11-26-2012 12:00 AM

Physical Therapy Following Shoulder Rotator Cuff Repair

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A thesis submitted in partial fulfillment of the requirements for the Doctor of Philosophy degree in Health and Rehabilitation Sciences

Title:

PHYSICAL THERAPY FOLLOWING SHOULDER ROTATOR CUFF REPAIR

Spine Title:

PHYSICAL THERAPY FOLLOWING SHOULDER ROTATOR CUFF REPAIR

(Thesis format: Integrated-Article)

By

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A thesis submitted in partial fulfillment of the requirements for the degree of Doctor of Philosophy

The School of Graduate and Postdoctoral Studies,
Western University,
London, Ontario, Canada.

WESTERN UNIVERSITY

SCHOOL OF GRADUATE AND POSTDOCTORAL STUDIES

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The thesis by
Ravindiran Appunni, PT.,
Entitled:

PHYSICAL THERAPY FOLLOWING SHOULDER ROTATOR CUFF REPAIR

Is accepted in partial fulfillment of the requirements for the degree of
Doctor of Philosophy

Date:_____

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Chair of the Thesis Examination Board

ABSTRACT

Rotator cuff (RC) tears are one of the common causes of pain and disability in the upper extremity. Currently there are no fixed guidelines for choosing testing positions for shoulder range of motion measurement. Optimal rehabilitation following RC repair is yet to be defined.

Purpose and Method

The purpose was to inform about postoperative Physical therapy following rotator cuff repair, with the following objectives:

- To systematically review the content of clinical research, which addresses various physical therapy programs.
- To describe validity and responsiveness of different testing positions for goniometric measurement of shoulder active external rotation.
- To pilot test study procedures and estimating effects of a land-based and an aquatic exercise program.

Results

- Fourteen studies were included in the systematic review.
- ROM measurements in sitting and supine positions correlated moderately (r= 0.40 - 0.53). The sitting position showed greater sensitivity to change with estimates of standardized response mean (SRM) and effect size (ES) (SRM: 0.66, 1.05 and ES: 0.50, 1.02) as compared to the supine position (SRM: 0.39, 0.74 and ES: 0.37, 0.76) at 3 and 12 months postoperatively, respectively.
- A total of 12 patients with a 67% recruitment rate, participated. Clinic visit adherence was 95%. No one was lost to follow-up. Both land-based and land plus aquatic exercise groups showed improved flexion AROM over time (Mean change= 21°, Standard Deviation (SD)= 25° and Mean change= 22°, SD= 33° respectively). For future studies, for having 80%

power (α= 0.05, β= 0.20), and to detect 20% between-group difference, a total of 33 patients per group would be needed.

Conclusions

- The systematic review found that exercise therapy including adjunctive interventions has small to moderate effect.
- 29% of the patients could not undergo active shoulder external rotation testing in supine, all patients could be tested in sitting. The sitting position has higher responsiveness than the supine position.
- Both land-based and aquatic exercise programs are shown to be feasible. To achieve power, we recommend future studies with larger sample size.

Keywords

Physical therapy, rotator cuff tear, land-based exercises, aquatic exercises, systematic review, pilot study.

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CHAPTER 2: PHYSICAL THERAPY FOLLOWING SHOULDER ROTATOR CUFF REPAIR: A SYSTEMATIC REVIEW

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CHAPTER 3: POSITION EFFECTS OF MEASURES OF ACTIVE EXTERNAL ROTATION FOLLOWING SHOULDER ROTATOR CUFF REPAIR

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CHAPTER 4: LAND-BASED AND AQUATIC EXERCISE PROGRAMS FOLLOWING SHOULDER ROTATOR CUFF REPAIR - A RANDOMIZED PILOT STUDY

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CHAPTER 5: GENERAL DISCUSSION AND IMPLICATION

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EPIGRAPH

“The happiness which comes from long practice, which leads to the end of suffering, which at first is like poison, but at last like nectar - this kind of happiness arises from the serenity of one's own mind.”

— Ved Vyasa, The Bhagavad Gita**.**

DEDICATION

This thesis is dedicated to my father Late Shri. Appunni Kuttikrishnan.

ACKNOWLEDGEMENTS

Without the following people, this thesis (and my research work) would not exist. I am truly fortunate to have the opportunity to serve the community with each of their help.

- My parents, Late Mr. Appunni K, and Mrs. Susila N, Who always taught me the value of hard work, and for being my inspiration.
- My wife Mrs. Anupama Kovattu. B. Sc. (Nursing)., RN., Who while wondering when I am ever going to be complete my post-professional school, have been my solid support and extremely understanding with my ever changing clinical, research, academic, regulatory work schedule.
- My parent-in-laws Mr. Vikraman K, and Mrs. Ratanam V, Who selflessly been helping us during the time when we needed them the most.
- Our daughter Baby. Shreya Ravindiran, for providing endless joy and relaxation in the midst of my professional career.
- Dr. Joy MacDermid, for always keeping me on my toes, pushing me to go the extra mile and sparking me to pursue my love for research, editing manuscripts numerous times, and being a brilliant supervisor.
- Ms. Toula Reppas, & Mr. Tony Melles, Presidents, Acheiva Health, for allowing me to take time-off my clinical work to pursue my research work.
- Ms. Michelle Vermeeren, Managing Director, Glendale Crossing Long-term home, and Ms. Jennifer Lanz, Director of Nursing Care, for allowing me to take time-off from my clinical work and pursue my research work.
- Mrs. Monique Prendergast, PT., Manager - Physical Therapy, London Health Sciences Centre., Who helped to flex my clinical hours to complete my first 2 years of Ph. D.
- Mrs. Lynn Stewart, OT (R), Coordinator, Hand and Upper Limb Centre, Mrs. Michelle Mahood, Director of Ambulatory Surgery, St. Joseph's Health Care, London, ON.
- Dr. George Athwal, Orthopedic Surgeon, Hand and Upper Limb Centre, St. Joseph's Health Care, London, ON., Who single-handedly referred the required patients for the pilot study & editing the manuscripts.

- Ms. Kate Kelly, Research coordinator, Hand and Upper Limb Center, St. Joseph's Health Care, London, ON, Who single-handedly evaluated the outcome measures for the pilot study and coordinated pilot study.
- Mr. Chris Pizzimitti, Kinesilogist, Out Patient Physiotherapy Department, St. Joseph's Health Care, London, ON., Who single-handedly managed the aquatic therapy sessions in the pilot study.
- Graduate (lab) mates who are working under Dr. Joy MacDermid; who helped me learn various research related issues, including statistical analysis and manuscript preparation; In particular, Mr. Joshua Vincent.
- Last but not least, the research clients who were part of the pilot study, without whom this study would not exist; and who kindly consented to be part of this research, gave me hours of education and knowledge.

TABLE OF CONTENTS

TABLE OF CONTENTS - CONTINUED

TABLE OF CONTENTS - CONTINUED

INTRODUCTION

1.1 BACKGROUND

Rotator cuff (RC) tears are one of the common causes of pain and disability in the upper extremity. [6,15] Rotator cuff (RC) tears are one of the debilitating shoulder injuries frequently encountered in outpatient settings, particularly among older populations; [12] and are the most common shoulder condition for which patients seek treatment.[38] Signs and symptoms related to RC tear affect individual's perception of health; [3,14,20,24] and can lead to a significant disability affecting activities of daily living, work, and sports, with implications on the quality of life.[34]

Exercise therapy is the first treatment approach for patients with rotator cuff tears.[1] However, a substantial number of patients in whom conservative management has failed, and have significant functional limitations proceed to surgery.[60] Surgical repair of the RC tear aims to restore the tendon function, by reducing pain, and ultimately improving function.[49] Following RC repair, physical therapists provide various postoperative rehabilitation programs to maximize the function of RC tendons aiming to provide optimal shoulder stability and mobility.[59] Factors that may influence the nature and content of these programs include the magnitude and location of the RC tear, preferences/training/experience of the Physical therapist and the surgeon, clinical symptoms and comorbidities of patients, and the surgical techniques used for the RC repair.

There have been previous efforts to define an optimal postoperative rehabilitation protocol for patients following RC repair but with limited success.[58] In current physical therapy practice, postoperative rotator cuff repair programs are directed by surgeons. These programs are based on the operated RC tendon healing time. Many available programs are based on clinician's previous experience and mentorship rather than being evidence-based.[58] Optimal

rehabilitation is in the best interest of patients and the society at-large, as the direct cost involved in the postoperative management of RC repair can be quite high while the indirect costs of failure to achieve a successful return-to-work would be even greater. In this context, the answer for the following question is particularly beneficial: “what is the optimal postoperative physical therapy management for patients following shoulder rotator cuff repair?”

Through this thesis, we tried to find the evidence-based answer to this question. Before going into the details about the studies included in this thesis, we will be discussing RC tear history, incidence, and prevalence.

1.2 ROTATOR CUFF TEAR– BRIEF HISTORICAL OVERVIEW

The occurrence of RC tendon rupture after shoulder injury was explained by Dr. Smith in the London Medical Gazette in 1834; [56] however, it is difficult to tell who coined and introduced the term RC tear. Based on the available literature, in 1909, Codman[9] carried out the first RC repair; and recommended early surgical repair for full-thickness RC tears. After having 25 years of experience in treating RC tears, in 1934, Codman[9] published a text book through which he summarized his knowledge on RC tear and its components; and discussed ruptures of the supraspinatus tendon, in-particular.[9] For the first time, in 1939, Lindblom et al categorized the RC tear using radiopaque contrast into partial-thickness, full-thickness, and massive tears.[33] In 1944, McLaughlin described detailed etiology of RC tears and their management.[39] Since then, there have been numerous studies published on different aspects of assessment and treatment of RC tears; however, the current knowledge of basic concepts of RC tear pathomechanics, diagnosis, and treatment is similar to those that Codman[9] proposed over 75 years ago.

1.3 ROTATOR CUFF TEAR - PREVALENCE AND INCIDENCE

Reilly et al[51] reported the prevalence of 12% full-thickness RC tears in 2553 cadaveric shoulders. Moosmeyor et al[44] reported that the highest prevalence of RC tears occurs in the elderly age group of 70-79 years, with prevalence decreasing as age decreases. Through a community survey, Chard et al[7] approximated that 70% of the cases of shoulder pain involved RC in a sample of 644 elderly people over the age of 70 years. In general, the majority of RC tears occurs within the supraspinatus tendon. Matava et al[36] in a study of 306 cadaveric shoulders, noted a 32% incidence of partial-thickness tears and a 19% incidence of full-thickness tears within the supraspinatus tendon; clinically, Matava et al[36] also noted that articular-sided tears are found to be 2 to 3 times more common than bursal-sided tears; among a population of young athletes, Matava et al[36] found that articular-sided tears constituted 91% of all partial-thickness tears. RC pathology accounts for more than 4.5 million clinic visits and approximately 40,000 surgeries per year in the United States.[46]

1.4 ROTATOR CUFF TEAR - POSTOPERATIVE REHABILITATION

1.4.1 Assessment

1.4.1.1 AROM measurement: The assessment of shoulder mobility is essential in the diagnosis of associated pathology and formulating appropriate physical therapy management for patients following rotator cuff repair. There have been a variety of evaluation tools recommended for measuring shoulder mobility, ranging from basic visual estimation to high speed photography.[45] Goniometric measurements are extensively used in rehabilitation to provide an objective measure of range of motion at synovial joints. [19,45] A variety of positions have been suggested for measuring shoulder ROM, including: sitting with neutral shoulder,[8,23,48] supine with 20° shoulder abduction,[33] supine with 90° shoulder abduction, [8,45,53,54] and prone with 90° shoulder abduction. [47,57] American

Association of Orthopedic Surgeons (AAOS)[2] recommends positions with neutral shoulder and 90° shoulder abduction for measuring shoulder external rotation, and Norkin et al[45] recommend the same positions for patients with various shoulder pathologies.

Currently there are no fixed guidelines or recommendations for choosing one position over the other for measuring shoulder active external rotation ROM in patients following RC repair. Goniometers are the primary measuring tools in physical therapy for measuring any joint motion. The majority of studies that addressed the effects of testing positions on goniometric measurement have focused only on rater reliability; and only a few have addressed the validity and the responsiveness. It is difficult to compare the results of treatment across studies that use different test methods if the impact of test position is not known.

1.4.2 Treatment

1.4.2.1 Current Evidence: A large systematic review covering different components of RC rehabilitation programs was published by Mitchener et al. [42] They found that the current literature supports the use of therapeutic exercise to strengthen the rotator cuff and scapular muscles, and to stretch the soft tissues of the anterior and posterior shoulder. They also found that the therapeutic exercise appears to be more effective when combined with joint mobilization techniques focused on the shoulder and upper quadrant. They concluded by stating that the evidence to support rehabilitation interventions for patients with rotator cuff tear is limited. Plessis et al[49] published a systematic review which addressed the effect of continuous passive movements (CPM) for patients following rotator cuff repair. They found that CPM helps to relieve pain, to increase range of motion, and to improve strength.

Van der Meijden et al[58] have published their clinical commentary and have attempted to make evidence-based rehabilitation guidelines for patients following

arthroscopic rotator cuff repair. The authors found little high-level scientific evidence to support or oppose current postoperative rehabilitation protocols, and they concluded that the existing protocols are based on clinical experience and expert opinion. The authors tried to provide an evidence-based postoperative rotator cuff rehabilitation protocol. Thus, therapists do not have the evidence required to make informed choices nor to justify their services to fund organizations in light of the need to practice within an evidence-based framework. To our knowledge, a systematic review that evaluates the effectiveness of different exercise therapy programs and adjunctive physical therapy interventions which is specific to patients who have undergone rotator cuff repair is yet to be published.

1.4.2.2 Land-based exercise programs: It has been traditionally accepted that ROM exercises (e. g., active range of motion exercises) improve mobility following rotator cuff repair, and land-based exercise was found to be a core element for patients following rotator cuff repair.[42] Paubian et al[48] found that an exercise therapy program is effective in patients following rotator cuff repair. Important factors (components) associated with land-based exercise programs are:

1.4.2.2.1 *Exercise Dosage:* A variety of dosages for land-based exercises have been recommended. Ellman[17] recommended a supervised four month postoperative physical therapy program of two to three sessions per week. Gazielly[21] advocates approximately 40 preoperative and 60 postoperative treatment sessions with a physiotherapist over three to six months of rehabilitation.

1.4.2.2.2 *Adjunctive therapy:* Very few studies have conducted rigorous comparative analyses on the effect of different adjunctive physical therapy programs along with the core, progressive land-based exercise programs. However, in a well designed randomized controlled trial, LaStayo et al[30]

compared rehabilitation using either continuous passive motion (CPM) or manual passive range of motion for patients following rotator cuff repair. This study concluded that both groups achieved equivalent improvements in shoulder motion, muscle force, and functional outcomes. Raab et al[50] compared CPM with manual passive range of motion. They found improvement in the range of motion and in pain scores with CPM as compared to manual passive movements. Both these studies found only short-term effects of CPM; no long-term effects were reported. Reinold et al[52] evaluated the effect of Neuromuscular Electrical Stimulation (NMES), and found increased shoulder muscle force; moderately supporting the use of NMES.

1.4.2.2.3 *Therapy:* There is extremely limited knowledge base supporting different therapy setup in the form of home-based versus institution based programs. In a randomized controlled trial, Roddey et al[55] determined that comparable short-term and long-term functional outcomes were demonstrated in 108 patients who were rehabilitated for full thickness RC repair with a standardized home exercise program that was conveyed via either videotaped instruction or at one of four post-operative physiotherapy sessions. Hayes et al[26] compared two different forms of rehabilitation for subjects with full thickness rotator cuff repair and determined that subjects allocated to individualized physiotherapy treatment were no better than subjects allocated to a standard home exercise regimen in terms of long-term shoulder joint range of motion, muscle force, or functional outcome.

1.4.2.2.4 *RC tendon loading timing:* In general, there is no direct evidence supporting a timeline to start mobility exercises following rotator cuff repair. Many postoperative protocols have analyzed the effect of different loading times on the operated tendons. However, there is no consensus in the literature about the most appropriate time to load the operated tendons during rehabilitation after rotator cuff repair.[58]

Early Postoperative Programs: Hatakeyama et al[25] advocate the use of early mobilization to prevent scar formation between the acromion and RC surface and adhesion of shoulder soft tissues. Millar et al[41] recommend the initiation of PROM during the 2nd postoperative week following RC repair. Millet et al[43] recommend that AROM exercises can be started between the sixth and eighth postoperative week. Klintberg et al[29] advocate that an early activation rehabilitation program produced comparable outcomes when compared with a late rehabilitation program. Overall, no strong evidence was found in the literature on the timing of tendon loading (to start the exercises) during the postoperative rehabilitation. Delayed Postoperative Programs: Some authors delayed muscle loading with immobilization.[5] van der Meijden et al[58] have stated that there is little scientific evidence available to guide the timing of postsurgical rotator cuff rehabilitation.

The primary goal of any RC repair surgery is to improve the shoulder ROM and prevent stiffness. To achieve these goals, traditionally, passive range of motion exercises (PROM), active assisted range of motion exercises (AAROM), and active range of motion exercises (AROM) have been the core aspect of postoperative physical therapy programs. Another key goal is to prevent the recurrence of an RC tear while minimizing shoulder muscle atrophy. Given the importance of land-based exercise programs in achieving the above mentioned goals, rigorous randomized controlled trials are needed to determine the effectiveness of different land-based exercise programs.

1.4.2.3 Aquatic exercise programs: Aquatic therapy is a treatment technique that dates back to the Hippocrates period (450-375 BC) and date back as far as 2400 BC.[27] Aquatic therapy is one of the commonly used adjunctive components of postoperative rehabilitation programs.[11] Currently, aquatic therapy programs are being used as an adjunct to land-based exercise programs. Generally, aquatic

exercises have potential advantages in facilitating ROM gain and muscle use during the early postoperative period. During aquatic therapy, significantly less muscle activity in the middle deltoid and supraspinatus occur during elevation in the scapular plane. [37] Kelly[28] found less activity of the supraspinatus, the infraspinatus, and the deltoid during aquatic therapy when compared to land-based exercises. These studies show that aquatic exercises can be a safe medium where active ROM exercises can be initiated safely without disturbing the operated RC tendons; while preventing shoulder stiffness and facilitating earlier return of shoulder mobility and function.

It has been argued that aquatic therapy is based on the physical properties of water to provide therapeutic effects. The main properties are: buoyancy, viscosity, temperature, and multidimensional resistance. The buoyancy of water is believed to facilitate movements by diminishing tensile strain, and therefore, protecting the operated tendons. Additionally, warm water aquatic activity provides a heating effect which may improve tissue extensibility.

Two published studies that addressed the role of aquatic exercises in the rehabilitation of patients following rotator cuff repair were identified. Brady et al[4] conducted a randomized feasibility study, to compare land-based and aquatic exercises; at 6 weeks postoperative follow-up, the authors found significant clinical improvement in passive forward flexion ROM with aquatic exercises. However, the authors found no significant difference in external rotation ROM or Western Ontario Rotator Cuff (WORC) function score. Delbrouck et al[13] compared inpatient aquatic therapy with outpatient aquatic therapy and found no significant difference in ROM between the groups. However, they found reduced pain on the postoperative 15th day for patients in the inpatient aquatic therapy group. One unpublished, underpowered thesis[11] was identified comparing an aquatic exercise program with a land-based exercise program; the author concluded that both the programs produced comparable outcomes.

Although many physical therapists use aquatic exercise as one of their adjunctive mode of therapy delivery, there has been remarkably little evidence to substantiate its benefits. While studies are emerging, there are large gaps in understanding the effects of different dosages of adjunctive aquatic exercise programs for patients following rotator cuff repair.

1.5 SUMMARY OF LIMITATIONS IN CURRENT KNOWLEDGE

Considering the high prevalence of RC tear and high volume of RC repair, the evidence-based knowledge about postoperative physical therapy programs following rotator cuff repair is limited. To the author's knowledge, a systematic review that evaluates the effectiveness of different land-based exercise programs and adjunctive physical therapy interventions for patients following rotator cuff repair, is yet to be published.

One of the outcomes measured in patients following rotator cuff repair is the shoulder joint range of motion. Using different testing positions, and universal goniometer, ROM can be measured. The majority of studies that addressed the effects of testing positions on goniometric measurement focused only on rater reliability. To this author's knowledge, no study has addressed the issues of validity and the responsiveness of different testing positions for measuring shoulder AROM for patients following rotator cuff repair.

There have been efforts to define an optimal postoperative physical therapy protocol for patients following RC repair, with limited success; various land-based exercise programs and many adjunctive physical therapy programs have been investigated in patients with rotator cuff repair. To this author's knowledge, an optimal postoperative RC rehabilitation program is yet to be defined. Furthermore, there is limited knowledge about the feasibility of conducting a large trial to find the efficacy of different physical therapy interventions for patients following rotator cuff repair.

1.6 PURPOSE OF THIS THESIS

The overall purpose of this thesis was to inform physical therapy management of patients who are recovering from rotator cuff repair. We tried to achieve this purpose with the following objectives:

- To systematically review the quality and content of clinical research, which addresses the efficacy of various physical therapy and adjunctive intervention programs for patients recovering from rotator cuff repair.
- To describe the validity and responsiveness of different testing positions for goniometric measurement of shoulder active external rotation in patients recovering from rotator cuff repair.
- To pilot test study procedures and estimate the effects of a land-based and an aquatic exercise programs by: evaluating recruitment strategies and enrollment rates; identifying barriers for clinicians and patients participating in a randomized study; determining the variability of study outcome measures and use them to determine sample size; providing a preliminary clinical estimate of the effects of different land-based exercise programs, including adjunctive an aquatic exercise program; and using all the above knowledge to proceed with a future randomized clinical study.

1.7 OVERVIEW OF THESIS CHAPTERS

There were remarkably few studies that focused on the physical therapy management of patients following RC repair. Therefore, at first, we decided to systematically review the available literature on the effects of different physical therapy programs for patients following rotator cuff repair. Then, we conducted a pilot study to find out the feasibility of a large study on the effect of land-based exercises and aquatic exercises as an adjunct, for patients following RC repair.

