8-23-2013 12:00 AM

Prognosis and Movement Patterns in Patients After Rotator Cuff Repair

Jayaprakash Raman, *The University of Western Ontario*

Supervisor: Dr. Joy C MacDermid, *The University of Western Ontario*

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

PROGNOSIS AND MOVEMENT PATTERNS IN PATIENTS AFTER ROTATOR CUFF REPAIR

(Thesis format: Integrated article)

by

Jayaprakash Raman

Graduate Program in Health and Rehabilitation Sciences

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

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

ABSTRACT

Rotator cuff repairs are done in patients who failed to achieve functional improvement with conservative management for rotator cuff tears. This thesis focuses on prognostic factors that predict outcomes after rotator cuff repair (RCR) and change in functional range of motion (ROM) and muscle endurance before and after RCR.

A meta-analysis was performed to statistically analyze all available evidence in the literature concerning prognostic factors that determine outcome after RCR. Based on this study, several factors were identified that had significant and moderate effects on outcomes after RCR.

Two prospective studies were conducted to analyze change in functional ROM and muscle endurance after RCR. The first study followed patients pre-op, 3 and 6 months after RCR. Patients performed 2 trials of 5 activities selected from Disabilities of Arm, Shoulder and Hand questionnaire. The activities were captured using 2D video motion system and analysed using Dartfish software. This study showed excellent intra-rater reliability while using the 2D video analysis system with improvement in ROM during all activities when compared before and after surgery with significant improvement in 2 activities when compared at different time points.

A prospective study to evaluate muscle endurance at 6 months after surgery was done using an endurance protocol on the Biodex system and compared with age- and gender-matched controls. Results of this study indicated that changes in muscle performances as measured by average isokinetic torque and total work before and after the protocol did not indicate muscle fatigue in patients after RCR and in the control group.

We also analysed the psychometric properties of Simple shoulder test (SST) using the Rasch model to assess its fit to the model and to examine the stability of the findings at different time points. Our results indicated that a number of properties of SST were supported and it appeared to be robust when tested against the Rasch model. Local dependency between light and heavy objects being lifted overhead fits with their conceptual overlap. Unless corrected some gender bias may exist on the lifting item.

KEYWORDS: prognosis, meta-analysis, functional ROM, Dartfish, muscle endurance, fatigue, Biodex, Rasch model, Simple shoulder test.

CO-AUTHORSHIP

The thesis question and design of the studies were formulated by me and my supervisor, Joy C MacDermid. Co-investigators were recruited when additional testers or raters with specific expertise were required. Thesis advisors are included as co-authors for specific chapters for which they contributed input prior to submission for publication. The authors and specific roles for each component of the thesis are listed below:

Chapter 1: Introduction:

Jayaprakash Raman – sole author

Chapter 2: Predictors of outcomes after rotator cuff repair – A Meta-analysis:

Jayaprakash Raman – primary author, study design, data collection, rater for critical appraisal of articles, data analysis, wrote manuscript

David Walton – assisted in meta-analysis, rater for critical appraisal of articles, reviewed manuscript

Joy C MacDermid – study design, rater for critical appraisal of articles, reviewed manuscript

Chapter 3: Functional movement analysis of shoulder kinematics before and after rotator cuff repair:

Jayaprakash Raman – primary author, study design, data collection/supervision, data analysis, wrote manuscript

Joy C MacDermid – study design, reviewed manuscript

David Walton – reviewed manuscript

Kathryn Sinden – reviewed manuscript

George Athwal – supplied patient list

Chapter 4: Shoulder muscle endurance in patients following rotator cuff repair:

Jayaprakash Raman - primary author , study design, data collection/supervision, data analysis, wrote manuscript

Joy C MacDermid – study design, reviewed manuscript

George Athwal – supplied patient list

Chapter 5: A Rasch analysis indicates that the simple shoulder test is robust; but its current format does not completely adhere to optimal measurement principles:

Jayaprakash Raman - primary author , study design, data collection, data analysis, wrote

manuscript

Joy C MacDermid – study design, reviewed manuscript

David Walton – reviewed manuscript

Chapter 6: Summary:

Jayaprakash Raman – sole author

EPIGRAPH

The woods are lovely, dark, and deep,

But I have promises to keep,

And miles to go before I sleep,

And miles to go before I sleep.

ROBERT FROST
(Stopping by Woods on a Snowy Evening)

ACKNOWLEDGEMENTS

I would like to thank my supervisor, Joy MacDermid, for accepting me as her student, for all the support and guidance that she provided me for the past four years. Her commitment to clinical research and clinical insight has provided tremendous inspiration to many students at HULC Clinical research lab. Her support and help were the major reasons that I survived my first year in graduate school.

My sincere thanks to David Walton for the efforts that he put in to teach the statistical elements in meta-analysis and supporting me in the statistical analysis and reviews of other papers. He had been kind enough to let me use his lab to complete my meta-analysis. I appreciate the support of Dr. Ruby Grewal (St. Joseph's Health Care, London, ON) and Dr. Olaf Kraus de Camargo (McMaster University, Hamilton, ON) for being the examiners in my comprehensive examinations and helping me to achieve an important milestone in my studies.

Thanks to all the professors in the School of Physical Therapy and Health and Rehabilitation Sciences for helping me at various stages during my study. Thanks to all my patients and friends who helped in my clinical studies. I appreciate all their effort to participate in my studies.

Special thanks to Nancy Inchley and Cathy Collins at the HRS office (Elborn College) for their tremendous support and help starting from day 1 of my graduate course. I also appreciate help from Kate Kelly (HULC) and Joshua Vincent for helping me in recruiting subjects for my studies for without their help I would not have completed my studies. Thanks to Dr. George Athwal for providing me with the list of patients to recruit in my studies. I also acknowledge help from Kathryn Sinden (McMaster University), Catherine Gelinas, Emily Lalone and Derek Cheung (HULC) for helping me at various times during my studies.

Three friends who had supported me all these years need special mention. Ravindiran Appunni, my friend for 20 years, Sandhya Vattikonda and Shrikant Chinchalkar have supported me through my tough times and given valuable help and advice that i would never forget at any point in my life.

It is tradition to thank family members at the end of any acknowledgement. It is not a sign of ignorance or formality, rather a sign that indicates family members stay with us till the end. I am grateful to my mother, Hamsa, and my wife's parents, Emily and Dhandapani, for their

love and support in all my endeavours. They may be distant in miles, in India, but always close to my heart. My father, Raman Kutty, though not with me physically, has been my inspiration, my role model, my guide and strength who laid the foundation for my education and has been my light all through my life. My daughter, Keerthana and wife, Malini are my pillars of support. All credits for whatever I achieve at any time in my life will go to them for without them I would not have been what I am today.

My prayers to God, the Almighty to lead us from the front and thanks to all his kindness.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

LIST OF APPENDICES

CHAPTER 1. INTRODUCTION

Background

Rotator cuff disease is a painful condition with a multifactorial aetiology in which severe or chronic impingement of the rotator cuff tendons on the under-surface of the coracoacromial arch is often a significant factor.[1] Rotator cuff tears (RCT) are a common contributing factor of occupational disability[2] and impair quality of life.[3] Rotator cuff tears are often the cause of debilitating shoulder pain, reduced shoulder function, and compromised joint mechanics[4] with clinical manifestations of shoulder stiffness, weakness, instability and roughness.[5] Causes responsible for tear include anatomical factors, age related degeneration, tendon hypovascularity, genetic factors and traumatic injuries.[1,6] Although cuff strength may be compromised by inflammatory arthritis and steroids, the primary cause of tendon degeneration is aging.[5]

Exercise therapy is the first treatment approach for patients with rotator cuff tears.[7,8] Surgery is indicated when conservative management fails or in cases of a large to massive tears. The types of surgery to be used, effect of different types of surgeries and clinical outcomes after repair have been topics of disputes and controversies in the literature.[9] Various authors have reported on prognosis of outcomes after repair depending on the type and method of surgery. The different outcomes that are used to explain prognosis are pain, range of motion of shoulder, strength of shoulder musculature, function and health related quality of life.

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. Treatment protocols after repair are decided by surgeons and depend on the tendon repaired, healing time of that tendon and preferences by surgeons.[8] Creating an optimal treatment protocol would benefit from evidence-based information on factors that predict prognosis after rotator cuff repair and quantified evidence on improvements in shoulder function in terms of muscle performances and range of motion which is lacking in the literature. Questions that are still to be answered in this context and which would help in formulating treatment protocols in the future are: “what are the prognostic factors that would predict outcomes after rotator cuff repair?,” “how does rotator cuff repair change the functional ROM in shoulder and how do patients adapt to change?,” “what are the effects of rotator cuff repair on muscle performances of the shoulder?” We have attempted to find answers to all these questions in this thesis through a meta-analysis of the existing literature

on prognosis and prospective clinical studies to quantify functional ROM and muscle performances before and after rotator cuff repair.

Rotator cuff anatomy

The shoulder complex, composed of the clavicle, scapula, and humerus, is an intricately designed combination of three joints linking the upper extremity to the thorax. The articular structures of the shoulder complex are designed primarily for mobility, allowing us to move and position the hand through a wide range of space. The glenohumeral (GH) joint, linking the humerus and scapula, has greater mobility than any other joint in the body.[10] Stability of the shoulder joint relies heavily on muscular control for securing the upper limb to the thorax to provide a stable base for upper extremity movements.[10,11]

The rotator cuff is a complex of four muscles, supraspinatus, infraspinatus, subscapularis and teres minor, that arise from the scapula and whose tendons blend in with the subjacent capsule as they attach to the tuberosities of the humerus. The insertion of these tendons as a continuous cuff around the humeral head permits the cuff muscles to provide an infinite variety of moments to the rotate the humerus and oppose unwanted components of deltoid and pectoralis muscle force. The long head of the biceps tendon may be considered a functional part of the rotator cuff. Tension in the long head of the biceps can help compress the humeral head into the glenoid.[5]

The strain within the rotator cuff increased in positions of greater abduction, even when the same force was applied throughout the range of movement of the shoulder.[12] The magnitude of force that can be delivered by a cuff muscle is determined by its size, health and position of the joint. Although, young healthy tendons seem to tolerate their complex loading situation without difficulty, structurally inferior tissue, tissues with compromised repair potential or tendons frequently subjected to unusually large loads can degenerate in their hostile mechanical environment.[5] The supraspinatus tendon is anatomically most affected by impingement which coincides with an area of reduced vascularity in this tendon.[1]

Historical overview of rotator cuff tears[5]

It is certainly not obvious who first used the term rotator cuff or musculo-tendinous cuff .[5] Credit for first describing ruptures of this structure is often given to J. G. Smith who in 1834 described the occurrence of tendon rupture after shoulder injury in the London Medical Gazette.[13] In 1924

Meyer published his attrition theory of cuff ruptures.[14] In his 1934 classic monograph, Codman summarized his 25 years of observations on the musculo-tendinous cuff and its components and discussed ruptures of the supraspinatus tendon.[15]

Codman was the first to point out that many cases of inability to abduct the arm are due to incomplete or complete ruptures of the supraspinatus tendon.[15] With Codman's findings it was proved that humeroscapular periarthritis was not only a disease condition localized in the subacromial bursa but that pathological changes also occurred in the tendon aponeurosis of the shoulder joint.[5] Pettersson has provided an excellent summary of the early history of published observations on subacromial pathology.[16] He has stated that the tendon aponeurosis of the shoulder joint and the subacromial bursa are intimately connected with each other and an investigation on the pathological changes in one of these formations will necessarily concern the other one also.

The term "impingement syndrome" was popularized by Charles Neer in 1972.[17] Neer emphasized that the supraspinatus insertion to the greater tuberosity and the bicipital groove lie anterior to the coracoacromial arch with the shoulder in the neutral position and that with forward flexion of the shoulder these structures must pass beneath the arch providing the opportunity for abrasion. He suggested a continuum from chronic bursitis and partial tears to complete tears of the supraspinatus tendon which may extend to involve rupture of other parts of the cuff.

Epidemiology of rotator cuff tears

In all clinical reports, the incidence of rotator cuff defects is relatively low before the age of 40 years, begins to rise in the 50- to 60- year old age group and continues to increase in the 70 years and older age group.[5] The incidence of full thickness tears increases with age with 6% incidence under 60 years of age as opposed to 30% in those over 60 years of age[18] and more than half of individuals in their 80s having a rotator cuff tear.[19] Keyes[20] has reported an incidence of 13.38% of torn supraspinatus tendons in 73 dissected cadavers. In a study involving 268 cadaveric specimens, the incidence of complete thickness tear was 6.7%, and that of incomplete thickness tear was 13.8% (bursal side tears: 2.6%, intratendinous tears: 7.5% and joint side tears: 3.7%).[21] Milgrom et al[22] has reported that subjects in their fourth and fifth decades of life showed a 5% to 11% prevalence of stage-3 impingement lesions, with a marked increase after this age, reaching 50% in the seventh decade and 80% prevalence in the ninth and tenth decades. Reilly et al[23] has

reported that the prevalence of full-thickness tears was 11.75% and partial thickness tears was 18.49% in a study involving 4629 shoulders out of which 2553 were included for the analysis. The total incidence percentage was 30.24%.[23] Moosmayer et al[24] reported an incidence of 7.6 % of full thickness tear out of 420 asymptomatic volunteers aged between 50 and 79 years with the incidence increasing with increasing age (50 to 59 years, 2.1%; 60 to 69 years, 5.7%; and 70 to 79 years, 15%). According to a systematic review by Mall et al,[25] traumatic rotator cuff tears are more likely to occur in relatively young (age 54.7), largely male patients who suffer a fall or trauma to an abducted, externally rotated arm.

Overview of rotator cuff tear treatment approaches

Treatment of rotator cuff tear is one of the most disputed topics in the literature. There is varied evidence on the treatment protocols after rotator cuff tear. Various studies have supported conservative management with exercise therapy to improve pain and function.[26-28] A systematic review on conservative management in full thickness rotator cuff tear by Ainsworth et al[7] has suggested that some evidence exists to support the use of exercise in the management of full thickness rotator cuff tears. Heveron et al[29] has suggested that the initial treatment for rotator cuff tear should be conservative and surgery can be indicated if non-operative management failed. Codman recommended early operative repair for complete cuff tears. He carried out what may have been the first cuff repair in 1909.[15] Current views of cuff tear, pathogenesis, diagnosis and treatment are quite similar to those that he proposed over 50 years ago. Ten years after the publication of Codman's book, McLaughlin[30] wrote on the aetiology of cuff tears and their management concluding that retracted tears of the musculo-tendinous cuff can be repaired regardless of their duration, size, shape, or amount of retraction so that uniformly good results may be obtained and that massive avulsion of the cuff, per se, does not warrant fusion of the shoulder. Rockwood and Matsen[5] state that arthrography was first carried out by Oberholtzer in 1933 using air as the contrast medium and that Lindblom and Palmer used radio-opaque contrast and described partial-thickness, full-thickness and massive tears of the cuff in 1939.

Arthroscopic rotator cuff repair

Shoulder arthroscopy has undergone dramatic growth since the first clinical report by Andren and Lundberg in 1965,[31] Conti in 1979,[32] and Wiley and Older in 1980.[33] Since the1980s, advances in technology and growing experience have led to an expansion of indications for use

of arthroscopic repair. Arthroscopic treatment and its effects on outcomes have been reported by several authors.[34-38] Arthroscopic-assisted mini open rotator cuff repair was initially reported by Levy and associates[39] in 1990. Arthroscopy allows a unique combination of maximal surgical visualisation with minimal soft tissue trauma. Arthroscopic rotator cuff repair offers a number of advantages over traditional open repair techniques. More thorough visualisation, diagnosis, and treatment of lesions within the joint are facilitated, which is critical because a high prevalence of concomitant intra-articular pathology has been reported in patients undergoing rotator cuff repair.[40] Arthroscopic repair allows a more comprehensive assessment of rotator cuff tear configuration by viewing from multiple angles. Tendon mobilisation is also facilitated by precise release of adhesions that limit tendon excursion, leading to an improved ability to anatomically reduce the edge and create a tension-free repair. It also frees the surgeon from spatial limitations offering superior visualisation of the entire cuff and aiding in tear-pattern recognition, tendon mobilisation and anatomic repair. The most important disadvantage of this method is the level of technical difficulty with the procedure. Another disadvantage is the inability to completely mirror the open procedure with regard to fixation options.[5]

Outcome measures for shoulder conditions

A number of instruments have been developed to measure the quality of life in patients with various conditions of the shoulder. Older instruments appear to have been developed at a time when little information was available on the appropriate methodology for instrument development. Much progress has been made in this area, and currently an appropriate instrument exists for each of the main conditions of the shoulder.[41] These tools assess pain, range of motion and the ability of patients to do particular tasks that relate to activities of daily living (ADL), sports, work, recreational activities and also attempt to capture the emotional aspect of doing such activities. Some of the shoulder outcome measures commonly used are The Rating sheet for Bankart repair (Rowe), The American Shoulder and Elbow Surgeons evaluation form (ASES), The University of California at Los Angeles shoulder rating scale (UCLA), The Constant score, Disabilities of the Arm, Shoulder and Hand (DASH), The Shoulder Rating Questionnaire, The Simple Shoulder Test (SST), The Western Ontario Osteoarthritis of the Shoulder Index (WOOS), The Western Ontario Rotator Cuff Index (WORC), The Western Ontario Shoulder Instability Index (WOSI), Rotator Cuff Quality of Life (RC-QOL), and The Oxford Shoulder Scores (OSS).[41] Some authors have used a visual analog scale for documenting pain in shoulder

conditions.[42-44] The psychometric properties of these questionnaires have been reported extensively in the literature.[45-49,50]

Outcomes after rotator cuff repair

Literature provides varied evidence on the incidence of re-tears and clinical outcomes after repair of rotator cuff.[51-53] Hanusch et al[54] reported incidence of re-tears as low as 17% after a mini-open procedure to repair rotator cuff whereas Chung et al[55] has reported that the anatomic failure rate was 39.8% in arthroscopically repaired massive rotator cuff tears with significant improvement in functional status regardless of cuff healing. Arthroscopic rotator cuff repair leads to substantial improvement in health related quality of life scores as measured by SF-36 questionnaire at 12 months after surgery.[56] Studies by Kim KC et al,[57] Musil et al[58] have reported significant improvement in shoulder outcome scores as measured by UCLA score, Constant score and ASES score after arthroscopic rotator cuff repair. A study by Jost et al[59] documents significant decreases in pain ($p = 0.0026$) and improvement in function ($p = 0.0005$) and strength ($p = 0.0137$) even if magnetic resonance imaging documents that the repair has failed. One study by Kim JR et al has reported poorer outcomes due to arthroscopic repair stating that arthroscopic repair of massive rotator cuff tears using a suture bridge technique has a relatively high re-tear rate, and these structural failures appear to have a significant difference in clinical outcomes compared with the healed group.[51]

Significant improvements in ROM and strength of shoulder after rotator cuff repair has been reported by many authors,[60,61] many of whom have attempted to compare two different treatment protocols on patients after rotator cuff repair[62,63] or 2 different techniques of surgery.[64-69] Improvements in pain-free flexion from an average of 92 degrees to an average of 142 degrees and in abduction from an average of 82 degrees to an average of 137 degrees with significant improvement in strength of shoulder abductors 2 years after surgery has been reported by Gerber et al.[70] Significant improvement in shoulder ROM and strength has been reported by Lee et al[71] who compared the effect of 2 different rehabilitation protocols with aggressive and limited passive rehabilitation after arthroscopic rotator cuff repair. They have concluded that different rehabilitation protocols does not have significant difference in improving shoulder ROM and strength with significant improvement in both groups. Chung et al has studied the incidence of post-operative stiffness in 288 patients and have reported that the incidence of postoperative

stiffness was 18.6% (54/288) at 3 months, 2.8% (8/288) at 6 months, and 6.6% (19/288) at 1 year after surgery.[72]

Importance of prognosis research

Prognosis is a medical term for predicting the likely outcome of one's current standing. Prognosis research provides information about the long-term health and well-being of individuals with specific diseases or conditions. Prognostic information is important for clinicians, health service providers and consumers.[73] Prognostic research is important for establishing clinical predication rules to determine the degree to which individuals are at risk for certain outcomes. Clinical predication rules also help to determine the likelihood that a patient will respond positively to a specific intervention.[74]

Summary of limitations in current literature

The incidence of rotator cuff tear and the volume of rotator cuff repair have been very high as reported in the literature. But evidence-based knowledge on the predictors of prognosis after rotator cuff repair has been very few and no study has yet attempted to pool and analyse all the studies to form a database of prognostic factors. This database will be very important and crucial in helping clinicians on deciding on what outcomes to expect after surgery and to determine the treatment protocol based on the presence of these prognostic factors.

Also, there are studies in the literature that have attempted to quantify the functional ROM in the shoulder in normal subjects during various activities of daily living. But to this authors' knowledge, there has been no study that has followed patients before and after rotator cuff repair to study functional ROM in the shoulder during daily activities and reported movement patterns before and after repair. A similar situation exists in terms of muscle performances after rotator cuff repair. Analysing muscle endurance and fatigue is employed in the fields of sports research and healthy people[75-77] with no studies attempting to follow changes in muscle performances after rotator cuff repair. Evidence-based knowledge on the functional ROM and response of muscles after repair of the rotator cuff would help clinicians in formulating protocols to improve function, strength and endurance in patients after rotator cuff repair.

Many self-reported outcome measures have been developed and used to capture outcomes in various shoulder conditions. The psychometric properties of these outcome

measures have been analysed and reported using traditional methods. New methods have been developed to analyse the psychometric properties of outcome measures of which Rasch model[78] is new and is used in construction of measures to ensure that the items cover a broad scope of quantity of a single construct and that there is no differential bias based on the type of respondent. Since Rasch was not in use when many of our current measures were created, it is essential that these outcome measures are also examined under the new model to ensure that their measurement qualities stay update to the current trend in research. We have chosen the Simple Shoulder Test (SST) for analyses under the Rasch model as it is one of the frequently used and reliable questionnaires used in shoulder conditions.[45, 47, 79-82]

Purpose of this thesis

The overall purpose of this thesis was to study prognosis after rotator cuff repair and to standardize an outcome measure used in shoulder conditions using Rasch model. This was achieved with four separate studies. The objectives of the studies were:

- To evaluate the quality and content of prognosis research on predictors of pain and disability after rotator cuff repair and to establish a set of predictors, both subjective and objective, that would have a role in predicting outcomes after rotator cuff repair.
- To perform a quantitative analysis of shoulder kinematics during functional tasks of the upper limb before and after rotator cuff repair using 2D video analysis procedures and to determine the test-retest reliability of using 2D video analysis software to assess shoulder motion during activities of daily living performed before and after rotator cuff surgery.
- To describe the endurance and fatigue patterns for shoulder abduction and external rotation in patients who underwent rotator cuff repair; and to compare muscle performance to that demonstrated by age- and gender-matched controls.
- To assess the fit of SST to the Rasch model in patients with shoulder problems at different time points before (pre-operative) and after surgery (up to one year after surgery) and across different genders.

Overview of thesis chapters

After deciding to study prognosis after rotator cuff repair, we decided to search the existing literature for available evidence on prognostic factors that would significantly predict outcomes

in patients undergoing rotator cuff repair. We could find many articles published in the literature with reports on individual prognostic factors. But there was no published literature that has attempted to pool all existing evidences to create a database of predictors. Hence, we decided to perform a meta-analysis on all existing published literature to pool and analyse possible prognostic factors that would positively or negatively affect outcomes after rotator cuff repair which is presented in the next chapter. The findings showed significant effect for fatty degeneration in the rotator cuff as a predictor with modest effects for other pre-operative factors such as pre-operative muscle strength, multiple tendon involvement in rotator cuff tear and workman's' compensation status.

Chapter 3 addresses the change in shoulder ROM for performing activities of daily living following rotator cuff repair. Subjects were followed at three different time points, before surgery, at 3 months and 6 months after surgery, and were evaluated for their functional ROM in shoulder while performing 5 different tasks from DASH and results analysed. We found out that movement patterns changed based on subjects' level of pain and shoulder stiffness after surgery and eventually functional ROM improved at 6 months after surgery compared to levels before surgery, with significant change in 2 activities at different time points and a trend towards significance improvement for one activity.

Chapter 4 discusses the change in muscle performances after rotator cuff repair. Subjects were tested at 6 months after surgery for their muscle performances in terms of endurance and fatigue and results compared with age- and gender-matched controls. A published endurance protocol which had reported fatigue in healthy subjects was tested on patients after rotator cuff repair. Muscle performances had improved after surgery with increase in mean peak torque and total work done when compared before and after the endurance protocol with no fatigue due to the protocol.

Chapter 5 presents the results of the analysis of the Simple Shoulder Test, one of the commonly used outcome measures in shoulder conditions, using the Rasch model which is one of the new methods for analyzing clinical measurement properties. This questionnaire has been reported to have good psychometric properties when analysed using traditional analytical methods, but has not been tested for its fit in the Rasch model. Results of the analysis indicate that a number of properties of the SST were supported in the analysis and the SST appears to be robust when tested against the Rasch model with areas for potential improvement to suit the questionnaire to all populations.

The final chapter provides a discussion on the results of all the studies with comparison from the existing literature. We have also suggested directions for future research based on the conclusion from our studies. In summary, through this thesis we attempted to widen the knowledge in the literature that exists for prognosis after rotator cuff repair. We have formed a database of prognostic factors, studied the change in functional ROM in terms of quantity and quality of movement and changes in muscle performances following rotator cuff repair. These information will help clinicians in developing a treatment protocol for patients following surgery for repair of the rotator cuff.

REFERENCES

1. Standring, S., & Gray, H. (2008). *Gray's anatomy :The anatomical basis of clinical practice* (40th , anniversary ed.). Edinburgh: Churchill Livingstone/Elsevier.
2. Smith, M. A., & Smith, W. T. (2010). Rotator cuff tears: An overview. *Orthopaedic Nursing / National Association of Orthopaedic Nurses, 29*(5), 319-22; quiz 323-4. doi: 10.1097/NOR.0b013e3181edd8b6; 10.1097/NOR.0b013e3181edd8b6
3. Piitulainen, K., Ylinen, J., Kautiainen, H., & Hakkinen, A. (2012). The relationship between functional disability and health-related quality of life in patients with a rotator cuff tear. *Disability and Rehabilitation, 34*(24), 2071-2075. doi: 10.3109/09638288.2012.670363; 10.3109/09638288.2012.670363
4. McCarron, J. A., Milks, R. A., Mesiha, M., Aurora, A., Walker, E., Iannotti, J. P., & Derwin, K. A. (2012). Reinforced fascia patch limits cyclic gapping of rotator cuff repairs in a human cadaveric model. *Journal of Shoulder and Elbow Surgery / American Shoulder and Elbow Surgeons ...[Et Al.], 21*(12), 1680-1686. doi: 10.1016/j.jse.2011.11.039; 10.1016/j.jse.2011.11.039
5. Rockwood, C. A. (2009). *The shoulder* (4th ed.). Philadelphia, PA: Saunders/Elsevier.
6. Gumina, S., Carbone, S., Campagna, V., Candela, V., Sacchetti, F. M., & Giannicola, G. (2013). The impact of aging on rotator cuff tear size. *Musculoskeletal Surgery, 97 Suppl 1*, 69-72. doi: 10.1007/s12306-013-0263-2; 10.1007/s12306-013-0263-2
7. Ainsworth, R., & Lewis, J. S. (2007). Exercise therapy for the conservative management of full thickness tears of the rotator cuff: A systematic review. *British Journal of Sports Medicine, 41*(4), 200-210. doi: 10.1136/bjsm.2006.032524

8. Appunni, R. (2012). *Physical therapy following shoulder rotator cuff repair*. London, Ont.: School of Graduate and Postdoctoral Studies, University of Western Ontario.
9. Seida, J. C., LeBlanc, C., Schouten, J. R., Mousavi, S. S., Hartling, L., Vandermeer, B., . . . Sheps, D. M. (2010). Systematic review: Nonoperative and operative treatments for rotator cuff tears. *Annals of Internal Medicine, 153*(4), 246-255. doi: 10.1059/0003-4819-153-4-201008170-00263; 10.1059/0003-4819-153-4-201008170-00263
10. Levangie P.K., & Norkin C.C (2005). *Joint Structure and function. A Comprehensive analysis (4th ed.).* F.A Davis Company, Philadelphia.
11. Stobbe, T. J. (1996). Occupational ergonomics and injury prevention. *Occupational Medicine (Philadelphia, Pa.), 11*(3), 531-543.
12. Bey, M. J., Song, H. K., Wehrli, F. W., & Soslowsky, L. J. (2002). Intratendinous strain fields of the intact supraspinatus tendon: The effect of glenohumeral joint position and tendon region. *Journal of Orthopaedic Research : Official Publication of the Orthopaedic Research Society, 20*(4), 869-874. doi: 10.1016/S0736-0266(01)00177-2.
13. Smith, J. G. (2010). The classic: Pathological appearances of seven cases of injury of the shoulder-joint: With remarks. 1834. *Clinical Orthopaedics and Related Research,* 468(6), 1471-1475. doi: 10.1007/s11999-010-1231-x; 10.1007/s11999-010-1231-x
14. Meyer AW. Further evidences of attrition in the human body. *Am J Anat* 1924:34:241-67.
15. Codman EA. The shoulder. Malibar, Florida: R.E. Kreiger; 1934. p 91-4.:34:241-67.
16. Pettersson G. Rupture of the tendon aponeurosis of the shoulder joint in anterioir-inferior dislocation. *Acta Chir Scand (Suppl)* 77:1-187, 1942
17. Neer, C. S.,2nd. (2005). Anterior acromioplasty for the chronic impingement syndrome in the shoulder. 1972. *The Journal of Bone and Joint Surgery.American Volume, 87*(6), 1399. doi: 10.2106/JBJS.8706.cl
18. Lehman, C., Cuomo, F., Kummer, F. J., & Zuckerman, J. D. (1995). The incidence of full thickness rotator cuff tears in a large cadaveric population. *Bulletin (Hospital for Joint Diseases (New York, N.Y.)), 54*(1), 30-31.
19. Tashjian, R. Z. (2012). Epidemiology, natural history, and indications for treatment of rotator cuff tears. *Clinics in Sports Medicine, 31*(4), 589-604. doi: 10.1016/j.csm.2012.07.001; 10.1016/j.csm.2012.07.001

20. Keyes, E. L. (1933). Observations on rupture of the supraspinatus tendon: Based upon a study of seventy-three cadavers. *Annals of Surgery, 97*(6), 849-856.
21. Yamanaka, K. (1988). Pathological study of the supraspinatus tendon. *Nihon Seikeigeka Gakkai Zasshi, 62*(12), 1121-1138.
22. Milgrom, C., Schaffler, M., Gilbert, S., & van Holsbeeck, M. (1995). Rotator-cuff changes in asymptomatic adults. the effect of age, hand dominance and gender. *The Journal of Bone and Joint Surgery.British Volume, 77*(2), 296-298.
23. Reilly, P., Macleod, I., Macfarlane, R., Windley, J., & Emery, R. J. (2006). Dead men and radiologists don't lie: A review of cadaveric and radiological studies of rotator cuff tear prevalence. *Annals of the Royal College of Surgeons of England, 88*(2), 116-121. doi: 10.1308/003588406X94968
24. Moosmayer, S., Smith, H. J., Tariq, R., & Larmo, A. (2009). Prevalence and characteristics of asymptomatic tears of the rotator cuff: An ultrasonographic and clinical study. *The Journal of Bone and Joint Surgery.British Volume, 91*(2), 196-200. doi: 10.1302/0301-620X.91B2.21069; 10.1302/0301-620X.91B2.21069
25. Mall, N. A., Lee, A. S., Chahal, J., Sherman, S. L., Romeo, A. A., Verma, N. N., & Cole, B. J. (2013). An evidenced-based examination of the epidemiology and outcomes of traumatic rotator cuff tears. *Arthroscopy : The Journal of Arthroscopic & Related Surgery : Official Publication of the Arthroscopy Association of North America and the International Arthroscopy Association, 29*(2), 366-376. doi: 10.1016/j.arthro.2012.06.024; 10.1016/j.arthro.2012.06.024
26. Itoi, E., & Tabata, S. (1992). Conservative treatment of rotator cuff tears. *Clinical Orthopaedics and Related Research, (275)*(275), 165-173.
27. Bartolozzi, A., Andreychik, D., & Ahmad, S. (1994). Determinants of outcome in the treatment of rotator cuff disease. *Clinical Orthopaedics and Related Research, (308)*(308), 90-97.
28. Hawkins, R. H., & Dunlop, R. (1995). Nonoperative treatment of rotator cuff tears. *Clinical Orthopaedics and Related Research, (321)*(321), 178-188.
29. Heveron, B., & Kaempffe, F. A. (1995). Tears of the rotator cuff. *Orthopaedic Nursing / National Association of Orthopaedic Nurses, 14*(6), 38-41.

30. McLaughlin, H. L. (1994). Lesions of the musculotendinous cuff of the shoulder. the exposure and treatment of tears with retraction. 1944. *Clinical Orthopaedics and Related Research, (304)*(304), 3-9.
31. Andren, L., & Lundberg, B. J. (1965). Treatment of rigid shoulders by joint distension during arthrography. *Acta Orthopaedica Scandinavica, 36*, 45-53.
32. Conti, V. (1979). Arthroscopy in rehabilitation. *The Orthopedic Clinics of North America, 10*(3), 709-711.
33. Wiley, A. M., & Older, M. W. (1980). Shoulder arthroscopy. investigations with a fibreoptic instrument. *The American Journal of Sports Medicine, 8*(1), 31-38.
34. Andrews, J. R., Broussard, T. S., & Carson, W. G. (1985). Arthroscopy of the shoulder in the management of partial tears of the rotator cuff: A preliminary report. *Arthroscopy : The Journal of Arthroscopic & Related Surgery : Official Publication of the Arthroscopy Association of North America and the International Arthroscopy Association, 1*(2), 117-122.
35. Ellman, H., & Kay, S. P. (1991). Arthroscopic subacromial decompression for chronic impingement. two- to five-year results. *The Journal of Bone and Joint Surgery.British Volume, 73*(3), 395-398.
36. Esch, J. C., Ozerkis, L. R., Helgager, J. A., Kane, N., & Lilliott, N. (1988). Arthroscopic subacromial decompression: Results according to the degree of rotator cuff tear. *Arthroscopy : The Journal of Arthroscopic & Related Surgery : Official Publication of the Arthroscopy Association of North America and the International Arthroscopy Association, 4*(4), 241-249.
37. Gartsman, G. M. (1990). Arthroscopic acromioplasty for lesions of the rotator cuff. *The Journal of Bone and Joint Surgery.American Volume, 72*(2), 169-180.
38. Ogilvie-Harris, D. J., & Wiley, A. M. (1986). Arthroscopic surgery of the shoulder. A general appraisal. *The Journal of Bone and Joint Surgery.British Volume, 68*(2), 201-207.
39. Levy, H. J., Uribe, J. W., & Delaney, L. G. (1990). Arthroscopic assisted rotator cuff repair: Preliminary results. *Arthroscopy : The Journal of Arthroscopic & Related Surgery : Official Publication of the Arthroscopy Association of North America and the International Arthroscopy Association, 6*(1), 55-60.
40. Miller, C., & Savoie, F. H. (1994). Glenohumeral abnormalities associated with full-thickness tears of the rotator cuff. *Orthopaedic Review, 23*(2), 159-162.

41. Kirkley, A., Griffin, S., & Dainty, K. (2003). Scoring systems for the functional assessment of the shoulder. *Arthroscopy : The Journal of Arthroscopic & Related Surgery : Official Publication of the Arthroscopy Association of North America and the International Arthroscopy Association, 19*(10), 1109-1120. doi: 10.1016/j.arthro.2003.10.030
42. Kim, K. C., Shin, H. D., Cha, S. M., & Kim, J. H. (2013). Repair integrity and functional outcomes for arthroscopic margin convergence of rotator cuff tears. *The Journal of Bone and Joint Surgery.American Volume, 95*(6), 536-541. doi: 10.2106/JBJS.L.00397; 10.2106/JBJS.L.00397
43. Lee, J. J., Yoo, Y. S., Hwang, J. T., Kim, D. Y., Jeon, S. J., Hwang, S. M., & Jang, J. S. (2013). Efficacy of direct arthroscopy-guided suprascapular nerve block after arthroscopic rotator cuff repair: A prospective randomized study. *Knee Surgery, Sports Traumatology, Arthroscopy : Official Journal of the ESSKA,* doi: 10.1007/s00167-013-2451-x
44. Cho, N. S., Ha, J. H., & Rhee, Y. G. (2007). Patient-controlled analgesia after arthroscopic rotator cuff repair: Subacromial catheter versus intravenous injection. *The American Journal of Sports Medicine, 35*(1), 75-79. doi: 10.1177/0363546506291632
45. Roy, J. S., MacDermid, J. C., & Woodhouse, L. J. (2009). Measuring shoulder function: A systematic review of four questionnaires. *Arthritis and Rheumatism, 61*(5), 623-632. doi: 10.1002/art.24396; 10.1002/art.24396
46. Roy JS, MacDermid JC, Woodhouse LJ. A systematic review of the psychometric properties of the Constant-Murley score. J Shoulder Elbow Surg 2010;19(1):157-164.
47. Roy, J. S., Macdermid, J. C., Faber, K. J., Drosdowech, D. S., & Athwal, G. S. (2010). The simple shoulder test is responsive in assessing change following shoulder arthroplasty. *The Journal of Orthopaedic and Sports Physical Therapy, 40*(7), 413-421. doi: 10.2519/jospt.2010.3209
48. Ekeberg, O. M., Bautz-Holter, E., Tveita, E. K., Keller, A., Juel, N. G., & Brox, J. I. (2008). Agreement, reliability and validity in 3 shoulder questionnaires in patients with rotator cuff disease. *BMC Musculoskeletal Disorders, 9,* 68-2474-9-68. doi: 10.1186/1471-2474-9-68; 10.1186/1471-2474-9-68

49. Raman, J., & Macdermid, J. C. (2012). Western ontario rotator cuff index. *Journal of Physiotherapy, 58*(3), 201-9553(12)70115-7. doi: 10.1016/S1836-9553(12)70115-7; 10.1016/S1836-9553(12)70115-7
50. Bot, S. D., Terwee, C. B., van der Windt, D. A., Bouter, L. M., Dekker, J., & de Vet, H. C. (2004). Clinimetric evaluation of shoulder disability questionnaires: A systematic review of the literature. *Annals of the Rheumatic Diseases, 63*(4), 335-341.
51. Kim, J. R., Cho, Y. S., Ryu, K. J., & Kim, J. H. (2012). Clinical and radiographic outcomes after arthroscopic repair of massive rotator cuff tears using a suture bridge technique: Assessment of repair integrity on magnetic resonance imaging. *The American Journal of Sports Medicine, 40*(4), 786-793. doi: 10.1177/0363546511434546; 10.1177/0363546511434546
52. Zumstein, M. A., Jost, B., Hempel, J., Hodler, J., & Gerber, C. (2008). The clinical and structural long-term results of open repair of massive tears of the rotator cuff. *The Journal of Bone and Joint Surgery.American Volume, 90*(11), 2423-2431. doi: 10.2106/JBJS.G.00677; 10.2106/JBJS.G.00677
53. Bartl, C., Senftl, M., Eichhorn, S., Holzapfel, K., Imhoff, A., & Salzmann, G. (2012). Combined tears of the subscapularis and supraspinatus tendon: Clinical outcome, rotator cuff strength and structural integrity following open repair. *Archives of Orthopaedic and Trauma Surgery, 132*(1), 41-50. doi: 10.1007/s00402-011-1400-8; 10.1007/s00402-011-1400-8
54. Hanusch, B. C., Goodchild, L., Finn, P., & Rangan, A. (2009). Large and massive tears of the rotator cuff: Functional outcome and integrity of the repair after a mini-open procedure. *The Journal of Bone and Joint Surgery.British Volume, 91*(2), 201-205. doi: 10.1302/0301-620X.91B2.21286; 10.1302/0301-620X.91B2.21286
55. Chung, S. W., Kim, J. Y., Kim, M. H., Kim, S. H., & Oh, J. H. (2013). Arthroscopic repair of massive rotator cuff tears: Outcome and analysis of factors associated with healing failure or poor postoperative function. *The American Journal of Sports Medicine,* doi: 10.1177/0363546513485719
56. Chung, S. W., Park, J. S., Kim, S. H., Shin, S. H., & Oh, J. H. (2012). Quality of life after arthroscopic rotator cuff repair: Evaluation using SF-36 and an analysis of affecting

clinical factors. *The American Journal of Sports Medicine, 40*(3), 631-639. doi: 10.1177/0363546511430309; 10.1177/0363546511430309

57. Kim, K. C., Shin, H. D., Lee, W. Y., & Han, S. C. (2012). Repair integrity and functional outcome after arthroscopic rotator cuff repair: Double-row versus suture-bridge technique. *The American Journal of Sports Medicine, 40*(2), 294-299. doi: 10.1177/0363546511425657; 10.1177/0363546511425657
58. Musil, D., Sadovsky, P., & Stehlik, J. (2006). Massive tears of rotator cuff - comparison of mini-open and arthroscopic techniques. part 1. mini-open technique. [Masivni ruptura rotatorove manzety - srovnani mini-open a artroskopicke rekonstrukce. Cast 1. Mini-open technika] *Acta Chirurgiae Orthopaedicae Et Traumatologiae Cechoslovaca, 73*(6), 387-393.
59. Jost, B., Pfirrmann, C. W., Gerber, C., & Switzerland, Z. (2000). Clinical outcome after structural failure of rotator cuff repairs. *The Journal of Bone and Joint Surgery.American Volume, 82*(3), 304-314.
60. Gartsman, G. M., Khan, M., & Hammerman, S. M. (1998). Arthroscopic repair of full-thickness tears of the rotator cuff. *The Journal of Bone and Joint Surgery.American Volume, 80*(6), 832-840.
61. Huberty, D. P., Schoolfield, J. D., Brady, P. C., Vadala, A. P., Arrigoni, P., & Burkhart, S. S. (2009). Incidence and treatment of postoperative stiffness following arthroscopic rotator cuff repair. *Arthroscopy : The Journal of Arthroscopic & Related Surgery : Official Publication of the Arthroscopy Association of North America and the International Arthroscopy Association, 25*(8), 880-890. doi: 10.1016/j.arthro.2009.01.018; 10.1016/j.arthro.2009.01.018
62. Kim, Y. S., Chung, S. W., Kim, J. Y., Ok, J. H., Park, I., & Oh, J. H. (2012). Is early passive motion exercise necessary after arthroscopic rotator cuff repair? *The American Journal of Sports Medicine, 40*(4), 815-821. doi: 10.1177/0363546511434287; 10.1177/0363546511434287
63. Cho, N. S., & Rhee, Y. G. (2008). Functional outcome of arthroscopic repair with concomitant manipulation in rotator cuff tears with stiff shoulder. *The American Journal of Sports Medicine, 36*(7), 1323-1329. doi: 10.1177/0363546508314402; 10.1177/0363546508314402

64. Shin, S. J. (2012). A comparison of 2 repair techniques for partial-thickness articular-sided rotator cuff tears. *Arthroscopy : The Journal of Arthroscopic & Related Surgery : Official Publication of the Arthroscopy Association of North America and the International Arthroscopy Association, 28*(1), 25-33. doi: 10.1016/j.arthro.2011.07.005; 10.1016/j.arthro.2011.07.005
65. DeHaan, A. M., Axelrad, T. W., Kaye, E., Silvestri, L., Puskas, B., & Foster, T. E. (2012). Does double-row rotator cuff repair improve functional outcome of patients compared with single-row technique? A systematic review. *The American Journal of Sports Medicine, 40*(5), 1176-1185. doi: 10.1177/0363546511428866; 10.1177/0363546511428866
66. Carbonel, I., Martinez, A. A., Calvo, A., Ripalda, J., & Herrera, A. (2012). Single-row versus double-row arthroscopic repair in the treatment of rotator cuff tears: A prospective randomized clinical study. *International Orthopaedics, 36*(9), 1877-1883. doi: 10.1007/s00264-012-1559-9; 10.1007/s00264-012-1559-9
67. Prasathaporn, N., Kuptniratsaikul, S., & Kongrukgreatiyos, K. (2011). Single-row repair versus double-row repair of full-thickness rotator cuff tears. *Arthroscopy : The Journal of Arthroscopic & Related Surgery : Official Publication of the Arthroscopy Association of North America and the International Arthroscopy Association, 27*(7), 978-985. doi: 10.1016/j.arthro.2011.01.014; 10.1016/j.arthro.2011.01.014
68. Walton, J. R., & Murrell, G. A. (2012). A two-year clinical outcomes study of 400 patients, comparing open surgery and arthroscopy for rotator cuff repair. *Bone & Joint Research, 1*(9), 210-217. doi: 10.1302/2046-3758.19.2000072; 10.1302/2046-3758.19.2000072
69. Saridakis, P., & Jones, G. (2010). Outcomes of single-row and double-row arthroscopic rotator cuff repair: A systematic review. *The Journal of Bone and Joint Surgery.American Volume, 92*(3), 732-742. doi: 10.2106/JBJS.I.01295; 10.2106/JBJS.I.01295
70. Gerber, C., Fuchs, B., & Hodler, J. (2000). The results of repair of massive tears of the rotator cuff. *The Journal of Bone and Joint Surgery.American Volume, 82*(4), 505-515.
71. Lee, B. G., Cho, N. S., & Rhee, Y. G. (2012). Effect of two rehabilitation protocols on range of motion and healing rates after arthroscopic rotator cuff repair: Aggressive versus

limited early passive exercises. *Arthroscopy : The Journal of Arthroscopic & Related Surgery : Official Publication of the Arthroscopy Association of North America and the International Arthroscopy Association, 28*(1), 34-42. doi: 10.1016/j.arthro.2011.07.012; 10.1016/j.arthro.2011.07.012

72. Chung, S. W., Huong, C. B., Kim, S. H., & Oh, J. H. (2013). Shoulder stiffness after rotator cuff repair: Risk factors and influence on outcome. *Arthroscopy : The Journal of Arthroscopic & Related Surgery : Official Publication of the Arthroscopy Association of North America and the International Arthroscopy Association, 29*(2), 290-300. doi: 10.1016/j.arthro.2012.08.023; 10.1016/j.arthro.2012.08.023
73. Cochrane prognosis methods group (August 2011). Retrieved May 15, 2013 from http://prognosismethods.cochrane.org/more-about-us.
74. Portney, L. G., & Watkins, M. P. (2008; 2009). *Foundations of clinical research :Applications to practice* (3rd ed.). Upper Saddle River, N.J.: Pearson/Prentice Hall.
75. Tsai, N. T., McClure, P. W., & Karduna, A. R. (2003). Effects of muscle fatigue on 3-dimensional scapular kinematics. *Archives of Physical Medicine and Rehabilitation, 84*(7), 1000-1005.
76. Dale, R. B., Kovaleski, J. E., Ogletree, T., Heitman, R. J., & Norrell, P. M. (2007). The effects of repetitive overhead throwing on shoulder rotator isokinetic work-fatigue. *North American Journal of Sports Physical Therapy : NAJSPT, 2*(2), 74-80.
77. Mullaney, M. J., & McHugh, M. P. (2006). Concentric and eccentric muscle fatigue of the shoulder rotators. *International Journal of Sports Medicine, 27*(9), 725-729. doi: 10.1055/s-2005-872870
78. Rasch G. *Probabilistic models for some intelligence and attainment tests.* Chicago: University of Chicago; 1960.
79. Lippitt SB, Harryman DT, Matsen FA. *A practical tool for evaluation of function: the simple shoulder test. The Shoulder: A Balance of Mobility and Stability.* Rosemont, IL: American Academy of Orthopaedic Surgery; 1993.
80. Beaton, D., & Richards, R. R. (1998). Assessing the reliability and responsiveness of 5 shoulder questionnaires. *Journal of Shoulder and Elbow Surgery / American Shoulder and Elbow Surgeons ...[Et Al.], 7*(6), 565-572.
81. Godfrey, J., Hamman, R., Lowenstein, S., Briggs, K., & Kocher, M. (2007). Reliability, validity, and responsiveness of the simple shoulder test: Psychometric properties by age

and injury type. *Journal of Shoulder and Elbow Surgery / American Shoulder and Elbow Surgeons ...[Et Al.], 16*(3), 260-267. doi: 10.1016/j.jse.2006.07.003

82. MacDermid, J. C., Drosdowech, D., & Faber, K. (2006). Responsiveness of self-report scales in patients recovering from rotator cuff surgery. *Journal of Shoulder and Elbow Surgery / American Shoulder and Elbow Surgeons ...[Et Al.], 15*(4), 407-414. doi: 10.1016/j.jse.2005.09.005

CHAPTER 2. PREDICTORS OF OUTCOMES AFTER ROTATOR CUFF REPAIR – A META-ANALYSIS

ABSTRACT

Study design

Systematic review and Meta-analysis.

