Optimizing care on rotator cuff pathology

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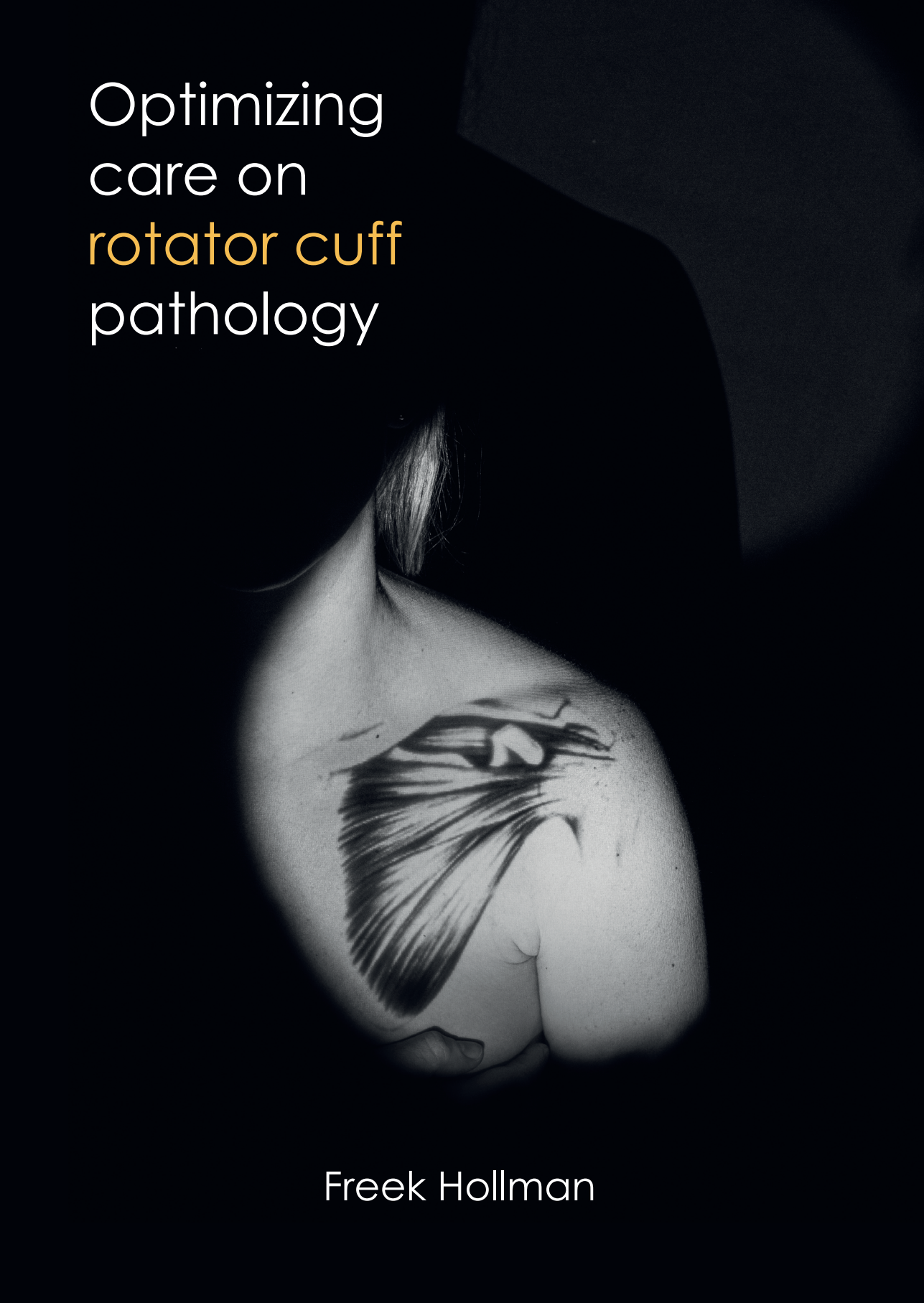

Freek Hollman

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Introduction and aims of this thesis

1. GENERAL INTRODUCTION

1.1. The functional anatomy of the shoulder

The shoulder joint is the only part of our body which consists of four different joints. In order to have an appropriate functioning shoulder joint and consequently to be able to position your hand in space, all these joints have to work together as a team. The combined movements of all these four joints generate shoulder movement and include glenohumeral, scapulothoracic, acromioclavicular and sternoclavicular articulation. Hippocrates was probably the first physician whose ideas regarding shoulder anatomy were perpetuated.[18] Another great artist, famous because of his detailed anatomic illustrations, which includes the shoulder, was of course Leonardo Davinci. In secret, Davinci dissected multiple shoulder specimens and illustrated them in great detail providing knowledge on basic anatomy and its variations, and were used for educational purposes by many. By including biomechanics in his paintings Davinci introduced the beginning of scientific anatomy. Consequently, from a surgeon's perspective it is of great importance to understand the (functional) anatomy of the shoulder joint in order to select the appropriate treatment and predict the intended outcome. Remaining within the anatomic concept, the starting position of the shoulder movement is described as the anatomic neutral position, from which the shoulder joint is moved in all possible directions (e.g. forward, backward, abduction, adduction, circumduction, and rotation). The founding fathers of describing and investigating shoulder movement have used a numerous of definitions and starting points of specific shoulder movements. Consequently, shoulder movement could grossly be divided into: 1) rotation on the long axis of the humerus; 2) the relative parts played by the four different joints in the motion of elevation; 3) lateral elevation in the coronal plane; 4) antero-posterior motion in the sagittal plane; 5) circumduction; 6) the motion at the acromio-clavicular joint; 7) the scapulo-humeral rhythm in which all the structures cooperate. These movements that control the position of the osseous structures are controlled by its muscles and tendons and consist of the humerus, the glenoid in continuum with the scapula and the collar bone. These muscles and tendons responsible for positioning these bony structures, originate from and insert on preset anatomical landmarks and clarify the direction of action. Scrutinizing these bone structures, the humeral head can grossly be divided into the lesser and greater tuberosity, separated by among others the bicipital groove. Whereas, the lesser tuberosity representing the insertion for the subscapularis tendon, and is responsible for internal rotation, the greater tuberosity maintains the insertion for the infra- and supraspinatus tendon, respectively responsible for external rotation and abduction. The bicipital groove contains the long head of the biceps tendon which contributes to shoulder depression and stabilization of the glenohumeral joint. Concerning external rotation, besides the infraspinatus, the teres minor tendon is responsible for external

rotation as well. The antagonists, or internal rotators, besides the subscapularis tendon, are the latissimus dorsi and pectoralis major tendon, attaching to respectively the posterior and anterior aspect of the proximal humeral diaphysis.

The rotator cuff

Appropriate understanding of the previous described anatomy is of paramount importance to understand the functional anatomy and clinical implication of the rotator cuff. The rotator cuff is a complex arrangement which consist of four muscles and may appear separately superficially however in deeper regions they are more associated with each other (*Figure 1*).[4]

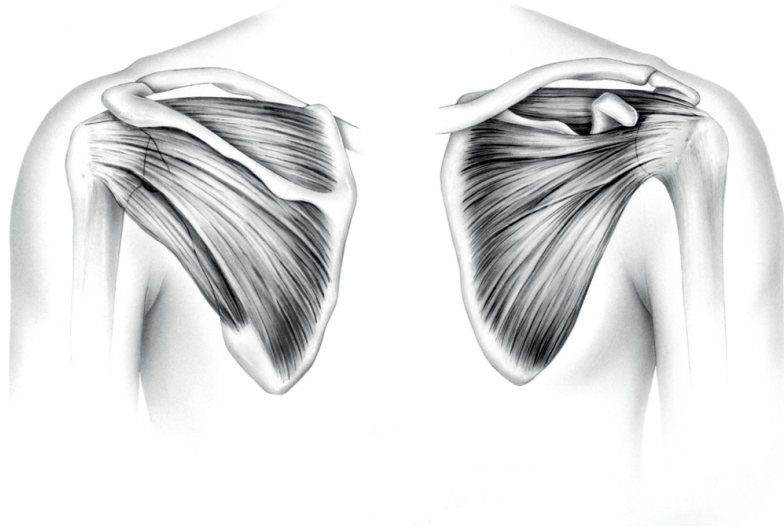

Figure 1. Anterior and posterior view of the rotator cuff.

From an arthroscopist's view, during surgery the upper part of the shoulder looks like, and is therefore described as, an suspension bridge or rotator cuff cable (*Figure 2*).[3] This cable is particularly formed by the supraspinatus and infraspinatus tendon and together with the subscapularis and the teres minor tendon these tendons form the rotator cuff.

The **supraspinatus** tendon forms the upper part of the rotator cuff and inserts on the greater tuberosity of the humeral head and is common with the more posterior insertion of the infraspinatus tendon and is involved in any form of active elevation. [5 10] At 30 degrees of elevation the tendon reaches maximum effort and also acts as an important secondary stabilizer of the glenohumeral joint. Furthermore, because the tendon is

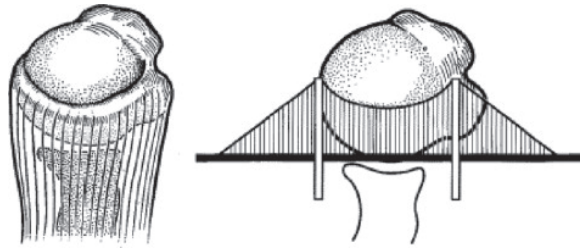

Figure 2. Rotator cuff cable - suspension bridge

superiorly confined by the acromion and inferiorly by the humeral head, especially this specific tendon is exposed to compression and attrition. In other words, this is defined as the extrinsic influence from the coracoacromial arch.

The second most active rotator cuff muscle is the **infraspinatus** muscle and responsible for external rotator with a common insertion with the supraspinatus tendon in the greater tubercle expanding to the posterior aspect of the humeral head. About 60% of external rotation is provided by this tendon and the other 40% by the **teres minor** muscle. [5] The infraspinatus, together with the teres minor muscle, is also considered an important humeral head depressor and posterior stabilizer of the glenohumeral joint. [11 1]

The fourth rotator cuff muscle is the **subscapularis** muscle which is responsible for active internal rotation and functions as the anterior glenohumeral stabilizer. The tendon inserts mainly on the lesser tubercle, although some tendon fibers cross the bicipital groove and insert on the greater tuberosity. Together with the infraspinatus muscle, the subscapularis tendon functions as humeral head depressor forming a force couples that is considered key for resisting cranializing forces of the deltoid muscle. [11 1]

In addition, two non-rotator cuff muscles which are functionally important for the shoulder function as well, are the **lattisimus dorsi** and the **pectoralis major** muscle. Firstly, the lattisimus dorsi muscle takes origin from the dorsal spines at level T7 through L5, sacrum and ilium. It inserts into the medial crest and floor of the bicipital groove. Thereby, this muscle acts as an internal rotator, adducts the humerus, extends the shoulder and downward rotation of the scapula. [20] Secondly, the pectoralis major muscle inserts just below the subscapularis tendon along the lateral tip of the bicipital groove and originate from the clavicle, manubrium and sternum and ribs two to four. The action of the muscle is mainly found in adduction and depression of the humeral head. Loss of this muscle seems to be well tolerated. These two tendons may be used to replace the irreparable anterosuperior or posterosuperior rotator cuff tears in terms of tendon transfer.

The rotator cuff interval also includes the bicipital groove and contains the long head of the biceps tendon. The biomechanical role of this complex is stabilizing the biceps tendon, which by itself acts as a depressor of the humeral head and stabilizes the humeral head during powerful elbow flexion and forearm supination. Sacrifice of the intraarticular segment of this tendon in surgical procedures of the shoulder may create instability and dysfunction. Nevertheless, in the presence of degenerative rotator cuff tears the intraarticular part is often pathologically involved and might contribute in some extend to shoulder complaints. In addition, spontaneous rupture of the biceps tendon in the presence of a degenerative rotator cuff tear is described in the literature with significant reduction in the amount of pain and increase in function. The role of the biceps tendon in the presence of degenerative rotator cuff tears will be discussed elaborately within this thesis.

1.2. Development of degenerative rotator cuff tears

Understanding shoulder anatomy and its function is of paramount importance to gain more insight into the possible pathological mechanisms in rotator cuff degeneration and to understand which treatment options should considered to be appropriate. These mechanisms can grossly be divided into intrinsic and extrinsic factors. Intrinsic factors refer to factors that predominantly lie within the rotator cuff muscle itself, while demographic and anatomic variables that interact to contribute to rotator cuff damage are considered extrinsic factors.

Impingement is an important extrinsic factor and elaborately described by Charles Neer. In 1972 Neer described a surgical technique to increase the subacromial space and change its contour in order to reduce compression on the rotator cuff tendons.[15] Back then, it was thought that by chronic subacromial impingement the critical area of particularly the supraspinatus tendon is damaged. In the coracoacromial arch the coracohumeral ligament prevents the shoulder from superior migration and might compress the superior rotator cuff as well. Over the last decades, better understanding of impingement has resulted in multiple definitions, all describing different forms of impingement. These could grossly be divided into static versus dynamic and primary versus secondary impingement. In 1997 Payne et al. investigated the combined contribution of dynamic muscular forces and static acromial structures on subacromial impingement.[17] They found that in the presence of a subacromial spur or more sharply angled acromion pressure increases on the rotator cuff. Dynamic factors contributing to this impingement were the biceps tendon, which by force reduces the subacromial pressure by depressing the humeral head. Furthermore, by modeling the rotator cuff and deltoid muscle forces this demonstrated the importance of the muscular force couple to center the humeral head during elevation of the arm. Additionally, the inferior forces of the infraspinatus,

teres minor, and subscapularis muscles were necessary to neutralize the superior shear force produced by the deltoid and supraspinatus muscles (*Figure 3*).[17] Nowadays, an isolated surgical decompression as described by Neer is considered obsolete and relieving secondary impingement should be obtained by mainly focusing on scapulothoracic and glenohumeral coordination for which physiotherapy can be considered.

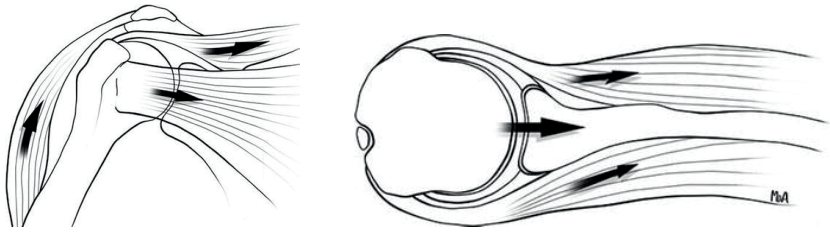

Figure 3. Modeling of the rotator cuff and deltoid muscle forces.

Another form of impingement, frequently used in the throwing athlete, is internal impingement, which might occur superoposterior or anterosuperior and is different from the external or subacromial impingement syndrome. Overhead sports often involve abduction and some extend of external rotation and it is thought the late cocking phase of the thrower's motion as a possible cause of posterior shoulder pain in this group of athletes is known as posterosuperior impingement. Consequently, anterosuperior impingement involves an impingement of the subscapularis tendon between the anterior humeral head and the anterosuperior glenoid and labrum during forward flexion of the arm. If the shoulder is in a position of horizontal adduction and internal rotation, the undersurface of the reflection pulley and the subscapularis tendon impinges against the anterosuperior glenoid rim. In this context, lesions of the long head of the biceps, the pulley, and the rotator cuff have been described.[12]

From all extrinsic demographic factors studied, only smoking, diabetes, dominant side involved, increasing age and chronic overuse are thought to contribute to the development of a degenerative rotator cuff tear. However, in general, there is a lack of in-depth epidemiological data on this condition, likely due to its multifactorial, insidious, and often asymptomatic presentation. Though, rather recently, a meta-analysis of the literature regarding risk factors for rotator cuff tears identified hand dominance and older age as risk factors that may contribute to the development of these tears. Additionally, a higher BMI, history of hypertension and history of smoking are associated with rotator

cuff tears, although these associations could not be generalized to the general population.[19]

The most supported intrinsic mechanism of cuff degeneration is of repetitive microtrauma in degenerating tissue which is exposed to an inflammatory environment and oxidative stress inducing tenocyte apoptosis. The other theory is the neural overstimulation leading to recruitment of inflammatory cells inducing tendon degeneration. Considering rotator cuff vascularization, it has been traditionally thought that there exists a "critical" or hypovascular zone 10 to 15 mm proximal to the insertion of the supraspinatus tendon, but these assertions have increasingly become an area of controversy and hypovascularity is thought to be a minimal contributor to cuff tears.[2]

All these mechanisms might finally lead to tearing of the rotator cuff and from an anatomical point of view a particular pattern is observed. Namely, after years of compression, traction, contusion, subacromial abrasion, age-related degeneration and others not yet mentioned a degenerative tear might be present. The lesions usually start where the loads are the greatest, which in case of the rotator cuff is thought to be the deep surface of the anterior insertion of the supraspinatus near the long head of the biceps tendon and expanding to posterior towards the infraspinatus. It is therefore, that degenerative tears are mostly superoposteriorly orientated. When tears expand, the cuff loses its spacer effect with superior migration of the humeral head and changing biomechanics due to a superior displaced center of rotation. In addition, the biceps tendon can become compressed in the subacromial space between the acromion and the humeral head and may become symptomatic and even lead to spontaneous rupture. The tear might also expand slightly anteriorly towards the biceps pully and upper part of the subscapularis tendon destabilizing the long head of the biceps leading to medial displacement.

It is hypothesized that all these factors, lead (from early cadaver studies) in 50% of the population over the age of 77 years to an asymptomatic rotator cuff tear. [9] Moreover, more recent published literature supports early degeneration and high prevalence of rotator cuff tears as well, which was described by among others Milgrom et al. who found partial- and full-thickness tears increased markedly after 50 years of age. Over 50% of dominant shoulders in the seventh decade of life were diagnosed with a tear, which was 80% amongst participants over 80 years of age.[14] Furthermore, Yamaguchi et al. noted that the average age for an individual without a rotator cuff tear was 48.7 years, 58.7 years for those with a unilateral tear and 67.8 years for those with a bilateral tear.[22] Moreover, meta-analysis revealed a 50% likelihood of a bilateral tears at 66.0 years of age.[19] Under the age of 40 years, 4% of all cuff injuries remain asymptomatic, which increases

up to 54% for patients aged 60 years or older.[21] This epidemiologic information reflects the extend of rotator cuff tears amongst our population. Apparently and interestingly, rotator cuff tears not always have to cause and impaired shoulder function. Nevertheless, if tears become symptomatic they may cause problems which affects functioning and participation in daily life with socioeconomic implications.

1.3.Diagnostics

Besides thorough physical examination several useful diagnostic tools to further evaluate the rotator cuff are available. Standard shoulder evaluation at consultation should include at least roentgenologic evaluation with an anteroposterior and axillary lateral view of the affected shoulder. Secondly, ultrasonography has gained popularity and is nowadays frequently incorporated in orthopedic practice with increasing imaging quality, higher resolutions and in some cases even the possibility to evaluate the tendon quality.[13] However, the golden standard for tissue quality quantification remains the MRI which is expressed by the level of atrophy and fatty degeneration. The level of fatty infiltration on MRI is described by Fuchs et al. and originally by Goutallier on CT.[7] The Goutallier classification stages the level of fatty infiltration from 0 to 4 in which stage 0 reflects a normal muscle and no fatty streaks; stage 1 describes some fatty streaks; stage 2 shows significant amount of fatty infiltration but still containing more muscle than fat; whereas stage 3 the muscle contains as much fat as muscle; and finally stage 4 in which there is more fat than muscle present.[8] Nowadays, the MRI is more frequently used as compared to the CT scan and the correlation between these two methods is rather fair which implicates that data from MRI and CT cannot be compared directly. The degree of fatty infiltration is of great clinical importance as it may direct and predict treatment outcome. Although, the treatment of stage 2-3 Goutallier degenerative tears is highly under discussion and no consensus exists. Therefore, a significant contribution of this thesis will focus on this particular subgroup. Furthermore, together with the level of fatty infiltration, level of atrophy, tendon retraction and structural abnormalities to the labral complex and long head of the biceps tendon these can be reliably evaluated on MRI.[7]

The previous mentioned functional anatomy, pathologic mechanisms of rotator cuff pathology and diagnostics provides basic knowledge for better understanding of the rotator cuff. Especially the rotator cuff is vulnerable to considerable morbidity because of its anatomy and function and might need consultation from an orthopedic surgeon at some point in a person's life. The first person describing the occurrence of a rotator cuff tear after shoulder injury is thought to be J. G. Smith in the London Medical Gazette. (Smith 1834) Thereafter, Codman studied the rotator cuff in his practice and recommended early operative repair for complete cuff tears. Codman claimed that he

carried out the first cuff repair even described in literature in 1909. Since then, numerous insights and hypothesis concerning rotator cuff repair have been proposed.

1.4. Current insight in treatment strategy degenerative tears

Treating patients with symptomatic rotator cuff tears is often challenging and several key factors need to be addressed when selecting the appropriate treatment. Furthermore, due to a lack on high level studies there are different believers and non-believers regarding a broad range of treatment options. These options range from grossly conservative, to a more aggressive surgical approach to establish a restored or reconstructed rotator cuff. This thesis will focus specifically on the treatment strategy of degenerative rotator cuff tears and will be further discussed in detail in the general discussion.

In general, treatment options can be divided in non-surgically, tendon repair, tendon transfer, reverse total shoulder arthroplasty and other potential solutions like subacromial spacers and superior capsular reconstruction for irreparable tears. It depends on several key factors like age, tendon quality, etiology of complaints, smoking, presence of diabetes whether the cuff is considered reparable or not. Traumatic rotator cuff tears are preferably treated with a direct repair of the torn tendons (schematically illustrated in *Figure 4 A-C*). Encouraging factors for performing a rotator cuff repair of the non-acute tears are among others age less than 55 years, no clinical atrophy, no smoking and good tendon quality on MRI. Particularly tendon quality plays an important role in guiding you to the most appropriate treatment for your patient. Fatty degeneration is thought to be the most important parameter to express tendon quality. Tendons with the presence of more fat than muscle are prone to failure following rotator cuff repair and other procedures should be considered. A less invasive surgical treatment could be a tenotomy of the long head of the biceps tendon reducing pain from the diseased intra-articular part this tendon which was caused by chronic inflammation in a degenerative join with the presence of a rotator cuff tear. In contrary, reverse total shoulder arthroplasty has proven its clinical value with good and predictive results although complications are described and long-term results in younger patients not broadly known. The philosophy of reverse total shoulder prosthesis is to medialize and lower the center of rotation to increase the delivered strength from the deltoid muscle because it needs to compensate for the absence of the rotator cuff. This prosthesis was developed by Charles Neer as a constrained design after which the French designed a second-generation type prosthesis and was named after Grammond (Figure 5-A). This second-generation reverse total shoulder prosthesis converts the humeral head into the glenoid and the glenoid is rebuild into a humeral head (Figure 5-B). Nowadays, due to scapular notching a third-generation prosthesis has been developed with promising long-term results, although not within the scope of this thesis.

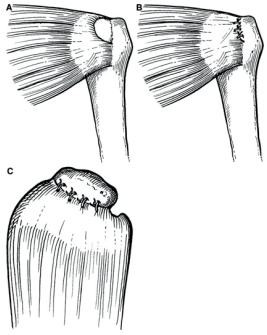

Figure 4 A-C. Schematic illustrations

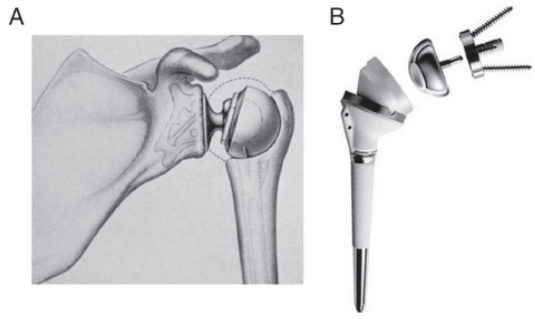

Figure 5 A. Original reverse shoulder prosthesis design by of a rotator cuff repair.
Charles Neer.
Figure 5 B. Second generation reverse shoulder prosthesis by Grammond.

1.5. Aftercare following rotator cuff repair

Rotator cuff repair can be rather painful, especially during the early postoperative rehabilitation phase. Rotator cuff surgery has evolved from grossly open to predominantly arthroscopic repair with rapid recovery protocols and early discharge from hospital care. The use of locoregional analgesics and temporarily intake of opioids has improved the perioperative surveillance of pain significantly. In order to manage perioperative pain ultimately and endeavor safe and expeditious discharge, the introduction of multimodal anesthesia has reduced pain and includes NSAIDs, COX-2 inhibitors, α2 agonists, glucocorticoids, N-methyl-d-aspartate (NMDA) antagonists, and opioids.[16] Locoregional anesthesia is known to be effective as well, especially regarding early postoperative pain. Additionally, a variety of perineural and subacromial continuous delivery systems of analgesics in the early postoperative rehabilitation phase, which could even be administered in out of hospital care, are proposed and described. Nevertheless, a rotator cuff repair remains a cumbersome procedure which might implicate other factors should be identified and further studied to optimize postoperative aftercare. Other causes for postoperative pain could be sought in high-tension cuff repairs. Reattaching the torn tendons under tension adversely changes the muscular length-tension relationship and diminishes active force generation. These repairs, exposed to high levels of tension, could result in increased levels of postoperative pain.[6] Usually, the supraspinatus tendon is repaired in a neutral position, although when extensive surgical releases need to be performed in order to mobilize the retracted tendon and accomplish a footprint repair, some level of abduction may be required. Therefore, the idea within this thesis came up to study the effect on pain and function by using an abduction brace, thereby reducing the amount of tension, instead of using an antirotation sling with the arm in

adduction and internal rotation. Consequently, evaluating the optimal postoperative shoulder posture is further studied in this thesis and little is known in literature regarding this topic.

1.6. Shoulder specific patient related outcome measurements

Finally, the outcome and effect of treatment of specific conditions need to be recorded with the accurate measurement tools. Several shoulder specific questionnaires are available to determine the amount of functional impairment from a patient's perspective as well as of a clinician's perspective. However, with the introduction of such parameters, questions are raised on what kind of effect is actually measured, its reproducibility and reliability. Within this thesis, two important and frequently used shoulder specific questionnaires on function and quality of life are investigated extensively. It is thought, these questionnaires are able to reliably quantify the patients shoulder disability and influence on general functioning in daily living. Consequently, because reliability and reproducibility are extremely important items, this thesis will focus on various elements of the Western Ontario Rotator Cuff index (WORC) and Constant-Murley Score (CMS).

In brief, the WORC is a health-related QoL patient-administered questionnaire that is validated for amongst others measuring the treatment effect of rotator cuff repairs. The WORC is specifically designed for patients with disorders of the rotator cuff and therefore defined as a disease-specific health-related QoL questionnaire and includes questions on 5 domains (physical symptoms, sports and recreation, work, social function, emotional disability). This thesis will specifically focus on the effect called perception shift, its reliability and construct validity compared to other shoulder specific questionnaires, internal consistency and effects of digitalization.

The second questionnaire to be elaborately studied is the CMS, a shoulder specific questionnaire, which is used to evaluate the effect on shoulder function influenced by shoulder pathology in general and treatment. The CMS is a combined patient-reported and objective (health professional administered) shoulder outcome measure and is widely used in literature. Nowadays, the CMS could be addressed as the standard functional outcome measure used in important studies regarding the rotator cuff and are commonly pooled in network- and meta-analyses. However, what do we actually know about the quality of all these individual studies? Did they conduct the CMS all in exactly the same way or did they use other settings and different answering scales? Could this have influence on the outcome? Consequently, this thesis aimed to study the interchangeability of the use of different answering scales within the CMS.

2. RESEARCH GOALS AND QUESTIONS TO BE ADDRESSED IN THIS THESIS

The studies included in this thesis studied several aspects which are involved in optimizing care for the diseased rotator cuff tendons, especially degenerative tears. This thesis aimed to study: 1) different treatment options for degenerative rotator cuff tears, 2) the optimal aftercare following arthroscopic rotator cuff repair, 3) the additional value of MRI in atraumatic shoulders complaints and 4) the reliability and reproducibility of shoulder specific patient related outcome measurements and 5) the functional outcome, quality of life and cost-effectiveness of performing a tenotomy of the long head of the biceps tendon with or without rotator cuff repair. Therefore, this thesis seeks to answer a number of research questions that can be divided in the following four general aims and subsequent questions:

1. To study the possible treatment options for degenerative rotator cuff tears:
    - What are the treatment options for stage 2–3 Goutallier fatty degenerated rotator cuff tears and what is their outcome?
    - Can we give a recommendation of the optimal treatment within this specific subgroup?

2. To study the influence of tension on the repaired tendons and their effect on pain and tendon healing following arthroscopic rotator cuff repair:
    - Is the level of pain and functional recovery influenced by the level of abduction during the postoperative rehabilitation period following arthroscopic rotator cuff repair?
    - Does abduction (versus adduction) lead to increased healing tendency after arthroscopic rotator cuff repair?

3. To study the additional value of MRI in atraumatic shoulder complaints:
    - Are there clinically relevant findings and predictive factors for these structural abnormalities on MRI amongst patients with atraumatic shoulder complaints under the age of 45 years?

4. To study the reliability and reproducibility of shoulder specific patient related outcome measurements with focus on the Constant-Murley score and Western Ontario Rotator Cuff index:
    - What Is the reliability and reproducibility of the WORC index?
    - What is the reliability and reproducibility of the CMS?
    - Digitalization of questionnaires, with impunity?

5. To determine whether performing an isolated biceps tenotomy result in comparable outcome as compared with biceps tenotomy in combination with an arthroscopic rotator cuff repair in patients with degenerative rotator cuff tears:
    - What is the functional outcome, quality of life and cost-effectiveness of performing a tenotomy of the long head of the biceps tendon with or without arthroscopic rotator cuff repair in patients with stage 2-3 Goutallier degenerative rotator cuff tears?

3. CONTENTS OF THIS THESIS

• Outline:

In the **first chapter** of this thesis an introduction and aims within this thesis are outlined. In this chapter we will provide general background on rotator cuff anatomy, function, tears, diagnostics, treatment, aftercare following rotator cuff repair and patient related outcome measures. **Chapter 2** starts with providing an overview of the results of all the treatment options for degenerative rotator cuff tears. It is commonly accepted to repair tendons with good tissue quality and to treat those with advanced level of fatty degeneration conservatively. Considering the moderate levels of fatty degeneration (stage 2-3 in a scale from 0-4) this is still under debate. Therefore, data was conducted from conservative treatment and several surgical options like isolated biceps tenotomy, rotator cuff repair, tendon transfer and arthroplasty. As we continue we reroute to the preoperative phase in order to optimize our indications for imaging in patients with shoulder complaints reducing unnecessary costs. The predicting factors to justify requesting an MRI in patients under the age of 45 years with atraumatic shoulder complaints are studied in **chapter 3**. Another element which is mentioned in this thesis concerns the amount of pain which patients often experience after performing an arthroscopic rotator cuff repair and outlined in **chapter 4**. We hypothesized pain might be a derivative of the amount of tension that is created on the repaired tendons, especially the supraspinatus tendon. This might be reduced by supporting the arm in abduction, thereby reducing the tension on the repaired rotator cuff. Thereafter, in order to reliably and reproducible measure these treatment outcomes we aimed to clarify the reproducibility and reliability of several rotator cuff specific patient related outcome measurements in **chapter 5, 6** and **7**. Finally, in **chapter 8**, we aimed to perform a randomized controlled multicenter trial in which we hypothesized that for stage 2-3 degenerative rotator cuff tears after non-responding to physiotherapy the results of an isolated biceps tenotomy is non-inferior after one year as compared with performing an additional rotator cuff repair. While the trial was preliminary terminated, only the study protocol is included in this thesis. Despite this difficult decision, learning points and future perspectives will be elaborately discussed in **chapter 9**.