Under Chapter 2, we have included a systematic review which has been submitted for publication, to review the quality and content of clinical research addressing the efficacy of physical therapy interventions for patients recovering from RC repair. The systematic review showed that there is limited and insufficient evidence available addressing the effect of different land-based exercise programs and various adjunctive interventions. However, the findings showed small to moderate evidence to support the effect of land-based exercises including various adjunctive physical therapy interventions. (Kindly refer chapter 2 for details)

Under Chapter 3, we have included a study that addresses the validity and the responsiveness of different testing positions for measurement of shoulder AROM in patients following rotator cuff repair. The correlation, agreement, and responsiveness of two testing positions namely, supine with 90° shoulder abduction, and sitting with neutral shoulder, were evaluated in this study. Both measurement positions provided different AROM measurement values which were moderately correlated; this study also demonstrated that the sitting position provided precise, and more responsive measurements than the supine position. (Kindly refer chapter 3 for details)

Under Chapter 4, we have included a pilot study which described the effect of a land-based and an aquatic exercise program, both of which produced comparable clinical improvement in shoulder outcomes. The intervention protocols are shown to be feasible and seem to be of value in improving health related quality of life in patients recovering from rotator cuff repair. Using the outcome measurement values, we calculated sample size for potential future studies. (Kindly refer chapter 4 for details)

Under the final Chapter, we have provided a general discussion and formulated conclusions based upon the previous research, including most the

significant findings. We have also provided research directions and recommendations which can be considered for future studies. (Kindly refer chapter 5 for details)

In summary, through this thesis we attempt: to inform about evidence-based information on the effect of different postoperative physical therapy programs; to describe the validity and the responsiveness of different AROM measurement positions; to determine the feasibility of a randomized clinical trial, and to estimate the effect of different physical therapy programs, for patients recovering from shoulder rotator cuff repair.

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2. 1. ABSTRACT

Study Design: Systematic review.

Objective: To systematically review the quality and content of clinical research addressing the efficacy of physical therapy interventions for patients following rotator cuff repair.

Methods: The peer-reviewed databases of Medline, AMED, PEDro, CINAHL, EMBASE, Scopus, the Cochrane Central Register of Cochrane Trials, and Cochrane database of systematic reviews (from inception to May 2012) were searched using relevant key words. Studies were selected for data extraction and critical appraisal if they reported on postoperative rehabilitation of patients following rotator cuff repair. Studies were randomly allocated to two pairs of reviewers who independently extracted data and appraised the studies using a structured critical appraisal form.

Results: Fourteen studies, which satisfied the inclusion criteria, were included and reviewed. Methodological quality varied from poor to good, as indicated by Structured Evaluation Quality of an Intervention Study score (SEQIS), with scores ranging from 16 to 34 (33% to 71%) out of 48. Continuous passive movement, aquatic exercises, and individualized exercise therapy had small to moderate effect in relieving pain, improving range of motion (ROM), improving strength, and improving function, when compared to manual passive ROM exercises, land-based exercises, and no exercise therapy groups, respectively. One study found a 22% increase in peak shoulder external rotation force with neuromuscular electrical stimulation (NMES) of shoulder muscle when compared to no NMES. Two studies found comparable outcomes when comparing the

effect of early rehabilitation with late rehabilitation. Most studies failed to report key elements in study design, including characteristics of subjects, and intervention. In particular, reporting of exercise parameters was poor.

Conclusion: This systematic review found that exercise therapy including adjunctive interventions has small to moderate effect in relieving pain, increasing range of motion, increasing muscle strength, and improving function for patients following rotator cuff repair. However, there is no strong evidence to differentiate the effectiveness of different exercise programs, or different adjunctive interventions. *J Orthop Sports Phys Ther 2012.*

Level of Evidence: Therapy, Level 1a-.

Key Words: *aquatic therapy, critical appraisal, evidence-based practice, land-based exercise, physical therapy, physiotherapy, rehabilitation, rotator cuff repair, systematic review*.

2. 2. INTRODUCTION

Rotator cuff (RC) disease is the most common pathology affecting the shoulder joint.[47] RC disease involves any type of irritation or tear to the RC muscles or tendons due to either trauma, repetitive use, or degeneration.[33] RC tears can lead to significant disability affecting the activities of daily living, work, and sports, thereby influencing the quality of life.[31] Surgical repair of the RC tear aims to restore the tendon, reduce pain, and ultimately improve function.[37] Factors that may influence healing include the magnitude and location of the RC tear, preferences/training/experience of physical therapist and surgeon, clinical symptoms and comorbidities of patients, and surgical techniques. Considering the volume of surgical repair of the rotator cuff, there have been limited efforts to define optimal postoperative management.[45]

Plessis et al[38] has published a systematic review which addressed the effect of CPM for patients following rotator cuff repair. They found that CPM helps to relieve pain, to increase range of motion, and to improve strength. Van der Meijden et al[45] have published their clinical commentary and have attempted to make evidence-based rehabilitation guidelines for patients following arthroscopic rotator cuff repair. The authors found little high-level scientific evidence to support or oppose current postoperative rehabilitation protocols, and they concluded that the existing protocols are based on clinical experience and expert opinion. The authors provided an evidence-based postoperative rotator cuff rehabilitation protocol. It should be noted that the authors[45] did not systematically (critically) appraise the quality of studies; rather they did a narrative review. Both the reviews [38,45] failed to address multiple physical therapy intervention strategies for patients following rotator cuff repair.

To the author's knowledge, a systematic review that evaluates the effectiveness of different exercise therapy programs and adjunctive physical therapy interventions which is specific to patients following rotator cuff repair is

yet to be published. Therapists do not have the evidence required to make informed choices nor to justify their services to fund organizations in light of the need to practice within an evidence-based framework. The purposes of this study were to perform a comprehensive systematic review and to summarize the evidence supporting the effectiveness of exercise therapy including adjunctive physical therapy interventions, for patients recovering from rotator cuff repair.

2. 3. METHODS

2. 3.1. Search Strategy

The following electronic databases were searched from inception to May 2012: MEDLINE, Allied and complementary Medicine Database - AMED, Cumulative Index to Nursing & Allied Health Literature - CINAHL, the Physiotherapy Evidence Database - PEDro, Scopus, EMBASE, Databases and Evidence Based Reviews, including the Cochrane Database of Systematic Reviews and the Cochrane Central Register of Cochrane Trials.

The search terms included: rotator cuff surgery, rotator cuff repair, physical therapy, physiotherapy, rehabilitation, therapeutic exercise, aquatic therapy, passive motion, active motion, shoulder outcomes, shoulder pain, shoulder, shoulder joint, rotator cuff, musculotendinous cuff, surgery, randomized controlled trial, controlled clinical trial, random allocation, double-blind method, single-blind method, clinical trial, comparative study, evaluation studies, follow-up studies, prospective studies, physical therapy techniques, musculoskeletal manipulations, exercise movement techniques, therapeutic ultrasound.

2. 3. 2. Study Selection

Two pairs of evaluators independently reviewed abstracts to identify studies meeting the inclusion and exclusion criteria and to exclude duplicates. All studies that reported clinical data on outcomes of patients undergoing rehabilitation

following rotator cuff repair were included. Studies published in the languages of English and French were included. Exclusion criteria were: expert opinions, cadaveric studies, biomechanical studies, and publications on secondary shoulder problems such as concomitant fractures of the shoulder joint. (See Table 1)

2. 3. 3. Data Extraction

Two pairs of independent evaluators extracted selected data from the included articles. A data extraction form[30,32] was used to extract information on the following areas: study question, study design, study subjects, intervention, outcomes, analysis, and recommendation.

2. 3. 4. Quality Assessment

The methodological quality of the studies was appraised using SEQIS. The SEQIS rates study quality under seven categories: study question, study design, subjects, intervention, outcomes, analysis, and recommendation. Each category has several criteria, and each criterion was scored with a grade of 0, 1, or 2. As a general principle, according to the published SEQIS interpretation guidelines,[30,32] a score of '0' means that the criterion was not met, '1' means that the criterion was partially met, and '2' meant that the criterion was met. The quality appraisal tool and interpretation guidelines are available from the developer (JMD) and have been published in several locations. [30,32] Using the SEQIS scores, high-, moderate-, and low-quality levels were assigned. The maximum SEQIS score was 48. High-quality study status was assigned if the SEQIS score was between 33 and 48, moderate-quality if the SEQIS score was between 17 and 32, and low-quality if the SEQIS score was below 17. [30,32] Each article was also assigned a level of evidence using the levels of evidence table published by the Center for

Evidence Based Medicine.[7] When the raters disagreed on any rating item, a resolution was achieved through discussion and consensus.

2. 4. RESULTS

2. 4. 1. Search Results

In the initial search strategy, 1596 studies were identified. Based on the review of the titles and abstracts, 1409 papers were excluded. After reviewing the full text of the remaining 187 studies, 173 of these were excluded as they did not satisfy the inclusion criteria. At the end of the selection process, 14 studies were retained for evaluation. Following Prisma guidelines, [28,35] we have provided a flow chart describing the search strategy and the search yield. (Figure 1)

2. 4. 2. Methodological Quality

Two studies provided level 1b evidence; eight studies were level 2b evidence; two studies were level 3b; and two studies were level 4 evidence. The SEQIS scores ranged from 16 (33%) to 34 (71%), out of the maximum score of 48. Two studies[11,21] achieved high-quality scores; eight studies[2,24,25,26,23,39,40,41] achieved moderate-quality scores; and four studies[12,14,15,18] achieved low-quality scores. (Table 4)

2. 4. 3. Scope of Physical Therapy Interventions Evaluated

The fourteen studies included in this study indicated a wide diversity in the nature of exercise therapy programs and adjunctive interventions: two studies with home-based exercises,[21,41] three studies with land-based supervised exercises,[14,18,34] three studies with aquatic exercises,[2,11,12] three studies with continuous passive motion,[15,25,41] one study with neuromuscular electrical stimulation,[40] and two studies with early loading exercises. [24,26] These exercise programs and adjunctive interventions were designed to improve the following

outcomes: pain relief, increase range of motion, strengthen muscles, and improve function. The exercise therapy programs and adjunctive interventions were provided at hospitals, at community clinics, and at home-based environments. The overall duration of the exercise therapy programs ranged from a minimum of six weeks to a maximum of 48 weeks. With institution-based interventions, treatment took place on an outpatient and inpatient basis for two to three 3 times a week, for a minimum of 30 minutes to a maximum of 75 minutes. When group therapy was performed, groups of four to 24 patients were supervised by either physiotherapists or trained instructors. With aquatic exercise programs, water temperature ranged between 28°C and 36°C, and water depth ranged between the iliac crest and the xiphisternum. (Tables 5, 6, 7, & 8)

2. 4. 4. Outcome Measures

The most commonly reported outcome measures were: pain (12 studies); range of motion (10 studies); muscle strength (10 studies); and function (8 studies). (See Table 3) A total of twelve (86%) studies used pain intensity as one of their outcome measures; the majority of studies (67%) used 10-cm Visual Analog Scale (VAS); [11,12,18,24,25,26,34,39] other studies have used various self-report questionnaires, such as the University of Pennsylvania Shoulder Scale,[41] the Shoulder Pain & Disability Index,[42] the University of California Shoulder Scale,[18] the Constant score,[24] and the American Shoulder & Elbow Surgeons Shoulder Scale. [14] A total of ten (71%) studies used ROM as one of their outcome measures; the majority of studies used a universal goniometer to measure ROM,[11,12,14,15,24,25,26] one study used the gravity referenced inclinometer,[2] and another study used the visual estimation method.[21] A total of ten (71%) studies used muscle strength as one of their outcome measures; to measure muscle strength, two studies used handheld dynamometers,[24,39] three studies used isokinetic dynamometers,[14,18,24] three studies used manual muscle testing

method,[15,21,34] and one study used a handheld Nottingham Mecmesin Myometer.[26] A total of eight (57%) studies assessed upper extremity function as one of their outcome measures using one of the following tools: The University of Pennsylvania Shoulder Scale,[41] the Shoulder Pain and Disability Index (SPADI),[25,41] the University of California Shoulder Scale (ULCA),[18,26] the American Shoulder and Elbow Surgeons Shoulder Scale (ASES-s),[14] the Constant score,[24] and the Western Ontario Rotator Cuff Index (WORC).[2]

2. 4. 5. Results of Specific Physical Therapy Interventions

Effect of Land-based Exercises: A total of three studies[14,18,34] evaluated the effect of individualized exercise programs, all of which found small to moderate improvements in pain, range of motion, muscle strength, and function. Ellenbecker et al[14] (study quality score of 38%) described an exercise therapy program consisting of active assisted exercises, active exercises, and muscle strengthening exercises; at 12 weeks post surgery, the final outcomes in motion were a mean AROM deficit of 5° to 7° in abduction, internal rotation, external rotation, and full return of forward flexion. The final outcomes in isokinetic strength were a mean deficit of 5% to 7 % in the external rotators and a mean improvement of 6% to 11% in the internal rotators. Glasoe et al[18] (study quality score of 33%) reported on a 12 week exercise therapy program consisting of passive exercises, active exercises, and strengthening exercises. At 6 months follow-up post surgery, the final outcomes in motion were a mean forward flexion improvement of 19°, and a mean external rotation deficit of 9°; the final outcomes in muscle strength were an improvement of one Nm and 15 Nm, in the internal and external rotators, respectively; the UCLA pain and function scores improved by seven and four points, respectively. Millar et al[34] (study quality score of 48%) described the effectiveness of an outpatient (OP) exercise therapy program, which included active exercises and manual therapy. The authors found that the

outcomes of pain, ROM, and function were improved in the subgroup with the OP exercise program, compared to no exercise group. (Table 5)

Effect of Early Versus Delayed Exercises: A total of two studies[24,26] evaluated the effect of early versus late exercise programs. Klintberg et al[24] (study quality score of 65%) compared an early exercise program that consisted of early activation of the operated RC tendons on the first postoperative day; with the delayed exercise program consisting of no RC muscle activation until postoperative six weeks. Lee et al[26] compared (study quality score of 54%) two early exercise programs; one with unrestricted PROM exercises, and another with limited Passive Range of Motion (PROM) exercises; both programs consisted of manual passive exercises, CPM, active exercises, and strengthening exercises. At six months, twelve months and two years post surgery, there was no significant ROM difference between these two groups (Table 5).

Effect of Continuous Passive Motion (CPM): A total of three studies[15,25,39] evaluated the effect of CPM, and found small to moderate improvements in pain, range of motion, and muscle strength, favoring CPM. These findings were noted during short-term follow-up: at postoperative 1st week, 3rd week, and 6th month. El-Zaaar et al[15] (study quality score of 31%) found that 92% of the participants experienced postoperative pain reduction, and 70% had improved shoulder function when CPM was used during rehabilitation. LaStayo et al[25] (study quality score of 58%) compared CPM with manual passive range of motion. They found significantly less pain with CPM, during the postoperative first week, compared to manual PROM. The authors also found a marginal increase in shoulder elevator strength with CPM, at sixth months follow-up. However, external rotation and forward flexion ROM demonstrated no significant between-group differences at one month, one year, or two years follow-up. Raab et al[39] (study quality score of 60%) compared CPM with manual passive range of motion. They found

improvement in the range of motion and in pain scores with CPM as compared to manual passive movements. Statistically, significant differences in outcomes occurred only at the 3 week postoperative time point. Although these studies[15, 25,39] found a short-term improvement, they did not find any long-term effects of CPM. (Table 5)

Effect of Neuromuscular Electrical Stimulation (*NMES*)*:* One study[40] evaluated the effect of NMES, and found increased shoulder muscle force; moderately supporting the use of NMES. Reinold et al[40] (study quality score of 46%) compared the muscle force of the external rotators using two groups, one with NMES and one without NMES. The authors[40] applied one session of NMES with maximal intensity within the participant's comfort level, at a frequency of 50 pulses per second, using a symmetrical waveform, and a one-second ramp time. They reported that peak shoulder external rotation force increased by 22% with the use of NMES. This significant change was achieved regardless of the patient's age, RC tear size, and time since surgery. (Table 5)

Effect of Aquatic Exercise: A total of three studies[2,11,12] evaluated the effect of aquatic exercises as compared to land-based exercises. During the 3rd and 6th follow-up weeks, two studies[2,12] found small to moderate improvements in range of motion and pain, favoring aquatic exercises. Brady et al[1] (study quality score of 58%) in an RCT (feasibility study) found that at 6 weeks postoperatively, the final outcome in motion was a mean forward flexion PROM increase of 46° (95% CI = 17°- 75°) with aquatic compared to land-based exercises. However, the authors found no significant difference in external rotation ROM or WORC function score. Dainty[11] (study quality score of 71%), with a randomized controlled trial, found no statistically significant difference between aquatic and land-based groups with respect to the Western Ontario Rotator Cuff (WORC) score for function, or with the Visual Analogue Scale (VAS) for pain. Delbrouck et al[12] (study quality score of 31%) compared inpatient aquatic therapy with

outpatient aquatic therapy and found no significant difference in ROM between the groups. However, they found reduced pain on the postoperative 15th day for the inpatient aquatic therapy group. (Table 5)

Effect of Home Exercise Program (HEP): A total of two studies[21,41] evaluated the effect of a home-based exercise program versus a supervised exercise program. Of these, one study[21] found a small statistical difference in ROM, favoring a supervised exercise program. Hayes et al[21] (study quality score of 71%) conducted an RCT evaluating the effect of supervised exercise versus unsupervised home exercise. Both programs consisted of active-assisted, active, and strengthening exercises. At 24 weeks follow-up, the outcomes in motion were a mean improvement of 3°, 12°, and 8°, for flexion, abduction, and external rotation respectively, favoring the supervised exercise program; however, they found no statistically significant difference in muscle strength between these two groups. Roddey et al[41] (study quality score of 60%) conducted an RCT evaluating the effect of a home-based exercise program and a supervised exercise program. The home-based exercise program was administered using videotape instruction, and the supervised exercise program was administered using personal instruction. Both groups had active-assisted, active, and strengthening exercises; the authors found no significant difference between these two groups at postoperatively 52 weeks follow-up. (Table 5)

2. 5. DISCUSSION

The results of this systematic review indicated that weak to moderate evidence exists to support the effectiveness of various physical therapy programs and adjunctive interventions for patients following rotator cuff repair. Most commonly, exercise formed a core element of physical therapy programs, although there was variation in methods of dosage and delivery. Inadequate reporting of the details of these programs made it difficult to directly compare different options. A

number of adjunctive interventions ranging from CPM to aquatic exercises have been used and found to be effective, but we did not find sufficient evidence to advocate for the use of one over the other.

Two reviews[38,45] have been published on the rehabilitation of patients following rotator cuff repair. Plessis et al[38] performed their review to find the effect of one of the adjunctive components (i. e., the CPM) on rotator cuff rehabilitation program; the authors did not perform the review on any other interventions, including the core intervention of land-based exercise programs; However, the findings of our systematic review on the effect of the CPM are in agreement with the results of Plessis et al.[38] Van den Meijden et al,[45] without mentioning their research strategy, performed a narrative review to recommend an evidence-based rehabilitation protocol. The authors concluded by stating that there is little scientific evidence available to guide postsurgical rotator cuff rehabilitation; expert opinion and clinical experience remain the basis of the available rehabilitation protocols. The result of our systematic review is in agreement with these findings; However, the results of our systematic review are more than the narrative review,[45] as in our current review two pairs of independent evaluators performed vigorous quality appraisals of all included studies using a valid and standardized tool.

All of the studies that were included in our review reported small to moderate improvement in one or more of the following outcomes: pain, range of motion, muscle strength, and function. The potential reasons for these improvements could be due to participants' adherence to exercise protocols; the expertise of the therapist in instructing the patients; and the use of appropriate exercise parameters, such as exercise intensity, exercise duration, and exercise frequency.[22] The improvements in ROM are affected by various factors. One decisive factor is the type of surgery. Patients in the Ellenbecker study[14] underwent a mini-open rotator cuff repair, where partial disruption occurs within

the deltoid muscle due to the surgery. In this study, patients gained ROM in a relatively short duration, when compared with patients who participated in the studies of Hayes,[21] Glasoe,[18] and LaStayo[25] who underwent a standard open rotator cuff repair, where complete detachment of the anterior deltoid muscle origin occurs. These findings may indicate that patients who had less or no disruption of the deltoid muscle regained ROM faster. Hayes et al[21] supports this finding by suggesting that a possible reason for the difference in ROM can be due to different surgical procedures for repairing rotator cuff tendons. We found very few clinical studies supporting the effect of physical therapy. Biomechanical studies related to the tendon loading time and the role of different exercises are important. But, we did not include these studies in our review.

It has been traditionally accepted that ROM exercises improve mobility following rotator cuff repair, a statement that our systematic review is in agreement with exercise was found to be a core element in the current review; and in a previous study which reflected that the exercise therapy protocol has been effective for patients following rotator cuff repair.[37] Following rotator cuff repair, CPM can be used as an adjunct to exercise during the joint protection phase. During the postoperative period of 1 week to 6 months, studies have shown clinically significant improvements in pain,[15,25,39] ROM,[39] strength,[25] and function[15] favoring the CPM. A potential reason for improved ROM and decreased pain could be the fact that the CPM facilitates the flow of inflammatory materials following surgery,[36] leading to reduction of postoperative edema. However, the overlapping effects of postoperative pain medications which could have been another reason for short term pain relief, which was not described. In addition to relieving pain and increasing range of motion during initial 6 weeks, all authors[15,25,39] had an opinion that CPM might be useful in protecting shoulder joints without putting undue stress on the healing RC tendons. This opinion was supported by an electromyography study by Dockery et al,[13] who conducted the

study of healthy individuals to find a less supraspinatus muscle activity during the use of CPM, in comparison to pulley and wand exercises.

