. Effect size ("d") was calculated by using the method for paired samples (i.e. mean baseline scores minus mean follow-up scores, divided by the pooled standard deviation (Cohen 1988). An effect size of 0.20 was considered small, 0.50 medium and 0.80 large. The normality of the sample distribution was tested by the Kolmogorov-Smirnov test or Shapiro-Wilk test as well as by Normal plot or Frequency histograms.

Study I: In assessing the reliability of the self-report section of the ASES, the "floor value" was defined as the worst possible value of the item or as the minimum total value of the scale. The "ceiling value" was the best possible value of the item or the maximum total value of the scale. The floor or ceiling effect was considered to be present when 15% of participants had the minimum or maximum score. The reliability of the scales was evaluated by calculating the intra-class correlation coefficient (ICC) and coefficient of reproducibility with bias-corrected and accelerated bootstrapping (5000 replications) confidence intervals. The internal consistency was estimated by calculating Cronbach's alpha. Item analysis of the ASES scales was performed by analysing the item discriminating power (corrected item correlation) and the item difficulty (item mean) depicted by the explanatory data analysis. Factor structure among the ASES items was analysed using a factor analysis with varimax rotation. 95 percent confidence intervals (95% CI) were obtained by bias-corrected bootstrapping (5000 replications). The correlation coefficients between the ASES and other patient-reported outcomes were calculated by the Spearman method using Sidak-adjusted probabilities.

Study II: Statistical significance for the hypotheses of linearity between the ASES disability groups was evaluated by bootstrap-type analysis of covariance (ANCOVA) with age and gender introduced into the model as covariates, or by the Cochran-Armitage trend test with a Monte Carlo *p*-value. Confidence intervals (CI) for the means were obtained by bias-corrected and accelerated bootstrapping (5000 replications) because of the skewed distribution of the variables. The ASES scores were expressed as continuous and divided into tertiles (ordinal disability levels).

Study III and IV: Outcomes were analyzed by intention-to-treat. Statistical comparisons between the groups were performed with the *t*-test, Mann–Whitney *U*-test, or chi-square test, as appropriate. Between-group differences in changes in the Short-Form 36 Health Survey domains and functional disability over the 12-month treatment period were compared using a bootstrap-type analysis of covariance with the baseline measurement as a covariate. Per-protocol analysis was used in comparing the strength and ROM outcomes between those who trained at least two times a week and those who trained once a week or less.

5 RESULTS

5.1 Psychometric properties of the Finnish version of the ASES (I)

A total of 105 patients participated in the study of shoulder disability assessment using the self-report section of the ASES score. The mean age of the patients was 52 years (range 18-88), and 57% were men. Mean (SD) shoulder pain was 56 (28) mm. The reasons for shoulder pain were rotator cuff disease (41%), glenohumeral or acromioclavicular arthritis (26%), glenohumeral instability (22%), and other reasons, such as adhesive capsulitis, (11%). Mean (SD) duration of shoulder pain was 56 (79) months. The response rate for the ASES was 100%.

During the process of translation from English to Finnish and backward translation into English, only minor linguistic and cultural differences between the translations occurred. The activities of daily living question asking about the ability to lift a load of 10 lbs above the shoulder was adapted to the metric system, whereas the original ASES uses the U.S. Unit system. The translated weight was 4 kg in the present study.

The ASES showed no floor or ceiling effect. The floor value (minimum) pain score of the ASES was reported by only five patients. The ceiling value (maximum) was reported by three patients in the pain score and one patient in the function score but by no patients for the total ASES index. The total ASES score ranged from 2 to 99 (Table 6).

When the questionnaire was administered for the first time, the mean (SD) total ASES score was 48 (23) for the patients with shoulder symptoms that had remained stable between the first and the second measurement. For these patients, the reproducibility intra-class correlation coefficient was 0.83 (95% Cl 0.70 to 0.90). For the patients with shoulder symptoms that had improved, the ICC was 0.69 (0.27 to 0.87), while for the patients with worsened symptoms, the ICC was 0.77 (0.59 to 0.87) (Table 6).

TABLE 6 Reproducibility of the ASES index.

	Baseline				Change from first to second measurement	Reproducibility
	Mean (SD)	**Range**	**Floor* N (%)**	**Ceiling** N (%)**	**Mean (95 % CI) [Effect Size]**	**ICC (95 % CI)**
Pain score	21.9 (14.1)	0-50	5 (5)	3 (3)	4.0 (1.8 to 6.1) [0.26]	0.66 (0.52 to 0.77)
Improved (N=25)	26.9 (14.4)	0-48	2 (8)	0 (0)	5.8 (0.5 to 11.2) [0.42]	0.50 (0.40 to 0.77)
Stable (N=55)	22.3 (14.7)	0-50	2 (4)	3 (5)	3.9 (0.9 to 7.0) [0.27]	0.68 (0.46 to 0.82)
Worsened (N=25)	15.9 (9.8)	0-36	1 (4)	0 (0)	2.2 (-1.6 to 6.0) [0.19]	0.67 (0.37 to 0.83)
Function score	25.5 (11.5)	2-50	0 (0)	1 (1)	0.2 (-1.3 to 1.6) [0.01]	0.81 (0.71 to 0.88)
Improved (N=25)	27.5 (11.4)	3-46	0 (0)	0 (0)	2.6 (-0.1 to 5.3)[0.23]	0.81 (0.51 to 0.93)
Stable (N=55)	26.0 (11.3)	3-50	0 (0)	1 (2)	-1.5 (-3.4 to 0.4) [0.13]	0.83 (0.64 to 0.92)
Worsened (N=25)	22.5 (12.1)	1-40	0 (0)	0 (0)	1.5 (-1.9 to 4.9) [0.12]	0.79 (0.57 to 0.90)
Total ASES	47.4 (22.8)	2-99	0 (0)	0 (0)	4.1 (1.4 to 6.9) [0.18]	0.79 (0.69 to 0.86)
Improved (N=25)	54.5 (24.1)	3-93	0 (0)	0 (0)	8.5 (1.5 to 13.4)[0.37]	0.69 (0.27 to 0.87)
Stable (N=55)	48.3 (22.8)	7-99	0 (0)	0 (0)	2.4 (-1.2 to 5.9) [0.10]	0.83 (0.70 to 0.90)
Worsened (N=25)	38.5 (19.2)	2-73	0 (0)	0 (0)	3.7 (-2.1 to 9.4) [0.17]	0.77 (0.59 to 0.87)

*Worst possible value (Pain and function: 0, Total ASES: 0) of the item or minimum total value of the scale.

**Best possible value (Pain and function: 50, Total ASES: 100) of the item or maximum total value of the scale.

ASES American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form, ICC intra-class correlation coefficient

The internal consistency of the ASES was 0.88 (95% Cl 0.84 to 0.91). The item analysis of the ASES showed that item 6 (reaching a high shelf) had the highest corrected item correlation and item 10 (doing usual sport) had the lowest correlation. Item 3 (washing back) had the lowest item mean value and item 4 (managing toileting) had the highest item mean value (Figure 8). The construct validity factor analysis showed that the ASES loaded on one factor that explained 66% of the total variance.

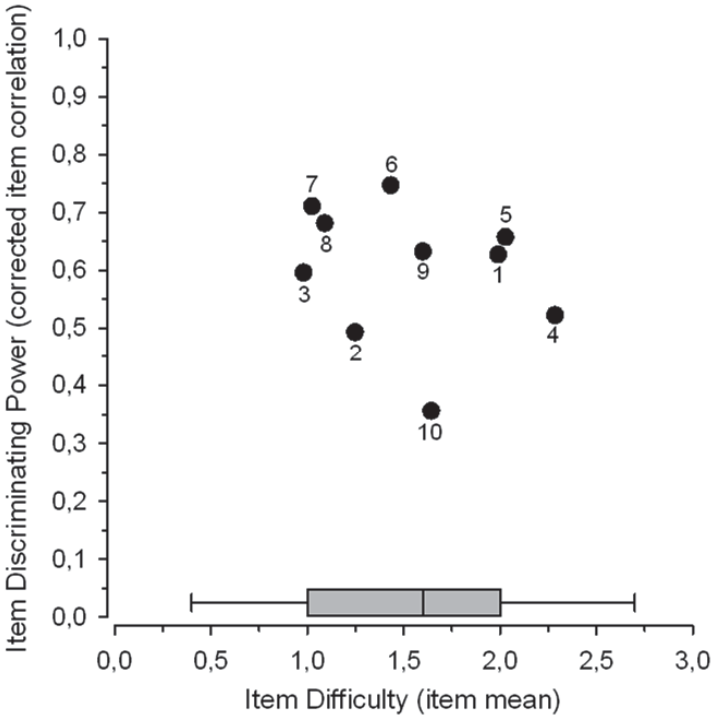


FIGURE 8 Item analysis for the function items of the ASES. The bar denotes median with interquartile range of all item means. Percentiles of 5% and 95% are presented. Numerals indicate the corresponding items on the ASES scale. (1= Put on a coat, 2=Sleep on a painful shoulder, 3=Wash back, 4=Manage toileting, 5=Comb hair, 6=Reach a high shelf, 7=Lift 4 kg above shoulder, 8=Throw a ball overhead, 9=Do usual work, 10=Do usual sport).

The total ASES index was lowest in the glenohumeral or acromioclavicular arthritis group and highest in the instability group. The function score was significantly higher in the instability group than other diagnostic groups (p=0.035) (Figure 9).

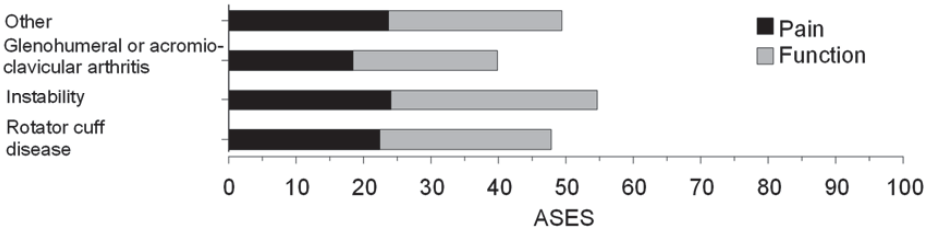


FIGURE 9 Pain and function scores of the ASES index in different diagnostic groups.

The correlations between the total ASES index and the SST scale and the single disability question "How severe was your shoulder disability during the last week" were 0.73 ($p<0.001$) and -0.74 ($p<0.001$), respectively. Mean shoulder disability scored by a single disability question was 54 (28). The correlations between the total ASES index and Physical Functioning, Role Physical, Role Emotional, Social Functioning and Bodily Pain from the SF-36 were statistically significant (Table 7). When the eight dimensions of the SF-36 were aggregated into summary scores, the correlations between the total ASES score and the Physical Component Summary was 0.57 ($p<0.001$), but there was no significant correlation with the Mental Component Summary.

TABLE 7 Disability and health-related quality of life and their correlations with the patient self-report section of the ASES.

	Mean (SD)	Correlations		
		The total ASES	Pain score	Function score
SST (scale 0-12)	5 (4)	0.73***	0.54***	0.81***
A single disability question (scale 0-100)	54 (28)	– 0.74***	– 0.67***	– 0.68***
Dimensions of SF-36 (scale 0-100)				
Physical Functioning	64 (25)	0.51***	0.38**	0.57***
General Health	58 (22)	0.27	0.22	0.32*
Vitality	60 (21)	0.58	0.21	0.32*
Mental Health	73 (21)	0.26	0.23	0.27
Role Physical	36 (39)	0.49***	0.41***	0.47***
Role Emotional	67 (42)	0.37**	0.28	0.42***
Social Functioning	75 (26)	0.44***	0.37**	0.46***
Bodily Pain	41 (21)	0.68***	0.63***	0.58***
Summary Score of SF-36				
PCS	36 (10)	0.57***	0.48***	0.56***
MCS	52 (12)	0.21	0.17	0.25

*p<0.05, ** p<0.01 and ***p<0.001. Sidak adjusted probability

SD, standard deviation; ASES, American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form; SST, Simple Shoulder Test; SF-36, Short form -36; PCS, Physical Component Score; MCS, Mental Component Score.

5.2 The relationship between functional disability and health-related quality of life (II)

Altogether 67 patients, who were on the waiting list for a RCR, enrolled in this study. Mean patient age was 54 (range 41–62) years, and 57% were males. In addition to the rotator cuff tear, 63% of the patients had one or more additional disorders in their affected shoulder. The most common disorders were osteoarthritis of the acromioclavicular joint (30%), impingement of the acromion (15%), lesions of the long head of the biceps tendon (15%) and labrum disorders (9%). Furthermore, 16% of the patients had one or more disorders in the contralateral shoulder, and the most common disorder was rotator cuff disease.

The mean (SD) score on the self-report section of the ASES index in the total group of the patients was 48 (17), and mean (SD) shoulder pain (VAS) was 52 (22) mm. When we considered the 10 individual function items of the ASES, we found that the patients had most difficulties in lifting 4 kg above the shoulder, throwing a ball overhead, sleeping on a painful shoulder, and washing their back. They had least difficulties in managing toileting (Figure 10).

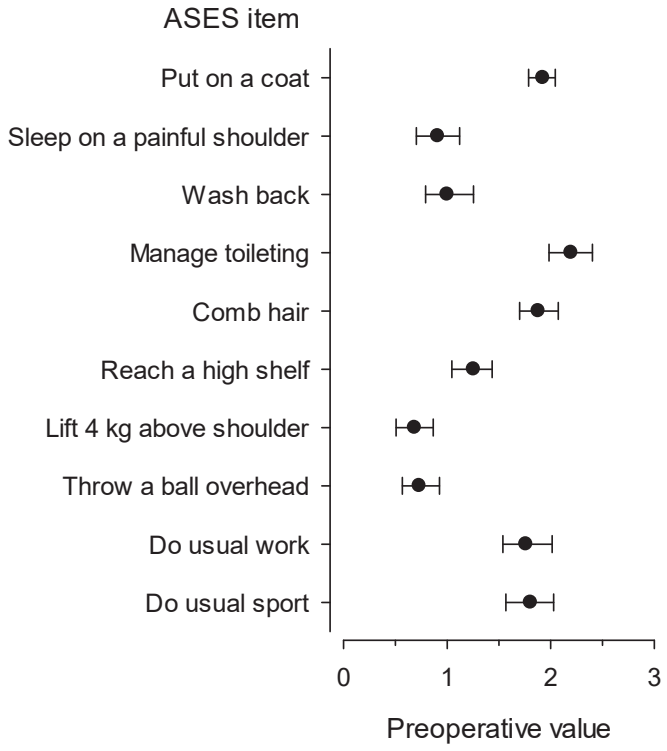


FIGURE 10 The mean (SD) preoperative values of the 10 ASES items addressing function.

When the patients were divided into three ordinal disability tertiles, or levels, based on their ASES values, the means (range) were 30 (12–38) for the highest disability level, 46 (39–51) for the middle level and 66 (52–82) for the lowest level. No statistically significant differences in the demographic and clinical data were observed between the three disability levels, except that shoulder pain was highest among those in the highest level, and that the use of physiotherapy differed between the levels, the lowest disability level using physiotherapy the least (Table 8).

TABLE 8 Baseline socio-democraphic and clinical data of patients with a rotator cuff tear categorized into three disability levels.

	ASES disability levels			***p* value for**
	I Highest	**II Middle**	**III Lowest**	**linearity***
Males, n (%)	13 (59)	9 (41)	16 (70)	0.55
Age, years, mean (SD)	53 (6)	54 (6)	54 (4)	0.25
BMI, mean (SD)	27.4 (4.5)	28.0 (4.5)	27.7 (3.7)	0.84
Education, years, mean (SD)	11.5 (3.4)	12.7 (3.6)	11.3 (2.3)	0.85
Employed, n (%)	13 (59)	16 (73)	12 (52)	0.65
Pain VAS (0–100), mean (SD)				
Shoulder	73.3 (14.0)	53.8 (11.7)	29.6 (13.4)	<0.001
Upper limb	32.0 (27.9)	36.5 (29.6)	22.8 (18.4)	0.24
Neck	11.3 (19.2)	11.8 (17.4)	5.3 (11.2)	0.22
Back	5.0 (13.6)	6.9 (17.0)	6.0 (16.3)	0.85
Trauma, n (%)	12 (55)	11 (50)	13 (57)	0.99
Duration of shoulder pain, months, median (IQR)	18 (12 , 24)	13 (10 , 24)	24 (8 , 72)	0.080
Tear location, n (%)				
Supraspinatus	20 (90)	19 (86)	21 (92)	0.69
Supraspinatus, subscapularis	1 (5)	1 (5)	1 (4)	0.99
Supraspinatus, infraspinatus	1 (5)	2 (9)	0	0.34
Infraspinatus	0	0	1 (4)	0.38
Additional shoulder disorders, n (%)				
Osteoarthritis of the acromioclavicular joint	6 (27)	6 (27)	8 (35)	0.58
Impingement of the acromion	6 (27)	2 (9)	3 (13)	0.21
Lesion of the long head of biceps	4 (18)	4 (18)	2 (9)	0.37
Labrum disorders	3 (14)	1 (5)	2 (9)	0.57
Conservative treatment, n (%)				
Cortisone	11 (50)	14 (64)	7 (30)	0.20
Physiotherapy	12 (55)	13 (59)	5 (22)	0.027

ASES, American Shoulder and Elbow Surgeons Standardized Shoulder Assessment; BMI, body mass index; VAS, visual analog score; IQR, interquartile range.
*age- and sex-adjusted

Patients with a higher ASES index showed higher HRQoL in all dimensions of the SF-36, except the General Health dimension. Patients with the highest functional disability had the lowest HRQoL, especially in the dimensions of Role Physical and Bodily Pain (Figure 11).

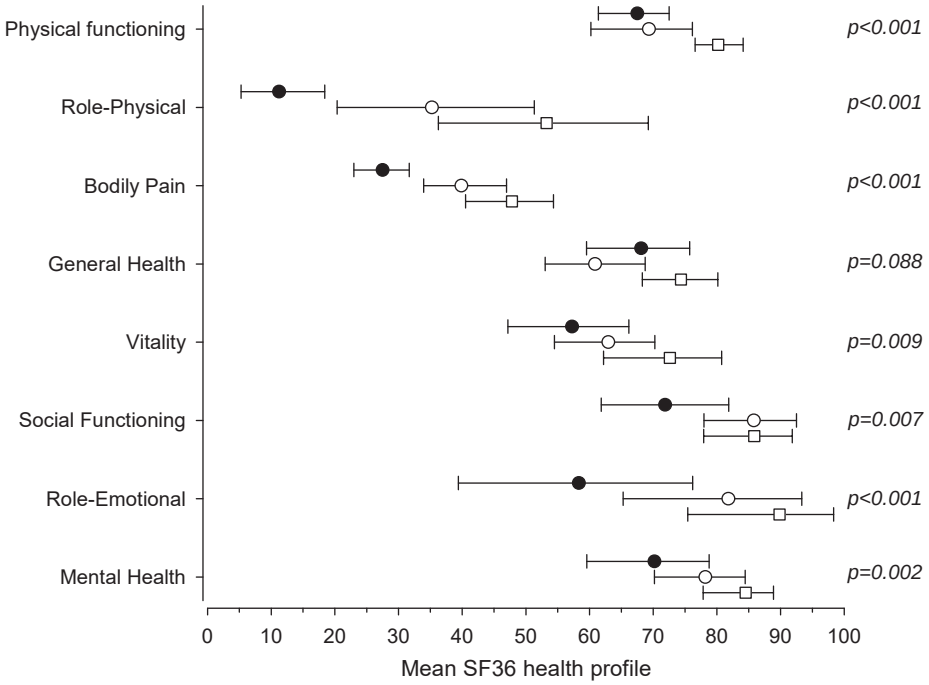
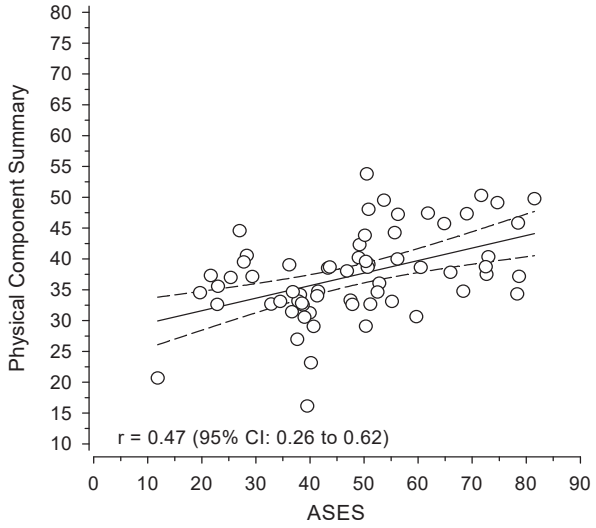


FIGURE 11 Mean (with 95% confidence intervals) SF-36 scales. *p* values include age- and sex-adjusted linearity. Filled circles, highest level; open circles, middle level; and open box, lowest level of the American Shoulder and Elbow Surgeons Standardized Shoulder Assessment (ASES) disability levels.

When the eight dimensions of the SF-36 were aggregated into summary scores, the mean (SD) PCS scores were 35 (5), 36 (8) and 41 (6) in the lowest, middle, and highest ASES levels (age- and sex-adjusted, *p* for linearity < 0.001), respectively, and the mean MCS scores were 50 (13), 56 (10) and 58 (8) (p = 0.011). The relationship between the ASES and the PCS was r = 0.47 and that between the ASES and the MCS was r = 0.37 (Figure 12).

a)



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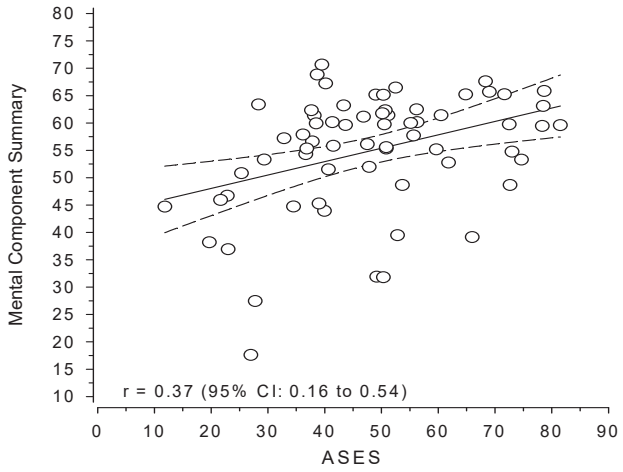

FIGURE 12 The relationship between functional disability (ASES) and a) Physical Component Summary and b) Mental Component Summary of the SF-36.

5.3 Effectiveness of a 12-month postoperative shoulder strength exercise program (III, IV)

The 12-month intervention study started two months postoperatively and 67 patients who had undergone a RCR were randomized into an exercise group (EG) or a usual care group (UCG). No between-group differences in the baseline socio-demographic or clinical data were found (Table 9). According to the training diaries, training adherence was rather low. A total of 20 (57%) of the patients in the EG performed the strength and stretching exercises at least twice a week during the first six months of the intervention. During the first training weeks, nine patients in the EG reported shoulder pain in the operated shoulder. Three patients reported neck pain, and two reported elbow pain. During the last six months of the intervention, only 8 (23%) of the patients were performing the strengthening exercises at least twice a week. The results for the patients in the EG who did not follow the exercise program were included in the intention-to-treat analysis, except at the three-year follow-up, which included only those who answered the ASES questionnaire.

TABLE 9 Baseline socio-demographic and clinical data of patients in the exercise and the usual care group.

