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Predicting Patient Outcome of Non-Operative Treatment for a Chronic Rotator Cuff Tear

by

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The undersigned certify that they have read, and recommend to the Faculty of Graduate Studies for acceptance, a thesis entitled "PREDICTING PATIENT OUTCOME OF NON-OPERATIVE TREATMENT FOR A CHRONIC ROTATOR CUFF TEAR" submitted by KRISTIE DAWN MORE in partial fulfilment of the requirements of the degree of MASTER OF SCIENCE.

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Abstract

Introduction

Rotator cuff tears of the shoulder are a common and debilitating injury. The purpose of the present study was to determine if clinical characteristics can predict the outcome (success or failure) of non-operative treatment in patients with a chronic, full-thickness rotator cuff tear.

Methods

Fifty patients were recruited prospectively, and underwent a three month program of non-operative treatment. Patients were classified as having been successful or as having failed non-operative treatment by an orthopaedic surgeon. The patient's clinical characteristics were analyzed using logistic regression to determine which characteristics were predictive of outcome.

Results

Univariate analyses showed that age, dominant arm involvement, and Rotator Cuff Quality of Life (RCQOL) questionnaire score were significant predictors of outcome

Conclusion

This study was not powered to examine more than one independent variable in a regression model. However, exploratory analyses suggest that further study of the factors age, dominance, and RCQOL score are warranted.

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Chapter One: PROJECT OVERVIEW

1.1 Introduction

Rotator cuff tears of the shoulder are a common and debilitating condition and affect many adults, particularly with advancing age [1-6]. Treatment options include surgical and non-surgical methods, however the existing literature is controversial as to which type of treatment is optimal for which patient at any given point in time.

1.2 Purpose

The primary objective of this study is to determine if the outcome of non-operative treatment in chronic, symptomatic, full thickness rotator cuff tears can be predicted based upon presenting clinical characteristics.

1.3 Rationale/Significance

It has been well documented in the orthopaedic literature that rotator cuff tears are both common and debilitating [1-5]. Not so well documented is the fact that this type of pathology is often managed suboptimally. This patient population is currently under intensive study at the University of Calgary Sport Medicine Centre. Work on a multi-centre, Canadian Institute of Health Research (CIHR) and Worker's Compensation Board of Alberta (WCB-Ab) supported, randomized controlled trial examining surgical techniques for rotator cuff repair is currently underway. It has revealed that of over 340 rotator cuff tear referrals recently reviewed, over 200 of these had not attempted adequate conservative treatment

in the orthopaedic surgeon's opinions. Whereas it is recognized that non-operative treatment is effective, this pilot work shows that it is not being utilized. This is of great concern given the extensive wait times for surgical consultation in the Canadian health care system. The local investigators (orthopaedic surgeons) have identified a clear need for more appropriate referral practices, including non-operative treatment, which to date remains the treatment of choice in our centre.

With the current state of the health care system, it is critical that patients exhaust the more easily accessible non-operative treatment options before progressing to surgical consultation and treatment which involves extensive wait times and potentially serious complications.

Predicting who is likely to be successful with non-operative treatment will help reduce wait lists and costs to the Canadian health care system and will improve patient care, and ultimately, a patient's shoulder related quality of life.

1.4 Assumptions

For the present study, the following assumption was made:

- A confirmed diagnosis of a full-thickness rotator cuff tear was made via ultrasound or magnetic resonance imaging (MRI). Full thickness tears were not confirmed via arthroscopy.

1.5 Operational Definitions

- **Success (of non-operative treatment):** Success was defined as any patient who, in the surgeon's opinion (and preferably with agreement from the patient), reached a level with the non-operative treatment where they were no longer interested or appropriate to seek operative care for their rotator cuff.

- **Failure (of non-operative treatment):** Failure was defined as any patient who, in the surgeon's opinion (and preferably with agreement from the patient), did not improve sufficiently with the non-operative treatment to eliminate the possibility of surgery. This may include patients who did not go on to surgery for other health/life issues, however did not receive enough relief of their symptoms to be considered successful.

- **Chronic, Full Thickness Rotator Cuff Tear**: will be herein referred to as a rotator cuff tear. All patients presented with a tear with at least three months duration of symptoms.

1.6 Research Question

Can the outcome (success or failure) of non-operative treatment of chronic, full-thickness rotator cuff tears be predicted using patient age, baseline range of motion measured passively as forward elevation in the scapular plane (ROM),

and baseline quality of life score on the Rotator Cuff Quality of Life questionnaire (RCQOL)?

1.7 Null Hypothesis

A patient's age, ROM, and RCQOL at baseline will not predict the outcome of non-operative treatment for a chronic, full-thickness rotator cuff tear.

Chapter Two: LITERATURE REVIEW

2.1 Review of Rotator Cuff Disease

2.1.1 Introduction

Rotator cuff disease is a common and debilitating shoulder problem and is among the most common causes of shoulder pain [1-6]. Rotator cuff disease spans a spectrum from impingement of the cuff tendons beneath the coroacromial arch, to full thickness tearing. The diagnosis and treatment of all stages and types of rotator cuff disease remains controversial.

2.1.2 Historical Perspective

The rotator cuff is a structure which has been studied and described by clinicians and authors for hundreds of years. Edwin Smith's Surgical Papyrus, one of the oldest known pieces of medical literature, first describes rotator cuff injury[7]. It was postulated that rotator cuff injury could accompany shoulder dislocations by both Hippocrates and Galen[7]. An illustration of the supraspinatus tendon first appeared in 1788, and in 1834, Smith described the first series of seven rotator cuff tears in the London Medical Gazette[7-10].

One of the most influential authors on the rotator cuff is Codman, stemming from his 1934 publication of his observations of 38 cases over 25 years, including the first definitive discussion of supraspinatus ruptures[11]. It is thought that he may have performed the first rotator cuff repair in 1909, and he recommended early operative repair for complete cuff tears[11]. His ideas on cuff tear pathogenesis,

diagnosis and treatment are still widely respected and form much of the basis of the current perspective on cuff disease[12].

The spectrum of partial thickness, full thickness and massive tears were described in 1939 by Lindblom and Palmer who used radio-opaque contrast mediums[13].

While the term "impingement syndrome" had been described many years earlier, it was popularized by Neer in 1972. It refers to the abrasion which occurs between the cuff tendons and the coracoacromial arch during forward flexion[14]. He further defined three stages of impingement syndrome:

- Stage 1: reversible edema and haemorrhage are present in a patient younger than 25 years of age
- Stage 2: fibrosis and tendonitis affect the rotator cuff of a patient typically in the 25 – 40 year age group. Pain often recurs with activity.
- Stage 3: bone spurs and tendon ruptures are present in the individual older than 40 years of age.

While Neer advocated non-operative treatment for cuff tendonitis, he also suggested specific indications for surgical acromioplasty.

2.1.3 Anatomy

The rotator cuff is a muscular/tendinous cuff that surrounds the shoulder, and is comprised of the supraspinatus, infraspinatus, subscapularis, and teres minor. The four muscles of the cuff arise from the scapula, and attach to the greater and lesser tuberosities of the humeral head along with the joint capsule[12]. The long head of the biceps tendon is sometimes considered to be a part of the rotator cuff, though for the purposes of this thesis, it will be considered separately.

The cuff muscles are each 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).

During shoulder movement in any plane, the rotator cuff tendons glide beneath the coracoacromial arch and are lubricated by the surfaces of the subacromial-subdeltoid bursa, as well as synovial fluid. With any type of superior translation of the humeral head, the rotator cuff tendons become compressed beneath the coracoacromial arch, which can lead to friction, impingement, and degeneration[12].

2.1.4 Biomechanics

The rotator cuff allows for both stability and mobility of the glenohumeral joint in multiple directions and acts to oppose forces generated by the deltoid and pectoralis muscles.

The cuff muscles perform three major functions[12]:

1. Rotation of the humerus in relation to the scapula.

2. Compression of the humeral head into the glenoid, which provides stabilization to the shoulder complex[15, 16].

3. Provision of muscular balance to avoid unwanted directions of humeral motion.

A healthy, intact cuff tendon can withstand extremely high loads/forces transferred through the fibres, without failure. However, with compromised integrity of the tendon (i.e. degeneration, tearing), reduced forces can cause disruption[17-20]. Pettersson suggested that age related degeneration of tendons may be due to changes in cell arrangement, calcium deposition, fibrinoid thickening, fatty degeneration, necrosis and rents, and results in decreased tensile strength and elasticity[21]. With age related degeneration, a lesser force is thereby required to cause disruption to the fibres of the cuff tendons, resulting in mild fraying, partial thickness tearing, or full thickness tearing.

2.1.5 Epidemiology

Studies have shown increasing failure of the rotator cuff with advancing age in both clinical and cadaveric studies [5, 6, 12, 22-28] and there are multiple estimates of the prevalence of rotator cuff disease in the population. Estimates generally range from approximately 5 – 40% and are age dependent.

Sher et al found that 4% of asymptomatic volunteers under 40 years of age and 54% of asymptomatic volunteers greater than 60 years demonstrated partial or complete tears on magnetic resonance imaging (MRI) [22]. Similarly, ultrasound testing on asymptomatic subjects by Tempelhof et al showed a prevalence of cuff tears in 40% of patients greater than 50 years of age. When stratified by age, a 13% prevalence of tears was seen in subjects in their fifth decade of life, 20% prevalence in subjects in their sixth decade, and 31% in the seventh decade[23]. Lehman showed a similar trend in cadaveric shoulders[29]. Neer demonstrated that 70% of defects occurred in sedentary patients, defects were often bilateral, and that half of patients did not recollect specific trauma to the shoulder[30, 31]. Harryman also demonstrated that 55% of patients who presented with a cuff tear on one side had evidence of cuff defects on the contralateral side via ultrasound imaging[32]. Many patients do not have an inciting event to attribute their rotator cuff tear to. Rather, it seems that use, or disuse, of the shoulder over time leads to partial and full thickness tearing of the tendon(s). Wirth et al state that less than half of the patients that they see can recall a specific event which initiated symptoms[5], and rather the patient presents with a longstanding history of intermittent pain that has become progressively more symptomatic[5].

However, clinical symptoms do not always correlate with the extent of cuff damage or degeneration[6]. A curious phenomenon with rotator cuff tears is the disconnect between the condition of the tendon and the presenting symptomatology of individual patients. Cuff damage has been found in a large

number of asymptomatic patients [6] however it is unclear why the presence of a structural full thickness tear may be associated with disabling pain and loss of function in some individuals and be asymptomatic in others [22, 33, 34]. Clinically, it is not clear why one patient may be symptomatic and another asymptomatic, which creates a challenge for clinicians to provide the best treatment options for each individual patient.

2.1.6 Clinical Evaluation

Diagnosing a rotator cuff tear usually involves a discussion of the history with the patient, a physical examination of the shoulder, and is often supplemented by imaging such as arthrogram, ultrasound, or MRI. X-rays should be reviewed to identify or rule out additional pathologies (such as a tumour, osteoarthritis, or superior migration of the humeral head).

Patients typically complain of shoulder pain, most prominently night pain, and inability to perform their activities. Active range of motion, especially in forward flexion or abduction, is sometimes compromised, typically by pain, and passive range of motion (ROM) is usually preserved. Tightness to internal rotation can be secondary to a tight posterior capsule and will limit the patient's ability to reach behind their back (i.e. reach a wallet, put on a belt, fasten a bra). Weakness, especially to external rotation, can indicate the extent of the tearing, however weakness can also be a function of pain which then does not help estimate the size of the tear[35]. A more accurate physical exam which is not

limited by pain can be performed following an injection of local anaesthetic into the joint[5].

2.1.7 Natural History

There is a dearth of literature regarding the natural history of rotator cuff tears, however it is generally thought that full thickness rotator cuff tears will not heal spontaneously[6, 36-40].

Previous work by Yamanaka et al examined partial thickness tears using repeat arthrography on 40 patients after at least one year. Their results showed that 10% healed, 10% became smaller, 53% became larger, and 28% progressed to full thickness tears[40]. However, all patients were followed during conservative treatment, so an argument could be made that this study does not illustrate a true natural history. Further, the authors themselves note that the very small sample size precludes statistical analysis.

However patient outcome scores were not necessarily representative of the integrity of the tendon. Despite generally diminished tendon integrity, pain and functions scores (measured by the Japanese Orthopaedic Association Shoulder Score) were improved over time[40].

Yamaguchi et al followed a cohort of 45 patients who had confirmed bilateral, full-thickness cuff tears via ultrasound, yet presented originally with symptoms in only one shoulder. Follow-up exams revealed that half (51%) developed symptoms

on the opposite side. Of the 45 original patients, 23 had a follow-up ultrasound, on which 9 of 23 had tear progression (as defined as increase in size > 5mm on either the longitudinal or transverse views), and 7 of those 9 had become symptomatic[39]. No patient demonstrated a decrease in the size of tear in this study. The authors note that a selection bias may have occurred in this study, as the asymptomatic patients were all seen originally because the contralateral shoulder was symptomatic. It may be that these patients had intrinsic weakness in the cuff and a predisposition toward both symptom and tear size progression over time.

2.2 Review of Treatment Options for Chronic Full Thickness Rotator Cuff Tears

There are many treatment options for chronic, full thickness rotator cuff tears, ranging from operative to non-operative.

In 1975, Rowe stated "...the more experienced the surgeon, the more emphasis he will place on the conservative management of rotator cuff lesions, and the slower he is to approach this problem surgically" [41], and in 1962, McLaughlin said "The wise surgeon, realizing that he may find little but rotten cloth to sew, will operate only by necessity..." [42].

Many surgeons agree that a patient should have exhausted a course of adequate non-operative or conservative management before surgery is considered. However, no standard definition of "adequate" exists, nor can one assume that

what is adequate for one patient is adequate for another. Therefore, 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 [2, 3, 5, 6, 43-45].

2.2.1 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 method over another remains inconclusive, despite past and present research in the area [46-53].