Objective

To evaluate the quality and content of prognosis research on predictors of pain and disability after rotator cuff repair and to establish a set of predictors, both subjective and objective, that would have a role in predicting outcomes after rotator cuff repair.

Background

Full-thickness rotator cuff tear is one of the most common conditions affecting the shoulder joint. The clinical outcomes of rotator cuff repair are generally favourable, but also variable. There are varied levels of evidence in literature about factors that can predict outcomes of rotator cuff repair (RCR), but no study has attempted to review the existing literature to establish a set of predictors that would play an important role in outcomes after RCR. The aim of this study was to statistically analyse articles available in the literature on factors affecting outcomes after rotator cuff repair and to establish a set of predictors, both subjective and objective, that would have a role in the outcomes after rotator cuff repair.

Methods

An extensive electronic literature search of 4 international databases of scientific literature (Medline, CINAHL, Scopus and Embase) was conducted to identify published articles on prognosis after rotator cuff repair from inception till October 2012. Pairs of raters independently evaluated retrieved abstracts that addressed at least one prognostic variable in primary cuff repair against specified inclusion and exclusion criteria. Those meeting eligibility were subject to full text review, and if outcomes on cuff integrity or function were recorded the data was entered into the meta-analysis. The measures used in these articles were Simple Shoulder Test (SST), Constant score, University of California at Los Angeles shoulder rating scale (UCLA) and American Shoulder and Elbow Surgeons Evaluation form (ASES). All these questionnaires

measure domains of pain, function, range of motion in shoulder and overall satisfaction. Summary data were extracted, transformed where necessary, and pooled to allow for estimation of odds ratio for any predictor that was identified from the studies.

Results

Forty two articles were selected for full text review out of which only fourteen articles presented sufficient data for inclusion in to the meta-analysis. Fatty infiltration was found to be a significant predictor of poor outcomes after RCR. Larger tear size, lower pre-operative strength of the rotator cuff muscles, multiple tendon involvement and involvement of workman's compensation had a moderate, negative impact on function and cuff integrity after RCR. Older age had a modest negative effect on cuff integrity and no significant effect on functional outcomes after surgery while trauma and duration of symptoms before surgery had no significant effect on outcomes after surgery. Several of these factors were studied in only 2 cohorts and need future studies to validate their effect. Gender, pre-operative range of motion in shoulder, pre-operative muscle atrophy and pre-operative muscle pain reduction after lidocaine injection were studied in only one cohort each and thus were not subject to meta-analysis.

Conclusion

Using a rigorous process for the identification and extraction of data from a homogenous subset of prognostic rotator cuff repair literature and statistical analysis, we were able to identify some predictors for which information is easy to collect clinically and could provide clinicians with a meaningful estimate of prognosis following rotator cuff repair. Fatty infiltration appears to be significant in predicting cuff integrity after RCR. Several other pre-operative factors such as tear size, pre-operative muscle strength, multiple tendon involvement in rotator cuff tear, age and workman's compensation status also have modest effect, but more studies are required to validate their effect.

Level of Evidence 1a

Keywords Meta-analysis, prognosis, rotator cuff repair, pain, disability.

INTRODUCTION

Rotator cuff tear is a common shoulder injury that influences patients' shoulder function and health related quality of life.[1] The incidence of full thickness tears appears to increase with age, with an incidence of only 6% of patients under 60, but 30% in those over 60 years of age.[2] Rotator cuff tears are treated conservatively and when conservative management fails, surgery is indicated. Surgery is indicated as early as 3 weeks to regain optimum shoulder function.[3] The clinical outcomes of the surgical methods of rotator cuff repair (open, mini-open, and all-arthroscopic cuff repair) vary, as each method provides an array of advantages and disadvantages.[4] Successful postoperative management following rotator cuff repair is reported to be dependent on several pre- and post-surgical variables.[4] A number of studies with differing research designs have attempted to find those factors that could be relied upon to predict outcomes after rotator cuff repair. [5-18]

To date, there is yet to be a synthesis of these results to inform policy makers and clinicians about prognostic factors following rotator cuff repair. Prognostic studies can provide information on the likelihood of a particular outcome or disease recurrence, can identify target groups for treatment, or suggest intervention strategies to modify factors associated with poor outcomes. Such information is required for health care decision-making and is not always available from clinical trials. Systematic review and meta-analysis methods are increasingly being used in many topic areas to synthesize prognosis study findings. However, application of systematic review methods in the area of prognosis is in its infancy. Although basic principles to reduce bias and random error are similar to those used for intervention reviews, there are several challenges unique to systematic reviews of prognosis: low quality of primary studies; poor reporting; and difficulties in combining results across different research designs, analyses, and presentations of results.[19]

A meta-analysis refers to methods focused on contrasting and combining results from different studies, in the hope of identifying patterns among study results, sources of disagreement among those results, or other interesting relationships that may come to light in the context of multiple studies.[20] The aim of this study was to statistically analyse articles available in the literature on factors affecting outcomes after rotator cuff repair and to establish a set of predictors, both subjective and objective, that would have a role in the outcomes after rotator cuff repair.

METHODS

Search strategy

An extensive electronic literature search was conducted of 4 international databases of scientific literature (Medline, CINAHL, Scopus and Embase) to identify published articles on prognosis after rotator cuff repair from inception till October 2012. The following search terms were used in different combinations, variations and with clinical queries: (shoulder OR rotator cuff OR/AND tear, repair, surgery) AND (pain OR disability OR outcomes OR function) AND (prognosis OR prognostic OR predictors). A secondary search was done manually from the reference list of articles that were identified from the initial search. A total of 546 articles were reviewed from the 4 databases with relevance to the topic and 42 were included for full text review. Out of the 42 articles, 14 studies, where outcomes could be combined, were included in the meta-analysis.

Inclusion criteria

Articles were included in the final review if: (1) the patients underwent surgery for their rotator cuff tear, (2) the authors had pre- and post-operative data on the outcomes of the patients, (3) all subjects were 18 years of age or older, (4) the studies were in English.

Articles that met the inclusion criteria for the systematic review were included into the meta-analysis if the authors performed a prospective evaluation of 1 or more prognostic factors or clinical risk factors or if sufficient data for calculation of effect sizes were presented in articles of other study designs. Studies were included if they had followed patients for at least 1 year to ensure that prognosis of final outcomes was being addressed. The studies were subject to meta-analysis if at least 1 or more of the following data types were present: frequency counts, means and standard deviations, odds ratios, regression coefficients and standard error, regression coefficients, ‘p’ values and‘t’ values. The pooled effect estimate calculated for each predictor was the odds ratio.

Exclusion criteria (from meta-analysis)

Articles were excluded from the meta-analysis if: (1) the patients with rotator cuff tear were treated conservatively and did not undergo surgery, (2) pre-operative data was not available, (3) the patients presented with associated shoulder conditions, (4) non-prognostic studies, (5) patients underwent revision surgery for rotator cuff tear.

Data extraction and quality scoring

The titles and abstracts of the studies identified by the search strategy were reviewed by the primary author (JP) to select articles that met the inclusion criteria. Studies were included for full-text review if they were classified as relevant by at least one of the other 2 reviewers. Forty two prognostic articles that identified predictors after rotator cuff repair (RCR) were included in the final review. Data regarding the study design, participants, methodology, predictors, outcomes and results from the selected articles were extracted by the primary author using a data extraction form developed for this purpose. The articles were numbered using a random number list and this list was then used to allocate articles to pairs of raters to evaluate for study quality. To assess the quality of the articles, we used an appraisal tool by Walton and Macdermid[21] to allow for better discrimination between the levels of quality of the articles (APPENDIX 2). The scoring tool consisted of 25 items covering areas of patient sampling, exposure to predictors, outcomes measured, statistical analysis and interpretation of results. Studies with quality ratings of more than 75% were considered high quality; those with rating of 51-75% were considered moderate; and less than or equal to 50% were considered low. The articles were scored for quality by 2 independent authors and the extent of inter-rater reliability was determined using ICC[22] for the total score of each study and by weighted kappa[23] for each categorical item of the scoring tool. The ICC value for the scoring tool was 0.91 between rater 1 (JP) and rater 2 (DW), 0.99 between rater 1(JP) and rater 3 (JM) for all the items. The weighted kappa value for the individual items was 0.67 between raters 1 and 2, 0.97 between raters 1 and 3. Discrepancies in scoring were settled by mutual consensus.

Effect size calculations

Comprehensive meta-analysis software was used for this meta-analysis. Data from different studies had to be synthesized using a common effect size estimator for statistical calculation of pooled odds ratio (OR). Different studies in the systematic review presented data in different indices which made conversion complicated. Statistical pooling was performed using a random effects model, which is a more conservative approach when heterogeneity of the population is thought to exist.[24] To statistically pool the predictors for meta-analysis, we chose those predictors which were followed by at least 2 cohorts. For any predictor that was followed by only 2 cohorts, heterogeneity of the effect size[25] was calculated and the predictor was included into the meta-

analysis if heterogeneity was not significant. The procedures used to convert data are described in APPENDIX 3.

Publication bias

It is possible that the results of a meta-analysis are biased due to publication bias. Publication bias represents the bias in systematic reviews and meta-analyses that arises as a result of the greater likelihood that studies with positive and significant findings are published, while negative findings remain unpublished.[26] In order to test for the existence of such a bias we calculated the fail-safe N statistic as suggested by Rosenthal.[27] The fail-safe N can be considered an omnibus test of the robustness of the result, providing an estimate of the number of unpublished studies of non-significant results that would be required to nullify the findings of significant pooled effect size. A large fail-safe number lends credence to the finding of significance even under the assumption of a biased collection of studies.[28,29] As a general rule, a fail-safe N statistic of at least five times the number of studies included in the effect suggests the results are robust to publication bias. For calculation of fail-safe N statistic a predictor should have been studied in 3 or more cohorts.

Moderator analysis

It is possible that effect sizes (magnitude of the odds ratio in this review) are influenced by systematic sources of bias that can be explored separately. In statistics and regression analysis, moderation occurs when the relationship between two variables depends on a third variable. The third variable is referred to as the moderator variable or simply the moderator.[30] The effect of a moderating variable is characterized statistically as an interaction; that is, a qualitative (e.g., sex, race, class) or quantitative (e.g., level of reward) variable that affects the direction and/or strength of the relation between dependent and independent variables. A moderator variable can be thought of as a stratification variable, in which data are grouped and analyzed within and between levels of the variable to determine what effect, if any, that variable has on the outcome. In this review, the presence of moderator variables was determined through evaluation of the Q statistic.[30]

In this analysis, we evaluated the moderating effect of 3 variables when the studies were significantly heterogeneous:

1. Study quality, based on our quality appraisal tool, categorized as high (>75%, n = 0), moderate

(51-75%, n = 8) and low (≤50%, n = 6).

2. Length of follow-up, categorized as up to 1 year (n = 8) and >2 years (n = 6). If outcomes were collected at multiple time points, the final follow-up was considered.

3. Type of surgery: The patients included in all the studies have undergone surgery for the rotator cuff tear. The type of surgery depended on the choice of the surgeon. The most performed surgery was arthroscopic rotator cuff repair (n = 9) with some surgeons opting for open repair or mini open repair (n = 5).

These moderators were chosen based on the possibility that they may function as confounding variables in interpretation of results. The Q statistic is a statistical test of the null hypothesis that the effect sizes from each cohort in the sample are the same. The test provides a 'p' value indicating the probability that the heterogeneity within the sample of effect sizes is truly greater than zero. We chose a 'p' value of 0.05 as significant for heterogeneity. In this case, the sample is categorized based on 1 of the moderator variables listed above, and the Q_{within} for each category is determined along with the $Q_{between}$ as an omnibus test of significance between the levels of the moderator variable. An appropriate moderator variable was identified when the Q_{within} for each level of the variable was non-significant, indicating homogeneity within levels, and the $Q_{between}$ was significant indicating heterogeneity between levels of the moderator.

Operationalization of outcome on function

The articles included for analysis in this meta-analysis measured shoulder function using different shoulder outcome measures. The measures included were Simple shoulder test (SST), Constant score, University of California at Los Angeles shoulder rating scale (UCLA) and American Shoulder and Elbow Surgeons Evaluation form (ASES). All these questionnaires measure domains of pain, function, range of motion in shoulder and overall satisfaction.[31] All these measures have a strong correlation among themselves,[32-34] thus enabling the results from these measures to be pooled together. Shoulder function can be graded into excellent, good, fair and poor based on the scores obtained from these measures.[17,35]

RESULTS

A total of 42 studies were included for full text review and 14 among them (from 13 cohorts) presented data that were sufficient to be included into the meta-analysis. The cohorts included for meta-analysis were obtained from 6 prospective, 5 retrospective and 3 therapeutic case series

studies (Figure 1). Seventeen predictors were identified, but only twelve had enough data for inclusion into the meta-analysis. We found 8 predictors that were studied in 2 or more cohorts and had enough information presented to allow for meaningful statistical pooling. All predictors that were followed in only 2 cohorts were homogeneous in their effect sizes and hence none were excluded from the analysis based on heterogeneity. The 8 predictors identified were fatty infiltration,[9,11,12,15] workman's compensation status,[16,18] multiple tendon involvement,[6,8,10] pre-operative muscle strength[13,17] size of the tear,[5,7,9,11,13,14,16,17] age,[6,9,10,11,13,16,17] duration of symptoms before surgery,[13,17] and trauma.[8,9]

The results for the effect of the predictors are presented according to the order of the size of their effect.

Variables with strong evidence of significant effect

The effect of predictors, based on their OR, was considered to be strong if they were studied in more than 2 cohorts and had a fail-safe N statistic more than 5 times the number of cohorts studied. The only predictor that showed strong effect with the above criteria was fatty infiltration with its effect on cuff integrity.

1. **Fatty infiltration**

Outcome: Cuff integrity. A graphic representation of the odds ratio and 95% CI with forest plot for the effect of fatty infiltration on cuff integrity is shown in figure 2(a). Fatty infiltration, as defined by Goutallier et al,[36] was investigated in 4 cohorts (n = 505).[9,11,12,15] The results showed a significant negative effect (OR = 9.34; 95% CI: 4.22 – 20.70) with insignificant heterogeneity (I^2 = 28.76, p = 0.24) suggesting that the odds of being in the group that experienced a post-operative re-tear of their rotator cuff increased by a factor of 9.3 in those with preoperative fatty infiltration compared to those without fatty infiltration. The fail-safe N statistic was 43 (table 3).

Variables with moderate evidence of significant effect

The effect of predictors, based on their OR, was considered to be moderate if they were studied in only 2 cohorts or if the fail-safe N statistic was less than 5 times the number of cohorts studied (in predictors that were followed in more than 2 cohorts). The predictors that showed moderate evidence of effect were tear size, workman's compensation status, multiple tendon involvement, pre-operative strength of the rotator cuff muscles and the effect of age on cuff integrity. The

effect of tear size on cuff integrity and function was studied in more than 3 cohorts but was considered to be moderate as it did not show robustness to publication bias with a fail-safe N statistic of less than 5 times the number of cohorts studied. Though the other predictors showed a significant OR, their effect was considered moderate in this meta-analysis since they were studied in only 2 cohorts as can be seen from the following description.

1. **Workman's compensation (WCB) status**

Outcome: Function. The effect of WCB status as a predictor of poor function after RCR was studied in 2 cohorts (n = 148).[16,18] The odds ratio for WCB status as a predictor and 95% CI with forest plot is showed in figure 2(b). WCB status presented with a significant odds ratio of 8.67 (95 % CI: 3.13 – 24.02, table 3). The values were homogenous among the 2 cohorts studied, suggesting that receiving WCB benefits increased the risk of poor function in patients after RCR.

2. **Multiple tendon involvement**

Outcome: Cuff integrity. Figure 2(c) provides a graphic representation of the odds ratio and 95% CI with forest plot for the effect of multiple tendon involvement on cuff integrity. Multiple tendon involvement, defined as the involvement of 2 or more tendons in rotator cuff pathology, was investigated in 2 cohorts (n = 176).[8,10] The odds ratio for multiple tendon involvement as a predictor for re-tear was 6.02 (95% CI: 2.47 – 14.69, table 3) with insignificant heterogeneity (I^2 = 29.23, p = 0.24), suggesting that multiple tendon involvement lead to more re-tears after RCR.

3. **Pre-operative muscle strength**

Outcome: Function. The effect of pre-operative muscle strength was studied in 2 cohorts (n = 99).[13,17] Patients were measured for pre-operative muscle strength by manual muscle testing and were divided into 2 groups (group 1 with muscle strength less than or equal to 3/5 and group 2 with strength greater than 3/5). The effect of pre-operative muscle strength as a predictor of function is graphically represented in figure 2(d). With an odds ratio of 3.99 (95% CI: 1.45 – 11.04, table 3) and homogeneity, low pre-operative muscle strength of <3/5 appears to be a moderately significant risk factor in predicting poor function after RCR.

4. **Tear size.** The effect of tear size was the most studied among all the predictors and its effect was studied on 3 different outcomes – cuff integrity, function and satisfaction. Tear size was graded according to the classification by DeOrio[37] and Post.[38]

Outcome: Cuff integrity. The effect of tear size as a predictor of cuff integrity after RCR was studied in 4 cohorts with a total sample size of 352.[5,9,11,14] Larger tear size appeared to be a moderately significant risk factor to predict re-tear after RCR with an odds ratio of 3.41 (95% CI: 1.91 – 6.08, table 3) and insignificant heterogeneity (I^2 = 19.47, p = 0.29) as shown in figure 2(e). Though the effect was significant, the cohorts were not robust to publication bias with a fail-safe N of 16.

Outcome: Function. The effect of tear size as a predictor of function after RCR was studied in 5 cohorts (n = 371).[7,11,13,16,17] Function was determined according to the scores obtained from various shoulder specific scales like UCLA, SST and ASES. Larger tear size, as a predictor of poor function, showed a moderate but significant odds ratio of 2.72 (95% CI: 1.31 – 5.66, table 3) indicating that larger tear size resulted in decreased function scores in the shoulder specific scales (figure 2(f)). The pool of effects was not significantly heterogeneous (I^2 = 51.58, p = 0.08). The fail-safe N value of 14 indicating the effect was not robust to publication bias.

Outcome: Satisfaction. Larger tear size as a risk factor for predicting low patient satisfaction after RCR, investigated in 2 cohorts (n = 185),[6,14] showed a small but significant effect (OR = 1.79, 95% CI: 1.01 – 3.18, table 3) with homogeneity as shown in figure 2(g).

5. Age: Age as a predictor of outcomes after RCR was studied in 5 cohorts. Four cohorts[9,13,16,17] divided age groups into different categories starting from 40 years of age. We have taken 60 years of age as our reference point for calculation of risk. Age above 60 years of age was considered as older group. One cohort[11] did not define the cut point but merely stated the results for "older age".

Outcome: Cuff integrity. Age, as a predictor of cuff integrity after RCR, was studied in 2 cohorts (n = 247).[9,11]The effect of older age showed a significant negative effect on re-tear with a OR of 2.57 (95% CI: 1.47 – 4.51, table 3, figure 2(h)) with homogeneity.

Variables with evidence of no significant effect

1. Age

Outcome: Function. The effect of age on function, as measured by different shoulder specific scales (UCLA, SST and ASES), was measured in 4 cohorts (n = 218).[11,13,16,17] Age had a non-significant effect on function as a risk factor with an OR of 1.45 (95%CI: 0.32 – 6.50, table 3, figure 2(i)) and significant heterogeneity (I^2 value of 75.38, p = 0.007). When the

studies were stratified by study quality, the Q_{within} became non-significant while the $Q_{between}$ remained significant (OR = 0.55, 95%CI = 0.27 – 1.14) for moderate quality studies, indicating that the quality of the studies was a significant moderator variable that would affect the effect size of age on function. Time to follow-up and type of surgery did not act as moderators.

2. Duration of symptoms before surgery

Outcome: Function. Duration of symptoms before surgery was graded as duration less than 1 year from onset of symptoms up to surgery and greater than 1 year. Duration of symptoms as a predictor of function was studied in 2 cohorts with a total sample size of 99.[13,17] The effect of duration of symptoms before surgery was not significant with an OR of 1.17 (95% CI: 0.48 – 2.90, table 3, figure 2(j)) with homogeneity.

3. Trauma

Outcome: Cuff integrity. Two cohorts (n=218) evaluated the prognostic value of traumatic compared to non-traumatic etiologies.[8,9] The values were homogeneous across the 2 cohorts studied showing a non-significant association with cuff integrity (OR = 0.80, 95% CI: 0.42 – 1.54, table 3). This suggests that the likelihood of re-tear is not dependent on the aetiology of the condition. The forest plot is shown in figure 2(k).

DISCUSSION

Despite limitations in the evidence, this meta-analysis provided more precise estimation of the prognostic effects for a range of variables considered as predictors of outcome following rotator cuff repair. In order to ensure that the above aims and qualities of a meta-analysis are met, we used a methodical and stepwise approach to searching the literature, performed a quality assessment of the studies included with a tool specifically designed for this purpose and identified a homogenous subset of cohorts from the prognostic rotator cuff repair literature for meaningful statistical pooling.

Our analyses indicate that 6 different variables have an association with outcomes after rotator cuff repair. The information regarding some of these factors are easy to collect clinically (for example: age, pre-operative muscle strength and workman's compensation status), whereas imaging techniques such as MRI and CT scan are required for some factors as fatty infiltration, tear size and number of tendons involved.

There are a number of studies widely available in the literature that have attempted to find predictors that would determine prognosis after RCR, but after application of rigorous

inclusion criteria we were able to include only 14 studies describing 13 independent cohorts. A number of variables were investigated in one cohort only. In an effort to identify a homogenous pool of literature, we included only those predictors that were analysed or followed in at least 2 or more cohorts. If a predictor was followed in only 2 cohorts, its effect as a significant predictor was considered if the effect sizes were not significantly heterogeneous to avoid a negating effect between the cohorts. Common clinical and demographic factors such as pre-operative range of motion of the affected shoulder, pre-operative rotator cuff muscle atrophy and gender were evaluated in only a single cohort and were therefore not considered in the final analysis. The lack of consistent selection and measurement of potential prognostic variables across prognostic studies meant that only a subset of studies designed to address clinical prognosis were suitable for meta-analysis. By limiting to these, we strengthened the rigor of our analysis, but must consider that potential useful clinical information is lost when studies are excluded.

Our findings that tear size and involvement of multiple tendons are moderate predictors of re-tear, function and satisfaction after RCR are consistent with the hypothesis that larger tear size indicating greater tissue damage has negative sequelae. Poorer outcomes could be attributed to more difficulty in achieving a sturdy repair, more degenerative changes in vascular and muscular structures that compromise healing or that larger tear sizes are associated with poor overall health that also contributes to recovery. Any of these additional factors might explain the nature of this relationship where tear size is associated with pain and threefold increase in incidence of re-tear.

Age may have a complicated relationship with function since the quality of tissue may decline with age, but occupational and life demands may decrease. These may create offsetting effect on outcome that would account for a lack of significance in heterogeneity depending on the sampling and definition of age and function across studies.

Worker's compensation has been associated with higher levels of pain and disability in many musculoskeletal populations.[39] Some assume that this indicates a role for secondary gain in self-reporting of pain and disability. However, patients on workers compensation may have different work demands than those not injured at work. The fact that patients on workers compensation were six times more likely to re-tear provide support for the latter since this is an outcome that is objective and unlikely to be influenced by patient or clinician bias .

Nho et al[10] and Gladstone et al[12] have stated that the inherent quality of a muscle whose tendon is to be repaired is critical in deciding the clinical and functional outcome after RCR

which is the same as the results of our findings. The quality of a muscle depends on several factors such as fatty infiltration in the muscle belly, pre-operative muscle atrophy and strength. Our results indicate that these factors that determine the quality of a muscle are predictive of poorer outcomes after RCR. It is important that clinicians and surgeons document these findings in pre-operative assessment in order to develop a rehabilitation protocol after surgery. It is also of significant importance that the progression or regression in muscle degeneration, fatty infiltration and strength after surgery are documented to aid in the rehabilitation process. There are also chances of potential interaction between the variables and outcomes. For example, older people tend to be over protective and hence would be more reluctant for rehabilitation than the younger age group resulting in poorer outcomes after surgery leading to poorer functional outcomes in older age groups. These factors need to be considered while planning a treatment protocol to improve clinical and functional outcomes after RCR.

Gender was found to be a common variable that was included in many studies to predict outcome after RCR. But the data provided in the studies were insufficient to be pooled for this meta-analysis. We could identify only one cohort each for the effect of gender on cuff integrity[8] and function.[11] The effect of pre-operative muscle atrophy,[12] pre-operative range of motion (ROM) of shoulder[17] and pre-operative pain reduction following a lidocaine injection,[7] fatty infiltration (predicting function),[13] tear size (predicting pain),[7] duration of symptoms before surgery (predicting cuff integrity)[9] and workman's compensation status (predicting return to work)[18] were also reported in only one cohort each and hence were not considered in the results of this analysis. We would need these variables to be studied in more cohorts to validate their effect as significant predictors.

We have used odds ratio as a measure of the effect size of the predictors on outcomes after RCR. OR can be used to provide an estimate of the relative increase in risk of a poor outcome for a patient with a specific risk factor, as compared to another individual who does not have that factor, but the absolute values should be interpreted with caution.[40] Odds ratios are a common measure of the size of an effect and are hard to comprehend directly.[41] The validity of odds ratio in estimating the relative risk has been a topic of debate in the literature. Sinclair et al[42] suggests that the odds ratio cannot substitute for the risk ratio in conveying clinically important information to physicians and that odds ratios do not approximate well to the relative risk when the initial risk is high. Further, it is unclear as to how these odds ratios can be combined for the patient with several risk factors beyond an appreciation that some factors

represent greater risk than others, and more risk factors present a greater risk of poor long-term outcome. Davies[41] however, suggests that serious divergence between the odds ratio and the relative risk occurs only with large effects on groups at high initial risk. Therefore, qualitative judgements based on interpreting odds ratios as though they were relative risks are unlikely to be seriously in error. It is important for clinicians to become familiar with the factors that increase risk of poor outcomes and the extent of increased risk to provide more accurate prognosis to their patients.

The effects of some of the predictors in the studies included for the systematic review were presented as continuous data. This required the identification of a meaningful cut point and a dichotomization of these data for the purpose of meaningful pooling. Our criterion for dichotomisation of the continuous data was to assume normal distribution of data. The reported results of the included primary studies were scrutinized to identify any indications of non-normally distributed (skewed or kurtotic) data that would have adversely affected the dichotomization procedure. Indicators would have been use of non-parametric tests of association, low mean values with large standard deviations, or means and medians that were widely discordant. We did not include any study or cohort if the given data did not indicate that the normal distribution of the data was not skewed by outliers. In the 14 studies included for the meta-analysis, all variables were given as either frequencies of occurrence / non-occurrence or odds ratio with confidence limits. The process used to pool such data is explained in APPENDIX 3.

It should be recognized that systematic reviews and meta-analyses are susceptible to publication bias, insofar as data for positive results are more likely to be published than are negative results. The calculation of the fail-safe N for significant findings lends confidence to the robustness of the findings from this review. Of the 8 predictors evaluated only one predictor (fatty infiltration with its effect on cuff integrity after RCR) demonstrated robustness to publication bias through evaluation of the fail-safe N statistic. We were not able to calculate fail safe N statistic for predictors studied in 2 cohorts because at least 3 cohorts were required for calculating this statistic. Until the problem of publication bias has been overcome, all reviewers and readers should be aware that they may be viewing a biased sample of experimental results and should moderate the strength of their conclusions accordingly. This is especially true when studying weak associations using the meta-analysis method, where the calculation of an overall estimate already endows the review with a semblance of accuracy that may not always be

warranted.[43]

We recommend that clinicians consider caution in interpreting the results of this meta-analysis. In all the studies that were reviewed and included in the meta-analysis, subjective pain as an individual predictor on outcomes was not extensively studied. Oh et al[7] have stated that pain is the most debilitating symptom after rotator cuff tear and have evaluated the correlation of pain reduction after lidocaine injection before surgery to level of pain reduction after RCR. But no study has attempted to study the correlation of the intensity of pre-operative pain on clinical and functional outcome after RCR. Another reason for caution is that the overall quality of the literature from which the data were extracted was moderate, with some common threats to internal validity, such as a lack of clear validity for the method of capturing many of the prognostic variables, or the lack of blinded assessors. Also, only 14 articles were selected from the 42 that were included for final review after applying the inclusion criteria. It is possible that these 28 articles that were not included could have some information that could be clinically valid in rehabilitation after RCR. A systematic review summarising the results of these studies is recommended.

Critical knowledge on the role, significance and effect of predictors on outcomes after RCR is important as it may lead to individualized rehabilitation programs for patients depending on the presence of these predictors before surgery. Clinicians and surgeons should incorporate an assessment process before surgery to detect the presence of potential predictors to device an effective rehab program following surgery. Also, a better understanding of these factors will help in counselling the patients on what to expect after their surgery.[12]

Limitations

The primary limitation in this meta-analysis arises from the lack of high-quality studies that attempted to predict the effect of various prognostic factors on outcomes after RCR. Of the fourteen studies that were analysed in this study, no studies were of high quality, 6 were moderate[6,8-11,17] and 8 were low quality.[5,7,12-16,18] A significant limitation in studies included in the review and meta-analysis was that the methodological limitations were considerable in all the studies. Many studies failed to provide information on adequate enrolment, information on the assessors and evaluators and did not use either sample or power calculations or sample size justification. Recruitment strategies were also often not described making it difficult to generalize results. The authors in most of the studies failed to explain the rationale for choosing

the prognostic factors that they decided to follow. Prognostic factors were chosen according to the interests and convenience of the authors and no valid reasons were given. A more holistic approach of including clinically significant predictors in high quality studies is required to standardize the effects of various factors in predicting outcomes after RCR.

Research gaps / directions

The following research recommendations arise from this review:

1. High quality RCTs and prospective cohort studies are required to study the effect of various predictors on outcomes after RCR. Future studies should attempt to report trials based on the CONSORT[44] or STROBE[45] criteria. Authors should also explain the mechanistic and clinical rationale for evaluating a particular predictor(s).
2. Data obtained that relates to the effect of a predictor(s) should be presented clearly to allow for statistical pooling in future meta-analysis.
3. Studies should attend to items of quality research design, in particular, use of independent evaluators, standardized outcome measures, and appropriate sample sizes.

CONCLUSION

A meta-analysis of cohort studies examining the effect of risk factors in predicting outcome in patients after rotator cuff repair suggests a few risk factors that might have an effect on outcomes after RCR. Our results indicate fatty infiltration to be a significant factor in predicting cuff integrity after RCR. Several other pre-operative factors such as tear size, pre-operative muscle strength, multiple tendon involvement in rotator cuff tear, age (on cuff integrity) and workman's' compensation status also have modest effect, but more studies are required to validate their effect. We have reported no association for several clinically relevant factors such as age (on function), trauma and duration of symptoms before surgery on outcomes after RCR. Gender did not have enough evidence to reach arbitrary threshold for inclusion in this meta-analysis. This does not translate to "evidence against" all these factors, a point that is especially relevant when considering the absence of hard physical signs as significant predictors in our review. More studies are required to ascertain the effect of all the predictors reported in this review.

REFERENCES

1. Piitulainen, K., Ylinen, J., Kautiainen, H., & Hakkinen, A. (2012). The relationship between functional disability and health-related quality of life in patients with a rotator cuff tear. *Disability and Rehabilitation,* doi:10.3109/09638288.2012.670363
2. Lehman, C., Cuomo, F., Kummer, F. J., & Zuckerman, J. D. (1995). The incidence of full thickness rotator cuff tears in a large cadaveric population. *Bulletin (Hospital for Joint Diseases (New York, N.Y.)), 54*(1), 30-31.
3. Bassett, R. W., & Cofield, R. H. (1983). Acute tears of the rotator cuff. The timing of surgical repair. *Clinical Orthopaedics and Related Research, (175)*(175), 18-24.
4. Ghodadra, N. S., Provencher, M. T., Verma, N. N., Wilk, K. E., & Romeo, A. A. (2009). Open, mini-open, and all-arthroscopic rotator cuff repair surgery: Indications and implications for rehabilitation. *The Journal of Orthopaedic and Sports Physical Therapy, 39*(2), 81-89. doi: 10.2519/jospt.2009.2918
5. Kim, K. C., Shin, H. D., & Lee, W. Y. (2012). Repair integrity and functional outcomes after arthroscopic suture-bridge rotator cuff repair. *The Journal of Bone and Joint Surgery.American Volume, 94*(8), e48. doi: 10.2106/JBJS.K.00158; 10.2106/JBJS.K.00158
6. Gulotta, L. V., Nho, S. J., Dodson, C. C., Adler, R. S., Altchek, D. W., MacGillivray, J. D., & HSS Arthroscopic Rotator Cuff Registry. (2011). Prospective evaluation of arthroscopic rotator cuff repairs at 5 years: Part II--prognostic factors for clinical and radiographic outcomes. *Journal of Shoulder and Elbow Surgery / American Shoulder and Elbow Surgeons ...[Et Al.], 20*(6), 941-946. doi: 10.1016/j.jse.2011.03.028; 10.1016/j.jse.2011.03.028
7. Oh, J. H., Kim, S. H., Kim, K. H., Oh, C. H., & Gong, H. S. (2010). Modified impingement test can predict the level of pain reduction after rotator cuff repair. *The American Journal of Sports Medicine, 38*(7), 1383-1388. doi: 10.1177/0363546509359071; 10.1177/0363546509359071
8. Tashjian, R. Z., Hollins, A. M., Kim, H. M., Teefey, S. A., Middleton, W. D., Steger-May, K., . . . Yamaguchi, K. (2010). Factors affecting healing rates after arthroscopic double-row rotator cuff repair. *The American Journal of Sports Medicine, 38*(12), 2435-2442. doi: 10.1177/0363546510382835; 10.1177/0363546510382835

9. Cho, N. S., & Rhee, Y. G. (2009). The factors affecting the clinical outcome and integrity of arthroscopically repaired rotator cuff tears of the shoulder. *Clinics in Orthopedic Surgery, 1*(2), 96-104. doi: 10.4055/cios.2009.1.2.96
10. Nho, S. J., Brown, B. S., Lyman, S., Adler, R. S., Altchek, D. W., & MacGillivray, J. D. (2009). Prospective analysis of arthroscopic rotator cuff repair: Prognostic factors affecting clinical and ultrasound outcome. *Journal of Shoulder and Elbow Surgery / American Shoulder and Elbow Surgeons ...[Et Al.], 18*(1), 13-20. doi: 10.1016/j.jse.2008.05.045
11. Oh, J. H., Kim, S. H., Ji, H. M., Jo, K. H., Bin, S. W., & Gong, H. S. (2009). Prognostic factors affecting anatomic outcome of rotator cuff repair and correlation with functional outcome. *Arthroscopy : The Journal of Arthroscopic & Related Surgery : Official Publication of the Arthroscopy Association of North America and the International Arthroscopy Association, 25*(1), 30-39. doi: 10.1016/j.arthro.2008.08.010; 10.1016/j.arthro.2008.08.010
12. Gladstone, J. N., Bishop, J. Y., Lo, I. K., & Flatow, E. L. (2007). Fatty infiltration and atrophy of the rotator cuff do not improve after rotator cuff repair and correlate with poor functional outcome. *The American Journal of Sports Medicine, 35*(5), 719-728. doi: 10.1177/0363546506297539
13. Ozbaydar, M. U., Tonbul, M., Tekin, A. C., & Yalaman, O. (2007). Arthroscopic rotator cuff repair: Evaluation of outcomes and analysis of prognostic factors. [Artroskopik rotator manset onarimi: Sonuclar ve belirleyici faktorlerin analizi] *Acta Orthopaedica Et Traumatologica Turcica, 41*(3), 169-174.
14. Klepps, S., Bishop, J., Lin, J., Cahlon, O., Strauss, A., Hayes, P., & Flatow, E. L. (2004). Prospective evaluation of the effect of rotator cuff integrity on the outcome of open rotator cuff repairs. *American Journal of Sports Medicine, 32*(7), 1716-1722.
15. Goutallier, D., Postel, J. M., Gleyze, P., Leguilloux, P., & Van Driessche, S. (2003). Influence of cuff muscle fatty degeneration on anatomic and functional outcomes after simple suture of full-thickness tears. *Journal of Shoulder and Elbow Surgery / American Shoulder and Elbow Surgeons ...[Et Al.], 12*(6), 550-554. doi: 10.1016/S1058274603002118
16. Shinners, T. J., Noordsij, P. G., & Orwin, J. F. (2002). Arthroscopically assisted mini-open rotator cuff repair. *Arthroscopy : The Journal of Arthroscopic & Related Surgery :*

Official Publication of the Arthroscopy Association of North America and the International Arthroscopy Association, 18(1), 21-26.

17. Pai, V. S., & Lawson, D. A. (2001). Rotator cuff repair in a district hospital setting: Outcomes and analysis of prognostic factors. *Journal of Shoulder and Elbow Surgery / American Shoulder and Elbow Surgeons ...[Et Al.], 10*(3), 236-241. doi: 10.1067/mse.2001.113963
18. Misamore, G. W., Ziegler, D. W., & Rushton, J. L.,2nd. (1995). Repair of the rotator cuff. A comparison of results in two populations of patients. *The Journal of Bone and Joint Surgery.American Volume, 77*(9), 1335-1339.
19. Cochrane prognosis methods group (August 2011). Retrieved November 5, 2012 from http://prognosismethods.cochrane.org/more-about-us.
20. Greenland S, O' Rourke K: Meta-Analysis. Page 652 in Modern Epidemiology, 3rd ed. Edited by Rothman KJ, Greenland S, Lash T. Lippincott Williams and Wilkins; 2008.
21. MacDermid JC, Walton DM. Critical Appraisal of Study Quality for Prognostic Articles. Interpretation guide. In: Law M, MacDermid J, editors. *Evidence-based Rehabilitation*. 3rd edition In Press. Thorefare, NJ: Slack Inc.; 2013.
22. Shrout PE, Fleiss JL: Intraclass correlations: Uses in assessing rater reliability. *Psychol Bull* 1979, 86: 420-428.
23. Cohen J: Weighted kappa: nominal scale agreement with provision for scaled disagreement or partial credit. *Psychol Bull* 1968, 70: 213-220.
24. Hedges L, Vevea JL. Fixed- and random-effects models in meta-analysis. *Psychol Meth.* 1998;3:486-504.
25. Higgins, J. P., & Thompson, S. G. (2002). Quantifying heterogeneity in a meta-analysis. *Statistics in Medicine, 21*(11), 1539-1558. doi: 10.1002/sim.1186
26. Portney, L.G & Watkins, M.P. (2009). *Foundations of Clinical Research. Applications to practice.* (3rd edition). New Jersey: Pearson Education, Inc.
27. Rosenthal R. The file drawer problem and tolerance for null results. *Psychological Bulletin.* 1979;86:638-641.
28. Rosenthal, R. (1984). Meta-analytic procedures for social research. Beverly Hills, CA: Sage.
29. Cooper HM, Hedges L. *The Handbook of Research Synthesis.* 1st ed. New York, NY: Russell Sage Foundation; 1994.