	EG N=35	UCG N=32	p value
Male, n (%)	20 (57)	18 (56)	0.94
Age in years, mean (SD)	55 (5)	53 (6)	0.06
Education, years, mean (SD)	11.5 (2.9)	12.2 (3.4)	0.42
Employed, n (%)	30 (86)	30 (94)	0.71
BMI, mean (SD)	27.7 (3.1)	27.7 (5.3)	0.94
Duration of shoulder pain before the operation, months, median (IQR)	15 (8, 60)	19 (12, 24)	0.81
Tear on the dominant side, n (%)	24 (69)	23 (72)	0.77
Shoulder trauma, n (%)	20 (57)	16 (50)	0.56

EG, exercise group; UCG, usual care group; SD, standard deviation; BMI, body mass index; IQR, interquartile range.

5.3.1 Disability

At 12 months, no differences between the two groups in the ASES scores were observed (treatment effect, p=0.33), as both groups improved by a statistically significant amount: mean (SD) ASES scores in the EG ranged from 74 (14) to 95

(10), and in the UCG from 70 (18) to 95 (6) (Figure 13). At 12 months, only 5 (14%) patients in the EG and 5 (16%) patients in the UCG had an ASES score under 90 points.

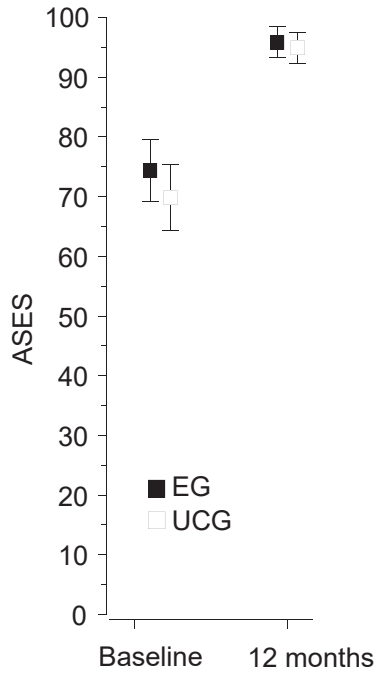

FIGURE 13
Functional disability (American Shoulder and Elbow Surgeons Standardized Shoulder Assessment [ASES] in the exercise group (EG) and the usual care group (UCG) at baseline and 12 months.

At the three-year follow-up, 49 patients (73%) completed the postal questionnaire. Both groups had maintained their post-intervention level over the three-year period. The mean (SD) ASES scores at the three-year follow-up were 95 (11) in the EG, and 96 (8) in the UCG.

When the 10 individual function questions of the ASES were analysed separately, throwing a ball overhead, lifting 4 kg above the shoulder, and washing the back were the most impaired functions at baseline (two months after the operation) in the EG and UCG patients. The changes at 12 months from the baseline were statistically significant in all the individual ASES items. The biggest changes in both groups were in the aforementioned functions, and in sleeping on a painful shoulder (Figure 14). In addition, at the three year follow-up the most impaired functions in the EG were lifting 4 kg above the shoulder, sleeping on a painful shoulder and throwing a ball overhead, and in the UCG throwing a ball overhead, doing usual sport and lifting 4 kg above the shoulder.

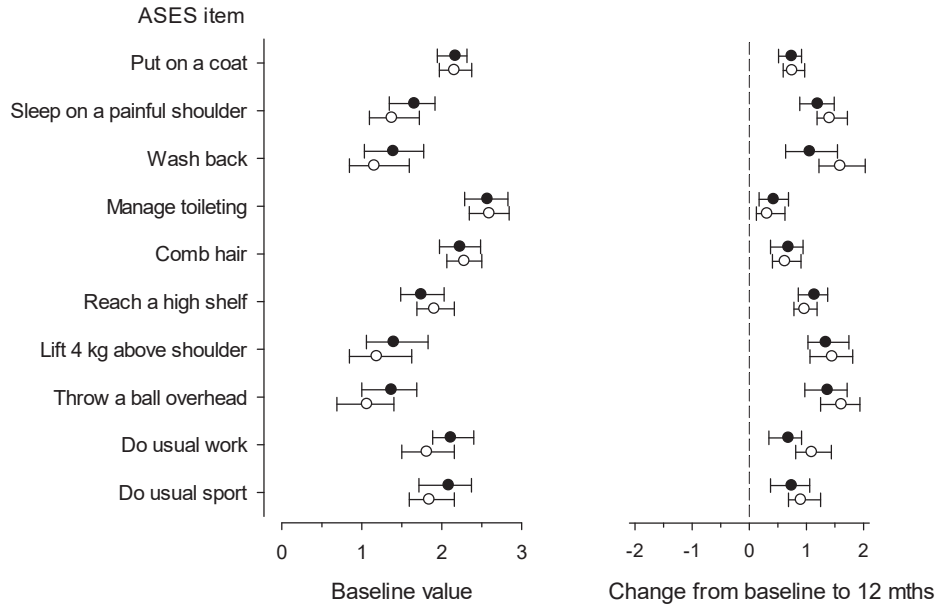

FIGURE 14 Mean (SD) baseline values and the changes with 95% Cl from the baseline values at 12 months for the 10 ASES items addressing function in the EG (filled circles) and the UCG (open circles).

5.3.2 Health-related quality of life

No significant between-group differences were observed in the changes in the eight dimensions or in the summary scores of the SF-36. Changes in the Physical Functioning, Role Physical and Bodily Pain dimensions showed significant improvements in both groups at 12 months (Table 11). In addition, the usual care group improved significantly in the Role Emotional (p=0.003) and Social Functioning (0.034) dimensions over the 12-month period. After aggregating the eight dimensions of the SF-36 into the summary scores, the physical component summary score improved significantly (p<0.001; treatment effect, p=0.79), whereas the mental component summary score remained unchanged in both groups (treatment effect, p=0.51) (Table 10).

TABLE 10 Scores at baseline and at 12 months in the eight dimensions and the two components of the SF-36 in the exercise group (EG) and the usual care group (UCG).

	Baseline		Change at months		*p*-value[a]
	EG Mean (SD)	**UCG Mean (SD)**	**EG Mean (95% CI)**	**UCG Mean (95% CI)**	**between the groups**
Dimensions					
Physical Functioning	80 (12)	78 (11)	8 (2 to 12)	10 (3 to 16)	0.66
Role Physical	41 (40)	35 (42)	41 (28 to 54)	48 (30 to 64)	0.55
Bodily Pain	57 (15)	55 (24)	15 (6 to 24)	20 (8 to 31)	0.50
General Health	69 (20)	69 (17)	- 0,1 (-4 to 5)	1 (-4 to 6)	0.77
Vitality	73 (18)	70 (19)	3 (-4 to 10)	1 (-5 to 6)	0.37
Social Functioning	88 (17)	85 (20)	4 (-6 to 12)	5 (1 to 11)	0.97
Role Emotional	71 (37)	72 (40)	14 (-3 to 30)	15 (6 to 25)	0.83
Mental Health	84 (14)	80 (18)	-2 (-11 to 5)	1 (-2 to 5)	0.82
Summary Scores					
Physical Component	42 (7)	41 (9)	7 (5 to 10)	9 (4 to 12)	0.59
Mental Component	56 (9)	55 (13)	-1 (-6 to 4)	0 (-3 to 2)	0.95

[a]Baseline values as covariate.

5.3.3 Muscle strength and ROM

At the end of the 12-month intervention, the changes in muscle strength in the operated shoulder did not differ between the treatment groups. In both groups the internal rotation, external rotation and flexion strength levels increased significantly by 16-38% ($p<0.001$) (Table 12). At 12 months, no significant difference was observed between the operated and contralateral shoulder in internal rotation strength in the EG (3 %, $p<0.116$) and the UCG (4%, $p<0.09$), whereas the external rotation and flexion strength of the operated shoulder were 9% and 17% lower in the EG, and 11% and 22% lower in the UCG compared to the contralateral shoulder (all $p<0.02$) (Figure 15). Furthermore, the strength values of the contralateral shoulder remained unchanged, although the patients performed the exercises for both shoulders. Pain during the strength measurements was already on a rather low level at the beginning of the intervention and at 12 months, mean pain ranged from 0 to 5 mm in both groups (Table 11). In the EG, no differences were observed in the strength and pain values during loading between those who trained at least two times a week (n=20) and those who trained less (n=15).

No between-group differences were found in the changes in active or passive ROM. After the 12-month intervention, significant increases were observed in all the shoulder ROMs ($p<0.001$), except in passive internal rotation in both groups (Table 11). The EG patients who trained at least two times a week had significantly lower ROM in active flexion, active and passive external rotation, and passive internal rotation, and higher ROM in active internal rotation than those who trained less.

At baseline, 9% of the patients in the EG and 25% in the UCG showed a positive painful arc test result (between groups $p=0.078$), while at 12 months the corresponding proportions were 3% and 0% (between groups $p=0.33$). The number of participants with a positive painful arc test result decreased significantly in the UCG ($p<0.003$).

TABLE 11 Changes in shoulder function and pain in the exercise group (EG) and the usual care group (UCG) at the end of 12-month inter-vention.

	Baseline		Change at 12 months		*p*-value*
	EG Mean (SD)	**UCG Mean (SD)**	**EG Mean (95 % CI)**	**UCG Mean (95 % CI)**	**between the groups**
Shoulder strength (kg)					
Internal rotation	12.5 (5.4)	13.3 (5.7)	3.1 (2.2 to 4.1)	2.6 (1.4 to 3.7)	0.46
External rotation	7.1 (2.4)	6.8 (2.7)	3.0 (2.4 to 3.6)	3.2 (2.3 to 4.1)	0.80
Flexion	4.9 (2.2)	4.4 (1.7)	2.5 (1.9 to 3.1)	2.7 (2.1 to 3.3)	0.52
Hand grip	39.4 (12.9)	38.8 (12.3)	3.5 (2.1 to 4.9)	5.4 (3.7 to 7.1)	0.08
Pain during strength measurement (VAS), mm					
Internal rotation	6 (10)	8 (15)	-5 (-8 to -2)	-7 (-12 to -2)	0.60
External rotation	8 (12)	13 (17)	-8 (-12 to -4)	-9 (-16 to -3)	0.13
Flexion	19 (23)	23 (26)	-14 (-24 to -5)	-20 (-29 to -10)	0.72
Shoulder mobility (°)					
Active flexion	141 (30)	139 (29)	29 (20 to 38)	33 (24 to 42)	0.50
Passive flexion	157 (22)	154 (21)	22 (16 to 28)	28 (22 to 34)	0.18
Active external rotation	63 (16)	60 (13)	15 (10 to 19)	17 (13 to 22)	0.66
Passive external rotation (90°)	69 (24)	63 (18)	25 (18 to 31)	32 (24 to 39)	0.41
Passive internal rotation (90°)	36 (10)	37 (13)	1 (-3 to 5)	2 (-1 to 6)	0.48
Active internal rotation, mm	303 (104)	305 (89)	-82 (-106 to -57)	-104 (-129 to -80)	0.12
Passive horisontal adduction, mm	333 (45)	338 (52)	-41 (-54 to -28)	-45 (-59 to -33)	0.72

*Baseline values as covariate.

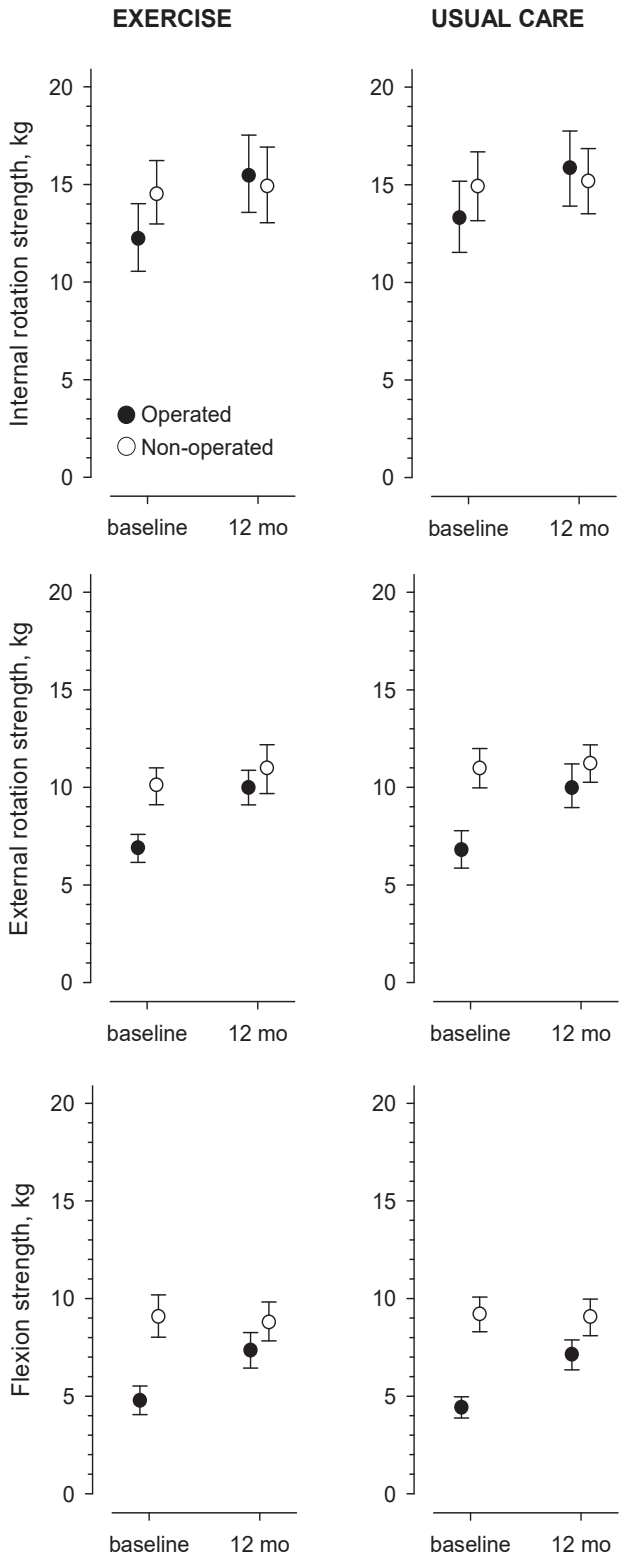

FIGURE 15
Muscle strength values in internal and external rotation, and flexion in the operated (filled circle) and non-operated (empty circle) shoulder at baseline and at 12 months in the exercise group and usual care group.

5.3.4 Effect sizes of the main shoulder outcomes

Effect size was used to analyse the relative size of the effect of the intervention on the main outcomes. In shoulder function assessed with the ASES, the improvement was large in both groups (ES 1.79 in the EG and 1.88 in the UCG). The changes in the Physical Component Score of HRQoL were also large (ES 0.88 in the EG and 1.04 in the UCG). For the objectively measured shoulder function outcomes, the changes in flexion and external rotation strength changes were large (ES 1.04 and 1.23 in the EG, and 1.35 and 1.07 in the UCG, respectively). Changes in shoulder ROM were the largest in passive external rotation (ES 1.24 in the EG and 1.80 in the UCG) (Figure 16).

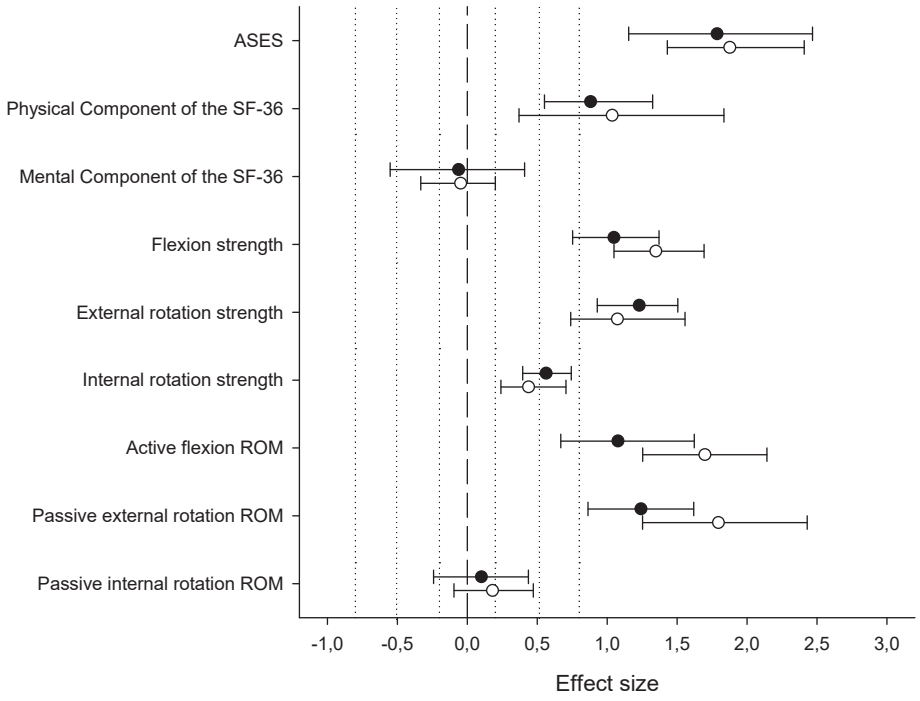

FIGURE 16 The effect sizes of the main outcomes of the 12-month strength training intervention. Filled circles, the EG; empty circles, the UCG.

5.3.5 Adverse events during home-based rehabilitation

The EG patients reported minor discomfort mainly at the beginning of the exercise period. Resistance training was well tolerated, and no serious training-related adverse events occurred during the one-year home-exercise period. During the first training weeks, nine patients reported shoulder pain in the operated shoulder, three reported neck pain and two reported elbow pain. Five of these patients had a break in shoulder training of up to one week and four of them a break of up to two weeks

6 DISCUSSION

This study showed that a home-based exercise program after RCR was equally as effective as usual care on functional disability, HRQoL, shoulder strength, and ROM. These results thus indicate that this type of rehabilitation intervention is not in most cases of greater benefit than usual care after RCR. The Finnish version of the self-report section of the ASES proved to be a reliable and valid shoulder-specific measurement tool. This study also showed that patients with higher functional disability of the shoulder had lower HRQoL.

6.1 Psychometric properties of the ASES

The self-report section of the ASES questionnaire is one of the most widely used and well understood shoulder-specific outcome tools. It is both well characterized and accepted in the scientific community. It is also easy and quick to fill in and has been validated across a wide variety of patient populations, including patients with rotator cuff disease, osteoarthritis, total shoulder arthroplasty, frozen shoulder, and shoulder instability (Angst et al. 2011). A limitation of the self-report section of the ASES is its time-consuming scoring system, if this is filled in and calculated manually, but it can also be easily implemented in any electronic database. The clinician-report section of the ASES was removed from the scoring system in this study as it had minor value for the assessment as a whole. Thus, when comparing studies that have used the ASES tool, it is important to note whether one or both sections have been used.

Although the ASES questionnaire has been widely used in Finland in both clinical work and research, it has not previously been validated in Finnish. The present study showed that the psychometric properties of the Finnish version of the self-report section of the ASES were acceptable, and thus this questionnaire can be used for patients presenting with different shoulder disorders. The DASH questionnaire is widely used in many languages for various upper-extremity disorders, e.g. rheumatoid arthritis, tennis elbow, carpal tunnel syndrome, fractures. The ASES, in turn, has been used for various shoulder-specific

disorders, e.g. rotator cuff disease, frozen shoulder, glenohumeral arthritis, instability. The DASH has been translated into Finnish (Hacklin et al. 2009), but it has not been validated in Finnish. We chose the ASES questionnaire over the DASH, as the latter is for use in patients with any disorder in any upper extremity joint, which makes it less responsive and less effective as a measurement tool for shoulder problems.

No floor or ceiling effect was observed in the total ASES score. The reproducibility (ICC) of the total ASES index was 0.79 (95% Cl 0.69 to 0.86) in all patients and 0.83 (0.70 to 0.90) in the stable group. According to Portney and Watkins (Portney & Watkins 2000), an ICC > 0.75 indicates an acceptable test-retest reliability score. The self-report section of the ASES has been previously cross-culturally translated into and validated in many languages, including Turkish (Celik et al. 2013), Portuguese (Moser et al. 2012), Arabic (Yahia et al. 2011), Italian (Padua et al. 2010), German (Goldhahn et al. 2008), and English (Kocher et al. 2005, Michener, McClure & Sennett 2002). In these studies, the ICC varied from 0.75 to 0.96, but the time interval between the first and the second measurement ranged from 1 day to 4 weeks. In the present study, the mean time interval between the first and second measurement was 16 days. Together, these observations indicate that the test-retest reliability of the ASES has been quite high in the languages in which it has been used (Celik et al. 2013, Yahia et al. 2011, Padua et al. 2010, Goldhahn et al. 2008, Kocher et al. 2005, Michener, McClure & Sennett 2002), although in the Portuguese version the ICC was barely 0.75 (Moser et al. 2012) with an interval of seven days between the first and the second measurement.

A Cronbach's alpha above 0.80 is recommended (Streiner & Norman 2003). However, too high a level of internal consistency may indicate that the items are too homogenous. In the previous studies, the α-values have ranged widely, from 0.61 to 0.96 (Celik et al. 2013, Moser et al. 2012, Yahia et al. 2011, Padua et al. 2010, Goldhahn et al. 2008, Kocher et al. 2005, Michener, McClure & Sennett 2002). This may in part be due to differences in the study samples, e.g. sample sizes varied from 50 to 1 066 subjects, and the overall age range was large, except in the study by Moser et al. (2012) which comprised only working-aged subjects. The lowest α-values reported were 0.61 (instability group), 0.62 (arthritis group) and 0.64 (rotator cuff disease group) in an English study by Kocher et al. (2005) where the sample size was 1 066. In the present study, Cronbach's alpha for internal consistency was 0.88 (95% Cl 0.84 to 0.91), thus, demonstrating that the items of the Finnish ASES are reasonably related while still yielding unique information about the patient's status. The present factor analysis showed that the ASES loaded on one factor that explained 66% of the total variance. However, loading on two factors has also been reported (Yahia et al. 2011). The reason for this might be that the content of five items of the ASES had been changed; from "Throw a ball overhead" to "Throw a ball with one hand", "Sleep on a painful shoulder" to "Sleep comfortably on your painful or affected shoulder", "Put on a coat" to "Get dressed unassisted", "Comb hair" to "Wash

one's hair alone", and "Do usual work" to "Do routine tasks throughout the day" (Yahia et al. 2011).

Convergent validity, a part of construct validity, was assessed by testing the power of the relationship between the ASES and other different questionaires. The ASES questionnaire showed a strong correlation with the Simple Shoulder Test and the Physical Component Score of the SF-36, and also with the single disability question "How severe was your shoulder disability during the last week" (expressed on a visual analogue scale). This confirmed the construct validity of the ASES and convinced us that these measurement procedures were measuring the same construct. The use of the single disability question does not replace the ASES, although the correlation between them was strong, as the latter gives more clinical information than the former. In the previous studies, correlations between the ASES and other shoulder-specific or upper limb-specific questionnaires have also been strong (Celik et al. 2013, Yahia et al. 2011, Goldhahn et al. 2008, Michener, McClure & Sennett 2002). No significant correlation was found between the ASES questionnaire and the Mental Component Score of the SF-36. This result demonstrates that the ASES is a disability questionnaire and the Mental Component Score of the SF-36 questionnaire does not measure the same phenomena. However, Çelik et al. (2013) reported a significant correlation between the ASES and the Mental Component Score of the SF-36 ($r = 0.53$, $p<0.001$), whereas the correlation between the ASES and the Physical Component Score of the SF-36 ($r=0.02$, $p=0.82$) was negligible. The mean (SD) ASES score in the latter study was 52 (22) while in the present study it was 48 (23). The differences in the correlations may be due to differences in, e.g. sample size, age, and the reason for the shoulder disorder. In Çelik et al., the sample size was 63, age range 18-74 years (mean age 48) and the reasons for the shoulder disorder were operated and non-operated shoulders, including rotator cuff disorder, frozen shoulder, labrum tear, whereas the corresponding data in the present study were 105, 18-88 (mean age 52 years), and rotator cuff disorder, glenohumeral or acromioclavicular arthritis, and glenohumeral instability.