Aquatic exercises have the potential for regaining ROM, and facilitating muscle use in the early postoperative period. The buoyancy of water is believed to facilitate movements by diminishing tensile strain, and therefore protecting the operated tendons.[37] Additionally, warm water aquatic activity provides a heating effect which may improve tissue extensibility. However, it is essential to establish a therapeutic range of water temperature to ensure that these effects are attained. Starkey[43] suggests that increasing skin temperature to between 39.6° C and 44.5° C results in substantial therapeutic benefits. In our current review, three studies[2,11,12] compared aquatic exercises with land-based exercises, and two studies agreed that aquatic exercises were a useful adjunct to rehabilitation. With aquatic exercise, Brady et al[2] found a statistically significant improvement in forward flexion ROM. The authors suggested that the increased forward flexion ROM might potentially play an vital role in gaining shoulder function by reducing secondary soft tissue complications such as contractions and adhesions. Dainty[11] observed a trend of shoulder ROM improvement immediately following aquatic exercises in a small randomized trial. However, this small pilot study that did not find any statistical differences between-groups, lacked power and had high attrition rates.

Neuromuscular electrical stimulation (NMES) may be used as an adjunct treatment to enhance muscle force. In our review, we found that NMES provides 22% muscle force increase in the operated rotator cuff muscles, which was reported during the early postoperative phase of rotator cuff surgery.[40] This suggests that the NMES may be an adjunctive for patients with rotator cuff repair; however, caution should be exercised while interpreting the outcome of this study as the authors found only a short term effect of the NMES.

The comparison of a PT supervised exercise program versus unsupervised exercise program is a paramount consideration since it has resource implications for both patients and insurers. Unfortunately, it can be difficult to compare these since terminology about what constitutes supervision is variable across studies. The term unsupervised exercise program and home-based program have been interchangeably used in the literature. Furthermore, clinic-based and supervised exercise is sometimes used interchangeably. In the current review, we assumed that unsupervised exercise was home-based exercise unless otherwise defined. Further complicating the comparison is that dosage is not always held constant when comparing these forms of exercise. This may be appropriate for external generalizability, but a lack of clarity on dosage and delivery makes it difficult to differentiate the optimal way of providing exercise. Given that there were contradictory conclusions about the need for supervised exercise; higher-quality studies with clear definitions are needed to address this issue. One potential advantage of the PT supervised exercise programs is the professional guidance may motivate patients, ensure the exercises are performed correctly and progressed according to the patient's individualized improvement. Patients who are involved in supervised therapy may become more invested in their rehabilitation by receiving proper and ongoing feedback. In a qualitative study of patient's with neck pain, patients reported that having someone measure their outcomes was an significant motivator to keep them on track with their home exercises. This suggests that the potential benefit of supervised exercise is the monitoring. However, depending how home programs are delivered the effect of monitoring may or may not be embedded.

A home-based program may imply that no one is overseeing what is being done by the patients; whereas in a clinic-based program, at least theoretically, a therapist or an instructor is monitored to make sure that the exercises are performed correctly. On the other hand, a home-based exercise program can be

somewhat supervised if patients are rechecking with their therapist on a regular basis. Advantages of a home-based exercise are that it is less resource intensive, saving time and costs. This was confirmed by a study[3] that found a cost differential that supervised exercise was more expensive than home-based exercise in rotator cuff rehabilitation; and also found no significant outcome difference between these two groups. In our review, no study performed a cost analysis; however, comparing a PT supervised program the patients with a home exercise program[41] had comparable outcomes. Given the importance of exercise in the postoperative recovery, rigorous randomized control trials, and cost-benefit analysis in determining the effectiveness of PT supervised versus nonsupervised exercise programs are needed.

The main aim of all rotator cuff rehabilitation protocols is to enhance healing of the repaired tendons and preventing recurrence of a RC tear while minimizing joint stiffness and muscle atrophy. There is no consensus in the literature on the most appropriate time to load the operated tendons during rehabilitation after rotator cuff repair.[45] Many postoperative protocols have analyzed the effect of different loading time of the operated tendons. Some authors delayed the muscle loading with immobilization; [4,44] another study[24] advocate that an early activation rehabilitation program produced comparable outcomes as a late rehabilitation program. A delicate balance is needed between maintaining the gains of surgery and preventing recurrence of a tear, as a result of the early loading of the repaired tendons. The failure rates for arthroscopic rotator cuff repair range from 17% to 94%.[1,16,29] While the failure rates for open and mini open rotator cuff repairs range from 6% to 32%. [10,17,20,46] Failure of a repair would result in high patient dissatisfaction; hence, when choosing rehabilitation protocols careful selection of the postoperative rehabilitation protocols is needed. Protocols should be selected by considering the following factors: type of surgery, postoperative therapy timing, compliance level of

patients, adjunctive therapy components. Van der Meijden et al[45] have stated that there is little scientific evidence available to guide the timing of postsurgical rotator cuff rehabilitation, a statement that author's systematic review is in agreement with.

2. 5.1. Limitations

One of the primary barriers to making definitive conclusions in this review was the limitation in the studies themselves. Postoperative rehabilitation studies are inherently difficult because some improvement in physical impairments, pain, and function are expected because of natural history regardless of physical therapy intervention. Therefore, it is difficult to make any conclusions from case series since they cannot differentiate natural history recovery from that attributable to physical therapy. The number of randomized trials comparing different physical therapy options is limited, and of these, most have small sample sizes. None of the studies described concealment of participant allocation, which is generally considered as a critical component in reducing the potential for bias. The majority of the studies did not report whether data was missing; nor had strategies to deal with missing data, potential crossovers or dropout effects. Participants might have introduced a Hawthorne effect, by altering their behavior (outcomes) because of knowing that they are being observed;[27] or respond to increased attention in the trial. Most studies did not adequately deal with this issue. Clinicians might have introduced attention bias by preferentially attending to participants who were in the treatment group, or due to the belief that the participants receive special treatment. In such cases blinding and using an independent evaluator play an decisive role. However, most of the studies did not use either blinding or an independent evaluator.

The CONSORT statement[42] provides guidelines for reporting clinical trials, calls for clarity, completeness, and transparency of reporting. This would

increase the repeatability of any intervention study and also would enhance the translation of research knowledge into clinical practice. In most of the studies we found that the exercise dosage and exercise descriptions were poorly documented. In many cases, an evidence-based rationale for choosing a particular exercise program was not provided by the authors. The most common reason cited by the authors for choosing an exercise program was that a particular exercise program had not been used previously. There was no rationale provided on how progression or regression of resistance was made as patients' symptoms or outcomes changed. Also, no studies described any contraindications for physical therapy program. Lack of definition of how exercise programs are initially prescribed and later modified, makes it difficult for clinicians make evidence-based decisions; and makes it difficult to generalize these findings to different clinical settings.

2. 5.2. Strengths

The strength of the current review is that we used two pairs of independent reviewers, with high (85 %) levels of agreement between the reviewers. This adds to the credibility of the results of this systematic review. However, the limited number of studies of low quality and inadequate reporting has made it difficult to make any conclusive statements about dosage; and would serve as a barrier for any evidence synthesis particularly meta-analysis. We limited the data extraction to studies published in English or French. We did not expect this to make a substantial impact on the conclusions given that we found no abstracts of high quality studies that were written in other languages (indexed abstracts are often presented in English even when the primary paper is in a different language). Therefore, it is possible, but unlikely that we missed high-quality studies in other languages. Finally, since few studies have specifically studied the natural recovery following rotator cuff repair without physical therapy

intervention, the extent to which natural recovery contributes to improvement in outcome is not clear.

2. 5.3. Future Research Directions And Recommendations

Rigorous RCTs that are designed to minimize bias and reported using CONSORT criteria[42] are needed to define the optimal method for postoperative rehabilitation following rotator cuff repair. Specific recommendations include the following:

Research Question Priorities: Studies that compare different treatment approaches are needed. Priority should be given to optimizing exercise because it is a core component of existing rehabilitation protocols. We know that optimal loading of the tendon will increase the tensile strength of the tendon, but the overly aggressive loading during an early postoperative period might result in rupture. Therefore, studies on the optimal timing and dosage of resistance exercises should be priority issues.

Reporting Recommendations: Better reporting of exercise protocols is needed: We suggest that all exercise studies should report the intended goal, method for assigning initial load, principles of progression, specifics of dosage (load, repetitions per set, number of sets per day, and duration of exercise program), precautions, contraindications, and outcomes. Better descriptions of patients are needed including the nature of the defect/repair, and distribution of known prognostic indicators (for recovery / response to treatment). In addition, a measure of adherence should be included.

Defining Optimal Combinations of Physical Therapy: Since postoperative rehabilitation is typically delivered as a multi- factorial treatment, the optimal combinations of different components of rehabilitation should be assessed. As such, the factorial design [4] may be useful in comparing whether individual treatments or their combination optimizes outcomes.

Defining standardized outcome measures: Better reporting of outcomes within trials is needed; including reliable and responsive measures of pain, motion, strength, disability, and functional performance. Standardized measurement instruments, protocols, and the timing would improve the quality of existing trials and contribute to the ability to conduct meta-analyses in the future. In addition, more careful reporting of return-to-work outcomes is needed and should include both time lost and at-work limitations.

2. 6. CONCLUSIONS

There is weak overall evidence to define the use of physical therapy interventions, and small to moderate evidence to support progressive exercise programs as a core element of rehabilitation with the potential addition of adjunctive components including continuous passive movements, aquatic exercises, and neuromuscular electrical stimulation. There is insufficient evidence to support a specific dosage or delivery method for progressive exercise. The anticipated benefits of physical therapy following rotator cuff repair include relieving pain, increasing range of motion, improving muscle strength, and improving function; and standardized outcome measures to assess these should be included in future studies to provide a more comprehensive assessment of the impact of postoperative rehabilitation. More rigorous research is warranted to address the gap between rotator cuff tear, repair, rehabilitation and recovery.

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FIGURE 1. The systematic review evidence flowchart

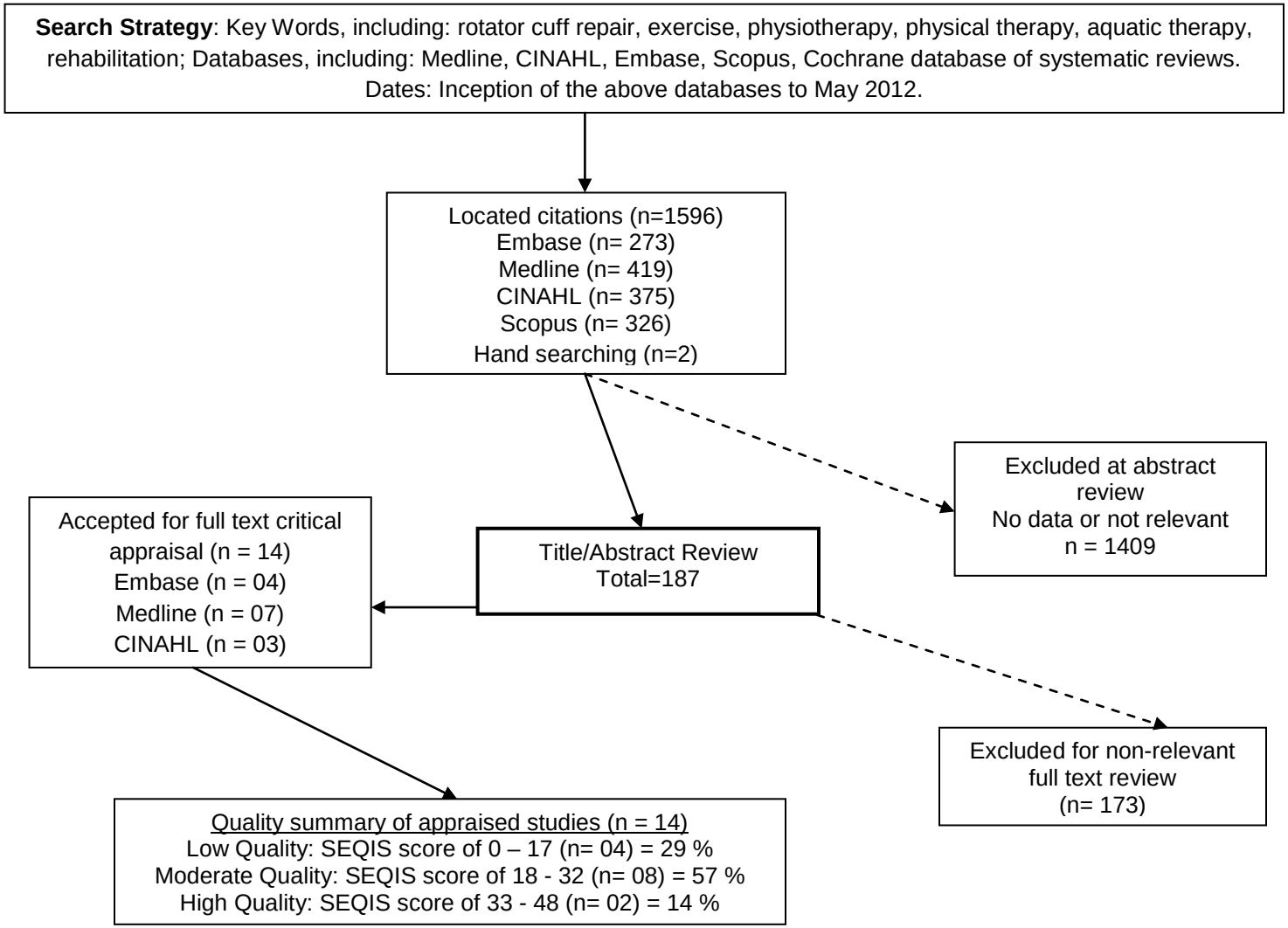

TABLE 1. Inclusion and Exclusion criteria

Inclusion criteria:	Exclusion criteria:
1. Type of study: CEBM level of evidence 1 to 5. 2. Type of injury: Partial and full thickness rotator cuff tears. 3. Type of surgery: Open, Mini-open, or arthroscopic surgery. 4. Publication of studies: studies published in the languages of English, French, between 1950 and 2012. 5. Type of research participants: Skeletally mature.	1. Type of study: expert opinions, cadaveric studies, biomechanical studies, and publications on secondary shoulder problems such as concomitant fractures of the shoulder joint. 2. Type of injury: massive non-reparable rotator cuff tear, associated nerve injuries, associated fractures. 3. Type of treatment: Secondary treatment including revision surgeries. 4. Publication of studies: studies published in languages other than English, and French. 5. Type of research participants: Skeletally immature.

TABLE 2. Patient Demographics, Diagnosis, and Surgical intervention

Study	Participant Details			
	Mean age (Years)	Gender ratio (M: F)	Diagnosis	Surgical intervention
Raab et al[39]	56.0	17: 09	Full thickness rotator cuff tear	Open
El - Zahaar et al[15]	22.3	23: 04	Full thickness rotator cuff tear	Open
LaStayo et al[25]	63.3	23: 18	Full thickness rotator cuff tear	Open
Dainty[11]	59.0	25: 08	Full thickness rotator cuff tear	Open & mini-open
Roddey et al[41]	57.9	69: 39	Full thickness rotator cuff tear	Arthroscopy
Delbrouck et al[13]	53.2	48: 31	Full thickness rotator cuff tear	Arthroscopy, open & mini-open
Hayes et al[21]	60.0	40: 18	Full thickness rotator cuff tear	Open
Glasoe et al[18]	56.0	01: 00	Full thickness rotator cuff tear	Open
Ellenbecker et al[14]	57.3	11: 26	Full thickness rotator cuff tear	Mini-open.
Millar et al[34]	51.9	100: 56	Full thickness rotator cuff tear	Not mentioned
Brady et al[2]	47.5	90: 08	Full thickness rotator cuff tear	Open
Reinold et al[40]	54.0	20: 19	Full thickness rotator cuff tear	Open
Klintberg et al[24]	55.0	09: 05	Full thickness rotator cuff tear	Mini-open & Arthroscopy
Lee et al[26]	58.0	41: 13	Full thickness rotator cuff tear	Arthroscopy

TABLE 3. Outcome Measures

Study	Outcome measures and their Reliability & Validity			
	Pain	Range of Motion	Muscle Strength	Function
R[39]	Shoulder Scale	Shoulder Scale	Shoulder Scale	Shoulder Scale
Ell[15]	Patient self report	Not mentioned	Manual Muscle Test	Patient self report
L[25]	Visual Analogue Scale	Universal Goniometer: Intra-rater ICC: 0.72 – 0.97 Inter -rater ICC: 0.11 – 0.56	Hand – held Dynamometer Intra-rater ICC: 0.72- 0.97 Inter -rater ICC: 0.11-0.56	Shoulder Pain and Disability scale
D[11]	Visual Analogue Scale	Universal Goniometer	Not mentioned	Western Ontario Rotator Cuff index
R[41]	University of Pennsylvania Shoulder Scale Shoulder Pain and Disability scale.	Not Assessed	Not Assessed	Shoulder Pain and Disability scale Internal Consistency: 0.88 – 0.95; ICC: 0.64 – 0.66. University of Pennsylvania Shoulder Scale - Internal Consistency 0.93; ICC: 0.88 – 0.94
D[13]	Visual Analogue Scale	Universal Goniometer:	Not Assessed	Not Assessed
H[21]	Shoulder Questionnaire.	Visual Estimation: Intra-rater ICC: 0.50 – 0.67 Inter -rater ICC: 0.57 – 0.70	Manual Muscle Test: Intra -rater ICC: 0.79-1.00 Inter- rater ICC: 0.55-0.73	Shoulder Questionnaire.
G[18]	University of California Shoulder Scale.	Universal Goniometer: Intra-rater standard error of measurement : 11°	Isokinetic Dynamometer Intra-rater Reliability: ICC more than 0.8	University of California Shoulder Scale.
E[14]	American shoulder & elbow surgeons' Society (ASES) shoulder scales.	Universal Goniometer: Test – retest reliability: 0.94 & 0.89	Isokinetic Dynamometer Reliability: 0.60 – 0.95	ASES Scale - Internal Consistency: 0.86; Intra-rater ICC: 0.84; Test-retest reliability: 0.96
M[34]	Patient self report	Universal Goniometer: Intra-rater reliability: 0.96 Inter-rater reliability: 0.97	Manual Muscle Test: Test–retest reliability: 0.98	Patient reported functional status and Work Status scale Validity
B[2]	Not mentioned	Gravity referenced inclinometer.	Not Assessed	Western Ontario Rotator Cuff index
R[40]	Not Assessed	Not Assessed	Hand – held dynamometer	Not Assessed
K[24]	Visual Analogue Scale	Universal Goniometer	Isokinetic Dynamometer	Constant score
L[26]	Visual Analogue Scale	Universal Goniometer	Handheld Nottingham Mecmesin Myometer	University of California Shoulder Scale.

TABLE 4. Quality of studies and evidence level

Quality of study	Study / Evaluation Criteria	H et al[21]	D[11]	K et al[24]	R et al[39]	R et al[41]	L et al[25]	B et al[2]	L et al[26]	M et al[34]	R Et al[40]	E et al[15]	D et al[12]	G et al[18]	E et al[14]
RQ	Research foundation	1	2	2	1	2	2	2	1	1	2	2	1	1	1
RD	Comparison group	2	2	2	2	2	2	2	2	0	2	0	2	0	0
	Follow-up Ax	2	2	2	2	2	1	2	2	2	0	1	1	2	1
	Data collection	2	2	2	2	2	2	0	2	0	2	2	1	2	0
	Randomization	2	2	2	2	2	2	1	2	0	0	0	0	0	0
	Patient blinding	1	1	1	2	0	1	0	1	1	1	1	1	1	1
	Treatment provider blinding	1	1	1	1	0	1	1	1	1	1	1	1	1	1
	Outcome evaluation	2	0	2	2	0	0	0	0	0	1	0	0	0	0
RS	Sampling bias	1	0	2	2	0	1	1	1	0	1	0	1	0	1
	Inclusion/ exclusion criteria	2	2	2	2	1	2	1	1	0	0	1	2	0	2
	Enrollment	1	2	1	0	1	0	2	1	0	0	0	0	0	0
	Retention/ follow-up	1	2	1	1	0	1	1	1	2	1	1	1	0	1
TI	Intervention	2	2	2	1	1	1	2	2	1	1	1	1	2	1
	Treatment provider bias	1	1	1	0	2	1	1	1	1	1	0	0	0	0
	Treatment comparison	2	2	1	2	2	2	2	1	0	0	0	1	0	0
O	Primary outcome	1	2	1	1	2	2	2	1	2	0	0	0	2	2
	Secondary outcome	1	2	1	0	1	1	1	1	2	0	0	1	1	0
	Follow-up period	2	2	1	1	2	1	1	1	1	0	1	0	2	1
A	Statistical analysis	2	2	1	2	2	2	1	1	1	1	1	0	0	1
	Power of Rx effects	1	0	0	0	2	1	0	0	1	0	0	0	0	0
	Size of Rx effects	1	0	1	0	1	1	2	1	2	0	1	0	0	0
	Missing data analysis	2	1	0	1	1	0	1	0	2	0	0	0	1	0
	Clinical significance	0	1	1	0	0	1	1	1	1	1	1	0	1	2
RN	Conclusion	1	1	1	2	1	0	1	1	2	1	1	1	2	1
Total quality score – maximum of 48 (%)		34 (71)	34 (71)	31 (65)	29 (60)	29 (60)	28 (58)	28 (58)	26 (54)	26 (54)	22 (46)	15 (31)	15 (31)	16 (33)	16 (33)
Level of Evidence		1b	1b	2b	2b	2b	2b	2b	2b	2b	2b	3b	3b	4	4

Abbreviations: Quality of study column: RQ = Research Question; RD = Research Design; RS = Research Subjects; TI = Therapy Intervention; O = Outcomes; A = Analysis; RN = Recommendation.