30. Cohen, Jacob; Cohen, Patricia; Leona S. Aiken; West, Stephen H. (2003). *Applied multiple regression/correlation analysis for the behavioral sciences*. Hillsdale, N.J: L. Erlbaum Associates. ISBN 0-8058-2223-2.
31. Kirkley, A., Griffin, S., & Dainty, K. (2003). Scoring systems for the functional assessment of the shoulder. *Arthroscopy : The Journal of Arthroscopic & Related Surgery : Official Publication of the Arthroscopy Association of North America and the International Arthroscopy Association, 19*(10), 1109-1120. doi: 10.1016/j.arthro.2003.10.030
32. Romeo, A. A., Mazzocca, A., Hang, D. W., Shott, S., & Bach, B. R.,Jr. (2004). Shoulder scoring scales for the evaluation of rotator cuff repair. *Clinical Orthopaedics and Related Research, (427)*(427), 107-114.
33. Roy, J. S., MacDermid, J. C., & Woodhouse, L. J. (2009). Measuring shoulder function: A systematic review of four questionnaires. *Arthritis and Rheumatism, 61*(5), 623-632. doi: 10.1002/art.24396; 10.1002/art.24396
34. Skutek, M., Zeichen, J., Fremerey, R. W., & Bosch, U. (2001). Outcome analysis after open reconstruction of rotator cuff ruptures. A comparative assessment of recent evaluation procedures. [Outcomeanalyse nach offener Rekonstruktion von Rotatorenmanschettenrupturen. Eine vergleichende Beurteilung neuer Bewertungsverfahren] *Der Unfallchirurg, 104*(6), 480-487.
35. Ellman, H., Hanker, G., & Bayer, M. (1986). Repair of the rotator cuff. End-result study of factors influencing reconstruction. *The Journal of Bone and Joint Surgery. American Volume, 68*(8), 1136-1144.
36. Goutallier, D., Postel, J. M., Bernageau, J., Lavau, L., & Voisin, M. C. (1994). Fatty muscle degeneration in cuff ruptures. pre- and postoperative evaluation by CT scan. *Clinical Orthopaedics and Related Research, (304)*(304), 78-83.
37. DeOrio, J. K., & Cofield, R. H. (1984). Results of a second attempt at surgical repair of a failed initial rotator-cuff repair. *The Journal of Bone and Joint Surgery.American Volume, 66*(4), 563-567.
38. Post, M., Silver, R., & Singh, M. (1983). Rotator cuff tear. diagnosis and treatment. *Clinical Orthopaedics and Related Research, (173)*(173), 78-91.

39. Nastasia, I., Coutu, M., Tcaciuc, R., Canadian Electronic Library, & Irsst. (2012; 2011). *Strategies for preventing prolonged disability in workers compensated for work related musculoskeletal disorders*. Montréal, Qué: Irsst.
40. Walton, D. M., Pretty, J., MacDermid, J. C., & Teasell, R. W. (2009). Risk factors for persistent problems following whiplash injury: Results of a systematic review and meta-analysis. *The Journal of Orthopaedic and Sports Physical Therapy, 39*(5), 334-350. doi: 10.2519/jospt.2009.2765
41. Davies, H. T., Crombie, I. K., & Tavakoli, M. (1998). When can odds ratios mislead? *BMJ (Clinical Research Ed.), 316*(7136), 989-991.
42. Sinclair, J. C., & Bracken, M. B. (1994). Clinically useful measures of effect in binary analyses of randomized trials. *Journal of Clinical Epidemiology, 47*(8), 881-889.
43. Thornton, A., & Lee, P. (2000). Publication bias in meta-analysis: Its causes and consequences. *Journal of Clinical Epidemiology, 53*(2), 207-216.
44. Consolidated Standards of Reporting Trials. CONSORT— transparent reporting of trials. Available at: www.consort-statement.org/. Updated January 20, 2012. Accessed February 12, 2013.
45. Strengthening the report of observational studies in epidemiology. STROBE Statement. Available at: http://www.strobe-statement.org/index.php?id=available-checklists. Version 4 as published in Oct/Nov 2007. Accessed July 3rd, 2013.

Figure 1: Flow Chart of Search Strategy:

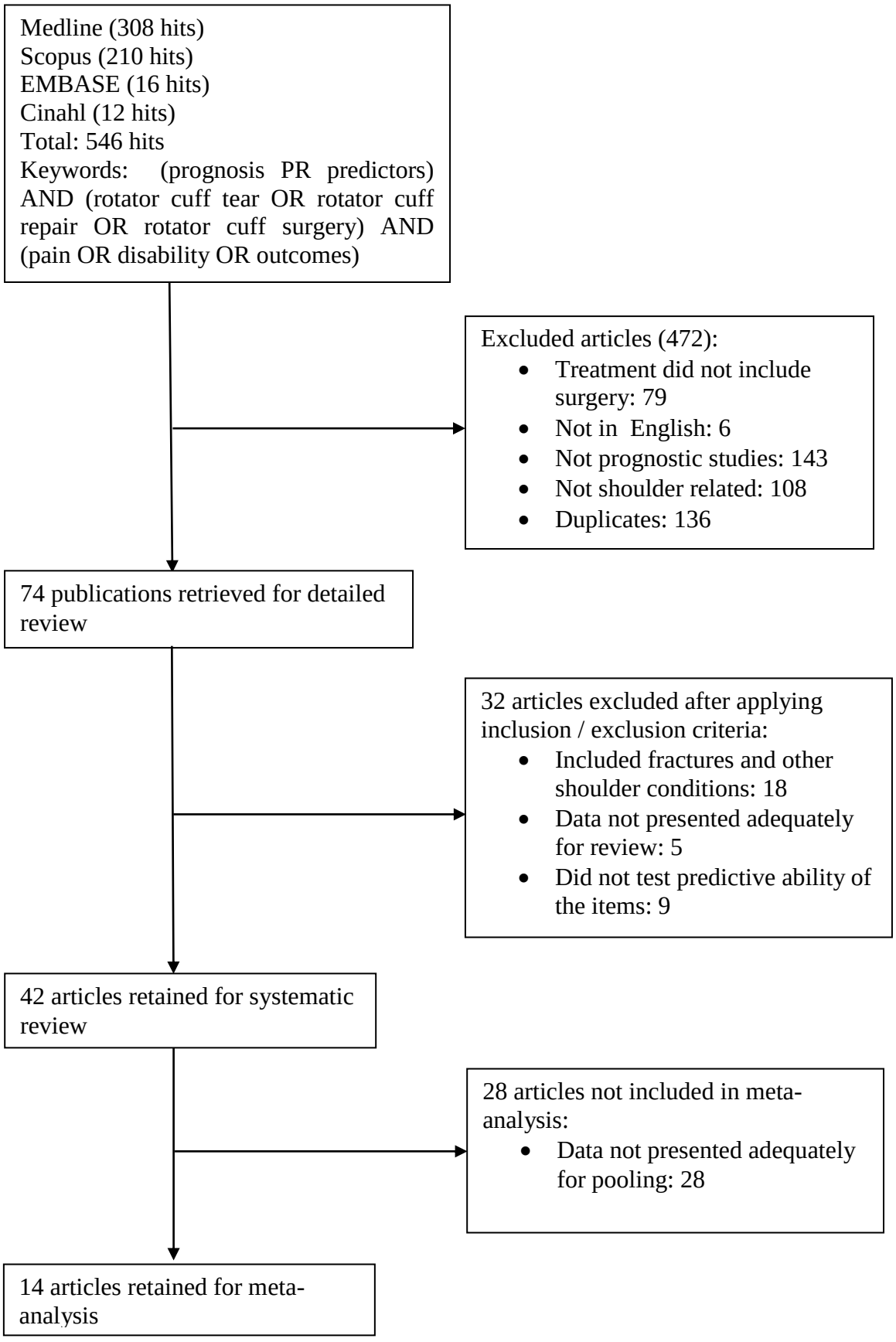


Figure 2(a): Effect of fatty infiltration on cuff integrity

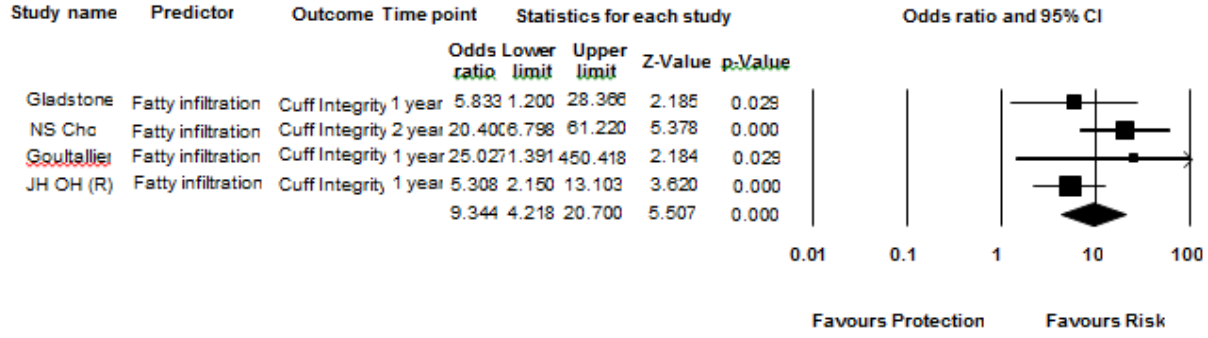


Figure 2(b): Effect of Workman's compensation status (WCB) on function

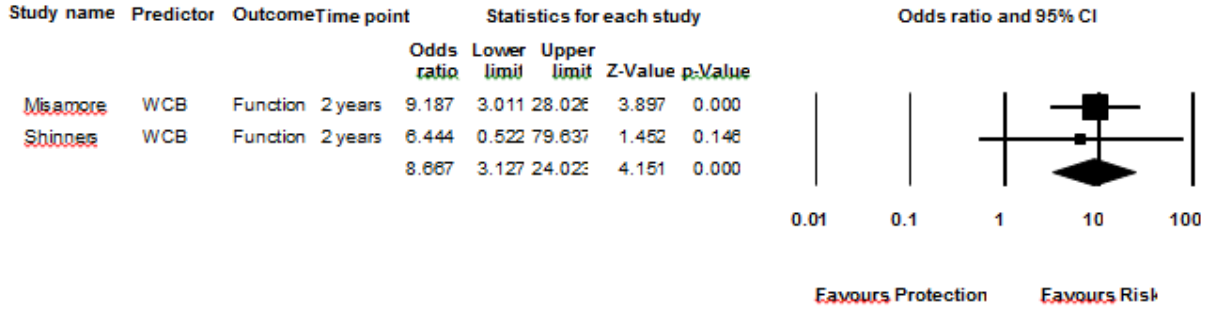


Figure 2(c): Effect of multiple tendon involvement on cuff integrity

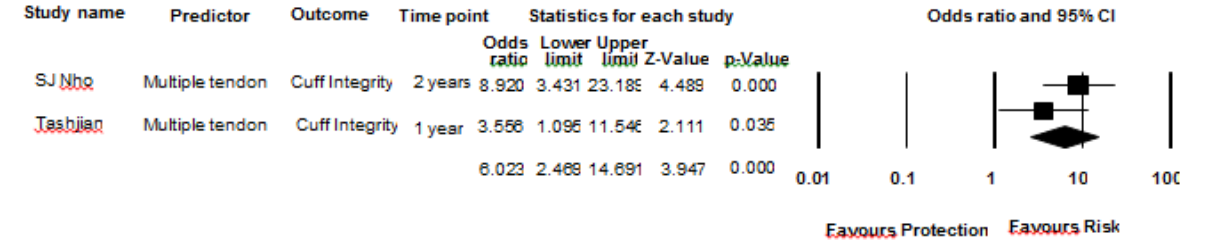


Figure 2(d): Effect of pre-op muscle strength on function

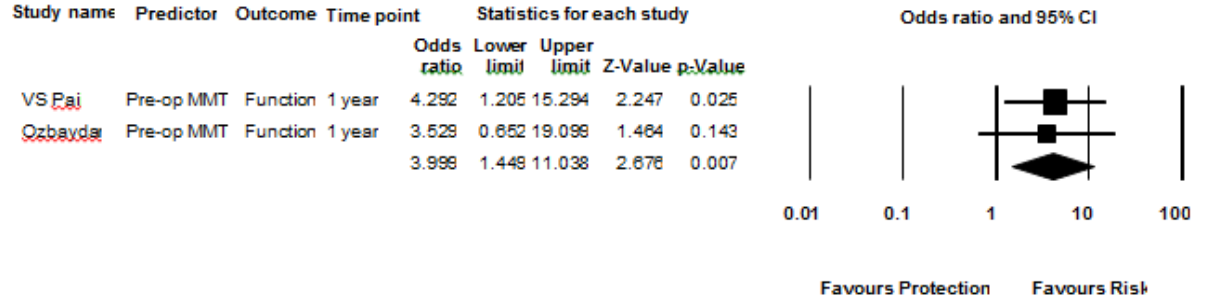


Figure 2(e): Effect of tear size on cuff integrity

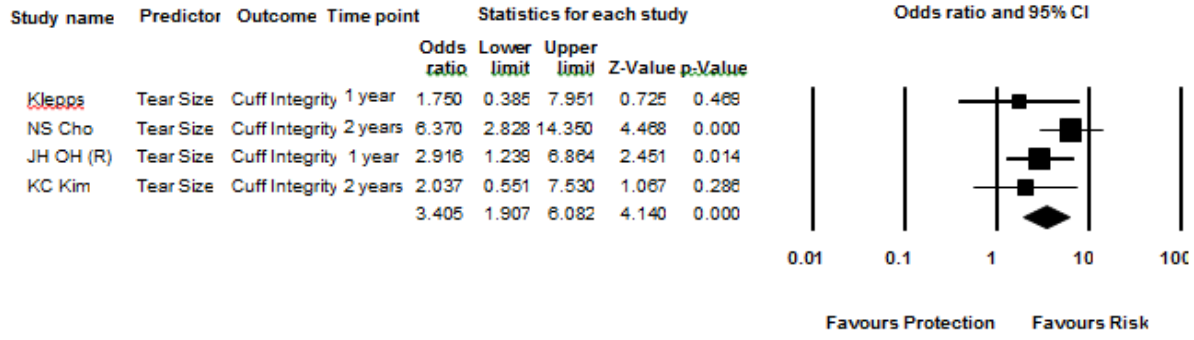


Figure 2(f): Effect of tear size on function

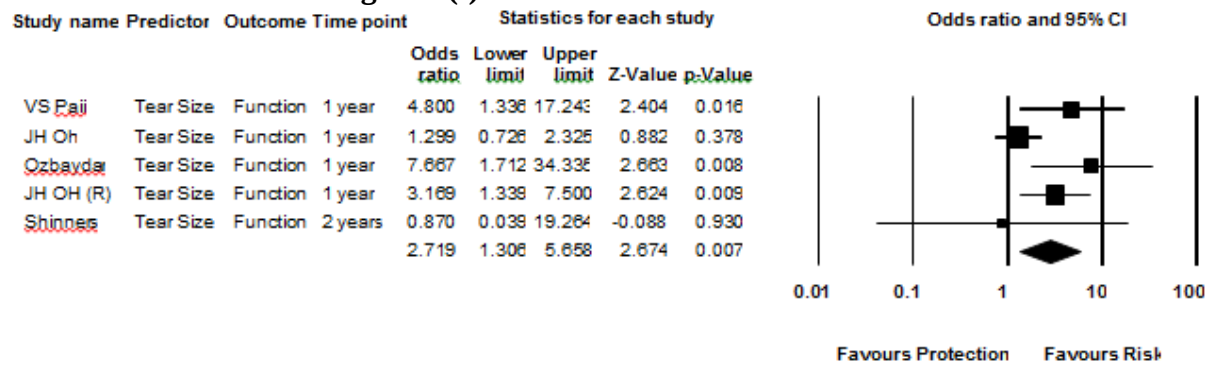


Figure 2(g): Effect of tear size on satisfaction

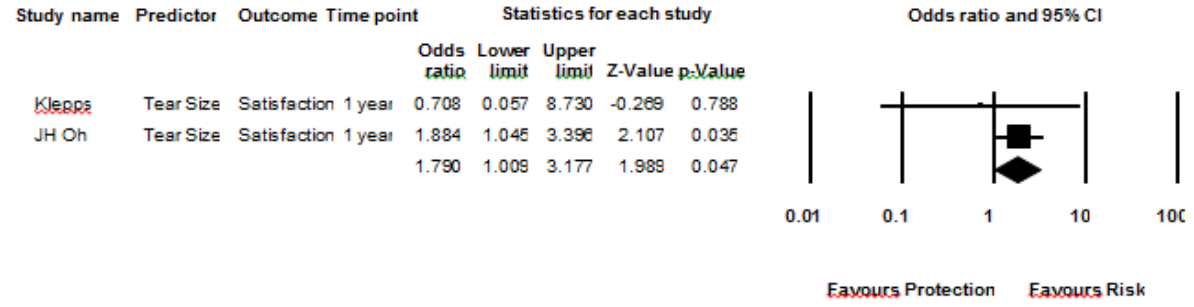


Figure 2(h): Effect of age on cuff integrity

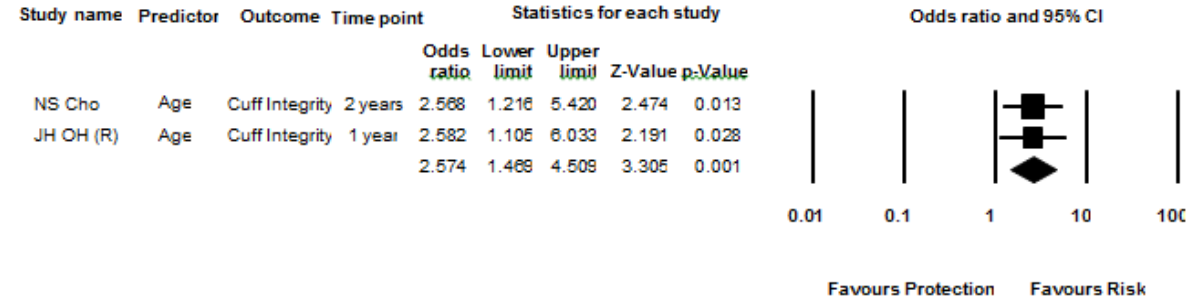


Figure 2(i): Effect of age on function

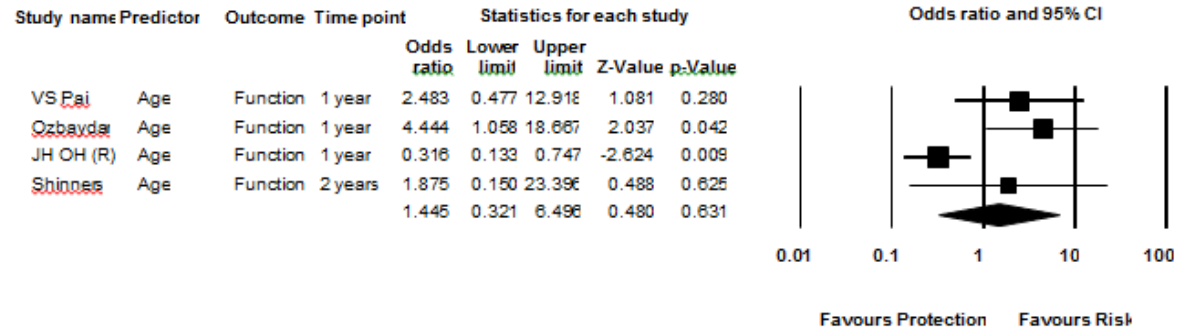


Figure 2(j): Effect of duration of symptoms before surgery on function

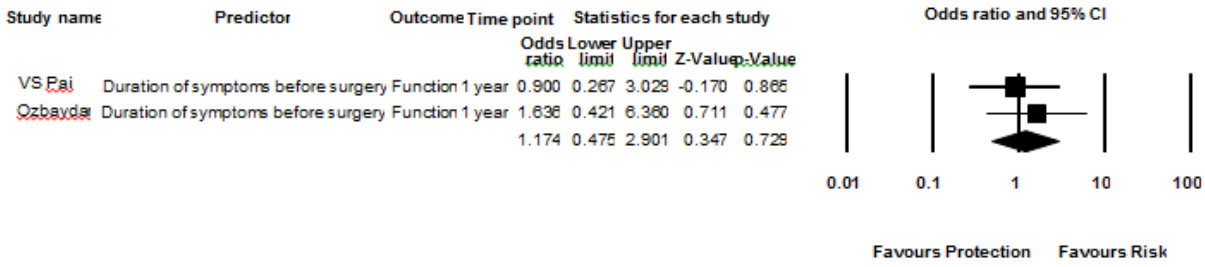


Figure 2(k): Effect of trauma on cuff integrity

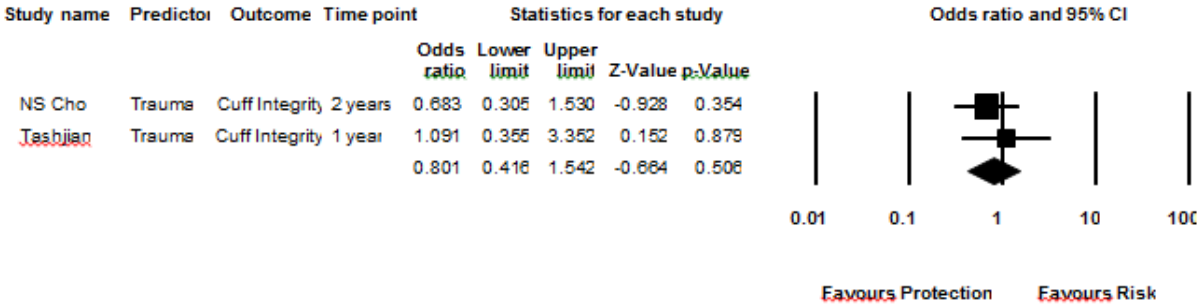


Table 1: Descriptions of Cohorts included in the Meta-Analysis

S.No	Cohort, Authors Year	Time to follow-up	Outcomes collected	Total sample size / completed study	Study quality
1	Kyung Cheon Kim, 2012	2 years	• Cuff integrity was evaluated with ultrasonography or MRI. • Functional outcome was evaluated with ASES, Constant score, UCLA.	79 / 73	22/50 Low
	Predictors followed: Tear size Level of Evidence: Level 4, Therapeutic case series Surgery performed: Arthroscopic repair.				
2	Lawrence V Gulotta, 2011	5 years	• Cuff integrity was evaluated with ultrasonography. • Functional outcome was evaluated with ASES, Goniometer for ROM and MMT for muscle strength.	193 / 106	31/50 Moderate
	Predictors followed: Age, tear size, multiple tendon involvement, concomitant biceps and AC joint procedures, patient satisfaction, muscle strength at 5 years. Level of Evidence: Level 2, Prospective cohort treatment study Surgery performed: Arthroscopic repair.				
3	Joo Han Oh, 2010	1 year	• Pain and satisfaction were evaluated using VAS • Functional outcome was evaluated with ASES, Constant score, UCLA and SST.	153 / 153	21/50 Low
	Predictors followed: The hypothesis was that the amount of pain reduction after the modified impingement test preoperatively correlates with the pain reduction and functional improvement after rotator cuff repair. Level of Evidence: Level 2, Prognostic cohort study Surgery performed: Arthroscopy-assisted mini-open repair and Arthroscopic repair.				
4	Robert Tashjian, 2010	6 months (cuff integrity) 1 year (function)	• Functional outcome was evaluated ASES and SST, VAS for pain. • Cuff integrity was evaluated with ultrasound.	49 / 49	32/50 Moderate
	Predictors followed: Gender, multiple tendon involvement, trauma, number of co-morbidities, duration of symptoms and smoking. Level of Evidence: Level 4, Case series Surgery performed: Arthroscopic repair.				
5	Nam Su Cho, 2009	2 years	• Pain was evaluated using VAS • ROM was measured using goniometer. • Muscle strength was measured using a Myometer.	169 / 169	25/50 Moderate

			• Functional outcome was evaluated using ASES, UCLA and SST scores. • Cuff integrity was evaluated using MRI. • Fatty infiltration was evaluated using MRI.		
	Predictors followed: Age, tear size, pre-operative fatty degeneration of cuff muscles, duration symptoms before surgery, trauma, and operative techniques. Level of evidence: Level 2b, Retrospective study Surgery performed: Arthroscopic repair				
6	Shane J Nho, 2009	2 years	• ROM • Muscle strength was measured using a hand held dynamometer. • Functional outcome was evaluated using ASES. • Cuff integrity was evaluated using ultrasonography.	193 / 127	34/50 Moderate
	Predictors followed: Age, tear size, number of tendons involved. Level of Evidence: Level 2, Prospective cohort treatment study Surgery performed: Arthroscopic repair				
7	Joo Han Oh, 2009	1 year	• Cuff Integrity was evaluated with computed tomographic arthrography. • Functional outcome was evaluated with ASES, Constant score, SST and VAS for pain and satisfaction. • Fatty infiltration was evaluated using Magnetic resonance arthrography.	78 / 78	30/50 Moderate
	Predictors followed: Age, fatty infiltration in rotator cuff muscles, gender and tear size. Level of evidence: Level 4, Prognostic case series Surgery performed: Arthroscopic repair				
8	James N. Gladstone, 2007	1 year	• ROM • Muscle strength was measured using a dynamometer. • Functional outcome was evaluated using ASES and Constant score. • Cuff integrity was evaluated using MRI. • Fatty infiltration was evaluated using MRI.	38 / 38	23/50 Low

	Predictors followed: Pre-operative muscle quality and fatty infiltration of the rotator cuff muscles. Level of evidence: Level 2, Cohort study Surgery performed: Arthroscopic repair				
9	Ugur Ozbaydar, 2007	1 year	• Functional outcome was evaluated using UCLA score • ROM was measured using a goniometer. • Muscle strength was measured with manual muscle testing. • Fatty degeneration was measured by MRI.	41 / 41	18/50 Low
	Predictors followed: Age, duration of symptoms before surgery, fatty infiltration in the rotator cuff muscles, pre-operative muscle strength of the rotator cuff muscles, pre-operative ROM, and tear size. Level of evidence: Level 2b, Retrospective study Surgery performed: Arthroscopic repair				
10	Klepps, 2004	1 year	• Functional outcome was evaluated using UCLA, Constant score, ASES. • Pain was evaluated using VAS. • Cuff integrity was measured using MRI. • ROM • Muscle strength was measured with dynamometer.	47 / 32	19/50 Low
	Predictors followed: Tear size Level of evidence: Level 2, Prospective nonrandomized clinical outcomes study. Surgery performed: Mini-open and open repair				
11	Daniel Goutallier, 2003	1 year	• Functional outcome was evaluated using Constant score • Cuff Integrity was evaluated with CT scan or MRI • Fatty degeneration was measured by CT scan.	220 / 220	16/50 Low
	Predictors followed: Fatty infiltration of rotator cuff muscles Level of evidence: Level 2b, Retrospective multicenter descriptive study Surgery performed: Open tendon to bone suture repair				
12	Theodore Shinners, 2002	2 years	• Functional outcome was evaluated with UCLA score.	41 / 41	16/50 Low
	Predictors followed: Age, tear size and workman's compensation status. Level evidence: Level 2b, Retrospective clinical review Surgery performed: Arthroscopic repair				
13	Vasudeva Shivaraya Pai, 2001	1 year	• Functional outcome was evaluated with UCLA and modified Constant score.	58 / 58	27/50 Moderate

			• Muscle strength was evaluated using manual muscle testing.		
	Predictors followed: Age, duration of symptoms before surgery, preoperative strength and ROM, tear size, and quality of the tendon. Level of evidence: Level 2, Prospective cohort study Surgery performed: Open repair				
14	Gary Misamore, 1995	2 years	• Functional outcome was evaluated with UCLA score. • Muscle strength was measured by MMT • ROM was measured by goniometer.	107 / 107	19/50 Low
	Predictors followed: Workman's compensation status. Level evidence: Level 2b, Retrospective study Surgery performed: Open repair.				

Abbreviations: UCLA – University of California, Los Angeles shoulder rating scale; SST – Simple shoulder Test; ASES - American Shoulder and Elbow Surgeons (ASES) score; MRI – Magnetic resonance imaging; MMT – Manual muscle testing; ROM – Range of motion; VAS - visual analog scale; CT- Computerised tomography

Table 2: Summary of study quality

Study	?	Subjects / Sampling								Exposure ascertainment				Outcome determination				Analysis						Interpre tation		T	Q %
Items	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25		
Kim KC et al, 2012	2	1	1	0	0	0	0	2	0	2	2	2	2	1	2	0	2	1	0	0	0	0	0	1	1	23	46
Gulotta et al, 2011	2	2	1	1	2	0	0	0	0	2	0	1	0	2	2	2	2	2	2	0	0	2	2	2	2	31	62
J H Oh et al, 2010	2	2	2	1	0	0	0	0	0	0	1	0	2	1	0	1	1	2	0	0	0	0	2	2	2	21	42
Tashjian et al, 2010	2	2	1	0	0	0	0	0	0	2	2	2	0	2	2	2	1	2	2	0	2	2	2	2	2	32	64
N S Cho et al, 2009	1	2	1	1	1	0	0	0	0	2	0	1	2	2	2	1	2	1	0	0	0	1	2	1	2	25	50
S J Nho et al, 2009	2	2	1	1	0	0	0	0	0	2	2	2	0	2	2	2	2	2	2	0	2	2	2	2	2	34	68
J H Oh et al, 2009	2	2	2	0	2	1	0	0	0	2	1	2	2	0	2	2	1	2	0	0	0	2	2	1	2	30	60
Gladstone et al, 2007	1	1	1	0	0	0	0	2	2	1	2	1	1	2	1	1	1	1	0	0	0	0	2	1	2	23	46
Ozbaydar et al, 2007	1	2	1	0	1	0	0	0	0	1	0	1	2	0	1	0	1	1	0	0	0	0	2	1	1	18	36
Klepps et al, 2004	2	0	2	0	0	0	0	0	0	2	0	0	1	1	0	2	2	0	0	0	0	2	2	2	1	19	38
Goutallier et al, 2003	1	1	1	1	0	0	0	0	0	1	0	2	0	0	1	1	1	1	0	0	0	1	2	1	1	16	32
Shinners et al, 2002	0	2	0	0	0	0	0	0	0	1	0	2	1	2	2	0	2	0	0	0	0	0	2	1	1	16	32
V S Pai et al, 2001	2	2	0	0	1	0	0	0	0	2	2	2	2	1	2	2	2	1	0	0	1	0	2	2	1	27	54
Misamore et al, 1995	1	2	1	1	0	0	0	0	0	1	0	2	2	0	2	0	2	1	0	0	0	0	2	1	1	20	40

Abbreviations: T – Total score; Q – Quality of study; ? – Study question

Table 3: Summary of key findings

Predictor	Outcome	Odds ratio in risk over someone without the factor (95% CI)	Number of Independent cohorts (Total subjects completed study)	Fail safe N*	I^2 for hetero-geneity (pvalue)	Mean Study Quality ‡
Variables with strong evidence of significant effect						
Fatty infiltration	Cuff Integrity	9.34 (4.22, 20.70)	4 (505)	43	28.76 (0.24)	23.5
Variables with moderate evidence of significant effect †						
Workman's compensation status	Function	8.67 (3.13, 24.02)	2 (148)	NA	0.00	18
Multiple tendon involvement	Cuff Integrity	6.02 (2.47, 14.69)	2 (176)	NA	29.23 (0.24)	33
Pre-operative strength of rotator muscles	Function	3.99 (1.45, 11.04)	2 (99)	NA	0.00	22.5
Tear size	Cuff Integrity	3.41 (1.91, 6.08)	4 (352)	16	19.47 (0.29)	24.25
Tear size	Function	2.72 (1.31, 5.66)	5 (371)	14	51.58 (0.08)	22.4
Age	Cuff Integrity	2.57 (1.47, 4.51)	2 (247)	NA	0.00	27.5
Tear size	Satisfaction	1.79 (1.01, 3.18)	2 (185)	NA	0.00	20
Variables with evidence of no effect						
Age	Function	1.45 (0.32, 6.50)	4 (218)	0	75.38 (0.007)	22.75
Duration of symptoms before surgery	Function	1.17 (0.48, 2.90)	2 (99)	NA	0.00	22.5
Trauma	Cuff Integrity	0.80 (0.42, 1.54)	2 (218)	NA	0.00	28.5

Abbreviations: CI – confidence interval

*The number of studies showing no significant effect of the predictor that would have to be included in this analysis to nullify these findings of significance.

†Fail-safe N cannot be calculated for predictors studied in ≤2 cohorts .

‡The highest possible score is 50.

CHAPTER 3. FUNCTIONAL MOVEMENT ANALYSIS OF SHOULDER KINEMATICS BEFORE AND AFTER ROTATOR CUFF REPAIR

ABSTRACT

Study design

Prospective longitudinal study.

Background

Rotator cuff tears are among the most common conditions affecting the shoulder. Patients having a rotator cuff tear can be treated either conservatively or surgically if conservative management fails. Reliable information on the range of motion (ROM) required to perform activities of daily living (ADL) is important to allow rehabilitation professionals to make appropriate clinical judgments of patients with limited ROM after rotator cuff repair (RCR). The purpose of this study was to perform a quantitative analysis of shoulder kinematics during functional tasks of the upper limb before and after RCR using 2D video analysis procedures and to determine the test-retest reliability of the 2D video analysis software to assess shoulder motion during activities of daily living performed before and after rotator cuff surgery.

Methods

Twenty subjects with rotator cuff tear scheduled for surgical repair of the rotator cuff volunteered for the study. The subjects were measured for pain, function and general health status using a visual analog scale (VAS), Disabilities of arm, shoulder and hand (DASH), Western Ontario rotator cuff index (WORC) and Short form health survey (SF-12) outcome measures preoperatively, 3 months and 6 months after surgery. The subjects performed 2 simulated trials of 5 tasks chosen from the DASH questionnaire which were recorded using 2 high definition cameras. Movement analysis using Dartfish® 5.5 ProSuite video software was used to analyze motion during task performance across all the time points. Intraclass correlation coefficients (ICC) were calculated for each trial to determine test-retest reliability. The effect of time of testing (pre-op vs post-op) on improvements in functional ROM for all activities was analysed using repeated measures analysis of variance (ANOVA) on SPSS.

Results

The functional ROM through which the subjects were able to move their shoulder to complete the different tasks at pre-op and 6 months after surgery were: 97.59°±35.12 (pre-op, mean ± standard deviation) and 116.67°±24.60° (post-op, mean ± standard deviation) of elevation for changing an overhead bulb, 38.98°±14.27°and 39.71°±10.73° of sagittal flexion for pushing open a heavy door, 86.74°±39.40° and 107.42°±20.30° of elevation for washing hair, 35.04°±11.52° and 42.70°±10.09° of shoulder extension for washing back, 39.75°±18.83° and 46.01°±11.40° of abduction for opening a tight jar. The change in functional ROM was significant across all time points for the activity of washing your back only. Post-hoc analysis suggested this change was significant when ROM was compared pre-op and 6 months after surgery. Significant change in functional ROM was also noted between 3 months and 6 months after surgery for the activity of changing an overhead bulb after Bonferroni post-hoc analysis. Though the change in ROM did not reach significance for the activity of washing your hair, a trend towards significance for change in ROM across all time points was seen with a p value of 0.06. The standard error of measurement (SEM) ranged between 2.26° and 5.92° for all 5 activities when measured across all time points except for 3 tasks (changing bulb and washing hair pre-operatively and changing bulb at 3 months after surgery) which had a SEM of greater than 7°. Analysis of data showed high test-retest reliability (ICC range: 0.61 to 0.97) between trials within the same session before and after surgery.

Conclusions

Analysis of patients' abilities to perform functional tasks before and after rotator cuff repair using 2D video analysis software proved to be a reliable means of measuring functional shoulder ROM before and after surgery. Mean functional ROM improved during all activities after surgery, but this change was significant only for activities of 'changing an overhead bulb' and 'washing your back' with a trend towards significance for the activity of 'washing your hair'. Patients tended to use compensatory movements to substitute for shortcomings in completing the activity before and immediately after surgery, but movement patterns improved 6 months after surgery with patients able to complete tasks without being restricted with pain or stiffness or using compensatory movements. Clinicians should be aware of these changes in functional ROM while developing a treatment protocol for patients recovering from rotator cuff surgery.

Level of Evidence 2b.

Keywords Rotator cuff tear, rotator cuff repair, shoulder kinematics,2D motion video capture, Dartfish software.

INTRODUCTION

The shoulder joint is a highly dynamic joint that depends on muscular control for stability.[1] The range of shoulder movements necessary for different activities of daily living (ADL) vary according to the task involved. Murray et al[2] has reported that shoulder flexion is the primary component of movement for tasks that involves hygiene, feeding and day-to-day activities like answering telephone and lifting weights. The maximum and minimum range of shoulder flexion for functional tasks of hygiene, feeding and day-to-day activities, as reported by Murray et al, was 111.9° and 14.7°. Shoulder abduction range for the same activities ranged from 39.7° to -20.1° while internal rotation was in the range of 85.9° to 18.7°.[2] It has been suggested that, a person requires approximately 120°of forward elevation, 45°of extension, 130°of abduction, 115°of cross-body adduction, 60°of external rotation, and 100°of internal rotation to complete all tasks of daily living.[3]

There are limitations in the benchmarks that have been set for functional shoulder motion. While lower limb studies concentrate almost exclusively on gait, the tasks performed by the upper limb are much more varied. While most of the studies in the literature have included kinematic analyses of everyday activities involved in feeding and personal hygiene,[4] only a few have included both kinematic and dynamic analysis to provide the data on functional range of motion (ROM).[2] Shoulder ROM is studied either in relation to scapula[5] or thorax[3] which has an effect on standardizing the range required to perform specific tasks. Studies employ various positions to study different tasks. For example, tasks like opening a door are done in standing and tasks which involve lifting weights are tested in sitting.[6] Use of various starting and test positions also has an impact in generalizing functional shoulder ROM.

The competing mobility and stability demands on the shoulder girdle and the intricate structural and functional design result in the shoulder complex being highly susceptible to dysfunction and instability.[1,7] Degeneration of the rotator cuff is the most common source of shoulder dysfunction.[8] The clinical manifestations of various clinical forms of rotator cuff disease include difficulties with shoulder stiffness, weakness, instability and roughness (crepitus).[9] This might lead to a significant disability affecting activities of daily living, work and sports and reduces quality of life.[8,10]

Shoulder function is measured using various self-reported outcome measures with the Disabilities of arm, shoulder and hand (DASH),[11] Simple shoulder test (SST),[12] American

Shoulder and Elbow Surgeons Evaluation form (ASES),[13] Shoulder Pain and Disability Index (SPADI)[14] and Constant[15] being most studied.[16,17] However, none has been accepted as the universal standard.[18] The difficulty lies in attempting to quantify a treatment result that - from the patient's viewpoint - is best expressed in subjective terms: the patient might express some concerns about the treatment received despite good regular outcome scores and good clinical and radiologic examination findings.[19] Understanding the motion requirements of different functional tasks is useful in surgical and rehabilitation planning and may help explain why patients perform differently in different outcome measures.

Human motion, its measurement, analysis and modeling is of interest in various fields, e.g. robotics, surgery, rehabilitation and sports.[20] Qualitative analysis involves a detailed, systematic and structured observation of the performer's movement pattern.[21] Assessment of movement patterns by kinematic analysis is advocated for injury risk factor evaluation.[22] Joint ROM is considered to be pathologic when motion at a joint either exceeds or fails to reach the normal anatomic limits of motion.[1] Various methods are employed to measure human motion which vary from simple goniometric measurements of joint angles[23] to capturing images using photography with still, cine or television cameras with 2D or 3D analysis.[24] Quantifying upper extremity dysfunction, as seen in orthopaedic and neurological disorders, is technically complex because of the multi-joint structure. Interpretation is hindered by the variability of possible movements.[24] Objective kinematic analysis of the shoulder complex could yield useful insights into its functionality that may assist clinical practice by providing new and more effective assessments that can be implemented easily in the clinical setting.[25]

The inter-rater standard error of the measurement (SEM) values of shoulder ROM with goniometer have been reported as high as 25° in subjects with shoulder pathology.[26] The gold standard for kinematic assessment of movement patterns during dynamic tasks is high speed three-dimensional (3D) motion analysis.[27] While 3D motion analysis has broadened our understanding of movement patterns, the clinical use of 3D motion analysis is limited by temporal and financial constraints. An alternative to 3D motion analysis is the use of two-dimensional (2D) video analysis procedures that involve a standard video camera and software to conduct the kinematic analysis.[22] Video analysis software that enables the user to take measurements such as angles, distances and timing directly on digital video recordings offers the potential to decrease the bias associated with subjective image assessments.[28] 2D video analysis

has been reported to have excellent intra-rater (ICC = 0.45 to 0.94) and inter-rater reliability (ICC = 0.68 to 1.00) in measuring shoulder ROM in normal healthy population.[29]

Studies have reported that rotator cuff repair (RCR) lead to a decrease in ROM of shoulder[30] leading to a decreased ability to perform functional activities after the surgery.[31] Gore et al[32] have reported that patients after rotator cuff repair were able to perform most common daily activities without much difficulty, but with less than normal active and passive range of motion and abductor-muscle strength was 86% of the normal strength both men and women. Highly reliable information on the range of motion (ROM) required to perform activities of daily living (ADL) is important to allow rehabilitation professionals to make appropriate clinical judgments of patients with limited ROM of the upper extremity joints.[33] There is no study in the available literature that has quantified the change in ROM of the shoulder during functional tasks after RCR. The purpose of this study was to perform a quantitative analysis of shoulder kinematics during functional tasks of the upper limb before and after RCR using 2D video analysis procedures and to determine the test-retest reliability of the 2D video analysis software to assess shoulder motion during activities of daily living performed before and after rotator cuff surgery.

METHODOLOGY

Study design

Prospective longitudinal study.

Subjects

Twenty subjects were enrolled in the study. The subjects were chosen if they were diagnosed with rotator cuff tear and scheduled for surgical repair of the rotator cuff. Subjects were excluded if they were diagnosed with any associated lesions like a labral tear of the shoulder. The mean age of the patients was 52.50 ± 10.38 years (range: 34 to 73 years). All subjects underwent a standardized physical therapy program which consisted of range of motion exercises started at week 2 after surgery and strengthening exercises for shoulder started at 6 weeks after their surgery. The subjects were seen pre-operatively, 3 months and 6 months after their surgery. At each visit they were measured for pain, function and general health status using a visual analog scale (VAS), Disabilities of Arm, Shoulder and Hand (DASH), Western Ontario Rotator Cuff

Index (WORC), and Short Form Health Survey (SF-12). This study was approved by the University of Western Ontario Ethics Board.