The questionnaire proved to be highly acceptable, easily understood, quick to complete, and capable of being self-administered. The results showed that this version of the ASES has good reliability and validity. No suggestions for improving the wording were given. The only cross-cultural change pertained to the question about lifting 10 lbs above the shoulder, which was adapted to the metric system. Thus, in the present study the weight on the questionnaire was 4 kg instead of 4,54 kg.

6.2 Relationship between disability and HRQoL in patients with a rotator cuff tear

The results showed a moderate relationship between functional disability of the shoulder and HRQoL in patients with a rotator cuff tear awaiting surgery. Indi-

vidual scores for the self-report section of the ASES ranged widely, from 12 to 82 points. The mean disability level of 48 points on the ASES index was rather similar to the levels of 46 to 58 points reported among patients awaiting surgery in two other studies (McRae et al. 2011, Moosmayer et al. 2010). Because the patients in the present study were awaiting surgery, they may have experienced more pain than the patients in the conservative treatment group. Moosmayer et al. (2010) studied patients with full-thickness RCT and found mean (SD) ASES scores of 47 (14) in symptomatic patients and 97 (3) in asymptomatic patients. The choice of 90 on the ASES scale as the asymptomatic cut-off point was based on age-related baseline values from studies of individuals with no history of shoulder problems (Sallay & Reed 2003, Thomas, Dieball & Busse 2003). Both the present and former studies showed that rotator cuff tears cause notable functional disability of the shoulder. Furthermore, many patients presented with other co-existing shoulder diseases, and functional disability in these cases was clearly higher.

With respect to the 10 individual items of the ASES, our patients with a rotator cuff tear reported most difficulties in lifting 4 kg load above the shoulder, throwing a ball overhead, sleeping on a painful shoulder, and washing the back. In activities performed above the shoulder, a common symptom is a painful arc. In sleeping on a painful shoulder, the reason for the pain is the pressure on the shoulder and the reduction in blood flow. Goldhahn et al. (2008) reported that lifting, washing the back, throwing a ball overhead, and reaching a high shelf were the most demanding activities for patients with shoulder problems.

In the present study, higher disability was related to lower HRQoL: the patients with the most difficulties in shoulder function also had lower scores in most of the HRQoL dimensions. These patients are also likely to have difficulties in various physical activities, e.g. work-related and household tasks, as well as in psycho-social aspects of life, such as participation in social activities.

As in the previous studies, the Role Physical and Bodily Pain dimensions of the SF-36 were the most impaired (Moosmayer et al. 2010, Baydar et al. 2009, Ryliskis et al. 2009). Baydar et al. (2009) found a mean (SD) Role Physical score of 11 (31), which is equal to the score of the highest ASES disability group in the present study. In the study by Yoo et al. (2013) the preoperative dimensions of Bodily Pain and General Health were the most impaired in patients who had subsequently undergone a RCR.

We found a moderate relationship between functional disability and the PCS of the SF-36, as well as between functional disability and the MCS of the SF-36. This indicates that in patients with a rotator cuff tear, the effects of their shoulder disability on their physical and mental quality of life are similar. In contrast, our ASES validation study found a moderate relationship between functional disability and the PCS of the SF-36, but not between functional disability and the MCS of the SF-36. Only one previous study by Chung et al. (2012) has investigated the relationship between the ASES and SF-36. In line with our study, the authors found moderate associations between the preoperative values of the ASES and the PCS and MCS of the SF-36 ($p<0.01$). The SF-36 does not

include shoulder-specific questions. Therefore, it is recommended that shoulder-specific measurements also be used to complement the generic impacts of extensive rotator cuff tear problems on patients' everyday life.

6.3 Disability during the intervention

The main result was that the home-based shoulder strengthening exercise program with booster sessions was equally effective when compared with usual care, as shoulder disability improved equally in both groups. At 12 months, both groups scored more than 90 ASES points, indicating that on average the patients had achieved normal shoulder function. This outcome was still present at three years.

The effectiveness of early postoperative rehabilitation on disability has been investigated in 13 randomized controlled trials. These have mainly studied immobilization of the shoulder for four or six weeks compared with immediate passive ROM exercises (De Roo et al. 2015, Sheps et al. 2015, Keener et al. 2014, Kim et al. 2012, Cuff & Pupello 2012, Klintberg et al. 2009) and CPM compared with passive self-assisted exercises alone or physiotherapy alone (Arndt et al. 2012, Garofalo et al. 2010, Lastayo et al. 1998, Raab et al. 1996) after RCR. Thus far, no single postsurgical rehabilitation method has been found to be superior to all others (Thomson, Jukes & Lewis 2015). Early rehabilitation after an arthroscopic RCR has been associated with some initial improvements in ROM and function. However, no between-group differences were observed at the one-year follow-up (Gallagher et al. 2015). There is some agreement that an immobilizing rehabilitation protocol is best for tears greater than 5 cm or involving more than two tendons, poor tissue quality or repairs with greater tension (Thigpen et al. 2016, Kluczynski et al. 2015a, van der Meijden et al. 2012). However, only two randomized controlled studies have investigated the long-term effectiveness of postoperative rehabilitation on functional disability (Hayes et al. 2004, Roddey et al. 2002). The results of the present study were in line with these previous findings on changes in functional disability of the shoulder following a postoperative rehabilitation intervention.

At 12 months, the mean ASES scores improved from 74 to 95 points in the EG and from 70 to 95 points in the UCG. The ASES scores of 95 points indicated good shoulder function in both groups. The mean increase of 21 points in the EG and 25 points in the UCG can be regarded as clinically significant. Michener et al. (2002) studied the ASES in operated and non-operated patients with a wide range of shoulder disorders. The minimal detectable change was 9.7 ASES points when the patients completed ASES questionnaires during the first physiotherapy session and during the second session 24 to 72 hours thereafter session. The minimal clinically important difference was 6.4 ASES points. Tashjian et al. (2010) showed that a change between 12 and 17 points in the ASES score indicates a minimal clinically important difference following conservative

treatment in patients with rotator cuff disease. The patients completed the questionnaires at baseline and at a minimum of six weeks after treatment.

In the present study, the mean ASES score of 95 points at 12 months was of the same magnitude as previously reported in 12-month follow-up studies (Chung et al. 2012, Moosmayer et al. 2010). Moosmayer et al. (2010) showed in their randomized controlled trial that rotator cuff surgery was more effective than physiotherapy on pain and shoulder function over a 12-month follow-up in patients with small or medium-sized rotator cuff tears. In the surgery group, the postoperative rehabilitation protocol included immobilization of the arm in a sling and the start of passive ROM exercises. Active assisted movements were initiated after six weeks, and complemented by strengthening exercises 12 weeks after surgery. For the physiotherapy group, a rehabilitation program detailing treatment goals and methods was planned before the study. However, in this program physiotherapy was given in a non-standardized manner according to clinical findings and progression. Treatment sessions of 40 minutes were held on average twice weekly for 12 weeks, and at increasing intervals during the following six to 12 weeks. Special attention was directed to correction of upper quarter posture and the restoration of scapulothoracic and glenohumeral muscular control and stability. The authors reported that the mean ASES score improved from 46 to 93 points in the surgery group and from 48 to 79 points in the physiotherapy group. Chung et al. (2012) investigated functional disability after an arthroscopic rotator cuff repair only and reported that the mean ASES score improved from 58 to 87 points over the 12-month follow-up. In both studies the baseline values were preoperative. In the present study, the mean preoperative ASES scores of 51 in the EG and 44 in the UCG were on the same level as in the study by Moosmayer et al. (2010).

Interestingly, in the present study the ASES scores at 12 months (95 in the EG and 96 in the UCG) remained unchanged at the three-year follow-up (ASES points). Moosmayer et al. (2014) similarly reported that the ASES scores of 93 points in the surgery group and 85 points in the physiotherapy group remained unchanged at the five-year follow-up. In the recent study by Saraswat et al. (2015), the ASES score remained constant at 10 years post RCR. Thus, it seems that functional ability of the shoulder improves considerably over the first year after RCR and that the improvement remains on the same level for several years.

Of the 10 individual items of the ASES questionnaire, throwing a ball overhead, lifting 4 kg above shoulder, and washing the back were the functions that were most disabled at baseline in both groups. These activities also showed the most improvement at 12 months. At the 3-year follow-up, the improvements were close to maximum values. These results are understandable, as overhead activities are the most demanding for the shoulder. The force couples of the glenohumeral joint need to work cooperatively in timing and level of intensity to produce downward translation of the humerus in the glenoid to perform an overhead activity successfully. Thus, compression of the humeral head against the coracoacromial arch is prevented and greater motion is allowed during overhead activities.

6.4 HRQoL during the intervention

Only one previous study has reported on exercise and HRQoL in RCR patients, and the results are in accordance with our results. Both in our study and in Moosmayer et al. (2010), the Physical Functioning, Role Physical, and Bodily Pain dimensions of the SF-36 increased significantly in both patient groups over the 12-month follow-up period, with no between-group differences.

The mental component summary score for quality of life was higher than the physical component summary score as early as two months postsurgery (at baseline) and remained unchanged, whereas the physical component summary score improved significantly during the 12-month training intervention. These results were in line with the study by Moosmayer et al. (2010), showing that the exercise intervention had no effect on the patients' mental or social quality of life.

In contrast, in the study by Chung et al. (2012) all the dimensions of the SF-36, with the exception of GH, showed significant improvment at both the 12-month post-operative follow-up and final follow-up at 26 months (range, 12-48 months). The SF-36 component summary scores of the PCS, and also MCS, showed significant improvement at 12 months from 40 to 48 and from 44 to 51, respectively (Chung et al. 2012). In the present study, the corresponding results for the PCS were from 42 to 49 in the EG and from 41 to 50 in the UCG, and for the MCS from 56 to 55 in the EG and with no change from 55 in the UCG.

6.5 Training adherence and other aspects of the exercise program

Training adherence during the intervention was unsatisfactory, as slightly more than half of the EG patients performed the strength exercises at least twice a week during the first six months, and only one-quarter during the last six months. The EG patients had four booster sessions with a physiotherapist during the first six training months, but no booster sessions during the last six training months before the 12-month measurement. This might have contributed to the decrease in training adherence during that period. Another reason for low adherence may have been too many exercises — eight shoulder and two core exercises — in the training program (van der Meijden et al. 2012, Koo & Burkhart 2010). In both groups, the mean ASES score was already approximately 90 points just six months after starting the exercises, and by 12 months, the ASES score had increased to 95 points in both groups. In asymptomatic patients, ASES scores have been reported to range from 90 to 100 (Moosmayer et al. 2010, Sallay & Reed 2003). Moreover, the intensity of shoulder pain reported by the patients at six months was rather low: mean pain was 8 mm in the EG. The fact that both groups had ASES levels comparable with those of asymptomatic persons after six months' training might, therefore, have decreased their motivation to exercise during the last six months.

The progressive loading of the exercises in the present study was designed in line with the known healing process of tendon tissue. The patients wore an immobilizing sling for the first three weeks after RCR. Resistant postoperative stiffness has commonly been reported in 1.5% of patients with an immediate passive ROM protocol, in 4.5% of patients with a six-week sling-immobilization protocol, and in 0% of patients with a modified protocol (Denard, Ladermann & Burkhart 2011). In the present study, all patients started passive shoulder ROM exercises on the first postoperative day, and in general the early phase of rehabilitation was characterized by acceleration, meaning an increase in load bearing capacity. As previously established, early gradual controlled loading of the repaired tendon, already in the proliferative healing phase, is likely to result in accelerated collagen synthesis, fibril neoformation, and proper fibre alignment, and thus increase in the final tensile strength of the tendon (Hsu, Horneff & Gee 2016, Kannus et al. 1997). Controlled loading can enhance healing in most settings; a balance must be achieved between loads that are too low (leading to a catabolic state) and too high (leading to micro-damage) (Killian et al. 2012b, Galatz et al. 2009). Thus, for patients with an increased risk of postoperative stiffness a more accelerated rehabilitation program is recommended (Huberty et al. 2009). In the present study, the additional training intervention started two months after the operation simultaneously with the remodeling phase of the tendon healing process. By that time, the tendon collagen is mature and realigned along the tendon's axis, and thus able to bear gradually increasing loads (Diegelmann & Evans 2004).

The resistance training was well tolerated, and no serious adverse events occurred during the one-year home-exercise period. During the first training weeks, nine patients reported shoulder pain in the operated shoulder, three reported neck pain and two reported elbow pain, after which they adapted to increasing load. Moreover, the resistance training protocol can be considered feasible and low cost, since the training was home-based, the physiotherapists gave instructions to the EG patients four times during the training year, and the equipment used was inexpensive.

However, the exercise program of the present study can also be considered appropriate, as it included several exercises that demand high to very high activity from the rotator cuff muscles (Escamilla et al. 2009). However, the intensity of loading of the training may have been insufficient, as the level of shoulder strength of the EG patients did not exceed that of the UCG patients. The object of this study was to obtain knowledge on the effects of long-term strength training. The hypothesis was that the changes in shoulder strength and ROM of the EG patients would be significantly higher than the corresponding values of the UCG patients.

6.6 Muscle strength and ROM during the intervention

The home strengthening exercise program with booster sessions was not more effective than usual care in increasing shoulder muscle strength and ROM. However, shoulder muscle strength, pain during loading, and ROM showed significant improvements in both groups. In addition, in both groups the strength of the operated shoulder remained on a lower level compared to the contralateral shoulder, except in internal rotation.

In the present study, the muscle strength of the operated shoulder showed a significant increase in all the strength measurements at 12 months. The highest relative improvements at 12 months were in flexion strength: 34% in the EG and 38% in the UCG. However, of the parameters tested, flexion strength had the lowest baseline values. Klintberg et al. (2009) studied the effectiveness on shoulder strength of early loading in physiotherapy treatment compared with traditional physiotherapy at 12 months after RCR. They reported the highest relative improvements in internal rotation: 32% in the progressive group and 24% in the traditional group.

In the present study, the strength values remained on a lower level compared to the values for the contralateral shoulder, except in internal rotation. External rotation and flexion strength of the operated shoulder were 9% and 17% lower in the EG, and 11% and 22% lower in the UCG compared to the contralateral shoulder (all $p<0.02$) at 12 months, respectively. This finding may be partly due to the fact that the supraspinatus was the operated tendon in 96% of all patients, and the supraspinatus is less involved in internal rotation than in external rotation or flexion. Bey et al. (2011) also reported that the isometric strength of the repaired shoulder was less than that of the contralateral shoulder at 24 months after RCR, although significant strength gains were observed from three to 12 months in abduction, external and internal rotation. From 12 to 24 months after RCR, further significant strength gain occurred only in internal rotation. In the same study, submaximal pain-free isometric exercises had been started at four weeks and an early strengthening phase at eight weeks, whereas in the present study submaximal isometric exercises were started at two weeks, an early strengthening phase at six weeks, and a progressive strengthening phase, i.e. the strength training intervention for the EG patients, at eight weeks. The results of a more recent study (Shin et al. 2016) showed that in patients with small rotator cuff tears, six months post RCR was required to reach the isometric muscle strength of the uninjured contralateral shoulder in flexion, internal and external rotation. In patients with medium tears, 18 months was required to reach the strength of the contralateral shoulder, while in patients with large-to-massive tears shoulder strength improved up to 18 months but did not reach that of the contralateral shoulder in any of the three planes of motion.

In the present study, pain during loading disappeared almost completely in both groups during the 12 months of training. Only three patients in both groups had pain above 25 mm during maximal effort at the 12-month strength

measurements. The reason for this may be that all the strength measurements were performed in lower positions: during the internal and external isometric rotation strength measurements the arm was kept beside the body, the shoulder in 20° flexion and the elbow in 90° flexion. Shoulder flexion strength was measured in full can position, which is a functional position (Timmons et al. 2015). Pain during maximal effort has not been reported in rehabilitation studies after RCR. However, Klintberg et al. (2009) showed that median pain during activity decreased from 24 mm to 10 mm in the progressive group and from 11 mm to 7 mm in the traditional group between 3 and 12 months after RCR.

In the present study, active and passive shoulder ROM increased significantly in all shoulder ROMs, except in passive internal rotation, in both groups. Active flexion increased by 17% and 19% in the EG and the UCG, passive flexion by 12% and 15%, and passive external rotation by 27% and 34%. Hayes et al. (2004) reported that visually measured passive flexion increased by 13% (from mean 130° to 150°) in the physiotherapy group and 23% (from mean 111° to 144°) in the home exercise group, and passive external rotation by 33% (from mean 34° to 51°) and 28% (from mean 31° to 43°), respectively, from six weeks to 24 weeks after the operation. These visually evaluated changes are on the same level as the corresponding results of our study from two months to 12 months after the operation. However, in the former study the final ROM values (at 24 weeks) of the ROM measurements were lower than those in the present study at two months. The reasons for this may be the difference in the method used to measure ROM, the different ages of the patients, and the differences in the sizes of the repaired tears. In Hayes et al. (2004), the measurement tool used was visual, the age range of the patients was from 41 to 83 years, and the repaired rotator cuff tears were of all sizes. In the present study, the measurement tool was an inclinometer, the patients were from 41 to 62 years of age, and the size of rotator cuff tear was less than 5 cm.

However, in measuring passive shoulder ROM the use of goniometers or inclinometers is recommended rather than vision (van de Pol, van Trijffel & Lucas 2010). At the beginning of the present intervention study, there were marked limitations in all the shoulder ROMs in both groups. Nevertheless, shoulder ROM reached the level of the contralateral shoulder at 12 months, with no further follow-up. However, the previous studies have shown that shoulder ROM may remain unchanged even at 10 years after RCR (Saraswat et al. 2015).

This intervention study was not able to establish which postoperative training protocol is better for working-age patients. The long-term postoperative results showed that usual care and a training program were sufficient to enable the majority of patients to attain normal shoulder function and the same strength levels as those who trained more intensively. It might be possible to improve training adherence through offering more frequent booster sessions or supervised training. Such an approach could also improve training intensity and progression, leading to better strength gains in the operated shoulder.

6.7 Methodological considerations

The aim of the present study was to investigate the effects of progressive muscle strength training in the post-acute healing phase when more strenuous loading of the shoulder muscles is possible. The patients in the EG and UCG received the exact same early rehabilitation program before the intervention started. Despite different study arms during the intervention, both groups showed similar improvement. The training intervention was long-lasting, and in any case, natural healing probably occurred over time (Ketola et al. 2015, Tashjian 2012). The training of the two groups may have been too similar, but it would be unethical not to give all patient the same basic instructions in the early rehabilitation phase.

The shoulder training program was started with a delay to enable soft tissue loading. Randomization of the study was possible as the baseline characteristics of the exercise and usual care groups were comparable. In the present study, the assessor was blinded to the patients' group allocation, whereas the patients, and the physiotherapists who instructed the patients, were not. The same physiotherapists gave the training intructions to both the EG and the UCG patients. It has been stated that the main difficulty in the randomized controlled trials is to ensure that the control group receives genuine usual care as supplied in everyday practise (Smelt et al. 2010). However, behavioral changes may be induced in control patients if they are briefed about the trial, asked to give an informed consent, asked to complete questionnaires or undergo examinations. Furthermore, behavioral changes in caregivers, owing to a learning effect, may occur when they are instructing both usual care patients and intervention patients (Smelt et al. 2010).

The results of the present study may be generalized to working-age patients who have undergone rotator cuff repair. However, the results must be interpreted cautiously with respect to older age groups, as the age of the present patients was below 65 years. In patients older than 65 years, the rotator cuff tears are mainly degenerative in origin, while the incidence of glenohumeral and acromioclavicular arthritis also increases with age (Killian et al. 2012a).

A further strength of this study is that the rotator cuff tears were confirmed during surgery. Furthermore, the study was randomized and controlled, the drop-out rate was low, and training adherence was reported for the EG. In addition, the study is one of the few to report the results of a long-term, 12-month exercise training program.

The rather small sample size is a limitation of this study. Generally, power calculations are based on group differences used in previous studies. However, no comparable studies, in which the ASES was the main outcome, had been published at the time this research was started. Thus, we followed the general recommendations of Altman (1999), according to which at least 50 subjects are required in a methods comparison study. The aim was to recruit 100 patients with a rotator cuff tear to the study. However, this aim was not reached. Owing,

for example, to the medical exclusion criteria applied and to patient refusal, we were only able finally to enrol 67 patients with a rotator cuff tear. In total, 115 patients from the original were excluded, of whom 66 failed to meet the inclusion criteria and 49 declined to participate.

The low training adherence in the home-exercise programme is also a limitation. In addition, the training frequency of the patients in the UCG, representing the normal care population, was not recorded during the intervention, as doing so might have increased the amount of exercise, thereby influencing the results.

Another aim of the present study was to cross-culturally adapt the self-report section of the ASES questionnaire and to investigate the reliability and validity of the ASES among Finnish-speaking patients with shoulder pain. A strength of the study is that the subjects represented a very large age range and many different shoulder diagnoses. Another strength is that the patients were grouped into the categories stable, improved, and worsened categories, which meant that we were able to assess the patients whose symptoms had changed. Furthermore, the literature recommends that functional status questionnaires be measured within a 2-week interval to test their reproducibility. In our study, the patients completed the ASES questionnaire twice: 2 weeks before and on their arrival at their outpatient clinic of physical medicine and rehabilitation or orthopaedics and traumatology. A strength of the study was that the shoulder disorders of the patients were all diagnosed. This procedure was applied to minimize the possibility of patients receiving new treatments between these two time points, as this would have potentially influenced their responses in the second assessment.

A limitation of the ASES validation study is that it was implemented in a hospital setting. The patients were collected from the outpatient clinics of a single hospital following there referral for specialized care. The patients had chronic shoulder problems, and had been examined by specialists. Thus, the sample assessed in this study may not represent subjects with shoulder pain across the general patient population.

6.8 Future directions

Future studies on post-operative therapeutic exercise should focus on the long-term effectiveness of different exercise protocols, including duration, intensity, frequency, exercise load, and different exercise modes, including concentric/eccentric exercises. A large study population would allow the use of sub-grouping. Also, longer post-intervention periods are needed to determine the long-term effects of different treatments. In the present study, the training adherence of the EG patients was low and the training was not progressive enough, which may weaken the outcomes of the home-based training component.

In future research with different exercise intervention protocols, subjects in the intervention groups could use a simple muscle strength measuring device during home-based training to capture the real loading instead of estimation by using 1 RM technique.

7 MAIN FINDINGS AND CONCLUSIONS

The main findings of the present study can be summarized as follows:

1. Rotator cuff patients who reported significant functional disability of the shoulder had lower scores in many dimensions of the HRQoL, indicating that patients with a rotator cuff tear may have extensive problems in performing both physical and mental activities.
2. The 12-month home-based strength training program was equally as effective as usual care after RCR, as self-rated disability and quality of life improved significantly in both groups.
3. No significant postoperative differences were observed between the groups in gains in objectively measured shoulder strength and ROM at 12 months, while the strength of the operated shoulder remained on lower level than that of the contralateral shoulder.
4. The self-report section of the Finnish ASES is a reliable, valid and feasible tool for assessing shoulder disability among Finnish patients with shoulder disorders.

This study showed that all patients do not need a routine prolonged training intervention after RCR, as the majority of the patients in both groups achieved full recovery during one year. More frequent booster sessions or supervised training may improve training intensity and progression, leading to better strength gains in the operated shoulder. A simple muscle strength measuring device could be used during home-based training to ensure progression of the load of rubber Thera-Band® or bulley exercises.