Operative repair is typically followed by four to six weeks in a sling, and months of rehabilitation. Most patients are able to return to their chosen activities between 6 and 12 months following surgery. Outcome of surgical repair has typically been shown to be beneficial, though success rates reported in the literature vary dramatically [54-57].

2.2.2 Non-Operative Treatment

The existing literature is full of conflicting results regarding the outcomes of non-operative treatment for chronic full thickness rotator cuff tears [1-3, 5, 6, 33, 44, 45, 58, 59]. Few research studies with small sample sizes and generally poor methodology (i.e. no blinding, poor randomization techniques) have examined the outcomes of non-operative treatment and have found conflicting results, with the reported success rate varying drastically between 33% [54] and 92% [60].

Postulated reasons for the variability in reported success rates may be due to the wide variety of treatments which are all considered non-operative treatment. Types of non-operative treatment examined have included: supervised physiotherapy including stretching and strengthening, home based exercise programs, ortho-therapy programs (stretching and strengthening exercises taught to the patient by an orthopaedic surgeon), steroid injections, sodium hylauronate injections, use of non-steroidal anti-inflammatories, and various combinations of the above.

Another reason for difficulty in evaluating the outcomes of non-operative treatment is the significant number of different outcome measures used, for example, the University of California Los Angeles Shoulder score (UCLA score), patient satisfaction, pain scores, or functional measures such as range of motion and strength, thus making comparison between studies very difficult.

Lastly, varying methods for defining or diagnosing a rotator cuff tear also make comparisons between studies difficult. Some studies define a cuff tear based on clinical presentation only, some use arthrography, some use ultrasound or MRI and some use arthroscopy. Clearly these three variables make comparisons between multiple studies next to impossible and may account for the significantly different success rates that are reported. Several reviews have discussed these factors as limitations within the current literature [6, 44, 59].

2.3 Summary of Existing Literature on Non-Operative Treatment of Rotator Cuff Tears

Work by Bokor et al examined non-operative treatment in 53 patients with full thickness tears determined via arthrography[45]. Non-operative treatment in this case consisted of non-steroidal anti-inflammatory medications, stretching, strengthening and occasional steroid injections. Patients were evaluated at an average of 7.6 years for outcomes including pain (improved in 77% of patients), range of motion (mean active elevation improved from 121°at initial visit to 149° at follow-up visit), strength (improved strength in 45% of patients), function (ability to perform activities of daily living with mild or no compromise improved 52% from initial visit to follow-up), and the UCLA score (improved from mean 14.6 at initial presentation to 28.1 at follow-up). The authors concluded that while their results support non-operative treatment, the population they followed was pre-selected and not representative of the entire population with rotator cuff tears (all patients were diagnosed for a full thickness tear using arthrography and any patients subsequently treated with surgery were excluded) [45].

Goldberg et al documented the functional outcome in 46 patients following a treatment regime of patient education and a home program of gentle stretching and strengthening. Using the Simple Shoulder Test, 59% of patients improved 2.5 ± 1.6 years later, while 30% of patients experienced worsening and 11% remained unchanged [2].

Bartolozzi, Andreychik, and Ahmad found that 136 patients with impingement syndrome and rotator cuff disease followed up at a minimum of 6 months following non-operative treatment (including combinations of physical therapy for strengthening and regaining range of motion, corticosteroid subacromial injections, and non-steroidal anti-inflammatory medications) showed 66% excellent/good and 34% fair/poor results based on the UCLA score. A subset of 68 of patients who were followed for a minimum of 18 months showed 76% excellent/good, and 24% fair/poor results [1].

Lahteenmaki et al suggest operative management of all full thickness tears, regardless of tear size, if patients present with any symptoms, especially pain [61]. However, this statement is made following a surgical review, not having examined any patients treated with non-operative care.

A 2007 Cochrane Collaboration Systematic Review by Ejnismann et al evaluated 8 trials (out of 21 identified) and concluded that there is little evidence to support or refute the efficacy of common interventions (both operative and non-operative) for tears of the rotator cuff in adults [59]. Ejnismann et al stated that the methodological quality of the included studies was disappointing, the large number of different scoring systems used to quantify treatment outcomes made it difficult to compare outcomes between studies, and that there is a lack of uniformity in the way that rotator cuff tears are labelled and defined [59]. Their concluding implication for practice is that there is poor data from non-controlled

studies favouring conservative interventions. They further state that because non-surgical interventions are less invasive and less expensive than surgical approaches, they could be the first approach for rotator cuff tears until there are more reliable results from better quality clinical trials [59].

2.4 Review of Existing Literature on Prognostic Factors

Very few studies examine prognostic factors, whether negative or positive, for non-operative treatment of rotator cuff tears.

Work by Bartolozzi et al including patients with impingement syndrome and rotator cuff disease (stages not specified) found that the following characteristics/factors were associated with an unfavourable outcome: tears >1cm^2, symptom history for >1yr, and significant functional impairment (as measured using the UCLA scoring system) at initial presentation. Factors that were not associated with clinical outcome included: patient age, occupation, gender, associated instability, dominance, chronicity of onset, active range of motion, or specific treatment modalities[1].

Hawkins and Dunlop studied 33 patients with full thickness rotator cuff tears following a supervised non-operative program of rotator cuff strengthening exercises, and found that patient satisfaction with non-operative treatment is best correlated with improved pain relief, the ability to carry a 10-15lb suitcase at one's side, the ability to use the arm at shoulder level and the ability to eat using

a utensil. Further, they found that objective variables such as strength and active motion are not correlated with patient satisfaction [3].

Itoi and Tabata found that conservative treatment affords satisfactory results when it is given to patients with full thickness cuff tears with well preserved motion and strength, although in some cases function may deteriorate with time[4].

Goldberg et al found that outcome of non-operative treatment could not be predicted from age, gender, or tear size, but they did find that a tear of the dominant arm, a lower average initial score on the Simple Shoulder Test, and initial difficulty tucking the shirt behind the back were all statistically associated with greater improvement [2]. Whether these improvements are clinically relevant is not explored.

Based on their review article, Wolf et al suggest that patients who present with strength less than 4/5 using manual muscle testing, a positive shrug on active elevation, positive lag signs, or a positive drop arm sign are unlikely to improve with non-operative treatment. They go on to suggest that factors that "seem to be important" include duration of symptoms, acuity of tear, weakness, size of tear and muscle atrophy and fatty infiltration as assessed on MRI [6].

Clearly, treatment of rotator cuff tears is a topic that has been explored to a great degree in the literature. However, the quality of the existing studies and the

inability to reach a consistent conclusion indicates that more work is required in this area.

2.5 Summary of Rotator Cuff Disease

Rotator cuff tears are a common and debilitating condition and occur more frequently with increasing age. They have been identified and discussed for hundreds of years, and yet it remains that our understanding of their natural history is limited.

Treatment options for chronic full thickness tears range from non-operative to operative, and most surgeons agree that patients should exhaust non-operative options before considering surgery. Conflicting literature reports a very wide range of outcomes of non-operative treatment, and prognostic factors for the outcome of non-operative treatment remain unclear despite past research in the area.

2.6 Review of Methodology of Existing Literature on Clinical Prediction Rules

According to Wasson et al [62], "Clinical prediction rules (CPR) are explicit empirical statements that are formulated to improve the efficiency and accuracy of physicians' judgements." They are intended to help physicians interpret clinical information, and can estimate the probability of a diagnostic outcome, or link clinical characteristics to a choice of treatment [62].

Portney and Watkins outline a three step process for developing a clinical prediction rule [63]. The first step involves identifying the factors that potentially contribute to the prediction of the outcome. The rule is then derived, which establishes the variables that are most predictive. The second step in developing a CPR is validation of the rule. This should occur in several cohorts in different settings to ensure it's applicability across various samples. Lastly, an impact analysis of the newly developed CPR should be performed, to illustrate if the rule has altered clinician behaviour and resulted in beneficial outcomes [63].

There are many examples of clinical prediction rules in the medical literature [64-81]. Two specific examples of the development and refinement of clinical prediction rules have been examined here, including work by Wells et al on pulmonary embolism and deep vein thrombosis diagnosis, and work by Kocher et al on diagnosis of septic hip arthritis in children [82-87].

The following two examples illustrate the process of developing a clinical prediction rule for diagnosis. The present thesis will utilize the same methodology to begin the process of developing a prediction rule for outcome of treatment.

2.6.1 Deep Vein Thrombosis/Pulmonary Embolism Literature

Wells et al have done extensive work on clinical prediction rules for deep vein thrombosis (DVT) and pulmonary embolism (PE) risk. They have published four

separate papers illustrating the process of deriving and revising their clinical prediction rules[84-87].

The original derivation of their first clinical model was done prior to the start of their published study[86], and included items obtained from a literature review as well as the collective experience of the participating investigators. From the model, a probability score was derived that grouped patients into low, moderate or high probability (of DVT) categories. The model was then pilot tested in a group of 100 outpatients with suspected DVT. The investigators identified certain combinations of clinical factors that were less predictive of DVT, and the final model included items that were designated as either major or minor, and included proven risk factors, and pertinent symptoms and physical signs at patient presentation. Unfortunately, they do not report and details around the methodology of how the items were analyzed for inclusion or exclusion from the final model.

They went on to test the model, in conjunction with venous ultrasonography, to determine the potential for an improved and simplified diagnostic approach. They stopped once they were satisfied they had achieved the most simplified model possible. As in many studies, they concluded by stating that a prospective validation study was needed to test the safety and clinical utility of the model[86].

Three years later, in 1998, Wells et al published two additional papers on clinical prediction. One was in follow-up to their 1995 paper previously discussed. The

goal of this study was to demonstrate the utility of their previously derived clinical model in conjunction with impedance plethysmography, and also to develop a simpler scoring system, while maintaining accuracy, of their original DVT prediction model[87].

The simplified clinical model was developed through retrospective analysis of clinical data collected prospectively on 453 patients. The authors state that they first revised the original clinical model by performing a simple regression analysis, then performing a multiple logistic regression analysis to devise the scoring system. The stepwise logistic regression analysis identified nine variables that were significantly associated with DVT.

Of the nine variables identified, eight related significantly and positively, while one related significantly and negatively to the outcome. The calculated regression coefficients for the eight variables related significantly and positively ranged from 0.62 to 3.2, however all were rounded to one, for simplicity sake, and so as not to provide undue weight to rarely encountered variables[87]. The one variable with a significant but negative relationship to DVT had a calculated coefficient of -1.8, and was rounded to -2.

The final scoring system was the sum of the rounded coefficient values, with a score of 0 or less corresponding to low probability of DVT, a score of 1 or 2 corresponding to moderate probability, and a score of 3 or more corresponding to high probability of DVT.

No significant difference was found when comparing the original clinical model to the revised model with respect to prevalence of DVT, and the accuracy of impedance plethysmograpghy in each of the three pretest probability categories[87].

In regards to their work on clinical prediction of pulmonary embolism (PE), Wells et al very closely followed the methodology they had used in developing their DVT prediction model. They utilized criteria from the published literature, and established a pilot model via consensus[85]. They pilot tested their preliminary PE model in a study of 91 patients and subsequently refined the model, however they do not report on the methodology of this process. In their second publication in 1998[85] they use their clinical PE model to classify 1239 patients into low, moderate or high PE risk. This model was able to distinguish low, moderate and high probability cohorts in whom the incidence rates of PE were 3%, 28%, and 78% respectively. The results of this study showed that they had developed a safe, effective, and largely non-invasive means of diagnosing patients with suspected PE.

Wells et al's follow-up paper in 2000 aimed to further simplify the PE prediction model they had previously developed, and to develop a scoring system, that when used in conjunction with D-dimer results, could safely exclude PE without the need for other tests[84]. A random sample of 80% of their original study population formed a derivation set and was utilized to perform univariate

regression analysis. This step analysed the 40 variables that were included in the original clinical model, and any variable with a p-value <0.15 was then included into a stepwise regression analysis. (The authors do not give any justification for choosing the p value of 0.15, however one would assume it is so they do not exclude variables too freely). The authors note that some of the more common variables that were significant in the univariate analysis did not reach significance in the stepwise analysis.

Any variable with a p-value <0.05 in the stepwise regression was considered significant, and a regression coefficient was obtained for each significant ($p<0.05$) variable. The variables that were significantly associated with PE in the stepwise logistic regression demonstrated calculated coefficients ranging from 0.81 to 1.5. Seven variables were shown to be significant and formed the final clinical prediction rule. The authors state that the calculated coefficients of the seven significant variables were doubled, then rounded to the nearest 0.5 to form the clinical prediction rule. The do not provide a justification for this step.

Cut points were then created to group patients into the probability groups of low, moderate, and high, with a similar distribution to their original study (3% low, 28% moderate, 78% high).

To validate this new clinical prediction rule, the 20% of the original sample population that had not been included in the derivation set was utilized as a validation set.

To further simplify the clinical model, the authors then developed a second scoring system where patients could be classified into one of two groups: PE unlikely, or PE likely (as opposed to low, moderate or high probability). Patients with an overall integer score of ≤ 4 were unlikely, while patient with a score >4 were likely to have PE.

The authors concluded that the clinical prediction rule of PE likely or PE unlikely, when used in combination with D-dimer should result in a safe, effective and largely non-invasive means to diagnose patients with suspected pulmonary embolism[84].

2.6.2 Paediatric Orthopaedic Literature (Septic Hips)

Kocher et al have published two separate articles on a clinical prediction rule for differentiating between septic arthritis and transient synovitis of the hip in children, in 1999 and 2004[82, 83]. The purpose of the first article was to develop an evidence based clinical prediction model based on presenting variables that would determine if a child had septic arthritis or transient synovitis in their hip[83]. The purpose of the second article was to validate the same prediction rule[82].

Two-hundred eighty-two patients were retrospectively reviewed for the development phase (paper 1), of which 168 were included. Approximately 22 variables were collected on all included patients, which were then analyzed with univariate methods. Two-sample student t-tests were used for continuous

variables, and Fisher's exact test was used for categorical variables. Any variable with a p value of <0.20 was included into the multivariate model (no justification given).