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2

The optimal treatment for stage 2-3 Goutallier rotator cuff tears: a systematic review of randomized and non-randomized trials.

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ABSTRACT

Fatty infiltration is an important prognostic factor for cuff healing after rotator cuff repair. Treatment options for stage 2-3 Goutallier rotator cuff tears vary widely and there is lack of decent comparative studies. The objective of this study was 1) to give an overview of the treatment options of stage 2-3 Goutallier rotator cuff tears and their clinical outcome and 2) to give a recommendation of the optimal treatment within this specific subgroup. We searched the databases of Medline, Embase, Cochrane library, NHS Centre for Reviews and Dissemination, PEDro from inception to December 12th, 2016. Two authors, F.H. and N.W., selected the studies after consensus. Data was extracted by one author (F.H.) and checked for completeness by a second author (N.W.). Our primary outcome was physical function, measured by shoulder-specific patient reported outcomes. Secondary outcomes were cuff integrity after rotator cuff repair, shoulder pain, general health, quality of life, activity level and adverse events. For the first research question 28 prospective as well as retrospective studies were included. For the clinical outcome of these treatments three randomized controlled trials were included. Despite the high reported retear rate, rotator cuff repair has comparable results (clinical improvement) as partial repair and isolated bicepstenotomy or tenodesis. These findings suggest that the additional effect of rotator cuff repair compared to the less extensive treatment options like isolated bicepstenotomy or tenodesis should be studied, as these might form a good alternative treatment based on this systematic review.

INTRODUCTION

Rotator cuff tearing is a highly prevalent disorder of the shoulder joint of which its incidence increases with age. These lesions do not always result in a symptomatic shoulder joint. Under the age of 40 years, 4% of all cuff injuries remain asymptomatic, which increases up to 54% for patients aged 60 years or older.[38] Amongst elderly, tendon quality is often poor as tears are mostly degenerative by nature. Important qualitative factors to specify the amount of degeneration are the level of fatty infiltration and atrophy of the involved muscle, and retraction of the tendon. These factors are considered important for selecting appropriate candidates for rotator cuff repair.

In the literature several independent factors to define an irreparable rotator cuff tear are described such as ≥50% of fatty infiltration (Goutallier stage ≥ 3)[15], retraction of the tendon to the height of the glenoid[41] and acromio-humeral interval being less than 7 mm.[4,24,43]

Amongst several identified negative prognostic factors for healing, fatty infiltration (FI) is frequently described as paramount predictor for healing, which implies anatomic integrity on the footprint after full recovery from surgery. The extend of FI in the rotator cuff was firstly classified by Goutallier et al.[14] Several clinical studies on rotator cuff repair described the functional and radiologic outcome for the subgroups of this classification separately.[2,7,8,12,14,20,26,35,37] In general, for stages 0-1 (0-25% FI) the clinical outcome is described good to excellent, while stage 4 (> 50% FI) is associated with poor outcomes, high retear rates and minor functional improvement.[7] Consensus has been reached that cuff repair of these severe fatty infiltrated tendons should not be performed. The appropriate treatment for the remaining stage 2 and 3 fatty infiltrated cuff tears (25-50% FI) is still under discussion. Despite a high retear rate after rotator cuff repair in this patient category, patients clinically improve significantly with only minor functional differences between patients with healed repairs and patients with a retear.[12,20,26] It is still poorly understood which element is responsible for this improvement.

Alternative treatments for restoring shoulder function after a full-thickness rotator cuff tear beside cuff repair are conservative treatment, debridement, bicepstenotomy, bicepstenodesis, subacromial decompression, tendon transfers, arthroplasty, and other new developments in the tissue engineering industry.

Objectives

The aim of this study was to perform a systematic literature review to 1) outline the treatment options for stage 2-3 Goutallier fatty degenerated rotator cuff tears and their

outcome and 2) to give a recommendation of the optimal treatment within this specific subgroup. Our hypothesis is that stage 2-3 Goutallier fatty degenerated rotator cuff tears can be treated with less extensive treatment options like conservative therapy and isolated bicepstenotomy achieving comparable functional results as compared with extensive treatment options like rotator cuff repair or tendon transfers.

METHODS

This systematic review is reported following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines.[23]

Eligibility Criteria

A literature search for studies describing the functional outcome for treated grade 2-3 Goutallier rotator cuff tears was conducted. Included treatments were: conservative treatment, open and arthroscopic rotator cuff repair, bicepstenotomy, bicepstenodesis, acromioplasty, debridement, partial repair, latissimus dorsi transfer, other tendon transfers, arthroplasty and tissue engineering or other new developments. Prospective as well as retrospective studies were included.

Search Strategy

A systematic search of Embase, PubMed, Web of Knowledge, and the Cochrane Library was performed from 1995 to June 2014. The search terms included Medical Subject Headings terms, free-text word variations, and combinations of these. Cross-references and "cited-by" articles of the included articles were screened to ensure that no relevant studies were missed. An expert in this field was consulted to check for missing relevant studies. The Netherlands Journal of Orthopaedics, which is not available via the above-mentioned bibliographic databases, was searched for relevant Dutch articles. National and international trial registries were checked for ongoing or unpublished trials. This search was performed in June 2014 and updated in January 2015 and December 2016 (APPENDIX 1).

Study Selection

After removing duplicates, titles and abstracts were screened according to the following criteria: (1) the publication was a clinical study, (2) the study population consisted of adult patients with a MRI or CT-scan confirmed rotator cuff tear, and (3) the publication contained information on the functional outcome; radiological information on the quality of the rotator cuff tendons and postoperative integrity was not prerequisite. Based on the titles and abstracts, manuscripts identified as potentially eligible underwent a

full-text review. Papers were included in the review based on the following criteria: (1) the study included stage 2-3 Goutallier fatty infiltration rotator cuff tears, described pre- or postoperatively; (2) in case of a cuff repair an arthroscopic, mini open or open surgical technique was used; (3) studies with mixed surgical techniques were included if data on the patients were separately available; (4) the article was written in English, Dutch, French or German; and (5) the full text of the paper could be obtained. For outlining the treatment options and their outcome, no selection was made in study designs. For the second objective, to give a recommendation of the optimal treatment within this specific subgroup, only randomized studies were selected.

Data Items

From the included full-text papers, the following study characteristics were systematically extracted, applying the evidence table for intervention studies: bibliographic reference, study type, number of patients, multi- or single-centre study, patient characteristics (including age and gender), tear characteristics (including retear rate and level of fatty infiltration), type of intervention, diagnostic tool(s) (pre- and postoperative), the comparison, the length of follow-up, outcome measures and effect size (scores on function and cuff integrity) and source of funding.[1] A data-extraction sheet was developed a priori. One author (F.H.) extracted the data and a second author (N.W.) verified the extracted data and added data when necessary.

Assessment of risk of bias and methodological quality

Methodological quality assessment of selected papers was performed using the "methodology checklist for randomized controlled trials (RCT's), cohort studies and prognostic studies."[1] The RCT and cohort study checklist consisted of 4 main items: selection bias, performance bias, attrition bias and detection bias. Based on the score of their respective subitems, the main items were scored as low, unclear and high risk of bias. For each main item, a low risk indicated that the study was designed and conducted in a manner that minimized the risk of bias for that item. An unclear risk was given when the information required to score an item was not reported or was not reported clearly. A priori it was decided that studies would be excluded if more than 2 out of 4 main items scored a high risk of bias (low methodological quality).

The checklist for prognostic studies consisted of 6 main items: study sampling, loss to follow-up, prognostic factors, outcome, confounders, and statistical analysis. Based on the score of their respective subitems, the main items were scored as yes, unclear or no. For each main item, a yes response indicated that the study was designed and conducted in a manner that minimized the risk of bias for that item. An unclear response was given when the information required to score an item was not reported or was not reported

clearly. A priori it was decided that studies with less than 3 yes responses on the 6 main items would be excluded from this review (low methodological quality). Screening of titles, abstracts, and full text, as well as the assessment of the methodological quality of the studies, was independently performed by 2 of the authors (F.H. and N.W.). Disagreements between reviewers were resolved by consensus. For the methodology assessment, consensus had to be reached on each subitem and main item of the methodology checklist.

Assessment of risk of bias across studies

In the retrieved studies, particular attention was paid to a clear description of the patient population, the in- and exclusion criteria and incomplete outcome data, concerning different risks of bias.

RESULTS

Study selection

The literature search yielded a total of 3576 studies. After removing duplicates, 2321 articles remained. Titles and abstracts of the remaining 2321 studies were screened. 1547 records were discarded because they did not meet the criteria for inclusion. Full-text screening was then performed for the remaining 774 studies. 48 papers were assessed for their quality and risk of bias (Table 1A-C). Based on the risk of bias assessment another 20 papers were excluded. An overview of the screening process is given in Figure 1. No unpublished relevant studies were obtained from trial registries. For the first question on possible treatment options randomized and non-randomized studies were included (n = 28) (Table 2).[4,6,8-13,16,17,19,21,22,25,27-34,36,40,42,44-46] For the first research question on functional outcome only randomized studies, describing the functional results of each stage of fatty infiltration separately (n = 3), were included (Table 3).[16,27,28]

Risk of bias assessment

Table 1A-C show the results of the assessed risk of bias of the individual trials.

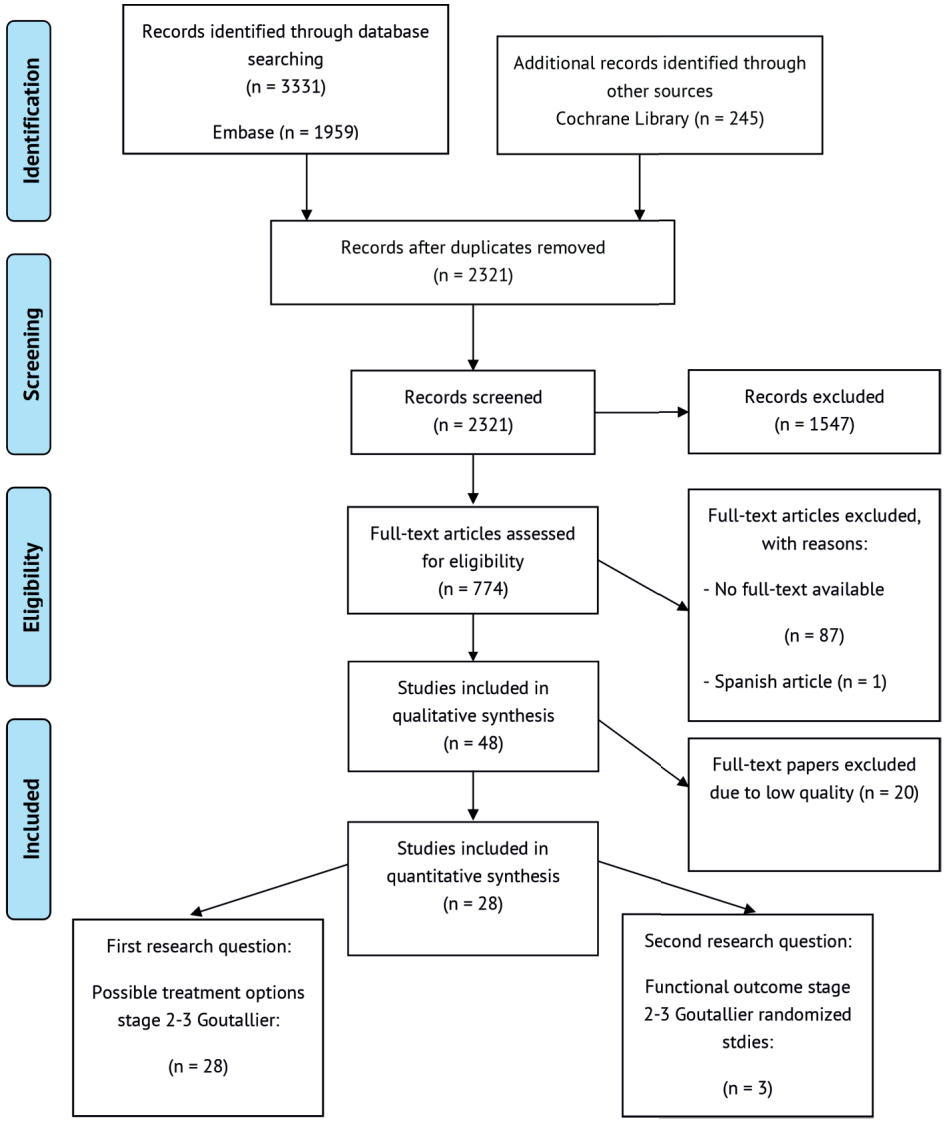

Figure 1. Flow diagram of literature search

Table 1A: prognostic studies: Quality assessment of the included studies according to the 'Methodology checklist for prognostic studies.' All items were scored with a 'yes', 'no', or 'unclear'. A 'yes' response indicates that the study has been designed and conducted in such a way as to minimize the risk of bias for that item. An 'unclear' response was given when the answer to an item is not reported or is not reported clearly.

Study	Population	Drop-out	Prognostic factor	Outcome	Confounders	Statistical analysis	Inclusion?
Iannotti 2013	yes	yes	yes	yes	yes	no	**Yes**
Toussaint 2011	yes	no	unclear	yes	unclear	no	**Yes**
Kim 2012	yes	yes	yes	yes	yes	yes	**Yes**
Cho 2009	yes	no	yes	yes	unclear	no	**Yes**
Edwards 2002	yes	unclear	unclear	unclear	yes	unclear	**No**
Koh 2014	yes	no	unclear	yes	unclear	unclear	**No**
Chung 2013	yes	no	yes	yes	unclear	unclear	**Yes**
Choi 2014	yes	no	yes	yes	unclear	unclear	**Yes**
Wiater 2014	yes	unclear	yes	yes	unclear	unclear	**Yes**
Lapner 2014	yes	unclear	yes	yes	yes	unclear	**Yes**
Vastamaki 2013	unclear	unclear	unclear	yes	unclear	no	**No**
Fuchs 2006	yes	yes	yes	yes	no	yes	**Yes**
Goutallier 2003	unclear	unclear	unclear	yes	unclear	no	**No**
Mellado 2005	yes	unclear	yes	yes	unclear	no	**Yes**
Goutallier 2009	yes	unclear	unclear	unclear	unclear	no	**No**
Zumstein 2008	unclear	yes	yes	yes	unclear	yes	**Yes**
Nich 2009	yes	unclear	yes	yes	unclear	no	**Yes**
Park 2015	yes	unclear	yes	yes	yes	yes	**Yes**
Chung 2013	yes	unclear	unclear	yes	yes	yes	**Yes**
Kim 2016	unclear	unclear	unclear	unclear	unclear	unclear	**No**

Table 1B: The cohort studies checklist consisted of 4 main items: selection bias, performance bias, attrition bias and detection bias. Based on the score of their respective subitems, the main items were scored as low, unclear and high risk of bias. For each main item, a low response indicated that the study was designed and conducted in a manner that minimized the risk of bias for that item. An unclear response was given when the information required to score an item was not reported or was not reported clearly. A priori, was decided that studies were excluded if more than 2 out of 4 main items would be scored as high risk of bias on the basis of low methodological quality.

Study	Selection bias	Performance bias	Attrition bias	Detection bias	Inclusion?
Park 2008	low	unclear	low	low	**Yes**
Franceschi 2012	unclear	unclear	unclear	unclear	**No**
Oh 2011	low	unclear	low	unclear	**Yes**
Cho 2010	unclear	unclear	low	low	**Yes**
Warner 2001	unclear	unclear	low	low	**Yes**
Ryu 2015	low	unclear	low	high	**Yes**
Taniguchi 2014	unclear	unclear	low	unclear	**No**
Hug 2014	unclear	unclear	unclear	low	**No**
Namdari 2014	high	unclear	unclear	low	**No**
Moirati 2014	unclear	unclear	low	low	**Yes**
Warner 2001	high	high	unclear	unclear	**No**
Boileau 2007	low	unclear	low	unclear	**Yes**
Lee 2016	high	high	high	unclear	**No**
Gasbarro 2016	unclear	unclear	unclear	unclear	**No**
Shin 2016	unclear	unclear	high	unclear	**No**
Paribelli 2015	high	high	low	unclear	**No**
Franceschi 2015	high	high	unclear	unclear	**No**

Table 1C: The randomized controlled trial checklist consisted of 4 main items: selection bias, performance bias, attrition bias and detection bias. Based on the score of their respective subitems, the main items were scored as low, unclear and high risk of bias. For each main item, a low response indicated that the study was designed and conducted in a manner that minimized the risk of bias for that item. An unclear response was given when the information required to score an item was not reported or was not reported clearly. A priori, was decided that studies were excluded if more than 2 out of 4 main items would be scored as high risk of bias on the basis of low methodological quality.

Study	Selection bias	Performance bias	Attrition bias	Detection bias	Inclusion?
Milano 2007	low	low	low	low	**Yes**
Van der Zwaal 2012	low	unclear	low	unclear	**Yes**
Gumina 2011	unclear	unclear	low	unclear	**No**
Gumina 2012	high	unclear	low	unclear	**No**
Milano 2012	low	low	low	low	**Yes**
Berth 2010	high	high	high	high	**No**
Grasso 2009	low	unclear	low	low	**Yes**
Milano 2013	low	unclear	low	low	**Yes**
Nicholas 2016	unclear	low	unclear	unclear	**No**
Bryant 2016	low	low	low	low	**Yes**
Kukkonen 2015	low	unclear	low	low	**Yes**

1. RESULTS ON TREATMENT OPTIONS FOR STAGE 2-3 GOUTALLIER CUFF TEARS

There are several options for treating Goutallier stage 2-3 rotator cuff tears. After a critical selection of literature, articles on arthroscopic cuff repair, partial cuff repair, debridement, bicepstenotomy, bicepstenodesis, lattisimus dorsi transfer, arthroplasty and conservative treatment, were included. Literature on other therapeutical options like, ligament augmentation and other tendon transfers were not included because they did not meet the inclusion criteria or were not included due to poor study quality.

1.1 Rotator cuff repair

Twenty-three out of twenty-seven included articles described a rotator cuff repair of which 12 were prognostic studies, 5 cohort studies and 6 RCT's. Four prognostic studies were on open rotator cuff repair.[13,25,31,46] There were three prognostic studies that focused on cuff integrity related to the stage of fatty infiltration.[8,17,19] Iannotti et al.[17] found more retears amongst patients with stage 2 Goutallier (50%) compared to stage 0 and 1 Goutallier (16%, 11%) with comparable functional outcomes. The two other studies, Kim et al.[19] and Cho et al.[8], reported higher retear rates with Kim et al.[19] reporting 100% failure of Goutallier stage 3 and Cho et al.[8] 62% failure of Goutallier stage 3 and 47% failure rate amongst stage 2, with excellent relief of pain and functional improvement to perform the activities of daily living, despite the structural failures. Within these two studies 44% to 56% of the patients underwent additional treatment of the biceps tendon (tenotomy or tenodesis).[8,19] Performing a meta-analysis was not possible due to heterogeneous data. Average fatty infiltration ranged from 0.34 to 3.24 with a mean absolute Constant score ranging from 66.1 to 93.3 and a retear rate from 12% to 86% without any linearly relation observed (see Table 2).

1.2 Partial repair

One retrospectively designed study was included comparing partial with complete rotator cuff repair, open approach. Mellado et al.[25] performed a partial repair in 6 out of 22 patients with massive rotator cuff tears. Results were comparable for the partial and complete repair group with a retear rate amongst the complete repair group of 68% after a mean follow-up of 44.4 months (range: 13-96).[25] The University of California at Los Angeles (UCLA) score improved from an average of 12.5 ± 2.8 point for the total study population to 29.7 ± 5.3 and 31.8 ± 3.6 ($p < 0.0001$) point at final follow-up for respectively complete and partial rotator cuff repair.[25]

1.3 Isolated bicepstenotomy or tenodesis

Boileau et al.[4] studied the outcome of isolated bicepstenotomy (n = 39) versus tenodesis (n = 33) for the treatment of irreparable massive rotator cuff tears without the presence of true pseudoparalysis. The reparability was determined by preoperative computed tomographic arthrography and direct arthroscopic evaluation. Functional results showed no significant differences between groups. For both groups the mean Constant score improved from 46.3 ± 11.9 points preoperatively to 66.5 ± 16.3 points postoperatively (P < 0.001). From the 72 patients treated with either tenotomy or tenodesis of the biceps tendon, stage 2-3 Goutallier FI of the infraspinatus tendon was described in 51% (n = 37) (stage 2: 29% (n = 21); stage 3: 22% (n = 16)) and FI of the subscapularis tendon in 40% (n = 29) (stage 2: 32% (n = 23); stage 3: 8% n = 6)). The extend of FI for the supraspinatus tendon was not specified. Functional results for these subgroups were not available.[5]

1.4 Lattisimus dorsi transfer

Scrutinizing the stages of FI of interest in the study by Warner et al.[44], functional outcome decreases with the severity of FI. For the 6 patients with stage 2 FI, the mean Constant score was 69% (range 48%-75%). In contrast, the 8 patients with stage 3 FI achieved a mean Constant score of 52% (range 38%-68%). Differences in functional outcome between stage 2 and stage 3 FI were statistically significant (P < 0.05).[44]

1.5 Arthroplasty (reverse and anatomic total shoulder replacement)

One article, by Wiater et al.[45], regarded reversed total shoulder arthroplasty. They studied the association between deltoid and rotator cuff muscle FI and clinical outcome. Quantitative fatty infiltration of the infraspinatus (30.47% ± 15.01% (range: 0-100%)) was correlated with decreased postoperative external rotation (P = 0.037). Correlation with increased level of supraspinatus fatty infiltration, which was found to have the highest degree of fatty infiltration, and functional impairment was not found.[45]

For anatomic total shoulder arthroplasty the condition of the supraspinatus tendon is paramount. Lapner et al.[22] described a negative association between a preoperatively greater supraspinatus percent of FI with preoperative shoulder strength (P = 0.001) and Constant score (P = 0.001). The postoperative infraspinatus percent of FI was negatively associated with postoperative strength (P = 0.021) and Constant score (P = 0.04). Multivariable regression analysis of possible predictive factors demonstrated that preoperative supraspinatus percent muscle area (P = 0.016) was associated with better follow-up Constant score, and preoperative supraspinatus strength was associated with postoperative strength (P = 0.002). Higher degrees of preoperative percent of FI were not associated with worse patient-reported outcomes postoperatively.[22] From the total study population stage 2-3 Goutallier FI of supraspinatus tendon was represented in 35% (stage 2: 32% (n = 21); stage 3: 3% (n = 2)). Results were not specified for each stage of FI separately.

Table 2. Results (possible treatment options, randomized and non-randomized studies)

Study	Study design	Treatment	Comparison	Sample size
Boileau et al. 2007	Cohort	Bicepstenotomy/ Bicepstenodesis	Tenotomy vs. Tenodesis	72
Bryant et al. 2016	RCT	Cuff repair	Repair alone vs. repair and augmentationporcine small intestine submucosa (SIS)	62
Cho et al. 2009	Prognostic	Cuff repair	Intact vs. Retear	169
Cho et al. 2010	Cohort	Cuff repair	Single vs. double row	64
Choi et al. 2014	Prognostic	Cuff repair	/	147
Chung et al. 2013	Prognostic	Cuff repair	/	288
Chung et al. 2013	Prognostic	Cuff repair	Intact vs. retear	108
Fuchs et al. 2006	Prognostic	Cuff repair (open)	/	32
Grasso et al. 2009	RCT	Cuff repair	Single vs. double row	72
Iannotti et al. 2013	Prognostic	Cuff repair	Intact vs. Retear	113
Kim et al. 2012	Prognostic	Cuff repair	Intact vs. Retear	66
Kukkonen et al. 2015	RCT	Cuff repair/ conservative/ acromioplasty	1. Conservative 2. Acromioplasty 3. Cuff repair	180

	Age at surgery	Length of follow-up (months)	Functional outcome (mean CMS and DASH score)	Retear rate	Average degree of FI	% stage 2-3 Goutallier	
						2	3
	Tenotomy: 73.1 ± 6.2 Tenodesis: 69.8 ± 6.4	35 ± 7	*CMS:* Overall: 66.5 ± 16.3	/	ISP 2.33	29	22
	56.6 ± 10.8	24	*CMS:* SIS: 79.3 ± 3.5 No SIS: 87.5 ± 3.7	60%	SSP: 1.5	61	3
	Intact 53.2 (38-67) Retear 58.4 (45-74)	39 (24-83)	/	22.5%	/	10	8
	Single: 58.1 ± 6.07 Double: 57.6 ± 10.39	7.5 (3-29)	*CMS:* Single: 77.4 Double: 76.2	39%	/	7	63
	62.8 (46-79)	23.4 (12-48)	*CMS:* 84.3 (11-100)	17.0%	SSP: 2.22	46	27
	59.53 ± 8.41	13.5 ± 2.7	/	22.9%	SSP: 2.35 ± 1.05	/	/
	63.7 ± 6.4	31.7 ± 15.8	*CMS:* Intact: 77.1 ± 32.9 Retear: 67.2 ± 27.2 (NS)	39.8%	SSP: 3.13 Intact: 2.84 Retear: 3.55	/	/
	59.0 (40-75)	38 (24-53)	*CMS:* 78.1	13%	SSP: Intact: 0.8 Retear: 1.0	/	/
	Single: 58.3 ± 10.3 Double: 55.2 ± 6.5	24.8 ± 1.4	*See table 3*	/	/	39	24
	Intact: 58.6 ± 9.4 Retear: 59.1 ± 9.09	12	/	17%	Intact: 2.13± 0.65 Retear: 2.39 ± 0.76	9	0
	61.2 (50-75)	23.5 (15-38)	*CMS:* Intact: 78.5 Retear: 70.6	42.4%	SSP: Intact: 1.74 ± 0.92 Retear 2.54 ± 0.84	/	/
	Conservative: 64 ± 5.6 Acromioplasty: 65 ± 5.1 Cuff repair 65 ± 5.8	24	CMS improvement: 1. 18.4 (14.2 -22.6) 2. 20.5 (16.4 - 24.6) 3. 22.6 (18.4 - 26.8) (p = 0.38)	31% cuff repair group	/	1. 32 (53%) 2. 29 (48%) 3. 30 (53%)	1. 1 (2%) 2. 5 (8%) 3. 2 (4%)

Table 2. Results (possible treatment options, randomized and non-randomized studies) (*continued*)

Study	Study design	Treatment	Comparison	Sample size
Lapner et al. 2014	Prognostic	Anatomic total shoulder	/	62
Mellado et al. 2005	Prognostic	Partial and complete cuff repair (open)	/	6 vs. 22
Milano et al. 2010	RCT	Cuff repair	Bio vs. metal anchors	110
Milano et al. 2007	RCT	Cuff repair	+/- subacromial decompression	80
Milano et al. 2013	RCT	Cuff repair	+/- Microfracture	80
Moraiti et al. 2014	Cohort	Cuff repair	Over 70 vs. under 50 years old	80
Nich et al. 2009	Prognostic	Cuff repair (open)	/	47
Oh et al. 2011	Cohort	Cuff repair	non-pseudoparalytic vs. pseudoparalytic	58
Park et al. 2008	Cohort	Cuff repair	Single vs. double row	78
Park et al. 2015	Prognostic	Cuff repair	Intact vs. retear	339

Age at surgery	Length of follow-up (months)	Functional outcome (mean CMS and DASH score)	Retear rate	Average degree of FI	% stage 2-3 Goutallier	
					2	3
67 (34-90)	12	/	/	SSP 1.41	34	3
59.8 ± 6.8	44.4 (13-96)	/	68%	SSP: 1.52 ± 0.8	/	/
Bio: 62.8 ± 7.9 Metal: 60.4 ± 8.6	24.4 ± 2.6	*See table 3*	/	/	34	29
61 ± 7.0 59.7 ± 9.7	24	*See table 3*	/	/	38	25
Microfracture 63.1 ± 9.2 Standard repair 60.6 ± 10.1	28.1 ± 3	*CMS:* Microfracture: 92.7 ±16.7 Standard repair: 94.5 ± 14 *DASH:* Microfracture: 28.6 ± 21.3 Standard repair: 23.3 ± 20.1	/	SSP: 1.97	34	25
/	> 70 yrs 13.8 <50 yrs 12.9	*CMS:* > 70 yrs 74.6_12.02 < 50 yrs 77.18_11.02	/	SSP: > 70 yrs 1.90 < 50 yrs 0.81	30	11
59	87 (60-133)	*CMS:* 73.7	12%	SSP: 0.81	/	/
Pseudo 64.6 ± 9.5 Non-pseudo 65.3 ± 7.0	30.5 ± 18.1 (12-72)	*CMS:* Pseudo: 53.2 ± 18.5 Non-pseudo: 79.0 ± 56.0	Healing rate: 33.3% in the pseudo-paralytic 47.4% in the non-pseu-doparalytic group	/	7	31
55.8	25.1 (22-30)	*CMS:* Single row: 76.68 ± 8.56 Double row: 79.66 ± 4.52	/	SSP: Single row 1.70 ± 1.07 Double row 1.95 ± 1.33	/	/
59.8 ± 7.9	20.8 (22-66)	*CMS:* Overall: 67.1 ± 12.2 (NS between groups)	13.3%	SSP: 1.91 ± 0.82	/	/

Table 2. Results (possible treatment options, randomized and non-randomized studies) (*continued*)

Study	Study design	Treatment	Comparison	Sample size
Ryu et al. 2015	Cohort	Cuff repair	Conventional vs. modified suture-bridge	71
Shin et al. 2016	Cohort	Cuff repair	Small vs. medium vs. large size tears	164
Van der Zwaal et al. 2012	RCT	Cuff repair	Arthroscopic (AA) vs. mini-open (MO)	100
Warner et al. 2001	Cohort	Latissimus dorsi transfer	Primary vs. revision	6 vs. 16
Wiater et al. 2014	Prognostic	Reverse total shoulder	/	30
Zumstein et al. 2008	Prognostic	Cuff repair (open)	/	27

Abbreviations: SSP: supraspinatus tendon; SSC: Subscapularis; ISP: infraspinatus; SIS: small intestine submucosa; yrs: years; +/- microfracturing: with or without microfracturing; +/- subacromial decompression: with or without subacromial decompression

* Tenosan: arginine L-alpha-ketoglutarate, methylsulfonylmethane, hydrolyzed type I collagen and bromelain

	Age at surgery	Length of follow-up (months)	Functional outcome (mean CMS and DASH score)	Retear rate	Average degree of FI	% stage 2-3 Goutallier	
						2	3
	Conventional 57.0 ± 4.4 Modified 57.6 ± 4.6	Conventional 58 (44-77) Modified 26 (15-35)	*CMS:* Conventional 73.4 ± 10.3 Modified 77.0 ± 9.8	15%	SSP: 0.34	/	/
	55.2 ± 9	24	*CMS:* No significant difference between groups	Exclusion criteria		3	0
	AA 57.2 ± 8.0 MO 57.8 ± 7.9	12	*CMS:* AA 66 (1.6) MO 62 (1.6) *DASH:* AA 65.6 (60.8-70.5) MO 69.1 (64.3-73.9)	13-17%	/	16	0
	Primary 62 (38-78) Revision 56 (26-75)	25 (18-31)	*CMS (age/gender adjusted):* Primary 69% (58-81) Revision 52% (37-75)	36%	SSP 3.09	27	36
	71 ± 10	30 ± 7	*CMS:* 67.27 ± 13.07	/	SSP 3.1	7	20
	53.7	9.9 years	*CMS:* Overall: 71 Intact 81 Retear: 64	57%	SSP: Intact: 1.5 Retear: 1.5	/	/

1.6 Conservative treatment

Kukkonen et al. performed a methodological high quality randomized controlled trial in which they compared three type of treatments (physiotherapy-only, acromioplasty and physiotherapy, rotator cuff repair combined with acromioplasty and physiotherapy). Population characteristics were, mean age 65 years (55-81) with a full-thickness supraspinatus tear on MRI with the absence of pseudoparalysis and 51% stage 2 and 5% stage 3 Goutallier FI. There were no significant differences in baseline and in outcome (VAS pain, Constant score, range of motion) up to 2 years after surgery. They did not specify outcome for stage of FI separately.

