Does early mobilisation after surgical repair of rotator cuff tears improve biomechanical and clinical outcomes?

By

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Student Declaration

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I declare that while registered as a candidate for the research degree, I have not been a registered candidate or enrolled student for another award of the University or other academic or professional institution.

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ABSTRACT

The number of rotator cuff repairs performed in the UK and worldwide is increasing every year. However, there are still controversies regarding when rehabilitation after surgery should start. Therefore, the aim of this thesis was to investigate the effectiveness of early rehabilitation compared to conservative after rotator cuff repairs.

First, a systematic review was performed to critically analyse and discuss the current literature. The systematic review demonstrated that early rehabilitation may be beneficial to improve ROM but not function; however, due to high risk of bias of existing primary studies further RCTs are still needed for consensus. Based on the systematic review findings an RCT was planned. The aim of the trial was to assess and to compare clinical and biomechanical outcomes of patients who were allocated to early or conservative rehabilitation after rotator cuff repairs. The objectives of the RCT were: to compare and to detail EMG and kinematic changes that occur during the rehabilitation period between groups, and to compare how much residual impairment patients still show after 6 months of surgery in comparison to a normal population. Ninety-nine patients were screened for inclusion, and 42 patients agreed to participate and had a baseline biomechanics assessment. Twenty-two patients who had the initial biomechanics assessment were excluded from the trial because they did not fit the inclusion criteria based on surgical requirements. Twenty patients were randomised to treatment with 10 in each group. The biomechanics assessments were performed before surgery and after 3 and 6 months. 3D kinematics and EMG activity of 5 muscles (upper trapezius, anterior deltoid, medium deltoid, posterior deltoid and biceps brachii) from six movement tasks. In addition, the Oxford Shoulder Score and EQ-5D-5L were also recorded. Overall, no differences were found between the Early and Conservative groups for biomechanical and clinical outcomes. However, at 6 months the postoperative patients in the Early group had better ROM than those in the Conservative group.

A further exploration of the data indicated that at 3 months patients who responded to treatment were those who used the sling for a shorter number of hours per day, independent of which group they were allocated to, had fewer surgical procedures and a shorter period between first symptoms and surgery.

The data from the 22 patients who underwent the initial assessment but did not meet the inclusion criteria were used in a third study to explore whether the biomechanics assessment used in the trial was capable of discriminating patients with different levels of tissue damage and therefore potentially support surgery planning. The discriminant analysis showed an accuracy of 91.9% of correct classification based on the tasks proposed.

In conclusion, early rehabilitation does not seem to improve outcomes more than a conservative protocol, although the amount of sling usage appears to be an important factor in recovery. The conclusions of the RCT must be considered carefully due to limitations. The RCT of this thesis was the first on the topic to use biomechanics to detail how patients progress from pre-surgery until 6 months post-surgery, therefore contributing to a thorough understanding of patients' rehabilitation and recovery processes. In addition, the method of assessment proposed showed important discriminatory capacity, which can aid surgery planning by identifying different movement patterns.

Keywords: Rotator Cuff, Rehabilitation, Biomechanics, EMG

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List of Abbreviations

2D	Two-dimensional
3D	Three-dimensional
ADLs	Activities of Daily Living
ASES	American Shoulder and Elbow Score
CM	Constant-Murley
CONSORT	Consolidated Standards of Reporting Trials
CPM	Continuous Passive Movement
DASH	Disabilities of the Arm, Shoulder, and Hand Questionnaire
DOF	Degrees of Freedom
EMG	Electromyography
GRADE	Grading of Recommendations Assessment, Development and Evaluation
iEMG	Integral Electromyography
MA	Meta-analysis
MCID	Minimal Clinically Important Difference
MRC	Medical Research Council
MRI	Magnetic Resonance Imaging
OSS	Oxford Shoulder Score
PNF	Proprioceptive Neuromuscular Facilitation
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
QALY	Quality-adjusted life year
R-AMSTAR	Revised Assessment of Multiple Systematic Reviews
RC-QOL	Rotator Cuff Quality of Life
RCT	Randomised Controlled Trial
RMS	Root Mean Square
ROM	Range of Motion
SAD	Subacromial Decompression
SDC	Smallest Detectable Change
SPADI	Shoulder Pain and Disability Index
SST	Simple Shoulder Test
TGF-β1	Transforming Growth Factor Beta-1
UCLA	University of California at Los Angeles Shoulder Score
VAS	Visual Analogue Scale
WORC	The Western Ontario Rotator Cuff Index

CHAPTER 1: INTRODUCTION

Shoulder pain is among the most common musculoskeletal complaints leading to a high number of GP and physiotherapy consultations in the UK. Shoulder pain has a prevalence of approximately 16-26% in the general population and has a significant economic impact on the National Health Service (NHS), estimated to be £100 million per annum (Littlewood, Lowe, and Moore, 2012; Rangan et al., 2016)

On the top of the list of disorders causing pain and shoulder dysfunction is rotator cuff tears. It is a common disorder that affects approximately 30% of people older than 60 years and has an increasing rate associated with ageing. It is also responsible for approximately 450,000 operations per year (Thigpen et al., 2016).

To recover the functional status of these patients, surgical repair is often recommended, but for optimal results, postoperative rehabilitation is also of great importance and must be adequately planned. Although it may seem obvious that rehabilitation must respect potential fragilities post-surgery, there is currently an impasse on how best to balance mobility and avoid complications that may occur because of excessive or lack of movement. After surgery, a period of movement restriction is recommended, however, the optimal time of immobilisation is unknown. This period is important to protect the tendon, allow good healing and possibly prevent retear episodes. In contrast, delaying mobilisation may increase the risk of postoperative shoulder stiffness, muscle atrophy and potentially postpones improvements on functionality (Acevedo et al., 2014).

Recently, the British Elbow and Shoulder Society in partnership with the British Orthopaedic Association, funded a study aiming to investigate what the main clinical questions are regarding shoulder surgery and rehabilitation, therefore defining what the 10 top UK research priorities are for the next decade. The process was patient-centric and involved not only clinicians but patients and carers. The fourth most important question, based on the response of 371 participants nationwide, was: "*Does early mobilisation and physiotherapy after shoulder surgery improve patient outcome compared to standard immobilisation and physiotherapy?*" (Rangan et al., 2016). This study highlights how there are many uncertainties about the post-surgical rehabilitation of rotator cuff tears and how high-quality evidence is needed to support clinicians.

Based on the available evidence, it is difficult to make a clinical decision for a well-designed programme of rehabilitation and establish the most favourable postoperative time to start it. Currently, there are almost the same number of systematic reviews as there are randomised controlled trials, which causes confusion. There are different definitions of what is considered early and what is considered standard/conservative mobilisation and the quality of primary studies varies.

In the clinical setting, it is common to use questionnaires to screen patient's impairments in activities of daily living (ADL), in addition, goniometers are used to quantify range of motion (ROM). These tools have the advantage of being easy to use, quick and relatively inexpensive. However, their simplistic nature may not fully capture the complexity of the problem. To date, none of the RCTs which have assessed the effects of early rehabilitation on patients after rotator cuff repairs have used highly accurate biomechanical instruments to measure patients' progression through rehabilitation. The consequences of rotator cuff problems can be analysed and detailed using biomechanical outcomes, which are able to measure alterations to muscle activity using electromyography (EMG) and joint angle modifications, with 3D kinematics.

The information about kinematic and electromyographic adaptations during the rehabilitation process is essential to understand the continued change to shoulder function status and muscle adaptations. Therefore, a consistent and detailed understanding of shoulder muscle activity, using EMG with 3D kinematics, could help clinicians to better understand the evolution of patients with rotator cuff tears from preoperative through to the late postoperative stages.

1.1. Thesis overall aims and objectives

Considering the uncertainties regarding the optimal rehabilitation after rotator cuff repair surgery and the lack of information on biomechanical outcomes, the overall aim of this thesis was to investigate the effectiveness of early rehabilitation compared to conservative following rotator cuff repairs on clinical and biomechanical outcomes.

The objectives were:

1. To critically assess the available evidence on rehabilitation following rotator cuff repairs, to build consensus around conflicting opinions and to inform the design and delivery of an interventional study;
2. To test, in an exploratory trial framework developed based on the findings from the systematic review, whether early rehabilitation is better than conservative

care in improving clinical and biomechanical outcomes following rotator cuff repairs.

3. To explore whether a biomechanical assessment is suitable for the clinical setting to inform the evaluation of patients with rotator cuff tears.

1.2. Thesis Structure

The thesis is outlined in 10 chapters: the first chapter is a brief presentation on the topics that underpin this thesis and a concise explanation of the content of the following chapters. Chapters 2 and 3 are the literature review that has been separated into two independent parts: the first brings details of the anatomy of the shoulder, epidemiology of rotator cuff tears, outcomes and biomechanics; the second part is a systematic review, performed especially to critically assess the available evidence and describe the effectiveness of early compared to conservative rehabilitation after rotator cuff repair surgery. The 4th chapter details the aims and objectives of the main study. Chapter 5 describes the methods used to develop the randomised controlled trial; consequently, chapter 6 shows the trial findings. Chapter 7 is the main discussion, it brings a debate about the main findings, how the results translate to a bigger scenario with different patients, how they are applicable to daily clinical practice and what future research must focus on. Chapter 8 describes further analyses using supplementary data from patients who did not fit the inclusion criteria and therefore were not allocated to one of the treatment arms. Further comparisons with subjects with no shoulder pain and different levels of shoulder impairment are presented. Chapter 8 also contains a complementary discriminant analysis highlighting how movement analysis methods may be used as a diagnostic tool. The thesis overall conclusions and key messages are described in chapter 9 and chapter 10, which bring relevant information and documents such as ethical approval certificates, etc.

CHAPTER 2: BACKGROUND

2.1. Introduction

This chapter brings details about the anatomical structures of the shoulder, but not just for the glenohumeral joint. This covers other joints, bones and muscles of the shoulder with a focus on the rotator cuff. It also describes what a rotator cuff tear is and discuss the epidemiology, pathogenesis and aetiology and the morphological/histological changes that are present in an impaired tendon. The chapter develops to discuss the clinical examination of rotator cuff tears and how clinicians may use special tests and questionnaires to identify this disorder. The final part of the chapter illustrates the movement characteristics of this patient population and explain how other tools, such as EMG and 3D kinematics, can help to better understand the changes from pre-surgery to post-surgery. In addition, information about the management of rotator cuff tears (non-surgical and surgical) is finally discussed leading to the third chapter where more critical methods are used to assess the quality of the evidence on rehabilitation after rotator cuff repairs.

2.2. The shoulder complex

2.2.1. Evolution

The shoulder complex has inherent characteristics integrating anatomical structures to allow the greatest ROM of the human body. Its mobility is responsible for supporting the spatial displacement of arms, permitting an ample scope of activities of the upper limbs. During the human evolution process, anatomical modifications were needed from the upper limb to cope with new activities. Previously, the upper limbs were also used for locomotion, but after this function became redundant, the arms became free to perform other tasks such as reaching, grasping and carrying objects (Roberts 2008). The demanded adaptations shaped the anatomical architecture as they are observed nowadays. For example, for the scapula, it is possible to observe a major change related to the ratio between length and breadth. Over the years, as human ancestors started to gradually adopt an orthograde posture, the scapula migrated to a more dorsal position and developed a longer medial border in contrast to a shorter superior border, the acromion increased in size and the infraspinatus fossa got deeper. Another example is the humerus, where the shaft angle relative to the humeral head changed; in quadrupedal monkeys, the humeral head is directed dorsally, while in humans it is rotated medially in relation to the elbow (Inman, Saunders, and Abbott 1944).

Although these changes made the upper limb more efficient in terms of expanding its freedom of movement, the major disadvantage of glenohumeral instability emerged, which makes the glenohumeral joint dependant mainly on muscles to address this issue. This dependence may be noticed as the insertion of the posterior cuff muscles in the greater tuberosity are not fused in quadrupedal species, while in advanced primates and humans, their insertion is much closer and almost indistinct, which suggests an adaptation to the necessity of having greater shoulder stability because of more frequent overhead tasks (Sonnabend and Young 2009). This observation was possible with the work carried out by Sonnabend and Young (2009) who dissected shoulders of 23 species to compare their anatomical characteristics. They found that the rotator cuff of quadrupedal species had a marked separation in their insertion to the humerus; a true cuff, with an almost indistinct division among the muscle and intertendinous connections, was only observed on advanced primates such as baboons, chimpanzees and orangutans.

2.2.2. Bones and joints

The shoulder complex comprises three joints: glenohumeral, acromioclavicular and sternoclavicular; apart from these is the scapulothoracic, which is often named as a false joint. This classification for the scapulothoracic joint is used as it does not have cartilage, synovium or capsule, but contains a bursa between the scapula and the thorax that allows sliding (Frank et al., 2013). Among the three synovial joints, the main one is the glenohumeral, which is formed by the humerus and the scapula (Figure 2.1). The humerus is the longest bone in the group and is attached to the glenoid fossa through its head surface. The scapula has a triangular shape and lies on the dorsal side of the thorax, over the 2^{nd} to the 7^{th} ribs; it has a fundamental role of supporting the extended shoulder ROM and is also the origin site of the rotator cuff muscles (Culham and Peat 1993). Although the humeral head and glenoid fossa have a congruent shape, their sizes are incompatible, the glenoid does not have enough depth and diameter to allocate the entire humeral head (Terry and Chopp 2000).

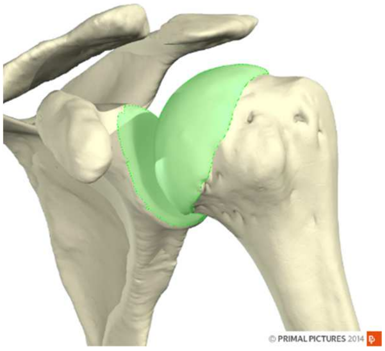


Figure 2.1. The glenohumeral joint highlighted in green.

This bony asymmetry is responsible for the greater mobility but at the expense of increased instability. Moreover, the instability regarding the anatomical format of the glenoid has a significant consequence on injury rates of tendons and joint cartilage. For instance, Moor et al. (2016) recently demonstrated that the direction (upwards or downwards) and angle of the glenoid inclination has direct influence in the superior stability of the humeral head in the glenoid fossa, which in turn may cause degeneration to surrounding structures. In their study, Moor et al. (2016) used a cadaveric model with to simulate different critical shoulder angles, which is a measurement of the glenoid inclination in relation to the acromion. When the inclination was greater towards the cranial direction, the superior stability was compromised and, as expected, when the glenoid was more inclined downwards it became more unstable inferiorly.

One of the accessory joints of the shoulder complex is the acromioclavicular, which is a connection point of the scapula (acromion) and the lateral end of the clavicle (Figure 2.2). The clavicle is a long-shaped bone, horizontally positioned over the 1st ribs; it is a strut between the scapula and the thorax. The acromioclavicular joint acts as a pivot, helping the scapula to rotate upwards, however, it does not support as much movement to the scapula as the sternoclavicular joint (Peat 1986).

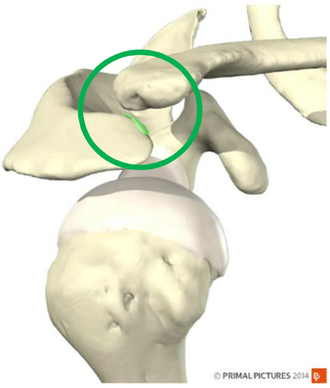


Figure 2.2. The acromioclavicular joint highlighted in green.

The sternoclavicular joint attaches the medial part of the clavicle with the manubrium, it is also the only true joint to link the upper limb to the thorax (Figure 2.3). The manubrium is the superior part of the sternum, which is a flat bone located in the middle of the rib cage. It protects the internal organs and is also a bridge between the rib cage sides (Culham and Peat 1993).

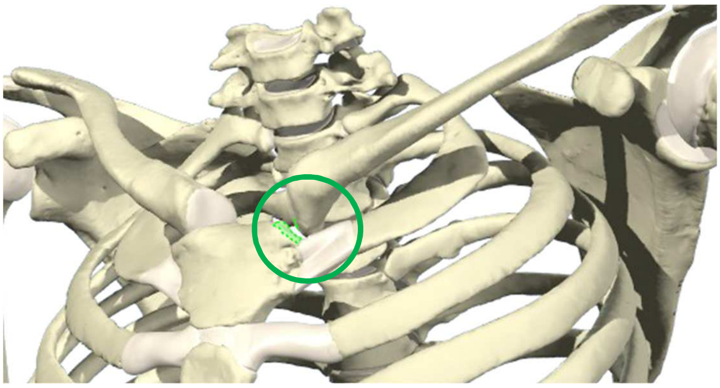


Figure 2.3. The sternoclavicular joint highlighted in green.

2.2.3. Muscles

2.2.3.1. Rotator Cuff

The rotator cuff muscles are essential to allow controlled and efficient movement of the shoulder. They maintain the dynamic stability by generating forces to preserve the intrinsic movement and contact between the humeral head and the glenoid fossa (Labriola et al., 2005). There are four muscles that act as a group, comprising of the supraspinatus, infraspinatus, subscapularis and teres minor (Figure 2.4.)(Peat 1986).

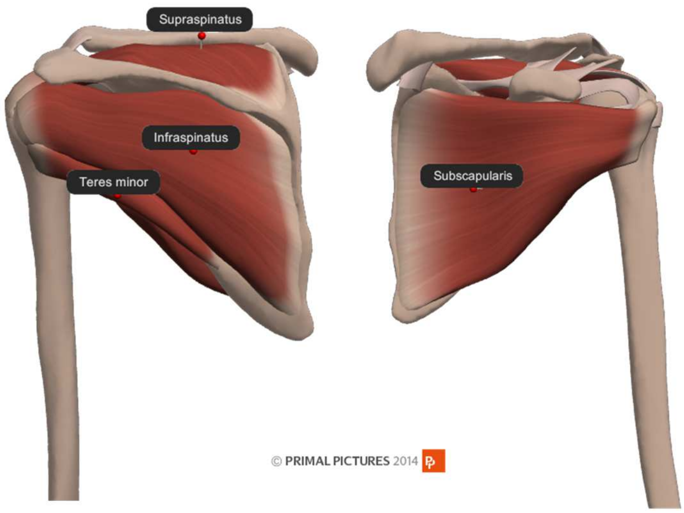


Figure 2.4. The rotator cuff muscles

Their tendon insertions merge on the humerus, displaying a cohesive form (Sonnabend and Young 2009). Therefore, because of this insertional arrangement, the descriptions of how the cuff muscles work during different tasks are complex. It is commonly assumed that the cuff muscles are activated at the same time, with equivalent intensity, regardless of the movement direction (Labriola et al., 2005). However, this concept overlooks the individual role of each muscle, suggesting a simplistic explanation that the resultant vector of the cuff muscles generates a compressive force by just opposing other muscles actions (Parsons et al., 2002; Edwards et al., 2016).

A few studies have challenged the inference about the functioning of the rotator cuff and their recruitment pattern as a block. Wattanaprakornkul et al. (2011a) investigated various muscles (upper, middle and lower trapezius, three portions of the deltoid, pectoralis major, supraspinatus, infraspinatus, subscapularis, serratus anterior and latissimus dorsi) during shoulder flexion only and under different loads using EMG in a sample of 15 healthy individuals with no shoulder pain. Wattanaprakornkul et al. (2011a) showed that regardless of the load applied (no load, 20% or 60% of subjects' maximum) the activity intensity increased for all muscles. Only the latissimus dorsi did not follow this tendency, showing very low activity for all loads; although, a low recruitment for this muscle is expected as its main action is shoulder extension. However, the most important finding in this study was that the supraspinatus, along with the infraspinatus, was significantly more active than the subscapularis. In addition, the supraspinatus was recruited earlier than the infraspinatus and worked in synchrony with the anterior deltoid to initiate the movement. In a further study, Wattanaprakornkul et al. (2011b) explored the behaviour of the rotator cuff group during active shoulder flexion and extension performed in a prone position using EMG in 15 healthy participants. The findings for shoulder flexion were similar to the previous study, but in addition, the results for extension demonstrated a significantly higher activity of the subscapularis, when compared to the posterior cuff. Day et al. (2012) further investigated the rotator cuff muscles during different tasks. Their study consisted of measuring the onset and intensity of EMG signals of the rotator cuff muscles, anterior and posterior deltoid of healthy individuals, in response to external perturbations towards internal or external rotations. The infraspinatus demonstrated significantly higher activity for perturbations in the internal rotation direction, while the subscapularis had opposite behaviour, showing higher activity for the external rotation. The onset of the infraspinatus and subscapularis started prior to the movement itself, suggesting their role as dynamic stabilizers in generating feedforward information (Sangwan, Green, and Taylor 2014). Moreover, Tardo et al. (2013) found that rotations performed at a position of 90° of abduction, causes higher activation of the rotator cuff, especially of the infraspinatus during external rotation and of the subscapularis during internal rotation, while the other shoulder muscles, such as the deltoid contribute to the glenohumeral stability in this position. Another interesting result was that the supraspinatus had the greatest contribution to stability among the rotator cuff muscles, while the infraspinatus was the muscle generating greatest power for external rotation among all shoulder muscles.

These studies ratify how the rotator cuff muscles are not just acting by compressing the humeral head to the glenoid, but in fact, the muscle recruitment is dependent on the movement direction, which confirms that the rotator cuff recruitment is task specific. For example, the rotator cuff muscles work to control and avoid translational movements that are consequences of other muscles acting on the humerus, rather than just opposing their forces. Each cuff muscle responds individually, although not in isolation, but in a coordinated fashion. The mechanism to balance their level of intensity relies on the feedback provided by proprioceptors. The receptors are responsible for sending information to the central nervous system regarding the limb position and how the movement is being performed, which in turn modulate and return the information to the rotator cuff muscles to balance their individual recruitment as needed; the modulation serves to adjust the joint surfaces alignment for the best congruence possible (Bachasson et al., 2015). This mechanism of feedforward and feedback control, that can also be described as neuromuscular control, highlights the neurological characteristic that a stabiliser muscle must present (Sangwan, Green, and Taylor, 2014).

Regarding their individual characteristics, the supraspinatus has its origin in the supraspinous fossa of the scapula and is inserted in the superior and medial portion of the greater humeral tubercle (Gates et al., 2010; Lumsdaine et al., 2015). It has two sub-regions; the anterior portion that is thicker and tubular shaped, and the posterior that is flatter and works closely with the infraspinatus (Sonnabend and Young, 2009; Gates et al., 2010).

The supraspinatus is a powerful humeral head depressor and its main action as a stabilizer is to avoid the upper migration of the humeral head, caused mainly by the deltoid during elevation. The depressing action is fundamental to avoid the structures that are under the acromion so that they are not affected by excessive pressure or impingement, which may cause pain and damage to the structures (Terrier et al., 2007). In addition, the supraspinatus, depending on the humeral head position, may also rotate the humerus internally or externally (Ihashi et al., 1998). According to Ihashi et al.

(1998) if the humerus is in an internal rotation of 30°, the supraspinatus fibres will be in front of the centre of rotation of the humerus, thus the line of action will be towards internal rotation; however if the humerus is in a neutral position, the line of action will be positioned slightly posteriorly, acting as an external rotator.

Since the classic work of Jobe and Moynes (1982) on exploring different positions to establish a diagnostic criteria for rotator cuff injuries, the best mechanical advantage of the supraspinatus fibres is thought to be in the scapular plane, which is 30° of horizontal adduction in relation to the coronal plane. Numerous studies using EMG have explored the role of the supraspinatus in different planes of movement during abduction and flexion, showing divergent results regarding its recruitment timing(Alpert et al., 2000; Wickham et al., 2010; Reed et al., 2013; Reed et al., 2016). For instance, Reed et al., (2013, 2016), assessed 14 healthy individuals, and showed that the supraspinatus does not have the intensity or recruitment pattern altered in response to different planes of abduction (scapular plane, scapular plane + 30° and scapular plane - 30°) nor the rotator cuff is activated significantly earlier than other shoulder muscles such as the deltoid; while Wickham (2010), also using EMG with healthy individuals, demonstrated that the supraspinatus is recruited before the start of the movement on the coronal plane. A possible explanation for the differences found across studies is related to the EMG data filtering. Reed et al. (2013, 2016) applied a 6 Hz low pass filter to produce an enveloped signal, while Wickham (2010) applied a 10 Hz low pass filter. The implications of using different filters are further detailed in section 5.7.2, page 123-127.

The infraspinatus has its origin in the infraspinous fossa and is inserted in the posterior portion of the greater tubercle. Based on studies with cadavers, it has been demonstrated that part of the infraspinatus' anterior fibres are inserted anteriorly on top of the greater tubercle, which highlights its function with the supraspinatus (Minagawa et al., 1998; Dugas et al., 2002; Lumsdaine et al., 2015). The infraspinatus stabilizing forces acts not just in the coronal plane helping to depress the humeral head, but it also compresses the humeral head in the transverse plane avoiding posterior dislocations and balancing forces from the subscapularis (Parsons et al., 2002; Reinold, Escamilla, and Wilk, 2009; Pandey and Willems, 2015). Another action of the infraspinatus is external rotation, which demands more activity when performed in 90° of flexion. This activity was demonstrated by Ha et al. (2013) using EMG to assess the infraspinatus, middle trapezius and posterior deltoid during 4 different tasks (prone horizontal abduction with external rotation, side-lying and shoulder flexion and external rotation, side-lying and external rotation only, and standing and external rotation).

The teres minor together with the infraspinatus form the posterior cuff, its origin is on the lateral border of the scapula and is inserted on the inferior facet of the greater tubercle. Similar to the infraspinatus it balances forces translating the humeral head upwards and also posteriorly in the transverse plane; in addition, it is a primary external rotator (Pandey and Willems, 2015). Although it is the cuff muscle which has been given less attention in research, a recent study has shown that patients with a posterosuperior tear and deficient infraspinatus strength may present a hypertrophic teres minor. Kikukawa et al., (2016) used MRI to measure the cross-sectional area of the rotator cuff muscles of individuals diagnosed with rotator cuff tears, their findings revealed that those individuals who present a hypertrophic teres minor (larger area) seems to have better ROM and strength values when compared to those patients with a rotator cuff tear, with a normal or atrophic teres minor.

The only muscle of the anterior cuff is the subscapularis, its origin is on the anterior face of the scapula (subscapularis fossa) and is inserted on the lesser tubercle. It is the largest and strongest among the rotator cuff muscles, with a predicted force of about 1725 N for internal rotation at a 90° abduction position, compared to only 155 N for the supraspinatus for external rotation (Hughes and An, 1996; Reinold, Escamilla, and Wilk, 2009). It is responsible for stabilising the humeral head, balancing forces of the posterior cuff muscles, and avoiding the anterior translation of the humerus during shoulder extension. This statement is supported by the study of Terrier et al. (2013), the authors performed a series of simulations using an EMG-driven model where they reproduced the forces of the rotator cuff muscles with and without a deficient subscapularis; when a deficient subscapularis was present, greater translations of the humeral head on the glenoid fossa were observed, which created a greater pressure on the posterior portion of the joint. The subscapularis also works in cooperation with the other cuff muscles to control superior translation during abduction, and it is the only cuff muscle that is a primary internal rotator (Terrier et al., 2013).

2.2.3.2. Deltoid

The deltoid is a large muscle that can be divided into three main portions: anterior, medial and posterior (Figure 2.5). The anterior portion originates from the distal third of the clavicle and anterior portion of the acromion, the medial head has its origin on the medial surface of the acromion, and the posterior originates from the scapular spine; they have a common insertion on the deltoid tuberosity, located at the proximal humeral shaft (Sakoma et al., 2011).

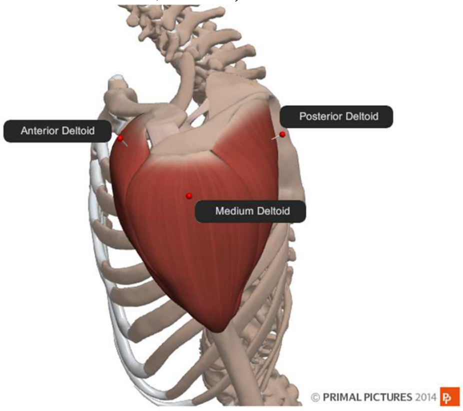


Figure 2.5. The deltoid muscle.

It has been reported that based on the intramuscular tendons in the deltoid, the three major parts can be reorganised into seven smaller sections (Figure 2.6). Sakoma et al., (2011) demonstrated, by assessing 60 cadavers, that the anterior tendon has a division in its distal aspect leading to two branches, where the most anterior portion is divided into another two parts. The posterior tendon has a similar pattern, but instead, it is the most posterior branch that separates into another two. The middle portion is the only tendon not presenting any additional divisions. From a clinical perspective, the peculiar subdivision may imply a new look on how to prescribe exercises focusing on the deltoid. There is still insufficient evidence on how each compartment performs and further research is needed (Kido et al., 2003).

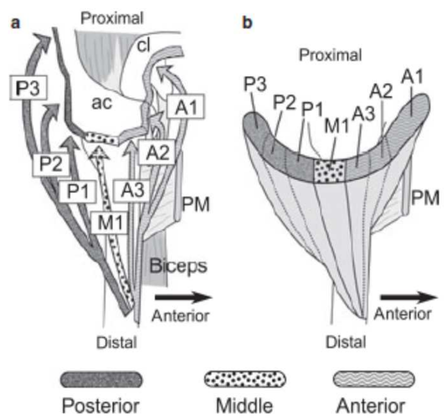


Figure 2.6. a) Different intramuscular tendons of the deltoid, b) Deltoid subdivisions. From Sakoma et al. (2011).

2.2.3.3. Scapulothoracic muscles

The scapulothoracic muscles are very important as they coordinate the scapular motion in tasks that demand humeral movements (Reinold, Escamilla, and Wilk, 2009). The main scapulothoracic muscles are: trapezius, rhomboids, levator scapulae, serratus anterior and pectoralis minor (Figure 2.7).

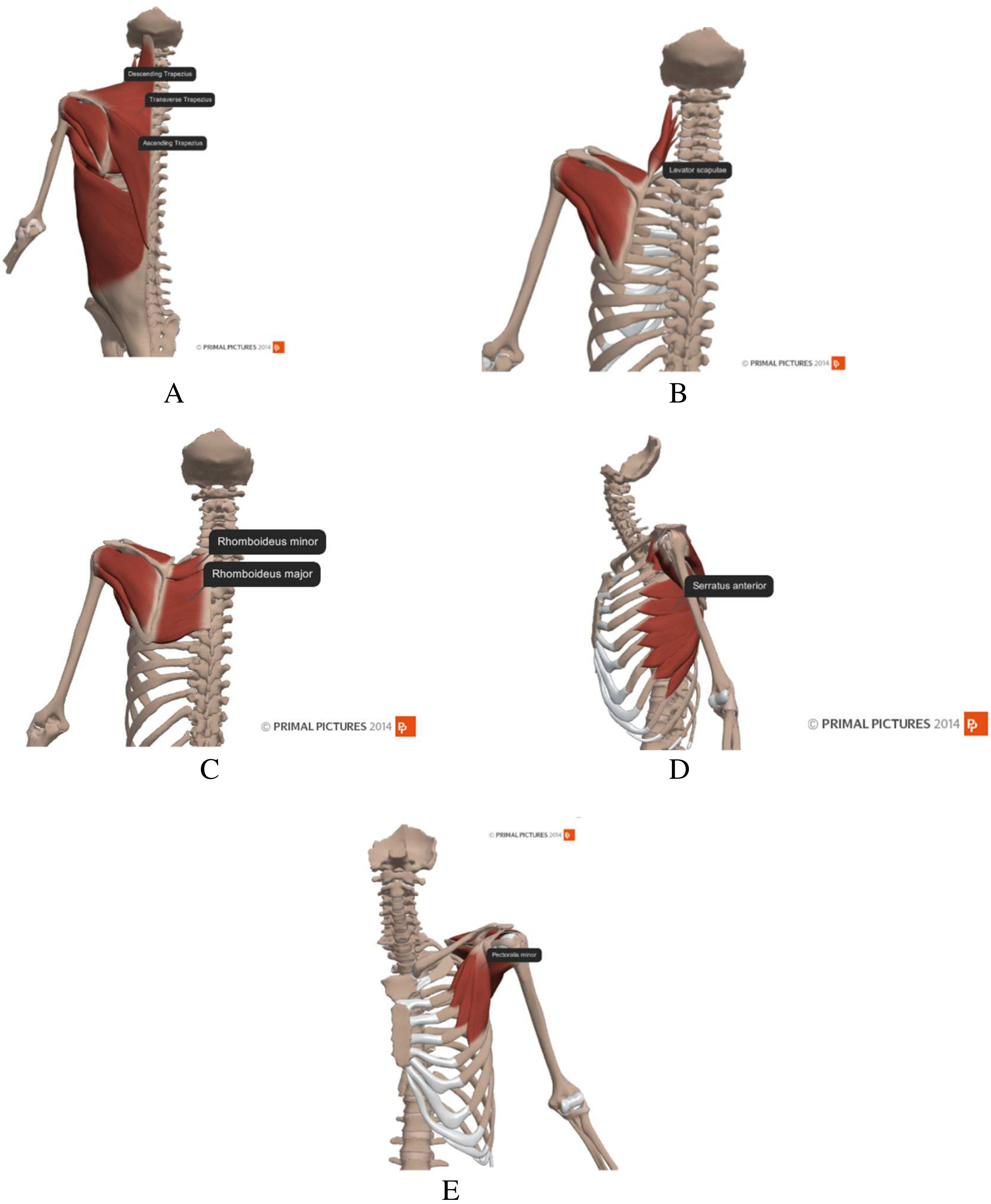


Figure 2.7. Scapulothoracic muscles. A) trapezius, B) levator scapulae, C) rhomboids, D) serratus anterior, E) pectoralis minor.

The trapezius is a large muscle composed of the descending, transverse and ascending parts. It originates mainly from supraspinous processes of the cervical and thoracic vertebras and has its insertion predominantly onto the scapular spinae. The main action of the descending and ascending portions is to rotate the scapula in the upward direction, while the medial is more involved in the scapular retraction. In contrast, the levator scapulae which originates from the spinous processes of C1 to C4 and is inserted on the superior angle of the scapula. This has the opposite action of rotating the scapula downwards and elevating it in the cranial direction (Halder, Itoi, and An 2000; Reinold, Escamilla, and Wilk, 2009). The rhomboids have a more horizontal line of action as its origin comes from the spinous processes of C6 to T4 and is inserted on the medial board of the scapula. Similar to the transverse trapezius, it also acts to retract the scapula and rotates it downwards.

The serratus anterior is essential for the scapula stability; it is responsible for avoiding anterior tilting and winging of the scapula and allows smooth sliding on the thorax. Regarding its subdivisions, it can be classified according to its fibre arrangements (superior, middle and inferior); it originates from the anterior aspects of the 1st to 9th ribs and is inserted on the superior angle through the inferior angle of the scapula. The serratus anterior has been extensively studied in relation to its activity alterations in different shoulder disorders (Ludewig and Cook, 2000; Lin et al., 2005; Lin et al., 2006; Whitman et al., 2006). The consequences of a dysfunctional serratus anterior can be noticed as compensations appear due to its insufficient activation. For instance, an overactivity of the upper trapezius is often observed in patients with shoulder impingement and rotator cuff tears (Diederichsen et al., 2009; Maenhout et al., 2012). Although the serratus anterior is not solely responsible for overloading the upper trapezius, the lack of scapular retraction and avoidance of exacerbated anterior tilting due to the inadequate serratus recruitment, especially in the lower fibres, may cause extra activity of the upper trapezius to cope with an increased scapular instability. This compensatory mechanism is described as a factor that potentially reduces the subacromial space, leading to pain, strength deficit, and impaired functional status (Ludewig and Reynolds, 2009).

The pectoralis minor has a relatively small lever arm in comparison to the other scapulothoracic muscles. It is originated from the third to the fifth ribs with the insertion on the coracoid process and works closely with the upper portion of the serratus anterior to protract the scapula. During the physical examination, particular attention must be given to this muscle as the shortage of its rest length may cause exacerbated scapular protraction, leading to alterations of shoulder posture (Borstad and Ludewig, 2005; Hodgins et al., 2017; Umehara et al., 2018).

2.2.3.4. Thoracohumeral muscles

The thoracohumeral muscles are broad in size and are powerful movers (Figure 2.8). The latissimus dorsi has a vast origin ranging from the spinous processes of T7 to T12, 10th to 12th ribs, thoracolumbar fascia and iliac crest; it is inserted on the intertubercular groove of the humerus (Halder, Itoi, and An, 2000). Its main actions are shoulder extension, adduction and external rotation. The pectoralis major is the main muscle involved in the shoulder flexion, internal rotation, and works with the latissimus dorsi in the adduction. Its fibres come from the anterior medial clavicle and sternum to insert on the lateral rim of the intertubercular groove (Halder, Itoi, and An, 2000). These two thoracohumeral muscles, together with the teres major, also act as humeral head depressors, which appear to act as compensators when rotator cuff activity is impaired (Spall, Ribeiro, and Sole, 2016).

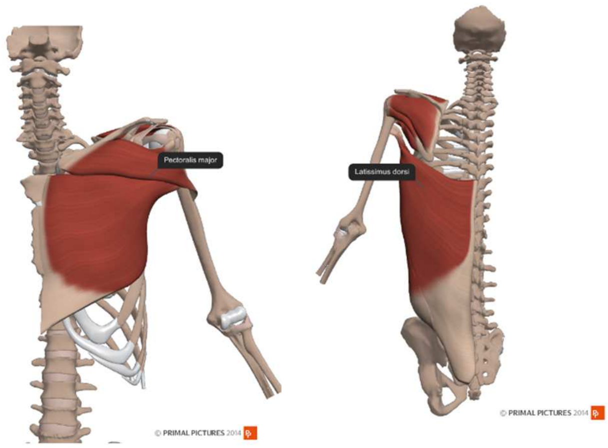


Figure 2.8. The thoracohumeral muscles. A) pectoralis major, B) latissimus dorsi.

2.2.4. Labrum, glenohumeral capsule and ligaments

The labrum is a fibrocartilaginous structure that is attached to the glenoid cavity. To some extent, it is an extension of the glenoid surface which increases the joint stability by making it deeper, with a larger area to allocate the humeral head, and by permitting a suction effect that produces a negative pressure to improve stability. The labrum and the joint itself are surrounded by the capsule that is formed by three layers, with each having different fibre arrangements. The capsule presents a slightly thickened areas in its extension that are the glenohumeral ligaments. These ligaments (superior, medial and inferior) are important for the glenohumeral stability when the shoulder reaches the extremes of its range of motion. Ligaments such as the coracohumeral, coracoacromial, trapezoid and conoid are also responsible for the static stability of the shoulder complex. Despite the fact that the muscle spindles are the main source of proprioceptive information, the ligament receptors are important limiting detectors which provide a protective and synergistic reflex muscle activity to avoid damage to the shoulder structures (Bachasson et al., 2015).

2.2.5. Conclusion

As detailed in this first section, the shoulder is not restricted only to the glenohumeral joint, it is composed of multiple structures that must work in harmony. The movers, i.e. the muscles, need to have their forces balanced to perform a smooth and controlled motion. Therefore, the muscles rely on information supplied not just by their own receptors, but also from other structures that support the safety of the joint when reaching the limits of the movement. When part of any of these structures do not work properly, possible damage may occur, which in turn may cause disabling symptoms such as pain.

2.3. Rotator cuff tears

Shoulder pain is the third most common musculoskeletal disorder in the UK, after back and knee complaints (Urwin et al., 1998; Murphy and Carr, 2010). Annually, it counts for about 199 cases per 10,000 people (Jordan et al., 2010). It can be a very debilitating problem, which may impair patients' quality of life, functional capacity, psychological health and social activity. Moreover, it also has a large economic impact; almost US$162 million are spent per year in the United States on imaging diagnosis and different pre-operative treatment modalities (Yeranosian et al., 2013). The operative treatment of rotator cuff tears is another example with an overall cost of £2567 per patient when using the arthroscopic technique, and £2699 when using open surgery (Carr et al., 2015)

One of the main causes of shoulder pain are rotator cuff tears, which can be defined as a rupture of one or more tendons of the rotator cuff muscles due to trauma or degenerative processes (Opsha et al., 2008). The tears may present different shapes and are described according to their variation, such as: extent (partial or full thickness), proximity to another anatomical structure (bursal or articular) and shape (crescent, U-shaped, L-shaped, massive). Furthermore, there are several different methods for their classification. Table 2.1 lists three of the most common scales used clinically, although Cofield's is generally more popular as it can be measured during the arthroscopy procedure (Vollans and Ali, 2016).

Table 2.1. Tear classification according to different methods.

Cofield method (tear size)	
Small	<1 cm
Medium	1 – 3 cm
Large	3 – 5 cm
Massive	>5 cm
Patte method (amount of muscle retraction in the frontal plane)	
Stage 1	Proximal stump lies close to its bony insertion
Stage 2	Proximal stump retracted to level of the humeral head
Stage 3	Proximal stump retracted to level of glenoid
Goutallier (amount of fatty infiltration)	
Stage 0	Normal muscle
Stage 1	Some fatty streaks
Stage 2	< 50% fatty muscle atrophy
Stage 3	50% fatty muscle atrophy
Stage 4	> 50% fatty muscle atrophy

2.3.1. Epidemiology

The epidemiology of rotator cuff tears has been reported in numerous studies (Reilly et al, 2006; Tashjian, 2012; Wani et al., 2016). The percentage of affected individuals has been shown to vary considerably from cadaveric studies to research using imaging techniques. Generally, the cadaveric studies show a higher prevalence in comparison to studies using MRI or ultrasound. This difference may be explained by the different tools used, but also by the fact that the cadaveric population is typically older than those assessed in studies with imaging methods, and rotator cuff tears seem to be affected mainly by age at symptom onset, functional status and degeneration of the tendon (Reilly et al., 2006; Teunis et al., 2014).

Among the four cuff muscles, the most affected is the supraspinatus, accounting for up to 36.7% of the cases (Schaeffeler et al., 2011). The reason why the supraspinatus is the most frequently torn muscle is possibly due to its anatomical topography as it lies just below the acromion and is more exposed to impingement, due to spurs or hypertrophic degenerative changes at the acromioclavicular joint (Opsha et al., 2008).

Another relevant issue on the epidemiology of rotator cuff tears is the number of asymptomatic cases and their progression through time. Yamamoto et al. (2010) demonstrated that asymptomatic full-thickness rotator cuff tears are common and are present in approximately 50% of patients over 65; 50% of asymptomatic full-thickness tears develop symptoms within approximately 2 to 3 years and 50% of those that develop symptoms have a progression in tear size. Moreover, full-thickness rotator cuff tears were present in approximately 25% of individuals in their 60s and 50% of individuals in their 80s, and have been shown to start developing from the age of 40. One possible explanation for the high rate of asymptomatic individuals is the rotator cuff cable hypothesis, which was first described by Burkhart, Esch, and Jolson (1993). Based on the examination of 20 cadavers, the authors observed an area of thicker bundles of fibres which were arch-shaped and ran perpendicular to the supraspinatus and infraspinatus tendons. The structure resembles a suspension bridge (Figure 2.9) and in a similar fashion, it seems to be able to transfer the forces from the tendon to the bone more evenly and avoid the stress on the crescent area, which is thinner and poorly vascularized compared to the other areas of the tendon. Therefore, because of the rotator cable, even an individual who presents a tear on the crescent area may not show any functional impairment as the rotator cable is still connecting the anterior and posterior cuff, distributing the forces along the surface. The individuals who then have symptoms are those who the tear has crossed the cable limit, which will weaken the structure that no longer will be able to balance the stress between the cuff muscles. This hypothesis is supported by the study of Denard et al. (2012), the authors assessed the integrity of the cuff and the ROM of 127 patients who had a repair for a massive tear; those patients who had a total or partial intact rotator cable had preservation of ROM for shoulder flexion, while those with a total disruption of the rotator cable presented pseudoparalysis of the shoulder.

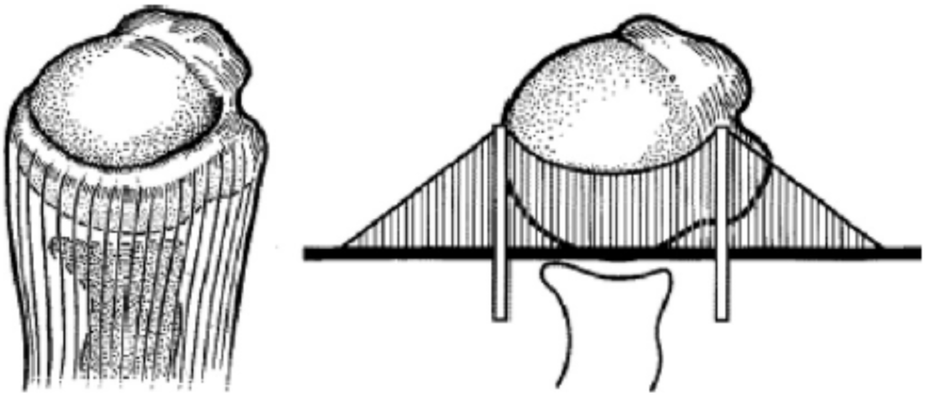


Figure 2.9. The rotator cable and the analogy with a suspension bridge. From Burkhart, Esch, and Jolson (1993).

Based on the description of the epidemiology, it is evident that rotator cuff tears are a common disorder that affects individuals over 40 years of age and becomes more frequent through senescence. Therefore, its impact on the general population is of great importance.

2.3.2. Pathogenesis and aetiology

There are two types of tears: traumatic or chronic. The traumatic tear has a defined origin, which by the name is the result of a traumatic episode; while chronic tears may have multiple factors involved in their onset (Bassett and Cofield 1983). This thesis will focus on chronic tears, which are more frequent, more complex to describe in terms of causative mechanisms and require better evidence for optimal rehabilitation. Currently, there are two categories to classify different factors that can explain the injury mechanism behind a chronic lesion, i.e. extrinsic and intrinsic. Extrinsic factors are those external to the tendon itself; in this category are included those related to the anatomy of other structures, such as acromion and presence of spurs (Maffulli et al., 2011; Seitz et al., 2011; Pandey and Willems 2015). The link between the acromial shape and rotator cuff tears was first explored by Neer (1972), where the author described that the majority of tendinopathies and tears that required surgical intervention occurred in the supraspinatus tendon, mainly in the area close to the coracohumeral ligament, followed by the area of the anterior region of the acromion and acromioclavicular joint. Based on this classic work, further studies classified the acromion in three different shapes: flat, curved and hooked or type 1,2 and 3, respectively (Bigliani et al., 1991) (Figure 2.10). Based on the literature, it may seem that the acromion shape has a significant influence on rotator cuff tears. Individuals with type 3 are thought to present a narrow subacromial space, which consequently would cause compression of the supraspinatus tendon and abrasion between muscle and bone. Even though correlations have been found mainly for the hooked form, it is still not possible to confirm that the acromion shape, or its size, is the main or sole cause of the disorder (Balke et al., 2013). In contrast to the view that the acromion shape causes a tear, other studies have raised the question that the acromion shape may be the consequence, not the cause, of an already injured tendon (Sarkar, Taine, and Uhthoff, 1990; Maffulli et al., 2011). For instance, when the supraspinatus is impaired, the force pulling the humeral head downwards during elevation will be reduced; in turn, it will induce an upward migration of the humeral head provoking compensations that may lead to dyskinesis. The dysfunctional shoulder would put additional stress over the coracoacromial ligament, especially on the acromion side, that has a smaller area of insertion in relation to the coracoid process due to its trapezoid shape. Therefore, the increased tension on the coracoid process would stimulate bony growth, potentially creating osteophytes or in a long-term the continuum traction could result in a deformed acromion (Maffulli et al., 2011; Lewis, 2016). Spurs can also be found on the acromioclavicular joint, which may also contribute to narrowing the subacromial space and compression of underlying structures (Pandey and Willems, 2015).

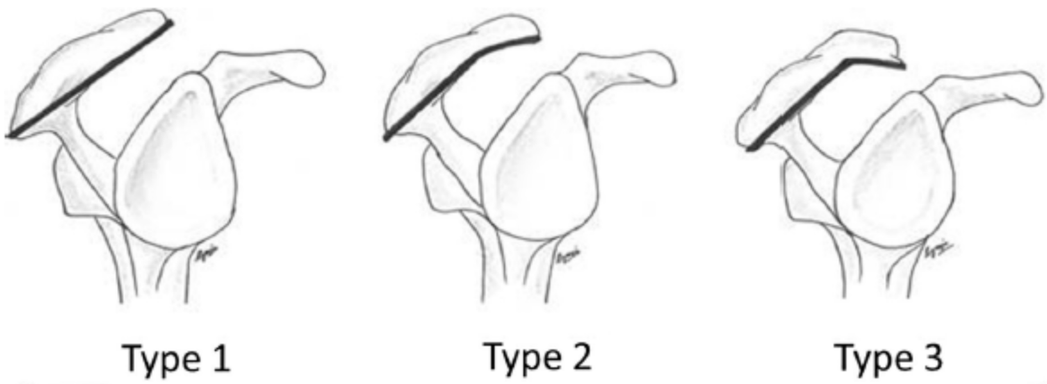


Figure 2.10. Classification of acromion types. From Pandey and Willems (2015).

Intrinsic factors are those with origin related to the tendon, such as microtrauma, mechanical properties, morphology and vascularity. The main intrinsic factor is microtrauma, this theory explains degenerative changes of the tendon based on the history of chronic cumulative microtraumas during life. The damage occurs when humeral elevation is required with greater activity, especially if it exceeds overhead height, where the tendon is more exposed to injury. In addition, the repetitive cycle of small injuries results in a modification of the cells biological environment due to the continuous activity of inflammatory mediators and oxidative stress (Nho et al., 2008).

Consequently, mechanical alterations are also observed, the fibres that suffer consecutive microruptures do not have enough time to heal before further injury; therefore, the remaining intact fibres have to sustain higher loads and are then more exposed to ruptures (Seitz et al., 2011). The healing process becomes deficient because of the short time available for recovery, making the collagen arrangement disorganised and leading to decreased quality of the tendon's mechanical property; the faulty mechanical property reduces the fibres loading capacity, making them more prone to injury (Seitz et al., 2011).

Another intrinsic factor, the vascular pattern of the supraspinatus, has been the theme of debate for a long time. First described by Codman in 1934, the supraspinatus was depicted as having an area of hypovascularity about 10 to 15 mm proximal to the tendon insertion. The *critical zone*, as it is called, was believed to be a fragile point of the tendon that contributed to a higher incidence of the number of supraspinatus cases (Lohr and Uhthoff, 1990). However, later studies showed no differences in vascularity or perfusion when compared to other parts of either supraspinatus or infraspinatus (Brooks, Revell, and Heatley, 1992). The question that is still not clear is whether the pressure caused by the inappropriate position of the humeral head may decrease supraspinatus blood supply and therefore contribute to tendon degeneration (Nho et al., 2008).

A few other factors that are not classified in the two main categories also need to be mentioned. Smoking habits have been associated with poorer outcomes of patients with rotator cuff disease. Baumgarten et al. (2010) administered a questionnaire to 586 patients who were diagnosed with shoulder pain and had an ultrasound to confirm if a rotator cuff tear was present. They found a strong relationship between smoking and cuff tears, and that a dose-dependent relationship exists between the number of cigarettes per day and risk of rotator cuff tears. Patients who complain of shoulder pain and who smoke less than one pack per day have an odds ratio of 1.08 of having a rotator cuff tear, between 1 and 2 packs the ratio rises to 1.66 and a further sharp increase to 3.35 is denoted in the subgroup of more than 2 packs a day. Nicotine has been shown to provoke chronic inflammation and significantly reduces the amount of Type-I collagen expression and cellular proliferation, the consequence is a weaker tendon, with poorer tensile properties (Galatz, 2006).

The glycaemic and lipid profiles also seem to influence on chronic tears and tendon healing, high level of glucose may change collagen cross-links and hypercholesterolemia may decrease tendon's vascularity, however, more studies in the area are needed (Maffulli et al., 2011).

The development of a chronic rotator cuff tear is likely to be a combination of factors. It is important to understand the mechanisms that cause the disorder as it may help with tailoring the treatment plan of a patient. For instance, the use of non-steroidal anti-inflammatory drugs will improve inflammation or acromioplasty arguably decreasing pain, but they do not resolve biomechanical imbalances presented by muscle incoordination nor improve proprioception or maybe improving patient's lifestyle, which may contribute to a faster tendon healing.

2.3.3. Morphological/Histological changes

Considering the pathogenesis and aetiology of rotator cuff tears, the tendons go through a series of changes regarding their collagen structure, tenocyte activity, cellularity and vascularity (Longo et al., 2011). Although the main topic of this thesis will focus on changes that are perceived on the macroscope level, the description of what happens at a cellular level is pertinent to understanding the problem.

Tendons are composed primarily of Type-I collagen, which has a greater capacity to transmit tensile loads from muscle to bone (Thakkar et al., 2014). The collagen orientation of cuff muscles fibres is predominantly on the transverse direction with a few others running perpendicularly. Whether a tear is present, degeneration and disorientation of the fibrils arrangement will appear, with more marked gaps among layers. The tenocytes will decrease in number proportional to the size of the tear, with larger sizes showing lower amounts. The Type-I collagen is replaced by a higher quantity of Type-III, which is weaker due to the reduced amount of tropocollagen units (Longo et al., 2011). The tissue's cellular metabolism has been shown to decrease in torn cuff muscles by demonstrating a lower number of fibroblast population and proliferative activity; this is more prominent on large to massive tears. Small tears preserve higher capacity of regeneration by presenting remarkable fibroblast activity and an increase in blood vessel formation (Longo et al., 2011). Vascularity has similar trends with larger tear sizes, showing a reduced number of vessels and areas of avascularity on the margins of the tear (Dean, Franklin, and Carr, 2012). A relevant point on the changes related to the tendon is that inflammatory manifestation is observed on small tears with an increased number of macrophages, but it seems to follow a declining pattern as the concentration of macrophages drops with the expansion of the tear size (Matthews et al., 2006).

Structural and metabolic changes of the cuff tendons are clearly observed in patients with tears, however as already discussed on the epidemiology section (section 2.3.1, page 7) it is still not completely known why some individuals are asymptomatic and others are not. The next section will focus on the typical signs and symptoms reported by patients and discuss the importance of the specific clinical tests and physical examination.

2.4. Examination/clinical assessment

The most common symptoms of rotator cuff tears are pain, disability and reduced upper limb mobility. As mentioned previously, shoulder pain has a high incidence and the source of the problem occasionally is not related to cuff structures and sometimes not to the shoulder itself.

To be able to discern the origin of the problem, the clinician first needs to find details on the history and onset of the pain, and explore what factors are contributing to exacerbate or relieve the symptoms. After investigating the potential cause, the physical examination is fundamental for a thorough inspection. For instance, by observing the scapula it may reveal atrophy of the supraspinatus and/or infraspinatus, a swollen area may indicate inflammation and a traumatic episode, weakness and numbness is often linked to neurological issues (Hermans et al., 2013). After palpation a visual inspection is performed, the clinician may use specific tests to identify which is the main structure affected.

2.4.1. Special Orthopaedics Tests

A vast number of orthopaedic clinical tests are available for the rotator cuff and the shoulder, each one advocating to be able to correctly identify what is the main source of the disorder. There is a vast range of tests that are well-known by clinicians to test the rotator cuff: Neer, Hawkins-Kennedy, Jobe/empty can, full can, internal rotation lag sign and external rotation lag sign, which are often used in clinical practice.

The orthopaedic tests are relevant for the clinical examination; however, they have been demonstrated by multiple systematic reviews to be unspecific and have poor accuracy with low sensitivity and specificity (Hegedus et al., 2008; Hegedus, 2012; Hegedus et al., 2015). For instance, Hegedus et al. (2008) performed individual meta-analyses for a range of shoulder tests; the authors pooled four articles which tested the sensitivity and specificity of the Neer and Hawkins-Kennedy tests. The sensitivity for the Neer test was 0.79 and the specificity was 0.53, the values for the Hawkins-Kennedy were similar with 0.79 and 0.59, respectively. For the external rotation lag sign only one study with high quality was found and showed good accuracy values (sensitivity and specificity=0.98). In the updated version of this review, the authors state that this test is recommended to confirm full-thickness rotator cuff tears of the infraspinatus (Hegedus, 2012). For the internal rotation lag sign, two studies (Miller, Forrester and Lewis, 2008; Bak et al., 2010) were reported with contradictive results, which make its utility still controversial.

Although the majority of the specific tests seem to be unable to support a correct diagnosis, they are generally not used alone and clinicians commonly use most of them as a group to exclude and find what is the cause (Hegedus et al., 2015). However, one should bear in mind that it is not possible to isolate the shoulder anatomical structures as the positioning of one test is likely to stress more than just the structure desired. Based on the anatomy that shows the integration between cuff tendons and the capsule (section 2.2.3.1. Rotator cuff, page 7), the pain from one of these locations may be referred to another. The subacromial bursa is possibly the main source of pain when performing shoulder clinical tests, because of its innervation which comes from the suprascapular nerve, which is the same nerve supplying the supraspinatus and infraspinatus muscles (Aszmann et al., 1996; Lewis, 2009).

Recently, Lewis (2016) proposed the use of the *Shoulder Symptom Modification Procedure*, which is “a series of four mechanical techniques that are applied while the patient performs the activity or movement that most closely reproduces the symptoms experienced by the patient" (Lewis, 2009). The four techniques assess the influence of the humeral head position in relation to the glenoid fossa, as well as changes of the scapular position, and cervical and thoracic alterations. Although the method seems promising, it still needs further evidence to support its use on clinical examination and to support the planning of rehabilitation protocols.

The orthopaedic clinical tests use mainly pain to drive the possible final diagnosis, but as mentioned at the beginning of this section other symptoms are reported by patients. It is necessary to use other tools such as questionnaires for functional status, a goniometer or other technologies for stiffness and limited ROM, and for a thorough understanding of muscle compensations, EMG is paramount to quantify and detail muscle activity.

2.5. Questionnaires

The deterioration of patient's functional capacity is another common complaint and to quantify how debilitated their physical and psychological conditions are, functional questionnaires are useful instruments.

Generally, questionnaires can be classified for general health or disease/joint specific. The most common questionnaires for general health or health-related quality of life are the EQ-5D and the SF-36. The SF-36 is a questionnaire with 36 questions that yields 8 components: physical functioning, role-physical, bodily pain, general health, vitality, social functioning, role-emotional and mental health. The sub-sections scoring scales varies from a binary *Yes* or *No* under the physical health section, to a six-level Likert scale for the questions about personal feelings. The final score ranges from 0% (worst possible level of functioning) to 100% (best functioning possible) (Ware and Sherbourne, 1992). The EQ-5D is a questionnaire with five questions about five different dimensions (mobility, self-care, usual activities, pain/discomfort and anxiety/depression) and a visual analogue scale (VAS) from 0 to 100 regarding health status. There are two available formats: 3L and 5L. The difference between them is that the 3L has three possible answers in each question, while the 5L has five levels on the Likert scale. If the 5L version is used, the final score will range from 5 (best functioning possible) to 25 (worst functioning possible) in addition to the answer regarding the VAS (Oemar, 2013). Although both instruments (EQ-5D and SF-36) measure health-related quality of life, and they have good capacity to show improvements postoperatively, they have different domains, which means that they should not be used interchangeably, but preferably as a complement to each other (Oberg and Oberg, 2001). However, if only one has to be chosen, an advantage of the EQ-5D is the index-based values, which is a conversion of the final score into a single index value. This index facilitates the calculation of quality-adjusted life years (QALY), that is used for economic evaluation purposes (Oemar, 2013). In addition, there is an ample database available that includes an extensive number of countries to serve as comparators. For the SF-36, to be able to calculate the same index another tool, the SF-6D, must be used to convert the data from one to another and then the results are applicable for QALY purposes. This extra task makes the entire process even longer for the SF-36, which has more questions and demands more time for scoring in comparison to the EQ-5D (Brazier, Roberts, and Deverill, 2002).

Regarding questionnaires for the upper limb and shoulder, a vast range is available. They can be generic and applicable for any disease, affecting any parts of the upper limb or can be limited for one joint or even a single disorder (Wright and Baumgarten, 2010). The most common questionnaire used for research on the upper limb is the Disabilities of the Arm, Shoulder, and Hand Questionnaire (DASH) together with its shorter version the Quick-DASH. Although these two instruments have been tested and have shown good results in relation to their psychometric properties, they are generic for any of the upper limb joints and not specific for the shoulder. For the shoulder itself, more than 30 instruments can be found, however, not many of them have their psychometric parameters established. Some of the most popular questionnaires on shoulder include: The American Shoulder and Elbow Surgeons (ASES), University of California Los Angeles (UCLA), Constant-Murley Score (CM), Simple Shoulder Test (SST), Shoulder Pain and Disability Index (SPADI) and Oxford Shoulder Score (OSS). The ASES is a questionnaire that contains one part that is answered by the patient and another that requires an examiner. It has items related to pain, instability, activities of daily living (ADLs), ROM, signs, and strength. Its score varies from 0-100 (worst to best) and its sensitivity and specificity have been reported as 91 and 75, respectively; its minimal clinically important difference (MCID) is 6.4 (Richards et al., 1994).

The UCLA is another questionnaire to combine patient self-reported and examiner items. It is composed of 5 items about pain, function, ROM, strength, and satisfaction with a score varying from 0 to 35, where the higher score is the better. Its psychometric properties have not shown good results and its MCID has not been established (Wylie et al., 2014).

Similar to ASES and UCLA, the CM uses patient-reported and examiner reported questions. It has four domains on pain, ADLs, ROM and strength, with a score ranging from 0 to a maximum of 100 indicating the best functioning possible. An issue of CM, like the UCLA, is that its responsiveness is poor and no data on the MCID is available.

The SST has 12 items on pain, function/strength and ROM, which have a binary response of yes or no. It does not have a Likert scale, which makes it difficult to quantify how much impairment a patient is experiencing; the SST is able to discriminate worker compensation status and has an MCID of 2 (St-Pierre et al., 2016).

The SPADI is a self-reported tool which has 13 items, 5 for pain and 8 for function. Firstly, the SPADI was scored using a VAS from 0 to 100 mm for each question, where the value in mm was then used as a score. In the second version, the VAS format changed to a discrete numerical rating system from 0 to 10. The final score goes from 0 to 100, with the highest value indicating worst status (Williams, Holleman, and Simel, 1995; Roller et al., 2013). The SPADI has been shown to be one of the most responsive among shoulder scores and has a sensitivity of 80% and specificity of 91% to diagnose shoulder disorders; its MCID is set at 20% (St-Pierre et al., 2016).

The OSS is a 12 item questionnaire about pain and function, each question is answered on a 5 level Likert scale which is scored from 0 to 4; the total score varies from 0 to 48 (worst to best disability) and the MCID has been reported as 6 (van Kampen et al., 2013). The advantage of the OSS is that it is a short questionnaire that can be answered in about 2 minutes and the scoring system is simple and easy to interpret. Moreover, it has good responsiveness and its psychometric properties have been tested demonstrating that it is valid and reliable (Booker et al., 2015; Frich, Noergaard, and Brorson, 2011).

The availability of questionnaires specific for rotator cuff conditions is more limited compared to the number of generic tools. The two most popular are the Western Ontario Rotator Cuff index (WORC) and the Rotator Cuff Quality of Life (RC-QoL). The WORC is composed of 21 items yielding physical symptoms, sport/recreation, work function, lifestyle function and emotional function. Each question is scored on a VAS scale of 100 mm; the final score ranges from 0 (best possible) to 2100 (worst possible). It has excellent reliability (ICC: 0.96), responsiveness (effect size: 0.96) and an established MCID of 245 (de Witte et al., 2012; Wylie et al., 2014).

The RC-QoL is similar to the WORC, it has 34 items regarding symptoms and physical complaints, sport/recreation, work-related concerns, lifestyle, and social and emotional issues. It also uses a VAS scale of 100 mm that can result in an overall result of 3400 indicating the worst possible QoL. However, there is no report on MCID or how reliable and responsive the tool is (Wylie et al., 2014). An advantage of the RC-QoL has been demonstrated by (Hollinshead et al., 2000) where their results showed that the RC-QoL is able to discriminate patients with massive tear from those with large. Although it seems logical that the best choice to assess functional status and quality of life of patients with rotator cuff problems would be the specific tools, there is evidence showing that disease-specific tools, i.e.: WORC, are no better and do not have higher responsiveness than other general questionnaires such as the SPADI and the OSS for this population (Ekeberg et al., 2010).

The vast range of questionnaires makes difficult choosing which is the best. When designing a study, if the quality of the instruments is similar, as it is in the case of some of the shoulder scores, the popularity of the instrument may be an important factor to be considered; however, the popularity can vary according to the country. For instance, in the US the most popular seems to be the CM, closely followed by the ASES; while the most used disease/joint specific questionnaire for shoulders in the UK is the OSS (Varghese et al., 2014; Makhni et al., 2015). As this thesis was carried out in the UK, the most convenient questionnaire to use would be the OSS. Another favourable point for the OSS is that it has equivalent results to the CM when used to measure the patient's progression after treatments related to rotator cuff disorders (Christiansen et al., 2015). Moreover, the OSS presents other advantages: 1) it is entirely self-reported, which avoid any influence from the clinical examiner, 2) it has low administrative burden as it is short, easy to score and interpret results, 3) it was designed to measure the impact of surgical interventions, which is also applicable for this thesis, and 4) it is endorsed by the Royal College of Surgeons of England, which means that the dissemination of the results and their applicability can be quicker with a greater impact within clinical practice in the UK.

Regarding general health questionnaires, the SF-36 seems to be used more frequently than the EQ-5D; however, in the article that measured the usage of different scores, the SF-36 and the SF-12 were counted as one, which may be a reason for a higher frequency in comparison to the EQ-5D (Varghese et al., 2014). The percentage of surgeons using the SF-36/SF-12 was 9% in contrast to 3% using the EQ-5D. Another important component that must be considered is the time taken for applying and scoring the questionnaire, i.e.: administration burden, the SF-36 is much longer and the scoring process is not straightforward compared to the EQ-5D. Considering that a study may use additional tests for physical examination, the whole section cannot be very long, if so, it might discourage patients from taking part as the assessment is too time-consuming. Moreover, the reliability of EQ-5D and SF-36 have been shown to be similar for patients with other arm and shoulder problems, such as humerus fractures (Slobogean, Noonan, and O'Brien, 2010).

The use of questionnaires is of high importance to measure how much the disease is impacting patient's functionality and quality of life. Furthermore, it helps to quantify how much a treatment may improve these outcomes deficits. Because ROM is a frequent component of questionnaires and mobility restriction is one of the major complaints, the clinician must be familiarised with the alterations on movement patterns caused by rotator cuff tears. Therefore, the following sections will describe the main changes on the shoulder complex kinematics and muscle coordination due to this disorder.

2.6. Movement characteristics of patients with rotator cuff tears

The pathognomonic movement of patients with rotator cuff tear is well described in the literature. Compared to individuals without shoulder impairments, those presenting a rotator cuff tear often have reduced ROM for flexion, abduction and rotations (Lin et al., 2005; Namdari and Green, 2010; Hall, Middlebrook, and Dickerson, 2011; Inawat, 2014; Kolk et al., 2016; Fritz et al., 2017) .

One compensation often observed is the increased motion displacement of the trunk. For example, during tasks that require reaching, when the shoulder is not able to provide enough range for the hand to reach the target object, what is then observed is an increase in trunk flexion and lateral bending (Fritz et al., 2016). These compensations may allow the patient to complete the task required, however, they will increase the load on other anatomical structures, which aggravates the shoulder condition (Ludewig and Braman, 2011). The force distribution on the glenohumeral joint will change, and other areas will be overloaded (Parsons et al., 2002).

Another compensatory problem is the amount of work done by the contra-lateral arm. According to Pichonnaz et al. (2015) at 3 months after rotator cuff surgery, patients still use their affected side about 10% less than the unaffected, and about 5% less even after 6 months, this trend gets back to normal only after one year. In their study, 21 patients used a body-worn sensor for 7 hours daily and data collection was performed at 3, 6 and 12 months after surgery. The difference on usage volume may be a possible explanation of why 38% of patients having a cuff repair also needed a cuff repair on their contra-lateral limb in a cohort of 140 patients (Ro et al., 2015).