Stepwise multiple logistic regression with backward selection identified independent variables, from which four independent clinical predictors were identified that would differentiate between septic arthritis and transient synovitis.

The regression model with the four predictive variables fit was estimated with the Hosmer-Lemeshow goodness of fit test and demonstrated no significant departure from good model fit (p=0.57). The receiver operating characteristic (ROC) curve was constructed to assess the diagnostic performance in identifying septic arthritis (sensitivity or true positive rate, versus 1 – specificity or false positive rate), and showed excellent diagnostic performance of the four multivariate predictors (area under curve = 0.96).

All combinations of the four variables were computed, resulting in 16 combinations of predictors. The predicted probability of septic arthritis was then determined: less than 0.2 % for zero predictors, 3.0 percent for one predictor, 40.0 percent for two predictors, 93.1 percent for three predictors, and 99.6 percent chance of a child having septic arthritis of the hip when all four predictor variables are present[83].

In follow-up, in 2004 Kocher et al published a paper on the validation of their previously constructed clinical prediction rule for septic arthritis of the hip in children[82]. They stated the importance of validating a clinical prediction rule in a new population, as prediction rules usually demonstrate diminished performance in a new patient population after having been optimally modeled for the derivation population[82].

The validation procedure was performed on a prospective cohort of 154 patients over a five year period. The same statistical methods described above from their 1999 paper were followed, and showed diminished, though very good ability to differentiate between septic arthritis and transient synovitis in the new patient population.

2.6.3 Summary of Clinical Prediction Rules Methodology

Both the PE/DVT and septic hip literature reviewed here follow similar methodology in development of a clinical prediction rule. First, independent variables are identified and evaluated for inclusion into a regression model. The regression model is evaluated for stability and predictive power in the study population. Finally, the model is evaluated in a larger population to determine general applicability. Over time the prediction rule may be modified to further simplify the included variables or outcome categories.

Both previous examples illustrate the effectiveness that a clinical prediction rule can achieve in assisting physicians with diagnosis. While the goal of the present

thesis is not to create a prediction rule for diagnosis, rather for predicting outcome of treatment, the methodology is the same.

The development of a full clinical prediction rule for predicting outcome of non-operative treatment of a chronic full thickness rotator cuff tear is of too great a scope for this thesis project. However, this thesis will use the examined methodology in an exploratory manner to develop a hypothesis generating model which can be utilized as a first step in the development of a clinical prediction rule.

2.7 Summary

Optimizing care for patients with a chronic, full thickness rotator cuff tear through the use of a clinical prediction rule would help to improve individual patient care as well as the efficiency of an overburdened Canadian health care system.

Chapter Three: METHODS

3.1 Study Design

This study was an observational prospective cohort design. It was conducted in a University based Sport Medicine Centre.

3.2 Procedures

3.2.1 "Consensus" Meeting on Adequate Conservative Treatment

In order to evaluate and discuss predictive factors for non-operative treatment outcomes it was imperative to begin by defining non-operative treatment. To do this a "consensus" on the question "what is adequate non-operative treatment?" was needed. To determine this "consensus", participants from the Calgary Health Region, including shoulder surgeons, sport medicine physicians, physiotherapists, athletic therapists, epidemiologists and health care administrators were invited to the March 2008 Shoulder Rounds at the University of Calgary Sport Medicine Centre. Topics discussed and agreed upon during this "consensus" meeting included types of treatment (i.e. stretching, strengthening, etc) and timing (length of treatment course). Each topic was discussed until general agreement was reached, and then participants were asked to raise their hand if they agreed with the final statement in question. If the majority of participants agreed, a "consensus" was declared.

It was agreed that anti-inflammatories, analgesics and/or modalities could be utilized to control pain and facilitate a patient specific exercise program. The goal of the exercise program was to address the physical limitations of the

individual patient, specifically to restore range of motion and improve functional strength. In follow-up at six weeks, if the patient was improving, they should be instructed to continue with the program. If six weeks of physical treatment had shown no benefits, it was reasonable to offer further pain management options such as a cortisone injection. Three months following the commencement of the exercise program the patient should again be re-evaluated. If the patient was improving, they should be instructed to continue with the program. If they were not improving at the three-month mark, surgery would be a reasonable consideration. Please see Appendix A for the full details of the "consensus" meeting.

3.2.2 Development of the Non-Operative Rotator Cuff Home Program

The non-operative rotator cuff home program was not intended to be a standardized formal physiotherapy program, but rather a guideline which doctors and physiotherapists could provide to patients to perform at home, at the office, on vacation, etc. The investigators understood acutely that the program would not be successful if patients did not perform it, therefore making it as easy and as accessible as possible was a major focus.

The protocol was developed based on existing rehabilitation protocols used at the University of Calgary Sport Medicine Centre for post-operative rehabilitation for rotator cuff surgery of small to medium, and large to massive, tears. The author worked with two physiotherapists to design an appropriate home program.

From the consensus meeting, it was determined that the first phase of the program had to address both pain and stiffness. Therefore, the two primary goals of phase one were to decrease shoulder pain, and increase shoulder range of motion (ROM). Exercises were included to achieve these goals, and it was anticipated that most patients would achieve this goal in six weeks (or less). If patients had not achieved a pain free status with improved ROM by six weeks, additional pain control (i.e. cortisone injection) would be an appropriate adjunct to the program.

Once pain control had been achieved and ROM was sufficient, patients could then move on to the second phase of the program. Goals of phase two included improving the strength and muscular control of the shoulder, and creating muscle fatigue while performing the exercises without considerable increases in pain. It was anticipated that most patients would achieve improved strength by 12 weeks of diligent performance of the program.

Multiple iterations of the program were created by the author and physiotherapists, with each iteration being thoroughly review by the four shoulder surgeons in the Shoulder Research Group at the University of Calgary Sport Medicine Centre. Once all four surgeons and both physiotherapists were satisfied with the program, it was professionally printed and put into use in the Sport Medicine Centre, not only for study patients, but also for any other patients

seen by the surgeons, physicians and physiotherapists. Please see Appendix B for a copy of the non-operative program.

3.2.3 Ethics

The study was submitted to and approved by the University of Calgary Office of Medical Bioethics. Patients did not loose their spot in queue on the surgeon's wait list by participating in this study so there was no risk of delayed care. Patients were free to withdraw from the study at any time.

3.2.4 Identification of Participants/Recruitment:

Patients were identified from new referrals to two sub-specialty shoulder surgeons at the University of Calgary Sport Medicine Centre between October 2008 and April 2009. The two involved surgeons reviewed their own referrals and then passed rotator cuff specific referrals on to the author. The author used a form which had been previously developed specifically to screen and evaluate rotator cuff referrals (appendix C), and telephoned all patients who were potentially eligible for further screening. During the telephone screening, the study was described to potentially eligible patients to determine their interest in participating. Those interested were booked to see a sport medicine physician (they were not yet consented for the study).

Previous review of patients on the waiting lists for the two shoulder specialized surgeons had demonstrated a very wide range of patient characteristics,

including age, duration of symptoms, severity of symptoms, desire for surgical treatment, and non-operative treatments tried prior to referral.

3.2.5 Inclusion Criteria (Appendix D)

- Age: 40 – 85 years.
- Full thickness rotator cuff tear, confirmed on ultrasound or MRI.
- Symptomatic for minimum of 3 months.

3.2.6 Exclusion Criteria (Appendix D)

- Already exhausted non-operative treatment (i.e. patient had already undertaken a 3 month program of stretching and strengthening exercises, with use of analgesics, anti-inflammatories, and/or modalities, plus or minus injections, which is consistent with the standards as outlined in Appendix A and B).
- Concomitant symptomatic pathology of the affected shoulder (i.e. instability, high riding humeral head indicating cuff tear arthropathy, osteoarthritis, etc).
- Full thickness tear of subscapularis or teres minor demonstrated on imaging.
- Acute injury (less than 3 months of symptoms).

- Significant medical issues precluding surgery.
- Secondary gain issues (i.e. worker's compensation, litigation).
- Unable or unwilling to complete study outcomes.
- Unable to provide informed consent.
- Elite athlete.
- Significant cervical spine pathology and/or radiculopathy.

3.2.7 Treatment Protocol

Patients who were included in the study attended a total of five appointments, including:

- An initial appointment with one of two Sport Medicine Physicians at the University of Calgary Sport Medicine Centre. At this appointment, the physician confirmed the patient's eligibility for participation, and the patient then provided informed consent (Appendix E) to participate. The author collected all study data, including, the Rotator Cuff Quality of Life questionnaire (RCQOL) (Appendix F), demographic information, and measurements of shoulder ROM and strength (Appendix G). The physician was free to provide any pain control that they deemed

necessary (i.e. anti-inflammatories), and the author recorded this on a data collection form (Appendix H).

- The second appointment occurred with a study physiotherapist as soon after appointment one as possible. Physiotherapists were available in three clinics in two quadrants of the city, including one physiotherapist at the Sunridge Physiotherapy Clinic (NE), three physiotherapists at Calgary Winter Club Sport Physiotherapy (NW), and four physiotherapists at the University of Calgary Sport Medicine Centre (NW). (These physiotherapists were all known to at least one member of the research team and were considered to be very good therapists). Patients were able to select the clinic which was most convenient for them. At this appointment an individualized approach was used. The physiotherapist assessed the patient, and taught them the appropriate exercises for their current condition (i.e. not every patient did every exercise). For example, if patients already had adequate pain control and ROM, the physio could teach them strengthening exercises from the second phase of the program. The physio instructed each patient on how to perform the exercises, and the frequency (including repetitions and number of sets per day) that the patients were expected to perform the exercises outside of the study visits. Any patient questions were addressed by the physiotherapist.

- The third appointment which the patient attended for the study was with the same physiotherapist that they had seen for their original physiotherapy appointment. This occurred approximately two to four weeks following the first physio appointment. The goal at this appointment was for the physio to evaluate the patient's progress with the non-operative program, make any modifications necessary to existing exercises, and provide instruction on the second phase of exercises. The study team debated the timing of this appointment, with the idea that the second phase of exercises may not start until six weeks, however it was determined that an earlier follow-up visit would be critical in encouraging compliance and correct performance of the exercises.

- The fourth appointment that the patient was required to attend was six weeks from their initial appointment with the physician, and was a follow-up appointment with the Sport Medicine Physician whom they had originally seen. The physician discussed any concerns that the patient had at this appointment, and was free to prescribe any type of pain control as necessary (i.e. anti-inflammatories, cortisone injection). The author collected the Rotator Cuff Quality of Life questionnaire, ROM and strength measurements, and a global rating of change score (Appendix I), and recorded any additional treatments prescribed by the physician, or any additional treatments the patient had sought outside of the study specifically for their shoulder.

- The fifth and final visit which the patient was required to attend for the study was three months following their inclusion into the study. This visit was to meet the surgeon to whom they had originally been referred. The author again collected the Rotator Cuff Quality of Life questionnaire, ROM and strength measurements, and a global rating of change score, as well as any additional treatments to the shoulder since the previous visit. The surgeon then assessed the patient as they would any new patient presenting to their clinic with a chronic, full thickness rotator cuff tear. The surgeon was free to collect any information they required (i.e. RCQOL score) for their assessment, however they were not given access to the previously collected study data. The surgeon discussed the shoulder history with the patient, performed a physical exam of the shoulder, and discussed the risks and benefits of surgery, as well as alternatives to surgery. At the end of the consultation, the surgeon made a decision in collaboration with the patient as to whether or not the patient had been successful or failed the non operative rehabilitation program.

All patients were expected to perform the exercises on their own between study appointments. All patients were given a log-book (Appendix J) at the first visit, to keep track of the number of times they performed the prescribed exercises as well as any additional treatments that they sought for their shoulder. They were asked to return the monthly pages of the log book at the next visit to the physician which fell in a new month (i.e. if first visit was in Oct, and next visit was

in Nov, they were asked to bring the Oct page). Patients were contacted via email or telephone each week in the first 6 weeks, and biweekly in the second 6 weeks, by the author, to encourage and monitor compliance.

3.3 Outcome Measures

3.3.1 Dependent Variable

The dependent variable was outcome of non-operative treatment – success or failure. This was determined by the surgeon (preferably in agreement with the patient), at the three month appointment. Patients who had experienced improvement in their symptoms to the point where it was most appropriate that they continue with non-operative treatment and avoid surgery were defined as having been successful. Conversely, patients who had not experienced an improvement in their symptoms and/or were appropriate for surgery were defined as failures. Patients who did not go on to surgery for other health or "life" reasons but who had not experienced improvement in their symptoms were considered failures.

3.3.2 Independent Variables

The literature shows conflicting results for many prognostic factors. While it is recognized that several factors likely play a role in the outcome of non-operative treatment, feasibility limited the number of variables that could be examined in the present study/model.

Participants at the consensus meeting were asked to rank a list of independent variables from most to least important, in terms of their influence on outcome of non-operative treatment. This ranking helped the investigative team to identify which factors should be considered for inclusion in the study. From the final rankings, the study team identified three factors a-priori for inclusion in the current study. These factors were agreed upon based on multiple discussions and are also supported by the literature [1-4, 6].

The following are the independent variables that were examined:

- ROM: Passive forward elevation in the scapular plane, measured with goniometry as per Hayes et al, with the exception that the patient's feet were not placed on a foot-stool [88].

- Shoulder specific Quality of Life: The RCQOL is a disease specific questionnaire that was developed to precisely assess the quality of life in those patients with rotator cuff repairs before and after surgery [89]. This questionnaire utilizes patient self assessment and has demonstrated excellent reliability, face validity, and ability to discriminate between large and massive cuff tears [89-91]. The comprehensive 34 item questionnaire has specific inquiries into symptoms and physical complaints, work related concerns, recreation and sport participation, lifestyle, and social and emotional domains. Patients completed the RCQOL based on their

current condition. The total score was converted to a score out of 100, where zero is as bad as can be, and 100 is perfect.