Table 2 presents the characteristics and reported outcomes of the included studies.

2. RESULTS ON FUNCTIONAL OUTCOME RELATED TO FATTY INFILTRATION

2.1 Characteristics of included studies

Table 3 presents the outcomes of the included studies. Only randomized studies are presented to answer the second research question of which only three described the functional outcome for each stage of fatty infiltration separately (Milano et al. 2010, Grasso et al. 2009, Milano et al. 2007).[16,27,28]

Table 3. Functional results stage 2-3 fatty infiltration.

	Sample size	Treatment	Age	Length of follow-up	Outcome parameter	Stage Goutallier fatty infiltration (n)	
						2	3
Milano et al. 2010[23]	101	Bio vs. metal anchors	61.6 ± 8.3	24.4 ± 2.6		(n=34)	(n=29)
					Constant*	104.4 ± 12.5	91.3 ± 25.3
					DASH	14.6 ± 14.1	28.9 ± 19.4
Grasso et al. 2009[13]	72	Single vs. double row	56.8 ± 8.7	24.8 ± 1.4		(n=28)	(n=17)
					Constant*	102.7 ± 24	106.4 ± 14.9
					DASH	14.5 ± 13.8	14.1 ± 13
					Strength (lb)	12.6 ± 6.6	12.8 ± 5.5
Milano et al. 2007[24]	71	+/-subacromial decompression	Group 1 61 ± 7.0	24		(n=27)	(n=18)
					Constant*	103.6 ± 12.2	94.2 ± 21.2
			Group 2 59.7 ± 9.7		DASH	18.1 ± 15.5	23.6 ± 20.1

*age and gender adjusted Constant score

2.2 Results of included studies

The included randomized studies all reported shoulder-specific physical function.[16,27,28] They all used the age and gender adjusted Constant score and DASH score. Table 3 presents the functional outcome for stage 2 and 3 of fatty infiltration separately. Milano et al. 2010[27] compared the clinical outcome of arthroscopic cuff repair with metal and biodegradable suture anchors. Functional outcome (DASH and Constant score) was significantly influenced by the level of FI after a mean follow-up of 24.4 ± 2.6 months. Functional outcome was significantly better for stage 2 FI of the supraspinatus tendon compared to stage 3 FI.[27] Grasso et al.[16] compared the clinical outcome of arthroscopic rotator cuff repair with single-row and double-row techniques in which no significant difference was found between the stage of FI and clinical results. Milano et al. 2007[28] compared the clinical outcome of arthroscopic cuff repair with and without subacromial decompression. Functional outcome and quality of life after 2 years was significantly influenced by the level of FI. The subitem Work-DASH score was significantly better for stage 2 FI of the supraspinatus tendon compared to stage 3 FI. The general DASH and Constant score were not significantly influenced by the level of FI.

DISCUSSION

The aim of this study was to perform a systematic literature review to outline the treatment options for stage 2-3 Goutallier fatty degenerated rotator cuff tears and their outcome and to give a recommendation of the optimal treatment within this specific subgroup. Currently, the appropriate treatment for stage 2 and 3 fatty infiltrated cuff tears (25-50% FI) is still under discussion. To answer our first question on treatment options for Goutallier 2-3 rotator cuff tears we included 28 studies on arthroscopic cuff repair, partial cuff repair, bicepstenotomy or -tenodesis, lattisimus dorsi transfer, arthroplasty and conservative treatment. [4,6,8-13,16,17,19,21,22,25,27-34,36,40,42,44-46] For the first research question on functional outcome, describing the functional results of each stage of fatty infiltration separately, only randomized studies were included which implicated three studies on rotator cuff repair.[16,27,28]

Considering the first research question most studies consisted of mixed and heterogeneous data, which made it difficult to compare their clinical outcome. Additionally, most studies presented an average degree of fatty infiltration for their study population with a clinical outcome in terms of means, while we were also in search of the clinical outcome for each subgroup of fatty infiltration separately. There were three well designed RCT's by Milano and Grasso et al. [16,27,28] describing these results. Milano et al.[27,28] showed that functional outcome was significantly influenced by the level of fatty infiltration using a

multivariate regression analysis. Grasso et al.[16] showed that functional outcome was not influenced by the level of fatty infiltration. Besides FI, age was the only other significant prognostic factor determining functional outcome. [16,27,28] Unfortunately they did not report integrity of the repaired tendons at follow-up. Recurrent tearing is not uncommon amongst the degenerative rotator cuff tendons, which surprisingly not always results in deterioration of functional outcome. Interestingly, 46% underwent additional tenotomy or tenodesis of the long head of the biceps tendon, which did not result in a significant difference in functional outcome as compared with an untreated biceps tendon. Although this did not result in increased functional improvement, an isolated tenotomy or tenodesis is suggested to give comparable results from at least stage 2 FI as shown by Boileau et al.[5] The other included non-randomized studies did not show a linear correlation between the level of fatty infiltration and functional outcome neither with the retear rate. Additionally, the length of follow-up amongst all included studies was not associated with increased retear rate. Again, included studies were very heterogeneous which makes it difficult to draw conclusions based on these data. Recently, Jacquot et al.[18] compared acromioplasty and bicepstenotomy with or without arthroscopic rotator cuff repair amongst patients older than 60 years of age. They found arthroscopic rotator cuff repair functionally superior to only performing a subacromial decompression and additional bicepstenotomy with a mean follow-up of 4 years. However, they excluded stage 3 and 4 Goutallier FI and did not mention the average degree of FI for their study groups which is, based on previous literature, the most important prognostic factor. This suggested they included patients with relatively good quality of their rotator cuff tendons for which cuff repair is known to be superior as compared to subacromial decompression in combination with a bicepstenotomy.

Only one article was included describing the results of partial cuff repair. Mellado et al.[25] included 6 patients with massive rotator cuff tears and reported good results. The small sample size and retrospectively design makes it difficult to draw conclusions. In contrary, Berth et al.[3], which was excluded due to methodological poor quality, prospectively included 42 patients and compared debridement with partial cuff repair. The study population had Goutallier stage 3 (n = 35) and 4 (n = 7) fatty infiltration. After a mean follow-up of 24 2 months both groups had similar pain relief and level of satisfaction (DASH). Regardless of high rates of structural failure of the partial rotator cuff repair, the results of arthroscopic partial rotator cuff repair demonstrated only slightly better functional outcome than debridement.[3] One should realize that performing a partial repair entails higher costs and longer period of patient recovery compared to only a debridement.

In case of subscapularis insufficiency latissimus dorsi transfer could be indicated. As shown in the included study by Wiater et al.[45] functional outcome is worse when the level of fatty infiltration increases. However, acceptable results are described even in case of increased fatty infiltration of the affected cuff.[45] In case of posterosuperior cuff deficiency and low degree of fatty infiltration of the infraspinatus tendon, latissimus dorsi transfer could also be combined with reverse total shoulder arthroplasty.[39]

The role of conservative treatment in degenerative non-traumatic tears has not been studied widely. The included study by Kukkonen et al.[21] suggest that in the absence of functional disability preoperatively, physiotherapy alone could be a good alternative treatment as compared to rotator cuff repair and acromioplasty. Unfortunately they did not specify their outcome for the stages of FI separately, although more than 50% had Goutallier stage 2 FI.

Based on the results from this systematic performed review, in which we scrutinized treatment options and clinical outcome for stage 2-3 Goutallier fatty infiltrated rotator cuff tears, we could recommend for this specific subgroup conservative treatment, partial repair and isolated bicepstenotomy or –tenodesis as appropriate alternative for rotator cuff repair with comparable results. The conservative treatment and isolated bicepstonotomy or –tenodesis are less extensive and with comparable results might be cost-effective (shorter duration of surgery, faster recovery and less absenteeism). RCT's are needed to observe the additional effect of rotator cuff repair compared to the less extensive treatment options like an isolated bicepstenotomy or tenodesis.

CONCLUSION

Our aim was to review the published literature optional treatments on stage 2-3 Goutallier fatty infiltrated rotator cuff tears describing the clinical results and to give a recommendation for optimal treatment within this subgroup. Despite the high reported retear rate, clinical improvement after rotator cuff repair is reported. Comparable results are reported after conservative treatment, partial repair and isolated bicepstenotomy or tenodesis. Amongst patients undergoing reverse total shoulder arthroplasty the level of supraspinatus fatty infiltration seems not to influence the outcome where in anatomic total shoulder arthroplasty it does. In conclusion, conservative treatment, partial repair, isolated bicepstenotomy and tenodesis seem good treatment options in patients with stage 2-3 Goutallier fatty infiltrated rotator cuff tears.

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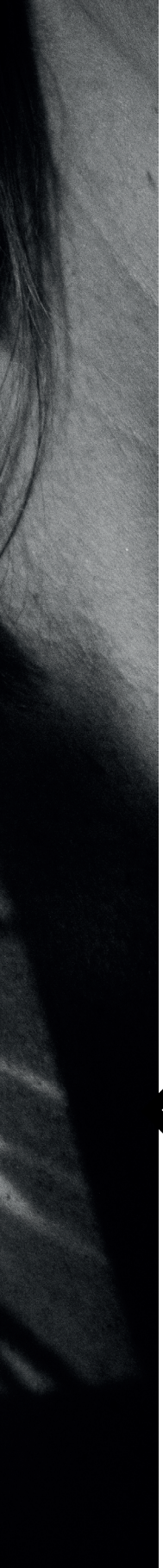
Appendix 1. Search strategy

Search pubmed **12-01-2015** **1072 hits**	((english[la] OR dutch[la] OR german[la] OR french[la]) NOT (animals[mesh] NOT humans[mesh])) AND ((massive[tiab] OR major[tiab] OR large[tiab] OR fatty infiltrat*[tiab] OR FI[tiab] OR fatty degenerat*[tiab] OR goutallier[tiab] OR thickness*[tiab]) AND ("Rotator Cuff"[Mesh] OR rotator cuff[tiab] OR cuff injur*[tiab] OR cuff lesion*[tiab] OR cuff rupture*[tiab] OR cuff tendon defect*[tiab] OR cuff tear*[tiab]) AND (conservative*[tiab] OR non operative[tiab] OR nonoperative[tiab] OR non-operative[tiab] OR nonsurgical[tiab] OR non surgical[tiab] OR no operative[tiab] OR no surger*[tiab] OR cuff repair*[tiab] OR cuff tear reconstruction*[tiab] OR cuff tear surger*[tiab] OR cuff technique*[tiab] OR cuff tendon repair*[tiab] OR "Tenotomy"[Mesh] OR tenotom*[tiab] OR bicepstenotom*[tiab] OR "Tenodesis"[Mesh] OR tenodes*[tiab] OR bicepstenodes*[tiab] OR acromioplast*[tiab] OR "Debridement"[Mesh] OR debridement*[tiab] OR "Arthroplasty"[Mesh] OR arthroplast*[tiab] OR prosthes*[tiab] OR reversed[tiab] OR "Tendon Transfer"[Mesh] OR tendon transfer*[tiab] OR latissimus[tiab])) (1995-2015) The following terms were not found in PubMed: bicepstenotom*[tiab], bicepstenodes*[tiab].
Search Embase **12-01-2015** **1524 hits**	massive:ab,ti OR major:ab,ti OR large:ab,ti OR 'fatty infiltration':ab,ti OR fi:ab,ti OR 'fatty degeneration':ab,ti OR goutallier:ab,ti OR thickness*:ab,ti AND ('rotator cuff'/exp OR 'rotator cuff':ab,ti OR 'cuff injury':ab,ti OR 'cuff injuries':ab,ti OR 'cuff lesion':ab,ti OR 'cuff lesions':ab,ti OR 'cuff rupture':ab,ti OR 'cuff ruptures':ab,ti OR 'cuff tendon defect':ab,ti OR 'cuff tendon defects':ab,ti OR 'cuff tear':ab,ti OR 'cuff tears':ab,ti) AND ('conservative treatment'/exp OR conservative*:ab,ti OR nonoperative:ab,ti OR 'non operative':ab,ti OR nonsurgical:ab,ti OR 'non surgical':ab,ti OR 'no operative':ab,ti OR 'no surgery':ab,ti OR 'cuff repair':ab,ti OR 'cuff tear reconstruction':ab,ti OR 'cuff tear reconstructions':ab,ti OR 'cuff tear surgery':ab,ti OR 'cuff tear surgeries':ab,ti OR (cuff:ab,ti AND technique*:ab,ti) OR (cuff:ab,ti AND tendon:ab,ti AND repair*:ab,ti) OR 'tenotomy'/exp OR tenotom*:ab,ti OR bicepstenotom*:ab,ti OR 'tenodesis'/exp OR tenodes*:ab,ti OR bicepstenodes*:ab,ti OR acromioplast*:ab,ti OR 'arthroscopic debridement'/exp OR debridement*:ab,ti OR 'arthroplasty'/exp OR arthroplast*:ab,ti OR prosthes*:ab,ti OR reversed:ab,ti OR 'tendon transfer'/exp OR 'tendon transfer':ab,ti OR latissimus:ab,ti) NOT ('animal'/exp NOT 'human'/exp) AND ([dutch]/lim OR [english]/lim OR [french]/lim OR [german]/lim) AND [1995-2015]/py
Search Cochrane **147 hits**	((massive or major or large or fatty infiltrat* or FI or fatty degenerat* or goutallier or thickness*) and (Rotator Cuff or cuff injur* or cuff lesion* or cuff rupture* or cuff tendon defect* or cuff tear*) and (conservative* or non operative or nonoperative or non-operative or nonsurgical or non surgical or no operative or no surger* or cuff repair* or cuff tear reconstruction* or cuff tear surger* or cuff technique* or cuff tendon repair* or tenotom* or bicepstenotom* or tenodes* or bicepstenodes* or acromioplast* or debridement* or arthroplast* or prosthes* or reversed or tendon transfer* or latissimus)) (in title abstract keywords)

Search pubmed **12-12-2016** **300 hits**	((english[la] OR dutch[la] OR german[la] OR french[la]) NOT (animals[mesh] NOT humans[mesh])) AND ((massive[tiab] OR major[tiab] OR large[tiab] OR fatty infiltrat*[tiab] OR FI[tiab] OR fatty degenerat*[tiab] OR goutallier[tiab] OR thickness*[tiab]) AND ("Rotator Cuff"[Mesh] OR rotator cuff[tiab] OR cuff injur*[tiab] OR cuff lesion*[tiab] OR cuff rupture*[tiab] OR cuff tendon defect*[tiab] OR cuff tear*[tiab]) AND (conservative*[tiab] OR non operative[tiab] OR nonoperative[tiab] OR non-operative[tiab] OR nonsurgical[tiab] OR non surgical[tiab] OR no operative[tiab] OR no surger*[tiab] OR cuff repair*[tiab] OR cuff tear reconstruction*[tiab] OR cuff tear surger*[tiab] OR cuff technique*[tiab] OR cuff tendon repair*[tiab] OR "Tenotomy"[Mesh] OR tenotom*[tiab] OR bicepstenotom*[tiab] OR "Tenodesis"[Mesh] OR tenodes*[tiab] OR bicepstenodes*[tiab] OR acromioplast*[tiab] OR "Debridement"[Mesh] OR debridement*[tiab] OR "Arthroplasty"[Mesh] OR arthroplast*[tiab] OR prosthes*[tiab] OR reversed[tiab] OR "Tendon Transfer"[Mesh] OR tendon transfer*[tiab] OR latissimus[tiab])) **AND 2015/01:2017/01[crdt]**
Search Embase **12-12-2016** **435 hits**	massive:ab,ti OR major:ab,ti OR large:ab,ti OR 'fatty infiltration':ab,ti OR fi:ab,ti OR 'fatty degeneration':ab,ti OR goutallier:ab,ti OR thickness*:ab,ti AND ('rotator cuff'/exp OR 'rotator cuff':ab,ti OR 'cuff injury':ab,ti OR 'cuff injuries':ab,ti OR 'cuff lesion':ab,ti OR 'cuff lesions':ab,ti OR 'cuff rupture':ab,ti OR 'cuff ruptures':ab,ti OR 'cuff tendon defect':ab,ti OR 'cuff tendon defects':ab,ti OR 'cuff tear':ab,ti OR 'cuff tears':ab,ti) AND ('conservative treatment'/exp OR conservative*:ab,ti OR nonoperative:ab,ti OR 'non operative':ab,ti OR nonsurgical:ab,ti OR 'non surgical':ab,ti OR 'no operative':ab,ti OR 'no surgery':ab,ti OR 'cuff repair':ab,ti OR 'cuff tear reconstruction':ab,ti OR 'cuff tear reconstructions':ab,ti OR 'cuff tear surgery':ab,ti OR 'cuff tear surgeries':ab,ti OR (cuff:ab,ti AND technique*:ab,ti) OR (cuff:ab,ti AND tendon:ab,ti AND repair*:ab,ti) OR 'tenotomy'/exp OR tenotom*:ab,ti OR bicepstenotom*:ab,ti OR 'tenodesis'/exp OR tenodes*:ab,ti OR bicepstenodes*:ab,ti OR acromioplast*:ab,ti OR 'arthroscopic debridement'/exp OR debridement*:ab,ti OR 'arthroplasty'/exp OR arthroplast*:ab,ti OR prosthes*:ab,ti OR reversed:ab,ti OR 'tendon transfer'/exp OR 'tendon transfer':ab,ti OR latissimus:ab,ti) NOT ('animal'/exp NOT 'human'/exp) AND ([dutch]/lim OR [english]/lim OR [french]/lim OR [german]/lim) AND [1-1-2015]/sd
Search Cochrane **12-12-2016** **98 hits**	((massive or major or large or fatty infiltrat* or FI or fatty degenerat* or goutallier or thickness*) and (Rotator Cuff or cuff injur* or cuff lesion* or cuff rupture* or cuff tendon defect* or cuff tear*) and (conservative* or non operative or nonoperative or non-operative or nonsurgical or non surgical or no operative or no surger* or cuff repair* or cuff tear reconstruction* or cuff tear surger* or cuff technique* or cuff tendon repair* or tenotom* or bicepstenotom* or tenodes* or bicepstenodes* or acromioplast* or debridement* or arthroplast* or prosthes* or reversed or tendon transfer* or latissimus)) (in title abstract keywords) Publication Year from 2015, in Cochrane Reviews (Reviews and Protocols), Other Reviews, Trials, Methods Studies, Technology Assessments, Economic Evaluations and Cochrane Groups

Total hits:

- Pubmed: 1372
- Embase: 1959
- Cochrane: 245



3

Structural abnormalities on MRI in patients aged 45 years or younger with atraumatic shoulder complaints.

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Submitted for publication

4.1

Abduction Brace Versus Antirotation Sling After Arthroscopic Cuff Repair: The Effects on Pain and Function.

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ABSTRACT

This randomized controlled trial studied the effects on pain as main outcome parameter and function and cuff integrity as secondary outcome parameters after arthroscopic rotator cuff repair on the short term comparing the abduction brace with an anti-rotation sling for postoperative shoulder immobilization. Eligible patients were between the age of 18 and 75 years, diagnosed with a traumatic or degenerative tear of the supraspinatus and/or infraspinatus tendon, confirmed by Magnetic Resonance Imaging, for which an arthroscopic footprint repair was indicated and performed. Patients were randomly allocated to the anti-rotation sling or abduction brace group. Postoperative pain and use of analgesics were accurately registered up to 3 months after surgery using a patient diary. Follow-up examinations including the Constant Murley score, Western Ontario Rotator Cuff index and glenohumeral range of motion were scheduled 6 weeks, 3 and 6 months and 1 year after surgery. The average level of pain measured directly postoperative up to one year after surgery was not significant different between groups. Postoperatively, function scores and glenohumeral range of motion improved significantly for both groups, however, no differences were observed between groups. There were no retears observed on ultrasound 3 months after surgery. On the short term the level of pain, function and quality of life was not significant different between the use of an abduction brace or anti-rotation sling after arthroscopic rotator cuff repair. Based on these findings, the abduction brace used in this study seems not to be the solution for decreasing pain experienced in the first postoperative weeks after arthroscopic rotator cuff repair and both are recommendable.

INTRODUCTION

Over the last decades the number of arthroscopic rotator cuff repairs (ARCR) has been growing. In more than 90% of the patients with rotator cuff tears ARCR resulted in improved clinical outcome.[3,5,31,32] However, the shifting from open to all-arthroscopic cuff repairs, which should induce less soft-tissue trauma, has not resulted in a decreased level of pain.[22] With the introduction of loco-regional anesthesial techniques the early postoperative pain and administration of opioids has effectively been reduced.[1,4,6,7,23,28] Nevertheless, during the following weeks high levels of pain are still reported.[7,10,12]

From previous literature several factors were identified which may contribute to an increased level of pain. These factors include an additional performed subacromial decompression, pre-existent extensive capsulitis or bursitis, female gender and early work resumption.[3,7,28]

Apart from the characteristics of the rotator cuff tear such as involved tendons, amount of fatty infiltration, retraction and atrophy, the quality of the repair itself is also important to accomplish a successful footprint repair. Reinserting the tendon on its footprint with an increased amount of tension can be challenging. Davidson et al.[10] found that an increased amount of passive tension, measured during surgery, is related to a significant higher level of postoperative experienced pain.[10]

From biomechanical perspectives the amount of tension measured on the rotator cuff tendons is influenced by the position of the shoulder. Subsequently, increased level of tension on repaired rotator cuff tendons is associated with a higher rate of repair failure.[17,18,26,27] Reilly et al.[26] showed in a cadaveric model that this tension can be modified by changing arm positioning. This was *in-vitro* illustrated by Jerosch et al.[18] who observed an increased amount of tension on the supraspinatus tendon with the humerus positioned in adduction. Jackson et al.[17] found an optimal posture of the shoulder, creating less tension on the tendons, when elevating (21-45°) and externally rotating (23-18°) the shoulder joint, which is based on a musculoskeletal model involving the supraspinatus and infraspinatus tendon. While the biomechanical and *in-vitro* studies suggest a role for immobilization in abduction after rotator cuff repair, there is only one non-randomized study investigating the level of pain and function related to the level of external rotation.[8] Furthermore, there is little knowledge about the postoperative course of pain on the short-, and long term after ARCR with accurate documentation of analgesics intake.[8,11,19,21]

This randomized controlled trial studied the effects on pain as main outcome parameter and function and cuff integrity as secondary outcome parameters after ARCR on the short term comparing the abduction brace with an anti-rotation sling for postoperative shoulder immobilization. It is hypothesized that by using the abduction brace there will be less pain on the short term compared to the anti-rotation sling after ARCR.

PATIENTS AND METHODS

Patients were recruited from our Department of Orthopedic Surgery from October 2012 through January 2014. The trial received ethical approval and was recorded in a public trial register (NL41658.100.12). Eligible patients were adults suffering from a traumatic or degenerative full-thickness tear of the supraspinatus and/or infraspinatus tendon, diagnosed by Magnetic Resonance Imaging (MRI), and were unresponsive to at least three months of conservative therapy. Exclusion criteria were: partial thickness tear, revision surgery, rupture of the subscapularis tendon, glenohumeral osteoarthritis, adhesive capsulitis, Body Mass Index (BMI) >35, fibromyalgia, current treatment with opiates, concomitant labral repair, lateral clavicle resection and the inability to complete Dutch questionnaires independently. Perioperative exclusion criteria were irreparable or partially reparable cuff lesions. Patients were informed during consultation and by letter regarding the study protocol and were asked to provide informed consent. Patients were randomly allocated to the treatment arms using block-randomization with a 1:1 ratio with block size 10. Randomization was performed with a random sequence generator (http://www.randomization.com). The surgeon, patient and executive researcher (orthopedic resident) were not blinded to group allocation. Patients were consulted and operated by one of three orthopedic surgeons specialized in arthroscopic shoulder surgery.

Preoperative

The shoulder joint was systematically evaluated by one of the orthopedic surgeons on contrast-enhanced MRI. Preoperative evaluation of imaging was performed by all orthopedic surgeons (J.Z., R.W.) and thereafter by the executive investigator (F.H.) after which consensus was reached on the scored items. Characteristics of the rotator cuff lesion were recorded such as tear size in the sagittal plane (Patte classification[9]), level of retraction (Patte classification[23]) in the coronal plane (stage 1-4), atrophy[30] (stage 1-3) and fatty degeneration (Goutallier classification[14], stage 0-4). All patients had no sign of arthropathy classified according to Hamada[15] (grade 1-5) on an antero-posterior radiograph. Outlet view was obtained for accessing the acromial shape (Bigliani classification[25]). Before surgery, the executive investigator or a physiotherapist, highly experienced in

shoulder pathology, performed thorough shoulder examination. The passive and active glenohumeral range of motion (ROM) was measured using a goniometer. Within the Constant Murley Score, the active range of motion was incorporated. The active range of motion was not measured separately. Subsequently, several questionnaires on shoulder function (Constant Murley Score (CMS)[17]) quality of life (Western Ontario Rotator Cuff (WORC) index[17]; European Quality of life-5 Dimensions (EQ-5D-3L) score) and level of pain (Visual Analogue Scale score 0-100mm (VAS)) were recorded.

Perioperative

In addition to general anesthesia, interscalene nerve blockade was performed in all patients, using 20-30 ml of Chirocaine (0.5%). Patients were placed in beach-chair position with the affected side fixed in a limb positioner (neutral rotation and slight abduction) (Spider, Smith&Nephew). From a posterior portal an arthroscope was inserted. An intra-articular and subacromial diagnostic arthroscopy was performed through the posterior portal. An anterior and a lateral working portal were established. If needed, a third viewing or working portal was added. After diagnostic evaluation and localization of the tear, mobility and need for additional release to establish a footprint repair was evaluated. The footprint was prepared by debridement with a shaver to improve tendon healing after reinserting the tendon. The choice for double or single was made by the surgeon based on their experience. After debridement the size of the lesion was measured in the coronal and sagittal plane using a ruler and classified according to Bateman[2] (grade 1: <1 cm; grade 2: 1-3 cm; grade 3: 3-5 cm; grade 4: >5 cm). The amount of tension required for footprint repair was subjective scored by the orthopedic surgeon and classified into no tension, minimal tension, moderate tension, much tension and severe tension. Following footprint preparation for adequate tendon reinsertion a 2 or 4 threaded SwiveLock anchored double- or single-row suture bridge with FiberTape (Arthrex, Naples, Florida) was created. If the tension was too high or the footprint could not be reached at all, margin convergence was performed by side-to-side stitches before footprint repair was performed.

Postoperative

Directly after surgery an abduction brace (Össur Smartsling, Iceland), with 30-40° of abduction and neutral rotation or anti-rotation sling (DJO Global ProCare Shoulder Sling, United States of America) holding the arm in a neutral level of adduction and internal rotation, was applied. The anti-rotation sling is in our clinic standard care after ARCR. The abduction brace is therefore the experimental treatment. Until this point patients were not informed about the group allocation. Postoperative pain and use of analgesics (Paracetamol, Non-Steroid-Anti-Inflammatory-Drugs (NSAID), morphine (subcutaneous, oral) or Patient-Controlled-Anesthesia (PCA)) were accurately registered up to 3 months

after surgery using a patient diary. Measuring points were: preoperative, twice daily after surgery during the first week, and thereafter weekly up to 3 months. Pain was recorded in rest and during activities.

Physical therapists were given standardized prescriptions outlining the recommended exercises and restrictions associated to each phase of rehabilitation. Physiotherapy was recommended to be twice a week; however, flexibility in the frequency of visits was left to the discretion of the therapist on the basis of individual patient progress. Directly after surgery, patients were instructed to start with pendulum exercises. From the first week after surgery patients started physiotherapy with restricted passive range of motion up to 70 degrees of abduction, 70 degrees of forward elevation and 20 degrees of external rotation in the scapular plane. Subjects were instructed to daily perform home exercises independently in accordance with their stage of rehabilitation. From 6 weeks the immobilization was phased out and (guided) active motion exercises were started. From 3 months on, active motion exercises above shoulder level were allowed. Their adherence to brace or sling use was scored ordinal at six weeks using a 5-points liker scale ranging from totally disagree till totally agree.

After 6 weeks, 3 months, 6 months and one year the patient visited the outpatient orthopedic department for functional assessment and administration of several questionnaires (VAS-pain; CMS; WORC index; passive glenohumeral ROM; patient's satisfaction; EQ-5D-3L). Three months after surgery also ultrasonography was performed by a physiotherapist with extensive experience with ultrasonography of the shoulder joint. Recurrent tears were defined as a distinct hypo-echoic or mixed hyper-echoic and hypo-echoic defect in both transverse and longitudinal planes or when compression on the deltoid muscle with the probe could separate the torn tendon ends.[24]

Sample size

According to the a-priori power analysis using a standard deviation of 20 points, alpha of 0.05, a power (1-β) of 80% and an expected difference between groups of 20 points on the VAS-pain score, 17 patients had to be included in each group.[29] Taking into account 10% dropout, the goal was to include 20 patients per group. All data analyses were performed according to intention-to-treat and conform the pre-established plan in the study-protocol.

Statistics

Statistical analysis was performed using the statistical program SPSS® (Statistical Package for the Social Sciences, Chicago, IL, Version 22.0). The results were considered significant at $P<0.05$. Equal distribution of baseline characteristics was checked using

the Student *t* test for continuous variables and the X^2 test for categorical variables. An additional analysis was performed for potential confounders (gender, performance of an additional subacromial decompression). Repeated-measurement ANOVA was used for the normally distributed pre- and postoperative data and when needed was further analyzed using a Tukey's post hoc test. Linear regression analysis was used to determine statistical correlation between the sling or abduction brace on the pre-established primary (VAS-pain score) and secondary outcome (CMS, WORC index, glenohumeral ROM, patients' satisfaction, EQ-5D-3L and retear rate). Subgroup analysis was done for tear size, surgical techniques, number of anchors, amount of retraction and perioperative subjectively classified mobility of the tendon.