Patient-reported outcome measures

Visual Analog Scale (VAS). The VAS consists of a 10cm straight line, with verbal anchors at either end, representing a continuum of pain intensity. One end of the line has the anchor *"no pain"* while the other end of the line has the anchor *"pain as bad as it could possibly be."* The patient is asked to make a single mark on the line indicating his or her present level of pain.[34] VAS has been used to measure pain levels in rotator cuff tears[35,36] and has a high reliability with ICC values ranging between 0.97 and 0.99.[37-39] and correlates well with other pain scales like Numeric rating scale.[39]

Disabilities of Arm, Shoulder and Hand (DASH). The DASH is a 30-item questionnaire designed to evaluate upper extremity-related symptoms and measure functional status at the level of disability. Concepts covered by the DASH include symptoms (pain, weakness, stiffness, and tingling/numbness), physical function (daily activities, house/yard chores, shopping, errands, recreational activities, self-care, dressing, eating, sexual activities, sleep, and sport/performing art), social function (family care occupation, socializing with friends/family) and psychological function (self-image).[40] DASH has been reported to be highly reliable with a high ICC values ranging between 0.77 and 0.98. [16,41] with high construct convergent validity with other shoulder specific scales like simple shoulder test, American Shoulder and Elbow Surgeons Evaluation form (ASES) and Shoulder Pain and Disability Index (SPADI) with high correlations of $r \geq 0.70$.[16]

Western Ontario Rotator Cuff Index (WORC). WORC was developed for use as the primary outcome measure in clinical trials evaluating treatments for patients with shoulder instability. WORC consists of 21 items measuring the domains of physical symptoms (6 items), sport/recreation (4 items), work (4 items), lifestyle (4 items) and emotion (3 items). The WORC has demonstrated good test-retest reliability across several studies with ICCs in the range of 0.84 to 0.96.[42-44] and correlates with the ASES ($r = 0.68$) and DASH ($r = 0.63$).[44]

Short Form Health Survey (SF-12). The SF- 12 is a generic quality of life (QoL) instrument that uses a subset of 12 items from the SF-36. The SF-12 covers 8 QoL domains: (1) physical functioning (2 items); (2) role-physical, that is, role limitations due to physical problems (2 items); (3) bodily pain (1 item); (4) general health (1 item); (5) vitality (1 item); (6) social

functioning (1 item); (7) role-emotional, that is, role limitations due to emotional problems (2 items); and (8) mental health (2 items). The psychometric properties of the SF- 12 have been tested in the general population and disease conditions and have proved to be highly reliable with ICC values of 0.63 to 0.91.[45,46] with relative validity estimates ranging from 0.43 to 0.93 (median=0.67) in comparison with the best 36-item short-form scale.[46]

Procedures for assessing functional motion

The subjects were required to perform 2 simulated trials of 5 tasks selected from DASH as examples of important activities of daily living (ADL). Items from DASH were used because it is the most extensively studied shoulder-specific function questionnaire, is available in 16 languages[16] and has the best ratings for its clinimetric properties among other shoulder questionnaires.[41] The 5 tasks chosen were: change a light bulb overhead, push open a heavy door, wash your hair, wash your back and open a tight jar. The tasks were described to the subjects and a demonstration for each was provided. They started from a relaxed anatomical position of the upper limb hanging by their side. The subjects were instructed to simulate the functional task as they would do in a real life situation and not to push into pain or do any trick movements during the task. The trick movements that the subjects were advised to avoid was not to bend/flex the trunk forward, backward or sideways and not to rotate or flex head and neck to complete the task.

Set-up and procedure

The tasks were recorded with 2 high definition video cameras simultaneously. One camera was positioned behind the patient to record the activities in a frontal plane and one camera was positioned on the side tested to record the activities in a sagittal plane. The distance of the two cameras from the subjects was standardized. Markers were placed at 5 different land marks: spine of C7 vertebra, acromion process of the scapula on the affected side, distal end of humerus between the epicondyles, dorsal aspect of wrist joint midway between ulnar and radial styloid process and dorsal aspect of the head of third metacarpal. Typical landmarks selected for digitization are those assumed to represent joint centers of rotation or segmental endpoints.[21] The angle formed between the markers at the distal end of humerus, acromion process of the scapula and a landmark marked at the midpoint between iliac crest and posterior superior iliac spine was measured for all the activities in the sagittal plane. This angle has been reported and measured

for analysis of shoulder ROM using Dartfish by Melton et al.[47] The arc of movement formed between these points was measured from the resting position to a point in space to which the arm moved and positioned the shoulder before moving the adjacent joints to complete the task. If any trick movements were observed, the angle formed at the shoulder before start of the trick movement was measured and recorded. During 2D video analysis, video capture of movement performance was downloaded to a computer and imported to a software package where kinematic data are extracted.[27, 48]

Data reduction using Dartfish analysis software (Dartfish® 5.5 ProSuite video software, Swiss Federal Institute of Technology in Lausanne, Switzerland)

Dartfish is a motion analysis software that allows tracking of joint angles throughout the movement task, with the use of an angle-tracking tool in the software.[22] The video clips were imported into the Dartfish software, edited into short clips of the individual activities for analysis. Tracking speed was set at fast (20% of image) and the landmarks were auto-tracked by selecting play. The tracking tool followed the anatomical landmarks mentioned above throughout the performance of the activity. When errors in tracking were observed, which happened when the tracking tool fell out of the markers or the marked anatomical landmark, auto tracking was stopped and the frame was rewound to that specific frame manually to correct the error and tracking resumed. This error happened in all cases and correction of the lost tracking was done manually. When tracking was completed, the angles measured during the activities were exported to Microsoft® Office Excel 2010, which was used for data analyses.

Statistical analysis

The effect of time on the change in mean functional ROM between 2 trials of each task before and after surgery was analysed using repeated measures ANOVA. Mauchly's test was used for analyzing the main effects of time on each task and when significant, degrees of freedom were corrected using Greenhouse-Geisser estimates. Post-hoc analysis using Bonferroni corrections were done for analysis of significance across each time point. Correlation between functional ROM at 6 months and scores in outcome measures was calculated using Pearson's correlation co-efficient. The test-retest reliability between the two trials for the angles measured during each functional task was calculated across all three time points (pre-op, 3 months and 6 months after surgery) using intra-class correlation coefficient (two way random model with consistency). This

model was used assuming that there would be no systematic differences between the same rater. For interpretation of reliability, an ICC value of less than 0.50 was considered poor agreement, between 0.50 and 0.75 was considered moderate agreement and above 0.75 was considered excellent agreement.[29,49] All analyses were conducted in SPSS (version 20, Chicago, IL). Descriptive data are presented as means and standard deviations (mean ± SD).

RESULTS

The functional ROM increased for all tasks when compared before- and 6 months after surgery. The standard error of measurement (SEM) ranged between 2.26° and 5.92° for all activities except for 3 tasks (pre-operatively for changing bulb and washing hair and at 3 months for changing bulb) which had a SEM of greater than 7° (table 2).

Mauchly's test indicated that the assumption of sphericity (table 3) had been violated for the main effects of time of testing during activities of changing an overhead bulb and washing your hair and hence degrees of freedoms were corrected using Greenhouse-Geisser estimates (p was considered to be significant at < 0.05, table 4). Sphericity refers to the equality of variances of the differences between levels. Mauchly's test should be non-significant to assume that the condition of sphericity has been met.[50]

The mean arc of movement that the subjects were able to move in the sagittal plane increased during all the tasks when compared before-, 3- and 6 months after surgery. The mean arc of movements that were measured during the tasks at different time points is as follows:

Change a light bulb overhead

The mean arc of movement used during the task of changing an overhead bulb was 97.59°±35.12° pre-operatively (time 1), 102.49°±33.83° at 3 months (time 2) and 116.67°±24.60° at six months (time 3) with a mean change of 19.08°±42.58° between time 1and time 3(table 2). One subject did not want to attempt the test pre-operatively due to pain while others moved their shoulder in flexion or in the scapular plane when tested pre-operatively and at 3 months. All subjects preferred to perform the activity in abduction at 6 months after surgery including the subject who did not perform the task before surgery. ANOVA results indicated violation of Mauchly's test of sphericity with a p value of 0.001 (table 3). Greenhouse-Geisser estimates showed insignificant difference in functional ROM across time points and when

Bonferonni corrections were applied, the difference in ROM was significant between 3 months and 6 months after surgery (table 4).

Push open a heavy door

Subjects preferred to perform this activity by moving their shoulder in flexion both before and after surgery. Mean shoulder flexion did not change significantly after surgery. Subjects performed shoulder flexion to place their palm on the door and tended to bend their elbows with forward flexion of the trunk to open the door. Pre-operatively, two subjects were not able to move their shoulders far enough to reach the door and could only manage to touch door with their finger tips and used their trunk to push open the door. The mean arc of shoulder flexion needed to open the door was 38.98°±14.27° pre-operatively and 39.71°±10.73° after surgery with a mean change of 0.73°±14.15° (table 2). Results of ANOVA indicated insignificant differences in functional ROM across all time points (table 4).

Wash your hair

The activity of washing one's own hair required elevation through abduction to reach overhead. Shoulder movement was measured from resting position to a point overhead when elbow starts to flex to reach the back of head. Two patients did not complete the task due to pain and 5 attempted the activity in flexion pre-operatively. The mean arc of movement for this task before surgery was 86.74°±39.40° which increased to 98.85°±26.49 and 107.42°±20.30 at 3 months and 6 months respectively with a mean change of 20.68°±37.70° (table 2). Greenhouse-Geisser estimates indicated that the change in functional ROM showed a trend toward significance with a p value of 0.06 (table 4).

Wash your back

One fourth of the subjects attempted to complete this task with compensatory movements both before and after surgery. Only 5 subjects were able to rotate their shoulder internally to touch their back with their palm pre-operatively, but rotation improved after surgery with 14 out of 20 subjects able to touch their back with their palm. To complete this activity, subjects needed to move and position their shoulder into extension before internal rotation could be attempted to touch the back. The mean arc of shoulder movement for this activity was 35.04°±11.52 pre-operatively, 37.94°±11.87 at 3 months and 42.70°±10.09° at 6 months after surgery with a mean

change of 6.12±10.88 (table 2). Time had a significant effect on functional ROM across different time points, as seen from table 4. Post-hoc analysis after Bonferroni corrections indicated that the difference was significant when compared between pre-op and 6 months after surgery.

Opening a tight jar

This activity of opening jar required the least amount of shoulder movement and was the least affected by rotator cuff tear and surgery. Subjects could move their shoulder in abduction or in the scapular plane to place their arm in space before flexing elbow to reach for the lid of the jar. Either way was considered to be within normal limits. The mean arc of movement was 39.75°±18.83 before surgery, 39.96°±16.86° at 3 months and 46.01°±11.40° at 6 months after surgery with a mean change of 6.26°±17.41° (table 2). No significant difference in change in functional ROM was observed when compared across all time points (table 4).

We did not find significant correlation between the change in functional ROM and scores in the outcome measures at 6 months after surgery (table 5). The test-retest reliability was calculated between the 2 trials for all the five tasks across all time points. The overall results on reliability showed an excellent agreement with ICC ranging between 0.61 and 0.97 (table 6). The only task to have an ICC of less than 0.80 was washing your back across all 3 time points (table 6).

DISCUSSION

This study demonstrates that video-analysis provided reliable measures of shoulder motion during dynamic functional tasks. Patients showed better task completion as evident from improved ROM and scores from self-reported measures, different movement patterns and greater arcs of motion during task performance as they recovered from cuff surgery.

The reliability of video-based motion analysis compared favourably with other forms of motion analysis. Goniometric measurements are used to assess motion during clinical examination and have reported mixed results for intra-rater and inter-rater reliability. Riddle et al[51] reported high intra-rater reliability (ICC = 0.87–0.89) with low and variable inter-rater reliability (ICC = 0.28–0.90) for shoulder ROM whereas MacDermid et al[52] have reported higher reliability with both intra-rater (ICC = 0.89–0.94) and inter-rater (ICC = 0.85–0.86) testing on shoulder rotation**.** Hayes et al[26] has reported high SEM for measurement of shoulder flexion,

abduction and external rotation of 17°, 23° and 14° respectively with moderate reliability during all shoulder ROM (ICC = 0.53-0.65).

In a study to measure performance during jumping activities, Miller and Callister[48] reported that two-dimensional movement analysis of thigh to horizontal movement angles, ankle-knee-quadriceps angle and jumping power calculated by jump off time using Dartfish software had high intra-rater reliability with an ICC in the range of 0.82 to 0.98. Similarly, concurrent validity of 2D angle analysis using Dartfish software has been supported by high correlations (Pearson $r \geq 0.95$) for sagittal plane hip and knee motion in a study by Norris et al.[22] Both intra-rater and inter-rater reliability values of hip and knee flexion angles were excellent with ICC values of 0.79 and 0.91 respectively.[22] In addition to reliability, a motion-analysis system should be able to identify differences in motion between groups. The relatively low measurement error of the motion-analysis systems should enable the detection of small, but important differences between patients, which would potentially be masked with goniometric evaluation because of its potentially large measurement error.[47]

In our study we have used Dartfish 2D video motion analysis software and have demonstrated that activities of daily living (ADL) tasks require substantial shoulder motion and that video analysis software can be used to obtain reliable measurements of this motion. Five functional tasks were analysed for changes in shoulder ROM before and after rotator cuff surgery. These five tasks were used because they were considered as examples of ADL and frequently tested in shoulder specific self-reported outcome measures.

These tasks were taken from the DASH and thus also inform our understanding of how patients with shoulder problems that affect motion might respond to these items. A previous study by Khadilkar et al[29] has quantified the functional shoulder ROM in terms of thoraco-humeral angle that will be required for the same 5 activities in DASH. They have reported a range of 118°±16° for sagittal plane flexion, 112°±14° for coronal plane abduction and 67°±9° for sagittal plane extension in normal subjects with no shoulder pathology. When we studied these activities in subjects with rotator cuff pathology, the ROM achieved at 6 months after surgery (116.67°±24.60° of elevation through abduction and flexion and a range of 42.70°±10.09° of shoulder extension, table 2) was similar to the range used by normal population with maximum change happening in the activity of washing hair followed by changing an overhead bulb and minimum change during pushing open a heavy door (table 2).

The task of pushing open a heavy door in DASH is representative of activities that require mid-range shoulder ROM.[29] Washing one's own hair or back are activities of personal grooming and require two different shoulder movements of abduction (107°) and extension (43°) respectively. Activities of washing hair (107°) and changing an overhead bulb (117°) require greater shoulder for completion of activity. The activity of washing one's own back seemed to be the most complex of all the 5 activities tested since it involved both extension and internal rotation at the shoulder for completion of the activity. It was also the task which required the longest time for improvement in terms of ROM required for completion of activity. Opening a tight jar is the only activity among these 5 tasks that need minimal shoulder movement. Shoulder ROM is required in the mid-range to position the shoulder in space for the forearm and wrist to complete this activity.

When performing the activities before surgery subjects appeared to be most often limited by pain in the shoulder as seen by high VAS scores before surgery (table1). They tended to stop the activity at a point where pain restricted them and did not try to overdo or compensate for not being able to complete the activity. But after surgery, it was observed that pain level during activity decreased compared to pre-surgical intensity (table 1) with increased shoulder stiffness due to periods of immobilization. Hence subjects tended to use compensatory movements pre-operatively and at 3 months after surgery with greatest trick movements occurring during the activity of washing one's own back. At six months after surgery, subjects were able to perform the activities with similar ROM required in normal subjects as reported by Khadilkar et al.[29] Also, movement patterns improved after surgery with subjects able to perform shoulder abduction for the activities of changing an overhead bulb and washing hair, place their palm on the door to push compared to using tips of fingers before surgery and used minimal compensatory movements for washing their back.

Our results indicate that the change in functional ROM did not correlate significantly with change in scores in the outcome measures at 6 months after surgery. This can be attributed to the fact that patients did not move their shoulder through the entire ROM to do the 5 activities that were tested. This might have contributed to the insignificant correlations due to the broader scope of the outcome measures like DASH in clinical conditions.[40]

Our results, while reliable with high test-retest reliability between trials during all tasks, do depend on accuracy of the motion capture and so we implemented some procedures to insure standardization while allowing subjects to perform natural movements. The vertical height of the

cameras was fixed for both the camera and the distance between each camera and the subjects was standardized. The markers used were as large as possible to make tracking easier and consistent. The cameras were focused to zoom into the required field of view and manually adjusted to suit each participant's image without the marker leaving the scope of the video monitor. These factors may have contributed to better precision and repeatability.

The SEM ranged between 2.26° and 5.92° for the mean arc of movement for all tasks except for 3 trials. Similar SEM values of less than 2^0 of the shoulder joint have been reported for 3D motion analysis systems.[53] This variability of 2.26° and 5.92° can be accounted to the manner in which each subject preferred to do the same task or between the 2 trials. Tasks were demonstrated to the subjects by the primary author, but they were also instructed to attempt the task as they would do in their daily life routine. Some subjects attempted the tasks in their pain-free range whereas a few attempted trick movements for completion. Also, losing the markers during auto-tracking may have resulted in variability during analysis.

Despite following all guidelines to maintain the consistency in capturing the videos and in analysis, one limitation in this study was losing the markers during auto-tracking. When this happened, the video had to be stopped, rewound to the frame in concern, markers had to be tracked back their original place and video re-started. Even though maximum precautions were taken to minimize variations, errors are bound to happen in manual correction which could result in variations in measurements and analysis. Also, the disadvantage of using markers is that individual shoulder anatomy is not taken into account and that results are greatly sensitive to markers placed on anatomical landmarks.[54]

Limitations

This study provided information on how patients with rotator cuff pathology move during functional tasks but these must be considered in light of study limitations. The sample, although consistent with other kinematic studies is small and may not reflect the larger population of patients undergoing surgery. The sample included patients that had both partial and full thickness tears. The effects of size and type of the tear, fatty infiltration and number of tendons involved on change in functional ROM were not accounted for during analysis. These prognostic factors would have had a significant effect on outcomes and hence should have been considered during analysis. Although video-analysis provides a detailed description of movement, we were required to distil this down to kinematic variables of interest and therefore focused on functional

ROM required for different activities and the improvement in ROM acquired before and after surgery. Although compensatory movements were evident in pre-surgical patients, there is no measure to quantify these movements and thus not all movement benefits of surgery were quantifiable.

Recommendations for future research

Future studies should focus on studying movement patterns and functional activities in patients' own environment instead of a clinical setting. This would give an opportunity to study how patients do their ADL in their own setting and any substitution that they might employ in those activities. Also, studies should attempt to create a check list for objective measures in the presence of compensatory movements during functional activities which is lacking in the present outcome measures used to measure health related quality of life.

CONCLUSION

The results of this study were consistent with reports of previous studies that have studied shoulder function in normal subjects. The functional ROM improved during all activities before and after surgery with significant change across time in activities of 'changing an overhead bulb' and 'washing your back' and a trend towards significance in the activity of 'washing your hair'. Movement patterns improved when compared before and after surgery with decreased pain and stiffness. Analysis of functional tasks before and after rotator cuff repair using 2D video analysis software proved to be a reliable means of measuring functional shoulder ROM before and after surgery. Clinicians should be aware of these changes in movement patterns during activities of daily living when deciding on treatment protocols for patients after rotator cuff repair. To the authors' knowledge, this is only the second study to study shoulder function using 2D video analysis on patients with shoulder conditions. Future studies are required to validate these findings.

REFERENCES

1. Levangie P.K., & Norkin C.C (2005). *Joint Structure and function. A Comprehensive analysis* (4th ed.). F.A Davis Company, Philadelphia.

2. Murray, I. A., & Johnson, G. R. (2004). A study of the external forces and moments at the shoulder and elbow while performing everyday tasks. *Clinical Biomechanics (Bristol, Avon), 19*(6), 586-594. doi: 10.1016/j.clinbiomech.2004.03.004
3. Namdari, S., Yagnik, G., Ebaugh, D. D., Nagda, S., Ramsey, M. L., Williams, G. R.,Jr, & Mehta, S. (2012). Defining functional shoulder range of motion for activities of daily living. *Journal of Shoulder and Elbow Surgery / American Shoulder and Elbow Surgeons ...[Et Al.], 21*(9), 1177-1183. doi: 10.1016/j.jse.2011.07.032; 10.1016/j.jse.2011.07.032
4. Buckley, M. A., Yardley, A., Johnson, G. R., & Carus, D. A. (1996). Dynamics of the upper limb during performance of the tasks of everyday living--a review of the current knowledge base. *Proceedings of the Institution of Mechanical Engineers.Part H, Journal of Engineering in Medicine, 210*(4), 241-247.
5. Magermans, D. J., Chadwick, E. K., Veeger, H. E., & van der Helm, F. C. (2005). Requirements for upper extremity motions during activities of daily living. *Clinical Biomechanics (Bristol, Avon), 20*(6), 591-599. doi: 10.1016/j.clinbiomech.2005.02.006
6. Cheng, P.L., 1996. Biomechanical study of upper limb activities of daily living. PhD Thesis, University of Strathclyde, Glasgow, Scotland.
7. Stobbe, T. J. (1996). Occupational ergonomics and injury prevention. *Occupational Medicine (Philadelphia, Pa.), 11*(3), 531-543.
8. MacDermid, J. C., Ramos, J., Drosdowech, D., Faber, K., & Patterson, S. (2004). The impact of rotator cuff pathology on isometric and isokinetic strength, function, and quality of life. *Journal of Shoulder and Elbow Surgery / American Shoulder and Elbow Surgeons ...[Et Al.], 13*(6), 593-598. doi: 10.1016/S1058274604001247
9. Rockwood, C. A. (2009). *The Shoulder* (4th ed.). Philadelphia, PA: Saunders/Elsevier.
10. Zakaria, D. (2004). Rates of carpal tunnel syndrome, epicondylitis, and rotator cuff claims in ontario workers during 1997. *Chronic Diseases in Canada, 25*(2), 32-39.
11. Hudak, P. L., Amadio, P. C., & Bombardier, C. (1996). Development of an upper extremity outcome measure: The DASH (disabilities of the arm, shoulder and hand) [corrected]. the upper extremity collaborative group (UECG). *American Journal of Industrial Medicine, 29*(6), 602-608. doi: 2-L
12. Lippitt SB, Harryman DT, Matsen FA. *A practical tool for evaluation of function: the simple shoulder test. The Shoulder: A Balance of Mobility and Stability.* Rosemont, IL: American Academy of Orthopaedic Surgery; 1993.

13. Richards, R. R., An, K. N., Bigliani, L. U., Friedman, R. J., Gartsman, G. M., Gristina, A. G., . . . Zuckerman, J. D. (1994). A standardized method for the assessment of shoulder function. *Journal of Shoulder and Elbow Surgery / American Shoulder and Elbow Surgeons ...[Et Al.], 3*(6), 347-352. doi: 10.1016/S1058-2746(09)80019-0; 10.1016/S1058-2746(09)80019-0
14. Roach, K. E., Budiman-Mak, E., Songsiridej, N., & Lertratanakul, Y. (1991). Development of a shoulder pain and disability index. *Arthritis Care and Research : The Official Journal of the Arthritis Health Professions Association, 4*(4), 143-149.
15. Constant, C. R., & Murley, A. H. (1987). A clinical method of functional assessment of the shoulder. *Clinical Orthopaedics and Related Research, (214)*(214), 160-164.
16. Roy, J. S., MacDermid, J. C., & Woodhouse, L. J. (2009). Measuring shoulder function: A systematic review of four questionnaires. *Arthritis and Rheumatism, 61*(5), 623-632. doi: 10.1002/art.24396; 10.1002/art.24396
17. Roy JS, MacDermid JC, Woodhouse LJ. A systematic review of the psychometric properties of the Constant-Murley score. J Shoulder Elbow Surg 2010;19(1):157-164.
18. Michener, L. A., & Leggin, B. G. (2001). A review of self-report scales for the assessment of functional limitation and disability of the shoulder. *Journal of Hand Therapy : Official Journal of the American Society of Hand Therapists, 14*(2), 68-76.
19. Jolles, B. M., Duc, C., Coley, B., Aminian, K., Pichonnaz, C., Bassin, J. P., & Farron, A. (2011). Objective evaluation of shoulder function using body-fixed sensors: A new way to detect early treatment failures? *Journal of Shoulder and Elbow Surgery / American Shoulder and Elbow Surgeons ...[Et Al.], 20*(7), 1074-1081. doi: 10.1016/j.jse.2011.05.026; 10.1016/j.jse.2011.05.026
20. Safaee-Rad, R., Shwedyk, E., & Quanbury, A. O. (1990). Three-dimensional measurement system for functional arm motion study. *Medical & Biological Engineering & Computing, 28*(6), 569-573.
21. Payton, C., Bartlett, R., & British Association of Sport and Exercise Sciences. (2008). *Biomechanical evaluation of movement in sport and exercise :The british association of sport and exercise sciences guidelines*. London ;; New York: Routledge.
22. Norris, B. S., & Olson, S. L. (2011). Concurrent validity and reliability of two-dimensional video analysis of hip and knee joint motion during mechanical

lifting. *Physiotherapy Theory and Practice*, *27*(7), 521-530. doi: 10.3109/09593985.2010.533745; 10.3109/09593985.2010.533745

23. Armstrong, A. D., MacDermid, J. C., Chinchalkar, S., Stevens, R. S., & King, G. J. (1998). Reliability of range-of-motion measurement in the elbow and forearm. *Journal of Shoulder and Elbow Surgery / American Shoulder and Elbow Surgeons ...[Et Al.], 7*(6), 573-580.
24. van Andel, C. J., Wolterbeek, N., Doorenbosch, C. A., Veeger, D. H., & Harlaar, J. (2008). Complete 3D kinematics of upper extremity functional tasks. *Gait & Posture, 27*(1), 120-127. doi: 10.1016/j.gaitpost.2007.03.002
25. Lovern, B., Stroud, L. A., Ferran, N. A., Evans, S. L., Evans, R. O., & Holt, C. A. (2010). Motion analysis of the glenohumeral joint during activities of daily living. *Computer Methods in Biomechanics and Biomedical Engineering, 13*(6), 803-809. doi: 10.1080/10255841003630637; 10.1080/10255841003630637
26. Hayes, K., Walton, J. R., Szomor, Z. R., & Murrell, G. A. (2001). Reliability of five methods for assessing shoulder range of motion. *The Australian Journal of Physiotherapy*, *47*(4), 289-294.
27. McLean, S. G., Walker, K., Ford, K. R., Myer, G. D., Hewett, T. E., & van den Bogert, A. J. (2005). Evaluation of a two dimensional analysis method as a screening and evaluation tool for anterior cruciate ligament injury. *British Journal of Sports Medicine, 39*(6), 355-362. doi: 10.1136/bjsm.2005.018598
28. Borel, S., Schneider, P., & Newman, C. J. (2011). Video analysis software increases the interrater reliability of video gait assessments in children with cerebral palsy. *Gait & Posture, 33*(4), 727-729. doi: 10.1016/j.gaitpost.2011.02.012; 10.1016/j.gaitpost.2011.02.012
29. Khadilkar, L. (2010). *Measuring the disabilities of shoulder related disorders*. London, Ont.: School of Graduate and Postdoctoral Studies, University of Western Ontario.
30. Warner, J. J., & Greis, P. E. (1998). The treatment of stiffness of the shoulder after repair of the rotator cuff. *Instructional Course Lectures, 47*, 67-75.
31. Ellman, H., Hanker, G., & Bayer, M. (1986). Repair of the rotator cuff. end-result study of factors influencing reconstruction. *The Journal of Bone and Joint Surgery.American Volume, 68*(8), 1136-1144.

32. Gore, D. R., Murray, M. P., Sepic, S. B., & Gardner, G. M. (1986). Shoulder-muscle strength and range of motion following surgical repair of full-thickness rotator-cuff tears. *The Journal of Bone and Joint Surgery.American Volume, 68*(2), 266-272.
33. Aizawa, J., Masuda, T., Koyama, T., Nakamaru, K., Isozaki, K., Okawa, A., & Morita, S. (2010). Three-dimensional motion of the upper extremity joints during various activities of daily living. *Journal of Biomechanics,43*(15), 2915-2922. doi: 10.1016/j.jbiomech.2010.07.006; 10.1016/j.jbiomech.2010.07.006
34. Flaherty, S. A. (1996). Pain measurement tools for clinical practice and research. *AANA Journal, 64*(2), 133-140.
35. Lee, J. J., Yoo, Y. S., Hwang, J. T., Kim, D. Y., Jeon, S. J., Hwang, S. M., & Jang, J. S. (2013). Efficacy of direct arthroscopy-guided suprascapular nerve block after arthroscopic rotator cuff repair: A prospective randomized study. *Knee Surgery, Sports Traumatology, Arthroscopy : Official Journal of the ESSKA,* doi: 10.1007/s00167-013-2451-x
36. Schwartzberg, R. S., Reuss, B. L., & Rust, R. (2013). Efficacy of continuous subacromial bupivacaine infusion for pain control after arthroscopic rotator cuff repair. *Journal of Shoulder and Elbow Surgery / American Shoulder and Elbow Surgeons ...[Et Al.],* doi: 10.1016/j.jse.2013.03.016; 10.1016/j.jse.2013.03.016
37. Bijur, P. E., Silver, W., & Gallagher, E. J. (2001). Reliability of the visual analog scale for measurement of acute pain. *Academic Emergency Medicine : Official Journal of the Society for Academic Emergency Medicine, 8*(12), 1153-1157.
38. Gallagher, E. J., Bijur, P. E., Latimer, C., & Silver, W. (2002). Reliability and validity of a visual analog scale for acute abdominal pain in the ED. *The American Journal of Emergency Medicine, 20*(4), 287-290.
39. Williamson, A., & Hoggart, B. (2005). Pain: A review of three commonly used pain rating scales. *Journal of Clinical Nursing, 14*(7), 798-804. doi: 10.1111/j.1365-2702.2005.01121.x
40. Kirkley, A., Griffin, S., & Dainty, K. (2003). Scoring systems for the functional assessment of the shoulder. *Arthroscopy : The Journal of Arthroscopic & Related Surgery : Official Publication of the Arthroscopy Association of North America and the International Arthroscopy Association, 19*(10), 1109-1120. doi: 10.1016/j.arthro.2003.10.030

41. Bot, S. D., Terwee, C. B., van der Windt, D. A., Bouter, L. M., Dekker, J., & de Vet, H. C. (2004). Clinimetric evaluation of shoulder disability questionnaires: A systematic review of the literature. *Annals of the Rheumatic Diseases, 63*(4), 335-341.
42. Ekeberg, O. M., Bautz-Holter, E., Tveita, E. K., Keller, A., Juel, N. G., & Brox, J. I. (2008). Agreement, reliability and validity in 3 shoulder questionnaires in patients with rotator cuff disease. *BMC Musculoskeletal Disorders, 9*, 68-2474-9-68. doi: 10.1186/1471-2474-9-68; 10.1186/1471-2474-9-68
43. Kirkley, A., Alvarez, C., & Griffin, S. (2003). The development and evaluation of a disease-specific quality-of-life questionnaire for disorders of the rotator cuff: The western ontario rotator cuff index. *Clinical Journal of Sport Medicine : Official Journal of the Canadian Academy of Sport Medicine, 13*(2), 84-92.
44. Raman, J., & Macdermid, J. C. (2012). Western ontario rotator cuff index. *Journal of Physiotherapy, 58*(3), 201-9553(12)70115-7. doi: 10.1016/S1836-9553(12)70115-7; 10.1016/S1836-9553(12)70115-7
45. Gandhi, S. K., Salmon, J. W., Zhao, S. Z., Lambert, B. L., Gore, P. R., & Conrad, K. (2001). Psychometric evaluation of the 12-item short-form health survey (SF-12) in osteoarthritis and rheumatoid arthritis clinical trials. *Clinical Therapeutics, 23*(7), 1080-1098.
46. Ware, J.,Jr, Kosinski, M., & Keller, S. D. (1996). A 12-item short-form health survey: Construction of scales and preliminary tests of reliability and validity. *Medical Care, 34*(3), 220-233.
47. Melton, C., Mullineaux, D. R., Mattacola, C. G., Mair, S. D., & Uhl, T. L. (2011). Reliability of video motion-analysis systems to measure amplitude and velocity of shoulder elevation. *Journal of Sport Rehabilitation, 20*(4), 393-405.
48. Miller, A., & Callister, R. (2009). Reliable lower limb musculoskeletal profiling using easily operated, portable equipment. *Physical Therapy in Sport : Official Journal of the Association of Chartered Physiotherapists in Sports Medicine, 10*(1), 30-37. doi: 10.1016/j.ptsp.2008.10.003; 10.1016/j.ptsp.2008.10.003
49. Portney, L.G., & Watkins, M.P., (2009). *Foundations of clinical research. Applications to practice* (3rd edition). New Jersey, Pearson Education Inc.
50. Field, A. P. (2009). *Discovering statistics using SPSS :(and sex, drugs and rock 'n' roll)* (3rd ed.). Los Angeles: SAGE Publications.

51. Riddle, D. L., Rothstein, J. M., & Lamb, R. L. (1987). Goniometric reliability in a clinical setting. shoulder measurements. *Physical Therapy*, *67*(5), 668-673.
52. MacDermid, J. C., Chesworth, B. M., Patterson, S., & Roth, J. H. (1999). Intratester and intertester reliability of goniometric measurement of passive lateral shoulder rotation. *Journal of Hand Therapy : Official Journal of the American Society of Hand Therapists, 12*(3), 187-192.
53. Lin, J. J., Hanten, W. P., Olson, S. L., Roddey, T. S., Soto-Quijano, D. A., Lim, H. K., & Sherwood, A. M. (2005). Functional activities characteristics of shoulder complex movements: Exploration with a 3-D electromagnetic measurement system. *Journal of Rehabilitation Research and Development, 42*(2), 199-210.
54. Rettig, O., Fradet, L., Kasten, P., Raiss, P., & Wolf, S. I. (2009). A new kinematic model of the upper extremity based on functional joint parameter determination for shoulder and elbow. *Gait & Posture, 30*(4), 469-476. doi: 10.1016/j.gaitpost.2009.07.111; 10.1016/j.gaitpost.2009.07.111

Table 1. Descriptive statistics

Descriptive statistics	
Age	52.50 ± 10.38 Range = 34 to 73 years
Dominant side	Right – 17 Left - 3
Dominant side affected	12
DASH*	Pre- op: 44.10 ± 23.66 3 months: 32.78 ± 15.53 6 months: 15.50 ± 12.83
WORC	Pre- op: 1370.72±497.65† (34.73% ± 23.70) 3 months: 1040.99± 529.30† (50.43% ± 25.20) 6 months: 571.03± 408.33† (72.81% ± 19.44)
SF – 12‡	Pre- op: PCS: 37.83±7.05 MCS: 50.80±10.80 3 months: PCS: 39.95±8.22 MCS: 52.48±9.79 6 months: PCS: 47.09±8.12 MCS: 52.33±8.77
VAS§	Pre- op: 7.4 ± 2.21 3 months: 2.7 ± 2.32 6 months: 1.05 ± 1.43

+

*scores converted to 100, †score out of 2100 for WORC, ‡maximum score is 70, §maximum score of 10, DASH - Disabilities of arm shoulder and hand (lower score indicates better outcome), WORC - Western Ontario rotator cuff index (lower score and higher % indicates better outcome), SF – 12 - Short form health survey questionnaire (higher score indicates better outcome), VAS – Visual analog scale (lower score indicates improved outcome)

Table 2. Functional range of motion of shoulder for all tasks before and after rotator cuff repair

Variable	Pre-op			3 months			6 months			Mean change (before surgery and 6 months after surgery)		
	Mean	SD	SEM	Mean	SD	SEM	Mean	SD	SEM	Mean	SD	SEM
Change a light bulb overhead	97.59†	35.12	7.85	102.49*	33.83	7.56	116.67†	24.60	5.50	19.08	42.58	9.52
Push open a heavy door*	38.98	14.27	3.19	40.90	14.18	3.17	39.71	10.73	2.40	0.73	14.15	3.16
Wash your hair†	86.74	39.40	8.81	98.85	26.49	5.92	107.42	20.30	4.54	20.68	37.70	8.43
Wash your back‡	35.04	11.52	2.57	37.94	11.87	2.65	42.70	10.09	2.26	7.66	10.73	2.40
Open a tight jar†	39.75	18.83	4.21	39.96	16.86	3.77	46.01	11.40	2.55	6.26	17.41	3.89

All data given in degrees for range of motion of shoulder, *shoulder flexion, †shoulder abduction, ‡shoulder extension

Table 3. Mauchly's test of sphericity

Within Subjects Effect	Task	Mauchly's W	df	p
Time	Change a light bulb overhead	0.472	2	0.001
	Push open a heavy door	**0.726**	**2**	**0.056***
	Wash your hair	0.324	2	0.000
	Wash your back	**0.717**	**2**	**0.05***
	Open a tight jar	**0.920**	**2**	**0.473***

p significant at <0.05, df = degrees of freedom, *Assumption of sphericity met

Table 4. Results of repeated measures ANOVA

Variable	Pre-op	3 months	6 months	p
	Mean	Mean	Mean	
Change a light bulb overhead	**97.59**	**102.49**	**116.67[§]**	**0.03***
Push open a heavy door	38.98	40.90	39.71	0.82[†]
Wash your hair	86.74	98.85	107.42	0.06*
Wash your back	**35.04**	**37.94**	**42.70[‡]**	**0.01[†]**
Open a tight jar	39.75	39.96	46.01	0.15[†]

*Assumption of sphericity was violated, degrees of freedom were corrected using Greenhouse-Geisser estimates of sphericity, †Assumption of sphericity met, ‡Significant difference between pre-op and 6 months after Bonferroni post-hoc correction, §Significant difference between 3months and 6 months after Bonferroni post-hoc correction

Table 5. Correlation between functional ROM at 6 months and scores in outcome measures (Pearson Correlation)

Task*	DASH at 6 months	WORC at 6 months	SF-12 at 6 months	VAS at 6 months
Change a light bulb overhead	0.10	0.05	0.25	0.02
Push open a heavy door	-0.28	-0.33	0.10	-0.44
Wash your hair	0.21	0.03	0.16	-0.06
Wash your back	-0.47	-0.15	0.14	0.16
Open a tight jar	-0.05	0.14	-0.40	0.32

*Mean ROM between 2 trials at 6 months after surgery

Table 6. Test-retest reliability for all tasks before and after surgery

Variable	ICC (95 % CI)		
	Pre-op	3 months	6 months
Change a light bulb overhead	0.97 (0.92 – 0.99)	0.96 (0.89 – 0.98)	0.92 (0.80 – 0.97)
Push open a heavy door	0.92 (0.81 - 0.97)	0.90 (0.76 – 0.96)	0.86 (0.67 – 0.94)
Wash your hair	0.84 (0.63 – 0.93)	0.94 (0.85 – 0.98)	0.91 (0.79 – 0.96)
Wash your back	0.69 (0.36 – 0.86)	0.77 (0.51 – 0.90)	0.61 (0.24 – 0.82)
Open a tight jar	0.96 (0.91 – 0.99)	0.92 (0.80 – 0.97)	0.80 (0.55 – 0.91)

ICC – Intra class correlation coefficient, CI – Confidence interval

CHAPTER 4. SHOULDER MUSCLE ENDURANCE IN PATIENTS FOLLOWING ROTATOR CUFF REPAIR

ABSTRACT

Study design

Cross-sectional study.

Background

Uncomplicated major surgery is followed by a pronounced increased feeling of postoperative fatigue in about one-third of the patients that correlates with the degree of surgical trauma but is not related to duration of general anaesthesia and surgery or to preoperative nutritional status, age, or sex. Fatigue also correlates with postoperative deterioration in nutritional parameters and impaired adaptability of heart rate during exercise. Furthermore, a postoperative decrease in muscle force and endurance is related to postoperative fatigue, whereas psychological factors are of minor importance.[28] Shoulder dysfunction and rotator cuff pathologies are possible results of altered joint mechanics that occur due to shoulder muscle fatigue.[20] Shoulder muscle fatigue has been proposed as a possible link to explain the association between repetitive arm use and the development of rotator cuff disorders. Researches have been done to study shoulder muscle fatigue in both normal subjects as well subjects with shoulder pathologies. But to date, there has been no research to study the effect of rotator cuff repair on shoulder muscle fatigue.

Purpose

The purpose of this prospective study was to describe the endurance and fatigue patterns for shoulder abduction and external rotation in patients who underwent rotator cuff repair; and to compare muscle performance to that demonstrated by age- and gender-matched controls.

Methods

Twenty subjects with rotator cuff tear who had surgical repair of the rotator cuff and twenty age and gender matched controls were chosen for the study. The subjects were measured for shoulder pain, function and general health status using Disabilities of arm, shoulder and hand (DASH), Western Ontario rotator cuff index (WORC), Simple shoulder test (SST) and Short form health survey (SF-12). The subjects' level of shoulder pain after the test was recorded on a VAS.

Muscle performances were measured using the Biodex system 3 which is a muscle strength testing and rehabilitation instrument used in the testing and rehabilitation services for shoulder, elbow, wrist, hip, knee and ankle. Patients who underwent surgery for rotator cuff repair were tested 6 months after surgery for their muscle performance using the endurance protocol developed by Jean-Sébastien Roy et al. The endurance protocol was performed in isotonic mode with the resistance set at 50% of each subject's peak torque as measured for shoulder abduction and external rotation (ER). The muscle performance was measured by calculating the average peak torque, total work done, average peak velocity, average power, change in muscle work between the first and last third of the endurance protocol, percentage of work fatigue and analyzed across the group of patients and controls. The data collected was compared to the muscle performance of age and gender matched controls.

Results

The changes in muscle performances as measured by average isokinetic torque and total work before and after the endurance protocol did not indicate fatigue in the muscles in patients after their rotator cuff surgery and in the control group. There was an overall increase in the mean peak torque in both the experimental and control groups during both abduction and external rotation. This increase in peak torque was not significant in abduction and external rotation in the experimental and control groups respectively. Similarly, the total work done before and after the protocol also increased in both abduction and ER in the experimental group and in abduction in the control group with a decrease in the total work done in the control group in ER.

Conclusion

An endurance protocol for shoulder abduction and external rotation done for 60 isotonic repetitions at 50 % of maximal isokinetic mean peak torque could be completed by 70% of patients six months after their rotator cuff surgery and 90% of age matched controls. Muscular fatigue was not demonstrated during their isokinetic muscle performances and patients performed similar to age matched controls. The mean peak torque and total work done did not decrease over the sixty repetitions. Alterations to the fatigue protocol or criterion measures may be needed to capture more subtle differences in fatigability. Although this test protocol may not optimally assess fatigability, this study indicated that six months following rotator cuff repair, patients were able to demonstrate normal performance over 60 consecutive isotonic repetitions at

50% repetition maximum which is an aspect of muscle performance that has not been previously reported.

Level of Evidence. 2b
Keywords. Muscle endurance, fatigue, Biodex.

INTRODUCTION

The glenohumeral (GH) joint, linking the humerus and scapula, has greater mobility than any other joint in the body. The contradictory requirements on the shoulder complex for both mobility and stability are met through active forces, or dynamic stabilization, which exists when a moving segment or set of segments is limited very little by passive forces such as articular surface configuration, capsule, or ligaments and instead relies heavily on active forces or dynamic muscular control.[1] Muscle forces serve as a primary mechanism for securing the shoulder girdle to the thorax and providing a stable base of support for upper extremity movements.[1,2] Factors specific to the job, work organization, and individual have all been implicated as potential risk factors for cumulative trauma disorder of the upper extremity (CTDUE),[3] an umbrella term used to describe disorders of the bones, joints, ligaments, muscles, tendons, bursae, blood vessels, and nerves, which result from the repeated use of the upper extremity over time rather than a specific incident.