- Patient age (years).

Additional clinical characteristics which help define the patient population were collected, including: gender, smoking status, duration of symptoms, size of tear, hand dominance versus side involved, onset (acute or insidious), and external rotation strength measured using manual muscle testing. These characteristics were examined using an exploratory analysis.

3.4 Data Management

All data was collected by the author. Data was visually assessed by the author at the time of collection to ensure completeness and correctness. The author was responsible for data entry.

Once data was entered electronically, it was visually inspected for completeness and correctness, with cross-referencing back to the original data collection forms as needed. The values of any outliers were verified. Missing data was dealt with on a case-by-case basis, and where it could be collected by a follow-up telephone call or email, the author did so.

All subjects were assigned a unique identifying study number upon enrolment into the study. Data collection forms were marked with the study identification

number and the patient initials and not the patient's full name to help protect confidentiality.

Data was stored in a locked office at the University of Calgary Sport Medicine Centre and was only accessible to the study investigators. Electronic data was stored on a password-protected computer which was also only accessible to the study investigators.

3.5 Sample Size

As per Peduzzi et al [92] and Hosmer and Lemeshow, [93] an accepted sample size for a dichotomous outcome in a logistic regression model is 10 events per independent factor included in the model.

Based on previous experience in recruiting patients with chronic full thickness rotator cuff tears for another trial, it was our clinical sense that approximately two of three patients are unsuccessful with non-operative treatment.

The sample size was calculated as follows:

1) 10 "failures" x 3 factors = 30 patients

2) 2/3 fail = 45 patients

3) add 10% for loss to follow-up/dropout = 45+5 = 50

The total sample size for this master's project was 50.

3.6 Data Analysis

Data was analyzed using PASW Statistics Data Editor 17 (formerly SPSS).

3.6.1 Primary Analysis

To examine the ability to predict outcome of non-operative treatment using the independent variables identified, patients were grouped based on their outcome (success or failure). With the dichotomous nature of the primary outcome (success or failure) logistic regression was used for analysis.

Each a-priori identified independent variable (ROM, age, and RCQOL) was examined for association with the dependent variable (outcome of non-operative treatment) in univariate logistic regression equations using the enter method. The additional variables collected (i.e. gender, smoking status, etc) were also examined in the same way for the secondary, exploratory analysis. The likelihood of the relationship being due to chance was determined using p-values. If the relationship was not likely to be explained by chance ($p<0.25$) it was concluded that the independent variable accounted for a statistically significant proportion of the variability in the dependent variable. This was performed separately for each independent variable. The p-value of 0.25 was selected so as not to exclude variables too freely at the first step of the analysis, and is supported in the literature [93-95]. Independent variables that reached significance were also considered practically as to whether it was logical that they be included in further modelling. Because of the process utilized to include

each independent variable originally, it was concluded that each of the variables reaching significance were reasonable to include in further analysis.

Next, all independent variables which demonstrated significance were examined together in pairs, using bivariate logistic regression analyses. All possible combinations of significant independent variables were examined.

Finally, all variables that demonstrated significance in the univariate comparisons were analyzed in a multivariate logistic regression model.

All models (univariate, bivariate and multivariate) were assessed for their goodness of fit (how well they classified the observed data) using -2 log-likelihood (-2LL). A small -2LL translated to a good model (high likelihood of the observed results). The models were also assessed using the Nagelkerke R^2 statistic which attempts to quantify the proportion of variance explained by the model (i.e. percentage of variance of the outcome which was explained by the model). -2LL and Nagelkerke R^2 were assessed to evaluate the overall fit of each model [96].

Odds ratios were examined in each model to estimate the odds of belonging to the target group based on a one-unit change in the value of the independent variable being examined.

95% Confidence intervals (CIs) were calculated around each odds ratio to determine the precision. Any confidence interval that contained the null value (1.0) was considered to be not significant.

With each model, the logit of the regression equation was determined ($Z = a + b1X1 + b2X2 + b3X3...$). This logit equation was then available to be utilized with data at the individual patient level to determine a specific patient's predicted probability ($e^z / 1 + e^z$). The calculated predicted probability produced a score between 0 (defined as failure) and 1 (defined as success). A score closer to 1 predicts that the subject is likely to be successful with non-operative treatment, where a score closer to 0 predicts that the subject is more likely to fail. A score of 0.5 suggests that the patient is just as likely to succeed as they are to fail.

Sensitivity and specificity were calculated for all statistically significant independent variables measured on a continuous scale. Receiver operating characteristic (ROC) curves were plotted to show the balance between sensitivity and specificity. Sensitivity was plotted on the y-axis and 1 minus specificity on the x-axis to determine the best cut-off points which would distinguish between success and failure.

3.6.2 Secondary/Exploratory analysis

For hypothesis generation for future work, the additional independent variables that had been collected were also examined using the techniques described above.

It should be stated very clearly that all secondary analyses were exploratory only, and no conclusions can be drawn from them.

Chapter Four: RESULTS

4.1 Patient Screening / Selection

A consort style diagram of patient screening and selection is shown in Figure 1.

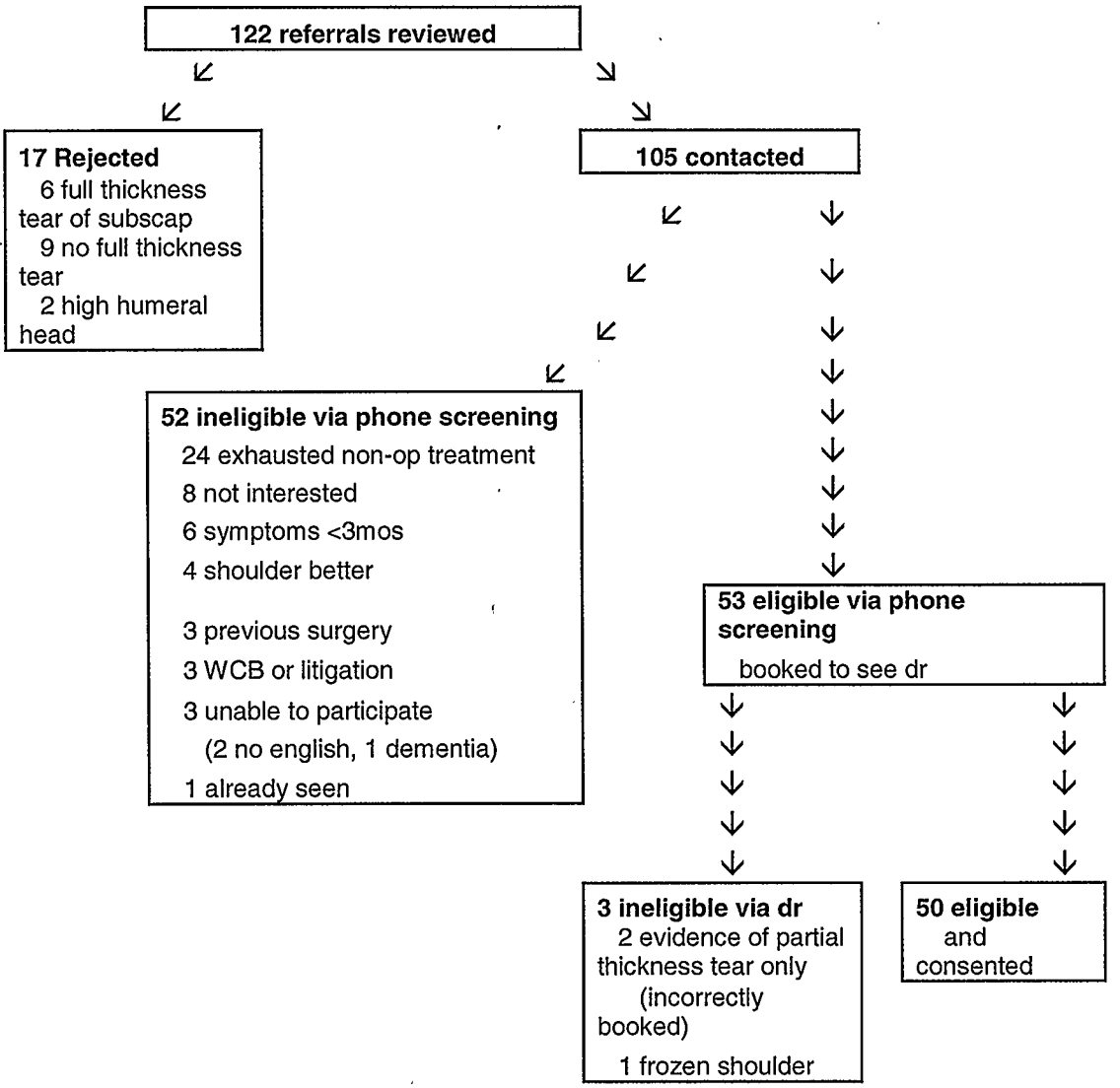

Figure 1: "Consort" Diagram of Patient Selection

In total, 122 referrals were reviewed by the author. Seventeen referrals were rejected before the patient was contacted (6 had full thickness subscapularis

tears on imaging; 9 had no evidence of a full thickness tear of supraspinatus or infraspinatus on imaging; 2 had a high riding humeral head on imaging). One hundred five patients were contacted by the author. Of these, 52 were deemed ineligible via the telephone screening (24 had already exhausted adequate non-operative treatment, 8 were not interested in participating; 6 had less than 3 months duration of symptoms, 4 declared that their shoulder was better and no longer needed an appointment; 3 had undergone previous surgery on the affected shoulder; 3 were Worker's Compensation or litigation cases; 3 were unable to complete the study outcomes (2 did not speak English, 1 suffered from dementia); and 1 had already been seen by another physician). The remaining 53 potential patients attended the initial appointment with the physician, where three patients were excluded (2 had been incorrectly booked -- both had evidence of a partial thickness tear but no evidence of a full thickness tear; and 1 had frozen shoulder). In total, 50 patients provided informed consent and were enrolled into the study (30 males; 20 females). Baseline characteristics are summarized in Table 1.

Age		**Dominant Side Involved**	
range	40 - 85	yes	32
mean	60.4	no	18
SD	10.97		
		Duration Symptoms (months)	
FE ROM		range	3 - 180
range	100 - 180	mean	22.9
mean	151.5	SD	37.9
SD	21.2		
		Size of Tear	
RCQOL		< 3 cm	41
range	0 - 83	≥ 3 cm	9
mean	44.4		
SD	21.5	**Onset**	
		acute	29
ER Strength		insidious	21
5	11		
4 (incl -/+)	35	**Smoker**	
≤3	4	yes	7
		no	43

Table 1: Baseline Characteristics of All Patients

Forty-eight of fifty patients (96%) attended the final (3 month) visit. The two patients who did not attend the final visit were followed-up with via telephone to determine their final outcome.

Patients were asked to record their performance of the non-operative treatment program exercises and any additional treatments they sought in a log book. 46% of patients returned at least one month worth of logbooks. From the completed logbooks, patients indicated that they performed the exercises on average of 2 times per day, every day of the week. The highest reported was 4 times per day, 7 days per week, while the lowest reported was 1 time per day, every other day.

This indicates that the program was being performed a reasonable amount, at least by the patients who returned their logbooks. No patient reported additional treatment sought outside of the study.

Thirty-eight (76%) patients were classified as being successful with non-operative treatment at their final visit, while 12 (24%) were classified as having failed non-operative treatment. The baseline demographic characteristics of patients in each group (success or failure) is shown in Table 2.

	Successful (n=38) # (SD)	**Failed**(n = 12) # (SD)	**Sig *(<0.25)**
Age (years)	61.45 (10.92)	57.25 (10.97)	0.249*
range	40 to 85	42 to 72	
FE ROM (degrees)	152 (21.9)	149 (19.4)	0.717
range	100 to 180	110 to 170	
RCQOL (/100)	48.71 (21.6)	30.73 (15.4)	0.017*
range	0 to 83	6 to 58	
Duration Symptoms (months)	25 (42.5)	15 (15.4)	0.432
range	3 to 180	3 to 48	
Size of Tear (mm)	13.8 (5.8)	16 (5.9)	0.352
range	4 to 29	12 to 30	
Gender			0.892
M	23 (60.5%)	7 (58%)	
F	15 (39.5%)	5 (42%)	
ER Strength			0.296
5	8 (21%)	3 (25%)	
4 (incl -/+)	28 (74%)	7 (58%)	
≤ 3	2 (5%)	2 (17%)	
Dominant Side Involved			0.125*
yes	22 (58%)	10 (83%)	
no	16 (42%)	2 (17%)	
Onset			0.521
acute	23 (60.5%)	6 (50%)	
insidious	15 (39.5%)	6 (50%)	
Smoker			0.761
yes	5 (13%)	2 (17%)	
no	33 (87%)	10 (83%)	

Table 2: Baseline Characteristics of Successful and Failed Patients

The distribution of the outcome of patients (i.e. 38 successful and 12 failed), created a statistical issue in regards to the sample size. With only 12 patients in the one group (failed), the regression analysis was only powered to examine one independent variable in a model.

4.2 Univariate Regression Analyses

Each independent variable was examined in a univariate logistic regression model. The results of the univariate comparisons are shown in Table 3.