Results

Patients with a suspected full-thickness rotator cuff tear on MRI were screened for eligibility during the period of inclusion. Forty-four consecutively enrolled patients were randomized. After allocation to treatment, eight patients were excluded perioperatively due to a partial-thickness tear (n=1), partially reparable (n=1), irreparable tear (n=3), repair of the subscapularis tendon (n=1) or they withdrew from surgery for personal or medical reasons (n=2) (Figure 1). Thirty-six patients remained for statistical analysis of which twenty patients received the abduction brace and sixteen the anti-rotation sling. Among the brace group there was one patient who postoperatively used the brace as anti-rotation sling (fully adduction). This patient remained in the brace group for analysis. There was no loss to follow-up (Figure 1).

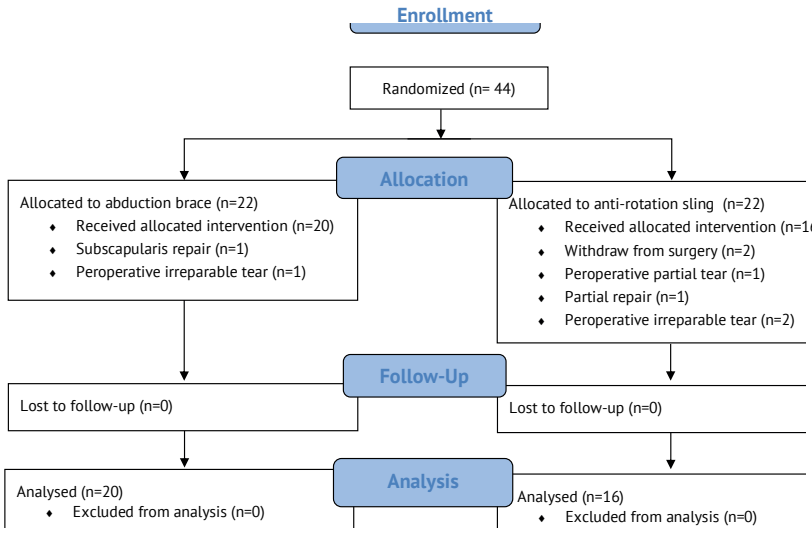

Figure 1. Study Flow Diagram

The mean age was 61.2 years (47-74 years). The dominant arm was affected in 86% of the study population; 50% of patients were right-handed with a mean duration of symptoms before surgery of 16.3 months (1-65). A double-row fixation was performed in 29 cases, single-row in 7 cases. As expected due to randomization, there were no statistically significant differences between groups in any of the measured baseline characteristics. However, there was a significant difference (*P*=0.010) in tear size (Table 1).

Table 1. Comparison between treatment groups for baseline characteristics.

Variable	*Sling (n=16)*	*Brace (n=20)*	*P-value*
Age (years)	62.5 ± 9.76	60.2 ± 6.84	Ns
Gender, M:F	5:11	11:9	Ns
Symptom duration	15.3 ± 12.81	17.1 ± 16.70	Ns
BMI	28.1 ± 4.56	27.0 ± 2.92	Ns
Smoking (n, %)	3 (19)	7 (35)	Ns
Diabetes mellitus	2 (13)	3 (15)	Ns
Nature of tear Traumatic : degenerative	7:9	8:12	Ns
Affected side - Right Dominant : Non-dominant - Left Dominant : Non-dominant	7 6:1 9 7:2	11 10:1 9 8:1	Ns
Preoperative function: Glenohumeral external rotation Glenohumeral abduction Pain (VAS score (0-100)) WORC index Constant score EQ-5D-3L (0-100)	 68.7 ± 16.16 81.3 ± 12.97 40.9 ± 26.30 38.5 ± 21.91 44.2 ± 20.62 76.4 ± 12.97	 65.9 ± 16.29 77.8 ± 15.52 40.6 ± 30.60 42.1 ± 15.46 43.4 ± 13.72 74.7 ± 11.16	Ns
MRI, tear location: Supraspinatus Infraspinatus Supraspinatus + infraspinatus	 14 0 2	 16 0 4	Ns
Supraspinatus Fatty degeneration (0:1:2:3:4) Retraction (1:2:3:4) Atrophy (1:2:3)	 6:9:1:0:0 6:6:2:0	 4:14:2:0:0 7:6:6:1	Ns
Infraspinatus Fatty degeneration (0:1:2:3:4) Atrophy (1:2:3)	 5:11:0:0:0	 7:10:2:0:1	Ns
X-ray characteristics Bigliani (1:2:3) Arthropathy (Hamada: 1:2:3:4:5)	 4:10:2 15:1:0:0:0	 7:10:3 19:1:0:0:0	Ns
Additional procedures: Subacromial decompression Biceps tenotomy Biceps tenodesis	 8 4 2	 9 8 0	Ns

Table 1. Comparison between treatment groups for baseline characteristics. (*continued*)

Variable	*Sling (n=16)*	*Brace (n=20)*	*P-value*
Findings tear:			
Size (Bateman:1-3cm, >3cm, 3-5cm, >5cm)	4:4:7:1	1:13:2:4	Ns
Shape tear			
o Crescent-shaped	10	14	Ns
o L-shaped	2	1	
o U-shaped	2	5	
o Massive	2	0	
Additional side to side, (nr of patients)	3	4	
Mobility cuff, 0-4			
0: no tension	5	3	Ns
1: minimal tension	6	9	
2: moderate tension	3	5	
3: tension	2	2	
4: lot of tension	0	1	
Adherence to therapy:			
o Adherent	15	17	Ns
o Not adherent	1	3	
Level of satisfaction with comfort			
o Satisfied	14	17	Ns
o Not satisfied	2	3	

The mean level of pain increased from a VAS score of 40.7 to 59.9 (*P*=0.003) in the morning on the day after surgery (Figure 2). During the following week after surgery, pain scores progressively decreased to a mean of 25.7 (0.0 - 83.0, SD 25.3; *P*<0.001) (Figure 2).

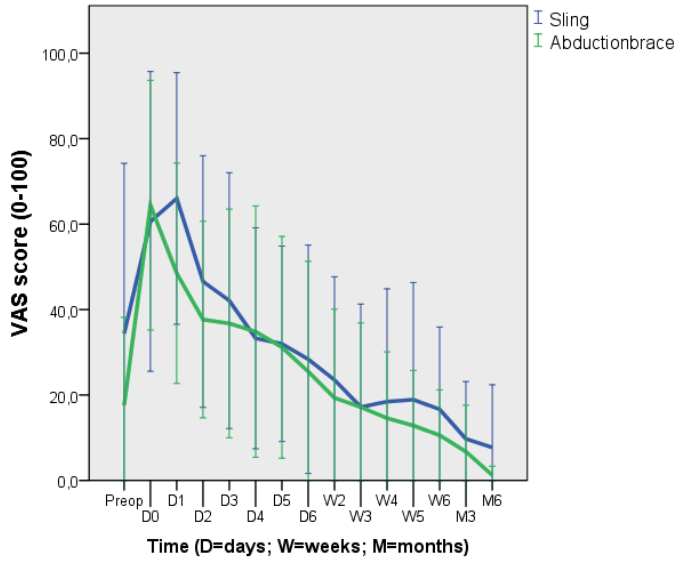

Figure 2. VAS score from patient diary

During follow-up analgesic intake was not found significantly different between groups (Figure 3). A significant improvement in both groups on the CMS and WORC index, as well as the active forward elevation, glenohumeral abduction and external rotation from 6 weeks to 3 months, from 3 to 6 and 6 to 12 months after surgery was observed (P<0.001 for all analysis) (Figure 4-7). No significant differences were found between groups for all post-intervention time points on pain, function and quality of life (Figure 4-7). Additional analyses were performed for tear size, surgical techniques, amount of anchors, amount of retraction and subjectively measured perioperative tension which we found no significant differences between groups on all outcome measurements.

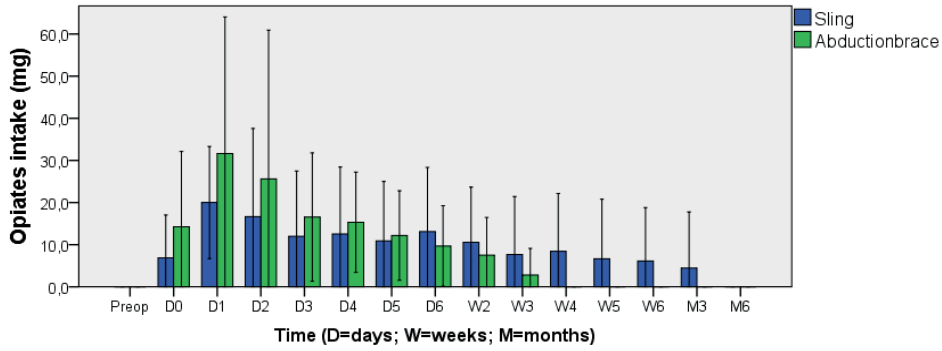

Figure 3. Analgesics intake

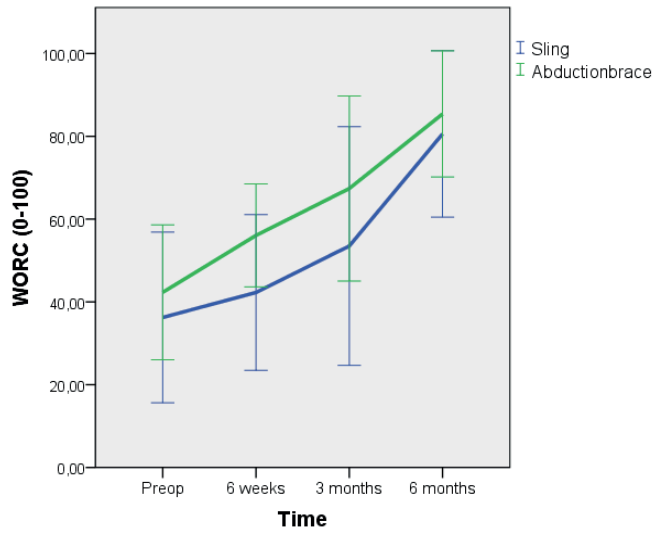

Figure 4. WORC score

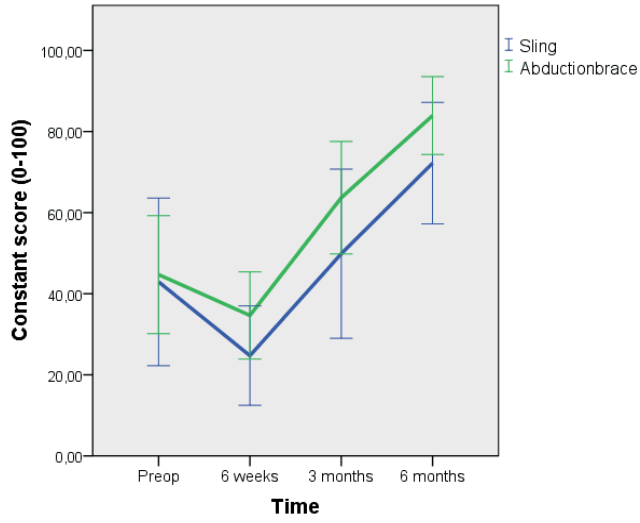

Figure 5. Constant score

When immobilization was phased out, patients were asked about their adherence to therapy. There was no significant difference between carriers of the abduction brace and anti-rotation sling on adherence to therapy during the six weeks of immobilization (Table 1). However, in general adherence to therapy in our population was high (high adherence n=32; low adherence n=4). Abduction brace carriers were less compliant to therapy during the nights due to discomfort. However, this difference was not statistically significant.

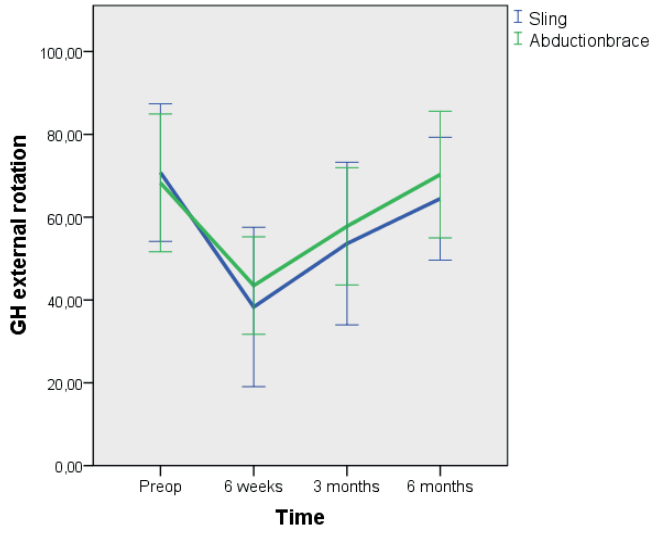

Figure 6. Glenohumeral external rotation

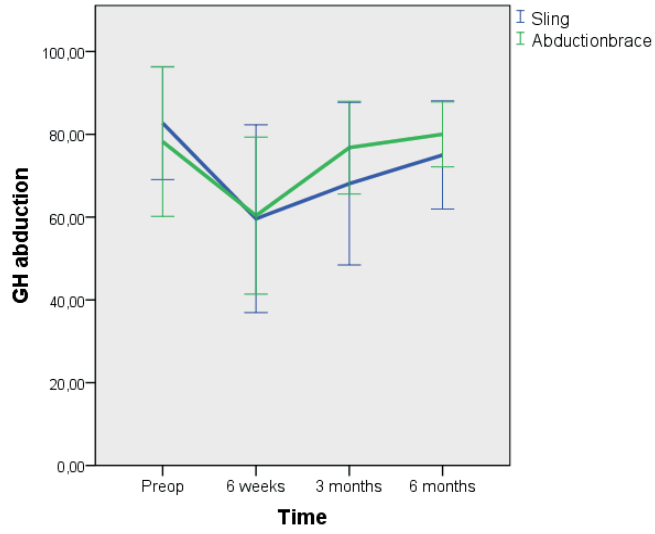

Figure 7. Glenohumeral abduction

The ultrasound at 3 months revealed no retears according to our pre-established definition. There was one patient with loosening of one of the anchors from the medial row without causing tendon discontinuity from only a small area of its footprint. This patient was asymptomatic and had no clinically suspected retear and was therefore left untreated.

After the period of immobilization, 3 patients with an anti-rotation sling and 2 with an abduction brace developed a frozen shoulder for which they followed prolonged physiotherapy surveillance. One patient (anti-rotation sling) received a corticosteroid injection. Six months after surgery all 5 patients regained normal shoulder function. No patients underwent additional surgery during the time frame of the study. Pain records were kept meticulously. Most pain was experienced during the first 24 hours after surgery (Figure 2). From then on the average pain declined and became less than 40 after 3-4 days. At day 4 13 out of 36 patients reported a VAS-pain of 40 or higher, equally divided among groups.

Discussion

No significant differences were found between patients receiving an abduction brace or anti-rotation sling for shoulder immobilization after ARCR with respect to the pre-established primary outcome (pain) and secondary outcome measurements (CMS, WORC index, glenohumeral ROM, patients' satisfaction and EQ-5D-3L).

From biomechanical perspective it was thought that some level of abduction and neutral rotation could reduce tension on the repaired supraspinatus and infraspinatus tendons thereby reducing the postoperative experienced pain. However, in this study no significant clinical benefit was found for abduction brace immobilization. Previously, Davidson et al.[10] studied the postoperative course of pain in relation to the amount of tension acquired for watertight (tendon fully compressed to the footprint without any gap formation between the reinsertion and the tendon) footprint repair. They found that an increased tension to a level of >8 lb was associated with significantly worse results on pain and function (CMS).[10] Perhaps in our study these levels of tension were not high enough to observe any clinical benefit from abduction and neutral rotation. On the other hand, our study population represented a broad range of tension required to accomplish a footprint repair. Although measured subjectively, the amount of tension did not differ between groups. The extent of abduction could be increased which might result in a significant reduction in pain in favor of the abduction brace. Based on the perioperative subjectively measured amount of tension to accomplish a footprint repair no conclusion on the relationship between tension and the postoperative preset outcome measurements could be drawn.

Over time, a diversity of postoperative immobilization techniques, like abduction orthoses and pillows, have been introduced supporting the repaired rotator cuff and several *in-vitro* studies were conducted searching for optimal shoulder posture during immobilization.[17,18,26,27] Firstly, Jackson et al.[17] simulated the optimal shoulder position in a musculoskeletal model for full-thickness tears depending on its location and gap length. Optimal postoperative shoulder posture for tears involving the supraspinatus and infraspinatus tendon was with the humerus elevated between the scapular and coronal plane and neutral or limited internal rotation.[17] Secondly, Jerosch et al.[18] recommended that neutral rotation and at least 30° of abduction is required to obtain a tensionless repair. For tear sizes >2cm, 60° of abduction was recommended.[18] Although we used about 30° of abduction no clinical effect was observed. Additionally, tear size and fixation technique were not correlated with an increased level of pain.

Comparing the level of pain after rotator cuff repair measured to other studies, VAS values remained less than 40 out of 100.[28] This is comparable with our findings with an average pain score of 30 out of 100. Even though the average pain score was under 40 at day 4, 13 out of 36 patients had a VAS score above 40, which is unacceptably high.[13] Placing a perineural catheter connected to elastomeric pump before surgery could prevent a sudden increase in pain by a continuous regulated flow of anesthetics.[11,16,20]

During the period of six weeks of immobilization several patients, equally divided over the groups, were not compliant to therapy (11%). Adherence to therapy for which was corrected during data analysis, had no significant influence on the outcome. Since adherence to therapy was about equal within both groups, the clinical effect of the abduction brace or anti-rotation sling measured was reliable.

This study only focused on supraspinatus tears with or without involvement of the infraspinatus tendon. Therefore, with the shoulder positioned in abduction and neutral rotation, which biomechanically reduces stress on the supraspinatus and infraspinatus tendon, our hypothesis could be appropriately tested.

According to our findings, immobilization in about 30°-40° of abduction does not influence the amount of early postoperative pain. Increased level of abduction might be needed to observe a clinical effect. However, this should be measured out against patient's comfort. Future research could be focused on different degrees of abduction or perhaps abduction does not influence any clinical parameter and a simple cuff and collar will suffice.

Limitations

Despite extensive selection criteria, this study could be limited by its diversity in terms of tear size, origin and number of anchors used to accomplish a footprint repair. This heterogeneity might modify the effect of the treatment on outcomes. However, the selected patient population in an accurate reflection of the patient population in our clinic. Another limitation is the sample size. Due to perioperative exclusion the anti-rotation sling group consisted of 16 patients instead of the a priori calculated 17. Furthermore, a larger difference in pain was expected between groups which should be considered in future studies as it has a great influence on the sample size.

CONCLUSION

On the short term the level of pain, function and quality of life was not significant different between the use of an abduction brace or anti-rotation sling after arthroscopic rotator cuff repair. Based on these findings, the abduction brace used in this study seems not to be the solution for decreasing pain experienced in the first postoperative weeks after arthroscopic rotator cuff repair and both are recommendable.

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4.2

Optimizing postoperative care after rotator cuff repair.

What do we know and understand?

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ABSTRACT

Optimizing the management of rotator cuff tears is still needed. Preoperative patient selection, perioperative surgical techniques and postoperative care are all important topic which are widely studies. This commentary will criticize the current status and important fields of interest for future research. Postoperative pain management is scrutinized in relation to the level of abduction using the abduction brace.

COMMENTARY

Within the last decade rotator cuff repair has evolved from open to arthroscopic surgery and the technique of its repair has been perfectioned. When focusing on the reparable rotator cuff tears we could conclude the perioperative care has reached excellence. We are performing the repair by a minimal invasive approach, using extensively discussed and studied fixation techniques. One should question if there are hiatus in the surgical technique which could lead to clinically relevant improvement. Although, optimizing the selection of appropriate candidates for rotator cuff repair is still needed.[3] The postoperative care however is an upcoming field of interest. For example, the search for adequate postoperative pain management and the described 'pain bounce' on the day after surgery which is intercepted with opiates and perineural catheters.[4,7] One should realize early return to daily living activities and work is a relevant and clinically important. In addition, participation in society has a major influence on Quality of Life experience. Furthermore, there have been several devices introduced for postoperative immobilization which vary within the amount of external rotation and abduction.[1,6,8-11] There seems to be a strong believe that the amount of tension on the performed repair could influence the level of pain experienced postoperatively. The length and technique of immobilization described varies widely and might influence this return.

Scrutinizing the immobilization techniques and strategies after rotator cuff repair in literature, it appeared to have been a 'popular' field of interest over the last years. We are still struggling with the period of immobilization and whether to allow passive supervised mobilization during the immobilization period in relation to tendon healing.[2,5] No major significant differences amongst these studies were found, additionally results are in my opinion certainly not clinically relevant. These studies focused on early versus conservative mobilization and the use of several levels of abduction during immobilization in relation to pain, function and tendon healing.

Since rotator cuff repair is experienced as very painful during the early postoperative phase, with commonly described retears, it is important to continue within this field of interest to optimize postoperative care. In order to manage this problem, we need to understand the cause of pain and the occurrence of retears. I think this might be multifactorial and dependent on tear characteristics (tear size, tissue quality, duration between trauma and repair, etcetera), repair technique and patient characteristics (behavioral, demographic, psychosocial). Up to date we have only focused on structural and functional aspects and theories. What we should take in consideration as well is to select the appropriate candidates for surgery. Patients adherence to therapy, expectations and coping with pain is underestimated.

Returning to the original motive writing this commentary is a well performed study on immobilization techniques. Ghandour and colleagues elaborately described the effect on pain, strength and function amongst patients with isolated and reparable degenerative rotator cuff tears which were postoperatively randomized for receiving and abduction brace or anti rotation sling (11).[2] Their study was titled: *'Does the type of shoulder brace affect postoperative pain and clinical outcome after arthroscopic rotator cuff repair?'* As mentioned before, and what I missed in this study by Ghandour et al.[2] is the theoretically based and supported theory behind the study. Although, no differences between groups were found, what does this imply? Apparently, within this study, abduction does not result in better outcome concerning pain reduction, function, strength and tendon healing. In our study we found comparable results for traumatic as well as degenerative tears with different repair techniques and tear characteristics. Considering the 'tension theory', I think that if you need that much level of abduction in order to subjectively achieve tendon healing one should not perform a footprint repair. With respect to the reparable tears, abduction is not obligatory during the postoperative period of immobilization.

Therefore, the abduction brace for postoperative immobilization after rotator cuff repair should not be advised to prescribe. An anti-rotation sling is cost-effective and from our study (Hollman et al.[4]) experienced comfortable amongst the participants. I have not used the abduction brace anymore after the results from our study and will continue not the use it for immobilization after the repair of degenerative rotator cuff tears. More importantly is the understanding of the postoperative pain which might be multifactorial could probably be more patient related. The search in understanding postoperative pain continues….

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5

Interchangeability of diverse analog scales used within the Constant-Murley Score.

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ABSTRACT

The purpose was to assess the interchangeability of various existing answering scales within the subjective part of the CMS. In this prospective, single-center, cross-sectional trial, patients with shoulder problems were included from June to September 2018. Subjects recruited were 18 years or older, presented various shoulder complaints e.g. diagnosis of osteoarthritis, Sub-Acromial Pain Syndrome, rotator cuff or biceps tendon problems or frozen shoulder. An extended version of the CMS was prepared including the same questions multiple times but with varying answer scales. Six versions were made with random order of the questions. The answering scales were a verbal and paper based visual analogue scale (VAS), smiley face scale, numeric rating scale (NRS) and categories. Internal consistency of the various CMS, spearman correlation coefficients, intra-observer and inter-observer agreement were assessed (ICC). In total 93 patients were included. The total CMS using the paper based VAS, smiley face score and NRS were 46.9±19.4, 45.2±18.5 and 45.0±18.7. Correlations of the total scores of the different versions varied from 0.98 to 0.99. CMS-category versus CMS-smiley face score and CMS-category versus CMS-NRS pain were significantly different (P=0.02 and P=0.01). Good internal consistency (0.76-0.79) and acceptable inter- and intra-observer reliability was found (ICC: 0.89-0.97, 0.98-0.99; P<0.001). The different answering scales for the subjective subscales within the CMS for pain, work and recreational activity were not interchangeable on item level and significantly influenced the total CMS score. Difference were below the smallest detectable change and interpreted as not clinically relevant. Particularly on item level, data from different studies cannot be pooled and compared when different answering scales are being used. The inter- and intra-observer reliability was excellent.

INTRODUCTION

The Constant-Murley Score (CMS) is a shoulder specific questionnaire, which is used to evaluate shoulder pathology and treatment outcome.[5] The CMS is a combined patient-report and objective (health professional administered) shoulder outcome measure. In 2008 the CMS has officially been updated by the original author.[4] A validated adjustment was made by replacing the categories for pain, work and recreational activities by a visual analogue scale (VAS). In addition, a score modification, adjusting for age and sex, was proposed. Currently, different versions of the CMS are used, namely the original version, the updated version and various mixtures of both. In particular, the subjective part is subject to variation. For these items different measurement scales are used, e.g. different numeric rating scales (NRS), visual analogue scales or the original ordinal structured rating system of the CMS. The reliability and validity of the CMS has been studied extensively with acceptable inter- and intra-observer reliability values. However, because of the variations in application and scoring, the CMS may not be interchangeable across studies.[12-14] This might implicate that comparing results on the CMS between studies should be interpreted with care.

The primary goal of this study was to investigate the interchangeability of the different answering scales of the measures of pain, work and recreational activity used. The secondary aim was to determine the effect of the different answering scales on the inter- and intra-observer reliability. It was hypothesized that the different answering scales of pain, work and recreational activity of the CMS were interchangeable and would not influence the total score. In addition, it was expected the inter- and intra-observer measurement of the different answering scales were reliable.

MATERIALS AND METHODS

This study was a prospective, single-center, cross-sectional study. Ethical approval (XXX) was obtained and subjects were fully informed about the study. All participants signed informed consent. Eligible patients with shoulder problems visiting the orthopaedic outpatient clinic of the St. Antonius Hospital during the period of June to September of 2018 were included. Subjects recruited were 18 years or older, presented various shoulder complaints e.g. diagnosis of osteoarthritis, Sub-Acromial Pain Syndrome (SAPS), rotator cuff or biceps tendon problems or frozen shoulder. Patients with shoulder instability (luxation) or patients that recently (<6 months) underwent surgery on the ipsilateral side (e.g. rotator cuff repair, shoulder prosthesis, osteosynthesis) were

excluded. Subjects with cognitive impairment or insufficient comprehension of the Dutch language were also excluded.

The CMS is a 100-point scoring system that is divided into four subscales: pain (15 points), general daily activities (20 points), range of motion (ROM; 40 points) and strength (25 points). In the original version of CMS the pain score was evaluated in four categories none (15), mild (10), moderate (5) and severe (0). This was replaced in the modified version by a VAS with a sliding cursor.[4] Since the VAS with the sliding cursor that was used by Constant et al., is not widely available it was replaced by a VAS on paper and by a smiley face score with a sliding cursor.[4] For the paper VAS, patients were asked to put a mark on a 15-centimetre line to indicate their pain score.[1] Additionally, the NRS pain (verbal score of 0-10 points, whole numbers) was used. Scores for activities of daily living (work and sports) were recorded using categories, the paper VAS and smiley face scores. To prevent bias due to the question sequence, six versions of the CMS were prepared with random ordering of the answering scales for the measures of pain, work and recreational activity. Therefore, each version contained four different answering scales for pain, three answering scales for daily work and three answering scales for recreational activities. The six versions were randomly allocated to the patients. A working protocol for assessing the CMS was developed and discussed by the observers before the inclusion of the first patient.

During the visit to the clinic, the same compiled CMS was completed twice for both shoulders. For intra-observer measurement it was completed firstly by the researcher before the consultation with the orthopaedic surgeon and secondly after the consultation. The inter-observer reliability was measurement by completion of the CMS during the consultation by the orthopaedic surgeon involved in this study and by the researcher before or after the consultation. To reduce bias, the evaluations of the observers were performed independently in separate rooms.

Statistical analysis

Results were analyzed using SPSS statistical software (IBM SPSS Statistics for Windows, Version 24.0. Armonk, NY: IBM Corp.). Studies determining measurement properties require at least 50 patients.[17] Internal consistency (Cronbach's alpha coefficient) of the CMS was calculated using the various answering scales of pain, work and recreational activity.[2] Spearman correlation coefficients were calculated to examine the convergent validity between the total scores. In addition, paired *t*-tests were used to determine whether the mean differences between the various pain, work and recreational scores could be considered insignificant. In order to assess systematic errors and agreement, Bland-Altman plots were compiled using the mean difference and the Limits of agree-

ment (mean difference ± 1.96 * standard deviation (SD) of the difference). Intraclass and interclass correlation coefficients (ICC) were calculated for intra- and inter-observer reliability (two-way mixed and random effects model, single measurements and consistency). Assessment of both shoulders (affected and non-affected) were used for intra- and inter-reliability only.

RESULTS

A total of 93 patients were assessed for eligibility. One patient was excluded, due to not fully understanding the questionnaires. Of the 92 patients, 37 (40%) were men and the mean age was 58 years (range 36 – 80 years) (Table1). Two patients did not complete the second CMS and 9 patients were infiltrated between the two examinations. Since this intervention could affect the outcome of the CMS these patients were excluded from the intra- and inter-observer analysis. Of these 81 patients there were 3 patients assessed by observer 4. Because of the low number of patients, it was decided to exclude observer 4 from the intra- and inter-observer analyses and did not affect the outcome (Figure 1).

Table 1. Descriptive statistics for demographic and clinical data (n=92)

	Value (N)
Mean age in years ± SD	58 ± 10.4
Gender (male/female)	37 (40%) / 55 (60%)
Dominant side (right/left)	81 / 11
Diagnosis*	
Arthritis	8
SAPS	16
Cuff problems	41
Biceps problems	12
Frozen shoulder	6
Other	32
Most affected shoulder (right/left)	58 (63%)/ 34 (37%)
Dominant shoulder affected	55 (60%)
Both shoulders affected	52 (57%)
Months with shoulder complaints	
≤6 months	31 (34%)
7-11 months	14 (15%)
1-2 years	22 (24%)
>2 years	25 (27%)

* There were 15 patients with multiple shoulder problems.

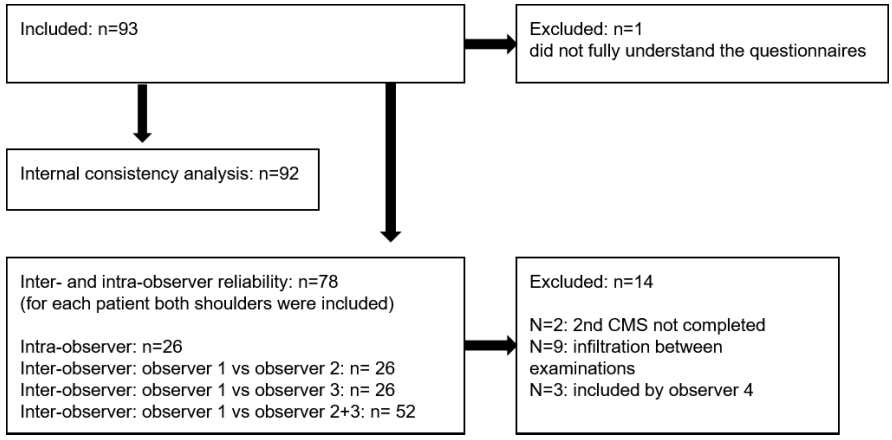

Figure 1. Schematic diagram for the populations that were included in this study.