TABLE 5. Physical Therapy program, Outcome evaluation, and Study result

Study	Physical Therapy program	Outcome Evaluation	Study Result		
			Clinical importance	Statistical Significance	Modifiers
R[39]	**Control group:** Immobilization, Passive range of motion and Active assisted range of motion. Study group: **Continuous passive movement -** 8 hours a day for 3 weeks and Active assisted range of motion. Both groups: after 3 weeks, Active assisted range of motion.	Shoulder Score: Total points – 100 Pre-surgical, 3 months post surgical. *Self report* Function - 50 points Pain - 20 points *Clinical test* Muscle strength -15 points Range of motion - 15 points	Not Mentioned	p=0.0138= Range of motion sub score for Continuous passive movement group compared to control group. p= 0.0128= improvement in shoulder range of motion for men p= 0.0185= improvement of shoulder pain for women in continuous passive movement group. p= 0.0364= improvement of shoulder pain for patients with more than 60 years of age in continuous passive movement group.	Not mentioned
El[15]	**Continuous passive motion:** until seventh postoperative day. Active range of motion- After 3 weeks of surgery. Muscle strengthening gradual progression with active range of motion until 4-6 months.	Shoulder pain: self reported scale. Shoulder function: self reported status of activities of daily living and status of sport activity with pain as indicator. Shoulder active range of motion. Shoulder muscle Strength.	92.20% patients were satisfied with the result of the operative procedure and pain reduction. All patients had full shoulder abduction and elevation range of motion. All patients had normal shoulder muscle power. 55.60% patients returned to their former level of sport performance. 33.35% patients		'Return to work' time: 4 to 6 months Non-response: 11.50% of patients did not have any improvement with the pain and activities of daily living.

			returned to their sports activities with some pain & reduced level of performance.		
L[25]	**Continuous passive motion group:** treatment performed at home 4 hours a day for 4 weeks. **Manual Passive range of motion group:** three times a day for 45 minutes each session. Both groups - Immobilization, Passive range of motion 1-2 days post – operatively with pendulum. Both groups after 4 weeks - Passive range of motion, Active range of motion, Active assisted range of motion, resisted exercises.	Pain: Visual analogue scale Pain and disability: Shoulder pain and disability index Active range of motion and Passive range of motion - elevation and external rotation. Strength: Isometric dynamometer for external rotation and elevation.	Pain: Both groups experienced a decrease in pain during 1-4 post-operative weeks. Shoulder pain and disability index: 27/32 subjects scored within the excellent. 1/32 subjects reported poor result. Passive range of motion - elevation and external rotation: increased to greater than150 and 100 degrees respectively at 24 months in both groups. Active range of motion - elevation and rotation increased to more than 125 degrees. Strength: Mean isometric strength increased favorably. By 3-4 months, all patients were using upper extremity for functional uses.	p = 0.046: pain - continuous passive motion group experienced less pain during the first post -operative week. p = 0.15 - 0.20: shoulder pain and disability index - no difference between groups. p = 0.06 - 0.20: strength - no difference between groups.	'Return to work' time: During 3-4 Months, postsurgical period.

D[11]	**Conventional Physical Therapy Group:** - Shoulder immobilization. - Gentle passive motion, active assisted motion, and active motion. - Strengthening exercises. **Hydrotherapy group:** - Shoulder immobilization. - Gentle passive motion, active assisted motion, and active motion, under water. - Strengthening exercises.	Active range of motion: using a standard full circle Goniometer. Function: Western Ontario Rotator Cuff index Quality of life: Western Ontario Rotator Cuff index	Combined with other therapeutic modalities, and treatment programs, the hydrotherapy can be useful for shoulder rehabilitation.	Combined with other therapeutic modalities, and treatment programs, the hydrotherapy can be useful for shoulder rehabilitation. No significant change with Western Ontario Rotator Cuff index, comparing two groups with the following values: p= 0.438 (6 weeks) p = 0.777 (3 months) p = 0.601 (6 months) No significant change with shoulder range of motion, comparing two groups with the following values: p = 0.330 (6 weeks) p = 0.712 (3 months) p = 0.950 (6 months)	Not mentioned
R[41]	**Group 1 -** videotape home exercise program instructions **Group 2 -** one on one PT with home exercise program instructions Home exercise program includes (groups 1 and 2): Passive range of motion, Active range of motion, Resisted range of motion with elastic tubing, and free weights.	Pain and function: - Shoulder pain and disability index - University of Pennsylvania Shoulder Scale Patient compliance: 10 cm Visual analogue scale.	Shoulder pain and disability index score, Group 2: 52.3 (21.6) to 12.4 (14.4) University of Pennsylvania Shoulder Scale score, Group1: 37.9 (15.7) to 85.6 (13.8) University of Pennsylvania Shoulder Scale score, Group 2: 40.9	p = 0.685: No significant difference in pain or disability with Shoulder pain and disability index p = 0.325: No significant difference in pain, satisfaction with University of Pennsylvania Shoulder Scale p = 0.18:No significant difference in compliance	Not mentioned
D[13]	Day hospital group: 5 times of physical therapy, a week. In-patient group: 5 times of physical therapy, a week	Active and passive range of motion: Goniometer. Pain: Visual analogue scale.	There is no significant difference in pain, active range of motion and passive range of motion between Day	p= 0.012: On day 15, comparing the day - hospitalization group, the Inpatient group had significant pain reduction.	Complications noted or factors affecting: Painful stiffness,

			hospitalization and Inpatient groups		shoulder capsulitis, and complex regional pain syndrome
H[21]	Both groups received home exercise program with - cryotherapy, active range of motion, active assisted range of motion, and resisted exercise with theraband. Physiotherapy group: Manual therapy, modalities, pain below resting pain intensity. Home exercise program group: cryotherapy, active range of motion, active assisted range of motion, and resisted exercise with theraband.	Shoulder passive range of motion: visual estimation. Shoulder strength: manual muscle testing grades Shoulder function: shoulder service Questionnaire	No difference between groups for range of motion, strength or functional outcome.	Both groups demonstrated the full range of motion and muscle force by 24 weeks. Both groups improved with overall shoulder status.	Complications noted or factors affecting: 10 subjects sought additional treatment
G[18]	Home exercise program: Active range of motion, Passive range of motion, pendulum exercise. Physical therapy intervention: Manual therapy, Joint mobilization, Active range of motion, Passive range of motion, resistance with elastic tubing, free weights, isometric and eccentrics.	Pain and function: University of California Shoulder Scale Shoulder range of motion: Universal goniometer Shoulder peak torque strength: Isokinetic dynamometer	Nonexperimental study. Descriptive statistics available for interpretation	University of California Shoulder Scale score: 8,8,10. Active range of motion - elevation: 143,150,162 Passive range of motion – External rotation: 93,80,84 Strength (Newton-meters): External rotation: 12,15,27 Internal rotation: 42,41,43	'Return to work' time: 15 days postoperatively, the patients were given shoulder abduction splint and sling, sent to work. No use of the affected side allowed.

E[14]	Therapy protocol - therapeutic exercises using a wand, Theraband and manual therapy for 2 - 3 times a week.	Passive range of motion: flexion, abduction, internal rotation and external rotation at 6 weeks. Active range of motion: flexion, abduction, internal rotation, and external rotation at 12 weeks. Strength: Isokinetic internal rotation, and external rotation at 12 weeks. Function: self-report section of American Shoulder Elbow Surgeons society's shoulder rating scale at 12 weeks.	Non- experimental study. Descriptive statistic available for interpretation	Passive range of motion - similar values to uninvolved upper extremity Active ranges of motion - compared to uninvolved shoulder abduction, internal and external rotation were within 5-7 degrees. Shoulder flexion was 9 degrees greater than uninvolved upper extremity. The external rotation strength was 5-7% less than uninvolved upper limb; Internal rotation was 6-11% greater than uninvolved Upper extremity;	Not mentioned
M[34]	Exercise, manual therapy, ultrasound therapy, phonophoresis, neuromuscular electrical stimulation, iontophoresis, ice therapy, heat therapy, client education.	Function: patient report. Active range of motion: flexion, abduction, external rotation. Passive range of motion: external rotation and internal rotation. Muscle Strength: Manual muscle testing	$P < 0.001$= change of the functional score from admission to discharge $P < 0.001$ = Improvement in range of motion, over time	Greater number of patients within the full level of work status. Less number of patients with more restricted level of work status.	Not mentioned

B[2]	**Conventional Land Physical Therapy Group:** - Passive range of motion, pendulum exercises, scapular stabilizers. - Active assisted pulley exercises. - Resisted exercises, scapular retraction, wall push ups. **Aquatic & Land exercise group:** - Passive range of motion, pendulum exercises, scapular stabilizers. - Buoyancy assisted exercises, scapular stabilizers, pendulum. - Active assisted pulley exercises. - Standing breaststroke, hand behind back, kickboard. - Resisted exercises using paddles - Resisted exercises, scapular retraction, wall push ups. - Ball proprioception and resistance wall push ups.	Health related quality of life: Western Ontario Rotator cuff Index. Passive range of motion: Gravity referenced inclinometer.	P < 0.001 = change of passive range of motion and Western Ontario rotator cuff index score over a 12 week period	No significant change in the passive range of motion and Western Ontario rotator cuff index score on health related quality of life, it may potentially accelerate forward flexion of the shoulder.	Not mentioned
R[40]	The patients had Neuromuscular electrical stimulation, with following technical details: Frequency – 50 Hz. Waveform – Asymmetrical. Pulse length – 300 microseconds. Ramp time – 1 second. Intensity – to patient's maximal perceived tolerance.	Shoulder muscle power: Hand held dynamometer	P < 0.001 = Peak force production of external rotation increased.	Neuromuscular electrical stimulation significantly increased force production of shoulder external rotators. It can be used concomitantly with exercises to enhance shoulder external rotators' force production and potentially minimize inhibition of the rotator cuff after rotator cuff repair.	Not mentioned

K[24]	**Progressive group:** - Home training program including activation of RC, Passive range of motion, increased RC loading: AROM, AAROM. - Aquatic training program: AAROM, strengthening exercises - Isometric exercises, Dynamic strengthening exercises, and Eccentric load on RC muscles. **Traditional group:** **-** Home training program, with PROM. AAROM, AROM. - Aquatic training program: AAROM, strengthening exercises - Isometric exercises, Dynamic strengthening exercises, and Eccentric load on RC muscles.	Pain : VAS. ROM: Handheld Goniometer. Muscle strength: Isokinetic goniometer. Function: Constant score.	P < 0.05: The progressive group showed significantly larger reduction in pain during activity, and during rest, comparing the traditional group, during 2 years follow-up.	The progressive group showed significant pain reduction at rest and during activity; significant increase in the Constant score;	Not mentioned
L[26]	Early loading PROM- Group A: - Passive stretching, manual PROM with no limitation. - Pendular exercises, AAROM, AROM exercises, muscle strengthening exercises. Limited early PROM - Group B: - CPM with limited PROM. Pendular exercise, AAROM, AROM exercises, muscle strengthening exercises.	Pain : VAS. ROM: Handheld Goniometer. Muscle strength: Handheld Nottingham Mecmesin Myometer. Function: University of California Shoulder Scale.	No statistical significance between groups in pain level.	In both groups, VAS score was reduced at postoperative periods of 3 months, 6 months, and 1 year during rest and activity. At 3 months postoperative period, forward flexion was decreased in both groups. At 3 months postoperative period, forward flexion muscle strength improved in both groups. At 3 months postoperative period, ULCA score improved in both groups.	Not mentioned

TABLE 6. Physical Therapy intervention during joint protection phase: from the day of surgery to postoperative 6th week

Study	Physical Therapy Intervention	
R[39]	Weeks 1 - 3 Early immobilization - Intermittent Passive range of motion - Experiment group: Continuous passive motion	Weeks 4 - 6 - Active assisted range of motion
El[15]	Muscle strengthening gradual progression with active range of motion until 4-6 months.	
L[25]	Week 0 - 4 Home exercise program: 3 sessions, 10-15 repetitions, three times a day, Passive range of motion: shoulder elevation, external rotation with cane.	Weeks 4 - 6 - Passive range of motion: external rotation with cane - Passive range of motion: elevation with pulleys or assistance
D[11]	Conventional Physical Therapy Group: Until 2 weeks post surgery: Shoulder immobilization. Until 6 weeks post surgery: Gentle passive motion, active assisted motion, and active motion.	Hydrotherapy group: Until 2 weeks post surgery: Shoulder immobilization. Until 6 weeks post surgery: Gentle passive motion, active assisted motion, and active motion, under water.
R[41]	Week 4 - 6 Home exercise program - sling - supine, passive shoulder elevation with a cane - supine, passive shoulder external rotation with a cane - shoulder pendulum exercises	
D[13]	Day hospital group: 5 times of physical therapy, a week. In-patient group: 5 times of physical therapy, a week	
H[21]	Home exercise program Week 0 - 1 - Sling from Day 1 - Ice therapy 10 repetitions, three times a day: Elbow flexion and extension, Hand Grip exercises, Scapular retraction, Shoulder pendulum exercise.	Phase II (Weeks 2 - 6) Home exercise program: 10 repetitions, 1-2 times a day - shoulder active assisted range of motion: flexion, external rotation - shoulder Isometric exercises : 10 repetitions, 5 second hold, 3 - 5 times a day: Flexion, Extension, Abduction, Adduction, External Rotation.
G[18]	Week 0 - 3 Home exercise program: 20 repetitions, three times a day. – Sling, Elbow and wrist active range of motion, Shoulder pendulum movement, Supine, active assisted passive shoulder flexion.	Weeks 3 - 6 Home exercise program: Self stretches, 10 second hold, 5 repetitions, Three times a day; Table slides, Side lying, hand behind back,

	Manual therapy: Shoulder passive range of motion in scapular plane, Inferior Gleno-humeral glides.	External rotation with a cane. Week 5 - Supine, hand behind the head.
E[14]	Week 0 - 1 - Internal rotation of shoulder, Shoulder Pendulum exercises. First post- operative Physical Therapy session: Active assisted range of motion - Overhead pulley; Supine, shoulder flexion with cane; Supine, shoulder scapation with cane Week 1 and 2: Passive range of motion exercise - Flexion, scapular and coronal plane shoulder abduction; Internal and external rotation between 90 and 45 degrees abduction Submaximal isometric exercises - Internal and external rotation, flexion/ extension, and adduction. Mobilization: Gleno - humeral joint and scapula - thoracic joint Stretching: Elbow, forearm, wrist. Resisted: side-lying scapular protraction and retraction Home exercise program: Passive range of motion and Active assisted range of motion with T-bar, pulleys, using the contralateral arm in supine; Weight bearing Codman exercises over a ball or countertop; Theraputty for grip strength exercises.	Week 3 - Continue isometric exercises and range of motion exercises - Progress to Active assisted range of motion - Upper body ergo meter - Active range of motion & scapular strengthening including retraction and retraction with depression. - Continue side-lying manual scapular stabilization exercise. - Resisted exercise with gleno-humeral joint completely supported, including Elbow flexors, extensors, wrist flexor, extensors and radial and ulnar deviators. - Begin sub maximal rhythmic stabilization in supine with the shoulder at 90 – 100 degrees elevation.
M[34]	Exercise therapy, manual therapy, ultrasound, phonophoresis, electrical stimulation, ice therapy, heat therapy, client education.	
B[2]	Conventional Land Physical Therapy Group: Weeks 1 - 3 post surgery: Passive range of motion, pendulum exercises, scapular stabilizers. Week 4 - post surgery: Active assisted pulley exercises. Aquatic & Land exercise group: Weeks 1 - 3 post surgery: Passive range of motion, pendulum exercises, scapular stabilizers. Day 10 Aquatic Therapy: Buoyancy assisted exercises, scapular stabilizers, and pendulum. Week 4 - post surgery: Active assisted pulley exercises. Week 6 Aquatic Therapy: Standing breaststroke, hand behind back, kickboard.	
R[40]	The patients had Neuromuscular electrical stimulation, with following technical details: Frequency – 50 Hz, Waveform – Asymmetrical, Pulse length – 300 microseconds, Ramp time – 1 second, Intensity – to patient's maximal perceived tolerance.	

K[24]	Progressive group: Postoperative 1st day: - Home training program including activation of RC, PROM. Postoperative 4 weeks: - Increased RC loading: PROM, AROM, AAROM; Aquatic training program: AAROM. Postoperative 6 weeks: - PROM, AROM, and Isometric exercises,	Traditional group: Postoperative 1st day: - Home training program including Passive range of motion. Postoperative 6 weeks: - Activation of internal and external rotators, AAROM.
L[26]	Aggressive early PROM (Group A): - Passive stretching, manual PROM with no limitation. - Pendular exercises, AAROM.	Limited early PROM (Group B): - CPM with 90° PROM restriction. - AAROM.

TABLE 7. Physical Therapy intervention during shoulder rehabilitative phase: from postoperative 6th week to 12th week

Study	Physical Therapy Intervention	
R[39]	Week 6 onwards: Active assisted range of motion	
E[15]	Muscle strengthening gradual progression with active range of motion until 4-6 months	
L[25]	Week 6 onwards: Active rotation of shoulder Week 8: Active assisted range of motion: elevation	Week 10 – 12: Active range of motion: elevation & Resisted rotation
D[11]	Conventional Physical Therapy group: After 6 weeks post surgery: strengthening exercises	Hydrotherapy group: After 6 weeks post surgery: strengthening exercises
R[41]	Week 6 – 12: Active range of motion: elevation and external rotation against gravity.	
D[13]	Day hospital group: 5 times of physical therapy/ week.	In-patient group: 5 times of physical therapy/ week
H[21]	Home exercise program - week 6 onwards: 5 repetitions, 10 seconds hold, once a day - Flexion, Horizontal abduction, External Rotation. 10 repetitions, Active assisted range of motion, 1-2 times a day - Flexion, Extension, External Rotation. 3 sets, 10 repetitions with theraband, 2 times a day - Retraction, Flexion, Abduction, Adduction, External rotation, and Internal rotation. Physical Therapy: Individualized treatment consisting of 16 treatments over 17 weeks including exercises, manual therapy, physical modalities of ice and moist heat, and advice related with advice regarding home exercise program.	
G[18]	Week 6 - 8: - Active assisted range of motion elevation w/overhead pulley:10 repetitions, 5 seconds hold - Proprioceptive Neuromuscular Facilitation: diagonal two with tactile and verbal cues Week 8 – 9: Home exercise program - Isometric strengthening: eccentric strengthening from elevation - Rhythmic stabilization	Week 9: - Self exercise: Active range of motion elevation - abduction and diagonal elevation. - Self exercise: Resisted internal and external rotation with elastic band Week 8 - 9 Physical therapy: Resisted Proprioceptive Neuromuscular Facilitation into flexion, extension, and horizontal abduction. Week 10 - Self exercise: Overhead press - Self exercise: Prone - extension of shoulder

E[14]	Week 6 onwards: - Isotonic resistance, with weight of arm progressing to sub maximal resistance applied with short lever arm or Theraband, 30 repetitions: Side lying: external rotation; Prone lying: extension; Prone lying: horizontal abduction; Supine lying: internal rotation; Flexion to 90 degrees - Full passive range of motion and active range of motion in all planes including - Internal and external rotation in neutral adduction progressing from 90 degrees abducted position - Resisted - external rotation with a towel roll under Axilla and oscillation device - Home exercise program with weights or Theraband: Strengthening of rotator cuff muscles; Strengthening of scapular muscles.	Week 8 - Weight bearing step ups - Quadruped rhythmic stabilization exercises - Plyometric chest pass - Two hand rotation tennis groundstroke or golf swing with small exercise ball (progress to medicine ball). Week 10 - Sub maximal isokinetic internal and external rotation in modified neutral, Progression to 90 degrees abducted rotational training, Prone external rotation, Standing internal and external rotation with 90 abduction in the scapular plane.
M[34]	Exercise therapy, manual therapy, ultrasound, phonophoresis, electrical stimulation, ice therapy, heat therapy, client education.	
B[2]	Conventional Land Physical Therapy Group: Week 10 – post surgery: Resisted exercises, scapular retraction, wall push ups.	Aquatic & Land exercise group: Week 10 – post surgery: Resisted exercises, scapular retraction, wall push ups. Week 10 – aquatic Therapy: Ball proprioception and resistance wall push ups.
R[40]	The patients had Neuromuscular electrical stimulation, with following technical details: Frequency – 50 Hz, Waveform – Asymmetrical, Pulse length – 300 microseconds, Ramp time – 1 second, Intensity – to patient's maximal perceived tolerance.	
K[24]	Postoperative 8 weeks (Progressive group): - Dynamic strengthening exercises, and Theraband exercises. Postoperative 10 weeks: Aquatic training program: AROM, water resisted exercise. Postoperative 12 weeks: Eccentric load exercises for RC muscles.	Postoperative 10 weeks (Traditional group): Aquatic training program: AAROM
L[26]	Postoperative 7 weeks: Aggressive early PROM - AROM exercises, muscle strengthening exercises.	Postoperative 7 weeks: Limited early PROM: - AROM exercises, muscle strengthening exercises.

Table 8. Physical Therapy intervention during functional maximization phase: postoperative 12th week onwards

Study	Physical Therapy Intervention	
R[39]	After 12 weeks post-surgery, no intervention has been included in this study.	
E[15]	Muscle strengthening gradual progression with active range of motion until 4-6 months	
L[25]	Week 12 – 14: Resisted elevation	Week 12-16 through 1 year: Functional use, Progressive strengthening
D[11]	Conventional Physical Therapy Group: strengthening exercises.	Hydrotherapy group: strengthening exercises.
R[41]	Week 12 – 24: All shoulder muscles: resisted exercises with elastic tubing	Week 24: Free weight exercises for shoulder muscles, Weight bearing: chair push ups and wall push ups
D[13]	Day hospital group: 5 times of physical therapy/week	In-patient group: 5 times of physical therapy, a week.
H[21]	After 12 weeks postsurgery, no intervention has been included in this study.	
G[18]	Restrictions removed. Physical therapy discontinued after 12 weeks	
E[14]	Week 12 onwards: Maximal Isokinetic internal rotation and external rotation, Begin interval return programs when internal and external rotation strength is no less than 85% of the uninvolved extremity; Ratio of external rotation to internal rotation is 60% or greater; Range of motion is pain- free; negative impingement and instability sings during exam. Week 16: Isokinetic reassessment; Return to full upper extremity sport activity; Discharge to home exercise program.	
M[34]	Exercise therapy, manual therapy, ultrasound, phonophoresis, electrical stimulation, ice therapy, heat therapy, client education.	
B [2]	Conventional land therapy group: Week 12 – post surgery: Resisted exercises, scapular retraction, wall push ups.	Aquatic & Land exercise group: Week 12 – post surgery: Resisted exercises, scapular retraction, wall push ups. Week 12 – aquatic Therapy: Ball proprioception and resistance wall push ups.
R[40]	The patients had Neuromuscular electrical stimulation, with following technical details: Frequency – 50 Hz, Waveform – Asymmetrical, Pulse length – 300 microseconds, Ramp time – 1 second, Intensity – to patient's maximal perceived tolerance.	
K[24]	Postoperative 16 weeks (Traditional group): - Dynamic strengthening exercises, Theraband exercises, and Eccentric load exercise of RC muscles. - Aquatic training program: AROM, Water resisted exercises.	
L[26]	After 12 weeks postsurgery, no intervention has been included in this study.	