							95% CI for Exp(B)	
Variable	**B**	**S.E.**	**Wald**	**df**	**Sig.**	**Exp(B)**	**Lower**	**Upper**
RCQOL	0.045	0.019	5.659	1	0.017	1.046	1.008	1.085
constant	-0.61	0.752	0.658	1	0.417	0.543		
Age	0.037	0.032	1.327	1	0.249	1.038	0.974	1.105
constant	-1.048	1.905	0.303	1	0.582	0.351		
FEROM	0.006	0.016	0.131	1	0.717	1.006	0.976	1.037
constant	0.306	2.353	0.017	1	0.897	1.358		
ER ST (5)	0.223	0.776	0.083	1	0.774	1.250	0.273	5.725
constant	0.981	0.677	2.099	1	0.147	2.667		
Gender	0.091	0.673	0.018	1	0.892	1.095	0.293	4.097
constant	1.099	0.516	4.526	1	0.033	3		
Onset	-0.427	0.666	0.412	1	0.521	0.652	0.177	2.406
constant	1.344	0.458	8.592	1	0.003	3.833		
Dom side	1.291	0.841	2.354	1	0.125	3.636	0.699	18.918
constant	0.788	0.381	4.274	1	0.039	2.2		
Duration	0.011	0.014	0.619	1	0.432	1.011	0.984	1.038
constant	0.947	0.399	5.637	1	0.018	2.578		
Smoker	0.278	0.911	0.093	1	0.761	1.32	0.221	7.874
constant	0.916	0.837	1.199	1	0.273	2.5		
Size tear	-0.064	0.069	0.868	1	0.352	0.938	0.819	1.073
constant	2.131	1.132	3.545	1	0.06	8.424		

Table 3: Univariate Regression Analysis for Each Independent Variable

From the univariate comparisons, RCQOL, age, and involvement of the dominant side were statistically significant at $p<0.25$. Odds ratios were calculated for all independent variables and are listed under the heading (Exp(B)). Ninety-five% confidence intervals cross the null value (1.0) on all variables except RCQOL.

Each univariate model was assessed using (-2 Log Likelihood) and Nagelkerke R^2. Results are presented in Table 4.

Variable	(-2LL)	Nagelkerke R^2
RCQOL	48.255	0.192
Age	53.714	0.041
FEROM	54.978	0.004
ER ST	47.558	0.210
Gender	55.090	0.001
Onset	54.697	0.012
Dom Side	52.307	0.082
Duration	54.243	0.026
Smoker	55.018	0.003
Size tear	36.232	0.038

Table 4: Assessment of Univariate Models.

4.3 Bivariate Regression Analyses

The three independent variables that reached significance in the univariate testing (age, dominant side, and RCQOL) were further explored using bivariate logistic regression analysis. All possible combinations of two, using the three significant variables, were examined.

							95% CI for Exp(B)	
Variable	**B**	**S.E.**	**Wald**	**df**	**Sig.**	**Exp(B)**	**Lower**	**Upper**
Age	0.03	0.034	0.777	1	0.378	1.03	0.964	1.101
Dom Side	-1.176	0.852	1.902	1	0.168	0.309	0.058	1.64
constant	0.223	2.185	0.01	1	0.919	1.25		
RCQOL	0.054	0.021	6.783	1	0.009	1.056	1.014	1.1
Age	0.058	0.033	3.018	1	0.082	1.06	0.993	1.132
constant	-4.469	2.381	3.523	1	0.061	0.011		
Dom Side	-1.351	0.897	2.266	1	0.132	0.259	0.045	1.504
RCQOL	0.044	0.019	5.514	1	0.019	1.045	1.007	1.085
constant	0.368	0.997	0.137	1	0.712	1.445		

Table 5: Bivariate Regression Analyses for Statistically Significant Independent Variables

As with the univariate analyses, the 95% confidence intervals of the odds ratios (Exp(B)) cross the null value (1.0) on all variables except RCQOL.

The bivariate models were also assessed using the -2LL and Nagelkerke R^2. Results are presented in Table 6, and show that the combination of dominant side involvement plus RCQOL score produce the best bivariate model (lowest -2LL and highest explanation of variance/Nagelkerke R^2).

Variables	(-2LL)	Nagelkerke R^2
Age + Dom side	51.512	0.104
RCQOL + Age	45.61	0.259
Dom Side + RCQOL	44.931	0.276

Table 6: Assessment of Bivariate Models

4.4 Multivariate Regression Analysis

All three independent variables that reached significance in the univariate test were analyzed together in a multivariate logistic regression.

							95% CI for Exp(B)	
Variable	**B**	**S.E.**	**Wald**	**df**	**Sig.**	**Exp(B)**	**Lower**	**Upper**
RCQOL	0.053	0.021	6.237	1	0.013	1.054	1.011	1.098
Age	0.05	0.034	2.097	1	0.148	1.051	0.983	1.124
Dom Side	-1.084	0.922	1.383	1	0.24	0.338	0.056	2.06
constant	-3.116	2.588	1.45	1	0.229	0.044		

Table 7: Multivariate Regression Analysis for Statistically Significant Independent Variables

In the multivariate model, RCQOL is the only independent variable that is significant in predicting the outcome of non-operative treatment ($p = 0.013$).

As with the univariate and bivariate analyses, the 95% confidence intervals of the odds ratios (Exp(B)) cross the null value (1.0) on all variables except RCQOL.

The multivariate model was assessed and results are given in Table 8. This multivariate model explains 31% of the variance of the outcome (success versus failed).

Variables	(-2LL)	Nagelkerke R^2
RCQOL + Age + Dom Side	43.406	0.312

Table 8: Assessment of Multivariate Model.

The logit of the multivariate logistic regression model is represented by the equation: Z = -3.1 + (0.053 x RCQOL) + (0.050 x Age) + (-1.084 x dominant side). The predicted probability of success can then be calculated using each individual's data in the regression equation. The product of the regression equation is then used in the formula ($e^{product}$ / 1 + $e^{product}$).

4.5 Receiver Operating Characteristic Curves

Receiver Operating Characteristic Curves (ROC curves) were generated for RCQOL (Table 9, Figure 2) and Age (Table 10, Figure 3) to determine cut-off scores which distinguish between success and failure of non-operative treatment.

ROC Curve for RCQOL

RCQOL	a	b	c	d	Sens (a/a+c)	Spec (d/b+d)	1 - Spec
<10	1	2	11	36	0.083333333	0.947368421	0.052631579
<20	4	4	8	34	0.333333333	0.894736842	0.105263158
<30	6	10	6	28	0.5	0.736842105	0.263157895
<40	8	11	4	27	0.666666667	0.710526316	0.289473684
<50	11	19	1	19	0.916666667	0.5	0.5
<60	12	25	0	13	1	0.342105263	0.657894737
<70	12	31	0	7	1	0.184210526	0.815789474
<80	12	35	0	3	1	0.078947368	0.921052632
<90	12	38	0	0	1	0	1

Table 9: Sensitivity and Specificity of RCQOL

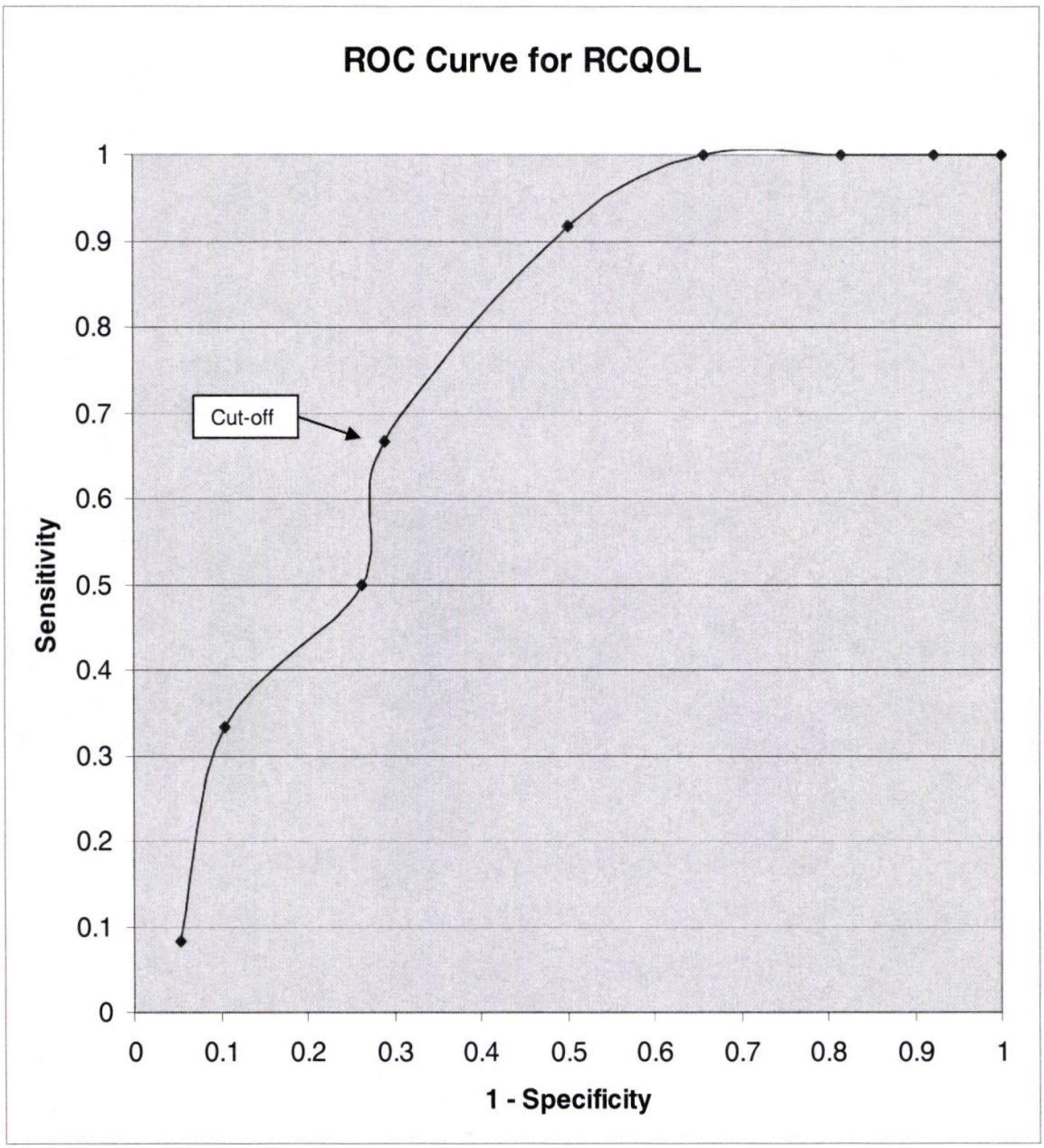

Figure 2: ROC Curve of RCQOL

From Figure 2, the RCQOL score cut-off that best distinguishes between success and failure is 40. This balances a true positive rate (i.e. sensitivity) of 71% with a false positive rate (i.e. 1 – specificity) of 29%.

ROC Curve for Age

Age	a	b	c	d	Sens (a/a+c)	Spec (d/b+d)	1 - Spec
<50	5	7	7	31	0.416666667	0.815789474	0.184210526
<55	6	11	6	27	0.5	0.710526316	0.289473684
<60	7	18	5	20	0.583333333	0.526315789	0.473684211
<65	8	26	4	12	0.666666667	0.315789474	0.684210526
<70	11	29	1	9	0.916666667	0.236842105	0.763157895
<75	12	33	0	5	1	0.131578947	0.868421053
<80	12	36	0	2	1	0.052631579	0.947368421

Table 10: Sensitivity and Specificity of Age

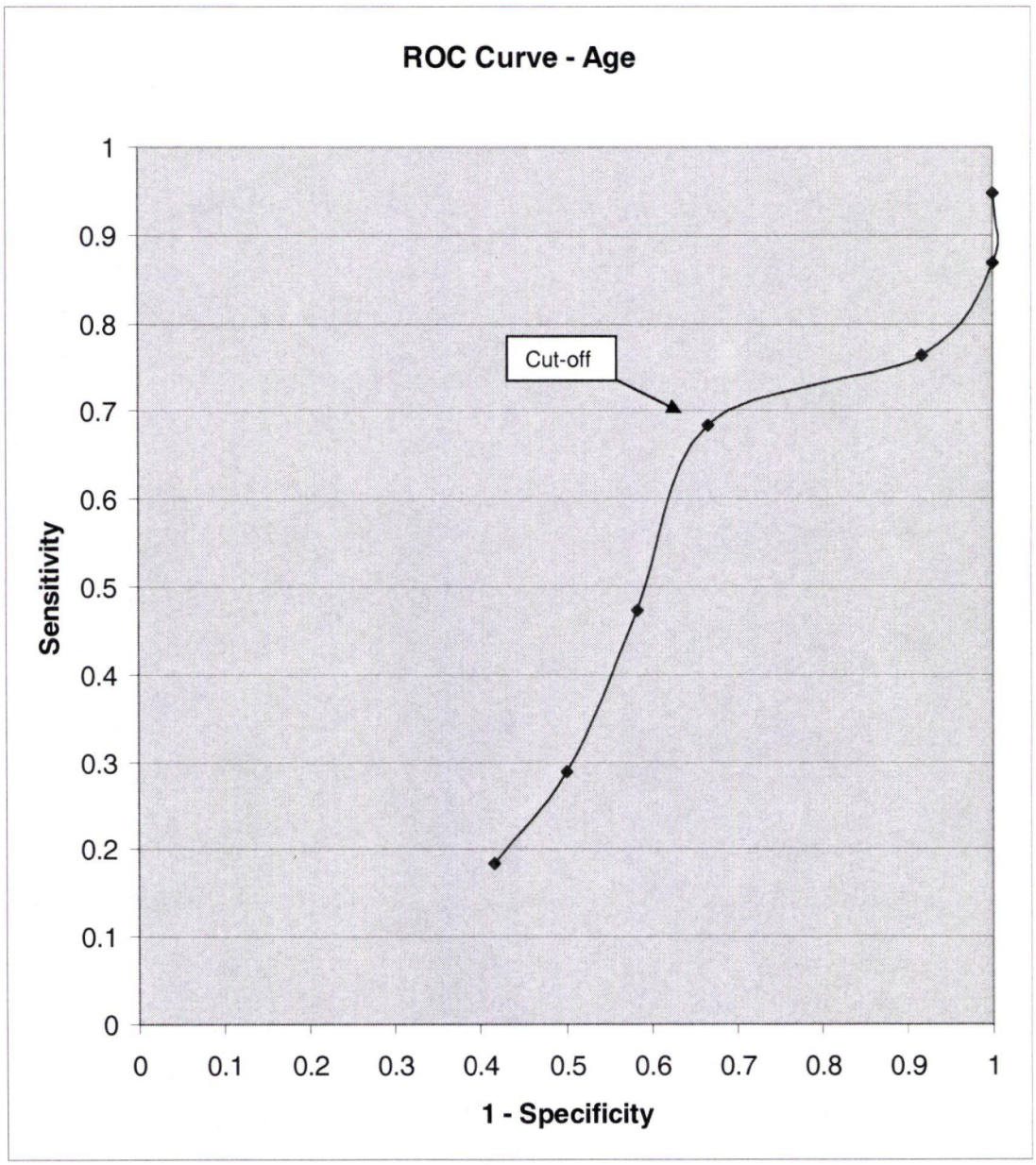

Figure 3: ROC Curve of Age

From Figure 3, the age cut-off that best distinguishes between success and failure is 65 years, which balances a true positive rate (i.e. sensitivity) of approximately 67% with a false positive rate (i.e. 1 – specificity) of 68%.

