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Assessing Validity and Responsiveness of the Rotator Cuff Quality of Life Index

by

Caitlin Dawn Campbell

A THESIS

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Abstract

Background: The Rotator Cuff Quality of Life Index (RC-QOL) was developed to evaluate quality of life in patients with rotator cuff disease (RCD). This study provides additional validity and responsiveness testing over a 2-year period in accordance with the Consensus-Based Standards for the Selection of Health Measurement Instruments (COSMIN) guidelines.

Methods: Sixty-six patients (mean age, 59±10) with RCD were evaluated. Methodology testing included criterion (concurrent) and content validity, and responsiveness.

Results: Content validity was confirmed with a Cronbach α of 0.91 (95% CI; range, 0.92-0.95) and an absence of floor and ceiling effects. Criterion (concurrent) validity was confirmed using the Western Ontario Rotator Cuff Index as a reference standard (r=0.85, $p<0.001$). The effect size of distribution-based methods of determining responsiveness were large (0.99-1.09) compared to mixed- and anchor-based methods (0.47-0.8). All responsiveness calculations met minimum requirements for acceptable thresholds.

Conclusion: The RC-QOL is a valid and responsive measure of health-related quality of life in patients with chronic RCD. The results of this study added to the methodologic quality assessment of the RC-QOL, completing 7 of 10 COSMIN criteria.

Keywords: shoulder, psychometric assessment, validity, responsiveness, quality of life, rotator cuff, outcome measurement

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Dedication

To my loving parents, Brenda and Alastair Campbell,

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Chapter 1 Project Overview

1.1 Introduction

Rotator cuff disorders – ranging from tendinopathy to massive tears – are among the most prevalent of musculoskeletal disorders.[1] Regardless of frequency of this shoulder pathology, management of rotator cuff disorders are complicated and a multitude of different treatment options are available for patients.[1] Determining what is considered "best practice" is difficult due to the variable nature of treatment. The use of patient-reported outcome measures (PROMs) may become increasingly useful in this regard. PROMs are used to evaluate the health status and quality of life for patients.[2] Disease-specific PROMs can allow for patient-centered care for patients by providing clinicians the ability to tailor treatment plans according to the patient's expectations.[3] There is no consensus on which PROM is most suitable for reporting measuring patient-reported health outcomes, yet they are still often employed as part of patient care. Only the Western Ontario Rotator Cuff Index (WORC)[4] and the Rotator Cuff Quality of Life Index (RC-QOL)[5] focus specifically on rotator cuff disease. Other instruments measure quality of life (QOL) for diseases such as post-operative labral pathology[6], instability[7,8], osteoarthritis[9], and some instruments measure quality of life with respect to general shoulder function, not specific to any disease or condition.[10–18]

A QOL measure evaluates a patient in multiple facets of their life including physical and psychological characteristics.[19] These measures provide the assessor with a glimpse of a patient's "health state".[20] Compared to generic outcome measures, disease-specific PROMs have been proven to provide more valid, reliable, and responsive measurements for patients across a number of diseases or conditions.[20–22] QOL measures can also facilitate economic decisions regarding the best type of care by evaluating the efficacy of various treatments via calculation of the quality-

adjusted life year.[19,20] Therefore, QOL measures are useful tools from both a clinical decision-making process by assessing the best treatments in addition to factoring in economic and policy implications.[19,20]

The RC-QOL is a disease-specific health-related PROM that was developed for use in patients with the varying degrees of RC pathology.[5] The RC-QOL is a 34-item patient-reported questionnaire scored with a 100-mm visual analogue scale (VAS) and converted to an overall score out of 100, where each question receives equal weight. The domains that comprise the RC-QOL include: symptoms and physical complaints (16 items), work-related concerns (4 items), recreational activity and sport participation or competition (4 items), lifestyle (5 items), and social and emotional (5 items). The initial validity and reliability of the RC-QOL were published in 1998 and have since been re-evaluated multiple times.[2,3,5,23–28] Of these evaluations, responsiveness of the RC-QOL has only been assessed on four other occasions[3,23,25,27] - a criticism of the RC-QOL that has been discussed by Kirkley et al and others.[3,29]

The Western Ontario Rotator Cuff Index (WORC) was also designed to measure quality of life for patients with rotator cuff pathology.[4] The WORC consists of 21 items represented in 5 domains: physical symptoms (6 items), sports and recreation (4 items), work (4 items), lifestyle (4 items), and emotions (3 items). The WORC uses a 100-mm VAS ranging from 0–100. The score can be reported as a percentage varying from 0%, the lowest functional status level, to 100%, the highest functional status level.[4]

The Consensus-Based Standards for the Selection of Health Measurement Instruments (COSMIN) initially submitted 10 criteria to be used to determine whether a study has met the standards for good methodologic quality.[30] However, the COSMIN guidelines were created to assess the quality of health-related PROM development and not to assess the quality of the health-

related PROM tools.[3,30,31] There is a lack of a current gold standards specifically related to health-related PROMs, however, the COSMIN guidelines can provide a realistic framework to evaluate PROMs such as the RC-QOL.[30]

1.2 Purpose

The purpose of this study was to provide further methodological analysis of the Rotator Cuff Quality of Life Index (RC-QOL) through determining validity and responsiveness at 2-year follow-up in both surgical and non-surgical rotator cuff patients within a specialist orthopaedic setting.

1.3 Rationale/Significance

Management and treatment of rotator cuff tears are in need of improvement through evidence-based decision making.[23] As a result, the effect of PROMs on comparative effectiveness research and routine clinical practice may be substantial. The RC-QOL has been evaluated as a valid and reliable questionnaire in multiple studies to help fully understand the impact of chronic conditions and to determine the effectiveness of different management strategies.

1.4 Research Question

Is the RC-QOL valid and responsive in detecting change in confirmed rotator cuff pathology patients 24 months after baseline assessment?

1.5 Specific Aims

1.5.1 Primary Objectives.

The overall goal of the project was to provide additional methodological assessment of the RC-QOL under the framework of COSMIN guidelines.

- Objective 1: Evaluate properties of content validity in the RC-QOL using internal consistency and floor/ceiling assessment.
- Objective 2: Evaluate properties of criterion/concurrent validity with the RC-QOL and WORC.
- Objective 3: Evaluate properties of responsiveness in the RC-QOL using both distribution-based and anchor-based methods.

1.5.2 Secondary Objectives.

To provide methodological assessment of the RC-QOL in patients that were treated non-operatively versus those treated surgically.

Chapter 2 Literature Review

2.1 Introduction

The literature was searched to understand both the nature of rotator cuff tears in terms of burden of the disease, pathology and clinical presentation, and management of rotator cuff tears as well as the development, assessment, and constructs of responsiveness in the context of patient-reported outcome measures (PROMs). Databases (PubMED, Medline, PsychINFO) and the Internet (via Google and Google scholar) were searched. Grey literature from national initiatives, government and committee reports and policy papers, and discussion papers were also searched. Scans of professional associations, academic resources, and research institutions were also conducted.

2.2 Overview of Rotator Cuff Disease

2.2.2 Anatomy, Mechanics, and Pathology.

The rotator cuff is a group of 4 muscle-tendon units in the shoulder, connecting the humerus to the scapula. These muscle-tendon units (supraspinatus, infraspinatus, teres minor, and subscapularis) contain the humeral head within the glenoid fossa and aid in movement of the upper extremity.[32] The cuff muscles are innervated by different nerves, including the upper and lower subscapularis nerves (subscapularis), suprascapular nerve (supraspinatus and infraspinatus), and a branch of the axillary nerve (teres minor).[33] The long head biceps tendon is often considered to be a part of the rotator cuff. The long head biceps is innervated by the musculocutaneous nerve.[33]

The causes of rotator cuff tears include both extrinsic factors such as repetitive stress and work or recreational overuse of the shoulder, as well as intrinsic factors such as age and poor vascularity.[32,34,35] A rotator cuff injury can occur after a single extreme overload, but typically is

the result of a degenerative process that compromises the tendon's integrity.[32,35,36] During shoulder movement, the rotator cuff tendons glide beneath the coracoacromial arch and may become compressed beneath the arch secondary to superior translation of the humeral head.[37] This type of mechanical impingement of the rotator cuff tendons leads to irritation, chronic inflammation, degeneration, and weakness of the tendons over time resulting in bursitis or tendinopathy.[36]

Partial-thickness or full-thickness tendon tears can occur as a result of slow degradation of the tendon over time or in a more acute event commonly on a weakened or compromised tendon.[32,36] The prime function of the rotator cuff is stabilization of the humeral head.[38] Once a rotator cuff tendon is torn, the humeral head may no longer be centred on the glenoid thus effectively altering the biomechanics of the shoulder joint.[38] This may result in pain, loss of strength, and reduced motion in the affected shoulder.[36]

There is variability in the clinical presentation of rotator cuff tears.[32,39] Most patients will present with pain and loss of strength while only a minority of patients present with decreased range of motion.[35,36] In addition, some patients experience only mild discomfort and momentary weakness, while others experience chronic pain and loss of function.[40]

2.2.3 Epidemiology and Burden of Disease.

Rotator cuff tears often have changes that are bilateral in nature and age dependent.[38,41,42] In addition to the high frequency of rotator cuff tear presentation, up to 4% of individuals under 40 years of age may have an asymptomatic rotator cuff tear and up to 50% of individuals over the age of 60 will develop an asymptomatic rotator cuff tear.[43,44] It has also been determined that pain may develop in half of these individuals within 5 years of developing a tear.[43]

Up to 70% of patients with rotator cuff tears are sedentary and half of these patients are

unable to recollect specific trauma to the shoulder.[41,42] Wirth et al indicates that more than half of patients are unable to recall a specific event which may have initiated symptoms, and rather the patient presents with a long-standing history of intermittent pain that has become progressively more symptomatic.[45]

Yamanaka et al observed partial thickness tears of 40 patients after at least one year from the onset of rotator cuff symptoms. Although the authors indicated that the very small sample size altered the interpretability of the results, they observed that 10% of tears healed, 10% became smaller, 53% became larger, and 28% progressed to full thickness tears.[46] Patient outcome scores (Japanese Orthopaedic Association Shoulder Score) were not always representative of the integrity of the tendon.[46]

Yamaguchi et al followed a cohort of 45 patients who had confirmed bilateral, full thickness cuff tears via ultrasound, yet presented originally with symptoms only in one shoulder.[47] Follow-up exams revealed that 51% of patients developed symptoms on the contralateral side. Of the 45 original patients, 23 had a follow-up ultrasound approximately 3 years later, of which 9 of 23 had tear progression. For those with tear progression, 7 of the 9 had become symptomatic.[47] There were no observations of tear size decreasing in the study. The authors noted that selection bias may have occurred as the asymptomatic patients were all seen originally due to the contralateral shoulder being symptomatic. These patients may have had intrinsic weakness in the cuff and/or a predisposition toward both symptoms and progression over time.

Shoulder pain is the second most frequent acute musculoskeletal complaint presenting to general practice physicians with shoulder injury most prevalent in working-age adults.[48,49] Rotator cuff disorders are the most common cause of shoulder pain evaluated by physicians and is second in frequency of injuries occurring in the workplace. [43,48] It is reasonable to expect that individuals

presenting with rotator cuff disorders can anticipate a decreased quality of life, presence of pain, discomfort, and disability. The societal impact is notable with such a high prevalence of rotator cuff disorders in workplace injuries.[43]

2.2.3 Managing Rotator Cuff Tears.

Currently, a universally accepted approach to the clinical management of rotator cuff tears does not exist; this is likely due to the low methodological quality of the intervention studies.[50,51] As a result, a wide variety of management options are available for the patients with rotator cuff tears, without evidence to determine best patient outcomes.[1] These management options differ from operative to non-operative. This lack of consensus often results in costly investigations such as magnetic resonance imaging (MRI) and other diagnostic tests, which in many cases will not offer a clear answer to the clinical question.[52]

2.2.3.1 Non-Operative Treatment.

Current literature conflicts greatly with regards to outcomes of non-operative treatment for chronic full thickness rotator cuff tears.[39,45,53–58] This is likely a result of high variability in treatments protocols that are classified as non-operative. Options include physical therapy, home-based exercise programs, and surgeon-led exercise therapy programs. Passive therapies include steroid injections, non-steroidal anti-inflammatories, and other therapeutic modalities.[59]

Further complicating the evaluation of non-operative outcomes is the significant number of outcome measures used to assess patient status. For example, the Western Ontario Rotator Cuff Index (WORC), RC-QOL, University of California Los Angles Shoulder score (UCLA score)[10], American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form (ASES)[13], and

Simple Shoulder Test (SST)[17], to name a few, have all been used to assess the efficacy of non-operative programs. This variability in the literature makes comparisons between studies difficult.

Outcomes for rotator cuff tears have shown to improve with both operative and non-operative treatment but non-operative treatment is often overlooked as an effective, non-invasive, and economical treatment option for patients with chronic, symptomatic, full-thickness rotator cuff tears .[39,45,60]

2.2.3.2 Operative Treatment.

Operative repair of a chronic, full-thickness rotator cuff tear can be achieved arthroscopically, with an arthroscopic assisted mini-open approach, or with an open approach. The superiority of one surgical technique over another remains inconclusive, though extensive research has been done in this area. Following operative repair, surgeons may require a patient be immobilized for up to six weeks in addition to months of physical rehabilitation.[61] Most patients are able to return to their chosen activities between 6 and 12 months following surgery. Surgery has typically demonstrated improved outcomes for patients with rotator cuff tears that have failed a course of non-operative care, though the extent to which the intervention is successful varies dramatically in the literature.

2.3 Patient-Reported Outcome Measures

2.3.1 Development of Patient-Reported Outcomes.

Outcome measures have traditionally relied on routinely collected clinical information such as hospital records including injury prevalence, procedural complications, survival, or other values.[62] The authors of some PROMs have argued that the content of an instrument should be

defined on the basis of interviews with patients who have the condition of interest.[62] However, others choose item inclusion based on a review of existing instruments based on the opinion of those who had expertise in the treatment of a variety of conditions involving the joint or disease in question.[21,63] These methodologies have been used to develop patient-reported measures of disability of the upper extremity in addition to the RC-QOL.[5,15]

2.3.1.1 Development of the Rotator Cuff Quality of Life Index (RC-QOL).

Hollinshead et al published a paper in 2000 reporting on the 6-year follow-up of large and massive rotator cuff tears.[5] In this article, authors introduced a disease-specific quality of life instrument for patients with rotator cuff tears. The instrument was developed and tested using methodology described by Guyatt et al[64] and was created as an outcome tool in patients with the "full spectrum of rotator cuff disease"[5].

Item generation was carried out in 3 steps: review of the literature and existing outcome tools, discussions with clinician experts, and patient input. Patients that were interviewed presented with primary rotator cuff impingement tendinopathy to massive rotator cuff defects. The number of patients interviewed or the number of items generated at this phase was not disclosed. A preliminary questionnaire was created using 100-mm VAS response format anchored numerically and written at each end (ex. 0, Severely troubled and 100 – Not troubled at all). This preliminary questionnaire was then pretested on 20 patients with documented rotator cuff disease. Following completion of the questionnaire, structured patient interviews were conducted. These patient interviews included 5 questions concerning whether the items were appropriate, whether the items were deemed important to his or her quality of life, ease of comprehension, and whether the patient would "suggest any modifications to the questionnaire"[5]. A 55-item questionnaire was developed

following initial revision. Further reductions to a 34-item questionnaire were then made. There are no details on the methodology but further reductions were done "[o]n the basis of qualitative and quantitative criteria"[5] in order to create "a smaller, more manageable questionnaire"[5]. Qualitative criteria included the importance of test items in demonstrating an issue specific to quality-of-life, the importance of each item to patients, and the minimizing of redundant questions. The quantitative criterion was based on reliability testing where items that had an average difference score of 15% or greater between the two test intervals were eliminated from the tool.

2.3.1.2 Development of the Western Ontario Rotator Cuff Index.

In 2003, the Western Ontario Rotator Cuff Index (WORC) was published as a primary outcome measure in clinical trials evaluating treatments for patients with degeneration of the rotator cuff.[4] The WORC was developed and evaluated using the methodology as described by Kirschner and Guyatt.[65] Similarly to the RC-QOL, item generation was carried out in 3 steps including a review of the literature and existing instruments, interviews with clinician experts, and interviews with 33 patients representing the full spectrum of patient characteristics. Item reduction was carried out using the frequency importance product (impact) from a survey of 100 patients representing the full spectrum of patient characteristics and a correlation matrix to eliminate redundant items. The response format selected for the instrument is also a 10-cm VAS anchored verbally at each end. The prototype form was pretested on 2 consecutive groups of 10 patients. The items required a response and were assigned equal weight based on the uniformly high impact scores.

2.3.2 Assessment of Patient-Reported Outcome Measures.

Standardization of PROMs provides the ability to determine improvement of care when used in homogenous populations.[66] Kirshner and Guyatt identified three characteristics of methods used for the assessment of health-related quality of life measures: discriminative, predictive, and evaluative components.[65] Since the initial attempts to standardize methodology of health- or patient-related outcome measures, the Consensus-Based Standards for the Selection of Health Measurement Instruments (COSMIN) guidelines[30] was published in 2010 and are widely used. The COSMIN submitted 10 criteria to be used to determine whether a study has met the standards for good methodologic quality: internal consistency, reliability (eg, test-retest, inter-rater, intra-rater), measurement error, content validity, construct validity (ie, hypothesis testing), structural validity, criterion validity, cross-cultural validity, responsiveness, and interpretability.[30] It is important to note, the COSMIN guidelines were created to assess the quality of a study and not to assess the quality specific to the PROMs.[30,31] Despite this criticism, with the lack of a current gold standards specifically related to health-related PROMs, the COSMIN guidelines can provide a realistic framework to assess PROMs such as the RC-QOL. [19,30]

2.4 Validity and Responsiveness

Validation studies provide information on measurement error of a tool.[67] Validity is not inherently built into the composition of an outcome tool, but rather it is an interaction between the PROM and the population that the tool is measuring.[68,69] Therefore, repeating validation studies on an outcome measurement tool is important to further support or oppose the overall validity of the tool..[70]

In an attempt to clarify the different purposes and interpretations affiliated with the validity of any one test, psychosocial scientists have developed at least 16 different prefixes for validity (i.e. content, construct, and criterion).[67,71] Consequently, the validation process can be complex and often incomplete. [67,71] One attribute of validity is accuracy, or the comparison between the observed result to the result obtained with a gold standard.[71] This however, cannot be achieved if an unequivocal gold, or reference, standard does not exist.

Responsiveness is a tool's ability to detect change.[66,67,72–75] Using this definition, a minimal clinically important difference (MCID) score can be used as a construct in determining responsiveness of such a tool.[73] MCID was first described by Jaeschke et al in 1989 and was then defined as "the smallest difference in score in the domain of interest which *patients* perceive as beneficial and which would mandate, in the absence of troublesome side effects and excessive cost, a change in the patient's *management*" [73]. This perception of change provides researchers insight into patient-centred outcomes.