Rotator cuff tears cause major disability and therefore use of the ASES questionnaire is recommended in primary health care to screen for patients with low shoulder function and so identify those patients early enough to administer optimal treatment, e.g. active rehabilitation.

YHTEENVETO (FINNISH SUMMARY)

Intensiivisen 12 kuukauden olkapään voimaharjoittelun vaikuttavuus toimintakyvyn haittaan, elämänlaatuun ja olkapään funktioon kiertäjäkalvosimen korjausleikkauksen jälkeen

Olkapääkipu on kolmanneksi yleisin tuki- ja liikuntaelinten vaiva selkä- ja niskakivun jälkeen. Se aiheuttaa merkittävän osan sairauskuluista läntisissä maissa. Terveys 2000 – tutkimuksessa edellisen kuukauden aikana olkapäävaivoja oli potenut kuudesosa miehistä ja lähes neljäsosa naisista. Työikäisillä suomalaisilla olkapääkivun esiintyvyys oli suurin 55–64 – vuotiailla, ja olkapään jännevaivoja oli noin 2 % työikäisistä. Olkapään kiertäjäkalvosimen repeämä on tavallisimpia olkanivelen kivun, voimattomuuden ja liikerajoituksen syitä. Kiertäjäkalvosimen jänne voi revetä suurienergisen vamman yhteydessä tai ikääntyessä tapahtuvan jänteen rappeutumisen seurauksena, jolloin vähäinenkin vamma tai rasitus voi aiheuttaa jänteen repeämisen. Konservatiivinen hoito, johon sisältyy fysioterapia, anti-inflammatorinen lääkitys, kortisoni-injektiot ja lepo, on suositeltavaa alkuvaiheessa. Kiertäjäkalvosimen korjausleikkausta harkitaan silloin, kun kipu sekä heikentynyt olkapään lihasvoima ja liikkuvuus aiheuttavat merkittävää toimintakyvyn laskua konservatiivisesta hoidosta huolimatta. Kiertäjäkalvosimen korjausleikkauksen jälkeisen pitkäkestoisen harjoittelun vaikuttavuudesta on tällä hetkellä vain vähän satunnaistettuja kontrolloituja tutkimuksia. Useiden tutkimusten mukaan olkapään kipu vähenee leikkauksen jälkeen merkittävästi, mutta toimintakykyyn, lihasvoimaan ja nivelliikkuvuuteen jää merkittäviä puutteita.

Väitöskirjatutkimuksessa selvitettiin tehostetun olkapään harjoittelun vaikuttavuutta toimintakykyyn, terveyteen liittyvään elämänlaatuun sekä olkapään lihasvoimaan ja nivelliikkuvuuteen. Tutkimukseen osallistui 67 työikäistä potilasta, joille oli tehty kiertäjäkalvosimen repeämän korjausleikkaus. Potilaat satunnaistettiin harjoittelu- tai kontrolliryhmään. Harjoitteluryhmäläiset tekivät vuoden ajan olkapään tehostettua voimaharjoittelua. Ensimmäisen puolen vuoden aikana harjoitteluryhmäläisillä oli neljä fysioterapeutin ohjauskertaa, jolloin tarkastettiin harjoittelun progressiivisuus. Kontrolliryhmäläiset saivat tavanomaisen leikkauksen jälkeisen ohjauksen. Lisäksi väitöskirjatutkimukseen liittyi olkapääkivun toiminnallista haittaa arvioivan The American Shoulder and Elbow Surgeons Shoulder Assessment Form (ASES) - kyselylomakkeen suomenkielisen version luotettavuuden ja pätevyyden tutkiminen 105 potilaalla, joilla oli diagnosoitu erilaisia olkapäävaivoja.

Tulokset osoittivat, ettei olkapään tehostettu voimaharjoittelu ollut tavanomaista leikkauksen jälkeistä harjoittelua vaikuttavampaa. Molemmilla ryhmillä toimintakyky, olkapään lihasvoima ja nivelliikkuvuus sekä elämänlaadun fyysinen komponentti lisääntyivät merkitsevästi vuoden aikana, mutta pieni osa potilaista toipui huonosti. Leikatun olkapään ulkokierto- ja nostovoima ei kuitenkaan palautunut vuodessa vastakkaisen olkapään voimien tasolle. Lisäksi suomenkielinen ASES-kyselylomake osoittautui luotettavaksi, päteväksi ja

käyttökelpoiseksi tutkimusmenetelmäksi tutkittaessa suomalaisten potilaiden erilaisia olkapäävaivoja.

Tutkimustulosten mukaan tehostettua voimaharjoittelua ei ole tutkimuksessa käytetyllä tavalla perusteltua ohjata leikkauksen jälkeen kaikille potilaille, sillä voimaharjoittelun ei todettu olevan tavanomaista ohjausta vaikuttavampaa kiertäjäkalvosimen repeämän leikkauksen jälkeisessä kuntoutuksessa.

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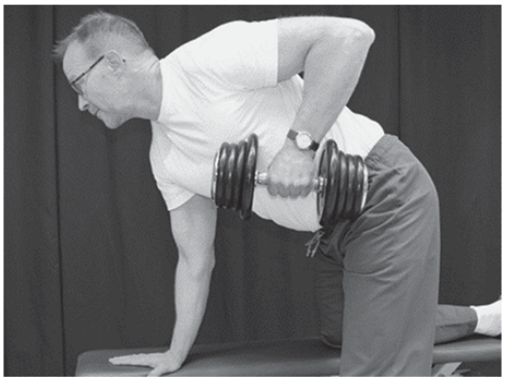
APPENDIX I

EXERCISES FOR SHOULDER PATIENTS, weeks 8-16 after the operation

Perform the exercises in a good posture. Choose a load with which you can perform 10 repetitions. Increase number of repetitions to 15. When you can easily perform 15 repetitions, increase the load by 0.5-1 kg. Then return to 10 repetitions. Perform 3 sets in every exercise session. Perform exercise 3 times a week.

Wall push-up
Standing at arm's length from a wall, extend your arms so that your hands are at shoulder height. Bend your elbows, and push back to the original position.

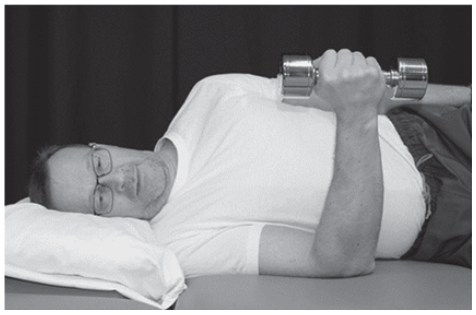


One-arm row
Place your contralateral hand and knee on the bench. Keeping your back straight, flex the elbow beside the body. Lower the dumbbell to full extension.

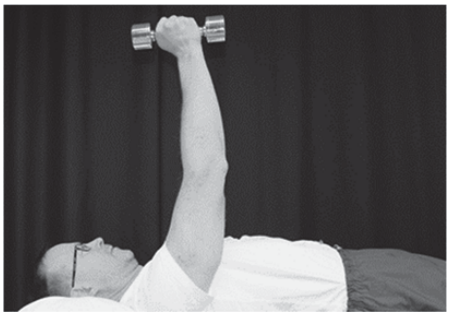
Shoulder adduction
Pull your arm down to your side, and slowly return to start position.

External rotation
Lie on the contralateral side. Keep a rolled up towel between your arm and body, keep the elbow in 90° flexion. Rotate your arm towards the ceiling, and slowly return to start position.

APPENDIX I

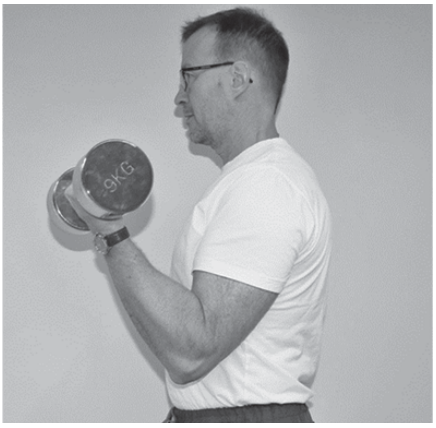


Internal rotation
Lie on the operated side. Keep the elbow in 90° flexion. Rotate your arm towards the ceiling, and slowly return to start position.

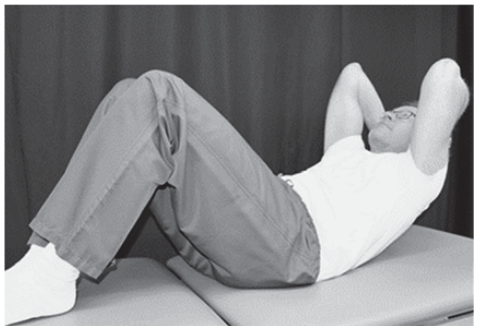


One-arm dumbbell shoulder press
Keep your arm beside the body and the elbow in 90° flexion. Extend your elbow towards the ceiling, and slowly return to start position.

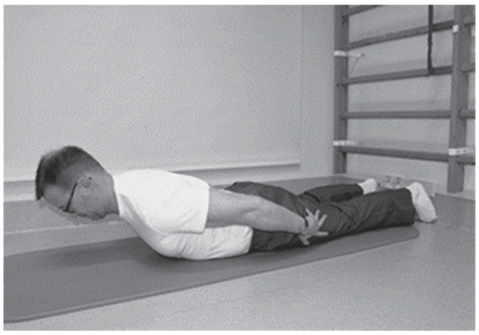
Dumbbell front raise
Maintain a tight core. Keep the arm beside the body and the elbow in 90° flexion. Flex your shoulder to 90°, and slowly return to start position.



Biceps curl
Maintain a tight core. Flex your elbow, and slowly return to start position.



Abdominal crunch
Contract the pelvic floor and abdominal muscles. Raise the upper body towards the ceiling, and slowly return to start position.

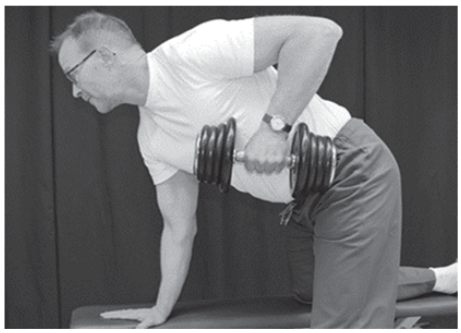


Back extension
Contract the pelvic floor and abdominal muscles. Raise the upper body straight from the floor.

APPENDIX I

EXERCISES FOR SHOULDER PATIENTS, weeks 16-60 after the operation

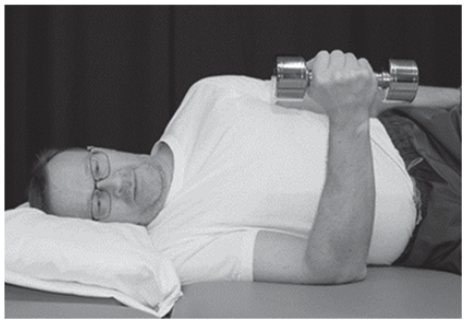
Remember to maintain a good posture. Choose a load with which you can perform 10 repetitions. Increase number of repetitions to 15. When you can easily perform 15 repetitions, increase the load by 0.5-1 kg. Then return to 10 repetitions. Perform 3 sets in every exercise session. Perform exercise 3 times a week.



One-arm row
Place your contralateral hand and knee on the bench. Keep your back straight, flex the elbow beside the body, and slowly return to start position.

Shoulder adduction
Pull the rubber band beside the body, and slowly return to start position.

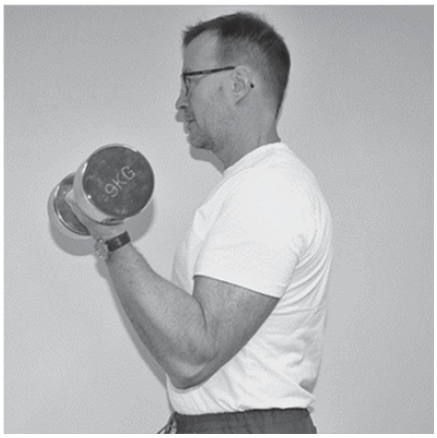
External rotation
Lie on the contralateral side. Keep a rolled up towel between your arm and body, keep the elbow in 90° flexion. Rotate your arm towards the ceiling, and slowly return to start position.



Internal rotation
Lie on the operated side. Keep the elbow in 90° flexion. Rotate your arm towards the ceiling, and slowly return to start position.

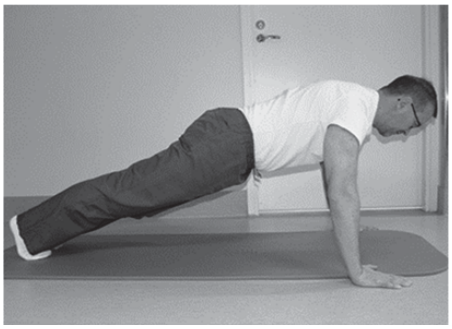
APPENDIX I

Dumbbell lift
Lift the dumbbell to a 45° horizontally adducted position at shoulder height, and slowly return to start position.

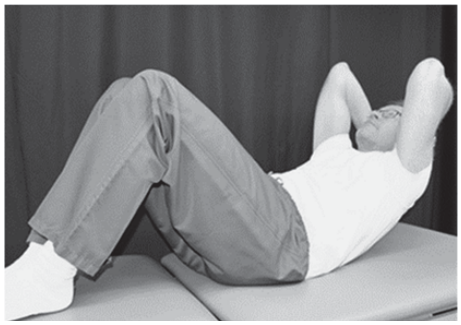


Biceps curl
Maintain a tight core. Flex your elbow, and slowly return to start position.

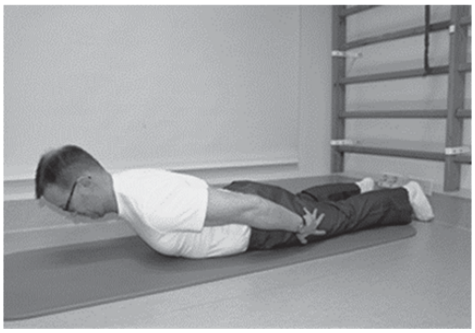
Dumbbell triceps kickback
Place your contralateral hand and knee on the bench. Keep your back straight. Keep your arm beside your body with the elbow in 90° flexion. Extend the elbow straight and slowly return to start position.



Push-up
Start in the plank position with your arms and legs straight. Bend your elbows lower your chest toward the floor and return to start position.



Abdominal crunch
Contract the pelvic floor and abdominal muscles. Raise the upper body towards the ceiling, and slowly return to start position.



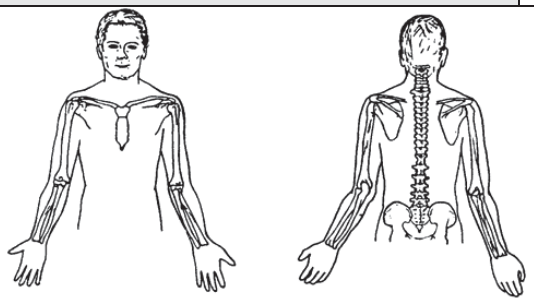
Back extension
Contract the pelvic floor and abdominal muscles. Raise the upper body straight from the floor.

APPENDIX II

KYSELYLOMAKE OLKANIVELPOTILAALLE

Onko sinulla tällä hetkellä olkakipua? (ympyröi oikea vastaus)	Kyllä	Ei

Merkitse viereiseen kuvaan kivulias alue:



Onko sinulla olkakipua öisin?	Kyllä	Ei
Käytätkö tavallisia kipulääkkeitä (Burana, Ibumax, Voltaren, Ketorin, Paratabs)?	Kyllä	Ei
Käytätkö vahvoja kipulääkkeitä olkakivun takia (Tramal, Panacod jne.)?	Kyllä	Ei
Montako kipulääketablettia otat keskimäärin / päivä		tablettia

Olkakipusi tänään (merkitse kiputasosi janalle poikkiviivalla)?

0 — Ei kipua ——— 10 — Pahin mahdollinen kipu

Tuntuuko olkanivelesi löysältä? (tuntuu kuin nivel menisi sijoiltaan)	Kyllä	Ei

Kuinka löysältä olkanivelesi tuntuu? (merkitse janalle poikkiviivalla)

0 — Erittäin tukeva ——— 10 — Erittäin löysä

Seuraavilla kysymyksillä selvitetään olkanivelesi toimintaa tällä hetkellä (ympyröi sopiva vaihtoehto):
0 **= En pysty**; **1 = Pystyn, mutta paljon vaikeuksia**
2 = Hieman vaikeuksia; **3 = Ei ongelmia (normaali tilanne)**

PYSTYTKÖ	**Oikea yläraaja**	**Vasen yläraaja**
1. pukemaan takin (käden pujottaminen hihaan)?	0 1 2 3	0 1 2 3
2. nukkumaan kyljellä, jos kipeä olkapää on alla?	0 1 2 3	0 1 2 3
3. viemään kätesi alakautta selän taakse lapojen väliin?	0 1 2 3	0 1 2 3
4. huolehtimaan WC-käynneillä henkilökohtaisesta hygieniasta (pyyhkiminen ulostamisen jälkeen)?	0 1 2 3	0 1 2 3
5. kampaamaan hiuksesi vieden käden pään päälle?	0 1 2 3	0 1 2 3
6. kurkottamaan tavaroita korkealta hyllyltä?	0 1 2 3	0 1 2 3
7. nostamaan 4 kg esineen olkapäätason yläpuolelle?	0 1 2 3	0 1 2 3
8. heittämään palloa yläkautta?	0 1 2 3	0 1 2 3
9. suoriutumaan normaaleista töistäsi (normaalit työt = ammatti ja kotityöt ennen olkavaivan alkamista)?	0 1 2 3	0 1 2 3
10. harrastamaan normaalia liikuntaasi (normaali liikunta = liikunta ennen olkavaivan alkamista)?	0 1 2 3	0 1 2 3

ORIGINAL PUBLICATIONS

I

RELIABILITY AND VALIDITY OF THE FINNISH VERSION OF THE AMERICAN SHOULDER AND ELBOW SURGEONS STANDARDIZED SHOULDER ASSESSMENT FORM, PATIENT SELF-REPORT SECTION

by

Piitulainen K, Paloneva J, Ylinen J, Kautiainen H, & Häkkinen A.
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BMC Musculoskeletal Disorders

RESEARCH ARTICLE Open Access

Reliability and validity of the Finnish version of the American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form, patient self-report section

Kirsi Piitulainen[1,2*], Juha Paloneva[3], Jari Ylinen[2], Hannu Kautiainen[4,5,6] and Arja Häkkinen[1,2]

Abstract

Background: The American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form (ASES) is one of the most widely used shoulder outcome tools in clinical work and in scientific studies. However, it has not been validated in the Finnish language. The aims of this study were to cross-culturally adapt the ASES to the Finnish language and to study the psychometric properties of the self-report section of the ASES.

Methods: A total of 105 patients with shoulder symptoms answered the questionnaires of the ASES, a single disability question, the Simple Shoulder Test (SST), and the Short-Form 36 Health Survey (SF-36). The reliability of the ASES questionnaire was studied using a test-retest procedure at 2-week intervals. Psychometric assessment was performed by testing the construct validity, internal consistency, the criterion validity, and the convergent validity of the ASES.

Results: The reproducibility and internal consistency of the ASES were 0.83 (95% CI 0.70 to 0.90) and 0.88 (95% CI 0.84 to 0.91). There were no significant differences between the diagnostic groups in the pain scores from the ASES, and the function score was significantly higher in the instability group compared to the other groups. The convergent validity of the ASES correlated with the SST, $r = 0.73$ ($p < 0.001$); the single disability question, $r = -0.74$ ($p < 0.001$); and the Physical Component Score of the SF-36, $r = 0.57$ ($p < 0.001$).

Conclusions: The Finnish version of the ASES proved to be a reliable and valid tool for assessing shoulder disabilities in patients with different shoulder diagnoses, including rotator cuff disease, instability, and osteoarthritis.

Keywords: The American Shoulder and Elbow Surgeons Standardized Assessment Form (ASES), Shoulder pain, Reliability, Validity

Background

Shoulder pain is the third most common musculoskeletal problem after low back pain and neck pain [1]. Shoulder pain is responsible for a remarkable amount of sick leave in western countries [2]. One-third of the population over 30 years of age reported shoulder pain during the last month [3]. When treating these patients, it is crucial to obtain information from the patient's point of view to assess the level of symptom severity and the level of disability.

There are two types of commonly used patient-based outcome tools. First, the generic measures (e.g., SF-36, EuroQol, and WHOQOL) evaluate general health, overall disability, and quality of life. However, they are not sensitive enough to react to clinically relevant changes in a specific disease [4]. Second, disease-specific measurement instruments connect the symptoms and disability to a specific disorder. One of the most frequently used questionnaires concerning the shoulder is the self-report section of the American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form (ASES) [5]. It has been validated in many languages and is considered

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to be a reliable, valid, and responsive outcome tool [5-12]. The psychometric properties of the ASES are reported to be acceptable for clinical use throughout every target language [6-8,11,12].

The ASES questionnaire has been used extensively in Finland. In addition it is easy and quick for a patient to complete. However, the ASES questionnaire has not been validated in the Finnish language. Compared to other questionnaires for the functional evaluation of the shoulder, e.g. the Disabilities of the Arm, Shoulder and Hand Questionnaire (DASH), which was developed to be used in patients with any disorder in any joint of the upper limbs, the ASES is more joint-specific instrument and therefore, more responsive and effective as a shoulder research tool [13]. The purpose of this study was to cross-culturally adapt the self-report section of the ASES questionnaire and to demonstrate the reliability and validity of the ASES among Finnish-speaking patients with shoulder pain.

Methods

Translation and cross-cultural adaptation

The translation and cross-cultural adaptation were performed based on the guidelines proposed by Beaton et al. [14]. The first stage was an independent translation (English to Finnish) of the self-report section of the ASES by two professionals (each with Finnish as their first language). In the second stage, synthesis of the two translations was performed. In the third stage, a person not working in the field of medicine, whose first language is English, and who masters the linguistic and cultural aspects of the Finnish language, back-translated (Finnish to English) the synthesised version blinded to the purpose of the instrument. In the fourth stage, the translation of the Finnish version of the ASES was accepted by an expert committee. The pre-final version of the ASES was tested in few subjects with shoulder problems to probe about the understanding of the questionnaire. As none of the comments required changes in this final stage of the adaptation, the equivalence of the Finnish questionnaire was ensured. Finally, the form was tested in a population of 128 patients with various shoulder disorders [15]. The Finnish version of the ASES is available on the Internet page of the Clinical Musculoskeletal Diseases Research Group of the Central Finland Health Care District (http://www.ksshp.fi/fi-FI/Ammattilaiselle/TULEStutkimus/Clinical_Musculoskeletal_Diseases_Resear(45030)) and in this article [see Additional file 1].

Patients, setting, and data collection

The psychometric characteristics of the Finnish version of the patient self-report section of the ASES questionnaire were examined in a sample of 105 consecutive patients who were clinically diagnosed with a shoulder disorder and referred for specialised care (the outpatient clinics in the Department of Physical Medicine and Rehabilitation or the Department of Orthopaedics and Traumatology in Central Finland Hospital, Jyväskylä, Finland). Our aim was to recruit a sample of at least 100 patients. The shoulder diagnoses were classified on the basis of information retrieved from the patient's medical records and, if needed, radiologic examinations (e.g., plain radiographs or magnetic resonance imaging) by an orthopaedic surgeon (JP). The inclusion criteria were age over 18 years, shoulder symptoms, and ability to communicate in the written Finnish language. The only exclusion criterion was previous surgery in the affected shoulder less than 1 year ago. The patients answered a questionnaire package that included the self-report section of the ASES, the Simple Shoulder Test (SST) [16], the Short-Form 36 Health Survey (SF-36) [17], and clinical and socio-demographic data. The self-report section of the ASES questionnaire was administered twice. The first questionnaires were mailed to the patients and the patients completed those 2 weeks before arriving at the outpatient clinic of Physical and Rehabilitation Medicine or orthopaedic surgery and again a second time when they came to the clinic. At the clinic the patients were contacted personally by a physiotherapist and asked to complete the ASES questionnaire for the second time.