Scapula dyskinesis is another major dysfunction observed (Kibler et al., 2013). The scapula has an important role in increasing motion amplitude and addressing changes that debilitate its control is paramount in rehabilitation. Although there is a consensus that scapula dyskinesis is a common finding, it is still not possible to determine whether it is caused by a rotator cuff deficit or the opposite, if a dysfunctional scapula contributes to rotator cuff tears and other shoulder problems (Kibler et al., 2013). However, because of the peculiar anatomy of the shoulder complex, what is clear is this association that whatever happens at the scapula has a direct impact on the humerus. For instance, Mell et al. (2005) assessed a sample of 42 individuals with rotator cuff tears, tendinopathy and controls using 3D kinematics; they showed that not just tears, but also tendinopathies of the rotator cuff, are able to change the normal movement pattern of the scapula in relation to the thorax and humerus. In comparison to individuals without shoulder problems, the scapula of patients with rotator cuff tear has increased upward rotation and anterior tilting, which consequently reduces humeral ROM (Mell et al., 2005). The increased upward rotation is an adaptation to bring the glenoid into a better position to support the humeral head rotations and the anterior tilting is possibly due to an inefficient serratus anterior (Spall, Ribeiro, and Sole, 2016).

As a result of scapula dyskinesis, other muscles are recruited to try to restore movement performance. Therefore, the upper trapezius is one of the main muscles compensating for rotator cuff deficits; however, even trying intensively, the upper trapezius is not able to support the demand imposed by the primary movers (Duc et al., 2014). In contrast, it affects the balance with the lower trapezius, which compromises the scapulohumeral rhythm. In this scenario, the upper trapezius has been shown to maintain longer periods of activation, which also demonstrates a correlation with the reduction in functional scores (Duc et al., 2014). Because one of the upper trapezius' actions is to rotate the scapula upward, this prolonged activity seems to confirm the changes observed on kinematic patterns of increased upward rotation. These findings regarding the overactivity of the upper trapezius was confirmed by Spall et al. (2016); the authors performed a systematic review of studies which used EMG to assess shoulder muscles of patients with symptomatic and asymptomatic rotator cuff tears. Nineteen studies were included in the final analyses, which showed the results previously mentioned.

Another muscle directly affected by rotator cuff tears is the deltoid, mainly if the supraspinatus is the muscle affected. Because the supraspinatus is not able to stabilise the humeral head during a rotation, what is then observed is an overactivation of the deltoid. The overactivation is an effort to cope with both functions: avoidance of humeral head translation and the elevation of the humerus at the same time (de Witte et al., 2014). This rationale is underpinned based on studies showing that blocking the suprascapular nerve resulted in increased activity of all three parts of the deltoid (McCully et al., 2007). After surgical repair, this pattern seems to return to normal after one year, which also corroborates with the findings of the increased usage of the contralateral arm cited before (page 30, first paragraph). In addition, other studies on rotator cuff tears and EMG have demonstrated that the deltoid's anterior and medial portion are more prone to fatigue because of the extra load imposed by dynamic tasks (Alpert et al., 2000; de Witte et al., 2014). When the anterior deltoid is fatigued, the biceps brachii may increase its participation on shoulder flexion, thus, adjusting the force deficiency from the anterior deltoid (Minagawa et al., 1998). However, what is commonly observed in surgeries for rotator cuff repairs is that the biceps also needs additional procedures; biceps tendinopathy is rarely isolated, 95% are combined with other shoulder problems (Zhang et al., 2015). Following the rationale that their increased activity is noticed when the anterior deltoid starts to fail, it seems that biceps tendinopathy is a consequence of an impaired rotator cuff. However, more research is needed to clarify this association.

Other muscles that also have shown alterations on their activation are the shoulder adductors. In the lack of adequate cuff activity, the adductors have demonstrated higher activity. In a series of studies de Witte et al. (2013) and de Witte et al. (2014) assessed individuals with no shoulder problems compared to patients with shoulder complaints, they used EMG during functional tasks and pure abduction and adduction; they found that mainly the latissimus dorsi had increased co-activation during shoulder abduction, this activity pattern was different when compared to normal individuals or even with shoulder impingement cases. Muscles such as the latissimus dorsi and pectoralis major are also humeral head depressors (section 2.2.3.4., page 15); they assume the role of maintaining the humeral head centralised when the cuff is debilitated.

Pain avoidance might be one of the main reasons for impaired muscle coordination. Cordasco et al. (2010) assessed the muscle activity before and after applying subacromial injection of anaesthetics on patients with symptomatic large rotator cuff tears. Comparing with the data prior to the procedure, the participants showed increased anterior deltoid firing patterns. Another study assessing patients with shoulder pain compared to controls using EMG has highlighted that rotator cuff disorders alter muscle latency, which was observed by an earlier recruitment of the upper trapezius and earlier deactivation of the serratus anterior during shoulder flexion (Phadke and Ludewig, 2013).

In summary, symptomatic rotator cuff disorders may trigger a cascade effect that deteriorates the normal biomechanics of the shoulder complex. There is a range of tools that can be used to quantify such modifications and aid in detailing how the dynamic interaction among muscles, joints and bones is functioning. Therefore, the next section will debate the main differences and characteristics of the different equipment used for movement analysis purposes.

2.7. Kinematics

By definition, kinematics is the branch of mechanics that investigate the motion of objects, or in the case of biomechanics, the body's motion (Winter, 2009). Research using movement analysis has evolved through the last decades and has proven to be of fundamental importance in supporting clinicians in their treatment planning. This section will focus on the pros and cons of different methods of assessing patients' movement and how 3D systems may support the development of rehabilitation programs.

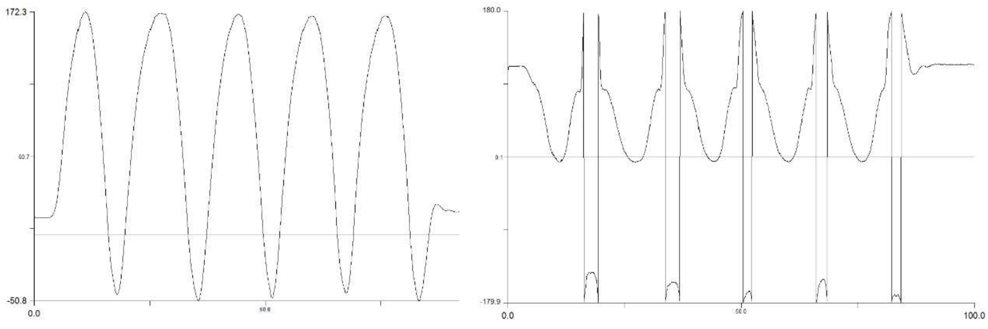
The simplest instrument that can be used to quantify the displacement of a segment is the goniometer, they are widely used by clinicians because of their ease in handling and low cost. However, for shoulder assessment these have poor reliability; if the measurement is undertaken by different assessors, the result may vary by as much as 25°, and even the same examiner may show variations of up to 23° (Hayes et al., 2001). Another disadvantage is their restriction to a single joint and axis at a time, thus, there is a limitation in the detection of further compensations that can be observed on other planes of the same segment or other segments.

Two dimensional (2D) cameras is another clinical system commonly used, but as it seems advantageous to have a visual record of the patient for possible observation of compensatory postures when applied to the shoulder, it is also a simple underestimated representation of a single plane of movement. It is restricted to a few degrees of freedom (DOF), which in turn shows similar limitation to goniometers (Cuesta-Vargas, Galán-Mercant, and Williams, 2010).

Tridimensional (3D) systems are often referred to as the best and most accurate option for movement analyses, where more DOF are available to describe the movement patterns of segments and joints. When more DOF are involved, the analyses become more complex in nature. The number of DOF represents how many motions can be used to fully describe the movement (Li, 2006). For example, if we consider the upper arm as an unconstrained rigid body and report its motion in relation to the thorax, three rotations on the anatomical axis (x, y, z) and three translations over those axis will be available (Li, 2006).

Due to its elaborated nature, 3D kinematic analyses need some steps to produce reliable results. First, it is necessary to define an orthogonal coordinate system as a reference to calculate how segments are displaced in three dimensions (Kontaxis et al., 2009). There are two different referencing options: 1) local, which is when two adjacent segments are used to define the joint kinematics, e.g.: humerus in relation to thorax; and 2) global, which is when two non-adjacent segments or a segment in relation to a global coordinate system is used to define the segment kinematics, e.g.: humerus in relation to the room (global) (Kontaxis et al., 2009). After selecting how the kinematics of the segment of interest will be referenced, the next step is to define its own orthogonal coordinate system. When a local coordinate is chosen, two coordinate systems must be defined; one for the segment of interest and one for the reference segment, thus it is possible to build the joint (Ludewig et al., 2010). Every orthogonal coordinate system is represented according to the definition of its axes; similar to the planes of movement there are three (sagittal, coronal and transverse), the axes follow the same rationale, but with different terms: anterior-posterior, medial-lateral and superior-inferior. This definition is important as it allows the description of the segment starting and ending angle positions, which is determined by a sequence of rotations, which must be clearly specified. The sequence of rotations is fundamental for movement interpretation; in the biomechanics of the shoulder, it is common to use the Euler and Cardan angles for this purpose (Phadke et al., 2011). Therefore, to make data from different studies comparable and translated for clinical application, the International Society of Biomechanics proposed a series of standards on the coordinate systems and rotations, which should be followed by researchers when reporting their results (Wu et al., 2005). The shoulder has standards for the thorax, clavicle, scapula and humerus. The humerus, in relation to the thorax, is one of the most common segments analysed for shoulder studies. The rationale to choose its rotation sequence depends on whether the segment is moving mainly in the sagittal or the coronal plane. In the sagittal plane, the sequence that must be used is X-Y-Z, while in the coronal plane the sequence is Y- X- Y (Wu et al., 2005).

Moreover, the importance of clearly defining the sequence of rotations is especially noted on Eulerian angles because of the Gimbal Lock effect. Gimbal Lock occurs when the three axes become redundant, thus, the resultant joint position is meaningless and not interpretable (Figure 2.11) (Phadke et al., 2011).



A B

Figure 2.11. Example of using the correct rotation sequence: A) Normal pattern following ISB recommendations, B) Gimbal Lock effect when applying an incorrect sequence.

When the 3D system chosen is based on an optoelectronic or inertial sensors system, the modelling process will be similar and can be created based on the same steps. Currently, the reference standard for kinematic analysis are 3D optoelectronic systems, they provide high-quality data based on the identification of active or passive markers placed on the body (Zhou et al., 2008; Garofalo, 2010; Cuesta-Vargas, Galán-Mercant, and Williams, 2010). Passive markers are spheres covered with a retroreflective material that reflects the light generated from the light source placed around the camera's lens; in contrast, active markers do not reflect the light back, as they act as the light source. It is noteworthy that despite optoelectronic systems providing accurate data, they also have counterpoints: time-consuming set-up, ample setting area and high-cost investment (Cutti et al., 2008).

Inertial sensors have recently emerged as an option for 3D movement assessment (Cuesta-Vargas, Galán-Mercant, and Williams, 2010). In contrast to the technology used in optoelectronic systems and electromagnetic units, inertial sensors are based on instruments such as: magnetometers, accelerometers and gyroscopes that combine their information to calculate angles, acceleration, velocity and orientation (Cutti et al., 2008). Furthermore, inertial sensors have the advantage of ecological validity; their portability makes their use outside the laboratory setting easier, which allows individuals to take the equipment to where the patient is, instead of the opposite. Moreover, various studies have tested the reproducibility and reliability of inertial sensors, showing that their measurement error is smaller than 3° and a correlation value of 0.99 compared to measurements from optoelectronic systems (Cutti et al., 2008; Zhou et al., 2008; Garofalo, 2010; Parel, 2012; Zhang et al., 2013).

Despite their proven validity and reliability, few studies have determined the relevance of inertial sensors for the shoulder joint during different ADLs. The first published study using sensors to assess the shoulder dates from 1990, where the authors used two electromagnetic sensors (on the sternum and humerus) to track abduction and rotations (Johnson and Anderson, 1990). Although electromagnetic sensors are an option, they are sensitive to metal interference and require filters for correction. Since then, technology has advanced and new sensors have been developed to what is now known as an inertial measurement unit.

Regarding their validity for shoulder assessment, Cutti et al. (2008) compared the differences between an optoelectronic and an inertial system during movements of flexion/extension, internal/external rotation, abduction and abduction associated with rotations (hand-to-nape and hand-to-top-of-head). However, other movements that are common on a daily basis as internal rotation associated with extension (hygiene purposes or reaching the wallet in the pocket) or horizontal adduction and abduction (carrying objects from a shelf or hanging clothes in the wardrobe) were not explored. An important concern in this study was the sample of only one person. Other studies by Garofalo (2010) and Parel (2012), have also proposed the validation of inertial sensors versus optoelectronic systems, but only focused on the scapular movement in two tasks: humeral flexion/extension and adduction/abduction, showing high intra and inter-assessors agreement (0.85).

Currently, there is some evidence published regarding the use of inertial sensors to specifically assess patients with rotator cuff tears. However, the majority of the studies describing changes related to this population are cross-sectional (Coley et al., 2007; Duc et al., 2014; Pichonnaz et al., 2015). For instance, the only paper until now on shoulder 3D kinematics comparing before and after (1 year) a cuff repair is from (Kolk et al., 2016). The authors used inertial sensors to measure shoulder ROM of 26 patients who underwent a rotator cuff repair; their findings show an increase in humeral elevation for abduction and flexion respectively of 20° and 13° after surgery. Moreover, the scapula also restored its pattern; less upward rotation was observed together with increased posterior tilt and decreased protraction. Therefore, considering that only one paper is available on the topic, further detailed analyses about how patients progress after a surgical intervention or how rehabilitation impacts their recovery is still lacking.

2.8. Electromyography

Recording 3D kinematics provides great detail about movement patterns. However, understanding muscle activation patterns is crucial to explore how muscles respond to different treatments and how effective they are in recovering to a normal standard. Therefore, EMG is key to complement biomechanical evaluations.

EMG is the recording of the motor unit action potentials generated in the muscle fibres. The electrodes detect the depolarization-repolarization waves from multiple fibres under their covering area, their signals are superposed and their sum results in the final EMG pattern (De Luca, 1997; Winter, 2009).

There are two main methods to collect EMG data: using surface or invasive electrodes. The invasive method requires the insertion of needles and fine wires in the muscle fibres. Their advantages are to avoid the influence of subcutaneous tissues on the signal and to be able to record the activity of deep muscles that lay under other muscles or bones, e.g.: supraspinatus or subscapularis, therefore it reduces cross-talk contamination. However, because it needs to be inserted in the muscle, it may cause pain and discomfort, which will influence the muscle activity recruitment. Moreover, because the electrodes are very thin, only a very small amount of motor units are recorded, which is not a comprehensive representation of the whole muscle activity (Konrad, 2006). Surface EMG uses sensors that are positioned on the skin. Because they are not invasive, this technique is widely used in biomechanical research. Although it is reliable and relatively simple to use, it has the limitation of only recording those muscles that are more superficial in relation to the skin. Moreover, it has the counterpoint of potential cross-talk from other muscles from deeper layers (Konrad, 2006).

In order to collect high-quality EMG signals, it is necessary to be aware of some factors that can affect their quality. Because surface EMG is the most common method used and because it was the choice of electrodes used in this thesis, the description of such factors will focus on surface EMG.

De Luca (1997) designed a comprehensive model to scrutinize how the factors affecting EMG quality can be classified in different groups and how their interrelations interfere in the final interpretation (Figure 2.12). The three categories are separated as: causative, intermediate and deterministic. The causative factors can be intrinsic or extrinsic. The intrinsic are related to the physiological, anatomical or biochemical characteristics of the muscle, some examples are: the number of active motor units at a particular time of contraction, fibre type composition and fibre diameter. Because of their character, they cannot be controlled such as the extrinsic causative can; the extrinsic are those related to the electrode structure and positioning on the skin.

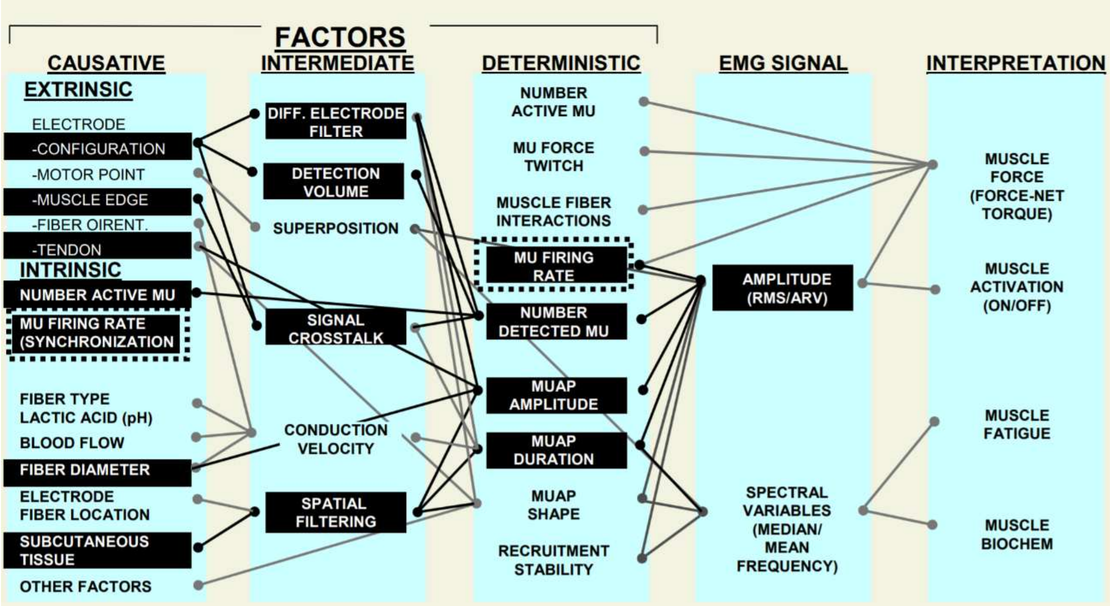


Figure 2.12. Diagram showing the factors affecting EMG signal. From De Luca (1997).

The electrode design is very important for the signal-to-noise ratio; it has to avoid signal distortion as much as possible while providing a high signal-to-noise ratio. One way of reducing potential noise from other sources is by using a differential detecting configuration. In this arrangement, the signal is detected in two sites (bipolar), if the same signal is observed on both sets of electrodes it will be removed, and if the signals are different they are subtracted and amplified. In contrast, monopolar electrodes will detect all signals in the vicinity but are incapable of differentiating real muscle activity from what is noise, therefore its use is not recommended for research purposes (Figure 2.13)(De Luca, 2006).

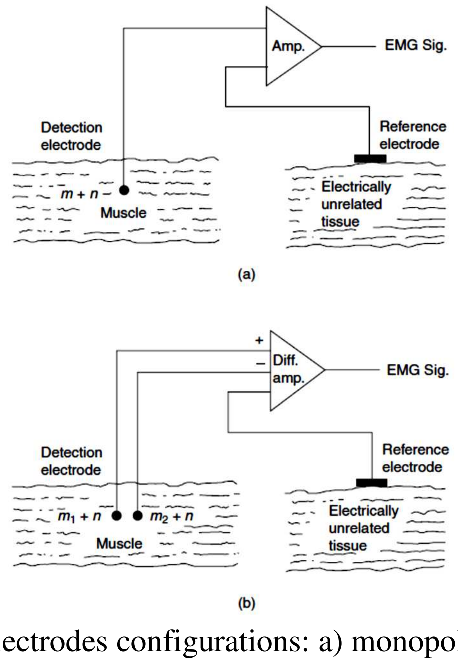


Figure 2.13. Different electrodes configurations: a) monopolar arrangement, b) bipolar arrangement. From De Luca (2006).

The distance between the detection area is also important as it is proportional to the EMG amplitude, i.e. as the distance increases the signal amplitude decreases. Furthermore, such distances cannot be too wide because of the muscle area; if assessing small muscles, the electrode may cover other muscles besides the one of interest. On the other hand, if the distance is too small, only a few fibres will be detected, and shorting path circuits may occur in the presence of sweat "linking" both electrodes. Therefore, the optimal inter-electrode distance is 1 cm (De Luca, 2003; De Luca et al., 2012).

The electrode positioning is another extrinsic causative factor which demands attention. The electrode should be positioned on an area that is between a motor point and the tendon insertion or between two motor points; the amplitude and frequency of the signal are directly affected by the electrode position. When the electrode is on a motor point, the frequency will be higher due to its proximity to the innervation zone, however, because it is the starting point from where the muscle fibres are depolarized, the difference between the positive and negative phases will be small, which results in reduced signal amplitude. If the electrode is close to the tendon, both amplitude and frequency will be low because this is the area where there is a reduced amount of muscle fibres. The most appropriate location is on the muscle belly; this is where the highest amplitude is observed and is also where the frequency is more stable. Furthermore, the electrodes orientation should be parallel to the muscle fibres; thus it will be capturing the travelling signal from the same fibres (Figure 2.14) (De Luca, 1997).

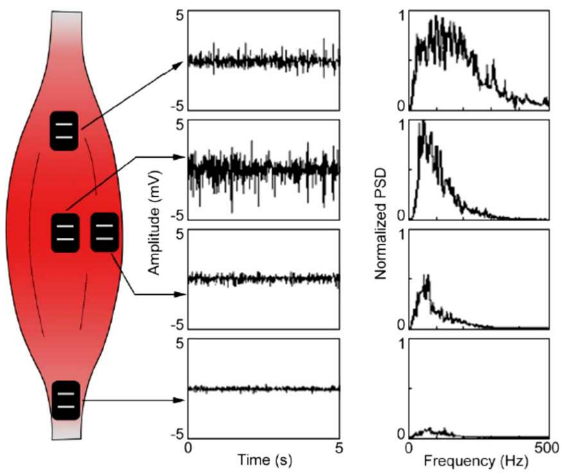


Figure 2.14. Influence of electrode positioning on EMG signal. From De Luca (1997).

The intermediate factors involve physical and physiological components that are influenced by one or more causative factors. Therefore, they are also dependent on factors related to electrodes such as band-pass filtering, detection volume capacity, superposition of action potentials and cross-talk. However, in this category, most importantly are the conduction velocity of the action potentials and spatial filtering effects. The first affects the amplitude and frequency characteristics of the signal, which can be clearly observed on individuals that present neuromuscular conditions (Fukada et al., 2016). The spatial filtering is a limitation on surface EMG, due to the electrodes rigid nature and because they are fixed on the skin, these do not allow for changes in muscle length during contractions (De Luca, 1997). The last group of factors is the deterministic; these are related to the characteristics of motor units, such as how many are active, force-twitch relationships and firing rates.

After the signal is collected, the next step is to process the data. Depending on the purpose of the study, different methods can be used. If the aim is to investigate how much work the muscle is doing, the most used methods are the Root Mean Square (RMS) and the Linear Envelope. They are measures of power, they show the amplitude of the EMG signal in relation to time, or in other words, how much the muscle worked during the contraction period (Burden, Lewis, and Willcox, 2014). In contrast, if the main reason for analysing the EMG signal is to know about muscle fatigue, the best option is to explore the frequency domain (von Tscharner, 2000). Another option is to evaluate muscle coordination or latency by analysing their activation/deactivation timing; in this case, when the muscle starts and stops contracting during a chosen task (Hug, 2011).

Even though the whole process from choosing the most appropriate sensor through to how to analyse the EMG signal seems complex, EMG adds valuable information. As described in section 2.5 on movement characteristics of patients with rotator cuff tears, compensatory strategies requiring the recruitment of other muscles to accomplish tasks are often observed. Although for rotator cuff tears the nociception concept is still the main philosophy, the rationale of repairing the tendon that is faulty seems the best choice to recover muscle function, however, the human body is not simple and straightforward. Therefore, the following section will describe the options for the rotator cuff tears management from a surgical and a conservative point of view.

2.9. Management

The management of rotator cuff tears is a topic of ample discussion. Although it seems logical that repairing a damaged structure that impairs muscle function is mandatory, this might not be the natural answer. Recent research has demonstrated that for functional scores and pain status, physiotherapy is as effective as surgery after one year, especially for chronic tears (Ryösä et al., 2016). With easier and cheaper access to imaging in the last decade, it is possible to show that a significant percentage of the general population do have structural changes, but do not necessarily have symptoms (Yamamoto et al., 2010). Hence, the paradigm that anatomical changes on musculoskeletal imaging are responsible for pain and symptoms has been challenged. The rehabilitation area is now taking a different direction to demystify what are the main predictors of musculoskeletal complaints and what can influence positive response to physiotherapy (Chester et al., 2013).

2.9.1. Non-surgical

The evidence comparing surgery to physiotherapy is still scarce, but their results look promising on indicating that physiotherapy may be a better first choice before trying surgical interventions for patients with rotator cuff tears. For instance, Kuhn et al. (2013) performed a cohort study where they recruited 452 patients with confirmed diagnosis of atraumatic rotator cuff tears. These patients were all offered physiotherapy as a treatment instead of surgery. In the first 6 weeks, 9% had surgery and at 12 weeks 15% of the grand total opted for rotator cuff repair. At the follow-up of 2 years, from the total sample size of 452 only 26% had surgery, therefore 74% avoided surgical intervention. Moreover, their survivorship analysis demonstrated that patients who decided to undergo surgery did so within 12 weeks. Another study comparing physiotherapy versus surgery demonstrated no superior results between interventions, but patients who had only physiotherapy had an average cost of €2,417, which avoided extra costs of about €2000 per patient compared to those who had surgery, and saving more than €3000 compared to those who had surgery and physiotherapy (Kukkonen et al., 2014).

Evidence suggests that a physiotherapy program for rotator cuff tears should include exercises focusing on postural awareness (Barrett et al., 2016), active-assisted motion (Baumgarten, Vidal, and Wright, 2009), exercises for the scapula (Struyf et al., 2013), stretches for the anterior and posterior shoulder muscles and strengthening exercises for rotator cuff and other scapular muscles (Kibler, 2000; Edwards, 2016; Sealey and Lewis, 2016). However, the therapist must always tailor the volume and difficulty of the exercises according to each patient aiming to address their limitations to specific movement challenges when performing functional tasks (Sealey and Lewis, 2016). Patients who present massive tears (> 5 cm) may benefit from a protocol that focuses on gradually strengthening the anterior deltoid, however the effect does not seem to last more than 12 months; the effectiveness of strengthening the anterior deltoid was demonstrated by Ainsworth, Lewis, and Conboy (2009); in this study 60 patients with massive tears were randomised to either physiotherapy or to receive ultrasound, advice and steroid injection if necessary without the exercise programme. Those patients allocated to exercise had better function at 3 and 6 months, but comparable score were observed at 12 months. A systematic review with 2 RCTs, 7 prospective and 2 retrospective cohorts from Abdul-Wahab et al. (2016) showed that besides physiotherapy, corticosteroids injections are also an option, however, their effectiveness is still limited and their adverse effect on damaging the tendon tissue must be carefully considered.

2.9.2. Rationale to plan rehabilitation after surgery

Due to limited high-level evidence, the reasoning to underpin an appropriate protocol after surgical repair should follow the mechanobiology of tendon healing and metabolic characteristics. The main function of tendons is to transmit forces from muscle to bone, they are also responsible for passively storing and dissipating energy during motion due to their viscoelastic properties (Sharma and Maffulli, 2006; Voleti, Buckley, and Soslowsky, 2012). Rotator cuff tendons are composed mainly of collagen type I, accounting for 95% of all collagen present in tendons and about 65-80% of the dry mass; their main purpose is to build tensile strength and structural integrity of the tissue (Gelse, Pöschl, and Aigner, 2003). The mechanical behaviour of intact collagen and tendons is illustrated in Figure 2.15. When the tendon is at rest the collagen fibres will remain in a crimped shape; from 2% to 4% of tension, fibres become more parallel and still perform in an elastic fashion, with no impairments. Failure is observed when loads exceed 4% of strain, and intrafibril gaps will occur when strain is greater than 8-10% (Sharma and Maffulli, 2005). After surgical repair, the tendon will have structural modifications that alter the normal stress/strain curve (Voleti, Buckley, and Soslowsky, 2012). In the first six weeks the tendons tensile capacity is limited to approximately 20% of that of normal, which indicates that the tendon may present failure with loads close to 1% of strain; from six to 10 weeks they improve to about 36% and after 12 weeks the rate raises to about 42% (Carpenter et al., 1998). Figure 2.16 from Gimbel et al. (2004), shows how the realignment of collagen fibres occurs over a period of 16 weeks. This illustration is from a rat supraspinatus, which was detached from its insertion. Although research about tendon healing is still controversial, studies with animal models consider that total recovery is only reached at around 12 months, but the tissue will have a scar-like formation and mechanical properties will not be of the same quality as those pre-injury (Leadbetter, 1992; Frank, McDonald, and Shrive, 1997). The explanation for this slow process is related to very low tendon metabolism. This feature is essential to manage load tension for longer periods and helps to avoid the risk of ischemia and necrosis, but as a consequence, their regenerative capacities are reduced (Sharma and Maffulli, 2005).

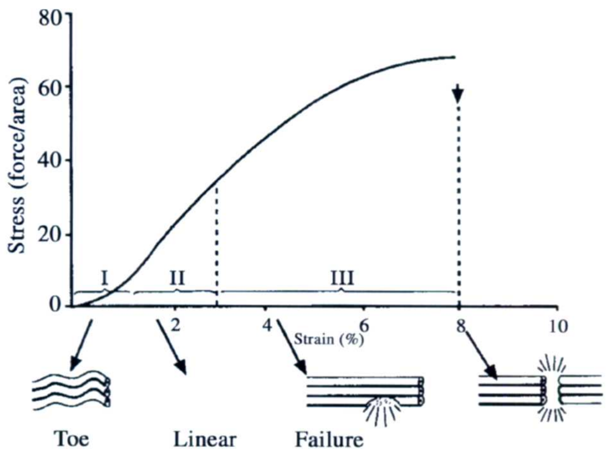


Figure 2.15. Stress-strain curve of normal tendons. From Sharma and Maffulli (2005).

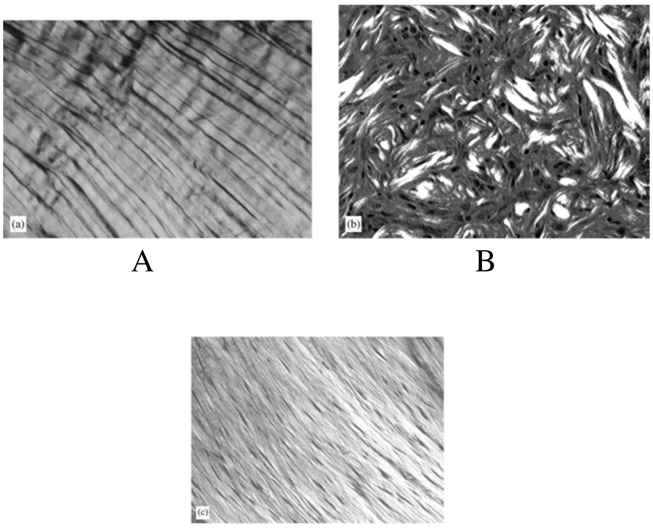


Figure 2.16. Collagen re-organisation: A) control subject showing ordinary crimp pattern, B) one-week post-injury showing fibres disorganization, C) 16 post-injury showing improved reorganisation. From Gimbel et al. (2004).

The healing sequence or cascade is divided into three overlapping phases: inflammatory, proliferative and remodelling (Sharma and Maffulli, 2006). In the inflammatory phase, which lasts about 1 week, a higher concentration of macrophages infiltrates the site; they secrete transforming growth factor β1 (TGF – β1), which is responsible for increasing collagen and scar tissue formation, and proteinase activity (Hays, 2008; Bedi et al., 2012). In the next 2-3 weeks, the proliferative phase takes place, it is the time point when fibroblast express different cytokines (Bedi et al., 2012). The last stage is the remodelling, it starts approximately after 3 weeks and continues over 12 months; in the beginning of this phase the tenocytes' metabolism stay high and it is when fibres start to become aligned with the direction of loading application (Sharma and Maffulli, 2006).

Based on this rationale, the optimal moment to initiate more substantial shoulder mobilisation is around three weeks post-surgery (Carpenter et al., 1998; van der Meijden et al., 2012). When the mechanical stimulus is applied concomitantly to the moment that collagen fibres begin to develop their structural arrangement, tendons may have their viscoelastic properties enhanced, avoiding further issues such as tissue adhesion, which compromise joint mobility resulting in stiffness. The protocol (described in the clinical message section below), aims to gradually increase patients shoulder range of motion, improve muscle strength and motor control while avoiding excessive stress in the repair site and pain status. Thus, it is assumed that patients with cuff tears will have better outcomes and possibly will prevent adverse effects that compromise their quality of life and can be costly if additional surgical interventions are needed in the future.

In conclusion, even though most patients may benefit from non-surgical interventions, there is still a fraction who do not respond well and, therefore, need surgical intervention. The reason why some patients still need surgery is not fully understood, but factors such as age, smoking and duration of symptoms seem to influence patients' response (Thomson, 2015). Hence, the next section will detail the different surgical methods.

2.9.3. Surgical Methods

Indications for surgery may vary according to surgeons' opinion. Dunn et al. (2005) demonstrated that factors such as the annual volume of rotator cuff repairs performed by surgeons can influence their decision on indicating patients for surgical repair; those who have higher volume are more positive about the outcome. Generally, the decision making is based on persistent symptoms that do not resolve with conservative treatment for at least 3 months. Symptoms such as severe pain, especially during night affecting sleep quality, weakness and low functional capacity are the main reasons for requiring surgical intervention (Carr et al., 2015).

The best time for having surgery is also uncertain and still requires primary high-quality studies for clear guidance; a systematic review has shown no benefit on having the procedure during the early stages of less than 3 months (Kweon et al., 2015). There are three approaches to performing the rotator cuff repair: open, mini-open and arthroscopic. The open is the most intrusive among them, it requires an incision of 3 to 6 cm that runs parallel to the lateral border of the acromion on the anterior superior aspect of the shoulder. After dividing the subcutaneous fat, the deltoid is detached from its acromion insertion posteriorly until the lateral side where it is then split by between 3 to 5 cm. After preparing the bone, the muscle is then reattached (Figure 2.17. A). The mini-open is a mix of techniques where the surgeons arthroscopic portals are extended by 1 to 2 cm and the deltoid is split to allow a secure bone to tendon fixation (Figure 2.17.B). The all-arthroscopic repair is nowadays the most common procedure. It is less invasive, does not require such an aggressive approach to the deltoid, and has fewer complications like deltoid avulsion infection (Figure 2.17.C) (Ghodadra et al., 2009).


A


B


C

Figure 2.17. A) Landmarks and incision line for an open repair, B) Landmarks and incision line for a mini-open repair, C) Landmarks and incision line for an all-arthroscopic repair. From Ghodadra et al. (2009).

Although the open-repair is described as more invasive, for patients with chronic rotator cuff tears who are older than 50 years, the open-repair in comparison to the all-arthroscopic does not have statistically significant differences for functional scores, retears rates, nor it is less clinical or cost-effective after 2 years follow-up (Carr et al., 2015).

The first step is to choose which approach to use, the second is what method will be applied to reattach the tendon. After examining the tear shape, the surgeon chooses how to connect the tendon, there are three main methods: single-row, double-row or transosseous equivalent (McCormick et al., 2014). By their names, it is possible to understand their main differences; the single-row uses a single row setting where usually two anchors are used. The double-row uses two pairs of sutures that attach to 4 anchors. The transosseous equivalent is performed similar to the single-row, however, the suture configuration requires extra sutures which can have a W or X shape (McCormick et al. 2014; Park et al., 2007) (Figure 2.18).

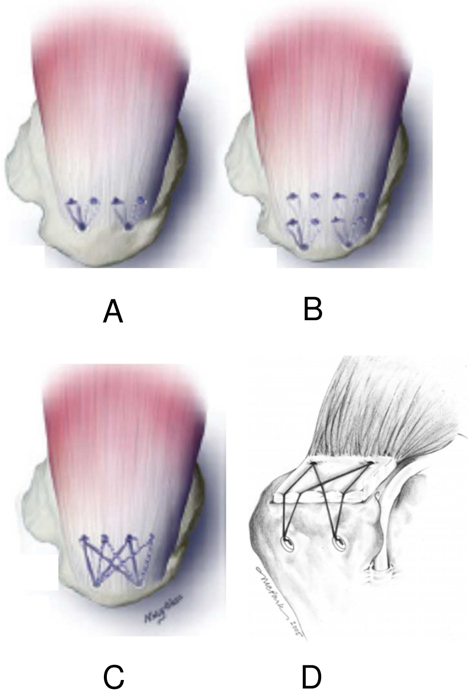


Figure 2.18. Techniques for reattaching the tendon to the bone: A) single-row, B) double-row, C) transosseous equivalent W shape, D) transosseous equivalent X shape. From McCormick et al. (2014) and Park et al. (2007)

The techniques have evolved to try to make the footprint stronger and more stable. Based on cadaveric studies, the double-row and transosseous equivalent have been shown to display stronger mechanical properties compared to the single-row (Lee, 2013). However, different fixation methods seem not to translate to better patient outcomes, but may possibly aid rehabilitation allowing earlier mobilisation by offering better footprint stability (Mascarenhas et al., 2014).

In summary, physiotherapy can be as effective as surgery for treating rotator cuff tears; however, some patients do not respond to conservative approaches and will require surgery. The number of rotator cuff repairs performed every year is increasing in many countries (Colvin et al., 2012; Ensor et al., 2013; Judge et al., 2014; Paloneva et al., 2015; Malavolta et al., 2016). After surgery, physiotherapy is needed to support patients in recovering their movements and functional capacity, but when clinicians try to develop the best protocol based on the evidence, it can be difficult to decide when and how to do it (Oliva et al., 2015). Besides applying the best evidence, the rationale must be discussed based on the expertise from the health professionals involved, which has recently been shown to be challenging. Mollison et al. (2017), applied a web-based survey to 704 orthopaedic surgeons in the USA asking questions about rehabilitation after rotator cuff repair. The results showed substantial variability and there was a low agreement rate of when to start physiotherapy. One of the major discrepancies shows that only 37% of the surgeons recommend physiotherapy in the first 2 weeks, 23% between 2-3 weeks, 21% between 4-5 weeks and 15% between 6-7. Further findings revealed that the majority of the therapists (69%) started with passive ROM within the first 2 weeks and progression onto unrestricted passive ROM happened only after 6 to 7 weeks. Active ROM was started only after 7 to 10 weeks, which may be considered a very conservative approach. In the UK, Littlewood, and Bateman (2015) conducted a similar study with 122 physiotherapists. They applied an online questionnaire using a clinical case to ask physiotherapists when they would start shoulder mobilisation and when passive, active and resisted exercises were commenced. They found that most clinicians had their patients in a sling from 4 to 6 weeks. Different from Mollison et al. (2017), 51% of the respondents stated starting passive ROM which started in the first week and active ROM mostly starting at 4 to 6 weeks (58%). These conflicting data are worrisome as delaying rehabilitation may impact patients health causing complications like stiffness and postponing their return to work (Seo et al., 2012). However, it is noteworthy that the study of Mollison et al (2017) collected responses mainly from orthopaedic surgeons and the population of Littlewood, and Bateman (2015) was composed of physiotherapists, which may be another factor for the divergent results.

2.10. Background summary

The rotator cuff is a complex muscle group and damage to their tendons may affect the whole shoulder performance. Rotator cuff tears are a common disorder impacting patients' quality of life. Different tools and questionnaires have been used to describe how rotator cuff tears affect patients function and pain status; however, there is a lack of information on how the progression from before surgery to postoperative periods, in particular when considering muscle activity and movement control, and how physiotherapy may impact these outcomes. In addition, there are uncertainties regarding post-operative physiotherapy protocols, which may confuse clinicians and delay patients' recovery. Therefore, the chapter 3 will focus only the effectiveness of early compared to conservative rehabilitation, which has been the subject of discussion, uncertainties and ranked as the 4th most important question that must be addressed within the field of shoulder surgery research (Rangan et al., 2016).

CHAPTER 3: LITERATURE REVIEW - EFFECTIVENESS OF EARLY COMPARED WITH CONSERVATIVE REHABILITATION FOR PATIENTS HAVING ROTATOR CUFF REPAIR SURGERY.

This chapter has been published in the British Journal of Sports Medicine. 2018 Jan;52(2):111-121. doi: 10.1136/bjsports-2016-095963. (Appendix 1).

3.1. Introduction

Following surgical rotator cuff repair, a period of movement restriction is advised (Parsons et al., 2010); however, the optimal time of immobilisation is unknown. It is common practice to ask patients to use a sling for six weeks and avoid activities with the affected shoulder (Keener, 2012; Acevedo et al., 2014). This period is important to protect the tendon, allow good healing and to possibly prevent retear episodes (Lin, Cardenas, and Soslowsky, 2004). However, the delayed motion may increase the risk of postoperative shoulder stiffness, muscle atrophy and potentially postpones improvements in function (Keener, 2012). Based on the available evidence it is difficult to make a clinical decision about the best rehabilitation regime and establish the most favourable time to start postoperative rehabilitation. One of the issues is the variation in the rehabilitation protocols and information from multiple systematic reviews. This lack of consensus may lead therapists to a variety of contradictory clinical decisions (Abtahi, Granger, and Tashjian, 2015). These inconsistencies in the literature are also noted in systematic reviews and different primary studies, which used different definitions of what is early (generally within the first 6 weeks) or conservative intervention (generally after 6 weeks). In addition, the majority of these systematic reviews were published between 2014 and 2015, which highlights this is currently an area of much debate.

The aim of this chapter is to critically analyse and discuss the current literature and assess the effectiveness of early compared to conservative physiotherapy when considering; pain, functional status, range of motion (ROM) and retear rates for this patient population. It uses an overview of systematic reviews design for a thorough inclusion and discussion of systematic reviews and RCTs. Throughout the chapter, the evidence is summarised in relation to the quality of published studies and comparisons between early and conservative physiotherapy for clinical outcomes. The conclusions of this review underpin the rationale for the development of the aims and objectives of the main trial, covered in the following chapter.

3.2. Methods

3.2.1. Design

The systematic review followed the Preferred Reporting Items for Systematic Review and Meta-Analyses (PRISMA) statement (Moher et al., 2009), which was used to fulfil all information required to report in a systematic review. The PRISMA is a guideline of a 27-item checklist. The items recommend how a systematic review must be structured according to all different sections of an article: title, abstract, introduction, methods, result, discussion/conclusions and funding sources. Moreover, the Revised Assessment of Multiple Systematic Reviews (R-AMSTAR) tool (Kung et al. 2010) was used for critical appraisal of the selected systematic reviews. The R-AMSTAR is composed of 11 domains to assess the quality of a systematic review; each domain is scored from one to four, higher values denote better quality (Kung et al., 2010).

3.2.2. Inclusion/exclusion criteria

Systematic reviews and randomised controlled trials (RCTs) with the objective of comparing the effectiveness of early vs. conservative rehabilitation, after surgical repair of the rotator cuff, under the supervision of a therapist were included. The definition of early or conservative rehabilitation was used according to what was described in each study.

For inclusion, studies should have:

1) Reported at least one of: shoulder ROM, pain, functional scores and retear rates.

2) Include patients who had surgical repair of the rotator cuff and who were allocated to groups that had different starting times for their rehabilitation (physiotherapy and exercises).

3) Reported a clinically relevant follow-up period of between three and twenty-four months; this follow-up period was chosen according to what is commonly used in clinical assessment and retear revision.

Studies that included patients with acute tears and those where the aim was not to compare the impact of the rehabilitation start time application were excluded. Only chronic tears were considered, which were defined as not being caused by a traumatic event (i.e.: accidents) and symptoms for more than 3 months.

3.2.3. Search strategy

The search strategy planning was supported by a librarian and applied independently by two reviewers in the databases. The main MeSH terms and key-words: Rotator cuff, Shoulder, Shoulder joint, Rehabilitat*, Physiotherapy, Physical Therapy, Immobili?ation, Stiffness, Accelerat* and Sling were used in the following databases: EBSCO, AMED, CINAHL, SPORTDiscus, EMBASE, Cochrane, LILACS, Medline, PEDro, Scielo, SCOPUS and Web of Knowledge. There were no restrictions of languages or date of publication. Secondary searching on references list of key articles and grey literature was undertaken to identify any additional studies missed on the electronic database search. In order to permit the search to return other primary studies, which were not included to the published reviews, MeSH terms and keywords such as review, systematic review and meta-analysis were not used in the search strategy. The last date that the searches were run was in 10/2015. Further information about how the searches were structured in each database is available in appendix 2. The selection process was based first on the title, then, the abstract and the full text were reviewed for inclusion.

3.2.4. Data extraction

The data extracted and synthesised was: author names and publication years, design of the included primary studies, inclusion criteria for primary studies, group intervention and comparison of the primary studies, tools used for outcomes assessment, the results for the variables of interest (i.e.: ROM, functional scores and retears rate) and references of the primary studies. Any discrepancies were discussed by the reviewers until consensus was reached.

3.2.5. Risk of bias assessment

Although every systematic review had its own risk of bias assessment for primary studies, the inconsistency on final rates from these reviews leads to the decision of independently scoring the primary studies already scored in other reviews, in addition to new studies that were included in the update. Whether a systematic review is able to determine robust conclusions about the effectiveness of therapies essentially depends on the quality of primary studies. A critical evaluation of the quality of the included studies is important to avoid misleading results and clinical recommendations. The internal validity or risk of bias must be addressed and adequately criticized in order to allow the applicability of the findings (Higgins and Green, 2011). Therefore, the risk of bias of the primary studies was assessed according to the Cochrane Handbook for Systematic Reviews of Interventions (Higgins and Green, 2011). The items assessed were: method of randomisation, allocation concealment, patient blinding, care provider blinding, outcome assessor blinding, dropout rate, intention-to-treat analysis, reports on the study free of suggestion of selective outcome reporting, similarity of participants at the baseline, co-interventions avoided, compliance, timing of the outcome assessment, and follow-up. Each item was scored as low, high or unclear risk (Higgins and Green, 2011). The rationale for the judgement of each item is described following the studies of Furlan et al. (2009) and Dias et al. (2013).

Two reviewers independently scored both the R-AMSTAR and risk of bias; the kappa coefficient was used to check the inter-reviewer's agreement and any disagreements were discussed until consensus. The classification of the kappa values is summarised in table 3.1, as suggested by Cohen (1988).

Table 3.1. Classification of kappa values.

Values	Classification
>0.81	Excellent
0.61-0.8	Good
0.41-0.6	Moderate
<0.4	Poor

The Grades of Recommendation, Assessment, Development and Evaluation (GRADE) approach was used to rate the quality and strength of the evidence synthesised from the primary studies. Following the GRADE system, when the outcome was based on a body of evidence of RCTs, the recommendation is rated as high; however, if factors affecting the quality of the study were observed (limitations in the design and implementation, indirectness of evidence, unexplained heterogeneity or inconsistency of results, imprecision of results and publication bias), the score was downgraded accordingly.

3.2.6. Meta-analyses

For the systematic review update, meta-analyses for the outcomes were performed. They were separated according to the different questionnaires and tools used to score the outcomes: the *American Shoulder and Elbow Surgeons* (ASES), the *Constant-Murley* score (CM), the *Simple Shoulder Test* (SST), *Visual Analogue Scale* (VAS) and ROM. Continuous data were expressed as mean differences and 95% confidence intervals (CI), while for dichotomous outcomes the odds ratio was used with 95% CI. The statistical test applied for heterogeneity control was the Higgins' I^2. When the studies were homogeneous ($P > 0.10$) the fixed effect was applied and if not, the random effect was used (Higgins and Green 2011). The software for the inter-reviewers' agreement on R-AMSTAR and risk of bias was the MedCalc, version 15.4 (MedCalc Software, Ostend, Belgium) and for all meta-analyses was the RevMan 5.3.5 (The Nordic Cochrane Centre, Copenhagen, Denmark).

3.3. Results

3.3.1. Review of systematic reviews

Initially, 1722 records were screened regarding the inclusion criteria; from the total, 13 were selected for a final decision (Figure 3.1.). Thirteen systematic reviews were analysed and three others were excluded. These were: van der Meijden et al. (2012) as the primary objective was not to compare the influence of the rehabilitation time during the recovery process, Ross et al. (2014) which used a non-systematic review method and Shen et al. (2014) which was published in Chinese. It is noteworthy that another review from Shen et al. (2014), was published in English in the same year. Comparing the available sections in the English from the excluded review, it is possible to observe that the objectives are very similar:

[sic] *"To systematically evaluate the differences in curative effects of early and delayed functional exercises after arthroscopic rotator cuff repairs."* and [sic] *"The present meta-analysis of data from randomized controlled trials (RCTs) was conducted to provide an evidence-based appraisal of the effects of immobilization after arthroscopic rotator cuff repair (…)".*

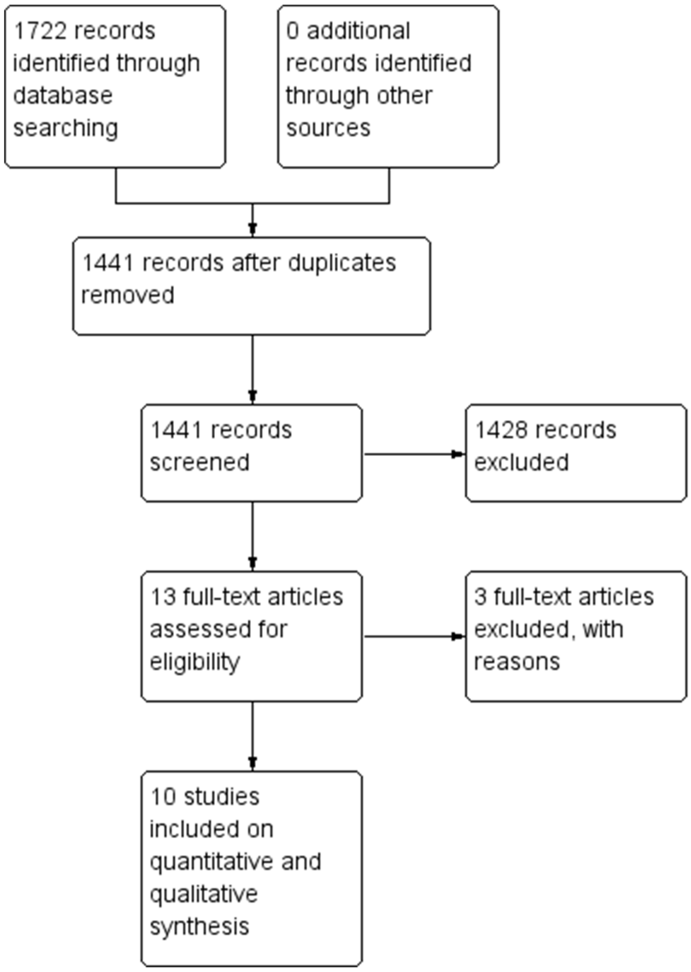


Figure 3.1. Flow diagram of selected systematic reviews.

Another important issue refers to the primary studies included. Although the review in Chinese states that the last search was performed in 15/08/2012 and the English 02/12/2013, both use RCTs published in 2012. Both reviews from Shen have studies in common from Cuff and Pupello (2012) and Kim et al. (2012), however the latest review (English version) used the study from Arndt et al. (2012) instead of Lee, Cho, and Rhee (2012) to perform the meta-analyses and report their results.

Nevertheless, the substitution of one RCT did not implicate different conclusions for most outcomes, apart from ROM:

[sic] *"Results confirmed that compared with delayed functional exercises, early functional exercises after arthroscopic rotator cuff repair did not have advantages on the improvement of joint function and range of motion, but also did not negatively affect cuff healing. Postoperative rehabilitation can be modified to ensure patient's compliance"* and [sic] *"We found no evidence that immobilization after arthroscopic rotator cuff repair was superior to early-motion rehabilitation in terms of tendon healing or clinical outcome. Patients in the early-motion group may recover ROM more rapidly."*; Chinese and English reviews, respectively.

However, the metanalyses of each review are contradictory to their conclusions. The review published in Chinese shows a statistically significant difference favouring the conservative group for shoulder flexion and external rotation at 6 months with a mean difference of 6.9° and 10.24°, respectively. However, at 1 year no statistically significant differences were found. In contrast, the review published in English shows a statistically significant difference for external rotation at 1 year (mean difference=8.29°) only. Therefore, the quality of these systematic reviews is low and the conclusion uncertain

3.3.1.1. Population

Table 3.2 shows a summary of the selected systematic reviews. The number of patients in each review varied between 265 and 1776. The majority did not stipulate an age range as one of the inclusion criteria, with the exception of two studies, Chan et al. (2014) and Littlewood et al. (2015) who included this information and both chose the age of 18 as the lower limit. Only Chang et al. (2015) used traumatic tears as exclusion criteria but did not consider different types of tear events.

3.3.1.2. Group categorisation

Classification of participants as early or conservative/delayed group had extensive variations; for the systematic review of this thesis the number of weeks using a sling reported in the primary studies was used to define the groups; considering the extensive variation on the physiotherapy protocols, it was not possible to use the starting of active exercises as a parameter to classify groups as early or conservative physiotherapy. Four studies did not specify how the groups were defined and the other six had different thresholds. It is noteworthy that none used the common application of six weeks. The starting time also had great variance among the primary studies, from the same day post-surgery to four weeks in the early management, and from four to eight weeks in the conservative group.

Table 3.2. Summary of systematic reviews and meta-analyses.

Author (year)	Sample Size	Evidence	Inclusion Criteria	Intervention/Comparison	Outcomes	Results
Chan et al. (2014)	370	RCTs or *quasi* RCTs	• 18 years and older • Full-thickness • Arthroscopic repair	**Early:** up to 2 wks of immobilisation **Delayed:** at least 4 wks of immobilisation	ASES, CM, DASH, retear rate, ROM, SST, WORC	No difference for functional outcomes, relative risk of retears and ROM.
Chang et al. (2015)	482	RCTs	• Non-traumatic tears • Arthroscopic repair	**Early:** up to 3 wks of immobilisation **Traditional:** after 3 wks	ASES, CM, DASH, retear rate, ROM, UCLA	Early rehabilitation improves stiffness, but not function. Higher retear rates for larger tears in early group.
Chen et al. (2015)	445	RCTs	• Arthroscopic repair • Comparison early x delayed	**Early:** mobilisation starting in the first day post-surgery **Delayed:** not earlier than 3 wks and not later than 6 wks,	ASES, ROM, retear rate	Early rehabilitation improves ROM, but has higher retears rate; Delayed group has better ASES

(***Continue***)

Table 3.2 (continue). Summary of systematic reviews and meta-analyses

Author (year)	Sample Size	Evidence	Inclusion Criteria	Intervention/Comparison	Outcomes	Results
Gallagher et al. (2015)	480	RCTs	• Minimum 6 months FU • Comparison early x delayed • Healing assessment	**Early:** NA **Delayed:** NA	ASES, CM, DASH, SST, UCLA, VAS, retear rate, ROM	Functional outcomes and ROM improves in favour of early rehabilitation in the first 3-6 months FU only. No difference for retear rate.
Huang, Wang, and Lin (2013)	611	RCTs	• Rotator cuff repair • English language • Full text	**Aggressive:** NA **Traditional:** NA	Shoulder function, retear rate, ROM, VAS	Aggressive protocol enhances ROM and shoulder function; traditional has lower retear risk.
Kluczynski et al. (2014)	1776	CS, PCS, RCTs	• Rotator cuff repair • Comparison of Rotator cuff healing	**Early:** within 1 week after surgery **Delayed:** between 3 to 6 weeks	Retear rate	For tears ≤ 3cm, retear is lower in the early group. For tears > 5cm, retear is higher in the early group.

(Continue)

Table 3.2 (continue). Summary of systematic reviews and meta-analyses

Author (year)	Sample Size	Evidence	• Inclusion Criteria	Intervention/Comparison	Outcomes	Results
Littlewood et al. (2015)	819	RCTS	• 18 years and older • Rotator cuff repair • RCTs • English Language	**Early:** NA **Delayed:** NA	Disability, pain, retear rate	No differences for pain, disability or retear ratio between early and late, for short or long FU.
Riboh and Garrigues (2014)	451	RCTs for MAs Non-RCTs for narrative analysis	• Arthroscopic repair • Randomisation • Minimum 1 year FU • English Language	**Early:** up to 4 wks of immobilisation **Immobilisation:** 4 to 6 wks	Retear rate, ROM	Early rehabilitation compared to conservative improves shoulder flexion at 3, 6 and 12 months FU, and external rotation at 3 months FU only. No difference for retear risk.
Shen et al., (2014)	265	RCTs	• Arthroscopic repair • Minimum 1 year FU	**Early:** NA **Immobilisation:** NA	ASES, retear rate, ROM, SST, VAS	Statistical difference in favour of early rehabilitation for external rotation at 6 months FU. No differences for functional outcomes or retear rate/tendon healing

(***Continue***)

Table 3.2 (continue). Summary of systematic reviews and meta-analyses

Author (year)	Sample Size	Evidence	• Inclusion Criteria	Intervention/Comparison	Outcomes	Results
Yi et al. (2015)	572	RCTs	• English language • Comparison early x delayed • Level of evidence 1 and 2	**Early:** according to study **Late:** according to study	ASES, CM, VAS, retear rate, ROM, UCLA	No difference between groups for all outcomes.

ASES: American Shoulder and Elbow Surgeons, CM: Constant-Murley Score, cm: centimetres, CS: Case series, FU: Follow-up, MA: Meta-analysis, NA: Not Available, PCS: Prospective Cohort Study, ROM: Range of Motion, SST: Simple Shoulder Test Score, RCT: Randomised Controlled Trial, VAS: Visual Analogue Scale, wks: weeks, vs.: versus.

3.3.1.3. Outcomes assessed

The most reported tool was the ASES questionnaire. However, the majority performed meta-analysis only for range of motion and retears ratio. Only Chan et al. (2014) reported separated meta-analyses (MA) for clinical scores (ASES, CM, SST). One systematic review evaluated retear rates only (Kluczynski et al., 2014).

3.3.1.4. Clinical disclosures

The conclusions were divergent about ROM, functionality and retear rate. For instance, Chan et al. (2014) found no differences between groups for all aforementioned outcomes, which was similar to the findings from Littlewood et al. (2015) and Yi et al. (2015). In contrast, the reviews from Chang et al. (2015); Huang, Wang, and Lin (2013); Riboh and Garrigues (2014) and Shen et al. (2014) found differences for ROM which favours the early group, especially in shoulder flexion. Kluczynski et al. (2014) found that retears ratio for small size tears was lower in the early group (mobilisation within 1 week after surgery), and the ratio was higher for the early group for those who had a large size tear. Three studies (Chang et al., 2015; Chen et al., 2015; Huang, Wang, and Lin, 2013) found higher retear rates for early rehabilitation; however, the definition of early varied for each review: first day post-operative (Chen et al., 2015), up to 3 weeks (Chang et al., 2015) and it was not available for the review from Huang, Wang, and Lin, (2013).

3.3.1.5. Methodological appraisal

The kappa values of reviewers' inter-agreement for the R-AMSTAR were: 1) κ= 0.86 (95% CI=0.6 – 1.0), 2) κ=0.76 (95% CI=0.53 – 0.99), 3) κ=0.68 (95% CI=0.35 – 1.0), 4) κ=0.78 (95% CI=0.55 – 1.0), 5) κ=0.73 (95% CI=0.35 – 1.0), 6) κ=0.86 (95% CI=0.59 – 1.0), 7) κ=0.63 (95% CI=0.23 – 1.0), 8) κ=0.84 (95% CI=0.54 – 1.0), 9) κ=0.78 (95% CI=0.49 – 1.0), 10) κ=0.90 (95% CI=0.71 – 1.0), 11) κ=0.92 (95% CI=0.78 – 1.0). The R-AMSTAR values ranged from 20 for Yi et al. (2015) to 38 for Chan et al. (2014) and Chang et al. (2015), of a possible total of 44; the individual scores are described in Table 3.3. The item with lowest scores was 10, which is about publication bias and statistical tests like Egger regression to address this issue; only the studies by Chang et al. (2015) and Chen et al. (2015) fulfilled this criterion. The item with the highest score in R-AMSTAR list was number 6, with all reviews apart from Shen etal. (2014) and Chen et al. (2015) scoring the maximum of 4; this item assesses whether the characteristics of primary studies were described.

Regarding the level of evidence, the majority of the reviews contained only RCTs for qualitative and quantitative analysis; the review of Chan et al. (2014) also comprised *quasi* RCTs, the review from Kluczynski et al. (2014) included case series and prospective cohorts and Riboh and Garrigues (2014) only used non-RCTs for narrative and qualitative reports. The study from Kluczynski et al. (2014) performed two separate meta-analyses: one only with RCTs and another which included other levels of evidence. However, no test for studies' heterogeneity was considered and their discussion and conclusions focused mainly on the results provided with biased evidence.

Table 3.4 shows the RCTs included in each systematic review. From the reviews assessed, only Cuff and Pupello (2012) were included in all reviews. The inclusion of other studies varies in a few systematic reviews. For instance, Huang, Wang, and Lin (2013) included the study from Garofalo et al. (2010); however, it was not listed in Table 3.5 because their objective was to assess the effectiveness of continuous passive motion, performed by a machine, on ROM and pain. Some studies cited by Littlewood et al. (2015) also were not included in this table: 1) Hayes et al. (2004), where the main aim was to assess the effectiveness of supervised and non-supervised physiotherapy, 2) Klintberg et al. (2009) which assessed traumatic tears, 3) Lastayo et al. (1998) and Raab et al. (1996), which also assessed the application of continuous passive motion, and 4) Roddey et al. (2002), which aimed to compare the effectiveness of two different programmes of home instructions.

Since the review of Kluczynski et al. (2014) used RCTs and studies with other levels of evidence, only the RCTs were added to Table 3.4; however, a detailed screening in the references demanded attention for the abstract from Deutsch et al. (2007), which is indeed an RCT. For this reason, this abstract in addition to an unpublished abstract from Cote and Mazzocca were also included. To use the unpublished abstract, the permission from the authors was requested by email, as shown in appendix 3.

Table 3.3. R-AMSTAR score of systematic reviews.

Author (year)	Items											
	1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**Total**
Chan et al. (2014)	4	4	4	2	4	4	4	4	4	1	3	38
Chang et al. (2015)	2	4	4	3	3	4	3	4	4	4	3	38
Chen et al. (2015)	4	4	3	1	4	2	2	1	4	4	1	30
Gallagher et al. (2015)	4	1	4	1	2	4	3	4	2	1	3	32
Huang, Wang and Lin (2013)	2	2	3	2	2	4	4	4	4	1	1	29
Kluczynski et al. (2014)	4	1	3	1	1	4	1	1	1	1	3	21
Littlewood et al. (2015)	4	1	4	2	2	4	4	4	4	1	3	33
Riboh and Garrigues (2014)	3	4	3	1	1	4	4	4	4	1	3	32
Shen et al. (2014)	3	4	3	3	2	3	3	2	4	1	1	29
Yi et al. (2015)	4	2	1	1	2	4	1	1	1	2	2	20

Table 3.4. Randomised controlled trials included in the systematic reviews.

Randomised Controlled Trials	**Systematic Reviews**									
	Chan et al. (2014)	Chang et al. (2015)	Chen et al. (2015)	Gallagher et al. (2015)	Huang, Wang and Lin (2013)	Kluczynski et al. (2014)	Littlewood et al. (2015)	Riboh and Garrigues (2014)	Shen et al. (2014)	Yi et al. (2015)
Arndt et al. (2012)		X	X	X	X		X	X	X	X
Cuff and Pupello (2012)	X	X	X	X	X	X	X	X	X	X
Cotte and Mazzoca	X									
Deutsch et al. (2007)						X				
Duzgun, Gü, and Ahmet (2011)		X		X	X		X			X
Keener et al. (2014)	X	X	X	X		X	X	X		X
Kim et al. (2012)	X	X		X	X	X	X	X	X	X
Klintberg et al. (2009)							X			
Koh et al. (2014)							X			
(Lee et al. (2012)		X	X	X	X	X	X	X		X

3.3.2. Systematic review update

The search for randomised controlled trials found 1722 records; for the final analysis, 11 full texts and two abstracts were assessed relative to inclusion criteria. To perform the meta-analysis seven out of 11 studies were used. Two RCTs (Klintberg et al., 2009; Sheps et al., 2015) were excluded as they assessed patients with traumatic tears. The flow diagram (Figure 3.2) describes the selection process.

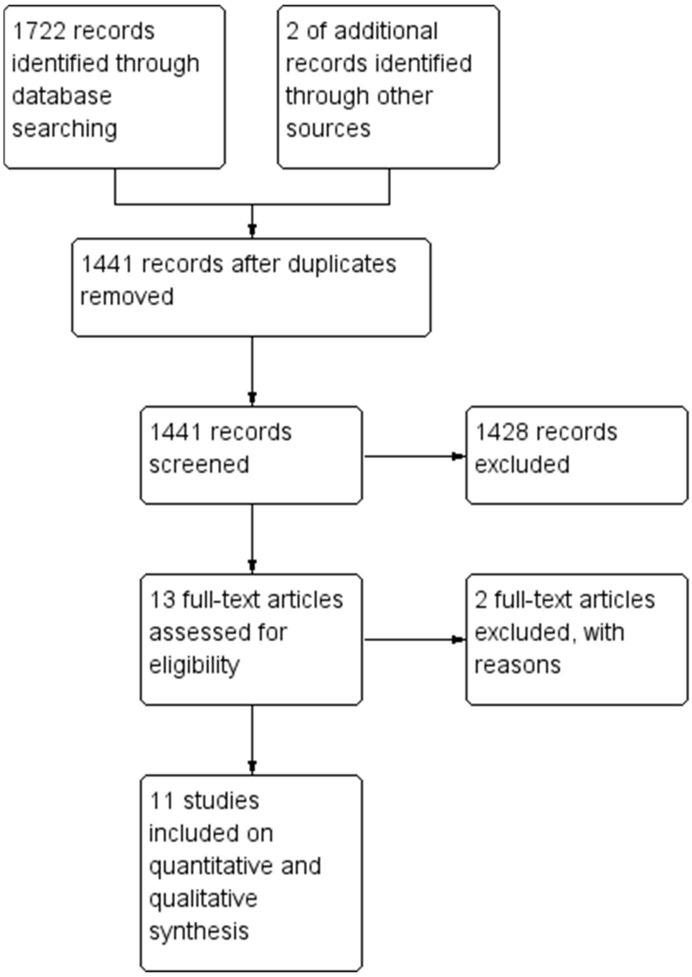


Figure 3.2. Flow diagram of selected randomised controlled trials.

The agreements between the reviewers regarding the risk of bias items, with their respective CI, were the following: adequate sequence generation κ= 1.0 (95% CI=1.0 – 1.0), allocation concealment κ=0.79 (95% CI= 0.41 – 1.0), patient blinding κ= 1.0 (95% CI=1.0 – 1.0), care provider blinding κ= 1.0 (95% CI=1.0 – 1.0), outcome assessor blinding κ= 0.69 (95% CI=0.37 – 1.0), dropout rate κ= 0.85 (95% CI=0.62 – 1.0), intention-to-treat analysis κ= 1.0 (95% CI=1.0 – 1.0), free of selective reporting κ= 0.76 (95% CI=0.51 – 0.96), similarity of participants at the baseline κ= 1.0 (95% CI=1.0 – 1.0), co-interventions avoided κ=0.64 (95% CI=0.41 – 1.0), compliance κ=

0.76 (95% CI=0.36 – 1.0), timing of the outcome assessment κ= 0.84 (95% CI=0.47 – 1.0), and follow-up κ=0.83 (95% CI=0.56 – 1.0). The figures 3.3 and 3.4 show the final risk of bias scores. The study with lower risk of bias was from (Koh et al. 2014) and the studies with higher risk of bias were abstracts from Cote and Mazzocca and Deutsch et al. (2007).