Chronic overuse injuries may involve repeated or sustained loads while the tissue is still in a deformed state. Time, not load alteration, may be the critical variable.[1] Repetitive motion-induced fatigue not only alters local motion characteristics, but also provokes global reorganization of movement.[4] The effects of fatigue on peripheral muscles include reduced maximal voluntary force production, velocity of muscle contraction, and power output.[5,6] Shoulder dysfunction and rotator cuff pathologies are possible results of altered joint mechanics that occur due to shoulder muscle fatigue.[7] Shoulder muscle fatigue has been proposed as a possible link to explain the association between repetitive arm use and the development of rotator cuff disorders.[8] Fatigue of the rotator cuff musculature alters the kinematics of the humeral head on the glenoid fossa, thus contributing to shoulder dysfunction.[9,10] Taken together, these data suggest that muscular fatigue impedes sensorimotor function and may predispose the shoulder to injury during activity.[11]

Rotator cuff tears are among the most common injuries affecting the musculoskeletal system.[12] Tears become more prevalent with increasing age[13,14] since rotator cuff pathology is related to degenerative changes in the tendons during the aging process.[15,16] A rotator cuff tear can lead to declines in muscle strength and shoulder mobility that have a negative impact on activities of daily living, work, and leisure activities.[17] Rotator cuff tears are often treated conservatively and produce the best results for patients with preserved range of motion and

muscle strength, regardless of severity of pain.[18] Patients who failed to achieve improvements in functional outcomes with conservative management typically proceed to surgical repair. With evidence of an acute and complete disruption of the rotator cuff early surgical repair (with 3 weeks of injury) affords the best opportunity for maximal recovery of shoulder function.[19] Tear size and acuity, the presence of irreparable changes to the rotator cuff or gleno-humeral joint, and patient age should all be considered in making a decision on surgery. Initial non-operative care can be safely undertaken in older patients (>70 years old) with chronic tears; in patients with irreparable rotator cuff tears with irreversible changes, including significant atrophy and fatty infiltration, humeral head migration, and arthritis; in patients of any age with small (<1 cm) full-thickness tears; or in patients without a full-thickness tear. Early surgical treatment can be considered in significant (>1 cm-1.5 cm) acute tears or young patients with full-thickness tears who have a significant risk for the development of irreparable rotator cuff changes.[20]

The goal of rotator cuff repair is to eliminate pain and improve function with increased shoulder strength and range of motion.[21] The repair of the cuff is done by various surgical methods (open, mini-open and arthroscopic) and the clinical outcomes of each repair vary, as each method provides an array of advantages and disadvantages.[21] The open technique may also require a longer period of limited motion resulting in greater stiffness. Also postoperative detachment of the deltoid repair has been reported and results in significant morbidity.[22] Arthroscopically assisted mini-open repairs and, more recently, completely arthroscopic repairs of the rotator cuff avoid detachment of the deltoid[11] and are less invasive.[23] The mini-open and arthroscopic approaches to rotator cuff repair have the added benefit of arthroscopic evaluation of the glenohumeral joint.[22] Prognosis after rotator cuff repair is dependent on several factors such as fatty infiltration in the rotator cuff, tear size, pre-operative strength of the rotator cuff muscles, multiple tendon involvement, presence of workman's compensation status.[24]

A number of studies have addressed the effect of shoulder muscle fatigue on the kinematics of the glenohumeral and scapulothoracic joint.[7,9,10, 25-27] Muscle weakness and muscle fatigue may be consequences of the postoperative decreased food intake, deterioration in nutritional status, and immobilization.[28] Postoperatively, muscle function declines by about 5% to 6% as measured by hand grip force[29] and by 15% to 50% when assessed by hip muscle endurance during isokinetic work within the first 10 postoperative days.[29] To date, no studies have addressed the effect of rotator cuff repair on shoulder muscle fatigue. The purpose of this cross-sectional study was to describe the endurance and fatigue patterns for shoulder abduction

and external rotation in patients who underwent rotator cuff repair; and to compare muscle performance to that demonstrated by age- and gender-matched controls.

METHODOLOGY

Study design

Cross-sectional study.

Subjects

The sample consisted of two groups of twenty subjects each. The experimental group consisted of twenty patients who were seen 6 months after their surgery for rotator cuff tear because majority of improvement in shoulder ROM, pain, and function occurred by 6 months after surgery.[30] The control group consisted of twenty age and gender matched controls with no history of shoulder pathology. The age range of the subjects in the experimental group was 34 to 70 years (mean age = 57.3 years, SD = 10.52). The subjects were measured for shoulder pain, function and general health status using Disabilities of arm, shoulder and hand (DASH), Western Ontario rotator cuff index (WORC), Simple shoulder test (SST) and Short form health survey (SF-12) questionnaires. The subjects' level of shoulder pain after the test was recorded on a VAS. All the participants read and signed an informed consent form. This study was approved by the University of Western Ontario Ethics Board.

Experimental design

All subjects performed the endurance tests in a single session. The subjects were tested for the isokinetic strength of shoulder abductors and external rotators. The subjects performed five repetition maximum (5RM) concentric contractions to determine their 5RM isokinetic peak torque. Then, they performed the endurance protocol developed by Jean-Sébastien Roy et al.[8] Immediately following the endurance protocol the changes in muscle performances were assessed with 5RM isokinetic contractions. The muscle performance was measured by calculating the average peak torque (in ft-lbs) and total work done (in ft-lbs) developed by the isokinetic contractions before and after the endurance protocol, average peak velocity (in degrees/second), change in muscle work between the first and last third of the endurance protocol, average power and percentage of work fatigue developed during the endurance protocol and analyzed across the group of patients and controls. Out of the 20 subjects in the

experimental group, 10 had surgeries in their dominant arm and 10 were in the non-dominant side. Hence to have a valid comparison in results between the experimental and control group, 10 subjects in the control group performed the test on their non-dominant arm to match with their age-and gender-matched subjects in the experimental group.

Strength measurement

Strength measurements before and after the endurance protocol were performed using the Biodex system 3 dynamometer (Biodex Medical Systems, 20 Ramsay Road, Shirley, NY, 11967-47). The shoulder adapter and shoulder attachment were attached to the dynamometer. For isokinetic testing of the shoulder abductors, the subjects were seated next to the dynamometer with their shoulder at zero degrees of abduction resting by their side. They were asked to move their shoulder into abduction up to ninety degrees. For testing shoulder external rotators, the subjects assumed a sitting position next to the dynamometer as before. The arm rested on their side with the elbow flexed to ninety degree with the forearm resting on a suitable attachment connected to the dynamometer. The subjects were to move their shoulder into external rotation with the elbow staying to their side. For both the movements, the subjects were to hold on to the hand grip attachment of the dynamometer. Before testing, the subjects performed two trials on the Biodex. Then, each subject performed five maximal isokinetic repetitions of concentric abduction and external rotation at 60^{o}/sec. The mean peak torque values for the five repetitions were recorded for both abduction and external rotation.

Endurance protocol[8]

The endurance protocol was performed on the same Biodex dynamometer with the subject in the same position as that used for the isokinetic strength measurements. The endurance protocol was performed in isotonic mode with the resistance set at 50% of each subject's 5RM mean peak torque as measured at baseline for each movement of shoulder abduction (ABD) and external rotation (ER). Each subject performed 60 continuous repetitions of ABD/ER. If the subjects were not able to complete 60 repetitions, they were asked to perform as many repetitions possible without any rest or break in between and stop when they could do no more repetitions. The number of repetitions was noted. Subjects were asked to maintain the velocity during the protocol to at least 60°/sec and to perform maximal contractions throughout the endurance test (i.e. not to pace themselves). Subjects were given feedback on their velocity of movement. There

was no maximal velocity for the test. Range of motion (ROM) was preset to the maximal abduction and external rotation that each subject was comfortable using. The following criterion measures were extracted from the endurance protocol data: 1) the average peak velocity in degrees/second, 2) the decrement in work done between the first third and the last third of the repetitions performed for the endurance protocol in ft-lbs, 3) percentage of work fatigue between the first and last third of repetitions during the endurance protocol and 4) the average power, measured in watts, developed during the endurance protocol.

Consistent standardized verbal encouragement was provided throughout the testing to encourage subjects to give maximal effort throughout the endurance protocol. The experimenter instructed the subject to "try your best" at the start and again after each block of ten trials (i.e. at the beginning, and again after 10, 20, 30, 40, and 50 repetitions).

Pilot study

A pilot study to test the endurance protocol as explained by Roy et al was conducted with eight healthy subjects. Out of the eight subjects, four were able to complete the protocol and four did not. The Biodex was not able to generate report for strength measurements if the protocol was not completed. When the machine was set at time to complete instead of the number of repetitions, a report was generated for the number of repetitions that the subjects were able to complete before stopping the repetitions. Hence for the study, the protocol was modified to be completed by time (200 seconds). The subjects were advised to perform 60 repetitions or stop when they were could do no more continuously. The number of repetitions was noted.

Statistical Analysis

Criterion measures of muscle performances were recorded by the Biodex and hard copies of test results were printed. These were entered in SPSS and a random statistical analyses for strength measurements and effects of endurance protocol were performed for the experimental group (n = 20), control group (n = 20) and comparison was made between the two. The effects of the endurance protocol was analysed by comparing the isokinetic strength (average peak torque and total work) before and after performing the fatiguing endurance protocol using the one-way repeated measures ANOVA with generalized linear model in SPSS. The effect of the endurance protocol was also evaluated by repeated measures one-way ANOVA for the decline in total amount of work performed during the first third (first 20 trials of session one) of the endurance

protocol compared to the total work during the last third of the protocol (last 20 trials of session one). Paired 't' tests were done for the variables when an interaction effect was established between the groups in one-way repeated measures ANOVA. Independent student t-tests were also used to compare the average peak velocity, average power developed during the endurance protocol and work fatigue (% change in total work between first third and last third of the repetitions during the protocol) between the experimental and control groups.

RESULTS

Strength measurements during the endurance protocol

Independent 't' tests showed that there were no significant differences in work fatigue, average peak velocity and average power generated by the shoulder abductors during the endurance protocol between the experimental and control groups. No values reached significance and all effect sizes were small. Similar results were found for external rotators with average peak velocity and work fatigue failing to reach significance. Only, average power developed by shoulder external rotators in the control group was significantly higher than that developed in the experimental group.

The difference in the work done between the first and the last third set of repetitions during the endurance protocol was analysed using one-way repeated measures ANOVA. Analysis showed that work done during the protocol increased in both the groups during both abduction and external rotation. This change was significant for time (1^{st} third and last third) during abduction and between patient groups during external rotation. The difference in work done (% work fatigue) increased in both groups during abduction and external rotation during the endurance protocol, but was not significant. Interaction effects were evident between the groups and hence paired 't' test was done for the experimental and control groups separately for their main effects which showed that the effect of time on work done was not significant during both movements in both groups.

Shoulder abduction

Work fatigue. The percentage difference in total work done between the first third and last third of the repetitions which represents the work fatigue induced by the endurance protocol was high in the experimental group (mean = -1.03, SD = 34.55, SE = 7.73, table 4) whereas in the control group the degree of fatigue was less with a mean value of -11.71 (SD = 31.95, SE = 7.14, table 4). This difference in work fatigue between the experimental and control

group did not reach significance, t(38) = 1.02, p>0.05. The effect size describing the difference between the two groups was small, r = 0.16 (table 4).

Average power. On average, the shoulder abductors of the participants in the control group showed a higher average power (mean = 8.65, SD = 7.03, SE = 1.57, table 4) compared to the experimental group (mean = 6.38, SD = 6.50, SE = 1.45, table 4) in the endurance protocol. This difference was not significant, t(38) = -1.06, p > 0.05, representing a small effect size of r = 0.17 (table 4).

Average peak velocity. The peak velocity developed by the shoulder abductors was higher in the control group (mean = 85.01, SD = 29.43, SE = 6.58, table 4) as compared that developed in the experimental group (mean = 73.21, SD = 40.78, SE = 9.12, table 4). The difference in average peak velocity between the groups was not significant, t(38) = 0.301, p>0.05, representing a small effect size of r = 0.17 (table 4).

Work between first third and last third set of repetitions. The mean work done during shoulder abduction in the first and last third of repetitions increased over time and was comparatively higher in the experimental group (1^{st} third: mean = 96.26, SD = 113.45, SE = 25.37; last third: mean = 107.34, SD = 132.65, SE = 29.66, table 3) than the control group (1^{st} third: mean = 86.41, SD = 63.97, SE = 14.30; last third: mean = 94.57, SD = 69.33, SE = 15.50, table 3). One-way repeated measures ANOVA results indicate that the difference in work done was significantly affected by the time of testing when both groups were analysed together, F(1, 38) = 4.22, p < 0.05 (table 3). Interaction between the groups was evident (graph 3) and hence paried't'test was done which suggested that the difference in work done was not significant in both the experimental (t(19) = -1.45, p > 0.05, with a moderate effect size of r = 0.32, table 3) and control groups (t(19) = -1.52, p > 0.05, with moderate effect size of r = 0.33, table 3) when groups were analysed separately.

External rotation

Work fatigue. On average, the experimental group exhibited less fatigue during the endurance protocol with a mean fatigue value of -39.79 (SD = 38.29, SE = 8.56, table 4) as opposed to a mean fatigue of -13.39 (SD = 55.98, SE = 12.52, table 4) in the control group. The difference was not significant, t(38) = -1.74, p > 0.05, with a small effect size of r = 0.27 (table 4).

Average power. The difference in average power developed during the endurance protocol was significant between the experimental and control groups. The mean

power developed in the experimental group was 3.19 (SD = 2.73, SE = 0.61, table 4) whereas the power developed in the control group was 7.55 with a SD of 6.79 (SE = 1.52, table 4). This difference was significant, $t(38) = -2.67$, $p < 0.05$; this represents a medium-sized effect, $r = 0.40$ (table 4).

Average peak velocity. The control group had a higher average peak velocity than the experimental group with a mean of 97.57 (SD = 31.16, SE = 6.97, table 4). The mean of the experimental group was 78.51 with a SD of 34.45 (SE = 7.70, table 4). This difference in average peak velocity was not significant, $t(38) = -1.84$, $p>0.05$ with a small effect size of $r = 0.29$ (table 4).

Work between first third and last third set of repetitions. In contrast to shoulder abduction, the mean statistic of the work done in the first and last third of repetitions was higher in the control group (1^{st} third: mean = 78.25, SD = 72.08, SE = 16.12; last third: mean = 79.78, SD = 71.01, SE = 15.88, table 3) than the experimental group (1^{st} third: mean = 35.12, SD = 30.82, SE = 6.89; last third: mean = 46.76, SD = 47.78, SE = 10.68, table 3). One-way analysis repeated measures ANOVA revealed that the difference in work done was not significant for time ($F(1, 38) = 2.53$, $p > 0.05$, table 3), but was significant for type of patients ($F(1, 38) = 4.54$, $p < 0.05$, table 3) with interaction between groups (graph 6) when the groups were analysed together. Paired 't' tests, when groups were analysed separately, showed that time did not significantly affect the difference in work done before and after the endurance protocol in the experimental ($t(19) = -1.99$, $p > 0.05$, with moderate effect size of $r = 0.42$, table 3) and control groups ($t(19) = -0.26$, $p > 0.05$, with small effect size of $r = 0.06$, table 3).

Effect of endurance protocol

The effect of endurance protocol on the average peak torque developed during isokinetic repetitions and the total work done before and after the protocol was analysed with one-way repeated measures ANOVA in SPSS. The results indicate that the average peak torque and total work done increased during abduction in both groups. During external rotation, the average peak torque increased in both groups with total work done decreasing only in the control group. The changes in average peak torque were significant for the effect of time in both movements and not significant for the type of patients during both movements when the groups were analysed together. Total work was significantly affected by time during abduction only and not by patient types during both movements. Paired 't' tests for analyzing the effect of time of testing on

average peak torque and total work done showed significant changes during abduction in control group and during external rotation in the experimental group.

Shoulder abduction

Average peak torque. The average peak torque developed by shoulder abductors was higher in the control group (pre-test: mean = 10.51, SD = 9.79, SE = 2.19; post-test: mean = 15.72, SD = 13.11, SE = 2.93, table 2) compared to the experimental group (pre-test: mean = 9.45, SD = 6.57, SE = 1.47; post-test: mean = 10.21, SD = 8.00, SE = 1.79, table 2) both at baseline and after the completion of the endurance protocol. Peak torque increased in both groups compared to baseline which indicated that the endurance protocol did not produce fatigue in the abductors. The increase in peak torque was significant over time when the groups were analysed together ($F(1, 38) = 17.05$, $p < 0.05$, table 2), but insignificant among patient groups ($F(1, 38) = 1.22$, $p > 0.05$, table 2). Paired 't' tests were done due to interaction effects between the groups (graph 1) and the results revealed that peak torque changed significantly over time (pre- and post-endurance protocol) in the control group ($t(19) = -4.12$, $p < 0.05$ with a large effect size of $r = 0.69$, table 2), but was not significantly affected by time in the experimental group ($t(19) = -1.09$, $p > 0.05$ with a small effect size of $r = 0.24$, table 2).

Total work. The mean statistic of the total work done before and after the endurance protocol increased in both the experimental (pre-test: mean = 33.06, SD = 43.20, SE = 9.66; post-test: mean = 43.33, SD = 64.03, SE = 14.32, table 2) and control groups (pre-test: mean = 24.39, SD = 39.73, SE = 8.88; post-test: mean = 40.58, SD = 53.98, SE = 12.07, table 2). The total work done before and after the protocol was significantly affected by time of testing ($F(1, 38) = 9.77$, $p < 0.05$, table 2) when the groups were analysed together but was insignificant for the type of patients that performed the test ($F(1, 38) = 0.13$, $p > 0.05$, table 2). Interaction effects were evident (graph 2) and hence analyses were also done with paired t tests. Paired 't'tests showed that the increase in total work was not significant in the experimental group ($t(19) = -1.70$, $p > 0.05$ with a moderate effect size of $r = 0.36$, table 2), but was affected significantly by time in the control group ($t(19) = -2.74$, $p < 0.05$ with a large effect size of $r = 0.53$, table 2).

External rotation

Average peak torque. Similar to shoulder abductors, the average peak torque developed by in external rotation was higher in the control group (pre-test: mean = 6.92, SD = 4.74, SE = 1.06; post- test: mean = 7.55, SD = 5.48, SE = 1.23, table 2) compared to that of the

experimental group (pre-test: mean = 4.63, SD = 3.20, SE = 0.72; post- test: mean = 7.01, SD = 5.09, SE = 1.14, table 2). The peak torque produced in the external rotators was significantly affected by the time of testing ($F(1, 38) = 6.93$, $p < 0.05$, table 2) and did not differ significantly among the patient groups ($F(1, 38) = 1.07$, $p > 0.05$, table 2) when groups were analysed together. Paired 't' tests performed due to interaction effects (graph 4) showed that the time of testing affected the torque significantly in the experimental group only ($t(19) = -3.26$, $p < 0.05$ with a large effect size of 0.60, table 2).

Total work. The total work done in external rotation before and after the endurance protocol varied differently in the experimental and control groups. The mean total work increased in the experimental group (pre-test: mean = 13.11, SD = 11.99, SE = 2.68; post-test: mean = 26.39, SD = 28.77, SE = 6.43, table 2) whereas it decreased in the control group (pre-test: mean = 20.49, SD = 24.01, SE = 5.37; post-test: mean = 19.25, SD = 19.95, SE = 4.46, table 2) indicating fatigue in the external rotators. Analyses showed that total work did not differ significantly for both time ($F(1, 38) = 3.12$, $p > 0.05$, table 2) and type of subjects ($F(1, 38) = 0.00$, $p > 0.05$, table 2) with interaction between groups evident (graph 5) when groups were analysed together. Paired 't' test showed that total work was significantly affected by time in the experimental group only ($t(19) = -2.79$, $p < 0.05$, with a large effect size of 0.54, table 2).

In summary, the endurance protocol did not cause fatigue in shoulder abductors and external rotators in both the experimental and control group. The average isokinetic peak torque and total work done improved after the protocol, rather than decreasing. The control group alone showed a decrease in total work done in external rotation after the protocol but the decrease was not significant. Similar results were seen in the work done during the first third and last third set of repetitions (first 20 and last 20 repetitions) in both shoulder movements in both groups with increase in work done in the last third set of repetitions during the endurance protocol. No significant differences in strength related measurements (average peak velocity, average power and percentage of work fatigue) during the endurance protocol were noticed when compared between the experimental and control groups except for average power during external rotation which reached significant difference with a p value of 0.01.

While shoulder muscles did not fatigue after the protocol, a few interesting trends concerning the experimental group were noted from the graphs. It can be seen from the graph 2 that the work done by the experimental group during abduction was higher when compared to control group after the protocol. The experimental group also showed a higher increase in

average peak torque in external rotation after the endurance protocol when compared to the control group (graph 4). While the total work done decreased in the control group following the protocol in external rotation, the experimental group showed a 2-fold increase in the total work done following the protocol (graph 5).

DISCUSSION

Establishing a reliable endurance protocol for the shoulder muscles has been a topic of interest and need over the past few years. Many authors have attempted to develop or study protocols in research settings that can be used in sports or in healthy people. Dale et al[31] have studied the effects of repeated overhead throwing upon isokinetic muscle performance of the shoulder rotators. Their results have indicated that even though work fatigue was significant before and after testing, peak torque developed in the rotators was not significant for time. Mullaney et al[32] studied the effect of 3 sets of 32 maximal isokinetic contractions between shoulder internal and external rotators concluding that the fatigue induced in the muscles was not significant between the different groups of muscles. A study by Tsai et al[27] measured fatigue in the external rotators using a fatigue protocol that used a Thera-band. Subjects performed ER against the resistance of the Thera-band and performed the task until exhaustion. The muscle performance was measured for isometric peak torque.

A functional fatigue protocol was studied by Szucs[26] et al to determine fatigue in serratus anterior. They used a push-up plus position to fatigue serratus anterior and the muscle fatigue was measured using median power frequency in EMG. Another study by Ebaugh et al[33] used a series of 3 functional tasks to induce fatigue. First, subjects stood with their arms elevated to 45° and manipulated small objects for 2 min. Second, subjects were asked to raise and lower their tested arm against resistance. Third, subjects were asked to raise and lower their arm through a diagonal pattern against resistance. Upon completion of the third activity, subjects immediately returned to the first activity and rotated through the three activities until the subjects reported that they were unable to continue to perform the required tasks or if they failed to correctly perform two tasks in a row. The fatigue in the muscles was measured through EMG. All these studies used protocols to fatigue shoulder girdle muscles for specific purposes that included research in sports or to evaluate kinematics in shoulder movements. No studies have yet attempted to study fatigue protocols in clinical set up or to study the effect of shoulder pathology on fatigue in shoulder muscles.

Roy et al[8] developed a reliable protocol for objective assessment of shoulder muscle endurance using healthy subjects and reported that changes in muscular performance observed during and after the endurance protocol indicated muscular fatigue with maximal isometric strength significantly decreasing after the endurance protocol. That study reported only small and insignificant changes in isokinetic mean peak torque of the internal and external rotators. We found similar findings in this study when applying the same endurance protocol to patients and an age and gender matched group. The fact that isometric strength is more sensitive to picking up reduced muscle performance as a result of fatigue may be related to the fact that a constant position and sustained contraction provides a more standardized assessment of maximum force generation that the muscle is capable and isokinetic peak torque which can vary in angle and timing. That is not to say that isokinetic strength measurements are not important to assessment of rotator cuff functionality since assessment of muscle performance throughout the range of motion has different advantages.

The difference in fatigue developed by isometric and isokinetic muscle contractions can be attributed to the difference in excitation rates and recruitment of motor units during different types of muscle activity. Vollestad[6] has stated that during isometric contractions an oscillating force is probably generated at the motor unit level, because the intervals between the excitation pulses are longer than the rise time of the force. Hence, force both rises and falls in response to each excitation pulse and this behaviour imposes a high energetic demand in relation to the mean force. On the other hand, during sustained contractions, in which contractile slowing are seen, motor unit excitation rate declines. Under these conditions one may hypothesize that central factors regulate the motor drive to match the altered contractile properties.[34] This is an indicator that muscle performances differ according to the type of muscle contraction during testing and that the same protocol will result in different muscle performances according to the type of contraction.

Lack of measurable fatigue in response to this protocol when measured by the isokinetic peak torque is similar to that reported by Roy et al.[8] Roy et al could find significant fatigue in the isometric strength, but reported only minimal changes in the isokinetic performances before and after the protocol. The reasons for lack of fatigue could be attributed to the following factors, the first two of which were also explained by Roy et al as possible causes. The first factor was the familiarity of the Biodex machine and the protocol as they performed the 60 repetitions. Unlike isometric tests which are simple to perform, there may be a larger learning component to

isokinetic testing. If subjects were not performing their maximum during the initial phase of repetitions but were learning to be more efficient and more confident about performing their maximum effort during isokinetic contraction throughout the testing, this could contribute to better performance throughout the testing. Hence, the true effect of muscle fatigue could be underestimated if learning happened throughout the test procedure. The second factor was the time gap between the end of the endurance protocol and commencement of the isokinetic post-testing. Set up of the dynamometer between the protocol and isokinetic torque testing procedure took approximately 45 seconds to 1 minute to complete. Since this particular test protocol evaluates short term muscle fatigue, substantial recovery of muscle capability may have occurred within this timeframe. This factor has been suggested by Dale et al[31] who have stated that comparing peak torque values across time is difficult when metabolic recovery is likely to occur. When there is an elapse of time between the protocol and isokinetic post-test, there is possibility for metabolic recovery and differences in peak torque may not occur.

An important finding of this study was the extent to which patients who had recovered from rotator cuff surgery demonstrated similar muscle performance compared to age and gender matched controls. This group had strengthening exercises for the rotator cuff muscles for at least two months prior to testing. This strengthening program may have been instrumental in improving muscle performance characteristics to be more similar to controls. The subjects in the control group were chosen to be similar to those in the experimental group. They were similar in terms of age, gender and the shoulder tested. Unfortunately, without preoperative evaluation of these fatigue parameters we were able to measure this impact through a repeated measures design. Another factor that would have helped the patients was their psychological motivation factor to recover from the surgery. The participants thought of the endurance protocol as an exercise regimen which when completed would eventually help them recover even faster. This resulted in them trying to perform the post testing with higher speed and velocity resulting in higher torque and work done.

Considering these physiological factors and possible explanations for metabolic recovery by Roy et al[8] and Dale et al,[31] testing of muscle fatigue and endurance is better done when the isometric maximal strength is measured immediately after a fatigue protocol. Test protocols that are performed within 2-5 minutes are still likely to rely on anaerobic pathways and so these tests do not represent endurance to perform intermittent activity throughout the day such as might be expected in a workplace. However, there is a need to have simple standardized muscle endurance

protocols that go beyond handheld dynamometry to assess muscle performance during repeated contractions and throughout range. Since recovery from these short-term endurance activities is likely to be rapid, protocols should attempt to minimize any delay between the end of protocol and the performance indicator. Future studies are required to study fatigue patterns using isometric muscle scores as a fatigue indicator after a fatiguing exercise protocol in patients with shoulder pathologies and those undergoing rehabilitation to determine the optimal indicators for monitoring fatigability.

Limitations and recommendations for future studies

This study was able to provide new information about muscle performance during sustained muscle activity in patients with rotator cuff pathology. However, important limitations should be considered when interpreting these findings. The sample included patients that had both partial and full thickness tears. The effects of size and type of the tear, fatty infiltration and number of tendons involved on muscle performances were not accounted for during analysis. These prognostic factors would have had a significant effect on outcomes and hence should have been considered during analysis. Muscles performances before, during and after the fatigue protocol was measured using values of isokinetic peak torque, total work done, average power and average peak velocity which are indirect indicators of muscle fatigue.[6] Muscle activity was not measured using surface electromyography (EMG)[35] or by comparing tetanic stimulation and maximal voluntary contraction force which might reveal whether fatigue is of central peripheral origin. The second limitation was the measurement of isokinetic muscle performance only before and after the fatigue protocol. Isometric muscle strength and maximal voluntary contraction was not measured and hence comparison between the two types of muscle contractions could not be made. Although, it is possible that use of an immediate isometric torque measurement as a criterion for fatigue would be an improvement to the methods we utilized. It is difficult to optimally target test difficulty for endurance activities. Although the extent of fatigue demonstrated during this protocol was less than anticipated, 6 patients were unable to complete the required number of repetitions due to pain and fatigue. Substantial increases in test difficulty would likely increase the number of cases where the test could not be completed which compromises its validity. Future studies could investigate whether increasing difficulty or changing the fatigue indicator is the optimal approach to ensure that fatigue is observed and the test can be applied to the majority of people who would be the target audience.

CONCLUSION

An endurance protocol for shoulder abduction and external rotation done for 60 isotonic repetitions at 50 % of maximal isokinetic mean peak torque could be completed by 70% of patients six months after their rotator cuff surgery and by 90% of age matched controls . Muscular fatigue was not demonstrated during their isokinetic muscle performances and patients performed similar to age and gender matched controls. The mean peak torque and total work done did not decrease over the sixty repetitions. Alterations to the fatigue protocol or criterion measures may be needed to capture more subtle differences in fatigability. Although this test protocol may not optimally assess fatigability, this study indicated that six months following rotator cuff repair, patients were able to demonstrate normal performance over 60 consecutive isotonic repetitions at 50% maximum which is an aspect of muscle performance that has not been previously reported.

REFERENCES

1. Levangie P.K., & Norkin C.C (2005). *Joint Structure and function. A Comprehensive analysis (4th ed.).* F.A Davis Company, Philadelphia.
2. Stobbe, T. J. (1996). Occupational ergonomics and injury prevention. *Occupational Medicine (Philadelphia, Pa.), 11*(3), 531-543.
3. Zakaria, D., Robertson, J., MacDermid, J., Hartford, K., & Koval, J. (2002). Work-related cumulative trauma disorders of the upper extremity: Navigating the epidemiologic literature. *American Journal of Industrial Medicine, 42*(3), 258-269. doi: 10.1002/ajim.10100
4. Fuller, J. R., Lomond, K. V., Fung, J., & Cote, J. N. (2009). Posture-movement changes following repetitive motion-induced shoulder muscle fatigue. *Journal of Electromyography and Kinesiology : Official Journal of the International Society of Electrophysiological Kinesiology, 19*(6), 1043-1052. doi: 10.1016/j.jelekin.2008.10.009; 10.1016/j.jelekin.2008.10.009
5. Blangsted, A. K., Sjogaard, G., Madeleine, P., Olsen, H. B., & Sogaard, K. (2005). Voluntary low-force contraction elicits prolonged low-frequency fatigue and changes in surface electromyography and mechanomyography. *Journal of Electromyography and*

Kinesiology : Official Journal of the International Society of Electrophysiological Kinesiology, 15(2), 138-148. doi: 10.1016/j.jelekin.2004.10.004

6. Vollestad, N. K. (1997). Measurement of human muscle fatigue. *Journal of Neuroscience Methods, 74*(2), 219-227.
7. Minning, S., Eliot, C. A., Uhl, T. L., & Malone, T. R. (2007). EMG analysis of shoulder muscle fatigue during resisted isometric shoulder elevation. *Journal of Electromyography and Kinesiology : Official Journal of the International Society of Electrophysiological Kinesiology, 17*(2), 153-159. doi: 10.1016/j.jelekin.2006.01.008
8. Roy, J. S., Ma, B., Macdermid, J. C., & Woodhouse, L. J. (2011). Shoulder muscle endurance: The development of a standardized and reliable protocol. *Sports Medicine, Arthroscopy, Rehabilitation, Therapy & Technology : SMARTT, 3*(1), 1. doi: 10.1186/1758-2555-3-1; 10.1186/1758-2555-3-1
9. Royer, P. J., Kane, E. J., Parks, K. E., Morrow, J. C., Moravec, R. R., Christie, D. S., & Teyhen, D. S. (2009). Fluoroscopic assessment of rotator cuff fatigue on glenohumeral arthrokinematics in shoulder impingement syndrome. *Journal of Shoulder and Elbow Surgery / American Shoulder and Elbow Surgeons ...[Et Al.], 18*(6), 968-975. doi: 10.1016/j.jse.2009.03.002; 10.1016/j.jse.2009.03.002
10. Teyhen, D. S., Miller, J. M., Middag, T. R., & Kane, E. J. (2008). Rotator cuff fatigue and glenohumeral kinematics in participants without shoulder dysfunction. *Journal of Athletic Training, 43*(4), 352-358. doi: 10.4085/1062-6050-43.4.352; 10.4085/1062-6050-43.4.352
11. Bowman, T. G., Hart, J. M., McGuire, B. A., Palmieri, R. M., & Ingersoll, C. D. (2006). A functional fatiguing protocol and deceleration time of the shoulder from an internal rotation perturbation. *Journal of Athletic Training, 41*(3), 275-279.
12. Fehringer, E. V., Sun, J., VanOeveren, L. S., Keller, B. K., & Matsen, F. A.,3rd. (2008). Full- thickness rotator cuff tear prevalence and correlation with function and co-morbidities in patients sixty-five years and older. *Journal of Shoulder and Elbow Surgery / American Shoulder and Elbow Surgeons ...[Et Al.], 17*(6), 881-885. doi: 10.1016/j.jse.2008.05.039; 10.1016/j.jse.2008.05.039
13. Moosmayer, S., Smith, H. J., Tariq, R., & Larmo, A. (2009). Prevalence and characteristics of asymptomatic tears of the rotator cuff: An ultrasonographic and clinical

study. *The Journal of Bone and Joint Surgery.British Volume, 91*(2), 196-200. doi: 10.1302/0301-620X.91B2.21069; 10.1302/0301-620X.91B2.21069

14. Smith, M. A., & Smith, W. T. (2010). Rotator cuff tears: An overview. *Orthopaedic Nursing / National Association of Orthopaedic Nurses, 29*(5), 319-22; quiz 323-4. doi: 10.1097/NOR.0b013e3181edd8b6; 10.1097/NOR.0b013e3181edd8b6
15. Tempelhof, S., Rupp, S., & Seil, R. (1999). Age-related prevalence of rotator cuff tears in asymptomatic shoulders. *Journal of Shoulder and Elbow Surgery / American Shoulder and Elbow Surgeons ...[Et Al.], 8*(4), 296-299.
16. Yamaguchi, K., Ditsios, K., Middleton, W. D., Hildebolt, C. F., Galatz, L. M., & Teefey, S. A. (2006). The demographic and morphological features of rotator cuff disease. A comparison of asymptomatic and symptomatic shoulders. *The Journal of Bone and Joint Surgery.American Volume, 88*(8), 1699-1704. doi: 10.2106/JBJS.E.00835
17. Razmjou, H., Bean, A., van Osnabrugge, V., MacDermid, J. C., & Holtby, R. (2006). Cross-sectional and longitudinal construct validity of two rotator cuff disease-specific outcome measures. *BMC Musculoskeletal Disorders, 7*, 26. doi: 10.1186/1471-2474-7-26
18. Itoi, E., & Tabata, S. (1992). Conservative treatment of rotator cuff tears. *Clinical Orthopaedics and Related Research, (275)*(275), 165-173.
19. Bassett, R. W., & Cofield, R. H. (1983). Acute tears of the rotator cuff. The timing of surgical repair. *Clinical Orthopaedics and Related Research, (175)*(175), 18-24.
20. Tashjian, R. Z. (2012). Epidemiology, natural history, and indications for treatment of rotator cuff tears. *Clinics in Sports Medicine, 31*(4), 589-604. doi: 10.1016/j.csm.2012.07.001; 10.1016/j.csm.2012.07.001
21. Ghodadra, N. S., Provencher, M. T., Verma, N. N., Wilk, K. E., & Romeo, A. A. (2009). Open, mini-open, and all-arthroscopic rotator cuff repair surgery: Indications and implications for rehabilitation. *The Journal of Orthopaedic and Sports Physical Therapy, 39*(2), 81-89. doi: 10.2519/jospt.2009.2918; 10.2519/jospt.2009.2918
22. Norberg, F. B., Field, L. D., & Savoie, F. H.,3rd. (2000). Repair of the rotator cuff. mini-open and arthroscopic repairs. *Clinics in Sports Medicine, 19*(1), 77-99.
23. Duralde, X. A., & McClelland, W. B.,Jr. (2012). The clinical results of arthroscopic transtendinous repair of grade III partial articular-sided supraspinatus tendon tears. *Arthroscopy : The Journal of Arthroscopic & Related Surgery : Official Publication of the Arthroscopy Association of North America and the International Arthroscopy*

Association, 28(2), 160-168. doi: 10.1016/j.arthro.2011.08.286; 10.1016/j.arthro.2011.08.286

24. Raman J, Macdermid JC, Walton, DM, Athwal G (2013). Predictors of pain and disability after rotator cuff repair – A meta-analysis. *PhD Thesis.* University of Western Ontario, Faculty of Health Sciences.
25. Ebaugh, D. D., McClure, P. W., & Karduna, A. R. (2006). Scapulothoracic and glenohumeral kinematics following an external rotation fatigue protocol. *The Journal of Orthopaedic and Sports Physical Therapy, 36*(8), 557-571.
26. Szucs, K., Navalgund, A., & Borstad, J. D. (2009). Scapular muscle activation and co-activation following a fatigue task. *Medical & Biological Engineering & Computing, 47*(5), 487-495. doi: 10.1007/s11517-009-0485-5; 10.1007/s11517-009-0485-5
27. Tsai, N. T., McClure, P. W., & Karduna, A. R. (2003). Effects of muscle fatigue on 3-dimensional scapular kinematics. *Archives of Physical Medicine and Rehabilitation, 84*(7), 1000-1005.
28. Christensen, T., & Kehlet, H. (1993). Postoperative fatigue. *World Journal of Surgery, 17*(2), 220-225.
29. Edwards, H., Rose, E. A., & King, T. C. (1982). Postoperative deterioration in muscular function. *Archives of Surgery (Chicago, Ill.: 1960), 117*(7), 899-901.
30. Baysal, D., Balyk, R., Otto, D., Luciak-Corea, C., & Beaupre, L. (2005). Functional outcome and health-related quality of life after surgical repair of full-thickness rotator cuff tear using a mini-open technique. *The American Journal of Sports Medicine, 33*(9), 1346-1355. doi: 10.1177/0363546505275130
31. Dale, R. B., Kovaleski, J. E., Ogletree, T., Heitman, R. J., & Norrell, P. M. (2007). The effects of repetitive overhead throwing on shoulder rotator isokinetic work-fatigue. *North American Journal of Sports Physical Therapy : NAJSPT, 2*(2), 74-80.
32. Mullaney, M. J., & McHugh, M. P. (2006). Concentric and eccentric muscle fatigue of the shoulder rotators. *International Journal of Sports Medicine, 27*(9), 725-729. doi: 10.1055/s-2005-872870
33. Ebaugh, D. D., McClure, P. W., & Karduna, A. R. (2006). Effects of shoulder muscle fatigue caused by repetitive overhead activities on scapulothoracic and glenohumeral kinematics. *Journal of Electromyography and Kinesiology : Official Journal of the*

International Society of Electrophysiological Kinesiology, *16*(3), 224-235. doi: 10.1016/j.jelekin.2005.06.015

34. Bigland-Ritchie, B., Johansson, R., Lippold, O. C., Smith, S., & Woods, J. J. (1983). Changes in motoneurone firing rates during sustained maximal voluntary contractions. *The Journal of Physiology, 340*, 335-346.
35. Minning S, Eliot CA, Uhl TL, Malone TR: EMG analysis of shoulder muscle fatigue during resisted isometric shoulder elevation. *J Electromyogr Kinesiol* 2007, 17:153-159.

Table 1. Descriptive statistics

Descriptive statistics	Experimental group	Control group
Age	Mean = 57.30 years SD = 10.52 Range = 34 to 70 years	Mean = 54.45 years SD = 9.81 Range = 29 to 65 years
Dominant side	Right – 18 Left - 2	Right – 15 Left - 5
Dominant side affected	11	
DASH*	Mean = 27.00 SD = 15.38	
WORC	Mean = 942† (55.13%*) SD = 438 (20.86)	
SF – 12	PCS‡ Mean = 40.07 SD = 8.22 MCS‡ Mean = 53.88 SD = 8.45	
SST	Mean = 8.0§ SD = 2.64	

*scores converted to 100, †score out of 2100 for WORC, ‡maximum score is 70, §maximum score of 12, DASH - Disabilities of arm shoulder and hand (lower score indicates better outcome), WORC - Western Ontario rotator cuff index (lower score and higher % indicates better outcome), SF – 12 - Short form health survey questionnaire (higher score indicates better outcome), SST – Simple shoulder test (higher score indicates better outcome), SD = Standard deviation

Table 2. Effect of endurance protocol on muscle performances and results of one-way repeated measures ANOVA and paired 't test

Variable	Movement	Groups	Time of testing	Mean	SD	SE	F (p value)† Time	F (p value) † Patient groups	t (p value for time)*
Isokinetic average peak torque (ft-lbs)	Abduction	Experimental group	Baseline	9.45	6.57	1.47	**17.05 (0.00)**	1.22 (0.28)	-1.09 (0.29)
			After protocol	10.21	8.00	1.79			
		Control group	Baseline	10.50	9.79	2.19			**-4.12 (0.001)**
			After protocol	15.72	13.11	2.93			
	External rotation	Experimental group	Baseline	4.63	3.20	0.72	**6.93 (0.01)**	1.07 (0.31)	**-3.26 (0.004)**
			After protocol	7.01	5.09	1.14			
		Control group	Baseline	6.92	4.74	1.06			-0.72 (0.48)
			After protocol	7.55	5.48	1.23			
Total work done (ft-lbs)	Abduction	Experimental group	Baseline	33.06	43.20	9.66	**9.77 (0.003)**	0.13 (0.72)	-1.69 (0.11)
			After protocol	43.33	64.03	14.32			
		Control group	Baseline	24.39	39.73	8.88			**-2.74 (0.01)**
			After protocol	40.58	53.98	12.07			
	External rotation	Experimental group	Baseline	13.11	11.99	2.68	3.12 (0.09)	0.00 (0.99)	**-2.79 (0.01)**
			After protocol	26.39	28.77	6.43			
		Control group	Baseline	20.49	24.01	5.37			0.25 (0.80)
			After protocol	19.25	19.95	4.46			

SD = Standard deviation, SE = Standard error of mean, p significant at < 0.05, *paired 't' test,

†one-way repeated measures ANOVA

Negative values indicate that subjects have improved (instead of fatigue) after the protocol

Table 3. Work done during endurance protocol and results of one-way repeated measures ANOVA and paired 't' tests

Variable	Movements	Groups	Period of testing	Mean	SD	F (p value) † Time	F (p value) † Patient groups	t (p value for time)*
Work done (ft-lbs)	Abduction	Experimental group	1st third	96.26	113.45	**4.22 (0.047**)	0.13 (0.72)	-1.45 (0.17)
			Last third	107.34	132.65			
		Control group	1st third	86.41	63.97			-1.52 (0.15)
			Last third	94.57	69.33			
	External rotation	Experimental group	1st third	35.12	30.82	2.53 (0.12)	4.54 (0.40)	-1.99 (0.06)
			Last third	94.57	47.78			
		Control group	1st third	78.25	72.08			-0.26 (0.80)
			Last third	79.79	71.01			

SD = Standard deviation, p significant at < 0.05, *paired 't' test

†one-way repeated measures ANOVA

Negative values indicate that subjects have improved (instead of fatigue).