Measurements

The self-report section of the ASES form is divided into two sections: pain and activities of daily living. The total ASES score is derived from a pain question using the Visual Analogue Scale (VAS) ranging from 0 mm (no pain) to 100 mm (worst pain), in addition to function during activities of daily living (1. Put on a coat, 2. Sleep on your painful shoulder, 3. Wash back, 4. Manage toileting, 5. Comb hair, 6. Reach a high shelf, 7. Lift 10 lb above shoulder, 8. Throw a ball overhand, 9. Do usual work, and 10. Do usual sport). These activities of daily living were assessed for each shoulder separately, and the 10 items were graded on a 4-point ordinal (Likert) scale. Scores ranged from 0 (unable to do the activity) to 3 (no difficulty in performing the activity). The pain score and the cumulative activities of daily living (ADL) score were weighted equally (50 points each) and combined for a total score (possible 100 points). The ASES score is equal to 5 ([100 - ASES pain VAS]/10 + ASES Cumulative ADL score/3). A single disability question ("How severe was your shoulder disability during the last week?"), the shoulder-specific Simple Shoulder Test (SST) [16], and the generic Short-Form 36 Health Survey (SF-36) [17] were used to check the convergent validity. The aforementioned SST has not been validated in the Finnish language; unlike the SF-36 has been validated [18]. The patients completed the ten items of activities of daily living in relation to both shoulders to find out how many patients

had disorders in both shoulders, though these results are not reported in the present study. A few patients had both shoulders affected, but in the analysis we chose the shoulder for which the patient had visited the outpatient clinic. The patients also answered an additional question about whether their shoulder symptoms had been stable, improved, or worsened during the past 2 weeks. According to these answers, the patients were divided into three groups.

The patients were divided into four categories according to the clinical diagnosis made in the outpatient clinics: rotator cuff disease, osteoarthritis of the glenohumeral or acromioclavicular joint, instability, and other.

Statistics

The results are expressed as means with standard deviation (SD) or with 95% confidence intervals (95% CIs), as counts with percentages, or frequency distributions. The 95% CIs were obtained by bias-corrected bootstrapping (5000 replications). The "floor value" was defined as the worst possible value of the item or as the minimum total value of the scale. The "ceiling value" was the best possible value of the item or the maximum total value of the scale. The reliability of the scales was evaluated by calculating the intra-class correlation coefficient (ICC) and coefficient of reproducibility with the bias corrected and accelerated bootstrapping (5000 replications) confidence intervals. The internal consistency was estimated by calculating Cronbach's alpha. Item analysis of the ASES scales was performed by analysing the item discriminating power (corrected item correlation) and the item difficulty (item mean) depicted by the explanatory data analysis. Factor structure among the ASES items was analysed using a factor analysis with varimax rotation. Effect size ("d") was calculated by using the method for paired samples: mean baseline scores minus mean follow-up scores, divided by the pooled standard deviation. Effect size of 0.20 was considered small, 0.50 medium and 0.80 large. 95 percent confidence intervals (95% CI) were obtained by bias-corrected bootstrapping (5000 replications). The correlation coefficients between the ASES and other patient-reported outcomes were calculated by the Spearman method using Sidak-adjusted probabilities.

Ethics

The study was approved by the ethics board of the Central Finland Health Care District (November 23, 2005, Dnro 46/2005). Written informed consent was obtained from all participants.

Results

A total of 105 patients were enrolled in the study (mean age 52 years, range 18-88). The mean (SD) shoulder pain was 56 (28) mm. The most common reason for shoulder pain was rotator cuff disease (41%). The demographic and clinical data of the study group are shown in Table 1.

Table 2 shows the floor and ceiling values of the initial assessment. The floor value was reached by five patients in the pain score of the ASES but not in the function score or in the total ASES index. Three patients reached the ceiling value in the pain section and one patient in the function score but not in the total ASES index. The total ASES score ranged from 2 to 99.

When the questionnaire was administered for the first time, the mean (SD) total ASES score was 48 (23) for the patients with shoulder symptoms that had been stable between the first and the second measurement. For these patients, the reproducibility intra-class correlation coefficient was 0.83 (95% Cl = 0.70 to 0.90). For the patients with shoulder symptoms that had improved, the reproducibility ICC was 0.69 (0.27 to 0.87). For the patients with worsened symptoms, the reproducibility ICC was 0.77 (0.59 to 0.87) (Table 2).

The internal consistency estimate of Cronbach's alpha was 0.88 (95% Cl 0.84 to 0.91). The item analysis of the ASES showed that item 6 (reaching a high shelf) had the highest corrected item correlation, whereas item 10 (doing usual sport) had the lowest corrected item correlation. In addition, item 3 (washing back) had the lowest item

Table 1 Socio-demographic and clinical data of patients with shoulder disorders

Variables	Values (N = 105)
Males, n (%)	60 (57)
Age, years, mean (SD)	52 (18)
Body mass index, mean (SD)	28 (5)
Education, years, mean (SD)	13 (4)
Employed, n (%)	38 (36)
Symptomatic shoulder, n (%)	
Right	65 (62)
Left	40 (38)
Pain, VAS (0-100), mean (SD)	
Shoulder	56 (28)
Upper limb	25 (33)
Neck	19 (26)
Back	16 (26)
Duration of shoulder pain, months, mean (SD)	56 (79)
Shoulder trauma, n (%)	51 (49)
Diagnosis, n (%)	
Rotator cuff disease	43 (41)
Glenohumeral or acromioclavicular arthritis	27 (26)
Glenohumeral instability	23 (22)
Other	12 (11)

SD standard deviation, *VAS* visual analogue scale.

Table 2 Reproducibility of the ASES index

	Baseline				Change from first to second measurement	Reproducibility	
	Mean (SD)	Range	Floor* N (%)	Ceiling** N (%)	Mean (95% CI) [Effect Size]	ICC (95% CI)	CR (95% CI)
Pain score, all patients (N = 105)	21.9 (14.1)	0-50	5(5)	3(3)	4.0 (1.8 to 6.1) [0.26]	0.66 (0.52 to 0.77)	23 (19 to 28)
Improved (N = 25)	26.9 (14.4)	0-48	2(8)	0(0)	5.8 (0.5 to 11.2) [0.42]	0.50 (0.04 to 0.77)	27 (19 to 38)
Stable (N = 55)	22.3 (14.7)	0-50	2(4)	3(5)	3.9 (0.9 to 7.0) [0.27]	0.68 (0.46 to 0.82)	23 (17 to 29)
Worsened (N = 25)	15.9 (9.8)	0-36	1(4)	0(0)	2.2 (-1.6 to 6.0) [0.19]	0.67 (0.37 to 0.83)	18 (14 to 23)
Function score, all patients (N = 105)	25.5 (11.5)	2-50	0(0)	1(1)	0.2 (-1.3 to 1.6) [0.01]	0.81 (0.71 to 0.88)	14 (11 to 18)
Improved (N = 25)	27.5 (11.4)	3-46	0(0)	0(0)	2.6 (-0.1 to 5.3)[0.23]	0.81 (0.51 to 0.93)	13 (8 to 20)
Stable (N = 55)	26.0 (11.3)	3-50	0(0)	1(2)	-1.5 (-3.4 to 0.4) [0.13]	0.83 (0.64 to 0.92)	14 (10 to 19)
Worsened (N = 25)	22.5 (12.1)	1-40	0(0)	0(0)	1.5 (-1.9 to 4.9) [0.12]	0.79 (0.57 to 0.90)	16 (11 to 22)
Total ASES, all patients (N = 105)	47.4 (22.8)	2-99	0(0)	0(0)	4.1 (1.4 to 6.9) [0.18]	0.79 (0.69 to 0.86)	29 (25 to 35)
Improved (N = 25)	54.5 (24.1)	3-93	0(0)	0(0)	8.5 (1.5 to 13.4)[0.37]	0.69 (0.27 to 0.87)	36 (24 to 52)
Stable (N = 55)	48.3 (22.8)	7-99	0(0)	0(0)	2.4 (-1.2 to 5.9) [0.10]	0.83 (0.70 to 0.90)	26 (21 to 31)
Worsened (N = 25)	38.5 (19.2)	2-73	0(0)	0(0)	3.7 (-2.1 to 9.4) [0.17]	0.77 (0.59 to 0.87)	28 (21 to 35)

*Worst possible value (Pain and function: 0, Total ASES: 0) of the item or minimum total value of the scale.
**Best possible value (Pain and function: 50, Total ASES: 100) of the item or maximum total value of the scale.
ASES American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form, *ICC* intra-class correlation coefficient, *CR* coefficient of repeatability.

means, and item 4 (managing toileting) had the highest item means (Figure 1).

The factor analysis performed for construct validity showed that ASES was loaded on one factor that explained 66% of the total variance.

The total ASES index was the lowest in the glenohumeral or acromioclavicular arthritis group and the highest in the instability group. There was no statistical difference between the diagnostic groups in pain score, and the function score was significantly higher in the instability group compared to the other groups (p = 0.035) (Figure 2).

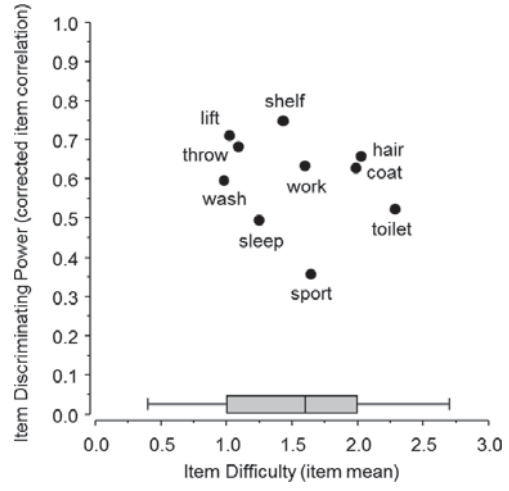

Figure 1 Item analysis for the function items of the ASES. The bar denotes the median and interquartile range.

The baseline data are presented in Table 3. The correlations between the total ASES index and the SST scale and the single disability question (How severe was your shoulder disability during the last week) were 0.73 (p < 0.001) and -0.74 (p < 0.001). The mean shoulder disability scored by a single disability question was 54 (28). The correlations between the total ASES index and Physical Functioning, Role Physical, Role Emotional, Social Functioning and Bodily Pain from the SF-36 were statistically significant (Table 3). When the eight dimensions of the SF-36 were aggregated into summary scores, the correlations between the total ASES score and the Physical Component Summary and Mental Component Summary of the SF-36 were 0.57 (p < 0.001) and 0.21 (p = ns).

During the translation process from English to Finnish and backward translation into English only minor linguistic and cultural differences between the translations emerged. The question of activities of daily living about lifting 10 lbs above the shoulder was adapted to the metric system. The original ASES uses the U.S. Unit system. The translated weight is 4 kg in our study.

Discussion

In the present study, we assessed the cross-cultural adaptation and the psychometric properties of the self-report section of the ASES questionnaire to the Finnish

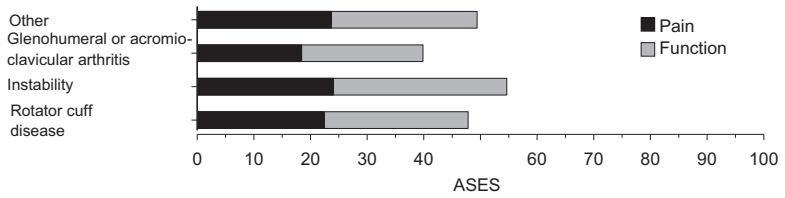

Figure 2 Pain and function scores of the ASES index in different diagnosis groups.

language. We demonstrated that this version of the ASES has good reliability and validity.

It has been suggested that a questionnaire reaching a floor or ceiling value of over 15% should be omitted [14]. The present study had even lower floor and ceiling effects than 15%. One possible interpretation of this might be that a real floor or ceiling effect does not exist when using the Finnish ASES questionnaire. Kocher et al. [9] examined the floor and ceiling effect of the total ASES scale with different patient subsets (shoulder instability, rotator cuff disease, glenohumeral arthritis), and they found that only 1.3% of the patients with shoulder instability had a ceiling effect. Thus, the ASES score seems to have enough categories to discriminate the patients with different disability levels and changes.

In the present study, the baseline values in the stable, improved, and worsened groups were consistent. By dividing the patients into three groups it was possible to find out, if the ASES could detect differences between patients who have reported to be stable and those whose symptoms have been changed. The change was statistically significant only in the improved group (Table 2). The reproducibility ICC of the total ASES index in all patients was 0.79 (95% Cl: 0.69 to 0.86), but it varied between moderate and good in the three groups. The reproducibility ICC (95% Cl) was 0.83 (0.70 to 0.90) in the stable group (Table 2). According to Portney and Watkins [19], an ICC > 0.75 indicates an acceptable test-retest reliability score. Although the time interval between the first and the second measurement varies from 1 day to 4 weeks, the reproducibility ICC is ≥0.84 in the previous studies (Table 4). This indicates that test-retest reliability of the ASES is quite high and stable in all studied languages [6,7,9-12].

In the present study, the internal consistency of the ASES was good, which indicates that several items that propose to measure the same general construct produce similar scores. The α-values measuring internal consistency varied considerably ranging from 0.61 to 0.96 in the previous studies [6,7,9,10,12] demonstrating

Table 3 Disability and health-related quality of life and their correlations with the patient self-report section of the ASES

	Mean (SD)	Correlations		
		The total ASES	Pain score	Function score
SST (scale 0-12)	5 (4)	0.73***	0.54***	0.81***
A single disability question (scale 0-100)	54 (28)	− 0.74***	− 0.67***	− 0.68***
Dimensions of SF-36 (scale 0-100)				
Physical Functioning	64 (25)	0.51***	0.38**	0.57***
General Health	58 (22)	0.27	0.22	0.32*
Vitality	60 (21)	0.58	0.21	0.32*
Mental Health	73 (21)	0.26	0.23	0.27
Role Physical	36 (39)	0.49***	0.41***	0.47***
Role Emotional	67 (42)	0.37**	0.28	0.42***
Social Functioning	75 (26)	0.44***	0.37**	0.46***
Bodily Pain	41 (21)	0.68***	0.630***	0.58***
Summary Score of SF-36 (scale 0-100)				
PCS	36 (10)	0.57***	0.48***	0.56***
MCS	52 (12)	0.21	0.17	0.25

*p < 0.05, **p < 0.01 and ***p < 0.001. Sidak adjusted probability.
SD standard deviation, *ASES* American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form, *SST* Simple Shoulder Test, *SF-36* Short Form 36 Health Survey, *PCS* Physical Component Score, *MCS* Mental Component Score.

Table 4 Summary of translation, cultural adaptation and validation studies of the ASES

	Number of subjects (age range, years)	Language/ validation study	Time interval between the first and the second measurement	Reproducibility ICC (95% CI)	Internal consistency (Cronbach's alpha)	Convergent validity ASES and other questionnaire	Convergent validity ASES and SF-36 PCS	Convergent validity ASES and SF-36 MCS
Piitulainen K et al. present data	n = 105	Finnish	2 weeks	0.83 (0.70 to 0.90), n = 55	0.88 (0.84 to 0.91)	SST		
	(18-88)					*r* = 0.73	*r* = 0.57	*r* = 0.21
				0.79 (0.69 to 0.86), n = 105		p < 0.001	p < 0.001	ns
Celik D et al. [6]	n = 63	Turkish	3-7 days	0.94	0.88	SPADI		
	(18–74)					*r* = – 0.82	*r* = 0.02	*r* = 0.53
						p < 0.001	p = 0.82	p < 0.000
Yahia A et al. [12]	n = 80	Arabic	1-3 days n = 30	0.96 (0.92 to 0.98)	0.76	SPADI	-	-
	(20-80)					*r* = –0.80		
						p < 0.001		
Padua R et al. 2010	n = 50	Italian	7 days n = 20	0.91	0.85	DASH		
	(33-78)					*r* = –0.92	*r = 0.48*	*r* = –0.20
						p < 0.02	*p < 0.01*	ns
						OSQ		
						r = 0.78		
						p < 0.02		
Goldhahn J et al. [7]	n = 118	German	7 days	0.93 (0.90 to 0.95)	0.96	SPADI		
	(33 to 89)					*r* = 0.92	*r* = 0.64	Overall SF-36
						DASH		*r* = 0.66
						r = 0.84		
Kocher et al. [9]	n = 1066	Validation study English	4 weeks	0.94 (n = 56) age range 15-78 years	0.61 instability 0.64 rotator cuff disease 0.62 arthritis	-	SF-12	SF-12
	(13-95)						*r* = 0.32-0.58	*r* = –0.09-0.11
							p < 0.001-0.002	p = 0.27-0.67
Michener et al. [10]	n = 63	Validation study English	24 to 72 hours, and after 3 to 4 weeks	0.84 (0.75 to 0.91)	0.86	Penn Score		
	(20-81)					*r* = 0.78	*r* = 0.40	*r* = 0.15
						p < 0.01	p = 0.001	p = 0.25

ASES American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form, *ICC* intra-class correlation coefficient, *CI* Confidence interval, SST, Simple Shoulder Test, *SPADI* Shoulder Pain and Disability Index, *DASH* Disability of Arm, Shoulder and Hand questionnaire, *OSQ* Oxford Shoulder Questionnaire, *Penn Score* the University of Pennsylvania Shoulder Score, *SF-36* Short Form 36 Health Survey, *PCS* Physical Component Summary, *MCS* Mental Component Summary, *SF-12* Short Form 12 Health Survey.

that the homogeneity of the ASES items in a scale varies in all the studies (Table 4). The main reason for this may be the differences in the study samples. The recommended Cronbach's alpha for group comparisons is higher than 0.80 [20]. However, "very good" internal consistency may indicate that the items are too homogenous. From that point of view, our study expresses good reliability and demonstrates that the items of the Finnish ASES are reasonably related and still contribute unique information about the patient's status. In the present study, the factor analysis showed unidimensionality of the ASES. However, it has been suggested that factor analysis for the ASES was loaded in 2 dimensions [12]. The reason for this may be due to study group differences.

Our a priori hypotheses were accomplished, as the ASES questionnaire had a strong correlation with the SST, the Physical Component Score of the SF-36, and also with the single disability question (expressed on a visual analogue scale). This confirmed the construct validity and reassured us that these measurement procedures were measuring the same construct. In the previous studies, correlations between the ASES and other shoulder-specific or upper limb-specific questionnaires have been strong [6,7,10,12]. Correlation between the SST and the ASES has been found to be strong, which is consistent with the similarity in their constructs [21]. In the present study the SST score was more related to function score than pain score of the ASES (Table 3). The reason for this may be the fact that a half of the ASES consists of single value of pain VAS and another half consists of function score that is quite similar to the SST. There was not a statistically significant correlation between the ASES questionnaire and the Mental Component Score of the SF-36 (Table 3). This result demonstrates that the ASES disability questionnaire and the Mental Component Score of the SF-36 questionnaire do not measure the same entity. On the contrary, Çelik et al. [6] reported significant correlation between the ASES and the Mental Component Score of the SF-36, meanwhile correlation between the ASES and the Physical Component Score of the SF-36 was weak (Table 4). The differences in correlations may be due to differences in, e.g. sample size, age, reason for shoulder disorder.

The questionnaire showed to be highly acceptable, easily understood, and capable of being self-administered. Any suggestions for improving the wording were not given, except the question about lifting 10 lbs above the shoulder was adapted to the metric system. Thus, the weight is 4 kg in our study. A variance of 4 to 5 kg has been used in most of the studies concerning the validation of the ASES questionnaire [6-9,11].

The strength of the present study is that the subjects represented a very large range of ages and many different shoulder diagnoses. Another strength of this study is that the patients were grouped into stable, improved, and worsened categories. Using this subgroup analysis, we could assess the patients whose symptoms had changed. Furthermore, earlier literature has recommended that functional status questionnaires be measured within a 2-week time interval to test their reproducibility [14]. In our study, the patients completed the ASES questionnaire twice: 2 weeks before and at the time of their arrival to the outpatient clinics of physical medicine and rehabilitation or orthopaedics and traumatology. This procedure was applied to minimise the possibility that the patients received new treatments, which would potentially influence the responses of the second assessment, between these two time points.

A limitation of our study is that it was performed in a hospital setting. The patients were collected from the outpatient clinics of a single hospital following referral to specialised care. The patients had chronic shoulder problems, and they were examined by specialists. Thus, the sample assessed in this study may not represent subjects with shoulder pain in the entire population.

Conclusions

The self-report section of the Finnish ASES is a reliable and valid tool and can therefore be used as an instrument to assess shoulder disability among Finnish patients of different ages with different shoulder diagnoses.

Additional file

Additional file 1: ASES suomi that presents the Finnish American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form.

Abbreviations

ASES: American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form; SST: Simple Shoulder Test; SF-36: Short-Form 36 Health Survey; EuroQol: European Quality of life scale; WHOQOL: World Health Organization Quality of Life; HRQOL: Health-Related Quality of Life.

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

KP: correspondent author, participated in the design of the study, participated in the patient collection, drafted the manuscript and finished the manuscript. JP, JY and AH participated in the design of the study and revised the manuscript critically. HK, KP and AH performed the statistical analysis. HK also drafted the manuscript and revised the manuscript critically. All authors read and approved the final manuscript.

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ORIGINAL PUBLICATIONS

II

THE RELATIONSHIP BETWEEN FUNCTIONAL DISABILITY AND HEALTH-RELATED QUALITY OF LIFE IN PATIENTS WITH A ROTATOR CUFF TEAR

by

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The relationship between functional disability and health-related quality of life in patients with a rotator cuff tear

Keywords: Shoulder pain, rotator cuff tear, functional disability, health-related quality of life

Implications for Rehabilitation

- Rotator cuff tears (RCTs) result from injury or degeneration, and tear prevalence increases with age.
- RCT causes disabling pain, decline in muscle strength and shoulder mobility.
- RCT patients with decreased functioning have impaired quality of life.

Purpose
To determine the relationship between functional disability and health-related quality of life (HRQoL) in rotator cuff tear (RCT) patients. *Method:* In 67 RCT patients (mean age, 54 years; 57% males), functional disability was self-reported with the American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form (ASES), HRQoL with the Short-Form 36 Health Survey (SF-36), and pain by visual analogue scale. ASES results were divided into tertiles (12–38, 39–51, and 52–82).

Results
Mean ASES score was 48 (range, 12–82). Patients with the highest functional disability and highest pain level had the lowest HRQoL. For the highest, middle, and lowest ASES categories, respectively, mean SF-36 Physical Component Summary (PCS) scores were 35 SD 5, 36 SD 8, and 41 SD 6 ($p < 0.001$) ($r = 0.47$ for ASES vs. PCS; $p < 0.001$), and Mental Component Summary (MCS) scores were 50 SD 13, 56 SD 10, and 58 SD 8 ($p = 0.011$) ($r = 0.37$ for ASES vs. MCS; $p = 0.003$).

Conclusions: Patients with higher functional disability had lower HRQoL. RCT extensively affects patients' lives; therefore, capturing both generic and shoulder-specific measures of RCT problems is recommended.