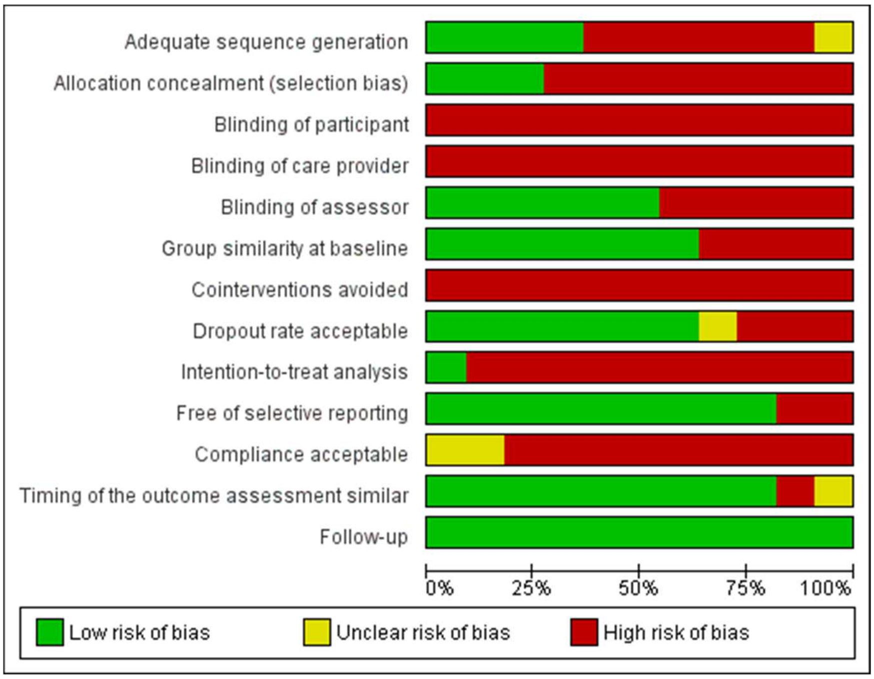


Figure 3.3. Risk of bias graph.

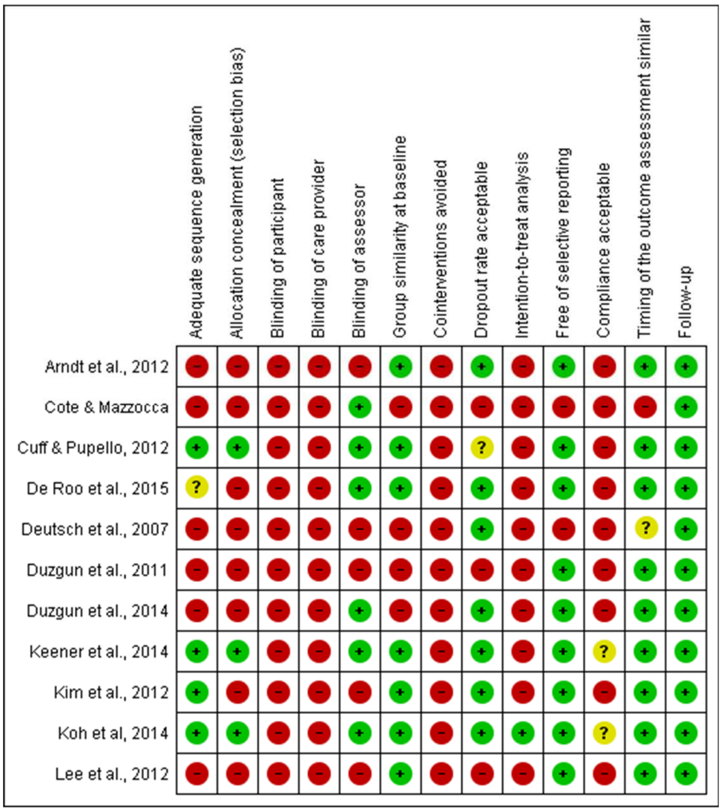


Figure 3.4. Risk of bias summary

3.3.2.1. Participants

Table 3.5 shows a summary of the main characteristics of the primary studies. The mean age of participants varied between 55.3 and 65.1; from the total 49.7% were men and 51.3% women. Three studies assessed only supraspinatus and the other eight did not use one of the muscles as inclusion criteria. The tear size varied, the majority included medium size and five studies included large tears in their groups. The surgery characteristics also varied: all used the arthroscopic technique; the footprint fixation was not homogeneous and multiple methods (single row, double row, suture bridge) were used. Additional procedures (long head of biceps tenodesis or tenotomy, acromioplasty and capsular release) were also reported, but only Lee, Cho, and Rhee (2012) excluded participants who had additional procedures in combination with the rotator cuff repair.

3.3.2.2. Orthoses and physiotherapy

The orthoses used to restrict shoulder movement were diverse. Four studies clearly stated the use of a sling: Cuff and Pupello (2012) described the use of a shoulder immobiliser; Deutsch et al. (2007) used an *Ultrasling*, and Kim et al. (2012) and De Roo et al. (2015) prescribed a brace. In addition to the sling and brace, Kim et al. (2012), Lee et al. (2012) and De Roo et al. (2015) made use of a pillow to maintain an abduction angle of 30° and Koh et al. (2014) to maintain an angle of 20°. No further information about the orthotics' material or design was available.

Table 3.6 summarises the rehabilitation programme. There was variation in the initiation of early rehabilitation: four studies started passive ROM in the first day postoperative, two studies started after two days, four waited to complete one-week post-surgery, and Koh et al. (2014) had the latest starts, after five weeks. Likewise, the conservative/delayed groups showed variations: one starting in the first day postoperative, five starting after four weeks, one starting after 5 weeks, three after six weeks, and one after nine weeks.

Despite the differences, the rationale for load increase was similar, starting with passive exercises, progressing to active ROM and then strengthening. The most common exercises in the first stage were the pendulum and active ROM for the hand, wrist and elbow. The most complete therapy description was from Duzgun, Gü, and

Ahmet (2011), who included soft tissue mobilization and cold packs in the first stage, and proprioceptive neuromuscular facilitation techniques in the strengthening stage.

Table 3.5. Selected randomised controlled trials.

Author (year)	No. of patients E/D – M/F	Age (years) E/D	Tear characteristics	Surgery characteristics	Outcomes
Arndt et al. (2012)	49/43 – 34/58	55.3	Non-retracted isolated tears of supraspinatus; partial-thickness: 24%, full-thickness: 76%	5 surgeons; 59% single row, 41% double row; LHB tenotomy: 65%, LHB tenodesys:11%; acromioplasty: 91%	CM, healing (arthrogram, CT or arthro-MRI, ROM
Cote and Mazzoca	73 - NA	NA	NA	NA	WORC, ASES, SST, SANE, healing (MRI)
Cuff and Pupello (2012)	33/35 – 38/30	63.2	Supraspinatus; full-thickness; crescent shape	Transosseous suture bridge	ASES, healing (US), ROM, SST
De Roo et al. (2015)	51/79 – 89/41	65.1/64.6	Small to large; full-thickness	Single or double row; acromioplasty at all times	CM, ROM, SPADI, SST, strength, UCLA, US
Deutsch et al. (2007)	37/33 - NA	57/56	Supraspinatus or 2 to 3 affected; 30 small, 17 medium, 33 large to massive	1 Surgeon; single row; 4 patients had acromioplasty	ASES, healing (US), ROM, VAS
Duzgun et al. (2014)	20/22 – 6/34	57.68/57.2	Medium and large	NA	ROM

Continue

Table 3.5 (continue). Selected randomised controlled trials.

Author (year)	No. of patients E/D – M/F	Age (years) E/D	Tear characteristics	Surgery characteristics	Outcomes
Duzgun, Gü, and Ahmet (2011)	13/16 – 3/26	55.85/56.63	Medium and large	NA	DASH, ROM, VAS
Keener et al. (2014)	65/59 – 73/51	54.8/55.8	Only subscapular tears were excluded; small and medium; full-thickness	3 surgeons; double row transosseous; acromioplasty; LHB tenodesis or tenotomy	ASES, CM, healing (US), ROM, SST, strength, VAS
Kim et al. (2012)	56/49 - 44/67	60/60.06	Small and medium; full-thickness	Different surgeons; single row: 17, double row: 2, suture bridge: 86; acromioplasty	ASES, CM, healing (US, MRI or CT), ROM, SST, VAS
Koh et al. (2014)	40/48 – 44/44	59.9	Posterosuperior; medium; full-thickness	Single row, acromioplasty, capsular release	ASES, CM, healing (MRI), VAS
Lee et al. (2012)	30/31 – 41/25	54.5/55.2	Medium: 41, large: 45; full-thickness	One surgeon; single row; patients who need LHB, acromion and/or clavicle procedures were excluded	ROM, strength, UCLA, VAS, healing (MRI)

ASES: American Shoulder and Elbow Surgeons, CT: Computed Tomography, CM: Constant-Murley Score, E/D: Early/Delayed, FIS: Functional Index of the Shoulder, LHB: Long Head of Biceps, MRI: Magnetic Resonance Imaging, M/F: Male/Female, NA: Not Available, ROM: Range Of Motion, RCT: Rotator Cuff Tear, SANE: Single Assessment Numeric Evaluation score, SST: Simple Shoulder Test Score, US: Ultrasound, UCLA: University of California Los Angeles, VAS: Visual Analogue Scale, WORC: Western Ontario Rotator Cuff index.

Table 3.6. Summary of rehabilitation programs postoperative.

Author (year)	Early Rehabilitation	Conservative Rehabilitation
Arndt et al. (2012)	**IP:** Sling for 6 weeks **First day postoperative-week 6:** Pendulum exercise **+** manual passive ROM **+** CPM (3-5x pw) **Week 6-4 Months:** Active ROM **4 months-on:** Strengthening exercises	**IP:** Sling for 6 weeks **Week 0-6:** Immobilisation **+** Pendulum exercise **Week 6-4 Months:** Active ROM **4 Months-on:** Strengthening exercises
Cote and Mazzoca	**IP:** NA Started after 2 to 3 days of surgery	**IP:** NA Started after 28 days of surgery
Cuff and Pupello (2012)	**IP:** Shoulder immobiliser for 6 weeks Started in the second day post-surgery; 3x pw **Week 0-3:** Pendulum exercise **+** passive flexion and external rotation **+** active elbow, wrist and hand ROM **Week 4-6:** Similar to week 0-3 **+** progressing ROM **+** active elbow, wrist and hand ROM **Week 6-10:** Active-assisted ROM **Week 10-12:** Active-assisted ROM **+** active ROM **Week 12-on:** Strengthening	**IP:** Shoulder immobiliser for 6 weeks Started after 6 weeks of surgery **Week 0-3:** Pendulum exercise 3x daily for 5 minutes **+** active elbow, wrist and hand ROM **Week 4-6:** Pendulum exercise 3x daily for 5 minutes **+** active elbow, wrist and hand ROM **Week 6-10:** Passive ROM **+ week 7** active assisted ROM 1x pw **Week 10-12:** Active-assisted ROM **+** active ROM **Week 12-on:** Strengthening

Continue

Table 3.6 (continue). Summary of rehabilitation programs postoperative

Author (year)	Early Rehabilitation	Conservative Rehabilitation
De Roo et al. (2015)	**IP:** Brace with abduction pillow (30°) for 4 weeks during day and night **+** 2 more weeks only at night **First day postoperative – week 5:** Pendulum exercise (3x pd, 10 minutes each, 20 cm diameter) **+** Passive shoulder flexion, abduction, internal and external rotation **+** scapular mobilization (5 days pw) **Week 5-8:** Specific capsular glenohumeral exercises **+** Active-assisted shoulder exercises **Week 8-on:** Started strengthening	**IP:** Brace with abduction pillow (30°) for 4 weeks during day and night **+** 2 more weeks only at night **Week 1-4:** Pendulum exercise **Week 5:** Gradual passive mobilization **Week 6-on:** Similar to early mobilisation group; no further details available
Deutsch et al. (2007)	**IP:** Ultrasling for 6 weeks **First day postoperative:** Pendulum exercise **Day 7:** Passive external rotation stretching **+** passive shoulder flexion ROM	**IP:** Ultrasling for 6 weeks **First day postoperative:** Pendulum exercise **Day 7:** Passive external rotation stretching **Week 4:** Passive shoulder flexion ROM
Duzgun et al. (2014)	**IP:** 2 weeks **Week 2-7:** Soft tissue mobilization for the scapulothoracic and glenohumeral joints along with motion exercises (3x week for all weeks). **Week 3:** Active ROM exercises with scapular plane elevation, flexion and abduction **Week 4:** Light resistive exercises with rubber bands.	**IP:** 4 weeks **Week 4-17:** Soft tissue mobilization for the scapulothoracic and glenohumeral joints along with motion exercises (3x week for all weeks). **Week 6:** Active ROM exercises with scapular plane elevation, flexion and abduction. **Week 8:** Light resistive exercises with rubber bands.

Continue

Table 3.6 (continue). Summary of rehabilitation programs postoperative

Author (year)	Early Rehabilitation	Conservative Rehabilitation
Duzgun, Gü, and Ahmet (2011)	**IP:** NA **Week 0-1:** Cold pack every 2 hours for 20 min **Week 1-2:** Cold pack **+** deltoid and biceps soft-tissue mobilisation **+** passive flexion and abduction ROM **+** active elbow and neck ROM **+** hand strengthening **Week 2-3:** Cold pack **+** passive flexion **+** active elbow and scapula ROM **+** GH mobilization **Week 3-4:** Cold pack **+** scapular mobilization **+** active flexion, internal rotation, abduction **+** strengthening for biceps, triceps and serratus anterior using rubber bands **Week 4-5:** Cold pack **+** active shoulder flexion **+** strengthening of shoulder abduction, internal rotation, external rotation with rubber bands **Week 5-6:** Cold pack **+** progression of strengthening exercises for shoulder with more resistant rubber bands **+** posterior capsule stretching **Week 6:** Week 5-6 **+** Resistive PNF patterns **Week 7:** Wall shoulder push-up **+** On-the-table press-up **+** on-the-table push-up	**IP:** NA **Week 0-4:** Week 0-1 **Week 4-6:** Week 2-3 **Week 6-8:** Week 3-4 **Week 8-10:** Week 4-5 **Week 10-14:** Week 5-6 **Week 14-18:** Week 6 **Week 18-22:** Week 7

__Continue__

Table 3.6 (continue). Summary of rehabilitation programs postoperative

Author (year)	Early Rehabilitation	Conservative Rehabilitation
Keener et al. (2014)	**IP:** Sling for 6 weeks **Immediate postoperative:** Pendulum exercise **+** active elbow, wrist and hand ROM **Week 1-6:** Passive shoulder ROM performed by a therapist **Week 6-12:** Active assisted and active shoulder ROM **3-4 Months:** Deltoid and scapular stabilizer strengthening **4 Months - on:** Full activities based on patient's progress	**IP:** Sling for 6 weeks **Immediate postoperative:** Active elbow, wrist and hand ROM **Week 1-6:** Shoulder immobilised **Week 6-12:** Early week 1-6 **3-4 Months:** Early week 6-12 **4 Months - on:** Early 3-4 months, full activities between 5 and 6 months based on patient's progress
Kim et al. (2012)	**IP:** Brace with abduction pillow (30°) during 4 or 5 weeks **First day postoperative- week 4/5:** Passive shoulder flexion, abduction and external rotation ROM **+** active elbow, wrist and hand ROM **+** shrugging of shoulders **Week 4/5:** Active-assisted shoulder ROM **Week 9/12:** Muscle strengthening **6 Months:** Return of activities	**IP:** Brace with abduction pillow (30°) during 4 or 5 weeks **First day postoperative- week 4/5:** Active elbow, wrist and hand ROM **+** shrugging of shoulders **Week 4/5:** Active-assisted shoulder ROM **Week 9/12:** Muscle strengthening **6 Months:** Return of activities

Continue

Table 3.6 (continue). Summary of rehabilitation programs postoperative

Author (year)	Early Rehabilitation	Conservative Rehabilitation
Koh et al. (2014)	**IP:** Sling with an abduction pillow (20°) during 4 weeks **Week 5-10:** Passive ROM with rope, pulley and cane **+** home-based exercise **Week 11- 6 Months:** Strengthening **6 Months:** Return to normal activities	**IP:** Sling with an abduction pillow (20°) during 8 weeks **Week 9-14:** Passive ROM with rope, pulley and cane **+** home-based exercise **Week 15 – 6 Months:** Strengthening **6 Months:** Return to normal activities
Lee et al. (2012)	**IP:** Sling with an abduction pillow (30°) during 6 weeks **First day postoperative – week 6:** Passive shoulder flexion and external rotation ROM by a physiotherapist (2x pd) **+** pendulum exercises **+** self-passive shoulder ROM (3x pd) **+** home-based exercises **Week 6-on:** Active-assisted shoulder ROM **+** passive ROM for all movements	**IP:** Sling with an abduction pillow (30°) during 6 weeks **First day postoperative – week 3:** Self-passive shoulder flexion **+** CPM (2x pd) **Week 3-6:** Self-passive shoulder ROM (2x pd) **Week 6-on:** Active-assisted shoulder ROM **+** passive ROM for all movements

CPM: Continuous Passive Motion, GH: glenohumeral, IP: Immobilisation Period, pd: per day, pw: per week, NA: Not Available, PNF: Proprioceptive neuromuscular facilitation, ROM: Range Of Motion.

3.3.2.3. Meta-analyses update and grading of evidence

The placement of the *early* and *conservative* labels in the forest plots is dictated by the direction of the final result in favour of the respective group. For instance, a lower pain score was observed for the conservative group in the first MA, then the label *conservative* was on the right side, which corresponded to the same side of the black diamond.

3.3.2.3.1. Pain (Visual Analogue Scale)

For this outcome, two meta-analyses were possible for the follow-up period of six and 24 months (Figures 3.5 and 3.6). Two studies were included, totalling 207 patients. No statistical differences were found for six (*P*= 0.26) or 24 months (*P*=0.49). Grading of evidence: there is moderate evidence that early rehabilitation does not improve pain compared with conservative rehabilitation.

	Early			Conservative				Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Fixed, 95% CI
Keener et al., 2014	1.4	1.6	59	1.1	1.4	50	68.6%	0.30 [-0.26, 0.86]
Koh et al., 2014	5.8	2.1	46	5.6	2.1	52	31.4%	0.20 [-0.63, 1.03]
Total (95% CI)			**105**			**102**	**100.0%**	**0.27 [-0.20, 0.74]**
Heterogeneity: Chi² = 0.04, df = 1 (P = 0.85); I² = 0%								
Test for overall effect: Z = 1.13 (P = 0.26)								

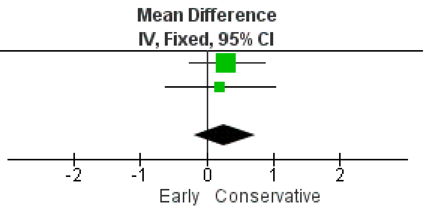


Figure 3.5. Meta-analysis of pain intensity at 6 months postoperative measured by visual analogue scale.

	Early			Conservative				Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Fixed, 95% CI
Keener et al., 2014	0.9	1.7	59	1.1	1.4	50	50.4%	-0.20 [-0.78, 0.38]
Koh et al., 2014	1.3	1.8	46	0.8	1	52	49.6%	0.50 [-0.09, 1.09]
Total (95% CI)			**105**			**102**	**100.0%**	**0.15 [-0.27, 0.56]**
Heterogeneity: Chi² = 2.76, df = 1 (P = 0.10); I² = 64%								
Test for overall effect: Z = 0.70 (P = 0.49)								

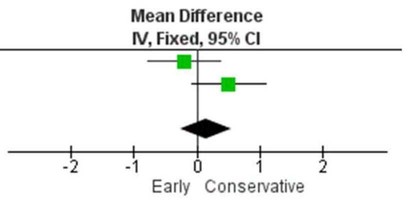


Figure 3.6. Meta-analysis of pain intensity at 24 months postoperative measured by visual analogue scale.

3.3.2.3.2. American Shoulder and Elbow Surgeons questionnaire

Three MA for the follow-up period of six, 12 and 24 months were performed (Figures 3.7 – 3.9). For 12 and 24 months, 2 studies were included totalling 214 and 207 patients, respectively. For 6 months three studies were used with 312 patients. No statistical differences were found for any MA (*P*= 0.29, 0.49 and 0.15).

	Early			Conservative				Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Fixed, 95% CI
Keener et al., 2014	81.1	16.2	59	84.3	15.1	50	43.4%	-3.20 [-9.08, 2.68]
Kim et al., 2012	67.08	20.0521	56	69.89	20.0882	49	25.3%	-2.81 [-10.51, 4.89]
Koh et al., 2014	68	17.34	46	68	17.6	52	31.3%	0.00 [-6.93, 6.93]
Total (95% CI)			**161**			**151**	**100.0%**	**-2.10 [-5.97, 1.77]**
Heterogeneity: Chi² = 0.52, df = 2 (P = 0.77); I² = 0%								
Test for overall effect: Z = 1.06 (P = 0.29)								

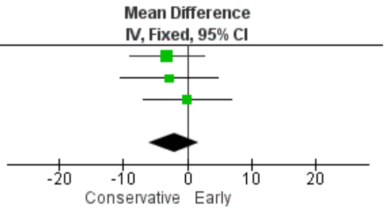


Figure 3.7. Meta-analysis of American Shoulder and Elbow Surgery questionnaire at 6 months**.**

	Early			Conservative				Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Fixed, 95% CI
Keener et al., 2014	88.1	15.8	59	89.1	14.1	50	89.7%	-1.00 [-6.62, 4.62]
Kim et al., 2012	73.29	56.1609	56	82.9	27.5386	49	10.3%	-9.61 [-26.22, 7.00]
Total (95% CI)			**115**			**99**	**100.0%**	**-1.88 [-7.20, 3.44]**
Heterogeneity: Chi² = 0.93, df = 1 (P = 0.34); I² = 0%								
Test for overall effect: Z = 0.69 (P = 0.49)								

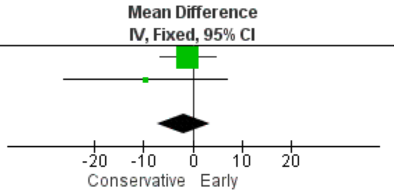


Figure 3.8. Meta-analysis of American Shoulder and Elbow Surgery questionnaire at 12 months**.**

	Early			Conservative				Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Fixed, 95% CI
Keener et al., 2014	91	15.3	59	93.3	10.6	50	55.4%	-2.30 [-7.19, 2.59]
Koh et al., 2014	88.9	16.2	46	92.1	10.2	52	44.6%	-3.20 [-8.64, 2.24]
Total (95% CI)			**105**			**102**	**100.0%**	**-2.70 [-6.34, 0.93]**
Heterogeneity: Chi² = 0.06, df = 1 (P = 0.81); I² = 0%								
Test for overall effect: Z = 1.46 (P = 0.15)								

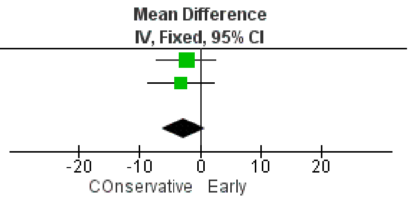


Figure 3.9. Meta-analysis of American Shoulder and Elbow Surgery questionnaire at 24 months.

3.3.2.3.3. Constant-Murley Score

Two meta-analyses were possible for the Constant-Murley score at six and twelve months (figures 3.10 and 3.11). Three studies, with a total of 312 patients, were used for the six months comparison and two studies, with a total of 214 patients, for the 12 months comparison. No statistical differences were found for both periods (*P*= 0.44 and *P*= 0.79).

	Early			Conservative				Mean Difference
Study or Subgroup	**Mean**	**SD**	**Total**	**Mean**	**SD**	**Total**	**Weight**	**IV, Fixed, 95% CI**
Keener et al., 2014	74.4	13.3	59	79.1	10	50	42.5%	-4.70 [-9.08, -0.32]
Kim et al., 2012	66.11	10.64	56	64.52	12.7	49	40.0%	1.59 [-2.93, 6.11]
Koh et al., 2014	65.1	17.5	46	63.7	16.9	52	17.5%	1.40 [-5.43, 8.23]
Total (95% CI)			**161**			**151**	**100.0%**	**-1.12 [-3.97, 1.74]**
Heterogeneity: Chi² = 4.47, df = 2 (P = 0.11); I² = 55%								
Test for overall effect: Z = 0.77 (P = 0.44)								

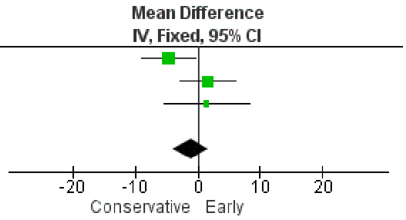


Figure 3.10. Meta-analysis of Constant-Murley score at 6 months.

	Early			Conservative				Mean Difference
Study or Subgroup	**Mean**	**SD**	**Total**	**Mean**	**SD**	**Total**	**Weight**	**IV, Fixed, 95% CI**
Keener et al., 2014	79.1	10	59	79.9	12.3	50	49.8%	-0.80 [-5.06, 3.46]
Kim et al., 2012	69.81	7.46	56	69.83	13.43	49	50.2%	-0.02 [-4.26, 4.22]
Total (95% CI)			**115**			**99**	**100.0%**	**-0.41 [-3.41, 2.60]**
Heterogeneity: Chi² = 0.06, df = 1 (P = 0.80); I² = 0%								
Test for overall effect: Z = 0.27 (P = 0.79)								

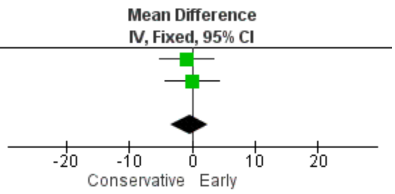


Figure 3.11. Meta-analysis of Constant-Murley score at 12 months.

3.3.2.3.4. Simple Shoulder Test

Two MA were performed for 6 and 12 months (figures 3.12 and 3.13); both included two studies and a total of 214 patients. No statistical differences were found for both analyses (*P*= 0.44 and 0.62, for 6 and 12 months respectively).

	Early			Conservative				Mean Difference
Study or Subgroup	**Mean**	**SD**	**Total**	**Mean**	**SD**	**Total**	**Weight**	**IV, Fixed, 95% CI**
Keener et al., 2014	9.1	2.7	59	9.3	2.9	50	59.9%	-0.20 [-1.26, 0.86]
Kim et al., 2012	7.81	3.17	56	6.7	3.55	49	40.1%	1.11 [-0.19, 2.41]
Total (95% CI)			**115**			**99**	**100.0%**	**0.32 [-0.49, 1.14]**
Heterogeneity: Chi² = 2.36, df = 1 (P = 0.12); I² = 58%								
Test for overall effect: Z = 0.78 (P = 0.44)								

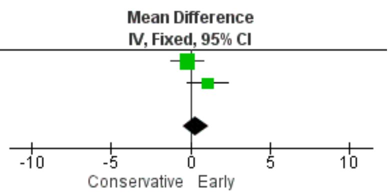


Figure 3.12. Meta-analysis of Simple Shoulder Test at 6 months.

	Early			Conservative				Mean Difference
Study or Subgroup	**Mean**	**SD**	**Total**	**Mean**	**SD**	**Total**	**Weight**	**IV, Fixed, 95% CI**
Keener et al., 2014	10.3	2.3	59	10	3.1	50	77.7%	0.30 [-0.74, 1.34]
Kim et al., 2012	9	5.4518	56	9	4.7	49	22.3%	0.00 [-1.94, 1.94]
Total (95% CI)			**115**			**99**	**100.0%**	**0.23 [-0.68, 1.15]**
Heterogeneity: Chi² = 0.07, df = 1 (P = 0.79); I² = 0%								
Test for overall effect: Z = 0.50 (P = 0.62)								

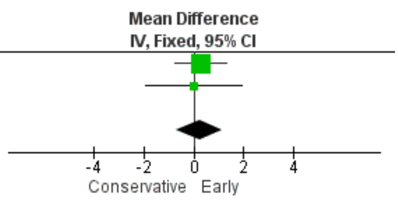


Figure 3.13. Meta-analysis of Simple Shoulder Test at 12 months.

3.3.2.3.5. Other functional scores

Meta-analysis was precluded for the DASH, SANE, SPADI, UCLA and WORC due to the heterogeneity of measurement tools. These instruments have been reported across different studies: Cote and Mazzoca in their abstract reported no difference for the WORC after six months follow-up; they did not describe any result for the SANE. Duzgun et al. (2011) showed a lower DASH score for the early rehabilitation group at the six months follow-up, although this difference was not statistically significant. Lee et al. (2012) who used the UCLA described that both groups improved their scores, but no statistical differences between groups were found at the six or 12 months follow-up. De Roo et al. (2015) did not find any differences for the SPADI score at 4 months follow-up.

Grading of evidence: there is moderate evidence that early rehabilitation does not improve function status compared with conservative rehabilitation.

3.3.2.3.6. Range of Motion

The meta-analyses were separated according to movements: flexion and external rotation; which were measured with a goniometer and expressed in degrees. Shoulder internal rotation was not considered as the measurements were related to the hand positioning of the patient to their own back and not described as a joint angle. Only De Roo et al. (2015) assessed the joint angle for internal rotation but did not find statistically significant differences at six weeks or four months post-operative.

Abduction was found only for Lee et al. (2012), which showed no statistically significant difference at six or 12 months, and for De Roo et al. (2015), which showed no statistically significant difference at six weeks and four months.

3.3.2.3.7. Flexion

Meta-analyses were possible for six (5 studies; 468 patients) and 24 months (2 studies; 207 patients) (Figures 3.14 and 3.15). No statistically significant differences were found at six (*P*= 0.09) or 24 months (*P*= 0.61).

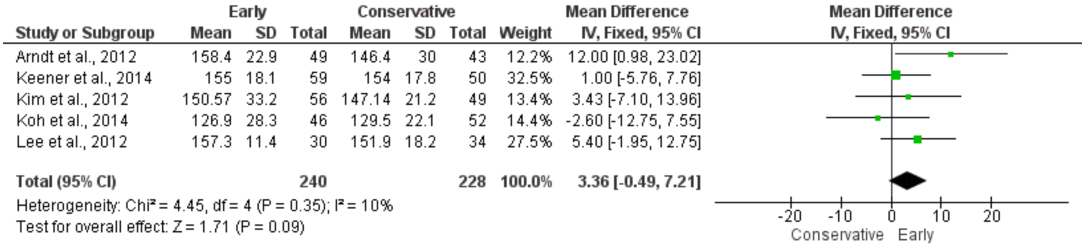


Figure 3.14. Meta-analysis of range of motion for shoulder flexion at 6 months.

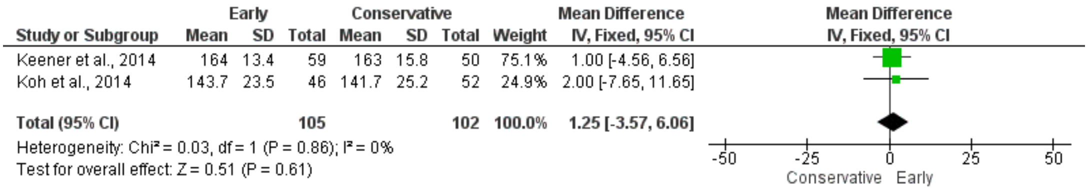


Figure 3.15. Meta-analysis of range of motion for shoulder flexion at 24 months.

3.3.2.3.8. External Rotation

A meta-analysis was possible at six and 24 months (Figures 3.16 – 3.17). For six months, five studies had the largest population of 468 patients, while for 24 months two studies combined 207 participants. No statistical differences were found for both analyses (*P*= 0.13 and *P*= 0.52, respectively). Grading of evidence: there is weak evidence that early rehabilitation improves ROM compared with conservative rehabilitation.

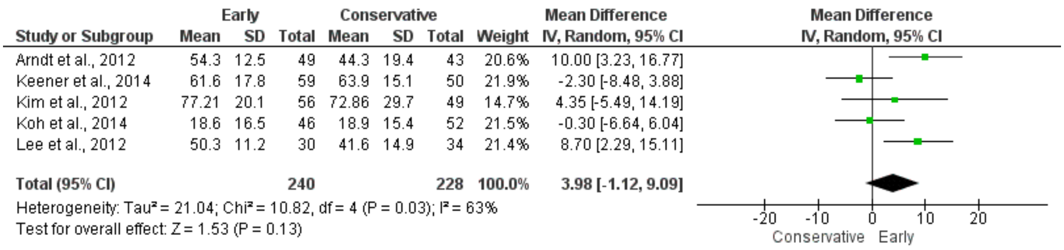


Figure 3.16. Meta-analysis of range of motion for shoulder external rotation at 6 months.

Study or Subgroup	Early Mean	Early SD	Early Total	Conservative Mean	Conservative SD	Conservative Total	Weight	Mean Difference IV, Fixed, 95% CI
Keener et al., 2014	62	16.4	59	66.2	14	50	65.8%	-4.20 [-9.91, 1.51]
Koh et al., 2014	33.1	18.8	46	29.5	21.2	52	34.2%	3.60 [-4.32, 11.52]
Total (95% CI)			**105**			**102**	**100.0%**	**-1.53 [-6.16, 3.10]**

Heterogeneity: Chi² = 2.45, df = 1 (P = 0.12); I² = 59%
Test for overall effect: Z = 0.65 (P = 0.52)

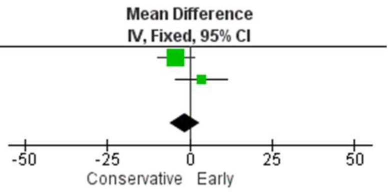


Figure 3.17. Meta-analysis of range of motion for shoulder external rotation at 24 months.

3.3.2.3.9. Retears rate

A meta-analysis was possible at 12 months follow-up (figure 18) (5 studies, 410 participants). There was no statistical difference (*P*=0.31) in retear rate between the early and conservative rehabilitation groups. Grading of evidence: there is moderate evidence that early rehabilitation does not cause higher retear rates. Additional details regarding the grading of evidence can be found in table 3.7.

Study or Subgroup	Early Events	Early Total	Conservative Events	Conservative Total	Weight	Odds Ratio M-H, Fixed, 95% CI
Cuff & Pupello, 2012	5	33	3	35	14.0%	1.90 [0.42, 8.70]
Keener et al., 2014	6	63	3	53	16.8%	1.75 [0.42, 7.38]
Kim et al., 2012	7	56	9	49	47.8%	0.63 [0.22, 1.86]
Koh et al., 2014	2	25	2	32	9.2%	1.30 [0.17, 9.97]
Lee et al., 2012	7	30	3	34	12.3%	3.14 [0.73, 13.49]
Total (95% CI)		**207**		**203**	**100.0%**	**1.37 [0.74, 2.53]**
Total events	27		20			

Heterogeneity: Chi² = 3.52, df = 4 (P = 0.47); I² = 0%
Test for overall effect: Z = 1.01 (P = 0.31)

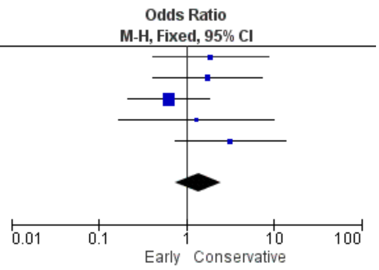


Figure 3.18. Meta-analysis of odds ratio for retears at 12 months**.**

Table 3.7. GRADE scores for Pain, function status, ROM and retears rate.

Number of studies (participants)	Outcome	Comparison	Type of evidence	Design's limitation	Indirectness	Inconsistency of results	Publication bias	GRADE	Comment
Does early mobilisation improve pain?									
2 (207)	Pain	Early vs. Conservative	4	-1	0	0	0	Moderate	Quality point deducted for methodological concerns (Risk of Bias)
Does early mobilisation improve function status?									
3 (312)	Function status	Early vs. Conservative	4	-1	0	0	0	Moderate	Quality points deducted for methodological concerns (Risk of Bias)
Does early mobilisation improve ROM?									
5 (468)	ROM	Early vs. Conservative	4	-1	0	-1	0	Low	Design's limitation point deducted for methodological concerns (Risk of Bias). Inconsistency point deducted for conflicting results among studies.
Does early mobilisation cause retears events?									
5 (410)	Retears rate	Early vs. Conservative	4	-1	0	0	0	Moderate	Quality point deducted for methodological concerns (Risk of Bias)

3.4. Discussion

3.4.1. Method

The aims of the literature review were to systematically analyse and determine the effectiveness of rehabilitation for patients who had a surgical repair of the rotator cuff. Currently, no differences were seen for ROM, functional status and retear rates between early and conservative rehabilitation.

Systematic reviews are the highest level of evidence, their final aim is to support policy and practice decisions for better health outcomes (Baker et al., 2014). Everyday around 75 trials and 11 systematic reviews are published (Bastian, Glasziou and Chalmers, 2010), with such high volume of new evidence it is difficult for the clinician to keep up to date and decide which is the best evidence they should use to base their decision making. The rationale for choosing to perform an overview of systematic reviews in this thesis was to support faster and more reliable decision-making for the clinician, particularly with the large increase in published material in the field of physiotherapy after rotator cuff repairs over the last 5 years. An overview of systematic reviews is a method that was created as a solution to reduce uncertainties, to summarise a large number of studies and to support faster creation of healthcare policies (Silva et al., 2012). However, the method also has its limitations, the quality and meaningfulness of the implications for clinical practice recommendations emerging from overviews of systematic reviews will depend on the methodological quality of the primary studies (RCTs) and systematic reviews; if the included studies did not follow rigorous standards to develop their method, the conclusions of the overview of systematic reviews will be limited (Baker et al., 2014). Another limitation is that different from the typical systematic review, which has clear methodological guidelines to be followed (e.g.: Cochrane handbook), an overview of systematic review design still need a specific guideline to be followed.

To try and overcome such limitations, the overview of systematic reviews in this thesis used the PRISMA statement to guide the construction. The PRISMA was developed based on the Quality of Reporting Meta-analyses (QUOROM), which was created as a guideline for reporting systematic reviews of randomised controlled trials (Liberati et al., 2009). The PRISMA was designed in 2005 by a panel of specialists involving review authors, methodologists, clinicians, medical editors, and consumers. After revisions, the group approved the final version that is in current use (Liberati et al.

2009). Other guides are also available: Critical Appraisal Skills Program (CASP), Systematic Review (of Therapy) Worksheet, Aggressive Research Intelligence Facility (ARIF) Checklist and Delphi list. However, the PRISMA was chosen as it is one of the most used methods by important editorial organisations, such as the Cochrane collaboration. In addition, top journals in the physiotherapy area, such as *Physical Therapy* and the *British Journal of Sports Medicine*, only publishes systematic reviews that use the PRISMA statement (Maher, 2009).

To assess the quality of each review the R-AMSTAR instrument was preferred, but other tools are also available, for example, the Overview Quality Assessment Questionnaire (OQAQ) (Oxman and Guyatt, 1991) and the AMSTAR (Shea et al., 2007, 2009). The OQAQ is composed of 10 items which are scored individually using a *Likert* scale from one to seven (small extent to large extent)(Oxman and Guyatt, 1991; Oxman et al. 1991), but this instrument does not have questions about publication status and language restriction. The AMSTAR comprises similar components and was developed based on the OQAQ and Sacks lists (Sacks et al., 1987) with additional questions on publication status and language inclusion. After factorial and exploratory analysis of 37 items combined from both tools, 11 items were identified as containing the best validity to measure the methodological quality of systematic reviews (Shea et al., 2007). However, the judgement employed by AMSTAR does not permit a scoring quantification as each question is classified as: Yes, No, Can't answer or Not applicable. Thus, the R-AMSTAR was a progression regarding this concern, making possible a ranking arrangement for quick and easier interpretation; moreover, sub-items were added to make the decision process clearer (Kung et al., 2010).

3.4.2. Systematic Reviews features

The agreement scores between reviewers about the systematic reviews quality were high, indicating good to excellent classification. While comparing the results from the ten selected reviews, it is important to highlight some differences that may influence the results and conclusions made. The first is related to methodological quality: The studies from Chang et al. (2015) and Chan et al. (2014), which had the highest scores of 38 from 44, are considered to have the most reliable method. Between Chang et al. (2015) and Chan et al. (2014), Chang et al. (2015) was the only study to assess publication bias using specific statistical tests: e.g., Egger test or funnel plot. This test shows whether small studies with unfavourable results (no significant differences) may impact the final result of a meta-analysis when multiple and more powerful studies are compared (Ioannidis and Trikalinos, 2007; Sterne et al., 2011). Although assessing publication bias would seem an important factor for a review, its use is not recommended with continuous data when the number of studies is fewer than 10, in this case, the regression test does not have enough power to show funnel asymmetry, which means that it can be a misleading result (Ioannidis and Trikalinos, 2007; Sterne et al., 2011). While none of the selected systematic reviews used more than 10 primary studies for meta-analysis, the publication bias is not a major concern for the purposes of this chapter's topic. Therefore, if the item 11 of the R-AMSTAR was not included, the study of Chan et al. (2014) would stay with the best score.

Another disparity is related to primary studies and their respective levels of evidence. Although the publication dates among the multiple reviews is not greater than two years, the variation of studies included was diverse. Only the RCTs from Cuff and Pupello (2012) was cited across all publications. For example, Huang, Wang, and Lin (2013) used the study of Garofalo et al. (2010) for the meta-analysis of ROM, however this RCT does not compare the effect of an early versus conservative rehabilitation; their main goal was to analyse the effectiveness of continuous passive motion (CPM) in the functional status of the target population. Littlewood et al. (2015) also used two studies which assessed the effectiveness of CPM: Lastayo et al. (1998) and Raab et al. (1996) and another study, Roddey et al. (2002) tested the influence of videotape instructions; their inclusion might be justified as the main objective of the review was to describe possible rehabilitation for patients who had a surgical repair of the rotator cuff; moreover, the authors did not use any of these studies in the meta-analysis for retears rate, comparing early to conservative. Chan et al. (2014) included RCTs and *quasi*-RCTs, they used the unpublished work from Cote and Mazzoca in a first analysis, but they performed further sensitivity analyses showing that the exclusion of the aforementioned study could lead to an incorrect result of better shoulder flexion, although not clinically relevant, in favour of the early management. Kluczynski et al. (2014) used case-series and cohorts, besides RCTs, as primary studies. They performed two analyses: one only with RCTs and another with all levels of evidence. Despite the fact that the analysis with high level studies does not show a statistically significant difference for retears ratio, the authors concluded based on their second analysis. The second analysis clearly has major issues, the studies do not have rigorous methods to detect true effects of therapies, and as the authors describe, they do not compare directly the effect of an early vs. conservative rehabilitation.

One explanation for the different studies could be the use of different search strategies and databases. For instance, Kluczynski et al. (2014) and Huang, Wang, and Lin (2013) used search terms and key-words but did not have a structured search strategy. In contrast Chan et al. (2014), Chang et al. (2015) and Shen et al. (2014) organised different strategies for each database. In order to have a broad but still relevant search result, researchers should approach each database according to their features. For example, in Medline, which is one of the major databases, the use of MeSH terms (Medical Subject Headings) regulated by the Boolean operators (AND, NOT, OR) is convenient, instead of just keywords (Neveol et al., 2009).

Another important point is related to the age range; only two studies (Chan et al. (2014 and Littlewood et al. 2015) used age as inclusion criteria, but limited the minimum on 18 years old. It is known that the rotator cuff tears is a shoulder disorder that starts to develop when people are in their 40s and the incidence grows according to the ageing process, having its higher prevalence on the 80s (Yamaguchi et al., 2006; Yamamoto et al., 2010). People younger than 40 years old are more prone to have tears due to a traumatic episode rather than a chronic failure. These differences in tissue quality may influence rehabilitation outcomes considering that muscles do not respond similarly to stimuli in people of different ages (Vidt et al. 2012).

3.4.3. Systematic review update

The kappa scores between reviewers varied from 0.64 to 1, which shows good to excellent agreement. The quality of the primary studies was classified as three been low risk and eight as high risk, following the criterion of Furlan et al. (2009). The majority of them failed to fulfil essential components such as proper method of randomisation and allocation concealment. Furthermore, other items such as *co-intervention avoided* and *compliance acceptable* were not reported. It is well established that these two items are crucial to ensure that the results of studies are reliable and valid (Higgins and Green, 2011). The component *compliance* should be reported for rehabilitation trials testing different protocols as it contributes to clarify how many sessions each participant of each group attended, thus it is possible to know if the groups are truly comparable. For example, if one group had a higher frequency of therapies for the same time period of the control/comparison group. The avoidance of co-interventions should also be detailed; for instance, if a patient has an additional treatment for pain management with injections or non-steroidal anti-inflammatory drugs, their outcomes may be altered and the efficiency of the treatment may be overrated (Furlan et al., 2009). The items *blinding of participant* and *blinding of care provider* were also scored as high risk for all studies, however, they are impossible to control in a trial where the therapist must know what the treatment is.

3.4.4. Meta-analyses update

Based on the information of the multiple studies, it was possible to separate meta-analyses in relation to each functional questionnaire, pain, ROM of different movements and retears ratio. No differences were found for any of them. The results of new meta-analyses presented were similar to those from Chan et al. (2014), however, new analyses have been done for 6, 12 and 24 months, not just for the final follow-up. Moreover, the review from Chan et al. (2014) has some flaws; they used the data of the follow-up of 24 months from Keener et al. (2014) to compare with the 12 months follow-up from Kim et al. (2012). They also combined results from Cuff and Pupello (2012) in the same analysis, but the original article does not contain information of the standard deviation, which makes the analyses challenging. Their further efforts were to input the *P*-value, but it did not show any alterations to their results. Chang et al. (2015) also did meta-analyses for functional scores; however, they used the standardised mean difference using multiple questionnaires in the same analysis. The standardised mean difference is a statistical analysis used to combine studies that assessed the same outcome but used different scales or tools to measure the same outcome. In this case, the values are standardised to a common scale by dividing the difference in mean between outcome for the standard deviation of outcome among participants; thus the means are assumed to have similar proportions irrespective to the original scale (Higgins and Green, 2011).

The screening of individual RCTs revealed the possibility of separated analyses for each questionnaire; although the use of the standardized mean difference is not incorrect, it will not inform how much improvement is necessary for every questionnaire, as the standardised mean difference will report results as a general unit rather than specific. The separated report, using the mean difference, is more advantageous as it provides the therapist with a choice of which instrument they would like to use; it also allows the decision to consider if the treatment could reach a minimal clinically important difference (MCID). For instance, the MCID for ASES, SST and Constant-Murley are respectively 6.4, 2.2 and 10.4 (Roy, MacDermid, and Woodhouse, 2009; Kukkonen et al. 2013; van Kampen et al., 2013), and for pain, measured with a 10-cm VAS, the value is 1.4 cm (Tashjian et al., 2009).

3.4.5. Assessment of movement

For ROM the meta-analyses were separated for different movements. The results were similar to Chan et al. (2014), who found no statistically significant difference for ROM. The results of this thesis meta-analyses were different from the review of Riboh and Garrigues (2014), Chang et al. (2015) and Huang, Wang, and Lin (2013). Riboh and Guarrigues (2014) presented meta-analyses for flexion and external rotation for 3, 6 and 12 months; Chang et al. (2015) and Huang, Wang, and Lin (2013) presented meta-analysis for 6 and 12 months. Riboh and Guarrigues (2014) showed statistically significant differences in favour of early management for flexion at three, six and 12 months, and external rotation only at three months. In the new meta-analysis of this thesis for six months (Figure 3.14, page 80) the inclusion of the data from Koh et al. (2014) changed the previous result from the three reviews which found statistically significant difference favouring early rehabilitation for flexion and external rotation to being not statistically significant (P=0.09, P= 0.61, P=0.13 and P=0.52). As no other data were added to three and 12 months for flexion and external rotation, only new MAs were performed for six (Figure 3.16, page 80) and 24 months (Figure 3.17, page 81). It is important to highlight that the difference between early and conservative rehabilitation for three months from Riboh and Garrigues (2014) was 14.7°, which is above the MCID of 14°. However, this difference was not consistent for the other follow-ups or movements. For external rotation, the MCID is 15°. The MCID values are based on the study of Muir, Corea, and Beaupre (2010), which was from a population with shoulder disorders measured with a goniometer.

Although no statistically significant differences were found for ROM, only simple movements were measured using a goniometer as an instrument. The use of biomechanical outcomes could bring a more thorough description, which may show the effectiveness of rehabilitation in improving both range of movement and movement control. To date, no study has explored muscle coordination and 3D kinematics during the recovery after surgical repair of rotator cuff tears. Therefore, the question of whether the movement patterns are better for patients having shorter immobilisation periods after surgery, measured in the three months follow-up in the review of Riboh and Garrigues (2014) remains unclear. As the rotator cuff muscles act by stabilising the glenohumeral joint, it is suggestive that adding a few more weeks of therapy will benefit the shoulder's movement control, however as observed in the other meta-analysis, the improvement is not superior compared to the conservative management in longer follow-ups.

Another aspect that the biomechanics outcome can support is related to the retears rate. In the present review, no difference was found for retear rate, which is similar to the meta-analysis findings of Littlewood et al. (2015). Although the study from Lee et al. (2012) included in the retears meta-analysis, differences in the final result were not seen. With the use of EMG, it is possible to determine if other muscles from the shoulder complex are being overused.

3.4.6. Rehabilitation aspects

3.4.6.1. Immobilisation

The type of orthoses varied among studies and there was no consensus on whether the shoulder should be angled in abduction or maintained besides the thorax. The most common reported method was the sling alone, but four studies (Kim et al., 2012; Lee et al., 2012; Koh et al., 2014; De Roo et al., 2015) described the use of an abduction pillow, with different angles.

The prescription of immobilisation posture should consider the characteristics of the repair. The mechanical stress in the surgical site must be avoided as much as possible, aiming at safe healing (Conti, Garofalo, and Castagna, 2015). According to a recent survey with physiotherapists and surgeons in the UK about the current practice on rotator cuff rehabilitation, 86% indicate that their patients use a sling, 18% use an abduction brace and 2% stated other forms of immobilisation (Littlewood and Bateman, 2015). Jackson et al. (2013) use a shoulder model to simulate what would be the best immobilisation positions to minimise stress on a supraspinatus and infraspinatus repair depending on the length of the tear. They showed that depending on factors such as muscle involved, tear size and surgical method applied, the positioning should be different. Isolated supraspinatus tears require a humeral positioning that is closer to the scapular plane, and as the lesion's severity is higher, the abduction angle should be above 60°. When there is more than one muscle affected, the posture varies: for supraspinatus + infraspinatus, lower loads are observed when the humerus is closer to parallel with the coronal plane, abduction angles greater than 60° and neutral rotation; for supraspinatus + subscapularis the position should be on the scapular plane and for more severe stages, staying almost parallel to sagittal plane, abduction angle from 58° to

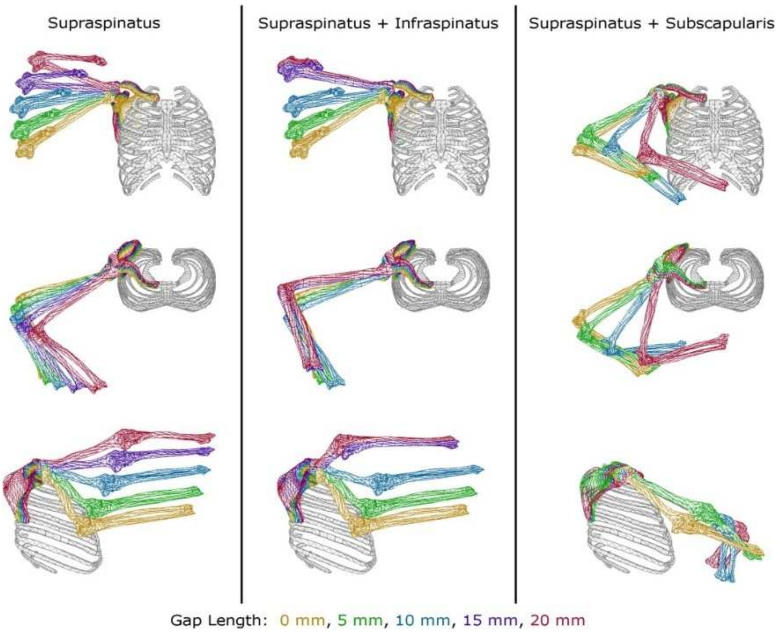


Figure 3.19. Optimal immobilization postures. From Jackson et al. (2013)

70°, and internal rotation varying between 35° and 60° (Jackson et al. 2013). Figure 3.19 from Jackson et al. (2013) illustrates the best postures for each condition mentioned above; the gap length represents the tear's size.

Another variable that cannot be neglected is the rotator cuff force vector's. If the superior or posterosuperior muscles are involved, an external rotation of 15° may contribute to lower pain and better ROM when patients start the rehabilitation. In contrast, if the subscapularis is involved, internal rotation is preferable (Jackson et al., 2013; Conti, Garofalo, and Castagna, 2015).

Moreover, the brace's daily wearing time should not be superior to 12 hours continuously; instruction should be given on how to avoid gravity effects on the affected limb when not wearing the immobilisation orthosis. For instance, the upper limb can rest on a table, without the brace/orthosis, while the patient performs active movements for hand, wrist and elbow. Long immobilisation periods are responsible for changing the brain's cortical plasticity and deteriorate motor performance, inter-joint coordination and proprioception (Huber et al., 2006). This is supported by the study by Huber et al. (2016), which demonstrated that by immobilising the arm of individuals for 12 hours, changes in motor performance and impaired motor somatosensory and motor evoked potentials over the contralateral sensorimotor cortex were seen. Hubers et al. (2016) assessed fifteen healthy participants who had their arm immobilised in a sling for 12 hours. Following the immobilisation period, the subjects were asked to perform a task consisting of moving a cursor on a digitising tablet to three targets on a screen. The targets were 8 cm away from the starting position (arm close to the body) and to measure the cortex activity, an electroencephalogram was used. Compared to the baseline test (before immobilisation), the participants had a deterioration of the motor performance and the motor evoked potentials of the contralateral sensorimotor cortex.

3.4.6.2. When should rehabilitation start?

The application of the first rehabilitation session varied among the studies from first day post-operative to four weeks in early protocols, and about three to eight weeks for conservative groups (Table 3.6, page 70). Although this might be an inconsistent criterion, according to a recent review from Thomson, Jukes, and Lewis (2015) on recommendations for postoperative rehabilitation, patients with small to moderate tears could start rehabilitation earlier if a strong fixation method is used. Passive exercises can be applied in the first day following surgery and active management may begin after several days. Based on the new meta-analysis (Figure 3.18, page 81) in this chapter, the recommendation of earlier mobilisation for smaller tears from Thomson, Jukes, and Lewis (2015) could be supported, as the number of retear rates is not statistically significant between groups, although ROM and clinical outcomes did not present statistically significant differences either.

According to the same study, for more severe stages, with more delicate repair sites, passive ROM is advocated to be applied after four to six weeks and active from six to eight. Although recommendations driven by the authors appear pertinent, it must be cautiously considered. The systematic review used to underpin this guidance was from Huang, Wang, and Lin (2013); in which the overall result of the meta-analysis of retears ratio shows a statistically significant difference with a higher risk related to aggressive/early protocols. Their review pooled three studies Arndt et al. (2012), Cuff and Pupello (2012) and Lee, Cho, and Rhee (2012); the only primary study to bring detailed information about tear sizes of their patients was the third, which included medium and large sizes. However, the rehabilitation protocol from Lee et al. (2012) was highly aggressive. In the very first day postoperative, passive ROM of shoulder flexion and external rotation were already implemented, in addition to stretching of shoulder muscles. The frequency was also high, being performed twice a day and self-passive ROM up to three times per day, already in the first week. In comparison to the meta-analysis of Huang, Wang, and Lin (2013), two new available studies were included (Kim et al., 2012; Koh et al., 2014) and one excluded (Arndt et al., 2012) in the updated retears meta-analyses. The reason for the exclusion of the primary study was due to lack of clear information about the absolute numbers of individuals who had retears in each group, as well as absolute total number of patients in each group that were assessed for retears. As an example, it states that: [sic] "*Ten patients refused to undergo this examination because it was invasive and painful.*" Therefore, tables displaying results only provide percentages; thus, the inputted data from Huang, Wang, and Lin (2013) of 41 patients in each arm is incorrect and is a conjecture. Other reviews from Chen et al. (2015) and Littlewood et al. (2015) that performed meta-analysis for retears also erroneously included the study by Arndt et al. (2012).

The agreement with the conclusion of Thomson, Jukes, and Lewis (2015) for more mild cases is ratified based on two parameters, which are calculated based on the results of the new MA (Figure 3.18): the absolute risk increase (ARI) and the number needed to treat (NNT) or in the specific case of retears ratio, that is an unfavourable outcome, this is referred to as the number needed to harm (NNH). The ARI is the difference between the groups event rates, which in this case is the retear ratio (McQuay and Moore 1997; Barratt et al. 2004). It can be calculated following the equation (Barratt et al. 2004):

$$ARI = \left(\frac{eE}{tE}\right) - \left(\frac{eC}{tC}\right)$$

Where, eE is the number of retears events in the early group and tE is the total number of participants in the early group, eC is the number of events in the conservative group and tC is the total number of participants in the conservative group. Substituting values from figure 3.18:

$$ARI = \left(\frac{27}{207}\right) - \left(\frac{20}{203}\right) = 0.032$$

The result indicates that the early group had 3.2% more retears cases. The NNH is the reciprocal of the ARI and can be calculated following the equation (McQuay and Moore, 1997):

$$NNH = \frac{1}{ARI}$$

Substituting the ARI:

$$NNH = \frac{1}{0.032} = 31.25$$

The value of 31.25 indicates that based on the meta-analysis for retears ratio with all the studies, 32 patients treated with early rehabilitation are needed for one to have a retear, which could possibly be caused by the early management. However, as stated previously, the study from Lee et al. (2012) had patients with larger tears and a very aggressive protocol. Hence, if the ARI and NNH are calculated without the inclusion of Lee et al. (2012), the results are: ARI=1.29% and NNH=77.5. This result reveals that early mobilisation for patients with smaller tears have just 1.29% more retears episodes, compared to those who had a more conservative approach. Furthermore, 78 patients needed to harm shows that the chances of having a recurrence because of more permissive mobilisation is very low, as the retears may be caused by other factors rather than the mobilisation itself.

In contrast, for more severe stages the recommendation from Thomson, Jukes, and Lewis (2015) must be considered carefully. Conclusions based only on the result from Lee et al. (2012), where values of ARI and NNH are 14% and 7.14 respectively, should not be taken further due to the presence of bias issues in addition to the concerns related to their protocol previously described. Considering the other studies included in the updated review in this thesis, it is still not possible to drive to definitive conclusions as all studies that included large tears also failed to fulfil fundamental methodological items (i.e.: adequate sequence generation, allocation concealment and blinding of assessor), which indicates important risk of bias.

3.4.6.3. Limitations

Although strict methods were used for this systematic review, it presents some limitations. It was not possible to perform meta-analysis only with high-quality RCTs; however, the objective was to review and critically analyse the available evidence. The majority of the primary studies failed to satisfy fundamental items such as adequate method of randomisation, allocation and blinding. Moreover, important items for physiotherapy trials such as compliance and co-intervention avoidance were not considered. Therefore, it is impossible to stipulate what is the ideal frequency and intensity of the treatment for any stage of rotator cuff tears. Furthermore, the results from the meta-analysis of pain must be carefully interpreted. It is not clear whether other treatments for pain management (e.g.: Steroid injections or NSAID) was used in any of the trials.

Based on the studies analysed, it is clear that mild stages may permit an early approach to recover ROM, but it was not possible to formulate recommendations of when mobilisation should start for patients with more severe stages, because of the lack of studies focusing in this subgroup.

Another limitation is related to sensitivity analysis, which was not performed for the functional outcomes due to the limited numbers of primary studies. However, a comprehensive discussion about the retears meta-analysis, that presents more divergences was explored.

3.4.6.4. Clinical message

3.4.6.4.1. Preoperative

The objective of the review was to discuss rehabilitation post-surgery; however, therapists must consider the influence of preoperative rehabilitation. From the selected primary studies only Duzgun et al. (2014) and Duzgun, Gü, and Ahmet (2011) clearly describes their application. Exercises aiming to improve strength, scapular stability, and manual therapy may be used before surgery to accelerate recovery, however, further research is needed.

3.4.6.4.2. Small/medium tears

Based on the review results and information available from the primary studies assessed (Table 3.6., page 70), early mobilisation may be recommended for patients with small or medium tears as it does not implicate higher risk of retears (Figure 3.18, page 81). Further suggestions based on general literature on the topic and based on the tendon metabolism and healing process (section 2.9.2, page 42) could be recommended as follows:

1) The immobilisation period should not be more than three weeks and possibly use sling only for comfort. For instance, to sleep or to avoid pain following surgery.
2) Passive ROM can start in 1st postoperative.
3) The loading ladder for the shoulder may start with passive movements, progressing to active-assisted and active exercises.
4) Hand, wrist and elbow active movements are encouraged since the first day postoperative.
5) Ice packs may be used for pain management.

3.4.6.4.3. Large tears

For patients with large tears the evidence is insufficient for recommending mobilisation earlier than six weeks, therefore conservative rehabilitation might be advised (pages 92-93, discussion on NNH). Further suggestions based on general literature on the topic and based on the tendon metabolism and healing process (section 2.9.2, page 42) could be recommended as follow:

1) Sling may be used for 6 weeks; abduction wedges might be needed.
2) Passive ROM can start in 1st postoperative.
3) Hand, wrist and elbow active movements are encouraged since the first day postoperative.
4) Ice packs may be used for pain management.

3.4.6.4.4. Massive tears

Massive tears are the most fragile stage and based on the evidence it is not possible to safely recommend early mobilisation (pages 92-93, discussion on NNH). However, surgery-related factors may have more impact on these patients (section 2.9.3., page 45). Hence, immobilisation periods longer than six weeks may be necessary and transition among stages may be delayed.

3.4.6.5. Clinical message conclusion

The recommendations for small, medium and large tears are suggestions for therapist guidance. Early rehabilitation might be advantageous for small/medium tears however further studies are needed to confirm their benefit, as well as for large and massive tears. Factors that can compromise patients' progression (section 2.9.2, page 42) must be considered and mutual consensus between the therapist and surgeon is appropriate.

3.4.6.6. Implications for research

It has been shown that there are no statistically significant differences for any of the outcomes (pain, functional scores, ROM and retears ratio) (Figures 3.5 to 3.18, pages 76 to 81). However, the majority of the RCTs are of low quality and their bias may drive to misleading conclusions (Figure 3.4, page 66). Further high-quality RCTs are necessary to safely recommend the best moment to start rehabilitation, specifically for more severe sub-groups, that may present a higher risk of having complications such as retear/non-healing (Lee et al., 2012; Chan et al., 2014). Important components of the risk of bias for rehabilitation trials such as compliance and co-intervention avoidance must be included; moreover, other fundamental components such as adequate random sequence generation, allocation concealment, and blinding of assessor must be fulfilled.

New studies should include other tools that can describe more precisely the quality of movement. As discussed in section 2.7., page 32, goniometers are widely used in the clinical setting; however, the result may vary by as much as 25°, and even the same examiner may show variations of up to 23° (Hayes et al., 2001). Other movements simulating ADLs and exploring how the muscle behaviour develops from pre-surgery to follow-up, and how this is influenced by different physiotherapy approaches must be assessed for a better description of movement control.

The use of biomechanics must be considered as it brings a thorough description of muscle functioning, which may help to demonstrate how effective the rehabilitation is in recovering the patterns of muscle activation and coordination (Bachasson et al., 2015, Fritz et al., 2017). As demonstrated in other primary studies and systematic reviews on biomechanics and rotator cuff tears and other shoulder problems (Kolk et al., 2016; Fritz et al., 2017; Keshavarz et al., 2017). A consistent and detailed understanding of shoulder muscle alterations in activity pattern and coordination using EMG and motion capture, with a 3D kinematic system, may help clinicians to better comprehend the transition of patients from preoperative through to late postoperative phases, focusing on control and quality of movement. It is known that chronic musculoskeletal disorders are strongly linked with central sensitisation (Nijs et al., 2012), and this anomalous activity of the nervous system changes muscle coordination, which may or may not recover after surgery (Littlewood et al., 2013; Nijs et al., 2012). Therefore, using EMG may help to observe changes in muscle activation and what is the influence of different physiotherapy approaches in muscle recruitment.

3.5. Conclusion

This review gives detailed information about the effectiveness of early mobilisation in comparison to conservative on clinical outcomes. It used a rigorous and comprehensive method to analyse the available evidence aiming to support a better clinical decision.

It has been shown that early mobilisation does not improve functional outcomes, pain or ROM nor increase the risk of retears/non-healing when compared to conservative rehabilitation. However, there is still no consensus on what the best physiotherapy approach after rotator cuff repairs is due to the heterogeneity of protocols and low methodological quality of primary studies. Therefore, new studies with appropriate power to identify true differences and avoid type II or type I errors are still needed to confirm the clinical effectiveness of early rehabilitation after rotator cuff repairs.

3.6. Acknowledgement of new studies

New searches (04/2018) have identified six additional articles that would fit the inclusion criteria of this chapter's overview of systematic review: one RCT (Mazzocca et al., 2017) and five systematic reviews (Houck et al., 2017; Nikolaidou, Migkou, and Karampalis, 2017; Saltzman et al., 2017; Jung et al., 2018; Li et al., 2018).

Mazzoca et al. (2017) randomised 73 patients (early=37 and conservative=36; follow-up: early=31 and conservative=27) and assessed ROM and clinical scores (WORC, ASES, SST, SANE and pain) before surgery, at 1, 3, 6 and 12 weeks, 6 months and 1 year. Patients in both groups used a sling for 6 weeks, the main difference between protocols was the time of initiation of active-assisted exercises; the conservative group started at 4 weeks from surgery, while the early group started after 2 or 3 days. After the 6th week, patients from both groups followed the same postoperative protocol, which overall consisted of progressing ROM exercises until week 12. Strengthening exercises started at week 13 with isometric contractions and progressed to dynamic contractions at week 14. Their findings showed better flexion ROM for early rehabilitation at 3weeks only (early=145° vs conservative=82°); no differences were observed at 6 weeks (early=156° vs conservative= 154°), 12 weeks (early=168° vs conservative=167°), 6 months (early=173° vs conservative=173°) and 1 year (early=176° vs conservative=173°). In addition, a statistically significant difference for function (WORC mean difference = 191; the WORC varies from 0 to 2100 and lower scores imply better function) at 1 year was found, favouring early rehabilitation, and retear rates were similar between groups and not statistically significant. Although their sample size was small, the study had a sound methodological quality following the Cochrane recommendations to avoid bias by using an appropriate method of randomisation, allocation concealment, blinding of the assessor, low dropout rates, reported compliance rates, long-term follow-up and was free of selective reporting (Higgins and Green, 2011).

Houck et al. (2017) and Saltzman et al. (2017) performed systematic reviews of overlapping metanalyses. Houck et al. (2017) classified the review from Riboh and Garrigues (2014) as with the best methodological quality and they concluded, based mainly on Riboh and Garrigues (2014), that early rehabilitation improves ROM but increases retear risk. Saltzman et al. (2017) ranked Chan et al. (2014) as the best review, which agrees with the qualitative analysis using the R-AMSTAR in this chapter (Table

3.3., page 63). Saltzman et al. (2017) also concluded that early rehabilitation is beneficial for ROM but no additional improvement, compared to conservative physiotherapy, is observed for functional outcomes and retear rates.

The article from Nikolaidou, Migkou, and Karampalis (2017) is a descriptive review, the authors did not use any systematic method to search on databases, identify studies or to assess the methodological quality of primary studies. They concluded that there are no differences in outcomes comparing early and conservative; however, their conclusions are biased considering the low methodological quality of their review.

Jung et al. (2018) used systematic methods to identify guidelines, reviews and primary studies. However, little information was provided on their results regarding the quality of the selected studies and why those excluded had low scores and therefore were rejected from the analysis. In addition, they used expert's opinion to formulate their clinical recommendations, which is not optimal and considered the lowest level of evidence for evidence-based practice (Higgins and Green, 2011).