Table 4. Strength related measurements during endurance protocol and results of independent 't' tests

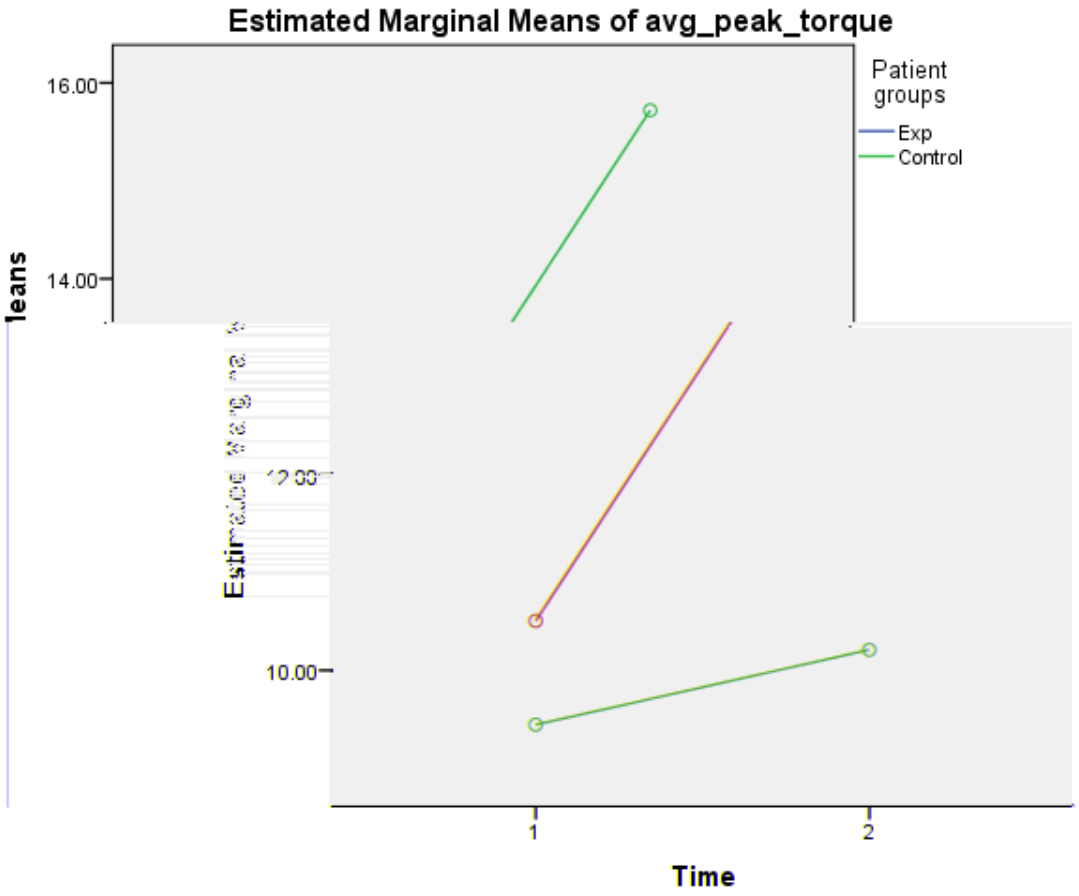
V ariable	Movement	Groups	Mean	SD	SE	t (p value for groups)*
Average power (watts)	Abduction	Experimental group	6.38	6.50	1.45	-1.06 (0.30)
		Control group	8.65	7.03	1.57	
	External rotation	Experimental group	3.19	2.73	0.61	**-2.67 (0.01)**
		Control group	7.55	6.79	1.52	
Average peak velocity (degrees/second)	Abduction	Experimental group	73.21	40.78	9.12	0.301 (0.30)
		Control group	85.01	29.43	6.58	
	External rotation	Experimental group	78.51	34.45	7.70	-1.84 (0.07)
		Control group	97.57	31.16	6.97	
Work fatigue (%)	Abduction	Experimental group	-1.03	34.55	7.73	1.02 (0.32)
		Control group	-11.71	31.95	7.14	
	External rotation	Experimental group	-39.79	38.29	8.56	-1.74 (0.09)
		Control group	-13.39	55.98	12.52	

SD = Standard deviation, p significant at < 0.05

*independent 't' test

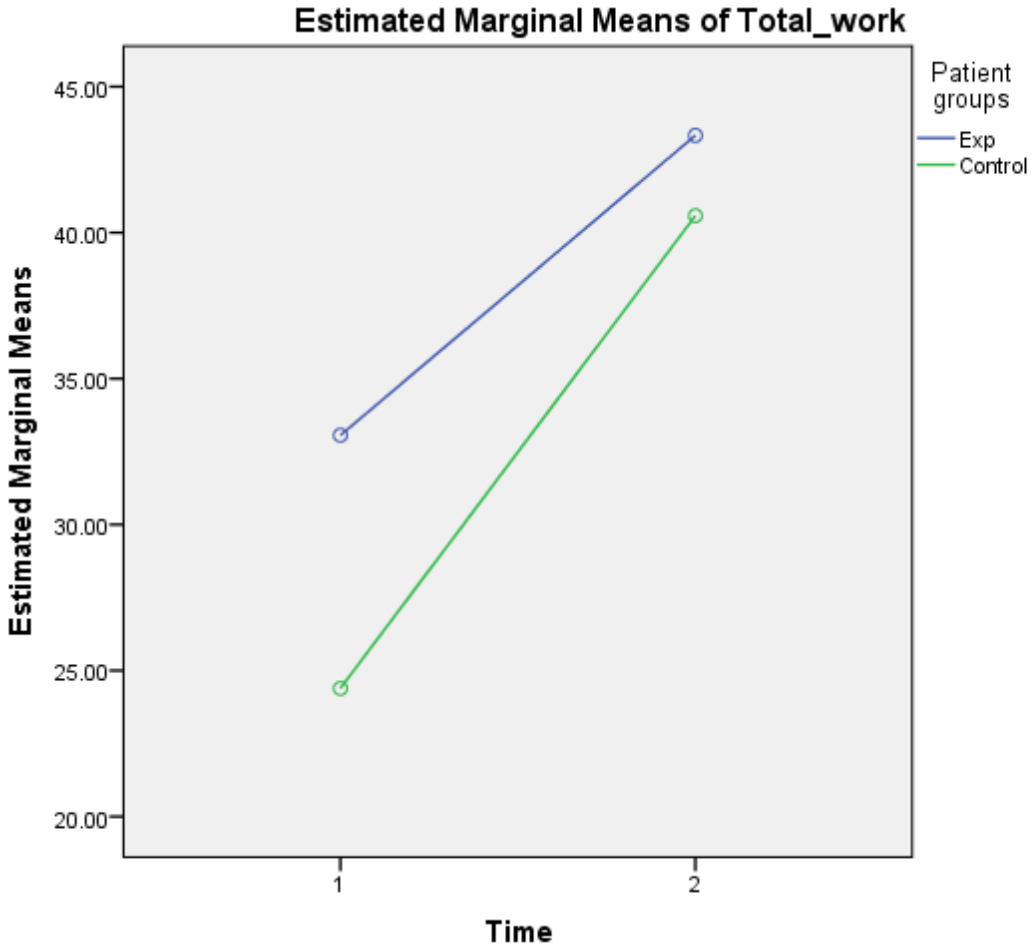
Negative values indicate that subjects have improved (instead of fatigue).

Graph 1. Profile plot for average peak torque before and after endurance protocol during abduction between experimental and control groups



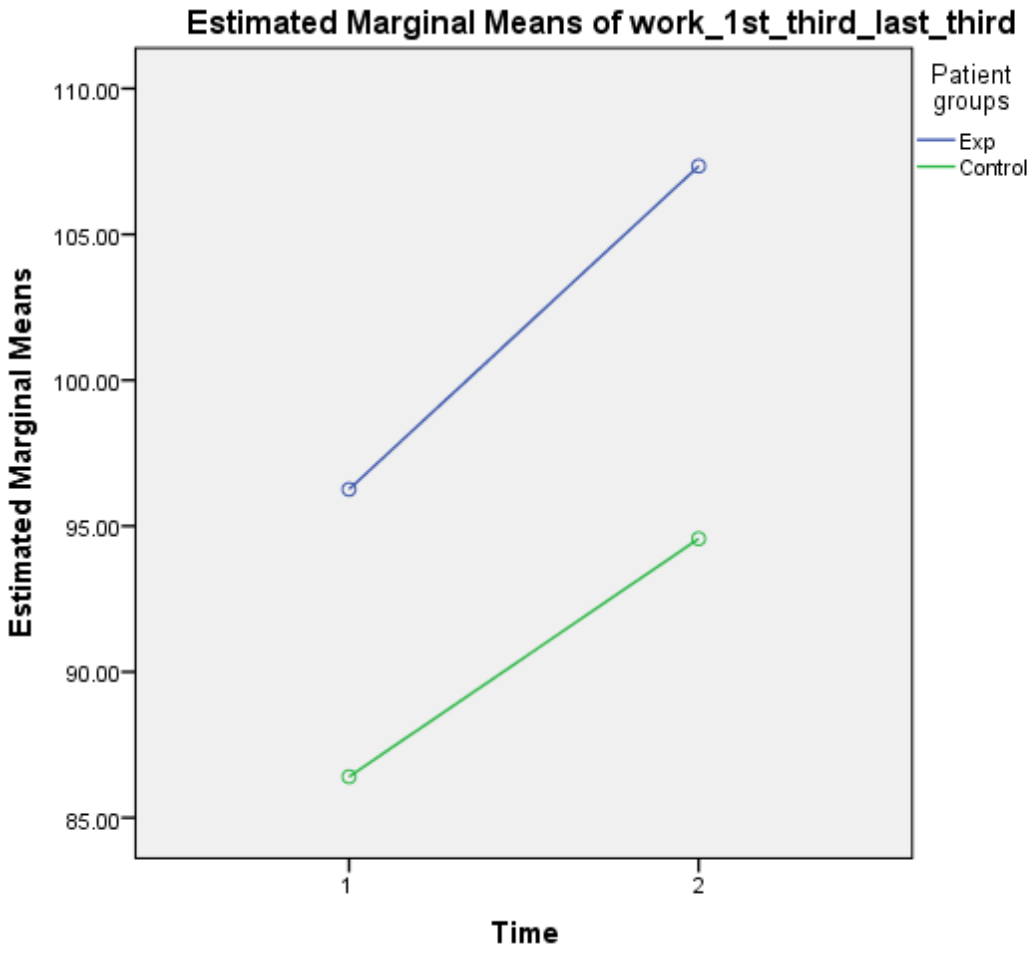
Time 1 – Before endurance protocol
Time 2 – After endurance protocol
Average peak torque measured in ft-lbs

Graph 2. Profile plot for total work done before and after endurance protocol during abduction between experimental and control groups



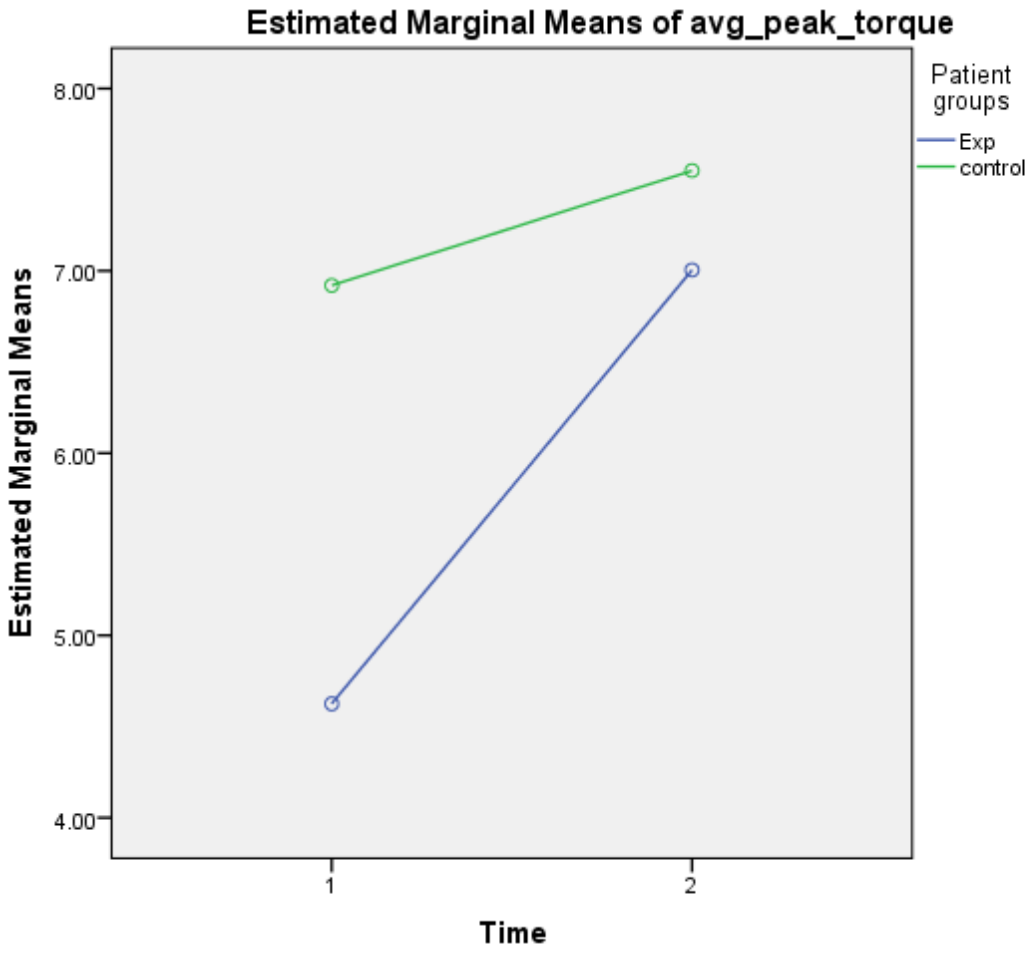
Time 1 – Before endurance protocol
Time 2 – After endurance protocol
Total work done measured in ft-lbs

Graph 3. Profile plot for work done during 1st third and last third of the endurance protocol during abduction between experimental and control groups



Time 1 – Before endurance protocol
Time 2 – After endurance protocol
Work done measured in ft-lbs

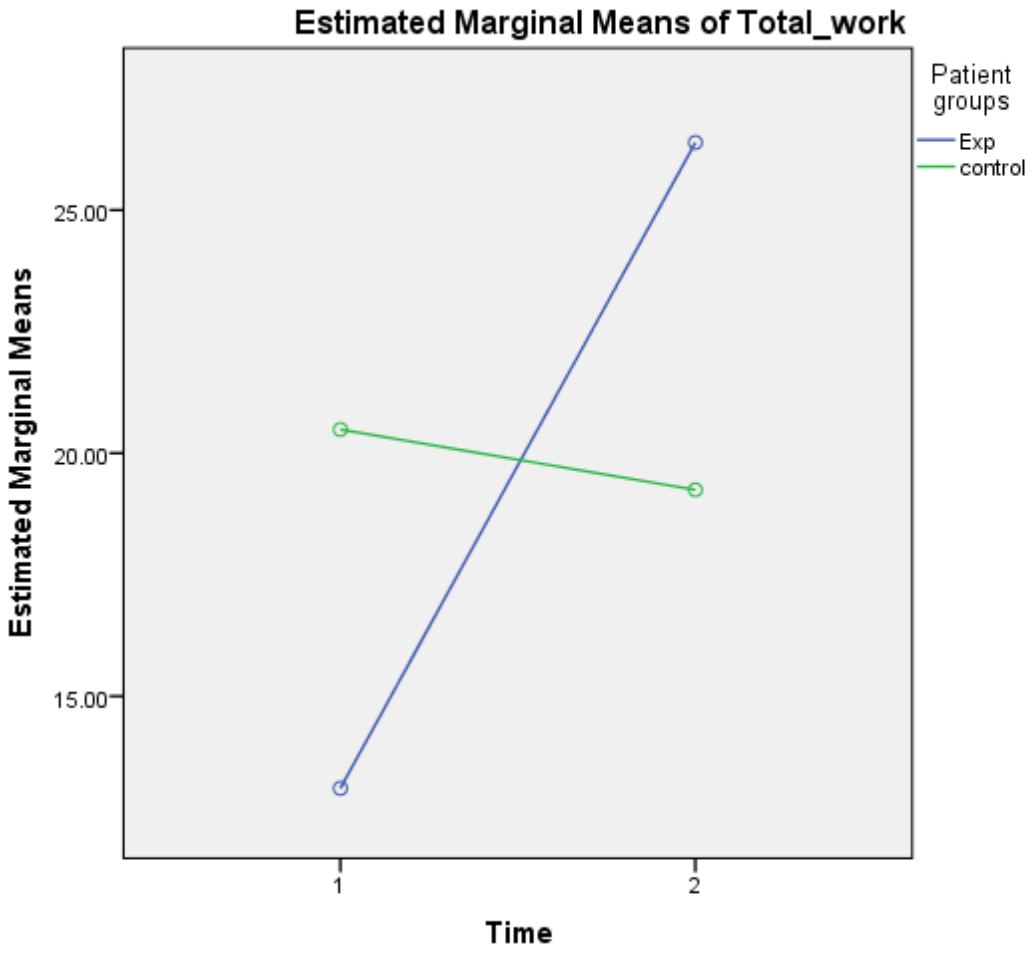
Graph 4. Profile plot for average peak torque before and after endurance protocol during external rotation between experimental and control groups



Time 1 – Before endurance protocol
Time 2 – After endurance protocol

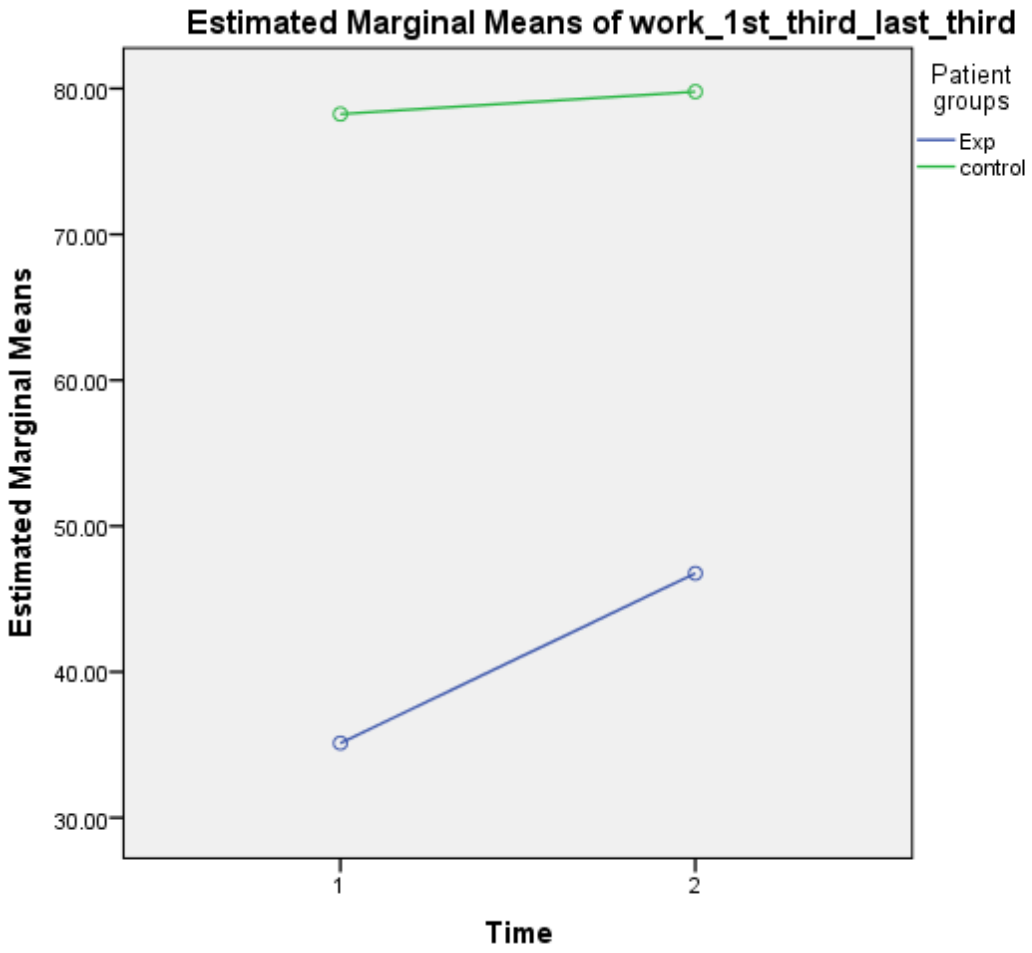
Average peak torque measured in ft-lbs

Graph 5. Profile plot for total work done before and after endurance protocol during external rotation between experimental and control groups



Time 1 – Before endurance protocol
Time 2 – After endurance protocol
Total work done measured in ft-lbs

Graph 6. Profile plot for work done during 1st third and last third of the endurance protocol during external rotation between experimental and control groups



Time 1 – Before endurance protocol
Time 2 – After endurance protocol
Work done measured in ft-lbs

CHAPTER 5. A RASCH ANALYSIS INDICATES THAT THE SIMPLE SHOULDER TEST IS ROBUST; BUT ITS CURRENT FORMAT DOES NOT COMPLETELY ADHERE TO OPTIMAL MEASUREMENT PRINCIPLES

ABSTRACT

Background

The Simple shoulder test (SST) is a shoulder-specific scale that has been used to assess pain and function in various shoulder conditions and to track changes after shoulder surgeries. Multiple studies have evaluated the psychometric properties of SST through traditional methods, with the majority concluding it as valid and reliable while a few studies have questioned its ability to detect minimal detectable change. A systematic review of shoulder scales concluded that some properties of the SST still need to be evaluated, particularly the absolute errors of measurement further stating that the SST is a highly reliable questionnaire and the quickest to complete, but its minimal detectable change (MDC) and minimal clinically important difference (MCID) have not yet been defined.

There are no studies in the literature that have analysed SST through the Rasch model. Rasch analysis is a newer method for analyzing the clinical measurement properties of self-report outcome measures and provides a framework for assessing different measurement properties than tested in classical test theory approaches. The purpose of this study was to provide evidence on the measurement properties of the SST using Rasch model to assess: the overall fit to the Rasch model, individual item fit, differential item functioning (DIF based on gender), local dependency and unidimensionality. A secondary purpose was to examine the stability of the findings by repeating the analysis at different time points.

Methods

The Simple shoulder test. The Simple Shoulder Test (SST) is a self-reported shoulder-specific questionnaire that measures functional limitations of the affected shoulder in patients with shoulder dysfunction. The SST consists of 12 questions with dichotomous (yes/no) response options.

Study sample. A consecutive series of 252 patients (male/female ratio of 100:152 and age range between 25 and 89 years) with gleno-humeral arthritis or rotator cuff tear were recruited for the study at The Hand and Upper Limb Centre, St. Joseph's Health Care, London,

Ontario, Canada. All patients provided informed consent as approved by Western University Research Ethics Board.

Study Procedures. One group of 126 patients completed the SST questionnaire before they underwent reverse shoulder arthroplasty or rotator cuff repair and the other group of 126 patients completed the questionnaire between 6 months and 1 year after their surgery. This data was used for Rasch analysis which was done using RUMM 2030 software.

Results

The SST data showed individual items misfit for 3 questions when analysed for item fit to the Rasch model with a highly significant chi square value of 76.8226 (df = 36, p = 0.000088). The questions were: question 4 (can you place your hand behind your head with the elbow straight out to the side? with a fit residual of -3.53), question 5 (can you place a coin on a shelf at the level of your shoulder without bending your elbow? with a fit residual of -2.55) and question 8 (can you carry twenty pounds at your side with the affected extremity? with a fit residual of 2.58). The data also showed local dependency between questions 4 & 5, and questions 5 & 6 (can you lift one pound (full pint container) to the level of your shoulder without bending your elbow?).The misfit of questions 4 & 5 was negated when questions 5 and 6 were combined together to form one super item addressing the person's ability to lift an object (light or heavy) to the level of the shoulder without bending the elbow (chi square value was 59.9309 with df = 33 and p = 0.002816, A = 0.97 indicating unidimensionality and PSI = 0.75 indicating good power of analysis of fit). The misfit of question 8 (can you carry twenty pounds at your side with the affected extremity?) was negated when it was split to account for gender differences in a person's response to the question (chi square value was 54.435 with df = 39 and p = 0.051293, PSI = 0.75 indicating good power of analysis of fit).

Conclusion

The results of this study should provide confidence in the SST to clinicians who wish to use a brief shoulder-specific measure in their practice. A number of properties of the SST were supported and it appears to be robust when tested against the Rasch model. Local dependency between light and heavy objects being lifted overhead fits with their conceptual overlap. Unless corrected some gender bias may exist on the lifting item. These are potential areas that could be explored to improve the SST if these findings are duplicated by others.

Keywords

Simple shoulder test, Rasch analysis, DIF, local dependency, Chi-square, Fit residual, Unidimensionality.

INTRODUCTION

A number of trends in health care have resulted in the development and growing use of patient based outcome measures to assess matters such as functional status and health-related quality of life (HRQoL).[1] "Patient-reported outcome" (PRO) is an umbrella term that covers a whole range of potential types of measurement but is used specifically to refer to self-reports by the patient. A PRO is any report of the status of a patient's health condition that comes directly from the patient, without interpretation of the patient's response by a clinician or anyone else.[2] PRO data may be collected via self-administered questionnaires completed by the patient themselves or via interviews. PROs are frequently used for evaluation in clinical trials, where valid change scores and access to parametric statistics are required.[3] PROs are usually constructed by having patients respond to a series of questions framed around a construct of interest where responses can range from yes/no, to likert scaling to numeric rating i.e.,0-10. The measurement properties of items and scales drive how PRO perform when used to measure constructs within clinical research and practice.

Clinicians and policymakers are recognizing the importance of measuring HRQoL to inform patient management and policy decisions. Self- or interviewer-administered questionnaires can be used to differentiate subgroup differences in HRQoL between patients at a point in time (discriminative instruments) or longitudinal changes in HRQoL within patients during a period of time (evaluative instruments). Both discriminative and evaluative instruments must be valid and have a high ratio of signal to noise.[4] Patient reported tests and measures are performed to determine a patient's status at the time of assessment, to predict a subsequent event and to detect change over time.[5]

When evaluating outcome tools, researchers are familiar with the traditional psychometric approaches to clinical measurement science that assesses validity, reliability, and responsiveness.[6] In these approaches structural and construct validity can be supported through factor analytic techniques that confirmed the presence of 1 or more valid unidimensional (sub)scales (a scale measuring a single construct).[7] Modern clinical measurement approaches have been adopted to supplement this traditional approach.[8] The Rasch measurement model,[9] usually referred to as Rasch analysis, is ideally used in construction of measures to ensure the items cover a broad scope of quantity of a single construct on a true numeric (interval) metric and that there is no differential bias based on the type of respondent. Since Rasch was not in use

when many of the current measures were created we must now re-examine them through a Rasch lens to see if they fit the model and thereby demonstrate these important measurement qualities that are sometimes missed in classical approaches.

Merbitz et al[10] have stated that while ordinal numbers may be put on a number line with assumed equal intervals, in practice the intervals are, by definition, unknown. Ordinal PRO represent counts of observed events that are transferred from one category to the next and summed across different variables, yet the actual interval across the category thresholds remain to be determined (hence the distinction between "ordinal" and true "interval" measures).

Parametric analysis assumes that the variables must have been measured in interval scale so that it is possible to interpret the results accurately.[11] Similarly, when applying measures to individual patients it is important that change scores on one end of the scale represent the same true change as changes on other parts of the scale. Rasch analysis can support this process by providing a transformation of an ordinal score into a linear, interval-level variable, given the fit of data to Rasch model expectations.[7]

A recent survey of research articles in the New England Journal of Medicine showed that a fifth of articles contained data that are treated as numbers but actually based on an ordinal scale.[12] When several items are measured on ordinal scales it is far from certain that the sum of scores retain ordinal properties. If items are correlated or have different weights, changes may appear in the total score without any simple and clear cut relation to fluctuations in the patient's overall condition.[13] Further, the use of mean and standard deviation to describe a sample is not a valid approach when the data is ordinal in nature.[13] Despite this, the use of parametric statistics and numerical operations on ordinal data continues to predominate analysis of patient reported data.

Rasch analysis allows for a unified approach to several measurement issues, all of which are required for the validity of the transformation of ordinal to interval scaling. Testing the internal construct validity of the scale for unidimensionality is important since it is a requirement for a valid summed raw (ordinal) score. Testing the invariance of items (that is, the ratio of difficulties between any pair of items remains constant across the ability levels of respondents) is important because it is also required for interval-level scaling. The category ordering is essential since determining whether polytomous items showed the expected gradient of change as you move from one level to other is fundamental to treating the scale like a number. Testing for

differential item functioning (DIF) determines whether bias exists for an item among subgroups in the sample.[7]

The simple shoulder test (SST) is a self-reported shoulder-specific questionnaire that measures functional limitations of the affected shoulder in patients with shoulder dysfunction.[14] The SST consists of 12 questions with dichotomous (yes/no) response options. For each question, the patients indicate that they are able or are not able to do the activity. The scores range from 0 (worst) to 12 (best).[14] The SST has been considered a valid,[15] reliable[15,16] and responsive[17,18] measure based on studies that have demonstrated strong clinical measurement properties using traditional psychometric methods. Roy et al[17] demonstrated large responsiveness for the SST (standardized response mean (SRM), 1.73) with a large effect size (2.23) in patients who improved after undergoing surgery for shoulder pathology. Beaton and Richards[16] found a SRM of 0.87 on a small cohort of improved patients (n = 33) with a high test-retest reliability (ICC = 0.99) following rotator cuff surgery and total shoulder arthroplasty (TSA). Godfrey et al[15] has reported that SST demonstrated overall acceptable psychometric performance with acceptable test-retest reliability (ICC >0.90) and content validity (floor and ceiling effects <10%). Correlations with the physical functioning component of the Short Form 12 were significant ($r = 0.439$, $P < .05$); correlations with the American Shoulder and Elbow Surgeons were also significant ($r = 0.807$, $P < .001$). The construct validity of the SST was acceptable demonstrating significance ($P < .05$). The SST was responsive to change (effect size, 0.81; standardized response mean, 0.81). Roy et al[19] have stated that some properties of the SST still need be evaluated, particularly the absolute errors of measurement. They have concluded that the SST is a highly reliable questionnaire and the quickest to complete, but its minimal detectable change (MDC) and minimal clinically important difference (MCID) have not yet been defined.

SST has been evaluated using the traditional psychometric methods,[15-18] but to date there is no study validating SST through the Rasch model. The purpose of this study was to perform a Rasch analysis of the SST to assess the overall fit to the Rasch model, individual item fit, differential item functioning (DIF; based on gender), local dependency of items and their unidimensionality. A secondary purpose was to find the fit of SST to the Rasch model in patients with shoulder problems at different time points before (pre-operative) and after surgery (up to one year after surgery).

METHODOLOGY

Study design

Cross sectional study at 2 different time points in 2 independent samples

Procedure

The sample consisted of 252 consecutive subjects (100 males and 152 females, age range between 25 and 89 years, (table 1)) who signed the consent forms in compliance with the approval by the University of Western Ontario ethics board. One group of 126 patients completed the SST questionnaire before they underwent reverse shoulder arthroplasty or rotator cuff repair and the other group of 126 patients completed the questionnaire between 6 months and 1 year after their surgery. Subjects were included in the study if they were aged 18 and above, had been diagnosed with gleno-humeral arthritis or rotator cuff tear and were able to read and understand English in order to complete the SST questionnaire. Subjects were excluded if they had been diagnosed with any neurological or cognitive disorder or if they have had previous surgery for the same shoulder.

Rasch Analysis

Rasch analysis is the formal testing of an outcome scale against a mathematical measurement model developed by Danish mathematician Georg Rasch.[9] The Rasch model shows what should be expected in responses to items if interval scale measurement is to be achieved.[7] The response patterns achieved from a set of items in a questionnaire that are intended to be summed together are tested against what is expected by the model, which is called Guttman scaling.[20] Establishing a hierarchy with a Guttman scale helps to legitimize the use of a summed score because the rank ordering of scale items is confirmed.[21] Guttman scaling is a deterministic pattern that expects a strict hierarchical ordering of items (e.g., from low to high levels of activity limitation) such that if (in the dichotomous case) a patient has affirmed an item representing a task of average difficulty, then all the items below that task on the scale (i.e., easier tasks) should also be affirmed. The Rasch model relaxes this to say that if a harder task is affirmed, then there is a high probability that easier tasks will also be affirmed.[7]

This study aims to find the fit of the data obtained from this cohort of patients who are to undergo surgery for their shoulder problem to the Rasch model. Specific tests were performed to assess the overall fit of the Rasch model, individual item fit, individual person fit,

unidimensionality and differential item functioning (DIF).[9, 22] Rasch analysis was performed using the RUMM 2030 software.[23] The data was loaded into the software and SST was analysed to see the fit into the model and sources of misfit were sequentially analysed using the following tests.

Tests conducted to assess the fit of SST to Rasch model

Class interval structure. RUMM software automatically sets the number of class intervals and distributes the sample into each of the class intervals. Class intervals are sets of intervals of arbitrary width into which the range of a sample of measurement is partitioned. The number of class intervals and the distribution of persons within them is an extremely important factor as it is an indication of how the sample is distributed across the class intervals and should be constantly monitored. By using class intervals it is possible to generate a plot for each group separately, if needed.[24] Therefore the class intervals are re-examined after each new analysis and for every amendment that is made within an analysis. It is preferable to have approximately equal sample sizes within each class interval, and preferably a minimum of 50 persons in each.[25]

Targeting of persons and items, and sample size. In Rasch software the scale is always centered on zero logits, representing the item of average difficulty for the scale. Comparison of the mean location score obtained for persons with that of the value of zero set for the items provides an indication of how well targeted the items are for people in the sample. For a well-targeted measure (not too easy, not too hard), the mean location for persons would also be around the value of zero. A positive mean value for persons would indicate that the sample as a whole was located at a higher level (e.g., of pain) than the average of the scale, while a negative value would suggest the opposite.[7]

Overall fit of summary statistics (Item fit statistics, person fit statistics and item-trait interaction statistics and reliability indices).[26] In RUMM2030 summary-, item- and person-specific fit statistics can be calculated to see if both items and persons are consistent with model expectations. Item fit assesses the degree of divergence (or the residual) between the expected or estimated value and the actual data value for each person-item when summed over all items (for a given person). Person fit identifies the degree of divergence or the residual between the expected or estimated value and the actual data value for each person-item when summed over all persons (for a given item).[25] If the data behave according to the model expectation, the mean of the overall item and the overall person fit statistics should be close to 0

and their standard deviation close to 1.

A third summary fit statistic is the item-trait interaction statistic which is reported as a chi square, reflecting the property of invariance across the trait. A significant chi-square indicates that the hierarchical ordering of the items varies across the trait, compromising the required property of invariance. Individual item chi-square statistics are also available, giving detailed information about item-deviation from model expectations.

An individual item residual fit statistic is also calculated, based on the standardized residuals (differences between the observed and expected responses divided by square root of variance and calculated for each patient for a given item). To obtain an overall statistic for an item, the standardized residuals are squared and summed over the patients. The individual item fit statistic is calculated by transforming this overall statistic to make it a standard normal deviate under the hypothesis that the data fit the model. Thus, it is concluded that the deviations between the responses and the model are no more than random errors. Residuals between ±2.5 are deemed to indicate adequate fit to the model. A person fit statistic is constructed for each person in a way similar to that of each item.

An estimate of the internal consistency reliability of the scale can also be calculated, based on the person separation index (PSI), where the estimates on the logit scale for each person are used to calculate reliability. PSI is indicative of the power of the construct to discriminate amongst the respondents with 0.7 being the minimum accepted level indicating that 2 groups can be statistically differentiated and a value of 0.9 indicates ability to differentiate between 4 or more groups.[25,27,28]

Differential item functioning. DIF, or item bias, occurs when different groups within the sample respond in different manners to an individual item, despite equal levels of the underlying characteristic being measured,[7] thus affecting the fit of the data to the model. Two types of DIF may be identified. One is where the group shows a consistent systematic difference in their responses to an item, across the whole range of the attribute being measured, which is referred to as uniform DIF.[29] When there is non-uniformity in the differences between the groups (e.g., differences vary across levels of the attribute), then this is referred to as non-uniform DIF.[30] This is more problematic than uniform DIF.

DIF can be detected by item characteristic curves in RUMM2030 and further confirmed statistically using the ANOVA table presented with the curves. Uniform DIF is indicated by statistically significant values for person factor and non-uniform DIF is indicated by significant

person factor-by-class interval values.[30] Uniform DIF can be addressed by splitting the items whereas non-uniform DIF is not easily resolved and usually requires removal of the items from the scale.[25] We were concerned with differential item functioning based on gender since we know gender difference exist in some musculoskeletal disorders and in shoulder conditions and that activity/work roles can vary by gender.[31-33]

Local dependency. A source of misfit within a scale could be due to the presence of local dependency in the data. This is where a person's response to one item in the scale will have a bearing upon their response to another different item within the scale.[25] This analysis is undertaken by a correlation of the item residuals, where high positive residuals (>0.2) would indicate a breach of local dependency.[22] Response dependency, where items are linked in some way, inflate classic reliability and affect parameter estimation in Rasch analysis. They are identified through the residual correlation matrix and dealt with by combining the items into a testlet.[34] It is important to deal with local dependency at the outset, as its presence may affect the item fit statistics[26] and can be dealt with by combining the items into a subtest.[7]

Tests for Unidimensionality. The Rasch model is a unidimensional measurement model, therefore the assumption is that the items summed together form a unidimensional scale.[7] Rasch programs usually provide a principal components analysis of the residuals which implies that once the Rasch factor has been taken into account there should be no further associations between the items other than random associations.[35] The absence of any meaningful pattern in the residuals will also be deemed to support the assumption of unidimensionality.[36] This test of unidimensionality takes the patterning of items in the residuals, examining the correlation between items and the first residual factor, and uses these patterns to define 2 subsets of items (i.e., the positively and negatively correlated items). These 2 sets of items are then used to make separate person estimates, and, using an independent *t*-test for the difference in these estimates for each person, the percentage of such tests outside the range -1.96 to 1.96 should not exceed 5%. A confidence interval for a binomial test of proportions is calculated for the observed number of significant tests, and this value should overlap the 5% expected value for the scale to be unidimensional. Given that the differences in estimates derived from the 2 subsets of items are normally distributed, this approach is robust enough to detect multidimensionality and appears to give a test of strict unidimensionality.[37,38]

Subtest analysis. A subtest analysis is performed for a number of reasons like grouping locally dependent items together or grouping items with DIF together to see if the DIF cancels

out within the subtest. Subtest analysis is done when there is still some misfit due to multidimensionality or DIF in spite of all the above steps.[25] In subtest analysis, items measuring similar constructs are combined together to create super items also known as testlets. These super items are considered as individual items and a new Rasch analysis is performed. In the new analysis with the testlets, special attention is directed towards the 'A' value in summary statistics. 'A' gives the proportion of common non-error variance out of total non-error variance which arises from adding different testlets together to make a total score. Values of A indicate how much multidimensionality has been absorbed. The commonly accepted value of 'A' is above 0.8, because when 'A' falls below 0.8, it indicates continuing multidimensionality, which means the data do not satisfy the model requirements.

RESULTS

The data obtained from 2 groups of 126 patients was analysed for fit to the Rasch model when two different person factors, gender (male vs female) and time point of collection of data (pre-op vs post-op) were considered for their effect on the data. The class intervals were checked throughout the analysis for consistency to see if the cases were nearly equally distributed between the groups. There were four groups with approximately equal number of cases shared between them.

Initial summary fit

The initial summary statistics showed a mean fit residual value of -0.60 with a standard deviation (SD) of 1.79 for all the items which is very high compared to the expected SD of 1indicating inadequate fit to the model. The mean fit residual for persons was -0.27 with a SD of 0.57 indicating excellent fit of the persons to the model. The chi square value was very high at 76.82 (df = 36) with a significant probability of 0.000088 indicating presence of variance of item difficulty across the scale (table 2). The misfit of the items was a result of questions 4 (can you place your hand behind your head with the elbow straight out to the side? with a fit residual of -3.53), 5 (can you place a coin on a shelf at the level of your shoulder without bending your elbow? with a fit residual of -2.55) and 8 (can you carry twenty pounds at your side with the affected extremity? with a fit residual of 2.58) (table 3). The reliability indices of PSI and Cronbach's alpha showed highly reliable scores of 0.75 and 0.85 (with extremes included) indicating that the power of analysis of fit was good.

In order to find the reason of the misfit of the 3 items, a DIF analysis (with time point and gender as separate person factors), test of unidimensionality and test for local dependency were performed.

Analysis for effect of time point as a person factor

The SST data showed a good fit to the Rasch model with time point as a person factor when the 12 item questionnaire was reduced to 11 items by combining questions 5 (can you place a coin on a shelf at the level of your shoulder without bending your elbow?) and 6 (can you lift one pound (full pint container) to the level of your shoulder without bending your elbow?) negating the misfit of the individual items to the model. The mean fit residual for items was -0.5899 (SD = 1.6727), for persons was -0.2849 (SD = 0.5643) with a chi square value of 59.9309 (df = 33 and p = 0.002816, 'A' value of 0.98) (table 2).

The steps to achieve fit to the Rasch model is as follows:

DIF analysis. A DIF analysis was performed to identify if the items were mis-fitting due to difference in response at different time points. The Bonferroni level of precision was set at 0.05. This did not identify any DIF among the items (table 4) and hence a test for unidimensionality was performed to identify the source of misfit.

Test for unidimensionality. To identify if the items in SST were unidimensional, a test of fit for residual principal components was performed. Questions 4, 5, 6, 7, 9 and 10 loaded positively on the first residual component (PC1) and questions 1, 2, 3, 8, 11, and 12 loaded negatively. The positively loaded items and the negatively loaded items were considered as two separate subsets and a paired't' test was performed. A total of 222 tests were performed with 6 tests below 5%. This shows that 2.7% of data was less than 5% per class interval which falls under the maximum accepted value of 5% indicating that the items were unidimensional. These results lead us to performing the test of local dependency to identify source of misfit.

Tests of local dependency and subtest analysis. Test of local dependency was performed with the test of fit for residual correlations. This identified that questions 4 and 5 (can you place your hand behind your head with the elbow straight out to the side?, can you place a coin on a shelf at the level of your shoulder without bending your elbow?) and questions 5 and 6 (can you place a coin on a shelf at the level of your shoulder without bending your elbow?, can you lift one pound (full pint container) to the level of your shoulder without bending your elbow?) were dependent on each other meaning that a person's response to one item had a

bearing on the persons' response to the other item (table 5). Hence, a super item was created combining questions 5 and 6 which would address the person's ability to lift an object (light or heavy) to the level of the shoulder without bending the elbow. When a subtest analysis was performed with the super item, the item and person fit was good; chi square was not significant; no DIF was observed; t-test showed a perC value of 2.25% (which falls within the acceptable range); and the local dependency between questions 4 & 5 and 5 & 6 was negated 1 (table 6). The 'A' value of the reliability indices was 0.98 clearly indicating that all multidimensionality that previously existed was negated justifying the combining of the questions 5 and 6 (table 2).