Chapter Five: DISCUSSION

5.1 Interpretation of Results

This prospective cohort study identified and followed 50 patients with a chronic full thickness rotator cuff tear who undertook a 3 month course of non-operative treatment. Seventy-six percent of patients were classified as having been successful with the non-operative program by the surgeon at the 3 month time-point. However, with only 12 patients in the failed group, the power to examine a regression model would be limited to including only one factor (one independent variable) in the model.

Therefore, all further analysis is exploratory in nature, and will be used to generate hypotheses for further work in the future.

5.2 Success Rate

Patients in the current study were very successful with the non-operative program. Thirty-eight out of 50 patients (76%) were deemed as successful following the three month course of treatment.

Published success rates of similar treatment groups vary significantly. Interestingly, Bartolozzi et al's study of 136 patients with impingement, partial thickness tears and full thickness tears demonstrates an identical success rate (76% successful, 24% failed) with the long term (minimum 18 months) follow-up group [1]. This group had better success rates than the shorter term follow-up group (minimum 6 months), suggesting that outcome may improve over time.

Further follow-up of the present study population will determine if this trend is consistent with the present study.

5.2.1 Variables

Of the three variables that had been identified for examination a-priori, two were statistically significant (age and RCQOL) in the univariate comparisons. Forward elevation range of motion was not significant on the univariate comparison. Involvement of the dominant side had not been selected a-priori as one of the primary independent variables however it demonstrated statistical significance in the univariate comparison and thus was examined in further steps of the exploratory analysis.

As was reviewed in chapter 2, the existing literature reports conflicting information as to which variables are important in the outcome of non-operative treatment. Age and involvement of dominant side are both factors which have previously been examined in the literature, with conflicting results as to their prognostic significance. To date, the RCQOL has not been examined in this context in the literature.

5.2.1.1 Age

Only the work by Bartolozzi et al [1] and Goldberg et al [2] examined the prognostic ability of age. Both Bartolozzi and Goldberg's studies concluded that age was not a contributing factor in the outcome of non-operative treatment. However, the present work suggests that age is an important factor.

5.2.1.2 Dominance

Once again, from all studies reviewed, only Bartolozzi and Goldberg's studies examined dominance as a prognostic factor. Bartolozzi's [1] study showed that dominance was not a significant factor, however Goldberg's [2] study showed that it was significantly related to outcome of non-operative treatment. Our study supports the latter finding.

5.2.2 Comparisons Between Bartolozzi, Goldberg and Present Work

There are some critical differences between the present study and Bartolozzi's study [1] which may explain the differing significance levels of age and dominance.

Bartolozzi's study population varied substantially from the current study. Patient ages ranged from 18 – 85 and were grouped into arbitrarily defined groups of <40 years, 40 – 60 years, and >60 years; duration of symptoms ranged from 2 days to 120 months; patients with impingement and partial thickness tears in addition to full thickness tears were included; and not all patients underwent imaging to determine the extent of tearing (35 patients had no imaging). Of the 136 patients, 105 had impingement, 15 had a partial thickness tear or a full thickness tear <1cm, and only 16 had a full thickness tear >1cm. The variability in these characteristics makes the population very different from the one in the present study. Had all patients had a confirmed full thickness tear, one wonders whether the prognostic factors may have come out differently. A young person (less than 60 years) with a full thickness tear is likely to be managed quite

differently from a young person with impingement. Therefore, age would not be seen as a prognostic factor when dealing with a less severe pathology. However, with a more serious pathology (full thickness tear), management strategies may be different, hence the difference between Bartolozzi's study and the present study.

Goldberg et al's work [2] also showed that age was not a statistically significant prognostic factor, however dominance was. One major difference between their study and the present study is that the outcome was based completely on patient self assessment, and the efficacy of non-operative treatment was defined as the difference between the final and initial function scores on the Simple Shoulder Test. Dominance is most likely closely related to a patient's functional abilities, and thus is a logical prognostic factor for this outcome. Age would likely not affect the performance of these activities from the baseline to follow-up time period (average 2.5 years) in any significant way.

5.3 Univariate Analyses

The equations produced from the univariate regression models explained between less than 1, to 21% of the variance of the outcome, using the Nagelkerke R^2 calculation. The estimate of how well each model classified the observed data, using the -2 Log Likelihood, (-2LL) ranged from 36 to 55. A small -2LL value translates to a good model because it results in a high likelihood of

the observed results. The 95% confidence intervals around the odds ratios crossed the null value of 1 for all variables, with the exception of the RCQOL.

From the results of the univariate analyses, one can see that the best single predictor of outcome is the RCQOL (reaches significance at 0.017, relatively low -2LL at 48.255, and 19% explanation of variance using Nagelkerke R^2), however this still only predicts 19% of the variance of the outcome. Further, the ROC curve shows that the best cut-off point on the RCQOL is 40, however this point on the curve is a long way from the top left corner, suggesting that it isn't that strong of a predictor on its own.

The ROC for age suggests that 65 years is the best cut-off point for determining success or failure. However, again the point representing <65 years is not fitted to the top left corner of the graph well, suggesting that this also is not a very strong predictor. Further, the univariate analysis shows that age only accounts for 4% of the variance of the outcome, and the 95% confidence interval around the odds ratio crosses 1. .

The dominant side data is categorical (i.e. yes/no) and therefore cannot be interpreted on an ROC curve. However, from the univariate model one can see that it explains only 8% of the variance of the outcome, and the odds ratio = 3.636, with 95%CI 0.699 – 18.918. The confidence interval crosses one, which indicates that the odds for dominant side involvement and non-dominant side involvement can not be said to be different. Further, such a wide confidence

interval around the odds ratio really gives very little confidence at all that dominant side will be a strong predictor of outcome on its own.

5.4 Bivariate Analyses

When all combinations of two of the independent variables that were significant on the univariate analyses were combined, the explanation of variance ranged from 10 – 27% using the Nagelkerke R^2. The -2 log likelihood of the models ranged from 44 – 51. The 95% confidence intervals around the odds ratios were significant only for RCQOL.

5.5 Multivariate Analyses

When all three variables that were statistically significant in the univariate equations were combined into an exploratory multivariate analysis, 31% of the variance of the outcome could be explained by the model, and the -2LL of the model was 43. Again, the 95% confidence interval around the odds ratio showed significance only for RCQOL. The logit of the regression equation produced from the multivariate model is Z = -3.1 + (0.053 x RCQOL) + (0.050 x Age) + (-1.084 x dominant side) and its use will be illustrated in the following example.

5.6 An Example

An example of the use of the final multivariate model and its predictive probability will be illustrated. This example is based on a hypothetical situation, where the patient is 75 years old, has an RCQOL score of 67/100, and is left-hand dominant, with a right sided tear.

$Z = -3.1 + (0.053 \times RCQOL) + (0.050 \times Age) + (-1.084 \times dominant\ side)$

$Z = -3.1 + (0.053 \times 67) + (0.050 \times 75) + (-1.084 \times 0)$

$Z = 4.201$

Then, Z is used in the predicted probability equation.

$Probability\ (success) = (e^{product} / 1 + e^{product})$

$Probability\ (success) = (e^{4.201} / 1 + e4^{.201})$

$Probability\ (success) = 0.985$

Failure has been defined as an outcome of 0, whereas success has been defined as 1. This hypothetical patient would be defined as likely to succeed with non-operative treatment, as his/her score is greater than 0.5, and in fact, quite close to 1.

Although this model is exploratory, the product is very encouraging for further work in the area.

5.7 Limitations of the Present Work

The investigative team put exhaustive effort into the development of the present study. Despite this, and as with any research study, there are many limitations of the present work which require discussion.

5.7.1 Methodological Limitations

5.7.1.1 Recruitment

This study recruited patients from referrals to two shoulder specialized surgeons only at the University of Calgary Sport Medicine Centre. While previous work has illustrated the diversity of patient characteristics that are referred to these surgeons, it is still a limitation of this study to only include patients at this centre.

Further, non-participants may introduce a selection bias, as those patients who choose not to participate (n = 8) may be systematically different from participants in some way. This would limit the ability to generalize findings beyond the study sample.

5.7.1.2 Confirmation of Full-Thickness Rotator Cuff Tear

Another limitation of this study is the use of ultrasound or Magnetic Resonance Imaging (MRI) to define the presence and size of the full thickness rotator cuff tear. Imaging reports can vary substantially based on the imaging techniques and the expertise of the radiologist. However, this represents the current clinical standard and therefore is reflective of the real world situation.

5.7.1.3 Selection of Prognostic Factors / Independent Variables

It is recognized that recovery from a full thickness rotator cuff tear is a complex process that is influenced by the interaction of many factors, not just the ones included in this study, and this is a limitation of the current work. However, in order to keep the study to a manageable size, it had to be limited to a small

number of factors. The examined factors were carefully selected based on expert consensus and the existing literature, with the acknowledgement that additional factors are also important contributors to outcome. It was anticipated that the outcome of this study would establish the need for further work examining treatment options for rotator cuff disease.

5.7.1.4 Compliance

A major limitation of the current study is that the non-operative treatment program that patients undertook was not controlled. While it was a standardized program that was given to patients, it was up to the patients to perform the exercises on a daily basis outside of the study visits. The goal of this study was not to evaluate the treatment program directly, rather to evaluate factors that indicate success or failure with the treatment program. The standard of care for non-operative treatment in the community can vary widely and this certainly is recognized as a significant limitation of the current work.

A rehabilitation program can only have a chance of being of successful if it is utilized by patients. Moreover, it must be utilized appropriately. However, relying on patient report of their own performance of the program has issues which have been discussed previously in many aspects of the medical literature [97-99].

The present study utilized log-books for patient report of how many times each day they performed the exercises. The log books were created with the intent of being as simplistic as possible, in the hopes that simplicity might increase usage.

It was hoped that patients realized it was in their best interest to perform the exercises, with the goal of reducing their shoulder pain and increasing their shoulder function. All patients had voluntarily enrolled into the study, and were being provided with excellent care and follow-up on a regular basis. Follow-up telephone calls were made weekly in the first 6 weeks, and bi-weekly in the second 6 weeks by the author to help encourage compliance. Despite these facts, it is probable that some patients did not comply with the non-operative program to an optimal degree. This is acknowledged as a fact of working with "real life" patients, and is acknowledged as a limitation of the study.

5.7.1.5 Definition of Outcome

When originally designing the study much consideration was given as to how to define the final outcome (success versus failure). Originally, the study team had determined that success should be defined as avoidance of surgery, and failure would be defined as having surgery. However, upon further thought, it was determined that a patient may avoid surgery, though not have necessarily been successful with the non-operative treatment program. There are many factors that contribute to the decision to pursue or avoid surgery, including health factors and lifestyle factors which may ultimately override the outcome of non-operative treatment.

A major consideration that must also be addressed in regard to outcome is that the outcome a patient reached at the three month visit (and final time point for

the present study) is not necessarily a permanent outcome. A patient who was defined as successful at three months may find that their symptoms gradually return over time, and may eventually seek surgery. Conversely, a patient who was defined as failed at three months may find that their symptoms improve while they are on the wait list for surgery, and may end up cancelling their surgery before it occurs.

Further, the decision made at the three-month appointment may be affected by any treatment provided to the patient at the 6 week appointment (i.e. cortisone injection). For example, in the success group, 7 patients (of 38; 18%) had a cortisone injection provided within the baseline to 3 months time period (all were between baseline and 6 weeks), whereas, in the failed group, four patients (of 12; 33%) had a cortisone injection (2 were between baseline - 6 weeks, and two were between 6 weeks - 3 months). The difference between groups was not significant when compared using a Mann-Whitney test.

Longer term follow-up (i.e. 2+ years) is optimal to address the above issue.

Of interest, the current patient population is being followed to two-years outside of the master's study. All patients have reached at least 6 months. 3 patients who had been defined as successful at 3 months have worsened according to their RCQOL scores, and would now potentially be defined as failures (to be confirmed by the treating surgeon at upcoming appointments). Conversely, two

patients who had been defined as failures at 3 months have since stated that their symptoms have greatly improved and would now be considered successful.

5.8 Biases

Misclassification bias may exist in the study, if patients are grouped into an "incorrect" group (success or failure) at the three month visit. However, this classification is made by the surgeon using the best possible information available to them at the time. The two patients who did not attend the final visit may have an increased risk of misclassification bias as their final outcome was determined by the author rather than one of the surgeons. However, they both declined attending the final appointment because their shoulders were doing well, and they chose not to continue with further treatment, thus the author feels confident that the surgeons would have agreed and classified both of these patients as successful. Further, potential misclassification bias can be examined closely with long term follow-up, identifying which patients switch groups and thus quantifying the extent of misclassification present.

Perhaps the most evident form of bias in the present work is a form of experimental bias which relates to expectations of either subjects or the study team. The Hawthorne effect refers to the tendency of persons who are singled out for special attention to perform better merely because they are being observed [63]. A subject may try their best to fulfill the researcher's expectations

or to present themselves in the best way possible, such that their responses are no longer representative of natural behaviour [63].