Li et al., (2018) have performed new meta-analyses for flexion and external at short (within 3 months), medium (3 to 6 months) and long-term (more than 6 months) after surgery. The difference between their meta-analyses and those produced in this chapter was the inclusion of the RCT from Mazzoca et al. (2017) and Duzgun et al. (2014) and the exclusion of Koh et al. (2014) for the ROM comparisons, which showed statistically significant differences in favour of early rehabilitation. At short-term, the mean difference between groups was 10.3° for flexion and 8.28° for external rotation; at mid-term the mean differences were reduced to 3.01° and 2.0°, respectively, and at long-term, the mean differences were 1.24° for flexion and 2.24° for external rotation. In their review, they also did not find statistically significant differences for patient-reported outcomes measures and retear rates.

The inclusion of new studies identified by updating the searches could potentially change the meta-analyses results for ROM, especially for flexion at 3 months. The new result could potentially be statistically significant; however, the addition of the two new RCTs would not alter the overall conclusion of this chapter that new high-quality and appropriately powered RCTs are needed. Moreover, none of the new RCTs explored biomechanical outcomes and both still restricted patients to a sling for 6 weeks.

3.7. Literature review summary

The literature review was a thorough analysis of the published evidence on physiotherapy after rotator cuff repairs, which showed no statistically significant differences between the two different approaches; however, the addition of a new study to the meta-analysis of ROM could potentially change this, indicating that early rehabilitation may be beneficial to improve patients' outcomes. It also highlights the low methodological quality of primary studies and that further RCTs are needed. Therefore, chapter 4 described the aims and objectives of an exploratory RCT using not just clinical, but also biomechanical outcomes to fill the gap in the knowledge of how early and conservative physiotherapy impact muscle activity and quality of movement.

CHAPTER 4: AIM AND OBJECTIVES

Based on the literature review it was possible to observe that there are gaps in the literature that need further investigation. Therefore, the aim and objectives of the next study are:

- Aim:

To assess and to compare in a randomised controlled trial at preoperative, three months postoperative and after six months follow-up period: the progression of biomechanical and clinical outcomes of patients who have undergone surgical repair for rotator cuff tears and were randomised to early or conservative rehabilitation.

- Objectives:

1. To characterize the function and quality of life at the 3 time points of patients randomised to early or conservative rehabilitation.
2. To determine the differences in kinematic, EMG and clinical scores between the two groups (Early and Conservative).
3. To determine 3D kinematic changes of the shoulder during ADLs between the 3-time points of patients randomised to early or conservative rehabilitation.
4. To determine the EMG activity of the three parts of the deltoid, upper trapezius and biceps bacchii at the 3 time points for the different tasks of patients randomised to early or conservative rehabilitation.
5. To explore if patients improve outcomes after rotator cuff repairs regardless of when their rehabilitation starts.
6. To explore the relationship between clinical outcomes with biomechanical outcomes.

CHAPTER 5: METHOD

5.1. Introduction

This chapter describes the steps followed to develop the exploratory RCT. This details the trial design, how participants were recruited, characteristics of the intervention, and how randomisation and allocation concealment were performed. Following trial design, information about data collection, procedures for processing biomechanical data and statistical tests used are reported.

Following the rationale of the framework for the development and evaluation of RCTs for complex interventions to improve health, from the Medical Research Council (MRC) (Figure 5.1), chapter 3 fulfil the first step of the framework (theory; pre-clinical) of exploring and establishing the theoretical basis of an interventional study. The theoretical basis is an important step to underpin and select the best choice of interventions and formulate the hypotheses (Campbell et al., 2000). The second step, the modelling stage, was also accomplished as the systematic review allowed the identification of the possible interventions and how interactions may affect outcomes.

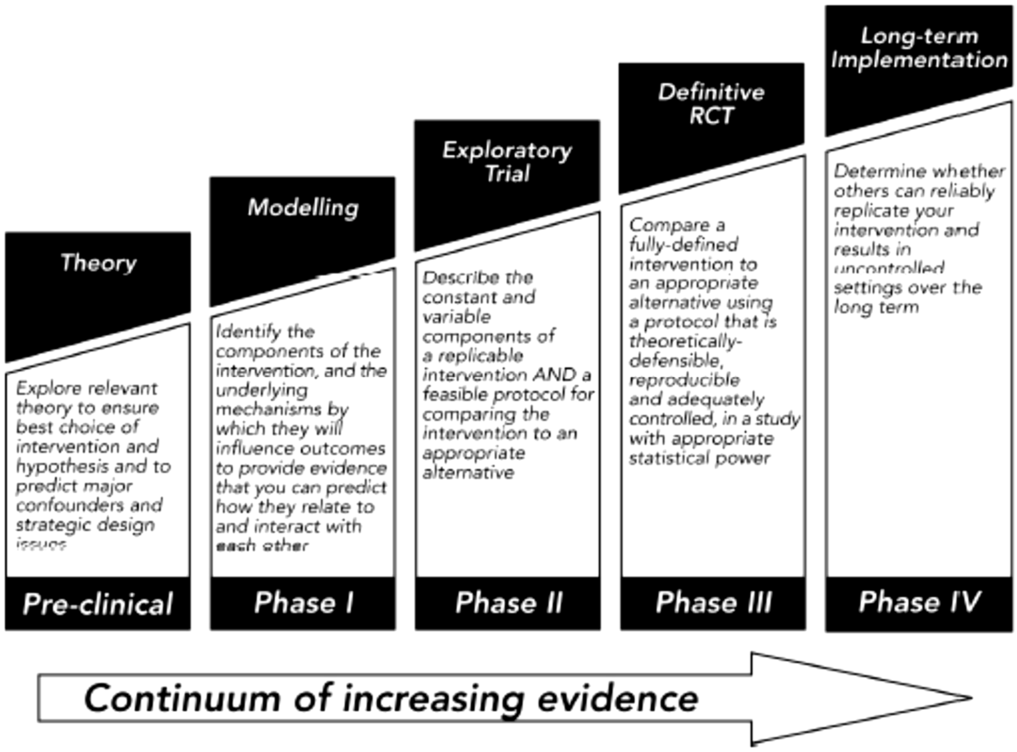


Figure 5.1. The MRC framework with the sequential steps to investigate complex interventions. From Medical Research Council (2000).

The MRC framework was developed in 2000 by members of the Medical Research Council Health Services and Public Health Research Board to serve as a guide for researchers who are planning to implement a trial comprising of complex interventions. A complex intervention can be defined as an intervention that consists of multiple elements that are essential for the intervention to work. These have several interacting components, however, it is often difficult to identify the active components (Campbell et al., 2000). In the case of the effectiveness of early rehabilitation for patients having rotator cuff repairs, it can be defined as a complex intervention due to the range of components that are interacting for a positive, or not, result. Some examples of the components have already been mentioned in section 3.4.6 (Rehabilitation aspects, page 89). Therefore, the steps of the MRC framework were used to guide the development of the project.

5.2. Trial design

After evaluating the available evidence and modelling the protocol, the third step is where the planned treatments are tested. This study was an exploratory trial with a parallel randomised controlled trial design. In order to avoid bias and produce reliable results, the Consolidated Standards of Reporting Trials (CONSORT) statement was followed. The CONSORT statement is a guide to report randomised controlled trials, it includes a checklist to support researchers in describing essential information of every section of a randomised controlled trial necessary for a thorough report. The aim of the CONSORT statement is to make the description of how the trial was conducted and analysed as transparent as possible for the reader (Moher et al., 2010).

5.3. Participants

5.3.1. Eligibility criteria

The inclusion criteria consisted of: patients of both genders, aged between 40 and 70 years old, who were in the waiting list for a rotator cuff repair surgery, with no other previous shoulder surgery on the same side and no other musculoskeletal impairment in the assessed limb or cervical and thoracic spine.

Patients who had a surgical repair which did not allow early mobilisation, who were listed for a rotator cuff repair, but the surgeon decided not to perform a cuff repair during the surgical procedure, who had had previous shoulder surgery and/or other musculoskeletal impairment in the assessed limb or cervical and thoracic spine, people with special needs that were unable to understand instructions or non-English speakers (lack of funding for interpreters) were excluded.

5.3.2. Recruitment

The study ran in collaboration with Wrightington Hospital. The patients' recruitment and screening for eligibility were made on the same day that patients attended their scheduled appointments with the consultant regarding their shoulder symptoms and need for surgery. Potential patients were approached and informed about the study, this included what would happen if they agreed to take part and how their rehabilitation would progress. After understanding the purpose of the study, patients took a copy of the patient information sheet (Appendix 4) and were required to sign the informed consent form (Appendix 5) on the day of the first assessment session, which was either on the same day of the surgery or immediately after their pre-op screening. Before signing the informed consent, the researcher asked if the participant fully understood what the study would involve, this gave the patient the opportunity to ask any questions and to clarify any possible doubts. Figure 5.2. illustrates patients' journey through the trial.

The study was approved by the North West Research and Education Committee in Lancaster (Appendix 6) and by UCLan's research ethics committee (Appendix 7) and was registered on the clinicaltrials.gov database (NCT02631486).

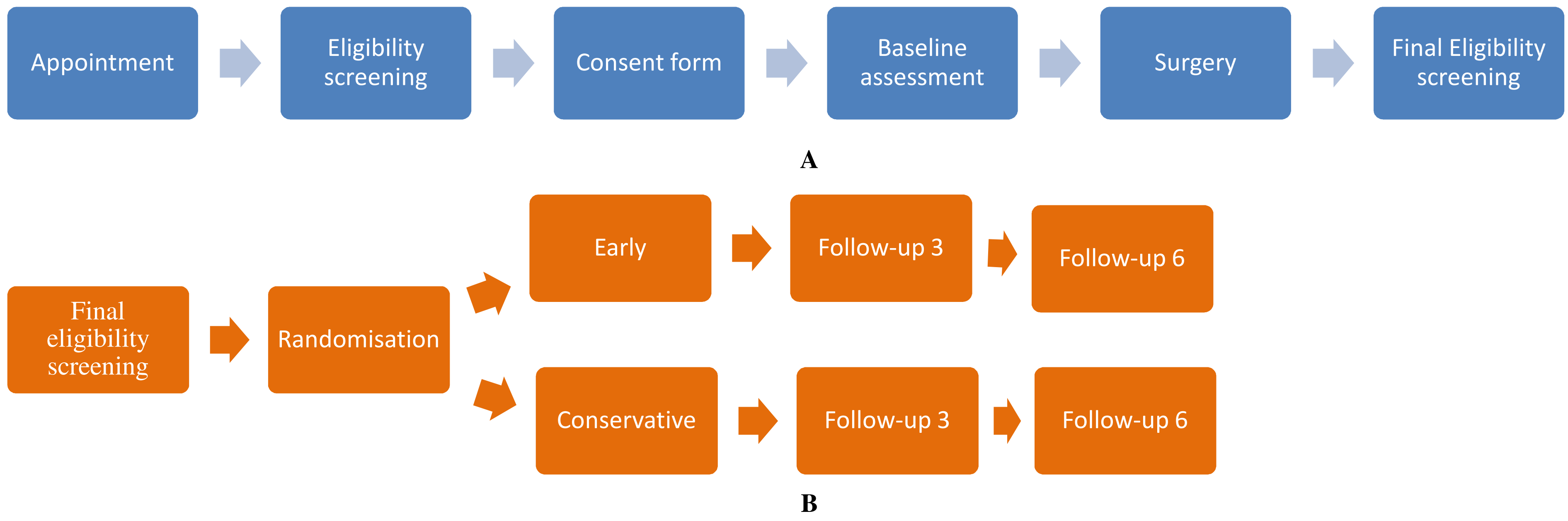


Figure 5.2. Flowchart of patients' journey. A) Initial stage prior to randomisation, B) Group allocation and follow-ups after randomisation.

5.4. Interventions

5.4.1. Operative treatment

All operative procedures were performed in an elective outpatient setting by one of the Upper Limb surgeons at Wrightington Hospital. Patients were operated on by an all-arthroscopic technique under general anaesthesia in a beach chair position. The method used to reattach the tendon was not restricted and was performed according to the surgeons' decision.

5.4.2. Postoperative treatment

The rehabilitation consisted of two groups who received physiotherapy with a planned frequency of once every two weeks for approximately 30-40 minutes, during about 3-4 months, which was in accordance to the normal practice used at Wrightington Hospital. The protocols were developed based on the evidence from the systematic review (chapter 3), especially regarding the number of weeks using the sling. However, due to the great variation found on the components of the protocols described in the primary studies (Table 3.6, page 71), a discussion and consensus with one of the orthopaedic surgeons and the physiotherapy team was sought to develop a protocol using evidence-based practice, where the best evidence available and clinical experience were combined to create an intervention (Sackett et al., 1996). The exercises described in other trials were reviewed regarding muscle recruitment and how much tension they would be applying to tendons. Then, based on the experience of the clinicians, the exercises were allocated to each stage of the protocol considering patients capacity to perform the exercise at each stage. Further discussion on how the protocol was developed is described in section 7.2.2. Physiotherapy protocol, page 180.

Patients who were allocated to the group receiving the early rehabilitation had the protocol as described on the left side of Table 5.1. Patients who were allocated to the group receiving the conservative rehabilitation were treated with the protocol as described on the right side of the same table; the main differences between protocols are described in Table 5.2. All movements and exercises respected patient's limitations, especially pain symptoms (i.e. no movements would exceed the patient's pain symptoms, when the patient started to report pain during the exercise, the therapist would reduce the range to the limit where the patient could comfortably perform the activity) and the safe ROM stipulated by the surgeon.

Table 5.1. Protocol used in the RCT.

	Early Rehabilitation		Conservative Rehabilitation
Stage 1 On Discharge – 4 weeks	• Sling for comfort only • Advice on sling management • Neck, elbow, wrist & hand exercises • Postural awareness and scapula control • Active assisted closed chain ROM in safe zone • Kinetic chain rehabilitation • Thoracic spine ROM' • Avoid combined abduction and external rotation and HBB	**Stage 1** On Discharge – 4 weeks	• Sling 6 weeks, if abduction wedge then reduce to standard sling at 2-3 weeks • Advice on sling management • Neck, elbow, wrist & hand exercises • Postural awareness and scapula control • Active assisted closed chain ROM in safe zone • Kinetic chain rehabilitation • Thoracic spine ROM • Avoid combined abduction and external rotation and HBB
Stage 2 4-6 weeks	• Progress from active-assisted to active ROM beyond safe zone (short to long lever). • HBB within limits of pain • Begin cuff control exercises and submaximal (approx. 30%) isometric strengthening in neutral through available range	**Stage 2** 4-6 weeks	• Continue with stage 1 • Light proprioceptive exercises • Remain in sling
Stage 3 6-8 weeks	• Commence open chain rotator cuff strengthening (short to long lever) • Active short lever kinetic chain rehabilitation of the affected arm progressing to long lever function movement • Begin stretching into combined movement ranges	**Stage 3** 6-8 weeks	• Wean from sling • Progress active-assisted ROM beyond safe zone (short to long lever). • HBB with limits of pain • Begin cuff control exercises and submaximal (approx. 30%) isometric strengthening in neutral through available range

Continue

Table 5.1(continue). Protocol used in the RCT.

Early Rehabilitation		Conservative Rehabilitation	
Stage 4 8-12 weeks	• Progression of full kinetic chain rehabilitation • Progression of stretching • Patient-specific functional/sports training • Begin combined abduction and external rotation	**Stage 4** 8-12 weeks	• Commence open chain rotator cuff strengthening (short to long lever) • Active short lever kinetic chain rehabilitation of the affected arm progressing to long lever function movement • Begin stretching into combined movement ranges
Stage 5 12 weeks +	• Continue and progress with stage 4 • Manual therapy to address ROM deficits	**Stage 5** 12 weeks +	• Begin combined abduction and external rotation • Full kinetic chain rehabilitation • Patient-specific functional/sports training • Manual therapy to address ROM deficits
	Milestones		**Milestones**
Week 4	• ROM 75%-80% of normal, sling discarded, return to driving as able, return to sedentary work	Week 8	• ROM 75%-80% of normal, sling discarded, return to driving as able, return to sedentary work
3-6 months	• Full active ROM, can consider return to non-contact sport. • Return to manual work as guided by surgeon/physiotherapist	3-6 months	• Full active ROM, can consider return to non-contact sport. • Return to manual work as guided by surgeon/physiotherapist
6 months	Unrestricted activity	6 months	• Unrestricted activity

HBB: hand behind back.

Table 5.2. Main differences and similarities between protocols at each stage.

Stage	Differences
Stage 1	At stage 1, patients in the Early group would use the sling for comfort only, while the Conservative should remain in the sling and remove to perform the exercises only. At this stage, both groups would perform active-assisted ROM respecting the safe zone.
Stage 2	At stage 2, the Early group would discard the sling completely if still sporadically using it. In addition, the Early group would start active exercises and progress ROM beyond safe zone. Patients in the conservative would continue with stage 1 and add proprioceptive exercises.
Stage 3	The main difference at stage 3 would be the implementation of stretching and progression of active exercises from short to long lever arm for the Early group. The Conservative group would start Early group stage 2.
Stage 4	At stage 4, the Early group would start training sports-specific activities and exercises incorporating the full kinetic chain. The Conservative would start the Early group stage 3
Stage 5	In the last stage, patients in the Early group would be progressing exercises and components of Stage 4, while the Conservative group would be starting sports-specific activities and exercises incorporating the full kinetic chain.

5.5. Randomisation and allocation concealment

A sequence of random numbers to determine a patient's group allocation was generated by an independent research team member, who had no involvement in treating or assessing the patients. The numbers were created using a random number generator (www.randomization.com) into blocks of ten, which means that for every ten, five patients would be assigned to each group (Appendix 8). The block randomisation method was chosen to create an equal distribution in each group (Kim and Shin, 2014). Following the creation of the random numbers list, the same investigator was responsible for the allocation concealment, which was completed by inserting the grouping information into opaque sealed envelopes.

Every patient who was approached who fitted the inclusion criteria and agreed to take part in the study had the initial biomechanical assessment performed. However, if the surgeon during the operation observed that the footprint was not safe enough for early rehabilitation (i.e.: the repair was not tension-free) or whether the patient did not need to have the repair, the patient did not receive an allocation number and therefore was excluded from the trial. Moreover, allocating the numbers after the surgery allowed the blinding of the surgeon, which avoided possible bias.

Following surgery, if the repair was suitable for the trial, a physiotherapist who was not involved in other stages of the study opened the respective envelope to allocate the patient to one of the two rehabilitation groups. Depending on the group the patient was assigned, the therapist gave advice on sling management and details about which exercises they should carry out at home until their first individual session at the outpatient department (Appendix 9). Prior to starting the trial, it was determined that every patient would have to receive the rehabilitation regime at Wrightington physiotherapy department; however, many patients were from other areas that are not close to the hospital, therefore travelling to Wrightington for physiotherapy sessions was not always convenient. This issue resulted in a low recruitment rate during the initial stage of the study, which then had to be revised to increase the number of patients recruited. Hence, after the first contact with one of the physiotherapists from Wrightington, patients could choose where they preferred to be referred, then the respective protocol was sent to their local physiotherapist. Allowing patients to have their treatment in places other than Wrightington led to the decision of carrying further intention-to-treat analysis, as per the protocol, as it was not possible to control their treatment with the level of detail required.

5.6. Procedures

Three assessment sessions were planned for each patient; a baseline, which was recorded before surgery; the first follow-up at 3 months post-surgery and the second follow-up at 6 months post-surgery. The follow-up time points were chosen according to previous studies (Keener et al., 2014; Koh et al., 2014), and based on the timings for routine follow-up appointments at the consultant's clinic.

Each assessment session consisted of completing two questionnaires and a biomechanical assessment whilst performing six movements, which are described in Table 5.3. Functional outcomes were assessed with the Oxford Shoulder Score and the EQ-5D-5L; which were further scored according to their reference specifications, as discussed section 2.5 (pages 25-29). The rationale for choosing these questionnaires was their reliability to assess the targeted population, the fact they were self-reported which avoided assessor bias, and low administrative burden; in addition, these questionnaires also have a good level of acceptance by health professionals in the UK.

Table 5.3. Range of motion tasks.

Task	Description	Movement involved	Instructions to patient
1) Combing	Simulated combing movement taking the hand to the back of the head.	Shoulder abduction (coronal plane) combined with external rotation (transverse plane).	Starting with your arm besides your leg, keep your elbow straight and take your hand to the top of your head, as far as your pain allows, slide it to the back of your head and return to the start position.
2) Abduction	Maximal abduction in the coronal plane.	Abduction only (coronal plane).	Starting with your arm besides your leg, keep your elbow straight and raise your arm to the side of your body as far as your pain allows, if possible, go above your head's height and return to the start position.
3) Carrying	With the arms resting besides the body, the participant took a dumbbell to the furthest point in a horizontal shoulder abduction and adduction movement with the elbow in complete extension.	Horizontal shoulder adduction and abduction (transverse plane).	Starting with your arm besides your leg, keep your elbow straight and raise your arm in front of you until you reach your shoulder height. Then, move your arm across your body as far as your pain allows. Next, take your arm as far as your pain allows to the opposite direction, maintaining it at your shoulder height. Return to the middle position and then return to the start position.
4) Reaching	The participants tried to reach their opposite back pocket.	Shoulder extension (sagittal plane) combined with internal rotation (transverse plane)	Starting with your arm besides your leg, try to reach the opposite pocket of your trousers, or as far as your pain allows, and return to the start position.
5) Flexion	Maximal forward flexion and extension in the sagittal plane.	Flexion only (sagittal plane)	Starting with your arm besides your leg, keep your elbow straight and raise your arm in front of you as far as your pain allows, if possible, go above your head's height.
6) Lifting	With the arm resting beside the body, the participant raised a dumbbell (1 kg) to the highest point above the head.	Flexion only (sagittal plane)	Same as task 5.

The biomechanical assessment used two different measurement systems: The Xsens MVN system (Xsens Tech®, Enschede, Netherlands) and the Trigno (Delsys®, Boston, USA) wireless EMG system. The Xsens/MVN system (Xsens Tech®, Enschede, Netherlands) was used to analyse 3D movements of the shoulder. The system was composed of 9 inertial sensors, with an acquisition sampling frequency set at 120 Hz, which is the highest rate possible for this system. The movements were performed at a comfortable speed for the participant, therefore the sampling frequency was considered appropriate for tracking the movements chosen. Each sensor has the dimension of 38 x 53 x 21 mm and weighs 30g (Figure 5.3 A) and houses a 3D accelerometer, 3D gyroscope and a 3D magnetometer. The information recorded by all sensors were synchronised and delivered by two Xbus masters (Figure 5.3 B) and received by two MVN WR-A which store the information in the computer (Figure 5.3. C).

A B C

Figure 5.3. A) MTx inertial tracker, B) Xbus Master, C) MVN WR-A.

Prior to starting the data collection, the calibration procedure was performed and only the upper body configuration was used. The sensors were placed on the back of the head, on top of the scapula spine, upper arms, forearms, hands, sternum and sacrum. All sensors were attached to the participant's body with Velcro® strips and were placed over the clothes (Figure 5.4). The sensor placement, body acquisition configuration (*upper body*) and calibrations procedures followed the recommendations from the equipment manual (MVN user manual, 2010).

A **B**

Figure 5.4. Xsens sensors placement, A) front view, B) back view.

The Trigno (Delsys®, Boston, USA) wireless EMG system was used to measure muscle activity (Figure 5.5). This was composed of 6 sensors with dimensions of 37mm x 26mm x 15mm with electrode bars made of silver set at a distance of 10 mm in a bipolar, single differential configuration (Figure 5.6). The sensors are non-invasive and record muscle activity through the skin surface. The acquisition frequency was set at 2000 Hz; the rationale for the frequency selection was based on the Nyquist theorem which states that for a given sinusoid signal to be correctly reproduced, a minimal acceptable acquisition sampling frequency of no less than twice the real signal frequency is necessary. If the acquisition frequency is too low in relation to the real signal, it will result in what is called aliasing, i.e.: a distortion of the real signal (De Luca, 2003). Moreover, this method has been endorsed by the International Society of Electrophysiology and Kinesiology (Merletti, 1999). The real spectrum frequency of the muscle signal ranges from 0 to around 500 Hz, therefore setting the acquisition rate at 2000 Hz satisfies the number needed to record reliable EMG data (De Luca et al., 2010). The common mode rejection ratio was >80 dB with a signal-to-noise-ratio <0.75 µV; these values are set by default on each electrode, both parameters are used to verify the signal quality and avoid noise contamination.

Figure 5.5. The Trigno (Delsys®, Boston, USA) wireless EMG system.

A **B**

Figure 5.6. Trigno sensors, A) anterior view, B) posterior view.

The muscles chosen were the three portions of the deltoid, upper trapezius and biceps brachii (Figure 5.7). These muscles were selected as they are easy to access, are superficial and because they are sensitive to changes to the rotator cuff muscles activation associated with the chosen movement tasks, as described in section 2.6., page 29. Therefore, they are able to depict relevant information to compare pre and post-surgery. Electrodes were positioned over the muscle belly to reduce crosstalk after the skin was cleaned with alcohol wipes to reduce impedance and improve signal detection. The sensors positioning followed the SENIAM recommendations (Hermens et al., 1999). Apart from the sensors used to measure muscle activity, one extra Trigno sensor was placed on top of the Xsens inertial sensor located on the dorsal side of the participant's hand. Both sensors on the hand were used to synchronise the data from the different equipment, as each system required a standalone computer and digital synchronisation was not possible. Further information on how the data was synchronised and processed is described in sections 5.6.1 and 5.6.2.

A B

Figure 5.7. EMG sensors placement, A) front view, B) side view.

Demographic data were recorded including age, weight, height, surgery features, smoking habits and if they were diabetic. Patients were assigned an ID number after recruitment to anonymise the data.

The movements that were assessed with the biomechanical equipment are described in Table 5.3. The decision about using tasks with an ordinary range of motion is based on what is generally used in the clinical assessment with goniometers. Moreover, these movements were also commonly measured in the primary studies of the systematic review. The other ADLs were chosen aiming to mimic tasks that are common in peoples' routine (Garofalo, 2010; Parel, 2012; Kolk et al., 2017).

Every participant was asked to perform each task five times, at a comfortable self-selected speed, only with their affected arm. The assessment sessions were carried out by the PhD candidate, in a standard room of the outpatient clinic. The time taken for each assessment was about 30 minutes. The tasks' order was random; thus, potential fatigue would not impact a specific task. The assessor was blinded to participants' group allocation until the final data analysis of the trial.

5.7. Biomechanical data analysis

5.7.1. Kinematics analysis

The kinematic data was recorded using the MVN Studio 3.5.3 software (Xsens® b.v., Enschede, The Netherlands) and exported as mvnx files; these files contained the information to reconstruct body segments and their respective tracked motion (Figure 5.8). Following the data export, the files were imported into Visual 3D version 6 (C-motion, Inc., Germantown, MD, USA) using a sequence of commands which was created by Xsens in partnership with C-motion. The sequence of commands, called pipeline, read the 3D information and applied a model that allowed the analysis of joint angles in 6 DOF and other kinematic variables. Each inertial sensor provides information (angular velocity and acceleration) which is assigned to a segment. In order to create joint angles for the shoulder, the angular velocity measured by the gyroscope of the sensor attached to the humerus was used in relation to the sensors attached to the sternum; by integrating the angular velocity over time, the angular velocity provides the change in angle with respect to an initially known angle (Roetenberg, Luinge, and Slycke, 2013). The initial known angle is defined by two steps: 1) enter anthropometrical data such as height and arm span and 2) by performing the initial calibration which consisted of maintaining a static standing position for 5 seconds

(Figure 5.3.A). The first step is used to scale the segments according to patients' body dimensions and the second step defines the initial position of the segment which is used as the starting point to calculate the changes in angular displacement.

The coordinate systems of both humerus and thorax were defined as the X-axis as anterior/posterior, Y-axis lateral/medial and Z-axis superior/inferior (Figure 5.8 and 5.9). For the X-axis, abduction was considered positive and adduction negative, for the Y-axis, flexion was positive and extension negative and for the Z-axis, external rotation was positive and internal rotation was negative.

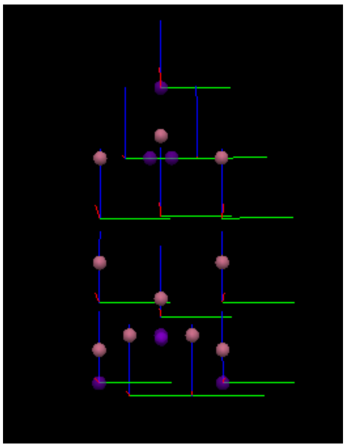


Figure 5.8. Example of points imported to Visual 3D from the mvnx file used to recreate body segments.

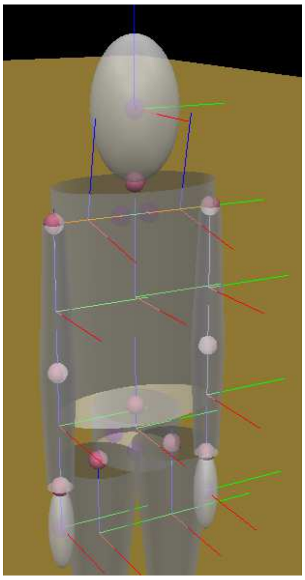


Figure 5.9. Coordinate system of the thorax and humerus using the model created in Visual 3D; red, green and blue respectively represent X, Y and Z axes.

The Cardan sequence to express joint angles of movements occurring mainly in the sagittal and transverse planes was Y-X-Z; for those that were mainly in the coronal plane, the sequence was Z-X-Z, as recommended by the International Society of Biomechanics (Wu et al. 2005). Therefore, the Cardan sequence for tasks 3, 4, 5 and 6 was Y-X-Z, while tasks 1 and 2 used Z-X-Z. The Cardan sequence is a method used to describe 3D joint movements. The final joint angle is defined by an order of rotations around the three different axes (x, y and z) (Phadke et al., 2011). For instance, the first Cardan sequence used for the sagittal plane in this thesis (Y-X-Z) indicates that first, the upper arm rotates around the Y-axis, then rotates about the X-axis and lastly rotates about the Z-axis. If a different sequence is used, for example X-Z-Y, the final joint angle will be different and therefore the results are not comparable (Phadke et al., 2011). Thus, it is recommended that the International Society of Biomechanics standards should be followed to produce data that are comparable across studies in the area (Wu et al. 2005) (see also section 2.7, page 32).

After applying the model and defining their respective rotation sequences, joint angles were created and plotted as a function of time. However, because the duration of trials was different among participants, time was normalised as percentage, from 0 to 100. In addition, to be able to compare the same instant of each repetition for the same individual and among individuals, events were created to define the same moments on every file. Every task started in an initial position with the patient standing and both arms beside their thorax. The events for the tasks are illustrated and highlighted in blue on the right side of Figures 5.10 to 5.18.

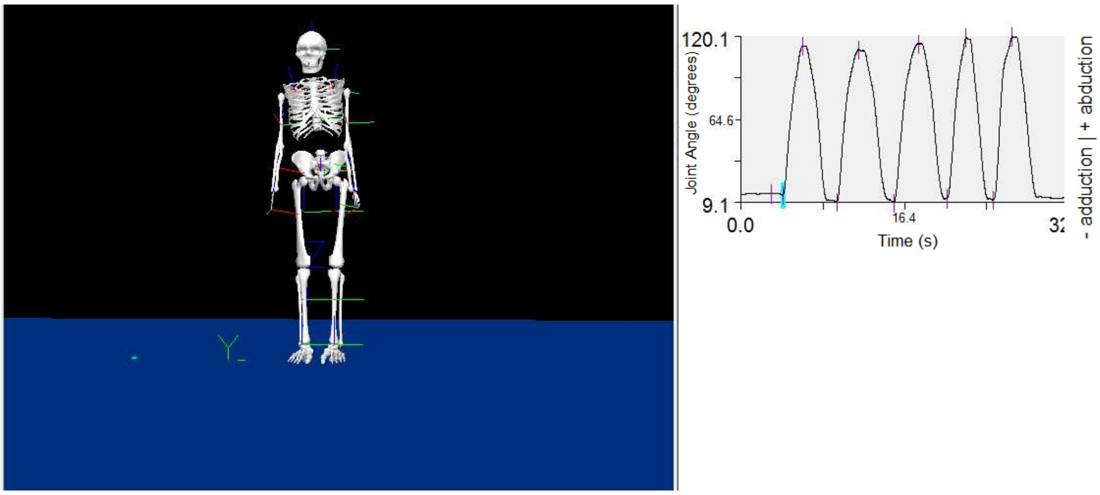


Figure 5.10. Initial event for the tasks combing and abduction.

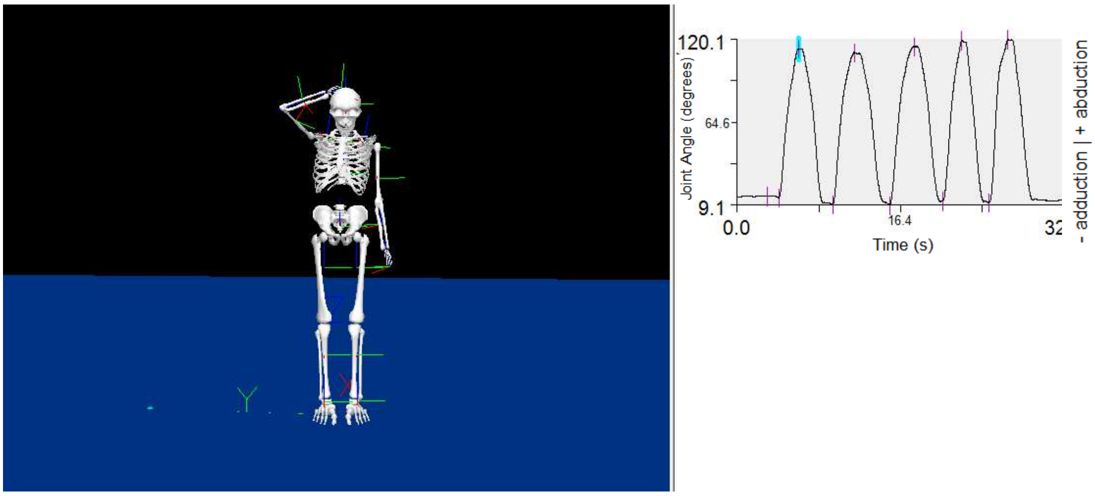


Figure 5.11. Final event for the task combing.

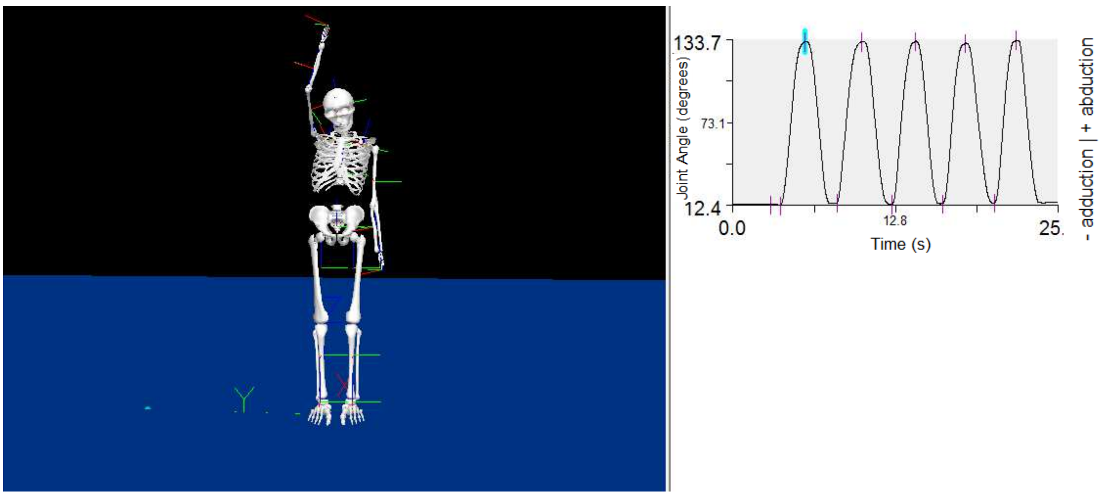


Figure 5.12. Final event for the task abduction.

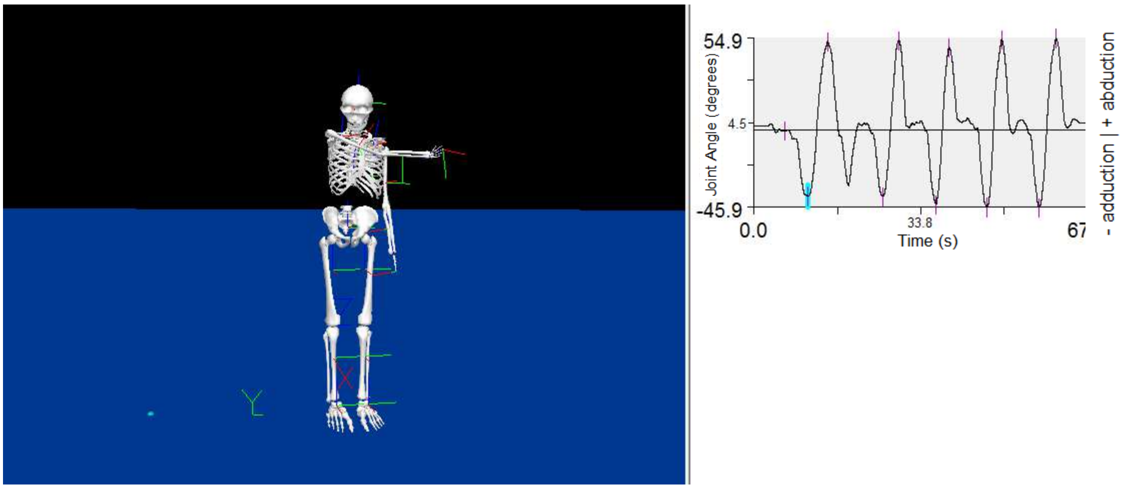


Figure 5.13. Initial event for the task carrying.

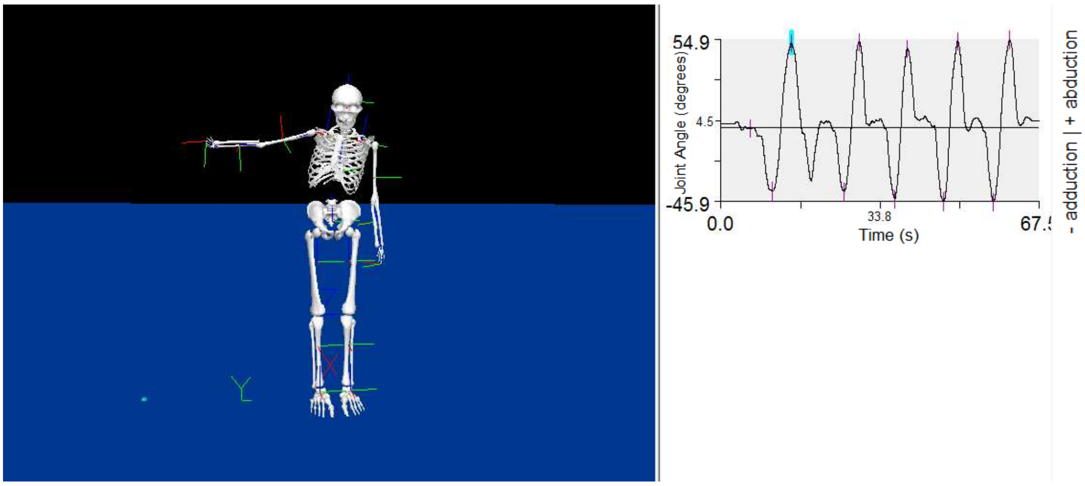


Figure 5.14. Final event for the task carrying.

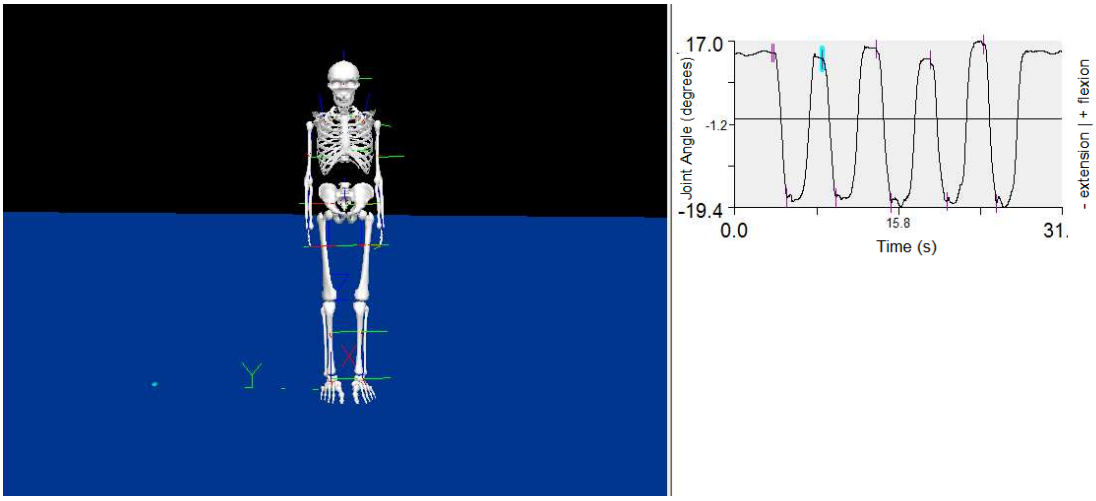


Figure 5.15. Initial event for the task reaching.

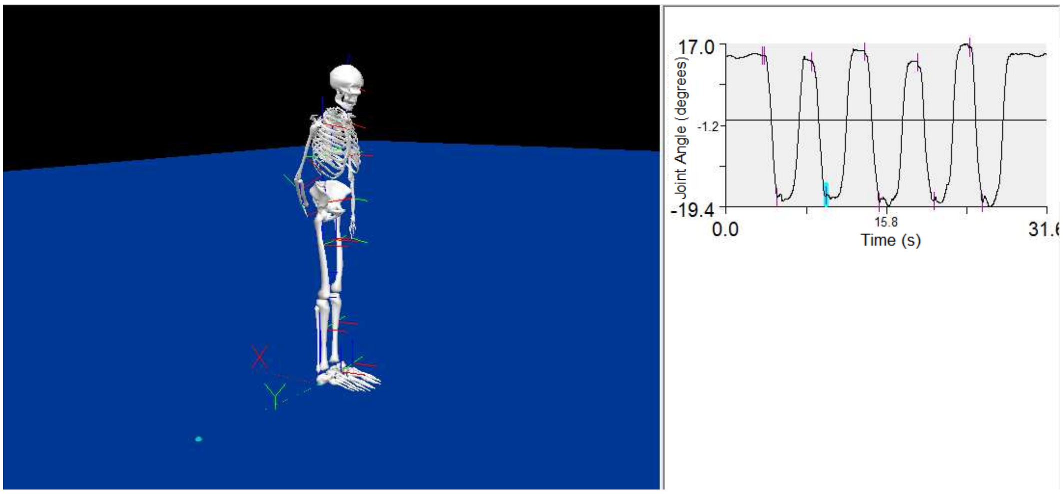


Figure 5.16. Final event for of the task reaching

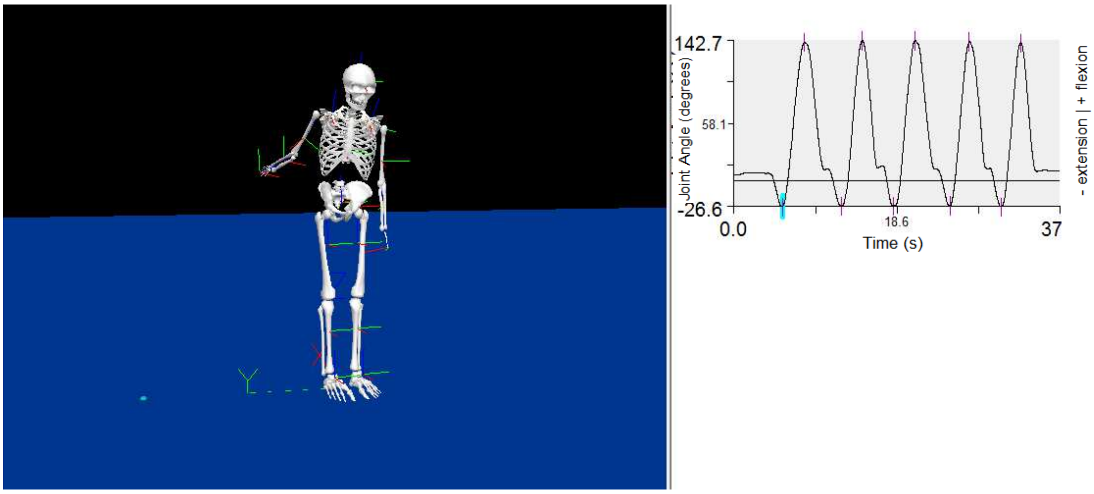


Figure 5.17. Initial event for the tasks flexion/extension and lifting.

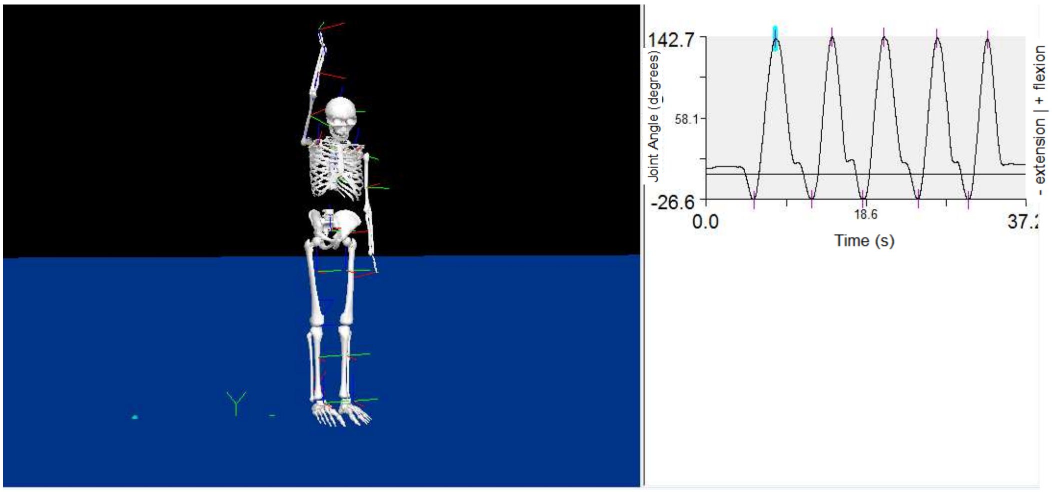


Figure 5.18. Final event for the tasks flexion/extension and lifting.

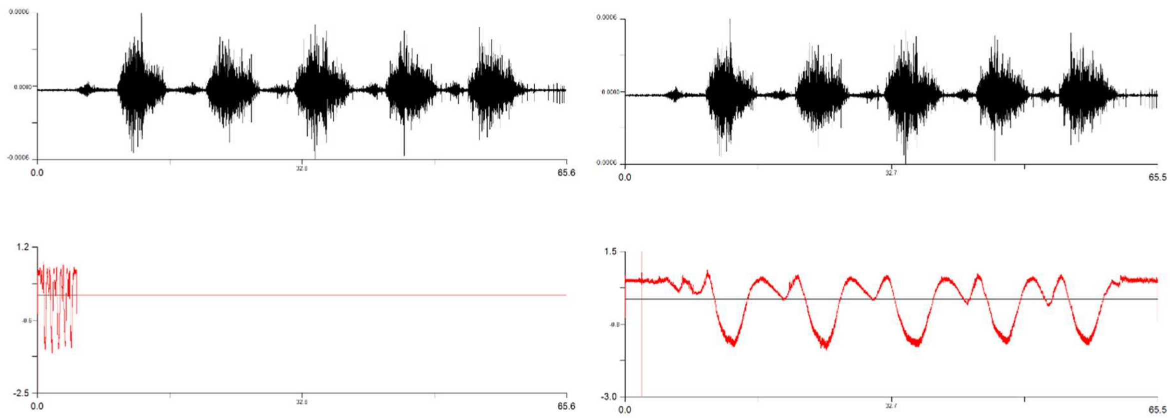
The initial events were identified using the Visual 3D pipeline command *Event_Minimum*, while final events were identified with the pipeline command *Event_Maximum*. Based on these two events the total ROM was calculated. No filtering was applied to the kinematic data. Although for some tasks such as flexion/extension and abduction choosing to not filter is unlikely to have influenced the identification of the starting and ending events. However, for other tasks such as reaching, where greater noise can be observed (Figure 5.16), not filtering the data may have subtly affected data variability. However, every trial was checked to ensure the events were correctly identified by the pipeline command, and other irrelevant and unsuitable events for the analyses were deleted. The optimal filter frequency for kinematic data collected using inertial systems is unknown, it is usually a decision made by comparing the filtered data to the raw data, therefore it is challenging to identify the frequency where the filter is removing noise and when it starts to remove relevant data (Schereven, Beek, and

Smeets, 2015). Thus, we decided not to filter the kinematic data to avoid removing information that could be meaningful to the analyses.

5.7.2. Electromyography analysis

Each EMG sensor used a bandwidth filter, which was set at 450 Hz for the low pass and at 20 Hz for the high pass bands. The bandwidth filter used improves EMG signal quality by reducing possible background electrical noise which is not associated with muscle activity. The low pass filter frequency was defined based on the threshold where noise may distort the EMG amplitude, which is typically around 400 to 450 Hz; the high pass filter is set at 20 Hz to remove movement artefacts and has a negligible effect on the EMG activity (De Luca et al., 2010).

The first step of the EMG analysis consisted of removing the mean from the signal, which was used to remove any offset observed on the signal. The accelerometer data from the Trigno sensor, which was required for synchronisation of the two systems, was recorded at 150 Hz, however in order to bring this data into Visual3d, it was essential to up sample the accelerometer data from the Trigno sensor to 2000 Hz, therefore the final length of both data files (EMG and accelerometer) were the same (Figure 5.19).



A B

Figure 5.19. Effect of resampling the accelerometer data for frequency matching. A) Accelerometer data at 150 Hz, B) Accelerometer data at 2000 Hz.

The next step required was the synchronisation of the EMG and kinematic files, therefore allowing the muscle activity to be described in relation to the movement patterns. In order to remove the time differences between files, the sharp disturbance observed on the accelerometer data of the Xsens and Trigno sensors located on the participant's hand was used. The sudden change observed on the data was produced by lightly tapping the top of both sensors at the same time, which was performed by the assessor, before starting each task. The lowest points observed on the accelerometer data of Xsens and Trigno sensors were identified using the Visual 3D pipeline command *Event_threshold*. This command identifies when a signal crosses a set threshold value, which for this thesis experiment was 2 standard deviations of the mean value of the entire signal (Figure 5.20) (Xu et al., 2013). Every signal was manually checked to ensure the lowest point was correctly identified by the software. This was a pragmatic solution used to synchronise the data from both systems which couldn't be done with a trigger. Identifying an event by setting a threshold value is a common method used in biomechanics, especially when trying to detect muscle activity onset and offset points (Xu et al., 2013). Further statistical tests were not used to check the accuracy of the synchronisation between systems, which may have introduced a time delay between the EMG and kinematics signals; however, as previously mentioned, every file was manually checked to correctly identify the starting point.

By adjusting the time difference between the data from both sensors, it was possible to translate the initial and final events to the muscle activity data for each repetition created from the joint angle data; thus, it was possible to match the muscle activation pattern to the movement profile.

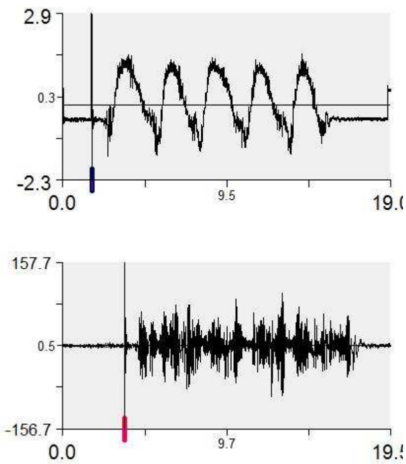


Figure 5.20. Events created to synchronise EMG and kinematics based on the disturbance observed on accelerometers data.

After creating EMG events, the EMG linear envelope was computed for the raw EMG signal by rectifying and applying a low-pass filter of 10 Hz. The EMG envelope is applied to smooth the raw signal and create the muscle activation profile which was further used to calculate the EMG related variables. The filter frequency was defined based on the velocity required from patients to perform tasks, which was self-paced (comfortable speed). Therefore, no movements were performed at fast speeds, which makes the choice of 10 Hz a sensible frequency selection that is suitable for creating and exploring EMG profiles, but at the same time it is not too strict to a point that could drastically reduce EMG variability and remove real data (Shiavi, Frigo, and Pedotti, 1998; Hug and Tucker, 2017). Other methods such as the Root Mean Square (RMS) can be used for data smoothing; however, when analysing the onset and offset phases of a muscle, it is appropriate to use the linear envelope (Figure 5.21) (Hug and Tucker, 2017). The low-pass filter is less affected by different cut-off frequencies and therefore it is less prone to shifting the detection instant that muscles start and stop their recruitment (Figure 5.22). Meanwhile, the window width for the RMS must be carefully considered as the values applied may cause drift in the events (Figure 5.23). Furthermore, considering that different studies may use the linear envelope as their method of EMG processing, even if the cut-off frequencies are different, the results may be directly comparable. Nonetheless, when using the RMS direct comparisons might be a handicap (Hug and Tucker, 2017).

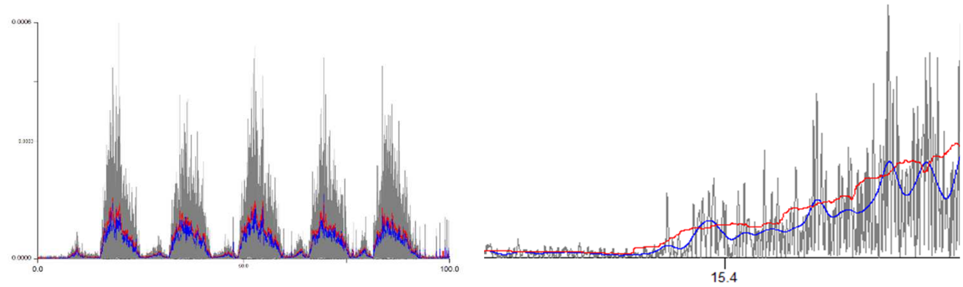


Figure 5.21. Example of phase shift when using RMS. The left figure is the entire trial with 5 repetitions; the right figure is a zoom-in on the starting phase of the first repetition. The grey lines represent the rectified EMG signal, the blue line is the linear envelope and the red line is the RMS.

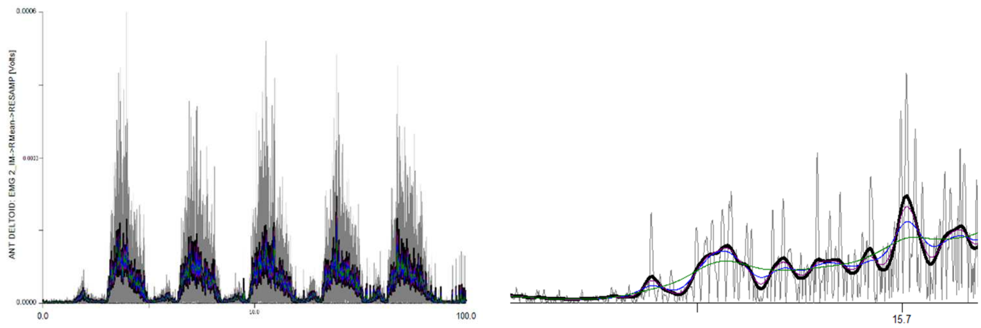


Figure 5.22. Example of different cut-off frequencies. The left figure is the entire trial with 5 repetitions; the right figure is a zoom-in on the starting phase of the first repetition. The grey lines represent the rectified EMG signal, the green, blue, purple and black lines are, respectively: 5, 10, 15 and 20 Hz filters.

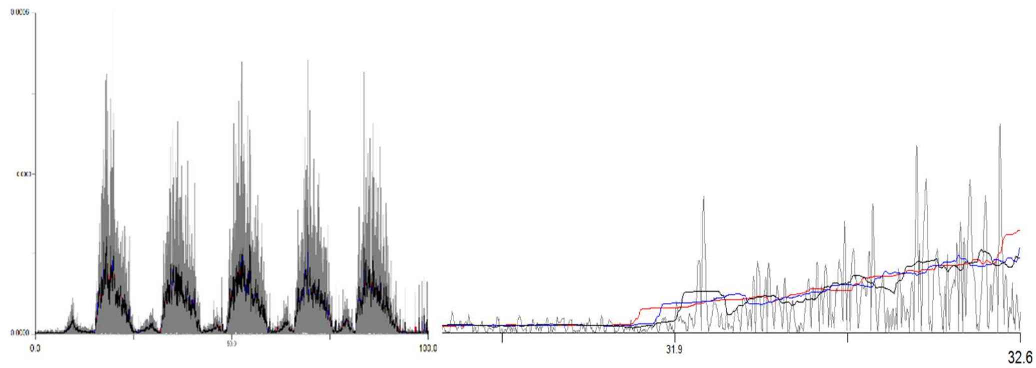


Figure 5.23. Example of different RMS windows. The left figure is the entire trial with 5 repetitions; the right figure is a zoom-in on the starting phase of the first repetition. The grey lines represent the rectified EMG signal, the black, blue and red lines are respectively 100, 200 and 300 ms.

After creating EMG events which were matched to the kinematic events, the EMG integral was calculated by the sum of the area under the curve of the rectified EMG signal between the initial and final events. The integral was used to determine the amount of work that each muscle was performing during tasks (De Luca, 2006). The EMG integral was exported from Visual 3D and imported to Microsoft Excel, where the calculation was performed. In order to make data comparable among individuals, the EMG was normalised for each muscle based on its maximum observed activity during all repetitions over all tasks, therefore it was possible to stipulate how much patients were recruiting their muscles during the movement in relation to the maximum activity observed. One of the most common methods of normalising EMG data is using the maximum voluntary isometric contraction (MVIC) (Suydam, Manal, and Buchanan, 2017). However, this method requires that individual muscle tests are performed to set their supposed maximum effort. Considering that in this study 5 muscles were recorded, it would be necessary to perform 5 muscle tests for each participant, which would make the assessment sessions more time-consuming. Moreover, if this method was chosen, the data collected at baseline would possibly be overestimated, because before surgery patients were experiencing higher pain levels in comparison to follow-up. Therefore, their maximum voluntary contraction would be inhibited by pain and the values observed during task trials would be close or even surpass 100%. Another drawback is that with the MVIC the peak value would be produced during an isometric contraction, while the tasks tested were dynamic and therefore used concentric and eccentric muscle actions (Suydam, Manal, and Buchanan, 2017).

There is much debate about what is the best method of normalising EMG data (Suydam, Manal, and Buchanan, 2017). Using the maximum peak obtained from all tasks is a pragmatic solution, the whole signal is normalised in relation to a dynamic contraction and the overall peak, regardless of what task. This point is where the muscles worked the hardest and therefore is likely to be its maximum effort (Halaki and Ginn, 2012).

Although the 10Hz frequency appeared to be a good option for filtering the EMG data, some noise was still present and were clearly observed as sudden spikes in the signal (Figure 5.24). When an isolated noise spike was observed in the EMG data, that was clearly not the maximum peak, the spike's data range was removed by using the pipeline command *Set_Data_To_New_Values*, this command allows the replacement of specific values. The value used to replace the removed spike data point was an average value that was calculated based on the other repetitions within the same trial. The presence of spikes can be explained due to the filtering selection, if lower frequencies than 10 Hz were chosen, the spikes could potentially be detected and removed by the filter; however, using a lower cut-off frequency also implies that actual muscle activity could potentially be removed together with the noise and valuable information about muscle activity could be lost, as discussed previously in the last paragraph of page 122.

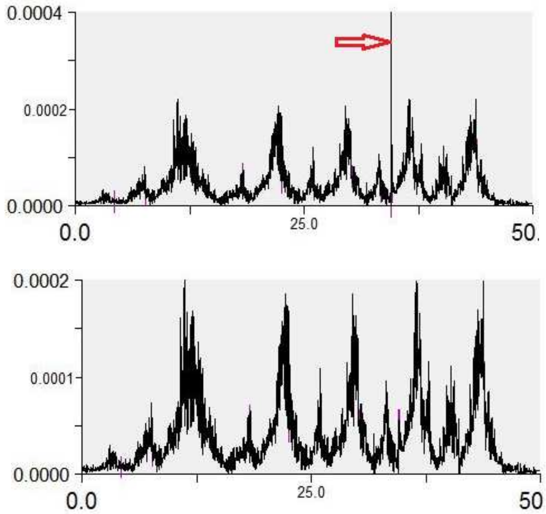


Figure 5.24. EMG signal before (top) and after (bottom) removing an isolated spike.

5.8. Sample size calculation

Little information exists on 3D kinematics of the shoulder during recovery from rotator cuff injuries. However, Keener et al. (2014) determined, using goniometry, the changes through a rehabilitation program similar to the method proposed. The RCT from Keener et al. (2014) tested early and conservative rehabilitation after rotator cuff repairs (more details in Table 3.6, page 70) and assessed ROM at baseline, 3, 6 and 12 months, which is similar to the scheduled follow-up points chosen for this thesis RCT. Based on this study, it was determined that 14 patients are needed in each group to detect an important difference of 25° of forward flexion range of motion, with a standard deviation of 23.6° at the 5% significance level, with 80% power; adding 20% for eventual follow-up loss, the final total sample needed is 34 participants. Although in their study they found a difference of 13° difference between groups, we estimated that 25° would represent a clinically important difference considering the high variability on ROM of this study and other similar trials (Figure 3.14 and 3.15).

It is noteworthy that because this is an exploratory study, its results can be used to calculate the sample size for further definitive RCTs. The sample size calculated above aims to estimate the potential number of individuals needed to observe possible clinically important differences.

5.9. Statistical analysis

Based on the study features of two independent groups (early or conservative) and 3 time points (baseline, 3 months and 6 months), the statistical analysis followed a mixed ANOVA method. For this design, the multiple time points were defined as the within-subject factor and the between-subject factor was defined as the treatment groups. First, the Shapiro-Wilk test was used to check for data distribution at baseline and follow-ups. Independent t-test were performed to check for differences between variables at baseline. When baseline differences were found between groups, or the data variability was high, the baseline values were used as a covariate to adjust the values and improve the precision of the ANOVA (Zhang et al., 2014). After deciding how to model the test, the mixed ANOVA was used to check for interactions between groups, time points or group and time points. The repeated covariance type was performed using the autoregressive heterogeneous method, this assumption verifies how the repeated measures relate to each other and their variance at each time point. The autoregressive heterogeneous method considers that the variance at each time point is constant and the covariance among measurement times are different. The reasoning for selecting this method was based on the restricted log likelihood which estimates the fitting criteria, where lower values mean better fitting criteria (Kincaid, 2005).

When statistically significant interactions were observed further tests were undertaken. However, due to the number of patients in each group non-parametric tests were chosen (Dancey and Reidy, 2004). Therefore, for repeated measures the Friedman test was applied; for independent between groups comparisons at isolated time points the Mann-Whitney U test was used and for within group comparisons between time points the Wilcoxon test was chosen.

To further investigate the relationship between clinical and biomechanical outcomes, the Pearson's correlation was applied using the OSS and ROM. The task chosen to include the ROM data for the correlation was Lifting; the decision of choosing Lifting was because this task showed the greatest mean difference between groups at 6 months follow-up, and between the follow-up at 6 months and baseline. The reasoning to choose the OSS instead of the EQ-5D was also based on the differences between groups at 6 months, and the differences between follow-up at 6 months and baseline.

The analysis was not performed to show discrepancies between groups, therefore, it did not consider patients group allocation. The objective was to explore the relationship between clinical and biomechanical outcomes. The strength of the correlation coefficient was classified as following: weak (0-0.3), moderate (0.4-0.6), strong (0.7-0.9) perfect (1) (Dancey and Reidy, 2004).

5.10. Pilot study

Before applying the biomechanics assessment on patients, and for further comparison purposes, a pilot study was carried out with subjects who did not have a history of shoulder symptoms, this enabled the exploration of how much residual impairment patients may still present at 6 months. These data were recorded to a) develop the protocol for the patient data collection and b) to serve as a comparison between healthy participants and the two arms of the RCT. The rationale is that early rehabilitation may provide extra benefits in relation to conservative, which will translate to better ROM at 6 months after surgery, therefore showing a smaller gap between patients in the Early group and normal subjects when compared to the difference between patients in the Conservative group and healthy participants.

For the pilot study, a convenience sample of 15 subjects was assessed. The inclusion criteria consisted of people of both genders, aged between 40 and 70 years old, which is the same age range as the majority of patients with rotator cuff tears. Potential participants were excluded if they presented with: neurological or musculoskeletal impairment in the upper limbs or spine, history of surgical procedures or fractures to the upper limbs or spine, and shoulder dislocation events. The exclusion criteria were confirmed based on the history report of each participant when they attended the assessment. The study was approved by the University of Central Lancashire ethics committee (Appendix 10).

There were 9 males and 6 females; 11 were right-handed and 5 were left-handed. More information about the participant's characteristics is shown in Table 5.4.

Table 5.4. Characteristics of patients from the pilot study.

	Mean	Standard Deviation
Age (years)	47.7	7.7
Height (m)	1.73	0.07
Weight (kg)	79.2	15.5

5.11. RCT method's summary

Chapter 5 gave details about the methods used to develop the RCT, following the MRC framework. The intervention was developed based on information from the systematic review and by discussing the practicality of implementing the intervention in clinical practice. Further information about which movements were chosen to be tested and the use of biomechanics equipment were discussed together with the rationale of the procedures for data analyses. The chapter ends with an explanation about statistical tests used then leading to the results chapters where the findings of the trial are described.

CHAPTER 6: RESULTS

6.1. Introduction

This chapter describes the main findings of the RCT, it focusses on objectives 1 to 4 (page 101). It starts by detailing the number of patients screened for eligibility, how many were recruited and how many attended the follow-up assessments. The next section, after recruitment, describes patients' characteristics followed by the surgical procedures used for patients in each group and compliance to the physiotherapy treatments. Next, comparisons between the Early and Conservative groups regarding the clinical scores (OSS and EQ-5D-5L) and for the biomechanical outcomes for each of the tasks assessed are reported (Table 5.3, page 112). The second part of this chapter explores the number of patients who responded positively in each group of the trial and continues with an observational analysis of which patients showed improved outcomes at 3 and 6 months, regardless of their primary allocation in the trial. The last analysis for the RCT specifically addresses objective 5; this is a correlation between the task which presented the greatest mean difference between groups at 6 months follow-up and the OSS total score at the same time point.

6.2. Recruitment

Initially, 99 patients were assessed for eligibility between May 2016 and January 2017; from this total, 57 were excluded as they did not agree to take part in the study. From the 42 who agreed to take part, further 22 had to be excluded for the following reasons: 17 did not need a rotator cuff repair and 5 had massive tears which were not considered appropriate for the early mobilisation protocol. Therefore, 20 patients were included in the RCT, 10 in each group. At the three months follow-up, 5 patients did not attend the biomechanics assessment: 2 from the Early group and 3 from the Conservative group. At six months, four patients were not reassessed due to non-attendance, 2 of each group (Figure 6.1). However, only two patients did not attend both follow-ups, both from the conservative group, all other patients had at least one reassessment (Table 6.1). Every patient who cancelled their appointment was contacted by phone to try to book a new date.

A possible explanation for the high refusal rate might be related to the fact that some patients live in areas far from Wrightington, as discussed in section 5.5, page 110. The missing data reduces the power of the analysis to detect differences and therefore the reader should consider this in context when reading the results (Dancey and Reidy, 2004).