Constant-Murley total score

The mean (±SD) score of the first assessment for the affected shoulder of the original CMS with pain, work and recreational scores given in categories was 44.2 ± 18.8. The total scores of the CMS using the paper VAS, the smiley face scores and NRS pain were 46.9 ± 19.4, 45.2 ± 18.5 and 45.0 ±18.7, respectively (Table 2). Mean differences for the paper VAS versus the other scores were significantly different (Table 3). In addition, CMS-category versus CMS-smiley face score and CMS-category versus CMS-NRS pain were significantly different (P=0.02; P=0.01). No floor or ceiling effects in total scores were found.

Table 2. Descriptive statistics of the total CMS outcomes for the affected side (n=92)

Measurement	Mean	SD	Minimum	Maximum	Cronbach alpha
CMS-category	44.2	18.8	10.0	88.0	0.78
CMS-paper VAS	46.9	19.4	10.0	95.4	0.79
CMS-smiley face score	45.2	18.5	10.0	89.8	0.76
CMS-NRS pain*	45.0	18.7	10.0	88.5	0.78

*In this version the answering scale for pain was a NRS scale, while for daily work and recreational activities the category scale was used.

Table 3. Paired *t*-tests of mean differences (±SD) of total CMS scores of various answering scales (n=92)

	CMS-category	CMS-paper VAS	CMS-smiley face score
CMS-paper VAS	2.7 (3.5); P<0.001	-	-
CMS-smiley face score	1.0 (4.0); P=0.02	1.7 (4.0); P<0.001	-
CMS-NRS pain*	0.8 (2.9); P=0.01	1.9 (3.3); P<0.001	0.2 (3.8); P=0.6

*In this version the answering scale for pain was a NRS scale, while for daily work and recreational activities the category scale was used.

To determine whether it is possible to convert the continuous outcome scale back to the original category scale, the outcome scores of the categories were compared in box plots with the outcome scores of the continuous data of the paper VAS, smiley face and NRS pain. Table 4 shows that the mean values measured on a continuous scale are increasing with increasing category values. However, the minimum and maximum score show that converting to categorical values cannot be reliable performed, as they overlap multiple categories. Only with regard to the NRS pain scores and the smiley face scores the lowest category (0) and highest (15) category are discriminative (Table 4).

Table 4. Comparison of pain scores completed in categories versus other pain scores of the affected shoulder (n=92).

Categories (points)	N		Mean	SD	Minimum	Maximum
No pain (0 points)	25	Paper VAS	3.4	2.8	0.0	12.3
		Smiley face	2.3	2.8	0.0	9.9
		NRS pain	2.9	1.7	0.0	6.0
Mild (5 points)	46	Paper VAS	7.0	2.5	1.0	11.8
		Smiley face	6.1	2.7	0.0	11.4
		NRS pain	5.6	2.4	1.5	12.0
Moderate (10 points)	17	Paper VAS	11.1	1.8	8.9	14.8
		Smiley face	8.7	2.9	3.6	11.4
		NRS pain	8.5	3.6	1.5	15.0
Severe (15 points)	4	Paper VAS	14.8	0.4	14.2	15.0
		Smiley face	15.0	0.0	15.0	15.0
		NRS pain	14.6	0.8	13.5	15.0

Internal consistency

Cronbach's alpha outcomes showed a good consistency for the various answering scales (range 0.76-0.79) (Table 2). The correlations of total CMS scores using the answering scales varied from 0.98 to 0.99 and were all significant P<0.001 (Table 5). The Bland-Altman plots indicated high levels of agreement and no systematic errors between answering scales. The Bland-Altman plot of the original CMS and the CMS using the paper VAS is presented in Figure 2.

Table 5. Spearman correlation coefficients (r) of total CMS scores using the various answering scales (n=92).

	CMS-category	CMS-paper VAS	CMS-smiley face score
CMS-paper VAS	0.98	-	-
CMS-smiley face score	0.98	0.98	-
CMS-NRS pain	0.99	0.99	0.98

*In this version the answering scale for pain was a NRS scale, while for daily work and recreational activities the category scale was used.

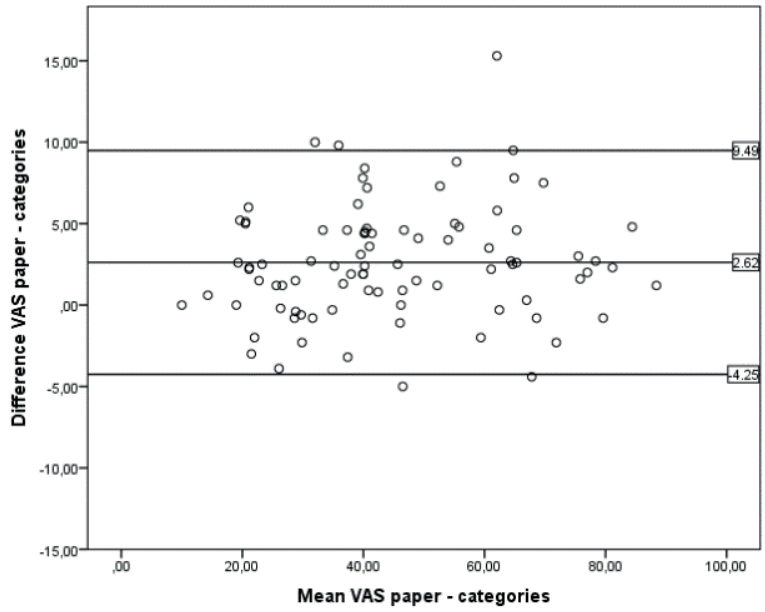

Figure 2. The Bland-Altman plot of the original CMS and the CMS using the paper VAS. The middle line indicates the mean difference of the two measurements (2.62 points). The upper (9.49) and lower (-4.25) lines are the limits of agreement (mean difference ± 1.96 * SD of the difference). Every patient is represented by a circle.

Intra- and inter-observer reliability

For intra-observer reliability there were 26 patients assessed twice by the researcher (observer 1). In this part of the analysis, both shoulders were included resulting in n=52 shoulders. No significant mean difference was found between the first and second examination and high ICC values between 0.98-0.99 (P<0.001). For inter-observer reliability, observers 2 and 3 included 26 patients each. All these patients were also assessed by observer 1, resulting in 52 patients with 104 shoulders for inter-observer reliability (Figure 1). The inter-observer correlation coefficient for the total scores were excellent (range 0.89-0.97) for the various CMS answering scales (P <0.001).

DISCUSSION

The results of this study indicated that different answering scales for the CMS subscales pain, work and recreational activity were not interchangeable. Changing the answering scale had minor, though significant, effect on the CMS total score. Nevertheless, the inter- and intra-observer reliability and correlations using the different answering scales were excellent. In addition, the Cronbach's alpha correlation coefficients of the CMS us-

ing the various answering scores were between 0.76 and 0.79. These small differences indicate that changing the answering scale did not influence the internal consistency of the CMS.

The original CMS measured pain in categories which was changed to a VAS score with a sliding cursor for pain and subdomains of activities of daily living in the updated version.[4,5] The VAS score with the sliding cursor was replaced by a 15-centimeter paper VAS by several authors.[1,11] Although this new method was introduced as an improvement, this new outcome scale was not validated.[18] In this study, changing the answering scale affected the CMS total score with 0.8 to 2.7 points. This was found to be significant; however, it is a small difference on a 0-100 scale. Furthermore, previously the minimal detectable change of the CMS has been determined to be 10 to 12 points, therefore, this significant effect of less than 3 points can be considered as not clinically relevant.[12] Despite the clinically irrelevant effect on the CMS total score, on item level the different answering scales cannot be used interchangeably. As presented in Table 4, the pain scores measured with the paper VAS, the smiley face score and NRS scale could not be converted to the consecutive categories. The lack of interchangeably between answering scales has been studied previously in patients with chronic pain disorders.[10] In that study, pain measured with a paper based continuous horizontal VAS (0-100) was compared with a 5-category verbal rating score. As in this study, the scores could not be converted to each other and could not be used interchangeable. In addition, they found that pain was scored higher when using a VAS scale compared to the categorized verbal rating score. This also in accordance with our findings. Yet, a VAS rating scale might be more appropriate in detecting changes over time compared to categorical scales.[7,16] This might be caused by a certain threshold for choosing a category compared to putting a line on a non-hatched VAS line. Results showed that with increasing pain, the difference between these two scores decreased. This might indicate that the VAS score might be more accurate, especially for detecting lower levels of pain.

Intra-observer and inter-observer reliability

Over the years, the CMS has been criticized due to poorly defined methods in the original version resulting in different methods of conduct and interpretations of the score by health professionals.[3,8,14] Results showed that the intra- and inter-observer reliability for the various answering scales were excellent. This is in accordance with results from several other studies.[6,12,14] For the 'paper VAS' version an inter-observer ICC of 0.94 was reported by Moeller et al..[12] Johansson et al. found intra-observer ICC ranges from 0.90 to 0.98 and inter-observer range of 0.89 to 0.97 with the original CMS in categories.[9] In these studies, like in our study, a pre-defined working protocol is used.[6,9,12,14] A pre-defined working protocol will remove a lot of variation within the trial that does normally exist in

standard clinical practice. Therefore, an overestimation of the inter-observer reliability could be made. In our study, the inter-observer reliability of the CMS was probably affected positively. Generally, due to the different interpretations between the examiners if the protocol is not accurately standardized in a clinical trial, performing a clinical trial without a standardized working protocol is not favorable.

The smiley face slider used in this study is mostly used for children. However, Sasaki et al. used the smiley face score with adults for quality of life questions and reported adequate test-retest results (ICC of 0.80).[15] In our study, the results from the smiley face score were comparable with the other scores with high intra-reliability (ICC of 0.99) and inter-reliability (ICC between 0.89 and 0.97) and therefore can be reliably used in adults.

Limitations

A limitation of this study might be the short time intervals between the assessments, i.e. before and after the consultation with the orthopaedic surgeon, which might cause recall bias and thereby overestimation of the measurement properties. Furthermore, the consultation with the orthopaedic surgeon could have influenced the second assessment. Patients might answer differently when they just heard that they e.g. need to have surgery compared to patients that just heard that the surgeon is very satisfied with the results or physical examination.

CONCLUSIONS

The different answering scales for the subjective subscales within the CMS for pain, work and recreational activity were not interchangeable on item level and significantly influenced the total CMS score. Difference were below the smallest detectable change and interpreted as not clinically relevant. Particularly on item level, data from different studies cannot be pooled and compared when different answering scales are being used. The inter- and intra-observer reliability was excellent.

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Response shift of the Western Ontario Rotator Cuff index in patients undergoing arthroscopic rotator cuff repair.

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ABSTRACT

The goal of this study was to determine the response shift in patients undergoing rotator cuff repair using the Western Ontario Rotator Cuff index (WORC), a disease specific Quality-of-Life (QoL) questionnaire. In this study it is hypothesized there will be a response shift with a positive recalibration (overestimated their preoperative disability) on the WORC and increases over time. Thirty-six patients undergoing arthroscopic rotator cuff repair were prospectively included. At baseline, 3 months (T1) and 1 year (T2) after surgery the WORC, EQ-5D-3L and patient's level of satisfaction after surgery were scored. To evaluate the response shift, patients also completed the WORC at 3 months (Pre-T1) and 1 year (Pre-T2) as how they perceived themselves to have been prior to surgery. The result on Pre-T1 and Pre-T2 revealed that patients retrospectively rated their overall WORC score comparable with the baseline WORC score (Pre-T0) (T0 = 40.53 ± 18.41, Pre-T1 = 44.99 ± 22.65, Pre-T2 = 34.29 ± 21.27). No response shift was observed on all domains except a negative recalibrated response shift for emotional disability on T1 ($p = 0.04$). This study demonstrated that no significant group-level response shift was observed using the WORC except for the subdomain emotional disability at 3 months after arthroscopic rotator cuff repair. With the absence of any shift in patient's perception on the self-administered QoL related WORC questionnaire, this study suggests one could retrospectively reliably conduct group-level preoperative baseline information on QoL up to one year after surgery.

INTRODUCTION

Patient reported outcome measures evaluate treatment interventions and are developed to determine the level of functioning from the patient's perspective instead of the therapist's. However, with the introduction of such parameters, questions are raised on what is actually measured and its reliability.

Previous literature has shown Quality-of-Life (QoL) assessments may not be in line with the patient's report of satisfaction.[18] It has also been noted that patients with terminal diseases and a deteriorating health status often report a QoL that is stable and not inferior to that of healthy people.[2,16] The change in internal standards, values, and conceptualization of health related QoL over the course of time is called "response shift".[16,17] Besides QoL this phenomenon is also applicable for physical functioning and psychological well-being (depression e.g.). A positive response shift might serve as a buffer to the stressful impact of deteriorating health on psychological well-being.[6] Response shift in patients with non-life-threatening conditions such as rotator cuff tears has not been extensively studied, and its implications are less clear. Current QoL outcome measures are based on the assumption that respondents use measurement scales consistently and that QoL scale scores are directly comparable over time. If there is a change in the respondent's internal standards of measurement or a scale recalibration, then bias is introduced into any longitudinal study in which self-reported outcome measures are used.[16,17] Patients may have recalibrated their baseline situation due to the clinical intervention or there might be a change because patients were giving socially desirable answers to the therapist. The response shift may be particularly important in repeated measures trials where efficacy over time for a specific treatment is measured as the change from a pre-treatment baseline.[13]

In evaluation research, retrospective measurements are obviously easier and more economical than serial measurements. Despite the apparent advantages of retrospective measurements of change in health-related functional status, there is a suspicion that global or transition questions are biased due to recall problems or present-state effects at follow-up. It is assumed that prospective or serial change assessed by repeated measurement is superior and that the use of retrospective assessment of change in health-related functional status with global or transition questions is definitely not advisable.[4]

Arthroscopic rotator cuff repair is performed to improve QoL. The Western Ontario Rotator Cuff index (WORC), which is validated for rotator cuff repair, is a health-related QoL patient-administered questionnaire.[21] The goal of this study was to determine if there was a response shift 3 months and 1 year after arthroscopic rotator cuff repair on the

WORC score. Since subjective evaluations of function and pain levels are scored with the WORC questionnaire its outcome may be easily influenced by a response shift. In this study it is hypothesized there will be a positive group-level response shift (overestimation of preoperative disability) after arthroscopic rotator cuff repair and it is expected to increase over time.

MATERIAL AND METHOD

Patients, procedure and rehabilitation

The prospective data collection for this study was incorporated into a randomized clinical trial that assessed the difference in pain and function between immobilization methods (abduction brace versus anti-rotation sling) after arthroscopic rotator cuff repair. After ethical approval was received patients were recruited from our Department of Orthopaedic Surgery from October 2012 till January 2014. All patients were asked to provide informed consent during consultation. Eligible patients were adults suffering for more than 6 months from a traumatic or degenerative full-thickness tear of the supraspinatus and/or infraspinatus tendon, diagnosed by Magnetic Resonance Imaging (MRI), and were unresponsive to at least three months of conservative therapy. Exclusion criteria were: partial thickness tear, perioperative irreparable or partially reparable, revision surgery, rupture of the subscapularis tendon, glenohumeral osteoarthritis, adhesive capsulitis, Body Mass Index (BMI) >35, fibromyalgia, current treatment with opiates, concomitant labral repair, lateral clavicle resection and patients with insufficient knowledge of the Dutch language. All patients underwent an arthroscopic rotator cuff repair in beach-chair position using a double- or single row suture bridge technique. Directly after surgery patients were immobilized and started physiotherapy for passive exercises. Six weeks after surgery, the immobilization could be phased out starting with active-assisted exercises and strengthening.

Outcome measures

Before surgery and 3 months after surgery the patients visited the outpatient orthopaedic department for a standard consult with the orthopaedic surgeon. Subsequently, patients were seen by an independent investigator for filling out the WORC questionnaire. At 1 year the patients completed the WORC at home which were send by post. Before surgery the patient filled out the WORC questionnaire once (Pre-T0), at 3 months (T1) and 1 year (T2) the patients completed two questionnaires: one for the current status (Post-T1/T2), and one on how they perceived themselves to have been prior to surgery (Pre-T1/T2). In addition to the WORC questionnaire, four separate questions on patient's satisfaction were administered at T1 and T2 to determine perceived change.

WORC

The Western Ontario Rotator Cuff index (WORC) is designed for patients with disorders of the rotator cuff.[21,22] It is a disease-specific Health Related Quality-of-Life (HRQL) questionnaire that has 21 items representing 5 domains, each with a visual analogue scale–type response option. The 5 domains are (1) physical symptoms, (2) sports and recreation, (3) work, (4) social function, and (5) emotional disability. Each item is scored on a 100-mm scale (ranging from 0 best to 100 worst). The most symptomatic total score is 2100, and the best or asymptomatic total score is 0. To present this in a more clinically meaningful format, the score is reported as a percentage by subtracting the total from 2100, dividing by 2100, and multiplying by 100. Total final WORC scores can, therefore, vary from 0%, the lowest functional status level, to 100%, the highest functional status level. In this article both the WORC total and domain scores are expressed as percentages (0-100%). The WORC was selected because it is a disease-specific instrument with a known sensitivity to detect change over time in patients undergoing a rotator cuff repair.[9]

Satisfaction

To determine perceived change and satisfaction, four separate questions were administered at T1 and T2. These questions were used to classify patients according to whether they had improved, deteriorated, or perceived no change and if they were satisfied with the performed surgery. The questions and statements were: how did your overall daily functioning change since the surgery on your shoulder?; the pain in or around my shoulder is reduced by the operation; I am satisfied with the result of the operation; would you choose to be operated on again if you were asked to make the decision now? The questions were scored on a 7 point likert scale. The total score was calculated by summarizing the 4 scores in which a high score indicates a high degree of perceived change and satisfaction.

Assessment of response shift

The postoperative Post-Tests and postoperative Pre-Tests were assessed directly after each other, presuming the same internal scale of measurement within the patient. The 3 months (Post-T1) and 1 year (Post-T2) postoperative evaluations gave an idea of the course of recovery of the surgery. The patient was asked at 3 months (Pre-T1) and 1 year (Pre-T2) retrospectively to rate their situation before surgery, not as they recall it, but as they now see it. The time-intervals are long enough for the patients to forget their preoperative answers and to provide a renewed judgment of their preoperative status. Differences between the original Pre-T0 rating and the retrospective Pre-T1 and Pre-T2 indicate response shift.

Statistics

Descriptive statistics were compiled for demographic and clinical characteristics of the study population. Data was tested on normally distribution using the Kolmogorov-Smirnov test. For statistical analyses, the level of significance was set at 5%. All data was analyzed with SPSS statistical software (SPSS, Inc., version 22).

Change in patients' internal standard of measurement or treatment-induced response shift was calculated by comparing the mean scores on the preoperative WORC (Pre-T0) and the retrospective renewed-judgment WORC at 3 months (Pre-T1) and 1 year (Pre-T2). The unadjusted treatment effect was measured by comparing the Post-Tests and Pre-T0 scores. The adjusted treatment effect was measured by comparing the Pre-Test scores and the 3 months and 1 year postoperative outcome score according to the equations:

Pre-T0 score – Pre-Tx score = Response Shift (RS)
Post-Tx score – Pre-Tx score = Adjusted Treatment Effect (ATE)
Post-Tx score – Pre-T0 score = Unadjusted Treatment Effect (UTE)

The mean differences between the Pre-Tests (T0, T1 and T2) and Post-Tests (T1 and T2) scores were tested with a two-tailed paired t-test. Effect size was calculated, defined as the mean difference between tests divided by the standard deviation of the Pre-T0. We used the original population estimate (i.e., baseline SD) to avoid violating the assumption of independence (since the two samples are correlated).[7] Repeated-measurement ANOVA was used for the normally distributed pre- and postoperative data and when needed was further analyzed using a Tukey's post hoc test. Scores of serial change items (ATE and UTE) were calculated by subtracting the baseline score from the follow-up score. Serial change score of zero was considered to indicate neither improvement nor deterioration, a high positive serial change score was indicative of a high degree of improvement and a high negative serial change score was indicative of a high degree of deterioration. Besides age and gender the impact of comorbid conditions (ASA classification), patients' satisfaction and general health status (EQ-5D-3L score) on the outcome was examined using a multiple linear regression analysis (backward method).

Individual-level effect

Previous study by Wessel et al.[22] found a minimal detectable change (MDC) on the WORC score of 16.7 points on a 0-100 scale amongst 50 patients with rotator cuff disorders. To investigate the occurrence of a possible individual-level effect for response shift, the absolute values of the response shift on Pre-T1 and Pre-T2 were compared with the MDC. The MDC's for the subdomains from D1 – D5 were respectively 27.6, 23.4, 23.3, 25.2 and 35.9.[21]

RESULTS

Forty-four consecutively enrolled patients were randomized. After allocation to treatment, eight patients were excluded perioperatively due to a partial-thickness tear (n = 1), partially reparable (n = 1), irreparable tear (n = 3), repair of the subscapularis tendon (n = 1) or they withdrew from surgery for personal or medical reasons (n = 2). Thirty-six patients, 16 males and 20 females, with a mean age of 61.2 ± 8.22 years remained for statistical analysis (Table 1). After 1 year there was no loss to follow-up. One year after surgery three patients did not fill out the Pre-T2. There was no difference in response shift observed on the WORC between the abduction brace group and anti-rotation sling group from the incorporated randomized controlled trial. The postoperative Pre-Tests at 3 months (Pre-T1) and 1 year (Pre-T2) revealed that patients retrospectively rated their overall WORC score comparable with the baseline WORC score (Pre-T0) (T0 = 40.53 ±

Table 1 - Demographics of study population (N=36)

Variables	N
Female : male	20:16
Age (years)	61.2 ± 8.22
BMI	27.5 ± 3.72
ASA I:II:III*	23:13:0
Comorbidities	
Hypertension	11
Diabetes Mellitus	5
Others	0
Affected side (n)	
- Right	18
Dominant : Non-dominant	16:2
- Left	18
Dominant : Non-dominant	15:3
Supraspinatus	
Fatty degeneration (0:1:2:3:4)	10:23:3:0:0
Retraction (1:2:3:4)	13:12:8:1
Atrophy (1:2:3)	29:5:2
Additional procedures (n):	
Subacromial decompression	17
Biceps tenotomy	12
Biceps tenodesis	2
Length of follow-up T1, months (mean & SD)	3.06 (0.026)
Length of follow-up T2, months (mean & SD)	12.22 (1.65)

*ASA = American Society of Anesthesiologists physical status classification system, range I-VI (I: Healthy person, II: Mild systemic disease, III: Severe systemic disease, IV: Severe systemic disease that is a constant threat to life, V: A moribund person who is not expected to survive without the operation, VI: A declared brain-dead person whose organs are being removed for donor purposes).

18.41, Pre-T1 = 44.99 ± 22.65, Pre-T2 = 34.29 ± 21.27) ($p > 0.05$) (Table 2). Comparison of the 3 months and 1 year postoperative scores with this adjusted and unadjusted baseline scores indicated a significant treatment effect ($p < 0.001$) (Table 3). No significant response shift was observed on the WORC 3 months (T1) and 1 year (T2) on all domains except for the subdomain emotional disability with a negative recalibration (underestimated their preoperative disability) at 3 months (T1) after arthroscopic rotator cuff repair ($p = 0.04$) (Figure 1, Table 3). Multiple regression analysis showed that the value found for the response shift on T1, which itself was not significant, was significantly influenced by the level of satisfaction (R-Square = 0.23, $p = 0.004$). This implies that a higher level of satisfaction result in an increased difference between Pre-T0 and Pre-T1.

Table 2 – Mean and standard deviations of the WORC. Total and domain scores are presented on a 0-100 scale.

Variable	Pre-T0	Then-T1	Then-T2	Post-T1	Post-T2
Total WORC	40.53 ± 18.41	44.99 ± 22.65	34.29 ± 21.27	69.12 ± 23.07	84.85 ± 19.65
D1 - Physical symptoms	48.33 ± 20.36	44.59 ± 23.84	38.03 ± 23.76	76.01 ± 21.71	87.05 ± 17.08
D2 - Sports and recreation	34.26 ± 20.21	40.41 ± 23.41	30.83 ± 21.90	63.28 ± 25.70	80.85 ± 22.59
D3 – Work	30.18 ± 16.60	36.53 ± 22.85	24.74 ± 21.81	58.63 ± 28.07	79.44 ± 23.92
D4 - Social function	34.75 ± 24.32	45.07 ± 29.38	26.28 ± 24.59	66.40 ± 27.51	85.60 ± 22.26
D5 - Emotions	52.88 ± 25.27	63.10 ± 27.08	54.86 ± 26.43	80.75 ± 23.87	91.56 ± 18.41

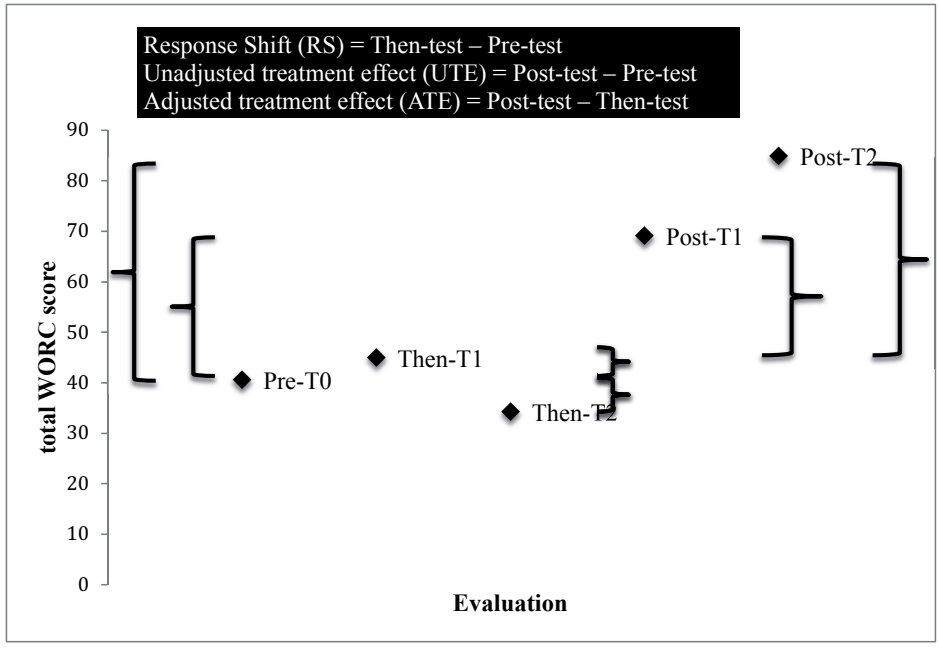

Figure 1. Response shift, Unadjusted and Adjusted treatment effect on the WORC score

Other factors on T1 and T2 had no influence on the response shift. Level of satisfaction increased significantly between T1 and T2 (p = 0.031). The current health state of patients, marked on a hatched scale ranging from 0-100, remained preoperative and postoperative comparable (p = 0.113).

Individual-level analysis

Response shift magnitude values were used to determine the number of patients that reported a shift greater than the MDC at T1 and T2 on the WORC. On T1, 14 patients and T2, 12 patients had a response shift greater than the MDC of 16.7.[22] Maintaining the MDC

Table 3 – Mean and standard deviation of the response shift, adjusted treatment effect and unadjusted treatment effect of the Western Ontario Rotator Cuff Index at 3 months (T1) and 1 year (T2) postoperatively.

Variable		Total WORC	D1 - Physical symptoms	D2 - Sports and recreation	D3 - Work	D4 – Social function	D5 - emotions
Response shift T1*	**Mean (SD)**	-4.46 (21.84)	3.74 (23.37)	-6.15 (22.78)	-6.35 (21.09)	-10.32 (32.89)	-10.22 (28.47)
	P-value	0.23	0.34	0.11	0.08	0.07	0.04
	Effect size	0.20	0.16	0.27	0.30	0.31	0.36
Response shift T2†	**Mean (SD)**	6.37 (23.38)	10.14 (28.99)	3.51 (22.52)	5.41 (22.22)	8.85 (28.92)	-1.51 (27.48)
	P-value	0.13	0.053	0.38	0.17	0.09	0.76
	Effect size	0.27	0.35	0.16	0.24	0.31	0.05
Adjusted treatment effect T1¥	**Mean (SD)**	24.13 (28.74)	31.43 (26.38)	22.87 (29.75)	22.10 (33.14)	21.33 (39.80)	17.65 (31.40)
	P-value	0.000	0.000	0.000	0.000	0.003	0.002
	Effect size	0.84	1.19	0.77	0.67	0.54	0.56
Adjusted treatment effect T2§	**Mean (SD)**	39.85 (28.48)	48.68 (29.02)	49.36 (30.78)	54.04 (30.40)	58.65 (33.71)	36.54 (27.45)
	P-value	0.000	0.000	0.000	0.000	0.000	0.000
	Effect size	1.40	1.68	1.60	1.78	1.74	1.33
Unadjusted treatment effect T1Ω	**Mean (SD)**	28.59 (18.62)	27.69 (19.44)	29.02 (21.41)	28.45 (23.91)	31.65 (25.51)	27.87 (23.67)
	P-value	0.000	0.000	0.000	0.000	0.000	0.000
	Effect size	1.54	1.42	1.36	1.19	1.24	1.18
Unadjusted treatment effect T2ƒ	**Mean (SD)**	44.32 (19.03)	38.72 (20.05)	46.59 (23.56)	49.26 (21.15)	50.85 (24.71)	38.68 (23.40)
	P-value	0.000	0.000	0.000	0.000	0.000	0.000
	Effect size	2.33	1.93	1.98	2.33	2.06	1.65

*Response shift T1 = Pre-T0 – Pre-T1; †Response shift T2 = Pre-T0 – Pre-T2; ¥Adjusted treatment effect T1 = Post-T1 – Pre-T1; §Adjusted treatment effect T2 = Post-T2 – Pre-T2; ΩUnadjusted treatment effect T1 = Post-T1 – Pre-T0; ƒUnadjusted treatment effect T2 = Post-T2 – Pre-T0

at threshold for a relevant response shift we additionally studied the individual direction of scale recalibration on the total WORC score. At 3 months (T1) approximately 28% (10/36) exhibited a positive recalibration (overestimated their preoperative disability), 11% (4/36) demonstrated a negative recalibration (underestimated their preoperative disability) and the majority (61%) had no response shift. At 1 year (T2) approximately 9% (3/33) exhibited a positive recalibration (overestimated their preoperative disability), 27% (9/33) demonstrated a negative recalibration (underestimated their preoperative disability) and the majority (67%) had no response shift. Besides the subdomain emotional disability on T1 there were no other significant response shifts observed on other subdomains. The individual direction of scale recalibration on the subdomain emotional disability with an MDC of 35.9 points on T1 was negative for 14% and positive for 3% amongst the participants.