2.4.1 Criterion and Concurrent Validity.

Criterion validity refers to the extent to which scores on a particular instrument relate to a gold standard. Concurrent and predictive validity are considered components of criterion validity.[67,76] Concurrent validity is used to assess the properties of a tool by administering the outcome measure at approximately the same time point as the reference standard in order to reflect the same experience of the patient.[67] This is particularly useful when assessing a lesser known outcome measure to determine its efficiency or practicality compared to the reference standard.[67] As mentioned previously, in terms of quality of life assessment tools for patients with rotator cuff disease, there is no specific golf standard.[30] Such an assumption would be unsubstantiated and as

a result, there is an absence of a gold standard in the present study. As there are only two Canadian English-based outcome measures to assess rotator cuff patient quality of life, the WORC can be considered the reference standard when assessing concurrent validity as a measure of criterion validity of the RC-QOL. A positive rating for criterion validity if convincing arguments are presented that the used standard really is ‘‘gold’’ and if the correlation with the gold standard is at least 0.70.[30,70,77]

2.4.1.1 Pearson Coefficient.

Developed by Karl Pearson in the 1880s, the Pearson correlation coefficient describes a relationship between two variables.[67,77] Correlations require two or more distributions and, in the case of RC-QOL versus the WORC, is a bivariate statistic. The Pearson correlation coefficient requires that the two variables – RC-QOL and the WORC – be measured at the interval level, and is denoted by the letter, *r*. The correlation coefficient describes the strength and direction of a linear relationship between two variables.[67,70,77] Assessing whether a line describes the pattern, or if some other curve might provide a better description, it must be done so by visually inspecting a scatterplot.[67] This visual inspection also provides information as to the presence of outliers – a feature of the distribution that easily compromises the accuracy of the coefficient. A positive correlation coefficient indicates a direct relationship, as X increases so does Y and as X decreases so does Y.[67] A negative correlation coefficient indicates an indirect relationship, as X increases, Y decreases and as X decreases, Y increases. The absolute value of correlation coefficient indicates the strength of the relationship.[67] Pearson correlation coefficients range from -1 to +1. Values close to -1 or +1 indicate a strong linear relationship - the associated scatterplot displays the pattern of dots in a nearly straight line.[67,78,79] A positive Pearson correlation coefficient isn't necessarily better

(i.e., stronger) than a negative correlation coefficient but simply the description of what happens to X when Y increases or decreases.[78] In order for there to be a strong argument for the presence of construct or content validity, the data must be linearly related, meaning that the scores in both tests move together.[77] This testing is used where the data is continuous and normally distributed.[77,78] It is recommended that a positive rating for criterion validity is present if the correlation coefficient with the "gold" standard is at least 0.70 when evaluating PROMs.[30,70,77]

2.4.1.2 Bland-Altman Plots.

The Bland-Altman plot, or difference plot, is a graphical method to describe the agreement between two quantitative measurements.[79–81] In this graphical method the differences between the two techniques (A-B) are plotted against the averages of the two measurement outcomes ((A+B)/2). Simply put, the Bland-Altman plot represents every difference between two paired measurements against the average of the measurement. Plotting difference against mean allows one to determine any possible relationship between measurement error and the true value of the correlation. Bland and Altman[82] recommended that 95% of the data points should lie within ± 2 standard deviations of the mean difference. The classic difference plot shows the difference between the methods on the vertical axis, against the best estimate of the true value on the horizontal axis. When one method is a reference method, it is used as the best estimate of the true value and plotted on the horizontal axis.[83] In this case, using the average of the methods as the best estimate of the true value, prevents an artificial relationship between the difference and magnitude.[82]

2.4.2 Content Validity and Reliability.

In the context of health-related PROMs, content validity examines the extent to which the concepts of interest are thoroughly represented by the items in the questionnaire.[21,70] Content validity demands that a test is free from the influence of factors that are irrelevant to the purpose of the measurement.[67] This is critical with respect to a PROMs ability to evaluate a large amount of information by a few questions. [67]As argued by Terwee et al, an indicator of a tool's content validity is the presence or absence of floor or ceiling effects.[70] The floor and ceiling effects are the degree above which variance in an independent variable is no longer measured or estimated.[67] If floor or ceiling effects are present, it is likely that extreme items are missing in the lower or upper end of the scale.[67,70] In addition, PROMS with the presence of floor or ceiling effects reduce the reliability and responsiveness of the tool because changes cannot accurately be measured in these patients.[70]

Internal consistency is often considered as a measure for content validity, however, it is considered as part of the domain of reliability as indicated by the COSMIN guidelines.[76] Cortina has argued that it is not suitable to consider internal consistency as a measure of validity as it does not indicate whether the items measure the intended construct but only if the tool measures any construct consistently.[84] Item analysis and internal consistency indices also provide essential information about the degree to which an item represents the proposed constructs.[85]

2.4.2.1 Cronbach's Alpha.

Cronbach's alpha is traditionally used as an estimate of the reliability of a psychometric test and is denoted by the symbol, α.[86] Cronbach's alpha generally increases as the inter-

correlations among test items increase and as such, measures internal consistency which provides an estimate of reliability of test scores.[67,84,87] The term 'item' is used as both the individual questions of each PROM as well as the separate domains. This provides the extent to which both items – questions or domains – measure the same thing. Because inter-correlations among test items are maximized when all items measure the same construct, Cronbach's alpha is widely believed to indirectly indicate the degree to which a set of items measures a single unidimensional underlying trait. Cronbach's alpha is most appropriate when the set of items measure more than one construct or when looking at the test outcome as a whole.[87–89]

2.4.2.2 Floor and Ceiling Effects.

Traditional definitions of floor and ceiling effects are intended to determine whether an evaluation instrument has the capability to measure patients at both ends of the spectrum.[67] The acceptable percentage of patients to exhibit floor and ceiling limits varies considerably in the literature from 15% to 33%.[70,90,91] Floor and ceiling effects occur when most patients score near the top or the bottom of the questionnaire. Floor scores are considered 0 out of a possible 100 on the RC-QOL. Ceiling scores are considered 100 out of a possible 100 on the RC-QOL. The presence of floor and ceiling effects indicate that the questions are either too difficult for the group that is being tested or too easy. It is likely that extreme items are missing in the lower or upper end of the scale, indicating limited content validity or conversely notable content validity with the absence of floor or ceiling effects.[70] If there is little variance amongst responses and an excess of random error, internal consistency is going to undoubtedly be poor.

2.4.3 Minimal Clinically Important Difference and Responsiveness.

The key constructs of the minimal clinically important difference (MCID) is that there is a minimal amount of patient reported change and 'something significant enough' to change the course of patient management.[73] The change noted in patients has been defined through clinician report, through change in clinical parameter (e.g., disease state)[92], or through effectiveness of clinical intervention (effect size).[93,94] In addition to these variety of defined outcomes, many discrepancies with time points assessed is present within the literature.[95] Up to 31 different measures of responsiveness are available and the methodology used greatly affects the ultimate calculated difference.[74,94,96–98] Though there is ample literature discussing the nature of MCID and responsiveness, there is no standard as to how to calculate these constructs.[70,98] It is argued that anchor-based methods should be used to confirm and validate the MCID and distribution based methods of a tool's responsiveness.[30]

2.4.3.1 Distribution-Based Methods for Calculating Responsiveness.

Distribution-based methods are techniques that are derived from statistical measures of spread of the data: standard deviation (SD), the measurement of the spread or variation of data, standard error of the measurement (SEM), the estimate of the standard deviation (SD), and effect size (ES) which is based on standard deviations.[67] Using the one-half standard deviation benchmark of an outcome measure requires that the patient to improve more than one-half of the outcome score's standard deviation in order to have achieved a minimal clinically important difference.[99]

The standard error of measurement is the variation in scores due to unreliability of the scale or measure used. This indicates that a change that is smaller than the SEM is likely due to the result

of measurement error as opposed to a true observed change. Patients achieving a difference in outcome score of at least one SEM would have achieved a minimal clinically important difference.[92]

The effect size is a measure obtained by dividing the difference between the means of the baseline and post-treatment scores by the standard deviation of the baseline scores. An effect size cut off point can be used to define minimal clinically important difference in the same way as the one half standard deviation and the standard error of measurement.[92]

2.4.3.2 Anchor-Based Methods for Calculating Responsiveness.

The anchor-based method compares changes in scores with an external marker as reference.[67,92] An anchor establishes if the patient is better compared to baseline according to the patient's own experience.[67]

One approach to the anchor-based method is establishment of an anchor prior to implementing treatment. The patient is consulted as what minimal outcome is required prior to undergoing the proposed treatment. This technique allows for more personal variation as patient goals and outcomes may vary drastically.[100] Different anchor questions and a different number of possible answers have been proposed.[67,100–102] Traditional external anchors vary between Likert-type scales and visual analogue scales. Research has shown no significant difference in type of scales and there is little consensus on the best mode of questioning in implementing external anchors.[64,73,103]

Anchor-based methods are not appropriate for conditions in which few patients report an unchanged health status and most patients show improvement or deterioration. These outcomes result in insufficient variability for calculation of a MCID.[104,105] The MCID varies according to

diseases and outcome instruments, but it does not depend on treatment methods.[95] Therefore, two different treatments for a similar disease can be compared using the same MCID if the outcome measurement instrument is the same. Also MCID may differ depending on baseline level and can vary over time after treatment for the same disease.[95] The calculated MCID varies widely depending on the method used. Currently there is no preferred method of establishing 'the' MCID.[76,106,107]

2.5 Limitations of Previous Research

Of the RC-QOL evaluations, concurrent validity has not been assessed. Convergent validity of the RC-QOL and WORC has been evaluated on one occasion.[2] In addition, responsiveness of the RC-QOL has only been assessed on four occasions - a criticism of the RC-QOL that has been discussed by Kirkley et al and others.[3,29] In each of these four studies, a distribution-based method determined the index's minimal clinically important difference (MCID).[3,23,25,27]

Chapter 3 Methods

3.1 Study Design

This study was a prospective observational cohort study within a specialist (orthopaedic) clinical setting.

3.2 Subjects

3.2.1 Demographics.

94 patients were entered in the study (36 females and 58 males) with an average age of 57 years (range 27 – 78 years). There were 44 non-surgical and 50 surgical patients.

3.2.2 Identification of Participants/Recruitment.

Baseline data was collected from 94 patients in a concurrent study using a convenience sample. These patients were identified from new and follow-up referrals from primary care physicians (general practitioners or sport medicine physicians) to 3 orthopedic surgeons at the University of Calgary Sport Medicine Centre. Non-surgical and surgical patients were targeted. Non-surgical patients did not require immediate surgical management and were treated conservatively with a non-operative program. Surgical patients had confirmed surgical dates or had already received surgical management for their shoulder problem.

3.2.3 Inclusion Criteria.

Inclusion criteria consisted of English-speaking and literate patients aged 18 years of age or older. Patients were included if they presented with a rotator cuff tears confirmed by

ultrasonography or magnetic resonance imaging (MRI). A chronic rotator cuff tear was defined as a patient that presents with shoulder pain of insidious or gradual onset or resulted from a previous traumatic episode or in patients with pre-existing rotator cuff pathology who experienced an injury to the ipsilateral shoulder.[3,108]

3.2.4 Exclusion Criteria.

Patients were excluded if they presented with concomitant symptomatic pathology of the affected shoulder (i.e., instability, osteoarthritis), significant cervical spine pathology and/or radiculopathy, or medical gain issues (ie, Workers' Compensation or litigation). Individuals who were either unable or unwilling to complete study outcomes or provide informed consent were also were excluded.

3.3 Outcome Measurement Techniques

Patients completed baseline questionnaires through a concurrent study evaluating the healthcare model for rotator cuff disease (REB 14-1828). Using these baseline scores, patients were asked to complete the Rotator Cuff Quality of Life Index (RC-QOL) (Appendix A) at a second interval – approximately 24 months ± 6 months. The RC-QOL consisted of 34 questions and 5 subscales: symptoms and physical complaints (SYMPTOMS), 16 items; work- related concerns (WORK), 4 items; recreational activities, sports participation, or competition concerns (SPORTS), 4 items; lifestyle concerns (LIFESTYLE), 5 items; and social and emotional concerns (SOCIAL/EMOTIONAL), 5 items. Patients were given the option of answering "not applicable" to 14 questions. All questions were scored on a 100-mm visual analogue scale from 0 to 100. The quality of life score was calculated by taking an average of items answered by respondents. For

example, if the patient answered all 34 items, 34 values were summed and then divided by 3400. If the patient answered "not applicable" to all 14 questions, these responses were treated as missing-by-design, and 20 values were summed and divided by 2000 (ie, [3400 − 1400] × 100). "Not applicable" responses were not used and were treated as if these items had never been offered to the patient. The most symptomatic score was 0, indicating the worst quality of life, and the best quality of life or asymptomatic score was 100.

In addition, patients were asked to complete the Western Ontario Rotator Cuff Index (WORC)[4]. The WORC consists of 21 items representing five domains each with a 100-mm visual analogue scale response option. The 5 domains include: physical symptoms (SYMPTOMS), 6 items; sports and recreation (SPORTS), 4 items; work (WORK), 4 items; lifestyle (LIFESTYLE), 4 items; and emotions (SOCIAL/EMTIONAL), 3 items. The WORC items are scored on a 100-point scale (0–100). The most symptomatic score is 2100 and the best or asymptomatic score is 0. However, for ease of comparison with the RC-QOL, the WORC score was reported as a percentage of normal by subtracting the total score from 2100, dividing by 2100 and multiplying by 100. The final WORC scores varied from 0%, the lowest functional status level, to 100%, the highest functional status level.

Finally, a 7-point global rating scale (GRS) (Appendix B), and a visual analogue GRS for evaluation of symptoms and function (Appendix C). The 7-point GRS (adapted from Greco et al[102])) was used in addition to a VAS GRS ranging from -100 to +100 points (-100, significantly worse and +100, significantly improved). Patients were contacted via telephone or email to complete either the paper or web versions of the RC-QOL, WORC and two GRSs. Both questionnaires were adapted from their original paper format to web-based administration. Computer-based formats of PROMs has demonstrated to yield comparable results to paper-and-

pencil administration.[109]

3.4 Independent Variables

The independent variables in this study include rotator cuff tears which was confirmed by ultrasonography or MRI. Operative status (non-surgical vs. surgical management) was also considered.

3.5 Data Management

Baseline data for this study was obtained from a convenience sample of patients from the University of Calgary Sport Medicine Centre in Calgary, Alberta, between March and October 2015. All study information was stored on the Research Coordinator's computer. The computer was password protected. The computer is stored in a locked office when not in use.

All follow-up data was collected by the author. Follow-up questionnaires completed electronically were submitted directly to and stored on a secure server in a password protected database owned by the University of Calgary Sport Medicine Centre. Completed questionnaires were assigned a unique identification number on the server. Paper-based questionnaires were completed by patients and given directly to the Research Coordinator to be filed in a locked cabinet. Questionnaires do not collect personal information that can be used to connect a patient with his or her responses.

Only the research team of Dr. Nicholas Mohtadi (Primary Investigator), Breda Eubank (PhD Student, Research Coordinator) and Caitlin Campbell (Masters student, Research Coordinator) have access to participants' personal information. All personnel completed the Tri-Council Policy Statement (TCPS) 2 Tutorial and have ensured that all appropriate measures were

taken to ensure participant's privacy and confidentiality. All other study personnel did not have access to personal information and thus, the participant's privacy and confidentiality was maintained.

3.6 Sample Size

Descriptive studies do not involve the comparison of different groups thus the concept of power, a null and an alternate hypothesis do not apply. Consensus-based guidelines for estimating sample size in observational studies analyzing PROM responsiveness using an anchor-based analysis method, are not available. Terwee et al indicated a sample size of 50 patients is adequate for determining a PROM's MCID – a construct of responsiveness – as well as floor and ceiling effects. [70] However, Herzog proposed that for a study to obtain an observed alpha of 0.75 when testing internal consistency (reliability), a sample size of at least 25-40 pairs of questionnaires should be analyzed per group.[110] Therefore, a maximum sample size of 80 patients (ie, 40 patients per group) was determined to be required for this study with a minimum of 50 patients to stay within proposed boundaries.[70,110]

3.7 Reliability and Validity

Both reliability and validity studies provide information on measurement error. The difference between reliability and validity is that while reliability provides information regarding a test's reproducibility, it does not indicate whether or not the test is measuring what it is intended to measure.[23, 27] Ideally, a test will be both reliable and valid, however, there are circumstances when a test may be reliable, but due to an error the test measures the wrong characteristic. In this situation, the test would be deemed reliable but not valid. Conversely, a test that is not reliable will

produce results that are not reflective of the characteristic of interest and thus, the test would be considered non reliable and non-valid. This situation demonstrates that without reliability, a test cannot be valid.

A measurement or index cannot be tested for validity unless it is first considered reliable.[67,71,111] Reliability was not addressed in the current study for the following reasons. Eubank et al assessed reliability using internal consistency, test reliability, and measurement error using the same sample of patients as this study.[3] Practically speaking, re-assessing reliability using the same group of patients would be redundant and would not provide any further quality assessment to the RC-QOL.

3.8 Data Analysis

Data analyses were computed using STATA 14.2 (TX) and statistical significance was accepted at the $P < 0.05$ level.

3.8.1 Primary Analysis.

Content Validity:

- Floor and ceiling effects were calculated at the 15%, 20%, 25%, and 30% stratifications for both time intervals using the RC-QOL at baseline and RC-QOL and WORC at 2-year follow-up.
- Using Cronbach's alpha (α) calculations at the initial consultation and approximately 24 months postoperatively.[70] The Cronbach α was calculated to examine internal consistency for each questionnaire in its entirety and for each subscale separately. An α of ≥0.90 was deemed a measure of good internal consistency.[67,112]

Criterion/Concurrent Validity:

- Criterion validity was measured by means of concurrent validity. This was done by comparing the RC-QOL with the WORC at the second time interval (24 ± 6 months). A Pearson *r* correlation coefficient was used to compare the mean score of the RC-QOL at 24 months and the mean score of the WORC at 24 months.
- Bland-Altman plots were used to estimate 95% boundaries of concurrence.[79]

Responsiveness:

- Responsiveness was determined using three strategies; (1) standardized response mean of the raw change scores (distribution-based method), (2) Guyatt's Responsiveness Index (GRI) (distribution-based method requiring anchor-based MCID), (3) and global rating scale of improvement correlated to QOL measure (anchor-based method).[74] Values of 0.2, 0.5, and 0.8 was used to represent small, moderate, and large effects.[113]
    i. SRM: The Standardized Response Mean of the raw change scores (SRMraw) was restricted to patients who change and was calculated as the ratio of the mean raw change score and the standard deviation of that raw change score. [67,74,114]
    ii. GRI: The MCID was determined by the smallest absolute change scores in patients that perceived change.[115] Variation of data was calculated using a one-way Analysis of Variance (ANOVA) of change scores in patients reporting little to no change.[67,115]

iii. GRS: A Pearson *r* correlation coefficient was used to compare the mean change score in the RC-QOL between the baseline and 24-month scores with the 7-point rating scale and again with the VAS GRS scale. [19,67,74,116]

3.8.2 Secondary Analysis.

All analyses completed in the primary analysis were subsequently stratified based on surgical status.

3.8.3 Mean vs. Median.

One method of summarizing a data set is to describe the 'centre' of the data. Two measures of central tendency are the mean and the median. The mean is a numerical average of the scores while the median represents the mid-point of a data set such that half of the scores fall below it and half are above.[67] Although the mean is calculated from all values in a data set, the median is unaffected by extreme values.[23, 30] As the design of this study includes a 2-year time interval, it is expected that the majority of patients will see an improvement. Based upon this information it was reasonable to predict that there would be skewed distributions in the current study. Therefore, the median was selected over the mean as the primary measure to represent the agreement for each structure. The median does not provide information on the range of values in a dataset therefore the range of agreements will also be reported.

3.8.4 Assumptions.

The assumption when testing content validity is that each test item measures the same latent trait on the same scale.[87] All variance unique to a specific item is therefore assumed to be the result

of error.[117] In determining criterion/concurrent validity of the RC-QOL, it is under the premise that the WORC scales are also able to capture those same traits for each patient within the sample. We implicitly assume that a change in health status or functioning is indirectly related to the patient's subjective experience of quality of life.

Chapter 4 Results

4.1 Patient Demographics

Ninety-four patients were entered in the study at baseline (58 males and 36 females) with an average age of 57 years (range 27-78). At the two-year follow-up interval, 66 patients participated (40 males and 26 females) with an average age of 59 years (range 29 – 80 years). There were 29 non-surgical patients and 37 surgical patients. As shown in Table 1, there are similar characteristics between the overall group and surgical group at baseline and 2-year follow-up group when considering age and sex. The sex breakdown is within 4% between the two time intervals for overall and surgical groups at baseline and 2-years. Although age is relatively consistent in the non-surgical group at the two time intervals, the sex distribution is not. At the 2-year follow-up, female patients increase to 48% in the non-surgical group (14 of 29 patients) compared to the 41% (18 of 44 patients) at baseline. Age means were reported as a result of the normally distributed data displayed in Figures 1, 2, and 3.

Table 1. Demographic data of up to 94 patients with confirmed rotator cuff tears at when completing rotator cuff-specific questionnaires at baseline and at approximately 2-year follow-up.

Demographic	Baseline			2-Year Follow-Up		
	Overall (*n*=94)	Non-Surgical (*n*=44)	Surgical (*n*=50)	Overall (*n*=66)	Non-Surgical (*n*=29)	Surgical (*n*=37)
Age (y), mean (SD)	57 (10)	56 (8)	58 (12)	59 (10)	59 (11)	59 (10)
Sex						
Male (% of *n*)	58 (62%)	26 (59%)	32 (64%)	40 (61%)	15 (52%)	25 (68%)
Female (% of *n*)	36 (38%)	18 (41%)	18 (36%)	26 (39%)	14 (48%)	12 (32%)

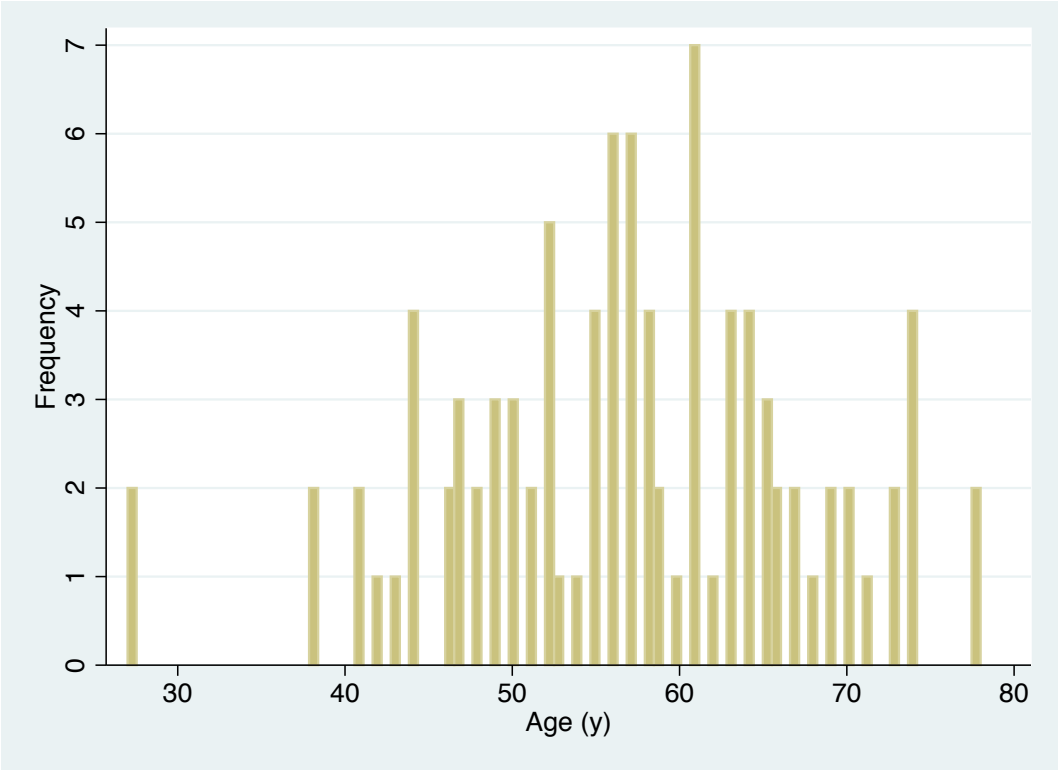

Figure 1. Age distribution (in years) of 94 patients with confirmed rotator cuff tears at baseline.