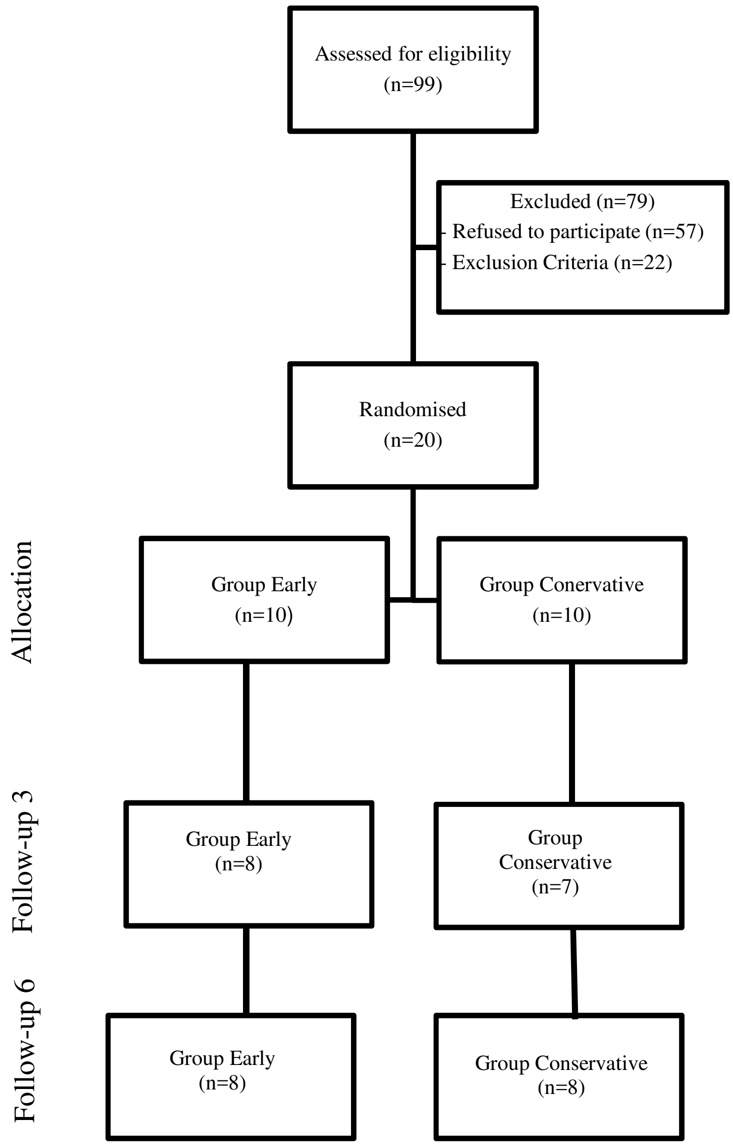


Figure 6.1 Flow diagram of patient recruitment, allocation and analyses.

Table 6.1 Patients' follow-up attendance.

Patient	Group	Baseline	Follow-up 3	Follow-up 6
P01	E	√	√	-
P02	C	√	√	√
P03	C	√	√	√
P04	E	√	√	√
P05	C	√	√	√
P06	E	√	√	√
P07	E	√	√	√
P08	C	√	√	√
P09	C	√	√	√
P10	E	√	√	√
P11	E	√	-	√
P12	C	√	-	-
P13	E	√	-	√
P14	C	√	-	√
P15	C	√	√	√
P16	C	√	√	√
P17	C	√	-	-
P18	E	√	√	√
P19	E	√	√	√
P20	E	√	√	-

C: conservative, E: early.

6.3. Patients characteristics

Table 6.2 shows the demographic details at baseline for both groups. From the descriptive data, it can be observed that most of the variables are similar between groups, however, there is a clear difference in the time length of first symptoms until the date of surgery, with the Conservative group having a shorter time compared to the Early group.

Table 6.2 Baseline characteristics.

	Group	
	Early	**Conservative**
	$\bar{x}$ (SD)	**$\bar{x}$ (SD)**
Demographics		
Age (years)	55.2 (8.1)	58.3 (11.7)
Weight (kg)	85.2 (13.7)	95.0 (14.2)
Height (m)	1.71 (0.08)	1.75 (0.08)
Gender		
Female (%)	3 (30)	3 (30)
Male (%)	7 (70)	7 (70)
Smoker		
Yes (%)	3 (30)	0
No (%)	7 (70)	10 (100)
Diabetes		
Yes (%)	0	0
No (%)	10 (100)	10 (100)
Side of surgery		
Right (%)	5 (50)	7 (30)
Left (%)	5 (50)	3 (30)
Dominance		
Right (%)	6 (60)	8 (80)
Left (%)	4 (40)	2 (20)
First symptoms (months)	19.5 (13.7)	9.7 (4.7)

SD: standard deviation

6.4. Surgery Characteristics

The surgery details were obtained based on the surgeons' reports from the information observed during the procedure. The most common lesions were found for the supraspinatus combined with the infraspinatus; the supraspinatus alone was observed in 7 cases; other 3 patients also had a debridement of the subscapularis in addition to the supra+infra repair. The most common tear size was medium, followed by small and large; the tear size was measured using a 5-mm arthroscope and its length reported. The single-row method was used in 14 patients and in 12 cases multiple additional procedures such as biceps tenotomy/tenodesis, excision of the acromioclavicular ligament/joint and subacromial decompression were performed (Table 6.3).

Table 6.3 Surgery characteristics.

	Early	**Conservative**	**Total**
Muscle Affected			
Supraspinatus	4	3	7
Supra+Infra	4	6	10
Multiple	2	1	3
Total	10	10	20
Tear Size			
Small (< 1 cm)	2	2	4
Medium (1-3 cm)	5	6	11
Large (3-5 cm)	3	2	5
Total	10	10	20
Thickness			
Full	10	9	19
Partial	0	1	1
Total	10	10	20
Fixation method			
Single-row	7	7	14
Double-row	3	3	6
Total	10	10	20

Continue

Table 6.3 (continue). Surgery characteristics

	Early	**Conservative**	**Total**
Additional procedure			
SAD	4	4	8
Multiple	6	6	12
Total	10	10	20
Contralateral repair			
Yes	3	1	4
No	7	9	16
Total	10	10	20

SAD: subacromial decompression.

6.5. Physiotherapy compliance

Treatment compliance was recorded by asking patients at the 3 and/or 6 months follow-up assessment the following questions:

1) How many days or weeks did you use the sling after surgery?
2) How many hours per day were you using the sling?
3) When did you have your first appointment with the physiotherapist?
4) How many sessions did you have with the physiotherapist?

Table 6.4 shows details of how many weeks patients used the sling for. Patients in the Early group reported a usage of 8.7 (SD=10.6) hours per day (h/d) in comparison to 22.1 h/d (SD=3.5) in the Conservative group. The Early group had an average of 6.5 (SD= 2.95) sessions with a physiotherapist and the Conservative had an average of 8.75 (SD= 4.26).

Table 6.4. Average number of weeks patients used the sling

	Group		
Weeks w/ sling	**Early**	**Conservative**	**Total**
<1	4	0	4
2	1	0	1
3	2	1	3
4	1	0	1
5	1	0	1
6	1	6	7
>6	0	1	1
Total	10	8	18

Table 6.5 shows the distribution of the time when patients had their first appointment with their local physiotherapist after surgery. However, their treatment had already started with the orientations given by physiotherapist in the ward at Wrightington.

Table 6.5. Frequency description of first appointment with a physiotherapist.

	Group		
Week started physio	**Early**	**Conservative**	**Total**
Week 1	1	0	1
Week 2	4	2	5
Week 3	3	4	7
Week 4	0	1	1
Week 6	2	1	3
Total	10	8	18

6.6. Clinical Scores

6.6.1. Oxford Shoulder Score

The Shapiro-Wilk test demonstrated a normal data distribution at baseline for the Early group (P= 0.364) and Conservative group (P= 0.118) and at all other time points, therefore, the data was considered appropriate for parametric statistical analysis. In addition, an independent t-test was used to check for initial differences at baseline, and if differences were seen the baseline data was added as a covariate. The difference between groups and time points was explored using a mixed methods ANOVA with post-hoc pairwise comparisons.

Table 6.6. Between groups comparison at baseline for the OSS.

	Group				
	Early $\bar{x}$ **(SD)**	**Conservative** $\bar{x}$ **(SD)**	**Mean Difference**	**t-value**	***P***
OSS	24.70 (10.87)	32.30 (11.10)	-7.60	-1.546	0.139

OSS: oxford shoulder score, SD: standard deviation.

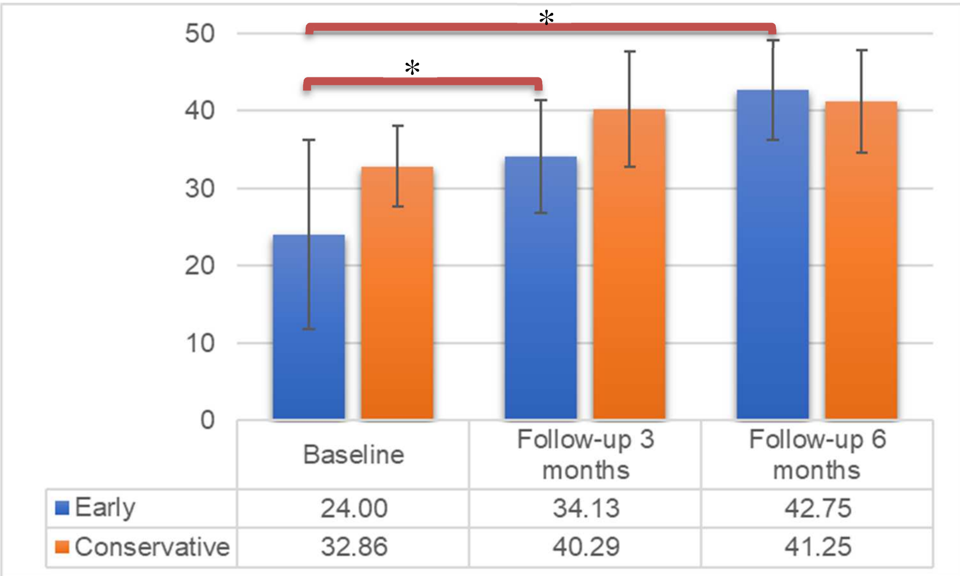


Figure 6.2. Mean Oxford Shoulder Score values at baseline, 3 and 6 months follow-up.

* statistically significant difference

The P value was not statistically significant for the OSS. However, it can be observed that there was a considerable mean difference and the standard deviation showed high variability (Figure 6.2). Therefore, to improve precision and better balance to the large absolute differences, the baseline was used as a covariate for adjustments within the mixed methods ANOVA. It was observed that the mean values at baseline from Figure 6.2 are different from Table 6.6; this difference was attributed to the adjustment made to the values due to the interaction between the covariate and the variable of interest itself (Zhang et al. 2014).

The mixed methods ANOVA showed interaction for time and between group and time (Group: F=0.542, *p*=0.472; Time: F=9.511, *P*=0.010; Group vs. Time: F=7.085, *P*=0.021).

A large improvement from baseline could be observed on both follow-ups for both groups, with the Early group showing a greater mean difference at 6 months compared to baseline. Due to the sample size of the two groups, non-parametric post hoc comparisons were used to further explore the data, section 5.9, page 128. The Friedman test was used to explore the effect within each group separately. This showed a statistically significant difference for the Early group (*P*=0.018), but not for the Conservative group (*P*=0.165). Further Wilcoxon tests for the Early group demonstrated statistically significant differences between baseline and follow-up at 3 months (*P*=0.027), baseline and follow-up at 6 months (*P*=0.043), but not for 3 months vs. 6 months (*P*=0.066). Other between groups comparison using the Mann-Whitney U test were not significant at the 3 month follow-up (*P*=0.163), and 6 months follow-up (*P*=0.491).

6.6.2. EQ-5D index

The Shapiro-Wilk test demonstrated a normal data distribution for the Early group (*P*= 0.131), but not for the Conservative (*P*= 0.014) group at baseline only, other time points showed normal data distribution, therefore, the data was considered appropriate for parametric statistical analysis. The independent t-test used to check for initial differences not assuming equal variances showed no difference (Table 6.7). The mixed methods ANOVA, using baseline as a covariate, showed no interactions (Group: F=0.0.1, *P*=0.972, Time: F=1.000, *P*=0.340; Group vs. Time: F=0.468, *P*=0.509). The mean values are detailed in Figure 6.3.

Table 6.7. Between groups comparison at baseline for the EQ-5D index.

	Group				
	Early $\bar{x}$ **(SD)**	**Conservative** $\bar{x}$ **(SD)**	**Mean Difference**	**t-value**	***P***
EQ-5D index	0.59 (0.28)	0.66 (0.29)	1.90	-0.543	0.594

SD: standard deviation.

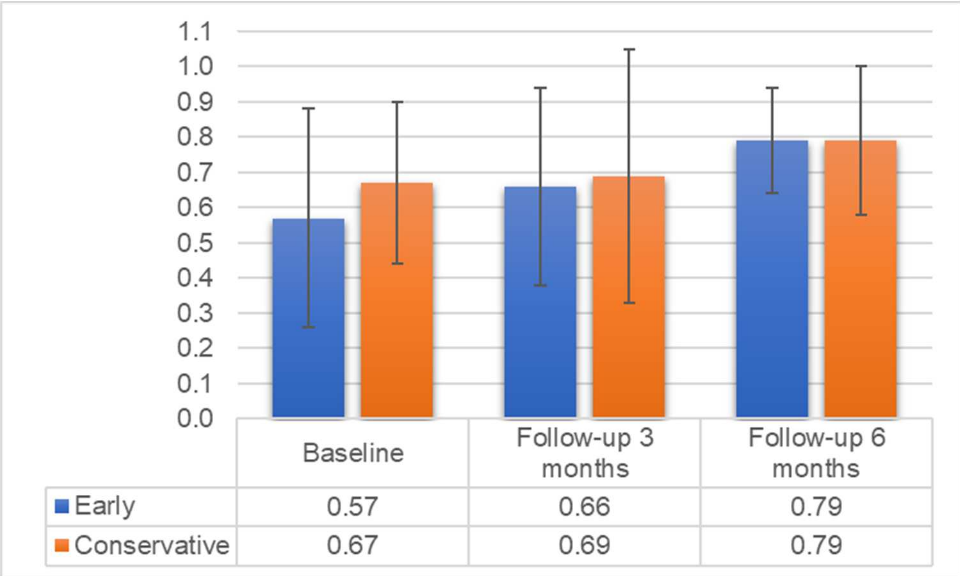


Figure 6.3. Mean EQ-5D index at baseline, 3 and 6 months follow-up.

6.7. Biomechanics

The Shapiro-Wilk tests showed that all ROM variables at baseline and other time points were normally distributed, except for during the Reaching tasks in the Conservative group at baseline (Appendix 11, Table 11.1). The Shapiro-Wilk tests for muscle activity had similar results with the vast majority showing normal distribution, except for the anterior deltoid in the Early group during Combing, the upper trapezius and medial deltoid of the Conservative group during Reaching and the anterior deltoid of both groups during Reaching at baseline (Appendix 11, Table 11.2).

Before planning how the mixed methods ANOVA would be set up, intergroup comparisons with independent t-test were performed to check for differences at baseline (Table 6.8 for ROM and Table 6.9 for muscle activity). Due to the sample size of the two groups, non-parametric post hoc comparisons were used to further explore the data, these included the Friedman test to explore the effect within each group separately, and Mann-Whitney U test for between groups comparisons, section 5.9, page 128.

Table 6.8. Between groups comparisons at baseline for ROM.

	Group				
	Early $\bar{x}$ **(SD)**	**Conservative** $\bar{x}$ **(SD)**	**Mean Difference**	**t-value**	***P***
Combing (°)	84.31 (28.50)	85.14 (20.54)	-0.83	-0.74	0.942
Abduction (°)	59.87 (27.45)	84.60 (37.49)	-24.73	-1.683	0.110
Carrying (°)	40.58 (21.66)	62.24 (24.97)	-21.66	-1.965	0.067
Reaching (°)	-21.86 (7.24)	-21.08 (5.01)	-0.78	-0.282	0.781
Flexion (°)	103.61 (33.59)	126.99 (36.28)	-23.38	-1.495	0.152
Lifting (°)	83.66 (28.08)	122.74 (36.07)	-39.08	-2.56	**0.021***

SD: standard deviation.
* statistically significant difference.

Table 6.9. Between groups comparisons at baseline for muscle activity.

	Group				
	Early $\bar{x}$ **(SD)**	**Conservative** $\bar{x}$ **(SD)**	**Mean Difference**	**t-value**	***P***
Combing					
UT (%)	35.31 (16.19)	32.43 (13.95)	2.87	0.425	0.676
AD (%)	38.61 (23.12)	26.49 (18.78)	12.12	1.286	0.215
MD (%)	39.39 (21.74)	29.55 (15.35)	9.84	1.169	0.258
PD (%)	29.15 (16.61)	20.34 (11.56)	8.81	1.376	0.186
BC (%)	41.01 (18.32)	38.34 (23.20)	2.66	0.285	0.779
Abduction					
UT (%)	44.14 (22.94)	55.99 (18.73)	-11.84	-1.265	0.222
AD (%)	33.07 (16.72)	48.88 (14.38)	-15.80	-2.267	**0.036***
MD (%)	51.77 25.76)	64.72 (16.00)	-12.95	-1.350	0.194
PD (%)	52.15 (24.89)	51.93 (21.13)	.224	0.022	0.983
BC (%)	22.10 (9.81)	34.66 (22.44)	-12.55	-1.621	0.122

Continue

Table 6.9 (continue). Between groups comparisons at baseline for muscle activity.

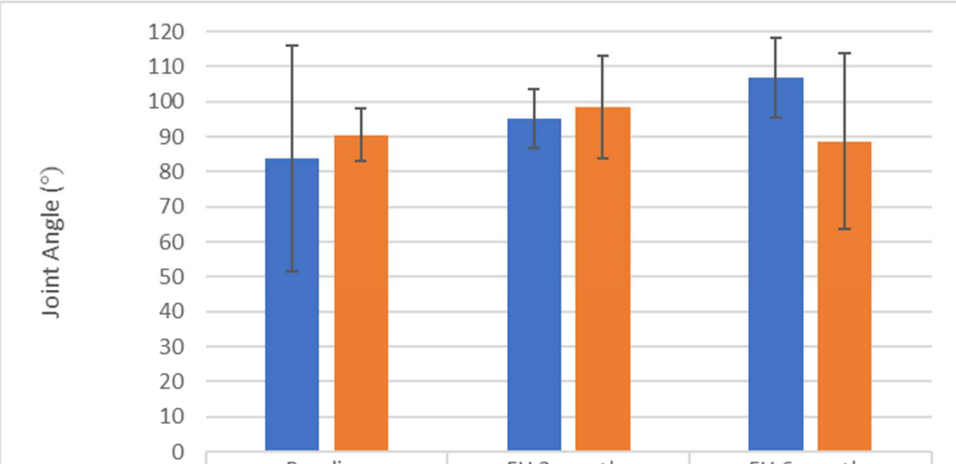
	Group Early $\bar{x}$ (SD)	Conservative $\bar{x}$ (SD)	Mean Difference	t-value	*P*
Carrying					
UT (%)	58.91 (25.40)	69.98 (11.86)	-11.06	-1.184	0.254
AD (%)	66.19 (22.57)	70.63 (20.03)	-4.44	-.442	0.665
MD (%)	45.41 (27.59)	57.45 (19.34)	-12.04	-1.072	0.299
PD (%)	41.49 (26.49)	57.08 (13,.53)	-15.58	-1.572	0.136
BC (%)	57.10 (22.87)	73.60 (20.73)	-16.49	-1.603	0.128
Reaching					
UT (%)	12.06 (8.41)	9.17 (10.93)	2.88	0.662	0.516
AD (%)	9.66 (14.39)	7.44 (11.48)	2.21	0.381	0.708
MD (%)	12.02 (7.03)	11.44 (13.83)	0.58	0.119	0.906
PD (%)	33.17 (19.03)	32.08 (26.08)	1.08	0.106	0.917
BC (%)	7.55 (7.76)	9.51 (11.88)	-1.95	-0.435	0.669
Flexion					
UT (%)	38.37 (13.39)	48.16 (19.46)	-9.78	-1.309	0.207
AD (%)	44.80 (17.17)	50.64 (16.15)	-5.84	-0.784	0.443
MD (%)	41.23 (20.98)	51.34 (17.32)	-10.10	-1.175	0.255
PD (%)	42.88 (20.98)	45.15 (17.47)	-2.27	-0.263	0.796
BC (%)	37.53 (16.91)	40.19 (16.48)	-2.65	-0.356	0.726
Lifting					
UT (%)	40.01 (19.04)	54.33 (13.35)	-14.31	-1.847	0.083
AD (%)	50.64 (18.92)	56.513 (20.11)	-5.87	-0.638	0.533
MD (%)	37.16 (15.50)	57.674 (20.63)	-20.50	2.384	**0.030***
PD (%)	46.10 (25.04)	65.89 (23.38)	-19.78	-1.73	0.102
BC (%)	54.46 (19.64)	61.63 (19.59)	-7.17	-0.776	0.449

AD: anterior deltoid, BC: biceps, MD: medial deltoid, PD: posterior deltoid SD: standard deviation, UT: upper trapezius.
* statistically significant difference.

None of the *P*-values were statistically significant for ROM and only the anterior deltoid during Abduction and the medial deltoid during Lifting showed differences in muscle activity. Similar to the clinical outcomes, high variability can be observed as well as large differences at baseline for the biomechanics variables. Therefore, the baseline was also used as a covariate to adjust for the mixed methods ANOVA. The following sections explore the results of each task; due to the use of the baseline as a covariate, the values described in the sections below are different from those displayed in Tables 6.10 and 6.11. The F and *P* values of the mixed methods ANOVA for each task and each muscle and time points are presented in Appendix 11.

6.7.1. Combing task – abduction with external rotation

Figure 6.4 shows the mean values of ROM during the combing task at baseline, 3 and 6 months follow-up. It can be observed in the graphs, that the Early group continue to improve, while the Conservative group had a reduction between 3 and 6 months. The mixed methods ANOVA showed an interaction between group and time only (Group: F= 1.19, *P*= 292; Time: F=0.124, *P*=0.732; Group vs. Time: F=5.121, *P*=0.045). The Friedman test, for both groups, showed no differences in the Early group (*P*=0.11) or Conservative group (*P*= 0.11); therefore, no further analyses were explored. Separate Mann-Whitney U tests were performed between groups at 3 and 6 months follow-up, but these did not show any statistically significant differences (*P*=0.897, *P*= 0.105).



	Baseline	FU 3 months	FU 6 months
Ealy	83.85	95.14	106.78
Conservative	90.53	98.49	88.67

Figure 6.4 Mean values of ROM for the task combing at baseline, 3 and 6 months follow-up.

The mean and standard deviation values for all muscles and time points are shown in Table 6.10. No statistically significant interactions were found for group, time or group vs. time for any muscle. The F and *P*-values of the mixed methods ANOVA for all muscles and time points are shown in Appendix 11, Table 11.3.

Table 6.10. Mean values of muscle activity for the task combing at baseline, follow-ups 3 and 6 months.

	Groups									
	Early $\bar{x}$ (SD)					Conservative $\bar{x}$ (SD)				
	UT	**AD**	**MD**	**PD**	**BC**	**UT**	**AD**	**MD**	**PD**	**BC**
Baseline (%)	33.43 (15.3)	44.37 (25.67)	39.82 (25.00)	25.61 (15.09)	43.71 (21.56)	26.33 (11.77)	32.20 (21.68)	31.64 (18.44)	22.94 (14.33)	37.96 (30.39)
Follow-up 3 (%)	39.09 (15.09)	47.58 (22.04)	32.63 (14.49)	20.62 (14.69)	38.09 (22.34)	32.80 (12.02)	35.33 (11.05)	36.17 (4.86)	26.32 (6.97)	43.82 (19.23)
Follow-up 6 (%)	32.95 (15.18)	43.59 (14.79)	35.59 (10.80)	25.98 (13.38)	34.43 (18.78)	33.27 (9.63)	45.49 (18.96)	30.56 (14.70)	26.69 (13.19)	49.04 (18.86)

AD: anterior deltoid, BC: biceps, MD: medial deltoid, PD: posterior deltoid SD: standard deviation, UT: upper trapezius.

6.7.2. Abduction task

The Figure 6.5 shows the mean values of ROM during the abduction task at baseline, 3 and 6 months follow-up. The Early group showed greater improvement than the Conservative group for both follow-ups. The mixed methods ANOVA showed no significant differences (Group: F=0.30, *P*=0.865, Time: F=2.77, *P*=0.128; Group vs. Time: F=1.514, *P*=0.248); therefore, no further analyses were explored.

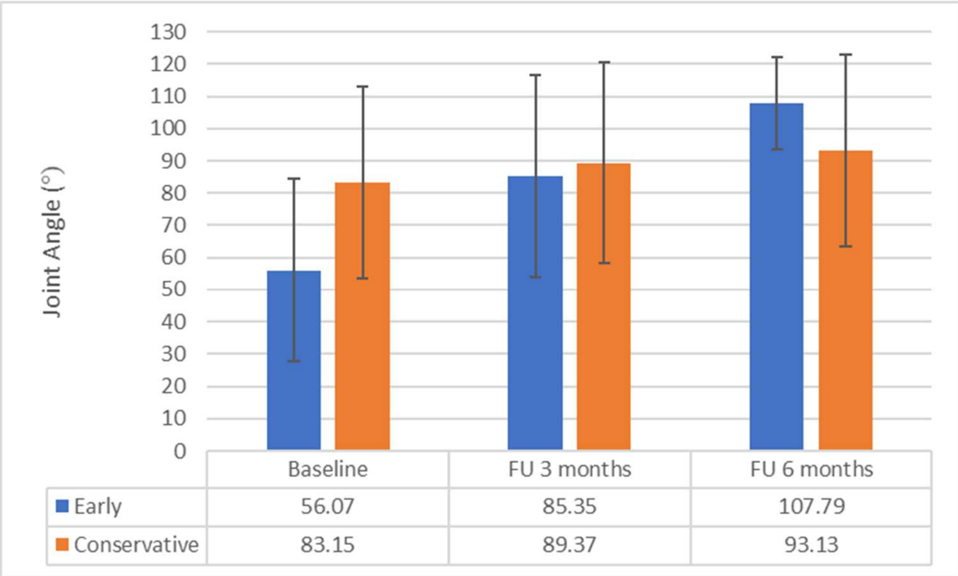


Figure 6.5. Mean values of ROM for the task abduction at baseline, 3 and 6 months follow-up.

The mean and standard deviation values for all muscles and time points are shown in Table 6.11. There was a significant interaction of group vs. time for the medial deltoid and biceps. The F and *P*-values of the mixed methods ANOVA for all muscles and time points are shown in Appendix 11, Table 11.4. Further Friedman tests did not show any statistically significant differences for both muscles between groups: Early: *P*=0.549 *P*=0.074 and Conservative: *P*=0.276 *P*=0.565 for medial deltoid and biceps, respectively.

Table 6.11. Mean values of muscle activity for the task abduction at baseline, follow-ups 3 and 6 months.

	Groups									
	Early $\overline{x}$ (SD)					Conservative $\overline{x}$ (SD)				
	UT	**AD**	**MD**	**PD**	**BC**	**UT**	**AD**	**MD**	**PD**	**BC**
Baseline (%)	45.62 (26.06)	36.94 (18.29)	51.26 (28.03)	52.34 (30.30)	20.78 (10.62)	54.74 (17.82)	50.49 (12.97)	66.63 (12.43)	59.59 (20.19)	33.50 (23.00)
Follow-up 3 (%)	54.999 (19.58)	48.12 (18.58)	53.78 (13.16)	50.96 (15.94)	22.45 (12.92)	62.23 (14.52)	54.88 (16.67)	64.01 (15.71)	52.69 (19.73)	28.73 (7.82)
Follow-up 6 (%)	50.18 (9.40)	60.79 (12.30)	61.12 (10.81)	55.64 (12.84)	42.04 (22.48)	56.00 (10.29)	49.85 (13.95)	51.00 (10.81)	53.37 (16.40)	24.41 (15.63)

AD: anterior deltoid, BC: biceps, MD: medial deltoid, PD: posterior deltoid SD: standard deviation, UT: upper trapezius.

6.7.3. Carrying task - horizontal adduction and abduction

The Figure 6.6 shows the mean values of ROM during the carrying task at baseline 3 and 6 months follow-up. When observing the mean values, the Early group shows improvement in every follow-up, while the Conservative group had a reduction from baseline to follow-up 3 months and an improvement at 6 months. The mixed methods ANOVA showed a significant interaction for time only (Group: F=0.423, *P*=0.526, Time: F=16.449, *P*=0.002; Group vs. Time: F=0.378, *P*=0.552). The Friedman test demonstrated a statistically significant difference for the Early group (*P*= 0.022), but not for the Conservative (*P*= 0.115). Further analyses using the Wilcoxon test demonstrated no statistically significant difference between baseline vs. follow-up 3 months (*P*=0.093) and follow-up 3 vs. follow-up 6months (*P*=0.173); the only difference was between baseline and follow-up at 6 months only (*P*=0.018).

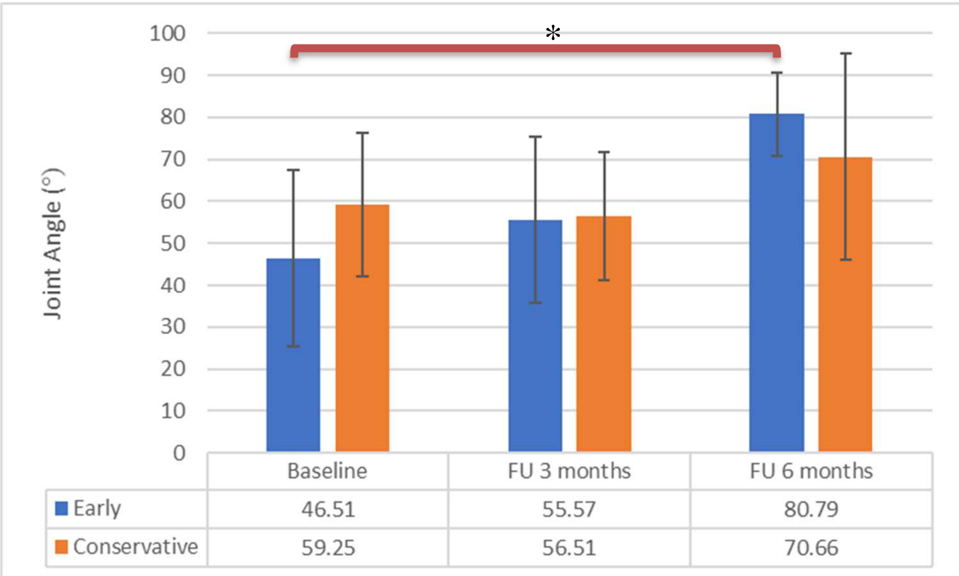


Figure 6.6. Mean values of ROM for the task carrying at baseline, 3 and 6 months follow-up.

* statistically significant difference.

The mean and standard deviation values for all muscles and time points are shown in Table 6.12. No statistically significant interactions were found for group, time or group vs. time for any muscle. The F and *P*-values of the mixed methods ANOVA for all muscles and time points are shown in Appendix 11, Table 11.5.

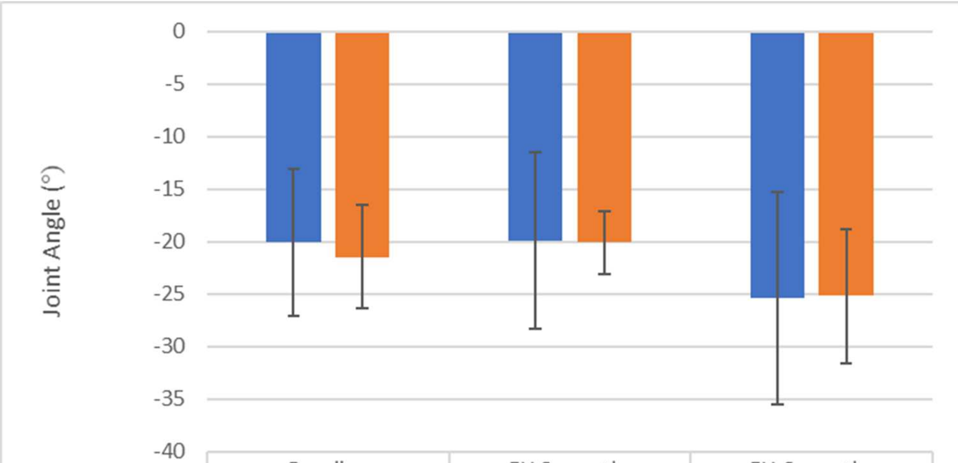
Table 6.12. Mean values of muscle activity for the task carrying at baseline, follow-ups 3 and 6 months.

	Groups									
	Early $\bar{x}$ (SD)					Conservative $\bar{x}$ (SD)				
	UT	**AD**	**MD**	**PD**	**BC**	**UT**	**AD**	**MD**	**PD**	**BC**
Baseline (%)	61.55 (25.58)	65.32 (19.43)	55.41 (28.94)	50.54 (28.11)	59.05 (18.19)	69.63 (14.46)	74.54 (17.17)	53.04 (17.08)	58.08 (14.22)	70.99 (20.70)
Follow-up 3 (%)	61.08 (24.74)	66.43 (23.91)	63.74 (32.33)	56.30 (30.38)	67.53 (16.89)	70.76 (13.50)	76.31 (15.32)	75.51 (15.95)	71.21 (15.77)	73.64 (13.82)
Follow-up 6 (%)	69.02 (23.26)	72.35 (17.29)	67.03 (18.91)	65.54 (7.75)	68.77 (6.56)	76.49 (12.34)	76.82 (19.03)	73.09 (29.36)	76.13 (16.89)	70.66 (21.95)

AD: anterior deltoid, BC: biceps, MD: medial deltoid, PD: posterior deltoid SD: standard deviation, UT: upper trapezius.

6.7.4. Reaching task – extension and internal rotation

The Figure 6.7 shows the mean values of ROM during the carrying task at baseline, 3 and 6 months follow-up. The mixed methods ANOVA showed a significant interaction for time only (Group: F=0.136, *P*=0.717, Time: F=11.581, *P*=0.005; Group vs. Time: F=0.002, *P*=0.967). The Friedman test demonstrated a statistically significant difference for the Conservative group (*P*= 0.050), but not in the Early (*P*= 0. 311). Further analyses using the Wilcoxon did not reveal any statistically significant differences between time points for the Conservative group; *P*=0.735, *P*=0.889 and *P*=0.866, respectively, for baseline vs. 3 months, baseline vs. 6 months and 3 months vs. 6 months.



	Baseline	FU 3 months	FU 6 months
Early	-20.10	-19.91	-25.41
Conservative	-21.47	-20.09	-25.21

Figure 6.7. Mean values of ROM for the task reaching at baseline, 3 and 6 months follow-up.

The mean and standard deviation values for all muscles and time points are shown in Table 6.13. There was a statistically significant interaction of group vs. time for the upper trapezius and anterior deltoid. The F and *P*-values of the mixed methods ANOVA for all muscles and time points are shown in Appendix 11, Table 11.6. Further Friedman test did not show any statistically significant differences for both muscles and for groups: Early: *P*=0.819; *P*=0.165 and Conservative: *P*=0.276; *P*=0.368 for upper trapezius and anterior deltoid, respectively.

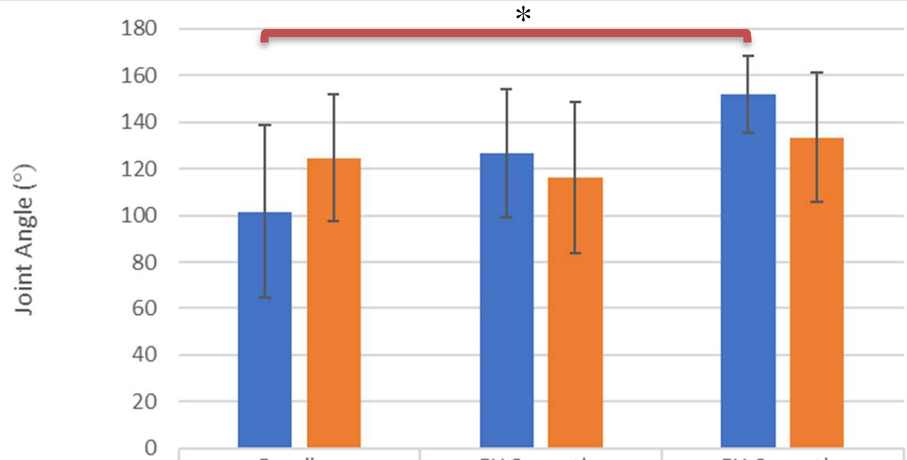
Table 6.13. Mean values of muscle activity for the task reaching at baseline, follow-ups 3 and 6 months.

	Groups									
	Early $\bar{x}$ (SD)					Conservative $\bar{x}$ (SD)				
	UT	**AD**	**MD**	**PD**	**BC**	**UT**	**AD**	**MD**	**PD**	**BC**
Baseline (%)	14.06 (9.16)	11.31 (16.80)	13.02 (7.42)	31.69 (19.99)	5.92 (8.86)	6.99 (6.61)	7.09 (11.93)	9.14 (8.67)	31.46 (19.35)	7.50 (6.53)
Follow-up 3 (%)	12.37 (10.00)	16.63 (17.54)	8.19 (5.22)	38.31 (18.81)	25.33 (20.41)	11.55 (9.07)	5.27 (3.37)	9.38 (6.90)	37.22 (29.31)	18.89 (12.67)
Follow-up 6 (%)	8.16 (6.32)	4.16 (3.72)	10.96 (16.91)	35.02 (18.91)	27.57 (26.39)	4.29 (1.61)	4.32 (2.37)	8.25 (5.30)	39.67 (23.84)	17.32 (12.16)

AD: anterior deltoid, BC: biceps, MD: medial deltoid, PD: posterior deltoid SD: standard deviation, UT: upper trapezius.

6.7.5. Flexion task – flexion and extension

The Figure 6.8 shows the mean values for ROM during the carrying task at baseline, 3 and 6 months follow-up. The mixed methods ANOVA showed a significant interaction for time only (Group: F=1.222, *P*=0.287, Time: F=7.754, *P*=0.019; Group vs. Time: F=0.064, *P*=0.804). The Friedman test demonstrated a statistically significant difference for the Early group (*P*= 0.030), but not for the Conservative group (*P*= 0.102). Further analyses using the Wilcoxon test revealed no statistically significant difference between baseline vs. follow-up 3 months (*P*=0.263) and follow-up 3 vs. follow-up 6 months (*P*=0.173); Although improvements in the mean ROM were seen between the three time points, the only statistically significant difference was observed between baseline and 6 months follow up (*P*=0.012). No statistically significant differences between groups were observed, however, the Early group showed greater improvements of more than 50° (mean value), while the Conservative group had less than 10°.



	Baseline	FU 3 months	FU 6 months
Early	101.63	126.63	152.03
Conservative	124.63	116.25	133.45

Figure 6.8. Mean values of ROM for the task flexion and extension at baseline, 3 and 6 months follow-up.
*statistically significant difference.

The mean and standard deviation values for all muscles and time points are shown in Table 6.14. There was a statistically significant interaction of group vs. time for the biceps. The F and *P*-values of the mixed methods ANOVA for all muscles and time points are shown in Appendix 11, Table 11.7. Further Friedman analysis did not show any statistically significant difference for the Early (*P*=0.819) and Conservative (*P*=0.276) groups.

Table 6.14. Mean values of muscle activity for the task flexion at baseline, follow-ups 3 and 6 months.

	Groups									
	Early $\bar{x}$ (SD)					Conservative $\bar{x}$ (SD)				
	UT	**AD**	**MD**	**PD**	**BC**	**UT**	**AD**	**MD**	**PD**	**BC**
Baseline (%)	40.40 (13.85)	46.63 (11.06)	38.83 (17.94)	46.26 (24.12)	35.56 (16.90)	40.27 (11.21)	48.83 (12.19)	45.07 (15.47)	42.85 (13.41)	34.94 (1086)
Follow-up 3 (%)	46.55 (14.04)	53.88 (10.70)	41.36 (12.29)	51.29 (20.78)	34.53 (9.48)	49.60 (13.98)	48.89 (15.73)	52.36 (12.92)	46.63 (8.85)	43.50 (13.75)
Follow-up 6 (%)	55.32 (19.46)	63.30 (9.64)	60.10 (12.51)	55.77 (21.71)	53.84 (24.96)	55.86 (8.62)	51.87 (17.80)	55.61 (20.94)	55.77 (21.71)	46.51 (14.08)

AD: Anterior Deltoid, BC: Biceps, MD: Medial deltoid, PD: Posterior Deltoid, SD: Standard Deviation, UT: Upper Trapezius.

6.7.6. Lifting task – flexion and extension lifting 1 kg

The Figure 6.9 shows the mean values of ROM during the lifting task at baseline, 3 and 6 months follow-ups. Similar to Flexion, the Early group improved was 60° (mean) and the Conservative group approximately 15°, comparing baseline to 6 months follow-up. The mixed methods ANOVA showed an interaction for time only (Group: F=0.703, *P*=0.415, Time: F=16.506, *P*=0.002; Group vs. Time: F=2.241, *P*=0.164). The Friedman test demonstrated statistically significant difference for Early (*P*= 0.007) and Conservative groups (*P*= 0.050). Further analyses using the Wilcoxon test for the Early group revealed no statistically significant difference between baseline vs. follow-up 3 months (*P*=0.128) and follow-up 3 vs. follow-up 6months (*P*=0.116); the only difference was between baseline and follow-up at 6 months only (*P*=0.018). Further Wilcoxon test did not reveal any statistically significant differences between time points for the Conservative group; *P*=0.398, *P*=0.123 and *P*=0.063, respectively, for baseline vs. follow-up 3 months, baseline vs. follow-up 6 months and follow-up 3 months vs. follow-up 6 months.

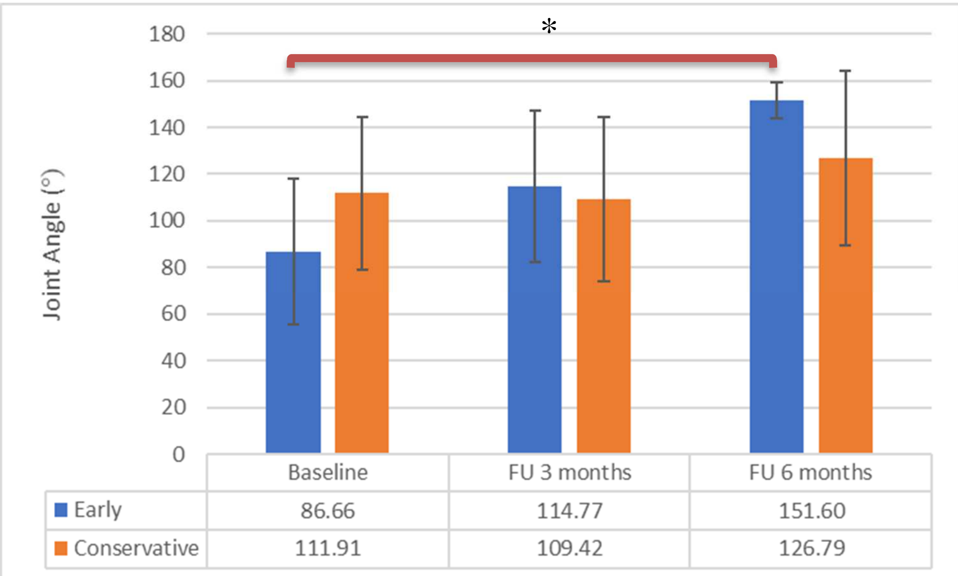


Figure 6.9. Mean values of ROM for the task lifting at baseline, 3 and 6 months follow-up.
*statistically significant difference.

The mean and standard deviation values for all muscles and time points are shown in Table 6.15. No statistically significant interactions were found for group, time or group vs. time for any muscle. The F and *P*-values of the mixed methods ANOVA for all muscles and time points are shown in Appendix 11, Table 11.8.

Table 6.15. Mean values of muscle activity for the task lifting at baseline, follow-ups 3 and 6 months.

	Groups									
	Early $\overline{x}$ **(SD)**					**Conservative** $\overline{x}$ **(SD)**				
	UT	**AD**	**MD**	**PD**	**BC**	**UT**	**AD**	**MD**	**PD**	**BC**
Baseline (%)	42.06 (23.70)	46.72 (19.44)	36.18 (19.25)	48.91 (31.01)	50.91 (20.00)	52.88 (14.35)	60.42 (12.22)	53.19 (21.50)	61.71 (24.50)	55.61 (16.11)
Follow-up 3 (%)	55.93 (21.94)	63.07 (18.52)	53.39 (27.81)	65.64 (33.96)	55.90 (19.08)	60.92 (6.79)	61.84 (20.90)	68.22 (13.94)	63.40 (5.31)	66.11 (20.72)
Follow-up 6 (%)	66.73 (38.19)	78.53 (15.29)	66.27 (10.97)	68.22 (18.01)	78.15 (14.05)	59.88 (15.27)	53.87 (11.91)	57.59 (21.16)	71.64 (11.54)	63.79 (15.77)

AD: Anterior Deltoid, BC: Biceps, MD: Medial deltoid, PD: Posterior Deltoid, SD: Standard Deviation, UT: Upper Trapezius.

6.7.7. Summary of initial RCT analyses

Overall, time interactions were found and no statistically significant differences between groups were observed for function, ROM and muscle activity. Due to the time interactions observed, further tests demonstrated statistically significant differences for function (OSS) and for three of the six tasks (Carrying, Flexion and Lifting) between baseline and 6 months follow-up for the Early group only.

Moreover, the mean values for ROM clearly showed that the Early group had greater and continuous improvements in both follow-ups. In contrast, the Conservative group showed a reduction in mean ROM between 3 months to 6 months for Combing and between baseline and 3 months follow-up for the tasks; Carrying, Reaching, Flexion and Lifting. Nevertheless, the high variability detected in ROM, observed by frequent overlapping of the standard deviations, may indicate that some patients from the Conservative group may have had equivalent improvement of their ROM compared to patients in the Early group. Therefore, this rationale led to the decision of scrutinising the data to verify whether patients were improving regardless of their primary group allocation.

6.8. Responders and Non-responders

6.8.1. Introduction

The initial repeated measures analyses of clinical and biomechanical variables revealed interactions mainly for the time component. Therefore, to address objective 5, individual subject observations were explored with the purpose of detecting whether there were patients improving regardless of their primary group allocation. The following sections will describe the results for the OSS and ROM by observations of individual responses to the questionnaire measuring function, tasks (ROM) and time points (follow-ups 3 and 6 months); these analyses were performed only for those outcomes that had statistically significant interactions, therefore, the task Abduction and the EQ-5D were not considered.

The next graphs in this section have the following arrangement: each bar represents a patient response; the bars are sorted from the smallest/negative response to those with the greatest/positive response to treatment; the Early group is displayed in blue and the Conservative in red. Patients who responded best and worst for one task may not be the same in another task. A summary of individual responses for the OSS and each task is available in Tables 6.16 and 6.17, respectively. The individual responses/results were calculated by subtracting the value from the time point of comparison from the time point of interest; hence, the difference was set as the result. For example, to analyse the responses at follow-up 3 months, values from baseline were subtracted from values of the follow-up 3 months. Apart from the task Reaching, positive bars represent a positive response; however, considering that shoulder extension was defined as negative in the sagittal plane (section 5.7.1, page 116 and Figure 5.16, page 121) the graphs in section 6.9.4. have opposite arrangement, with negative responses representing a better outcome.

6.8.2. Oxford Shoulder Score

At 3 months, 2 patients from the Early group had no response according to the OSS and in the Conservative, only 1 patient had a negative response (Figure 6.10). At six months, again, only one patient had a negative outcome compared to baseline (Figure 6.11), but when compared both follow-ups it can be observed the reduction for two patients in the Conservative group. Patients of the Early group showed greater improvement at both follow-up points compared to patients in the Conservative (Figure 6.12).

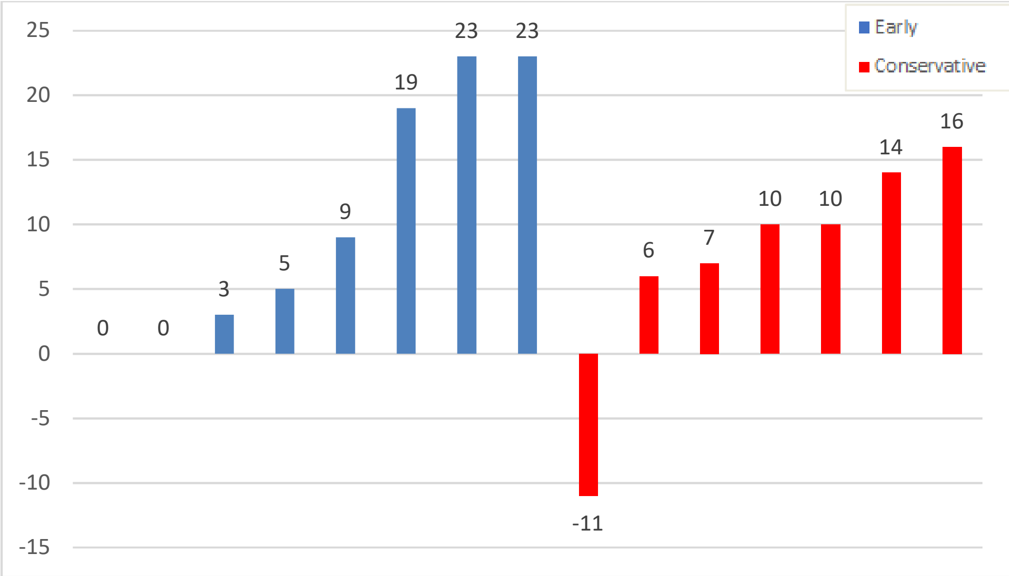


Figure 6.10. Patients' individual response measured by the OSS at 3 months follow-up compared to baseline.

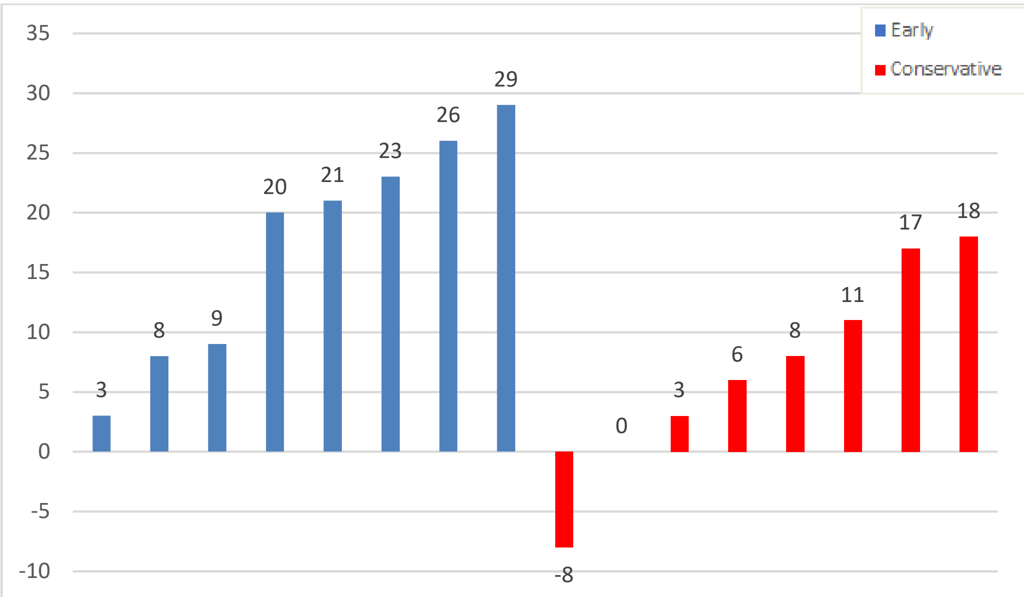


Figure 6.11. Patients' individual response measured by the OSS at 6 months follow-up compared to baseline.

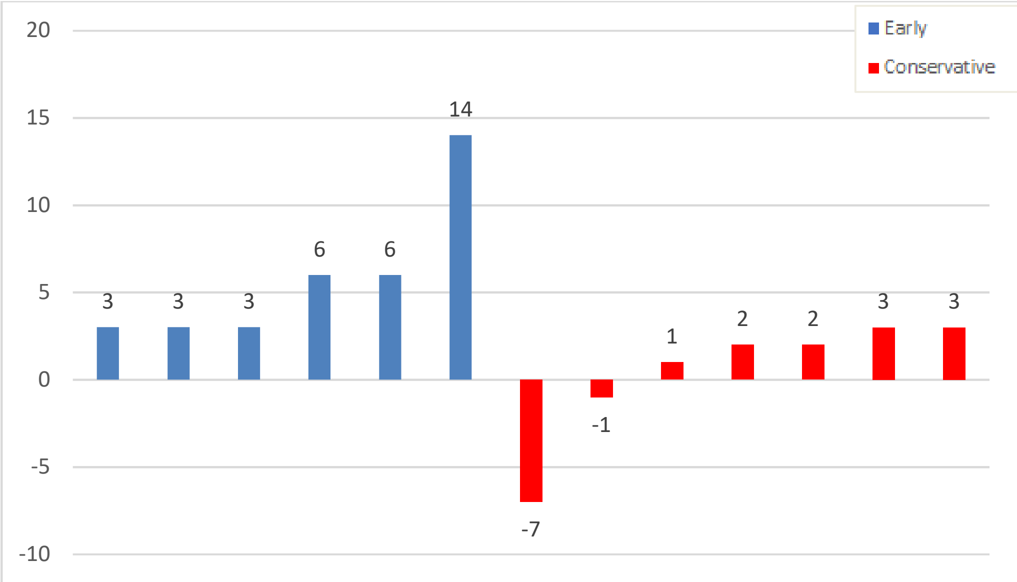


Figure 6.12. Patients' individual response measured by the OSS at 6 months follow-up compared to 3 months follow-up.

6.8.3. Combing task – abduction with external rotation

At 3 months, all recorded patients from the Conservative group responded positively; in the Early group, 5 had a positive response and 3 a negative response (Figure 6.13). At 6 months, the majority of patients from the Early group improved, while in the Conservative group 3 patients had a reduction (Figure 6.14). When comparing the difference between 3 and 6 months, a similar trend compared to the 6 months vs baseline comparison is observed (Figure 6.15). It is noteworthy that patients in the Early group had higher values at both time points than the Conservative group.

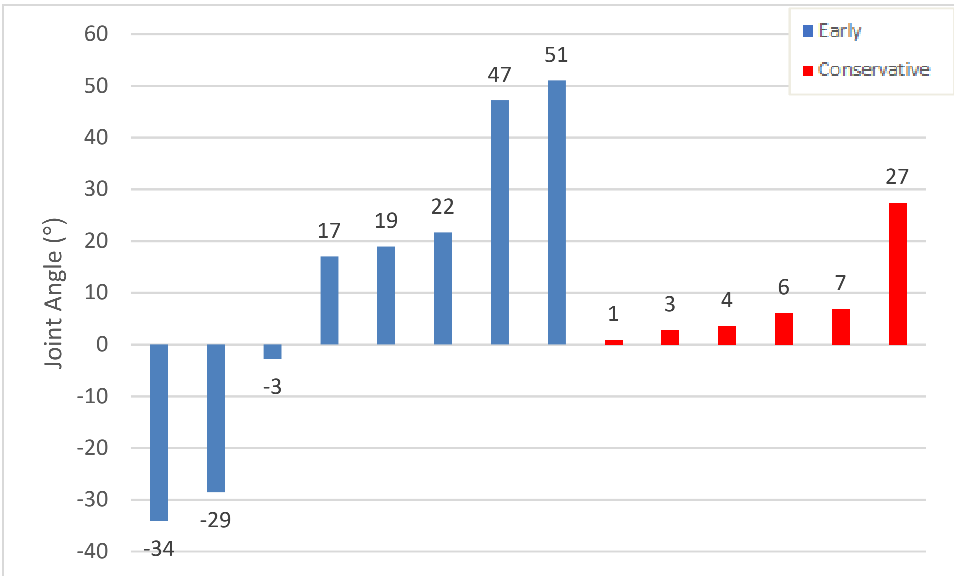


Figure 6.13. Patients' individual response for the task combing at 3 months follow-up compared to baseline.

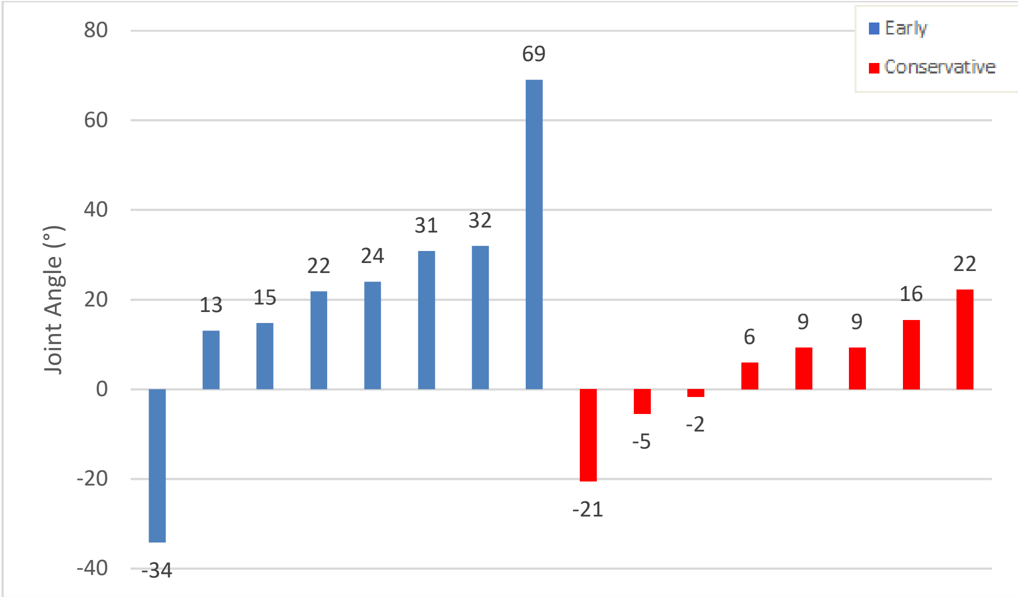


Figure 6.14. Patients' individual response for the task combing at 6 months follow-up compared to baseline.

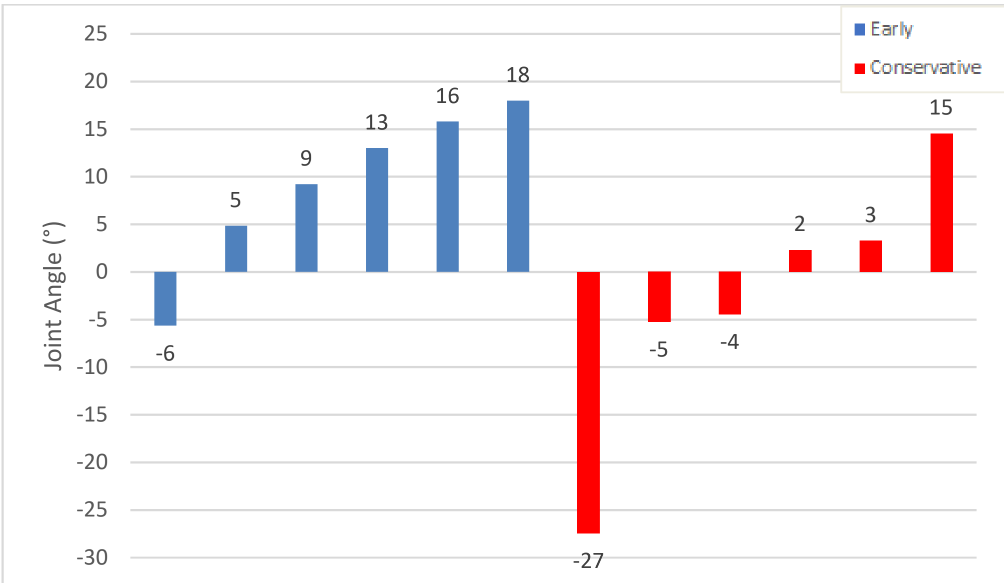


Figure 6.15. Patients' individual response for the task combing at follow-up 6 months compared to follow-up 3 months.

6.8.4. Carrying task – horizontal adduction and abduction

Half of the patients recorded at 3 months had a negative response (Figure 6.16). However, at 6 months every patient, from both groups, responded positively compared to baseline (Figure 6.17), but when comparing 6 months to 3 months it could be observed that 3 patients had a reduction of their ROM (Figure 6.18). However, the improvement is much higher in the Early group where patients were getting over 60°, while in the Conservative patients were under 30°.

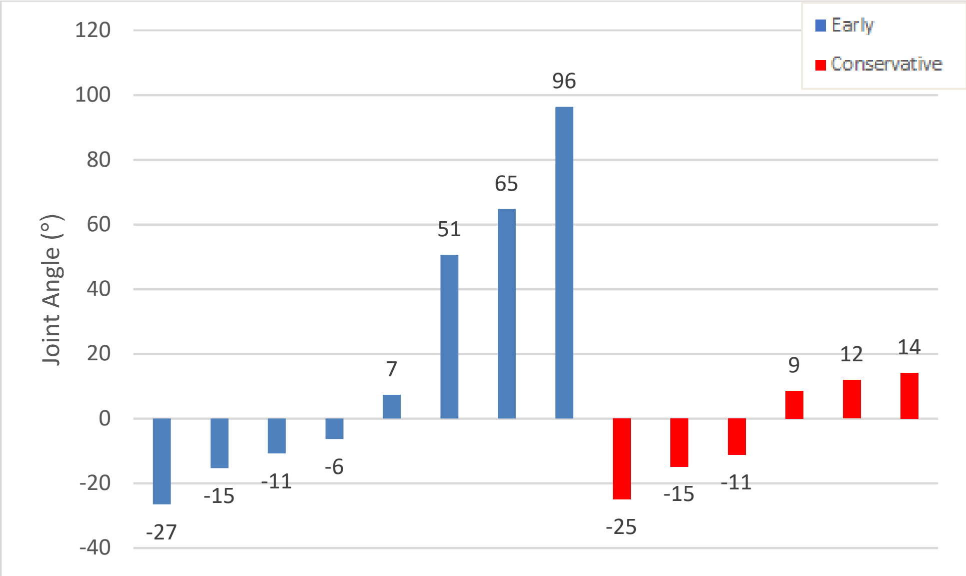


Figure 6.16. Patients' individual response for the task carrying at 3 months follow-up compared to baseline.

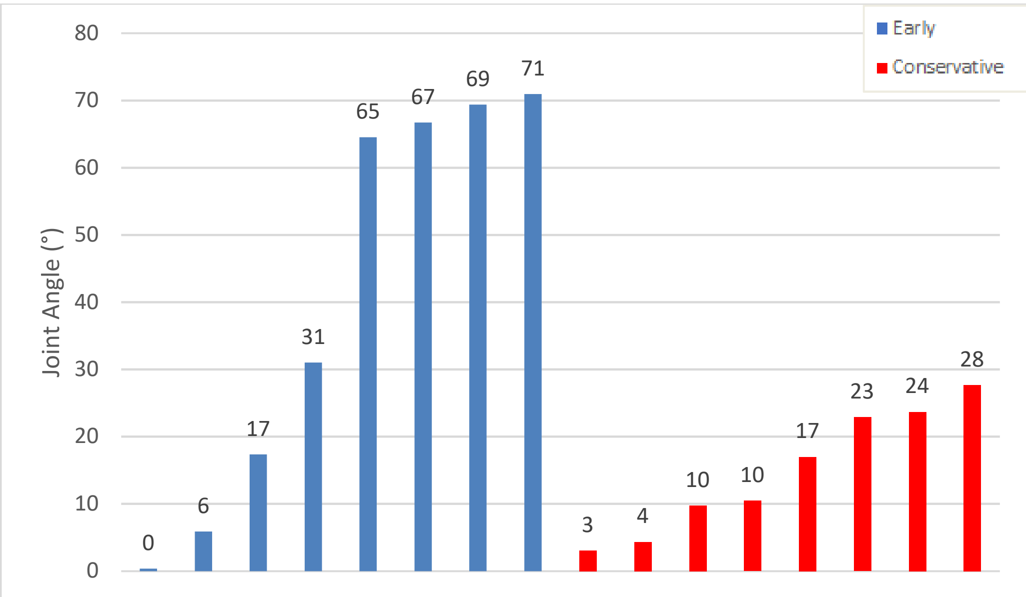


Figure 6.17. Patients' individual response for the task carrying at 6 months follow-up compared to baseline.

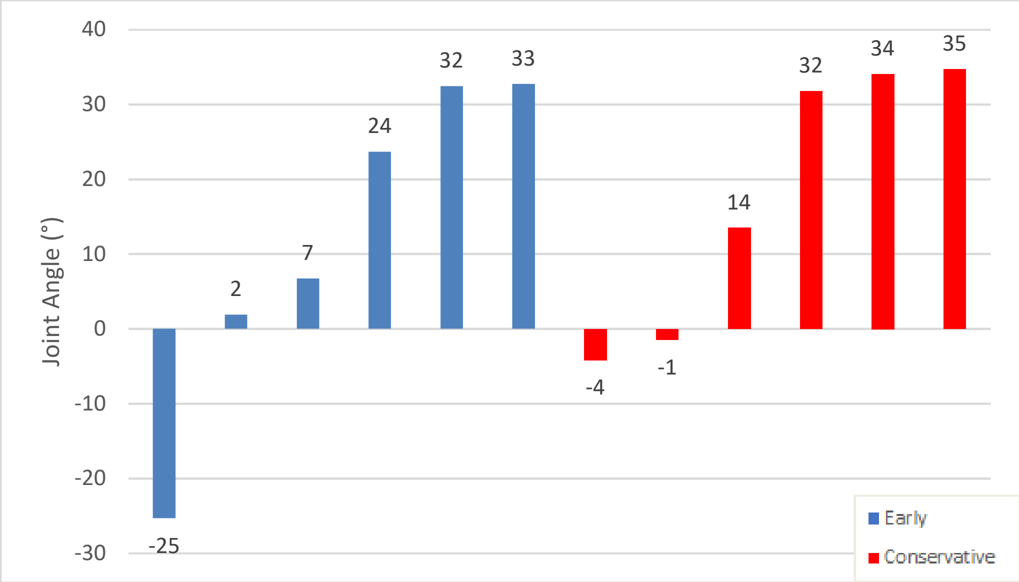


Figure 6.18. Patients' individual response for the task carrying at 6 months follow-up compared to 3 months follow-up.

6.8.5. Reaching task – extension and internal rotation

The task reaching measured mainly shoulder extension which was defined as negative on the sagittal plane, a positive value in this task means a reduction of the ROM. It can be observed that only one patient from the Conservative group had an improvement at 3 months (Figure 6.19). At 6 months, 4 patients overall did not improve (Figure 6.20). This ROM improvement is confirmed by the inter-follow-up comparison, which shows only 2 patients not having a better outcome (Figure 6.21).

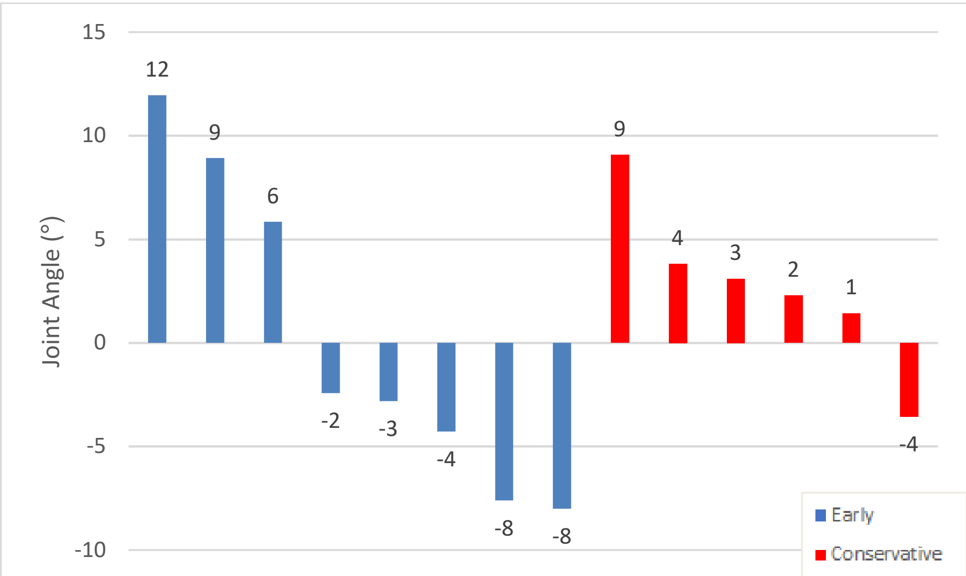


Figure 6.19. Patients' individual response for the task reaching at 3 months follow-up compared to baseline.