3. 1. ABSTRACT

Study design: Retrospective cohort study**.**

Background: Shoulder active range of motion (AROM) assessment is a core measure to assess the outcomes of rotator cuff (RC) repair and rehabilitation. Supine positioning has been recommended for motion assessment; however, in some cases sitting is necessary. The clinical measurement properties, including validity and responsiveness, of different test positions for motion assessment are not adequately described.

Objective: To describe the validity and the responsiveness of two positions (sitting with neutral shoulder, and supine with 90° shoulder abduction) for goniometric measurement of active shoulder external rotation in patients recovering from rotator cuff repair.

Method: A series of 144 patients with rotator cuff tears were recruited. Active shoulder external rotation measurements were completed sitting with neutral shoulder rotation, and supine with 90° shoulder abduction preoperatively, three, and twelve months postoperatively. A universal goniometer was used for all measurements. The correlation between the two positions was evaluated using the Pearson correlation coefficient (r). The average discrepancy between the two positions was evaluated using the limits of agreement approach of the Bland-Altman method. Responsiveness of the two positions was evaluated using Standardized Response Mean (SRM) and Effect Size (ES).

Setting: Single center study, at a tertiary-care hospital.

Results: A total of one-hundred-and-two patients with a mean age of fifty-six years could complete active shoulder external rotation measurement in both positions. Forty-two patients were unable to complete motion measurements in the supine shoulder-abducted position. ROM measurements differed between these positions and correlated moderately (r= 0.40 - 0.53). The average mean differences between the two positions as indicated by the Bland-Altman plots

were remarkably low at all three time points (0.8°, -1.5°, -4.1°, respectively); however, the limits of the agreement were wide. The sitting position showed greater sensitivity to change with relatively larger estimates of SRM and ES (SRM: 0.66, 1.05 and ES: 0.50, 1.02) as compared to the supine position (SRM: 0.39, 0.74 and ES: 0.37, 0.76) at 3 and 12 months postoperatively, respectively.

Conclusion: A substantial portion (29%) of the patients could not undergo active shoulder external rotation motion testing in the supine with 90° shoulder abducted position. The sitting position allowed active shoulder external rotation motion testing in all patients. The two testing positions provided different active shoulder external rotation values that are only moderately correlated, with the sitting position having higher responsiveness to assess the changes in motion than the supine position.

Key words: glenohumeral joint, active range of motion, goniometry, external rotation, shoulder rehabilitation, rotator cuff tear, physical therapy, rotator cuff repair.

3. 2. INTRODUCTION

Goniometric measurements are extensively used in rehabilitation to provide objective measures of joint range of motion. [13,29] Shoulder range of motion (ROM) is a core measure that is used to evaluate the outcomes of rotator cuff repair and rehabilitation. A variety of different positions has been suggested for measuring shoulder ROM, including: sitting with neutral shoulder rotation,[9,15,32] standing with 90° shoulder abduction,[15] supine with 20° shoulder abduction,[25] supine with 90° shoulder abduction,[9,29,36,37] and prone with 90° shoulder abduction. [31,42] The American Association of Orthopedic Surgeons (AAOS)[1] recommends two positions for measuring shoulder external rotation, shoulder adduction and 90° shoulder abduction. Norkin et al[29] recommend the same positions for patients with various shoulder pathologies. Currently there are no fixed guidelines or recommendations for choosing a measuring position for shoulder active external rotation in patients following rotator cuff repair.

Rater effects of different goniometric measurement procedures suggest high intra-tester reliability, and low to high inter-tester reliability of ROM measurements. Pandya et al[33] measured passive shoulder motion in patients with Duchenne muscular dystrophy, using a universal goniometer. The authors reported a high intra-tester reliability (ICC= 0.84), and moderate inter-tester reliability (ICC= 0.67) for shoulder abduction. Greene et al[15] measured upper extremity movements using the Ortho Ranger and a standard goniometer. For measuring shoulder flexion and abduction, using the standard goniometer, they found high intra-tester reliability (ICC= 0.96). Riddle et al[37] measured shoulder PROM using two different-sized universal goniometers (long arm and short arm) by having sixteen physical therapists measuring shoulder flexion, abduction, and external rotation. The authors found high intra-tester reliability (ICCs= 0.94-0.99), and high inter-tester reliability (ICCs= 0.84-0.90) for both goniometers. For shoulder extension, horizontal abduction, and internal rotation, they found high

intra-rater reliability (ICCs= 0.87-0.94), and low inter-tester reliability (ICCs= 0.26-0.55).

The effects of position on shoulder goniometry have been addressed within some studies, and are also informed by measurement properties reported across studies that used different test positions. MacDermid et al[25] measured passive shoulder rotation in patients with different shoulder pathologies, using a universal goniometer, with the shoulder at 20° to 30° abduction; and found high intra-tester reliability (ICCs= 0.88-0.93), and high inter-tester reliability (ICC= 0.80-0.85). Sabari et al[39] evaluated the reliability of shoulder flexion and abduction ROM in supine and sitting positions; regardless of measuring position, the authors found moderate to high intra-rater reliability (ICCs= 0.64-0.79). A similar finding was reported by Hayes et al[16] who reported moderate intra-rater (ICCs= 0.53-0.65), and moderate inter-rater (ICCs= 0.64-0.69) reliability for shoulder measurements in standing and supine using goniometry. One of the concerns that might affect the reliability in different positions is how stable the position is; and whether motion substitutions can be avoided. Boon et al[6] measured passive shoulder rotation on high school athletes to find the reliability, with or without manual scapular stabilization; and found that the intra-rater reliability was low for a nonstabilized movement (ICC= 0.23), and moderate for a stabilized movement (ICC= 0.53). Inter- rater reliability also improved from a nonstabilized (ICC= 0.13) to a stabilized (ICC= 0.38) shoulder. This study did not find high reliability for any of the measures, but the low variability in a young healthy sample which might have contributed to the lower ICCs since the ICC is a ratio and affected by sample variability.[44]

In our study, we used a neutral zero method for the sitting position. Assessment of shoulder active external rotation using this position allows greater consistency in the measurement technique. The neutral zero method was first introduced by Silver,[40] reinforced by Cave et al,[7] and supported by the American Academy of Orthopedic Surgeons[1] with the emphasis on measurement

standardization. The authors of the current study believe that a valid ROM measurement could be achieved due to standardized sitting position. Furthermore, the sitting position evaluates patient's functional mobility;[5] which allows the testers to observe and correct ipsilateral abnormal movements; and if needed, the measurements can be compared with contralateral shoulder movements.

Goniometers are the primary range of motion measuring tools used in physical therapy. The majority of studies that addressed the effects of testing positions on goniometric measurement have focused only on rater reliability; and only a few have addressed the validity and the responsiveness. It is difficult to compare the results of treatment across studies that use different test methods if the impact of test position is not known. Therefore, the purposes of this study were to describe the effects of sitting with neutral shoulder and supine with 90° shoulder abduction.

3. 3. METHODS

3. 3. 1. Research Approval and Participants

This research study was approved by the ethics committee of Western University, London, ON, Canada. All subjects signed an informed consent form. A total of 144 patients who had undergone rotator cuff repair at St. Joseph's Health Care, London, ON, Canada were recruited. We considered a sample size of greater than hundred to be large enough to provide valid results and to highlight the differences between the two positions. We did not do a formal sample size calculation but used studies with similar methodology as a guiding factor in deciding the sample size. The mean age of the sample was 56 years (range 27 – 76) (See Table 1). Rotator cuff repair was performed using one of the following three surgical techniques: open, mini-open, or arthroscopic repair.

3. 3. 2. Inclusion and Exclusion Criteria: Inclusion criteria included, subjects who were able to be tested in supine and sitting positions, ability to follow testing instructions, age between 18 and 80 years, and had undergone a shoulder rotator cuff repair.

Exclusion criteria included an acute shoulder injury, previous history of the proximal humerus fracture and/or glenoid fracture, shoulder joint infection, any neurological condition affecting shoulder function, inability to speak and read English, psychiatric illness or any co-morbid health condition that precluded participation.

3. 3. 3. Procedure

A universal goniometer was used for measuring active external rotation. The goniometer was a standard 10", circle, double-armed goniometer, constructed of clear plastic. The scale of the goniometer was marked in 1° increments. The measurements were performed by one of the three independent research assistants following a standard study procedure manual for the test positions. The assessors measured active shoulder external rotation preoperatively; and again at 3 and 12 months postoperatively.

For both the sitting and supine positions, the elbow was positioned in 90° of flexion, the forearm, the wrist and the finger joints were positioned in neutral position. The stable arm of the goniometer was aligned parallel to the ground; the mobile arm of the goniometer was aligned parallel to the ulna. The goniometer was placed after maximal shoulder active external rotation was achieved, and the testers read and recorded data to the nearest 1°.

For sitting measurements, the subjects were seated on a standard chair with a back rest supporting both scapula, without arm rests. The starting position was the shoulder in neutral and the arm by the side. For supine measurements, the subjects were lying on a standard examination table. The starting position was the shoulder in 90°abduction and neutral rotation.

3. 3. 4. Statistical Analysis

Descriptive statistics (means/standard deviations) and Pearson correlation coefficients (r) were calculated using SPSS software, version 19.0 (SPSS Inc, Chicago, Ill, USA). Pearson's correlation coefficients were interpreted as follows: 0.00 to 0.19 indicating extremely weak correlation; 0.20 to 0.39 indicating weak correlation; 0.40 to 0.69 indicating moderate correlation; 0.70 to 0.89 indicating a strong correlation; and 0.90 to 1 indicating exceptionally strong correlation.[11] The level of significance was fixed at $p < 0.05$.

Bland-Altman analysis was performed using MedCalc software, version 12.3.0 (MedCalc Software, Broekstraat 52, 9030 Mariakerke, Belgium). Bland-Altman graphs were plotted to describe the mean difference and limits of agreement (LOAs) between the supine and the sitting measurements.[4,41]

Responsiveness was evaluated by calculating the Standardized Response Means (SRM) and the Effect sizes (ES).[19,20] Effect sizes were interpreted as follows: < 0.2 indicating small, 0.2 to 0.8 indicating medium, and > 0.8 indicating large.[10] SRM was calculated by dividing the mean change score (from baseline to postoperative 3 months and 12 months) with SD of change score. ES was calculated by dividing the mean change score (from baseline to postoperative 3 months and 12 months) with SD of baseline score. Confidence intervals (95%) around the point estimates for SRM and ES were calculated for both supine and sitting positions assuming that the data was distributed normally. The following formula was used: 95% CI= 1.96x1/sqrt(n); Where: CI= Confidence interval, n= sample size. For the two measurement positions to be different, it is expected that their confidence intervals would not overlap.

3. 4. RESULTS

3. 4. 1. Descriptive Statistics

Supine and sitting positions provided different goniometric measurements of shoulder active external rotation during all three measurement time points. In the supine position, the SDs were 28°, 29° and 29° at baseline, postoperatively 3, and 12 months respectively. In the sitting position, the SDs were 16°, 15° and 15° at baseline, postoperative 3, and 12 months respectively. (See Table 2)

3. 4. 2. Correlation

Supine and sitting positions showed moderate correlations ($r = 0.40 - 0.53$) between each other, during all three measurement time points. All these correlations were statistically significant ($p < 0.01$). (See Table 3)

3. 4. 3. Agreement

The Bland-Altman analysis revealed extremely minimal mean differences between the supine and the sitting position. The mean difference was low during all three measurement time points (from -4.1° to 0.8°); however, the limits of agreement (LOAs) were wide. At baseline, the LOA ranged between -50.8° and 52.5°; at postoperative 3 months, the LOA ranged between -49.3° and 46.3°; and at postoperative 12 months the LOA ranged between -55.8° and 47.6° (See Graphs 1, 2, & 3). These facts show that the mean difference between the two positions were low, with minimal outliers; however, with wider LOAs.

3. 4. 4. Responsiveness

Standardized Response Mean: Both measurement positions showed moderate responsiveness at postoperative 3 months with the SRM being 0.39 and 0.66 for the supine and the sitting position, respectively. For postoperative 12 months, the responsiveness for the supine still remained moderate with the SRM of 0.74, but the responsiveness for the sitting turned out to be large with the SRM of 1.05. These values suggest that the sitting position had larger estimates of SRMs when compared to the supine; which might indicate that the sitting position is

more responsive in capturing true clinical change in measuring shoulder active external rotation.

Effect Size: Both the measuring positions showed moderate responsiveness at postoperative 3 months with the ES being 0.37 and 0.50 for the supine and the sitting, respectively. For postoperative 12 months, responsiveness still remained moderate for the supine with the ES being 0.76; while it turned out to be large for the sitting, with the ES is 1.02.

At postoperative 3 & 12 months, the confidence intervals of SRM were narrower for the sitting (0.47 to 0.85), (0.86 to 1.24), respectively, than the supine (0.20 to 0.58), (0.55 to 0.93), respectively. For postoperative 3 & 12 months, the confidence intervals of ES were narrower for the sitting (0.31 to 0.69), 0.83 to 1.21) respectively, than the supine (0.18 to 0.58), (0.57 to 0.95) respectively. These narrow confidence intervals show that shoulder active external rotation measured both in the sitting and the supine seemed to be precise; however, the smaller overlap between the confidence intervals of sitting and the supine shows that both positions can be different in measuring the shoulder AROM (See Table 4).

3. 5. DISCUSSION

This study analyzed the position effects of supine and sitting positions on shoulder active external rotation goniometric measurements. The study found that the supine and the sitting positions provided different estimates of joint motion that were moderately correlated. When translated to individual patients, the limits of agreement between the two measures suggest that up to a 50° difference might be expected between the test positions. This finding indicates that one position cannot replace the other for measuring shoulder active external rotation. Additionally, measures in the sitting position tended to have higher responsiveness.

This study did not determine the test-retest reliability of the two measures; so we cannot be sure which measure had more error. However, the standard deviation of the supine measurement was twice as much as the standard deviation of the sitting position. The correlations are expected to be closer to 1 when two measures are similar. However in this study, both the positions exhibited only moderate correlations. The above mentioned measurement variation can be due to normal fluctuation in ROM as suggested by Boone et al.[7]

Measuring active shoulder external rotation at the sitting position may have advantages. Firstly, 29% of the recruited patients could not be tested in the supine position because they could not tolerate or achieve 90° of shoulder abduction; whilst all could be tested in sitting. Therefore, relying entirely on supine active shoulder external rotation testing would exclude 1/3rd of patients. Some reasons for patient's inability to be tested in abduction were other orthopedic disabilities (such as back and neck pain), postoperative pain, stiffness, weakness, apprehension, and obesity. Since an important reason for measuring joint motion is to determine the effects of an intervention, a testing position that cannot be achieved by a large number of patients is problematic. Additionally, our results confirm that comparing scores in sitting to those in supine would be inappropriate as they measure different external rotation states. Hence, the sitting position could be used routinely; whereas the role for the abducted position is more limited.

The surgical approach with the open and mini-open rotator cuff repair will result in the incision through the deltoid muscle, leading to inflammation and a healing response. Moreover, increased electromyographic activity of the middle and the posterior deltoid muscles have been reported during the ER movement with shoulder 90° abduction comparing to the ER movement with neutral shoulder.[28] During the joint protection phase following rotator cuff surgery, protection of the deltoid muscle is warranted. The supine position with 90° shoulder abduction may aggravate inflammation in the deltoid muscle, leading to

pain; due to the above mentioned muscular factors. The sitting position with neutral shoulder would limit this effect. This factor makes a strong argument favoring the sitting position for measuring shoulder active external rotation in patients recovering from mini-open or open rotator cuff repair.

There are biomechanical factors, which can increase the forces acting on the glenohumeral joint structures. Firstly, with the shoulder at 90° abduction, a greater amount of gravitational force acts on the GHJ, as compared to the neutral shoulder position. A combination of 90° shoulder abduction and ER places increased stress on the shoulder capsule, particularly on the anterior and posterior gleno-humeral ligaments. [27,30] The second biomechanical factor is the resultant force on the GHJ, which can vary with arm position.[3,21] The joint compressive force increases to a maximum at 90° shoulder abduction; and the resultant force also peaks at 90° shoulder abduction.[34] Considering the weight of the arm as a passive lever, the resultant force at 90° abduction is one times body weight.[12] During the joint protection phase following rotator cuff surgery, protection of the GHJ structures is warranted. The supine position with 90° shoulder abduction may place undue stresses and loads on the repair with resultant pain and inflammation, due to the above mentioned biomechanical factors. The sitting position with neutral shoulder would limit these potential complications. These factors make an argument favoring the sitting position for measuring shoulder active external rotation, for patients following rotator cuff repair.

The results of this study show that the sitting with neutral shoulder had a slightly (9%) lower measured ROM than the supine with 90° shoulder abduction. This difference could be due to the bony anatomy of the shoulder, the static soft tissue stabilizers, and kinematics. With neutral shoulder position, the humeral head and the greater tuberosity rotate beneath the acromion process and the movement of the head of the humerus is limited. However, when the shoulder is abducted to 90°, the greater and lesser tuberosities can clear the coroco-acromial

arch, leading to increased external rotation movement. Also, different gleno-humeral soft tissues are taut and relaxed during adduction versus abduction, allowing different active shoulder external rotation ROM. During abduction of the arm, the middle and inferior glenohumeral ligaments become taut while the superior glenohumeral ligament relaxes; during adduction the opposite action occurs. During abduction of the arm, the coracohumeral ligament relaxes; while during adduction, the ligament gets taut. These factors would help clinicians and researchers understand that the supine and the sitting position can stress different tissues influencing goniometric measurements of shoulder active external rotation.

For patients with rotator cuff repair, measuring shoulder active external rotation in the supine with 90° shoulder abduction can lead to abnormal scapulo-thoracic movements which should be avoided during the joint protection phase. Various biomechanical investigations[21,22,23,26] have shown that the active external rotation with 90° shoulder abduction produces posterior tilt and upward rotation at the scapulo-thoracic joint. These abnormal scapulo-thoracic movements can lead to a superior translation of the humerus; reducing sub-acromial space; potentially leading to shoulder impingement and stress on the repair site. These findings support the results of the current study and strengthen the argument that the sitting position can be used for measuring shoulder active external rotation. In the Bland-Altman plots, we observed a linear pattern formed by different measurements. We checked of data entry to find the correct entry. So, we are suspecting some random measurement error for this observation.

3. 5. 1. Strengths

- One of the strengths of the current study is its sample size, which enabled us to capture enough variability in terms of patient characteristics, and it provided results that were more precise with narrower confidence intervals making the results more credible.
- Secondly, this study used three independent assessors.

- Finally, the participants in this study were adults referred from a tertiary-care hospital, with an age range of 27-76 years; this age group represents the usual rotator cuff patient population in most clinical settings, allowing for the greater generalizability of the results of this study.

3. 5. 2. Limitations

- This study included only patients with rotator cuff tears; when interpreting the validity and the responsiveness values of our study, one must recognize that the consistency of AROM in individuals with rotator cuff repair may not correlate with those who have any other shoulder pathology. When studying a different (other than rotator cuff repair) symptomatic population, the ability of an individual to achieve and maintain their arm in a specific plane may not be possible secondary to restrictions in joint mobility, muscle power, and/or pain.
- Moreover, this current study required the participants to hold their shoulders at end-range active external rotation position while conducting the goniometric measurements. Holding this position may not be possible in patients with different shoulder pathologies.
- When comparing two different measurement positions for using an instrument such as goniometer, it is crucial to consider the limitations related to the usage of goniometric instrument. Universal goniometry requires visualization of the vertical reference point, which may compromise measurement reproducibility. Another limitation can be the potential effect of body types (ectomorphs versus endomorphs versus mesomorphs) on goniometer measurements. Ectomorphic body types tend to have a linear frame with sparse muscular development; whereas, mesomorphs and endomorphs have a greater amount of tissue surrounding their body frame. Goniometric measurements may vary due to the differences in tissue mass. The participants were a mix of all three types, so the current results may not be generalized to any one subgroup

with a particular body type. Future studies should account for the effects of different body types.

3. 6. CONCLUSIONS

This study evaluated the validity and the responsiveness of the sitting position versus the supine position for measuring active external rotation in patients recovering from rotator cuff repair. The results demonstrated that the two positions provided substantially different active external rotation values that were moderately correlated. This study also demonstrated that the sitting position provided precise, and more responsive measurements than the supine. This study does set the groundwork for further research to evaluate the role of different goniometric testing positions and their responsiveness for measuring active shoulder range of motion in patients recovering from rotator cuff repair.

3. 7. ACKNOWLEDGEMENT

The authors thank the research assistants who served and are serving at HULC, St. Joseph's Health Care, London, ON, Canada, who tested research participants for this study.

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Table 1: Participant Demographics

Demographics	**n=102**
Gender (n) Male	87
Gender (n) Female	15
Age range (years)	27 – 76
Mean age (years)	56

Table 2: Mean (M), and Standard deviation (SD) of shoulder active external rotation; for supine and sitting; at preoperative, postoperative 3 months, postoperative 12 months, and change of measurement.

Measurement time & Change	Supine	Sitting
	Mean (SD)	Mean (SD)
Baseline	35° (28°)	36° (16°)
Post operative Three months	45° (29°)	44° (15°)
Post operative Twelve months	57° (29°)	52° (15°)
Change (post operative 3rd month measurement - baseline)	10° (27°)	08° (12°)
Change (post operative 12th month measurement - baseline)	22° (36°)	16° (16°)

Table 3: Pearson correlation coefficient (r) between the supine and the sitting at preoperative, postoperative 3 months, and postoperative 12 months.