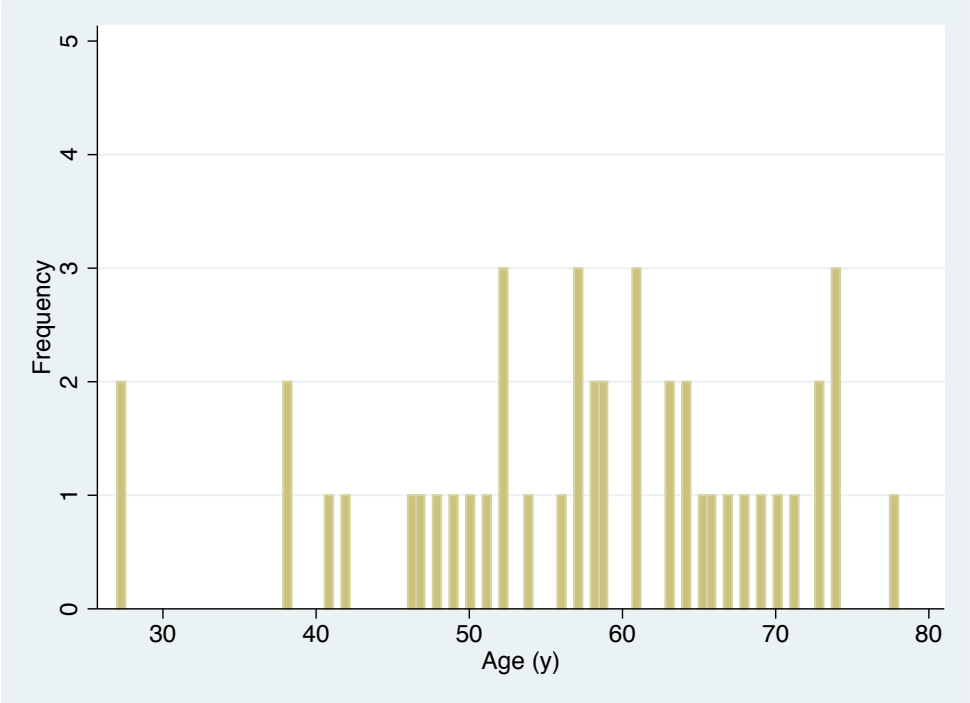

Figure 2. Age distribution (in years) of 44 non-surgical patients with confirmed rotator cuff tears at baseline.

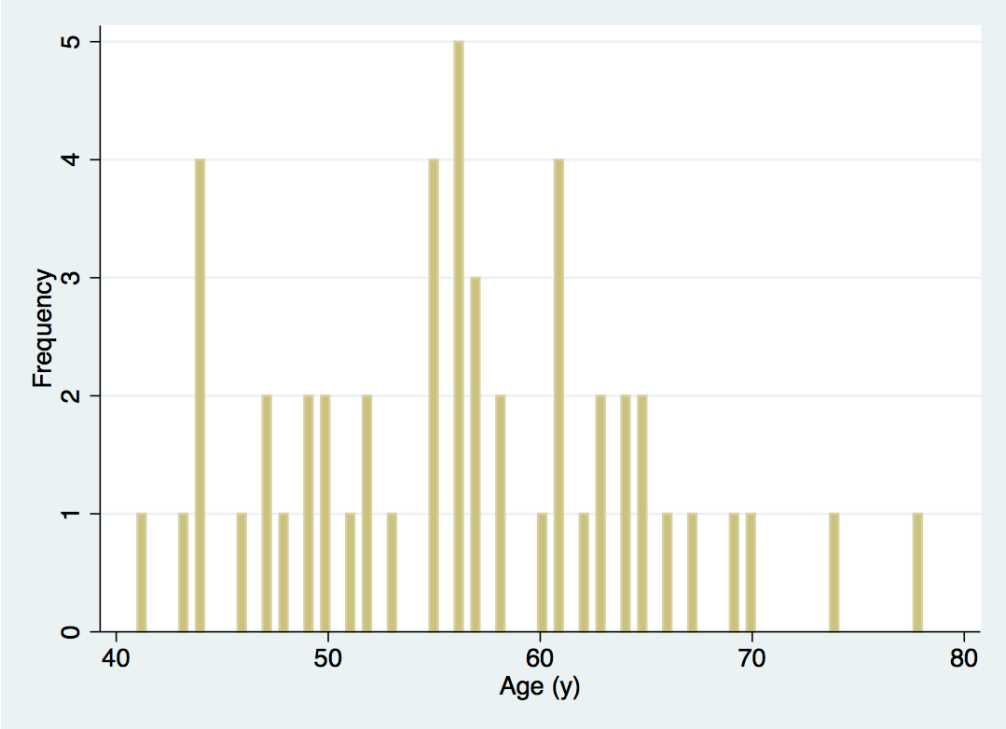

Figure 3. Age distribution (in years) of 50 surgical patients with confirmed rotator cuff tears at baseline.

4.2 Descriptive Analysis

Rotator Cuff Quality of Life Index (RC-QOL) scores of the sample at baseline, reported as means due to the normal distribution of data (Figure 4 and 5), are similar and not statistically different between the overall, surgical, and non-surgical groups (Table 2). This is also true for the baseline score of the 66 patients that also completed the 2-year follow-up questionnaires (Table 2). When comparing scores of the whole baseline sample (n=94) to the 66 patients that also participated at the 2-year interval, RC-QOL mean scores are almost identical with non-surgical patients representing the only group to show a difference from the whole sample. This difference is a mere +2 points out of a possible 100 (Table 2). This indicates that the 66 patients that participated at the 2-year interval were scoring similarly to all 94 patients that were entered into the study at baseline.

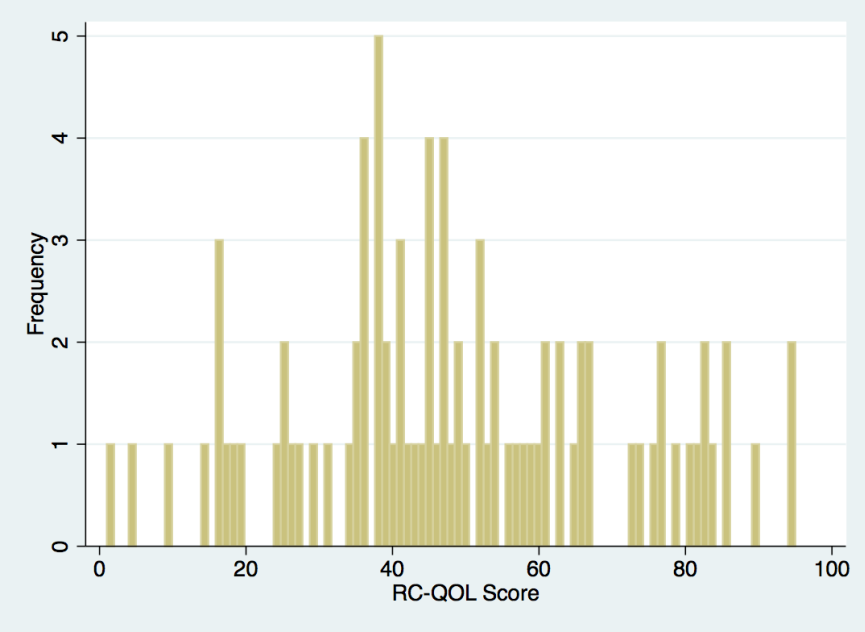

Figure 4. RC-QOL scores of 94 patients with confirmed rotator cuff tears at baseline.

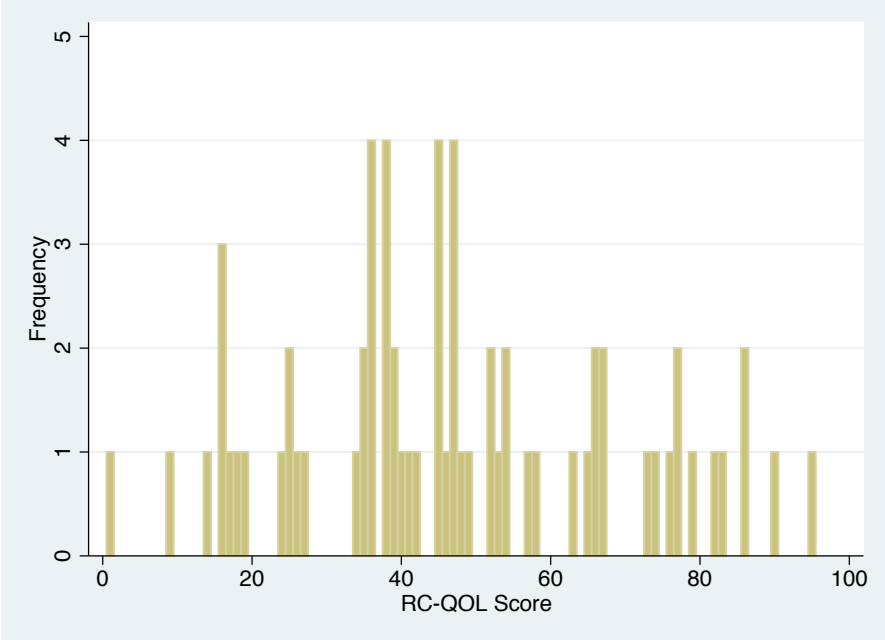

Figure 5. Baseline RC-QOL scores of the 66 patients with confirmed rotator cuff tears that completed 2-year follow-up questionnaire.

Table 2. Baseline RC-QOL scores of the initial sample (n=94) compared to patients that also completed 2-year follow-up questionnaires.

Total Patient Sample (*n*=94)			
Demographic	Overall (*n*=94)	Non-Surgical (*n*=44)	Surgical (*n*=50)
Baseline RC-QOL score (0-100) mean (SD)	47 (22)	51 (21)	43 (22)
Patients in 2-Year Follow-Up (*n*=66)			
Demographic	Overall (*n*=66)	Non-Surgical (*n*=29)	Surgical (*n*=37)
Baseline RC-QOL score (0-100) mean (SD)	47 (22)	53 (20)	43 (23)

4.2.1 Outliers.

Three outliers were identified of the 66 patients at the 2-year follow-up interval. One was identified as a result of the timing of administration, and completion, of the 2-year follow-up RC-QOL and Western Ontario Rotator Cuff Index (WORC). This patient completed questionnaires 1 month post-operatively. It has been shown that change reported from 0-3 months post-operatively in patients that have undergone rotator cuff repairs is not statistically significant in groups similar to those in this study when using the RC-QOL.[25] This indicates that the patient report is unlikely to represent true quality of life status. The second and third outliers provided inconsistent reports in quality of life. One patient reported a change score of +60 points on the RC-QOL while reporting no change on both the 7-point and visual analogue global rating scale (VAS GRS). It is reasonable that a change score as substantial as 60 points out of a possible 100 points, is expected to have a similar representation with respect to both global rating scales. The other patient reported "Somewhat better" on the 7-point GRS and +90 on the VAS GRS, however, only improved by +1 point on the RC-QOL between time points. This change score of 1 point is unlikely to be clinically

relevant if the patient is reporting notable differences on 2 separate global rating scales. All outliers have been removed.

Table 3 provides demographic information of the 2-year follow-up group without outliers. The demographic information and scores are similar between the baseline group and 2-year follow-up group provided in Table 3. Baseline scores in all three groups – Overall, Non-Surgical, and Surgical – show the greatest range of mean scores (Table 3). Median timeline for completed follow-up questionnaires was 27 months following baseline (SD 2; range 22-30 months). The median for 2-year follow-up data was reported due to the non-normal, or left skewed, distribution of data for both the RC-QOL and WORC scores (Figures 6 and 7) as well as RC-QOL and WORC for non-surgical and surgical groups (Figures 8, 9, 10, 11). As shown in Table 3 and Figures 6 and 7, little differences are exhibited between RC-QOL scores at 2-years when looking at the overall group. This is also true when comparing the RC-QOL and WORC scores when separating subjects based on surgical status at the 2-year time interval (Figures 8, 9,10, and 11).

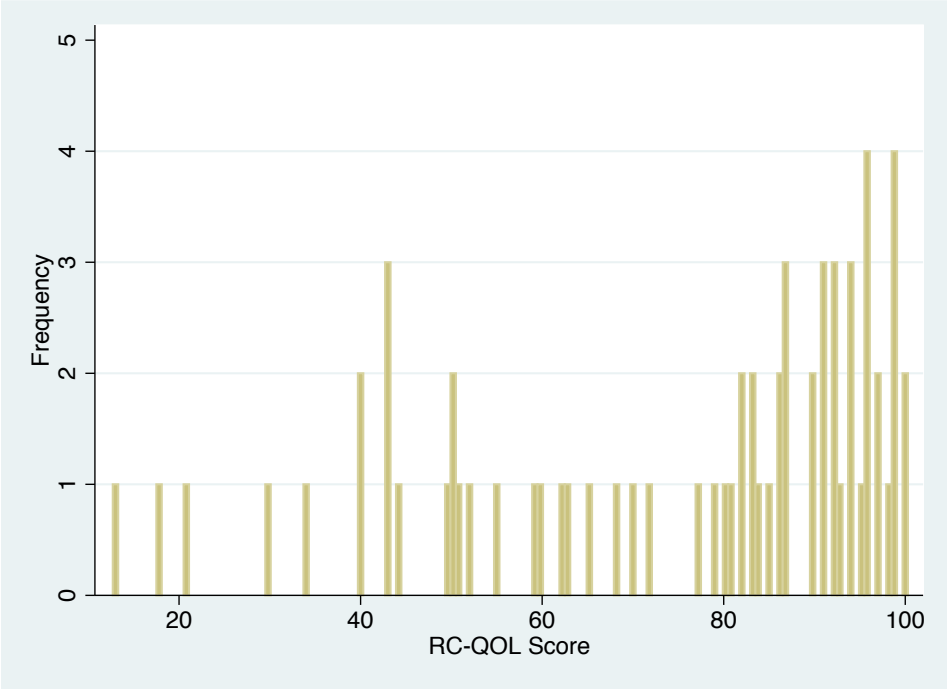

Figure 6. Rotator Cuff Quality of Life Index scores for 66 patients with confirmed rotator cuff tears at the 2-year follow-up interval.

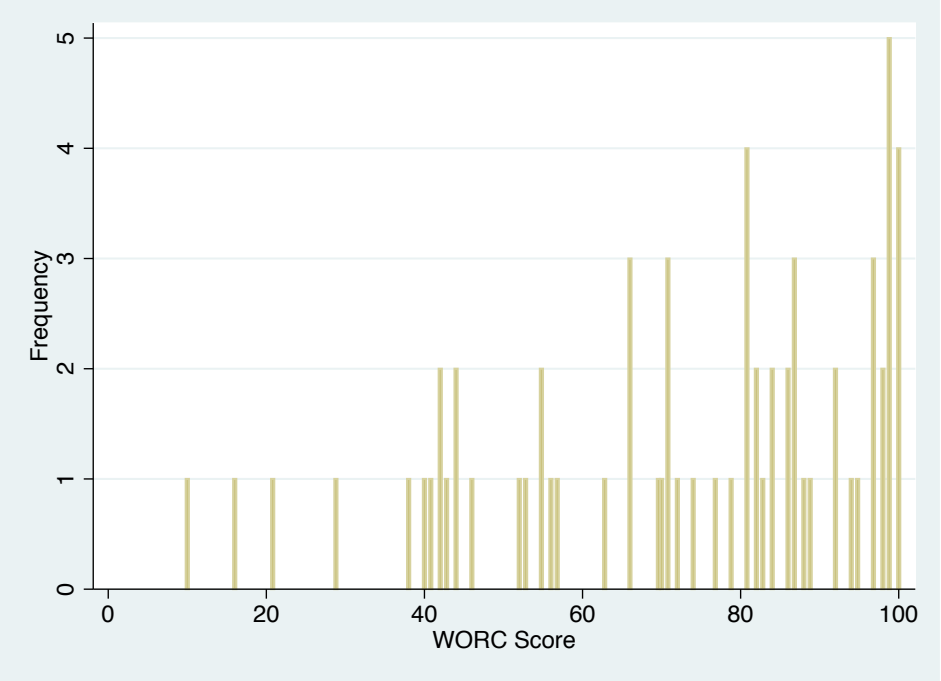

Figure 7. Western Ontario Rotator Cuff Index scores for 66 patients with confirmed rotator cuff tears at the 2-year follow-up interval.

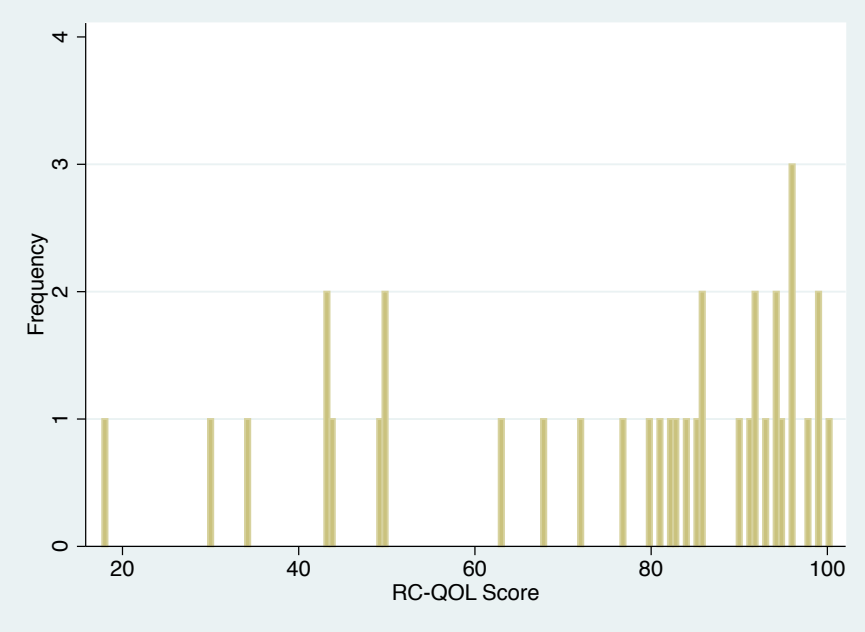

Figure 8. Distribution of RC-QOL scores of 36 surgical patients with confirmed rotator cuff tears at 2-year follow-up interval.

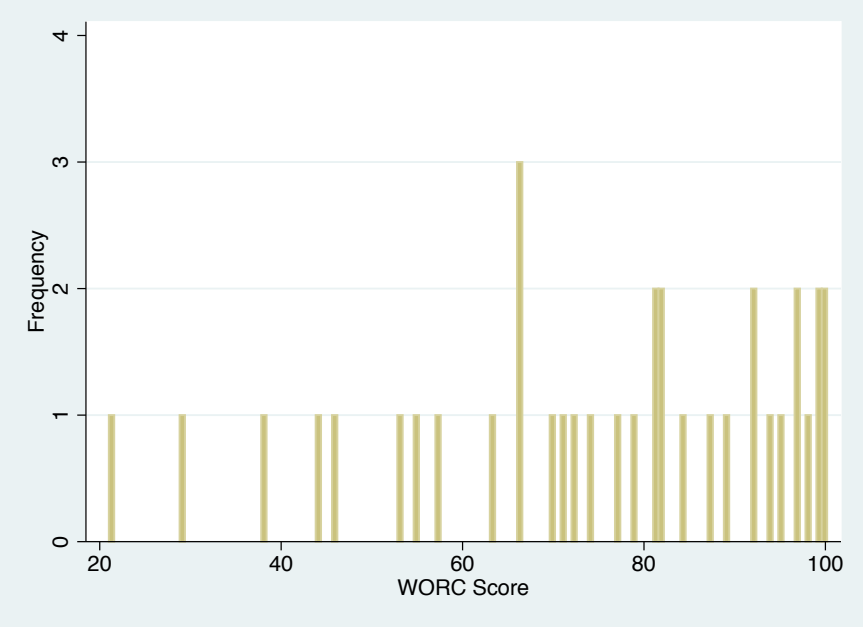

Figure 9. Distribution of WORC scores of 36 surgical patients with confirmed rotator cuff tears at 2-year follow-up interval.