DISCUSSION

This study demonstrated that no response shift was observed up to 1 year after arthroscopic rotator cuff repair on the WORC on all domains except for the subdomain emotional disability at 3 months which was recalibrated negatively (underestimated their preoperative disability). This result does not support the pre-established hypothesis, namely there would be a positive group-level response shift that was expected to increase over time. Other findings were a significant improvement at 3 months and 1 year on the WORC and general health status, compared with the adjusted and unadjusted baseline scores. This indicates a significant treatment effect of the arthroscopic rotator cuff repair. This study also studied the individual-level effect which showed a scale recalibration in the overestimated direction after 3 months and underestimation after 1 year for the Pre-Tests. Additional analysis on potential predictive factors for the presence of a response shift (age, gender, ASA score, patient's satisfaction and general health status) were performed and revealed a significant correlation with the level of satisfaction on the value found for the response shift on T1.

The absence of a group level response or perception shift insinuates that patients estimate their initial level of functioning appropriately, their memory of their preoperative levels of functioning was accurate and the patients did not bias their reports to provide the treatment with favorable results. However, the individual-level analysis showed nuances should be made. Namely, 39% of the patients at Pre-T1 and 36% at Pre-T2 reported a relevant different (> MDC) score than their baseline score. Apparently, the assumption that prospective or serial change assessed by repeated measurement is superior could be questioned. According this study, with the absence of a group level response shift,

a postoperative Pre-Test for the WORC could be used as a reliable measuring tool in retrospective studies on rotator cuff repair.

The phenomenon response shift has not been studied extensively after elective orthopaedic surgery. Previous reports were conducted after total knee arthroplasty,[11,12] spinal disorders,[18] autologous chondrocyte transplantation,[5] microfracture for full thickness cartilage lesions in the knee,[1] rotator cuff repair[10] and subacromial decompression.[10] The results from this study can be compared with the results found by Razmjou et al.[10] who studied the phenomenon response shift after rotator cuff repair.[10] They observed a response shift 2 years after rotator cuff repair using disease specific functional outcome measurements. A significant shift was observed on the domain pain of the American Shoulder and Elbow Surgeons (ASES) questionnaire. Functional domains did not show presence of recall bias and thereby no response shift. A response shift characterized by overrating of preoperative pain was associated with lower levels of residual disability at two years following cuff repair.[10] They only used the ASES score to measure the presence of a possible response shift for which we used the WORC score. Both questionnaires are self-reported tools for measuring shoulder function. Although, the ASES score contain a functional assessment part performed by a clinician which makes it more functional as compared with the WORC.[20] Razmjou et al.[10] found a significant response shift on pain after 2 years after rotator cuff repair as in the current study only a significant response shift was found on the subdomain emotional disability after 3 months and absence of a response shift at 1 year after surgery. Comparing the results from Razmjou and colleagues with our findings is difficult due to the difference in time interval and use of the ASES score. Furthermore, the WORC uses a visual analogue scale–type response option on a 0-100 mm unhatched scale. This makes it almost impossible to give the exact answer on the postoperative Pre-Test as the baseline Pre-Test score and makes this questionnaire more prone to the presence of a response shift as compared to the ordinal organized response options used in the ASES score.

Other studies that looked for the presence of a response shift after elective orthopaedic interventions were on total knee arthroplasty and were conducted by the same colleagues as the previous mentioned study on rotator cuff repair and subacromial decompression.[9,11] In 2006 and 2009 Razmjou et al.[11,12] used the Then-Test design to study the response shift 6 months and 1 year after total knee arthroplasty. Interestingly, for knee arthroplasty a response shift was observed on both measuring points on the WOMAC score and increased over time. Surprisingly, the direction of scale recalibration at 6 months after surgery was comparable with the direction of recalibration at 6 months and 1 year found by Razmjou et al.[11] Of those who demonstrated a response shift in this study at 3 months (39%), the majority overestimated their preoperative disability

(28%). At 1 year 27% of our study population negatively recalibrated their preoperative disability, versus 9% percent who positively recalibrated their preoperative disability. This insinuates there is a shift in direction of recalibration from 3 months to 1 year in which patients are tending to switch from overestimation to underestimation of their preoperative disability status. This was not observed from 6 months to 1 year after total knee arthroplasty.

The WOMAC score has also been used in other studies on measuring response shifts in knee pathology. Howard et al.[5] studied the influence of response shift on patient related outcome measures (WOMAC, IKDC, SF-36 Physical Component Summary) following autologous chondrocyte implantation. After 6 and 12 months there was no group-level effect for response shift.[5] There was however evidence for an individual-level or patient-by-patient bias effect on particular the WOMAC (34%) and SF-36 (56%) at 1 year after surgery. In our study approximately one third reported higher scores than the MDC on the WORC on Pre-T1 and Pre-T2. Perhaps the severity of preoperative disability and complaints experienced by patients undergoing total knee arthroplasty might explain the presence of a response shift. In general, patients undergoing rotator cuff repair are younger, less disabled and have a better general health status as compared to candidates for total knee arthroplasty.

One of the problems with the phenomenon response shift is its interpretation on group-level to correctly interpret the overall treatment effect. The direction of a response shift in a population might be in both directions and may neutralize an actually present response shift making it an individual phenomenon. This is what also occurred in the current study. Second, personal and environmental factors may be responsible in this study for the presence of an individual-level response shift. The impact of the functional disability caused by a rotator cuff tear on QoL differs from terminal diseases where every aspect of QoL has been affected. For patients undergoing rotator cuff repair personal and environmental factors, described by Sprangers and Schwartz[17] as *antecedents* in their model of response shift and HRQL, might influence the presence of an individual response shift.[17] Examples of such antecedents include sociodemographics (e.g. gender, education) and personality (e.g. optimism, self-esteem, sense of control, mastery), expectations or spiritual identity.[3,8,14,15,19] This emphasizes the importance of scrutinizing the presence of as well a group-level as individual-level response shift.

Since there was a significant response shift on the subdomain emotional disability the individual-level effect on this subdomain was scrutinized and showed that patients underestimated their emotional status. They were more in the dumps then they remembered. From the patient's perspective this may also reflect the need for help from the

surgeon before surgery. This means patients experienced less treatment effect on this subdomain 3 months after surgery which disappeared 1 year after surgery.

A limitation of the current study might be the absence of an incorporated placebo-treatment group. In no-treatment or placebo-treatment conditions, due to the absence of true change, patients might become more pessimistic about the possibilities of positive change, and might show a difference in response shift. On the other hand, gains in control groups where no change is expected, is a common occurrence and makes it more difficult for researchers to find significantly greater gains in experimental groups.

Results of this study showed that retrospective pre-testing can be considered in study designs where repeated measurements are not feasible, such as in the assessment of change in patients who are referred to the hospital after acute trauma (traumatic rotator cuff tear, humeral fracture, e.g.). Retrospective cohort studies or therapeutic case series on arthroscopic rotator cuff repair could be upgraded by retrospectively collecting reliably preoperative baseline information.

Additionally, the results from this study are only applicable to this specific population and time points investigated. We only measured the response shift at 3 months and 1 year after arthroscopic rotator cuff repair and therefore we cannot draw conclusions concerning the effect of response shift on longer-term outcomes.

CONCLUSION

In conclusion, this study demonstrated that no significant group-level response shift was observed on the WORC score 3 months and 1 year on all domains except for the subdomain emotional disability at 3 months after arthroscopic rotator cuff repair. The results of this study also showed level of satisfaction and general health status improved significantly over time. With the absence of any shift in patient's perception on the self-administered QoL related WORC questionnaire, this study suggests one could retrospectively reliably conduct group-level preoperative baseline information on QoL up to one year after arthroscopic rotator cuff repair.

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7

Equivalence between electronic and paper-based Western Ontario Rotator Cuff index (WORC): a two-way crossover equivalence trial.

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Submitted for publication

8

Non-inferiority and cost-effectiveness trial of isolated biceps tenotomy versus tenotomy with rotator cuff repair in patients with stage 2-3 Goutallier fatty degenerative cuff lesions (TenCuRe study): protocol of a multicentre randomised controlled trial.

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ABSTRACT

For patients who are diagnosed with lesions of the rotator cuff that present advanced levels of fatty degeneration, arthroscopic repair of the rotator cuff remains controversial. This controversy can be attributed to the frequently reported high failure rate of the tendon fixation and the fact that it remains unclear why repair for these tears result in significant clinical improvement independent of the occurrence of such a re-tear. Recent publications have reported comparable clinical improvements when merely a tenotomy of the long head of the biceps tendon was performed and the rotator cuff tear was left untreated. These observations raise questions on the value of performing the more extensive cuff repairs in degenerative cuff tears. Even more, rehabilitation after an isolated tenotomy is much less cumbersome as compared to rehabilitation after rotator cuff repair and, therefore, might result in improved patient satisfaction. The goal of this trial is to study function and quality-of-life of patients undergoing arthroscopic biceps tenotomy with or without an additional cuff repair and to include an economic evaluation. This multicentre randomised controlled non-inferiority trial, including an economic evaluation, is designed to compare the short and long term outcome of patients who underwent an arthroscopic tenotomy of the long head of the biceps tendon with or without a cuff repair. We will include 172 patients with stage 2-3 Goutallier fatty infiltration cuff tears and with clinical symptoms of biceps pathology. Primary outcome is the rotator cuff specific quality-of-life (Western Ontario Rotator Cuff index) on the short term (6 months postoperatively). Secondary outcomes are quality-of-life 1, 2 and 5 year postoperatively and function (Constant-Murley score, glenohumeral range of motion), recovery status, pain (Visual Analogue Scale), economic evaluation, satisfaction of treatment on the short and long term and re-tear rate at 6 months determined with an ultrasound.

This trial has been approved by the Medical Research Ethics Committees United (MEC-U), Nieuwegein, the Netherlands (NL54313.100.15) and will be performed in accordance with the Declaration of Helsinki with the Medical Research Involving Human Subjects Act (WMO). The results of this study will be reported in peer-reviewed journals and at (inter)national conferences. Furthermore, we will share our findings with the appropriate guideline committees.

Strengths and limitations of this study:

- This will be the first randomised controlled trial to study the function and quality of life of patients undergoing arthroscopic biceps tenotomy with or without an additional cuff repair.
- The study is carefully designed including adequate sample size, permuted block randomisation stratified for centre, blinded analyses and prospective trial registration to reduce selection and confounding bias.
- Due to the obvious differences in postoperative rehabilitation protocols, patients, surgeons and researchers will not be blinded for treatment.

INTRODUCTION

Rotator cuff pathology is a common condition which prevalence increases with age.[28,34,41] The aetiology, incidence and the clinical significance of fatty degeneration of the rotator cuff muscles are still relatively unknown due to the lack of reliable measurements. Tendon quality can be assessed on magnetic resonance imaging (MRI) by the level of fatty infiltration, atrophy and retraction. In most studies the rotator cuff tear is defined irreparable if fatty infiltration ≥ stage 3 Goutallier,[15] the tendon is retracted to the height of the glenoid (Thomazeau stage 3-4, on the coronal plane[37]) and the acromio-humeral interval (AHI) is less than 7 mm.[4,25,39] Furthermore, the severity of cuff arthropathy and the motivation to comply with the intensive rehabilitation program after arthroscopic cuff repair (ACR) determines whether a cuff repair or other surgical treatment such as arthroplasty or superior capsular reconstruction is indicated.[17,37]

Among several identified negative prognostic factors for healing, fatty infiltration is frequently described as a predictor for healing of the rotator cuff. Healing implies anatomic integrity on the footprint after full recovery from surgery. Several clinical studies described the functional and radiographic outcome after ACR for the level of fatty infiltration.[2,5,8,9,14,20,27,30,33] Fatty infiltration stages 0-1 Goutallier (0-25% fatty infiltration) have good to excellent clinical outcomes. Among patients with fatty infiltration stage 4 Goutallier (>75% fatty infiltration) the clinical outcome after ACR is poor with high failure rates and minor functional improvement.[5] Within the remaining group, fatty infiltration stage 2-3 Goutallier, it is still under discussion whether cuff repair is indicated, mainly caused by the high retear rate. However, despite this high retear rate, patients seem to improve significantly with only minor functional difference compared to healed repairs.[9,19,27]

The biceps tendon is often involved in the presence of cuff arthropathy, especially in shoulders with stage 2-4 Goutallier.[32] Therefore, in this patient group, biceps tenotomy or tenodesis could be considered as an alternative treatment instead of a cuff repair. Results of isolated tenotomy or tenodesis are comparable to the long-term results of cuff repair in this specific patient group.[4,26,39] In addition, patients with a rotator cuff tear and good quality tendons for which an ACR and additional biceps tenotomy or tenodesis was performed also show comparable results.[6,11,12,19,21,31] Furthermore, there are several cases described in which a spontaneous ruptured long head of the biceps tendon (LHBT) from its insertion, in shoulders with a conservatively treated rotator cuff tear, has led to a significantly relieve of pain and improvements on function.[38] These observations raise questions on the value of performing the more extensive and therefore expensive cuff repairs in degenerative cuff tears.

Rehabilitation after an isolated tenotomy is much less cumbersome compared to rehabilitation after rotator cuff repair. Patients undergoing an isolated biceps tenotomy might be able to resume work and daily activities much faster after surgery as their shoulders are directly functional without any restrictions. The patients who undergo a rotator cuff repair will be immobilized for 6 weeks in an anti-rotation sling and will need an additional 3-6 months for functional recovery, which will lead to more productivity losses. Therefore, the goal of this non-inferiority trial is to study the short-term function and quality of life in patients not responding to conservative therapy undergoing arthroscopic biceps tenotomy with or without an additional cuff repair and to include an economic evaluation.

We hypothesize that patients who undergo an isolated tenotomy of the long head of the biceps tendon in the presence of a degenerative rotator cuff tear, stage 2-3 Goutallier fatty infiltration, will have non-inferior functional results and quality of life 3, 6 and 12 months after surgery as compared to patients undergoing tenotomy combined with a rotator cuff repair. At 1 year after surgery we assume reduced costs with isolated tenotomy treatment.

METHODS AND ANALYSIS

Study design

This study is a multicentre randomised controlled non-inferiority trial, including an economic evaluation. Prior to the start of inclusion, the trial was registered at the Dutch Trial Registry (NL4010).

Setting

Patients are recruited at the orthopaedic outpatient clinics of the participating medical centres. Recruitment started in six Dutch hospitals. To ensure recruitment, additional hospitals will be added to the trial. Eligible participants are randomised into two equal groups receiving either arthroscopic biceps tenotomy with an additional cuff repair or arthroscopic biceps tenotomy without an additional cuff repair at the hospital of inclusion. The first patient was included on 22 October 2018. It is estimated that the inclusion period will be 3 years. Taken into account the 5 years follow-up period, the total study duration will be 8 years.

Study population

Patients ≥60 years of age with MRI-confirmed symptomatic, stage 2-3 Goutallier FI rotator cuff tears will be recruited. Other inclusion criteria are:

Preoperative inclusion criteria:

- History of shoulder complaints > 6 months suggestive for a degenerative rotator cuff with or without non-significant preceding trauma
- Cuff lesion, involving the supraspinatus and or infraspinatus tendon, with at least one of the involved tendons having stage 2-3 Goutallier fatty infiltration
- Not responding to conservative treatment (e.g. physiotherapy, corticosteroid injection)
- Willing and able to comply with the study protocol
- Sufficient understanding of the Dutch language

Perioperative inclusion criteria:

- Perioperative pathologic involvement of the long head of the biceps tendon including: (minor signs of) degeneration, or signs of inflammation, or instability (subluxation or dislocation), or partial tears or SLAP lesions.

Patients will be excluded if one or more of the following exclusion criteria are met:

Preoperative exclusion criteria

- Cuff arthropathy according Hamada classification ≥ grade 3[17]
- Pseudoparalysis (active elevation limited to 45 degrees)
- Full subscapularis tendon tear (delamination or partial avulsion accepted)
- Injury of the teres minor tendon
- Mainly complaints from an osteoarthritis acromioclavicular joint and less from a subacromial origin, determined clinically or by subacromial/acromioclavicular infiltration
- Shoulder instability for which labral repair is indicated
- Irreparable rotator cuff tear, based on MRI (fatty infiltration Goutallier stage 4, retraction on the coronal plane to the level of the glenoid, severe atrophy)
- Unsuccessful surgery in the affected shoulder in history or surgery in the affected shoulder < 1 year ago
- Ipsilateral neurological pathology possibly affecting functional outcome
- Full tear of the biceps tendon
- Frozen shoulder
- Cervical spine pathology affecting the functional outcome
- Body Mass Index (BMI) > 35 kg/m^2
- Time between surgery and MRI > 6 months
- Fracture of the humeral head involved in the cuff tear

Perioperative exclusion criteria

- Perioperative fully healthy macroscopic aspect of the long head of the biceps tendon
- Irreparable rotator cuff tear, based on perioperative findings

Recruitment and consent

At the initial presentation, when it is suspected that the patient might be eligible, the patient will be verbally informed about the study and will receive the study specific information letter. As part of standard care, not as part of this study, an MRI will be conducted to confirm the diagnosis of a rotator cuff tear and for establishing a treatment plan. During the second visit (approximately 2 weeks later), when the results of the MRI are discussed, it will be established whether the patient is actually eligible. If eligible, the study protocol is explained in detail and informed consent is signed if patient is willing to participate. Participants are given a copy of the informed consent form and are informed that they can withdraw at any time during the study.

Randomisation and blinding

Randomisation is performed in a 1:1 ratio by a computerized software program (REDCap)[18] using random permuted blocks with block size 8, stratified for centre. After informed consent is signed, patients will be entered in the online randomisation program by the orthopaedic surgeon or study coordinator and are assigned to either arthroscopic biceps tenotomy with or without an additional cuff repair. Due to the obvious differences in postoperative rehabilitation protocols, patients, surgeons and researchers will not be blinded for treatment. Statistical analysis will be performed blinded.

Treatment groups

The procedures are only performed by orthopaedic surgeons experienced in arthroscopic rotator cuff surgery. Surgical techniques, such as patient positioning, portal placement and the use of assistive instruments such as knives, forceps, shavers, RF-probe and technique used for repair will be done or used according to the standard protocol at the site. During arthroscopy some of the degenerative tissue will be collected which would otherwise be removed during debridement. This include tissue from the supraspinatus muscle, footprint and 2 - 3 cm of the insertion from the LHBT on the glenoid. The obtained tissue will be stained in paraffin and used for future research. The use of preoperative antibiotics and postoperative rehabilitation protocols will be standardized. The rehabilitation protocol consists of immobilization using an anti-rotation sling directly after surgery and patients were instructed to start with pendulum exercises. From the first week after surgery, patients started physiotherapy with restricted passive range of motion up to 70 degrees of abduction, 70 degrees of forward elevation and 20 degrees of external rotation in the scapular plane. From 6 weeks, the immobilization was

phased out and (guided) active motion exercises were started. From 3 months on, active motion exercises above the shoulder level were allowed. The use of analgesics are allowed during the study. Patients will be asked for the use of analgesics during the study.

Group 1: biceps tenotomy with cuff repair:
A biceps tenotomy with an additional cuff repair is performed. After surgery patients will be immobilized for 6 weeks in an anti-rotation sling. Two weeks after surgery the patients will visit the outpatient department for wound inspection and removal of stitches. After six and twelve weeks they will be checked on function and persistence of symptoms. Patients will be referred to a physiotherapist immediately after discharge of the hospital to assist in the passive mobilization of the shoulder during the first 6 weeks, and the active mobilization after 6 weeks.

Group 2: biceps tenotomy without cuff repair:
An isolated biceps tenotomy is performed. After surgery shoulders are directly functional without any restrictions. A simple sling can be given to support the arm during the recovery period from surgery.

Study outcomes

The study outcomes at the different follow-up moments are shown in table 1.

Table 1: Evaluation schedule.

	Baseline	6 Weeks	12 Weeks	6 Months	1 year	2 years	5 years
WORC	X	X	X	X	X	X	X
Pain score	X	X	X	X	X	X	X
Constant-Murley score	X		X	X	X		
Passive glenohumeral motion	X		X	X	X		
Subjective Shoulder Value (SSV)	X	X	X	X	X	X	X
EQ-5D-L5	X	X	X	X	X	X	X
Hospital Anxiety and Depression Scale (HADS)	X				X		
Pain Catastrophyzing Scale (PCS)	X				X		
MRI	X						
Ultrasound				X			
Radiograph	X						
Expectations / level of satisfactory	X		X	X	X	X	X
Cost-effectiveness (TiC-P)					X		

Primary outcome

The primary outcome is quality of life measured by the Western Ontario Rotator Cuff (WORC) Index 6 months after surgery. The WORC index is a disease-specific shoulder questionnaire, originally developed at the University of Western Ontario and has been validated in Dutch.[40] The standard error of measurement for the WORC is 6.0 points.[40] For this study, a difference of more than 10 points in WORC 0-100 score between groups is considered clinically relevant.

Secondary outcomes

The secondary outcomes are:

- Difference in:
  - Quality of life, measured by EQ-5D-5L[16]
  - Presence of anxiety and depression, measured by HADS[35]
  - Pain catastrophyzing scale (PCS)[29]
  - Pain during rest and during activity, measured on an 11–point Numeric Rating Scale (NRS)
  - Subjective shoulder value (SSV)
  - Function short term (≤ 6 months) and long term (> 6 months – 1 year), measured by the Constant-Murley score and glenohumeral range of motion
- Re-tear rate at 6 months determined by ultrasound in the repair group. Recurrent tears were defined as a distinct hypoechoic or mixed hyperechoic and hypoechoic defect in both transverse and longitudinal planes or when compression on the deltoid muscle with the probe could separate the torn tendon ends
- Cost-effectiveness measured by TiC-P part II[22]
- Relation between participants functional change, their expectation and their satisfaction of treatment
- Complication rate and adverse events
- Inter- and intra-observer reliability on reparability of stage 2-3 fatty degenerative rotator cuff tears among orthopaedic shoulder surgeons.
- Histological assessment of residual tissue derived from the rotator cuff tendons, biceps tendon and footprint (only in the main centre). The histological findings will among others be used for classifying rotator cuff tears in combination with imaging and perioperative findings.

At baseline a radiograph in antero-posterior and outlet view will be made. The presence of calcifications, stage of arthropathy, presence of arthrosis in the acromioclavicular joint, type acromion and acromio-humeral interval are scored.[17] All MRI's will be systematically checked on the location of the tear in the sagittal plane, the amount of retraction of the supraspinatus tendon in the coronal plane, the amount of atrophy, pathology

of the biceps tendon, acromio-humeral distance and presence of acromioclavicular arthrosis.[7,10,37] All data management will be recorded online, unless patients are unable or unwilling to complete the questionnaires online. In that case, patients are asked to complete the questionnaires on paper.

Sample size

Sample size calculations (continuous outcome non-inferiority trial) were performed using Sealed Envelope.[1] The sample size was based on a power of 80%, an alpha of 0.05, a standard deviation of 25 points and a non-inferiority limit (d) of 10 points on the mean WORC (0-100) index. This data was obtained from previous studies using the WORC index.[3,24,40] We calculated that with 10% loss to follow-up, 86 patients were needed per group. This corresponds with a total of 172 patients that need to be included. Patients in both groups will be excluded per-operatively, when a cuff repair seems technically not possible, partial repair is performed or the biceps tendon is unimpaired. These patients will be monitored according to this protocol. However, these patients do not count towards the total number of patients. Inclusion finishes when both groups consist of 86 eligible patients.

Data-analysis

All statistical analysis will be performed using SPSS 24.0 or newer (SPSS inc, Chicago, Illinois). The Kolmogorov-Smirnov test will be used to determine whether continuous variables are normally distributed. Skewed data will be presented as median (range), normally distributed data will be presented as means (standard deviation). For all analyses, a two-tailed value of $p \leq 0.05$ is considered to be significant.

To study the effect of the surgical interventions, the values from the baseline, and all follow-up moments in the tenotomy group will be compared with the effect in the group undergoing an additional cuff repair. To investigate the effect of the two surgical interventions, generalized estimating equations (GEE) for longitudinal analysis will be used. This method takes into account the dependency of observations within a patient and the fact that not all patients may be assessed at each time point (missing data). In the primary GEE model, the outcome variable studied (e.g. WORC index) will be analysed as a dependent variable, using treatment allocation (1, tenotomy; 0, tenotomy combined with cuff repair) and time as independent variables. In the secondary GEE model, the outcome variables studied (e.g. Constant-Murley score, glenohumeral range of motion, pain score, ultrasound outcome (healed or non-healed cuff repair), EQ-5D-5L, patient's expectation and satisfaction and adverse events) will be analysed in a similar way. To evaluate whether the two groups differed in change over time, the interaction term of

group and time (group * time) will be assessed. All models will be corrected for hospital of inclusion.

Both intention-to-treat and per-protocol analysis will be performed. The intention-to-treat approach will be the main analysis and provides unbiased comparisons among the treatment groups (avoid the effects of crossover and dropout, which may break the random assignment to the treatment groups). Patients who are excluded perioperatively will be excluded and replaced to prevent the risk of bias in allocation concealment.

Cohen's weighted kappa (κ; ordinal categories) will be used to calculate inter- and intra-observer agreement of the two raters of the MRI based variables (stage Goutallier fatty infiltration, tear size (Thomazeau A-E), retraction (Thomazeau 1-4), atrophy (Thomazeau 1-3), pathology of the biceps tendon (Chen 1-6), acromio-humeral distance and presence of acromioclavicular arthrosis. A kappa of 0 represents agreement equivalent with random change alone, whereas a kappa of 1 represents perfect agreement.

Using the histological assessment, imaging and perioperative findings, the rotator cuff tears will be classified. The impact of this classification, the MRI based variables and other patient related variables (e.g. gender, age) as prognostic factors on the dependent variables WORC, Constant-Murley score and pain will be evaluated using regression analysis.

Cost-effectiveness analysis

The cost-effectiveness analysis will be conducted from a societal perspective. To establish the costs, relevant cost items are identified, after which these costs are measured and valued. These relevant cost items are: the total surgery time, use of surgical devices (e.g. anchors, cannula's, sutures) and length of stay in the hospital. In addition, medication use, physiotherapy, GP care, costs of visits to other primary care providers, ambulatory and inpatient hospital care are taken into account. By dividing the difference in mean total costs between the groups by the difference in mean effects the Incremental cost-effectiveness ratios (ICERs) will be calculated. The time horizon of the economic evaluation is 12 months. Utility values will be calculated for the health states of the EQ-5D-5L based on the Dutch tariff for the EuroQol.[16,23] The utility values will be used to compute quality-adjusted life-years (QALY-EQ-5D-5L) by means of the area under the curve method. TiC-P part II is used to measure costs and consequences of productivity losses (indirect costs).[22] It has 4 modules: absenteeism from paid work, production losses without absenteeism from paid work, unpaid work and nuisance in paid and unpaid work and contains of 11 questions. A Budget Impact Analysis will be performed from societal, government and insurer perspective. Resource utilization is calculated by

multiplying the number of eligible patients with the resource utilization rates obtained from the cost-effectiveness analysis.[13,36]

We expect that for all relevant cost categories the costs of an isolated biceps tenotomy are lower than those of the biceps tenotomy with cuff repair. We expect that direct healthcare related costs are lower, because surgery for patients undergoing an isolated biceps tenotomy will be shorter and less surgical instruments and materials are needed. We expect that direct non-healthcare related costs are lower, because we hypothesize that the complication rate is lower, which leads to fewer hospital visits and thus less travel time. We expect that indirect healthcare related costs are absent, because both biceps tenotomy treatments do not affect life expectancy. We expect that indirect non-healthcare related costs are lower, because patients undergoing an isolated biceps tenotomy treatment resume work much faster, which leads to lower productivity losses. We expect that an isolated biceps tenotomy treatment leads to increased patient utility.

Handling and storage of data

Data will be collected using a web based electronic data collection system (REDCap). REDCap has been designed to ensure the security of patient health information and allows for direct entry by the subject, investigator and study coordinator.[18] Precautions are in place to secure the data and prevent unauthorized access, use, and information disclosure, including use of web-based passwords and encryption. All subject data will be anonymised by assigning study numbers to each subject. The key to these study numbers is only available to the coordinating investigator and the principal investigators. Outcome data, anonymised, is only accessible for the coordinating investigator, principal investigators and statistical analysers. Data will be processed and stored in SPSS which will be password protected. The handling of personal data will comply with the General Data Protection Regulation (GDPR). Data will be collected and stored for a period of 15 years. Signed informed consent documents, paper copies with patient names and unique identifiers as well as paper questionnaires will be stored at the centre of inclusion. Documents will be maintained in a locked cabinet outside the medical record area. Digital data will be maintained on password protected, secure computers.

Ethics and dissemination

The Medical Research Ethics Committees United (MEC-U), Nieuwegein, the Netherlands, has approved this trial. Furthermore, all Institutional Review Boards of the participating centres gave approval. The study will be performed in accordance with the Declaration of Helsinki with the Medical Research Involving Human Subjects Act (WMO). All adverse events, other than pain, muscle cramp and loss of strength which are normal findings after these treatments, reported by the subject or observed by the investigator or his

staff will be recorded. All SAEs will be reported to the accredited Ethics Committee that approved the protocol. We will inform the subjects and the reviewing accredited Ethics Committee if anything occurs, on the basis of which it appears that the disadvantages of participation may be significantly greater than was foreseen in the research proposal. The study will be suspended pending further review by the accredited Ethics Committee, except insofar as suspension would jeopardise the subjects' health. The investigator will take care that all subjects are kept informed. All substantial amendments to the study protocol will be notified to the Ethics Committee that gave a favourable opinion. The results of this study will be reported in peer-reviewed journals and at (inter)national conferences. Furthermore, we will share our findings with the appropriate guideline committees.

Patient and Public Involvement

This study has been developed because we noticed that patients experienced the rehabilitation after cuff repair as difficult and they struggle with the fact that rehabilitation takes so long. As we read in literature and experienced excellent results of the isolated tenotomy of the biceps tendon in the same patient group, we decided to start this clinical trial. With the exception of the emergence of the research question, patients were not involved in the design or set-up of the study. The burden of the study was not assessed before commencement. After finishing the study, patients will be informed about the general results of the study using a pamphlet.

Authors' contributions

All authors have contributed to the design of this trial protocol. FH, NW and KGAY have contributed to writing the protocol and this manuscript. KGAY is the principal investigator of this trial. All authors have contributed to the manuscript and read and approved the final manuscript.

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Competing interests statement

None declared.

Ethics approval

The Medical Research Ethics Committees United (MEC-U), Nieuwegein, the Netherlands gave approval for this trial; registration number NL54313.100.15. The start date (inclusion of the first patient) was 22 October 2018.

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9

General discussion, conclusions and recommendations, future perspectives

GENERAL DISCUSSION

This thesis was conducted to broadly study some aspects on how to optimize treatment of rotator pathology and provide tools for daily orthopaedic shoulder practice. Suggestions to optimize future treatment of degenerative rotator cuff tears, visualizing the shoulder and analyzing results accurately are proposed. Additionally, emphasizing the importance of revealing where pain originates from should be considered key, as well as determining scientific proof justifying certain treatment options. In this final chapter the main findings of the previous chapters are discussed, and general conclusions and recommendations as well as directions for future research are provided.