Measurement time & Position	Baseline - supine	Postoperative 3rd month - supine	Postoperative 12th month - supine
Baseline - sit	0.40*		
Postoperative 3rd month - sit		0.53*	
Postoperative 12th month - sit			0.40*

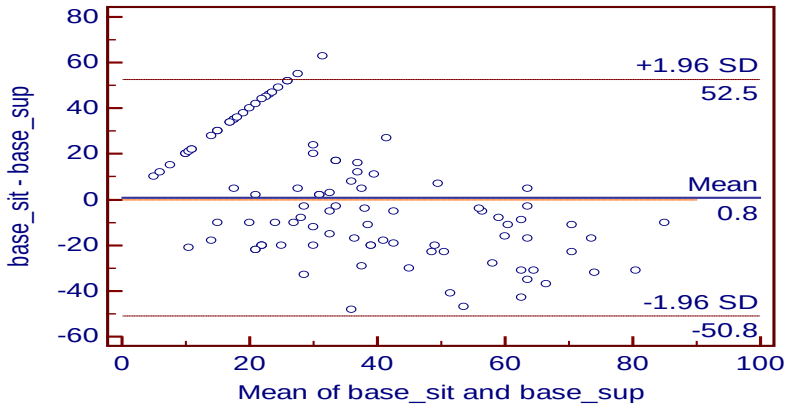
* Correlation is significant at $p < 0.01$ level

Table 4: SRM & ES of the supine and the sitting positions of shoulder active external rotation measurement, at postoperative 3 months, & at postoperative 12 months.

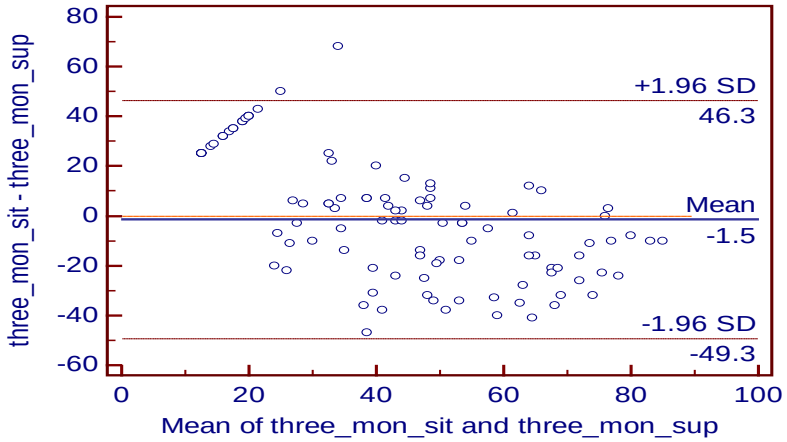
Measurement position	Postoperative 3rd month		Postoperative 12th month	
	SRM (95 % CI)	ES (95 % CI)	SRM (95 % CI)	ES (95 % CI)
Supine	0.39 (0.20 to 0.58)	0.37 (0.18 to 0.58)	0.74 (0.55 to 0.93)	0.76 (0.57 to 0.95)
Sitting	0.66 (0.47 to 0.85)	0.50 (0.31 to 0.69)	1.05 (0.86 to 1.24)	1.02 (0.83 to 1.21)

Graph - 1, 2, and 3: Bland-Altman plots. Comparison of difference between the supine & the sitting (vertical axis) versus the average of the supine & the sitting positions (horizontal axis) - during preoperative, postoperative 3 months, postoperative 12 months, for measuring shoulder active external rotation. The mean difference between the two positions is shown as a solid line in the center; systematic bias is shown as a small dotted line in the center; 95% limits of agreement are given by the ± 1.96 SD.

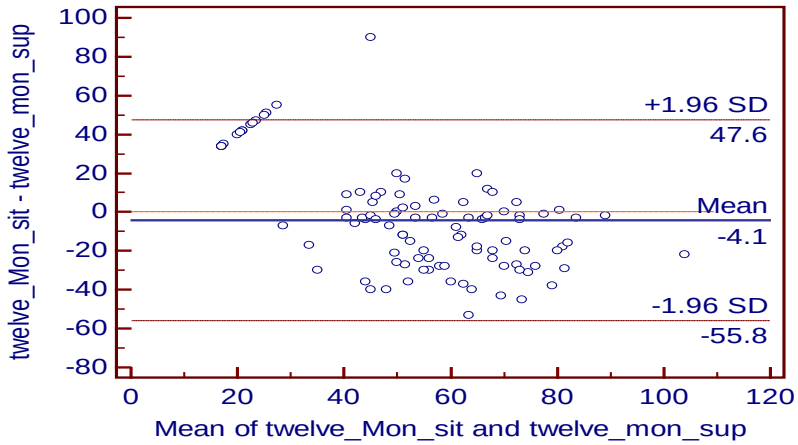
Graph - 1:



Graph - 2:



Graph - 3:



4. 1. ABSTRACT

Study Design: Prospective randomized pilot study.

Background: Rotator cuff (RC) tears are one of the most common causes of pain and disability in the upper extremity. Advances in arthroscopic shoulder surgery and rehabilitation have placed increased emphasis on different land-based exercise programs, including adjunctive aquatic exercise programs. Therefore, evaluating the effectiveness of different land-based exercise programs and aquatic exercise programs by conducting a prospective randomized trial is essential.

Purposes: To determine the feasibility of conducting a high quality, prospective, randomized trial and to provide enrollment estimates; to describe the effectiveness of aquatic exercises as an adjunct to land-based exercises for patients who are recovering from rotator cuff repair.

Methods: Twelve participants (seven men and five women, with a mean age of 51 years) were included; they were randomly allocated either to a land-based plus aquatic exercise program or to land-based exercise program only. Shoulder active range of motion (AROM) was the primary outcome as measured using a universal goniometer; while health related quality of life (HRQOL) was the secondary outcome as measured using the Western Ontario Rotator Cuff (WORC) Index. Data was collected at baseline (preoperative) and postoperative 12 weeks. Repeated measures ANOVA were used to compare the groups.

Setting: Single center study at a tertiary-care hospital.

Results: A total of 18 patients were contacted with study details, only 12 patients accepted to be part of this study, with a 67% recruitment rate.

Adherence with scheduled clinic visits was excellent (95%). No one was lost to follow-up. Both land-based and land plus aquatic exercise groups showed improved shoulder forward flexion AROM scores over time (Mean change= 21°, SD= 25° and Mean change= 22°, SD= 33° respectively). Using the outcome measurement data, we calculated sample size for future studies: For having 80% power (α= 0.05, β= 0.20), and to detect a 20% between-group difference, a total of 33 research participants per group would be needed.

Conclusions: Both land-based and aquatic exercise programs are shown to be feasible, and both programs seem to have clinical value in improving active shoulder range of motion and health related quality of life in patients recovering from rotator cuff repair. To achieve enough power, we recommend future randomized studies with larger sample size and longer follow-up period.

Key Words: Land-based exercises, aquatic exercises, pilot study, rotator cuff tear, physical therapy.

4. 2. INTRODUCTION

Rotator cuff (RC) tears are one of the most common causes of pain and disability in the upper extremity. [8,15] They are one of the most common debilitating shoulder injuries encountered in outpatient settings, particularly among older populations.[11] RC tears can lead to substantial disability, affecting activities of daily living, work, and sports, thereby influencing the quality of life.[35]

Most patients with RC pathology will see a Physical Therapist for nonsurgical management. However, a substantial number of patients proceed to surgery. Surgical repair of the RC tear aims to restore the tendon integrity, reduce pain, and ultimately improve function.[41] After surgical repair, postoperative physical therapy is an integral component of recovery. Factors that may influence the nature of these treatments and rehabilitation include the magnitude and location of the RC tear, preferences/ training/ experience of physical therapist and surgeon, clinical symptoms and comorbidities of patients, and surgical techniques used for the repair. Considering the high volume of surgical repair of the rotator cuff, there have been minimal efforts to define an optimal postoperative rehabilitation program.[52]

Van der Meijden et al[52] did a narrative review of rehabilitation practices following arthroscopic rotator cuff repair and attempted to outline evidence-based guidelines. The authors found little high-level scientific evidence to support or oppose current postoperative rehabilitation protocols. The authors of the current study conducted a systematic review to describe the effect of physical therapy for patients following shoulder rotator cuff repair, and found overall-weak evidence. Thus, there is insufficient evidence on the dosage and the effects of land-based exercise and the potential adjunctive role of aquatic exercise in the rehabilitation of patients with rotator cuff repair. Hence, therapists currently can not make evidence-based informed choices, making them rely heavily on expert opinion, which is the lowest form of evidence.[52]

We know that the optimal study design for establishing precise estimates of postoperative therapy effects for patients following rotator cuff repair, is a

prospective randomized design. Potential use of large resources to conduct such a study and due to the inherent difficulty, it would make sense for it to be conducted using a larger trial. An important prerequisite in conducting such a trial is establishing the feasibility by conducting a pilot study.

The specific objectives of this pilot study were:

- To pilot test the study procedures that can be used for a future randomized study: by evaluating recruitment strategies and rates, and by finding potential barriers for clinicians, researchers, and patients who are participating in the study.
- To determine the variability of study outcome measures and use them to determine sample size for a future randomized study.
- To provide a preliminary clinical estimate of the effects of aquatic exercises as an adjunct to land-based exercises; also to use these estimates to inform one's understanding about the importance of proceeding with a future randomized study.

4. 3. METHODS

4. 3. 1. Design

This study was approved by clinical research ethics committee of Lawson Health Research Institute, London, ON, Canada; and by the Research Ethics Board for Human Subjects of Western University, London, ON, Canada.

A prospective randomized study design was employed to compare the effect of land-based and aquatic exercises versus land-based exercises only. These groups were chosen as they represent the commonly recommended rehabilitation programs for patients recovering from rotator cuff repair.[3,52]

A computer software program generated randomized blocked assignments, and assignments were placed in numbered opaque envelopes. The physical therapist opened the numbered envelopes to inform the patients about their treatment group (Figure 1).

Informed written consent was obtained from all the participants. Eligible volunteer participants were allocated to one of two postoperative physical therapy programs: land-based plus aquatic exercise program or land-based exercise only program. The land-based exercise group were further randomized to high and low intensity exercise programs. At the end of 12 weeks, six patients were randomized to the land-based plus aquatic exercise group, and six patients were recruited to the land-based exercise only group.

All the outcome measurements were obtained by an independent assessor who was blinded to all group allocations. An intention-to-treat analysis principle was used.

The treating therapist and the patients were not blinded due to (inability of blinding) the therapy setup of aquatic and land-based exercises.

4. 3. 2. Inclusion and Exclusion criteria

Inclusion criteria: 1. Undergone arthroscopic shoulder rotator cuff repair; 2. Mentally competent; 3. Able to read and write English; 4. Able to return for follow-up; 5. Age between 30 and 80 years; 6. Ability to follow treatment instructions; and 7. Subjects comfortable being immersed in warm water up to the suprasternal notch.

Exclusion criteria: 1. Acute injury of shoulder; 2. Previous history of proximal humerus fracture and/ or glenoid cavity; 3. Intra-articular and/or Extra-articular glenohumeral joint infection; 4. Any neurological condition affecting shoulder functions; 5. Irreparable massive rotator cuff tear; 6. Inability to speak and read English; 7. Psychiatric illness; 8. Metabolic bone disease, and collagen disease; or 9. Any other co-morbid health condition that precluded participation.

4. 3. 3. Therapy setup

Aquatic exercises: Participants who were randomized to the aquatic exercise program were treated in the aquatic pool at St. Joseph's Health Care, London, ON, Canada. The aquatic therapy pool is 9.0 metres in length, 2.5 metres in

width, divided into a shallow and deep end with 4' and 6' depth respectively. The temperature of the pool is maintained between 28° C and 32° C.

Land-based exercises: Participants who were randomized to the land-based exercise program had their treatments within the outpatient physical therapy department (OPD) of St. Joseph's Health Care, London, ON, Canada. The treatment rooms at the OPD provided privacy during therapy and were kept at a constant temperature of 23° C.

4. 3. 4. Interventions

A Physical Therapist and a Kinesiologist who provided the treatment were instructed on the exercise programs to ensure standardized interventions. All participants were instructed to attend either individually administered land-based exercises or a group administered aquatic exercises.

Participants began therapy within 2 days from the day of surgery with an initial PT assessment. Once the initial assessment was completed by the Physical Therapist, a standardized home exercise program with elbow, forearm, wrist, and finger AROM exercises was provided to all the participants (See Appendix 3), irrespective of their group; during this 2 week period, they were immobilized with a shoulder sling.

All therapy visits were of approximately 20 - 30 minutes in duration, and each participant completed the prescribed exercise protocol under the supervision and guidance of the Physical Therapist. Once every 3 weeks, reassessments were completed to ensure appropriate therapy progress was made. No electrical modalities or any other additional form of treatments was provided, other than the prescribed exercise programs, which are following:

4. 3. 4. 1. Standard land-based exercise program: Total of 12 weeks; each exercise session was with 20 - 30 minutes of direct PT contact, and additional home exercise program as defined by assignment and stage. Clients were randomized into two subgroups: low therapy dosage or high therapy dosage. Patients received one physical therapy session per week, and an average of 2-3

sessions per week, under low and high therapy dosage subgroups, respectively. From the day of surgery to the end of postoperative week 2, both groups received a standardized home program; which involved elbow, wrist, forearm, and hand exercises along with shoulder joint immobility using a sling. For both groups, the physical therapy progression consisted of shoulder pendular exercises (week 3 onwards), manual passive exercises and active-assisted exercises (week 3 onwards), active exercises (week 7 onwards), isotonic strengthening exercises (week 13 onwards), and proprioceptive exercises (week 17 onwards). The focus of physical therapy visits was to monitor the postoperative clinical change, teach home exercise program, and its progression (Appendices 2, and 3).

4. 3. 4. 2. Standard Land-based Exercise Plus Aquatic Exercise Program: Participants in the aquatic exercise group participated in an aquatic exercise program in addition to the above mentioned, land-based exercise programs. The aquatic exercise group program was commenced at the start of the postoperative 3rd week, which was conducted twice weekly; and each session was for 40-50 minutes emphasizing range of motion exercises, primarily focussing on the shoulder mobility. The program started with general mobility of other upper extremity joints to allow time for preconditioning of the painful shoulder. Shoulder exercises emphasized with forward flexion, extension, external rotation, internal rotation, adduction, and abduction; and a slow transition was allowed from pain-free to restricted range of motion to maximize the effectiveness of water heat and buoyancy. Participants in the aquatic exercise group were instructed and supervised by a Kinesiologist as they performed each phase of their rehabilitation. (Appendices 2, and 3)

4. 3. 4. 3. Control Over Cointerventions and Contamination: Some patients might have had access to a pool or Jacuzzi. Exposure to this study may influence their perception of the desirability of these. While neither directly mimics the total therapeutic effect of an aquatic exercise program (e. g., heat, body immersion, buoyancy, and aquatic exercise), they could affect our study

outcomes. Similarly, participation in land-based exercise classes that include shoulder activity may affect this study results. While the pain and disability following surgery typically limit early participation in these activities, it may occur as patients improve. Therefore, patients were instructed not to participate in additional land-based exercise classes, aquatic exercise classes, swimming, and use of hot tubs or whirlpools during this research (rehabilitation) program.

4. 3. 5. Outcome Evaluation

4. 3. 5. 1. Primary Outcome: Shoulder active range of motion (AROM) was used as the primary outcome, which was measured using a universal goniometer. Goniometric measurements are extensively used in rehabilitation to provide objective measures of range of motion at synovial joints. [19,40] Rater effects of different goniometric measurement procedures suggest high intra-tester reliability, and low to high inter-tester reliability of ROM measurements.[23,42] Pandya et al[42] measured PROM in patients with Duchene muscular dystrophy, using a universal goniometer; for shoulder abduction and found high intra-tester reliability (ICC= 0.84), and moderate inter-tester reliability (ICC= 0.67). Greene et al[23] measured upper extremity movements using the Ortho Ranger and a standard goniometer. For measuring shoulder flexion and abduction, using the standard goniometer, they found high intra-tester reliability (ICC= 0.96). Riddle et al[45] measured shoulder PROM using two different-sized universal goniometers by having sixteen physical therapists measuring shoulder flexion, abduction, and external rotation; the authors found high intra-tester reliability (ICCs= 0.94-0.99), and high inter-tester reliability (ICCs= 0.84-0.90) for both goniometers; for shoulder extension, horizontal abduction, and medial rotation, they found high intra-rater reliability (ICCs= 0.87-0.94), and low inter-tester reliability (ICCs= 0.26-0.55).

For forward flexion measurement, the affected arm was positioned at the side of the body. The forearm was positioned in neutral rotation. The acromion process was used as the axis. The stable arm of the goniometer was aligned

perpendicular to the ground; the moving arm was aligned with the lateral humeral midline, using the lateral epicondyle of the humerus as a reference point.[40] Participants were instructed to raise their arms to the best of their ability in a straight line, towards their head. No abnormal or compensatory movements were allowed, in the form of spinal movements, or glenohumeral joint (GHJ) abduction.

For measurement of abduction, the affected arm was positioned in neutral abduction, rotation, and adduction at the side of the body. The forearm was positioned in neutral rotation. The goniometer was centered near the acromion process. The stable arm of the goniometer was aligned perpendicular to the ground; the moving arm was aligned with the anterior humeral midline. Participants were instructed to raise their arms sideways, to the best of their ability in a straight line, towards their head. No abnormal or compensatory movements were allowed, in the form of spinal extension, or GHJ abduction.

For measurement of external rotation, the following positions were used, the goniometer was placed on the olecranon process after active shoulder external rotation was performed and maximal range of motion was achieved, and the tester read and recorded data to the nearest 1°. *Sitting measurements:* Subjects were positioned in sitting on a standard chair with back rest supporting both scapula, without arm rests. Measuring shoulder was with neutral position, arm by the side of the subjects, elbow at 90° flexion, and forearm in neutral pronation & supination. The olecranon process was used as the axis of rotation. The stable arm of the goniometer was maintained parallel to the ground; the mobile arm of the goniometer was aligned parallel to the ulna. *Supine measurements:* Subjects were positioned in supine lying, on a standard examination table with the shoulder abducted to 90°, elbow flexed to 90°, and forearm in neutral pronation & supination. The mobile arm of the goniometer was aligned parallel to the ulna; the stable arm of the goniometer was aligned parallel to the ground. No abnormal or compensatory movements were allowed, in the form of spinal extension, or shoulder abduction.

4. 3. 5. 2. Secondary Outcome: Health related quality of life (HRQOL) was used as the secondary outcome, which was measured using the Western Ontario Rotator Cuff (WORC) Index.[27] The WORC is a valid and reliable 21-item disease specific questionnaire which evaluates subjective pain, function, and overall HRQOL. WORC Index has high intra-rater reliability (ICCs 0.84 to 0.96).[27] The WORC correlates with the American Shoulder and Elbow Surgeons score (ASES) (r = 0.68) and the Disabilities of the arm, shoulder and hand (DASH) (r = 0.63).[27] The overall score out of 2100 is the sum of individual item measure on a 100mm Visual Analogue Scale (VAS). A score of 0 represents no reduction in HRQOL, while a score of 2100 represents the worst possible HRQOL.[27]

4. 3. 6. Data Collection and Analysis

All the patient evaluations and data collection were completed by a blinded evaluator, who was not aware of the group allocation. Data was analyzed using the SPSS software, version 19.0 (SPSS Inc, Chicago, Ill, USA). Repeated measures ANOVA was performed to investigate the effect of two different treatment groups; and the possibility of an interaction between the land-based exercise dosage and aquatic exercises. For analysis, we used the mean difference in AROM scores and the WORC total scores in order to assess the efficacy of the aquatic exercise program as an adjunct to the land-based exercise program.

4. 4. RESULTS

4. 4. 1. Participants

Eighteen consecutive patients scheduled for RC repair were approached by two orthopedic surgeons between March 2012 and August 2012. Of the 18 patients contacted with study details, only 12 patients accepted to be part of this study, with a 67% recruitment rate. Adherence with scheduled clinic visits was excellent with a 95% attendance rate. Adherence with outcome evaluation was excellent with a 100% attendance rate, as no one missed follow-up evaluation.

4. 4. 2. Therapy (land versus aquatic exercise) Variability

Patients within both the treatment groups showed increased shoulder AROM and improved WORC total score, over 3 months postoperative time. For aquatic plus land-based exercise group, the mean difference in WORC total scores from baseline to 3 months follow-up was 213; the mean difference in AROM of forward flexion, abduction, and external rotation (measured in supine) were 22°, 19°, and 23° respectively (See Table 2). For land-based exercise only group, the mean difference in function (WORC total) scores from baseline to 3 months follow-up was 681; the mean difference in AROM of forward flexion, abduction, and external rotation (measured in supine) were 21°, -9°, and 35° respectively (See Table 2). The WORC total score and the AROM scores (forward flexion, abduction, and external rotation) were not statistically significant between the two treatment groups. (See Table 2)

4. 4. 3. Therapy Dosage Variability

For the high dosage group, the mean difference in WORC total scores from baseline to 3 months follow-up was 223; the mean difference in AROM of forward flexion, abduction, and external rotation (measured in supine) were 21°, 5°, and 11° respectively (See Table 2). For low dosage group, the mean difference in function (WORC total) scores from baseline to 3 months follow-up was 676; the mean difference in AROM of forward flexion, abduction, and external rotation (measured in supine) were 14°, -16°, and 48° respectively (See Table 2). There were no significant effects of land-based exercise dosage on the total WORC score and the AROM score; there was also no significant interaction found between different land-based exercise groups and aquatic exercise group; the p-values for the AROM score between groups were: 0.44, 0.11, 1.00 for forward

flexion, abduction, and external rotation, respectively. The p-value for WORC total scores between groups was 0.63. (See Table 2)

4. 5. DISCUSSION

This pilot study determined that it is feasible to compare land and aquatic-based exercise programs as participant consent was high, and there were no dropouts. For a future study, we need a sample size of 66 (33 research participants per group), to detect 20% difference between-groups. Considering that we recruited two participants per month, a future trial could be conducted at one center if recruitment was extended for 33 months or would need a multicenter approach.