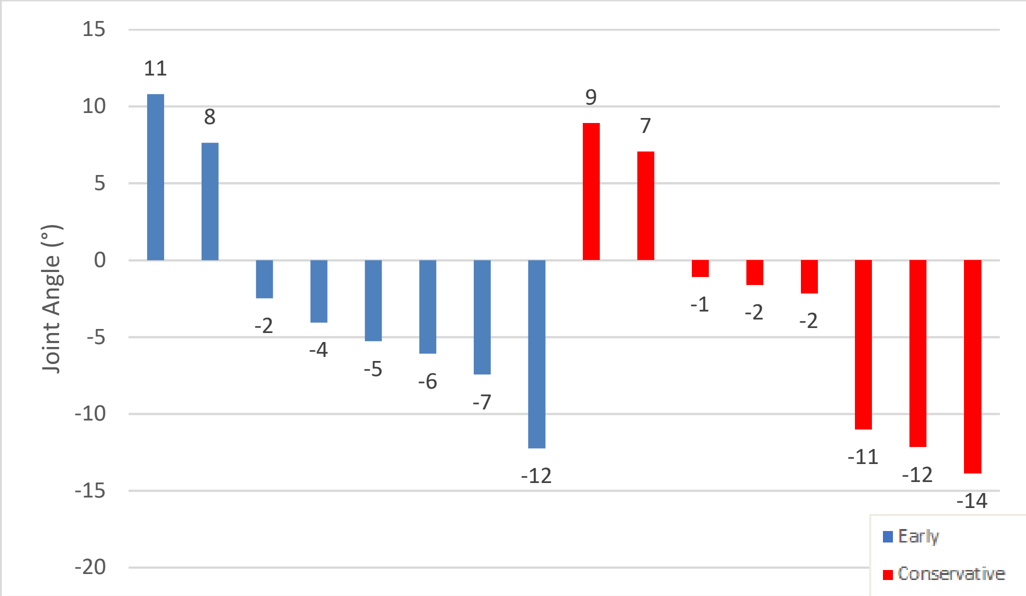


Figure 6.20. Patients' individual response for the task reaching at 6 months follow-up compared to baseline.

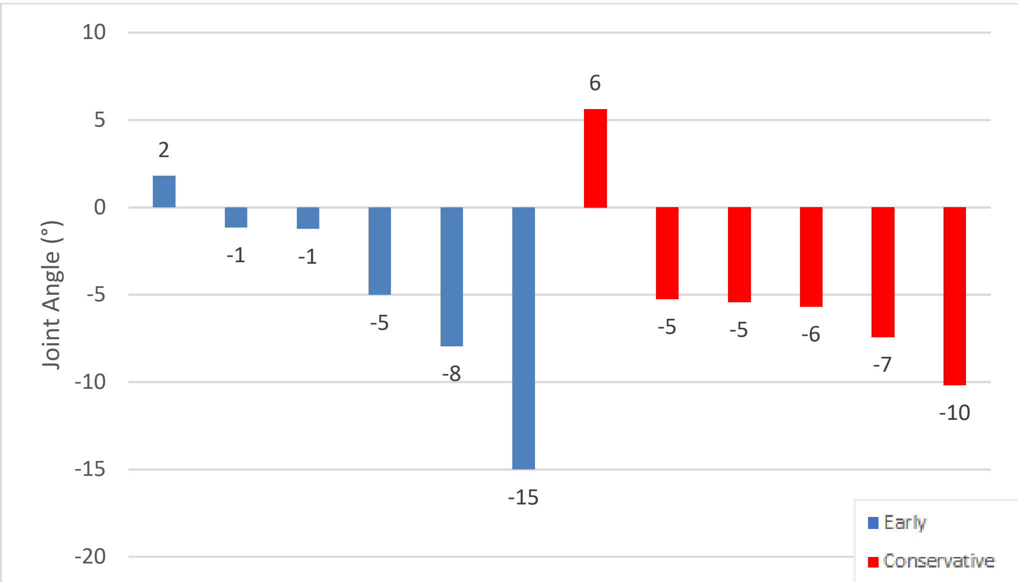


Figure 6.21. Patients' individual response for the task reaching at 6 months follow-up compared to 3 months follow-up.

6.8.6. Flexion task – flexion and extension

The individual observation of the task flexion revealed an important difference between groups. At 3 months, 2 patients did not improve in the Early group; at the same time, only 1 patient from the Conservative group had a positive response (Figure 6.22). At 6 months, all patients from the Early group benefitted from the treatment in comparison with baseline while half of the patients in the Conservative were worse than pre-operatively (Figure 6.23). Nonetheless, it can be observed that 2 patients from the Early group had worse responses at 6 months compared to their 3 months results (Figure 6.24).

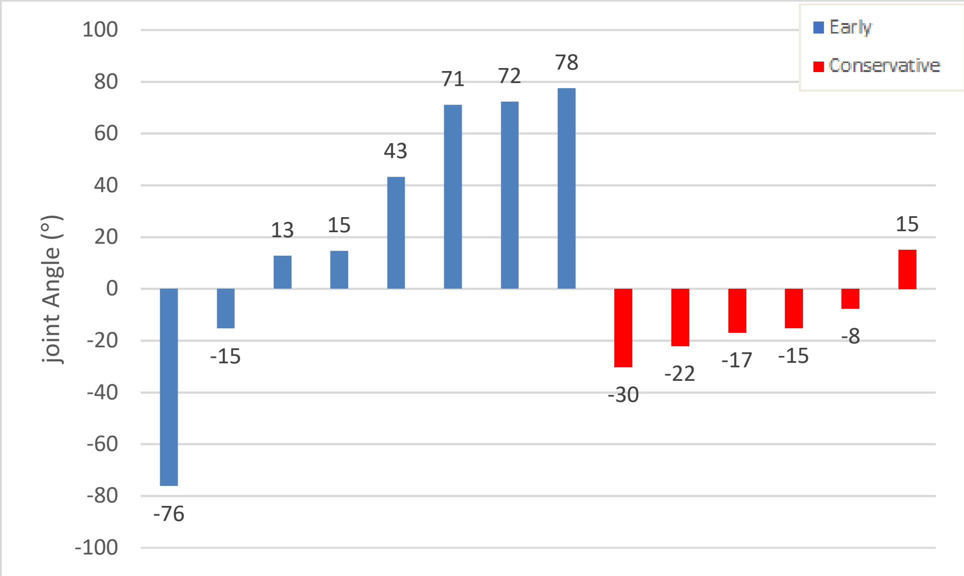


Figure 6.22. Patients' individual response for the task flexion at 3 months follow-up compared to baseline.

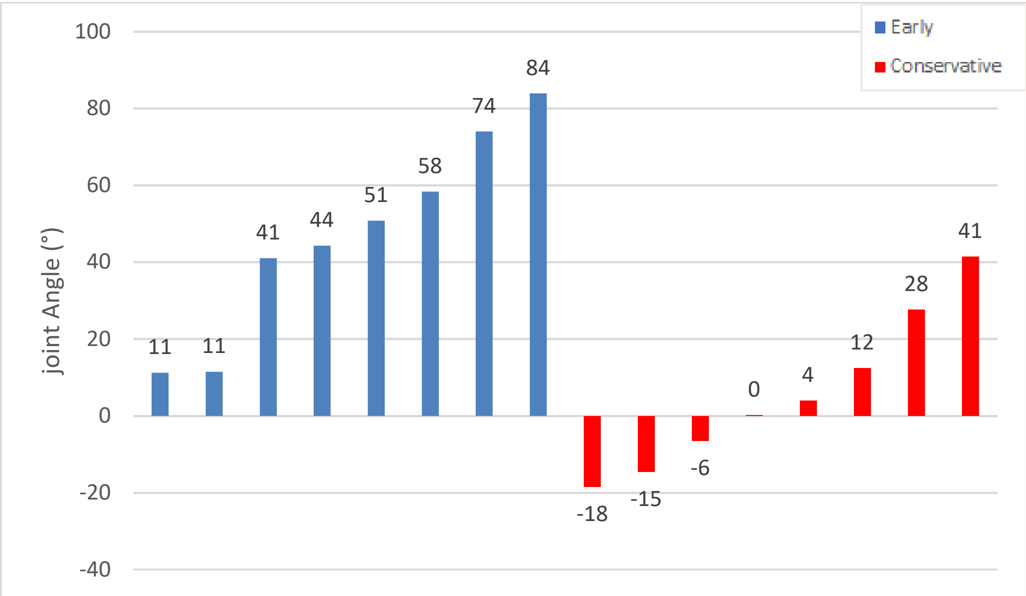


Figure 6.23. Patients' individual response for the task flexion at 6 months follow-up compared to baseline.

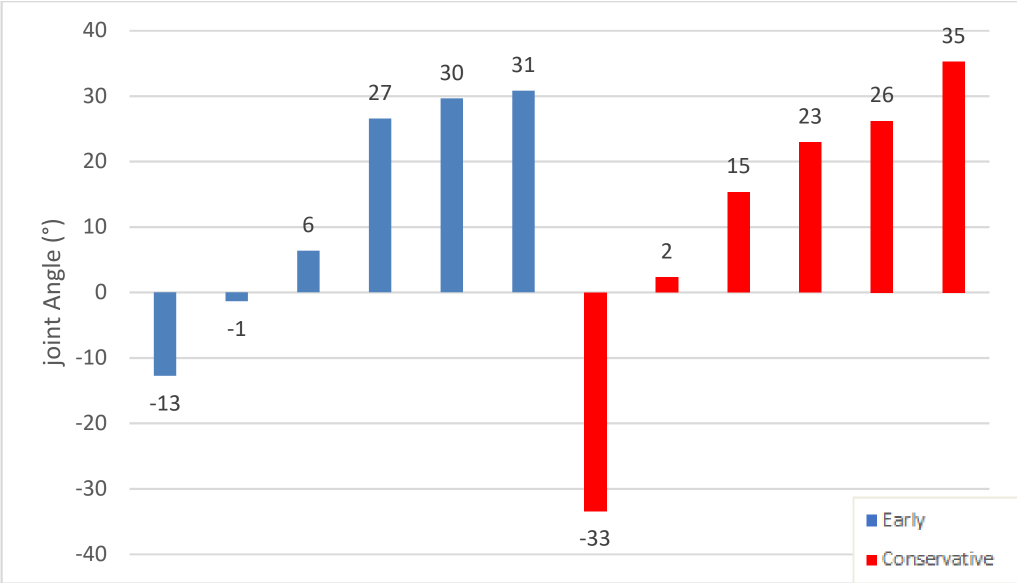


Figure 6.24. Patients' individual response for the task flexion at 6 months follow-up compared to 3 months follow-up.

6.8.7. Lifting task – flexion and extension lifting 1 kg

The task lifting had similar results to the task flexion. One patient from the Early group did not improve and only one patient from the Conservative group had a positive response, although very small (Figure 6.25). At 6 months, every patient from the Early group had significant improvement in comparison to baseline; in contrast, two patients were still not any better than their first assessment (Figure 6.26). When comparing only follow-up data, it can be noticed that one patient of each group had a reduction of their ROM (Figure 6.27).

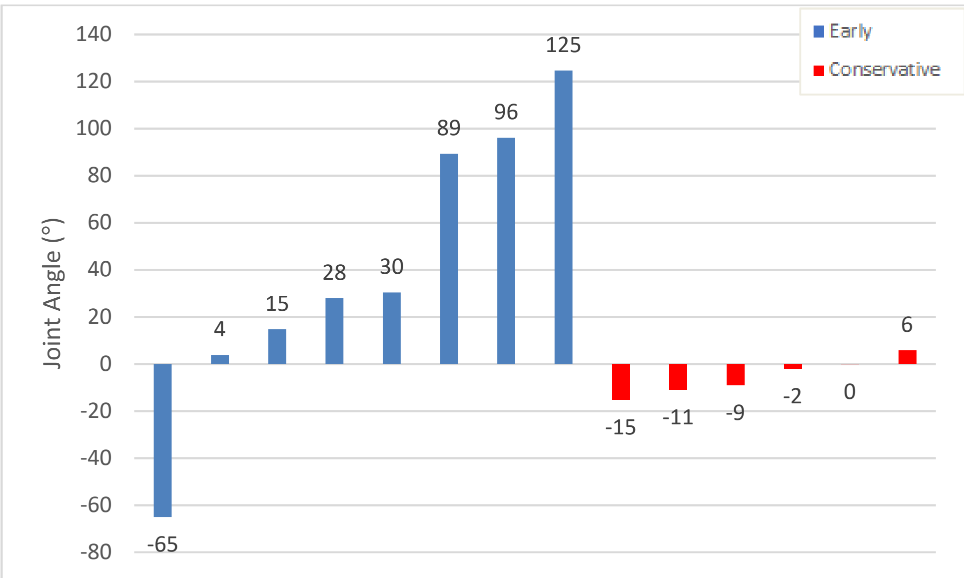


Figure 6.25. Patients' individual response for the task lifting at 3 months follow-up compared to baseline.

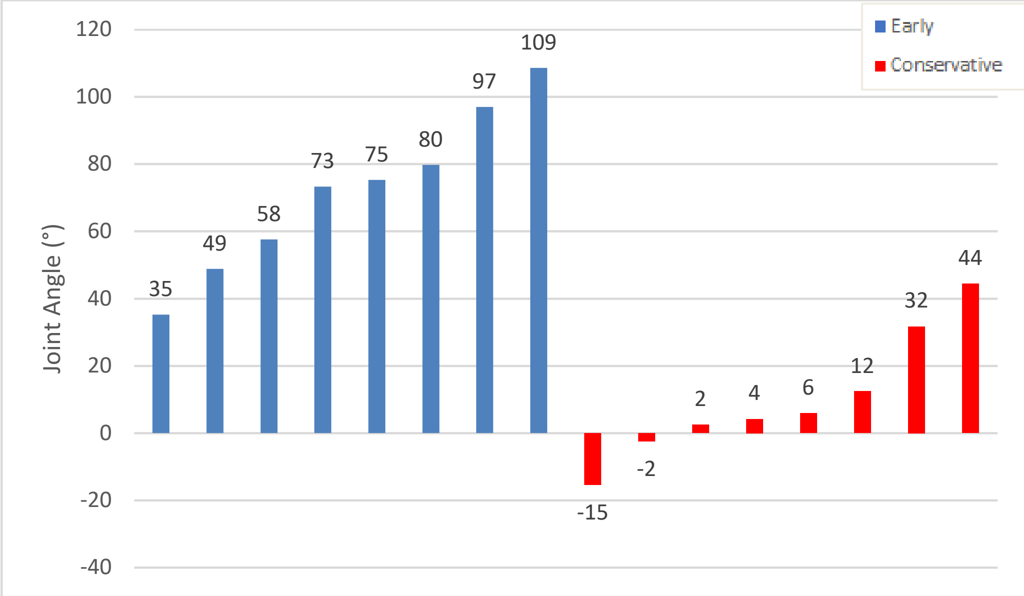


Figure 6.26. Patients' individual response for the task lifting at 6 months follow-up compared to baseline.

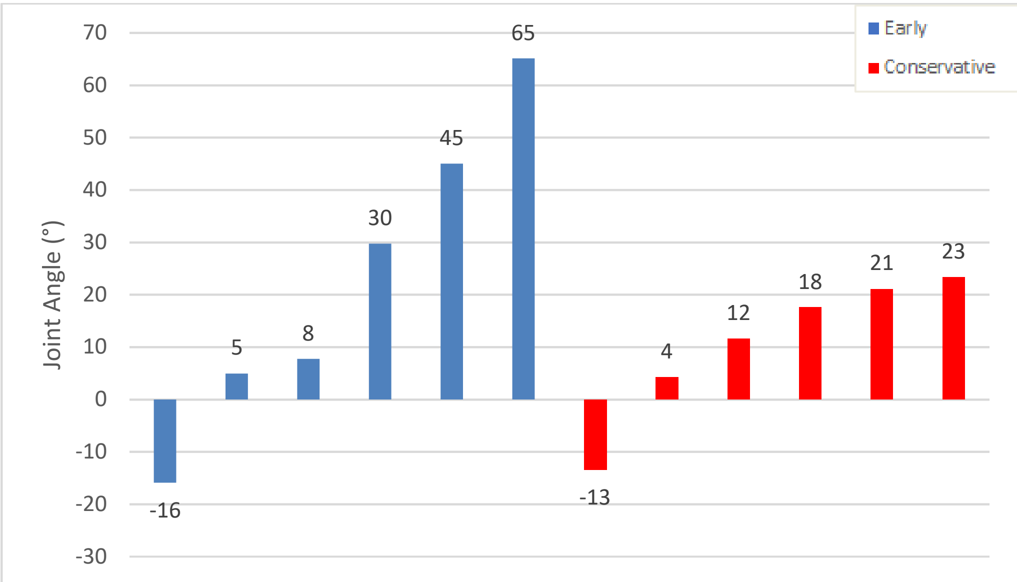


Figure 6.27. Patients' individual response for the task lifting at 6 months follow-up compared to 3 months follow-up.

Table 6.16. Summary of individual responses measured with the OSS.

	Clinical Score	
	Oxford Shoulder Score	
Subject	FU3	FU6
1	19	-
2	14	17
3	7	6
4	3	9
5	6	8
6	9	23
7	23	26
8	-11	-8
9	16	18
10	5	8
11	-	21
12	-	-
13	-	20
14	-	0
15	10	3
16	10	11
17	-	-
18	23	29
19	0	3
20	0	-

FU 3: follow-up 3 months, FU6: follow-up 6 months.

Key:
- Positive change
- No change
- Negative change
- Missing

Table 6.17. Summary of individual responses by tasks for ROM. FU 3: follow-up 3 months, FU6: follow-up 6 months.

	Task									
	Combing		Reaching		Carrying		Flexion		Lifting	
Subject	FU3	FU6	FU3	FU6	FU3	FU6	FU3	FU6	FU3	FU6
1	47.2	-	-7.61	-	50.53	-	72.28	-	132.91	-
2	3.62	5.93	3.82	-1.6	14.18	27.68	-15.15	140.5	131.99	143.58
3	6.1	9.36	1.43	7.06	-11.22	22.86	-22.21	167.75	142.4	165.75
4	17.02	21.84	8.92	-6.09	64.77	66.68	77.5	83.89	144.08	151.83
5	2.76	-1.71	3.1	-2.16	11.92	10.46	-16.86	126.59	119.9	124.17
6	21.65	30.85	-4.29	-12.25	7.3	30.98	43.18	169.99	98.47	163.59
7	18.94	31.94	-2.82	-4.06	-26.57	5.87	14.66	159.89	124.56	154.27
8	-	-5.45	2.3	-13.89	-	3.06	-30.33	90.83	49.49	70.6
9	0.96	15.5	9.09	-1.08	-25	9.73	-7.63	139.45	95.64	134.36
10	-2.79	13.01	-2.43	-7.45	-6.38	0.35	12.82	150.14	149.03	153.98
11	-	23.95	-	-5.28	-	64.5	-	167.97	-	153.83
12	-	-	-	-	-	-	-	-	-	-
13	-	14.77	-	-2.48	-	69.35	-	147	-	141.11
14	-	9.32	-	8.91	-	23.71	-	142.39	-	145.2

Continue

Table 6.17 (continue). Summary of individual responses by tasks. FU 3: follow-up 3 months, FU6: follow-up 6 months.

	Task									
	Combing		Reaching		Carrying		Flexion		Lifting	
Subject	FU3	FU6	FU3	FU6	FU3	Subject	FU3	FU6	FU3	FU6
15	6.88	-20.58	-3.57	-11.02	8.51	4.33	15.02	96.99	82.96	69.54
16	27.46	22.2	-6.49	-12.17	-14.78	17	18.48	163.08	143.55	161.12
17	-	-	-	-	-	-	-	-	-	-
18	51.05	69.03	11.95	10.79	96.25	70.92	71.07	116.99	124.56	108.61
19	-28.58	-34.24	5.84	7.64	-15.37	17.36	-15.36	150.99	97.58	142.58
20	-34.15	-	-8.01	-	-10.84	-	-76.17	-	56.78	-

Key:
- Positive change
- Negative change
- Missing

6.8.8. Subgrouping

Based on the observational analyses of those who had a positive response, which indicated that some patients in the conservative group were improving, further subgrouping was explored with the objective to detail what characteristics, other than just when their rehabilitation started, these individuals may share and might be impacting their outcomes. Therefore, based on the mapping of the individual responses for ROM (Table 6.18), the subgrouping classification to responders or non-responders was pragmatically estimated by selecting those subjects who had at least three positive responses out of the five tasks (responder) in the follow-up vs baseline comparisons; those who had three or more negative responses were defined as non-responders. Thus, the subgroups were separated as detailed in Table 6.18.

Table 6.18. Subjects subgrouping based on their ROM result.

Follow-up 3 months		Follow-up 6 months	
Responder	Non-responder	Responder	Non-responder
1-E 9-C	19-E 2-C	4-E 2-C	14-C
4-E 15-C	20-E 3-C	6-E 3-C	15-C
6-E 16-C	5-C	7-E 5-C	
7-E	8-C	10-E 8-C	
10-E		11-E 9-C	
18-E		13-E 16-C	
		18-E	
		19-E	

C: conservative, E: early.

6.8.8.1. Subgrouping characteristics based on 3 months results

The number of individuals in the subgroups was not balanced; therefore, any statistical test used for comparisons would not be appropriate (Dancey and Reidy, 2004). The subgrouping observational and exploratory analyses revealed that a positive outcome potentially may be linked with the length from having the first symptoms until having surgery, having multiple additional surgical procedures, number of hours per day using the sling and better EQ-5D-index (Table 6.19).

Table 6.19. Characteristics of responders and non-responders according to results at follow-up 3 months.

	Group	
	Responders (N=9) $\bar{x}$ **(SD)**	**Non-responders (N=6)** $\bar{x}$ **(SD)**
Age (years)	56.33 (10.83)	58.83 (97.19)
Weight (kg)	90.60 (14.35)	93.90 (14.43)
Height (m)	1.75 (0.07)	1.73 (0.11)
Smoker		
Yes (%)	2 (22.2)	0 (0)
No (%)	7 (77.7)	6 (100)
Muscle affected		
Supraspinatus (%)	4 (44.44)	2 (33.33)
Supra+Infra (%)	3 (33.33)	3 (50)
Multiple (%)	2 (22.22)	1 (16.6)
Tear Size		
Small (%)	1 (11.11)	1 (16.66)
Medium (%)	5 (55.55)	4 (66.66)
Large (%)	3 (33.33)	1 (16.66)
Fixation method		
Single row (%)	7 (77.77)	4 (66.66)
Double row (%)	2 (22.22)	2 (33.33)
Additional surgical procedure		
SAD (%)	4 (44.44)	1 (16.66)
Multiple (%)	5 (55.55)	5 (83.33)

Continue

Table 6.19 (continue). Characteristics of responders and non-responders according to results at follow-up 3 months.

	Group	
	Responders (N=9) $\bar{x}$ **(SD)**	**Non-responders (N=6)** $\bar{x}$ **(SD)**
Contralateral repair		
Yes (%)	2 (22.22)	1 (16.66)
No (%)	7 (77.77)	5 (83.33)
First symptoms (months)	11.88 (6.25)	20.5 (17.22)
Number of physiotherapy sessions	7.11 (3.95)	9.00 (3.84)
Sling usage (h/d)	8.66 (9.70)	19 (9.61)
Week started rehabilitation		
Week 1 (%)	1 (11.11)	0
Week 2 (%)	4 (44.44)	2 (33.33)
Week 3 (%)	3 (33.330	2 (33.33)
Week 4 (%)	0	1 (16.66)
Week 6 (%)	1 (11.11)	1 (16.66)
OSS	38.62 (6.92)	36.8 (10.03)
EQ-5D index	0.74 (0.30)	0.57 (0.32)

OSS: Oxford Shoulder Score, SAD: subacromial decompression, SD: standard deviation.

6.8.8.2. Subgrouping characteristics based on 6 months results

At 6 months, only two patients did not have positive outcomes, both from the Conservative group. The observational exploratory analysis shows that being over 65 years old may be an important factor to consider (Table 6.20). However, it is important to highlight that two patients may not be a representative sample and other factors (e.g. other comorbidities or lifestyle) that have not been recorded may be involved.

Table 6.20. Characteristics of responders and non-responders according to results at follow-up 6 months.

	Group	
	Responders (N=14) $\bar{x}$ **(SD)**	**Non-responders (N=2)** **(14-C and 15-C)**
Age (years)	55.85 (9.26)	65 and 70
Weight (kg)	88.15 (16.02)	89.1 and 96.60
Height (m)	1.71 (0.09)	1.70 and 1.88
Smoker		
Yes (%)	2 (14.28)	0 (0)
No (%)	12 (85.72)	2 (100)
Muscle affected		
Supraspinatus (%)	6 (42.86)	1 (50)
Supra+Infra (%)	6 (42.86)	1 (50)
Multiple (%)	2 (14.28)	0 (0)
Tear Size		
Small (%)	3 (21.43)	0 (0)
Medium (%)	8 (57.14)	1 (50)
Large (%)	3 (21.43)	1 (50)
Fixation method		
Single row (%)	9 (64.29)	1 (50)
Double row (%)	5 (35.71)	1 (50)
Additional surgical procedure		
SAD (%)	6 (42.86)	0 (0)
Multiple (%)	8 (57.14)	2 (100)

Continue

Table 6.20 (continue). Characteristics of responders and non-responders according to results at follow-up 6 months.

	Group	
	Responders (N=14) $\bar{x}$ **(SD)**	**Non-responders (N=2) (14-C and 15-C)**
Contralateral repair		
Yes (%)	2 (14.28)	1 (50)
No (%)	12 (85.72)	1 (50)
First symptoms (months)	13.42 (8.82)	12 and 18
Number of physiotherapy sessions	8.14 (3.79)	7 and 6
Sling usage (h/d)	15.21 (10.31)	24 and 24
Week started rehabilitation		
Week 2 (%)	5 (35.71)	0 (0)
Week 3 (%)	5 (35.71)	2 (50)
Week 4 (%)	1 (7.15)	0 (0)
Week 6 (%)	3 (21.43)	0 (0)
OSS	42.14 (6.63)	45 and 37
EQ-5D index	0.79 (0.19)	0.83 and 0.73

OSS: Oxford Shoulder Score, SAD: subacromial decompression, SD: standard deviation

6.9. Correlation analysis

To explore the association between clinical scores and ROM (objective 6) a correlation analysis was undertaken. The Pearson's correlation showed a moderate and positive association (r=0.609, *P*=0.006) between ROM and the OSS (Table 6.21 and Figure 6.28). Therefore 37% (r^2=0.371) of the OSS variance can be explained by the ROM variance.

Table 6.21. Pearson's correlation analysis between the OSS and Lifting ROM.

Correlations

		Oxford Shoulder Score - 6 months follow-up	Lifting Range of Motion - 6 months follow-up
Oxford Shoulder Score 6 months follow-up	Pearson Correlation	1	.609**
	Sig. (1-tailed)		.006
	N	16	16
Lifting Range of Motion 6 months follow-up	Pearson Correlation	.609**	1
	Sig. (1-tailed)	.006	
	N	16	16

** Correlation is significant at the 0.01 level (1-tailed).

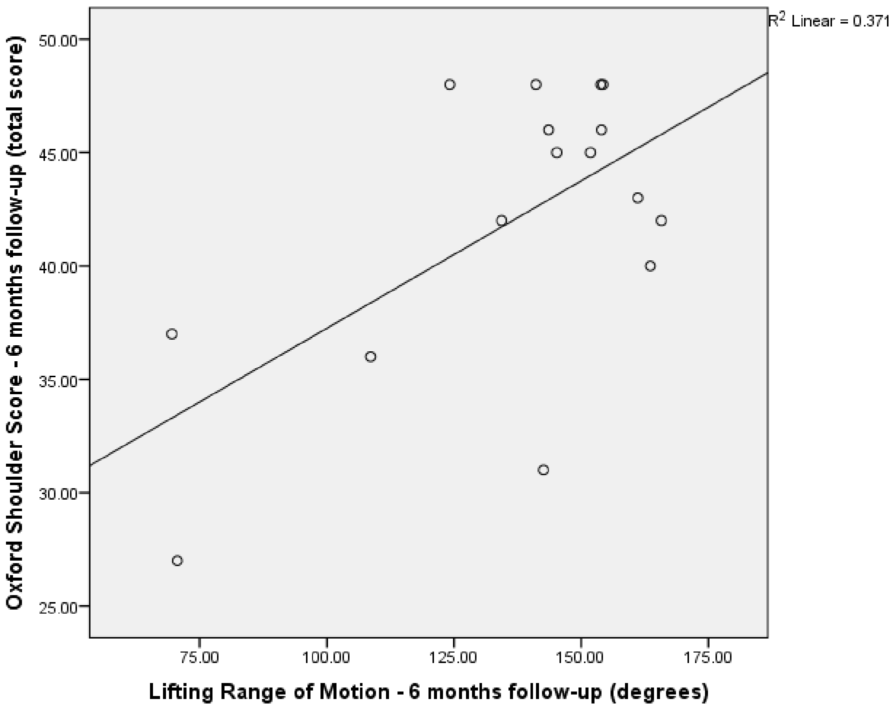


Figure 6.28. Scatterplot graph between Oxford Shoulder Score and Lifting ROM at 6 months follow-up.

6.10. Summary of Responder/Non-Responder analysis and Correlation analysis

The observational analyses classified patients as responders or non-responders based on the number of positive responses they showed on ROM for the tasks assessed (Table 6.17, pages 168-169). Those who had a positive response in at least three out of five tasks were considered responders.

Exploring individual patients' data revealed that there were patients who also improved their ROM in the Conservative group; although those allocated to the Early group had greater improvements and were the majority of the responders at the 3 months follow-up.

At 3 months, potential factors impacting a positive response might be related to sling usage (number of hours per day) and number of additional procedures during surgery, which reflected in a superior EQ-5D index and consequently better quality of life (Table 6.19, page 171). At 6 months, only 2 patients were classified as non-responders, apart from the difference between the groups' age (Table 6.20, page 173) no other outcomes seem to impact on patients results. However, as mentioned previously, the analyses of responders and non-responders were observational and descriptive, and a group of only 2 patients at 6 months follow-up may not be representative of the overall population.

Finally, the correlation analysis showed a moderate association (0.6) between ROM and function, which indicates that 37% of the variance of the questionnaire can be explained by the variable ROM during the Lifting task.

Chapter 6 focused on the results of the randomised controlled trial. The next chapter will discuss the method used in the RCT and the results of the various comparison and analyses undertaken for the RCT data.

CHAPTER 7: DISCUSSION - RANDOMISED CONTROLLED TRIAL

7.1. Introduction

Chapter 7 starts by discussing the randomised controlled trial method and about patients' compliance and adherence to the intervention. The chapter progresses to discuss the rationale used for choosing the exercises for the physiotherapy protocol and to discuss the clinical scores (objective 1) and the biomechanical results of the RCT (objectives 2 – 4). Following a similar arrangement to the results chapters, after the discussion on the biomechanics results, the next sections discuss the responders and non-responders, subgrouping (objective 5) and the relationship between clinical and biomechanical outcomes (objective 6). The chapter finishes by discussing the RCT limitations, the implications for practice and future research based on the results, and the conclusions of this study.

The aim of this thesis was to assess and to compare outcomes of patients who had a rotator cuff repair and were randomised to either early or conservative rehabilitation. The initial systematic review thoroughly examined the literature, which aided a robust rationale to underpin the RCT methodology. Moreover, the use of movement analysis with EMG had never been previously used in an RCT exploring the effectiveness of different rehabilitation regimes in patients undergoing a rotator cuff repair. Including a more complex method of conducting a clinical examination showed to be beneficial in providing more detailed information regarding muscle activity and accurate ROM measurements.

7.2. Randomised controlled trial method

7.2.1. Risk of bias

The RCT method strictly followed the CONSORT statement aiming to produce high-quality results with the lowest risk of bias possible, i.e. good internal validity (Moher et al., 2010). Bias is a systematic error and it is crucial to minimise them as much as possible. By doing so, the trial will produce reliable results and when other studies try to replicate the methods used, the further comparison between studies will show true differences rather than discrepancies that may be contaminated with over or underestimations (Higgins and Green, 2011).

In contrast to other RCTs on physiotherapy after rotator cuff repairs, this exploratory trial covered key components such as generation of random numbers, allocation concealment to avoid selection bias, and blinding the assessor (detection bias) and surgeon (performance bias), preventing their potential interference on treatment effects and results.

However, one major issue with the RCT of this thesis is related to the high loss to follow-up, which could be classified as attrition bias (Dumville, Torgerson, and Hewitt, 2006). Five patients at 3 months and 4 patients at 6 months did not have their follow-up assessments. In addition, the number of physiotherapy sessions each patient had in the Early and Conservative groups of this thesis varied. This is potentially associated with the fact that it was not possible to control where patients had their physiotherapy appointments. Initially, when the study was designed, the decision was that all patients would have their rehabilitation at the same centre; therefore, strict control of the number of sessions and protocol compliance would be possible. However, because of the recruitment rate, the strategy needed to be revised and the next best option was to send protocols to local physiotherapists. Although it was not ideal, it was a good opportunity to observe and understand how a future definitive RCT could be done and how the protocol can be implemented into clinical practice.

Compared to other RCTs, Duzgun et al. (2011) and Cuff and Pupello (2012) did not report their loss to follow-up; Lee et al. (2012) was the study with the highest loss to follow-up with 24% (21 out of 85 patients) and Duzgun et al (2014) the lowest with 5% loss (2 out of 42 patients). Attrition bias indicate that there is imbalance between groups and the findings may be affected (Dumville, Torgerson, and Hewitt, 2006); hence, the results of the RCT should be carefully interpreted due to attrition bias and the insufficient power to precisely detect the treatment effects, as the targeted sample size was not reached.

Apart from attrition bias, the RCT of this thesis covered other items that have received little or no attention in other studies, such as co-intervention and compliance. These last two items mentioned were not covered by any of the trials that were included in the systematic review (Figure 3.4, page 66). However, more recently, Mazzocca et al. (2017) published an RCT where they reported whether patients received co-interventions (pain medication) and whether they were compliant to sling usage. In their study, the majority of patients in both groups used the sling as requested (6 weeks); only

10 out of 58 patients assessed in the follow-ups did not follow the instructions. From these 10, 8 were in the conservative group and 2 were in the early group. However, there was no information about what they meant about compliance with sling usage; and no information regarding the number of hours per day or number of days with the sling, which makes the data on sling usage from this thesis an original contribution to knowledge. This information of how number of hours per day contributes to understanding how the sling usage affects patients' recovery, as discussed in section 3.4.6.1, page 89, keeping a limb immobilised for periods longer than 12h may affect brain plasticity and the shoulder's representation on the brain cortex. Thus, further RCTs with larger samples sizes should consider recording the number of hours patients are spending with a sling, in addition to how many days and weeks, to investigate whether it has an impact on outcomes.

Another study reporting compliance was from Raschhofer et al. (2017). In their RCT with 29 patients, compliance was recorded with a log that should be completed by patients at home when they performed the prescribed home exercises program; patients were excluded from the study if they have not completed at least 75% of their appointments and the home exercises.

In the RCT of this thesis, compliance regarding sling usage and number of physiotherapy sessions was checked and recorded at the follow-up assessments. This was the first time that the number of hours per day and number of physiotherapy sessions have been reported in an RCT comparing the effect of different periods of sling usage following a rotator cuff repair. According to patients own reports, patients in the Early groups used the sling on average 8.7 h/d in comparison to 22.1 h/d in the Conservative group. Regarding the number of weeks with the sling, only one patient in the Conservative group did not use the sling for 6 weeks, all other patients in that group used the sling as described in their protocol (Table 6.4., page 137). The same was observed for the Early group, with 40% of patients not using the sling for more than one week, only one patient used for 5 weeks and another single case used for 6 weeks.

Apart from RCTs, the only other study that measured sling compliance after having rotator cuff repair surgery was from Silverio and Cheung (2014). In their cohort (N=50), patients were instructed to use a sling for 6 weeks. In order to measure patients' adherence, the authors used the Medical Adherence Measurement Questionnaire. This tool consists of 10 questions, based on the responses, a score ranging from 0 to 100% of adherence is calculated (Zelikovsky and Schast, 2008). In addition, they used other functional scales (ASES, UCLA, SST) to explore whether poor adherence would result in poor function. Their results showed an average adherence of 88% and no association between adherence and reduction of function was observed. However, their study had a small sample size and the study did not have enough power to detect if the association between adherence and function was not a type II error.

The RCT of this thesis checked patient compliance based on patients' self-report, which is not the best method to be used as the data is based on patients' memory of events, i.e. recall bias (Rodrigues et al., 2018). Recall bias is a systematic error caused by the inaccuracy of patients reporting previous events (Spencer, Brassey, and Mahtani, 2017). However, currently, there is no available tool that had their psychometric properties validated and are recommended for research purposes to mitigate recall bias (McLean et al., 2016). One option is the Medical Adherence Measurement Questionnaire, this is a tool that has been adapted from another scale (Zelikovsky and Schast, 2008) however the Medical Adherence Measurement Questionnaire has not been validated. Recently, the Exercise Adherence Rating Scale had its initial psychometric evaluation in a group of 8 people with low back pain; it is a questionnaire about adherence to home exercises (Newman-Beinart et al., 2017). However, validating a tool with only 8 patients requires further investigation with a greater number of individuals. Therefore, future studies on creating and validating scales to measure adherence are needed.

An alternative to the method to check compliance could be the use of a diary, similar to Raschhofer et al. (2017). This could be designed to be filled by patients themselves at home or by the therapist or independent assessor when patients attended appointments or even by phone contact. The use of a diary would also give the opportunity to develop a protocol that instead of being therapist-led, could be patient led. As an example, Littlewood et al. (2014) conducted a pilot RCT comparing a self-managed exercise regime compared to usual physiotherapy. Twelve patients were randomised to the patient led intervention, for this group patients had to record in a diary when they performed the exercises; the results showed an adherence of 92% and the SPADI results for the self-managed group showed superior values than the usual physiotherapy group. Patient-led protocols seem to improve compliance, however, the study from Littlewood et al. (2014) had a limited sample size (N=24) and further studies are needed to test self-management with patients with shoulder disorders. In addition, with rotator cuff repairs patients, patient-led programs may increase the risk of retears as patients would be unsupervised on a large portion of the rehabilitation program (Jordan et al., 2010; Littlewood et al., 2014). Moreover, there is no valid instrument to assess self-reported adherence and recording this variable would still be a concern (Bollen et al., 2014).

7.2.2. Physiotherapy protocol

The combination of best research with clinicians' expertise and experience is the basis of evidence-based practice (Sackett et al., 1996). The rehabilitation protocol of this thesis was designed by discussing the integration of what had been done in previous trials (Table 3.6, pages 71-75) and what was already in place at Wrightington's physiotherapy department. Nevertheless, there was no patient or public involvement in the development of the rehabilitation regime at this point.

The experimental protocol developed (Early group) aimed to avoid possible joint stiffness and gradually progress tendon loading to aid tissue repair and healing, but at the same time aimed not to expose the surgery footprint site to excessive strain. The amount of load and tension applied to tendons needs to be controlled to stimulate healing and repair, and at the same time avoid overstressing the tendon (Khan and Scott, 2009). Measuring how much tension an exercise directly inflicts to tendons is challenging, however, a practical and acceptable way of doing so is by using muscle activity levels to classify how demanding the exercise is (McCann et al., 1993; Edwards et al., 2017). When normalised muscle activity is lower than 20% of the maximum it can be classified as low activation, between 21 to 40% moderate, between 41 to 60 % as high and greater than 60% is very high (Di Giovine et al., 1992). The greater the muscle activity the greater the tension is been applied to the muscle (Escamilla et al., 2009; Engelhardt et al., 2015).

Based on the concepts of EMG thresholds, exercises that were found within protocols of other trials were reviewed regarding their suitability for inclusion at each stage of rehabilitation and discussed with the physiotherapy team.

7.2.2.1. Physiotherapy protocol – stage 1

During the first stage, the aim is to have exercises that will not exceed 20% of muscle activity in the rotator cuff muscles to avoid high loads to the repaired tendons and consequently increasing the risk of retear/non-healing (Edwards et al., 2017). One common exercise that was described in many trials for the first phase of the rehabilitation was the "pendulum". The pendulum exercise, also called Codman, consists of patients staying in a standing position with their torso bent forward while helping their balance with the unaffected arm holding or resting on a chair or table, the affected arm stays hanging unsupported; then, the patient uses their body weight to start moving the hanging arm by shifting the body weight from side to side and forward and backward; the idea is that by using momentum, the glenohumeral joint will be mobilised while preventing activation of the rotator cuff muscles (Codman, 1934). However, Long et al. (2010) tested the muscle activity of the deltoid, supraspinatus and infraspinatus during the pendulum exercise of 13 individuals with no history of shoulder problems. They showed that rotator cuff muscles are indeed recruited during the pendulum exercise and are their activation are higher than the deltoid; the infraspinatus can reach almost 25% of the maximum voluntary isometric contraction, while the deltoid goes to a maximum of 6%. The authors conclude that pendulum exercises performed with large ROM or done incorrectly will generate higher rotator cuff activity (Long et al., 2010). Moreover, due to patients lack of appropriate motor control in the initial postoperative phase, when performing this exercise they may lose control of the movement range and can exceed the ROM safe zone, especially when performing the exercise in unmonitored situations at home, which may lead to adverse events on the repair (Chou et al., 2015). Therefore, regardless of its popularity, it was decided not to include the pendulum exercise within the rehabilitation protocol.

In contrast, in the first stage of rehabilitation, closed chain active assisted movements were chosen. According to previous EMG studies, active assisted exercises are good options to improve shoulder mobility, but still keep muscle activation under the low activation threshold (Murphy et al., 2013; Jung et al., 2016; Wells et al., 2016). The closed chain modality is a good indication for active assisted exercises initial phases. This can be performed with patients supporting their hands, for instance on a table, which allows improved control of the joint movement and how much weight support is applied on the affected limb.

In this thesis' trial, the main active assisted exercise was the table slide for shoulder flexion (Appendix 9, exercise 2), which has been shown to be the exercise that causes less stress to cuff tendons and can be easily progressed from assisting with the unaffected arm to using the affected arm alone only, with no support from the other arm. Jung et al. (2016), assessed the rotator cuff activity (supraspinatus, infraspinatus and subscapularis) of 18 healthy subjects during the table sliding exercise. They found very low activation of these muscles 4, 1% and 8% for the supraspinatus, infraspinatus and subscapularis, respectively. Another progression would be going from a seated position to a standing position, sliding through a wall and using gravity as resistance to start building muscle strength (Jung et al., 2016).

The focus of rotator cuff repair rehabilitation is undoubtedly the shoulder, however, making such an assumption does not mean that exercises should solely target muscles and joints of that region. The kinetic chain approach is an important concept that integrates the whole body as an interdependent linked system, where actions from distal segments impact those of proximal segments (McMullen and Uhl, 2000). The inclusion of kinetic chain exercises at the very first stage was used with the purpose of starting to improve motor control as soon as possible. By teaching patients how to use the power generated by their lower limbs, and having trunk muscles capable of transmitting these forces effectively, any future movements with their arms, that includes the shoulder complex, would be more efficient and easier to accomplish. Additionally, being more efficient means that the rotator cuff will need lower recruitment for the same task and would be less likely to be overloaded (De Mey et al., 2013; Turgut et al., 2016; Oliver, Plummer, and Gascon, 2016). However, this hypothesis of lower activation is unclear. For instance, De Mey et al. (2013) tested scapular retraction exercises involving the kinetic chain compared to exercises not involving the kinetic chain, they found that the lower and upper trapezius were more active during the exercises involving the kinetic chain. Similarly, Oliver, Plummer and Gascon (2016) also found greater activity of the upper trapezius and serratus anterior during shoulder exercises involving lunges and one leg stance balance. Nevertheless, further studies specifically assessing the activity of the rotator cuff muscles during kinetic chain exercises are still lacking.

An example of kinetic chain exercise that patients could perform at this stage was the *shoulder-dump*, which was described by McMullen and Uhl (2000). In this exercise, patients start in a standing position with one foot in front of the other, separated by about 30-40 cm, and trunk flexion and rotation to the same side of the front foot; the exercise consists on performing trunk extension and rotation while changing weight bearing from the front leg to the back leg and retracting the scapula. Patients can also externally rotate the humerus during scapula retraction, but at this stage, they were not allowed to. The rotational feature of the *shoulder dump* exercise mimics the proprioceptive neuromuscular facilitation (PNF) patterns that may translate to easier humeral rotations and faster increase of ROM (McMullen and Uhl, 2000; Hindle et al., 2012), PNF exercises were also present in the study from Duzgun, Gü, and Ahmet (2011), but at later stages.

The scapula focused exercises were prescribed to improve scapulothoracic function by training muscles directly involved in its motion, therefore, improving the overall shoulder movement smoothness (Cools et al., 2007). Due to the humerus ROM restrictions which need to remain within “safe zones”, the scapula control exercise (Appendix 9, exercise 1) was limited to a slow scapular circumduction which incorporated mainly movements in the coronal plane (adduction-abduction, depression-elevation), and to a less extent in the sagittal plane (protraction-retraction)(van der Meijden et al., 2012). Based on the study of Smith et al. (2006), where the authors recorded the activity of various shoulder muscles (supraspinatus, infraspinatus, upper subscapularis, deltoid, trapezius, biceps and serratus anterior) of 5 healthy individuals performing scapular movements (scapular rotation simulating a clock movement, elevation, depression, protraction and retraction), the isolated scapula exercise demonstrated low recruitment ratios especially for the infraspinatus and supraspinatus, but moderate to very high for the serratus anterior and the upper trapezius, respectively.

Associated with the scapular exercises, orientations regarding postural awareness were explained. The influence of posture alignment, especially the thoracic spine, on shoulder pain and function is controversial; however, it seems to have an important role on ROM improvement and muscle recruitment. Therefore, besides postural awareness, additional thoracic ROM exercises were also included (Lewis, Green, and Wright, 2005; Reinold, Escamilla, and Wilk, 2009; Barrett et al., 2016;).

A very important point on this stage was that patients were asked to avoid the combination of abduction with external rotation and extension with internal rotation (hand behind the back). These two movements may increase the risk of re-ruptures as they increase tension on the rotator cuff tendons (Edwards et al., 2017). Haering et al.

(2015) used a musculoskeletal model, based on data of 16 healthy individuals, to simulate and identify which positions were more likely to impose stress on rotator cuff tendons. Their findings demonstrated that elevations with internal rotation were the most likely to cause retears. However, cadaveric studies have demonstrated that the most hazardous positions are external rotation and abduction; these movements are thought to increase gap formations on the tendon-to-bone insertion, especially on the anterior portion of a supraspinatus repair (Reilly et al., 2003; Park, Jun, et al., 2007).

7.2.2.2. Physiotherapy protocol – stage 2

In the second rehabilitation stage (4-6 weeks), exercises could be progressed if the therapist considered that the patient was able to cope with an incremental load and volume. Although more substantial changes were recommended to be implemented at week 6, which is when the tendon tensile capacity is supposed to be around 36% of normal, as described in section 2.9.2, page 42.

Within the second stage of rehabilitation, proprioceptive exercises for rotator cuff motor control could be implemented for the Conservative group. For example, one exercise could be; placing a ball on a table, where patients would be required to press it, stabilising the object while performing scapular movements. Therefore, lightly loading the glenohumeral joint and permitting a proprioceptive input and at the same time activating the scapular muscles and keeping the ROM within the safe zone (McMullen and Uhl, 2000). Exercises focusing on proprioception are important to restore neuromuscular control and improve movement quality (Proske et al., 2012; Lin and Karduna, 2016). It has been shown that patients with rotator cuff related shoulder disorders have impaired proprioception, especially on the end limits of range of motion (Anderson and Wee, 2011). This finding may confirm that if the rotator cuff ability to control humeral upward migration is impaired by poor joint position sense, the subacromial space may be reduced and the underlying structures will be compressed causing pain and inflammation on the affected tissues. Therefore, proprioception is highly important in rehabilitating the rotator cuff.

Submaximal isometric contractions were also applied at phase 2 to start muscle strengthening without risking the repair integrity. Isometric contractions are generally the first strengthening exercise used on various post-surgical scenarios, it is a safe option to use as it does not involve joint motion, but still stimulates muscles adaptations to increasing loads (Gibson, 2004; Voight et al., 2010; Manske, Prohaska, and Lucas, 2012). Additionally, at this point, patients were asked to perform only submaximal contractions through the available range; therefore, avoiding excessive stress to rotator cuff muscles and improving muscle strength on different ROM positions (Tucci et al., 2011; Kang, Oh, and Jang, 2014).

7.2.2.3. Physiotherapy protocol – stages 3 to 5

After 6 weeks, strengthening exercises would start to move from closed chain to open chain and could also increase the lever arm, when applicable. The cuff maximum load stress capacity at 6 weeks is estimated to be around 36% (Carpenter et al., 1998). In the 4th stage, exercises demanding higher muscle recruitment, going from moderate to high and very high, are adequate as the tendon tensile capacity is close to 42%. Towards the end of the fourth stage (8-12 weeks), strengthening and stretching continues to progress and abduction combined with external rotation were allowed as the supraspinatus is considered to be strong enough to support loads associated to that position (Kim et al., 2014). Functional exercises reproducing patients' profession or sports activity could be trained. Besides different activities, stretching could be employed on appropriate ranges, avoiding the end limits, and respecting pain levels.

At the last stage (more than 12 weeks), if residual limitations on ROM were observed, manual therapy could be used to address such restrictions and provide extra sensory input (Ribeiro et al., 2017). The use of manual therapy on shoulder rehabilitation is controversial. Page et al. (2016) published a Cochrane systematic review on the benefits of manual therapy and exercises, combined or alone, for the treatment of shoulder disorders related to rotator cuff dysfunction. The analysis reviewed that the majority (43 out of 60) of the studies have a high risk of bias and they conclude that manual therapy combined with exercise improves only function after 22 weeks compared to placebo, but there is no difference for pain. In agreement with the Cochrane review, another review from Desjardins-Charbonneau et al. (2015) found equivalent results. Another study, from Camargo et al. (2015), showed that combining manual therapy with exercises do not improve scapula ROM, pain or function. Similarly, Guimarães et al. (2016) also showed, in an RCT, that shoulder mobilisation is no better than a sham technique for the same outcomes. However, in contrast, an RCT from Delgado-Gil et al. (2015) showed that manual therapy does improve pain and

ROM although the effects are on the short-term only. All three RCTs mentioned above on the effectiveness of manual therapy are of good quality, they fulfil most of the items regarding risk of bias.

Even though there is controversy with high-quality studies showing conflicting results, based on the physiotherapist experience it was decided to maintain manual therapy as an adjunct to the protocol, which could be used when a plateau on ROM improvement and stiffness was observed. For example, mobilisation such as anterior and posterior translational glides could be used, as there is an indication that they do not increase the stress applied on rotator cuff tendon and may help to improve ROM (Johnson et al., 2007; Muraki et al., 2007). No RCT included in the systematic review of this thesis describes the use of manual therapy focusing on improving ROM. The only studies to mention some kind of manual therapy is from Duzgun et al. (2014), but it was soft tissue mobilisation only. The other study was Duzgun et al. (2011), the authors reported using manual therapy preoperatively aiming to stretch the posterior capsule.

The milestones to move stages were defined based on the healing process, as described previously in section 2.9.2, page 42, but also based on therapist perception whether the patient was prepared to increase and change the amount of loading applied. This thesis protocol tried to adopt an evidence-based approach where possible, it aimed to optimise patients' recovery and potentially avoid the detrimental effects of using a sling for long periods on brain plasticity and shoulder representation in the brain cortex, as discussed in section 3.4.6.1, page 89. The results of the effects of the protocol are now discussed for the clinical scores and biomechanical outcomes.

7.3. Clinical Scores Results (objectives 1 and 2)

The RCT of this thesis was the first to use the Oxford Shoulder Score and the EQ-5D-5L to report the effectiveness of early rehabilitation after rotator cuff repair; these two instruments are valid and reliable tools to measure treatment effectiveness, as described in section 2.5, page 25. Their use is important as these tools are patient-reported outcome measures and show whether patients are perceiving improvements to their health and function. In addition, considering their easy applicability, clinicians can use the data obtained in this study to compare with their patients' results.

Overall, both groups improved function at follow-ups 3 and 6 months, when measured by the OSS. However, only the Early group had statistically significant differences between time points, which might be explained by the fact that the Early group had a lower score at baseline, almost 8 points less than the Conservative; therefore, the interval for improvement available to the Early group was 8 points greater than for the Conservative.

Regarding OSS MCID, some controversy exists as the original paper from Dawson et al. (2009) does not bring any reference values. Recently, the UKUFF trial (Carr et al., 2015), which was developed by the OSS authors, stated on their sample size calculation that the MCID is 3 points; however, there are no references to support their decision and the authors state that this threshold was defined based on their experience with the tool development: "*We did not propose any amendment to that clinically important difference in the reconfigured study. This defined difference was based on our experience of developing the OSS score and using it in a variety of settings; a 3-point score difference (0.33 of a SD) was deemed a clinically important difference*" (Carr et al., 2015). In contrast, van Kampen et al. (2013) determined the smallest detectable change (SDC), i.e. the measurement of the scale variation that is not due to error, and the MCID of the OSS based on a cohort of 95 patients. Their results suggested that the SDC and the MCID of the OSS were 6 points. This reference value has been confirmed by Christiansen et al. (2015), who found the same value. Thus, for the sake of comparison with the thesis RCT, a 6 points MCID was adopted.

Both groups improved above the OSS MCID from baseline to follow-ups at 3 and 6 months, and between 3 months and 6 months. Considering previous studies that have evaluated the effectiveness of rotator cuff repairs only, regardless of what type of physiotherapy was receive post-operatively, rotator cuff repair surgery has been shown to be effective at improving function and quality of life of those patients who fail to respond to conservative treatment for rotator cuff tears (Carr et al., 2015; Ryösä et al., 2016; Gurnani, van Deurzen, and van den Bekerom, 2017). The results for the OSS from this thesis at 6 months (Early= 42.75 and Conservative= 41.25) were similar to values found in the UKUFF trial at 24 months (Open=41.5 and Arthroscopy= 41.7) although the UKUFF trial compared the clinical effectiveness of two different surgical methods of performing a rotator cuff repair.

The MCID for the EQ-5D index has been investigated for many musculoskeletal disorders, mostly for surgical studies and low back conditions, but for shoulder dysfunctions, it is still to be explored (Coretti, Ruggeri, and McNamee, 2014). The MCID values have great variation ranging from 0.03 to 0.54; therefore, the value chosen for analogy was 0.08, from Larsen, Hansen, and Søballe (2008). The value of 0.08 was chosen as Larsen (2008), reported data from patients who needed a hip arthroplasty and who were split into two different procedures, this was the only study with a similar design to the RCT of this thesis; the other musculoskeletal studies on EQ-5D index MCID were cohort or cross-sectional.

Similar to the OSS, both groups in this current work improved above the MCID from baseline to follow-up 6 months. However, from baseline to 3 months follow-up a different trend was observed; with the Early group improving 0.09 points while the Conservative improved only by 0.02 points. These different increase ratios (0.09 vs 0.02) indicate that patients in the Early group perceived their improvement as significant, while patients in the Conservative did not perceive a clinically important change. It is noteworthy that a large variability is observed for the Conservative group, which suggests that some patients responded positively to treatment. In comparison to other studies regarding rotator cuff repairs effectiveness, but not including different physiotherapy protocols, both groups (Early and Conservative) had a score of 0.79 at 6 months, which is similar to 0.76 and 0.77 for the arthroscopic and open groups from the UKUFF trial (Carr et al., 2015).

Other RCTs on the topic have used different questionnaires, as described in Table 3.5, pages 69-70, therefore, it is difficult to directly compare clinical scores as the tools have different structures and even different domains. However, based on the MCID of each scale some estimations are possible. For example, the MCID for the Constant-Murley Score is 11 points and for the Shoulder Simple Test is 2.2 (van Kampen et al., 2013; Christiansen et al., 2015). Using this approach, it is possible to observe the same trend on the RCTs from Kim et al. (2012) and Koh et al. (2014). These authors did not find statistically significant differences between groups at follow-ups, but both groups in both studies improved more than the MCID score after 6 months, respectively for the SST and the CM. Keener et al. (2014) used both the SST and CM, but did not find differences between groups nor did patients improve above MCID at 6 months.

Clinical scores are important tools to measure patient response to interventions. However, they do not show the full picture as patients may be functional based on questionnaire results, but they may still have poor movement quality. Therefore, the next section will discuss the findings regarding the impact of early rehabilitation from the biomechanical assessments.

7.4. Biomechanics Results (objectives 2 to 4)

As described in sections 2.7 and 2.8, pages 32 to 40, three-dimensional kinematics and electromyography can record accurate movements and show whether motor control improves after treatment. This was the first RCT to use biomechanical variables to demonstrate the progression of patients having a rotator cuff repair from pre-operatory to post-operatory and to detail how two different protocols affect muscle recruitment and quality of movement.

Previously, in section 2.9.2, page 42, it was described how patients' and surgical factors may impact rehabilitation outcomes. However, in this RCT factors such as tear size, number of additional procedures, muscles involved, fixation method and smoking did not seem to have an influence on biomechanical outcomes as their distribution was balanced between groups.

Trying to compare the results of the activities of daily living from this RCT to other previously published studies is difficult due to the lack of similar design and hypothesis tested. Most studies with a similar method of assessment compared differences between patients who had the injury but were still untreated or patients with healthy groups or comparison after surgery versus healthy group. For example, Vidt et al. (2016) assessed 7 functional activities comparing patients with rotator cuff tears to a healthy control group, which included two similar tasks to those used in this thesis (combing and upward reach). In the Vidt et al. (2016) study, 5 patients and 5 healthy controls were assessed using reflective markers and seven 3D cameras; due to the use of cameras instead of inertial sensors, the upper limb model was different from the one used in this thesis, no further detail about how the model was defined is available. Their results showed that for upward reaching, which was similar to the tasks Flexion and Lifting, patients with rotator cuff tears had approximately 60° on the sagittal plane; for combing, only the external rotation is described, there is no information about the abduction ROM.

Another example is from Fritz et al. (2017), they measured 3D kinematics (reflective markers and 14 cameras) and EMG at 9-12 weeks post-surgery for 10 patients who had rotator cuff repairs compared to 10 healthy subjects, using 10 activities which included Combing and Reaching. As expected, patients showed lower ROM for Combing, Reaching and for all the other tasks included in their study. Moreover, they found higher muscle activity for the subscapularis, especially during external rotation, and for the infraspinatus during a writing activity in the patients with a rotator cuff repair. The higher recruitment of the cuff muscles during this activity may be due to compensatory strategies, balancing the insufficient activation of other cuff muscles and trying to maintain the humeral head stability.

These two cross-sectional studies (Vidt et al., 2016; Fritz et al., 2017) add valuable information regarding the quality of movement of patients with rotator cuff disorders; however, they only show a moment in time of patients' journey to recover. In contrast, using biomechanics during different ADLs before and after surgery and assessing the impact of different physiotherapy approaches, gives a thorough understanding of what factors may be compromising patients to return to their full capacity.

Considering the lack of RCTs on shoulder disorders using biomechanical outcomes, most of the comparisons in this section will be in relation to other research comparing the effects of early and conservative rehabilitation but which used other forms of measuring ROM. The use of 3D kinematics and EMG in the RCT of this thesis is the first to report with highly accurate equipment how patients progress from before surgery to 3 and 6 months after surgery regarding quality of movement during ADLs, which fills the previous gap on knowledge of how different physiotherapy protocols impact biomechanical outcomes and, therefore, addressing objectives 2, 3 and 4.

From the six tasks proposed in this thesis, none showed any statistically significant differences between Early and Conservative groups for ROM nor EMG activity. However, by observing the changes over time, a clear pattern reveals a different interpretation from the statistical narrative that early rehabilitation does not improve outcomes more than conservative. Overall, the Early group continually improved ROM at every follow-up time point, while the Conservative showed slight deterioration at 3 months for the tasks Carrying, Reaching, Flexion and Lifting, and at 6 months for Combing; with the only task to improve in the Conservative group at both follow-up time points being Abduction.

At 3 months, the differences in ROM between groups were small for all tasks except Flexion, which showed a mean difference of 10° in favour of early mobilisation. The MCID for shoulder flexion reported by Muir, Corea, and Beaupre (2010) is 14° when measured with a goniometer. Considering that the glenohumeral relative angle was defined as the humerus in relation to the thorax, the 10° difference might be translated to an absolute angle of 14° measured with goniometers. Therefore, patients in the Early group may be considered as having a clinically important improvement for shoulder flexion compared to Conservative treatment at 3 months.

Despite the difference in shoulder flexion favouring the Early group, the narrow margin for other tasks may explain why the OSS score still was superior for the Conservative group at that point. Patients may not see ROM as "the greater movement equals the better outcome"; as long as they reach a functional range that permits the return to some of their basic activities, and more importantly a reduction in pain, they may present similar total scores. For instance, during the tasks corresponding to activities of daily living (Combing, Carrying and Reaching) the mean differences between groups for ROM, at 3 months, were less than 4° and were also the tasks which the Conservative group had a reduction in at 3 months in comparison to baseline. Therefore, even though the Early group had greater improvements, the ROM indicates that at this stage both groups were functionally equivalent and consequently one rehabilitation regime does not seem to be superior to the other on meeting patients' expectations. Moreover, at this stage, patients may consider that a better improvement on pain status and quality of sleep is more relevant than having greater ROM (Lowe, Moser, and Barker, 2014; Imam et al., 2017). However, this RCT did not include a visual analogue scale to directly measure pain and determine whether it could be associated with the biomechanics outcomes. The only two RCTs on the topic to include VAS were Keener et al. (2014) and Koh et al. (2014), but these lacked information at the 3 months post-surgery time point (Figure 3.5 and 3.6).

Comparing the ROM to other RCTs at 3 months, the meta-analysis from Riboh and Garrigues (2014) showed supporting evidence for results for shoulder flexion found in the RCT in this thesis. When the authors pooled other RCTs data, the mean difference was 14.7°, measured by a goniometer, in favour of early rehabilitation; which is similar to the 10° difference found using inertial sensors in this thesis. The only RCT to show a smaller difference for flexion was Kim et al (2012) (4.86°). In addition, Riboh and Garrigues (2014) also found greater improvement at 3 months for external rotation in patients in an early rehabilitation group.

The movement analysis protocol used in this thesis was the first to quantify how early mobilisation of the shoulder complex before and 6 weeks post-surgery impacts on patients' capacity to maintain ROM in a loaded condition (Lifting task). Interestingly, when measuring the effect of a relatively light weight on ROM at 3 months, it was observed that patients in the Conservative group showed a reduction of about 5°, while the Early group reduced about 12°. This finding is surprising, after 12 weeks, patients in the Early group were expected to be stronger and have better function. At this point, patients in the Early group would be in an advanced stage of their rehabilitation programs with full kinetic chain and strength exercises demanding higher muscle activation. However, as the Early group presented worse mean ROM at baseline, it might be possible that a period of 3 months was not enough time to recover strength and muscle coordination to be equivalent to the Conservative group. It is important to highlight that even though the Early group had a greater reduction between Flexion to Lifting, they improved almost 30° in the Lifting task alone, comparing follow-up 3 to baseline, while the Conservative group had a reduction of 2° for the Lifting task at 3 months compared to baseline.

Both groups were relatively equal movement wise at the first follow-up, but the Early group showed a remarkable greater improvement at 6 months. The Early group had superior outcomes for ROM in every single task assessed at 6 months, besides better OSS. Apart from Reaching, all other movements for the Early group showed a minimum of 22° (Combing) and up to 64° mean improvement (Lifting), in contrast, the Conservative had a mean of -1.86° (Combing) and a maximum of 14.88° (Lifting). Statistically significant interactions were found between time points and group for the tasks Carrying, Flexion and Lifting, and further tests showed differences for only the Early group between baseline and second follow-up (6 months). Lifting was the task with the greatest improvement in both groups, which may indicate that the shoulder muscles were stronger (David et al., 2000). A possible explanation for Lifting having the greatest increase may be related to mechanical improvements of the rotator cuff. After 6 months, when the repaired tendons are closer to their normal strain support capacity, the deltoid may be able to reduce its participation as a glenohumeral stabiliser, due to lack of rotator cuff activity before surgery, and therefore becomes more efficient on its primary action as shoulder flexor and extensor (Bitter et al., 2007). This argument can be confirmed by the continuous higher activity (mean values) for the three deltoid muscles for the Early group, translating to superior ROM; in contrast, the Conservative group had a reduction of the anterior deltoid recruitment, and subsequently inferior progress of ROM. Thus, it is possible that the application of an early physiotherapy protocol may improve the mechanical properties of the muscle faster than when using a sling for 6 weeks.

In addition to the Lifting task, other tasks that showed over 50° mean difference from baseline for the Early group were Flexion (50.4°) and Abduction (51.72°). The mean differences between groups at 6 months ranged from 0.2° (Reaching) to 24.81° (Lifting), but apart from Reaching, which does not require a large ROM, the second task that had the lowest mean difference was Carrying (10.16°); therefore, most tasks had substantial differences between the groups that may be considered over the MCID for shoulder ROM. Compared to other studies data after 6 months of surgery, Figure 3.14 shows that when combining results from multiple RCTs there is no difference between early and conservative rehabilitation, which is contrasting to what was found in this thesis. Regarding shoulder flexion, Arndt et al. (2012) found the highest mean difference (12°) between groups in favour of early rehabilitation, and Koh et al. (2014) describe higher ROM for the Conservative group, although the difference is no greater than 2°.

Regarding patients' capacity to maintain ROM in a loaded condition, at 6 months opposite results were observed from the first follow-up. Three months further, Early patients showed better performance in keeping ROM, which resulted in almost no change from Flexion (152.03°) to Lifting (151.6°). The Conservative showed slight improvement, but they still showed a reduction on the mean ROM at this point (6.6°). Another task that confirms Early rehabilitation's superiority on recovering muscle strength was Carrying, which at 3 months showed less than 1° difference between groups, but the gap increased to 10° at 6 months, also in favour of the Early group.

The main rationale to explain why patients in the Early group in the RCT of this thesis showed that the greater improvement is underpinned by the graded and timed tendon loading plan, as discussed in section 7.2.2. If the loading stage is applied when the remodelling phase starts, it will assist with the reorganisation of the collagen fibres, with a better matrix structure and fibre orientation (Sharma and Maffulli, 2006). This argument is underpinned by animal models showing that during the remodelling phase is when new collagen synthesis occurs and better alignment of the fibres can be achieved through mechanical stimulation (Carpenter et al., 1998; Butler, Juncosa, and Dressler, 2004). Consequently, loading the appropriate time will aid the mechanical strength of the tendons and improve their ability to cope with higher tensions produced by muscles when elevating the upper limb to higher positions, with increased lever arms in loaded conditions (Funk, 2012; Sharma and Maffulli, 2006). Moreover, the greater improvement of the Early group corroborates with the hypothesis that shorter periods of immobilisation are more effective in recovering movement more efficiently, which in turn also helps patients in regaining their function quicker as well as giving them the opportunity of returning to their professional activities sooner (Keener et al., 2014).

In addition to the rationale of improving tendon and muscle mechanical properties, another benefit from starting controlled loading before six weeks is related to neurophysiological changes (Pelletier, Higgins, and Bourbonnais, 2015b). Considering the variable time since first symptoms (Table 6.2, page 134) it can be observed that patients had a chronic tendinopathy before having surgery. It is well described in the literature that chronic tendinopathies cause changes to both the motor and somatosensory cortex, which in turn alters motor control and muscle recruitment (Berth et al., 2009; Lewis et al., 2015; Rio et al., 2016).