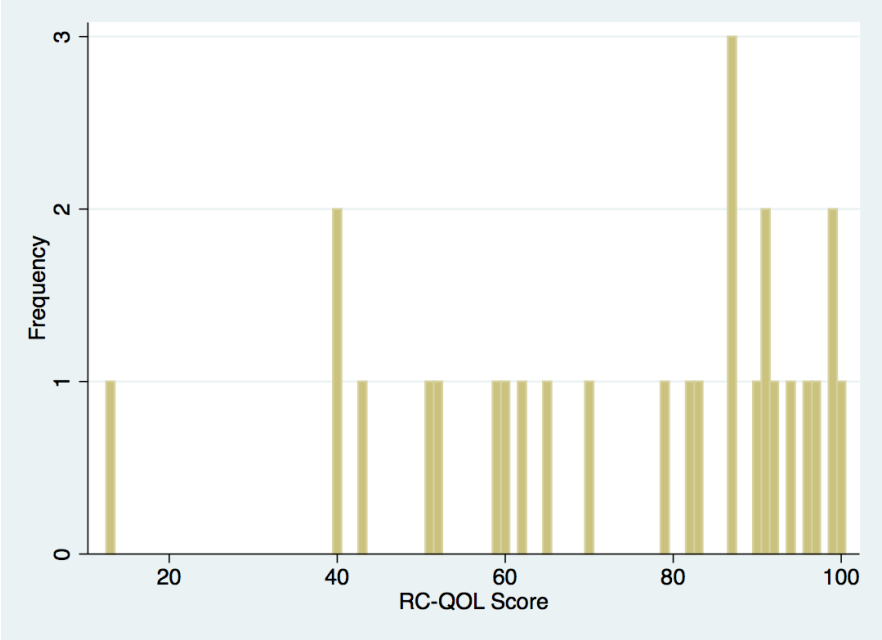

Figure 10. Distribution of RC-QOL scores of 27 non-surgical patients with confirmed rotator cuff tears at 2-year follow-up interval.

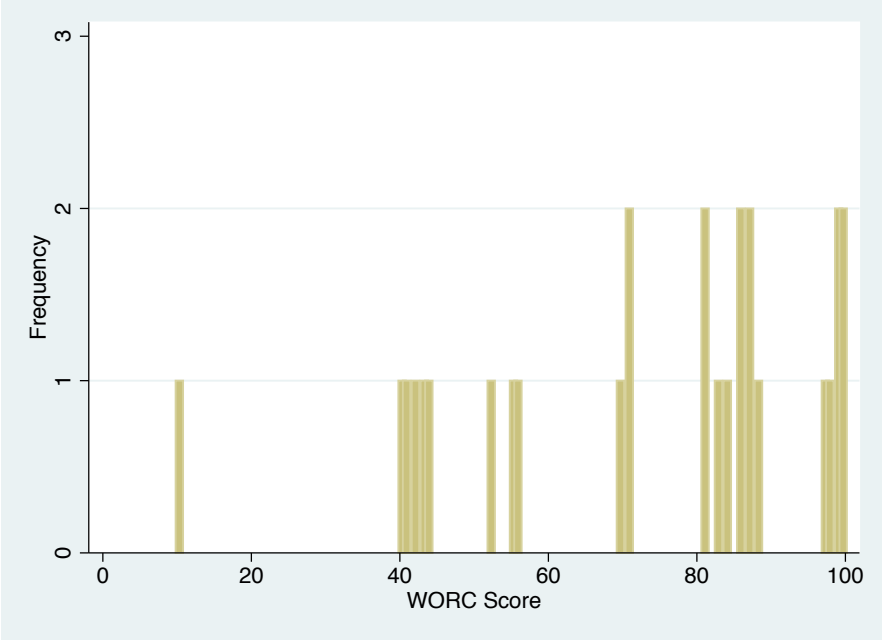

Figure 11. Distribution of WORC scores of 27 non-surgical patients with confirmed rotator cuff tears at 2-year follow-up interval

Table 3. Demographic data and index scores of 63 patients with confirmed rotator cuff tears that completed baseline and 2-year follow-up questionnaires (Rotator Cuff Quality of Life Index and Western Ontario Rotator Cuff Index).

Demographic	Overall (*n*=63)	Non-Surgical (*n*=27)	Surgical (*n*=36)
Age (y) at follow-up, mean (SD)	59 (10)	58 (11)	59 (9)
Sex			
Male (% of *n*)	40 (63%)	13 (48%)	24 (67%)
Female (% of *n*)	26 (37%)	14 (52%)	12 (33%)
Baseline RC-QOL score (0-100)			
mean (SD)	47 (22)	53 (20)	43 (23)
Follow-up (months)			
mean (SD)	27 (2)	27 (2)	27 (2)
2-Year RC-QOL score (0-100)			
median (SD)	84 (23)	83 (23)	85 (23)
2-Year WORC score (0-100)			
median (SD)	81 (23)	81 (24)	80 (21)
RC-QOL change score (raw)			
mean (SD)	28 (28)	22 (24)	33 (30)

4.3 Validity Testing

4.3.1 Content Validity.

Primary Analysis:

Cronbach's α of the RC-QOL at baseline, and the RC-QOL and WORC at the 2-year interval, are listed in Table 4. The nature of work-related questions in the RC-QOL can deem some

responses as not applicable. At the 2-year interval, 24 patients reported work-related questions as not-applicable and the sample size for calculating α for this specific domain dropped to 39 patients. Cronbach's α for the RC-QOL ranged from 0.90 to 0.95 at baseline and 2-year intervals indicating that the RC-QOL possesses uni-dimensionality.

Table 4. Cronbach's Alpha of the Rotator Cuff Quality of Life Index (RC-QOL) at baseline and the RC-QOL and Western Ontario Rotator Cuff Index at the 2-year follow-up interval in up to 63 patients with rotator cuff tears.

Domain	Cronbach's α	Observations (n)
RC-QOL (Baseline)	0.888	63
SYMPTOM	0.902	63
WORK	0.941	63
SPORTS	0.911	63
LIFESTYLE	0.902	63
SOCIAL/EMOTIONAL	0.935	63
RC-QOL (2-Year)	0.910	63
SYMPTOM	0.928	63
WORK	0.940	39
SPORTS	0.941	63
LIFESTYLE	0.919	63
SOCIAL/EMOTIONAL	0.946	63
WORC (2-Year)	0.943	63
SYMPTOM	0.932	63
WORK	0.930	63
SPORTS	0.938	63
LIFESTYLE	0.932	63
EMOTIONAL	0.943	63

Floor and ceiling effects were calculated to further determine content validity of the RC-QOL and WORC. There is no evidence of floor or ceiling effects in the RC-QOL at baseline. As shown in

Table 5, there is some evidence of ceiling effects (<15%) in the WORC SOCIAL/EMOTIONAL scores at the 2-year interval.

Table 5. Floor and ceiling effects of the Rotator Cuff Quality of Life Index and Western Ontario Rotator Cuff Index in up to 94 patients at baseline and 2-year intervals.

	RC-QOL (Baseline)		RC-QOL (2-year)		WORC (2-Year)	
DOMAIN	Floor Effect (%)	Ceiling Effect (%)	Floor Effect (%)	Ceiling Effect (%)	Floor Effect (%)	Ceiling Effect (%)
Overall	0.0	0.0	0.0	3.2	0.0	6.3
SYMPTOM	1.1	1.1	0.0	4.8	0.0	6.3
WORK	6.4	0.0	0.0	0.0	0.0	9.5
SPORTS	5.3	1.1	0.0	9.5	0.0	4.8
LIFESTYLE	0.0	1.1	0.0	6.3	1.6	11.1
SOCIAL/EMOTIONAL	0.0	3.2	0.0	14.3	1.6	19.0

Secondary Analysis:

Cronbach's α of the RC-QOL at baseline, and the RC-QOL and WORC at the 2-year interval, are listed in Table 6. At the 2-year interval, sample sizes dropped to 16 for non-surgical and 23 patients for surgical patients. For surgical patients, Cronbach's α ranged from 0.89 to 0.94 at baseline and 2-year intervals for surgical patients indicating that the RC-QOL possesses uni-dimensionality or all items measure the same processes to the same extent. This range is similar to the WORC at the 2-year interval (0.92-0.95). Cronbach's α ranged from 0.87 to 0.97 when assessing non-surgical patients at baseline and 2-year intervals. This indicates that the RC-QOL possesses uni-dimensionality. This also holds true for the WORC (0.94-0.96).

Table 6. Cronbach's α on Rotator Cuff Quality of Life Index (RC-QOL) at baseline and the RC-QOL and Western Ontario Rotator Cuff Index at the 2-year follow-up interval in up to 36 surgical and up to 27 non-surgical patients with rotator cuff tears.

Domain	**Cronbach α**	
	Non-surgical (*n*)	Surgical (*n*)
RC-QOL (Baseline)	0.871 (27)	0.889 (36)
SYMPTOM	0.885 (27)	0.901 (36)
WORK	0.935 (27)	0.942 (36)
SPORTS	0.892 (27)	0.915 (36)
LIFESTYLE	0.891 (27)	0.900 (36)
SOCIAL/EMOTIONAL	0.929 (27)	0.934 (36)
RC-QOL (2-Year)	0.936 (27)	0.899 (36)
SYMPTOM	0.943 (27)	0.923 (36)
WORK	0.953 (16)	0.932 (23)
SPORTS	0.963 (27)	0.930 (36)
LIFESTYLE	0.944 (27)	0.907 (36)
SOCIAL/EMOTIONAL	0.968 (27)	0.935 (36)
WORC (2-Year)	0.942 (27)	0.946 (36)
SYMPTOM	0.943 (27)	0.924 (36)
WORK	0.943 (27)	0.919 (36)
SPORTS	0.952 (27)	0.925 (36)
LIFESTYLE	0.937 (27)	0.928 (36)
EMOTIONAL	0.957 (27)	0.931 (36)

Floor and ceiling effects were calculated to further determine content validity of the RC-QOL and WORC for non-surgical and surgical groups. As shown in Table 7, there is no evidence of floor or ceiling effects in the RC-QOL at baseline. There is evidence of ceiling effects in both non-surgical and surgical patients using the WORC at the 2-year interval within the SOCIAL/EMOTIONAL domain.

Table 7. Floor and ceiling effects of the Rotator Cuff Quality of Life Index (RC-QOL) at baseline and the RC-QOL and Western Ontario Rotator Cuff Index at the 2-year follow-up interval in up to 36 surgical and up to 27 non-surgical patients with rotator cuff tears.

	RC-QOL (Baseline)				RC-QOL (2-Year)				WORC (2-Year)			
	Non-Surgical (% of *n*=27)		Surgical (% of *n*=36)		Non-Surgical (% of *n*=27)		Surgical (% of *n*=36)		Non-Surgical(% of *n*=27)		Surgical (% of *n*=36)	
	Floor	**Ceiling**	**Floor**	**Ceiling**	**Floor**	**Ceiling**	**Floor**	**Ceiling**	**Floor**	**Ceiling**	**Floor**	**Ceiling**
Overall	0.0	0.0	0.0	0.0	0.0	3.7	0.0	2.8	0.0	0.7	0.0	5.6
SYMPTOM	0.0	3.7	0.0	2.8	0.0	3.7	0.0	5.6	0.0	0.0	0.0	2.8
WORK	11.1	0.0	8.3	0.0	0.0	0.0	0.0	0.0	0.0	11.1	0.0	8.3
SPORTS	7.4	3.7	8.3	0.0	0.0	7.4	0.0	11.1	0.0	11.1	0.0	5.6
LIFESTYLE	0.0	3.7	0.0	0.0	0.0	7.4	0.0	5.6	0.0	11.1	2.8	11.1
SOCIAL/ EMOTIONAL	0.0	11.1	0.0	0.0	0.0	14.8	0.0	13.9	0.0	18.5	2.8	19.4

4.3.2 Criterion Validity.

Primary Analysis:

The relationship between the RC-QOL and WORC scores at the 2-year time interval is visually represented in Figure 12. The Pearson *r* Correlation coefficient indicated a strong positive correlation (0.85, $p<0.001$) between the RC-QOL and WORC scores at the 2-year follow-up interval.[67] Although the Pearson *r* Correlation is commonly used to represent correlation, as shown in Figures 13 and 14, the 2-year data for the RC-QOL and the WORC are not normally distributed – a requirement for a Pearson *r* Correlation. This was also confirmed mathematically using Shapiro-Wilk W test for normal data. The findings of the Shapiro-Wilk W tests are outlined in Table 8. These two findings indicate that the Pearson *r* Correlation is not the most appropriate test for assessing correlation in this data set. Instead, the non-parametric Spearman Rank Correlation

test (r_S), which does not require normal distribution, was used. The Spearman Rank Correlation does require that the data set is monotonic. As shown in Figure 12, the data is monotonically increasing - as the WORC scores increase the RC-QOL scores never decrease. Assessing the RC-QOL and WORC scores using the Spearman Rank Correlation again shows a similar, strong correlation between scores at the 2-year interval (0.88, $p<0.001$) (Table 9). [67]

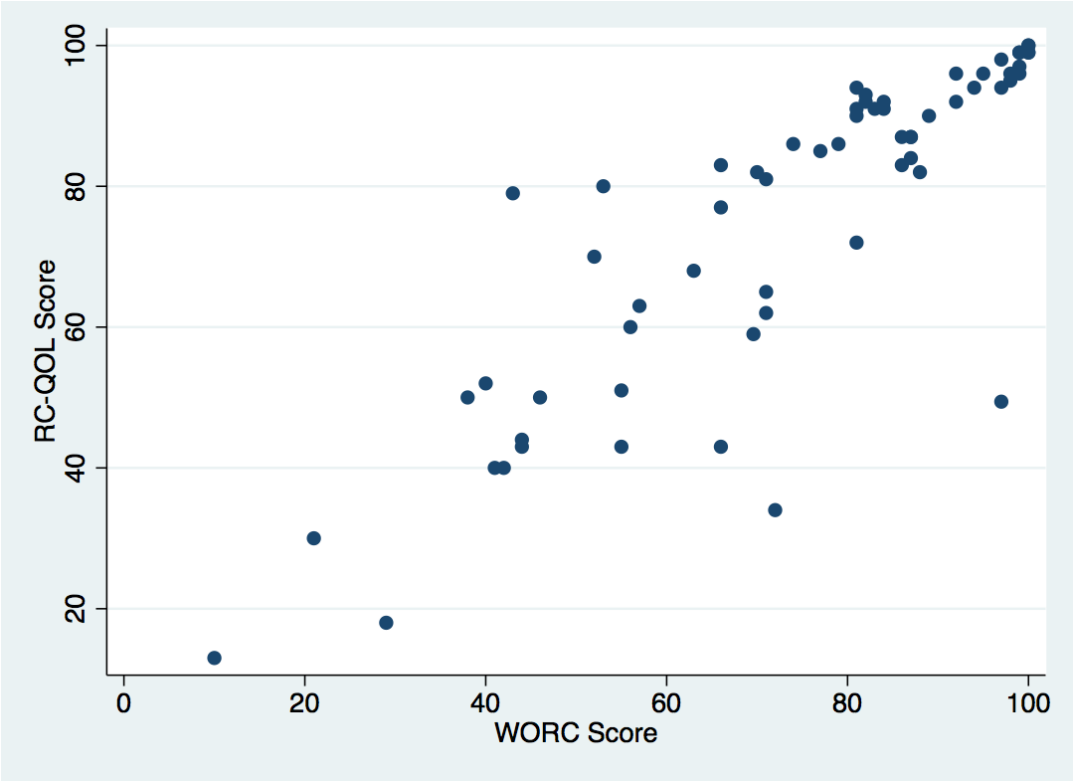

Figure 12. Rotator Cuff Quality of Life Index scores correlated to Western Ontario Rotator Cuff Index scores in 63 patients with confirmed rotator cuff tears at 2-year follow-up interval.

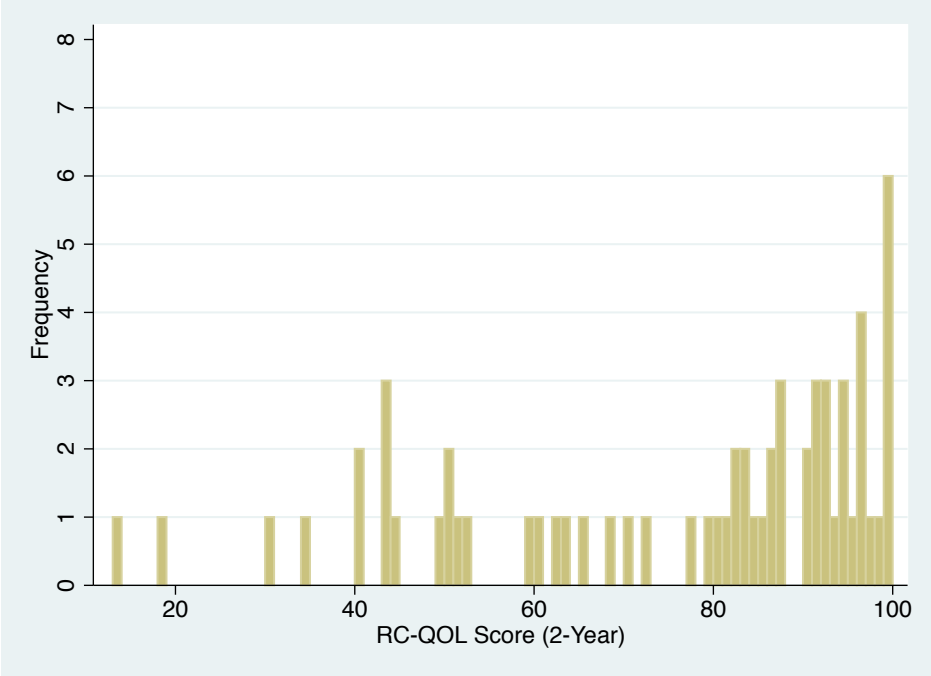

Figure 13. Distribution of Rotator Cuff Quality of Life Index scores of 63 patients with confirmed rotator cuff tears at 2-year follow-up interval.

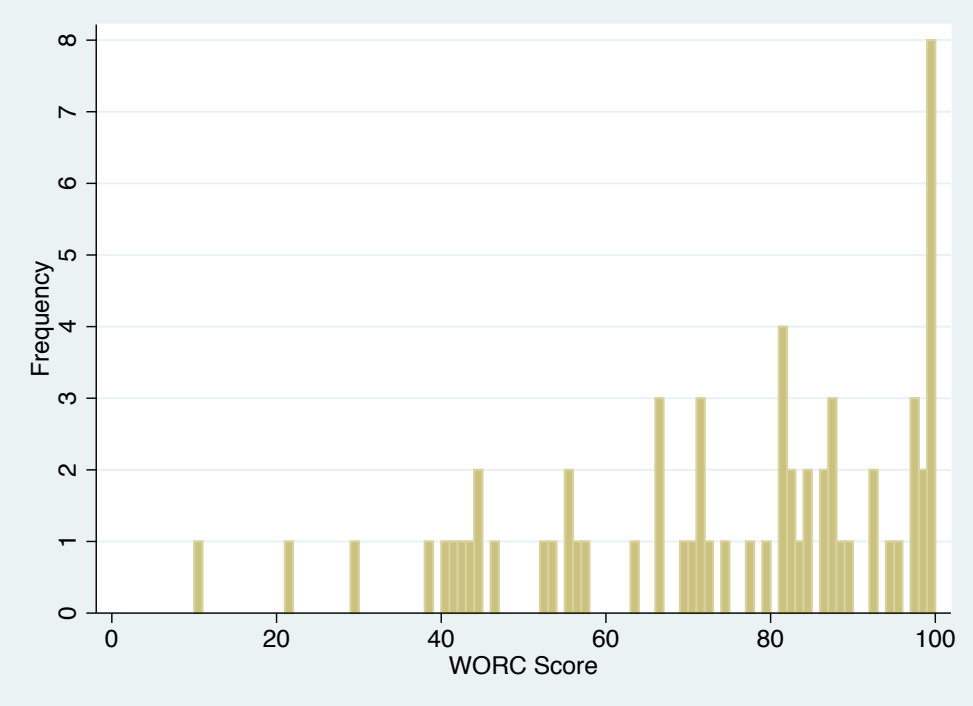

Figure 14. Distribution of Western Ontario Rotator Cuff scores of 63 patients with confirmed rotator cuff tears at 2-year follow-up interval.

Table 8. Shapiro-Wilk W test for normal data in 63 patients with confirmed rotator cuff tears at 2-year follow-up interval.

Shapiro-Wilk W Test for Normal Data (*n*=63)	
RC-QOL	0.88 (p<0.001)
WORC	0.92 (p<0.001)

Table 9. Correlation of Rotator Cuff Quality of Life Index and Western Ontario Rotator Cuff scores at the 2-year time interval using the Pearson r Correlation and Spearman Rank Correlation coefficients.

Group	Correlation	RC-QOL vs WORC
Overall (*n*=63)	Pearson *r*	0.85 (p<0.001)
	Spearman r_S	0.88 (p<0.001)
Non-surgical (*n*=27)	Pearson *r*	0.92 (p<0.0001)
	Spearman r_S	0.90 (p<0.0001)
Surgical (*n*=36)	Pearson *r*	0.80 (p<0.001)
	Spearman r_S	0.85 (p<0.0001)

The Bland-Altman Plot provides a visual representation of the level of agreement between two different measures. This comparison is important because comparing a new PROM with an established one is needed to see whether they agree sufficiently for the new to replace the old.[79] Prior to completing Bland-Altman Plot analyses, the difference scores (WORC minus RC-QOL) were plotted to determine normal distribution. As seen in Figure 15, and confirmed by the Shapiro-Wilk test (Table 10), the difference scores are not normally distributed and a Bland-Altman Plot analysis would not be appropriate for this data set. This is important to note while interpreting the analysis.