This pilot study demonstrated that irrespective of the treatment group, at the end of twelve-week exercise program, all patients (clinically) improved with increased shoulder AROM, and improved shoulder function (in the form of HRQOL). These findings show that land-based exercise and aquatic exercise programs are worthy of investigation for future randomized trials. The sample size was too small which resulted in a lack of power to detect treatment differences, to make any definitive conclusions about treatment differences, and the potential that the groups were different at baseline.

With the proposed methodology, we could not recruit the required number of research participants. In our study, the challenge of patient recruitment is clear. Although our consent rate was acceptable (67%), not all patients agreed. Some of the reasons cited by patients for refusal are: time commitment to the study, travel distance to reach the research site, nonavailability of transport for the participants during the early postoperative phase. The reasons for nonparticipation suggest that funding to support patient travel might increase participation.

Recruitment has always been a concern in conducting any clinical trial, what was unexpected, however, was the low participation by treating surgeons, who initially accepted to enrol participants for this study: out of three surgeons accepted to enrol, one surgeon recruited eleven participants, one surgeon

enrolled another patient, and the other surgeon did not enroll. However, we do not know the exact figure of how many eligible participants were contacted by two surgeons; so we do not know the recruitment rate by these surgeons. We are not confident about the reasons for the surgeons not participating in this research. Possible barriers to patient enrollment could be: too busy to get consent, extra paperwork or lack of eligible patients. Despite showing initial interest in the study, possibly due to their busy clinic schedule, they could not enroll the patients. With this current study, the fact is that either the principal investigator/ treating physiotherapist was not part of the recruitment team, and he was not at the research site all the time during the research. This might be one of the reasons for not recruiting the required number of participants. As this is an critical issue, considerable resources may be allocated to compensate clinicians/ researchers for recruiting the required number of participants.

Generally, there is an expectation of research participation by clinical therapists; on the contrary, in publicly funded teaching hospitals we found it difficult to get clinical physiotherapists to participate in this research trial. The rationale provided by therapists (for nonparticipation) was the high volume of clinical caseload that had resulted from clinical staff cutbacks leading to fewer hospital-based therapists; so they can devote no or acutely less time to research. In Canada, as the patient care moves towards privatization, it can be anticipated that participation of these clinical staffs in research would be even more challenging, and in- fact, a recent feasibility study in physical therapy private clinics showed exactly the same finding.[7] In this trial, we managed that barrier by having a clinical physiotherapist/ principal investigator who provided all the treatments without any reimbursement. In future large funded trials, it might be preferable to hire a therapist who can provide treatments to insure treatment protocol adherence. This is particularly necessary in cases like this current trial, where one intervention was to be delivered three times per week and the hospital therapists reported that due do to staff cutbacks, patients were often put on home-based exercise programs. Hence, participation in this current research

would have required that they change their current clinical practice. Another potential reason for lack of enthusiasm among therapists can be due to the lack of knowledge about the importance of research; thus, the therapists were unwilling to use their personal time to support research. However, in Canada, there is increased number of registered physical therapists who are pursuing advanced research-based programs, which may change this attitude towards research.

In our study, response from research participants was optimal. The rate of recruitment (67 %) was acceptable. The rate of noncompliance (5 %) was extremely low, and there were no patients lost to follow-up. The burden of participation on subjects required an initial and a postoperative three month follow-up assessment; with some treatment groups, the treatment sessions were many, involving time and effort from participants. Considering these facts, this pilot study suggests that with the current methodology, a future study is feasible. With this being the case, attaining statistically significant results in future studies with larger sample sizes seems achievable.

In our study, we had a blinded evaluator, who completed all the preoperative and postoperative evaluation and data collection, on-site. This was critical because we could not blind the treatment provider and research participants, due to the treatment surface being land and water. By blinding the outcome evaluator, we were able to prevent potential measurement bias.

In our study, the surgeons, the physical therapist, the kinesiologist, and the blinded evaluator were all trained and experienced in the field of shoulder rehabilitation. They deal with patients with different shoulder problems on a routine basis, including patients with rotator cuff repair. This (training and experience factor) is one of the important factors for the successful conduct of this current study.

A variety of dosages for land-based exercises has been recommended in the literature. Ellman[17] have recommended supervised postoperative rehabilitation of 2 to 3 sessions per week for four months. Gazielly[21] advocates

approximately 40 preoperative and 60 postoperative treatment sessions with a physiotherapist. In our study, participants in the high dosage group, on average, had 82 sessions of postoperative land-based exercise sessions; conversely, the low intensity group had 24 sessions of postoperative land-based exercise. It was hypothesized that participants with higher dosage land-based exercise would achieve a lower score on the WORC Index, and would gain greater shoulder AROM, compared to participant in the low dosage land-based exercises. The sample size was small leading to inadequate power; hence, we could not find any statistically significant difference between these two groups. Subjects in both groups improved over 3 months' time irrespective of their exercise dosage. Other than the sample size, the factor for not finding any between-group difference can be due to shorter follow-up period. Unfortunately, due to the time constraint, we do not have any long term follow-up data available for this present study.

The main aim of all rotator cuff rehabilitation protocols is to enhance healing of the repaired tendons and preventing recurrence of RC tear, while minimizing joint stiffness and muscle atrophy. There is no consensus in the literature on the most appropriate time to load the operated tendons during rehabilitation after rotator cuff repair.[52] In this study, with both treatment groups, we started with partial load on the operated RC tendons at the 3rd postoperative week with active assisted exercises; and gradually the loading was increased during the 7th postoperative week with active range of motion exercises. Clinically, we did not find any negative results due to failure of the RC repair; however, we did not image the repair to assess the integrity at final follow-up.

It was hypothesized that the participants in the aquatic exercise group would have benefitted from the physical properties of water to gain shoulder AROM more quickly and that this would be reflected in better WORC total scores. Contrary to this hypothesis, this study did not show any statistical difference between two groups. One of the possible reasons for the participants in aquatic not having significant improvement is that the aquatic program may be ineffective, or the duration of the aquatic program may be insufficient to attain

therapeutic values of the aquatic therapy, as each aquatic exercise session lasted only for 30 minutes. This protocol was chosen because it has been recommended by the surgeons and physical therapists and being a routine clinical practice on-site. It is in the opinion of the current study's authors that the other potential reason for not finding any statistically significant difference can be due to the small sample size leading to low power.

4. 5. 1. Strengths

The strengths of this study are: (1) All surgical procedures were performed by one surgeon (except one patient) to exclude any technical differences between the two treatment groups; (2) All postoperative rehabilitation programs were performed by one Physical Therapist and one Kinesiologist, to exclude any technical differences between the two treatment groups; (3) This study prevented any selection bias, by having a computerized randomization process; (4) This study prevented any measurement bias, as all the outcome evaluations were completed by a blinded evaluator.

4. 5. 2. Limitations

There are few limitations to this pilot study that may affect its generalizability: (1) Due to time constraint, we could recruit only 12 patients overall; having small sample size has reduced the power of this study. (2) Another limitation of this study was inability to blind the therapist and patients.

4. 6. KEY MESSAGES

4. 6.1. What is already known about this research area

- Very little high-level evidence available to support the use of physical therapy interventions for patients following rotator cuff repair.
- Small to moderate evidence to support land-based exercise programs as a core element of rehabilitation with the potential addition of an adjunctive component of aquatic exercises for patients following rotator cuff repair.

- Insufficient evidence to support a specific dosage for land-based exercise programs for patients following rotator cuff repair.
- To the knowledge of the authors of this pilot study, there is no previous pilot study evaluating the feasibility of conducting a randomized controlled study to find the efficacy of different exercise programs for patients with rotator cuff repair.

4. 6. 2. What this study adds

- Suggests that both land-based and aquatic exercise programs were feasible for patients following rotator cuff repair; this study provided estimates of the effect of land and aquatic exercise program in improving shoulder AROM and function.
- Participating clinicians, researchers identified some barriers to participant enrollment. Future studies should be aware of the possible challenges of conducting research in publicly funded hospitals.
- Based on the findings of this pilot study, we have calculated the sample size for future randomized studies; for a study to have 80% power (α= 0.05, β= 0.20), and to detect 20% difference between-groups, it would require a minimum of 33 research participants per group and 66 participants in-total.
- Established that conducting a large-scale study single-center study with longer duration is feasible.

4. 6. 3. Recommendations and Directions for Future Research

Rigorous randomized controlled trials that are designed to minimize bias and reported using CONSORT criteria[47] are needed to define the optimal method for postoperative rehabilitation following rotator cuff repair. Specific recommendations include the following:

1. Future studies should be aware of the possible challenges of conducting research in publicly funded hospitals. Funding may be a challenge given the resources needed, and professional commitment from the clinicians to

conducting research in a cost-effective manner must be considered. Areas to be examined include therapist and surgeon incentives that would fit within acceptable ethical framework.

2. Research question priorities: Studies that compare different treatment approaches are needed. Priority should be given to optimizing exercise because it is a core component of existing rehabilitation protocols.
3. Reporting recommendations: Better reporting of exercise protocols is needed: We suggest that all exercise studies should report the intended goal, method for assigning initial load, principles of progression, specifics of dosage (load, repetitions per set, number of sets per day, and duration of exercise program), precautions, contraindications, and outcomes. Better descriptions of patients are needed including the nature of the defect/repair, and distribution of known prognostic indicators (for recovery/ response to treatment). In addition, a measure of adherence should be included.
4. Defining optimal combinations of physical therapy: Since postoperative rehabilitation is typically delivered as a multi- factorial treatment, the optimal combinations of different components of rehabilitation should be assessed. As such, the factorial design[6] may be useful in comparing whether individual treatments or their combination optimizes outcomes.
5. Defining standardized outcome measures and measurement timing: Better reporting of outcomes within trials is needed; including reliable and responsive measures of pain, strength, and disability. Standardized measurement instruments, protocols, would improve the quality of existing trials and contribute to one's ability to conduct meta-analyses in the future. Standardized measurement timings including during the shoulder muscle strengthening phase and the functional rehabilitation phase would be beneficial in measuring the long-term outcomes of the rotator cuff repair. In addition, more careful reporting of return-to-work outcomes is needed and should include both time lost and at-work limitations.

4. 7. CONCLUSIONS

This pilot study was designed to assess the feasibility of conducting a future study, by defining the effect of a land-based exercise program and a potential adjunctive aquatic exercise program for patients following rotator cuff repair. This study established that conducting a large-scale single-center study with longer duration and larger sample size is feasible for patients with rotator cuff repair. This current study suggests that the combination of land-based exercise and aquatic exercise as an adjunct may be equally effective in improving shoulder AROM and HRQOL, when compared to land-based exercises only. Areas to be examined include clinician, researcher, and patient participation; and appropriate incentives that would fit within acceptable ethical behavior. Answering these questions may help conduct a future randomized study, to find statistical significance between land-based exercise program and potential adjunctive aquatic exercise program for patients following rotator cuff repair.

4. 8. ACKNOWLEDGEMENT

The authors would like to thank all patients who participated in the study. A special thanks to Ms. Lynn Stewart, the coordinator of outpatient physical therapy department at St. Joseph's Health Care, London, ON, Canada for her contribution towards accessing the treatment facility. The primary author (AR) would also like to thank the American Hand Therapy Foundation for their financial support through "North coast grab-the-evidence scholarship", which was awarded towards conducting this research study.

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Table 1: Demographic details of the participants

Demographic details	Land plus aquatic therapy (n= 6)	Land therapy (n= 6)
Male (n/ group)	3	4
Female (n/ group)	3	2
Mean Age (years)	49	51
Mean tendon tear size (cm)	1.4	1.4

Table 2: Descriptive statistics & Repeated measure ANOVA summary comparing the effect of therapy: Primary and secondary outcome measures

Group	Outcome Measures	Minimum		Maximum		Mean		Standard Deviation		p-value (Group & therapy dosage @ 3 months
		Pre-op	Post-op 3 Months Follow-up	Pre-op	Post-op 3 Months Follow-up	Pre-op	Post-op 3 Months Follow-up	Pre-op	Post-op 3 Months Follow-up	
Land plus Aquatic therapy	WORC Total score	858.0	403.0	1767.0	1437.0	1224.0	1011.6	364.9	429.1	0.56
	Flexion AROM	70.0	80.0	155.0	175.0	115.0	136.7	33.2	32.5	0.52
	Abduction AROM	60.0	50.0	100.0	160.0	75.0	94.2	13.8	37.2	0.75
	ER AROM (Supine)	0.0	50.0	90.0	80.0	39.2	61.7	37.5	11.3	0.89
	ER AROM (Sitting)	40.0	30.0	70.0	70.0	55.0	49.2	11.8	13.2	-
Land therapy	WORC Total score	1180	232.0	2033.0	1741.0	1701.8	1020.3	358.9	491.4	-
	Flexion AROM	70.0	100.0	170.0	165.0	122.0	141.0	39.6	24.6	-
	Abduction AROM	40.0	50.0	165.0	165.0	108.0	99.0	52.9	48.7	-
	ER AROM (Supine)	0.0	15.0	90.0	80.0	20.0	55.0	39.4	25.0	-
	ER AROM (Sitting)	40.0	10.0	75.0	60.0	56.0	36.0	15.6	19.2	-
High Dosage	WORC Total score	858.0	403.0	1767.0	1741.0	1271.0	1048.2	360.5	462.4	0.24
	Flexion AROM	70.0	80.0	150.0	165.0	115.0	136.7	31.5	30.3	0.44
	Abduction AROM	40.0	50.0	130.0	165.0	80.0	85.8	31.1	43.2	0.11
	ER AROM Supine	00.0	50.0	75.0	70.0	47.5	58.3	42.9	06.8	0.54
	ER AROM Sitting	40.0	30.0	75.0	60.0	54.2	45.8	14.9	10.7	-
Low Dosage	WORC Total score	1024	232.0	2033.0	1437.0	1654.8	978.2	427.4	464.1	-
	Flexion AROM	70.0	80.0	150.0	165.0	122.0	136.7	41.3	30.3	-
	Abduction AROM	60.0	50.0	165.0	165.0	101.0	85.8	48.0	43.2	-
	ER AROM Supine	0.0	50.0	40.0	70.0	10.0	58.3	17.3	06.8	-
	ER AROM Sitting	45.0	30.0	70.0	60.0	57.0	45.8	11.5	10.7	-

FIGURE 1. Study Protocol

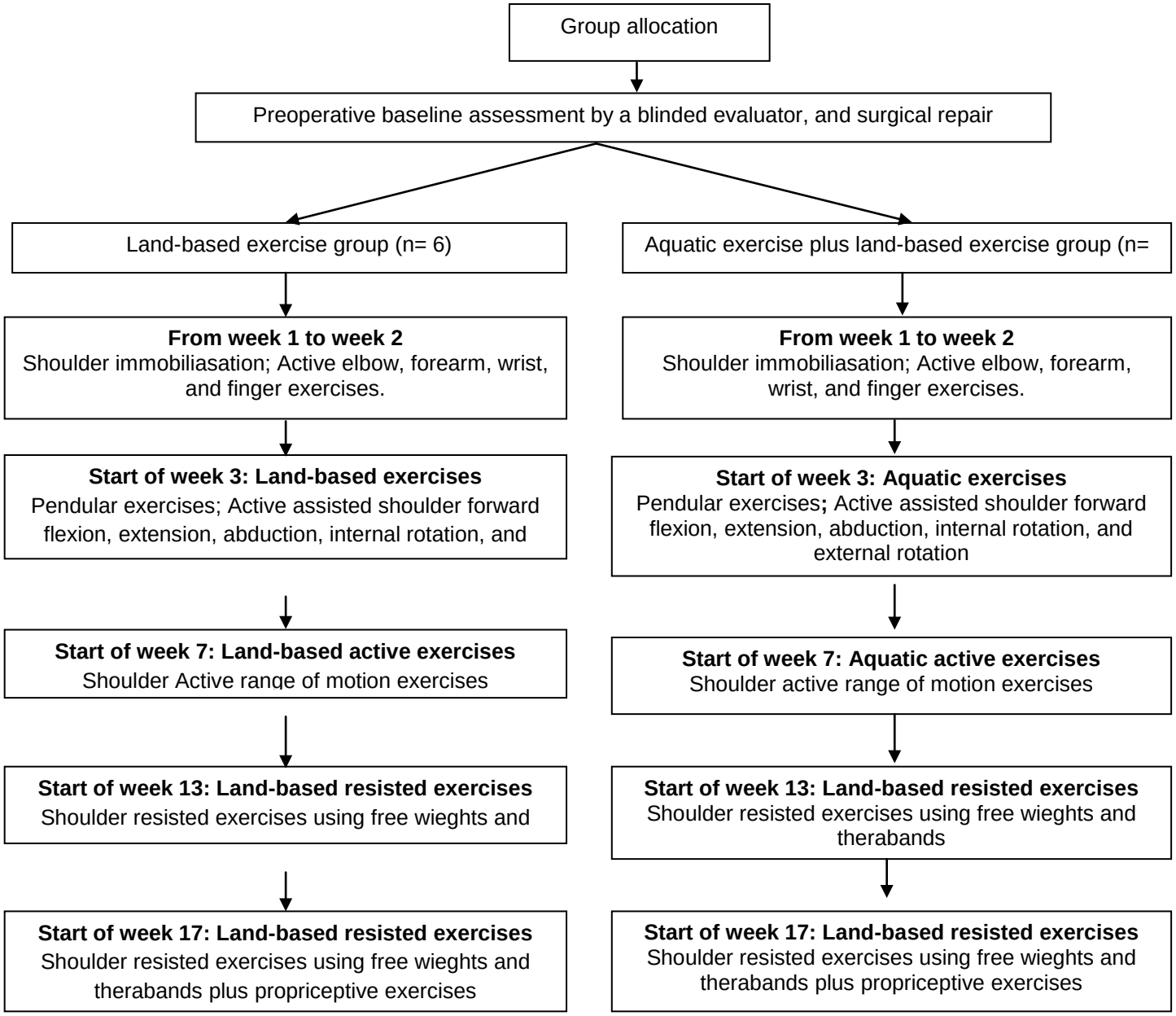

Table 3 – Brief details about the exercise programs

Postoperative period	Land-based exercise group (Provided at a outpatient physical therapy department by a Physical Therapist)	Aquatic exercise group (Provided in a warm water pool, supervised by a Kinesiologist)
From the day of surgery to the end of the second week	- Home training program (appendix 3), including active movements of elbow, forearm, wrist, and finger joints; performed 3 times/ day. - Shoulder immobility was achieved using shoulder sling.	- Home training program (appendix 3), including active movements of elbow, wrist, forearm, wrist, and finger joints; performed 3 times per day. - Shoulder immobility was achieved using shoulder sling.
From the start of the third week to the end of six weeks	- Supervised physiotherapy on an outpatient was started: - Passive ROM (depending on the subgroup, 1–3 times/week) throughout the physiotherapy period or until full ROM was achieved. - AAROM exercises using a cane.	- Supervised physiotherapy on an outpatient was started: - Passive ROM (depending on the subgroup, 1–3 times/week) was performed by the physiotherapist throughout the physiotherapy period or until full ROM was achieved. - AAROM exercises using a cane. - Plus: Aquatic exercises in the form of AAROM exercises using a cane; all the AAROM exercises were performed 10 repetitions each.
From the start of the seventh week to the end of twelve weeks	- Passive ROM, if needed. - AAROM exercises using a cane, if needed. - AROM exercises.	- Passive ROM, if needed. - AAROM exercises using a cane, if needed. - AROM exercises. - Plus: Aquatic exercises in the form of AROM exercises; all the AROM exercises were performed 10 repetitions each.
From the start of the thirteenth week to the end of sixteen weeks	- Passive ROM, if needed. - AAROM exercises using a cane, if needed. - AROM exercises, if needed. - Dynamic strengthening exercises for the rotator cuff and scapular muscles using theraband and free weights.	- Passive ROM, if needed. - AAROM exercises using a cane, if needed. - AROM exercises, if needed. - Dynamic strengthening exercises for the rotator cuff and scapular muscles using theraband and free weights.
From the start of seventeenth week onwards	- Dynamic strengthening exercises for the rotator cuff and scapular muscles using theraband and free weights plus proprioceptive exercises.	- Dynamic strengthening exercises for the rotator cuff and scapular muscles using theraband and free weights plus proprioceptive exercises.

Home exercise program for patients in both the treatment groups

Home exercises program:

From the day of surgery to the end of 2nd postoperative week:

- Raising and lowering the shoulders
- Flexion and extension of the elbow
- Supination and pronation of forearm
- Flexion, extension, ulnar, and radial deviation of wrist
- Flexion, extension, deviations of thumb and fingers

From the start of 3rd postoperative week to the end of 6th week:

- Raising and lowering the shoulders
- Pendular exercises - towards the directions of flexion, extension, abduction, adduction, circumduction.
- Active assisted range of motion (using a cane): Flexion, extension, abduction, adduction, internal and external rotation: either in lying or in standing.

From the start of 7th postoperative week to the end of 12th week:

- Active assisted range of motion (using a cane): Flexion, extension, abduction, adduction, internal and external rotation: either in lying or in standing (if needed).
- Active range of motion: Flexion, extension, abduction, adduction, internal and external rotation: either in lying or in standing.

From the start of 13th postoperative week to the end of 16th week:

- Active range of motion: Flexion, extension, abduction, adduction, internal and external rotation: either in lying or in standing, if needed.
- Dynamic muscle strengthening exercises, using theraband: External and Internal rotation with elbows at 90° flexion; Forward flexion, Elevation in the plane of the scapula in standing or supine with elbow extension; Extension with elbow extension.

From the start of 16th week onwards:

- Dynamic muscle strengthening exercises, using theraband: External and Internal rotation with elbows at 90° flexion; Forward flexion, Elevation in the plane of the scapula in standing or supine with elbow extension; Extension with elbow extension.
- Proprioceptive exercises.