Targeting. SST proves to be an optimally targeted measure for the population when used at different time points both before and after a shoulder surgery fulfilling its intended purpose. This is evident from the mean location value in the person-item distribution graph (figure 1). When the person-item location threshold distribution graph was plotted with distributions of persons on the top half of the graph and item thresholds at the bottom half of the graph, the average person location (-0.985) indicated that the SST was optimally targeted for use in this kind of patient population. This means that patients on an average were at a slightly lower level of ability than the average of the scale items (zero logits).

Analysis for effect of gender as a person factor

The gender difference was due to the fact that question 8 was about carrying twenty pound weight with the affected extremity. From the data, we could see that men scored better in this question (both before and after surgery) as carrying a twenty pound weight was easier for them compared to females. This difference resulted in the misfit of this question in the Rasch model. Splitting question 8 based on gender to calibrate for differences between males and females showed good fit of the SST to the Rasch model negating the misfit of the individual item to the model. The mean fit residual for items was -0.5325 (SD = 1.5735), for persons was -0.2812 (SD = 0.5871) with a chi square value of 54.4355 (df = 39 and p = 0.051293) (table 2).

The steps to achieve this fit of question 8 to the Rasch model is as follows:

DIF analysis. A DIF analysis was performed to identify the effect of gender differences in responding to questions in SST. The bonferroni level of precision was set at 0.05. This identified one item, question 8 (can you carry twenty pounds at your side with the affected extremity?) to be mis-fitting to the model with a p value of 0.000040 (table 7). The chi square value was also highly significant indicating variance between the expected and actual scores.

Tests of unidimensionality and tests for local dependency. Tests of unidimensionality and tests for local dependency performed at this stage showed that question 8 was unidimensional (with acceptable perC value of 2.25%) and that it did not have bearing on a person's response to any other item. Hence, it was deemed that uniform DIF was the reason for misfit of question 8.

Question 8 was split to calibrate for the effect of gender differences on a person's response to the item. This split cleared DIF (table 8) with a significant chi square value of 54.435 with df = 39 and p = 0.051293. The reliability indices also showed acceptable range of PSI value of 0.75 which indicated that SST was reliable to discriminate between at least 2 distinct groups of patients (table 2).

Targeting. After splitting question 8 (can you carry twenty pounds at your side with the affected extremity?) to account for gender differences, the SST was optimally targeted for the shoulder population in this study. This was evident from the average person location value of -0.934 in the person-item distribution graph (figure 2) when plotted with distributions of persons on the top half of the graph and item thresholds at the bottom half of the graph. This means that patients on an average were at a slightly lower level of ability than the average of the scale items (zero logits).

DISCUSSION

This study adds to the body of evidence supporting the SST with robust measurement properties since there was adequate fit to the Rasch model after minor adjustments. The psychometric properties of SST has been previously supported using classical test methods.[15-18] These studies have indicated that the SST is reliable, valid and is able to detect clinically important differences. Godfrey et al[15] has questioned the responsiveness of SST after analyzing its performance across age groups and injury types. They have reported lower responsiveness in younger patients and in patients with instability injuries. Similarly Cook et al[39] and Kirkley et al[40] commented that the SST could not differentiate between patients with varying severity.

Since there has been mixed reports on the psychometric properties of SST in the literature and since the development of SST pre-date the common use of Rasch, there is a need to validate the fit of SST to the Rasch model and provide an analysis of measurement traits on aspects less attended by previous psychometric analyses.

We hypothesized that the fit of SST to the Rasch model will vary across different time points of measurement (pre-op and post-op) and across different genders which was proved in the analysis of our data. Rasch analysis of the SST illustrated misfit of 3 questions out of the total 12 questions in the scale. The causes of misfit for 2 of these were based on local dependency between questions 4 (can you place your hand behind your head with the elbow straight out to the side?), 5 (can you place a coin on a shelf at the level of your shoulder without bending your elbow?) and 6 (can you lift one pound (full pint container) to the level of your shoulder without bending your elbow?) while the third misfit was due to gender difference in response to question 8 (can you carry twenty pounds at your side with the affected extremity?).

The local dependency between questions 4 (can you place your hand behind your head with the elbow straight out to the side?), 5 (can you place a coin on a shelf at the level of your shoulder without bending your elbow?) and 6 (can you lift one pound (full pint container) to the level of your shoulder without bending your elbow?) can be explained by the fact that all the items question a person's ability to lift the arm above the shoulder level. Though questions 5 and 6 vary in the weight of the object being lifted to shoulder level, they still measure the same ability of the person – to lift arm above shoulder level. Hence, combining these 2 questions into one super item addressing the ability of the person to lift arm to shoulder level (without considering the weight lifted) negated local dependency between the questions 4, 5 and 6.

The cause of misfit of question 8 (can you carry twenty pounds at your side with the affected extremity?) to the model was found to be uniform DIF which means that the SST did not work the same across different genders of the population. Gender may be a potential source of misfit for question 8 because carrying a twenty pound bag is a standardized activity but will represent a different proportion of total capability when considering mean strength differences for males compared to females. Also, gender differences in roles and resultant experience differences with lifting might also affect how males and females interpret this question. Thus, when scoring the tool males tend to score on this question while females answer 'no' and hence score a zero. This difference in scoring will have an impact on the total score. To avoid this effect on scoring and misfit, splitting question 8 into 2 items separately for males and females negated the problem of DIF across the population.

SST was shown to be an optimally targeted measure for the population when used at different time points both before and after a shoulder surgery and also across different genders

fulfilling its intended purpose. This increases confidence that the items are relevant across a broad spectrum of patients with shoulder disorders (pre- and post-surgery).

The SST did not fit the Rasch model initially and later when 2 questions were combined and another question split to accommodate gender differences, the misfit was negated. This opens up a few channels in which SST could be improved to serve as a better outcome measure to capture changes in specific patient populations. One option is to collapse questions measuring a person's ability to lift his or her arm above shoulder level into one item (4 questions measure this ability in the questionnaire), the second option is to consider making changes to questions that specify the ability of a person to carry a particular weight with the affected shoulder (3 questions measure this ability in the questionnaire). It might be worthwhile exploring the stability of our findings before implementing substantial changes- particularly in light of the good psychometric properties demonstrated in previous studies.

Limitations and recommendations for future research

There were a few limitations in the current study. We studied patients enroute to a reverse shoulder arthroplasty or rotator cuff repair. There are a number of additional shoulder disorders where the SST is commonly used. Studies that cover a wide spectrum of these disorders are needed to validate our findings. We recommend that future studies include a variety of shoulder disorders, evaluate other person factors like occupational demand, severity of injury, level of education, Workman's compensation insurance board (WCIB) claims and other social factors that might determine DIF.

CONCLUSION

The results of this study should provide confidence to clinicians on SST who wish to use a brief shoulder-specific measure in their practice. The SST appears to be robust when tested against the Rasch model despite some potential areas for improvement. The potential areas that should be explored in future Rasch analyses are the questions that measure the ability of a person to lift the arm above shoulder level and the potential for gender differences when measuring the ability to carry weights with the affected arm. Studies in different settings and populations are needed before these changes can be endorsed as permanent alterations in a scale that is widely used and reported in the literature.

REFERENCES

1. Fitzpatrick, R., Davey, C., Buxton, M. J., & Jones, D. R. (1998). Evaluating patient-based outcome measures for use in clinical trials. *Health Technology Assessment (Winchester, England), 2*(14), i-iv, 1-74.
2. U.S. Food and Drug Administration. *The Patient Reported Outcomes Consortium*. Retrieved from http://www.fda.gov/AboutFDA/PartnershipsCollaborations/PublicPrivatePartnershipProgram/ucm231129.htm. Updated on November 1, 2010. Accessed on April 11, 2013.
3. Svensson, E. (2001). Guidelines to statistical evaluation of data from rating scales and questionnaires. *Journal of Rehabilitation Medicine : Official Journal of the UEMS European Board of Physical and Rehabilitation Medicine, 33*(1), 47-48.
4. Guyatt, G. H., Feeny, D. H., & Patrick, D. L. (1993). Measuring health-related quality of life. *Annals of Internal Medicine, 118*(8), 622-629.
5. MacDermid, J. C., & Stratford, P. (2004). Applying evidence on outcome measures to hand therapy practice. *Journal of Hand Therapy : Official Journal of the American Society of Hand Therapists, 17*(2), 165-173. doi: 10.1197/j.jht.2004.02.005
6. Nunnally JC, Bernstein IH: *Psychometric theory:* 3rd ed. New York: McGraw-Hill; 1994.
7. Tennant, A., & Conaghan, P. G. (2007). The rasch measurement model in rheumatology: What is it and why use it? when should it be applied, and what should one look for in a rasch paper? *Arthritis and Rheumatism, 57*(8), 1358-1362. doi: 10.1002/art.23108
8. Tennant A, McKenna SP, Hagell P. Application of Rasch analysis in the development and application of quality of life instruments. *Value Health* 2004;7 Suppl 1:S22–6.
9. Rasch G. *Probabilistic models for some intelligence and attainment tests.* Chicago: University of Chicago; 1960.
10. Merbitz C, Morris J, Grip JC. Ordinal scales and foundations of misinference. *Arch Phys Med Rehabil* 1989: 70: 308–312.
11. Siegel S, Castellan NJ: *Nonparametric statistics for the behavioral sciences.* 2nd ed. New York ; Montreal: McGraw-Hill; 1988.
12. Moses, L. E., Emerson, J. D., & Hosseini, H. (1984). Analyzing data from ordered categories. *The New England Journal of Medicine, 311*(7), 442-448. doi: 10.1056/NEJM198408163110705

13. Forrest, M., & Andersen, B. (1986). Ordinal scale and statistics in medical research. *British Medical Journal (Clinical Research Ed.), 292*(6519), 537-538.
14. Lippitt SB, Harryman DT, Matsen FA. *A practical tool for evaluation of function: the simple shoulder test. The Shoulder: A Balance of Mobility and Stability.* Rosemont, IL: American Academy of Orthopaedic Surgery; 1993.
15. Godfrey, J., Hamman, R., Lowenstein, S., Briggs, K., & Kocher, M. (2007). Reliability, validity, and responsiveness of the simple shoulder test: Psychometric properties by age and injury type. *Journal of Shoulder and Elbow Surgery / American Shoulder and Elbow Surgeons ...[Et Al.], 16*(3), 260-267. doi: 10.1016/j.jse.2006.07.003
16. Beaton, D., & Richards, R. R. (1998). Assessing the reliability and responsiveness of 5 shoulder questionnaires. *Journal of Shoulder and Elbow Surgery / American Shoulder and Elbow Surgeons ...[Et Al.], 7*(6), 565-572.
17. Roy, J. S., Macdermid, J. C., Faber, K. J., Drosdowech, D. S., & Athwal, G. S. (2010). The simple shoulder test is responsive in assessing change following shoulder arthroplasty. *The Journal of Orthopaedic and Sports Physical Therapy, 40*(7), 413-421. doi: 10.2519/jospt.2010.3209
18. MacDermid, J. C., Drosdowech, D., & Faber, K. (2006). Responsiveness of self-report scales in patients recovering from rotator cuff surgery. *Journal of Shoulder and Elbow Surgery / American Shoulder and Elbow Surgeons ...[Et Al.], 15*(4), 407-414. doi: 10.1016/j.jse.2005.09.005
19. Roy, J. S., MacDermid, J. C., & Woodhouse, L. J. (2009). Measuring shoulder function: A systematic review of four questionnaires. *Arthritis and Rheumatism, 61*(5), 623-632. doi: 10.1002/art.24396
20. *Guttman LA. A basis for scaling quantitative data. Am Sociol Rev.* 1944*;*9*:*139*–150.*
21. Gothwal, V. K., Wright, T. A., Lamoureux, E. L., & Pesudovs, K. (2009). Guttman scale analysis of the distance vision scale. *Investigative Ophthalmology & Visual Science, 50*(9), 4496-4501. doi: 10.1167/iovs.08-3330
22. Andrich D: *Rasch models for measurement:* Newbury Park: Sage Publications; 1988.
23. Andrich D, Sheridan B, Luo G: RUMM 2030. *Perth, WA: RUMM Laboratory Pty Ltd* 2010.
24. Martin Clark. By the Numbers: The rationale for Rasch analysis in placement testing. *Second Language Studies,* 22 (2), Spring 2004, pp. 61-90.

25. Tennant A, Horton MC, Pallant JF: *Introductory Rasch Analysis: A workbook.* Department of Rehabilitation Medicine, University of Leeds, UK, 2011.
26. Elhan AH, Kucukdeveci AA, Tennant A. The Rasch Measurement Model. In Franco Franchignoni (Ed), *Advances in Rehabilitation. Research issues in Physical & Rehabilitation Medicine* (pp. 89 – 102). Maugeri Foundation Books Vol. 19, 2010, Pavia, Italy.
27. Wright BD: Interpreting reliabilities. *Rasch Measurement Transactions* 1998, 11(4):602.
28. Fisher W: Reliability statistics. *Rasch Measurement Transactions* 1992, 6(3):238.
29. Teresi JA, Kleinman M, Ocepek-Welikson K. Modern psychometric methods for detection of differential item functioning: application to cognitive assessment measures. *Stat Med* 2000; 19:1651–83.
30. Pallant JF, Tennant A: An introduction to the Rasch measurement model: an example using the Hospital Anxiety and Depression Scale (HADS). *Br J Clin Psychol* 2007, 46(Pt 1):1-18.
31. Kazakia, G. J., Nirody, J. A., Bernstein, G., Sode, M., Burghardt, A. J., & Majumdar, S. (2013). Age- and gender-related differences in cortical geometry and microstructure: Improved sensitivity by regional analysis. *Bone, 52*(2), 623-631. doi: 10.1016/j.bone.2012.10.031; 10.1016/j.bone.2012.10.031
32. Razmjou, H., Davis, A. M., Jaglal, S. B., Holtby, R., & Richards, R. R. (2011). Disability and satisfaction after rotator cuff decompression or repair: A sex and gender analysis. *BMC Musculoskeletal Disorders, 12*, 66-2474-12-66. doi: 10.1186/1471-2474-12-66; 10.1186/1471-2474-12-66
33. Kirchhoff, C., Braunstein, V., Milz, S., Sprecher, C. M., Kirchhoff, S., Graw, M., . . . Hinterwimmer, S. (2012). Age and gender as determinants of the bone quality of the greater tuberosity: A HR-pQCT cadaver study. *BMC Musculoskeletal Disorders, 13*, 221-2474-13-221. doi: 10.1186/1471-2474-13-221; 10.1186/1471-2474-13-221
34. Wainer H, Kiely G. Item clusters and computer adaptive testing: A case for testlets. *J Educ Meas* 1987; 24: 185-202.
35. Wright BD. Local dependency, correlations and principal components. *Rasch Measurement Transactions* 1996;10:509–11.
36. Smith EV. Detecting and evaluating the impact of multidimensionality using item fit statistics and principal component analysis of residuals. *J Appl Meas* 2002;3:205–31.

37. Tennant A, Pallant JF. Unidimensionality matters. *Rasch Measurement Transactions* 2006;20:1048–51.
38. Stout WF. A new item response theory modelling approach with applications to unidimensionality assessment and ability estimation. *Psychometrika* 1990;55:293–325.
39. Cook KF, Gartsman GM, Roddey TS, Olson SL. The measurement level and trait-specific reliability of 4 scales of shoulder functioning: an empiric investigation. *Arch Phys Med Rehabil* 2001;82:1558-65.
40. Kirkley A, Griffin S, Dainty K. Scoring systems for the functional assessment of the shoulder. *Arthroscopy* 2003;19:1109-20.

Table 1. Baseline demographics

Pre-op patients:	
Age Range Mean (SD)	 25 – 89 years 67.2 (10.31)
Gender Male Female	 56 70
Dominant side affected	78
SST* Mean (SD) Range	 2.30 (2.31) 0-11
Post-op patients:	
Age Range Mean (SD)	 37-88 years 67.42 (11.52)
Gender Male Female	 44 82
Dominant side affected	79
SST* Mean (SD) Range	 6.10 (3.15) 0-12

SST – Simple shoulder test, SD – Standard deviation,
*higher scores indicate improved outcomes

Table 2. Summary statistics of fit of SST to Rasch model

Analysis	Item fit residual		Person fit residual		Item-trait interaction			PSI	'A'
	Mean	SD	Mean	SD	Chi square	df	P value		
Initial	-0.6032	1.7886	-0.2725	0.5736	**76.8226**	36	0.000088	0.75	-
After combining questions 5 & 6 (subtest analysis)	-0.5899	1.6727	-0.2849	0.5643	59.9309	33	0.002816	0.75	0.98
After splitting question 8	-0.5325	1.5735	-0.2812	0.5871	54.4355	39	0.051293	0.75	-

For the data to satisfy Rasch model requirements:

- Mean is expected to be approx. around zero (can range between $\pm$ 2.5);
- S.D. should be approximately 1;
- Chi square value is expected to be small and statistically non-significant;
- PSI (Person separation index) should be greater than 0.70 for the summary statistics to be reliable;
- 'A' is the proportion of common non-error variance out of total non-error variance which arises from adding the three testlets together to make a total score and 'A' should be greater than 0.8, then the independent t-test may indicate unidimensionality.

Table 3. Individual item fit for initial SST statistics

Item	Location	SE	Fit residual	DF	Chi Square	df	P
1. Is your shoulder comfortable with your arm at rest by your side?	-2.791	0.188	-0.009	202.58	1.648	3	0.648515
2. Does your shoulder allow you to sleep comfortably?	-0.710	0.163	1.626	202.58	7.813	3	0.050031
3.Can you reach the small of your back to tuck in your shirt?	-0.096	0.169	0.496	202.58	4.889	3	0.180129
4.Can you place your hand behind your head with the elbow straight out to the side?	**-0.712**	**0.163**	**-3.532**	**202.58**	**17.368**	**3**	**0.000595**
5.Can you place a coin on a shelf at the level of your shoulder without bending your elbow?	**-0.831**	**0.163**	**-2.553**	**202.58**	**13.746**	**3**	**0.003273**
6.Can you lift one pound (full pint container) to the level of your shoulder without bending your elbow?	-0.487	0.165	-2.398	202.58	11.408	3	0.009715
7.Can you lift eight pounds (full gallon container) to the level of your shoulder without bending your elbow?	1.870	0.230	-0.094	202.58	2.333	3	0.506189
8.Can you carry twenty pounds at your side with the affected extremity?	**-0.280**	**0.167**	**2.583**	**202.58**	**5.656**	**3**	**0.129578**
9.Do you think you can toss a softball under-hand twenty yards with the affected extremity?	0.272	0.175	-1.885	202.58	4.516	3	0.210844
10.Do you think you can toss a softball over-hand twenty yards with the affected extremity?	2.791	0.294	-1.290	202.58	2.358	3	0.501437
11.Can you wash the back of your opposite shoulder with the affected extremity?	0.606	0.183	-0.019	202.58	2.247	3	0.522740
12.Would your shoulder allow you to work full-time at your regular job?	0.368	0.177	-0.164	202.58	2.840	3	0.416971

SE-standard error; DF-Degrees of freedom

Misfitting items are in bold. An item was considered misfitting if it had a significant p value even after applying Bonferroni correction to it.

Questions 4, 5 and 6 (bolded) showed misfit initially.

Table 4. Uniform and non-uniform DIF for time

Item	Uniform DIF for gender				Non-uniform DIF for gender			
	MS	F	DF	P	MS	F	DF	P
1. Is your shoulder comfortable with your arm at rest by your side?	4.60016	5.25025	1	0.022919	2.75313	3.14220	3	0.026191
2. Does your shoulder allow you to sleep comfortably?	7.64414	7.28814	1	0.007497	4.72036	4.50052	3	0.004382
3.Can you reach the small of your back to tuck in your shirt?	1.77208	1.81403	1	0.179452	0.79716	0.81603	3	0.486257
4.Can you place your hand behind your head with the elbow straight out to the side?	3.33903	6.70577	1	0.010270	-0.95787	-1.92369	3	0.999999
5.Can you place a coin on a shelf at the level of your shoulder without bending your elbow?	2.78888	4.81428	1	0.029297	0.49582	0.85590	3	0.464834
6.Can you lift one pound (full pint container) to the level of your shoulder without bending your elbow?	1.73171	2.86410	1	0.092034	0.77299	1.27846	3	0.282695
7.Can you lift eight pounds (full gallon container) to the level of your shoulder without bending your elbow?	1.73787	1.95746	1	0.163232	0.25785	0.29044	3	0.832284
8.Can you carry twenty pounds at your side with the affected extremity?	10.48013	8.01856	1	0.005074	-1.15752	-0.88564	3	0.999999
9.Do you think you can toss a softball under-hand twenty yards with the affected extremity?	1.38487	2.13208	1	0.145715	-0.10305	-0.15865	3	0.999999
10.Do you think you can toss a softball over-hand twenty yards with the affected extremity?	0.03716	0.10085	1	0.751118	1.61482	4.38306	3	0.005112
11.Can you wash the back of your opposite shoulder with the affected extremity?	1.72646	1.87730	1	0.172080	0.42050	0.45724	3	0.712456
12.Would your shoulder allow you to work full-time at your regular job?	1.54856	1.74647	1	0.187733	0.78281	0.88285	3	0.450792

An item was considered to exhibit DIF if P values are significant after applying bonferroni correction factor.

No items exhibited DIF when analysed for the effects of different time points as a person factor.

.

Table 5. Initial residual correlation matrix for local dependency

	I0001	I0002	I0003	I0004	I0005	I0006	I0007	I0008	I0009	I0010	I0011	I0012
I0001												
I0002	-0.069											
I0003	0.016	-0.082										
I0004	-0.108	-0.065	-0.097									
I0005	-0.042	-0.123	-0.158	0.16								
I0006	-0.101	-0.156	-0.116	0.03	0.26							
I0007	-0.162	-0.128	-0.155	-0.012	-0.083	0.064						
I0008	-0.127	-0.219	-0.147	-0.179	-0.217	-0.235	0.008					
I0009	-0.1	-0.122	-0.113	-0.076	-0.043	-0.032	0.009	-0.01				
I0010	-0.262	-0.118	-0.079	0.074	-0.085	-0.057	0.085	-0.122	0.054			
I0011	-0.148	-0.082	0.018	-0.059	-0.122	-0.169	-0.088	-0.053	-0.231	0.006		
I0012	-0.084	-0.126	-0.066	-0.187	-0.161	-0.103	-0.128	0.071	-0.015	-0.123	-0.023	

Note: Shaded boxes show the local dependency of question 4 &5, 5 &6. Local dependency was determined by values that are greater than 0.2 than the average of all the values.

Table 6. Residual correlation matrix for local dependency after combining questions 5 & 6 for subtest analysis

Item	ST01	ST002	ST003	ST004	ST005	ST006	ST007	ST008	ST009	ST010	ST011
ST01											
ST002	-0.106										
ST003	-0.157	-0.066									
ST004	-0.17	0.016	-0.082								
ST005	0.073	-0.096	-0.056	-0.081							
ST006	-0.009	-0.162	-0.134	-0.161	-0.003						
ST007	-0.27	-0.13	-0.232	-0.151	-0.172	0.011					
ST008	-0.055	-0.094	-0.12	-0.109	-0.061	0.014	-0.004				
ST009	-0.11	-0.249	-0.115	-0.075	0.081	0.092	-0.121	0.06			
ST010	-0.185	-0.144	-0.086	0.021	-0.046	-0.092	-0.057	-0.232	0.01		
ST011	-0.163	-0.089	-0.131	-0.07	-0.175	-0.135	0.073	-0.011	-0.122	-0.02	

ST01 – Super item after combining questions 5 & 6
No Local dependency was observed on subtest analysis after combining items 5 & 6.

Table 7. Uniform and non-uniform DIF for gender

Item	Uniform DIF for gender				Non-Uniform DIF for gender			
	MS	**F**	**DF**	**P**	**MS**	**F**	**DF**	**P**
1. Is your shoulder comfortable with your arm at rest by your side?	3.12702	3.53350	1	0.061499	2.61737	2.95759	3	0.033345
2. Does your shoulder allow you to sleep comfortably?	6.49635	5.95093	1	0.015526	2.04954	1.87747	3	0.134369
3.Can you reach the small of your back to tuck in your shirt?	1.99802	2.06748	1	0.151931	1.46867	1.51972	3	0.210356
4.Can you place your hand behind your head with the elbow straight out to the side?	0.00604	0.01218	1	0.912217	0.30797	0.62120	3	0.601995
5.Can you place a coin on a shelf at the level of your shoulder without bending your elbow?	0.09061	0.15189	1	0.697128	0.16589	0.27809	3	0.841175
6.Can you lift one pound (full pint container) to the level of your shoulder without bending your elbow?	0.15685	0.25255	1	0.615802	0.12601	0.20290	3	0.894313
7.Can you lift eight pounds (full gallon container) to the level of your shoulder without bending your elbow?	7.42181	8.68651	1	0.003563	0.74635	0.87353	3	0.455608
8.Can you carry twenty pounds at your side with the affected extremity?	**21.78221**	**17.77382**	**1**	**0.000040**	0.88612	0.72306	3	0.539215
9.Do you think you can toss a softball under-hand twenty yards with the affected extremity?	1.50016	2.32431	1	0.128842	0.15241	0.23614	3	0.871111
10.Do you think you can toss a softball over-hand twenty yards with the affected extremity?	0.91144	2.39697	1	0.123047	0.47975	1.26167	3	0.288495
11.Can you wash the back of your opposite shoulder with the affected extremity?	0.02902	0.03147	1	0.859359	0.81017	0.87859	3	0.452988
12.Would your shoulder allow you to work full-time at your regular job?	0.60454	0.67732	1	0.411429	0.67837	0.76003	3	0.517651

Items exhibiting DIF are bolded. An item was considered to exhibit DIF if P values are significant after applying bonferroni correction factor.

Question 8 exhibited uniform DIF when analysed for the effects of different genders as a person factor.

Table 8. Uniform and non-uniform DIF after splitting question 8 for gender

Item	Uniform DIF for gender				Non-uniform DIF for gender			
	MS	F	DF	P	MS	F	DF	P
1. Is your shoulder comfortable with your arm at rest by your side?	1.98212	2.20012	1	0.139469	0.57440	0.63757	3	0.591580
2. Does your shoulder allow you to sleep comfortably?	4.26494	3.86419	1	0.050617	3.06292	2.77511	3	0.042311
3.Can you reach the small of your back to tuck in your shirt?	0.96649	0.97122	1	0.325489	0.88309	0.88741	3	0.448451
4.Can you place your hand behind your head with the elbow straight out to the side?	0.21321	0.40368	1	0.525874	0.01984	0.03757	3	0.990241
5.Can you place a coin on a shelf at the level of your shoulder without bending your elbow?	0.48486	0.78271	1	0.377310	0.49374	0.79705	3	0.496726
6.Can you lift one pound (full pint container) to the level of your shoulder without bending your elbow?	0.63447	0.98084	1	0.323110	0.01057	0.01634	3	0.997146
7.Can you lift eight pounds (full gallon container) to the level of your shoulder without bending your elbow?	9.03262	9.81321	1	0.001975	0.65439	0.71094	3	0.546427
9.Do you think you can toss a softball under-hand twenty yards with the affected extremity?	2.56935	3.93629	1	0.048532	-0.07374	-0.11296	3	0.999999
10.Do you think you can toss a softball over-hand twenty yards with the affected extremity?	0.64981	1.75104	1	0.187159	0.89663	2.41616	3	0.067415
11.Can you wash the back of your opposite shoulder with the affected extremity?	0.04028	0.04247	1	0.836920	0.14911	0.15719	3	0.924966
12.Would your shoulder allow you to work full-time at your regular job?	0.14799	0.16329	1	0.686547	0.71366	0.78747	3	0.502079
8.Can you carry twenty pounds at your side with the affected extremity? (FEMALE)	0.00000	0.00000	0	0.999999	0.00000	0.00000	0	0.999999
8.Can you carry twenty pounds at your side with the affected extremity? (MALE)	0.00000	0.00000	0	0.999999	0.00000	0.00000	0	0.999999

An item was considered to exhibit DIF if P values are significant after applying bonferroni correction factor. No items exhibited DIF when analysed for the effects of gender differences as a person factor after splitting question 8 for sex.

Figure 1. Person item distribution maps: Person item distribution after combining questions 5 & 6

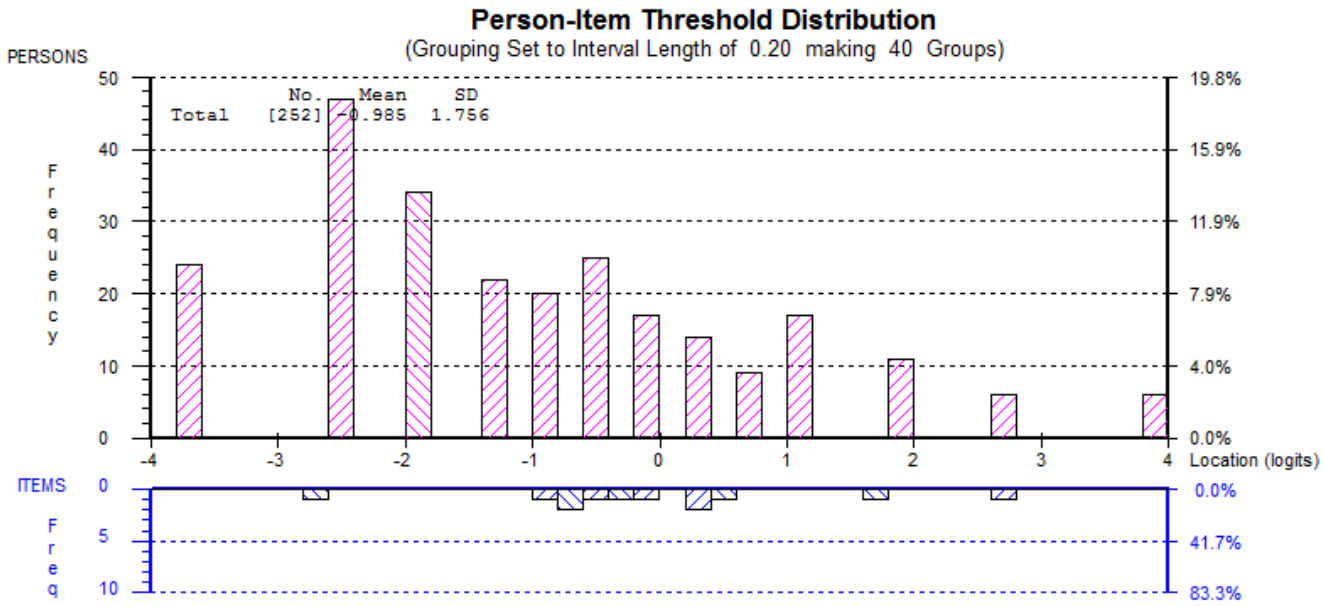


Figure 1: Person item distribution after combining 5 & 6. Scale targeting map illustrating the range and frequency distribution of person (top) and item location parameters (bottom) for the Simple shoulder test after items 5 and 6 were combined to form one item plotted on the same logit scale (x-axis). The y-axis represents the frequency of sample at various person locations (top) and the number of items at various location parameters (bottom). Abbreviation: SD – Standard Deviation

Figure 2. Person item distribution maps: Person item distribution after splitting question 8

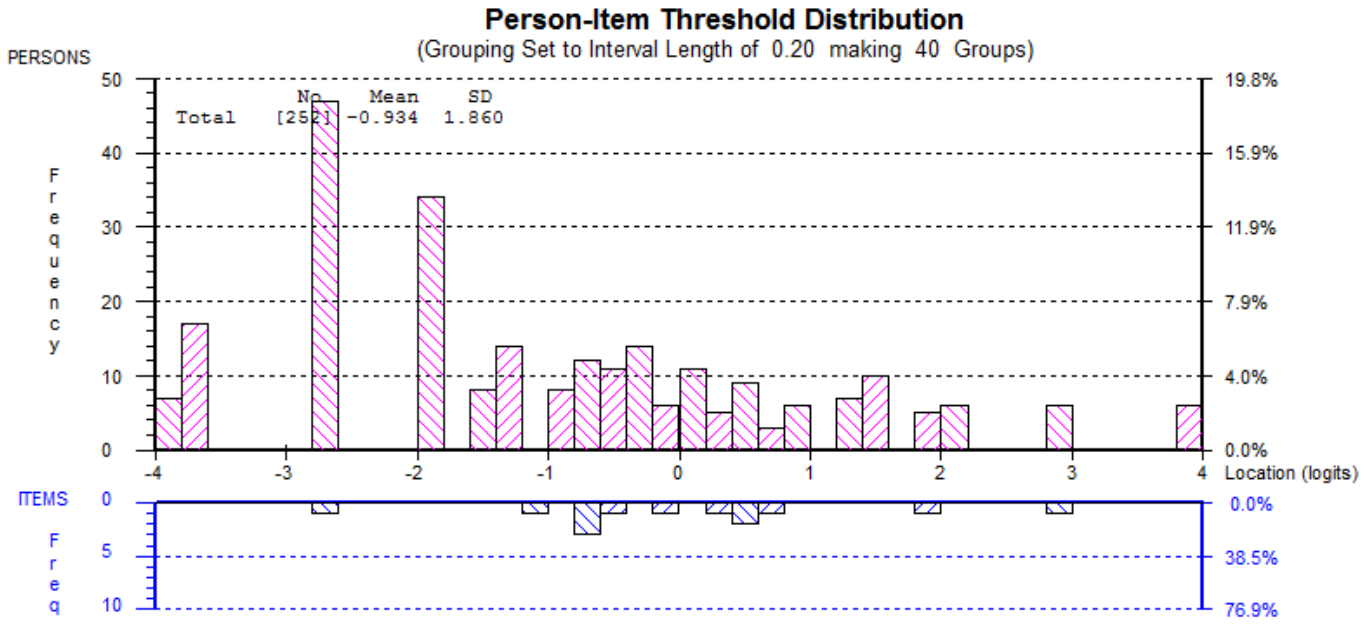


Figure 2: Person item distribution after splitting item 8. Scale targeting map illustrating the range and frequency distribution of person (top) and item location parameters (bottom) for the Simple shoulder test after splitting item 8 for gender plotted on the same logit scale (x-axis). The y-axis represents the frequency of sample at various person locations (top) and the number of items at various location parameters (bottom). Abbreviation: SD – Standard Deviation

CHAPTER 6. SUMMARY

Overview of thesis findings

The focus of this thesis was to study prognosis after rotator cuff repair in terms of pain, function range of motion and muscle performances. With this focus as an objective, we studied the existing literature for reports on prognostic factors, functional range of motion in shoulder and performances of shoulder muscles before and after rotator cuff repair. Based on the available evidence in these domains related to rotator cuff repair, our descriptive process included pooling all available evidence about prognostic factors that would predict pain and disability after rotator cuff repair and performing a meta-analysis to establish a set of factors that would predict outcome after rotator cuff repair, performing a prospective study on the effect of rotator cuff repair on functional range of motion in shoulder and studying the change in movement pattern in the shoulder due to surgery, and conducting a prospective study on the effect of surgery on shoulder muscle performances using an endurance protocol and comparing it to age- and gender-matched controls. We also analysed the clinical measurement properties of one of the commonly used self-reported outcome measures in shoulder – the simple shoulder test (SST) – using Rasch analysis to test its fit to the new model and to examine the stability of its findings across different time points.

Our results of the meta-analysis suggest that fatty degeneration was significant in predicting cuff integrity after rotator cuff repair. A few other pre-operative factors such as tear size, pre-operative muscle strength, multiple tendon involvement in rotator cuff tear, workman's' compensation status and age (on cuff integrity) were found to have a moderate effect on outcomes while no significant association was found between clinically relevant outcomes and factors such as age (on function), trauma and duration of symptoms before surgery. Gender did not have enough evidence to reach arbitrary threshold for inclusion in this meta-analysis.

The second part of the thesis was on the effect of surgery on functional shoulder ROM and movement pattern during activities of daily living. Shoulder function was captured through 2D motion capture system and analysed using Dartfish Prosuite video software. Analysis of patients' abilities to perform functional tasks before and after rotator cuff repair showed that the functional ROM improved during activities before and after surgery with significant change in ROM during activities of 'changing an overhead bulb' and 'washing your back' and a trend toward significant change in the activity of 'washing your hair'. The test-retest reliability for

using 2D video motion capture system was excellent when compared between 2 trials of each activity at pre-op, 3 months and 6 months after surgery.

Results of the third part of the thesis on the effect of surgery on muscle performances in terms of fatigue and endurance during an endurance protocol suggested that performing 60 isotonic repetitions of shoulder abduction and external rotation did not cause fatigue in the shoulder musculature with no decrease in mean isokinetic peak torque and total work done in the muscles when compared before and after the protocol.

The results of the fourth part of the thesis which is the analysis of the Simple Shoulder Test using the Rasch model adds to the body of evidence supporting the SST with robust measurement properties since there was adequate fit to the Rasch model after minor adjustments. The SST appears to be robust when tested against the Rasch model despite some potential areas for improvement. The potential areas that should be explored in future studies are the questions that measure the ability of a person to lift the arm above shoulder level and the potential for gender differences when measuring the ability to carry weights with the affected arm.

Key messages

Study 1. Predictors of pain and disability after rotator cuff repair - A Meta-analysis

Existing knowledge on this subject. Many authors have studied the effect of factors that lead to good or bad outcomes after rotator cuff repair. Authors have attempted to follow a few predictors of choice and have reported their outcomes in terms of pain and function. The choice of predictors depended on the authors with no particular rationale described in the literature as to the choice of the predictor. Limitations existed in the quality of these studies that attempted to describe a predictor after rotator cuff repair. Also, there is no study in the existing literature that has attempted to pool all the predictors that have been described in the literature.

Knowledge added to the existing literature through this thesis. One predictor, pre-operative fatty degeneration of the rotator cuff, was found to have significant effect on cuff integrity after surgery while factors such as tear size, pre-operative muscle strength, multiple tendon involvement in rotator cuff tear, workman's' compensation status and age with its effect on cuff integrity have modest effect on outcomes after rotator cuff repair. The effects of age (on function), trauma and gender were not significant in predicting outcomes, but considering the small number of studies included in the meta-analysis future studies are required to validate this finding.

Study 2. Functional movement analysis of shoulder kinematics before and after rotator cuff repair

Existing knowledge on this subject. The range of motion in the shoulder needed for various activities of daily living depend on the task that is performed. There are many limitations and variations in the benchmarks provided in the literature regarding functional ROM in the shoulder. Studies have reported that rotator cuff repair (RCR) lead to a decrease in ROM of shoulder[1] leading to a decreased ability to perform functional activities after the surgery.[2] Highly reliable information on the range of motion (ROM) required to perform activities of daily living (ADL) is important to allow rehabilitation professionals to make appropriate clinical judgments of patients with limited ROM of the upper extremity joints.[3] There is no study in the available literature that has quantified the change in ROM of the shoulder or change in movement patterns during functional tasks after RCR.

Knowledge added to the existing literature through this thesis. This study provided information on how patients improved after rotator cuff repair in terms of range of motion and movement patterns. Functional ROM of shoulder improved following surgery when compared to pre-surgical levels. Patients tended to use compensatory movements before surgery and 3 months after surgery, but overall we could see an improvement in functional ROM at 6 months after surgery with significant changes in activities of 'changing an overhead bulb' and 'washing your back' and a trend towards significance in the activity of 'washing your hair'. The change in functional ROM was analysed using 2D video motion capture system and analysed using Dartfish analytical software, the reliability of both systems have been validated in the literature and this study adds to the literature with high test-retest reliability of using the 2D video analysis software. Clinicians should consider this change in movement pattern immediately after surgery when deciding on treatment protocols.

Study 3. Shoulder muscle endurance in patients following rotator cuff repair

Existing knowledge on this subject. Major surgeries result in muscle fatigue due to surgical trauma, deterioration in nutritional parameters and, to a small extent, due to psychological factors.[4] The effect of shoulder muscle fatigue on kinematics of glenohumeral and scapulothoracic joints has been reported in the literature with published protocols for healthy subjects and sports personnel. No protocol has been tested on patients with rotator cuff tear to

study changes in muscle performances after rotator cuff repair. To date, there has been no research to study the effect of rotator cuff repair on shoulder muscle fatigue.

Knowledge added to the existing literature through this thesis. The endurance protocol developed by Roy et al[5] was followed to study fatigue in shoulder musculature 6 months after surgery. The original protocol produced significant changes in shoulder muscle performances when measured for isometric muscle strength whereas isokinetic measurements were not significant. This study produced similar results when measured for isokinetic performances whereas isometric strength was not measured in this study. This suggests that isokinetic muscle performances are not significantly affected by continuous muscle activities which can be attributed to various contributing factors as discussed in the study.

Study 4: A Rasch analysis indicates that the simple shoulder test is robust; but its current format does not completely adhere to optimal measurement principles

Existing knowledge on this subject. Simple shoulder test is one of the commonly used self-reported outcome measures and is considered a valid,[6] reliable[6,7] and responsive[8,9] measure based on studies that have demonstrated strong clinical measurement properties using traditional psychometric methods. Rasch analysis, used in construction of measures, allows for a unified approach to several measurement issues, all of which are required for the validity of the transformation of ordinal to interval scaling. No study has yet attempted to study the fit of SST using the Rasch model.

Knowledge added to the existing literature through this thesis. A number of properties were supported in the Rasch model with scope for improvements in the questionnaire in regards to certain items. Local dependency between items on light and heavy objects being lifted overhead fits with their conceptual overlap. Unless corrected some gender bias may exist on the lifting item. These are potential areas to improve the SST that could be explored if these findings are duplicated by others.

Limitations

We have explored one of the commonly studied genres in shoulder surgery and tried to provide specific details regarding various aspects related to rotator cuff repair. Inspite of providing excellent insight into prognosis after rotator cuff repair, we had a few limitations in the studies. We tried to pool and analyse the available evidence in the literature on prognostic factors. But

many studies and hence some of the predictors reported in those studies were not included due to various reasons like the quality of the studies and criteria for inclusion for meta-analysis. Although a set of factors that would predict prognosis after rotator cuff repair was established, the gap in the literature in this aspect is yet to be filled. Due to time constraints we could not do an inter-rater reliability for trials of the functional tasks in our second study. Though test-retest reliability was high in the study, an excellent inter-rater reliability would have added to the credentials of the results obtained in the study. In the third study the isometric muscle performances were not studied before and after the endurance protocol in addition to the isokinetic mean peak torque. Even though patients were compared with age-and gender-matched controls, the muscle performances of the affected shoulder were not compared with that of the unaffected shoulder in the same patient which would have helped us to better understand muscle performances after rotator cuff repair. We recommend future studies that would take these limitations into consideration while studying prognosis after rotator cuff repair. Also, the sample sizes for both these studies were small. Despite these limitations, we have made strong recommendations in terms of prognostic factors, functional ROM and movement patterns, muscle performances in patients undergoing rotator cuff repair and have suggested changes to the existing SST to make it more robust to measure pain and function in shoulder pathologies.

Clinical implications of this thesis

Improved outcomes in terms of pain and disability are the objectives of all rotator cuff repairs. Knowledge on factors that would help in better prognosis after surgery would benefit clinicians in standardizing treatment protocols to better assist patients in the process of recovery. This thesis has attempted to provide clinicians with such a set of predictors through the meta-analysis of prognostic factors. Clinicians can base their therapy programs based on the presence of pre-operative factors that are reported in this thesis.

Similarly, knowledge on functional ROM, movement patterns and muscle performances after rotator cuff repair will help clinicians to know what they can expect from the patients at each stage of recovery. Patients tend to use more flexion and scapular plane movements during early stages after surgery and use more of abduction movements as they recover. Treatment programs can be tailor-made according to each patient's skill, need and ability if clinicians have an idea on the change in these movement patterns in the shoulder and how the shoulder would be behave in terms of ROM and muscle performances. Analysis of the SST using Rasch analysis

would improve confidence in the clinicians who would prefer to use a brief self-reported measure to track progress after rotator cuff repair.