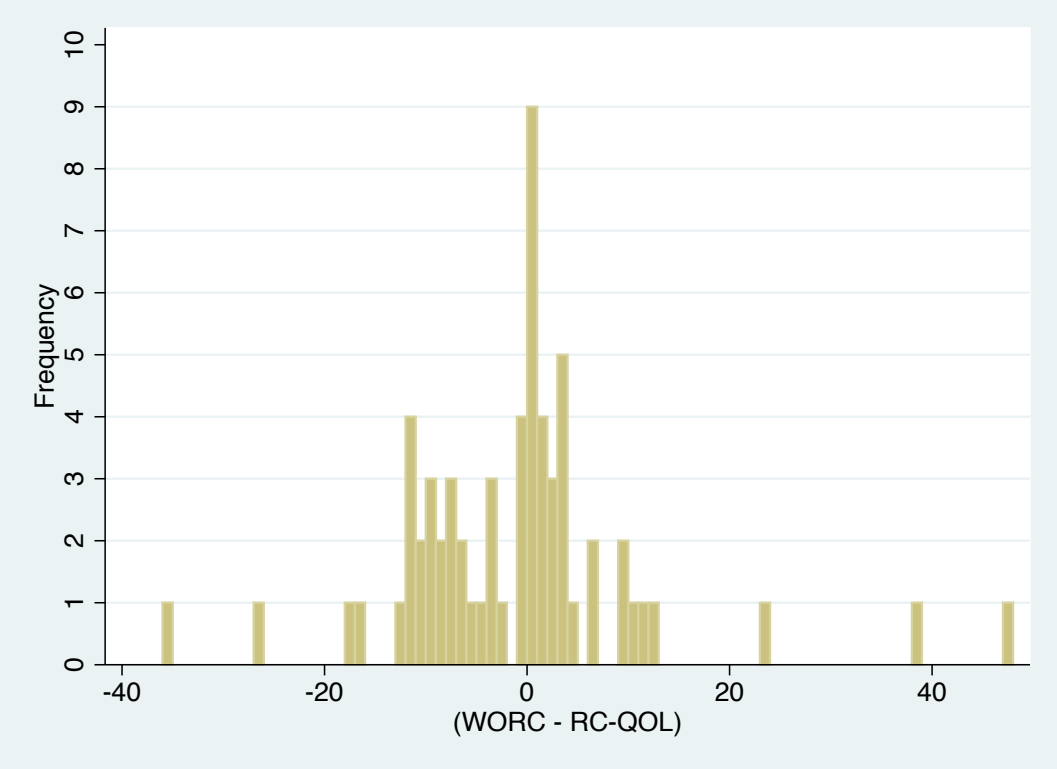

Figure 15. Distribution of difference scores between the Western Ontario Rotator Cuff Index and the Rotator Cuff Quality of Life Index at the 2-Year follow-up period in 63 patients with confirmed rotator cuff tears.

Table 10. Shapiro-Wilk W test for normal data of the difference score between the Western Ontario Rotator Cuff Index and Rotator Cuff Quality of Life Index in 63 patients with confirmed rotator cuff tears at 2-year follow-up interval.

Shapiro-Wilk W Test for Normal Data (*n*=63)	
(WORC-RC-QOL) Scores	0.88 (p<0.001)

As shown in the Bland-Altman plot (Figure 16), WORC scores tend to very slightly overestimate the RC-QOL scores. The distance between the upper and lower limits of agreement range from -26 to +23 and would likely indicate a difference large enough to be clinically important thus indicating poor agreement between the WORC and RC-QOL.[79]

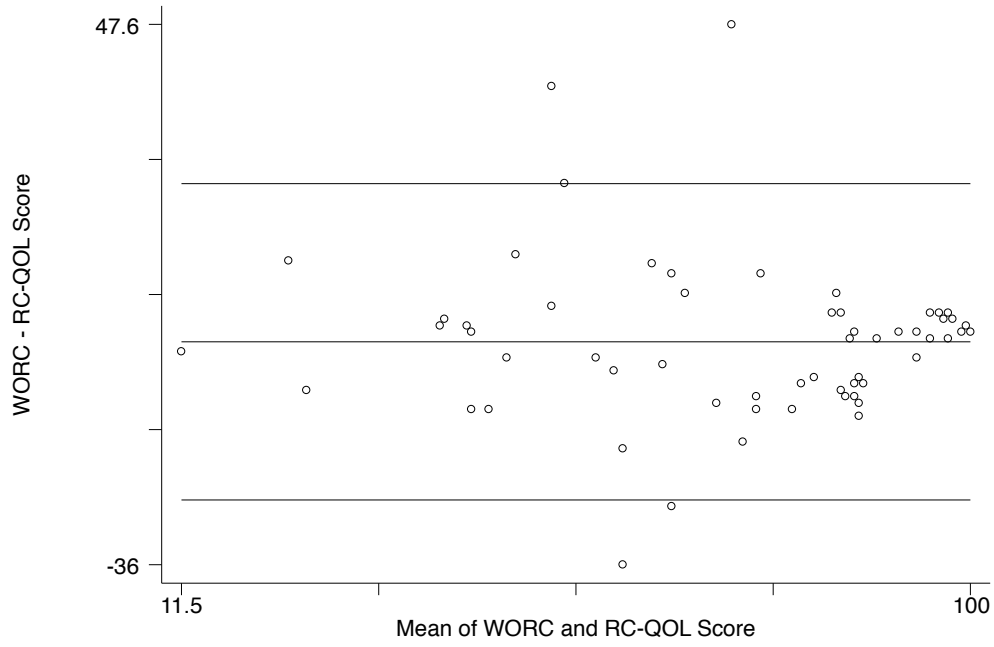

Figure 16. Bland-Altman Plot of Western Ontario Rotator Cuff Index (WORC) scores and Rotator Cuff Quality of Life Index (RC-QOL) score for 63 patients with confirmed rotator cuff tears at 2-year follow-up.

Secondary Analysis:

For surgical patients, the Pearson *r* Correlation indicated a strong positive relationship[67] (0.80, $p<0.001$) between the RC-QOL and WORC scores at the 2-year follow-up interval. Non-surgical patients also displayed a strong positive correlation (0.92, $p<0.0001$). These correlations are visually represented in Figures 17 and 18. Distribution of scores for surgical and non-surgical groups were visually inspected for normal distribution using both the RC-QOL and the WORC (Figures 19-22). The distribution of data for both the RC-QOL and the WORC in surgical and non-surgical patients at this time period are not normal – confirmed again by the Shapiro-Wilk W test for normal data (Table 11). The Spearman Rank Correlation is the preferred analysis. Using the Spearman Rank Correlation, the coefficient still shows a strong correlation between scores at the 2-year interval in both surgical and non-surgical groups, 0.85 ($p<0.0001$) and 0.90 ($p<0.0001$)

respectively, when comparing the RC-QOL and WORC (Table 9).[67] As in the primary analysis, all assumptions were met for this correlation coefficient.

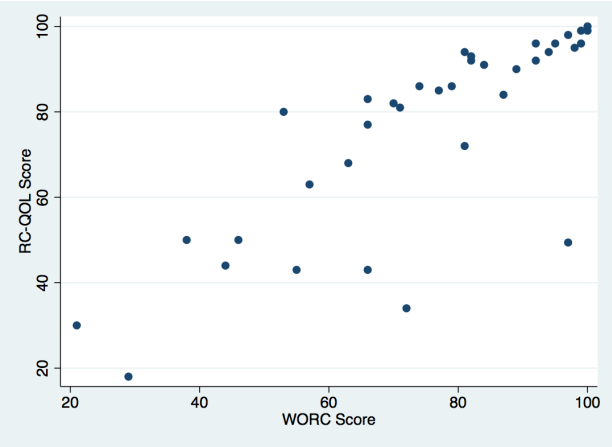

Figure 17. Rotator Cuff Quality of Life Index scores correlated to Western Ontario Rotator Cuff Index scores in 36 surgical patients with confirmed rotator cuff tears at 2-year follow-up interval.

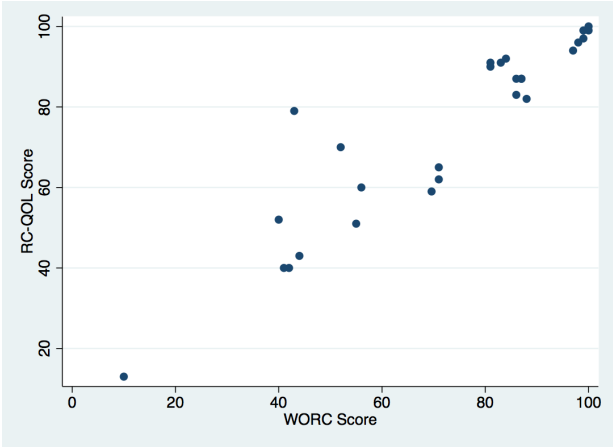

Figure 18. Rotator Cuff Quality of Life Index scores correlated to Western Ontario Rotator Cuff scores in 27 non-surgical patients with confirmed rotator cuff tears at 2-year follow-up interval.

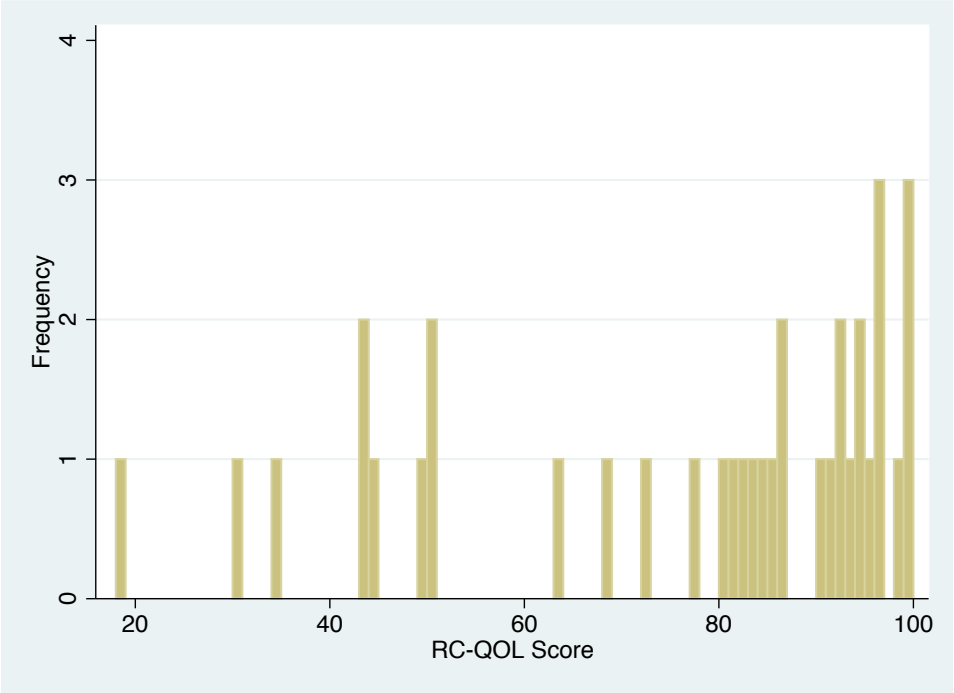

Figure 19. Distribution of Rotator Cuff Quality of Life Index scores of 36 surgical patients with confirmed rotator cuff tears at 2-year follow-up interval.

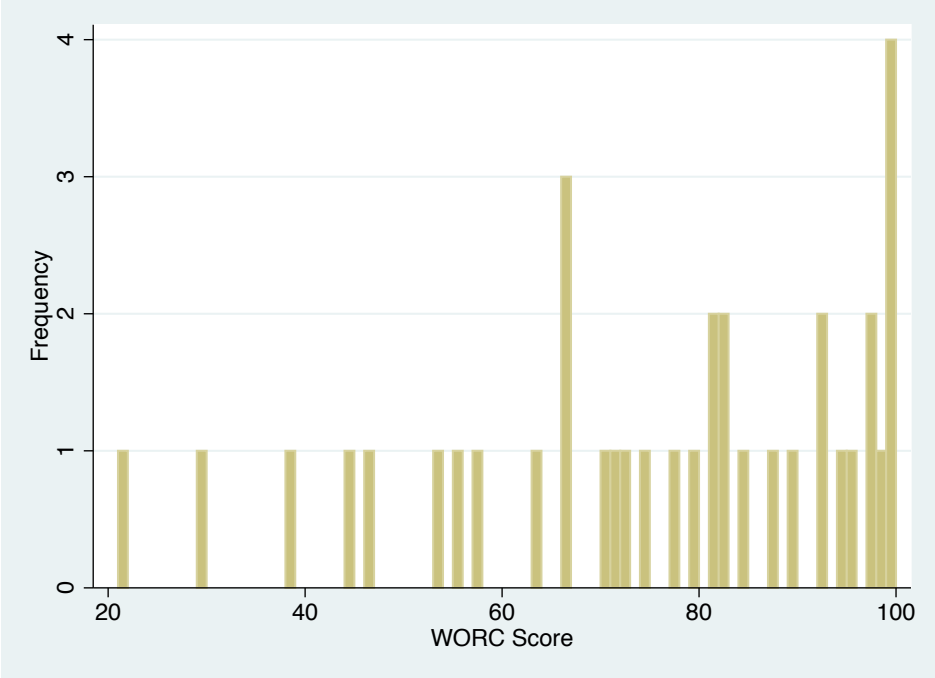

Figure 20. Distribution of Western Ontario Rotator Cuff Index scores of 36 surgical patients with confirmed rotator cuff tears at 2-year follow-up interval.

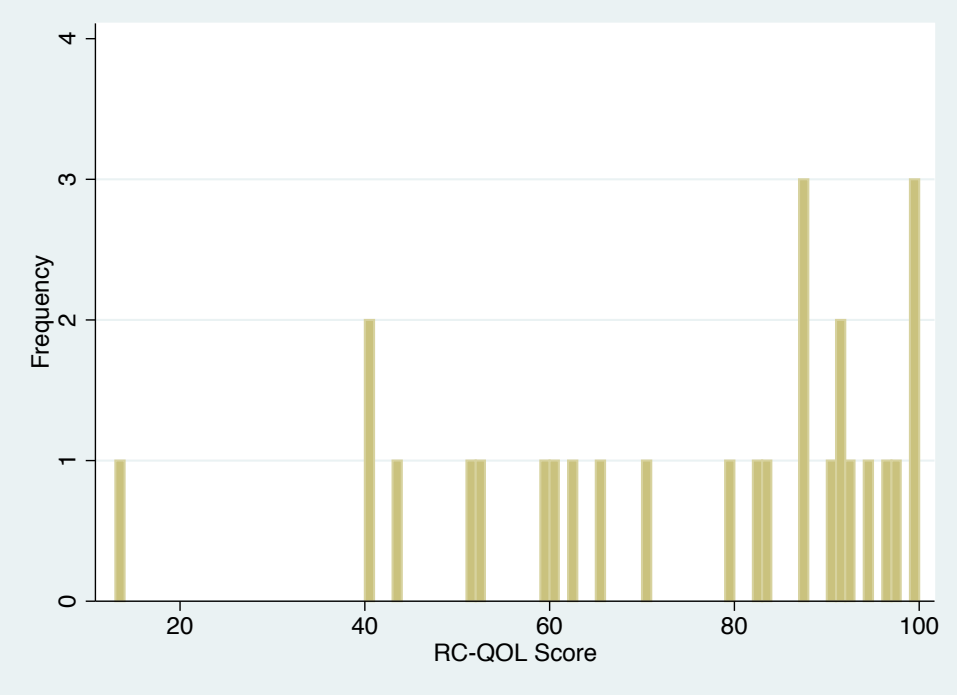

Figure 21. Distribution of Rotator Cuff Quality of Life Index scores of 27 non-surgical patients with confirmed rotator cuff tears at 2-year follow-up interval.

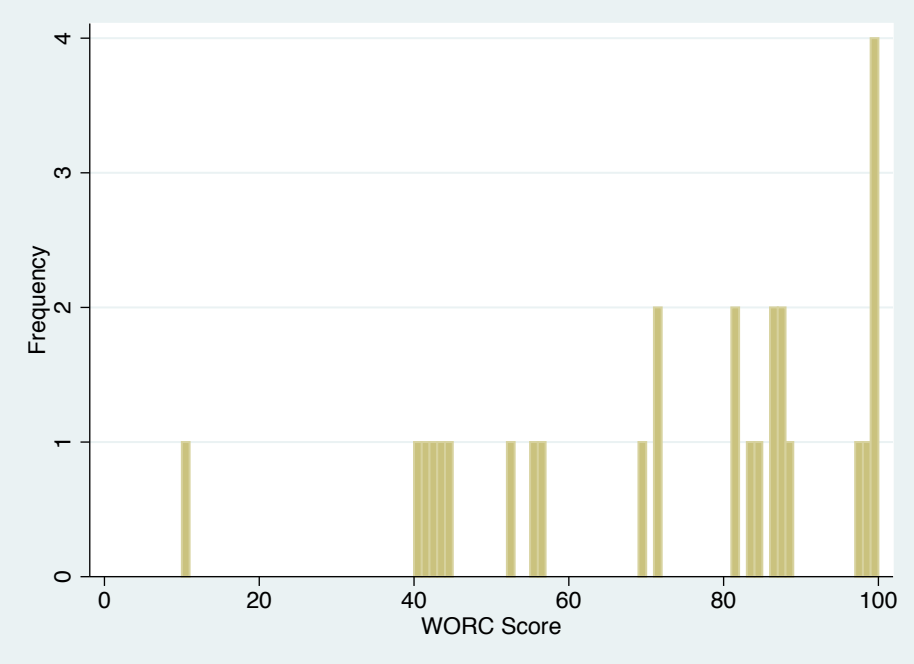

Figure 22. Distribution of Western Ontario Rotator Cuff Index scores of 27 non-surgical patients with confirmed rotator cuff tears at 2-year follow-up interval

Table 11. Shapiro-Wilk W test for normal data in surgical and non-surgical patients with confirmed rotator cuff tears at 2-year follow-up interval.

Shapiro-Wilk W Test for Normal Data		
Non-Surgical (n=27)	RC-QOL (2-Yr)	0.89 ($p<0.01$)
	WORC	0.90 ($p<0.01$)
Surgical (n=36)	RC-QOL (2-Yr)	0.88 ($p<0.001$)
	WORC	0.92 ($p<0.001$)

4.4 Determination of Stable and Change Patients

The change group was defined as patients who were included in the extremes of the 7-point GRS. These were patients reported either "Very much worse" or "Very much better" on the scale. Similar to Beninato et al, patients that reported "A little worse", "No change", and "A little bit better" were considered 'unchanged' or 'stable' as there would be no reported change by the patient or the change would be perceived as little to none.[118] In calculating MCID, patients that reported "Somewhat worse" or "Somewhat better" were defined as those patients who reported the smallest detectable change as those categories were the next available point above/below responses that were considered stable. Frequency of responses using the 7-Point Global Rating Scale (GRS) is outlined in Table 12.

Table 12. Frequency of responses on the 7-Point Global Rating Scale of patients with confirmed rotator cuff tears at 2-year follow-up interval.

7-Point Global Rating Scale	Overall group (*n*=63)	Non-surgical group (*n*=28)	Surgical group (*n*=36)
Very much worse	2	1	1
Somewhat Worse	4	3	1
A little bit worse	1	1	0
No change	7	5	2
A little bit better	2	2	0
Somewhat better	14	7	7
Very much better	35	9	26

4.5 Responsiveness

4.5.1 Descriptive Analysis.

RC-QOL Change scores are normally distributed which is confirmed visually in Figure 23 as well as using the Shapiro-Wilk W test (0.99, $p<0.69$). The summary of change scores for the domains of RC-QOL are listed in Table 13. Mean change scores were consistently higher in all domains for surgical patients when comparing scores to non-surgical patients (Figure 24).

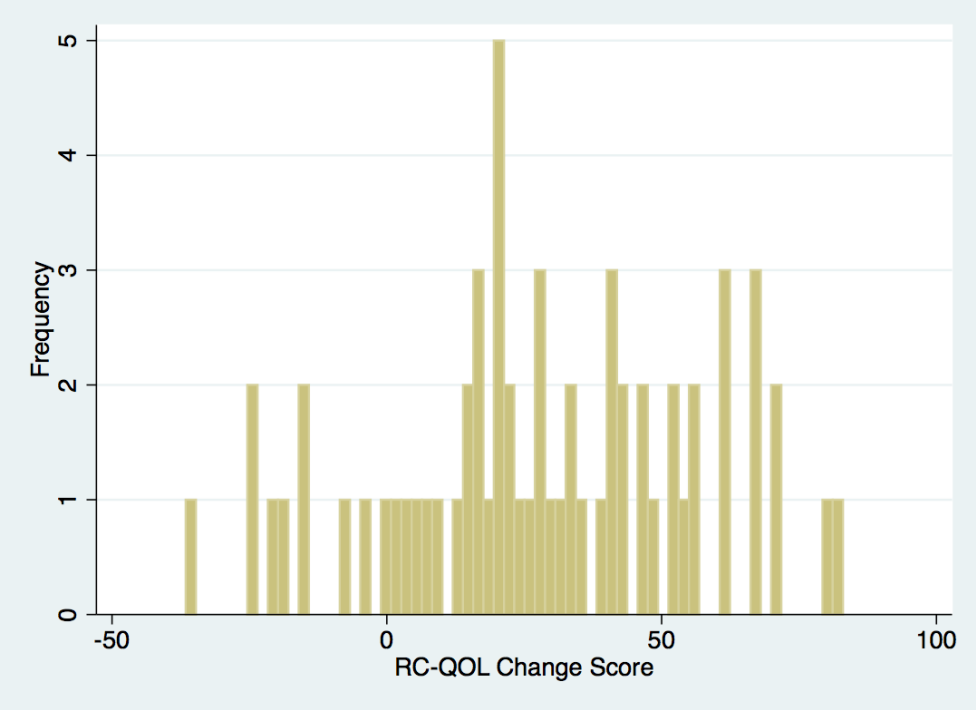

Figure 23. Frequency distribution of Rotator Cuff Quality of Life Index change scores (raw) in patients with confirmed rotator cuff tears from approximately 2-years following baseline assessment.