5. 1. DISCUSSION

5. 1. 1. Overview Of This Thesis Findings

The focus of this thesis was to describe the optimal physical therapy management for patients who are recovering from rotator cuff repair. This description process included: finding the relevant evidence supporting postoperative physical therapy, describing the effects of different testing positions for measuring shoulder AROM by describing the reliability and responsiveness of the positions, and describing the effect of a land-based exercise program including an adjunctive aquatic exercise program. The details of the findings of this thesis are including the following:

- Through the first part of the thesis we found that there is small to moderate evidence supporting progressive land-based exercise as a core element of rehabilitation; with the potential addition of adjunctive components including continuous passive movements, aquatic exercises, and neuromuscular electrical stimulation.
- Through the next part of this thesis, we focused on physical impairments, in-particular shoulder joint range of motion. The issue we addressed was the measurement properties of two different testing positions for measuring shoulder active ER ROM. We described the reliability and the responsiveness of supine position with 90° shoulder abduction and sitting position with neutral shoulder. We found that both the measurement positions provided different AROM measurements, which are moderately correlated. We also found that the sitting position provides precise, and more responsive measurements than the supine position.
- Through the final part of this thesis, we focused on establishing the feasibility of conducting a large-scale randomized clinical trial. We provided estimates of the effect of the combination of land-based and aquatic exercise programs for patients with rotator cuff repair, to find the sample size for future studies. We also found that the combination of land-

based and aquatic exercise program as an adjunct may be equally effective in improving shoulder AROM and function, comparing the land-based exercise program only.

5. 2 KEY MESSAGES

5. 2. 1 What is Already Known on This Subject

- The occurrence of rotator cuff and its surgical repair has gained scientific attention during the past decades; however, the evidence supporting postoperative physical therapy programs is weak and inconclusive.
- Goniometers are the primary measuring tools in physical therapy for measuring joint motion. The majority of studies that addressed the effects of testing positions on goniometric measurement have focused only on rater reliability; and only a few have addressed the validity and the responsiveness for patients following rotator cuff repair. It is difficult to compare the results of treatment across studies that use different test methods if the impact of test position is not known.
- It is essential to establish specific data to provide adequate treatment profiles of the benefits of different postoperative physical therapy programs for patients following rotator cuff repair. There are currently no rigorous estimates of the effects of these programs.

5. 2. 2 What This Thesis Adds to knowledge Base

- Small to moderate evidence available to support progressive land-based exercise program as a core element of rehabilitation with the potential addition of adjunctive components including continuous passive movements, aquatic exercises, and neuromuscular electrical stimulation. Insufficient evidence available to support a specific dosage or delivery method for progressive postoperative exercise programs.
- Supine position with 90° shoulder abduction and sitting position with neutral shoulder provided different AROM measurements, which are

moderately correlated. The sitting position provides precise, and more responsive measurements than the supine position.

- It is established that conducting a large-scale study is feasible for patients with rotator cuff repair. Although progressive land-based exercises have been the core component of postoperative rehabilitation, this pilot study suggests that the combination of land-based exercise program and aquatic exercise as an adjunct may be equally effective in improving shoulder AROM and function. Participating clinicians, researchers identified some barriers to participant enrollment. Future studies should be aware of the possible challenges of conducting research in publicly funded hospitals. Based on the findings of this pilot study, we have calculated the sample size for future randomized studies; for a study to have 80% power (α= 0.05, β= 0.20), and to detect 20% difference between-groups, it would require a minimum of 33 research participants per group and 66 participants in-total.

5.3. LIMITATIONS

In spite of providing excellent insight into the rehabilitation practice following RC repair, this thesis on the whole had few inherent limitations besides specific limitations of the individual studies included in it. Firstly we could not define an optimal rehabilitation protocol following rotator cuff repair as the systematic review found only studies that were of low quality and found only small to moderate effects. Secondly, we had time constraints that prevented us from recruiting enough subjects for the pilot study that looked at the dosage and the interaction between land and land plus aquatic exercise in rehabilitation following RC repair. Moreover, this being a pilot study, has less clinical significance and now compounded by the fact that we were underpowered. However, we have strong recommendations for future trials that can be based on the experience that we gained from the pilot study. This thesis forms the groundwork in the development of clinical practice guidelines for rehabilitation following RC repair.

5.4. IMPLICATIONS OF THESIS FINDINGS

- In the recent years, interest in the area of postoperative physical therapy for patients following shoulder rotator cuff repair has increased rapidly, due to the high volume of RC tear incidence and repair. Various adjunct components, including aquatic exercise are being added to the core land-based exercise programs for postoperative physical therapy management. When used with adjunct component of aquatic exercise, land-based exercise programs can be truly effective for patients who are recovering from rotator cuff repair.
- Between supine and sitting testing positions for the shoulder active range of motion measurement, one position cannot replace the other. However, clinicians can consider using sitting testing position as it is precise and responsive than the supine position.

5. 5 FUTURE RESEARCH DIRECTIONS AND RECOMMENDATIONS

Rigorous RCTs that are designed to minimize bias and reported using CONSORT criteria[2] are needed to define the optimal method for postoperative rehabilitation following rotator cuff repair. Specific recommendations include the following:

Research Question Priorities

- Studies that compare different treatment approaches are needed.
- Priority should be given to optimizing land-based exercise because it is the core component of existing postoperative physical therapy protocols.
- We know that optimal loading of the operated RC tendon will increase the tensile strength of the tendon, but the aggressive loading during an early postoperative period might result in recurrence of tears. Therefore, studies on the optimal timing and dosage of resistance exercises should be priority issues.

Reporting Recommendations

- Better reporting of exercise protocols is needed: We suggest that all exercise studies should report the intended goal, method for assigning initial tendon load, principles of exercise progression, specifications of exercise dosage (tendon load, repetitions per session, number of sessions per day, and duration of exercise program), precautions, contraindications, and outcomes. In addition, a measure of exercise adherence should be included.
- Better descriptions of patients are needed: We suggest including descriptions of RC defect and repair, and distribution of known prognostic indicators for recovery and response to postoperative treatment.

Defining Optimal Combinations of Physical Therapy

- Since postoperative rehabilitation is typically delivered as a multi- factorial treatment, the optimal combinations of different components of physical therapy intervention should be assessed. As such, the factorial design[1] may be useful in comparing whether individual treatments or their combination optimizes shoulder outcomes.

Defining standardized outcome measures

- Better reporting of outcomes within trials is needed; including reliable and responsive measures of pain, motion, strength, disability, and functional performance. Standardized measurement instruments, protocols, and the timing would improve the quality of existing trials and contribute to one's ability to conduct meta-analyses in the future.
- Considering the long duration of the postoperative physical therapy program, and different outcomes are being measured at each phase of the rehabilitation, different outcome measuring tools can be used; these tools should be sensitive and appropriate for patients with postoperative rotator cuff repair.

- More careful reporting of return-to-work outcomes is needed and should include both time lost and at-work limitations.

Reporting patient recruitment rate

- Considering 25% patients refused to participate in this current pilot study, future clinical trials should keep this patient acceptance ratio in mind, before deciding on their sample size. A larger multicenter randomized clinical trial or single-center trial with long trial period can help to recruit the required number of participants which in-turn can increase the power of any study.

5. 5 REFERENCES

1. Cadman D, Goldsmith C. Construction of social value or utility-based health indices: the usefulness of factorial experimental design plans. J Chronic Dis. *1986*; 39(8):643-651.
2. Schulz KF, Altman DG, Moher D. CONSORT 2010 statement: Updated guidelines for reporting parallel group randomized trials. BMJ. *2010*; 340.

6. Appendices

Use of Human Participants - Ethics Approval Notice

Principal Investigator: Dr. Joy MacDermid
Review Number:18466
Review Level: Full Board
Approved Local Adult Participants:70
Approved Local Minor Participants:0
Protocol Title: Rehabilitation of reconstructed shoulder rotator cuff : optimizing physical therapy dosage and effect of aquatic physical therapy - A randomized, factorial study
Department & Institution: Surgery,University of Western Ontario
Sponsor: American Hand Therapy Foundation

Ethics Approval Date: January 06, 2012
Ethics Expiry Date: July 31, 2012

Documents Reviewed & Approved & Documents Received for Information:

Document Name	Comments	Version Date
UWO Protocol	Including all instruments listed in section 8.1	
Letter of Information & Consent		2011/10/24
Other	Research Participant Record Form	
Other	Visual Analog Scale	

This is to notify you that the University of Western Ontario Health Sciences Research Ethics Board (HSREB) which is organized and operates according to the Tri-Council Policy Statement: Ethical Conduct of Research Involving Humans and the Health Canada/ICH Good Clinical Practice Practices: Consolidated Guidelines; and the applicable laws and regulations of Ontario has reviewed and granted approval to the above referenced study on the approval date noted above. The membership of this HSREB also complies with the membership requirements for REB's as defined in Division 5 of the Food and Drug Regulations.

The ethics approval for this study shall remain valid until the expiry date noted above assuming timely and acceptable responses to the HSREB's periodic requests for surveillance and monitoring information. If you require an updated approval notice prior to that time you must request it using the UWO Updated Approval Request form.

Member of the HSREB that are named as investigators in research studies, or declare a conflict of interest, do not participate in discussions related to, nor vote on, such studies when they are presented to the HSREB.

The Chair of the HSREB is Dr. Joseph Gilbert. The UWO HSREB is registered with the U.S. Department of Health & Human Services under the IRB registration number IRB 00000940.

Signature

Ethics Officer to Contact for Further Information

This is an official document. Please retain the original in your files.

The University *of* Western Ontario
Office of Research Ethics

Research Western

Use of Human Participants - Ethics Approval Notice

Principal Investigator: Dr. Joy MacDermid
File Number: 101834
Review Level: Delegated
Approved Local Adult Participants: 70
Approved Local Minor Participants: 0
Protocol Title: Rehabilitation of reconstructed shoulder rotator cuff : optimizing physical therapy dosage and effect of aquatic physical therapy - A randomized, factorial study
Department & Institution: Schulich School of Medicine and Dentistry\Surgery,Western University
Sponsor: American Hand Therapy Foundation

Ethics Approval Date: July 11, 2012 **Expiry Date:** December 31, 2012
Documents Reviewed & Approved & Documents Received for Information:

Document Name	Comments	Version Date
Revised Study End Date		

This is to notify you that The University of Western Ontario Research Ethics Board for Health Sciences Research Involving Human Subjects (HSREB) which is organized and operates according to the Tri-Council Policy Statement: Ethical Conduct of Research Involving Humans and the Health Canada/ICH Good Clinical Practice Practices: Consolidated Guidelines; and the applicable laws and regulations of Ontario has reviewed and granted approval to the above referenced revision(s) or amendment(s) on the approval date noted above. The membership of this REB also complies with the membership requirements for REB's as defined in Division 5 of the Food and Drug Regulations.

The ethics approval for this study shall remain valid until the expiry date noted above assuming timely and acceptable responses to the HSREB's periodic requests for surveillance and monitoring information. If you require an updated approval notice prior to that time you must request it using the University of Western Ontario Updated Approval Request Form.

Members of the HSREB who are named as investigators in research studies, or declare a conflict of interest, do not participate in discussion related to, nor vote on, such studies when they are presented to the HSREB.

The Chair of the HSREB is Dr. Joseph Gilbert. The HSREB is registered with the U.S. Department of Health & Human Services under the IRB registration number IRB 00000940.

Signa

Ethics Officer to Contact for Further Information

This is an official document. Please retain the original in your files.

The University *of* Western Ontario
Office of Research Ethics

LAWSON HEALTH RESEARCH INSTITUTE

FINAL APPROVAL NOTICE

RESEARCH OFFICE REVIEW NO.: R-11-589

PROJECT TITLE: Rehabilitation of reconstructed shoulder rotator cuff: Optimizing physical therapy dosage and effect of aquatic physical therapy - A randomized, factorial study.

PRINCIPAL INVESTIGATOR: Dr. Joy MacDermid

DATE OF REVIEW BY CRIC: February 2, 2012

Health Sciences REB#: 18466

Please be advised that the above project was reviewed by the Clinical Research Impact Committee and the project:

Was Approved

PLEASE INFORM THE APPROPRIATE NURSING UNITS, LABORATORIES, ETC. BEFORE STARTING THIS PROTOCOL. THE RESEARCH OFFICE NUMBER MUST BE USED WHEN COMMUNICATING WITH THESE AREAS.

Dr. David Hill
V.P. Research
Lawson Health Research Institute

All future correspondence concerning this study should include the Research Office Review Number and should be directed to Sherry Paiva, CRIC Liaison, LHSC, Rm. C210, Nurses Residence, South Street Hospital.

cc: Administration

LETTER OF INFORMATION

Study Title:	Study Site:
Rehabilitation of shoulder rotator cuff repair - effect of land-based and aquatic exercise programs: A randomized, pilot study.	Clinical Research Lab Hand and Upper Limb Centre 268 Grosvenor Street London, ON N6A 4V2.
Funded By: American Hand Therapy Foundation, United States of America.	Principal Investigator: Dr. Joy C. MacDermid, PhD. Co - Investigators: Mr. Ravindiran Appunni, PhD(C). Dr. Darren Drosdowetch, M.D. Dr. George Athwal, MD. Dr. Kenneth Faber, MD. Dr. Trevor Birmingham, PhD.

What is the purpose of the study?

You are being invited to voluntarily be in a research study because you have a tear in your rotator cuff. This study involves assessing and reporting your shoulder movements and muscle performance and the extent to which they are affected by your rotator cuff pathology. In order to decide whether or not you want to be a part of this research study, you should know what is involved and the potential risks and benefits. This letter of information gives you detailed information about the research study, which will be discussed with you and will be asked to sign the consent form if you wish to participate. Please take your time to make your decision. Feel free to discuss it with your friends and family, or your family physician. This study proposes to compare two methods of rehabilitating the operated shoulder tendons with the aim defining optimal rehabilitation for clients with full thickness rotator cuff reconstruction, with two goals: Finding the optimal physical therapy dosage in enhancing post-operative outcomes of shoulder pain, shoulder joint range of motion, shoulder muscle strength, upper extremity function; & Finding the effect of aquatic physical therapy in enhancing the post-operative outcomes. Both land physical therapy and aquatic therapy following rotator cuff repair are considered appropriate methods of rehabilitation for rotator cuff tears. The difference between land physical therapy and aquatic therapy is the place of performing exercises following rotator cuff surgery. Land physical therapy, a rehabilitation program used after the repair of small to moderate tears of rotator cuff tendons, is a standard rehabilitation method following rotator cuff reconstruction. However, there has been a move towards the use of aquatic therapy to manage the same problem and aquatic therapy has become the treatment of choice in many centers. This study will determine whether land physical therapy and aquatic therapy is more effective in improving the quality of life in patients with small or moderate-sized rotator cuff tears.

What is involved?
In this study we will include only small to moderate-sized full-thickness rotator cuff tears. If you agree to participate in this study, you will be assigned to the traditional randomized controlled trial. You will be randomly assigned (like the flip of a coin) to either land physical therapy or to aquatic therapy, so you will have a 50:50 chance of receiving either method to rehabilitate the repaired rotator cuff tendon. Your participation in the study may be discontinued if surgeons or physical therapists find other pathologies during surgery and rehabilitation. Your surgeons and physical therapists will treat your shoulder with appropriate treatment that best suits your condition. The rehabilitation program will be the same for both procedures. A sling will be used for 4 weeks but will be removed for exercise.

1. *Standard physical therapy program:* Total of 12 weeks; each exercise session will be 20 -30 minutes of direct contact and additional supervised exercise as defined by assignment and stage. Clients are randomized into two groups: low therapy dosage or high dosage. Both groups will receive a standardized home program for Day 0-14 which involves elbow, wrist and hand exercises and shoulder protection. In the low dosage group clients will receive 1 visit per week. The treatment progression will consist of active assisted shoulder exercise (Week 3-4), Active exercise and isometrics (week 5-8) and maximizing mobility and strengthening (Week 8-12). The focus of visits will be teaching of the home exercise program and its progression. In the high therapy dosage patients will be seen 3 times/week once mobilization begins and have a 4-week work reconditioning program at 12 weeks. The progression will be staged in the same way, but the high intensity group will have more hands-on techniques selected by the therapist such as joint mobilization, PNF exercise and will perform supervised exercises (the same as provided to low dosage). The strengthening program over weeks 8-12 will use free weights/resistance bands, and at 12 weeks a personalized 4-week work hardening will take place. The home program of active exercises is progressed according to patient tolerance, will be the same for both groups and is documented in a patient instruction booklet.

2. Standard physical therapy program plus aquatic physical therapy: The above PLUS a aquatic physical therapy program which will be conducted twice weekly for 10 weeks and will include a 40-50 minute hydrotherapy session emphasizing range of motion and light resistive exercises of the arm, primarily focussing on the shoulder. The program will start with general mobility of the other upper limb joints to allow time for preconditioning of the painful shoulder. Shoulder exercises will emphasize flexion, rotation and abduction and a slow transition from pain-free range to the restricted range of motion to maximize the effectiveness of the heat and buoyancy. Follow-up clinical evaluations will take place at 6 weeks, 3, 6, 12, 18, and 24 months postoperatively at Hand and Upper Limb Centre Hand where we routinely test your shoulder motion and strength, and use

questionnaires that ask about your pain and disability. The questionnaires will take approximately 15-20 minutes to complete. These visits are routine components of evaluation after surgery and will take approximately 20 minutes. For the study, you will also be asked to fill out additional surveys about your shoulder pain and level of recovery. You will be asked to complete the same forms at each visit.

How many people will be in this study?
There will be 70 local participants (35 in each group) in this study.

What are the benefits of participating in this study?
You may not directly benefit from your participation in this study. Your participation would help researchers to compare two commonly used procedures for postsurgical rotator cuff rehabilitation.

Is there any compensation?
You will be reimbursed for parking expenses associated with this study.

Are there any risks of discomfort associated with this study?
Research related injuries are not anticipated. The movements performed will be simple tasks of everyday life and pose no risk. The available range of movements and the muscle performances at your shoulder will be measured using the Biodex (a simple machine helps measuring shoulder muscle power). The range of movement at the shoulder will be tested during normal activities of daily living. The muscle performances will be tested at pain free limits on the Biodex. These are extremely common movements and are not expected to result into any injury.

What is the estimated time commitment for participation in this study?
At Hand and Upper Limb Centre Hand where we routinely test your shoulder motion and strength, and use questionnaires that ask about your pain and disability. The questionnaires will take approximately 15-20 minutes to complete. These visits are routine components of evaluation after surgery and will take approximately 20 minutes. For the study, you will also be asked to fill out additional surveys about your shoulder pain and level of recovery. You will be asked to complete the same forms at each visit.

Will your results be kept confidential?
The overall results of the study will be available to you upon request. Your individual results will be held in strict confidence. No person, other than your therapist and the study co-investigators will have access to your records without your permission. Your data that is sent into the study database will have your personal identifying information removed or coded so that the information in the study database will not contain any personal identifying information. The

Representatives of the University of Western Ontario Health Sciences Research Ethics Board may contact you or require access to your study-related records to monitor the conduct of the research. Information collected during the study may be presented to other Physical Therapists or Doctors in a presentation or paper. Your results would be part of a group of anonymous data, and would not identify you in any way.

What if you do not wish to participate in the study?
Participation in this study is voluntary. You may refuse to participate, refuse to answer any questions or withdraw from the study at any time with no effect on your future care.

What will happen in the event of a study-related injury?
In the event that you suffer an injury as a result of participating in this research, no compensation will be provided to you by St. Joseph's Health Centre London, University of Western Ontario, or the Researchers. But, care will be provided by St. Joseph's Health Care. You do not waive any legal rights by signing the consent form.

Whom may you contact to find out more about this study?
You will be given a copy of this letter.

CONSENT FORM

I have read the letter of information, have had the nature of the study explained to me, and I agree to participate. All questions have been answered to my satisfaction. I will receive a copy of Letter of Information and consent from once it has been signed.

_____	_____	_____
Name of participant	Signature	Date

_____	_____	_____
The person obtaining consent	Signature	Date

7. 0. CURRICULUM VITAE

Name: Ravindran Appunni

Professional Education

- Bachelor of Physiotherapy (1994 - 1998): Dr. MGR Medical University, Chennai, India.
- Doctor of Philosophy - Candidate (2008 - 2012): The Western University, London, Canada.

Academic Experience

- Teaching Assistant - 2011: School of Physical Therapy, Western University, London, ON.
- Teaching Assistant - 2009: School of Physical Therapy Western University, London, ON.
- Teaching Assistant - 2008: School of Physical Therapy, Western University, London, ON.

Awards

- Western Graduate Research Scholarship – 2008 - 2012 (4 years): University of Western Ontario, London, ON, Canada. (Value: $19,000/ year)
- North Coast Medical Grab-the-Evidence Scholarship - 2008: American Hand Therapy Foundation, United States of America (Value: US$ 4000.00).

Manuscripts under preparation for publication

- Appunni R, MacDermid JC, Birmingham T, Roy S, Athwal G, and Walton D. 2012. Physical Therapy following shoulder rotator cuff repair: A Systematic Review. Submitted for publication. Journal of Orthopedic and Sports Physical Therapy.
- Appunni R, MacDermid JC, Athwal G, Birmingham T, and Faber K, Drosdowech D. 2012. Position effects of measures of active external rotation following shoulder rotator cuff repair. Being submitted for publication. Journal of Shoulder and Elbow Surgery.

- Appunni R, MacDermid JC, Athwal G, and Birmingham T. 2012. Effect Of Land-Based And Aquatic Exercise Programs on Patients Recovering From Shoulder Rotator Cuff Repair - A Randomized Pilot Study. Being submitted for publication. International Journal of Orthopedic Surgery.

Conferences Attended & Papers presented:

- Appunni R, MacDermid JC, Athwal G, and Birmingham T. 3rd World Congress of International Federation of Reconstructive, Plastic, and Aesthetic Surgeons, India. 2010. Rehabilitation of Reconstructed Rotator cuff: A Systematic review – part 2.
- Appunni R, MacDermid JC, Athwal G, and Birmingham T. 8th Triennial Congress of International Federation of Societies of Hand Therapists, Florida, USA. 2009. Rehabilitation of Reconstructed Rotator cuff: A Systematic review – part 1.
- Appunni R, MacDermid JC, Athwal G, and Birmingham T. 2nd national conference of Canadian Society of Hand Therapists, Toronto, Canada. 2009. Rehabilitation of Reconstructed Rotator cuff: A Systematic review – part 1.