The present study may have been subject to the Hawthorne effect, if patients wanted to do well to fulfill the author's expectations. However, one would assume that the patients first and foremost concern was the disability in their own shoulder, and that their overarching concern was focused on receiving appropriate care for their shoulder. It is doubtful that a patient would have altered their responses in an effort to please the researchers to the point that it would have affected their final outcome.

5.8.1 Statistical Limitations

5.8.1.1 Power

Perhaps the greatest limitation of the present study lies within the statistical analysis of the data. Having only 12 patients fail significantly limited the precision of the estimates possible. Originally, it was anticipated that 2 of 3 patients would fail the non-operative program. This assumption was based on previous work by the study team in the same type of patient population, however this did not involve a structured non-operative program as in the present study.

With only 12 patients reaching one of the outcome options, the study was only statistically powered to look at one factor in the logistic regression analysis. While it is interesting to be able to comment with statistical power on one factor,

the goal of the study was to begin the process of creating a clinical prediction rule based on multiple factors.

Therefore, the goal was pursued through an exploratory analysis, recognizing the major limitation that no definitive conclusions can be drawn from the present work. It is likely that the study team will use the results of the present work to form a theoretical basis for a new, larger study in the future.

5.8.1.2 Over Fitting

Along with being under-powered, the present study runs the risk of being over fitted. Over fitting refers to asking too much of the data, or capitalizing on the idiosyncratic characteristics of the sample [100].

Peduzzi et al have shown that relative bias increases as the number of events per predictor decrease, and that bias is unacceptably high when there are fewer than 10 to 15 events per predictor [101]. The limited sample size in the case of the present work is the number of non-events (i.e. 12 failures). However, because it has been deemed that the analysis is fully exploratory in nature, no conclusions are being made from the present data, and the study team fully recognizes that there is not enough data to fit an appropriate model which contains more than one predictive factor.

For argument sake, if the study team decided to make conclusions based on the multivariate model produced (containing three predictive factors), over fitting

could result in overly optimistic model results. The over fit model could increase the chance of the regression weights being very large and fluctuating over repeated samples. That is, if an attempt was made to estimate too many unknowns (3) for the number of observations (12 in the smallest group), findings that are true in the current sample of 50 would misleadingly appear to belong to the entire population. The results would not be stable or reproducible in subsequent analyses, and the model could not be trusted.

5.9 Strengths

Despite a lengthy list of limitations of the present work, there were several strengths as well.

5.9.1 Unique Contribution to the Existing Literature

As reviewed in chapter two, there is a significant amount of literature examining the concept of non-operative treatment for chronic, full-thickness rotator cuff tears. However, the literature has widely disparate findings with an unclear take home message for clinicians.

The present study, though not definitive, was built on strong methodology and shows clear trends for future investigation. The strengths listed below will make this study an important contribution to the literature on non-operative treatment for rotator cuff tears.

5.9.2 Methods

Many previous studies examining non-operative treatment are performed retrospectively, and simply follow-up with patients who were previously prescribed non-operative treatment. These studies all exclude any patient who subsequently elected to undergo surgery, and thus have biased populations from the outset. Further, many of these studies include any combination of the many modalities that are considered non-operative treatment, without defining a specific program and without any measures of compliance.

The present study was designed specifically to avoid the problems listed above. The study was completed prospectively, with all patients newly referred to the participating surgeons. All patients voluntarily undertook the defined non-operative program, with guidance from experienced physicians and physiotherapists, and continual contact with the author throughout the duration of the program.

5.9.3 Follow-Up

Perhaps due to the structure of the present program, the overall percentage of attended appointments was 97.6% (244 of 250 total patient appointments from baseline through 3 months). This is an excellent rate of follow-up and indicates that patients were very compliant with the structure of the program. Though two patients did not attend the final appointment with the surgeon, both were telephoned by the author and determined to have been successful with non-operative treatment (they would not attend the final visit with the surgeon as they

were no longer seeking any type of treatment, thus an outcome of successful was deemed appropriate), therefore, 50 of 50 patient's data were analyzed.

Many of the studies presented in chapter two had very low rates of initially eligible patients being followed-up through the entire duration of the study. For example, Hawkins and Dunlop's study [3] stated that approximately half of eligible patients were automatically excluded due to unreasonably large travelling distance for follow-up, which left an "initial sample" of 50 patients. Of the 50 enrolled, the final report is on 33 patients, which represents approximately 1/3 of total "eligible" patients.

Itoi and Tabata [4] initially report that 124 shoulders in 114 patients were identified with full thickness tears and underwent non-operative treatment, but follow up occurred on only 62 shoulders in 54 patients, half of the total initial population. They do, however, state the reasons for not following-up on the remaining 62 shoulders.

5.9.4 "Buy-In"

Perhaps the most important strength of the present work was the quality of the non-operative program that was developed at the outset of the project. The involvement of many experts in the development of this program helped to contribute to its success, because the physicians and physiotherapists who subsequently delivered it to the study participants were fully committed to seeing it utilized to its full potential. If the professionals delivering the program had not

had confidence in it, it is doubtful that the patient results would have been so successful.

As an interesting note, since the program has been developed, several health care professionals external to the study centre have contacted the centre requesting permission to use it in their own practices / settings. It is gratifying to see that professionals outside of this centre recognize the strengths of the program and are committed to providing quality non-operative care to their own patients.

5.9.5 Anecdotes

Although not necessarily sound in scientific merit, the author feels that it bears mentioning anecdotally that many patients mentioned that they were extremely satisfied with the program, and were thrilled that their shoulder symptoms had resolved to the point where they were comfortable avoiding surgery.

Further, one of the surgeons involved, who has almost 30 years of experience in shoulder surgery, mentioned to the author that he has changed his practice in the way that he approaches non-operative treatment due to the outcomes of this study. While again not scientifically sound, it was very rewarding and encouraging to see that the results of this study are being taken so seriously by a true expert in the field.

5.9.6 Success

Although it is a very small drop in the vast bucket of the Canadian health care system, 38 patients were removed from surgical consultation wait lists due to this study. While this number is not going to change the overall situation in the health care system, it certainly is a step in the right direction, and has the potential to increase with further work which will be defined by the present study.

5.10 Clinical Interpretation

Translating research results into day-to-day use in a clinical setting can be challenging.

Because of the statistical challenges with the present study, it would be premature to utilize the regression equation and predicted probability in a clinical setting without further work.

However, clinicians can interpret a few take home messages from the present work:

- Patients with a chronic full-thickness rotator cuff tear should undertake a course of adequate non-operative treatment.

- Attention should be paid to the patient's baseline score on the rotator cuff quality of life questionnaire. The best cut-off score between success and failure as indicated by the receiver operating characteristic curve is 50, however this alone is not enough to predict the patient's outcome.

- In regards to a patient's age, the cut-off score between success and failure as indicated by the receiver operating characteristic curve is 65 years. However, as with RCQOL, age alone is not enough to predict the patient's outcome.

- Involvement of the dominant side is also an important factor in determining a patient's likelihood of success versus failure. However, once again the ability of this variable to predict outcome on its own is not strong.

5.11 Future Directions

5.11.1 Long Term Follow-Up Study

A critical next step in this work is to complete longer term follow-up. This is currently underway on the present study population. Patients will be followed until they reach the two-year time point.

Over this extended time frame it will be critical to see how many patients switch from one outcome group (success or failure) to the other. While seeing patients progress from failure to success will be noteworthy, it is the patients who switch from success to failure who need to be considered most carefully. It will be critical to note if an additional "injury" has occurred to the shoulder, or if the patient is simply experiencing increasing symptoms. The study team will need to closely observe the number of patients who are "crossing over" from success to failure. If the numbers are significant, then the study team will need to very

closely evaluate the merits of non-operative treatment, to ensure that the non-operative program does not delay inevitable surgical fixation.

5.11.2 Full Development and Testing of a Clinical Prediction Rule

Based on the outcome of the long term follow-up study (and the assumption that that outcome of it shows that non-operative treatment is indeed more beneficial than not), a new study can be instituted to fully develop and test a clinical prediction rule for non-operative treatment. This would follow the steps outlined in chapter two, including derivation (establishing which variables are most predictive), validation (in several cohorts in different settings), and finally, impact analysis (to determine if the rule has changed clinician behaviour and resulted in beneficial outcomes).

5.11.3 Development of a Complimentary Clinical Prediction Rule for Surgery

Another future study which would be very complimentary would be to develop a clinical prediction rule for predicting a patient's outcome of rotator cuff surgery. It would be unwise to assume that the same factors which predict a patient's potential outcome of non-operative treatment would correspond to their potential outcome with surgery. Therefore, identifying clinical characteristics which indicate that a rotator cuff patient would be successful or "fail" surgery would further assist clinicians in their decision making process.

For those patients whose clinical situations are complicated, predicting the probability of a successful outcome with non-operative treatment and comparing to the predicted probability of a successful outcome with surgery might prove a very useful tool for the clinician managing their case.

5.11.4 Knowledge Translation

Undoubtedly, research of any type is of no use if it is not translated beyond the immediate study team. Many of the results of the present study are preliminary, and exploratory in nature, and therefore are not ready or appropriate to share with the broader scientific community as definitive.

However, certain outcomes of the present work are conclusive, and will be shared through a manuscript submitted to a peer reviewed journal.

5.12 Conclusions

The goal at the outset of this project was to develop a clinical prediction rule for non-operative treatment of chronic, full thickness rotator cuff tears. However, it quickly became apparent that the goal was beyond the scope of this present project. Therefore, this project is setting the groundwork for a future study which will be larger in scope and will have increased numbers, thereby allowing for properly powered statistical analyses.

However, the present study has shown that non-operative treatment of chronic full thickness rotator cuff tears can be appropriate and very successful.

The final distribution of patients in outcome groups (success of failed) limited the ability to answer our original research question: Can the outcome of non-operative treatment of chronic, full-thickness rotator cuff tears be predicted using patient age, baseline range of motion measured passively as forward elevation in the scapular plane (ROM), and baseline quality of life score on the Rotator Cuff Quality of Life questionnaire (RC-QOL)?

However, an exploratory analysis identified three important factors for further investigation in future work, including two that had been identified a-priori in the research question (RCQOL, and age). Involvement of dominant side should also be considered in future work.

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Appendix A: Consensus Meeting Summary

"Consensus" Meeting Summary: 19-Mar-2008

Attendees:

3 Shoulder specialized Orthopaedic Surgeons

5 Athletic Therapists

12 Athletic Therapy students

8 Physiotherapists

1 Radiologist

2 Research Associates

2 Calgary Health Region Rehabilitation Program Administrators

2 Surgical Fellows

1 Surgical Resident

1 Family Medicine Resident

6 Sport Medicine Physicians

Presentation on Modalities by Paul Hunter BSc, MSc(PT), CAFCI

Discussion:

- modalities are useful for short term pain control
- no evidence in the literature for ultrasound
- no supporting evidence for use of iono/phonophoresis

"Consensus": Modalities may be used to facilitate pain relief to allow the patient to perform the appropriate exercises.

Presentation on Exercises by Martin Zacharias BSc(PT), BPE, BEd, CAFCI, RCAMT, IMS

- Cochrane Review:
- no good quality randomized controlled trials exist in the literature
- observational studies only
- some publications show that exercises in full thickness tear patients have benefit, however no guidance as to when to start, and duration varied from 3 – 10 months

Discussion:

- A holistic approach to managing the patient should be used
- Goals of the exercise program should be to 1) maintain mobility, 2) decrease pain, 3) increase functional strength, 4) increase resistance to fatigue/control of shoulder girdle
- The exercise program is case/patient specific and should address the physical limitations of each patient
- Primary goal: restore range of motion
- Secondary goal: improve functional strength (including cuff strength, scapular stability, and motor control)

"Consensus": A patient specific program to restore range of motion and improve functional strength should be utilized.

Presentation of Corticosteroids by Dr. John Trantalis (MD, Orthopaedic Fellow)

- there is no level 1 evidence regarding corticosteroid use in full-thickness tears
- most of the existing literature does not include full thickness tears

Discussion:

- use of corticosteroids as pain relief/control?
- What potential harm can these cause?
- Contraindicated, except in non-surgical patients using palliatively, or very stiff patients trying to re-gain range of motion prior to surgery
- Use as pain management during wait for surgical consultation, stop-gap pain relief

"Consensus": If reasonable physical treatments have failed to show improvement at 6 weeks and pain is the limiting factor, then a corticosteroid injection could be offered.

Appendix B: Non-Operative Rotator Cuff Home Program

help reduce pain if there is a flare-up. If you are progressing well (i.e. exercises are getting easier with no increase in pain) you can increase the resistance on a weekly basis. Once resistance is significant, reduce exercises to once every second day.

STAGE 2 EXERCISES:

Find a resistance that allows 3 sets of 10 – 15 repetitions. Start by holding each for 2 seconds per rep, increase to 5 seconds per rep once you are comfortable.

- **1) External Rotation with Towel**

Bend the elbow of your injured side to 90° and tuck a rolled towel between your elbow and your side. Grasp a piece of rubber tubing that runs in front of your body, then slowly pull by rotating your arm outward. Make sure the towel doesn't slip out!

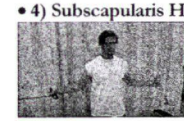
- **2) Abduction**

Grasp rubber tubing, and lift your arm straight out to the side. Start by lifting to 20°. Progress to 30°-60°, then 60°-80°.

- **3) Forward Flexion**

Grasp rubber tubing, and lift your arm straight in front of you. Start by lifting to 30°-60°, then progress upwards as comfortable. This exercise is easiest wit h your palm facing up, and your elbow bent.. Straighten elbow or face palm down for increased difficulty.

- **4) Subscapularis Hug**

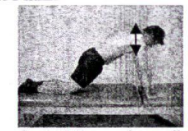


Start in your available external rotation grasping rubber tubing in your injured arm hand. Pretend you are hugging your arms around a large tree.