Table 13. Summary of absolute Rotator Cuff Quality of Life Index change scores from baseline to 2-year follow-up for patients with confirmed rotator cuff tears.

Domain Change Score	**Overall Absolute Mean Change Score ± SD (*n; 95% CI*)**	**Non-Surgical Absolute Mean Change Score ± SD (*n; 95% CI*)**	**Surgical Absolute Mean Change Score ± SD (*n; 95% CI*)**
Symptom	34 ± 23 (63; 28-40)	25 ± 23 (28; 19-33)	40 ± 26 (36; 31-48)
Work	30 ± 21 (40; 24-37)	27 ± 17 (17; 18-36)	33 ± 24 (23; 23-44)
Sport	40 ± 26 (63; 33-46)	32 ± 22 (28; 23-40)	47 ± 29 (36; 37-56)
Lifestyle	40 ± 25 (63; 34-46)	35 ± 22 (28; 26-43)	44 ± 27 (36; 35-54)
Social/Emotional	25 ± 20 (63; 20-30)	20 ± 17 (28; 13-26)	30 ± 21 (36; 23-37)
RC-QOL	33 ± 21 (63; 27-38)	26 ± 18 (28; 19-33)	38 ± 23 (36; 30-46)

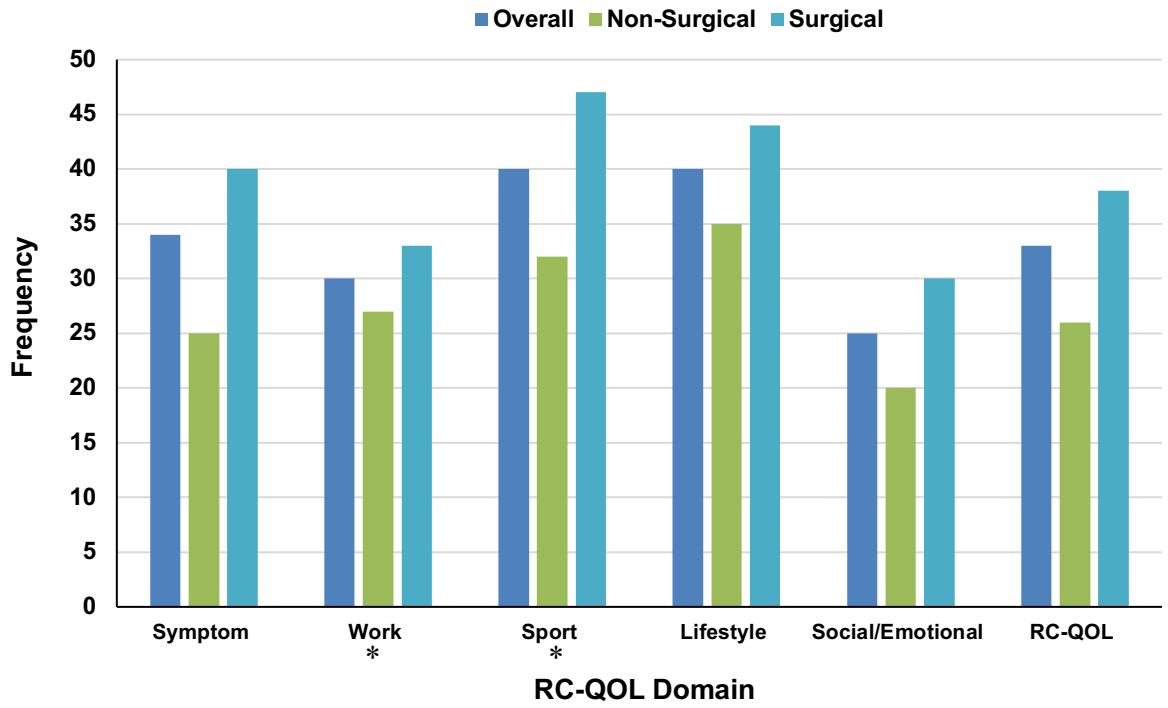

Figure 24. Rotator Cuff Quality of Life Index change scores (absolute values) from baseline to 2-year follow-up for patients with confirmed rotator cuff tears.

** Domains were not significantly different (p>0.05).*

4.5.2 Standardized Response Mean.

Primary analysis:

Distribution-based methods of responsiveness are techniques that use statistical measures of spread of the data to calculate the ability to detect change. Standardized response mean (SRM) was calculated to represent distribution-based methods using standard deviation of the sample (*s*). This calculation was done using the following equation:

Equation 1. Standardized response mean equation for calculating important difference.[119]

$$SRM = \frac{\bar{x}_{post} - \bar{x}_{pre}}{s_{change}}$$

Calculations using 63 observations provided an SRM of 0.99. This represents a large effect size or large difference between baseline and 2-year follow-up scores.[120]

Secondary analysis:

SRM was calculated for both surgical (*n*=36) and non-surgical groups (n=27). Non-surgical and surgical groups provided an SRM of 0.91 and 1.09 respectively. Both groups represent a large effect size.[120] SRM for all groups is outlined in Table 12.

Table 14. Standardized Response Mean calculations for patients with confirmed rotator cuff tears over a 2-year time period.

Group (*n*)	SRM
Overall (63)	0.99
Non-surgical (27)	0.91
Surgical (36)	1.09

4.5.3 Gyatt's Responsiveness Index.

Primary Analysis:

Minimal clinically important difference (MCID) values are required for calculating the Guyatt's Responsiveness Index (GRI) and differ depending on anchor-based or distribution-based methods. An anchor-based method of calculating MCID can be done using the smallest difference between baseline and posttest that represented meaningful change in a group using the anchor-based method of the 7-point GRS.[67,115] In this study, patients reporting "Somewhat worse" or "Somewhat better" on the 7-point GRS (Appendix B) were used to represent the group that reported the smallest meaningful change. This use of an external anchor in combination with the statistical spread of the data provides a mixed approach to responsiveness. In absence of an external

anchor, or for comparative purposes, MCID can be calculated using a distribution-based approach using the mean change scores.[67] The GRI was calculated using both mixed (GRI_{Mixed}) and distribution-based ($GRI_{Distribution}$) methods and results are outlined in Table 15. These calculations were done using the following equation:

Equation 2. Guyatt's Responsiveness Index equation for calculating important difference.[115]

$$GRI = \frac{MCID}{\sqrt{2 * MS_E}}$$

GRI_{Mixed} was calculated using an MCID of 13 points. This provided a GRI of 0.48, a small effect.[120] $GRI_{Distribution}$ was calculated using an MCID representing mean change scores (27.97 points). $GRI_{Distribution}$ was calculated as 1.03, a large effect.[116,120] The denominator representing the variation of scores for stable patients is not statistically significant ($p<0.49$).

Secondary Analysis:

The nature of the GRI requires information on the spread of data in patients that are considered 'unchanged' or 'stable'. Of the surgical patients at the 2-year interval, only one patient reported as stable. As a result, the author was unable to calculate variation in data and consequentially unable to determine the GRI for surgical patients. The GRI was re-calculated for non-surgical patients. Using both mixed- and distribution-based methods, results for non-surgical patients are outlined in Table 15. Using the same cut-off points as in the primary analysis, GRI_{Mixed} was calculated using an MCID of 13 points. This provided a GRI of 0.43, a small effect.[120] $GRI_{Distribution}$ was calculated using an MCID representing mean change scores (26.85 points). $GRI_{Distribution}$ was calculated as 0.89, a large effect.[116,120] The denominator representing the variation of scores for stable patients is not statistically significant ($p<0.41$).

Table 15. Guyatt's Responsiveness Index calculations of the Rotator Cuff Quality of Life Index using mixed- and distribution-based methods in up to 63 patients with confirmed rotator cuff tears.

Group (*n*)	GRI Method	MCID	MS_E of Stable Patients	GRI
Overall (63)	GRI_{Mixed}	13	371.07 (p<0.49)	0.48
	$GRI_{Distribution}$	27.97		1.03
Non-surgical (27)	GRI_{Mixed}	13	451.33 (p<0.41)	0.43
	$GRI_{Distribution}$	26.85		0.89

4.5.4 Global Rating Scale Correlation

Primary Analysis:

An anchor-based method of determining responsiveness compares changes in scores with an external marker as reference.[67,92] The distribution of RC-QOL change scores is shown in Figure 25. With the data's normal distribution, confirmed by the Shapiro-Wilk W test (0.98, p<0.49), a correlation using Pearson *r* Coefficient calculation was completed between the 7-Point GRS and raw RC-QOL change scores as well as the VAS GRS and the raw RC-QOL change scores. The correlation between the 7-Point GRS and raw RC-QOL change scores is 0.47 (p<0.001) (Table 16). This represents a fair positive relationship. The correlation between the VAS GRS and raw RC-QOL change scores is 0.45 (p<0.0001) (Table 16). This represents a fair positive relationship (p<0.0002). These correlations are visually represented in Figures 26 and 27.

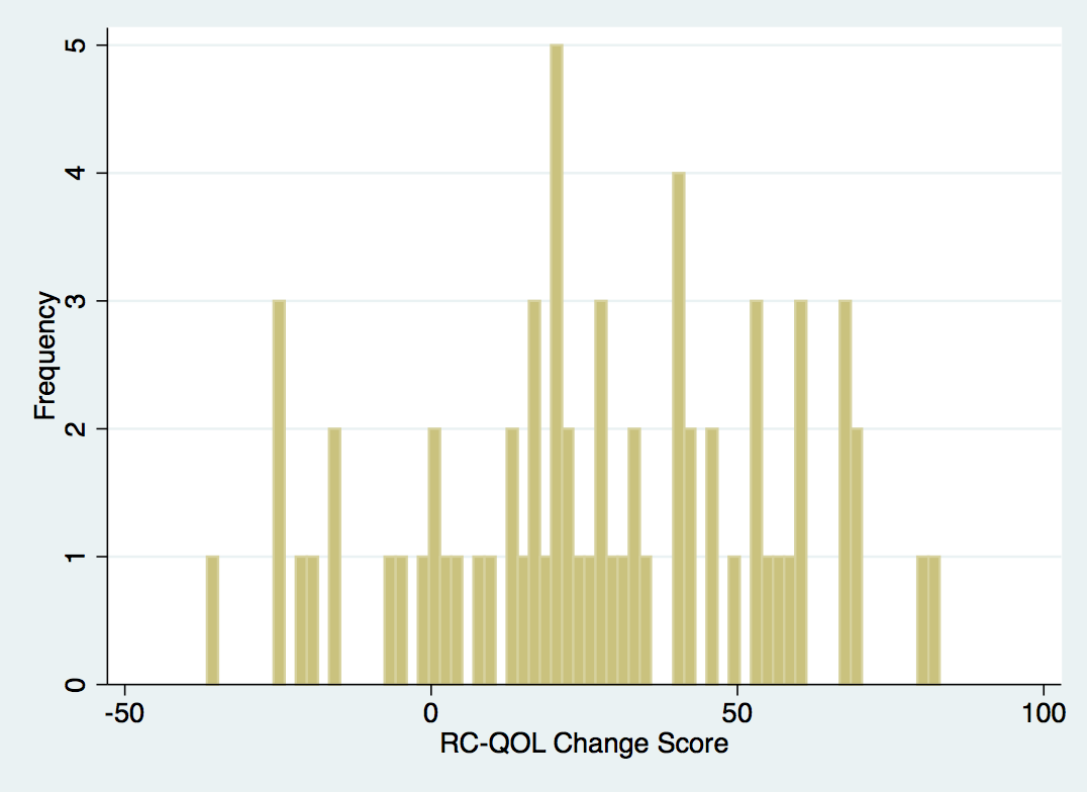

Figure 25. Distribution of Rotator Cuff Quality of Life Index Change Score in 63 patients with confirmed rotator cuff tears.

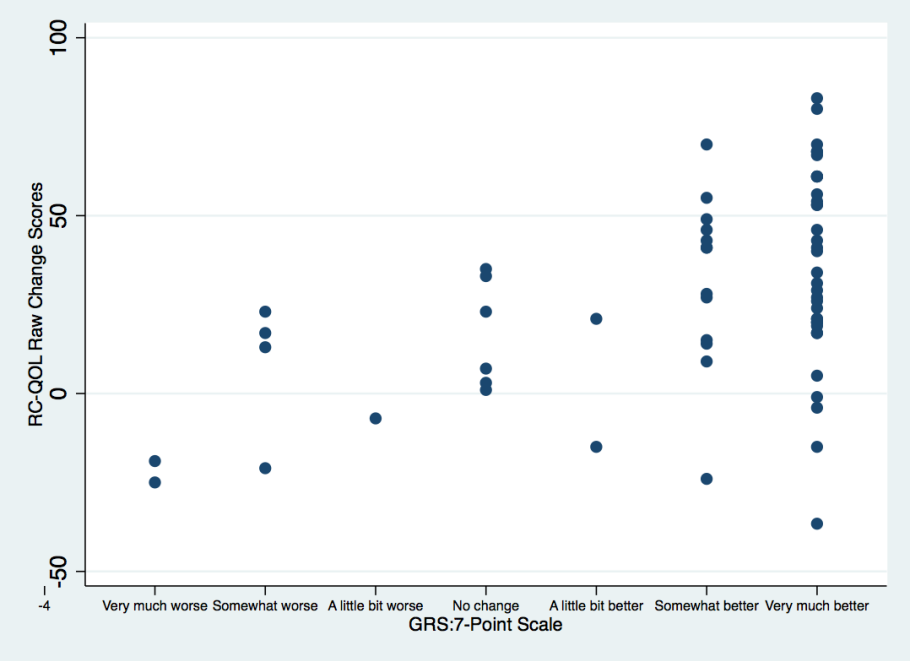

Figure 26. Raw Rotator Cuff Quality of Life Index change score between 2-year time intervals versus the 7-point global rating scale in patients with rotator cuff tears.

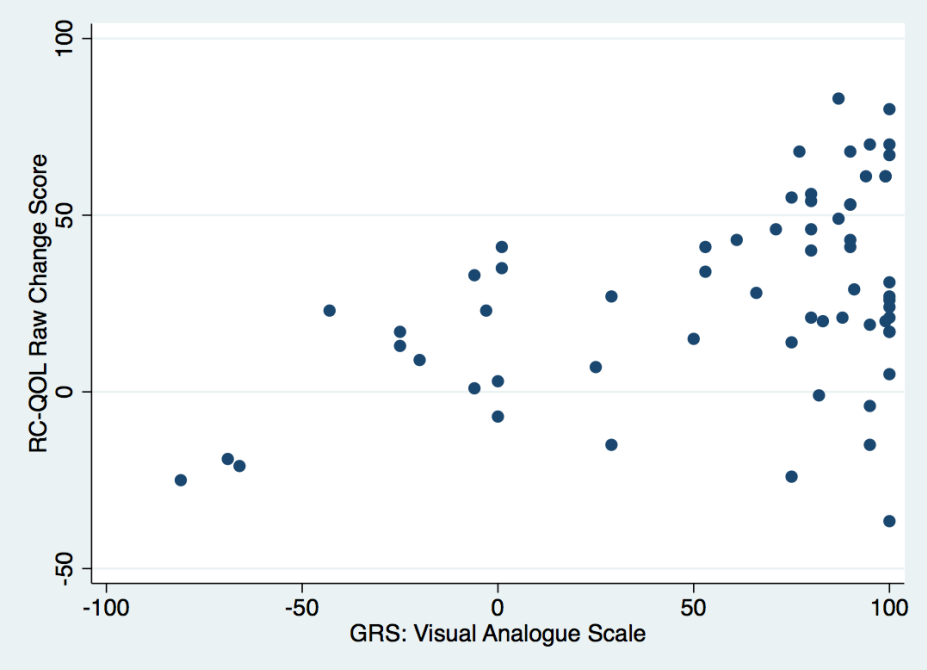

Figure 27. Raw Rotator Cuff Quality of Life Index change score between 2-year time intervals versus the visual analogue global rating scale in patients with rotator cuff tears.

Table 16. Correlation of raw Rotator Cuff Quality of Life Index change scores over a 2-year period and the 7-point and visual analogue global rating scales.

Group (*n*)	Global Rating Scale	Correlation (*r*)
Overall (63)	7-Point	0.47 ($p<0.001$)
	VAS	0.45 ($p<0.0001$)
Non-surgical (27)	7-Point	0.45 ($p<0.02$)
	VAS	0.44 ($p<0.02$)
Surgical (36)	7-Point	0.45 ($p<0.0056$)
	VAS	0.42 ($p<0.0111$)

Secondary Analysis:

A correlation using Pearson *r* Coefficient calculation was completed between the 7-Point GRS and raw RC-QOL change scores as well as the VAS GRS and the raw RC-QOL change scores for both surgical and non-surgical patients. The correlation between the 7-Point GRS and raw RC-QOL change scores is 0.45 ($p<0.01$) for surgical patients (Table 16). This represents a positive, fair relationship.[67] The correlation between the VAS GRS and raw RC-QOL change scores for surgical patients is 0.42 ($p<0.01$) (Table 16). This represents a positive, fair relationship. These correlations are visually represented in Figures 28 and 29.

The correlation between the 7-Point GRS and raw RC-QOL change scores is 0.45 ($p<0.02$) for non-surgical patients. This represents a positive, fair relationship.[67] The correlation between the VAS GRS and raw RC-QOL change scores is 0.44 ($p<0.02$). This represents a positive, fair relationship ($p<0.0002$). These correlations are visually represented in Figures 30 and 31.

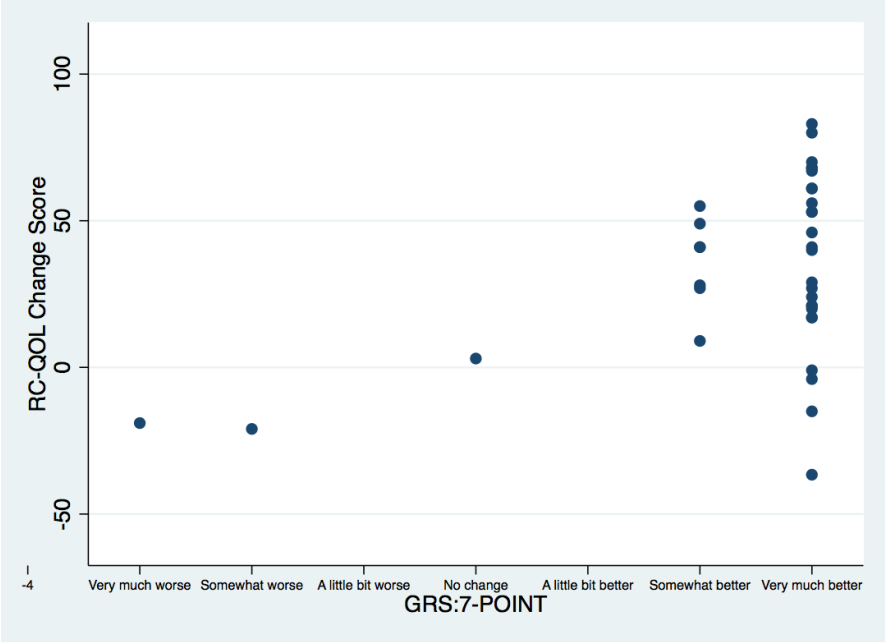

Figure 28. Raw Rotator Cuff Quality of Life Index change score between 2-year intervals versus the 7-point global rating scale in surgical patients with rotator cuff tears.

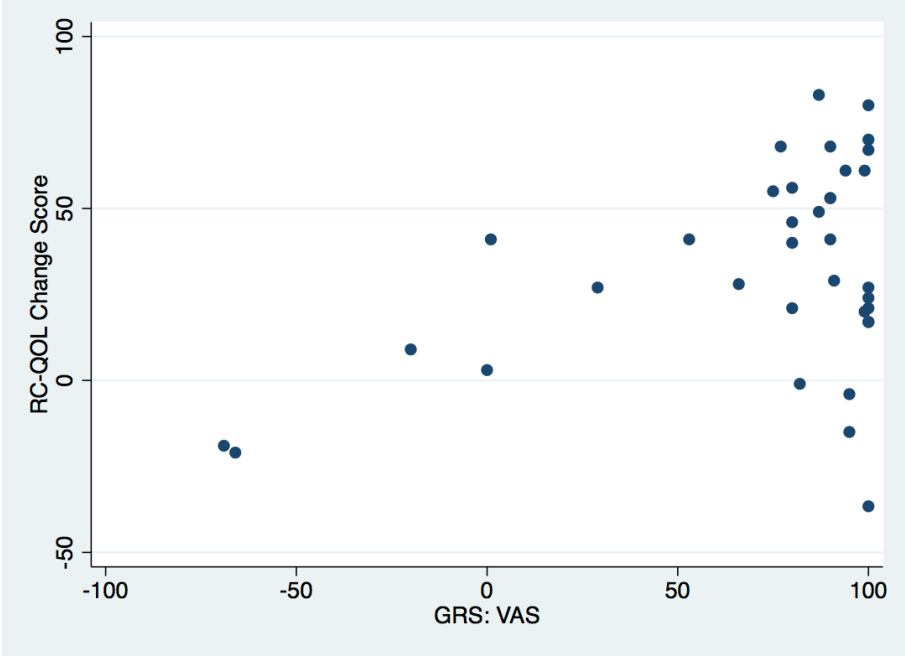

Figure 29. Rotator Cuff Quality of Life Index change score between 2-year intervals versus the visual analogue global rating scale in surgical patients with rotator cuff tears.