Introduction

Rotator cuff tears (RCTs) are among the most common injuries affecting the musculoskeletal system [1]. Tears become more prevalent with increasing age [2,3], since rotator cuff pathology is mostly related to degenerative changes in the tendons during the aging process [4,5]. Age, gender, rotator cuff size, and medical and social comorbidities are associated with worse preoperative shoulder function and quality of life [6,7]. A RCT has an impact on patient impairment and quality of life that is comparable to that of diabetes, myocardial infarction, congestive heart failure, or depression [8–11]. A RCT not only causes pain, but over time can lead to declines in muscle strength and shoulder mobility. These symptoms may have a negative impact on activities of daily living, work, and leisure activities [12]. Specifically, RCT patients experience great difficulties in lifting a load and doing overhead activities [13,14]. Although decreased functioning and health-related quality of life (HRQoL) have been reported in RCT patients [15,16], further research is needed to fully understand the impact of RCTs on the HRQoL. The aim of the present study was to test our hypothesis that the HRQoL is related to subjective functional disability of the shoulder in patients with a RCT.

Patients and methods

Subjects

Of the 181 consecutive working-age patients screened for this study, sixty-seven (38 men and 29 women) consented to participate according to the criteria from the Central Finland Hospital District. Meanwhile, 48 patients refused to participate to the study, 43 patients were excluded because of medical reasons, and 23 were excluded due to being over the age of 65 years.

The inclusion criteria were age of 18–65 years and a RCT of less than 5 cm. The exclusion criteria were previous surgery in the affected s houlder, cervical intervertebral disc prolapse, status post-cervical spine surgery, spinal canal stenosis, signs of remarkable joint arthritis, rheumatoid arthritis, fibromyalgia, pregnancy, serious mental illness or social problem, and severe cardiac disease or neurological disorder. The exclusion criteria were based on clinical findings. Patients were referred to the hospital from health centers or occupational health care practices. They were examined by surgeons in the orthopedic outpatient clinic, and RCT was diagnosed by clinical examination, magnetic resonance imaging (MRI), ultrasound scans, or arthrography. At that time, a decision was made regarding rotator cuff reconstruction. Th e st udy was approved by the regional health ethics board of the Central Hospital of Central Finland, and written informed consent was obtained from all participants.

Methods

The score from the self-report section of the ASES questionnaire was used to evaluate condition-specific pain and function during activities of daily living. The pain score was calculated from the single pain question, and the function score from the sum of the 10 questions addressing function. The pain score and function composite score were weighted equally (50 points each) and combined for a possible total score of 100 points, with a higher score indicating better functional ability [17]. The ASES questionnaire is considered to be a reliable, valid, and responsive outcome tool [18].

The SF-36 is the most widely-evaluated, generic, patient-assessed measure of HRQoL [19]. It reflects the patient´s health condition through eight health concepts: Physical Functioning (PF), Role Physical (RP), Bodily Pain (BP), General Health (GH), Vitality (VT), Social Functioning (SF), Role Emotional (RE), and Mental Health (MH). Scores range from 0 to 100, with a higher score associated with better health. The eight scales of t he SF-36 c an be a ggregated into two summary measurements; PF, RP, BP, and GH comprise the Physical Component Summary (PCS), and VT, SF, RE, and MH comprises the Mental Component Summary (MCS) [20].

A visual analogue scale (VAS) was used to assess average shoulder, upper limb, neck, and back pain. The scale ranged from 0 to 100, with a score of 0 defining no pain at all, and a score of 100 defining the worst possible pain [21].

Statistical methods

The results are expressed as the mean and standard deviation (SD). Statistical significance for the hypotheses of linearity was evaluated by bootstrap-type analysis of covariance (ANCOVA) with age and gender introduced into the model as covariates, or by the Cochran-Armitage trend test with a Monte Carlo *p*-value. Confidence intervals (CI) for the means were obtained by bias-corrected and accelerated bootstrapping (5000 replications) because of the skewed distribution of the variables. The ASES scores were expressed as continuous and divided into tertiles (ordinal disability levels).

Results

Of the 67 patients enrolled in the trial, the mean age was 54 (range, 41–62) years, and 57% were males. Fifty-eight (87%) of the patients had a tear only of the supraspinatus tendon, three (4%) of both the supraspinatus and subscapularis ten-dons, three (4%) of both the supraspinatus and infraspinatus tendon, two (3%) of the biceps long-head tendon, and one (2%) of the infraspinatus tendon**.** Moreover, 63% of patients had one or more additional disorders affecting the shoulder with the RCT, and 59% had previously received conservative treatment of the affected shoulder (Table I).

The mean score from the self-report section of the ASES index in the total group of RCT patients was 48 SD 17. When the patients were divided into three ordinal disability levels according to tertiles of the ASES values, the mean (range) was 30 (12–38) for the highest disability level, 46 (39–51) for the middle level, and 66 (52–82) for the lowest disability level. There were no statistically significant differences in the demographic and clinical data between the three disability levels, except that shoulder pain was highest in the highest disability level and the use of physiotherapy differed significantly between the groups.

Patients with higher ASES index scores showed higher HRQoL in all dimensions of the SF-36, except the GH dimen-sion. Patients with the greatest functional disability had the lowest HRQoL, especially in the dimensions of RP and BP (Figure 1).

When the eight dimensions of the SF-36 were aggregated into summary scores, the mean PCS scores were 35 SD 5, 36 SD 8, and 41 SD 6 in the lowest, middle, and highest ASES lev-els (p for linearity <0.001, age- and sex-adjusted), respectively, and those of the MCS were 50 SD 13, 56 SD 10, and 58 SD 8 (p = 0.011). The relationship between functional disability and the PCS of the HRQoL was r = 0.47 and that between functional disability and the MCS of the HRQoL was r = 0.37 (Figure 2).

Discussion

The results of the present study showed a relationship between functional disability of the shoulder and the HRQoL. This indicates that functional disability of the shoulder affects not only the physical, but also the mental and social qualities of life in people with a RCT. Health care professionals need to use a wide-ranging approach to this issue.

We observed wide individual variation in the scores of the self-report section of the ASES, ranging from 12 to 82; the mean ASES index (48 points) showed moderate disability. These results were similar to those of two other studies in patients awaiting surgery, which showed mean ASES indexes of 46 to 58 points [22,23]. Because the patients in the present study presented with an indication for surgery, their conditions might have been more painful than average, and thus the results might not be valid when considering RCT patients that only require more conservative treatment. Moosmayer et al. [24] studied patients with full-thickness RCT and found mean ASES scores of 47 SD 14 in symptomatic patients and 97 SD 3

TABLE 1. Baseline demographic and clinical data of patients with a rotator cuff tear categorized into three disability groups.

	ASES disability groups			*p* value for linearity*
	I Highest	II Middle	III Lowest	
Males, *n* (%)	13 (59)	9 (41)	16 (70)	0.55
Age, years, mean (SD)	53 (6)	54 (6)	54 (4)	0.25
BMI, mean (SD)	27.4 (4.5)	28.0 (4.5)	27.7 (3.7)	0.84
Pain VAS (0–100), mean (SD)				
Shoulder	73.3 (14.0)	53.8 (11.7)	29.6 (13.4)	<0.001
Upper limb	32.0 (27.9)	36.5 (29.6)	22.8 (18.4)	0.24
Neck	11.3 (19.2)	11.8 (17.4)	5.3 (11.2)	0.22
Back	5.0 (13.6)	6.9 (17.0)	6.0 (16.3)	0.85
Duration of shoulder pain, months, median (IQR)	18 (12, 24)	13 (10, 24)	24 (8, 72)	0.080
Tear location, *n* (%)				
Supraspinatus	20 (90)	18 (81)	20 (88)	0.68
Supraspinatus and subscapularis	1 (5)	1 (5)	1 (4)	0.99
Supraspinatus and infraspinatus	1 (5)	2 (9)	0	0.34
Long head of biceps brachial	0	1 (5)	1 (4)	0.60
Infraspinatus	0	0	1 (4)	0.38
Additional shoulder disorders, *n* (%)				
Osteoarthritis of the acromioclavicular joint	6 (27)	6 (27)	8 (35)	0.58
Impingement of the acromion	6 (27)	2 (9)	3 (13)	0.21
Lesion of the long head of biceps tendon	4 (18)	4 (18)	2 (9)	0.37
Labrum disorders	3 (14)	1 (5)	2 (9)	0.57
Conservative treatment, *n* (%)				
Cortisone	11 (50)	14 (64)	7 (30)	0.20
Physiotherapy	12 (55)	13 (59)	5 (22)	0.027
Education, years, mean (SD)	11.5 (3.4)	12.7 (3.6)	11.3 (2.3)	0.85
Employed, *n* (%)	13 (59)	16 (73)	12 (52)	0.65
Trauma, *n* (%)	12 (55)	11 (50)	13 (57)	0.99

ASES, American Shoulder and Elbow Surgeons Standardized Shoulder Assessment; BMI, body mass index; VAS, visual analog score; IQR, interquartile range.
*age and sex adjusted.

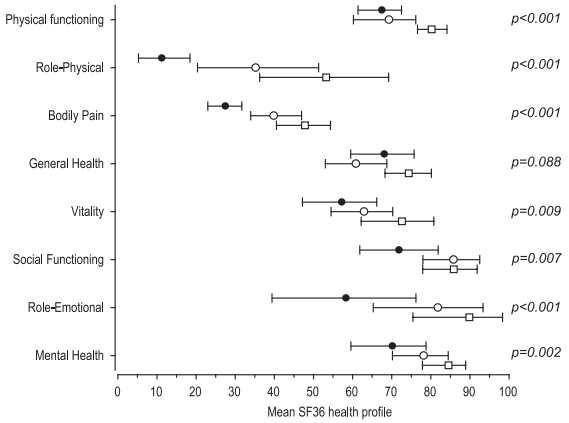

FIGURE 1. Mean (with 95% confidence intervals) SF-36 scales. *p* val-ues include age- and sex-adjusted linearity. Filled circles, highest level; open circles, middle level; and open box, lowest level of the American Shoulder and Elbow Surgeons Standardized Shoulder Assessment (ASES) disability levels.

in asymptomatic patients. The choice of 90 on the ASES scale as a cut-off point to deem a patient asymptomatic was based on age-related baseline values from studies of individuals with no history of shoulder problems [25,26]. Patients in the aforemen-tioned studies were older compared with those in the present study, although the functional disability of the shoulder was on the same level. The present and former studies showed that RCTs cause remarkable functional disability of the shoulder. Furthermore, many patients presented with other co-existing shoulder diseases, and functional disability in these cases was clearly increased. In patients with impingement syndrome of the shoulder and non-operative superior labrum anterior-posterior (SLAP) tears, the respective ASES scores of 56 and 59 [27,28] showed moderate functional disability. Patients with adhesive capsulitis had a mean score of 35 SD 25 [29].

In the present study, low HRQoL was related to higher disability; patients with the most difficulties in shoulder function also had lower scores in most dimensions of the HRQoL. Those patients are likely to have difficulties in physi-cal activities, e.g. work-related and household tasks, as well as

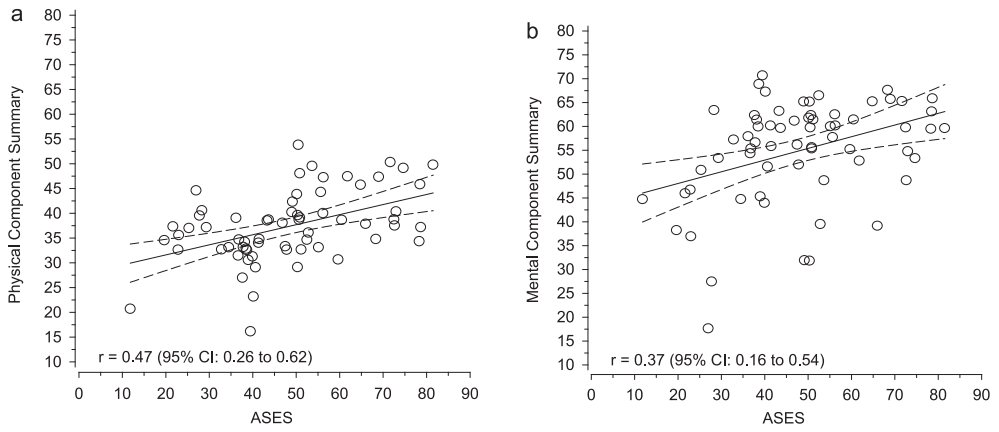

FIGURE 2. The relationship between functional disability (American Shoulder and Elbow Surgeons Standardized Shoulder Assessment; ASES) and (a) the Physical Component Summary and (b) the Mental Component Summary of health-related quality of life assessed with the SF-36.

in psycho-social aspects, such as participation in social activi-ties. As in former studies, the dimensions of RP and BP were the most impaired. Baydar et al. [15] found a mean RP score of 11 SD 31, which is equal to the score of the highest ASES disability group in the present study.

We found a moderate relationship between functional disability and the PCS of the HRQoL, as well as between functional disability and the MCS of the HRQoL. This indicates that functional disability of the shoulder has similar effects on both physical and mental quality of life. It is important that health care professionals be aware that RCTs may have wide-ranging impacts on patients. Screening patients with low shoulder function or quality of life can enable health care professionals to catch those patients early enough to get optimal treatment, e.g. active rehabilitation. Early screening also enables more complete recovery, and return to work and previous activities. It is important to note that the SF-36 does not include shoulder-specific questions. Therefore, it is recommended to use of measurements of both generic health status and shoulder-specific disability to fully assess the impact of extensive RCT problems.

In the present study, the mean duration of shoulder pain was over 1 year at all ASES disability levels, and the patients also experienced pain in their upper limbs and neck. Pain caused by RCT usually radiates to the lateral side of the upper arm, as far as to the fingers, and up to the neck and shoulder blade. Ergonomic changes caused by shoulder pain may increase the pain in the upper limb and neck. Furthermore, over half of the patients in this study had other shoulder disorders in combination with the RCT on the affected shoulder, which may have increased their upper limb and neck pain. Half of the patients had previ-ously received conservative treatment, with the patients who exhibited greater shoulder disability having received more physiotherapy. Each of the patients in the present study was scheduled for a rotator cuff reconstruction.

Adequate preoperative assessment is critical for properly planning postoperative rehabilitation. Patients who preoperatively exhibit high functional disability and low HRQoL will require additional postoperative therapy because the tendon quality, muscle strength, and mobility of the shoulder will obviously have deteriorated after prolonged disuse of the shoulder [30,31].

The rather small sample size was a limitation of this study; however, it was medium-sized in relation to previous studies in which the sample size varied from 20 to 103 patients [15,16,22]. The strength of the present study is that the subjects were all working-age people, whereas other studies have included a large age variation, ranging from 33 to 78 years [15,16,22]. Of course, this means that the results of the present study must be interpreted cautiously when considering older age groups. Another strength of this study is that the RCTs were diagnosed by clinical examination and confirmed by imaging techniques.

Conclusion

Our results showed that RCT patients who reported signifi-cant functional disability of the shoulder had lower scores in many dimensions of the HRQoL. This indicates that patients with a RCT may have extensive problems with physical activities, as well as with mental activities and social participation. Based on our findings, we recommend the use of both generic health status measures (like the SF-36) and condition-specific measures to fully assess the extensive problems of RCT.

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ORIGINAL PUBLICATIONS

III

DOES ADDING A 12-MONTH EXERCISE PROGRAMME TO USUAL CARE AFTER A ROTATOR CUFF REPAIR EFFECT DISABILITY AND QUALITY OF LIFE AT 12 MONTHS? A RANDOMIZED CONTROLLED TRIAL

by

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Does adding a 12-month exercise programme to usual care after a rotator cuff repair effect disability and quality of life at 12 months?

A randomized controlled trial

Kirsi Piitulainen[1,2], Arja Häkkinen[1,2], Petri Salo[2], Hannu Kautiainen[3,4,5] and Jari Ylinen[2]

Abstract

Objective: To compare a 12-month home-based exercise programme with usual care for disability and health-related quality of life after rotator cuff repair.

Design: Randomized controlled trial.

Setting: Outpatient physical and rehabilitation medicine clinic.

Subjects: Consecutive patients ($n = 67$, mean age 54 years) who underwent rotator cuff repairs were randomized into an experimental group (EG) or a usual care group (UCG).

Interventions: The UCG received ordinary postoperative instructions, while the EG were given advice and instructions on a shoulder muscle strengthening programme to be undertaken at home.

Main measures: Disability was assessed with the American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form (ASES), and quality of life with the Short-Form 36 Health Survey (SF-36).

Results: At the follow-up, no between-group differences were observed in any of the outcomes. The mean (SD) ASES score improved by 21 points (95% CI, 16 to 27, $p < 0.001$) in the EG from the 74-point baseline (14) and by 25 points (95% CI, 20 to 30, $p < 0.001$) in the UCG from the 70-point baseline (18). Both groups exhibited significant improvements ($p < 0.001$) in the SF-36 physical component score. In the UCG, improvements were observed in the Social Functioning ($p = 0.034$) and Role Emotional ($p = 0.003$) dimensions. In the EG, 57% of the patients completed the exercises twice weekly for the first six months, after which training adherence declined.

Conclusions: The home exercise programme and usual care were equally effective in improving disability and quality of life after rotator cuff repair. The extra time involved in teaching the home exercise programme is not warranted.

Introduction

Shoulder pain is the third leading musculoskeletal complaint after lower back pain and neck pain.[1] Rotator cuff tears are among the most common causes of shoulder pain. It is estimated that symptomatic rotator cuff tears affect between 4% and 32% of the population in the United States.[2] Conservative treatment, including physiotherapy, anti-inflammatory medication, cortisone injections, and relative rest are recommended for small partial tears.[3] A rotator cuff repair is considered when the pain and decline in shoulder movements and muscle strength cause serious functional disability despite conservative treatment.[4] Rotator cuff repairs comprise approximately one-quarter of all shoulder operations.[5]

There is little evidence regarding the effectiveness of postoperative exercise interventions on self-perceived functional disability and health-related quality of life.[6] Only two randomized controlled studies have reported the outcomes of postoperative exercise after rotator cuff repair. Hayes et al.[7] found no significant differences between individualized supervised physiotherapy and standardized home exercise for the functional ability of the shoulder, as measured by the Shoulder Service Questionnaire after six months of training. Roddey et al.[8] reported that two different instructional approaches aiming to improve shoulder function (one using a videotape and the other using personal instructions from a physiotherapist) led to equal improvements in pain and in the functional ability of the shoulder, as measured by the Shoulder Pain and Disability Index at a 12-month follow-up. Moosmayer et al.[9] observed that a rotator cuff repair was more effective than physiotherapy for pain and shoulder function, as assessed by the Constant Score and the American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form (ASES) at 12-month follow-ups in patients with a small or medium-sized rotator cuff tear. Moosmayer et al.[9] was also the only study to examine the effect of exercise on health-related quality of life after rotator cuff repair; the authors reported that surgical repair was as effective as physiotherapy.

The aim of this study was to determine whether a progressive muscle strengthening exercise programme after rotator cuff repair improved disability and health-related quality of life compared with usual care.

Patients and methods

Patients in this randomized controlled study, comparing self-administered postoperative rehabilitation and usual care following rotator cuff repair, were recruited from the outpatient clinic of the Department of Orthopedics and Traumatology in Central Finland Central Hospital between May 2006 and December 2009. The inclusion criteria were applied: age 18 to 65 years with a <5-cm symptomatic rotator cuff tear (anterior-to-posterior dimension) in the supraspinatus and/or infraspinatus tendons. The following exclusion criteria were applied: previous surgery on the affected shoulder, cervical intervertebral disc prolapse, previous operations of the cervical spine, stenosis of the spinal canal, signs of marked osteoarthritis, rheumatoid arthritis, fibromyalgia, pregnancy, serious mental illness or social problems, and severe cardiac disease or neurological disorders.

At baseline (two months after the operation), the study participants were stratified by gender and their preoperative ASES indices (dichotomized as < or >50 points) and randomized into an experimental group ($n=35$) or a usual care group ($n=32$) using a computer-generated randomization list by Medstat.[10] The randomization was performed by a person who was not working with the patients. The study was approved by the regional health ethics

board of the Central Finland Health Care District, and written informed consent was obtained from all patients.

The score from the self-report section of the ASES questionnaire was used to evaluate pain and condition-specific disability. The pain score was calculated from the visual analogue scale in the ASES score and the function score was the sum of the 10 questions addressing function. The pain and function composite scores were equally weighted (50 points each) and combined to form a possible total score of 100 points, with a higher score indicating better functional ability.[11] The ASES questionnaire is considered to be a reliable, valid, and responsive outcome tool.[12]

The Short-Form 36 Health Survey was used to measure quality of life[13] and indicates a patient's state of health evaluated on eight scales: Physical Functioning, Role Physical, Bodily Pain, General Health, Vitality, Social Functioning, Role Emotional, and Mental Health. The scores range from 0 to 100, with a higher score indicating better health. The eight Short-Form 36 Health Survey scales were aggregated into two summary measurements: the physical component summary score and the mental component summary score.[14]

The patients completed clinical, socio-demographic and workload data questionnaires, the ASES and the Short-Form 36 Health Survey questionnaires at baseline two months after the operation and at 12 months after starting the training (Figure 1). The patients in the experimental group recorded in training diaries the frequency with which they performed the strength and stretching exercises.

The rotator cuff repairs were performed in a standard manner using either arthroscopic ($n=3$) or mini-open ($n=64$) approaches. All operations were performed with the patient placed in the beach chair position with a general or an interscalene block regional anaesthesia. Single-row suture anchors were used for the tendon-to-bone repair. Acromioplasty was associated with the procedure in 33 (94%) of the experimental group patients and 30 (94%) of the usual care group patients. In addition, tenotomy or tenodesis of the long head of the biceps was performed in three cases (9%) in the experimental group and six cases (19%) in the usual care group.

After the operation, all individuals underwent the same early postoperative rehabilitation protocol. The upper arm was maintained beside the body in a suspension bandage for three weeks, however, the patients were allowed to perform light domestic work without wearing the bandage. Patients were advised to perform postoperative home exercises (active elbow and finger flexion and extension, shoulder and scapula retraction, pendulum exercises, passive/assisted shoulder flexion, external rotation 60°, functional internal rotation), according to instructions, three times a day. The exercises were started on the first postoperative day. Two weeks after the operation, each patient met with a physiotherapist for a normal control visit at the outpatient clinic. Light isometric contractions of the shoulder muscles in flexion, extension, internal, and external rotation, three times a day, were added to the exercise programme. At six weeks, each patient visited the outpatient clinic again and was instructed to start dynamic range of motion exercises and strength exercises with a light resistance using yellow resistance bands (Thera-Band®, The Hygenic Corporation Akron, Ohio, USA). Range of motion exercises were to be performed once a day and strength exercises two to three times a week. At two months, each patient visited a physiotherapist. If the patients fulfilled the study criteria, they were recruited into the study and randomized into an experimental group or a usual care group (Figure 1).