- **5) Wall Pushups**

Ensure your shoulder blades are moving towards each other and down your back as you perform your pushup. Place your feet a comfortable distance from the wall, and increase difficulty by moving feet further away. Keep your elbows close to your sides.

- **6) 4 Point Plank**



On your hands and knees, lean slightly forward. Push your arms down into the bed, feeling like you are increasing the distance between the bed and your chest. Hold for 5 seconds.

Non-Operative Rotator Cuff Home Program

UNIVERSITY OF CALGARY

SPORT MEDICINE CENTRE
FACULTY OF KINESIOLOGY

This program is intended to be used as a home exercise rehabilitation **guide** that will help you to achieve a functional shoulder. A physiotherapist can be consulted throughout to teach and individually modify the exercises listed.

What is the Rotator Cuff?

The rotator cuff is made up of four muscles (supraspinatus, infraspinatus, subscapularis, teres minor) that help to stabilize the shoulder.

Stage 1: Weeks 0 - 6

- **Goal 1:** Decrease your shoulder pain

- **Goal 2:** Increase your shoulder range of motion (ROM) through stretching and high repetition movement patterns.

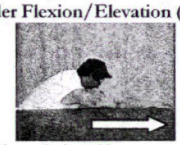
STAGE 1 STRETCHES/EXERCISES:

Stretches should be done multiple times each day. **Do each stretch 4 times in a row, holding for 30 seconds each time. Try to do this at least 4 times each day.**

- **1) Range of Motion Using Pulleys**

- Attach pulleys overhead (directly above your knees). Sit in a chair and hold the ropes in each hand.
- Pull your good arm downward and allow the injured arm to be lifted upward.
- Slowly lower your injured arm down, making your good arm do the work.
- Repeat for up to 5 minutes.

- **2) Shoulder Flexion/Elevation (Bent over)**

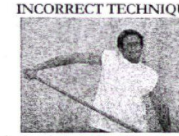


Sit on a stool or chair, with your arm on a level surface (bed, counter, desk). Use your good arm

to push your upper arm down into the bed. Slowly lean your body forwards until you feel a comfortable stretch in your shoulder.

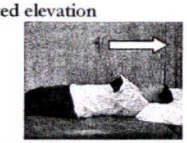
- **3) Abduction**

PROPER TECHNIQUE INCORRECT TECHNIQUE



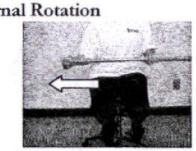
Grasp a broom handle in both hands. Slowly use your good arm to raise your injured arm straight out to the side. *Make sure you don't let your injured shoulder ride upwards.

- **4) Assisted elevation**



- Lie on your back clasping your hands together. Slowly raise your arms over your head, using your good arm to do most of the work. Lower and repeat 10 - 15 times.
- As this becomes easier, allow the injured shoulder to more and more of the work.
- To make this even more difficult, prop your upper body up using pillows. The closer your upper body is to vertical, the harder the exercise will be.

- **5) External Rotation**



Bend the elbow of your injured side to 90° tucking your elbow against your side. Grasp a broom handle in both hands. Use your good arm to slowly push outwards, making the injured arm pivot outwards from the elbow. Make

sure that the elbow stays tucked tightly against your side.

- **6) Internal Rotation**

Grasp a towel with your good arm over your shoulder and your injured arm behind your lower back. Slowly pull upwards with your good arm until you feel a comfortable stretch in your injured shoulder.

- **7) Scapular Retraction:**

Sit tall. Squeeze your shoulder blades towards each other, hold, then relax.

Stage 2: Weeks 6 - 12

- **Goal 1:** Improve the strength and muscular control in your shoulder

- **Goal 2:** Create muscle fatigue when performing each exercise, without considerable increase in pain.

Initially, exercises should be done **at least once every day.** The resistance, range of motion and pace with which you perform the exercises should be comfortable. If the exercises cause a flare-up in your shoulder pain, you should decrease the activity to the level where there was previously no pain. You can also use ice after the strengthening exercises and/or anti-inflammatory medication to

Appendix C: Telephone Screening Form for Rotator Cuff Referrals

U of C Sport Medicine Centre
Rotator Cuff Intake Clinic Referral Evaluation Form

Referred to: _____ Date received: _____

Patient Name: _____

Affected Shoulder: ___ Left Right Both

Lives: _____

Symptom Onset or Duration: _____

Nuisance or Disability?

Can you lift your arm above your head? YES NO

Please rate your pain on a scale of 0 -10 _____
(where 0 is no pain and 10 is the worst pain you can imagine)

If indicated, do you wish to pursue surgical treatment for your shoulder? YES NO

Conservative Treatment:					
Physiotherapy		Helpful:	Yes	How long:	No
Cortisone:	How many:	Helpful:	Yes	How long:	No
Anti-Inflammatories		Helpful:	Yes	How long:	No
Other (please list):					
_____		Helpful:	Yes	How long:	No
_____		Helpful:	Yes	How long:	No
_____		Helpful:	Yes	How long:	No

Investigations		
Xrays	When	Where
U/S	When	Where
MRI	When	Where
Arthrogram	When	Where

Contact Attempts

PLAN:

Appendix D: Inclusion / Exclusion Criteria Form

Initials:_____

ID: _____

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Non-Operative Treatment of Full-Thickness Rotator Cuff Tears

INCLUSION CRITERIA	YES	NO
1. Age 40 - 85 years	☐	☐
2. Full thickness tear of supra or infraspinatus: confirmed on U/S or MRI	☐	☐
3. Symptomatic for minimum of 3 months	☐	☐
If any shaded areas are marked NO, the patient is ineligible.		

EXCLUSION CRITERIA	YES	NO
1. Already exhausted non-operative treatment: min 3 mos stretching and strengthening with use of analgesics, anti-inflammatories, and/or modalities, plus or minus injections	☐	☐
2. Full thickness tear of subcapularis or teres minor	☐	☐
3. Concomitant symptomatic pathology of affected shoulder (i.e. instability)	☐	☐
4. Significant cervical spine pathology and/or radiculopathy	☐	☐
5. Elite Athlete	☐	☐
6. Acute injury (less than 3 months symptoms)	☐	☐
7. Significant medical issues precluding surgery	☐	☐
8. Secondary gain issues (WCB, litigation)	☐	☐
9. Unable or unwilling to complete study outcomes	☐	☐
10. Unable to provide informed consent	☐	☐
If any shaded areas are marked YES, the patient is ineligible.		

Research Coordinator:
Kristie More
(403) 220-8954

Appendix E: Informed Consent Form

Non-Op

UNIVERSITY OF CALGARY
KINESIOLOGY
SPORT MEDICINE CENTRE
Fax: (403) 282-6170
Website: www.sportmed.ucalgary.ca

TITLE: Predicting the outcome of non-operative treatment for chronic, full-thickness rotator cuff tears.

INVESTIGATORS: Dr. Rich Boorman, Dr. Dianne Bryant, Dr. Nick Mohtadi, Dr. Preston Wiley, Kristie More

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

Rotator cuff tears are a painful condition and surgery is often thought of as the primary form of treatment. However, we feel that many patients can successfully manage their rotator cuff tear through a non-operative treatment program and thus avoid surgery all together.

WHAT IS THE PURPOSE OF THE STUDY?

The primary purpose of this study is to examine factors associated with unsuccessful outcome of non-operative treatment for patients with a chronic, symptomatic, full thickness rotator cuff tear.

WHAT WOULD I HAVE TO DO?

If you agree to participate, you will be required to see a sport medicine physician who will assess the quality of treatment you have already tried on your shoulder. If the physician feels your previous treatment does not meet the standards of our clinic, you will be asked to try three additional months of non-operative treatment which will be directed by the physician and taught to you by a qualified therapist. You will need to perform the exercises every day, and keep a log book of your exercises. After six weeks of non-operative treatment you will return to the clinic to see the physician for a follow-up appointment. After three months of non-operative treatment, you will be seen by the shoulder surgeon you were originally referred to where you will decide together if you should have shoulder surgery or not. By participating in this study you will not loose your place in line on the surgeon's waiting list. You will be asked to complete the study outcomes again at 6 months, 12 months, and 24 months after enrolling into the study.

WHAT ARE THE RISKS?

There are no risks associated with your involvement in the study. Participation in the project poses no threat to you, as you are potentially receiving a greater degree of care than you would by not participating. You will not loose your spot in queue on the surgeon's wait list by participating in this study so there is no risk of delayed care.

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. Your shoulder problem may or may not improve during the study and there is no guarantee that this research will help you. The information we get from this study may help us to provide better treatments in the future for patients with rotator cuff tears.

DO I HAVE TO PARTICIPATE?
Your participation in this study is voluntary and you may withdraw your participation 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. We may withdraw you from participation in this study if we feel it is necessary. This may happen if we determine that your shoulder problem is getting worse. If new information becomes available that may affect your willingness to participate in this study you will be informed as soon as possible.

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

WILL I BE PAID ANYTHING 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. Parking tokens will be provided to you free of charge for your study visits at the Sport Medicine Centre.

WILL MY RECORDS BE KEPT PRIVATE?
All information is confidential. Patient charts and electronic records at the Sport Medicine Centre are password protected and only accessible to the treating doctors, nursing aides, and research assistants. 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 University of Calgary Conjoint Health Research Ethics Board will have access to the records.

IF I SUFFER A RESEARCH RELATED INJURY, WILL I BE COMPENSATED?
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 Sport Medicine Centre, the Calgary Health Region, the sponsor, or the researchers. You still have all 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:

Dr. Richard Boorman	or	Kristie More
Principle Investigator		Research Coordinator
(403) 210-9717		(403) 220-8954

If you have any questions concerning your rights as a possible participant in this research, please contact: Director, Office of Medical Bioethics, University of Calgary, at (403) 220-7990.

Participant's Signature	Printed Name	Date
Investigator/Delegate's Signature	Printed Name	Date
Witness' Signature	Printed Name	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 F: Rotator Cuff Quality of Life Questionnaire (RCQOL)

DATE: _____/_____/_____

NAME/ID #: _____

QUESTIONNAIRE # _____

QUALITY OF LIFE ASSESSMENT

IN

ROTATOR CUFF PATIENTS

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.

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**

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**

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 <u>overall</u> present level of shoulder pain.

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

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**

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...

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**

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**

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!

Appendix G: Data Collection Form for Initial Visit

Initials: _____

ID: _____

UNIVERSITY OF CALGARY

FACULTY OF KINESIOLOGY
SPORT MEDICINE CENTRE

Non-Operative Treatment of Full-Thickness Rotator Cuff Tears

Patient Info

Age: _____

Gender ☐ F ☐ M

Dominant Side: ☐ Rt ☐ Lt Involved Side: ☐ Rt ☐ Lt

Duration of symptoms: _____

Onset: ☐ acute ☐ insidious

Smoker: ☐ no ☐ yes

RCQOL score: /100

Largest tear size reported on imaging: _____

Passive FE-ROM: _____

ER-strength: _____

Notes: _____

Research Coordinator:
Kristie More
(403) 220-8954

Appendix H: Data Collection Form for All Appointments

Initials: _____

ID: _____

UNIVERSITY OF CALGARY
FACULTY OF KINESIOLOGY
SPORT MEDICINE CENTRE

Non-Operative Treatment of Full-Thickness Rotator Cuff Tears

Initial Physician visit: _____

Physician: _____

Treatment Provided (including previous): _____

Initial Physio visit: _____

Physiotherapist:

Additional Treatments Provided: _____

2 week Physio visit: _____

Additional Treatments Provided: _____

6 week Physician visit: _____

Global rating of change score: _____

Additional Treatments provided: _____

3 month Surgeon visit: _____

Surgery ☐ YES ☐ NO

If NO: ☐ surgery not needed at this time

☐ surgery not realistic at this time due to other health or life "issues; please list:

_____

Research Coordinator:
Kristie More
(403) 220-8954

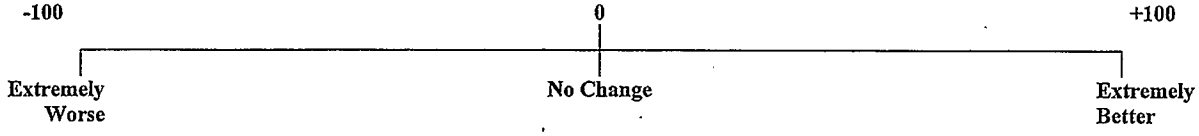
Appendix I: Global Rating of Change Scale

Patient Initials: _____
Study ID: _____
Date: _____

Global Rating of Change: Shoulder

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 J: Patient Log Book

Rotator Cuff Non-Operative Program

Exercise logbook for _____

Please record the number of times that you do your shoulder exercises each day on the enclosed calendars as well as any additional treatments you have on your shoulder. Please return any completed monthly sheets to Kristie at each visit.

Name _____

April 2009

Sun	Mon	Tue	Wed	Thu	Fri	Sat
			1	2	3	4
5	6	7	8	9	10	11
12	13	14	15	16	17	18
19	20	21	22	23	24	25
26	27	28	29	30		

Please record the number of times each day that you perform your shoulder exercises. Please return this calendar back to Kristie at your next appointment!!!

Name _____

May 2009

Sun	Mon	Tue	Wed	Thu	Fri	Sat
					1	2
3	4	5	6	7	8	9
10	11	12	13	14	15	16
17	18	19	20	21	22	23
24	25	26	27	28	29	30
31						

Please record the number of times each day that you perform your shoulder exercises. Please return this calendar back to Kristie at your next appointment!!!

Name _____

June 2009

Sun	Mon	Tue	Wed	Thu	Fri	Sat
	1	2	3	4	5	6
7	8	9	10	11	12	13
14	15	16	17	18	19	20
21	22	23	24	25	26	27
28	29	30				

Please record the number of times each day that you perform your shoulder exercises. Please return this calendar back to Kristie at your next appointment!!!