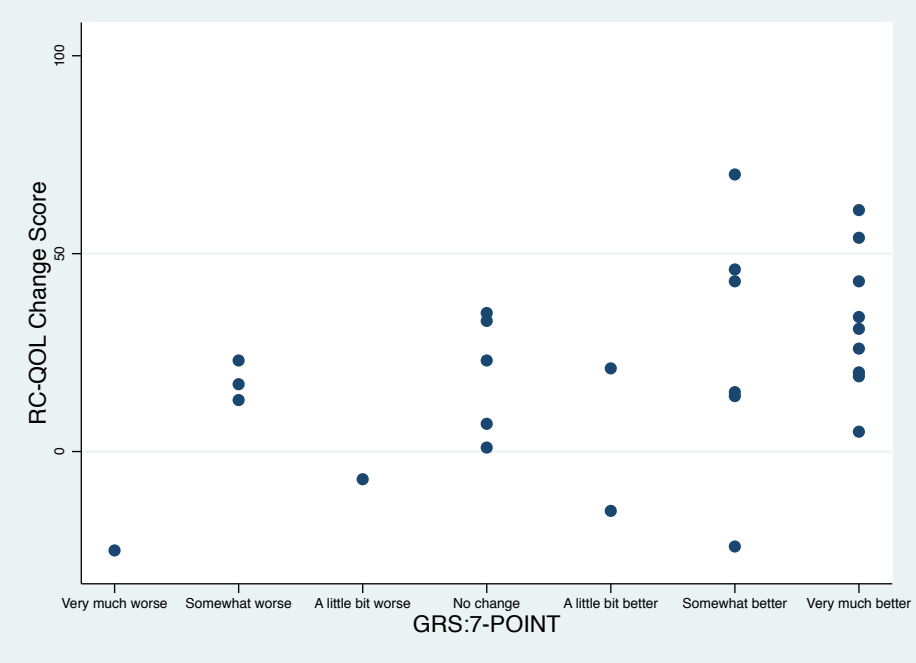

Figure 30. Raw Rotator Cuff Quality of Life Index change score between 2-year intervals versus the 7-point global rating scale in non-surgical patients with rotator cuff tears.

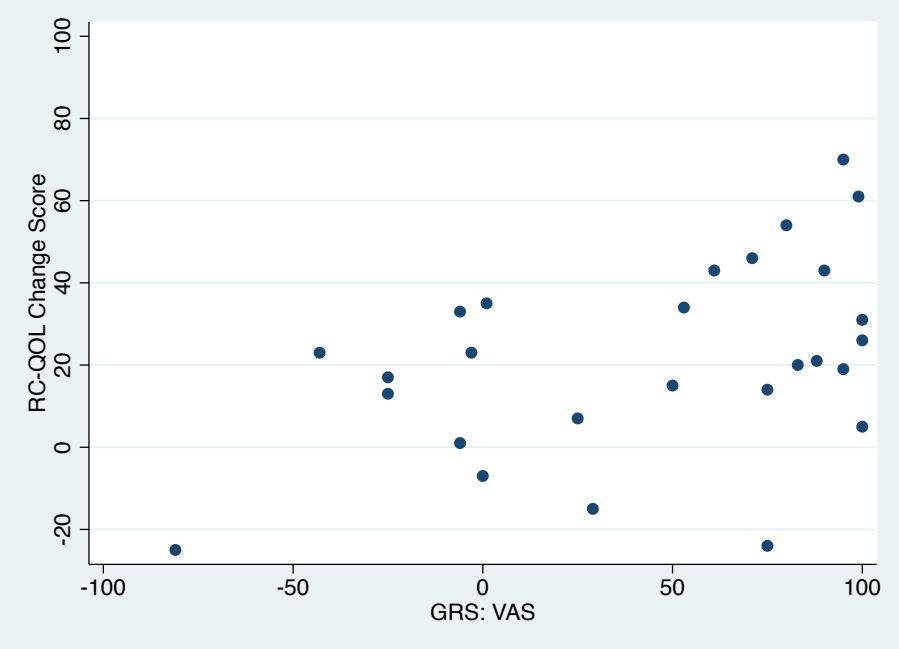

Figure 31. Raw Rotator Cuff Quality of Life Index change score between 2-year intervals versus the visual analogue global rating scale in non-surgical patients with rotator cuff tears.

Chapter 5 Discussion

Before a health-related patient-reported outcome measure (HR-PROM) can be used in research or clinical practice, it should possess good measurement properties.[30] Specifically, the methodologic quality of a HR-PROM should be assessed and considered adequate.[30] The goal of this study was to evaluate validity and responsiveness of the Rotator Cuff Quality of Life Index (RC-QOL) in the context of the Consensus-Based Standards for the Selection of Health Measurement Instruments (COSMIN) guidelines on a sample of patients presenting to a tertiary health care setting with confirmed rotator cuff tears.

5.1 Reliability

As mentioned in previous chapters, an index cannot be tested for validity unless it is first considered reliable.[71,121] Although this study does not specifically address reliability of the RC-QOL – or the Western Ontario Rotator Cuff Index (WORC) – reliability of the RC-QOL has been documented by 4 other studies.[3,24,26,28] Eubank et al findings supported the overall reliability of the RC-QOL confirming good test-retest reliability with scores well above the minimum value of 0.70 required to be acceptable.[3] Eubank et al also assessed reliability using internal consistency. Cronbach's α was calculated at 0.96 overall and each subscale ranged from 0.72 to 0.94, demonstrating excellent internal consistency.[3] The intraclass correlation coefficient (ICC) for the RC-QOL was calculated as 0.87 (95% CI, 0.79-0.85), which demonstrated good test-retest reliability.[3] Eubank et al, demonstrated excellent reliability testing using the baseline cohort of patients used in this study. Re-assessing reliability would be superfluous and would not provide any further reliability assessment RC-QOL.

5.2 Validity

According to the COSMIN guidelines, content validity (including face validity), construct validity (including structural, hypothesis-testing, and cross-cultural validity), and criterion validity (including concurrent and predictive validity) are required to provide sound methodological basis for HR-PROMs.[30] Validity has since been assessed on 8 separate occasions.[2,3,5,23,24,26–28] Of these assessments, construct validity has been assessed 6 times[2,3,5,24,27,28], content validity has been assessed twice[3,5], and criterion validity – in the form of predictive validity – has been assessed once[23].

5.2.1 Content Validity.

Content validity is a process that encompasses quantitative and qualitative characteristics as well as requires frequent testing.[122] Hollinshead et al, who described the initial development of the RC-QOL, assessed content validity using patient interviews.[5] This was done to provide expert judgements about the relevance and comprehensiveness of the items in the RC-QOL. In this study, content validity was assessed using Cronbach's α. The RC-QOL had excellent consistency at both time intervals, with a Cronbach α ranging from 0.89 to 0.91. Although slightly lower than prior validation studies, the Cronbach α calculated in this study also confirmed their findings, which ranged from 0.95 to 0.98.[24,26,28] Often a Cronbach α of >0.90 is described as being too high an α value, implying that some items in the scale may be redundant. Clark and Watson[123] noted that there are no clear standards regarding what cut-off value for α is considered acceptable, however, other authors have proposed an α of 0.90 as the minimal level for scales used for clinical purposes and 0.95 as an ideal level for these scales. [67,112,121] This agreement would further support that the

questions in each domain consistently assess the same content and the questions within the RC-QOL consistently assess effects of rotator cuff tears on quality of life.

Content validity of the WORC was also assessed using Cronbach's α. This was only done at the 2-year interval. The WORC had excellent consistency with a Cronbach α that was relatively stable between domains, ranging from 0.93 to 0.94. This higher score compared to that of the RC-QOL at the 2-year interval may indicate that although there are fewer questions on the WORC, there appears to be more redundancy. The questions in the EMOTIONAL domain of the WORC, although few, do not provide a large enough variety within this trait thus indicating the redundancy with fewer questions compared to the RC-QOL.

Floor and ceiling effects were also calculated to assess content validity in this study. A presence of floor and ceiling effects indicates that there is difficulty in interpreting differences in health status between relatively poor or good patients at the extreme ends of the scoring system.[124] The exact percentage of patients that is considered within normal floor and ceiling limits varies considerably in the literature from 15% to 33%.[70,90,91,125] Therefore, the absence of floor or ceiling effects in the RC-QOL (overall and within each domain) at baseline testing in this study added to the methodologic quality of the RC-QOL. This means that the RC-QOL was not only able to measure the entire spectrum of a patient's condition, but also to discriminate between patient types (those doing poorly and those doing well). All percentages were also below 15% for the RC-QOL, overall and in each domain, at the 2-year time interval. Again, these findings continue to support content validity of the RC-QOL. Conversely, there is some evidence of ceiling effects at the 2-year time interval in the WORC, specifically the EMOTIONAL domain. This indicates that the three questions asked within this domain are unable to distinguish the emotional effect that rotator cuff tears has on one's quality of life in poor versus good patients. However, it is reasonable to

expect that the majority of patients improve over a 2-year period resulting in a higher likelihood of ceiling effects.

With respect to the exploratory analysis, the RC-QOL had excellent consistency at both time intervals. Cronbach's α ranged from 0.87 to 0.94 at baseline and 0.91 and 0.97 at the 2-year interval, when assessing surgical status. These results are within normal limits when used for clinical purposes as this questionnaire is intended. The WORC demonstrated similar ranges at the 2-year interval (0.92-0.96). Again, these results support that the questions consistently assess the content of each domain as well as the questionnaire as whole.

5.2.2 Criterion Validity.

At the 2-year time interval, patients were asked to complete the WORC in addition to the RC-QOL. This allowed for the WORC to act as a 'reference standard'. Strong positive correlations were found between the RC-QOL and the WORC using the Pearson *r* Correlation coefficient (0.85, $p<0.001$) in the overall group.[67] These correlations indicate that as WORC scores increase, RC-QOL scores also increase. The data was not normally distributed. This distribution indicated that the Pearson *r* correlation coefficient was not the appropriate statistic. Although not appropriate for this data set, Pearson *r* correlation is the most common and is often used in methodological testing of outcome measures. The Spearman Rank Correlation found a similar relationship (0.88, $p<0.001$). Both analyses provide substantial methodological support for criterion validity of the RC-QOL when comparing it to a reference standard.

When assessing correlations based on surgical status, Pearson *r* correlations are stronger for non-surgical patients (0.92) compared to those of surgical patients (0.80).[67] These trends again indicate that as WORC scores increase, RC-QOL scores also tend to increase. These trends hold

true for Spearman Rank correlations for both non-surgical and surgical groups (0.90 and 0.85). Although not the purpose of distribution diagrams, these trends can also be seen when looking at score distributions in the overall, non-surgical, and surgical groups in Figures 13, 14, and 19-22. This provides additional methodological support for criterion validity when comparing surgical groups using RC-QOL compared to a reference standard.

Razmjou et al, assessed correlations between the WORC and the RC-QOL for what the authors called convergent validity or the "extent to which the outcome of interest agrees with the result of another measure that is believed to be assessing the same attribute"[2]. This definition appears to be what the COSMIN group refers to as hypothesis testing of construct validity or "the degree to which the scores of an [HR-PROM] are consistent with hypotheses … based on the assumption that the [HR-PROM] validly measures the construct to be measured"[76]. In this study, Pearson *r* and Spearman Rank correlations were used as a means to evaluate criterion validity under the premise that the WORC is an acceptable reference standard. While both studies used correlation scores for different conceptual purposes, the use of the same analysis allows for a comparison of scores. Razmjou et al found similar Spearman Rank correlations (0.7-0.9) between the RC-QOL and WORC as was found in this study (0.8-0.9).[2] The Pearson *r* correlation found within this sample group also reflects correlation scores between the Turkish versions of the RC-QOL and the WORC.[28]

The Pearson *r* correlation coefficient studies the relationship between the RC-QOL and the WORC, but not the differences between the two measures. As a result, the Bland-Altman analysis was chosen as a method for assessing the comparability between these measures. This method analyses mean difference and provides information on limits of agreement. Although the Bland-

Altman Plot analysis was performed and indicated poor agreement between the WORC and RC-QOL. An important requirement of the Bland-Altman Plot analysis that the difference scores – in this case, the difference between the WORC and RC-QOL scores at the 2-year time interval – must be normally distributed. This lack of normal distribution was visually confirmed in Figure 15 and using the Shapiro-Wilk test for normal data thus rendering results of this analysis invalid.

A slight majority (34 of the 63 patients) of WORC score were lower than RC-QOL scores at the 2-year interval (Figure 15). As displayed in Figure 13 and 14, the overall WORC scores, while similar to RC-QOL scores at the 2-year interval, are not as drastically skewed. This is perhaps due in part to the requirement of patients to speculate in questions that do not typically apply to them. For example, the WORC requires patients to respond to the question "How much difficulty do you have with someone or something coming in contact with your affected shoulder?" under the SPORTS/RECREATION domain of the questionnaire. If this is not an aspect of sport or recreation for a patient, they may have caused speculation of a much lower score. Similar requirements to speculate on function are present within the WORK domain.

5.3 Responsiveness

Mean change scores of the RC-QOL were consistently higher in all domains for surgical patients compared to non-surgical patients. Overall, patients improved by a mean score of +37. Surgical patients improved by a mean of +38 points compared to +26 in their non-surgical counterparts. While this study does not specifically assess surgical intervention compared to conservative non-operative treatments, it is an important clinical observation that patient perception of quality of life resulted in a higher change in the surgical group.

In comparing responsiveness results, it is important to understand the term effect size. In quantitative research, the context of this study, effect size is often described as the magnitude of the difference between groups.[126,127] This is in contrast to the absolute effect size which was described above as the mean change score. Absolute effect size does not take into account the variability in scores, in that not every subject achieved the average outcome.[126]

Cohen's term *d* is an example of this type of effect size index. Cohen classified effect sizes as small (0.2), medium (0.5), and large (0.8).[120] According to Cohen, "a medium effect of [0.5] is visible to the naked eye of a careful observer. A small effect of [0.2] is noticeably smaller than medium but not so small as to be trivial. A large effect of [0.8] is the same distance above the medium as small is below it".[120,127] These categories do not take into account other variables such as the accuracy of the PROM nor the varying characteristics of the study population. The purpose of effect size cut-offs is to provide a benchmark for comparative purposes.

Distribution-based techniques that included the Standardized Response Mean (SRM), as well as Guyatt's Responsiveness Index ($GRI_{Distribution}$), demonstrated a large effect size of the RC-QOL in all groups. SRM ranged from 0.91 to 1.09 amongst the three groups. The $GRI_{Distribution}$ was calculated as 0.89 in the overall group, a large effect.[116,120] Although the $GRI_{Distribution}$ score appears to be more conservative, both calculations indicate that the RC-QOL was able to detect a statistically large difference between baseline and 2-year follow-up scores using two different distribution-based methods.[120]

The use of external anchors highlights a major difference in calculating responsiveness of the RC-QOL. Correlation of the RC-QOL to two external anchors – a 7-Point Likert-style global rating scale (GRS) and a 100 mm visual analogue scale (VAS) as the second GRS – showed fair[120], positive correlations for all groups. All correlations were statistically significant. The low

correlation of these tests in comparison to those of the distribution-based methods does not necessarily indicate that the RC-QOL demonstrates poor sensitivity to change but rather that the external anchor may not be able to capture the same snapshot of quality of life in these patients.[128,129] Revicki et alrecommend 0.30-0.35 of Cohen's[120] cut-off points as a minimum correlation threshold as an acceptable association between an external anchor and a HR-PROM change score.[129] Using these guidelines, the correlation to both external anchors exceeds the minimum threshold indicating a responsive tool.

Lastly, the literature has indicated the usefulness of the mixed-method calculations to confirm minimal clinically important difference (MCID).[130] These methods allow for external, anchor-based information regarding change in conjunction with sample variance, or statistical characteristics, to provide a responsiveness score. In the context of this study, Guyatt's Responsiveness Index using mixed methods (GRI_{Mixed}) provided scores using anchor-based MCID of the RC-QOL and the variance of the change scores. Ultimately, this method exhibited small effect sizes, or a small difference between baseline and 2-year follow-up scores, in the overall group as well as in non-surgical patients (0.48 and 0.43).

5.4 Methodological Considerations

This study did not include patients presenting with acute rotator cuff tears. These patients require a different model of care which often is expedited and warrants surgical repair within 2 to 12 weeks after injury.[3,26,108] An acute tear occurs when a patient presents with a discrete traumatic injury to a previously asymptomatic shoulder.[108] Acutely injured patients are likely to experience challenges and difficulties that are different from those experienced by patients with chronic rotator cuff tears.[3] It is reasonable to consider that patients with acute injuries may not have

experienced all the facets of their life that may be limited as a result of a recent injury. This situation specific to acute injuries may not provide patients with the information that clearly outlines whether there is a change in their quality of life. Similarly, patients following an acutely traumatic event such as surgery also show little to no significant change in quality of life.[25]

A convenience sample of patients presenting to a tertiary health care facility was used in this study. An issue for any cohort study is loss to follow-up usually due to two concerns; the dropout rate is different between groups that are being evaluated or the patients that chose to drop out are not the same as the group that chose to participate.[131] What is considered a reasonable loss to follow-up differs within the literature but is typically as little as 5% with minor concerns for validity to >20% causing extreme concerns to the validity of the study.[131] A loss of 30% to follow-up occurred at the 2-year follow-up interval of this study. While this appears to violate certain guidelines, it is important to note that patient groups that participated at the two-year time interval were similar in age and sex characteristics as those that participated at baseline. When looking at groups based on surgical status, the non-surgical group, although similar in age, has a noted increase in the portion of female respondents (54%) compared to baseline (41%). Surgical group analyses were completed in the secondary analysis of this study and as such should not take away from the validity and responsiveness testing of the RC-QOL overall.

With respect to responsiveness, distribution-based methods are valuable for early clinical studies. This method can be used to assist in research and serve as an initial standard when little evidence is present in the literature regarding instrument performance.[28,99]

The appropriate use of anchor-based methods ultimately depends on the quality of the external anchors. Within the confines of this study, we cannot distinguish between the possibility of a poor Index and the possibility of poor external anchors when evaluating these techniques.

5.5 Implications of Collapsing the GRS Categories

In determining 'stable' or 'unchanged' patients, those that reported "A little worse", "No change", and "A little bit better" were considered 'unchanged' or 'stable'. This is similar to Beninato et al, in the event that there would be no reported change by the patient or the change would be perceived as little to none in each of those three self-reported groups.[118] In addition, the number of patients that reported "A little bit better" or "A little bit worse" were so few (n=3) that true change is difficult to discern in such a small number of patients.

5.6 Clinical Implications of Findings

The RC-QOL provides clinicians with an insight into the symptomatic, functional, and psychological aspects pertain specifically to patients with rotator cuff tears. This is most important in developing appropriate treatment and management strategies. The RC-QOL also provides a combined score in addition to individual subscale scores, allowing it to serve as an evaluative, discriminative, and predictive instrument.[5,132] While the WORC has been shown in this study to correlate well with the RC-QOL, they differ in several aspects. First, the RC-QOL evaluates activities that are more physically demanding (ie, mopping the floor, carrying 10 to 15 lbs) in comparison to the WORC. These activities are said to significantly affect symptoms in patients with rotator cuff tears.[5]

Second, the RC-QOL provides patients with the option of answering "not applicable" for questions. While "Not applicable" options can increase the risk of satisficing behavior because it gives respondents or patients a way to respond to questions without having to thoroughly critique their answers.[133] This satisficing behaviour, first described by Herbert Simon[134], indicates that

people often satisfice, or settled for a good enough option, when making decisions. Typically this occurs in respondents who lack the cognitive capacity to comprehend what is being asked or lacks the motivation to answer it thoughtfully.[46] Patients completing questionnaires within a specialist setting are less likely to satisfice because they are motivated by the perception that their answers will likely influence their medical care.

Deviating from the original purpose of this study to provide methodological support for the RC-QOL, there are a few findings in which clinicians may use from this study:

- Patients that undergo surgery for rotator cuff repair may improve more than a non-surgical counterpart over a 2-year time period.
- The WORC and RC-QOL correlate well, however, the RC-QOL may be favoured due to less redundancy indicated by a lower Cronbach's α. In addition, the RC-QOL has demonstrated a better ability to discriminate patients in SOCIAL/EMOTIONAL domain than the WORC at 2-year follow-up intervals.
- The RC-QOL is an easy-to-administer, economical or affordable tool that accurately evaluates quality of life and is responsive.

5.7 Limitations

Although the results of our study add to the methodologic quality of the RC-QOL, the study has some limitations. Firstly, criterion validity was assessed on the premise that the WORC would work as the reference standard as it is important to note that there are no real gold standards for rotator-cuff specific HR-PROMs.[102] Structural validity of the RC-QOL via exploratory factor analysis was not assessed due to sample size. Three to five subjects per question (up to 170 patients total), is required for confirmatory factor analysis which was far above the original sample size

used.[136] Cross-cultural validity was also not assessed because the RC-QOL was tested in its original language (ie, English) and in its original cultural context (ie, Canadian).

Secondly, this study used a convenience sample of patients presenting to a tertiary health care facility resulting in possible sampling bias. A truly random sampling of patients would have been superior.