The new experimental intervention was started at two months, and was based on muscle strengthening exercises performed individually at home. The exercise programme was designed according to best practices at that time.[15,16] After two postoperative months, the patients were instructed to perform the muscle strength exercises three times a week. The physiotherapist demonstrated the exercises to the patients in person, after which the patients tried the exercises, with correction of load where necessary. All the training information was repeated in the subsequent booster sessions. The training began with ten-repetition dumbbell exercises, after which the number of repetitions was

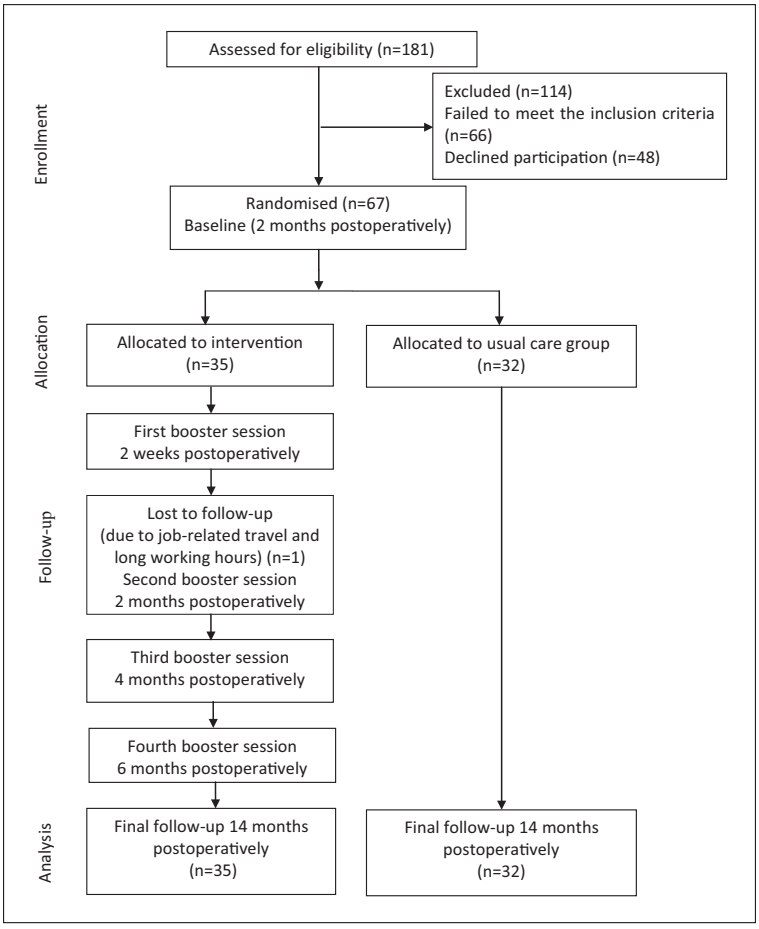

Figure 1. CONSORT diagram summarizing the flow of the patients.

gradually increased to 15. When the patient was able to perform 15 repetitions, s/he was advised to increase the load by 0.5 to 1 kg. Males could increase the load up to 18 kg and females up to 11 kg, which were the highest possible loads for the adjustable dumbbells used. The strength exercises consisted of wall push-ups, one-arm dumbbell rows, shoulder adductions with black rubber Thera-Bands®, internal and external shoulder rotations with a dumbbell (lying on side), one-arm dumbbell shoulder presses (in the supine position), bicep curls, abdominal crunches (in the supine position), and back extensions (in the prone position). Two weeks after starting the exercises, the patients had the first booster session, when the physiotherapist checked that the patient was able to perform the exercises properly.

Furthermore, the patients in the experimental group were seen two months later (i.e. at four months postoperatively) for a second individual

session focusing on exercise progression. Dumbbell rises in a 45° horizontally adducted position, military push-ups, and dumbbell triceps kickback exercises were added to the training programme. The shoulder mobility movements consisted of range-of-movement and stretching exercises to be performed daily. The patients in the experimental group met with the physiotherapist for an additional booster session six months after starting the exercise programme to check training progression. No further exercises were added to the exercise programme. Neither the patients nor physiotherapists were blinded to the patients' group allocation. Only the assessor was blinded. Data were collected at baseline (two months after the operation) and at 12 months thereafter.

The patients in the usual care group did not receive advice beyond the usual care, which included the range of motion and light strength exercises using yellow resistance bands (TheraBand®). The patients received the bands six weeks after the operation. Both groups also received pictorial exercise manuals.

Outcomes were analysed by intention-to-treat and were expressed as means with standard deviation (SD) and 95% confidence intervals (CIs) and medians with interquartile ranges (IQRs). Statistical comparisons between the groups were performed with the *t*-test, Mann–Whitney *U*-test, or chi-square test, as appropriate. Between-group differences in changes in the Short-Form 36 Health Survey domains and functional disability over the 12-month treatment period were compared using a bootstrap-type analysis of covariance with the baseline measurement as a covariate. Effect size ('d') was calculated by using Cohen's method for paired samples (i.e. mean baseline scores minus mean follow-up scores divided by the pooled SD).[17] An effect size of 0.20 was considered small, 0.50 was considered medium, and 0.80 was considered large.

Results

Of the sample of 181 consecutive patients, 67 eligible patients consented to participate in the study. A total of 48 patients refused to participate because of long travelling distances or irregular working hours; 23 patients were excluded because they were older than 65 years, and 43 patients were excluded for medical reasons. The 67 patients comprising the study sample comprised 38 men and 29 women (Figure 1). There were no significant differences between the groups in baseline demographic or clinical data (Table 1). One patient in the experimental group discontinued training after two months. He was included in the intention-to-treat analysis.

At 12 months, no differences between the two groups in the ASES scores were observed, with both groups improving by a statistically significant amount (treatment effect, $p=0.33$) (Table 2). At the 12-month follow-up, only 5 (14%) patients in the experimental group and 5 (16%) patients in the usual care group had an ASES score under 90 points.

No significant between-group differences were observed in the changes in the eight dimensions or in the summary scores of the Short-Form 36 Health Survey. Changes in the Physical Functioning, Role Physical, and Bodily Pain dimensions of the Short-Form 36 Health Survey showed significant improvements in both groups at 12 months (Table 3). In addition, the usual care group improved significantly in the Role Emotional ($p=0.003$) and Social Functioning (0.034) dimensions over the 12-month period. After aggregating the eight dimensions of the Short-Form 36 Health Survey into the summary scores, the physical component summary score improved significantly ($p<0.001$; treatment effect, $p=0.79$), and the mental component summary score remained unchanged in both groups (treatment effect, $p=0.51$).

According to the training diaries, 20 (57%) of the patients in the experimental group performed the strength and stretching exercises at least twice a week during the first six months of the intervention. Up to 14 patients interrupted their training for a period of one or two weeks. Only one of these patients stopped training completely (after experiencing shoulder pain for six months). During the first training weeks, nine patients reported shoulder pain in the operated shoulder. Three patients reported neck pain, and two reported elbow pain.

Table 1. Baseline demographic and clinical data of patients in the experimental group and the usual care group.

	EG	UCG	*P*-value
	N = 35	*N* = 32	
Male, *n* (%)	20 (57)	18 (56)	0.94
Age, years, mean (SD)	55 (5)	53 (6)	0.06
Education, years, mean (SD)	11.5 (2.9)	12.2 (3.4)	0.42
Employed, *n* (%)	30 (86)	30 (94)	0.71
Workload, *n* (%)[a]			
Low	11 (37)	10 (33)	
Moderate	11 (37)	14 (47)	
Heavy	8 (27)	6 (20)	
BMI, mean (SD)	27.7 (3.1)	27.7 (5.3)	0.94
Duration of shoulder pain before the operation, months, median (IQR)	15 (8, 60)	19 (12, 24)	0.81
Tear on the dominant side, *n* (%)	24 (69)	23 (72)	0.77
Shoulder trauma, *n* (%)	20 (57)	16 (50)	0.56

[a]Only in patients who are employed.
BMI, body mass index; EG: experimental group; IQR, interquartile range; SD, standard deviation; UCG: usual care group.

Table 2. Baseline scores and changes at 12 months in the ASES score in the experimental group and the usual care group.

	Baseline		12 months		Change at month 12		P value[a] between the groups
	EG Mean (SD)	UCG Mean (SD)	EG Mean (SD)	UCG Mean (SD)	EG Mean (95% CI)	UCG Mean (95% CI)	
Scale 0–100							
ASES score	74 (14)	70 (18)	95 (10)	95 (6)	21 (16 to 27)	25 (20 to 30)	0.98

[a]Baseline values as covariate.
ASES: American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form; CI: confidence interval; EG: experimental group; SD, standard deviation; UCG: usual care group.

During the last six months of the intervention, only 8 (23%) of the patients were performing the strengthening exercises at least twice a week. The results of the patients in the experimental group who did not follow the exercise programme were included in the intention-to-treat analysis.

Discussion

The home strengthening exercise programme with booster sessions did not result in any additional benefit compared with usual care, as shoulder disability and health-related quality of life improved equally in both groups. This result was in line with the findings of Hayes et al.[7] and Roddey et al.[8] on changes in the functional ability of the shoulder following a postoperative exercise intervention.

In the present study, the experimental group patients had the same strength exercise programme, but the loading was individualized. The patients in the experimental group also visited the physiotherapist individually, i.e. the patients had one-to-one sessions to the physiotherapist. Hayes et al.[7]

Table 3. Baseline scores and changes at 12 months in the eight dimensions and two components of the Short-Form 36 Health Survey in the experimental group and usual care group.

	Baseline		12 months		Change month 12		
	EG Mean (SD)	UCG Mean (SD)	EG Mean (SD)	UCG Mean (SD)	EG Mean (95% CI) [Effect size]	UCG Mean (95% CI) [Effect size]	*P*-value[a] between the groups
Dimensions (scale 0–100)							
Physical Functioning	80 (12)	78 (11)	88 (18)	89 (17)	8 (2 to 12) [0.52]	10 (3 to 16) [0.73]	0.66
Role Physical	41 (40)	35 (42)	81 (33)	85 (28)	41 (28 to 54) [1.15]	48 (30 to 64) [1.37]	0.55
Bodily Pain	57 (15)	55 (24)	71 (22)	75 (21)	15 (6 to 24) [0.80]	20 (8 to 31) [0.91]	0.50
General Health	69 (20)	69 (17)	69 (22)	70 (18)	–0.1 (–4 to 5) [0.00]	1 (–4 to 6) [0.05]	0.77
Vitality	73 (18)	70 (19)	76 (21)	71 (18)	3 (–4 to 10) [0.17]	1 (–5 to 6) [0.05]	0.37
Social Functioning	88 (17)	85 (20)	91 (19)	90 (20)	4 (–6 to 12) [0.21]	5 (1 to 11) [0.26]	0.97
Role Emotional	71 (37)	72 (40)	85 (31)	86 (34)	14 (–3 to 30) [0.42]	15 (6 to 25) [0.40]	0.83
Mental Health	84 (14)	80 (18)	82 (20)	81 (16)	–2 (–11 to 5) [0.09]	1 (–2 to 5) [0.08]	0.82
Summary Scores							
Physical Component	42 (7)	41 (9)	49 (9)	50 (8)	7 (5 to 10) [0.90]	9 (4 to 12) [1.05]	0.59
Mental Component	56 (9)	55 (13)	55 (11)	55 (8)	–1 (–6 to 4) [0.06]	0 (–3 to 2) [0.05]	0.95

[a]Baseline values as covariate.
CI: confidence interval; EG: experimental group; SD, standard deviation; UCG: usual care group.

studied the efficacy of individualized supervised physiotherapy and standardized home exercise after rotator cuff repair. The difference in training protocols between the present study and that of Hayes et al.[7] was that in the latter the individualized physiotherapy group received customized physiotherapy, comprising all aspects of physiotherapy management with any combination of exercises, manual therapy techniques, physical modalities, and home exercise regimen. The standardized home experimental group received only a postoperative exercise programme at the six-week visit, as did the usual care group in the present study.

In both groups, the ASES scores at 12 months indicated good shoulder function. The mean increases of 21 points in the experimental group and 25 points in the usual care group can be regarded as clinically significant. In the study by Michener et al.,[12] the minimal detectable change was 9.4 ASES points, and the minimal clinically important difference was 6.4 ASES points. The study by Michener et al.[12] included operated and non-operated patients across a wide range of shoulder disorders, such as impingement syndrome and humeral fracture. According to Tashjian et al.,[18] a change between 12 and 17 points in the ASES score indicates a minimal clinically important difference after conservative treatment in patients with rotator cuff disease.

In the present study, the mean ASES score of 95 points at 12 months was of the same magnitude as previously reported in 12-month follow-up studies.[9,19] Moosmayer et al.[9] showed that rotator cuff surgery was more effective than physiotherapy on pain and shoulder function over a 12-month follow-up in patients with small or medium-sized rotator cuff tears. The authors reported that the mean ASES score improved by 47 points (ranging from 46 to 93 points) in the surgery group and 31 points (ranging from 48 to 79 points) in the physiotherapy group. Chung et al.[19] studied functional disability and health-related quality of life after an arthroscopic rotator cuff repair only and reported that the mean ASES score improved by 29 points (ranging from 58 to 87 points) at the 12-month

follow-up. In the present study, the mean improvements in the ASES score were approximately half of that in the previously mentioned studies. This difference is most likely owing to research design differences in the present study compared with the previous studies, where the baseline values were assessed preoperatively. However, in our study, the patients began more intensive exercise at two months postoperatively, when the study arms of the two groups differed.

Only one previous study has reported on exercise and health-related quality of life in rotator cuff repair patients, and the results are in accordance with our results. Both in our study and in Moosmayer et al.,[9] the Physical Functioning, Role Physical, and Bodily Pain dimensions of the Short-Form 36 Health Survey increased significantly in both patient groups over the 12-month follow-up period, but with no between-group differences in either study. In the present study, the mental component summary score for quality of life was higher than the physical component summary score as early as two months postsurgery (at baseline) and remained unchanged, whereas the physical component summary score improved significantly during the 12-month follow-up.

Slightly more than half of the experimental group patients performed the strength exercises twice a week during the first six months, while during the last six months, only one-quarter were training twice a week. The experimental group patients had three booster sessions with a physiotherapist during the first six training months. However, there were no booster sessions during the last six training months before the 12-month measurement. This difference might have contributed to the decrease in training adherence during that period. Another reason for the low exercise adherence may have been too many exercises in the training programme (at least nine exercises).[20] In addition, several patients believed that their shoulder disability had recovered well enough to enable them to cope at work and in their leisure time activities. This belief is supported by the finding that the mean ASES score in both groups was approximately 90 points six months after starting the exercises. By the 12-month follow-up, the ASES score had increased to 95 points in both groups. In asymptomatic patients, ASES scores have been reported to range from 90 to 100.[21,22] Thus, the fact that both groups already had ASES levels comparable with those of asymptomatic persons might have decreased their need to exercise during the last six months.

Little scientific evidence is available to guide the feasibility of postsurgical rotator cuff rehabilitation.[23] The progressive loading of the exercises in the present study was designed in line with the known healing process of tendon tissue. Moreover, the early light training during the first two months was aimed at increasing the load-bearing capacity. Early gradual loading, already in the proliferative healing phase of the repaired tendon, is likely to result in acceleration of collagen synthesis, fibril neoformation, and proper fibre alignment, and thus increase the final tensile strength of the tendon.[24,25] However, it has been shown that the ideal rehabilitation protocol to prevent stiffness and encourage healing after rotator cuff repair includes an initial period of immobilization, e.g. six weeks. Controlled loading can enhance healing in most settings; balance must be achieved between loads that are too low (leading to a catabolic state) and too high (leading to micro-damage).[26,27]

The results showed that the home-based muscle strengthening programme did not differ from the usual care in improving disability and health-related quality of life. Thus, the exercise programme studied here cannot be recommended for use with all patients as a matter of routine. However, these results do not exclude the possibility that patients whose recovery is poor may need more intensive rehabilitation compared with usual care. During the first two months after the operation, which is a period of immobilization, all the patients received a similar home-based exercise programme, including range of motion exercises and dynamic strength exercises with only a light resistance. In addition, during the intervention, the usual care group patients received instructions on light home exercises, whereas the experimental group patients were expected progressively to increase the loading of the exercises. However, the exercises of the two groups were home-based,

unsupervised, and standardized. These two issues might have influenced the fact that no differences between the groups were found.

The strengths of the present study are that it was randomized and controlled, the drop-out rate was low, and training adherence was reported for the experimental group. In addition, this study is one of the few to report the results of a 12-month training regimen. This study also has its limitations. The power calculation was based on the general recommendations of Altman that at least 50 subjects are required in a methods comparison study.[28] The power of the study may not have been sufficient, and some possible between-group differences may have been overlooked. The recruitment of the study subjects took longer than initially expected because of the medical exclusion criteria and patient refusals to participate for reasons that included long travelling distance to the hospital or long working days. Thus, the size of the study population was smaller than initially planned. Another limitation of the present study is that information on tear size was recorded in the medical histories of only half of the patients and thus had to be excluded from the analysis. The low training adherence for a home-exercise programme is also a limitation. A further limitation is the fact that the training frequency, during the first two months after the operation, was not recorded. In addition, the training frequency of the patients in the usual care group, representing the normal care population, was not recorded during the intervention, as the recording might have increased exercising, thereby influencing the results.

The results of the present study may be extrapolated to all working-age patients who have undergone rotator cuff repair owing to rotator cuff tear. However, the results must be interpreted cautiously when considering older age groups, as the age of the present patients was below 65 years. In patients older than 65 years, the cause of a rotator cuff tear is usually degenerative, while also the incidence of glenohumeral and acromioclavicular arthritis also increases with age.[29] Further comparative research is needed in other settings and in different training modalities.

Clinical messages

- Adding a 12-month strength exercise programme to the standard advice on exercise to be undertaken at home does not affect outcomes one year later, as shoulder disability and quality of life showed significant improvements in both groups.
- Future research should focus on supervised rehabilitation with different shoulder training modalities.

Conflicts of interest

The authors have declared no conflicts of interest.

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ORIGINAL PUBLICATIONS

IV

EFFECTIVENESS OF 12 MONTHS' INTENSIVE HOME TRAINING PROGRAM ON SHOULDER MUSCLE STRENGTH AND RANGE OF MOTION AFTER ROTATOR CUFF REPAIR

by

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EFFECTIVENESS OF 12 MONTHS' INTENSIVE HOME TRAINING PROGRAM ON SHOULDER MUSCLE STRENGTH AND RANGE OF MOTION AFTER ROTATOR CUFF REPAIR

ABSTRACT

A 12-month home-based shoulder training program was compared with usual care for recovery of shoulder strength and range of motion (ROM) after rotator cuff repair (RCR). Consecutive patients (n=67, mean age 54 years) who had been submitted to RCR, were randomized into an exercise group (EG) or a usual care group (UCG). The EG were given advice and a home-based shoulder muscle strengthening program, while the UCG received ordinary postoperative instructions. The isometric internal and external rotation and flexion strength of both shoulders was measured with a dynamometer, and shoulder ROM with a digital inclinometer. At 12 months, no between-group differences were found in the changes in muscle strength of the operated shoulder, as internal and external rotation and flexion strength increased by 16-38% ($p<0.001$) in both groups. The external rotation and flexion strength of the operated shoulder was 9% and 17% lower in EG, and 11% and 22% lower in UCG compared with the contralateral shoulder (all $p<0.02$). No significant difference was observed in internal rotation strength between the operated and contralateral shoulder in either group. No between-group differences were found in the changes in active or passive ROM. Significant increases were observed in all the shoulder ROMs ($p<0.001$), except in passive internal rotation in both groups. The home exercise program and usual care were equally effective in improving muscle strength and ROM after RCR, and hence the additional exercise yielded no extra benefit for patients with a rotator cuff tear.

Key words: Rotator cuff, shoulder muscle strength, range of motion, exercise, training adherence

INTRODUCTION

Rotator cuff tears (RC tears) are among the most common causes of shoulder pain (1), and the prevalence of RC tears increases with age (2). In the general population, RC tears have been shown to associate with weaker muscle strength and decreased active range of motion (ROM) (3). Some RC tear patients may be effectively treated non-operatively with, for example, nonsteroidal, anti-inflammatory drugs, local injections and physiotherapy.

Rotator cuff repair (RCR) is considered when the pain and decline in shoulder muscle strength and ROM continue to cause serious functional disability despite of conservative treatment for at least three months (4). Bey et al. (5) reported that shoulder strength increased over time after RCR, although strength deficits compared to the contralateral shoulder persisted up to 24 months. Borgmästars et al. (6) reported further that alleviation of pain was long-standing in most patients at a long-term follow-up, but that the level of function initially achieved postoperatively had been lost, as ROM and shoulder strength had decreased to less than their preoperative values. Preconditions for good shoulder function are that rotator cuff strength is strong enough to stabilize the glenohumeral joint by centralizing the humeral head in the glenoid fossa during the performance of different tasks, and that shoulder ROM is large enough to permit, e.g., movements behind the back and overhead (7).

In the few short-term randomized controlled studies comparing early postoperative rehabilitation with an immobilization period of four to six weeks on shoulder muscle strength and ROM no between-group differences in muscle strength were found (8-11), whereas active shoulder elevation and external rotation improved significantly more in the early than delayed rehabilitation group at 3 months, but not at any later time point (9,12-14). However, only one study has applied a randomized controlled procedure to investigate the long-term effects of different forms of exercise on shoulder muscle strength and ROM after RCR. Hayes et al. (15) investigated the effectiveness of individualized supervised physiotherapy versus standardized home exercise in patients who had been submitted to a RCR. No between-group differences were found in individualized physiotherapy and standardized home exercise on visually estimated ROM and manually tested shoulder

muscle strength at the 24-week follow-up. For the present, no single postsurgical rehabilitation method has been found to be superior to all others (16,17). Therefore, more research related to postoperative shoulder rehabilitation modalities are needed. In their systematic review and meta-analysis on early versus delayed rehabilitation, Chang et al. (18) showed that early passive ROM exercise accelerated recovery from postoperative stiffness after RCR, but tended to result in worse tendon healing in shoulders with large-sized tears. In contrast, the present study focused on the effects of long-term rehabilitation. Specifically, the aim of this study was to find out whether a progressive muscle strengthening exercise program starting two months after RCR would be more effective than usual care in increasing muscle strength and ROM over a one-year training intervention.

METHODS

Patients were recruited from the outpatient clinic of the Department of Orthopedics and Traumatology in the Central Finland Health Care District. The inclusion criteria were age 18 to 65 years with a symptomatic rotator cuff tear (anterior-to-posterior dimension) in the supraspinatus and/or infraspinatus tendons. The following exclusion criteria were applied: previous surgery on the affected shoulder, cervical intervertebral disc prolapse, previous surgery on the cervical spine, stenosis of the spinal canal, signs of marked osteoarthritis, rheumatoid arthritis, fibromyalgia, pregnancy, serious mental illness or social problems, and severe cardiac disease or neurological disorders.

Of a sample of 181 consecutive patients, 66 eligible patients consented to participate in the study. Forty-nine patients refused participation because of distance from the study center or irregular working hours and 114 patients were excluded, 23 because they were older than 65 years and 43 patients for medical reasons. Of the 67 patients comprising the study sample, 38 were men and 29 women. (Figure 1).