Therefore, the objectives of rehabilitation for patients after rotator cuff repairs should not focus only on the physical properties of muscles and tendons, but it also needs to consider all neuromuscular and motor alterations that have occurred over a long period, possibly since first symptoms started (Littlewood et al., 2013; Pelletier, Higgins, and Bourbonnais, 2015b).

Other factors that affect brain neuroplasticity and consequently may impair patients' physical recovery are linked to mental health (Wylie et al., 2016). According to Chester et al. (2016), psychological factors such as patient expectation and pain self-efficacy are associated with outcomes for people with chronic shoulder pain. Although the RCT of this thesis involves patients in their post-operatory period, psychological factors may have an influence on follow-up outcomes as well. For instance, regardless of what group they were part of, patients' expectancy that surgery would resolve their pain and improve their function could influence results. Furthermore, Wylie et al. (2016) demonstrated that patients' mental health, measured by the SF-36 mental component summary, had a stronger association with pain and function status than tear characteristics such as size and retraction.

The impact of anxiety and depression has been shown to predict outcomes after subacromial decompression and is also linked to worse clinical outcomes before rotator cuff repairs. Dekker et al. (2016) demonstrated that high scores of both psychological factors before subacromial decompression were associated with worse clinical outcomes at 6 weeks and 6 months. Cho et al. (2013) explored the impact of the 2 psychological factors on people waiting for a rotator cuff repair. They found that this patient population had a high prevalence of depression and anxiety; in addition, depression was a strong predictor of worse pain, disability and quality of life. A new cohort has been planned in Australia to observe patients who will undergo subacromial decompression, excision of the distal clavicle or rotator cuff repairs and explore in more detail how depression affects pain, sleep quality and possible complications regarding movement, such as frozen shoulder (Hiscock, Bell, and Coghlan, 2015). The RCT in this thesis did not directly measure the influence of mental health on the outcomes; however, the EQ 5D-5L has a component regarding anxiety/depression, which asks whether the patient is feeling anxious or depressed. Consequently, mental health was measured indirectly and if patients scored low on the anxiety/depression question, it would reflect on the overall EQ-5D index result.

Psychological factors have not been fully explored as a factor influencing early or conservative physiotherapy post-rotator cuff repair. It would be strongly recommended that future research includes such outcomes. Moreover, based on the studies discussed on the psychological factors influencing clinical outcomes, it seems that using questionnaires in the clinical setting may help surgeons and physiotherapists to identify which patients may need additional professional psychological support prior and after surgeries and during physiotherapy, thus, potentially improving treatment effectiveness.

7.4.1. The Central Nervous System role on biomechanics (objective 4)

The classic biomedical model which determines that tissue injury is the only cause of pain symptoms has been challenged. Currently, there is evidence that changes to the peripheral an central nervous system associated with chronic tendinopathies, such as rotator cuff tears, play an important role in pain and consequently on motor control (Lewis et al., 2015; Pelletier, Higgins, and Bourbonnais, 2015a).

Due to muscle and tendon shortening on a tear, the proprioceptors and nociceptors that are present on the rotator cuff and the shoulder region will go through anatomical changes that halt their optimal functioning (Bachasson et al., 2015). On chronic lesions, a series of changes may be observed on proprioceptors and nociceptors structures, such as atrophy of intrafusal fibres, degeneration of supplying axons, increased sensitivity to stimulus and changes to the monosynaptic reflex (Bachasson et al., 2015). Therefore, the consequence is an increase in the transduction of nociceptive stimuli by peripheral receptors (Pelletier, Higgins, and Bourbonnais, 2015a). The increased transmission of nociceptive inputs on the dorsal horn of the spinal cord, via spinothalamic tract, creates a sensory amplification which results in sensitization. Thus, the increased sensitivity, due to a lower pain threshold, allows a higher number of stimulus that was not previously sent upwards to the brain, are now being sent as a pain impulse, and what was perceived as not harmful starts to be interpreted as noxious. This increased sensitivity would be expected to settle after the injury is healed (Pelletier, Higgins, and Bourbonnais, 2015a). However, in addition to the peripheral and central sensitisation from the spinal cord, what happens in chronic tendinopathies is that descending modulation information that would regulate the nervous system overactivity do not work as expected, which allows the spinal cord dysfunction to continue. As a result, the somatosensory and motor cortex are affected by neuroplastic changes causing alteration on how the body is represented in the brain (Ngomo, Mercier, and Roy, 2013; Ngomo et al., 2015; Pelletier, Higgins, and Bourbonnais, 2015a)

By changing muscles and limbs representation in the brain, motor control and muscle recruitment will be impaired (Hodges and Tucker, 2011; Hodges, 2011; Ngomo et al., 2015). In this thesis RCT, muscle recruitment was assessed with EMG. Overall, the integral of the 5 muscles (iEMG) did not present any statistically significant differences, which indicates that the amount of work done by each muscle was similar between groups and time points. However, as mentioned previously, the Conservative group showed a reduction in ROM for a few tasks. Therefore, although no statistically significant differences were observed, the implication of similar amount of work done and EMG amplitude but with better ROM for the Early group indicates that their shoulder muscles were more efficient than the Conservative group; the Early group needed similar muscle activity intensity to perform greater joint excursions (Wakeling et al., 2012). This rationale is underpinned by the study of Wakeling, Blake, and Chan. (2010); in this study, the authors assessed 8 subjects while cycling at maximum exertion for 25 min. EMG was collected from the quadriceps, hamstrings, soleus and gastrocnemius and gluteus maximus. The results demonstrated that the amount of power generated while cycling was not associated with an increase of EMG intensity.

Although the area under the rectified EMG curves does not explain much about inter-muscle coordination, by using this method, it was possible to observe that early rehabilitation could improve muscles performance by producing similar activation levels of peak EMG for more extensive ROM, however, there are other methods of analysing EMG and motor control. A well-known method is the qualitative assessment of muscle timing; in this method, by observing the onset and offset periods of each muscle it is possible to determine the order of muscle recruitment (Hodges and Bui, 1996). Some examples in the shoulder show that rotator cuff muscles are not recruited earlier than the deltoid, lower trapezius and serratus anterior during abduction (Reed et al., 2013) and the supraspinatus and deltoid also have the same timing when performing flexion (Wattanaprakornkul et al., 2011). As described in page 10, Reed et al., (2013, 2016), showed that the supraspinatus does not have their intensity or recruitment pattern altered in response to different planes of abduction and the supraspinatus does not start shoulder abduction, in addition Wattanaprakornkul (2011) found that the supraspinatus was in synchrony with the deltoid to start shoulder flexion.

The observation of muscle timing might give a better indication of which muscles are active and inactive during the movement, however, this does not give information about the intensity and therefore an estimation of the peak force muscle during the muscle recruitment, nor does it give details about the EMG curve shape and work done by the muscle. To address the problem, the cross-correlation method can be used to check for shape similarities and timing (Wren et al., 2006). A cross-correlation is a useful approach, but it is limited to the association of only two time series; therefore, if cross-correlation was the method used to check muscle inter-coordination for the 5 muscles chosen in this thesis, the conclusions could be inaccurate as they would not calculate inter-coordination based on the 5 muscles inter-variability. In addition, it has been shown that if two EMG signals have a similar shape and the contraction has the same duration but are shifted in time, the cross-correlation and the onset-offset method would produce the same result (Hug et al., 2010; Hug, 2011). A novel and very promising method of analyses that is able to overcome these issues is the Statistical Parametric Mapping (SPM) vector-field analysis (Pataky, Robinson, and Vanrenterghem, 2013; Robinson, Vanrenterghem, and Pataky, 2015). The SPM corrects for the multiple comparisons problem and tests for differences on the entire time-series and not only for single values (Pataky, 2016). For example, if the SPM vector-field analysis was used in this thesis dataset, to create a vector combining information from the 5 muscles time-series, therefore considering not just the variability of each muscle, but also the inter-muscle covariance. The advantage of using such a method is that this does not ignore the inter-muscle covariance and dependence, which allows further detail of how movement is coordinated by multiple muscles (Pataky, Robinson, and Vanrenterghem, 2013; Robinson, Vanrenterghem, and Pataky, 2015). Unfortunately, the Statistical Parametric Mapping is still under development for clinical biomechanics signals, it has not been validated for repeated measures designs and still does not support unbalanced datasets. (Pataky - SPM1D webstite), but it has been already used in other study designs that are exploring the shoulder and upper arm (Ribeiro, Day, and Dickerson, 2017; Simon-Martinez et al., 2017).

The use of the iEMG indicated how much work the shoulder muscles were exerting; however, it gave limited information about muscle coordination and muscle recruitment strategies; further studies should use other methods to explore the EMG activity of patients receiving early or conservative physiotherapy after rotator cuff repairs. Despite the fact that statistical tests did not show significant differences and the Early group showed an increasing trend on ROM, the high variability observed on data of both groups led to the decision to further explore what factors could be influencing patients having a differential response to treatments regardless of what group they were allocated to.

7.5. Responders and Non-responders (objective 5)

Identifying patients that may or may not respond to physiotherapy interventions has been explored for various musculoskeletal problems such as low back pain, patellofemoral pain and shoulder pain (Foster, Hill, and Hay, 2011; Chester et al., 2016; Selfe et al., 2016). Stratified treatment is advantageous as it uses characteristics that patients share in their subgroups to try to maximise treatment benefits (Foster et al., 2013). These set of observational subanalyses showed that it is possible that individuals responding positively to treatment share some common factors.

7.5.1. Follow-up 3 months

At 3 months, as shown on the previous analysis in section 6.8, page 157, the Early group had greater improvement with 6 patients classified as responders and only 2 as non-responders. In contrast, the Conservative group had 3 patients classified as responders and 4 as non-responders.

Regarding sling usage, the number of hours per day using the sling seems to influence clinical outcomes. The non-responders group used the sling more than twice the number of hours than responders. As discussed elsewhere in this thesis (section 3.4.6.1, page 89 and 7.4.1, page 197), prolonged periods using a sling can be detrimental to the central nervous system (Huber et al., 2006). Therefore, it seems that those patients who received more sensory input, by using the sling for fewer hours, recovered their ROM faster. Hence, the rehabilitation was acting not just on the mechanical aspect of the muscle and tendon, but also possibly addressing proprioceptive/joint position sense change due to cortical/motor control changes. Confirming this rationale, another variable that seems to have influenced the results was the time from first symptoms, the non-responders group showed an average of almost 2 years, for the time of first symptoms to having surgery, compared to 11 months for the responders. The chronicity of symptoms, especially pain, have been indicated as a possible factor to explain lower excitability of the infraspinatus on the cortex of patients with rotator cuff tendinopathy (Ngomo et al., 2015). This argument is underpinned by the study of Ngomo et al. (2015); in this study, transcranial magnetic stimulation was used, the brain representation of the supraspinatus was assessed bilaterally in 39 patients with rotator cuff tendinopathy. They showed that those patients who reported having symptoms for 24 months had lower excitability of the infraspinatus area on the brain cortex.

Moreover, patients that present central sensitisation before surgery are more likely to have worse results after three months than before the procedure; this was highlighted by the study of Gwilym et al. (2011). In this study, the Pain DETECT questionnaire, which is used to measure neuropathic pain, was applied to 17 patients with shoulder pain compared to healthy controls, before and after 3 months of a subacromial decompression surgery. They found that those patients who presented central sensitisation before surgery were those with worse outcomes at 3 months after surgery.

If confirmed in a further larger study, this finding that the time from first symptoms to time of surgery will create great debate not only about rotator cuff rehabilitation post-surgery but also pre-surgery. Currently, research has shown that physiotherapy is as good as surgery in the treatment of rotator cuff tears and should be considered as the first option of treatment (Kuhn et al., 2013; Kukkonen et al., 2014; Ryösä et al., 2016). The counter-argument to this is, if a full-thickness tear is not repaired, after two years, patients may develop symptoms due to further increase in tear size, and with greater fat infiltration the tear may become irreparable (Tashjian, 2012; Nakamura et al., 2015; Tan et al., 2016; Kim et al., 2017). However, to date, there is not enough evidence to prove that the amount of fatty infiltration before surgery will affect post-operative results (Khair et al., 2016). This trial did not control or record if patients had pre-operatory physiotherapy, however, based on the subgrouping findings, further studies should control this factor and even use it to plan randomisation stratification.

Another factor affecting outcomes was the number of additional procedures concomitant to rotator cuff repairs. Procedures such as biceps tenodesis/tenotomy and acromioplasty are contradictory, as discussed in section 3.4.6.2, page 91. Recently, Gialanella et al. (2017) compared outcomes of patients who did and did not need a biceps procedure associated with a rotator cuff repair, their findings showed that patients who had a biceps intervention showed worse functional outcomes. Acromioplasty also does not seem to have additional effects on rotator cuff repairs (Mardani-Kivi et al., 2016). The CSAW (Beard et al, 2018) randomised 313 patients into placebo surgery (N=103), decompression surgery (N=106) and no treatment (N=104); the authors found that there was a small improvement (2.8 points) on the OSS for the surgery group compared to placebo, but this was not clinically important.

Important steps towards understanding factors impacting rotator cuff tears outcomes have been taken by research on the shoulder field in general. However, it is still difficult to know when patients who do not respond to treatment how much of their symptoms are related to muscle mechanical deficiency, and how much is related to neuroplasticity changes. Potentially, the key to getting better outcomes after rotator cuff repairs is to use the sling for fewer hours to improve proprioceptive stimulation; however, further studies are needed.

7.5.2. Follow-up 6 months

At 6 months only two patients, both from Conservative group, were classified as non-responders, and the only factor that seems to influence their outcomes was related to being over 65 years old. Various studies have described age as a determinant for successful healing of the rotator cuff (Luime et al., 2004; Yamaguchi et al., 2006; Fehringer et al., 2008; Teunis et al., 2014). Diebold et al. (2017) performed a large cohort with 1600 patients to check the integrity of their repairs. The authors' findings showed that repair integrity was strongly linked to age and the retear ratio increased by 5% per decade. The age of patients who had a retear at 6 months was 65 and 70, which is almost similar to the age of the non-responders patients at 6 months from this RCT. Therefore, although patients were not assessed regarding repair integrity in this RCT, it might be possible that their non-response is associated with a retear episode. However, having worse function outcomes or strength does not necessarily means a retear episode. According to Colliver et al., (2015), the repair integrity does not correlate with the OSS. In this study, 60 patients who had a rotator cuff repair responded the OSS, SF-12 and DASH questionnaires, pain levels (VAS scale), isokinetic test for muscle strength and an MRI scan before and after surgery. They found that the clinical outcomes could not predict whether after surgery the patient had a retear 16 weeks later, and the amount of fatty infiltration did not influence shoulder strength results.

Most patients had a positive response at 6 months in the data sample of this thesis. Following a few months after postoperatively, patients treated using a more conservative physiotherapy fashion will regain tendon strength and probably after 12 months it may not make a difference when they started their physiotherapy (Koh et al., 2014; Pichonnaz et al., 2015). For instance, Koh et al. (2014) found no differences for clinical scores between early and conservative physiotherapy at 24 months.

During conservative rehabilitation, the tendon is loaded at a slower pace but is still loaded. Hence, in the long term, adaptations to tension stimulus will improve patients' strength and ROM (Verdano et al., 2013). However, early rehabilitation appears to bring patients back to their normal activities faster, without compromising tendon integrity. Early rehabilitation is not the cause of retears, or non-healing, as described in the systematic review performed in this thesis. Furthermore, the probability of having a retear is almost by chance when using the arthroscopic approach (46%); as recently shown by the UKUFF, which is one of the biggest studies performed in the UK regarding rotator cuff (Carr et al., 2015). Therefore, early rehabilitation does not appear to be jeopardizing patients' wellbeing or health. In fact, using early rehabilitation may have a better impact on patients' mental health, they can return to their social life faster without restrictions to their participation in activities. Furthermore, early rehabilitation may be more cost-effective as patients are discharged in a shorter period and may require fewer appointments with health professionals (Larsen et al., 2009). However, further studies need to investigate the cost-effectiveness of early rehabilitation on rotator cuff repairs. It seems that some conditions, such as knee and hip arthroplasty (Larsen et al., 2009), show better cost-effectiveness with early physiotherapy, but others like tendon transfers in the hand (Sultana et al., 2013) and spinal fusion (Oestergaard et al., 2013) do not benefit from this approach.

There are pros and cons of trying to stratify patients to improve treatment effect (Saragiotto et al., 2017). Trying to identify possible factors may help clinicians to shape their rehabilitation programs accordingly and make the most of it for each patient. This trial has a small sample, but some of the variables found in common may help further studies to use such information to stratify randomisation and better adjust for possible confounding factors that may contaminate final results. Similar to the study of Colliver et al. (2015), one of the objectives of this thesis was to investigate if a clinical score (OSS) was associated with ROM. The following section will discuss the findings of the analysis addressing objective 6.

7.6. Association between clinical and biomechanical outcomes (objective 6).

To address objective 6, the ROM of the task showing the greatest mean difference between follow-up, 6 months and baseline was chosen (Lifting) to investigate if better ROM is associated with a better function (OSS). The correlation analysis showed that there is a moderate association ($r=0.609$) between ROM and function and the correlation is linear ($P=0.006$) (Dancey and Reidy, 2004).

Another study which did a similar analysis was Fayad et al. (2008). In this study (N=88) the shoulder kinematics (electromagnetic sensor) and the DASH score of patients with shoulder pain showed a correlation of -0.45, which is lower than the value found in this thesis, but it is still considered a moderate association. However, -0.45 implicates that only 20% of the data variance of a ROM can be explained by the DASH score (Dancey and Reidy, 2004). For the DASH score, lower values mean better function, which explains why the correlation was negative. Runqist and Ludewig (2005) assessed 21 patients with adhesive capsulitis or rotator cuff tendinopathy. They investigated the association of shoulder kinematics (flexion), measured with electromagnetic sensors, and the Shoulder Rating Questionnaire, which scores between 17 to 100 with a higher value indicating better function. The correlation value was 0.53 (moderate), corroborating with the findings of this thesis.

The aim of the correlation analysis was to explore whether using the biomechanics assessment was associated with function and whether the ROM could predict what would be the functional status of the patient. However, a moderate correlation was found, which can be attributed to the OSS different components (pain and disability). Therefore, ROM is not the only variable that can explain a better function. Only 36% of the data variance of ROM could be explained by the OSS, and vice-versa. The relatively low shared variance explained by both outcomes indicates that using both tools, questionnaire and ROM, is beneficial to obtain a thorough understanding of patients' functional capacity and quality of movement.

7.7. Randomised controlled trial limitations

This thesis aimed to use high-quality methods to provide the most reliable results possible. Although all efforts were undertaken to avoid limitations to internal and external validity, some drawbacks need mentioning:

- The sample size planned was not achieved. Therefore, the study has limited power to determine whether the non-significant statistical differences between groups are not truly different. The study potentially was unable to detect such differences due to type II error, which is related to sample restriction and low power (Akobeng, 2016).

- The follow-up dataset was incomplete. Therefore, the final results might have been different if the dataset was complete. It is possible that due to missing values the treatment effects have been underestimated or overestimated, nevertheless, it will not be possible to know in which direction the differences would appear (Higgins and Green 2011; Fielding, Fayers, and Ramsay 2012).

- Patients were not statistically different at baseline, but high variability was noticed; therefore, baseline values were used as covariates. Using analysis of covariance to adjust for differences on the baseline is valid and has been shown to be the most appropriate method for this purpose (Zhang et al., 2014).

  There are other methods that can be used for baseline differences. The three most common are: difference (change) between post-treatment and baseline scores, change of percentage post-treatment and baseline, and analysis of covariance. The first two methods mentioned set the baseline values as zeros and compare how much improvement patients achieve post-treatment. However, the issue with these methods is if one group is closer to the limit of what is considered a complete recovery, the room for improvement is smaller to the group with better baseline values, therefore, the comparison is not fair as one group has greater chances of improving than the other. In contrast, using baseline as a covariate corrects precision by adjusting the values for initial discrepancies and provides an unbiased estimation of the true treatment effect (Vickers and Altman, 2001; Zhang et al., 2014)

- The alpha levels were not corrected for the multiple comparisons. However, the RCT was an exploratory trial. Further feasibility and definitive trials are needed to confirm the effectiveness of early rehabilitation.

- Tendon integrity was not screened for retears. The impact of using a sling for shorter periods on the healing process was not possible due to limited time and resources. Therefore, it is not possible to know if the Early group had higher retear rates. However, as discussed previously, the number needed to harm is 78, which is unlikely to be related only to early rehabilitation.

- EMG normalisation used peak activity from submaximal contractions. The most common method to normalise muscle activity is Maximal Voluntary Isometric Contraction. However, considering patients' condition, the pain levels that they might experience during maximal efforts and the time taken to perform individual tests for each muscle would make the Maximal Voluntary Contraction method unfeasible. Furthermore, a recent study showed that normalisation using dynamic contractions is more reliable than isometric contractions (Suydam, Manal, and Buchanan, 2017)

- The EMG signals from upper trapezius may have had cross-talk from the supraspinatus. Although sensor positioning protocol was strictly followed, the supraspinatus lies under trapezius and it is unavoidable that the sensor will also record supraspinatus activity. Only one person performed all the biomechanics assessment, therefore inter-assessor variability was attenuated, however, due to the intervals between assessment sessions sensor positioning may have been slightly affected.

- The intra-assessor and inter-assessor reliability of the biomechanical assessment was not tested. This could potentially influence the data recorded for EMG and kinematics and future studies should consider testing the reliability of their protocols. However, Al-Amri et al. (2018) recently investigated the intra- and inter-reliability of the Xsens MVN Biomech with 26 participants. They found that the equipment had excellent reliability for movements in the sagittal plane and other tasks involving multiple planes, they also found fair-to-excellent reliability for day-to-day and within-day assessments.

- The kinematics were measured with inertial sensors and processed with a model developed by Xsens in conjunction with C-motion (Xsens - Visual3D Wiki Documentation). Therefore, different 3D systems and different models may have minor discrepancies on measurements (Cutti et al., 2008; Lin and Karduna, 2013; Zhang et al., 2013).

7.8. Implications for practice

Based on the results of this thesis RCT, early rehabilitation does not seem to have a greater impact on outcomes compared to a more conservative approach based on the statistical analyses. However, after scrutinising for variables that could be elementary on recovery, it is suggested that even if a more conservative approach is required by the decision of the health care team, information towards the number of consecutive hours using the sling and regular intervals should be revised and periods of no more than 12 hours are advisable.

Exercises with focus on improving proprioception in the first weeks may potentially provide additional benefits as they will aid the recovery of the sensory cortex and consequently the motor cortex and motor coordination. In addition, the protocol used in this thesis was developed using an evidence-based approach and after revising the exercises from previous studies in the topic, the selection of exercises was based on the description of EMG activation demonstrated by studies in the topic and based on the experience of physiotherapist specialised in shoulder rehabilitation. This approach enhances the quality of the protocol and their application to clinical practice and may help patients' recovery to be more effective. Thus, both protocols (early and conservative, page 107) of this thesis could be applied to those patients who the healthcare team consider that early rehabilitation could be used or if a more conservative approach is advisable.

Another implication is in relation to time from first symptoms to having surgery and number of additional surgical procedures associated with the rotator cuff repair. The healthcare team should be aware that these variables may influence patients results on the short-term after surgery. Offering pre-operative physiotherapy may potentially help to mitigate the effects of a chronic tendinopathy aiming to improve outcomes post-surgery.

7.9. Implications for future research

Further research on rehabilitation after rotator cuff repairs is needed. Future studies following the MRC ladder should include a feasibility study where more centres are involved to recruit a larger sample. Based on their results, the feasibility study could give further indication of subgroups and whether rehabilitation needs to be tailored to these subgroups. Another approach that could be tested would be creating a protocol that is patient-led, which may have better adherence in relation to the therapist-led approach.

The biomechanics assessment should still be used in future RCTs in order to explore the motor patterns within this population and the influence of different physiotherapy protocols in a higher number of individuals. Moreover, further clinical biomechanics studies should apply the Statistical Parametric Mapping method to investigate differences in the whole kinematics time series and muscle inter-variability.

Thus, not having to change the hypothesis from one-dimension to zero-dimensional and observing how multiple muscles respond to multiple interactions.

Considering the high variability observed for the outcomes, future studies should assess the influence of pain levels on ROM data variability, this could be performed for within groups and between groups (e.g. baseline compared to follow-up 3 and 6 months).

7.10. Conclusions

No statistically significant differences for clinical scores, ROM and muscle activity were observed between early rehabilitation compared to a more conservative approach. However, observational analyses indicate that early rehabilitation may offer additional benefits in improving outcomes, especially in the short-term. The Early group showed continuous improvement up to 6 months; in contrast, the Conservative group showed reductions on ROM at 3 months but improved at 6 months.

Subgrouping analyses revealed that using a sling for shorter periods may be advantageous to help patients to recover faster and have better outcomes in the short-term (3 months). Patients older than 65 years, may potentially be at higher risk of stiffness if treated with a more conservative protocol.

This RCT had a small sample size and presented attrition bias, although it appears that early rehabilitation may be appropriate after rotator cuff repairs, the findings should be considered carefully; further studies are needed to confirm the clinical and cost-effectiveness of early rehabilitation after rotator cuff repairs.

7.11. Summary of RCT discussion and conclusions sections.

Chapter 7 discussed the findings of the RCT. The discussion highlighted that Early rehabilitation may potentially be beneficial to improve ROM, muscle activity and clinical scores at 3 and 6 months. In addition, the number of hours using a sling seems to be an important factor to considered after surgery and that patients older than 65 years may potentially be at higher risk of developing stiffness. However, further studies are needed to confirm the findings.

As described in section 6.2, page 131, 22 patients had to be excluded due to not needing a rotator cuff repair or because the repair would be at higher risk of not healing if early rehabilitation was applied. However, the data for these patients was recorded and in addition to the data from the normal subjects obtained in the pilot study. These additional datasets provided an opportunity to undertake further comparisons to investigate how patients at 6 months compared to individuals with no shoulder complaint, and whether the proposed biomechanics assessment had the capacity to identify different levels of shoulder impairment based only on the kinematic data. Therefore, chapter 8 will describe how these data were compared and the findings.

CHAPTER 8: FURTHER COMPARISONS WITH SUPPLEMENTARY DATASETS

8.1. Introduction

The following sections of chapter 8 will explore two supplementary comparisons using other datasets available from data recorded along the course of the PhD. The chapter starts by describing the specific objectives of the comparisons, followed by the methods. Next, the results section presents the analyses of the trial groups at 6 months in relation to healthy controls for the same tasks assessed in the randomised controlled trial. The following section shows the results for ROM of three different groups, which were formed by patients who underwent a subacromial decompression only, those who had a rotator cuff repair (trial participants) and those who had a massive tear and the repair was considered inappropriate for early rehabilitation. The chapter finishes with a discriminant analysis, leading to the discussion of the comparisons of supplementary datasets.

For the first set of analyses, the dataset of individuals with no shoulder complaint was compared to the RCT dataset from the 6 months follow-up. These analyses aimed to investigate how much residual impairment those patients in the Early group (N=8) and Conservative group (N=8) still had at that point. No EMG data was available for the healthy subjects (N=15), therefore only the kinematics were compared. For these comparisons, the null hypothesis is that there is no difference among patients treated with early and conservative rehabilitation, after 6 months from surgery, and individuals with no shoulder complaint.

The data from the subacromial decompression (SAD) and Massive groups were primarily recorded with the intention to serve as the baseline assessment, considering that these patients would be included in the trial. However, as previously mentioned, they did not fit the inclusion criteria, which was later determined by the surgeon. Hence, the second set of sub-analyses compared 3 groups: SAD (N=15), Massive (N=5) and Trial (N=20). The Trial group was composed of patients who were included in the RCT, but on these next comparisons, they formed a single group of 20 patients (baseline data). The rationale to merge Early and Conservative groups was to allow a comparison among 3 main groups which differed by the level of the impairments to their shoulder anatomical structures. This cross-sectional study had the objective to investigate whether the biomechanics assessment designed for the RCT was capable of discriminating/classifying patients into the pre-established groups (i.e.: SAD, Massive and Trial) based on their performance. Therefore, the data of the Trial group comprises their baseline information only.

The null hypothesis is that there are no differences in biomechanical variables among the three groups. The second null hypothesis is that a discriminant function constructed with the biomechanical variables has no discriminatory ability.

8.2. Objectives

Considering the rationale for each of the subanalysis, the objectives of this chapter are:

1. To compare how much residual impairment patients randomised to early or conservative rehabilitation have at 6 months compared to subjects with no shoulder complaints.
2. To determine whether a biomechanical assessment is capable of discriminating/classifying patients with different levels of shoulder impairment.

8.3. Method

Considering that the data was collected from: 1) patients who were part of the RCT, 2) patients who were supposed to be part of the RCT but were ineligible and 3) healthy individuals from the pilot study, which used the same equipment and tasks proposed, the movement analysis was exactly the same as described in sections 5.6 and 5.7, pages 111-126.

8.3.1. Statistical analyses

8.3.1.1. Group comparisons

For the comparisons Early vs Conservative vs Normals and Trial vs SAD vs Massive, the statistical analyses checked for the homogeneity of the variance using the Levene's test. When the assumption of homogeneity was attended a one-way ANOVA with Bonferroni post-hoc was applied to assess differences among groups, if the homogeneity was not attended the Kruskal-Wallis test was used to check for differences along with Mann-Whitney tests.

8.3.1.2. Discriminant function analysis

The discriminant analysis used the Wilk's Lambda method to identify which if the ROM variables would be able to significantly discriminate the groups Trial, SAD and Massive only. The canonical correlation was applied to measure the association between the discriminant function and the group of variables. Following this, classificatory analysis and cross-validation demonstrated the allocation accuracy for the discriminant analysis (Mazuquin et al., 2015).

8.4. Results

8.4.1. Normal subjects compared to Early and Conservative patients

8.4.1.1. Combing task – abduction with external rotation

The means and standard deviations are shown in Figure 8.1 and Table 8.1. Before deciding whether a parametric or a non-parametric test would be performed, the homogeneity of the variance was checked using the Levene's test, which showed that the variance among the three groups was not statistically different (P=0.088); therefore, a one-way ANOVA was applied.

The ANOVA showed a statistically significant difference between groups ($F=8.846$, $P= 0.01$), the Bonferroni post-hoc analysis showed a significant difference between the Conservative and Normal groups (Table 8.2).

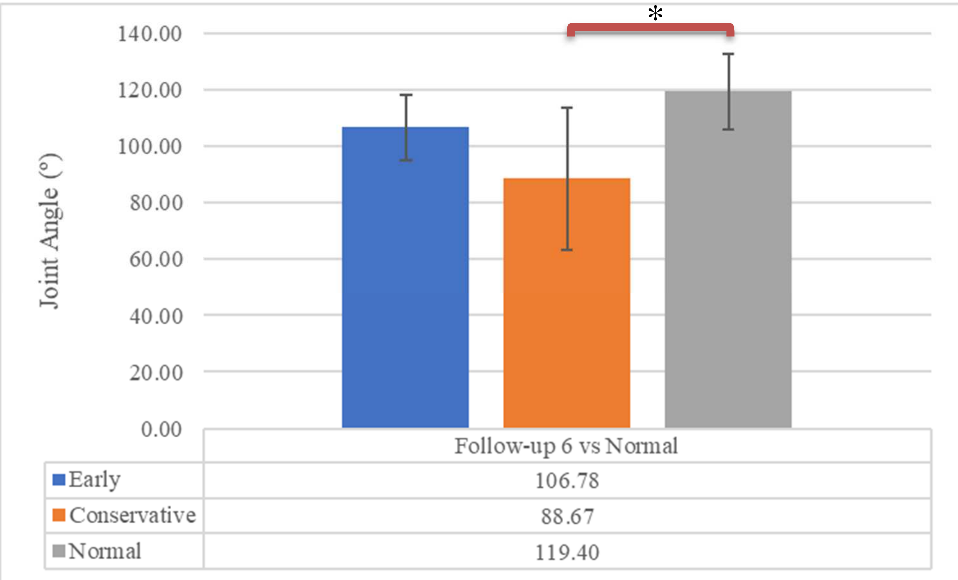


Figure 8.1. Mean and standard deviation of the three groups for the combing task.

*statistically significant difference

Table 8.1. Descriptive data of the three groups for the task combing.

Task	Group	n	$\bar{x}$ (°)	Std. Deviation
Combing	Early	8	106.78	11.47
	Conservative	8	88.66	25.16
	Normal	15	119.40	13.30
	Total	31	108.21	20.64

Table 8.2. Post-hoc comparisons for the task combing.

Multiple Comparisons

Bonferroni

Dependent Variable	(I) Group	(J) Group	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval	
						Lower Bound	Upper Bound
Combing	Early	Conservative	18.11	8.36	0.117	-3.18	39.40
		Normal	-12.61	7.32	0.288	-31.26	6.02
	Conservative	Early	-18.11	8.36	0.117	-39.40	3.18
		Normal	-30.73*	7.32	**0.001**	-49.37	-12.08
	Normal	Early	12.61	7.32	0.288	-6.02	31.26
		Conservative	30.73*	7.32	**0.001**	12.08	49.37

* The mean difference is significant at the 0.05 level.

8.4.1.2. Abduction task

The means and standard deviations are shown in Figure 8.2 and Table 8.3. The homogeneity of the variance for the task Abduction showed no statistically significant difference (*P*= 0.106). The one-way ANOVA showed a statistically significant difference between groups (F= 23.331, *P*<0.001); the post-hoc analysis indicated differences for both RCT groups in comparison to the Normal group (Table 8.4).

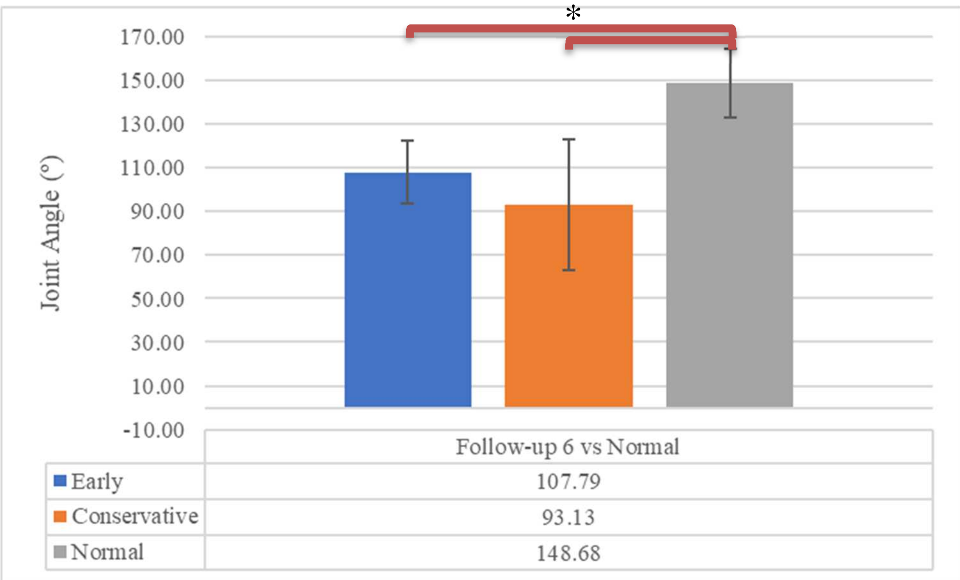


Figure 8.2. Mean and standard deviation of the three groups for the combing task. *statistically significant difference.

Table 8.3. Descriptive data of the three groups for the task abduction.

Task	Group	n	$\bar{x}$ (°)	Std. Deviation
Abduction	Early	8	107.79	14.39
	Conservative	8	93.13	29.89
	Normal	15	148.68	16.057
	Total	31	123.79	31.71

Table 8.4. Post-hoc comparisons for the task abduction.

Multiple Comparisons

Bonferroni

Dependent Variable	(I) Group	(J) Group	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval Lower Bound	95% Confidence Interval Upper Bound
Abduction	Early	Conservative	14.65	10.05	0.468	-10.94	40.25
		Normal	-40.89*	8.80	**<0.001**	-63.30	-18.47
	Conservative	Early	-14.65	10.05	0.468	-40.25	10.94
		Normal	-55.54*	8.80	**<0.001**	-77.96	-33.13
	Normal	Early	40.89*	8.80	**<0.001**	18.47	63.30
		Conservative	55.54*	8.80	**<0.001**	33.13	77.96

* The mean difference is significant at the 0.05 level.

8.4.1.3. Carrying task – horizontal adduction and abduction

The means and standard deviations are shown in Figure 8.3 and Table 8.5; the medians and interquartile ranges are shown in Table 8.6. The Carrying task did not have a homogeneous variance (*P*=0.022); therefore, the Kruskal-Wallis test was used to check for differences. The non-parametric test showed a statistically significant difference between groups (χ^2=12.946, *P*=0.002); further Mann-Whitney tests revealed differences for both RCT groups in comparison to the Normal database (Table 8.7).

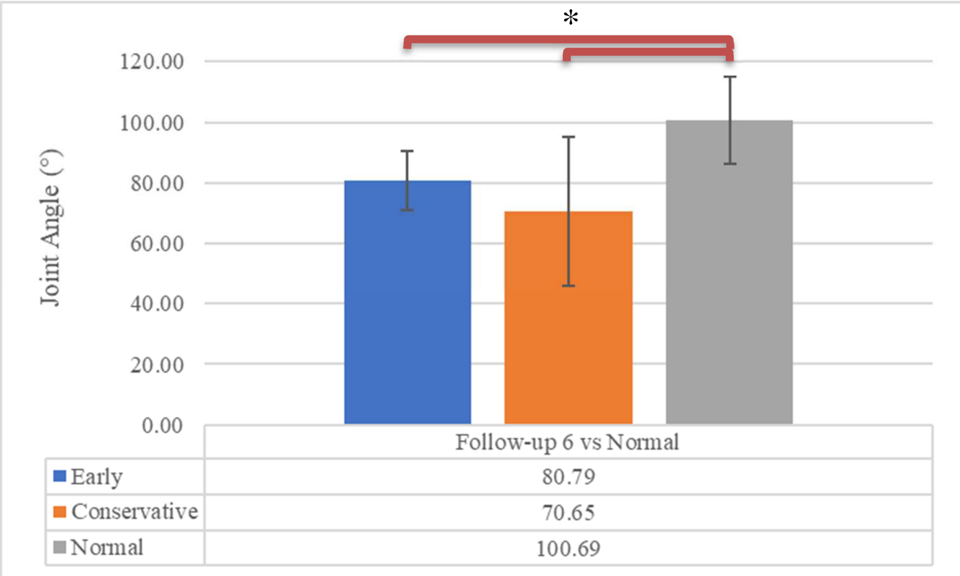


Figure 8.3. Mean and standard deviation of the three groups for the carrying task. *statistically significant difference.

Table 8.5. Descriptive data of the three groups for the task carrying.

Task	Group	N	$\bar{x}$ (°)	Std. Deviation
Carrying	Early	8	80.79	9.73
	Conservative	8	70.65	24.45
	Normal	15	100.69	14.50
	Total	31	87.48	20.96

Table 8.6. Descriptive data of the three groups for the task carrying.

Task	Group	Median (°)	Quartiles	
			25%	75%
Carrying	Early	78.62	71.07	87.91
	Conservative	80.53	43.30	90.22
	Normal	102.58	89.57	112.34

Table 8.7. Mann-Whitney tests for independent groups comparisons.

Dependent Variable	Group	Group	Mann-Whitney U	Sig.
Carrying	Early	Conservative	29.00	0.753
		Normal	13.00	**0.002***
	Conservative	Early	29.00	0.753
		Normal	16.00	**0.005***
	Normal	Early	13.00	**0.002***
		Conservative	16.00	**0.005***

* statistically significant difference.

8.4.1.4. Reaching task – extension and internal rotation

The means and standard deviations are shown in Figure 8.4 and Table 8.8. The Levene's test showed no statistically significant difference for the Reaching task (*P*= 0.540). The one-way ANOVA also showed no statistically significant difference (F= 2.246, *P*=0.125); therefore, no post-hoc analysis was undertaken.

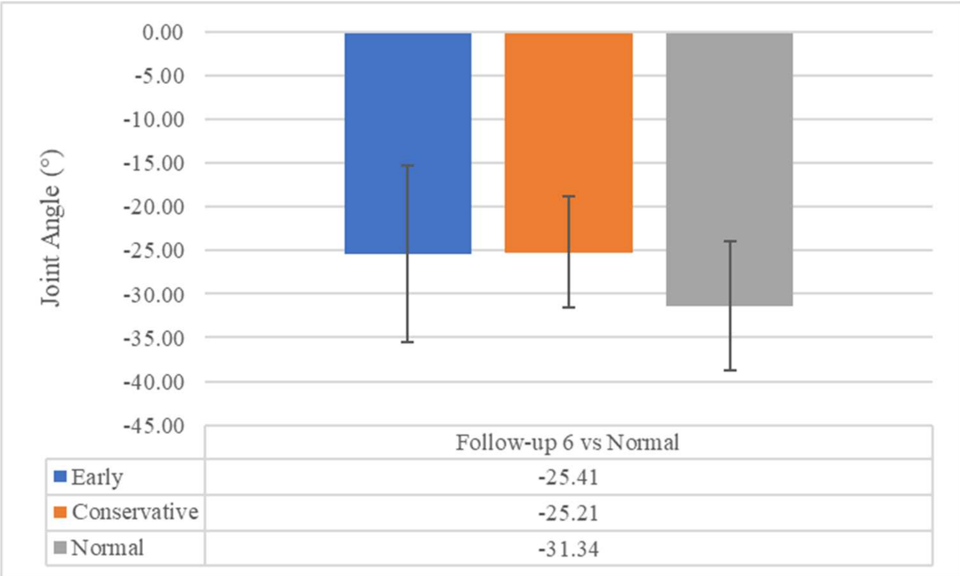


Figure 8.4. Mean and standard deviation of the three groups for the reaching task.

Table 8.8. Descriptive data of the three groups for the task reaching.

Task	Group	N	$\bar{x}$ (°)	Std. Deviation
Reaching	Early	8	-25.41	10.09
	Conservative	8	-25.21	6.40
	Normal	15	-31.34	7.34
	Total	31	-28.22	8.23

8.4.1.5. Flexion task – flexion and extension

The means and standard deviations are shown in Figure 8.5 and Table 8.9. The Flexion task had a homogeneous covariance (*P*= 0.240). The one-way ANOVA indicated a statistically significant difference between groups (F=13.525, *P*<0.001) and the post-hoc analysis showed that these differences were between the experimental groups in comparison to the normative data. The post-hoc analysis results are displayed in Table 8.10.

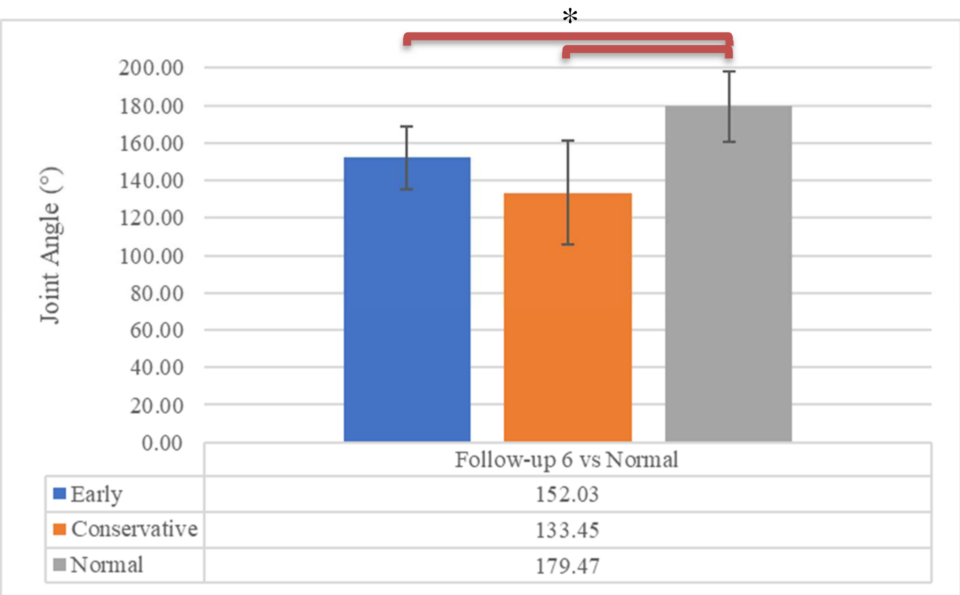


Figure 8.5. Mean and standard deviation of the three groups for the flexion task.

*statistically significant difference.

Table 8.9. Descriptive data of the three groups for the task flexion.

Task	Group	n	$\bar{x}$ (°)	Std. Deviation
Flexion	Early	8	152.03	16.46
	Conservative	8	133.45	27.80
	Normal	15	179.47	18.76
	Total	31	160.51	28.32

Table 8.10. Post-hoc comparisons for the task flexion.

Multiple Comparisons

Bonferroni

Dependent Variable	(I) Group	(J) Group	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval Lower Bound	95% Confidence Interval Upper Bound
Flexion	Early	Conservative	18.58	10.45	0.259	-8.03	45.20
		Normal	-27.43*	9.15	**0.017**	-50.74	-4.12
	Conservative	Early	-18.58	10.45	0.259	-45.20	8.03
		Normal	-46.02*	9.15	**<0.001**	-69.33	-22.71
	Normal	Early	27.43*	9.15	**0.017**	4.12	50.74
		Conservative	46.02*	9.15	**<0.001**	22.71	69.33

* The mean difference is significant at the 0.05 level.

8.4.1.6. Lifting task – flexion and extension lifting 1 kg

The means and standard deviations are shown in Figure 8.6 and Table 8.11. The covariance was homogeneous among groups (*P*=0.089); however, the parametric test showed statistically significant differences (F=8.798, *P*=0.001), further analysis confirmed a statistically significant difference between the Conservative vs. Normal groups only. The post-hoc analysis results are displayed in Table 8.12.

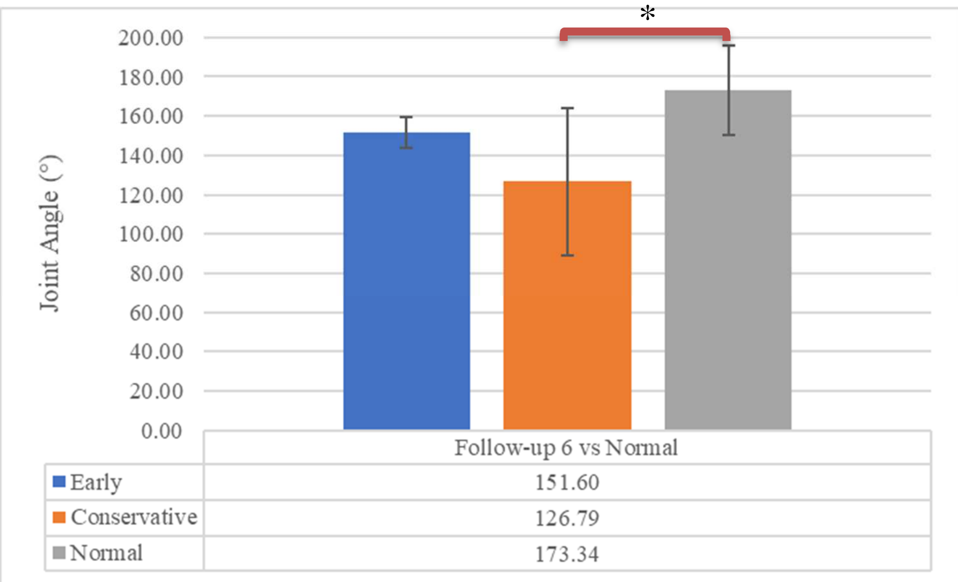


Figure 8.6. Mean and standard deviation of the three groups for the task lifting. *statistically significant difference.

Table 8.11. Descriptive data of the three groups for the task lifting.

Task	Group	n	$\bar{x}$ (°)	Std. Deviation
Flexion	Early	8	151.60	7.67
	Conservative	8	126.79	37.44
	Normal	15	173.34	22.87
	Total	31	154.32	32.21

Table 8.12 Post-hoc comparisons for the task lifting.

Multiple Comparisons

Bonferroni

Dependent Variable	(I) Group	(J) Group	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval	
						Lower Bound	Upper Bound
Flexion	Early	Conservative	19.43	13.06	0.444	-13.83	52.70
		Normal	-27.11	11.43	0.075	-56.24	2.01
	Conservative	Early	-19.43	13.06	0.444	-52.70	13.83
		Normal	-46.54*	11.43	**0.001**	-75.67	-17.42
	Normal	Early	27.11	11.43	0.075	-2.01	56.24
		Conservative	46.54*	11.43	**0.001**	17.42	75.67

* The mean difference is significant at the 0.05 level.

8.4.1.7. Summary of comparisons among Normal vs. Early vs. Conservative patients' analyses.

Section 8.4.1. was a cross-sectional study with analyses including data from subjects with no shoulder complaints (Normal) and data from the RCT patients at 6 months follow-up only. The only task which did not show statistically significant difference among the three groups was Reaching. The analyses showed that the Early group is closer to normal standards than the Conservative group at 6 months. This affirmation is supported by the statistically significant differences found between the Normal and Conservative groups in 5 out of 6 tasks (Combing, Abduction, Carrying, Flexion and Lifting). However, in three tasks (Abduction, Carrying and Flexion) statistically significant differences were also observed between the Early and Normal groups, which indicates that after 6 months patients having rotator cuff repairs were still presenting deficits in ROM.

8.4.2. Trial, Subacromial decompression and Massive tears groups

The following set of comparisons include data from the Trial (Early and Conservative combined), SAD and Massive groups; these data were obtained at baseline (before surgery).

8.4.2.1. Homogeneity of Variance

Similar to the previous section, the Levene's test was used to check for the homogeneity of variance. The Levene's test results for kinematics and EMG are shown in Appendix 12, Tables 12.1 and 12.2, respectively. In the following subsections, those variables which had a homogeneous variance (i.e.: $P > 0.05$) were further tested using a one-way ANOVA; otherwise, the Kruskal-Wallis' was used, with further Mann-Whitney tests when appropriate.

8.4.2.2. Combing task – abduction with external rotation

The descriptive data for kinematics is shown in Figure 8.7 and Tables 8.13 and 8.14. The Kruskal-Walli's test showed a statistically significant difference among groups for ROM (χ^2=13.792, *P*=0.001); further Mann-Whitney tests revealed differences for the SAD group in comparison to Trial (U=49.00, *P*=0.001) and Massive (U= 9.00, *P*=0.011), but not for Trial vs. Massive (U=33.00, *P*=0.248).

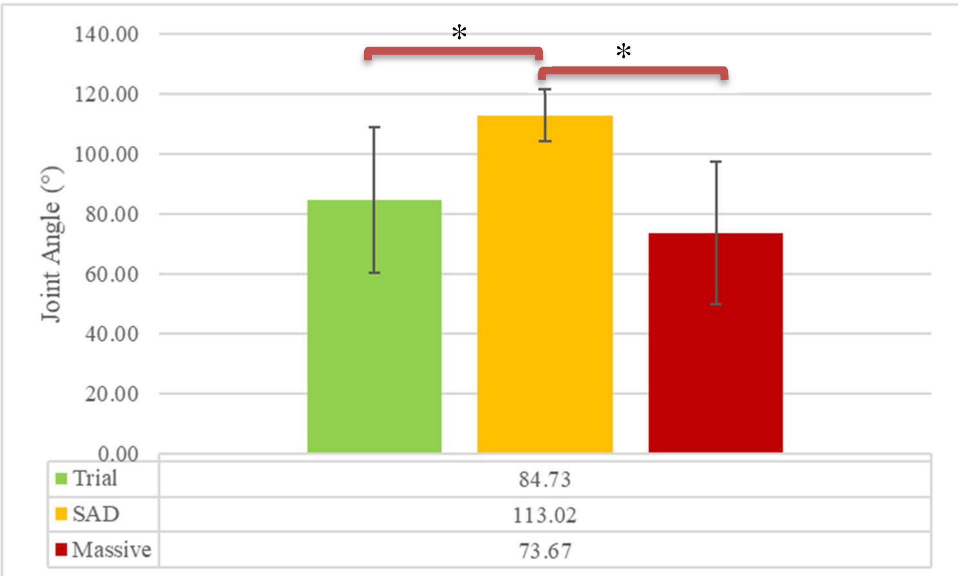


Figure 8.7. Mean and standard deviation of the three groups for the task combing. *statistically significant difference

Table 8.13. Descriptive data of the three groups for the task combing.

Task	Group	Median (°)	Quartiles	
			25%	75%
Combing	Trial	83.62	70.51	97.33
	SAD	111.87	109.21	116.99
	Massive	70.41	54.81	94.15

SAD: subacromial decompression.

Table 8.14. Descriptive data (median and quartiles) of the three groups for the task combing.

Task	Group	n	$\bar{x}$ (°)	Std. Deviation
Combing	Trial	20	84.73	24.19
	SAD	15	113.02	8.73
	Massive	5	73.67	23.83
	Total	40	93.95	24.63

SAD: subacromial decompression.

The descriptive data of muscle activity is shown in Tables 8.15 and 7.16. For muscle activity, no muscle showed statistically significant differences (Appendix 12, Table 12.3).

Table 8.15. Mean values of muscle activity for the task combing.

Groups	**Muscle $\bar{x}$ (SD)**				
	UT	**AD**	**MD**	**PD**	**BC**
Trial (%)	33.87 (14.78)	32.55 (21.43)	34.47 (19.00)	24.75 (14.64)	39.67 (20.39)
SAD (%)	30.66 (12.78)	33.41 (12.29)	36.61 (11.38)	23.86 (9.09)	41.06 (22.04)
Massive (%)	37.19 (9.94)	33.69 (8.50)	21.89 (2.71)	16.47 (5.12)	41.07 (15.37)

AD: anterior deltoid, BC: biceps, MD: medial deltoid, PD: posterior deltoid, SAD: subacromial decompression, SD: standard deviation, UT: upper trapezius.

Table 8.16. Median values of medium and posterior deltoids for the task combing.

Groups	Muscle Median (25%,75%)	
	MD	**PD**
Trial	34.99 (18.36, 49.10)	22.21 (11.36, 33.33)
SAD	40.38 (28.80, 44.44)	22.50 (18.57, 32.50)
Massive	22.82 (19.65, 24.14)	15.38 (11.68, 21.82)

MD: medial deltoid, PD: posterior deltoid, SAD: subacromial decompression.

8.4.2.3. Abduction task

The descriptive data for kinematics is shown in Figure 8.8 and Table 8.17. The one-way ANOVA showed a statistically significant difference for the ROM group comparison (F=6.597, *P*=0.004). Further post-hoc analysis showed a statistically significant difference between Trial vs SAD only (Table 8.18).

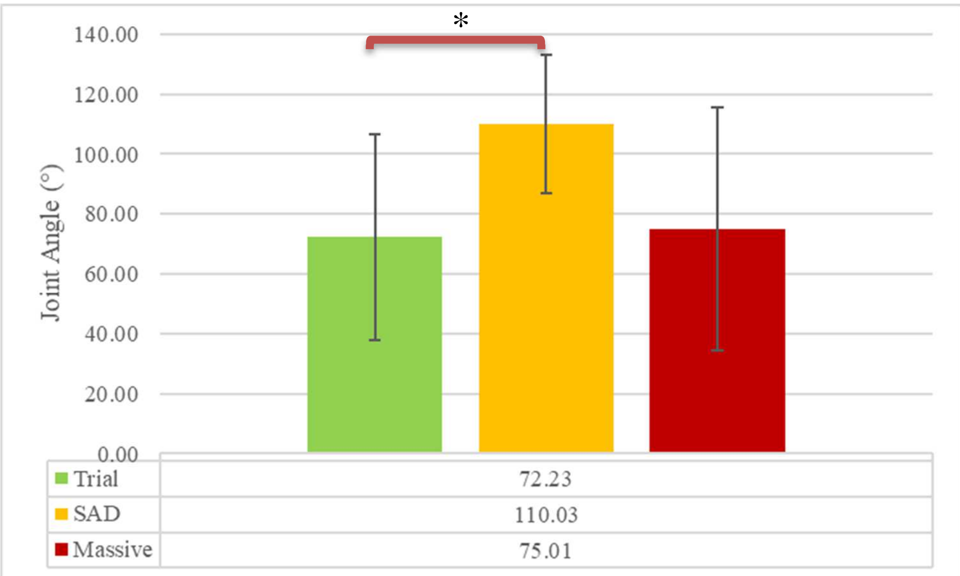


Figure 8.8. Mean and standard deviation of the three groups for the task abduction.

*statistically significant difference.

Table 8.17. Descriptive data of the three groups for the task abduction.

Task	Group	n	$\bar{x}$ (°)	Std. Deviation
Abduction	Trial	20	72.23	34.40
	SAD	15	110.03	23.09
	Massive	5	75.01	40.56
	Total	40	72.23	34.40

SAD: subacromial decompression.

Table 8.18. Post-hoc comparisons for the task abduction.

Multiple Comparisons

Bonferroni

Dependent Variable	(I) Group	(J) Group	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval	
						Lower Bound	Upper Bound
Abduction	Trial	SAD	-37.79*	10.73	**0.003**	-64.71	-10.87
		Massive	-2.77	15.71	1.000	-42.18	36.62
	SAD	Trial	37.79*	10.73	**0.003**	10.87	64.71
		Massive	35.01	16.22	0.113	-5.67	75.71
	Massive	Trial	2.77	15.71	1.000	-36.62	42.18
		SAD	-35.01	16.22	0.113	-75.71	5.67

* The mean difference is significant at the 0.05 level.

The descriptive data is shown in Table 8.19. No statistically significant differences were found in muscle activity during the Abduction task (Appendix 12, Tables 12.4).

Table 8.19. Mean values of muscle activity for the task abduction.

Groups	Muscle $\bar{x}$ (SD)				
	UT	**AD**	**MD**	**PD**	**BC**
Trial (%)	50.07 (21.26)	40.98 (17.20)	58.24 (21.90)	52.04 (22.47)	28.38 (18.05)
SAD (%)	47.40 (18.88)	45.92 (18.96)	58.69 (21.97)	50.06 (21.82)	21.22 (11.12)
Massive (%)	45.96 (15.73)	50.90 (25.98)	46.74 (13.97)	44.75 (11.88)	19.87 (10.58)

AD: anterior deltoid, BC: biceps, MD: medial deltoid, PD: posterior deltoid, SAD: subacromial decompression, SD: standard deviation, UT: upper trapezius.

8.4.2.4. Carrying task – horizontal adduction and abduction

The descriptive data for kinematics is shown in Figure 8.9 and Table 8.20. The ANOVA for ROM showed a statistically significant difference (F=4.802, P=0.015). Further post-hoc analysis showed a difference between Trial vs SAD only (Table 8.21).

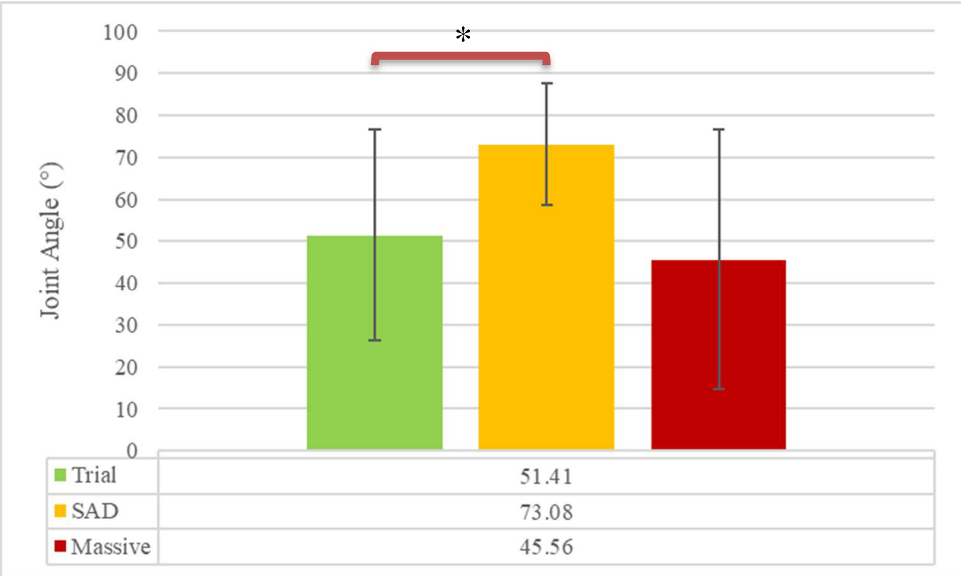


Figure 8.9. Mean and standard deviation of the three groups for the task carrying. *statistically significant difference.

Table 8.20. Descriptive data of the three groups for the task carrying.

Task	Group	n	$\bar{x}$ (°)	Std. Deviation
Carrying	Trial	20	51.41	25.27
	SAD	15	73.08	14.59
	Massive	5	45.56	31.00
	Total	40	59.56	24.40

SAD: subacromial decompression.

Table 8.21. Post-hoc comparisons for the task carrying.

Multiple Comparisons

Bonferroni

Dependent Variable	(I) Group	(J) Group	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval	
						Lower Bound	Upper Bound
Carrying	Trial	SAD	-21.67*	7.75	**0.025**	-41.2009	-2.1517
		Massive	5.84	12.25	1.000	-25.0269	36.7153
	SAD	Trial	21.67*	7.75	**0.025**	2.1517	41.2009
		Massive	27.52	12.47	0.103	-3.9068	58.9479
	Massive	Trial	-5.84	12.25	1.000	-36.7153	25.0269
		SAD	-27.52	12.47	0.103	-58.9479	3.9068

* The mean difference is significant at the 0.05 level.

The descriptive data for muscle activity is shown in Table 8.22. No statistically significant differences were found (Appendix 12, Table12.5).

Table 8.22. Mean values of muscle activity for the task carrying.

Groups	Muscle $\bar{x}$ (SD)				
	UT	**AD**	**MD**	**PD**	**BC**
Trial (%)	64.44 (20.06)	68.41 (20.83)	51.43 (23.93)	49.29 (21.92)	65.35 (22.81)
SAD (%)	60.19 (20.22)	63.97 (16.87)	56.13 (23.46)	55.82 (26.00)	69.13 (15.50)
Massive (%)	57.25 (22.71)	59.30 (28.47)	68.31 (16.82)	59.40 (21.18)	65.89 (21.85)

AD: anterior deltoid, BC: biceps, MD: medial deltoid, PD: posterior deltoid, SAD: subacromial decompression, SD: standard deviation, UT: upper trapezius

8.4.2.5. Reaching task – extension and internal rotation

The descriptive data for kinematics is shown in Figure 8.10 and Table 8.23. No statistically significant differences between groups were found for the Reaching task (*P*= 0.449); therefore, no post-hoc analysis was performed.

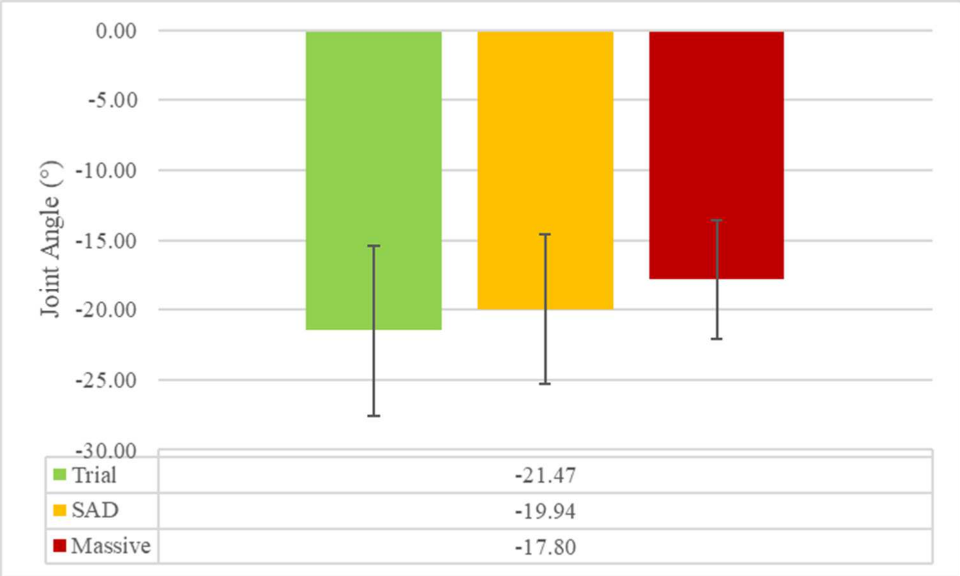


Figure 8.10. Mean and standard deviation of the three groups for the task reaching.

Table 8.23. Descriptive data of the three groups for the task reaching.

Task	Group	n	$\bar{x}$ (°)	Std. Deviation
Reaching	Trial	20	-21.47	6.08
	SAD	15	-19.94	5.37
	Massive	5	-17.80	4.26
	Total	40	-20.50	5.64

SAD: subacromial decompression

The descriptive data of muscle activity is shown in Tables 8.24 and 8.25. The analyses of muscle activity showed no statistically significant differences (Appendix 12, Table 12.6).

Table 8.24. Mean values of muscle activity for the task combing.

Groups	Muscle $\bar{x}$ (SD)				
	UT	**AD**	**MD**	**PD**	**BC**
Trial (%)	10.62 (9.61)	8.55 (12.72)	11.73 (10.68)	32.62 (22.23)	8.53 (9.82)
SAD (%)	5.90 (4.82)	5.37 (3.90)	5.62 (3.97)	23.39 (15.04)	19.96 (19.85)
Massive (%)	6.91 (6.86)	9.27 (12.55)	6.78 (4.89)	31.16 (22.82)	12.80 (10.44)

AD: anterior deltoid, BC: biceps, MD: medial deltoid, PD: posterior deltoid, SAD: subacromial decompression, SD: standard deviation, UT: upper trapezius.

Table 8.25. Median values of medium and posterior deltoids for the task combing.

Groups	Muscle Median (25%,75%)	
	UT	**BC**
Trial	7.59 (2.97,17.20)	4.88 (0.57,12.75)
SAD	5.78 (2.08,6.73)	12.50 (5.00,34.00)
Massive	3.12 (1.75,13.97)	12.50 (3.52,22.22)

BC: biceps, SAD: subacromial decompression, UT: upper trapezius.

8.4.2.6. Flexion task – flexion and extension

The descriptive data for kinematics is shown in Figure 8.11 and Table 8.26. The one-way ANOVA for Flexion showed a statistically significant difference for ROM (*P*= 0.047). Further post-hoc analysis indicated that only the SAD group was different from the Massive group (Table 8.27).

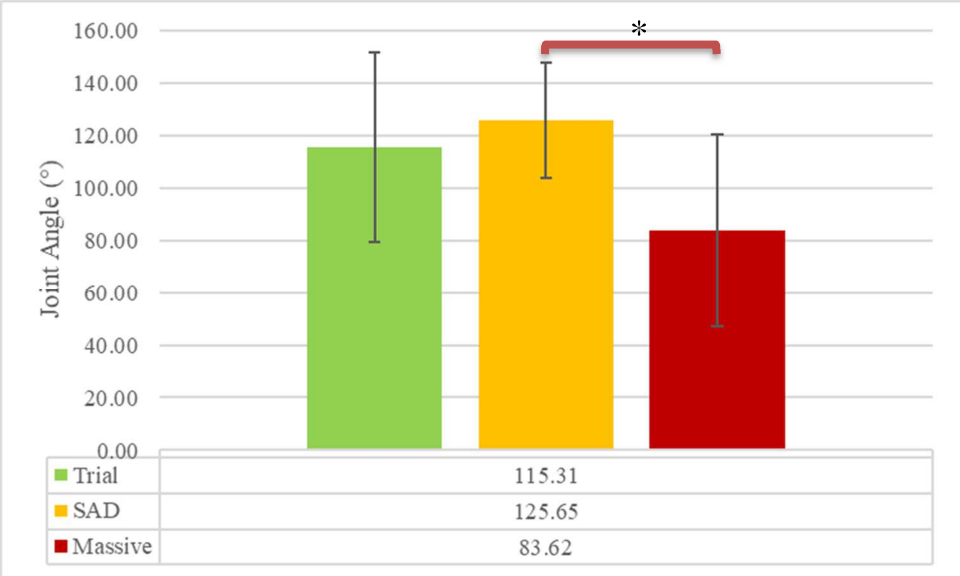


Figure 8.11. Mean and standard deviation of the three groups for the task flexion.