Retrospective patient self-reports are also known to exhibit to recall bias.[67] In theory, retrospective change scores should correlate positively at the 2-year interval and have a negative correlation of equal magnitude with the baseline score.[129] In reality, retrospective self-reports tend to correlate more strongly with the follow-up than they do with the baseline testing because current status overly influences the retrospective perception of change.[129]

5.8 Strengths

Anchor-, mixed-, and distribution-based methods were used to estimate the MCID and responsiveness. The literature indicates that in addition to distribution-based methods, anchor-based approaches must also be used in complement to ensure the strength of the MCID estimates.[70,128,129,137,138] No previous responsiveness testing has been done using external anchors as a means to calculate MCID as well as responsiveness.

Chapter 6 Conclusions and Future Recommendations

6.1 Concluding Statements

This study found that the RC-QOL demonstrated good validity and responsiveness over a 2-year time period in patients with confirmed rotator cuff tears. The complexity of the anatomical and biomechanical characteristics of the rotator cuff contribute to its unique etiology and varying clinical presentation.[32,38,39,139] An instrument designed specifically for patients presenting with rotator cuff tears would more accurately measure the effect of surgical and non-surgical treatments and procedures on quality of life. Generic upper extremity PROMs, can easily be used across different populations but generally have been found to be poor at detecting clinically meaningful changes in the quality of life of patients and are not able to paint a complete picture of the tears.[21,140] Several generic shoulder instruments, such as the Disabilities of the Arm, Shoulder, and Hand (DASH)[15] and the Oxford Shoulder Score[141] have also been used to assess the effect of rotator cuff pain in patients[142,143]; however, these have not been validated specifically for patients with rotator cuff tears.

The psychometric properties of the RC-QOL, although tested extensively already[2,5,24,26–28,132], should always be tested within the context of a research question. Many outcome measures used in clinical studies make blanket statements that the outcome measure being used valid, reliable, or responsive, however, validity is considered an interaction between the instrument and the environment or patients being measured.[144] The RC-QOL provides clinicians an appreciation of facets of one's life that are specific to patients with rotator cuff tears, which is important in developing appropriate treatment and management strategies. The RC-QOL is an easy-to-administer, economical tool that is accurately evaluates quality of life, discriminates between

patients based on function, and has predictive properties that can provide insight into the extent to which patients will likely be successful with non-operative rehabilitation programs.[5,23]

6.2 Knowledge Translation

It important that research of any type is not translated for use beyond the immediate study team. Many of the results of the present study are conclusive, and will be shared through a manuscript submitted to a peer reviewed journal. In addition to publication, findings may be presented to a variety of clinical orthopaedic research groups that include the Alberta Bone and Joint Strategic Clinical Network and the Canadian Shoulder and Elbow Society.

6.3 Future Recommendations

Future research in with respect to the RC-QOL include the following:

1. Further anchor-based methods using 9- or 15-point Likert-style scales in patients with full-spectrum rotator cuff disease to further determine the value of anchor-based responsiveness.
2. With the lack of consensus on appropriate measures of responsiveness, more testing using alternative distribution- and anchor-based analyses is important to further bolster the quality of the RC-QOL.
3. Structural validity of the RC-QOL via exploratory factor analysis should be assessed as next steps in evaluating the RC-QOL as it is the last remaining validity testing required to complete the COSMIN checklist.

Future research with respect to assessing responsiveness of the WORC using mixed- and anchor-based methods is required to continue to differentiate the abilities of two rotator-cuff PROMs.

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Appendix A: The Rotator Cuff Quality of Life Index (RC-QOL)

DATE: _____/_____/_____

NAME/ID #: _____

QUESTIONNAIRE # _____

QUALITY OF LIFE ASSESSMENT

IN

ROTATOR CUFF PATIENTS

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DIRECTIONS: Please answer each question with respect to the current status, function, circumstances and beliefs surrounding your shoulder. Consider the last three months.

Indicate, with a slash (/) on the line, the point ranging from 0 to 100 which most closely represents your situation.

For example, the following question:

What is the temperature today?

0 ——————————————————— 100
Very cold Very hot

If a slash is placed in the middle of the line, this indicates that the temperature is average, or in other words, between the extremes of very cold and very hot. It is important to put your slash at either end of the line if the extreme descriptions accurately reflect your situation.

In those situations where the question may not be applicable to your particular circumstances circle the **N/A** response as noted beside the question.

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SECTION A:
The first section is related to: SYMPTOMS AND PHYSICAL COMPLAINTS

1. With any prolonged activity (i.e. greater than half an hour) how much pain or discomfort do you experience in your shoulder?

N/A

0 ——————————————————— 100
Severe Pain **No pain at all**

2. With respect to your overall shoulder function, how much are you troubled by stiffness or loss of motion?

0 ——————————————————— 100
Severely troubled **Not troubled at all**

3. With respect to your overall shoulder function and considering the strength of your muscles, how weak is your shoulder?

0 ——————————————————— 100
Totally weak **Not weak at all**

4. With respect to bathing or taking a shower, how much pain/difficulty do you experience because of your shoulder?

0 ——————————————————— 100
Severe Pain/difficulty **No Pain/difficulty at all**

5. With respect to putting on or removing clothing over your head, how much pain/difficulty do you experience because of your shoulder?

0 ——————————————————— 100
Severe Pain/difficulty **No Pain/difficulty at all**

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6. With respect to putting on a belt through the loop holes of a pair of pants that you are wearing, how much pain/difficulty do you experience because of your shoulder?

0 ——————————————————— 100
Severe Pain/difficulty **No Pain/difficulty at all**

7. With respect to cutting food for preparation or at meals, how much pain/difficulty do you experience because of your shoulder?

0 ——————————————————— 100
Severe Pain/difficulty **No Pain/difficulty at all**

8. With respect to doing household chores (i.e. mopping floor/vacuuming the rug, ironing clothes, making a bed, scrubbing pots/pans, cleaning bathtub/toilet), how much pain/difficulty do you experience because of your shoulder? **N / A**

0 ——————————————————— 100
Severe Pain/difficulty **No Pain/difficulty at all**

9. With respect to carrying 4.5 to 6.8 kg (10-15 lb.), with arm at your side (i.e. carrying a heavy briefcase, small suitcase or shopping bags), how much pain/difficulty do you experience because of your shoulder?

0 ——————————————————— 100
Severe Pain/difficulty **No pain/difficulty at all**

10. With respect to cutting the grass, raking the lawn, or shoveling snow, how much pain/difficulty do you experience because of your shoulder? **N / A**

0 ——————————————————— 100
Severe Pain/difficulty **No Pain/difficulty at all**

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11. Do you have pain/difficulty falling asleep because of your shoulder?

0 ——————————————————— 100
Severe Pain/difficulty **No Pain/difficulty at all**

12. Are you awakened from sleep because of your shoulder?

0 ——————————————————— 100
Always awakened **Never awakened**

13. With respect to driving a motor vehicle, how much pain/difficulty do you experience because of your shoulder? **N / A**

0 ——————————————————— 100
Severe Pain/difficulty **No Pain/difficulty at all**

14. With respect to opening and closing a door with your affected arm, how much pain/difficulty do you experience because of your shoulder?

0 ——————————————————— 100
Severe Pain/difficulty **No Pain/difficulty at all**

15. With respect to reaching (i.e. into the back of a car) with your affected arm, how much pain/difficulty do you experience because of your shoulder? **N / A**

0 ——————————————————— 100
Severe Pain/difficulty **No Pain/difficulty at all**

16. Indicate the point ranging from 0 to 10 which most closely describes your overall present level of shoulder pain.

0 ——————————————————— 100
Severe Pain/difficulty **No Pain/difficulty at all**

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Are there any other physical issues that you feel should be addressed?

_____

_____

_____

_____

_____

SECTION B: The following questions are being asked with respect to your job or vocation (i.e., **WORK RELATED CONCERNS**). The questions are concerned with your ability to function at work and how your shoulder has affected your current work-related concerns. If you are a full-time student/homemaker, then consider this and any part-time work together. Consider the last three months.

If you are not working for reasons other than your shoulder problem, proceed to question 21.

Indicate, with a slash on the line, the point ranging from 0 to 10 which most closely represents your situation.

17. With respect to working with your arm at shoulder level, how much pain/difficulty do you experience because of your shoulder? **N / A**

0 _____ 100

Severe Pain/difficulty **No Pain/difficulty at all**

18. With respect to working with your arm above shoulder level, how much pain/difficulty do you experience because of your shoulder? **N / A**

0 _____ 100

Severe Pain/difficulty **No Pain/difficulty at all**

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19. How much of the time are you concerned with missing days from work due to problems or re-injury to your shoulder? (Make a slash at the extreme left if you are unable to work because of your shoulder) **N / A**

0 ——————————————— **100**
Greatly concerned **Not concerned at all**

20. How much of the time are you concerned about the activities that you do at work, resulting in the state of your shoulder to be worse? (Make a slash at the extreme left if you are unable to work because of your shoulder) **N / A**

0 ——————————————— **100**
All of the time **None of the time**

Are there any other occupational issues that you feel should be addressed?

_____

_____

_____

_____

_____

Please continue to Section C…

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SECTION C: The following questions are being asked with respect to your **RECREATIONAL ACTIVITIES, SPORT PARTICIPATION OR COMPETITION.** The questions are concerned with your ability to function and participate in these activities as they relate to your painful shoulder. Consider the last three months. **If you are not involved in any sporting activities what so ever, proceed to question 25.**

21. With respect to participating in general sports activities, how much pain/difficulty do you experience because of your shoulder? **N / A**

0 ——————————————— **100**
Severe Pain/difficulty **No Pain/difficulty at all**

22. With respect to participating in upper extremity sports (i.e. baseball, tennis, golf, squash, volleyball, swimming, throwing, etc.), how much pain/difficulty do you experience because of your shoulder? **N / A**

0 ——————————————— **100**
Severe Pain/difficulty **No Pain/difficulty at all**

23. How much of the time are you concerned about the sporting/recreational activities resulting in the status of your shoulder to be worse? **N / A**

0 ——————————————— **100**
All of the time **None of the time**

24. With respect to your current level of athletic or recreational performance, how do you compare to your pre-injury level?

0 ——————————————— **100**
Totally limited **No limitations**

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SECTION D: The following questions are being asked with respect to your **LIFESTYLE**. The questions are concerned with your lifestyle in general and should be considered outside of your work and sport/recreational activities as they relate to your painful shoulder. Consider the last three months.

25. How often do you have to concern yourself with general safety (i.e. carrying small children, working in the yard, climbing a ladder, using power tools, etc.) with respect to your injured shoulder? **N / A**

0 ——————————————— 100
All of the time **None of the time**

26. How much has your enjoyment of life been limited by your shoulder problem?

0 ——————————————— 100
Totally limited **No limitations**

27. How often are you aware of your shoulder problem?

0 ——————————————— 100
All of the time **None of the time**

28. With respect to your life style as it relates to you and your family together, how often are you concerned about your shoulder?

0 ——————————————— 100
All of the time **None of the time**

29. You have had your problem shoulder for some time. During this time, have you modified your life style to avoid potentially damaging activities to your shoulder?

0 ——————————————— 100
Totally modified **No modifications**

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SECTION E: The following questions are being asked with respect to the **SOCIAL AND EMOTIONAL** aspects of your shoulder problem. The questions are concerned with your attitudes and feelings as they relate to your painful shoulder. Consider the last three months.

30. Do you experience difficulty making decisions at home or at work because of your shoulder problem?

0 ——————————————— 100
Extremely difficult **Not difficult at all**

31. Do you have the peace of mind or are you too worried to sleep at night because of your shoulder problem?

0 ——————————————— 100
Extremely worried **Not worried at all**

32. Are you afraid of "re-injuring" your shoulder?

0 ——————————————— 100
Extremely afraid **Not afraid at all**

33. Are you experiencing psychological difficulty when engaging in sexual activity because of your shoulder problem? **N / A**

0 ——————————————— 100
Extremely difficult **Not difficult at all**

34. Does your shoulder problem interfere with your ability to socialize with friends and family?

0 ——————————————— 100
Unable to socialize **Able to socialize fully**

THANKYOU FOR COMPLETING THE QUESTIONNAIRE!

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Appendix B: Global Rating Scale (7-Point)

Patient Initials: _____
Study ID: _____
Date:_____

Global Rating Scale (7-point)

Please select one option. Since your initial appointment with us has your quality of life been:

○	○	○	○	○	○	○
Very much worse	Somewhat worse	A little bit worse	No change	A little bit better	Somewhat better	Very much better

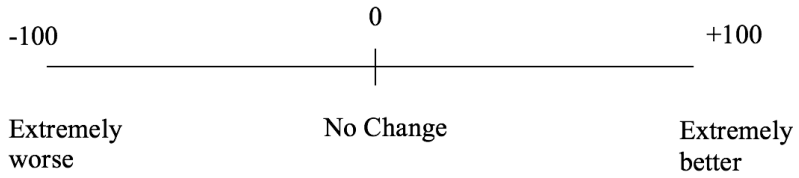
Appendix C: Global Rating Scale (Visual Analogue Scale)

Patient Initials: _____
Study ID: _____
Date:_____

Global Rating Scale (VAS)

Indicate with a slash (/) on the line, the amount ranging from -100 to +100 which most closely represents your answer to the following question:

Since the last time you were seen, how would you rate the overall change in your shoulder?



Appendix D: Informed Consent Form

INFORMED CONSENT FORM

TITLE: Development of a clinical pathway for patients with rotator cuff disorders. (REB 14-1828)

INVESTIGATORS:
Dr. J. Preston Wiley, MD, MPE, CCFP, Dip. Sport Med
Dr. Nicholas Mohtadi, MD, MSc, FRCSC
Dr. Mark Lafave, PhD, CAT(C)
Dr. J. C. Herbert Emery, PhD
Dr. David Sheps, MD, MSc, MBA, FRCSC
Dr. Richard Boorman, MD, Msc, FRCSC
Dr. Aaron Bois, MD, FRCSC
Breda Eubank, PhD(c), CAT(C)
Caitlin Campbell, MSc student, CAT(C)

This consent form is only part of the process of informed consent. It should give you the basic idea of what the research is about and what your participation will involve. If you would like more detail about something mentioned here, or information not included here, please ask. Take the time to read this carefully and to understand any accompanying information. You will receive a copy of this form.

BACKGROUND
Quality healthcare is about delivering the best possible care and achieving the best possible outcomes. Quality healthcare is about getting patients the right care from the right person at the right time in the right place. Too many patients suffering rotator cuff disorders are not getting the right care they need to stay healthy. Many patients seeking care experience difficulty accessing appropriate care, which results in long wait times and increased costs to both the patient and healthcare system. Many patients waiting for care suffer pain, disability, and lower quality of life. Therefore, we need to improve the quality of care for patients suffering rotator cuff disorders.

WHAT IS THE PURPOSE OF THE STUDY?

In order to improve the quality of care for patients suffering rotator cuff disorders in Alberta, we need to evaluate the current state of care. This requires that we evaluate the following dimensions of quality: acceptability, accessibility, appropriateness, effectiveness, efficiency, and safety. We currently have a valid and reliable survey tool called the Rotator Cuff Quality of Life Questionnaire (RCQOL) that can help us measure effectiveness. Unfortunately, there is not an optimal tool we can use to help us capture information required for evaluating the other five dimensions of quality. Therefore, we require your help in creating a Healthcare Access and Patient Satisfaction Questionnaire (HAPSQ v.RC). In addition to the RCQOL, the Western Ontario Rotator Cuff Index (WORC) also assesses quality of life in patients with rotator cuff disease. Comparisons of the WORC and RCQOL will provide us with better insight as to which tool is more appropriate to use.

WHAT WOULD I HAVE TO DO?

There are four different phases to the development of the HAPSQ v.RC: Phase 1: Pre-testing the HAPSQ v.RC; Phase 2: Establishing reliability and validity of the HAPSQ v.RC; Phase 3: Surveying patients with both the HAPSQ v.RC and the RCQOL. Phase 4: Surveying patients with both the WORC and the RCQOL. You may be asked to participate in one or more phases of development. Your participation in any of the phases will help us to better understand your experience with the health system. This will require you to tell us about the continuum of care you have received for your rotator cuff disorder. You will be asked to answer questions about the care you received from the various healthcare providers you have seen for your rotator cuff disorder. You will also be asked about difficulties in accessing care, test, services, or procedures; wait times you experienced; satisfaction levels with regard to access and wait times; your quality of life; and costs incurred as a result of your rotator cuff disorder.

Your involvement may include:

- **Phase 1: Pre-testing the HAPSQ v.RC**
  In Phase 1, you will be asked to complete the HAPSQ v.RC and think about each question. Upon completion of the HAPSQ v.RC you will be asked to provide feedback about question clarity, wording, interpretation, and ease. You can also tell us about concerns you may have about the questionnaire or a particular question. This will help us to identify problem areas within the questionnaire and to determine if the questionnaire is being filled out properly, whether the questions are understood by you, and whether the question asks what we think we are asking.

- **Phase 2: Establishing reliability and validity of the HAPSQ v.RC**
  In Phase 2, you will be asked to complete the HAPSQ v.RC on two separate occasions. You will be asked to complete the first HAPSQ v.RC either before your appointment or on the day of your appointment. You will be asked to complete a second HAPSQ v.RC one week after you first completed the questionnaire. We will analyze both sets of answers to determine if the HAPSQ v.RC is reliable. To determine if the HASPQ v.RC is valid, your participation during this phase will require you to release medical record information in order to confirm your responses on the HAPSQ v.RC.

- **Phase 3: Surveying patients with both the HAPSQ v.RC and the RCQOL**
  In Phase 3, you will be asked to complete two questionnaires: the HASPQ v.RC and the RCQOL. Your answers will help us evaluate the quality of care you have received. We anticipate that it will take 10-20 minutes to complete the HAPSQ v.RC and 10-15 minutes to complete the RCQOL. You will be required to complete all parts of the questionnaire as accurately as possible.

- **Phase 4: Surveying patients with both the RCQOL and WORC**
  In Phase 4, you will be asked to complete two questionnaires: the RCQOL and the WORC. Your answers will help us evaluate the appropriate tools for assessing quality of life in patients with rotator cuff disease. We anticipate that it will take 10-15 minutes to complete the WORC and 10-15 minutes to complete the RCQOL. You will be required to complete all parts of the questionnaire as accurately as possible.

WHAT ARE THE RISKS?
There are no risks to your involvement with participating in this study. Participation in the project poses no threat to you as your responses will remain confidential and in no way affect the care that you will receive.

ARE THERE ANY REPRODUCTIVE RISKS?
There are no reproductive risks with participating in this study.

WILL I BENEFIT IF I TAKE PART?
If you agree to participate in this study there may or may not be a direct medical benefit to you. The information that we get from this study may help us to identify challenges in accessing healthcare, and help us to locate areas in need of improvements within the current healthcare delivery system. We hope that the information you have provided in the questionnaire will allow us to better evaluate the quality of care for rotator cuff disorders in Southern Alberta.

DO I HAVE TO PARTICIPATE?
Participation in this project is voluntary and you may withdraw from the study at any time without jeopardizing your care. To withdraw from the study just tell your doctor or the research coordinator you no longer wish to participate. You can also withdraw from the study by choosing not to complete your questionnaires.

WHAT ELSE DOES MY PARTICIPATION INVOLVE?
Your participation involves nothing greater than stated above.

WILL I BE PAID FOR PARTICIPATING, OR DO I HAVE TO PAY FOR ANYTHING?
There are no anticipated costs to your involvement in this study, and no compensation will be provided to you.

WILL MY RECORDS BE KEPT PRIVATE?
All information is confidential. Only the research team of Dr. Wiley and Breda Eubank will have access to this information. Upon enrollment into the study, you will be assigned a study identification number which will maintain the confidentiality of your identity on all forms and data related to the study. The information that you provide us will be stored on a secure server in

a password protected database and analyzed without your name. In any presentation or publication, your name will not be used and every effort will be made to maintain your anonymity. The University of Calgary Conjoint Health Research Ethics Board will also have access to the records.

IF I SUFFER A RESEARCH-RELATED INJURY, WILL I BE COMPENSATED?

It is unlikely that you will suffer an injury as a result of participating in this research. In the event that you suffer an injury as a result of participating in this research, no compensation will be provided to you by the University of Calgary, Alberta Health Services, or the Researchers. You still have all of your legal rights. Nothing said in this consent form alters your right to seek damages.

SIGNATURES

Your signature on this form indicates that you have understood to your satisfaction the information regarding your participation in the research project and agree to participate as a subject. In no way does this waive your legal rights nor release the investigators, or involved institutions from their legal and professional responsibilities. You are free to withdraw from the study at any time without jeopardizing your health care. If you have further questions concerning matters related to this research, please contact one of the following:

Dr. Preston Wiley	Breda Eubank	Caitlin Campbell
Principle Investigator	Research Coordinator	Research Coordinator
[redacted]	[redacted]	[redacted]

If you have any questions concerning your rights as a possible participant in this research, please contact the Chair, Conjoint Health Research Ethics Board, University of Calgary at 403-220-7990.

Participant's Name	Signature and Date
Investigator/Delegate's Name	Signature and Date
Witness' Name	Signature and Date

The University of Calgary Conjoint Health Research Ethics Board has approved this research study. A signed copy of this consent form has been given to you to keep for your records and reference.

Appendix E: Copyright Forms

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Jul 17, 2018

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The requesting person/organization is:	Caitlin Campbell
Title or numeric reference of the portion(s)	Quality-of-Life Assessment in Rotator Cuff Patients Section A-Section E
Title of the article or chapter the portion is from	Appendix
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Author of portion(s)	N/A
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Title	Assessing Validity and Responsiveness of the Rotator Cuff Quality of Life Index
Instructor name	Caitlin Campbell
Institution name	University of Calgary
Expected presentation date	Jul 2018
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