Recommendations for future research

Studies attempting to report prognostic factors should provide rationale for choosing to follow particular predictors. Also, the quality of study is of particular concern in prognostic studies in the existing literature. Hence, future studies should be high quality with complete details on recruitment of subjects, sample size calculations, power of the study, sampling procedures, exposure ascertainment, outcomes studies and details of analysis. These would improve the confidence with which their results can be interpreted.

Studies attempting to follow changes in functional ROM before and after rotator cuff repair should study how patients perform activities of daily living in their own environment and report the compensatory movements or change in movement patterns employed by patients as they would tend to develop different patterns of movements to overcome their limitation at home than in a clinical setting. Also, studies should attempt to create a checklist for objective measures to track compensatory movements during functional activities. Future studies should also use video motion-capture systems when tracking changes to functional ROM as this has been proved to be valid and reliable in shoulder conditions.[10-12]

Future studies should recruit 2 groups of patients with the same shoulder pathology to study isometric and isokinetic performances and results need to be compared with a control group. Also, the unaffected shoulder should also be studied for muscle performances and comparison made between both shoulders in the same subject. It is also recommended that future studies develop a fatigue protocol that will significantly affect the isokinetic performances of the shoulder musculature in clinical settings.

Studies should attempt to analyse the fit of SST in other shoulder pathologies, should also study the effect of various person factors such as occupational demands, severity of injury, level of education, Workman's Compensation Insurance Board (WCIB) claims and other social factors on the fit of items in SST to the Rasch model.

REFERENCES:

1. Warner, J. J., & Greis, P. E. (1998). The treatment of stiffness of the shoulder after repair of the rotator cuff. *Instructional Course Lectures, 47*, 67-75.

2. Ellman, H., Hanker, G., & Bayer, M. (1986). Repair of the rotator cuff. end-result study of factors influencing reconstruction. *The Journal of Bone and Joint Surgery.American Volume, 68*(8), 1136-1144.
3. Aizawa, J., Masuda, T., Koyama, T., Nakamaru, K., Isozaki, K., Okawa, A., & Morita, S. (2010). Three-dimensional motion of the upper extremity joints during various activities of daily living. *Journal of Biomechanics,43*(15), 2915-2922. doi: 10.1016/j.jbiomech.2010.07.006; 10.1016/j.jbiomech.2010.07.006
4. Christensen, T., & Kehlet, H. (1993). Postoperative fatigue. *World Journal of Surgery, 17*(2), 220-225.
5. Roy, J. S., Ma, B., Macdermid, J. C., & Woodhouse, L. J. (2011). Shoulder muscle endurance: The development of a standardized and reliable protocol. *Sports Medicine, Arthroscopy, Rehabilitation, Therapy & Technology : SMARTT, 3*(1), 1. doi: 10.1186/1758-2555-3-1; 10.1186/1758-2555-3-1
6. Godfrey, J., Hamman, R., Lowenstein, S., Briggs, K., & Kocher, M. (2007). Reliability, validity, and responsiveness of the simple shoulder test: Psychometric properties by age and injury type. *Journal of Shoulder and Elbow Surgery / American Shoulder and Elbow Surgeons ...[Et Al.], 16*(3), 260-267. doi: 10.1016/j.jse.2006.07.003
7. Beaton, D., & Richards, R. R. (1998). Assessing the reliability and responsiveness of 5 shoulder questionnaires. *Journal of Shoulder and Elbow Surgery / American Shoulder and Elbow Surgeons ...[Et Al.], 7*(6), 565-572.
8. Roy, J. S., Macdermid, J. C., Faber, K. J., Drosdowech, D. S., & Athwal, G. S. (2010). The simple shoulder test is responsive in assessing change following shoulder arthroplasty. *The Journal of Orthopaedic and Sports Physical Therapy, 40*(7), 413-421. doi: 10.2519/jospt.2010.3209
9. MacDermid, J. C., Drosdowech, D., & Faber, K. (2006). Responsiveness of self-report scales in patients recovering from rotator cuff surgery. *Journal of Shoulder and Elbow Surgery / American Shoulder and Elbow Surgeons ...[Et Al.], 15*(4), 407-414. doi: 10.1016/j.jse.2005.09.005
10. Norris, B. S., & Olson, S. L. (2011). Concurrent validity and reliability of two-dimensional video analysis of hip and knee joint motion during mechanical lifting. *Physiotherapy Theory and Practice, 27*(7), 521-530. doi: 10.3109/09593985.2010.533745; 10.3109/09593985.2010.533745

11. Miller, A., & Callister, R. (2009). Reliable lower limb musculoskeletal profiling using easily operated, portable equipment. *Physical Therapy in Sport : Official Journal of the Association of Chartered Physiotherapists in Sports Medicine, 10*(1), 30-37. doi: 10.1016/j.ptsp.2008.10.003; 10.1016/j.ptsp.2008.10.003
12. Melton, C., Mullineaux, D. R., Mattacola, C. G., Mair, S. D., & Uhl, T. L. (2011). Reliability of video motion-analysis systems to measure amplitude and velocity of shoulder elevation. *Journal of Sport Rehabilitation, 20*(4), 393-405.

APPENDICES

APPENDIX 1. Ethics approval forms

Research Western

Use of Human Participants - Ethics Approval Notice

Principal Investigator: Dr. Joy MacDermid
Review Number: 18337E
Review Level: Delegated
Approved Local Adult Participants: 60
Approved Local Minor Participants: 0
Protocol Title: Functional movement before and after rotator cuff repair and muscle fatigue in patients with rotator cuff pathology.
Department & Institution: Surgery, University of Western Ontario
Sponsor:
Ethics Approval Date: October 27, 2011 **Expiry Date:** August 31, 2012
Documents Reviewed & Approved & Documents Received for Information:

Document Name	Comments	Version Date
UWO Protocol		
Letter of Information & Consent	Rotator Cuff Patient - Repair	2011/10/18
Letter of Information & Consent	Rotator Cuff Patient - No Repair	2011/10/18
Letter of Information & Consent	Control	2011/10/18

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

[redacted]

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

The University *of* Western Ontario
Office of Research Ethics
Support Services Building Room 5150 • London, Ontario • CANADA - N6G 1G9
PH: 519-661-3036 • F: 519-850-2466 • ethics@uwo.ca • www.uwo.ca/research/ethics

Research Western

Use of Human Participants - Ethics Approval Notice

Principal Investigator: Dr. Joy MacDermid
File Number:101473
Review Level: Delegated
Approved Local Adult Participants:60
Approved Local Minor Participants:0
Protocol Title: Functional movement before and after rotator cuff repair and muscle fatigue in patients with rotator cuff pathology.
Department & Institution: Schulich School of Medicine and Dentistry\Surgery,Western University
Sponsor:
Ethics Approval Date: May 10, 2012 **Expiry Date:**August 31, 2012
Documents Reviewed & Approved & Documents Received for Information:

Document Name	Comments	Version Date
Revised Western University Protocol	The muscle strength testing has been changed from 6 weeks post surgery to 6 months post surgery.	
Letter of Information	Revised	2012/04/05
Other	Instrument - DASH	
Other	SF-12 Health Survey Scoring Demonstration	
Other	Rotator Cuff Index	

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.

[redacted]

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

The University *of* Western Ontario
Office of Research Ethics
Support Services Building Room 5150 • London, Ontario • CANADA - N6G 1G9
PH: 519-661-3036 • F: 519-850-2466 • ethics@uwo.ca • www.uwo.ca/research/ethics

LAWSON HEALTH RESEARCH INSTITUTE
FINAL APPROVAL NOTICE

RESEARCH OFFICE REVIEW NO.: R-11-552
PROJECT TITLE: Functional movement before and after rotator cuff repair and muscle fatigue in patients with rotator cuff pathology.
PRINCIPAL INVESTIGATOR: Dr. Joy MacDermid

DATE OF REVIEW BY CRIC: November 4, 2011

Health Sciences REB#: 18337e

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

c: Administration

APPENDIX 2

CRITICAL APPRAISAL TOOL: PROGNOSIS STUDY

(CHAPTER 2: Predictors of outcomes after rotator cuff repair – A Meta-analysis)

Evaluation Criteria	Score		
Study question	2	1	0
1. Was the relevant background work cited to establish a foundation for the research question?			
Subjects / Sampling			
2. Were sample characteristics clearly stated?			
3. Were inclusion/exclusion criteria adequately defined?			
4. Was an adequate study sample size enrolled?			
5. Was the source population clearly described?			
6. Did sampling procedures minimize sample/selection biases?			
7. Were the characteristics of the refusers / acceptors stated; and investigated statistically?			
8. Was appropriate retention/follow-up of subjects obtained?			
9. Is there evidence that lost-to-follow-up was adequately addressed and did not bias results?			
Exposure ascertainment			
10. Was an appropriate scope and distribution of the predictor(s) present in the sample?			
11. Was the evaluator / process used to measure exposure independent from treatment (if indicated)?			
12. Was the exposure (potential predictors) captured using valid and reliable instruments?			
13. If the patients received intervention during the study, was it standardized; or alternatively were intervention variations controlled for statistically?			
Outcome determination			
14. Was the outcome ascertainment independent from measurement of potential predictors and treatment?			
15. Was a valid and reliable primary outcome defined?			
16. Were appropriate secondary outcomes considered?			
17. Was an appropriate follow-up period incorporated?			
Analysis			
18. Was an appropriate statistical test performed to detect the significance of the effect of each potential prognostic variable?			

19. Were appropriate analyses used to estimate the error around the risk estimates?			
20. Was it established that the study had significant power to identify predictors?			
21. Were secondary analysis conducted to inform the understanding of the relative/absolute risk?			
22. Were the central tendency/variability of the predictive factors clearly presented?			
23. Was the distribution of the outcomes clearly presented?			
Interpretation			
24. Were clinical and practical significance considered in interpreting results?			
25. Were the conclusions/clinical recommendations supported by study objectives, analysis and results?			
Total Quality Score (Sum of above) =			

Evaluation Guidelines for Rating the Quality of an Intervention Study

This guide helps you interpret the correct score for each critical appraisal item on your checklist. To decide which score to choose read the following descriptors for each item. Pick the descriptor that sounds most like what was reported in the study. In general, a "2" refers to adherence to the preferred methodological standard, "1" represents partial compliance and a "0" infers that the quality item was either not adhered to, or not reported. We advise all raters to perform at least one Calibration review together to clarify how the items would be interpreted for specific area. Following adequate calibration, a minimum of two independent raters complete independent appraisals. A consensus process is used to arbitrate any differences between these dependent ratings.

Question		**Descriptors**
#	Score	
		Research Question
1	2	The authors: -performed a thorough literature review indicating what is currently known about the exposure (potential predictors) and the outcome (s)(of interest; -presented a critical, but unbiased, view of the current state of knowledge; -indicated how the current research question evolves from the current knowledge base; -established a clear research question(s) based on the above.
	1	All of these above were not fulfilled, but a clear rationale for studying for the prognostic research question was provided
	0	An adequate rationale for the current research question was not developed.
		Subjects / Sampling
2	2	Includes: key demographics (e.g. age, gender),an indicator of the subtype or severity of the condition; and distribution of potential prognostic variables

	1	More than two of the key descriptors above are present; but characterization of sample is inadequate
	0	< 2 or less of the above descriptors are Provided
3	2	Specific inclusion and exclusion criteria for the study were defined.
	1	Some information on the type of patients included and excluded in the study was defined, but specific inclusion and exclusion criteria were not provided.
	0	No information on inclusion and exclusion criteria and limited patient's descriptors are provided.
4	2	Authors performed a sample size calculation and obtained sufficient numbers of patients to fully power each of the predictors evaluated after correcting for multiple statistical evaluations. Samples over 300 are assumed to be sufficiently powered except for rare exposures/outcomes.
	1	The authors performed a sample size calculation and were sufficiently powered for some of the predictors evaluated. Samples of 100-300 subjects can be scored as 1; except for rare exposures/outcomes or where the sample is clearly underpowered)
	0	The size of the sample is less than 100 and not rationalized; or is underpowered.
5	2	The source population was described in terms of place of recruitment (geographical), time-period of recruitment and source population (i.e. ER, primary care).
	1	Any 2 of the features of the source population are given.
	0	< 2 features of the source population are given.
6	2	The authors documented a specific recruitment strategy that was clearly an inception cohort that recruited a defined specific target population using sampling procedures was applied equally across exposure subgroups.
	1	The study is a cohort that appears representative of the population of clinical interest; but adequate information on sampling procedures, inception criterion or description of the reference population is not provided.
	0	Sampling biases are evident; systematic differences occurred between the exposures groups; and/or selection procedures used make it impossible to determine what types of patients were included.
7	2	1. Characteristics of the refusers were stated in terms of age, gender and initial severity, AND 2. Refusers were shown be similar to acceptors statistically (i.e. did not differ significantly).
	1	1. Characteristics of refusers were stated only without investigation of statistical differences, OR 2. Characteristics of refusers were shown to be statistically different than acceptors OR 3. Characteristics of refusers were stated in term of only 2 of age, gender or initial severity.
	0	None of the above occurred.
8	2	90% or more of the patients enrolled or eligible for study were evaluated for outcomes.
	1	70% to 90% of the patients eligible for study or enrolled were evaluated for outcomes.
	0	Less than 70 percent of patients eligible for study or enrolled were evaluated.
9	2	Characteristics of drop-outs are reported; AND the reasons for lost to follow up/drop-outs are unrelated to the outcome of recovery (complaints and disabilities).

	1	Characteristics of those lost-to-follow-ups are reported and appear similar; but differences between completers and drop-outs are not investigated statistically. OR Characteristics of those lost-to-follow-ups are shown to be significantly different than completers and this is considered in the analysis (e.g. sensitivity analysis)
	0	Dropouts are not addressed; OR a difference in the completers was not considered in the analysis
		Exposure ascertainment
10	2	Subjects included a broad spectrum of the predictor variables (i.e. meaningful numbers of patients in all discrete categories or across the range of continuous responses)
	1	Either the range of exposures or the distribution of subjects across the range was limited
	0	Both the range and distribution of subjects across the range was limited
11	2	Exposure ascertainment was defined prior to inception of the cohort using a process or evaluator that was independent from treatment.
	1	Exposure was determined by a process independent from outcome ascertainment (either a factor that could be non-influenced by reporting e.g. age) or prospective data collected for another purpose (retrospective cohort design) but not predetermined specifically for the current study. OR Exposures were self-reported; but administered by treatment provider prior to treatment.
	0	Exposure was determined after study inception with opportunity for recall bias/ ascertainment error.
12	2	All exposure variables were determined using a process or tools that have demonstrated validity and reliability- including minimizing recall bias. For physical measures this may include inter-rater reliability for self-report measures test-retest reliability).
	1	At least one, but less than all, of the MAIN predictive factors (in a multi-factor study) is captured using a tool with stated evidence for validity and reliability.
	0	Reliability /validity information is not provided; and exposures were determined with unvalidated tools.
13	2	One of the following conditions is met: 1. Treatment is provided according to a standardized algorithm or treatment plan that includes a description of being the type/range of treatments provided their progression, if indicated. 2. No treatment is provided (natural history) or 3. Treatment is not standardized but data is measured and included as a covariate in the analysis
	1	Subjects received different treatments subsequent to inclusion in the cohort, and the treatments type and distribution are described; BUT the treatment effect has not been explored statistically (either as a co-variate or stratification variable).
	0	Treatment is not described or controlled for; OR unclear whether treatment was provided.
		Outcome determination
14	2	The outcome was measured by a process independent from collection of both the prognostic variables and treatment. It is explicitly stated that investigators capturing outcome were blinded to the presence/intensity of predictive factors (other than those not possible e.g. age and gender).
	1	Outcome was captured using self-report measures, or other measures where response bias would be minimal (e.g. death / imaging), but explicit blinding / independence issues not addressed. OR outcome was independent of treatment; but not assessment of prognostic variables

	0	No evidence that outcomes were measured in a manner that was blinded to either prognostic variables or treatment.
15	2	A primary outcome measure which represented an important clinical outcome was selected and supported by evidence of appropriate psychometric properties (reliability, validity, responsiveness).
	1	A relevant primary outcome measure was evident, but was insufficient in either its clinical relevance (questionable surrogate or conceptually limited) or its psychometric properties.
	0	A primary outcome was not evident or was inappropriate, because it was irrelevant or methodologically unsupported.
16	2	Appropriate secondary outcome measures were identified that augmented the perspective provided by the primary outcome measure, ensuring a comprehensive view of outcomes was obtained; and these secondary outcome measures had sound psychometric properties.
	1	Secondary outcomes were considered, but were not identified as being secondary or were deficient either in terms of their relevance or methodological properties OR there was a single outcome of interest and this limitation was justified.
	0	Appropriate secondary outcomes were not considered.
17	2	Patients were followed for sufficient time to ensure the outcomes of interest had developed. A rationale and/or discussion of the appropriateness of the follow-up periods were included.
	1	At least one relevant follow-up evaluation was incorporated, but the study did include other important clinical time points or the rationale for the specific follow-up time was not specified.
	0	The follow-up period was insufficient to establish the true outcome of the intervention.
		Analysis
18	2	A statistical indicator of risk was calculated to determine whether exposures were statistically related to the outcome of interest. The indicator selected was appropriate to the type of data collected and the stated research objectives (e.g. RR or odds ratio for proportions of cohort or case control respectively; b-coefficients for continuous). The authors documented important elements on the statistical tests (software used, whether statistical assumptions underlying tests were met, and Alpha levels).
	1	The statistical indicator used was potentially appropriate; but there was insufficient documentation of data properties, whether statistical assumptions met, or methods of calculation to be confident of its adequacy.
	0	Statistical tests were not performed or those selected were not appropriate to the research question or data collected.
19	2	Statistical analysis included used appropriate technique to estimate the error around the individual risk indicator (e.g. confidence intervals). The authors documented important elements on how these error estimates were calculated.
	1	Confidence intervals or other error estimates were provided; but were incomplete or methods unspecified.

	0	Error estimates were not calculated around the primary risk estimate
20	2	Power was established: A justified sample with statistically significant findings on all investigative predictors OR, a post-hoc power that identified that the study was appropriately powered.
	1	The sample size appeared adequate (no insignificant predictors; or sample >300); but power was not specifically addressed
	0	Power was not addressed in the presence of insignificant predictors and a sample size less than 300.
21	2	Supplemental statistical tests were used to examine the size or impact of the exposure using an alternative statistical method that would account for potential deficiencies in the primary statistical indicator (e.g. attributable risk or number needed to treat added to a risk ratio; a receiver operator curve to examine different risk thresholds etc). The rationale, statistical assumptions and methods of calculation for the supplemental tests are adequately described.
	1	Supplemental risk estimates were calculated; but inadequately described or justified.
	0	No supplemental risk estimates were performed.
22	2	The central tendency and variability for all important predictive factors were presented clearly. At a minimum, "important" predictive factors should include all factors identified as being significant in univariate or multivariate analyses. Means with estimates of variability (range, median, SD or CI) for continuous variables, and frequencies for dichotomous variables are required.
	1	The central tendency and variability for most, but not all, important predictive factors were presented clearly.
	0	The central tendency and variability of predictors were not presented clearly. i.e. not all predictors in a final regression model or list were described in terms of central tendency/variability.
23	2	The summary distribution of the main outcomes (as indicated in the purpose or hypothesis section) was presented clearly. This includes the number of patients who fell into categories of recovered/non-recovered (if categorical outcome), or the central tendency/variability for continuous outcomes.
	1	The results for most, but not all, important outcomes were presented clearly.
	0	The results of the outcomes were either not reported, or not reported clearly, in such a way as to allow pooling of results with other papers (for example, frequencies or percentages of patients recovered/non-recovered are not presented).
		Interpretation
24	2	The authors fully addressed clinical significance by relating the observed risk/protection to established (referenced) benchmarks; and considered the meaning of more than one statistical indicator of risk (e.g. relative risk and attributable risk or number needed to screen) to provide a clear indication of the overall impact of the risk/protective factor
	1	Clinical and practical significance were addressed in the discussion of the study results, but in a limited way (only conceptually or on the basis of one statistical indicator)

	0	Clinical and practical significance were not considered when interpreting the results.
25	2	Specific conclusions that identify specific predictors and the nature (size and direction) of their impact on outcomes are specified. All studied predictors are addressed. Recommendations neither 1. Ignored observed results 2. Overstated their generalizability / clinical application or 3. Stated that exposures were important where this had not been statistically established
	1	Conclusions and clinical recommendations were non-specific or incomplete, or generalize beyond the domain of the study or the results actually obtained.
	0	Conclusions and or clinical recommendations were not founded on the results of the study or contradict findings of the study.

APPENDIX 3

STATISTICAL CONVERSION PROCEDURES FOR DETERMINING EFFECT SIZE[1]

(CHAPTER 2: Predictors of outcomes after rotator cuff repair – A Meta-analysis)

Effect size is defined as a quantitative reflection of the magnitude of some phenomenon that is used for the purpose of addressing a question of interest.[2] Effect size measures play an important role in meta-analysis studies that summarize findings from a specific area of research, and in statistical power analyses. The reporting of effect sizes facilitates the interpretation of the substantive, as opposed to the statistical, significance of a research result.[3] Effect size gives clinicians an estimate of the actual amount of risk modulation expected, given the presence or absence of the different risk factors.[3]

The pooled effect size was calculated for the various predictors in one of the following ways:

When results for categorical risk variables were presented as frequencies of occurrence/non-occurrence,[4-13] a 2-by-2 table is constructed, in which the rows represent the subject's status on the predictor (positive/negative), and the columns represent the status on the outcome (recovered / not recovered). The table provides a graphic representation, with boxes labeled A, B, C and D, representing the number of subjects that fall into each category. To calculate the odds ratio, the formula (A/B) ÷ (C/D) is used.

		Status on outcome measure	
		Recovered	Not recovered
Status on Predictor	Positive	A	B
	Negative	C	D

In studies where computed odds ratios were presented with 95% confidence limits,[14,15] these data were entered directly into the database.

In studies where effect sizes were given as correlation coefficients,[16,17] data were entered directly into the database.

References

1. Walton, D. M., Pretty, J., MacDermid, J. C., & Teasell, R. W. (2009). Risk factors for persistent problems following whiplash injury: Results of a systematic review and meta-analysis. *The Journal of Orthopaedic and Sports Physical Therapy, 39*(5), 334-350. doi: 10.2519/jospt.2009.2765
2. Kelley, K., & Preacher, K. J. (2012). On effect size. *Psychological Methods, 17*(2), 137-152. doi: 10.1037/a0028086.

3. Ellis, Paul D. (2010). *The Essential Guide to Effect Sizes: An Introduction to Statistical Power, Meta-Analysis and the Interpretation of Research Results*. United Kingdom: Cambridge University Press.
4. Kim, K. C., Shin, H. D., & Lee, W. Y. (2012). Repair integrity and functional outcomes after arthroscopic suture-bridge rotator cuff repair. *The Journal of Bone and Joint Surgery.American Volume, 94*(8), e48. doi: 10.2106/JBJS.K.00158; 10.2106/JBJS.K.00158
5. Tashjian, R. Z., Hollins, A. M., Kim, H. M., Teefey, S. A., Middleton, W. D., Steger-May, K., . . . Yamaguchi, K. (2010). Factors affecting healing rates after arthroscopic double-row rotator cuff repair. *The American Journal of Sports Medicine, 38*(12), 2435-2442. doi: 10.1177/0363546510382835; 10.1177/0363546510382835
6. Cho, N. S., & Rhee, Y. G. (2009). The factors affecting the clinical outcome and integrity of arthroscopically repaired rotator cuff tears of the shoulder. *Clinics in Orthopedic Surgery, 1*(2), 96-104. doi: 10.4055/cios.2009.1.2.96
7. Gladstone, J. N., Bishop, J. Y., Lo, I. K., & Flatow, E. L. (2007). Fatty infiltration and atrophy of the rotator cuff do not improve after rotator cuff repair and correlate with poor functional outcome. *The American Journal of Sports Medicine, 35*(5), 719-728. doi: 10.1177/0363546506297539
8. Ozbaydar, M. U., Tonbul, M., Tekin, A. C., & Yalaman, O. (2007). Arthroscopic rotator cuff repair: Evaluation of outcomes and analysis of prognostic factors. [Artroskopik rotator manset onarimi: Sonuclar ve belirleyici faktorlerin analizi] *Acta Orthopaedica Et Traumatologica Turcica, 41*(3), 169-174.
9. Klepps, S., Bishop, J., Lin, J., Cahlon, O., Strauss, A., Hayes, P., & Flatow, E. L. (2004). Prospective evaluation of the effect of rotator cuff integrity on the outcome of open rotator cuff repairs. *American Journal of Sports Medicine, 32*(7), 1716-1722.
10. Goutallier, D., Postel, J. M., Gleyze, P., Leguilloux, P., & Van Driessche, S. (2003). Influence of cuff muscle fatty degeneration on anatomic and functional outcomes after simple suture of full-thickness tears. *Journal of Shoulder and Elbow Surgery / American Shoulder and Elbow Surgeons ...[Et Al.], 12*(6), 550-554. doi: 10.1016/S1058274603002118
11. Shinners, T. J., Noordsij, P. G., & Orwin, J. F. (2002). Arthroscopically assisted mini-open rotator cuff repair. *Arthroscopy : The Journal of Arthroscopic & Related*

Surgery : Official Publication of the Arthroscopy Association of North America and the International Arthroscopy Association, 18(1), 21-26.

12. Pai, V. S., & Lawson, D. A. (2001). Rotator cuff repair in a district hospital setting: Outcomes and analysis of prognostic factors. *Journal of Shoulder and Elbow Surgery / American Shoulder and Elbow Surgeons ...[Et Al.], 10*(3), 236-241. doi: 10.1067/mse.2001.113963
13. Misamore, G. W., Ziegler, D. W., & Rushton, J. L.,2nd. (1995). Repair of the rotator cuff. A comparison of results in two populations of patients. *The Journal of Bone and Joint Surgery.American Volume, 77*(9), 1335-1339.
14. Gulotta, L. V., Nho, S. J., Dodson, C. C., Adler, R. S., Altchek, D. W., MacGillivray, J. D., & HSS Arthroscopic Rotator Cuff Registry. (2011). Prospective evaluation of arthroscopic rotator cuff repairs at 5 years: Part II--prognostic factors for clinical and radiographic outcomes. *Journal of Shoulder and Elbow Surgery / American Shoulder and Elbow Surgeons ...[Et Al.], 20*(6), 941-946. doi: 10.1016/j.jse.2011.03.028; 10.1016/j.jse.2011.03.028
15. Nho, S. J., Brown, B. S., Lyman, S., Adler, R. S., Altchek, D. W., & MacGillivray, J. D. (2009). Prospective analysis of arthroscopic rotator cuff repair: Prognostic factors affecting clinical and ultrasound outcome. *Journal of Shoulder and Elbow Surgery / American Shoulder and Elbow Surgeons ...[Et Al.], 18*(1), 13-20. doi: 10.1016/j.jse.2008.05.045
16. Oh, J. H., Kim, S. H., Kim, K. H., Oh, C. H., & Gong, H. S. (2010). Modified impingement test can predict the level of pain reduction after rotator cuff repair. *The American Journal of Sports Medicine, 38*(7), 1383-1388. doi: 10.1177/0363546509359071; 10.1177/0363546509359071
17. Oh, J. H., Kim, S. H., Ji, H. M., Jo, K. H., Bin, S. W., & Gong, H. S. (2009). Prognostic factors affecting anatomic outcome of rotator cuff repair and correlation with functional outcome. *Arthroscopy : The Journal of Arthroscopic & Related Surgery : Official Publication of the Arthroscopy Association of North America and the International Arthroscopy Association, 25*(1), 30-39. doi: 10.1016/j.arthro.2008.08.010; 10.1016/j.arthro.2008.08.010

APPENDIX 4

LETTER OF INFORMATION – EXPERIMENTAL GROUP

Dr. Joy C. MacDermid,
Principal Investigator
Jayaprakash Raman, PhD Student
Health and Rehabilitation Sciences,
Faculty of Health Sciences,
University of Western Ontario, London,
Canada

PARTICIPANT INFORMATION SHEET

Title of Project: Functional movement before and after rotator cuff repair and muscle fatigue in patients with rotator cuff pathology.

Principal Investigator: Dr. Joy MacDermid, PhD, MSc, BScPT, BSc, Professor, Health and Rehabilitation Sciences, Faculty of Health Sciences, University of Western Ontario, London, Ontario, Canada.

Co-Investigator: Jayaprakash Raman, MPT, PhD Student, Health and Rehabilitation Sciences, Faculty of Health Sciences, University of Western Ontario, London, Ontario, Canada.

Co-Investigator: Dr. David Walton, PhD, FCAMT, Assistant Professor of Physiotherapy, Faculty of Health Sciences, University of Western Ontario, London, Ontario, Canada.

Co-Investigator: Dr. George Athwal, M.D., FRCSC, Assistant Professor of Surgery, Faculty of Health Sciences, University of Western Ontario, London, Ontario, Canada.

You are invited to participate in a research study conducted by Jayaprakash Raman involving assessing and reporting shoulder movements and muscle performance and the extent to which they are affected by rotator cuff pathology. This study involves two parts. You are included in the study since you are undergoing surgery for your rotator cuff tear. For the first part of the study, you will be assessed for your shoulder movements during functional activities prior to, 3 months and 6 months after surgery using a video analysis software called Dartfish. For the second part of the study, six months after surgery you will be made to work on a machine called Biodex to improve your shoulder muscle performance and your muscle activity will be recorded.

In order to decide whether or not you want to be a part of this research study, you should understand what is involved and the potential risks and benefits. This form gives you detailed information about the research study, which will be discussed with you. Once you understand the study, you will be asked to sign this 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.

Background and Need for the study:

Rotator cuff tears are the most common condition affecting the shoulder. There has been limited research on the effects of surgery on shoulder movements during functional activities. Dartfish is a new video analysis software which is used in sports coaching to study shoulder movements. This study uses this software to analyze the effects of rotator cuff repair on the shoulder movements during functional activities.

Also, in about one-third of patients undergoing uncomplicated major surgery for rotator cuff tears, a pronounced increase in fatigue extends throughout the first month. A postoperative decrease in muscle force and endurance is related to postoperative fatigue. There has been no study to analyze the effect of rotator cuff repair on fatigue of the shoulder muscles. The second aim of this research is to study the effect of rotator cuff repair on muscle performances and compare it with that of patients with rotator cuff pathology who do not undergo surgery and age matched controls.

What is the purpose of the study?

- To perform a quantitative analysis of shoulder kinematics during functional tasks before and after rotator cuff repair using Dartfish.
- To analyse muscle endurance using Biodex system in patients with rotator cuff tear, patients with rotator cuff pathology but not torn, and compare that to age matched controls.

How many people will be in this study?

The total number of participants will be 60. They will be split into 3 groups:

Group 1: Subjects who undergo rotator cuff repair

Group 2: Subjects with rotator cuff pathology who do not undergo surgery

Group 3: Control group with age matched controls with no rotator cuff pathology.

Inclusion criteria:

1. Patients with rotator cuff pathology (one shoulder only involved) who undergo rotator cuff repair.

2. Patients with rotator cuff pathology (one shoulder only involved) who do not undergo surgery.

3. Subjects of both sexes.
4. Age between 18 and above.
5. Should be able to understand and communicate in English.

Exclusion criteria:

1. Patients with shoulder pain due to pathology other than rotator cuff involvement.
2. Any other associated shoulder dysfunction.
3. Cancer or neurological or cardiovascular disease.
4. Patients who are unable to follow instructions.

What am I expected to do?

For the ADL tasks using Dartfish, you will have to perform simple tasks like picking up a glass of water to drink with the reflective markers attached to the skin on the upper limb and torso. When the tasks are being performed the video cameras placed in the plane of movement for Dartfish analysis will be recording the activities. The minimum and maximum joint angles and arc of motion produced during performance of each task will be collected from both the measurement systems for further analysis. This data will be used to obtain reference functional ROM using Dartfish motion analysis software.

For measuring muscle performance, you will be expected to perform 60 contractions of a specific shoulder movement on the Biodex. The resulting muscle activity will be recorded and analyzed by the software incorporated in the machine.

Will I be paid to participate in this study?

No.

Will there be any costs?

No.

Are there any risks associated with the 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 a video analysis software (Dartfish) and the Biodex. 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.

How will my personal information be protected?

The investigators of the study will assign a 'code' that will act as a unique identifier to you. The physical data sheets and electronic data will **not** be labeled with your name.

Location of the study:

You will be assessed at the Hand and Upper Limb Center, St. Joseph's Hospital, London, ON.

How long I will have to spend?

You will be required to come to HULC twice and each visit will take 30 minutes.

Participation in concurrent or future studies:

If you are participating in another study at this time, please inform the study doctor or nurse right away to determine if it is appropriate for you to participate in this study.

Publication of results:

If the results of the study are published, your name will not be used. If you are interested, you may provide an e-mail address where we can e-mail the final study results when they are available. The final results will summarize the outcomes of the study and how the results will benefit health care providers. Your individual results will not be provided.

Voluntary Participation:

Your participation in the study is completely voluntary and you may choose to stop participating or withdraw your consent at any time during the period of the study. Your decision of not participating in the study will not influence the treatment you may be receiving either now, or in the future at St. Joseph's Hospital, London, ON.

Withdrawal from the Study:

You can stop participating in the study at any time, for any reason, if you decide to do so. Your decision to stop participating, or to refusal to answer particular questions, will not affect your relationship with the researchers, rehabilitation centre, or any other group associated with this project.

Confidentiality:

All information you provide during the research will be held in confidence and your name will not appear in any report or publication of the research. Your data will be safely stored in a locked

facility and only research staff will have access to this information. Once your data is entered into a database and analyses are completed; original records containing your personal identifiers will be destroyed. Your data in the database will be associated with a code number, not your personal identifying information. Confidentiality will be ensured to the fullest extent possible. 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.

APPENDIX 5

LETTER OF INFORMATION – CONTROL GROUP

Dr. Joy C. MacDermid,
Principal Investigator
Jayaprakash Raman, PhD Student
Health and Rehabilitation Sciences,
Faculty of Health Sciences,
University of Western Ontario, London,
Canada

PARTICIPANT INFORMATION SHEET

Title of Project: Functional movement before and after rotator cuff repair and muscle fatigue in patients with rotator cuff pathology.

Principal Investigator: Dr. Joy MacDermid, PhD, MSc, BScPT, BSc, Professor, Health and Rehabilitation Sciences, Faculty of Health Sciences, University of Western Ontario, London, Ontario, Canada.

Co-Investigator: Jayaprakash Raman, MPT, PhD Student, Health and Rehabilitation Sciences, Faculty of Health Sciences, University of Western Ontario, London, Ontario, Canada.

Co-Investigator: Dr. David Walton, PhD, FCAMT, Assistant Professor of Physiotherapy, Faculty of Health Sciences, University of Western Ontario, London, Ontario, Canada.

Co-Investigator: Dr. George Athwal, M.D., FRCSC, Assistant Professor of Surgery, Faculty of Health Sciences, University of Western Ontario, London, Ontario, Canada.

You are invited to be in a research study conducted by Jayaprakash Raman involving assessing and reporting your shoulder movements and muscle performance and the extent to which they are affected by rotator cuff pathology. You are included in the study as part of the control group as you have no shoulder pathology and have normal shoulder movements. You will be made to work on a machine called Biodex to measure your shoulder muscle performance and your muscle activity will be recorded.

In order to decide whether or not you want to be a part of this research study, you should understand what is involved and the potential risks and benefits. This form gives you detailed information about the research study, which will be discussed with you. Once you understand the study, you will be asked to sign this 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.

Background and Need for the study:

Rotator cuff tears are the most common condition affecting the shoulder. There has been limited research on the effects of surgery on shoulder movements during functional activities. Dartfish is a new video analysis software which is used in sports coaching to study shoulder movements. This study uses this software to analyze the effects of rotator cuff repair on the shoulder movements during functional activities.

Also, in about one-third of patients undergoing uncomplicated major surgery for rotator cuff tears, a pronounced increase in fatigue extends throughout the first month. A postoperative decrease in muscle force and endurance is related to postoperative fatigue. There has been no study to analyze the effect of rotator cuff repair on fatigue of the shoulder muscles. The second aim of this research is to study the effect of rotator cuff repair on muscle performances and compare it with that of patients with rotator cuff pathology who do not undergo surgery and age matched controls.

What is the purpose of the study?

- To perform a quantitative analysis of shoulder kinematics during functional tasks before and after rotator cuff repair using Dartfish.
- To analyse muscle endurance using Biodex system in patients with rotator cuff tear, patients with rotator cuff pathology but not torn, and compare that to age matched controls.

How many people will be in this study?

The total number of participants will be 60. They will be split into 3 groups:

Group 1: Subjects who undergo rotator cuff repair

Group 2: Subjects with rotator cuff pathology who do not undergo surgery

Group 3: Control group with age matched controls with no rotator cuff pathology.

What am I expected to do?

For measuring muscle performance, you will be expected to perform 60 contractions of a specific shoulder movement on the Biodex. The resulting muscle activity will be recorded and analyzed by the software incorporated in the machine.

Will I be paid to participate in this study?

No.

Will there be any costs?

No.

Are there any risks associated with the 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. 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.

How will my personal information be protected?

The investigators of the study will assign a 'code' that will act as a unique identifier to you. The physical data sheets and electronic data will **not** be labeled with your name.

Location of the study:

You will be assessed at the Hand and Upper Limb Center, St. Joseph's Hospital, London, ON.

How long I will have to spend?

You will be required to come to HULC twice and each visit will take 30 minutes.

Participation in concurrent or future studies:

If you are participating in another study at this time, please inform the study doctor or nurse right away to determine if it is appropriate for you to participate in this study.

Publication of results:

If the results of the study are published, your name will not be used. If you are interested, you may provide an e-mail address where we can e-mail the final study results when they are available. The final results will summarize the outcomes of the study and how the results will benefit health care providers. Your individual results will not be provided.

Voluntary Participation:

Your participation in the study is completely voluntary and you may choose to stop participating or withdraw your consent at any time during the period of the study. Your decision of not participating in the study will not influence the treatment you may be receiving either now, or in the future at St. Joseph's Hospital, London, ON.

Withdrawal from the Study:

You can stop participating in the study at any time, for any reason, if you decide to do so. Your decision to stop participating, or to refusal to answer particular questions, will not affect your

relationship with the researchers, rehabilitation centre, or any other group associated with this project.

Confidentiality:

All information you provide during the research will be held in confidence and your name will not appear in any report or publication of the research. Your data will be safely stored in a locked facility and only research staff will have access to this information. Once your data is entered into a database and analyses are completed; original records containing your personal identifiers will be destroyed. Your data in the database will be associated with a code number, not your personal identifying information. Confidentiality will be ensured to the fullest extent possible. 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.

APPENDIX 6
CONSENT STATEMENT

Title of the project: Functional movement before and after rotator cuff repair and muscle fatigue in patients with rotator cuff pathology.

Investigators:

Principal Investigator: Dr. Joy Macdermid

Co Investigators: Jayaprakash Raman, Dr. David Walton, Dr. George Athwal

SIGNATURE OF RESEARCH PARTICIPANT:

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.

My signature below indicates my consent and I am not waiving any of my legal rights by signing this form.

Participant's Name: _____

_____ _____
Participant's Signature Date

Consent form administered and explained in person by: _____

_____ _____
Signature Date

SIGNATURE OF THE PRINCIPAL INVESTIGATOR:

_____ _____
Signature of Principal Investigator Date

APPENDIX 7

CURRICULUM VITAE

Name: JAYAPRAKASH RAMAN

Professional Education

- BACHELOR OF PHYSIOTHERAPY (1994 – 1998), The Tamilnadu Dr.M.G.R.Medical University, Chennai, India.
- MASTER OF PHYSIOTHERAPY (SPORTS PHYSIOTHERAPY, 2004 – 2006), The Tamilnadu Dr.M.G.R.Medical University, Chennai, India.
- PhD IN HEALTH AND REHABILITATION SCIENCES SPECIALISING IN PHYSICAL THERAPY – Candidate (2009 – 2013), Western University, London, Ontario, Canada.

Publications:

- Journal : The Journal of Hand Therapy
  Article: *Effectiveness of Different Methods of Resistance Exercises in Lateral Epicondylosis – A Systematic Review.*
  Issue: 2012;25:5–26.
- Journal: Journal of Physiotherapy (Australian Physiotherapy Association).
  Article: Clinimetrics on Western Ontario Rotator Cuff Index.
  Issue: Volume 58, Issue 3, 2012, Pages 201

Manuscripts ready for publication:

- Raman J, MacDermid JC, Walton DM. 2013. *Predictors of pain and disability after rotator cuff repair: A Meta-Analysis.* To be submitted to The Journal of Bone and Joint Surgery.
- Raman J, MacDermid JC, Walton DM. 2013. *Functional movement before and after rotator cuff repair.* To be submitted to The Journal of Shoulder and Elbow Surgery.
- Raman J, MacDermid JC, Walton DM. 2013. *Muscle fatigue in patients with rotator cuff pathology.* To be submitted to The Journal of Orthopedic and Sports Physical Therapy.
- Raman J, MacDermid JC, Walton DM. 2013. *A Rasch analysis indicates that the simple shoulder test is robust; but its current format does not completely adhere to optimal measurement principles.* To be submitted to Physical Therapy.

Papers and posters presented in conferences:

- Poster presentation on *The evaluation of simple shoulder test using Rasch analysis – A cross sectional study* at 6th Annual Canadian Society of Hand Therapists Conference Calgary, Canada in May 2013.
- Podium presentation on *Predictors of Outcomes after Rotator cuff repair – A meta-analysis* at the 12th Triennial Congress of the IFSSH and 9th Triennial Congress of the IFSHT, New Delhi, India, March 2013.
- Poster on *Muscle fatigue in patients with Rotator Cuff Pathology* at The Combined Meeting of The Canadian Society for Surgery of the Hand & The Canadian Society of Hand Therapists, Toronto, Canada, May 2012.
- Podium presentation on *Effectiveness of Different Methods of Resistance Exercises in Lateral Epicondylosis – A Systematic Review* at The 34th Annual meeting of ASHT, Nashville, TN, USA, September 2011.
- Podium presentation on *Effectiveness of Different Methods of Resistance Exercises in Lateral Epicondylosis – A Systematic Review* at The 13th Rehabilitation Research Colloquium, Queens University, Kingston, Canada, May 2011.
- Poster on *Effectiveness of Different Methods of Resistance Exercises in Lateral Epicondylosis – A Systematic Review* at The 2011 Combined Meeting of Canadian Society of Hand Therapists and Canadian Society for Surgery of the Hand, Vancouver, Canada in April 2011.
- Poster on *Predictors of pain and disability after rotator cuff repair: A Systematic Review* at The 3rd National Canadian Society of Hand Therapists Conference, Montreal, Quebec, Canada in April 2010.

Awards:

- Western Graduate Research Scholarship – 2009 to 2013 (4 years), Western University, London, Ontario, Canada.
- Best poster award for the poster on *The evaluation of simple shoulder test using Rasch analysis – A cross sectional study* at 6th Annual Canadian Society of Hand Therapists Conference Calgary, Canada in May 2013.

- Best poster award for the poster on *Effectiveness of Different Methods of Strengthening Exercises in Lateral Epicondylosis – A Systematic Review* at The 2011 Combined Meeting of Canadian Society of Hand Therapists and Canadian Society for Surgery of the Hand, Vancouver, Canada in April 2011.