Table 8.26. Descriptive data of the three groups for the task flexion.

Task	Group	n	$\bar{x}$ (°)	Std. Deviation
Flexion	Trial	20	115.31	36.08
	SAD	15	125.65	22.09
	Massive	5	83.62	36.53
	Total	40	115.22	33.41

SAD: subacromial decompression.

Table 8.27. Post-hoc comparisons for the task flexion.

Multiple Comparisons

Bonferroni

Dependent Variable	(I) Group	(J) Group	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval Lower Bound	Upper Bound
Flexion	Trial	SAD	-10.34	10.78	1.000	-37.39	16.71
		Massive	31.68	15.79	0.156	-7.91	71.28
	SAD	Trial	10.34	10.78	1.000	-16.71	37.39
		Massive	42.02*	16.31	**0.042**	1.12	82.93
	Massive	Trial	-31.68	15.79	0.156	-71.28	7.91
		SAD	-42.02*	16.31	**0.042**	-82.93	-1.12

* The mean difference is significant at the 0.05 level.

The descriptive data of muscle activity is shown in Table 8.28. No statistically significant differences were observed in muscle activity for the Flexion task (Appendix 12, Table 12.7).

Table 8.28. Mean values of muscle activity for the task flexion.

Groups	Muscle $\bar{x}$ (SD)				
	UT	**AD**	**MD**	**PD**	**BC**
Trial (%)	43.26 (17.02)	47.72 (16.50)	46.28 (19.43)	44.02 (18.83)	38.86 (16.31)
SAD (%)	37.41 (13.00)	63.11 (19.98)	50.22 (17.22)	44.36 (15.80)	37.28 (15.54)
Massive (%)	33.49 (10.67)	45.23 (26.21)	30.38 (13.07)	29.34 (13.35)	30.25 (21.69)

AD: anterior deltoid, BC: biceps, MD: medial deltoid, PD: posterior deltoid, SAD: subacromial decompression, SD: standard deviation, UT: upper trapezius.

8.4.2.7. Lifting task – flexion and extension lifting 1 kg

The descriptive data for kinematics is shown in Figure 8.12 and Table 8.29. The variable ROM did not show a statistically significant difference (*P*= 0.125).

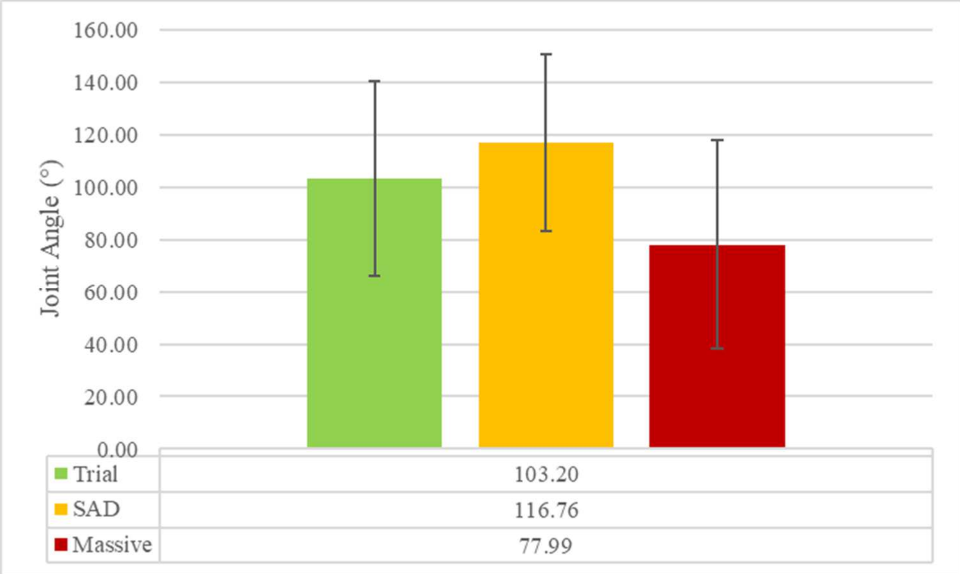


Figure 8.12. Mean and standard deviation of the three groups for the task lifting.

Table 8.29. Descriptive data of the three groups for the task lifting.

Task	Group	n	$\bar{x}$ (°)	Std. Deviation
Lifting	Trial	20	103.20	37.25
	SAD	15	116.76	33.78
	Massive	5	77.99	39.73
	Total	40	105.23	37.36

SAD: subacromial decompression

The descriptive data for muscle activity is shown in Table 8.30. The one-way ANOVA for muscle activity revealed statistically significant differences for the anterior deltoid and the biceps, *P*=0.009 and *P*<0.001, respectively (Appendix 12, Table 12.8). Post-hoc analysis revealed differences between the SAD vs Trial and SAD vs Massive for the anterior deltoid, and between Massive vs Trial and Massive vs SAD for the biceps (Tables 8.31 and 8.32). The post-hoc analysis showed a statistically significant difference between SAD and Trial and between SAD and Massive. The post-hoc analysis for the biceps revealed statistically significant differences between Massive and Trial groups and between Massive and SAD.

Table 8.30. Mean values of muscle activity for the task lifting.

Groups	Muscle $\bar{x}$ (SD)				
	UT	**AD**	**MD**	**PD**	**BC**
Trial (%)	47.17 (17.57)	53.57 (19.18)	47.42 (20.60)	56.00 (23.31)	58.05 (19.38)
SAD (%)	49.53 (15.87)	72.18 (21.08)	55.38 (23.08)	51.47 (20.52)	70.01 (14.92)
Massive (%)	29.04 (10.92)	41.73 (19.01)	27.13 (9.59)	37.82 (17.93)	26.87 (10.80)

AD: anterior deltoid, BC: biceps, MD: medial deltoid, PD: posterior deltoid, SAD: subacromial decompression, SD: standard deviation, UT: upper trapezius.

Table 8.31. Post-hoc comparisons for the anterior deltoid during the task lifting.

Multiple Comparisons							
Bonferroni							
						95% Confidence Interval	
Dependent Variable	(I) Group	(J) Group	Mean Difference (I-J)	Std. Error	Sig.	Lower Bound	Upper Bound
Lifting – Anterior Deltoid	Trial	SAD	-18.60*	6.98	**0.035**	-36.19	-1.01
		Massive	11.84	11.04	0.873	-15.96	39.65
	SAD	Trial	18.60*	6.98	**0.035**	1.01	36.19
		Massive	30.44*	11.24	**0.032**	2.13	58.75
	Massive	Trial	-11.84	11.04	0.873	-39.65	15.96
		SAD	-30.44*	11.24	**0.032**	-58.75	-2.13

* The mean difference is significant at the 0.05 level.

Table 8.32. Post-hoc comparisons for the biceps during the task lifting.

Multiple Comparisons

Bonferroni

Dependent Variable	(I) Group	(J) Group	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval Lower Bound	95% Confidence Interval Upper Bound
Lifting - Biceps	Trial	SAD	-11.96	5.90	0.151	-26.80	2.87
		Massive	31.17*	8.53	**0.003**	9.71	52.63
	SAD	Trial	11.96	5.90	0.151	-2.87	26.80
		Massive	43.13*	8.71	**<0.001**	21.21	65.05
	Massive	Trial	-31.17*	8.53	**0.003**	-52.63	-9.71
		SAD	-43.13*	8.71	**<0.001**	-65.05	-21.21

* The mean difference is significant at the 0.05 level.

8.4.2.8. Discriminant function analysis

Considering the comparison between the three groups, most of the statistically significant differences were for kinematics variables. Therefore, the discriminant analysis did not include EMG data. Two patients from the Trial group and one from the Massive were not included because they could not perform the Carrying task.

The homogeneity of the covariance matrices was significant (*P*= 0.001). The first function was chosen as the best to discriminate groups based on its capacity of explaining the percentage of variance and the high Canonical correlation value (Table 8.33). Moreover, the Test of Function proved that the function can significantly discriminate groups (Table 8.34).

Table 8.33. Function percentage of variance and Canonical correlation values.

Eigenvalues				
Function	Eigenvalue	% of Variance	Cumulative %	Canonical Correlation
1	2.699[a]	87.6	87.6	0.854
2	0.382[a]	12.4	100.0	0.526

a. First 2 canonical discriminant functions were used in the analysis.

Table 8.34. Test of function result.

Wilks' Lambda				
Test of Function(s)	Wilks' Lambda	Chi-square	df	Sig.
1 through 2	.196	51.399	12	<0.001
2	.723	10.198	5	0.070

The selection of the discriminant variable followed a two-step method:

1) The function threshold to select the discriminant variables was defined based on the results of the Functions at Group Centroids (Table 8.35);
2) Based on that, if the threshold value was positive, the variables that were above the group threshold were chosen as discriminant, if the threshold was negative, the

standardized canonical discriminant function coefficients values that were below that point were selected as adequate (Table 8.36).

Table 8.35. Function at Group Centroid Values.

Functions at Group Centroids		
	Function	
Group	1	2
Trial	-1.580	.130
SAD	1.740	.294
Massive	.587	-1.688

Table 8.36. Standardized canonical discriminant function coefficients.

Standardized Canonical Discriminant Function Coefficients		
	Function	
	1	2
Combing ROM	1.062	.799
Abduction ROM	1.775	-.794
Carrying ROM	.689	.001
Reaching ROM	-.514	-.199
Flexion ROM	-3.033	1.025
Lifting	.084	-.263

Therefore, the discriminant variables for each group were:

- Trial: Flexion ROM
- SAD: Abduction ROM
- Massive: Combing ROM, Abduction ROM and Carrying ROM

Based on the discriminant analysis a classificatory analysis was carried out to assess how accurate it was in classifying individuals into their primary groups considering the discriminant variables. The classificatory analysis could correctly classify 91.9% of the individuals, while the cross-validated analysis showed an accuracy of 75.7% (Table 8.37).

Table 8.37. Classificatory and cross-validated analyses.

Classification Results [a,c]

			Predicted Group Membership			
		Group	Trial	SAD	Massive	Total
Original	Count	Trial	16	1	1	18
		SAD	0	15	0	15
		Massive	0	1	3	4
	%	Trial	88.9	5.6	5.6	100.0
		SAD	0	100.0	0	100.0
		Massive	0	25.0	75.0	100.0
Cross-validated [b]	Count	Trial	14	2	2	18
		SAD	1	13	1	15
		Massive	1	2	1	4
	%	Trial	77.8	11.1	11.1	100.0
		SAD	6.7	86.7	6.7	100.0
		Massive	25.0	50.0	25.0	100.0

a. 91.9% of original grouped cases correctly classified.

b. Cross-validation is done only for those cases in the analysis. In cross-validation, each case is classified by the functions derived from all cases other than that case.

c. 75.7% of cross-validated grouped cases correctly classified.

SAD: subacromial decompression.

8.4.2.9. Summary of Trial, Subacromial decompression and Massive tears groups comparisons and discriminant analysis.

Overall, the SAD group showed superior mean values for ROM compared to the Trial and Massive groups for all tasks, except Reaching. Statistically significant differences were observed for ROM between:

- SAD and Trial for Combing, Abduction and Carrying.
- SAD and Massive for Combing and Flexion.

No statistically significant differences were observed for ROM between the Trial and Massive groups, which may be due to the high variability found in the data of the Massive tears group. However, the Trial group showed better mean ROM values in five out of the six tasks (Combing, Carrying, Reaching, Flexion and Lifting) compared to the Massive group.

The comparisons for muscle activity revealed no statistically significant differences among groups for the tasks Combing, Abduction, Carrying, Reaching and Flexion. The task Lifting showed a statistically significant difference for the anterior deltoid (SAD vs. Trial and SAD vs Massive) and biceps (Trial vs. Massive and SAD vs Massive). The SAD group showed higher mean values for muscle activity of the anterior deltoid and biceps compared to both groups. Patients in the Massive group showed reduced mean values for muscle activity compared to both groups.

The section finished with a discriminant function analysis which showed that the proposed biomechanical assessment (kinematic variables) used in this thesis is capable of discriminating patients with different levels of anatomical impairment.

8.5. Discussion - Further comparisons with supplementary datasets

Additional data sets presented in this thesis provided further opportunities to compare how early and conservative patients were at the end of their treatments in relation to healthy subjects, and to explore how the method of movement analysis used in this thesis could be of use to discriminate different levels of anatomical impairments.

8.5.1. Residual impairment

The first additional comparison included both trial groups in relation to subjects with no history of shoulder pain. As expected at 6 months, the Early group was closer to normal movement standards, however, a big gap was observed between recovery within the trial groups and that of Normal.

Rotator cuff repair patients continue to improve their ROM and function up to 24 months after surgery, as demonstrated in other trials (Keener et al., 2014; Koh et al., 2014). Kolk et al. (2016) used inertial sensors to compare data from the affected shoulder to the non-affected side before and after rotator cuff repairs. The authors found that the ROM improved 20° and 13° for abduction and flexion, respectively, and the scapula kinematics recovered its symmetry compared to the contralateral side after 1 year. Although kinematics was adequately restored, EMG seems not to go in the same direction. Compared to the data of this thesis, at 6 months post-operative, patients with a rotator cuff repair had a restricted ROM with a mean difference of 40.89° for the Early group and 55.54° for the Conservative group compared to the Normal subjects for Abduction. For Flexion, the difference was 27.43° and 46.02° for the Early and Conservative, respectively, compared to the Normal group.

No EMG for the Normal group was available for comparison with this thesis. However, according to Fokter, Cicak, and Skorja (2003), who assessed 51 patients who underwent rotator cuff repairs. They assessed muscle activity of the supraspinatus and infraspinatus during shoulder flexion lifting a 4 kg weight. The authors found that the infraspinatus activity after a minimum of 24 months post rotator cuff repair was different in the affected side compared to the unaffected side. The authors stated that the supraspinatus did not show any differences, but the affected infraspinatus had lower firing rates, which suggests that the infraspinatus may have worse motor control recovery in comparison to the supraspinatus.

Unfortunately, no later follow-ups were available in this RCT for further ROM comparisons at one or two years. It is likely that the difference to the between the trial groups compared to the normal database have reduced along the following months, but perhaps the ratio of improvement may have been different as the Early group showed superior ratio of improvement at both follow-ups than the Conservative group. However, considering that at 6 months the majority of patients responded positively, it would be possible that the difference in the ratio of improvement would be reduced or even become equal between the trial groups close to one-year post-surgery.

Nevertheless, the comparisons undertaken in this thesis is the first to show how patients receiving different physiotherapy protocols 6 months after a rotator cuff repair compare to people with no shoulder complaints regarding ROM in different ADLs.

8.5.2. Groups with disorders related to the rotator cuff and discriminant function analysis

The second set of additional analyses explored if before surgery patients with various rotator cuff related problems would demonstrate similar movement patterns on the tasks proposed. Patients that only had a subacromial decompression showed better ROM in every task except Reaching. The Trial group was better than Massive for most tasks except Abduction, where the Massive group performed slightly better. The only task to show statistically significant difference regarding EMG was Lifting; the SAD group had higher activity for those muscles demonstrating statistical differences, which might be due to their greater ROM, but may also indicate that pain was inhibiting muscle recruitment if we consider that patients with a rotator cuff tear present worse pain status, however, this was not measured (Scibek, Carpenter, and Hughes, 2009).

The considerable differences among groups in ROM led to the decision of undertaking a discriminant analysis to investigate whether the tasks and equipment used have the potential to be used as diagnostic tools. Generally, discriminant analyses are used to identify talents in sports and is useful to select which variables are the best to classify subjects to groups (Carter and Ackland, 1998; Mazuquin et al., 2015).

The classificatory analysis correctly classified almost 92% of the cases and cross-validation confirmed almost 76% of them carrying a case-by-case step. These values are high and substantially greater than a classification by chance, which in this analysis of 3 groups would be 33.33%. Successful classifications should be above 80% (Carter and Ackland, 1998); the classificatory analysis did fulfil the criteria, but the cross-validation did not. The possible reason for the cross-validation not reaching at least 80% might be due to the low number of patients in the Massive group.

The discriminant analysis showed great applicability for inertial sensors and tasks to be used in classifying patients based on their movement patterns. However, this method was not tested regarding its classificatory accuracy against the gold standard. The gold standard tool to diagnose anatomical structural changes of the rotator cuff would be Magnetic Resonance Imaging (MRI). MRI has high specificity and sensitivity to identify which structures on rotator cuff problems are altered (Lenza et al., 2013). Although MRI is a great tool, the cost of each exam is still high. Cheaper, but still accurate, methods could be useful in reducing costs that can be avoided if a simpler and easier method is available (Yeranosian et al., 2013).

The discriminant analysis used in this thesis is the first on the topic to evaluate whether 3D kinematics is capable of discriminating patients with different levels of anatomical impairment of their shoulder structures. The only other study to use discriminant analysis to classify patients with shoulder disorders was Colliver et al. (2016). In this study, the discriminant analysis was used to check whether the repair integrity could be predicted by clinical questionnaires. The results of this study showed that the discriminant analysis could correctly classify only 36% of the intact repairs.

Three-dimensional movement analysis has been proven to aid clinicians in identifying altered patterns of shoulder disorders (Keshavarz et al., 2017). Therefore, inertial sensors could be an alternative in the future to substitute more expensive methods of identifying shoulder dysfunctions. Inertial sensors are a relatively new tool that can be easily used in the clinical setting due to their good ecological validity (Mayagoitia, Nene, and Veltink, 2002; Chung et al., 2011).

Similar to this study, Kolk et al. (2017) also performed an analysis where they used inertial sensors to assess movement differences of patients with isolated supraspinatus lesions, massive tears and a group with shoulder pain, but no anatomical alterations to cuff muscles or tendons. They found that the massive tears group had a greater reduction on flexion and abduction compared to the other two groups. The isolated supraspinatus and shoulder pain groups did not present differences for the two tasks, which contrasts with the results found in this thesis.

Further studies are needed to confirm inertial sensors as a diagnostic tool, which includes whether inertial sensors show high sensitivity and specificity. Future studies should focus not only on testing the 3D system against MRI or ultrasound but also compared to goniometry or other clinical tests to explore if clinical examinations commonly used by clinicians are able to be as good as other equipment that requires additional technical training.

8.6. Limitations

The secondary analyses used data that were collected along the course of the PhD. The objectives and hypothesis were formulated based on the data and not a priori to the data been collected. No sample size calculation was performed to establish the appropriate number of participants needed to avoid type I and type II errors.

In addition, considering that the method and protocol for movement analyses were the same as the RCT, the issue related to the inter and intra-assessor is still a limitation.

The alpha levels were not corrected for the multiple comparisons and is a limitation that the reader should consider when reading the findings of the comparisons using the supplementary datasets.

8.7. Implications for practice

Based on the comparisons Early vs. Conservative vs. Normal, physiotherapists treating patients after rotator cuff repairs should expect at 6 months that patients' ROM will not be completely recovered in relation to healthy subjects.

Based on the comparisons Trial vs. SAD vs. Massive and discriminant analysis, health professionals responsible for the treatment plan of patients with shoulder pain should be aware that ROM limitations could predict how much patients' anatomical structures are impaired. The mean values could be used as parameters to identify in each category and patients could be classified accordingly. However, further studies are needed to establish accurate values for basic clinical tools such as goniometers and to check whether goniometers are also capable of correctly classifying patients using ROM mean values for ADLs.

8.8. Implications for future research

Further studies using inertial sensors and surface EMG for patients with rotator cuff tears compared to healthy subjects, should consider analysing the intra- and inter-reliability of their protocol used for movement assessment to mitigate the inherent variability of the method, thus ensuring that the variability observed is related to patients' variability only.

The study of the use of inertial sensors as a diagnostic tool on shoulder disorders based on comparisons with gold standard instruments should be further explored. This may, in turn, reduce assessment and screening costs and produce a more cost-effective method of diagnosis. Depending on results, additional studies could then target specific clinical examinations.

8.9. Conclusions

Compared to subjects with no shoulder complaint, patients who underwent rotator cuff repairs present ROM deficits at 6 months postoperative regardless of when their physiotherapy started or how many weeks they have used a sling. However, patients treated with Early rehabilitation have better ROM compared to Conservative rehabilitation at 6months postoperative.

Patients with lower levels of impairment to their shoulder anatomical structures present better mean values for ROM when performing activities of daily living. In addition, 3D kinematics, using inertial sensors, is a valuable tool to accurately classify patients in different groups according to the level of impairment of the shoulder anatomical structures.

8.10. Summary of chapter 8

Chapter 8 was the second part of the results section of this thesis. The chapter starts with the analysis for the ROM data from individuals with no shoulder complaints compared to those included in the trial. The analyses showed a statistically significant difference between the Normal group in comparison to the Conservative group in 5 out of 6 tasks (Combing, Abduction, Carrying, Flexion and Lifting).

Following the Normal vs. Trial comparisons, the chapter showed the results between patients who had different levels of anatomical impairments (Subacromial decompression, Trial and Massive tears). The SAD group showed greater mean values of ROM for all tasks compared to both groups, except for Reaching.

The chapter finished with a discriminant function analysis which showed that the proposed biomechanical assessment used in this thesis is capable of differentiating patients with different levels of anatomical impairment. The chapter finishes by describing the limitations, implications for practice, implications for future research and conclusion of the secondary analyses. The next chapter is the final chapter of the main body of the thesis which describes the final conclusions of the PhD work (chapter 9).

CHAPTER 9: THESIS OVERALL CONCLUSIONS – KEY MESSAGES

- Based on the systematic review, there is little evidence to confirm whether early mobilisation improves outcomes.
- Early mobilisation is not the direct cause of higher retear rates. Patient factors that compromise recovery must be considered.
- Based on the exploratory randomised controlled trial, from baseline to the last follow-up both groups improved clinical scores, ROM and showed proportionally higher muscle activity.
- Early rehabilitation did not provide superior benefits on clinical scores and biomechanical outcomes compared to conservative, based on the results of the statistical tests.
- The 5 muscles assessed showed greater activity at both follow-up time points compared to baseline, for both groups.
- The Early group continuously improved through every follow-up, but the Conservative group first showed reductions on ROM at 3 months and then improved at 6 months.
- Patients treated with early mobilisation have a greater ratio of improvement and therefore showed better muscle efficiency in relation to joint excursion.
- Nonetheless, the results from this trial should be interpreted with caution due to its sample size limitations and possible Type II error.
- Individual analysis revealed that some patients in the Conservative group had positive response regardless of starting mobilisation later.
- Subgrouping analysis informed that the factors linked to positive response at 3 months are likely to be: the number of hours per day using the sling, time from first symptoms until having surgery and number of additional surgical procedures.
- At 6 months only two patients, both from the Conservative group, had a negative response to rehabilitation compared to baseline. This negative outcome appeared to be related to the patient's age, with patients over 65 years appearing to have a greater risk of developing shoulder stiffness.
- Further analysis comparing Early and Conservative groups to a Normal sample confirmed that patients treated with early rehabilitation have less residual impairment at 6 months.
- The biomechanics method of assessment proposed may be useful in supporting surgery planning; as it appears to be able to discriminate patients with different

levels of muscle tissue damage. The discriminatory analysis showed high classificatory accuracy.

CHAPTER 10: APPENDICES

Appendix 1. Literature Review (chapter 3) published as an article in the British Journal of Sports Medicine.

BJSM Online First, published on December 30, 2016 as 10.1136/bjsports-2016-095963
Review

OPEN ACCESS

Effectiveness of early compared with conservative rehabilitation for patients having rotator cuff repair surgery: an overview of systematic reviews

Bruno Fles Mazuquin,[1] Andrew Charles Wright,[2] Sarah Russell,[3] Puneet Monga,[3] James Selfe,[4] Jim Richards[1]

▶ Additional material is published online only. To view please visit the journal online (http://dx.doi.org/10.1136/bjsports-2016-095963).

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Accepted 30 October 2016

ABSTRACT

Aim/objective The aim is to critically analyse and discuss the current literature and determine the effectiveness of rehabilitation for patients after surgical repair of rotator cuff tears for range of motion (ROM), pain, functional status and retear rates; in addition, an update of new literature is included.

Design Overview of systematic reviews.

Data sources A search was performed with no restrictions to date of publication and language in the following databases: EBSCO, AMED, CINAHL, SPORTDiscus, EMBASE, Cochrane, LILACS, MEDLINE, PEDro, Scielo, SCOPUS and Web of Knowledge. The PRISMA guideline was followed to develop this review and the R-AMSTAR tool was used for critical appraisal of included reviews.

Eligibility criteria Only systematic reviews and randomised controlled trials (RCTs) comparing the effectiveness of early with conservative rehabilitation, after surgical repair of the rotator cuff, were included. Moreover, the studies should report ROM, pain, functional status and/or retears rates before and after 3–24 months of the surgery.

Results 10 systematic reviews and 11 RCTs were included for the final analysis. Conflicting results and conclusions were presented by the systematic reviews, the use of primary studies varied; also the methodological quality of the reviews was diverse. This updated review, with new meta-analysis, showed no difference for function, pain, ROM or retears ratio between early and conservative rehabilitation.

Summary/Conclusions Early mobilisation may be beneficial, particularly for small and medium tears; however, more studies with higher quality are required, especially for patients with large tears who have been given less attention.

INTRODUCTION

Following surgical rotator cuff repair, a period of movement restriction is advised;[1] however, the optimal time of immobilisation is unknown. It is common practice to ask patients to use a sling for 6 weeks and avoid activities with the affected shoulder.[2 3] This period is important to protect the tendon, allow healing and to prevent retear episodes.[4] However, delayed motion may increase the risk of postoperative shoulder stiffness, muscle atrophy and delay functional recovery.[2] Based on the available evidence, it is difficult to make a clinical decision about the best rehabilitation regime and establish the most favourable time to start postoperative rehabilitation. One of the problems is the variation in the rehabilitation protocols and evidence provided from multiple systematic reviews. This lack of consensus may lead therapists to a variety of contradictory clinical decisions.[5] Previous systematic reviews have included different primary studies and focused on different periods within which early or conservative intervention were applied, and these discrepancies may account for some of the inconsistent findings. In addition, the majority of these systematic reviews were published between 2014 and 2015, highlighting that this is currently an area of much debate.

Therefore, the aims of our systematic review of systematic reviews were to (1) comprehensively review the available evidence in the topic and (2) assess the effectiveness of early mobilisation for pain, functional status, range of motion (ROM) and retears rate for this patient population.

METHODS

Design

This study is a review of systematic reviews which followed the Preferred Reporting Items for Systematic Review and Meta-Analyses (PRISMA) statement[6] requirements. Moreover, each systematic review included was assessed and scored using the Revised Assessment of Multiple Systematic Reviews (R-AMSTAR) tool.[7]

Inclusion/exclusion criteria

Systematic reviews and randomised controlled trials (RCTs) that compared the effectiveness of early rehabilitation with conservative rehabilitation, after surgical repair of the rotator cuff, under supervision of a therapist were included. The definition of early rehabilitation and conservative rehabilitation was used according to what was described in each study.

For inclusion, studies must have:

- ▶ Reported at least one of: shoulder ROM, pain, functional scores and retear rates.
- ▶ Included patients who had a surgical repair of the rotator cuff and were allocated to groups that had different starting times of their rehabilitation (physiotherapy and exercises).
- ▶ Reported a clinically relevant follow-up period of between 3 and 24 months.

Studies that included patients with acute tears and studies where the aim was not to compare the impact of the rehabilitation start time application were excluded. Only chronic tears were considered, which were defined as not being caused by a traumatic event (ie, accidents).

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Appendix 2. Search strategies used in the respective databases.

MeSH terms and keywords

Rotator cuff, Shoulder, Shoulder joint, Rehabilitat*, Physiotherapy, Physical Therapy, Immobili?ation, Stiffness, Accelerat*, Sling.

Database: EBSCO= AMED, CINAHL, SPORTDiscus

Search Strategy:

S1 = Rotator Cuff

S2= Shoulder

S3= Rehabilitat*

S4= Physiother*

S5= Physical Therapy

S6= Immobili?ation

S7= Stiffness

S8= Accelerat*

S9= S1 OR S2

S10= S3 OR S4 OR S5

S11= S6 OR S7

S12= S9 AND S10 AND S11

Database: EMBASE

Search Strategy:

1= *rotator cuff/

2= shoulder/

3= rehabilitation/ or therapy/

4= physiotherapy/

5= physical therapy.mp.

6= immobilization/

7= Stiffness.mp. or rigidity/

8= 1 or 2

9= 3 or 4 or 5

10= 6 or 7

11= 8 and 9 and 10

Database: Cochrane

Search strategy:

#1 = Rotator Cuff

#2= Shoulder

#3= Rehabilitat*

#4= Physiother*

#5= Physical Therapy

#6= Immobili?ation

#7= Stiffness

#8= #1 OR #2

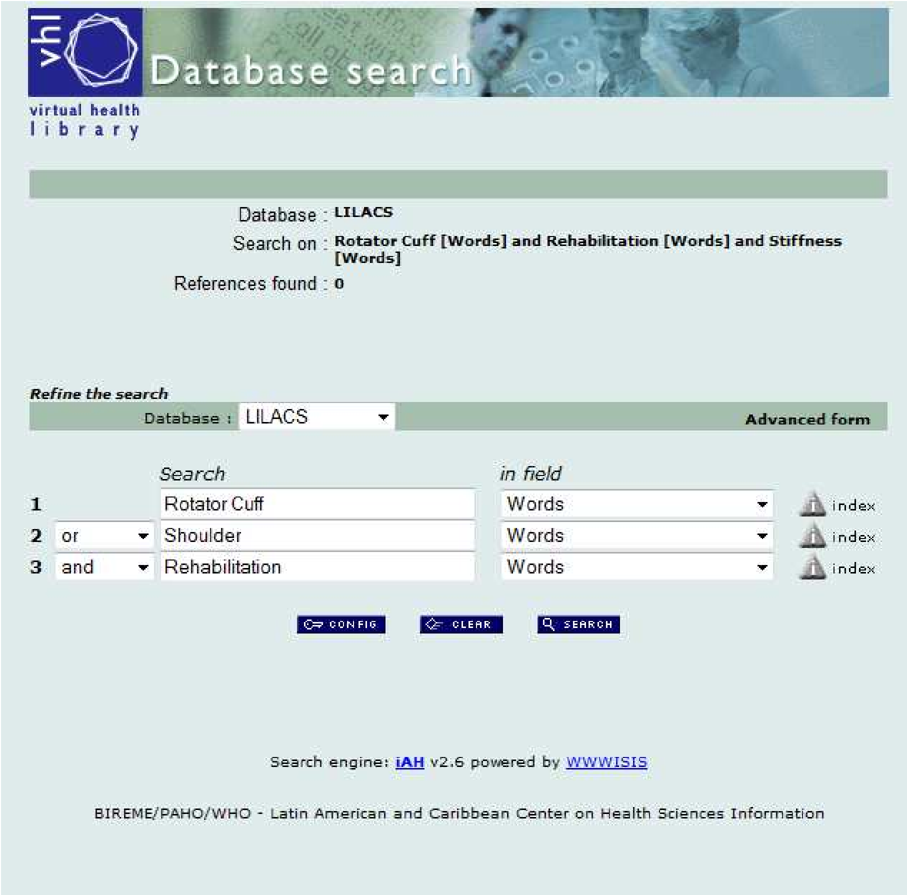
#9= #3 OR #4 OR #5

#10= #6 OR #7

#11= #8 AND #9 AND #10

Database: LILACS

Search Strategy:



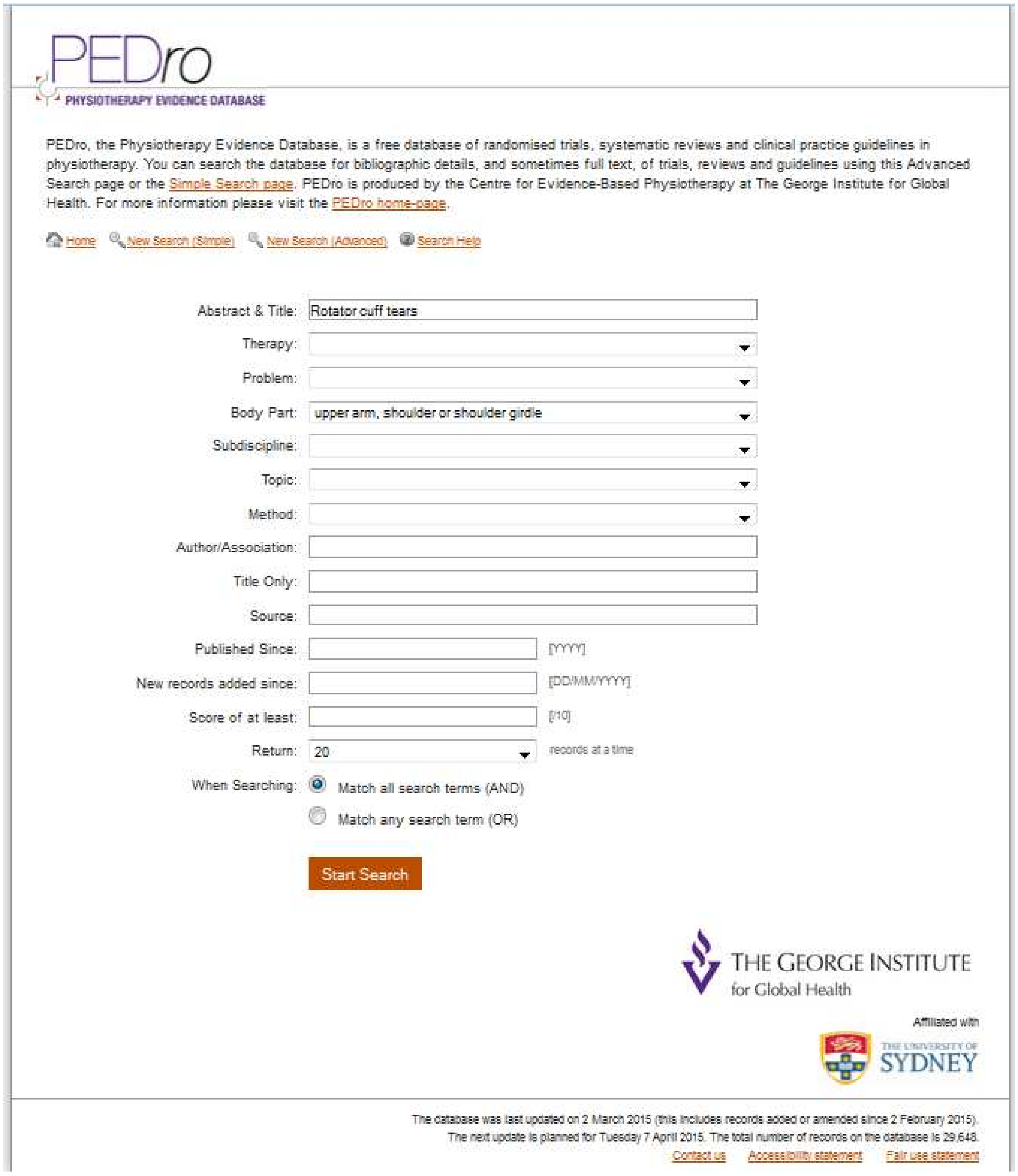
Database: Medline

Search Strategy:

"rotator cuff"[MeSH Terms] OR ("shoulder"[MeSH Terms] OR "shoulder"[All Fields]) AND ("physical therapy modalities"[MeSH Terms] OR "physiotherapy"[All Fields]) AND "immobilization"[MeSH Terms]

Database: PEDro

Search strategy:


PEDro

PHYSIOTHERAPY EVIDENCE DATABASE

PEDro, the Physiotherapy Evidence Database, is a free database of randomised trials, systematic reviews and clinical practice guidelines in physiotherapy. You can search the database for bibliographic details, and sometimes full text, of trials, reviews and guidelines using this Advanced Search page or the Simple Search page. PEDro is produced by the Centre for Evidence-Based Physiotherapy at The George Institute for Global Health. For more information please visit the PEDro home-page.

Home | New Search (Simple) | New Search (Advanced) | Search Help

Abstract & Title:	Rotator cuff tears
Therapy:	
Problem:	
Body Part:	upper arm, shoulder or shoulder girdle
Subdiscipline:	
Topic:	
Method:	
Author/Association:	
Title Only:	
Source:	
Published Since:	[YYYY]
New records added since:	[DD/MM/YYYY]
Score of at least:	[/10]
Return:	20 records at a time
When Searching:	(•) Match all search terms (AND)
	( ) Match any search term (OR)

Start Search

THE GEORGE INSTITUTE for Global Health

Affiliated with THE UNIVERSITY OF SYDNEY

The database was last updated on 2 March 2015 (this includes records added or amended since 2 February 2015). The next update is planned for Tuesday 7 April 2015. The total number of records on the database is 29,648.

Contact us | Accessibility statement | Fair use statement

Database: Scielo

Search Strategy:

(Rotator cuff Tears) OR (Shoulder) AND (Rehabilitat*) OR (Physiother*) OR (Physical Therapy) AND (Immobili?ation) OR (Stiffness)

Database: SCOPUS

Search Strategy:

TITLE-ABS-KEY(Rotator cuff) OR TITLE-ABS-KEY(Shoulder) AND TITLE-ABS-KEY(Rehabilit*) OR TITLE-ABS-KEY(Physioter*) OR TITLE-ABS-KEY(Physical Therapy) AND TITLE-ABS-KEY(Immobili?ation)

Database: Web of Knowledge (320)

Search Strategy

#1 = Rotator Cuff

#2= Shoulder

#3= Rehabilitat*

#4= Physiother*

#5= Physical Therapy

#6= Immobili?ation

#7= Stiffness

#8= #1 OR #2

#9= #3 OR #4 OR #5

#10= #6 OR #7

#11= #8 AND #9 AND #10

Appendix 3. Author's permission to use the unpublished study from Cote.

From: mcote@uchc.edu
Sent: terça-feira,10 de março de 2015 14:21
To: Bruno Fles Mazuquin

Bruno,

You can use our study in your review. Let me know if you need any more information.

Thanks.

Mark

On 3/10/15 7:18 AM, "Bruno Fles Mazuquin" <BFMazuquin@uclan.ac.uk> wrote:

\> Dear Dr Cote,
\>
\> Few months ago I requested an unpublished abstract from your authorship.
\> Recently, many reviews have been published about the topic, however only
\> the review from Dr. Kevin Chan (Delayed versus early motion after
\> arthroscopic rotator cuff repair: a meta-analysis) cited your publication.
\>
\> As your study could be considered as grey literature, it should be
\> included in reviews too. I would like to ask your permission to use your
\> study in a review that I am preparing, which discuss some flaws detected
\> in the available literature.
\>
\> Best Regards
\>
\> Bruno Mazuquin

Appendix 4. Participant information sheet.

Wrightington, Wigan and Leigh NHS
NHS Foundation Trust

PARTICIPANT INFORMATION SHEET

TITLE OF STUDY:
Does early mobilisation after surgical repair of rotator cuff tears improve biomechanical and clinical outcomes?

NAME OF RESEARCHERS:
Mr B Mazuquin, Prof J Richards, Prof J Selfe, Dr Ambreen Chohan, Dr Subhasis Basu, Mr P Monga

You are being invited to take part in a research study that is being carried out for an educational qualification. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with us if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. Thank you for reading this.

What is the purpose of the study?
This study is a randomised controlled trial, which means that you will be randomly allocated to a treatment group. We want to know if rehabilitation applied earlier for patients undergoing surgery for rotator cuff repair will be more beneficial than standard care. This will focus on your shoulder muscles and joint movement. The rehabilitation consists of exercises to recover your shoulder movements and improve pain status. Currently, the standard rehabilitation starts more substantial mobilisation after 6 weeks post-surgery, however little is known about whether this is the optimal time point for all patients. This study aims to assess if patients might benefit from this mobilisation starting earlier. The exercises will not differ between groups, the difference is that one group will use a sling for a shorter period of time than the other and mobilisation will start earlier.

Why have I been chosen?
You have been chosen because you have been elected to have a surgical rotator cuff repair and will need further rehabilitation.

Do I have to take part?
It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and asked to sign a consent form. If you decide to take part you are still free to withdraw at any time. A decision not to take part will not affect the standard of care you receive now or in the long term.

What will happen to me if I take part?
We will invite you to have your shoulder movements examined in detail with specialist equipment on the day of your surgery (i.e. in a room in outpatient clinic) and at your follow up appointments with your Surgeon. This will involve performing specific movements with detailed recording equipment attached. You will be also required to answer questionnaires regarding the function of your shoulder and your health state. This separate assessment should take around 60 minutes.

Version 2 22/03/2016

What do I have to do?

These examinations will happen at your normal hospital appointments so you will not have to make another specific visit for the research. You will be asked to perform nine movements of your shoulder and fill in two questionnaires.

A clinical researcher will carry the assessment sessions and a consultant radiologist will carry an ultrasound assessment. Sensors will be placed over your clothes on your shoulders, arms, waist, chest and head (figure B and C), therefore we would ask you to use a t-shirt. These will be attached using Velcro® strips and hypoallergenic double sided tape. Three sensors will be placed under the sleeves of your t-shirt however you will not need to take off your top for their correct placement.

The data from these equipment will not look like normal video; the only visible information will be a digital illustration. The illustration allows us to model you as a skeleton (figure A) and analyse the movement at your joints. You will be asked to perform a shoulder flexion/extension, abduction/ adduction (similar to flexion, but with your arm doing the movement on the side of your body), internal and external rotation, circumduction (big circle in the air), a flexion holding a 1kg dumbbell, a movement carrying the same dumbbell horizontally, a simulation of the movement of combing the back part of your head and a movement trying to reach the opposite back pocket of your trousers. You will be required to do each task approximately 5 times.

A B C

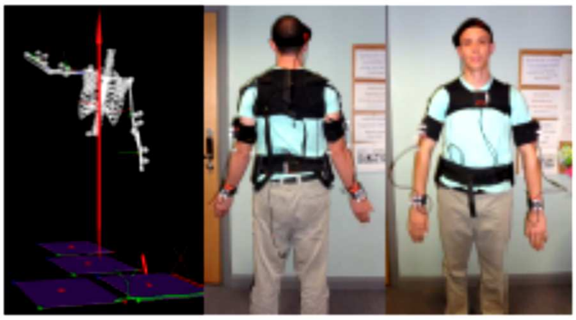


Figure 1. A-Model of the upper body, B-Equipment back view, C-Equipment front view

Moreover, taking part of this study means that you will be allocated in one of the two different groups mentioned earlier (section *What is the purpose of the study?*). The possibility of being assigned to any of the groups is equal and is determined by chance. After your surgery, when you start your rehabilitation, your therapist will inform you of what group you were included.

What are the possible disadvantages and risks of taking part?

After the rehabilitation session you might feel some pain or discomfort on your shoulder, but it is common to any rehabilitation and not a particular issue from this study. If you continue to feel pain, we advise you to contact your therapist in order to book another session for pain management.

During the assessment sessions no movement will exceed your limitations, it will respect any limitations you may have.

What are the benefits of taking part?
The research may benefit you or future patients as the aim to determine the best rehabilitation treatment. It will give physiotherapist and surgeons, both in this hospital and those in other countries, information of how the rehabilitation helps shoulder movement during functional tasks. This will help specialists make decisions on the treatment of other patients in the future. Both groups will benefit from rehabilitation and exercises. The more conservative group is what is considered as a standard treatment in the hospital; the other group may benefit of a faster movement, pain and quality of life recovery, but this is still unknown.

What happens when the research study stops?
You will be continued to be cared for under standard treatment by the NHS.

What if something goes wrong?
If you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal NHS complaints mechanism will be available to you. In addition, you can also contact the University of Central Lancashire office for ethics.

The Patient Relations/PALS Manager
Wrightington Wigan and Leigh NHS Foundation Trust
Royal Albert Edward Infirmary
Wigan Lane
Wigan
WN1 2NN
01942 822376

University Officer for Ethics
OfficerforEthics@uclan.ac.uk
University of Central Lancashire,
Preston
PR1 2HE.

Will my taking part in this study be kept confidential?
All information which is collected about you during the course of this research will be kept strictly confidential. Any information about you, which leaves the hospital, will have your name and address removed so that you cannot be recognized from it.
If a scientific paper is written about the results your name and details will be removed completely.

What will happen to the results of the research study?
The results of the study will be presented in a PhD thesis. Further, it will also be presented at conferences, and the aim will be to publish a scientific paper. All information about you, your name and personal details will be removed.

Who has authorised this study?
The North West Research and Education Committee (REC) in Lancaster have reviewed this study.

Wrightington, Wigan and Leigh NHS
NHS Foundation Trust

Please feel free to contact us for more information.

Sandra Latham
Research and Development
Wrightington Hospital
01257 256465
Email to Sandra.Latham@wwl.nhs.uk

Mr Bruno Mazuquin (Student Researcher)
Tel: 07951 486896
Email to bfmazuquin@uclan.ac.uk

If you would like some general information about being involved in a research project please contact your local Research & Development Department on 01257 256465 or see www.nres.org.uk or www.involve.org.uk

Thank you for taking the time to read about this study, if you have any questions please do not hesitate to ask. If you agree to take part you will be given a copy of this information sheet as well as the consent form for taking part in the study.

Should you have a suggestion or complaint about the research please contact the Patient Relations Department on 01942 822376.

Version 2 22/03/2016

Appendix 5. Participant informed consent form.

Wrightington, Wigan and Leigh **NHS**
NHS Foundation Trust

Version 1 and Date 22/01/16

PARTICIPANT CONSENT FORM

Centre Name: Wrightington Hospital

Patient Identification Number for this trial:

Title of Project: Does early mobilisation after surgical repair of rotator cuff tears improve biomechanical and clinical outcomes?

Name of Researchers: B Mazuquin, J Richards, J Selfe, A Chohan, Subhasis Basu, P Monga.

Please initial box

I confirm that I have read and understood the information sheet dated 22/01/16 (version 1) for the above study and have had the opportunity to ask questions. ☐

I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. ☐

I understand that relevant sections of my medical notes and data collected during the study may be looked at by responsible individuals from the trust, or from regulatory authorities, where it is relevant to my taking part in this research, I give permission for these individuals to have access to my records. ☐

I agree to take part of the above study ☐

Name of Patient	Date	Signature
Name of Person taking consent (if different from Researcher)	Date	Signature
Researcher	Date	Signature

1 for patient, 1 for researcher, 1 to be kept with hospital notes

Chairman: Les Higgins   Chief Executive: Andrew Foster CBE

Appendix 6. North West Research Ethics Committee approval.

Page 1

NHS
Health Research Authority

North West - Lancaster Research Ethics Committee
Barlow House
3rd Floor
4 Minshull Street
Manchester
M1 3DZ

Telephone: 020 71048008

23 March 2016

Mr Bruno F Mazuquin
1 Avenham Mills
Avenham Road
PR1 3TZ

Dear Mr Mazuquin

Study title: **Does early mobilisation after surgical repair of rotator cuff tears improve biomechanical and clinical outcomes?**
REC reference: **16/NW/0143**
IRAS project ID: **186086**

Thank you for your revised Participant Information Sheet. I can confirm the REC has received the documents listed below and that these comply with the approval conditions detailed in our letter dated 18 March 2016

Documents received

The documents received were as follows:

Document	*Version*	*Date*
Participant information sheet (PIS) [Participant information sheet]	2	22 March 2016

Approved documents

The final list of approved documentation for the study is therefore as follows:

Document	*Version*	*Date*
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Insurance Certificate]	1	12 February 2016
Other [CV academic supervisor JS]	1	26 January 2016
Other [CV academic supervisor PM]	1	26 January 2016
Participant consent form [Consent form]	1	22 January 2016
Participant information sheet (PIS) [Participant information sheet]	2	22 March 2016
REC Application Form [REC_Form_12022016]		12 February 2016
Referee's report or other scientific critique report [Transfer approval]	1	16 November 2015
Research protocol or project proposal [Protocol]	1	22 January 2016
Summary CV for Chief Investigator (CI) [CV]	1	26 January 2016

Summary CV for student [CV]	1	22 January 2016
Summary CV for supervisor (student research) [CV]	1	26 January 2016
Validated questionnaire [Oxford Shoulder Score]	1	
Validated questionnaire [EQ-5D-5L]	1	22 January 2016

You should ensure that the sponsor has a copy of the final documentation for the study. It is the sponsor's responsibility to ensure that the documentation is made available to R&D offices at all participating sites.

16/NW/0143	**Please quote this number on all correspondence**

Yours sincerely

Carol Ebenezer
REC Manager

E-mail: nrescommittee.northwest-lancaster@nhs.net

Copy to: *Mrs Denise Foreshaw*
Ms Sandra Latham, Wrightington, Wigan and Leight NHS FOundation Trust

Appendix 7. UCLan Research Ethics Committee approval.

uclan
University of Central Lancashire

29th March 2016

James Richards/Bruno Fles Mazuquin
School of Health Sciences
University of Central Lancashire

Dear James/Bruno,

Re: STEMH Ethics Committee Application
Unique reference Number: STEMH 462

The STEMH ethics committee has granted approval of your proposal application 'Does early mobilisation improve outcomes after rotator cuff repair?'. Approval is granted up to the end of project date* or for 5 years from the date of this letter, whichever is the longer. It is your responsibility to ensure that:

- the project is carried out in line with the information provided in the forms you have submitted
- you regularly re-consider the ethical issues that may be raised in generating and analysing your data
- any proposed amendments/changes to the project are raised with, and approved, by Committee
- you notify roffice@uclan.ac.uk if the end date changes or the project does not start
- serious adverse events that occur from the project are reported to Committee
- a closure report is submitted to complete the ethics governance procedures (Existing paperwork can be used for this purposes e.g. funder's end of grant report; abstract for student award or NRES final report. If none of these are available use e-Ethics Closure Report Proforma).

Please also note that it is the responsibility of the applicant to ensure that the ethics committee that has already approved this application is either run under the auspices of the National Research Ethics Service or is a fully constituted ethics committee, including at least one member independent of the organisation or professional group.

Yours sincerely,

Colin Thain
Chair
STEMH Ethics Committee

Appendix 8. The random numbers sequence.

A Randomization Plan

from

http://www.randomization.com

1. Early Rehabilitation ____________________
2. Conservative Rehabilitation_____________
3. Conservative Rehabilitation_____________
4. Early Rehabilitation ____________________
5. Conservative Rehabilitation_____________
6. Early Rehabilitation ____________________
7. Early Rehabilitation ____________________
8. Conservative Rehabilitation_____________
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31. Conservative Rehabilitation_____________
32. Early Rehabilitation ____________________
33. Early Rehabilitation ____________________
34. Conservative Rehabilitation_____________
35. Early Rehabilitation ____________________
36. Early Rehabilitation ____________________
37. Conservative Rehabilitation_____________
38. Conservative Rehabilitation_____________
39. Early Rehabilitation ____________________
40. Conservative Rehabilitation_____________

Appendix 9. Information sheet about exercises and sling management.

Wrightington, Wigan and Leigh NHS Foundation Trust

Physiotherapy Department
Wrightington Hospital
Hall Lane,Appley Bridge, Wigan,Lancashire, WN6 9EP

July 11 2013 Page: 1
wrightington physio early a/a ROM

http://www.physiotec.ca

Notes:

1. Active ROM Circumduction

- Stand with your arms relaxed on each side of your body.
- Make backward circles with your shoulders.
- Relax and repeat

Sets: 1 Repetition: 10 Frequency: 4

2. Table slide flexion

- Start sitting or standing with the arm/hand supported on the counter top or table.
- Slowly slide arm in front until you feel a stretch.
- Use a towel or similar to reduce friction.

Sets: 1 Repetition: 10 Frequency: 4

3. Assisted ROM External rot.

- Resting elbow into your side on a rolled up towel. Hold a stick in your hands and push operated hand outwards.

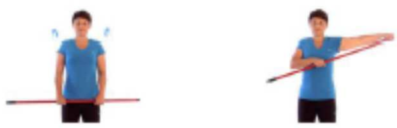
Sets: 1 Repetition: 10 Frequency: 4

4. Assisted ROM Flexion

- Lie on your back with knees bent and hold the stick firmely with both hands.
- Keep your shoulder blades together while you slowly bring the stick over the head as far as possible helping yourself with the good arm.
- Maintain the position and relax.

Sets: 1 Repetition: 10 Frequency: 4

5. Assisted ROM Abduction



- Stand and Hold a stick with both of your hands keeping your arms at your sides,
- Pull the tip of your shoulder backwards and raise your arm to the side by using the unaffected arm to swing the stick upwards and sideways away from your body.
- Slowly return to the starting position and repeat.

Sets: 1 Repetition: 10 Frequency: 4

Prepared by: Julia Walton 01257 256305

Notes:

6. Active ROM Flexion

- Sit on a chair with your arm straight along the side.
- Bend your elbow keeping the palm of your hand facing upwards.
- Lower your hand slowly and repeat.

Sets: 1 Repetition: 4 Frequency: 4

7. Flexion

- Make a fist then straighten fingers

Sets: 1 Repetition: 4 Frequency: 4

8. AA Active Rotation

- Stand or sit tall.
- Slowly turn your head to bring chin over shoulder and look over shoulder.
- Return to neutral position and repeat.

Sets: 1 Repetition: 4 Frequency: 4

9. Active ROM Extension

- Stand or sit tall.
- Move your head backwards as to look up to the ceiling.
- Return to initial position and repeat.
- NOTE: Do not tilt or turn your head.

Sets: 1 Repetition: 4 Frequency: 4

10. Active ROM Flexion

- Stand or sit tall.
- Slowly bend chin to chest to look down at floor.
- Return to neutral position and repeat.

Sets: 1 Repetition: 4 Frequency: 4

Prepared by: **Julia Walton** **01257 256305**

Notes:

11. Active ROM Side bending

- Stand or sit tall.
- Without turning the head, slowly tilt your head sideways to bring ear to shoulder.
- Return to neutral position and repeat.

Sets: 1 Repetition: 4 Frequency: 4

PATIENT INFORMATION FOLLOWING SHOULDER SURGERY

The aim of physiotherapy following surgery is to maintain and improve the movement in your shoulder joint at the right rate for your surgical procedure. You will be taught exercises by the physiotherapist. It is important that you begin the exercises as advised as they can prevent the shoulder from becoming stiff.

If you have had a nerve block as part of your surgery, only start the exercises once you have regained control of the movement in your arm. This may be up to 48 hours after the nerve block was given.

Your arm may be supported in a sling. The physiotherapist will advise you on the length of time you are required to use the sling for.

You should expect some degree of discomfort when you perform the exercises.

You will be provided with a pack of analgesics at the point of discharge home following your surgery. These are designed to reduce discomfort; you are advised to use these regularly within the limits of the prescription provided.

Intense and lasting pain (e.g. for more than 30 minutes) can be an indication to change the exercise by doing it less forcefully or less often.

If you find that pain is preventing you from doing the exercises then you are advised to visit your GP for further advice on pain relief or anti-inflammatory medication.

During your recovery from surgery you are encouraged to maintain good standards of axillary (armpit) hygiene, be aware of your posture when performing exercises and at rest, and to maintain movements in your other joints.

After you have been discharged from hospital you will require some follow up outpatient physiotherapy; a referral will be sent to your chosen physiotherapy department.

If you do not hear from the physiotherapists within 2 weeks of discharge then please contact your chosen physiotherapy department.

If they have not received your referral then you **must** contact Wrightington In-Patient Physiotherapy on 01257 256307. There is an answer machine service when therapists are out of the office.

Wrightington Physiotherapy Department

Your surgical procedure
____

Out-patient physiotherapy referral to
____

Sling information provided ☐

<u>Sling Use:</u>

☐ Discontinue ASAP

☐ Discontinue once movement control regained (block)

☐ Use for ____ weeks removing for axillary hygiene, dressing

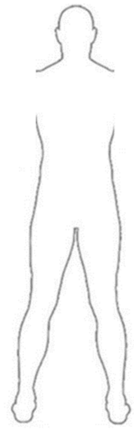
☐ Use for ____ weeks removing for axillary hygiene, dressing & physiotherapy exercises

Safe Zones:

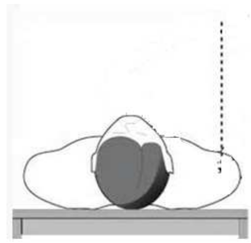
Ranges of movement in each direction that do not compromise the surgical procedure at this stage. Apply these to the exercises taught by the physiotherapist.

Flexion

Abduction



External Rotation



IT IS NOT RECOMMENDED THAT YOU PROGRESS FROM THESE UNTIL REVIEWED BY A PHYSIOTHERAPIST/ AT CLINIC

Appendix 10. Ethical committee approval for the pilot study.

uclan
University of Central Lancashire

4TH December 2014

Professor Jim Richards, Mr. Bruno Fles Mazuquin, Professor James Selfe, Dr. Ambreen Chohan & Mr. Puneet Monga
School of Sport, Tourism & the Outdoors
University of Central Lancashire

Dear Jim, Bruno, James, Ambreen & Puneet

Re: STEMH Ethics Committee Application
Unique Reference Number: STEMH 277

The STEMH ethics committee has granted approval of your proposal application 'Biomechanical features of the shoulder joint of healthy people'. Approval is granted up to the end of project date* or for 5 years from the date of this letter, whichever is the longer.

It is your responsibility to ensure that

- the project is carried out in line with the information provided in the forms you have submitted
- you regularly re-consider the ethical issues that may be raised in generating and analysing your data
- any proposed amendments/changes to the project are raised with, and approved, by Committee
- you notify roffice@uclan.ac.uk if the end date changes or the project does not start
- serious adverse events that occur from the project are reported to Committee
- a closure report is submitted to complete the ethics governance procedures (Existing paperwork can be used for this purposes e.g. funder's end of grant report; abstract for student award or NRES final report. If none of these are available use e-Ethics Closure Report Proforma).

Yours sincerely

Gillian Thomson
Vice Chair
STEMH Ethics Committee

* for research degree students this will be the final lapse date

NB - Ethical approval is contingent on any health and safety checklists having been completed, and necessary approvals as a result of gained.

Appendix 11. *P*-values of the Shapiro-Wilk test for normality distribution analysis of ROM, muscle activity and F and P values of the mixed methods ANOVA for each task and each muscle and time points.

Table 11.1. *P*-values of the Shapiro-Wilk test for normality distribution analysis of ROM.

	Group	
	Early (*P*)	**Conservative (*P*)**
Combing	0.795	0.452
Abduction	0.304	0.688
Carrying	0.236	0.407
Reaching	0.314	**0.044***
Flexion	0.196	0.979
Lifting	0.871	0.757

* statistically significant difference.

Table 11.2. *P*-values of the Shapiro-Wilk test for normality distribution analysis of muscle activity.

	Group	
	Early (*P*)	**Conservative (*P*)**
Combing		
Upper Trapezius	0.51	0.937
Anterior Deltoid	**0.002***	0.184
Medial deltoid	0.941	0.773
Posterior Deltoid	0.740	0.149
Biceps	0.853	0.227
Abduction		
Upper Trapezius	0.900	0.535
Anterior Deltoid	0.625	0.851
Medial deltoid	0.771	0.748
Posterior Deltoid	0.062	0.715
Biceps	0.264	0.813

Continue

Table 11.2 (continue). *P*-values of the Shapiro-Wilk test for normality distribution analysis of muscle activity.

	Group	
	Early (*P*)	**Conservative (*P*)**
Carrying		
Upper Trapezius	0.344	0.785
Anterior Deltoid	0.188	0.588
Medial deltoid	0.355	0.445
Posterior Deltoid	0.491	0.244
Biceps	0.486	0.091
Reaching		
Upper Trapezius	0.401	0.005
Anterior Deltoid	**0.001***	**<0.001***
Medial deltoid	0.426	**0.047***
Posterior Deltoid	0.774	0.392
Biceps	0.250	0.132
Flexion		
Upper Trapezius	0.308	0.165
Anterior Deltoid	0.597	0.563
Medial deltoid	0.993	0.296
Posterior Deltoid	0.789	0.660
Biceps	0.380	0.883
Lifting		
Upper Trapezius	0.161	0.097
Anterior Deltoid	0.397	0.122
Medial deltoid	0.448	0.376
Posterior Deltoid	0.589	0.254
Biceps	0.550	0.739

* statistically significant difference.

Table 11.3. F and *P*-values of the mixed methods ANOVA interactions for the task combing.

	Type III Tests of Fixed Effects				
	UT	**AD**	**MD**	**PD**	**BC**
Group					
F	0.128	0.522	0.004	0.326	2.663
P	0.725	0.482	0.948	.0576	0.129
Time					
F	0.442	2.933	0.363	0.410	0.012
P	0.522	0.121	0.559	0.534	0.914
Group x Time					
F	0.516	1.114	0.888	0.007	0.402
P	0.489	0.319	0.366	0.935	0.536

AD: anterior deltoid, BC: biceps, MD: medial deltoid, PD: posterior deltoid SD: standard deviation, UT: upper trapezius.

Table 11.4. F and *P*-values of the mixed methods ANOVA interactions for the task abduction.

	Type III Tests of Fixed Effects				
	UT	**AD**	**MD**	**PD**	**BC**
Group					
F	1.614	0.138	0.009	0.104	0.787
P	0.231	0.716	0.925	0.753	0.389
Time					
F	1.243	0.439	0.130	0.588	2.606
P	0.288	0.518	0.723	0.459	0.129
Group x Time					
F	0.027	2.366	5.452	0.007	5.989
P	0.872	0.146	**0.035***	0.933	**0.028***

AD: anterior deltoid, BC: biceps, MD: medial deltoid, PD: posterior deltoid SD: standard deviation, UT: upper trapezius.
* statistically significant difference.

Table 11.5. F and *P*-values of the mixed methods ANOVA interactions for the task carrying.

	Type III Tests of Fixed Effects				
	UT	**AD**	**MD**	**PD**	**BC**
Group					
F	1.321	1.236	0.924	2.322	0.502
P	0.286	0.285	0.357	0.150	0.491
Time					
F	0.321	0.189	0.000	0.936	0.065
P	0.598	0.673	0.993	0.365	0.803
Group x Time					
F	0.598	0.195	0.088	0.007	0.121
P	0.858	0.668	0.773	0.935	0.734

AD: anterior deltoid, BC: biceps, MD: medial deltoid, PD: posterior deltoid SD: standard deviation, UT: upper trapezius.

Table 11.6. F and *P*-values of the mixed methods ANOVA interactions for the task reaching.

	Type III Tests of Fixed Effects				
	UT	**AD**	**MD**	**PD**	**BC**
Group					
F	0.473	2.377	0.098	0.006	1.665
P	0.502	0.143	0.759	0.937	0.234
Time					
F	6.055	5.096	0.567	3.304	0.058
P	0.30	0.042	0.463	0.099	0.816
Group x Time					
F	0.820	3.931	1.231	0.101	0.197
P	0.383	0.069	0.285	0.757	0.671

AD: anterior deltoid, BC: biceps, MD: medial deltoid, PD: posterior deltoid SD: standard deviation, UT: upper trapezius.

Table 11.7. F and *P*-values of the mixed methods ANOVA interactions for the task flexion.

	Type III Tests of Fixed Effects				
	UT	AD	MD	PD	BC
Group					
F	0.110	2.466	0.335	0.124	0.007
P	0.746	0.138	0.572	0.730	0.936
Time					
F	1.969	1.786	4.014	3.733	4.943
P	0.190	0.204	0.065	0.081	**0.046***
Group x Time					
F	0.016	0.351	1.994	3.482	2.302
P	0.902	0.563	0.180	0.091	0.155

AD: anterior deltoid, BC: biceps, MD: medial deltoid, PD: posterior deltoid SD: standard deviation, UT: upper trapezius.
* statistically significant difference.

Table 11.8. F and *P*-values of the mixed methods ANOVA interactions for the task lifting.

	Type III Tests of Fixed Effects				
	UT	AD	MD	PD	BC
Group					
F	0.016	3.891	0.129	0.004	0.112
P	0.903	0.074	0.726	0.950	0.744
Time					
F	0.737	0.312	0.028	0.863	3.301
P	0.410	0.587	0.869	0.376	0.096
Group x Time					
F	1.043	3.109	2.377	0.945	3.673
P	0.330	0.105	0.146	0.356	0.081

AD: anterior deltoid, BC: biceps, MD: medial deltoid, PD: posterior deltoid SD: standard deviation, UT: upper trapezius.

Appendix 12. *P*-values of the Levene's test for homogeneity of variance analysis and F and P-values of one-way ANOVA tests for the Trial, Subacromial and Massive tears groups comparisons.

Table 12.1. *P*-values of the Levene's test for homogeneity of variance analysis of ROM.

Task	***P***
Combing	**0.011***
Abduction	0.209
Carrying	0.181
Reaching	0.440
Flexion	0.214
Lifting	0.898

* statistically significant difference

Table 12.2. *P*-values of the Levene's test for homogeneity of variance analysis of muscle activity.

Task	***P***
Combing	
Upper Trapezius	0.325
Anterior Deltoid	0.130
Medial deltoid	**0.007***
Posterior Deltoid	**0.044***
Biceps	0.621
Abduction	
Upper Trapezius	0.693
Anterior Deltoid	0.544
Medial deltoid	0.590
Posterior Deltoid	0.361
Biceps	0.176

Continue

Table 12.2 (*continue*). *P*-values of the Levene's test for homogeneity of variance analysis of muscle activity.

Task	*P*
Carrying	
Upper Trapezius	0.744
Anterior Deltoid	0.386
Medial deltoid	0.372
Posterior Deltoid	0.392
Biceps	0.257
Reaching	
Upper Trapezius	**0.048***
Anterior Deltoid	0.058
Medial deltoid	0.070
Posterior Deltoid	0.533
Biceps	**0.031***
Flexion	
Upper Trapezius	0.827
Anterior Deltoid	0.529
Medial deltoid	0.662
Posterior Deltoid	0.760
Biceps	0.515
Lifting	
Upper Trapezius	0.535
Anterior Deltoid	0.846
Medial deltoid	0.070
Posterior Deltoid	0.247
Biceps	0.176

* statistically significant difference

Table 12.3. F, χ^2 and *P*-values of one-way ANOVA and Kruskal-Wallis tests for the task combing.

	F	*P*	χ^2	*P*
Upper Trapezius	0.500	0.610	NA	NA
Anterior Deltoid	0.014	0.986	NA	NA
Medial deltoid	NA	NA	4.73	0.094
Posterior Deltoid	NA	NA	2.056	0.358
Biceps	0.023	0.978	NA	NA

NA: not applicable.

Table 12.4. F and *P*-values of one-way ANOVA tests for the task abduction.

	F	*P*
Upper Trapezius	0.126	0.882
Anterior Deltoid	0.607	0.550
Medial deltoid	0.667	0.519
Posterior Deltoid	0.236	0.791
Biceps	1.256	0.297

Table 12.5. F and *P*-values of one-way ANOVA tests for the task carrying.

	F	*P*
Upper Trapezius	0.297	0.745
Anterior Deltoid	0.381	0.686
Medial deltoid	0.889	0.420
Posterior Deltoid	0.476	0.625
Biceps	0.151	0.860

Table 12.6. F, χ^2 and *P*-values of one-way ANOVA and Kruskal-Wallis tests for the task reaching.

	F	*P*	χ^2	*P*
Upper Trapezius	NA	NA	2.166	0.339
Anterior Deltoid	0.488	0.618	NA	NA
Medial deltoid	2.557	0.091	NA	NA
Posterior Deltoid	0.959	0.393	NA	NA
Biceps	NA	NA	4.553	0.103

NA: not applicable.

Table 12.7. F and *P*-values of one-way ANOVA tests for the task flexion.

	F	*P*
Upper Trapezius	1.165	0.323
Anterior Deltoid	3.139	0.056
Medial deltoid	2.284	0.116
Posterior Deltoid	1.627	0.210
Biceps	0.531	0.592

Table 12.8. F and *P*-values of one-way ANOVA tests for the task lifting.

	F	*P*
Upper Trapezius	3.114	0.057
Anterior Deltoid	5.390	**0.009***
Medial deltoid	3.069	0.059
Posterior Deltoid	1.237	0.303
Biceps	12.264	**<0.001***

* statistically significant difference.

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