Re-stating the previously described aims of this thesis and consequently paraphrasing them into three main themes:

1. **Treatment of degenerative rotator cuff tears.** To study different modalities for treatment optimization for degenerative rotator cuff tears by:
- Reviewing and evaluating the scientific evidence for the various described treatment options for degenerative rotator cuff tears in literature.
- This review led to the design of a RCT which aims to determine whether performing an isolated biceps tenotomy result in comparable outcome as compared with biceps tenotomy in combination with an arthroscopic rotator cuff repair in patients with degenerative rotator cuff tears.

2. **Optimizing diagnostic strategy and aftercare following surgery.** To accomplish further optimization of the diagnostic strategy and aftercare by:
- Scrutinizing the prevalence of structural abnormalities on MRI regarding patients with atraumatic shoulder pain and possible positive predictive factors.
- Study the effect on pain, function and healing rate between the use of abduction brace and antirotation sling following arthroscopic rotator cuff repair.

3. **Patient related outcome measures.** Evaluating existing shoulder specific patient related outcome measures by:
- Evaluating the reliability and reproducibility of shoulder specific patient related outcome measurements with focus on the Constant-Murley score and Western Ontario Rotator Cuff index.

1. Treatment of degenerative rotator cuff tears

1.1. Rationale review of the literature and TenCuRe trial

Degenerative rotator cuff tears have been studied extensively over the last years and nowadays this challenging condition remains an ongoing topic of debate. This thesis was originally initiated to mainly study the possible and most optimal treatments of degenerative rotator cuff tears, which is elaborately discussed in **Chapter 2**. Within this systematically conducted review, specifically performed to search for the most optimal treatment strategy regarding degenerative rotator cuff tears, it is concluded that less extensive treatments options show comparable results as compared with more extensive treatment options. Nevertheless, since an enormous lack of evidence exists regarding the most optimal treatment of these tears, **Chapter 8** was conducted. Several patient-, and tear specific aspects are known to be involved in selecting the most appropriate treatment, and amongst these aspects or prognostic factors, the degree of fatty infiltration is widely described as an important parameter to reflect tendon quality. Therefore, as well as **Chapter 2** as **Chapter 8** were designed to focus on a particular degree of fatty infiltration, since this is found a paramount prognostic factor for a successful rotator cuff repair. In general, it is accepted to consider over 50% of fatty infiltration as an irreparable tear which was described by McMaughlin as the rotten cloth to sew and less then 25% fatty infiltration as a reparable tendon if symptomatic. The most appropriate treatment for the remaining 25-50% (Goutallier stage 2-3) is still highly under discussion and scrutinized in the review in **Chapter 2**. From this thoroughly conducted review, a wide range of possible treatment options were identified regarding this specific subgroup and it is concluded that despite the high reported retear rate, favorable results have been described for rotator cuff repair. Surprisingly, various studies have shown comparable results (measured by clinical improvement) for partial repair and isolated bicepstenotomy or tenodesis. These findings suggest that the additional effect of rotator cuff repair, as compared with less extensive treatment options like isolated bicepstenotomy or tenodesis, should be further studied as these might form a good alternative treatment based on this systematic review. Since the original search, which was conducted in 2016, many studies have been published on this topic proposing and describing a wide range of alternative treatment options, not included in **Chapter 2**. Nevertheless, these studies mainly focused on rotator cuff tears which were considered irreparable, suggesting and introducing several interesting augmentation techniques (e.g. biceps augmentation, hamstrings and superior capsular repair or reconstruction).

The outcome from the conducted review raised questions on the most optimal treatment for stage 2-3 Goutallier fatty degenerative rotator cuff tears. Which treatment should be considered most optimal and cost-effective? Since the biceps tendon is often involved

in the presence of cuff arthropathy, especially in shoulders with stage 2–4 Goutallier fatty infiltration, biceps tenotomy or tenodesis could be considered instead of a cuff repair. [11] Results of an isolated tenotomy or tenodesis have proven to be comparable with long-term results of a cuff repair, regarding these particular patients.[2,28,45] Additionally, patients diagnosed with good tendon quality rotator cuff tears and cuff repair was combined with or without a biceps tenotomy or tenodesis, comparable results were described.[5,11,15,21,22,34] Furthermore, there are several cases described in which a spontaneous ruptured long head of the biceps tendon from its insertion, in shoulders with a conservatively treated rotator cuff tear, has led to a significantly relieve of pain and improvements on function.[43] These observations raise questions on the value of performing more extensive and therefore expensive cuff repairs in degenerative cuff tears. The goal of this non-inferiority trial was to study the short-term function and quality-of-life in patients not responding to conservative therapy undergoing arthroscopic biceps tenotomy with or without an additional cuff repair and to include an economic evaluation. It is hypothesized that patients who underwent an isolated tenotomy of the long head of the biceps tendon in the presence of a degenerative rotator cuff tear, with stage 2–3 Goutallier fatty infiltration, will have non-inferior functional results and quality-of-life 3, 6 and 12 months after surgery as compared with patients undergoing tenotomy combined with a rotator cuff repair. At 1 year after surgery it was assumed reduced costs with isolated tenotomy treatment could be expected. Patients below 60 were considered potential candidates for undergoing a tendon repair, therefore these patients were not included in this study. Retrospectively, implementing an age restricted based inclusion could be questioned since age by itself does not always reflects the patient's vitality or tendon quality.

Furthermore, the TenCuRe trial was also conducted to provide a possible decision tree based on the patient's profile, physical impairment, structural findings on MRI, macroscopic findings perioperatively, microscopic tissue analysis and postoperative results. In other words, which structure or patient characteristics are or is responsible for the patients' complaints? From previous literature it is known that the macroscopic appearance of the intra-articular part of the long head of the biceps tendon is difficult to estimate and does not correlate with the histological findings.[27] Again, this brings along clinical difficulties with respect to the per-operative decision whether to perform a tenotomy or not. Despite, biceps pathology is frequently seen in combination with rotator cuff tears and it is therefore thought that treatment is justified, although no consensus exists. Degeneration, inflammation and neuro-inflammation are thought to be key in causing symptoms. However, only few people become symptomatic in the presence of a degenerative rotator cuff tear, so why do these people become symptomatic and from which structure does pain originate? Several pathways are described that might

contribute to a painful shoulder after a rotator cuff tear without the presence of osteoarthritis. Following a rotator cuff tear, nociceptors in the damaged and inflamed tendon are sensitized by a variety of substances decreasing the activation threshold (peripheral sensitization) resulting in hyperalgesia at the site of the injury. This study was therefore conducted to provide fundamental knowledge for better understanding where pain originates in patients with degenerative rotator cuff tears.

1.2. Evaluation TenCuRe trial

Two years after initiation of the TenCuRe trial only ten patients were included. This finding has led to the conduction of an interview amongst the participating centers. A structured and thorough qualitative interview was performed with six shoulder surgeons from these hospitals. The results of this interview, titled, '*Current treatment of degenerative rotator cuff tears. A scientifically based treatment strategy or cultural change amongst shoulder surgeons?',* revealed that all participating centers fully supported the study protocol due to the existing knowledge gap regarding this specific condition. Potential causes for the low inclusion rate were 1) increasing rate of successful conservative treatment, 2) decline in potential candidates, 3) in case of surgery there was a surgeons' and patients' preference for repair instead of an isolated tenotomy, 4) threshold to perform an MRI which is obligatory within this study protocol and 5) lack of follow-up of conservatively managed tears. Important prognostic factors were considered age, smoking, diabetes, traumatic or atraumatic cause, level of fatty infiltration and amount of tendon retraction. From all these factors, fatty infiltration was considered the most important by all. Consequently, 5 out of 6 surgeons defined Goutallier stage 3 and 4 as irreparable tears and only one surgeon defined ≥ 2 as irreparable. Regarding the amount of retraction, 4 out of 6 considered retraction at the level of the glenoid as irreparable, while others did not use a limit in their daily practice. Age was discussed in great detail and many maintained ages above 65 as threshold for performing a rotator cuff repair. The upper limit for degenerative tears was set by 2 out of 6 at 70 years. Regarding the patient profile, gender and presence of diabetes and smoking were considered negative prognostic factors and could influence the age limit for performing a surgical repair. The length of conservative therapy before considering surgery varied from 3-6 months in which an accurate training program was considered mandatory. Furthermore, several cases with posterosuperior degenerative tears were discussed including variance in age, length of conservative therapy before considering surgery, and level of fatty infiltration. These patients could all be potential candidates for enrollment in the TenCuRe trial. Consensus exists to repair rotator cuff tears with stage 2 Goutallier, Patte stage 2 retraction, no signs of arthritis, not responding to an accurate physiotherapy program for 6 months and age ≤ 55 years. The same patient, now 65 years old, most surgeons would consider to perform a rotator cuff repair although comorbidities like diabetes and smoking could

affect the outcome. Additionally, perioperatively, if the tear is considered irreparable an isolated tenotomy could be performed rather routinely. If the same patient would be 70 years of age some would perform a repair in case of a traumatic tear with good tendon quality and some would consider an isolated tenotomy of the biceps if clinically suspected to be pathologic.

The expected potential candidates to be included based on current practice ranged between 1 to 5 participants and the average number of cuff repairs yearly performed was grossly estimated at 43 patients (range: 20-60), which has declined significantly over time. Concerning the logistics, only minor problems were issued related to the effort completing questionnaires. Based on these findings, it was concluded that completion of this study would not be feasible and preliminary determination of the study was therefore decided. So why does this sharp decline in surgical treatment and disappointing number of inclusions occur? A remarkable down-ward trend is seen in the indications for surgery. Nowadays, degenerative tears are mainly treated conservatively and relative contra-indications for tendon repair are considered age above 65-70, also depending on the biologic age and influenced by negative prognostic factors for tendon healing, such as smoking and diabetes. By only including candidates from 60 years of age, where by many an age limit of 65 years was maintained, the range of potential inclusion is rather small. In retrospect, removing age limit from the inclusion criteria would have been a good option, relying much more on tendon quality instead of age. From all the prognostic factors, fatty infiltration is considered the most important parameter to express tendon quality and paramount in deciding for a particular treatment. From stage 3 fatty infiltration consensus exists that these tears should be considered irreparable and usually conservative therapy would be proposed. Although, if the patient was considered a potential candidate for inclusion, and MRI described stage 3 fatty infiltration, this was not considered an issue from the participating centers to allocate this patient to treatment and perform surgery.

One should consider this cultural change from surgical, as Codman in the early nineties proposed, to mainly conservative not completely fair. Of course, there are many patients who are satisfied with the results of non-operative treatment, however worldwide many different joint-preserving surgical options are studied to improve shoulder function with satisfactory results. Apparently, the more you know and read the less you understand of this challenging pathologic condition. The list of questions regarding this theme increases and much remains unclear, which might reflect that no superior treatment modality is currently available. Nevertheless, this cultural change and current trend towards conservative therapy is a current trend without sufficient scientific proof. In fact, the only comparative study reporting the conservative and surgical therapy with

long term follow-up is conducted by Moosmayer et al. and they presented the benefit of early surgical repair as compared to delayed repair or solely conservative therapy.[32] Therefore, as well for degenerative tears as for acute traumatic tears, surgical approach should be considered justified.

1.3. Recent literature and insights.

After performing the review and conduction of the TenCuRe trial in **Chapter 2** and **8** some of our questions could be considered answered. Nevertheless, whether to repair the rotator cuff or not and defining the role of the biceps tendon still remains unclear. Apparently, from previous studies a relatively simple tenotomy of the long head of the biceps tendon could reduce pain and increase function, although it has proven to be extremely difficult to evaluate the biceps tendon intraoperatively on its macroscopic aspect and to predict the pathologic extend of the tissue. Consequently, always considering the tendon pathologic in the presence of a degenerative rotator cuff tears, might be a false assumption. Additionally, the biceps could have a biomechanical role by its position, stabilizing and depressing the humeral head, so perhaps not every biceps should be 'killed' routinely. Consequently, if clinically suspected pathologic, the biceps tendon should be treated on itself and could even be simultaneously used as autograft augmentation to support rotator cuff repair. A recently published study by Veen et al. showed that elderly grossly improve on pain and function after performing an isolated tenotomy in the presence of a degenerative and left untreated rotator cuff tear.[44] They suggested that by removing the diseased intra-articular part of the tendon from its joint, complaints will resolve in most cases. However, pain may also be derived from the bicipital groove and by performing a tenotomy you delete the biomechanical role of the tendon as a humeral head depressor. The presence of neuroinflammation in the specific parts of the biceps tendon and correlation with the macroscopic aspect and clinical treatment effect could hopefully clarify this in the near future. Overall, the role of this tendon in the presence of degenerative rotator cuff tears in an inflammatory environment and clinical expansion of implication should be further studied.

So, what about cuff repair and advanced fatty infiltration?

Apparently, from the results of **Chapter 2, 8** and the interview, these days, the number of rotator cuff repairs has declined. As mentioned in **Chapter 2,** a tear is considered irreparable from stage 3 fatty infiltration, the tendon is retracted at the level of the glenoid and cuff tear arthropathy Hamada stage 2 is present. Indirect factors, such as general health of the particular patient including healing tendency, among others influenced by smoking and diabetic mellitus, will guide us as a surgeon what treatment should be advised. Conservative treatment should be particularly preserved for more advanced fatty degenerative, slowly progressive and atraumatic tears. This group of patients are

rather often initially treated conservatively with guided physiotherapy and when not responding appropriately, other options could be considered. Regarding these tears, no specific period is determined whether patients should respond. Like with many other chronic tendon ruptures, results tend to become less favorable if delayed, like with distal biceps tendon ruptures.[18] Concerning rotator cuff tears, Moosmayer et al. suggested that delayed surgical repair would eventually lead to inferior functional results as compared to aggressive surgical approach at 10-years of follow-up amongst patients with small to medium size cuff tears.[32] Another study comparing the effect of a surgical repair with a non-operative treatment is conducted by Lambers Heerspink et al. amongst patients averagely aged 60 years, with a minimum follow-up of 1 year reporting a slight improvement on shoulder function.[25,32] Concomitant biceps tenotomy was performed almost as standard additional procedure within these studies. Another recently published study, comparing both treatment options, found equivalent improvements on pain and function and therefore recommended non-surgical treatment as the primary choice. In contrary, because surgery yielded superior improvements in pain and function regarding full-thickness rotator cuff tears, rotator cuff repair may be suggested after failed non-surgical treatment.[3] Another specifically age-related study regarding arthroscopic rotator cuff repair was conducted by Nicholson et al. who found that rotator cuff repair above the age of 65 had similar excellent outcome two years after surgery and was cost-effective regarding age.[33] Unfortunately, the level of fatty infiltration was not determined. Furthermore, pushing age to a limit, Stone et al. recently published their work of rotator cuff repairs performed amongst patients beyond 75 years of age and showed reliable improvements in pain and function with a low reported conversion rate to reverse total shoulder arthroplasty.[40] This study indicates a role for rotator cuff repair in an elderly population and argues against the routine use of reverse arthroplasty for repairable rotator cuff tears in this population. Comparable with the previous mentioned study the preoperative findings on MRI were not described which might have led to an enormous selection bias that favors the effect of the repair. Nevertheless, according to these studies, even in the elderly, a rotator cuff repair seems to be a viable option, although results should be interpreted with great care.

Finally, alternative joint preserving options like superior capsular reconstruction could be considered. Multiple augmentation techniques have been proposed like the use of a tensor fascia lata graft, long head of the biceps, hamstrings.[30,7,10,13,19,26,29,35,41] However, no comparative studies are presently available concerning the various surgical techniques and no technique could be considered superior, neither as compared to other treatment options like conservative treatment and other joint preserving options. Nevertheless, one could consider the use of the long head of the biceps tendon rather promising, since its autologous availability and thereby cost-effective implementation could be relatively

easily performed and removes the possibly diseased part from the bicipital groove, which is often considered a potential cause of complaints if left untreated.[17] More studies on biomechanics and comparative studies with generally accepted and widely used outcome measures should be conducted, since this technique could still be considered quite experimental.

2. Optimizing diagnostic strategy and after care following surgery

Beside focusing on optimizing treatment strategies, other aspects should be considered equally important in order to select the appropriate candidates for the most applicable treatment and ultimately guide them true postoperative rehabilitation. This is elaborately discussed in **Chapter 3 and 4** in this thesis.

2.1. Diagnostics

Finding the correct diagnosis in patients with shoulder complaints can be rather challenging and widespread use of potentially unnecessary MRI pushes health care expenses, increases waiting lists and patients burden. Therefore, **Chapter 3** was conducted to study the use of MRI regarding patients with atraumatic shoulder pain. On beforehand, a much lower prevalence of structural abnormalities was expected as compared to the identified 72% within the study population, so apparently early signs of degenerative tissue are present in atraumatic, symptomatic shoulders in the young adult population (18-45 years, mean age 33 years). Comparable prevalence was found for the general and sporting population and a higher age was an overall predictive factor for structural abnormalities on MRI. Conducting an MRI could be considered justified, since the presence of structural abnormalities could influence the treatment strategy. Nevertheless, the findings on MRI did not always match with the clinical findings and therefore we should realize and be aware not to treat every pathologic finding on MRI. It should be used as a tool to clarify your prior diagnosis as it might influence your treatment strategy. Approximately two-third of the population was accurately diagnosed by their surgeon, which signifies that in about one-third of the cases the diagnosis was wrong.

Scrutinizing patients with rotator cuff pathology within this study, pathology ranged from tendinopathy, to partial tear and full-thickness tears. Particularly, those with solely tendinopathy, where rotator cuff pathology was suspected, it seems rather useless and MRI should be avoided unless other underlying causes are suspected. The MRI in orthopedic shoulder practice is of paramount importance since it can be bitterly challenging to diagnose the patient correctly based on the interview and physical examination. Logically, an appropriate interview regarding the symptoms and etiology of complains should be thoroughly discussed after which an accurate physical examination will guide you into a probability diagnosis prior to imaging. Before performing a MRI, ultrasound imaging

could be used as an extension in orthopedic practice to rule out partial or full thickness tears.[4] Additionally, presence of subacromial bursitis, rotator cuff tendinopathy and subacromial impingement can be easily detected. Ultimately, the additional value of the ultrasound was discussed in **Chapter 3**, however due to many missing reports the findings on MRI could not be correlated with potential findings on dynamic ultrasonographic imaging. From previous literature, inaccurate use of MRI amongst orthopaedic surgeons is common, although the role of the ultrasound in rotator cuff pathology has been proven strongly effective.[39] The quality of dynamic ultrasound imaging is dependent on the level of expertise of the examiner and patient's accessibility, though favorable due to its wide availability and low cost. From previous studies comparing the accuracy of the office-based ultrasound with the MRI, the ultrasound appears to be highly effective in detecting full-thickness and partial tears lager than 1 cm, although the smaller tears are difficult to detect.[20] Therefore, one could suggest to perform an ultrasound first at consultation and if complaints persist one could opt for a MRI. Other reasons that rectify MRI are especially traumatic shoulder complaints, persistent complaints in atraumatic cases (**Chapter 3**), glenohumeral instability, suspicion of bony or soft tissue tumors and preoperative imaging to access tissue quality.

2.2. Postoperative pain and after care

Within this thesis **Chapter 4** was conducted to optimize postoperative care and to enhance understanding the mechanism that might be responsible for these high levels of pain. At time of publication, the study in **Chapter 4.1** was the first randomized controlled trial conducted on this topic. Thereafter, solely one additional comparable study was performed by Ghandour et al., which was discussed in great detail in the invited comment in the same journal in **Chapter 4.2**. Both studies reported comparable results on comparable study populations and techniques of immobilization. Apparently, the authors were not able to confirm their soluble explanation or managed to reduce the level of pain. As previously stated with respect to the mobile and easily reparable tears, abduction and neutral rotation is not obligatory during the postoperative period of immobilization. Therefore, based on the current literature, it is not advisable to prescribe an abduction brace for postoperative immobilization after rotator cuff repair. The use of an antirotation sling is cost-effective and our study revealed that patients were comfortable with its use. Therefore, the hospital in which this particular study was conducted abandoned the use of an abduction brace for immobilization after regular rotator cuff repair. Whereas our study in **Chapter 4** was conducted to study the potential effect on pain by some level of abduction, other strategies studied in randomized controlled trials, focused on the length of immobilization or even direct postoperative mobilization. Firstly, Jenssen et al. found no difference concerning pain, function and healing rate between 3 and 6 weeks of immobilization 12 months after surgery. Secondly, Tirefort

et al. even showed that no immobilization after rotator cuff repair is associated with better early mobility and functional scores in comparison with sling immobilization. Therefore, regarding the small and medium sized cuff tears, direct mobilization might be considered.

Factors that may contribute to an increased amount of tension on repaired rotator cuff tendons, which are thought to contribute to increased levels of pain, have been studied based on plausible concepts, though seems to be multifactorial and therefore requires a different approach for better understanding of shoulder pain. Psychosocial factors have been shown to be important in the amount of pain experienced before and after treatment as well.[23] Other factors which may contribute to pain based on current literature are younger patients, women, work-related injuries and higher preoperative level of pain. However, like with other orthopedic surgical procedures such as total knee arthroplasty[42], patients' expectations of postoperative pain and preoperative subjective pain tolerance, and emotional well-being were found strong predictors of postoperative pain. [8,14,36]

3. Patient related outcome measures

Appropriate patient related outcome measures are essential to accurately measure the aimed treatment effect. Worldwide, numerous shoulder specific questionnaires exist, although correct interpretation is paramount in order to reliably and reproducibly produce data before it is translated into clinical practice. The CMS and WORC were elaborately studied within this thesis and particularly focused on reproducibility, reliability and digitalization.

Therefore, three main questions were formulated:
3.1 What is the reliability and reproducibility of the CMS?
3.2 What Is the reliability and reproducibility of the WORC index?
3.3 Digitalization of questionnaires, with impunity?

3.1. Constant-Murley score

Out of all the existing shoulder specific questionnaires, the most frequently used combined functional and subjective questionnaire, which could be considered the golden standard at least in Europe, is the CMS. The subjective patient-reported component of the CMS documents pain and difficulty in activities of daily living, work, sport, and sleep. Due to variations in application and scoring of this measure, information on its validity may not be comparable across studies. Therefore, **Chapter 5** elaborately studied the internal consistency and the effect on the subdomains with the use of different answering scales like the paper-based VAS, smiley face score, and NRS. It is concluded that the

different answering scale scores for the subjective subscales within the CMS were not interchangeable on item level and significantly influenced the total CMS score. Nevertheless, differences were below the smallest detectable change and interpreted as not clinically relevant. Particularly on item level, data from different studies can therefore not be pooled and compared when different answering scales have been used. Regarding internal consistency, the CMS is widely used in literature to determine shoulder function and low internal consistency of the subjective subcategories is reported, whereas results from **Chapter 5** show high internal consistency.[37] The use of a standardized study protocol could has resulted in this high consistency amongst and between the examiners. Furthermore, results were comparable with previous studies regarding inter- and intra-observer reliability, which was considered excellent.[9,31,38]

Although not included in **Chapter 5**, additional analyses on construct validity were performed between the CMS, subjective shoulder value (SSV) and WORC. Whereas internal consistency provides information on reproducibility of the specific questionnaires, the construct validity shows the amount of intended measured effect regarding a specific condition. Although there is no official golden standard for self- and/or examiner-assessed shoulder function to determine the validity of the CMS, from previous literature, a strong correlation was found between the CMS and the validated WORC index [37,48] and the SSV [16]. In **Chapter 5**, similar results were found concerning patients with solely rotator cuff pathology, as Spearman rank correlation Coefficients showed strong correlations ($r>0.6$) between the CMS and the WORC and SSV. The SSV consists of only one question and expresses the impaired shoulder as a percentage of an entirely normal shoulder, which would score 100%.

The ideal combined functional as well as subjective assessment tool has yet to be developed. Multiple appropriate developed and validated shoulder questionnaires have been developed over time, although the current set of questionnaires do not measure the same effect and are poorly interchangeable with overall low construct validity. Furthermore, ultimately, they should be available digitally and preferable self-assessment based to reduce the clinicians work load and include items on quality of life, disease specific impairments on daily life, general health status, etcetera. In other words, this compromises the conversation between the patient and clinician and includes indirect as well as direct communication. Unfortunately, it is extremely difficult to include this in a certain questionnaire. In terms of ease, the easiest questionnaire which is currently available and most soluble to measure the effect of your treatment could be considered the SSV, which is strongly correlated with the CMS and WORC as shown from unpublished results in **Chapter 5**. Ultimately, one is able to predict specifically on a certain domain on how to satisfy their patient and capture this treatment effect within the SSV.

If one knows on which domain(s) the desired improvement is needed, this knowledge can be used to inform and guide individual patients to their optimal treatment. Therefore, one could implement an extension within the format of the SSV that comprises impairment caused by shoulder complaints, on function, mental well-being, quality of life, daily participation in life, impact on work and recorded on a 0-100 non-hatched line. Additionally, this could be extended with an age and gender adjustable score as previously used for the CMS. Patient expectations are extremely important and should be separately included, because it is known to influence the final result of the *shared-decided* treatment. Interestingly, the design of one-question questionnaires like the SSV have already been used regarding other joints, for example in hip and knee pathology with acceptable validity.[24] Furthermore, short questionnaires could increase responsiveness and reduce burden involved in participating in clinical trials in high volume centers without impairing the efficiency.

Overall, the main issues regarding the CMS is the use of different answering scales circulating around and the missing official validation causing unawareness of small, though significant, differences between these different answering scales. Furthermore, internal consistency concerning the subjective part varies and functional assessment focusses highly on measurement of strength, which varies as well the reported intra- and interobserver reliability and is above all time-consuming. The use of the CMS in current practice could be considered out dated and already patient reported digital alternatives have been suggested like the non-validated auto-CMS.[6] World-wide consensus should be endeavored for the subset of questions used in literature in order to compare studies results and work together in terms of meta- and network analyses to optimize the treatment of rotator cuff tears and other shoulder related pathologies. Consequently, the CMS was used more often in Europe as compared with the ASES score, which was more commonly used in studies conducted in the USA, reflecting cultural differences in the use of questionnaires.[1]

3.2. Western Ontario Rotator Cuff (WORC) index

The WORC index is developed to measure disease specific quality of life on five domains, which consist of physical symptoms, sports and recreation, work, social function, and emotional disability. The reliability and reproducibility on various domains were studies extensively in **Chapter 6** and **7**. In **Chapter 6** the phenomenon perception shift was investigated and in **Chapter 7** the effect of digitalization was evaluated. The WORC index is frequently used in literature since its introduction in 2003 by Kirkley et al. However, the presence of recall bias, which is often defined as perception shift, has not been studied previously. It could be of great value, regarding the conduction of retrospective studies, whether recall bias is expected. Therefore, in **Chapter 6** this phenomenon is studied

and on beforehand it was hypothesized there would be a positive group-level response shift (overestimation of preoperative disability) after arthroscopic rotator cuff repair and expected to increase over time. Interestingly, no significant group-level response shift was observed using the WORC and with the absence of any shift in patient's perception this study suggests one could retrospectively reliably conduct group-level preoperative baseline information on quality of life up to 1 year after surgery. Individually based, at 3 and 6 months after surgery patients were more likely to overestimate their functional disability which shifted towards a slight positively recalibrated disability estimation at 1 year after surgery. This finding is very useful for the clinician if baseline measurements are absent in retrospectively conducted studies and as a finding on itself regarding recall-bias. Especially, since the WORC index has proven its validity, specifically regarding rotator cuff pathology.[12] With this knowledge, De Witte et al. reported that the WORC is a reliable, valid, and responsive measure of disease specific health-related quality of life in patients with rotator cuff lesions of various origins and found good construct validity with among others the CMS.[12] Recall bias has been recently studied within the American Shoulder and Elbow Surgeons (ASES) scores in arthroscopic rotator cuff repair surgery and interestingly, they found that the retrospectively reported ASES score was subject to a significant extend of recall bias. The recalled questionnaire was almost always lower than their prospectively recorded counterparts. Additionally, the recalled ASES were more likely to be accurate when reported by younger patients, those with a longer duration of symptoms, and those with more severe preoperative conditions. This implies, recall bias is questionnaire dependent.

Furthermore, responsiveness was studied extensively by Wessel et al. and has proven the WORC is disease specific and has a high responsiveness in patients undergoing rotator cuff repair and patients with a diseased rotator cuff without a rotator cuff tear.[47] So, overall, the WORC could be considered an accurate measurement tool which tend to measure the same effect concerning patients with rotator cuff pathology, as compared to the combined objective and subjective CMS. Comments have been posed on the 5-domains structured questionnaire by Wessel et al by proposing a 3-domains structured version to reduce variance, which appears to be 1) symptoms and emotions, 2) strenuous shoulder tasks, and 3) difficulty with daily tasks [46]. Additionally, to reduce variance and to simplify the WORC one could even restructure this proposed 3-domains questionnaire to a solely one question questionnaire on each domain, similarly as with the use of the SSV.

3.3. Digitalization

Nowadays, digitalization of questionnaires is widely implemented within our current electronic health record programs or software like REDCap. By digitalizing paper-based

outcome tools, it is inevitable that minor changes occur. Therefore, since the WORC was considered appropriate regarding rotator cuff pathology, the WORC was digitalized for future digital implementation and results presented in **Chapter 7**. The results of this study indicated that there were no significant differences in WORC scores between the electronic and paper-based mode of administration. The advantages of efficient electronic based data collection exceed possible small introduced clinically irrelevant differences and a digitalized WORC can therefore be reliably used for outcome collection in orthopedic practice. Nevertheless, it is not recommended to change the mode of administration without careful consideration, as an outcome tool should only be used in the validated format. From future perspective, it is highly likely that digitalization will extend and implementation of apps, tele-consulting and other forms of deep learning will show a steep rise. Therefore, worldwide collaboration should by thrived, using heterogenous, easily reproducible and reliable disease specific measurement tools, illuminating different aspects regarding patient's well-being and easy accessibility for as well as health practitioners as patients in shared decision making. Additionally, this implies practically that based on certain patient profile, a prediction could be made regarding the expected outcome (e.g. functional improvement, risk of complications, effect of smoking cessation). Already implemented in our current practice is Keuzehulp from Patient plus, which also exists specifically for rotator cuff tears and provides basic knowledge regarding this particular disease for our patients. Whereas, the patient is given several questions on preferences and ability to decide for a particular treatment, several important parameters are not mentioned. These parameters are supposed to be completed by the orthopedic shoulder surgeon and based on his experience, advise will be given. Ultimately, prediction models could be used and provided on beforehand by deep learning models.