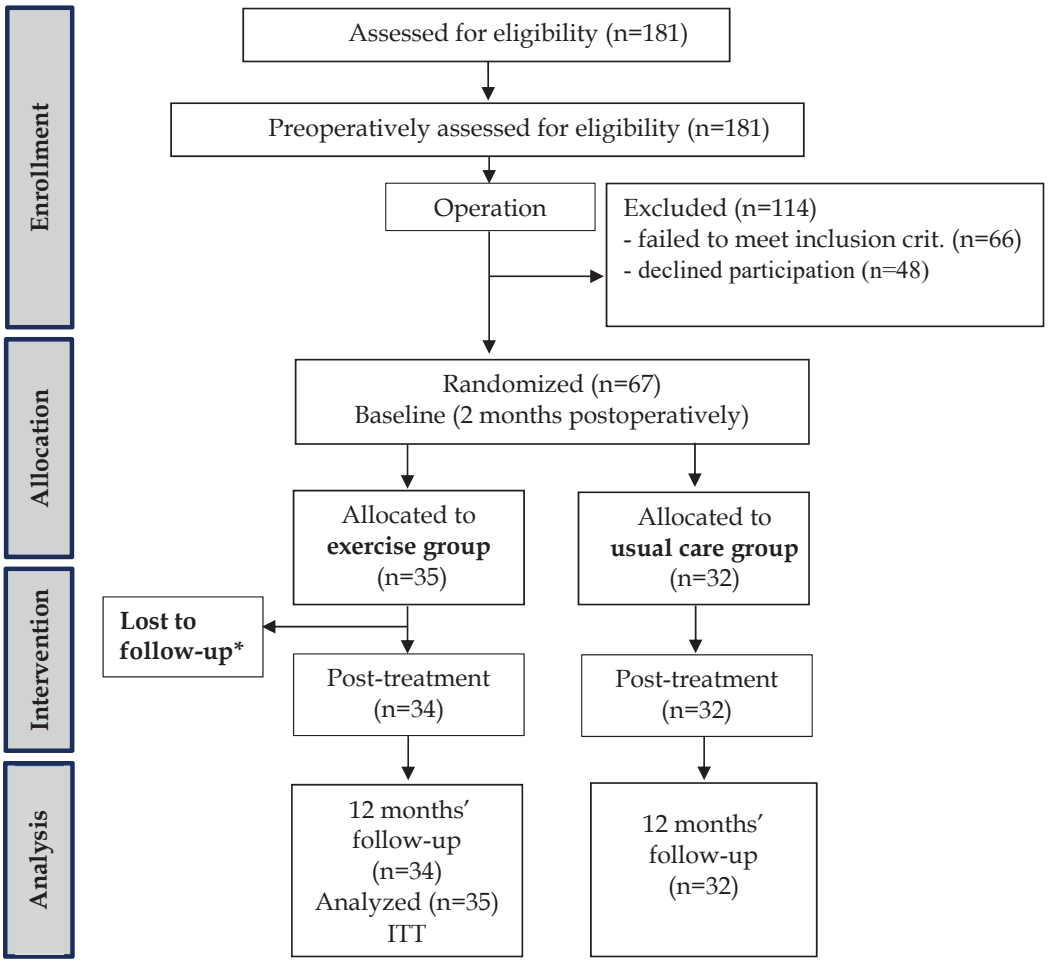

FIGURE 1. CONSORT diagram summarizing the flow of the study.
*Interrupted the training (n=1), but was analyzed (ITT).

At baseline (two months after the operation), the participants were stratified by gender and their preoperative ASES indices (dichotomized as < or >50 points) and randomized into an exercise group (EG, n=35) or a usual care group (UCG, n=32) using a computer-generated list by Medstat (19). The randomization was performed by a person who was not working with the patients. This study was approved by the regional health ethics board of the Central Finland Health Care District, and all patients gave their written informed consent. The CONSORT Statement was used in designing and reporting this intervention study. The study is registered in the ClinicalTrials.gov database: NCT00624117.

Measurements

All measurements were performed by an assessor who was familiarized with the procedures before the measurements. The operated and nonoperated side was measured. The measurements were performed at baseline (two months after the operation) and 12 months thereafter.

Isometric shoulder strength measurements were carried out with a dynamometer (Ds Europe, Mod. 546QTD strain gauge, Milano, Italy) and analyzed with an isometric strength measurement program (Protacon Inc., Jyväskylä, Finland). During the measurement of internal and external rotation of the shoulder, the patient was sitting in an upright position, with a sturdy barbell placed between the body and upper arm to prevent use of the body during the measurement. The shoulder was in 20° flexion and elbow in 90° flexion. The measurement sensor was placed above the wrist at the level of the processus styloideus. During the isometric shoulder flexion strength measurement, the patient was sitting with the upper arm in 90° flexion, 30° horizontal abduction, and the elbow straight (Figure 2). The measurement sensor was placed at the level of the processus styloideus. Two warm-up contractions were performed prior to the maximal tests. Three maximal trials were made in each measurement direction and a one-minute rest period was taken between each trial. If the third trial showed an improvement of more than 5% over the best of the two previous results, additional trials were performed. The best result of each measurement was used in the final analysis. Grip strength was measured with a Saehan dynamometer (Model SH5001,

Masan, Korea). Pain during the strength measurements was assessed on a visual analogue scale (VAS scale from 0 to 100 mm).

FIGURE 2. Isometric shoulder flexion measurement with a dynamometer.

The ROM measurements included shoulder flexion, abduction, internal and external rotation performed by a digital inclinometer to within an accuracy of 1° (800-98-JTECH, North American Fork, Utah), and functional internal rotation and horizontal adduction measured by a tape measure. During the measurement of active and passive shoulder flexion, the patient was standing with the body supported on a bar to prevent bending of the body backwards. Active abduction was measured and simultaneously the painful arch sign was recorded. Active external rotation was measured in the supine position with the arm beside the body and the elbow in 90° flexion. The inclinometer was attached to an alignment rail and tied onto the radial side of the elbow. Passive external and internal rotation was measured in the supine position with the arm in 90° abduction and the elbow in 90° flexion with a wedge under the elbow. During the former measure, the inclinometer with the alignment rail was tied onto the palmar side of the elbow and in the latter measurement on the dorsal side of the elbow. Functional active internal rotation was performed in the standing position and the distance between the thumb and the upper edge of the spinosus Th1 was measured. Passive horizontal adduction was performed in the sitting position and the distance between the epicondylus lateralis and the opposite

acromion was measured. The painful arc test from 60 to 120 degrees was measured in the standing position.

At baseline, the patients filled in a questionnaire designed to elicit sociodemographic and clinical information: body weight, body height, duration of shoulder pain before the operation, education, working status and possible shoulder injuries. The patients in the EG recorded the frequency with which they performed the strength and stretching exercises in training diaries.

Surgery and self-administered early postoperative rehabilitation

The rotator cuff repairs were performed in a standard manner using either arthroscopic (n=3) or mini-open (n=64) approaches. All operations were performed with the patient placed in the beach chair position with general or an interscalene block regional anesthesia. Single-row suture anchors were used for the tendon to bone repair. Acromioplasty was associated with the procedure in 33 (94%) of the EG patients and 30 (94%) of the UCG patients. Furthermore, tenotomy or tenodesis of the long head of the biceps was performed in 3 (9%) of cases in the EG and 6 (19%) of cases in the UCG.

After the operation, all individuals were submitted to the same early postoperative rehabilitation protocol. The upper arm was kept beside the body in a suspension bandage for three weeks. However, the patients were allowed to perform light domestic work without wearing the bandage and given instructions on how to perform the postoperative home exercises (e.g., passive/active assisted shoulder flexion, pendulum exercises, active elbow flexion-extension and finger flexion-extension exercises). The exercises were started on the first postoperative day. Two weeks after the operation, each patient met with a physiotherapist for a normal control visit at the outpatient clinic, and light isometric contractions of the shoulder muscles in flexion, extension, and internal and external rotation were added to the exercise program. At the six-week follow-up, each patient visited the outpatient clinic again and was instructed to start active ROM (shoulder flexion, internal and external rotation, and strength exercises (shoulder internal and external rotation, biceps curl, and wall push-up) with a light resistance, i.e., using yellow-colored resistance bandages (Thera-Band®, The Hygenic Corporation Akron Ohio 44310 USA). At the two-

month follow-up, each patient visited a physiotherapist. If the patients fulfilled the study criteria, they were recruited into the study and randomized to the EG or UCG.

Intervention

The intervention was based on a program of muscle strengthening exercises to be performed individually at home that had been designed in accordance with the best practices at the time. After two postoperative months, the patients were instructed to perform the muscle strength exercises three times a week. The physiotherapist demonstrated the exercises to the patients in person, and all the training information was repeated in the booster sessions. The training began with ten-repetition dumbbell exercises, after which the number of repetitions was gradually increased to 15. When able to perform 15 repetitions, the patient was advised to increase the load by ½ to 1 kg. Males could increase the load up to 18 kg and females up to 11 kg, which were the highest possible loads of the adjustable dumbbells used. The strength exercises consisted of wall push-ups, one-arm dumbbell rows, shoulder adductions with black rubber Thera-Bands®, internal and external shoulder rotations with a dumbbell (lying on the side), one-arm dumbbell shoulder presses (in the supine position), dumbbell front raises with short lever arm (standing), bicep curls, abdominal crunches (in the supine position) and back extensions (in the prone position). Two weeks after starting the exercises, the patients had the first booster session, when the physiotherapist checked that the patient was able to perform the exercises properly.

Two months after the initial exercise instructions, patients had a second individual session that focused on exercise progression. Dumbbell lifts in a 45° horizontally adducted position, military push-ups and dumbbell triceps kickback exercises were added to the training program (Appendix 1). The shoulder mobility movements consisted of range-of-movement and stretching exercises instructed to be performed daily. The patients in the EG met with the physiotherapist for an additional booster session six months after starting the exercise program to check the progression of the training. No further exercises were added to the exercise program. The assessor was blinded to the patients' group allocation. Blinding was not possible for either the patients or the physiotherapists giving instructions. The physiotherapists collected the data at baseline (two months after the operation) and 12 months thereafter.

The patients in the UCG did not receive advice beyond the usual care, which included mobility and light strength exercises (without dumbbells), which they were instructed in six weeks after RCR. Both groups were also issued with pictorial manuals showing their exercises.

Statistical analysis

Outcomes were expressed as means with standard deviation (SD) and 95% confidence intervals (CIs) and medians with interquartile ranges (IQRs). Statistical comparisons between the groups were performed with the *t*-test, Mann–Whitney *U*-test, or chi-square test, as appropriate. The 95 per cent confidence intervals for muscle strength, pain and ROM were obtained by bias-corrected and accelerated bootstrapping, with 2000 replications. Between-group differences were tested by bootstrap-type analysis of covariance with the baseline value as a covariate. According to the ITT analysis, every subject who was randomized was included in the analysis.

RESULTS

No between-group differences in the baseline socio-demographic or clinical data were found (Table 1). According to the training diaries, 57% of the patients in the EG trained at least twice a week during the first six months of the intervention. During the last six months of the intervention, only 23% of the EG patients were training at least twice a week.

The EG patients reported minor discomfort during the 12 months' training intervention, mainly during the first two months of the exercise period. Resistance training was well tolerated, and no serious training-related adverse events occurred during the one-year home-exercise period. During the first training weeks, nine patients reported shoulder pain in the operated shoulder, three reported neck pain and two reported elbow pain. Five of these patients had a break in shoulder training of up to one week and four of them a break of up to two weeks.

Table 1. Baseline socio-demographic and clinical data of patients in the exercise group (EG) and the usual care group (UCG).

	EG n=35	**UCG n=32**	**P-value**
Male, n (%)	20 (57)	18 (56)	0.94
Age, years, mean (SD)	55 (5)	53 (6)	0.06
Education, years, mean (SD)	11 (3)	12 (3)	0.42
Employed, n (%)	30 (86)	30 (94)	0.71
Duration of shoulder pain before the operation, months, median (IQR)	15 (8 , 60)	19 (12 , 24)	0.81
Shoulder pain, VAS (0-100), mean (SD)	14 (16)	18 (19)	0.31
Tear on the dominant side, n (%)	24 (69)	23 (72)	0.77
Shoulder trauma, n (%)	20 (57)	16 (50)	0.56

SD, standard deviation; IQR, interquartile range; VAS, visual analogue pain

At the end of the 12-month intervention, the changes in muscle strength in the operated shoulder did not differ between the treatment groups. In both groups, the flexion, external and internal rotation strength levels showed significant increases of 16-38% ($p<0.001$) (Table 2).

At 12 months, the external rotation and flexion strength of the operated shoulder were 9% and 17% lower in EG, and 11% and 22% lower in UCG compared to the contralateral shoulder (all $p<0.02$), whereas no significant difference was observed between the operated and contralateral shoulder in internal rotation strength in either EG (3%, $p<0.116$) or UCG (4%, $p<0.09$) (Figure 3). Furthermore, the strength values of the contralateral shoulder remained unchanged, although the patients performed the exercises for both shoulders. Pain during the strength measurements was already on a rather low level at the beginning of the intervention and at 12 months, mean pain ranged from 0 to 5 mm in both groups (Table 2).

Table 2. Changes in shoulder function and pain in the exercise group (EG) and usual care group (UCG) at the end of the 12-month intervention.

	Baseline		Change at 12 months		*p*-value*
	EG Mean (SD)	**UCG Mean (SD)**	**EG Mean (95 % Cl)**	**UCG Mean (95 % Cl)**	**between the groups**
Shoulder strength (kg)					
Internal rotation	12.5 (5.4)	13.3 (5.7)	3.1 (2.2 to 4.1)	2.6 (1.4 to 3.7)	0.46
External rotation	7.1 (2.4)	6.8 (2.7)	3.0 (2.4 to 3.6)	3.2 (2.3 to 4.1)	0.80
Flexion	4.9 (2.2)	4.4 (1.7)	2.5 (1.9 to 3.1)	2.7 (2.1 to 3.3)	0.52
Hand grip	39.4 (12.9)	38.8 (12.3)	3.5 (2.1 to 4.9)	5.4 (3.7 to 7.1)	0.08
Pain during strength measurement (VAS), mm					
Internal rotation	6 (10)	8 (15)	-5 (-8 to -2)	-7 (-12 to -2)	0.60
External rotation	8 (12)	13 (17)	-8 (-12 to -4)	-9 (-16 to -3)	0.13
Flexion	19 (23)	23 (26)	-14 (-24 to -5)	-20 (-29 to -10)	0.72
Shoulder mobility (°)					
Active flexion	141 (30)	139 (29)	29 (20 to 38)	33 (24 to 42)	0.50
Passive flexion	157 (22)	154 (21)	22 (16 to 28)	28 (22 to 34)	0.18
Active external rotation	63 (16)	60 (13)	15 (10 to 19)	17 (13 to 22)	0.66
Passive external rotation (90°)	69 (24)	63 (18)	25 (18 to 31)	32 (24 to 39)	0.41
Passive internal rotation (90°)	36 (10)	37 (13)	1 (-3 to 5)	2 (-1 to 6)	0.48
Active internal rotation, mm	303 (104)	305 (89)	-82 (-106 to -57)	-104 (-129 to -80)	0.12
Passive horizontal adduction, mm	333 (45)	338 (52)	-41 (-54 to -28)	-45 (-59 to -33)	0.72

*Baseline values as covariates.

No between-group differences were found in the changes in active or passive ROM (Table 2). After the 12-month intervention, significant increases were observed in all the shoulder ROMs ($p<0.001$), except in passive internal rotation in both groups. At baseline, 9% of the patients in the EG and 25% in the UCG showed a positive painful arc test result (between groups $p=0.078$), while at 12 months the corresponding proportions were 3% and 0% (between groups $p=0.33$). The number of participants with a positive painful arc test result decreased significantly in the UCG ($p<0.003$).

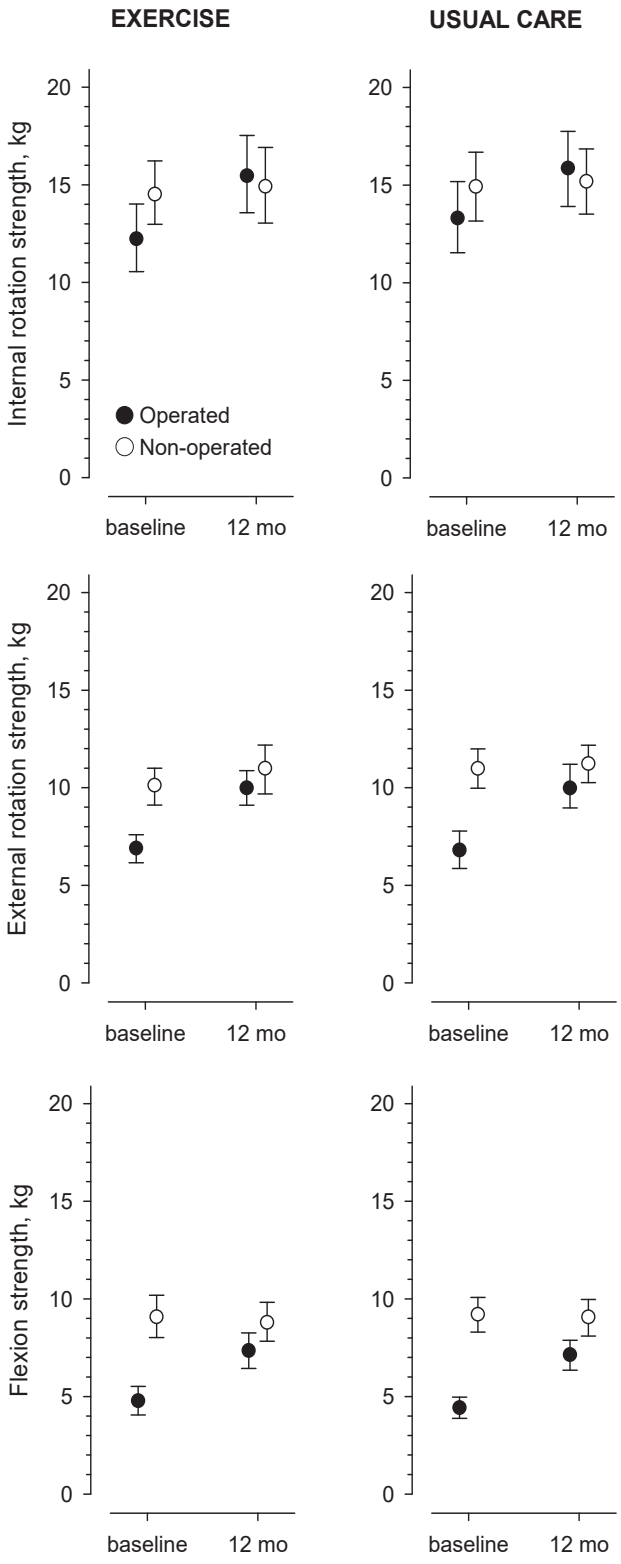

FIGURE 15.
Muscle strength values in internal and external rotation, and flexion in the operated (filled circle) and non-operated (empty circle) shoulder at baseline and at 12 months in the exercise group and usual care group.

DISCUSSION

The home strengthening exercise program with booster sessions was not more effective than usual care in increasing shoulder muscle strength and ROM. However, shoulder muscle strength, pain during loading, and ROM showed significant improvements in both groups. Furthermore, in both groups the strength of the operated shoulder remained on a lower level compared to the contralateral shoulder, except in internal rotation.

In the present study, shoulder muscle strength increased significantly in all the strength measurements at 12 months. Flexion strength had the lowest baseline values but the highest relative improvements at 12 months: 34% in EG and 38% in UCG. Klintberg et al. (11) studied the effectiveness of progressive physiotherapy versus traditional physiotherapy on shoulder strength at 12 months after RCR. The authors reported the highest proportional improvements were in internal rotation: 32% in the progressive group and 24% in the traditional group. In the present study, internal rotation strength increased by 20% in EG, and 16% in UCG.

In both groups, the strength values remained on a lower level than the values for the contralateral shoulder, except in internal rotation. The external rotation and flexion strength of the operated shoulder were 9% and 17% lower in EG, and 11% and 22% lower in UCG compared to the contralateral shoulder at 12 months. This finding may partially be due to the fact that the supraspinatus was the repaired tendon in 98% of all patients, and is less involved in internal rotation than in external rotation or flexion. The muscle strength of the contralateral shoulder did not improve during the 12-month intervention, although the EG patients performed the exercises for each of upper limbs. Bey et al. (5) reported that the isometric muscle strength of the operated shoulder was less than that of the contralateral shoulder at 24 months after RCR, although significant strength improvements were measured in abduction, external and internal rotation from three to 12 months (5). Further significant strength gains were observed in internal rotation from 12 to 24 months. In the same study, submaximal pain-free isometric exercises had been started at four weeks and the early strengthening phase at eight weeks, whereas in the present study submaximal isometric exercises were started at two weeks, and the early strengthening phase at six weeks, followed by a progressive strengthening phase at eight weeks (5). Shin et al. (20)

reported that in patients with a small rotator cuff tear, six months after RCR was required to achieve the isometric muscle strength of the uninjured contralateral shoulder in flexion, internal and external rotation, while in patients with medium tears, 18 months was required to attain the strength of the contralateral shoulder. However, in patients with large-to-massive tears shoulder strength improved up to 18 months but did not attain that of the contralateral shoulder in any of the three planes of motion (20). In the study by Verdano et al. (21), the muscle strength of the operated shoulder recovered to the level of the contralateral shoulder after RCR at 12 months (range 6-23 months). In the latter study, the patients had received ordinary postoperative instructions for shoulder exercise. In all the studies cited above, the patients had undergone arthroscopic rotator cuff repair, in contrast to the present study, where a mini-open procedure was used in 96% of the patients.

Pain during loading disappeared almost completely in both groups during the present 12-month follow-up. Only three patients in both groups had pain ≥ 25 mm during maximal effort at the 12-month strength measurements. The reason for this may be that all the strength measurements were performed in lower positions: during the internal and external isometric rotation strength measurements, the arm was kept beside the body, the shoulder in 20° flexion and the elbow in 90° flexion. Shoulder flexion strength was measured in the full can position, which is a functional position (22). Pain during maximal effort has not been reported in postoperative RCR rehabilitation studies. However, Klintberg et al. (11) showed that mean pain during activity decreased from 24 to 10 mm in the progressive group and from 11 to 7 mm in the traditional group between 3 and 12 months after RCR. At the beginning of the intervention, pain during loading was the highest and also decreased most, in shoulder flexion at 12 months in both groups. Thus, pain during strain in flexion did not differ from pain in internal and external rotation.

In the present study, active and passive shoulder ROM, measured by a digital inclinometer, improved significantly in both groups in all the shoulder ROMs, except in passive internal rotation. At the beginning of the present intervention study, both groups showed marked limitations in all the shoulder ROMs. Nevertheless, at 12 months, with no further follow-up, shoulder ROM reached the level of the contralateral shoulder. Active flexion increased by 17% and 19% in EG and UCG, passive flexion by 12% and 15%, and passive external rotation by 27% and 34%. Hayes et al. (15) reported that, between weeks

six and 24 after RCR, visually measured passive flexion increased by 13% (from a mean of 130° to 150°) in the physiotherapy group and 23% (from 111° to 144°) in the home exercise group, and passive external rotation by 33% (from 34° to 51°) and 28% (from 31° to 43°). These visually evaluated changes are of the same magnitude as the corresponding results of our study obtained for the period two months to 12 months after surgery. However, in the former study the final ROM values (at 24 weeks) of the ROM measurements were lower than those at two months in the present study. The reasons for this may be the difference in the method used to measure ROM. The use of goniometers or inclinometers is recommended rather than vision when measuring passive shoulder ROM (23). The different ages of the patients and the differences in the sizes of the repaired tears may also have been reasons for the differences in shoulder ROMs in the present and previous studies (15). However, it has been shown that postoperative improvements in shoulder ROM may remain unchanged even at 10 years (24).

Training adherence during the intervention was unsatisfactory, as only slightly more than half of the EG patients performed the strength exercises at least twice a week during the first six months, and only one-quarter during the last six months. The EG patients had four booster sessions with a physiotherapist during the first six training months, but no booster sessions during the last six training months before the 12-month measurement. This might have contributed to the decrease in training adherence during that period. Furthermore, the inclusion of too many exercises – eight shoulder and core exercises – in the training program may have decreased training adherence (25,26).

The strength training with the adjustable dumbbells was well tolerated, and no serious adverse events occurred during the one-year home-exercise period. During the first training weeks, nine patients reported shoulder pain in the operated shoulder, three reported neck pain and two reported elbow pain. The content of the exercise program can be considered appropriate, as it included several exercises that demand high to very high activity from the rotator cuff muscles (27). However, the intensity of loading of the training had been inadequate, as the level of shoulder strength of the EG patients did not exceed that of the UCG patients.

CONCLUSION

These results suggest that most of the patients attained remarkable pain relief and good recovery in muscle strength and ROM within one year after RCR. Adding a 12-month home-based strength exercise program to usual care was not found to have brought any extra benefit one year later for the patients with a rotator cuff tear.

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