CONCLUSIONS AND RECOMMENDATIONS

Treating rotator cuff pathology is considered challenging regarding multiple aspects. Therefore, this thesis was conducted to study broadly some of these aspects on how to optimize treatment and provide tools for daily orthopaedic shoulder practice. Suggestions to optimize future treatment of degenerative rotator cuff tears, visualizing the shoulder and analyzing results accurately are proposed. Additionally, emphasizing the importance of revealing where pain originates from should be considered key, as well as determining scientific proof justifying certain treatment options. Understanding the biomechanics of the biceps and the rotator cuff tendons, and the process towards tissue degeneration is highly important. In current orthopaedic shoulder practice it is a tremendous challenge to manage this specific condition and recent times has shown

that treatment strategy has evolved from early aggressive surgical treatment to a predominantly conservative treatment culture. The role of the biceps tendon in the presence of degenerative rotator tears should be further clarified as well. According to the current literature regarding the treatment of degenerative rotator cuff tears which was extensively reviewed in this thesis, a wide range of treatment options might be indicated. Do no further harm is deeply seated in our work, although unawareness of cultural habits regarding treatment should be broken and curiosity encouraged to accomplish optimization and prevent unknowingly further harm.

From this thesis we have gained important knowledge regarding optimizing rotator cuff pathology and therefore, several recommendations can be made.

- From this thesis we have learned that, despite well designed study protocols based on current concepts, expert opinions vary widely and fluctuate over time. Logically, these opinions generally influence daily practice and consequently affects how clinical trial protocols are executed. What has yet to be studied may be already outdated as soon as we practice these concepts regardless of the presence of substantiate scientific evidence.
- Despite the high reported retear rate, rotator cuff repair in stage 2-3 Goutallier rotator cuff tear has comparable results as partial repair and isolated bicepstenotomy or tenodesis. Conservative treatment is advised initially and if considered a non-responder, alternative surgical treatment options could be initiated. (**Chapter 2**)
- Surgeons that justify killing tendons, those who support repairing them and the ones that stay conservative should work together to solve the mystery of degenerative rotator cuff tears. (**Chapter 8**)
- The additional effect of rotator cuff repair compared to the less extensive treatment options like isolated bicepstenotomy or tenodesis should be clarified. (**Chapter 8**)
- Early tissue degeneration in and around the shoulder has shown to be rather common and age dependent on advanced imaging modalities, though the clinical implication should be scrutinized in great detail. (**Chapter 3**)
- Having visualized the shoulder by image and by word, better understanding is provided, which should be done with the use of accurate tools. This thesis has shown us that with great care, these tools should be used in the correct setting in order to optimize care by all means. **(Chapter 3 – 7)**
- Revealing the patient's complaints and expectations accurately from us as shoulder specialist and translating this into reliable and reproducible measurement tools is of paramount importance. While current validated tools are provided, they should be used in the appropriate manner. In order to improve international interchangeability and inter-study comparability such questionnaires need to be further generalized and incorporated in daily clinical practice. **(Chapter 5 – 7)**

- Factors that may contribute to an increased amount of tension on repaired rotator cuff tendons, which are thought to contribute to increased levels of pain, have been studied based on plausible concepts, though seems to be multifactorial and therefore requires a different approach for better understanding of shoulder pain. Although tension on repaired tendons theoretically might influence pain, immobilizing the shoulder in a certain posture apparently does not seem to play a significant role by itself. **(Chapter 4)**

FUTURE PERSPECTIVES

Treatment of rotator cuff pathology is challenging and this thesis aimed to optimize several aspects regarding this condition, especially degenerative rotator cuff tears. As compared to the previous century an upward trend is observed towards conservative treatment of degenerative rotator cuff tears although decent proof remains absent. Therefore, future research should be aimed on revealing fundamental knowledge on pain deriving structures in and around the shoulder, including expectations and other behavioral aspects which should be clarified to predict the effect on a certain conducted treatment. Additionally, the exact role of the biceps tendon in the presence of degenerative rotator cuff tears should be further clarified, scrutinizing neuroinflammation, biomechanics and potential implication as augmentation.

Furthermore, not solely preoperative pain but also postoperative pain should be better understood and is thought to be multifactorial and therefore may be influenced by the same patient profile characteristics, which are involved in preoperative functional and mental impairment, reflecting the general well-being.

Accurate use of advanced imaging modalities for suspected rotator cuff derived shoulder pain is of paramount importance to reduce costs and prevent unnecessary use.

Finally, worldwide collaboration should be thrived, using heterogenous, easily reproducible and reliable disease specific measurement tools, illuminating different aspects regarding patient's well-being and easy accessibility for as well as health practitioners as patients in shared decision making. While the CMS and WORC have proven to be valid, reproducible and reliable shoulder specific measurement tools, shorter questionnaires like the SSV should be considered and ultimately, prediction models could be used and provided at consultation before treatment is initiated by deep learning models.

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10

Valorization

VALORIZATION

The treatment and understanding of rotator cuff pathology can be challenging and the path towards tissue degeneration and presence of shoulder complaints still remain partially unclear. The optimal approach towards degenerative rotator cuff tears is an ongoing topic of debate and the current evidence on how to treat these tears ultimately is scares. This thesis has provided supportive knowledge that is paramount to improve care on rotator cuff pathology and not solely includes treatment strategy.

In the early nineties, shoulder surgeons like Codman were rather surgically aggressive regarding the treatment of degenerative rotator cuff tears. Over the last years a tremendous effort has been put to solve the mystery of the most optimal treatment of these difficult to treat tears. The need for further clarification of this challenging condition in a population where age increases and shoulder dysfunction may lead to further increase in health expenses is obvious. From socioeconomical perspective rotator cuff pathology and probable concomitant functional impairment might have enormous effect on general well-being in daily life. The estimated lifetime societal savings of the approximately 250.000 rotator cuff repairs performed in the U.S. each year is $3.44 billion and approximately 4.5 million patient visits related to shoulder pain occur each year in the United States. On the one hand it should be aimed to gain functionality as soon as possible but on the other hand indirect as well as direct health care costs should be kept low. In other words, both sides should be well balanced to be considered cost-effective. With the knowledge from the review article included in this thesis regarding several treatment options for degenerative rotator cuff tears it has shown us that multiple treatment options have comparable results. The TenCuRe trial was therefore conducted to study the cost-effectiveness of the isolated biceps tenotomy with or without rotator cuff repair. Unfortunately, preliminary termination of this trial did not answer this question, although much is learned from this rather large multidisciplinary designed project. From this thesis it is known that there is a tendency towards conservative treatment preferences which is based on experience rather than scientific evidence. Nuances from aggressive surgical repair towards non-surgical management should be made and further studied before conclusions are drawn. Even though the design of the TenCuRe trial was conducted with great care together with several highly appreciated shoulder experts, unfortunately an insufficient number of patients were enrolled. Revising its design by including a third conservative section and adjusting the inclusion criteria, could be considered. After a thorough evaluation, which was conducted before termination, valuable expert opinions were shared and elaborately discussed. Lessons learned from those who were involved in this trial could be spread amongst colleagues from the Dutch Shoulder and Elbow Society and residents, and thoughts provided for future

research goals. The societal and economic value of performing a rotator cuff repair is of paramount importance to support this treatment in future for the elderly, while below 60 years of age this treatment has proven its superiority. Many indirect and direct expenses should be considered in order to support this treatment in future as well as other joint- and non-joint preserving options. Support should be acquired from surgeons as well as health care insurance companies to continue our work the way we believe is best for our patients.

Optimizing rotator cuff pathology does not only include treatment, rotator cuff pathology specific health care improvement relies on optimal use of diagnostics as well. This thesis has shown that the prevalence of structural abnormalities is extremely and unexpectedly high which reflects that early tissue degeneration is rather common. While the MRI has proven its accuracy when it concerns detecting pathologic abnormalities, many of these findings do not implicate and clarify particular complaints in relation to atraumatic shoulder complaints. In general, one should thrive to reduce costs and use advanced imaging modalities as cost-effective as possible. Therefore, the use of other less costly options like the ultrasound as extension of our physical examination should be effectively incorporated on our daily out-patient care. Therefore, with great preservation, the MRI should be used to prevent overtreatment of unsuspected structural abnormalities so that expenses on diagnostics and treatment are kept fairly low. Having said that, highly accurate determined diagnoses prior to MRI should be correlated with the actual structural abnormalities revealed by the MRI.

Beside diagnostics and choosing the most optimal treatment modality, insight on pain and how to measure complaints and physical disability is provided in this thesis. Rotator cuff pathology, especially rotator cuff tears which are treated with a rotator cuff repair, could cause high levels of pain. Of course, pain can be managed with accurate analgesics but some postoperative immobilization devices are introduced to support the construct, contribute to comfort and reduce pain as well. From this thesis it is known that the abduction brace is not superior as compared to a simple and much cheaper antirotation sling, thereby reducing costs. Pain is believed to be multifactorial, though shoulder posture by itself does not seem to have significant influence. Widespread use and introduction of new and existing immobilization devices should be used with great care since their potential benefits, with cost-effectiveness in mind, should be studies extensively before its use should be incorporated in standard daily practice.

Research on rotator cuff pathology is conducted all over the world and many different measurement tools are used within different settings and scales. Of course, it is highly important that data is interpreted correctly and derived information is measured reli-

able and reproducible. Nevertheless, unawareness of unintended manipulations that causes misinterpretation of data may lead to false conclusions which have societal and economic impact. Therefore, two commonly used shoulder specific questionnaires were studied in great detail on reliability, reproducibility and effects of digitalization. While these questionnaires have proven to be reliable and reproducible, one should be aware of diversity in completion, use of different answering scales and administration modalities since they might influence outcome.

When taken together, rotator cuff pathology, especially degenerative rotator cuff tears, is a challenging condition, although this thesis managed to answer several important questions that contribute to optimize care and provide clinicians useful knowledge to improve their daily practice, reduce health care burden and increase quality of life.

In my view, future research should be aimed on personalized medicine and in order to accomplish such strategy, worldwide collaboration is of paramount importance. Similar and simplified measurement tools should be used and data should be stored in shared databases from where relevant research questions are formulated by expert opinion panels. Crossing borders and international collaboration should be endeavored. With great care, existing and new alternative joint preserving options should be studied and biomechanical background understood. Many ideas and lots of enthusiasm left to solve to mystery of the degenerative rotator cuff.

11

Summary, Nederlandse samenvatting

SUMMARY

The treatment of rotator cuff pathology can be rather challenging and involves multiple aspects. This thesis was conducted to optimize care on rotator cuff pathology and provide tools for daily orthopaedic shoulder practice regarding some of these aspects. Suggestions on optimizing the treatment of degenerative rotator cuff tears, visualizing shoulder pathology and analyzing results accurately, are proposed. Additionally, emphasizing the importance of revealing where pain originates from should be considered key, as well as determining scientific proof justifying certain treatment options. Rotator cuff tears, particularly degenerative tears, are highly common within our general population and better understanding of all aspects involved regarding these tears is paramount to optimize shoulder function and secure people to remain physically active. Prevalence of degenerative tears increases with age and consequently implicates that a substantial burden could be expected because of an upwards shift in age structure. Whereas in the beginning of the previous century tears were aggressively repaired, nowadays an upward trend has evolved towards conservative treatment, although no world-wide consensus exists. This thesis provides insight in optimizing diagnostics, treatment, after care and shoulder specific patient related outcome measures in the rotator cuff diseased shoulder.

This thesis can be grossly divided into three main topics, respectively 1) treatment of degenerative rotator cuff tears, 2) diagnostic imaging and aftercare following arthroscopic rotator cuff repair, 3) shoulder specific patient related outcome measures. Firstly, an overview is provided of the possible treatment options for stage 2-3 Goutallier degenerative rotator cuff tears (**Chapter 2**) and consequently a study protocol is presented comparing bicepstenotomy with or without rotator cuff repair regarding the same degenerative tears (**Chapter 8**). Thereafter, the diagnostic process is scrutinized and the clinical value of the MRI regarding patients with atraumatic shoulder pain clarified (**Chapter 3**). Furthermore, postoperative immobilization is extensively studied (**Chapter 4**). Finally, a considerable contribution of this thesis focuses on two commonly used shoulder specific patient related outcome measures (**Chapter 5-7**).

Tissue quality in relation with degenerative rotator cuff tears is often expressed by the amount of fatty infiltration and is known to be an important prognostic factor in the treatment of degenerative rotator cuff tears. When 25-50% (Goutallier stage 2-3) of the tendon consist of fatty infiltrative tissue, current literature fails to provide accurate support on how to manage these tears. Therefore, **Chapter 2** was conducted, providing an overview of the literature on treatment outcome regarding these tears. Data was derived from non-operative treatment, less extensive surgical options like isolated biceps

tenotomy, debridement and more extensive options like rotator cuff repair, tendon transfer and arthroplasty. Despite the high reported retear rate following rotator cuff repair, comparable results on pain and function are reported for less extensive surgical treatment options as partial repair and isolated bicepstenotomy or tenodesis.

Widespread use of potentially unnecessary MRI pushes health care expenses, increases waiting lists and patients burden. Therefore, routinely use of costly and time-consuming diagnostic tools such as MRI should be studied extensively amongst rotator cuff pathology and other type of shoulder complaints. Previous investigations on shoulder MRI amongst the atraumatic population is scarce and mainly focus on asymptomatic professional athletes or the elderly population with an extremely high prevalence of structural abnormalities for both groups. In **Chapter 3**, the prevalence of structural abnormalities on MRI amongst patients with atraumatic shoulder complaints is described and possible predictive factors for structural abnormalities are provided. Low prevalence of structural abnormalities was expected. Paradoxical, 72% showed structural isolated or combined abnormalities on MRI and only a higher age is correlated with an increased number of structural abnormalities, which could be clarified by early tissue degeneration. Additionally, practicing overhand sports is predictive for a SLAP (Superior Labrum from Anterior to Posterior) tear and significantly more SLAP tears were observed amongst patients with sports derived complaints.

Besides treatment and diagnostics, optimizing care on rotator cuff pathology also includes after care following arthroscopic rotator cuff repair. Hypothetically, the amount of tension on the repaired construct could be correlated with increased levels of pain, impaired shoulder function and even lower tendon healing. Consequently, in **Chapter 4**, the effects on pain, function and tendon healing regarding the use of an abduction brace or antirotation sling following arthroscopic rotator cuff repair were evaluated. At follow-up, the two examined shoulder postures did not influence the level of pain, function and tendon healing during early postoperative immobilization.

In **Chapter 5, 6** and **7** shoulder specific patient related outcome measures are critically evaluated and particularly focused on reliability, reproducibility and effect of digitalization regarding the Constant-Murley Score (CMS) and Western Ontario Rotator Cuff index (WORC). **Chapter 5** elaborately studied the internal consistency and the effect on the subdomains with the use of different answering scales like the paper-based Visual Analog Scale, smiley face score, and Numeric Rating Scale. It is concluded that the different answering scale scores for the subjective subscales within the CMS were not interchangeable on item level and significantly influenced the total CMS score. Nevertheless, differences were below the smallest detectable change and interpreted as not clinically

relevant. Particularly on item level, data from different studies can not be pooled and compared when different answering scales are being used. In **Chapter 6** and **7** the WORC index was evaluated on the presence of recall bias and the effect of digitalization. Interestingly, in **Chapter 6** no significant group-level response shift was observed using the WORC and with the absence of any shift in patient's perception this study suggests one could retrospectively reliably conduct group-level preoperative baseline information on quality of life up to 1 year after surgery. This finding is very useful for the clinician if baseline measurements are absent in retrospectively conducted studies and as a finding on itself regarding recall-bias. Nowadays, digitalization of the questionnaires is widely implemented within our current electronic health record programs or software. The results of **Chapter 7** indicated that there were no significant differences in WORC scores between the electronic and paper-based mode of administration. The advantages of efficient electronic based data collection exceed the possible small introduced clinically irrelevant differences. An electronic WORC can therefore be reliably used for outcome collection in orthopedic practice.

Finally, results derived from **Chapter 2** were used to conduct a multicenter randomized controlled trial on the treatment of stage 2-3 degenerative rotator cuff tears. In **Chapter 8**, a study protocol is provided to compare the pain, function and cost-effectiveness of performing an arthroscopic tenotomy of the long head of the biceps tendon with or without arthroscopic rotator cuff repair. This study was initiated in 2018, although due to an insufficient amount of inclusions, despite a highly motivated, committed and dedicated team, the study was officially terminated in 2021. This decision was made after a thorough interview with all participating hospitals, providing insight in the current treatment strategy of these particular tears. On the one hand, an important question remains unanswered but on the other hand this particular research question showed the transition to conservative treatment strategy over the last years because of satisfying results.

NEDERLANDSE SAMENVATTING

De behandeling van rotator cuff-pathologie kan uitdagend zijn en omvat diverse aspecten. Dit proefschrift is uitgevoerd om de zorg rondom rotator cuff-pathologie te optimaliseren en een aantal handvatten te bieden voor de dagelijkse orthopedische praktijk. Suggesties worden gedaan voor het optimaliseren van de behandeling van degeneratieve rotator cuff-scheuren, het visualiseren van schouderpathologie en het nauwkeurig analyseren van resultaten met de juiste meetinstrumenten. Het belang om te achterhalen waar pijn vandaan komt bij degeneratieve rotator cuff-scheuren en het wetenschappelijk bewijs dat bepaalde behandelingsopties gerechtvaardigd zijn worden benadrukt. Rotator cuff-scheuren, met name in degeneratieve vorm, komen veel voor onder onze bevolking waarbij het begrip van alle aspecten die met deze scheuren samenhangt van groot belang is om de schouderfunctie te optimaliseren en ervoor te zorgen dat mensen fysiek actief blijven. De prevalentie van degeneratieve scheuren neemt toe met de leeftijd waarbij een aanzienlijke belasting kan worden verwacht vanwege een vergrijzing in de maatschappij. Dit proefschrift geeft inzicht in het optimaliseren van diagnostiek, behandeling, nazorg en schouder specifieke patiëntgerelateerde uitkomstmaten met betrekking tot rotator cuff-pathologie.

Binnen dit proefschrift worden drie hoofdonderwerpen besproken, respectievelijk 1) behandeling van degeneratieve rotator cuff-scheuren, 2) diagnostiek middels beeldvorming en nazorg na arthroscopisch rotator cuff-herstel, 3) schouder specifieke patiënt gerelateerde uitkomstmaten. Allereerst wordt een overzicht gegeven van de mogelijke behandelingsopties voor Goutallier stadium 2-3 degeneratieve rotator cuff-scheuren (**Hoofdstuk 2**). Daarna zal het diagnostisch proces onder de loep genomen worden en de klinische waarde van de MRI voor patiënten met atraumatische schouderpijn worden besproken (**Hoofdstuk 3**). Verder wordt postoperatieve immobilisatie uitgebreid bestudeerd (**Hoofdstuk 4**). Een aanzienlijke bijdrage van dit proefschrift richt zich op een tweetal veelgebruikte schouder specifieke patiënt gerelateerde uitkomstmaten (**Hoofdstuk 5-7**). Ten slotte wordt naar aanleiding van de resultaten uit **Hoofdstuk 2** een onderzoeksprotocol gepresenteerd waarin het verrichten van een bicepstenotomie met of zonder rotator cuff-herstel met elkaar vergeleken kan worden (**Hoofdstuk 8**).

De kwaliteit van het peesweefsel in relatie tot degeneratieve rotator cuff-scheuren wordt vaak uitgedrukt met behulp van de mate van vettige degeneratie dat bekend staat als een belangrijke prognostische factor als het gaat om de behandeling van degeneratieve rotator cuff-scheuren. Wanneer 25-50% (Goutallier stadium 2-3) van de pees bestaat uit vettige infiltratie, biedt de huidige literatuur geen eenduidige ondersteuning over hoe deze scheuren het beste te behandelen zijn. In **Hoofdstuk 2** wordt een overzicht

gegeven van de literatuur over behandelresultaten met betrekking tot dit type peesscheuren. De resultaten in de literatuur van een niet-operatieve behandeling versus minder uitgebreide chirurgische opties zoals geïsoleerde biceps-tenotomie, debridement en uitgebreidere opties zoals rotator cuff-herstel, peestransfer en artroplastiek zijn hierbij onderzocht. Ondanks de hoge kans op het opnieuw scheuren van de pees na een operatief herstel, worden vergelijkbare resultaten op gebied van pijn en functie gezien in vergelijking met minder uitgebreide chirurgische behandelingsopties zoals het gedeeltelijke repareren van de pezen en het geïsoleerd doornemen of vastzetten van de lange kop van de bicepspees.

Het inzetten van onnodige diagnostiek zoals MRI-scans verhoogt de zorgkosten, vergroot de wachtlijsten en de last voor patiënten. Routinematig gebruik van deze kostbare en tijdrovende diagnostische hulpmiddelen zoals MRI dient vermeden te worden en juist te worden ingezet als het gaat om rotator cuff-pathologie en andere typen schouderklachten. De huidige literatuur gericht op het verrichten van een MRI onder de atraumatische patiëntpopulatie is schaars en richt zich vooral op asymptomatische professionele sporters of de oudere populatie. In **Hoofdstuk 3** wordt de prevalentie van structurele afwijkingen op MRI bij patiënten met atraumatische schouderklachten beschreven en worden mogelijke voorspellende factoren voor structurele afwijkingen besproken. Een lage prevalentie van structurele afwijkingen werd verwacht. Daarentegen werd bij 72% van de populatie geïsoleerde of gecombineerde afwijkingen op de MRI gevonden. Alleen een hogere leeftijd is gecorreleerd met een verhoogde kans op een afwijkende MRI hetgeen mogelijk verklaard kan worden door vroege degeneratie van het weefsel. Daarnaast is bovenhands sporten voorspellend voor een SLAP-laesie (Superior Labrum from Anterior to Posterior tear) en werden er significant meer SLAP-laesies waargenomen bij patiënten met sport gerelateerde klachten.

Naast behandeling en diagnostiek omvat het optimaliseren van zorg voor rotator cuff-pathologie ook de nazorg na bijvoorbeeld een operatief herstel van de rotator cuff, een frequent uitgevoerde operatie onder de meeste schouderspecialisten. Hypothetisch zou de hoeveelheid spanning op de gerepareerde pees gecorreleerd kunnen zijn met verhoogde pijnniveaus, verminderde schouderfunctie en zelfs lagere peesgenezing. Daarom werden in **Hoofdstuk 4** de effecten op pijn, functie en peesgenezing geëvalueerd met betrekking tot het gebruik van een abductiebrace of antirotatie sling na operatief herstel van de rotator cuff via een kijkoperatie. De onderzochte methoden van immobiliseren bleken geen invloed te hebben op het niveau van pijn, functie en peesgenezing tijdens vroege postoperatieve immobilisatie en tot 1 jaar na de operatie.

In **Hoofdstuk 5, 6** en **7** worden twee schouder specifieke patiënt gerelateerde uitkomstmaten kritisch geëvalueerd gericht op betrouwbaarheid, reproduceerbaarheid en het effect van digitalisering. Het betreft de Constant-Murley Score (CMS) en de Western Ontario Rotator Cuff-index (WORC). In **hoofdstuk 5** wordt uitvoerig ingegaan op de interne consistentie van de CMS en het effect op de subjectieve subdomeinen van verschillende antwoordschalen zoals de papieren Visual Analog Scale, smiley face score en Numeric Rating Scale. Uit dit onderzoek kan geconcludeerd worden dat de verschillende antwoordschaalscores niet onderling uitwisselbaar waren op itemniveau en dat de totale CMS-score significant beïnvloed werd. Desalniettemin waren de verschillen kleiner dan de kleinst detecteerbare verandering en werden ze geïnterpreteerd als klinisch niet relevant. Met name op itemniveau kunnen gegevens uit verschillende onderzoeken niet worden samengevoegd en vergeleken wanneer verschillende antwoordschalen worden gebruikt. In **Hoofdstuk 6** en **7** is de WORC-index geëvalueerd op de aanwezigheid van recall-bias en het effect van digitalisering. In **Hoofdstuk 6** wordt beschreven dat er geen significante responsverschuiving op groepsniveau werd waargenomen en met de afwezigheid van enige verschuiving in de perceptie van de patiënt, suggereert deze studie dat men retrospectief betrouwbaar preoperatieve baseline-informatie op groepsniveau over kwaliteit van leven zou kunnen uitvoeren tot 1 jaar na chirurgie. Deze bevinding is erg nuttig voor de clinicus als nulmetingen ontbreken in retrospectief uitgevoerde onderzoeken en als een bevinding op zichzelf met betrekking tot recall-bias. Tegenwoordig wordt het digitaliseren van vragenlijsten op grote schaal geïmplementeerd binnen onze huidige elektronische patiëntendossierprogramma's of software. De resultaten van **Hoofdstuk 7** gaven aan dat er geen significante verschillen waren op de WORC-scores tussen de elektronische en papieren versie. De voordelen van een efficiente elektronische manier van het verkrijgen van data, overtreffen de mogelijke kleine geïntroduceerde klinisch irrelevante verschillen. Een elektronische WORC kan daarom betrouwbaar worden gebruikt voor het verzamelen van uitkomsten in de orthopedische schouder praktijk.

Ten slotte gaven de resultaten, afgeleid van **Hoofdstuk 2,** aanleiding om een multicenter gerandomiseerde gecontroleerde studie uit te voeren naar de behandeling van stadium 2-3 degeneratieve rotator cuff-scheuren. In **Hoofdstuk 8** wordt een onderzoeksprotocol beschreven om de mate van pijn, functie en kosteneffectiviteit te vergelijken tussen het uitvoeren van een arthroscopische tenotomie van de lange kop van de bicepspees met of zonder arthroscopisch herstel van de rotator cuff. Dit onderzoek is gestart in 2018, maar door onvoldoende inclusies, ondanks een zeer gemotiveerd, betrokken en toegewijd team, is het onderzoek in 2021 officieel stopgezet. Dit besluit is genomen na een grondig interview met alle deelnemende ziekenhuizen, waarbij inzicht is gegeven in de huidige behandelingsstrategie van deze specifieke scheuren. Enerzijds blijft een belangrijke

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A

Acknowledgement - Dankwoord

About the author

List of publications

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ABOUT THE AUTHOR

Freek Hollman was born in 's-Hertogenbosch, the Netherlands, on February 22nd, 1988. In 2006, he graduated from secondary school (Athenaeum, St. Jans Lyceum, 's-Hertogenbosch) and started his medical training at Utrecht University, the Netherlands. In 2013 he started his scientific career at the Orthopaedic department of the St. Antonius Hospital under supervision of dr. Nienke Wolterbeek and dr. Gie K. Auw Yang. By the end of his medical training he temporarily stopped his training for 6 months to work as a full-time researcher. Subsequently, to broaden his orthopedic view he completed an internship in Orthopedics in Ghana for another 6 months. In March 2014 Freek completed his medical degree and started as a medical trainee at the Surgical department at the St. Antonius Hospital (under supervision of dr. Go) until September. Thereafter he worked from September for one year at the Orthopaedic Department of the St. Maartenskliniek, the Netherlands (under supervision of dr. A.B. Wymenga).

In 2016 Freek started his general surgical training at Zuyderland Medical Center, Heerlen and Sittard, the Netherlands (under supervision of dr. M.N. Sosef) as part of his Orthopaedic training program. He continued his Orthopaedic training at the MUMC+ (under supervision of dr. H.M. Staal), Zuyderland Medical Center (under supervision of prof. dr. I.C. Heyligers), Maxima Medical Center, Veldhoven (under supervision of dr. R.P.A. Janssen) and currently prolonged his residency at the MUMC+. During his training program he specialized in shoulder and knee pathology and traumatology.

During his residency he continued his research under supervision of prof. dr. Lodewijk W. van Rhijn, dr. Nienke Wolterbeek and dr. Gie K. Auw Yang, at MUMC+ and St. Antonius Hospital. Additionally, during and after his stay in Ghana he conducted several projects on Blount's disease and is actively involved in the Orthopaedics Overseas Collaboration to stimulate bilateral learning regarding scientific knowledge in Low- and Middle-Income Countries. He is actively involved in FORTE (Federation of Orthopeadic and Trauma Trainees in Europe) as the current Secretary General and as the chairman of the Fellowship Committee he has established to organize a traveling fellowship on shoulder pathology ('*Around the shoulder in 7 days*'). Additionally, he is part of the organizing

committee of the FORTE Summit which will take place in the Netherlands by the end of November. Finally, he is selected for NVA traveling fellowship.

He will complete his Orthopaedic training program in December 2021 at MUMC+ and will continue learning as Shoulder Fellow in 2022 in Brisbane, Australia (under supervision of dr. A. Gupta and dr. K. Cutbush).

Besides his career, Freek grew up together with his brother Arne in ‘s-Hertogenbosch where he also met his wife Dominique during secondary school. During their study in Utrecht they went to the same student’s society and traveled around the world, especially to Africa. They got married on her birthday in 2018 in Maastricht and have two daughters, Lieve (2019) and Rosa (2021).

In his leisure time he likes to play tennis with his friends, skiing, diving, running and cycling through the hills of Limburg.

LIST OF PUBLICATIONS

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LIST OF PRESENTATIONS

Oral presentations

- NVA 2021 – Structural abnormalities on MRI in patients aged 45 years or younger with atraumatic shoulder complaints.
- EFORT 2021 – FORTE session, Shoulder Arthroplasty, about the basics.
- Bovenste Extremiteit Limburgse Genootschap (BELG) 2021 – Proximale humerus fracturen. Behandel protocol.
- NOV najaarscongres WOO 2020 – Wetenschappelijk onderzoek in de tropen. Een gestructureerde aanpak in Ghana – MUMC+. How we collaborate.
- EORS 2019 – Equivalence between electronic and paper-based Western Ontario Rotator Cuff index (WORC): a randomized controlled equivalence trial.
- EORS 2019 – Different answering scales used within the Constant-Murley Score are not Interchangeable.
- NVA 2015 – Abduction Brace Versus Antirotation Sling After Arthroscopic Cuff Repair: The Effects on Pain and Function.
- NOV 2015 – Abduction Brace Versus Antirotation Sling After Arthroscopic Cuff Repair: The Effects on Pain and Function.
- EFORT 2014 – Abduction Brace Versus Antirotation Sling After Arthroscopic Cuff Repair: The Effects on Pain and Function.
- St. Antonius wetenschapsavond 2014 – Postoperative urinary retention in men undergoing total hip arthroplasty.

Poster presentations

- NOV najaarscongres 2019 – Gelijkwaardigheid tussen de digitale en op papier gebaseerde Western Ontario Rotator Cuff (WORC) index.
- NOV najaarscongres 2019 – Verschillende antwoordschalen die in de Constant-Murley Score worden gebruikt zijn niet uitwisselbaar.
- St. Antonius wetenschapsavond 2019 – Gelijkwaardigheid tussen de digitale en op papier gebaseerde Western Ontario Rotator Cuff (WORC) index.
- St. Antonius wetenschapsavond 2019 – Verschillende antwoordschalen die in de Constant-Murley Score worden gebruikt zijn niet uitwisselbaar.
- ESSKA Madrid 2019 – Different answering scales used within the Constant-Murley Score are not Interchangeable.
- ESSKA Madrid 2019 – Equivalence between electronic and paper-based Western Ontario Rotator Cuff index (WORC): a randomized controlled equivalence trial.
- ICCBH Salzburg 2015 – Infantile Blount's disease: histopathological changes in the proximal tibial metaphysis. Comparison between medial and lateral specimens.

- EPOS Bruges 2014 – A prospective study on the W/M Serrated Osteotomy for correction of varus deformities in Ghanaian patients. Preliminary results of the first 14 patients with infantile Blount's.